Management of the mandibular Kennedy Class I situation using a removable partial denture supported by short implants and retained with a resilient attachment system: A within-subject crossover clinical trial.

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ABSTRACT

The mandibular Kennedy Class I (KCI) situation is regarded as one of the more challenging clinical situations to successfully manage with a conventional removable partial denture (CRPD). Acceptance of this treatment option is generally poor. Stabilising the distal extension bases of such dental prostheses through association with strategically placed dental implants has been described; however, the evidence-levels supporting this treatment concept are low. Clinical trials employing multiple objective and subjective measures comparing implant-retained removable partial dentures (IRRPD) with CRPDs, and even with the baseline situation (shortened dental arch (SDA)), are rare. The objective of this research project was to use multiple objective and subjective measures to compare these three situations and to determine if a) a removable dental prosthesis (CRPD and/or IRRPD) can significantly improve function, Oral Health Related Quality of Life (OHRQoL), and patient satisfaction relative to the SDA situation, and b) if implant association significantly improves the function, OHRQoL, and patient satisfaction over the CRPD. This clinical trial was conducted as a within-subject crossover trial, whereby each subject experienced both a CRPD and an IRRPD to manage a mandibular KCI situation comprising of less than twenty teeth. Seventeen subjects completed the clinical trial. Subjects were randomly allocated into one of two groups; group A – CRPD first, and group B – IRRPD first. At the completion of the first phase of the trial, the dental prosthesis being worn was converted to the other design. Both objective and subjective measurements were recorded at baseline, the time of each dental prosthesis insert, and after a minimum adaptation time of three months. Based on the objective tests, the presence of a lower dental prosthesis shows a tendency to improve the SDA situation, however this improvement is not significant when using a chewing test and when assessing maximum bite pressure. The CRPD demonstrated no significant improvement in OHRQoL and satisfaction relative to the SDA situation, whilst the IRRPD demonstrated significant improvements in physical pain and physical disability domains. When comparing the CRPD and IRRPD head-to-head, it is obvious that the IRRPD is significantly superior in terms of OHRQoL and patient satisfaction, however similar in terms of objective measures. As a result of this research, a decision-making treatment-planning rubric has been proposed to help assist patients, clinicians, and funding bodies (i.e., governments, insurance industry, etc.) in providing appropriate treatment in a cost-effective manner.

DECLARATION

This is to certify that this thesis comprises only of my original work towards the PhD except where indicated in the Preface; due acknowledgement has been made in the text to all other material used. The thesis is fewer than 100,000 words in length, exclusive of tables, figures, references, and appendices.

Dr George Alexopoulos

April 2021

PREFACE

Management of the Kennedy Class I (KCI) mandibular situation with conventional removable partial dentures (CRPD) has proven to be a significant challenge with questionable success as evidenced by relatively poor acceptance of this treatment option. The strategic use of osseointegrated dental implants to support the distal extensions of such dental prostheses has been documented, however the objective and subjective evidence available to support this treatment approach is of low level. The purpose of this project was to investigate the treatment concept of providing implant support to the distal extension bases of CRPDs in the management of mandibular KCI situations. This investigation took the form of a within-subject crossover clinical trial designed such that each subject can experience and compare both the CRPD and the implant retained removable partial denture (IRRPD), and thereby adding to the evidence base either supporting or refuting this treatment concept.

The first part of the thesis reviews the relevant literature pertaining to the current and future treatment needs for managing partial edentulism, the changing patterns of the diseases responsible for tooth loss, and the challenges in managing the distal extension partially edentulous condition. The literature review then assesses current knowledge regarding the use of short implants and the use of implants in association with removable partial dentures. The final sections of the literature review provide an overview and context for the objective and subjective methods used in this clinical trial to assess denture performance and the impact on oral health-related quality of life.

An in-depth methodology section provides an overview as to the structure of the trial and a description on how each of the tests was implemented. Following on from this, the results section presents the key outcomes. The discussion section allows for interpretation of the results, provoking thought, and providing a basis for rationalising and explaining the outcomes. The discussion section also touches on the potential cost-benefit of the implant retained removable partial denture design relative to the conventional removable partial denture design. The conclusion section summarises the key findings of this body of work. The appendices contain many of the key documents, subject characteristics, subject charts, and data tables relevant to this trial.

Due to the late availability of data, it was decided to present this research in the form of a traditional thesis; there is intention however to publish scientific papers arising from this body of research.

DEDICATION

This body of work is sincerely dedicated to my wife, sons, parents, extended family, and friends, which have all shown extraordinary patience, tolerance, and understanding throughout this period of my life.

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I would like to take this opportunity to express great appreciation and gratitude to my supervisors, Associate Professor Roy Judge, Professor Menaka Abuzar, and Associate Professor Joseph Palamara, who all supported this study. As challenging as it is to undertake a clinical trial, their support, guidance, and encouragement enabled me to finally complete and submit this body of research.

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I would like to thank Dental Health Services Victoria (DHSV) for its support and permission to treat its patients (the subjects in this trial) and to have access to the necessary clinical facilities and materials. I would also like to thank Mr Warren Crossley, Mr Ricky Kumar, and Dr Krati Garg (Oral Surgery Department – The Royal Dental Hospital of Melbourne (RDHM)) who assisted in assigning surgical cases to appropriate senior surgical registrars. I would like to thank the surgical registrars that performed the surgical implant placements and the many skilled and enthusiastic dental assistants that assisted me throughout the clinical phase of the trial. I would like to express my appreciation to the DHSV laboratory team, particularly Greg Hanson, Octavian Teodorescu, and Sasko Jovevski, who all helped ensure smooth and seamless management of the laboratory aspects of the trial.

I would like to acknowledge DENTSPLY-Implants for providing the necessary implant components required for this trial; a contract was entered into between DENTSPLY-Implants and The University of Melbourne for this purpose.

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TABLE OF CONTENTS

ABSTRACT……2
DECLARATION……3
PREFACE……4
DEDICATIONS……5
ACKNOWLEDGEMENTS……6
TABLE OF CONTENTS……7
ABBREVIATIONS……10
LIST OF FIGURES……13
LIST OF TABLES……15

CHAPTER 1: INTRODUCTION……17

CHAPTER 2: LITERATURE REVIEW

2.1 OVERVIEW……21
2.2 POPULATION DEMOGRAPHICS OF RELEVANCE FOR FUTURE PROSTHODONTIC TREATMENT NEED: POPULATION SIZE, GROWTH RATES, AND AGE PROFILES……23
2.3 CAUSES OF TOOTH LOSS AND TOOTH LOSS EXPERIENCE: AN OVERVIEW. ……29
2.4 THE MANDIBULAR KENNEDY CLASS I (KCI) SITUATION: A CONTEMPORARY REVIEW……36
2.5 THE SHORTENED DENTAL ARCH (SDA) CONCEPT……50
2.6 ASSOCIATION OF DENTAL IMPLANTS WITH KCI REMOVABLE PARTIAL DENTURES: A REVIEW OF CURRENT CONCEPTS AND CLINICAL EVIDENCE……60
2.7 A CONTEMPORARY REVIEW OF THE USE OF SHORT DENTAL IMPLANTS WITH A FOCUS ON THE POSTERIOR MANDIBLE……82
2.8 OBJECTIVE ASSESSMENT OF MASTICATORY FUNCTION: CHEWING TESTS UTILISING SIEVING METHODOLOGIES……106
2.9 OBJECTIVE ASSESSMENT OF MASTICATORY FUNCTION: ASSESSING BITE PRESSURE AND OCCLUSAL CONTACT AREA (OCA) WITH PRESCALE PRESSURE-SENSITIVE FILM……130

2.10 SUBJECTIVE ASSESSMENT OF DENTAL TREATMENT AND THE ORAL CONDITION: USE OF THE ORAL HEALTH IMPACT PROFILE (OHIP) AND VISUAL ANALOGUE SCORE (VAS) QUESTIONNAIRES……145
2.11 CONCLUSION……154

CHAPTER 3: MATERIALS AND METHODS……155
3.1 RATIONALES AND GENERAL DESIGN OF THE CLINICAL TRIAL……155
3.2 ETHICS CONSIDERATIONS AND TRIAL REGISTRATIONS……156
3.3 INCLUSION AND EXCLUSION CRITERIA……156
3.4 TRIAL VENUES/LOCATION AND SOURCING OF SUBJECTS……158
3.5 SAMPLE SIZE CONSIDERATIONS AND RANDOMISATION PROCESS……159
3.6 SCREENING PROCESSES AND CONSENTS……160
3.7 GENERAL MANAGEMENT OF THE UPPER DENTAL ARCH……162
3.8 PRELIMINARY PROSTHETIC ASSESSMENT……163
3.9 SURGICAL PHASE……163
3.10 PROSTHETIC PHASE……166
3.11 SEQUENCING AND TIME-POINTS OF DATA COLLECTION……174
3.12 DENTURE DESIGN CONVERSION (CROSSOVER) PROCESS……176
3.13 OBJECTIVE TEST USING OPTOSIL® COMFORT (CONDENSATION SILICONE) TO ASSESS MASTICATORY PERFORMANCE……176
3.14 OBJECTIVE TEST USING PRESCALE PRESSURE SENSITIVE FILM TO ASSESS MASTICATORY PERFORMANCE (MAXIMUM BITE PRESSURE, LOAD, AND OCCLUSAL CONTACT AREA)……181
3.15 SUBJECTIVE TEST UTILISING THE OHIP-14 QUESTIONNAIRE TO ASSESS EACH DENTURE DESIGN IN TERMS OF PATIENT SATISFACTION……184
3.16 SUBJECTIVE TEST UTILISING A VISUAL ANALOGUE SCALE (VAS) QUESTIONNAIRE TO ASSESS EACH DENTURE DESIGN IN TERMS OF PATIENT SATISFACTION……185
3.17 CLINICAL DATA COLLECTION……186
3.18 SATISTICS……187

CHAPTER 4: RESULTS……188
4.1 SAMPLE CHARACTERISTICS……188
4.2 SUBJECT DATA – AGE PROFILE, SEX BREAKDOWN, AND GROUP DESIGNATIONS……188

4.3 SUBJECT DETAILS, ARCH CONFIGURATIONS, IMPLANT SITES, AND LOCATOR™ ABUTMENTS……189
4.4 MASTICATORY PERFORMANCE TEST USING OPTOSIL® COMFORT PUTTY……191
4.5 MASTICATORY PERFORMANCE TEST USING PRESCALE PRESSURE SENSITIVE FILM - MAXIMUM BITE PRESSURE (MBP)……194
4.6 MASTICATORY PERFORMANCE TEST USING PRESCALE PRESSURE SENSITIVE FILM – LOAD……196
4.7 MASTICATORY PERFORMANCE TEST USING PRESCALE PRESSURE SENSITIVE FILM - OCCLUSAL CONTACT AREA (OCA)……198
4.8 SUBJECTIVE ASSESSMENT USING THE OHIP-14 QUESTIONNAIRE (SUM) ……200
4.9 SUBJECTIVE ASSESSMENT USING THE OHIP-14 QUESTIONNAIRE (BY DOMAIN) – CRPD VS BASELINE……202
4.10 SUBJECTIVE ASSESSMENT USING THE OHIP-14 QUESTIONNAIRE (BY DOMAIN) – IRRPD VS BASELINE……204
4.11 SUBJECTIVE ASSESSMENT USING THE OHIP-14 QUESTIONNAIRE (BY DOMAIN) – IRRPD VS CRPD……206
4.12 SUBJECTIVE ASSESSMENT USING VISUAL ANALOGUE SCALES – IRRPD VS CRPD……207
4.13 TESTING ORDER EFFECTS……208
4,14 CORRELATIONS BETWEEN OBJECTIVE AND SUBJECTIVE MEASURES…..210
4.15 RADIOGRAPHIC BONE LEVELS AROUND IMPLANTS (MESIAL AND DISTAL)……212
4.16 CLINICAL FINDINGS OF RELEVANCE……213

CHAPTER 5: DISCUSSION……215

CHAPTER 6: CONCLUSIONS……256

APPENDICIES……262

REFERENCES……286

ABBREVIATIONS

3mths	3 months
ABS	Australian Bureau of Statistics
BIC	Bone-to-Implant Contact
CAI	Comminuting Ability Index
CBCT	Cone Beam Computed Tomography
CFPD	Cantilevered Fixed Partial Denture
CI	Confidence Interval
CIR	Crown-to-Implant Ratio
CONFIG.	Configuration
CPITN	Community Periodontal Index of Treatment Needs
CRPD	Conventional Removable Partial Denture
CSR	Cumulative Survival Rate
D	Distal
DHSV	Dental Health Services Victoria
DIDL	Dental Impact on Daily Living
DIP	Dental Impact Profile
DMFT	Decayed, Missing, and Filled Teeth (Permanent)
dmft	decayed, missing, and filled teeth (Deciduous)
DMFS	Decayed, Missing, and Filled Surfaces (Permanent)
ERA	Extracoronal Resilient Attachment
F/-	Maxillary Complete Removable Denture
F	Female
FD	Full Denture (Complete Denture)
FEA	Finite Element Analysis
GMD	Geometric Mean Diameter
GOHAI	Geriatric (Generic) Oral Health Assessment Index
HA	Hydroxyapatite
IARPD	Implant Assisted Removable Partial Denture
IME	Index of Masticatory Efficiency
ID	Identifier
IRFD	Implant Retained Full Denture
IRRPD	Implant Retained Removable Partial Denture
ISRPD	Implant Supported Removable Partial Denture

ITSRPD	Implant-Tissue Supported Removable Partial Denture
KCI	Kennedy Class I
KCI Mx	Kennedy Class I – Maxilla
KCI Md	Kennedy Class I - Mandible
KCIII	Kennedy Class III
M	Male
MBF	Maximum Bite Force
MBP	Maximum Bite Pressure
Md	Mandible (Mandibular)
Me.	Mesial
mm	millimetre
MPa	Mega Pascal
MPI	Masticatory Performance Index
MPS	Median Particle Size
Mths	Months
Mx	Maxilla (Maxillary)
N	Sample Size
Ncm	Newton centimetre
No.	Number
NOM	Net Overseas Migration
NSAOH	National Survey of Adult Oral Health
NL	The Netherlands
NZ	New Zealand
OCA	Occlusal Contact Area
OHIP	Oral Health Impact Profile
OHIP-14	Oral Health Impact Profile (Short Form)
OHIP-49	Oral Health Impact Profile (49 item questionnaire)
OHIP-NL49	Oral Health Impact Profile (49 item questionnaire – adapted for Dutch population)
OIDP	Oral Impacts on Daily Performance
OMFS	Oral and Maxillofacial Surgeon
OHRQoL	Oral Health-Related Quality of Life
OPG	Orthopantomogram
PLS	Plain Language Statement
PVS	Polyvinylsiloxane
Q3	Quadrant 3

Q4	Quadrant 4
QOL	Quality of Life
RCT	Randomised Controlled Trial
RDHM	(The) Royal Dental Hospital of Melbourne
RN	Regular Neck (Implant)
RPD	Removable Partial Denture
SD	Standard Deviation
SDA	Shortened Dental Arch
SI	Short Implant
SIP	Sickness Impact Profile
SLA	Sandblasted, large grit, acid-etched
SPS	Sintered Porous Surfaced
SR	Survival Rat
St. I.	Standard Length Implant
TFR	Total Fertility Rate
TPS	Titanium Plasma-sprayed
TIRPD	Tissue-Implant-Retained Partial Dentures
VAS	Visual Analogue Scale
vs	versus
WWII	World War
yr	year

LIST OF FIGURES

Figure	Description	Page
2.1	Structure of mono-sheet type Prescale pressure-sensitive film	132
2.2	Structure of two-sheet type Prescale pressure-sensitive film	132
2.3	Standard continuous pressure chart for LLW Prescale pressure-sensitive film	135
2.4	Standard momentary pressure chart for LLW Prescale pressure-sensitive film	136
3.1	Mandibular radiographic stent (view from posterior)	161
3.2	Mandibular radiographic stent (right lateral view)	162
3.3	Intra-operative photograph demonstrating the placement of dental implants together with cover screws	165
3.4	Closure of the 'H'-shaped flap with two simple-interrupted sutures	165
3.5	Denture design using Computer Assisted Design (CAD) software	168
3.6	Locator™ retention cap *in situ*	172
3.7	Access hole created for application of the chemically activated polymerisation acrylic	172
3.8	Relieving of denture extension base to ensure passive seating of denture over the LocatorTM retention cap	173
3.9	Flow diagram depicting general trial design, time-points, data collection, and crossover	175
3.10	Optosil® Comfort putty (Kulzer GmbH, Hanau, Germany)	177
3.11	Prepworks™ onion chopper (Progressive International Corp., Kent WA, USA)	177
3.12	Example of sieves used to create the sieve stack through which the recovered chewing test material was sieved	180
3.13	Retsch Vibratory Sieve Shaker Model: AS 200 control (Retsch GmbH, Haan, Germany)	181
4.1	95% Confidence interval plots for changes in mean Median Particle Size (MPS) for the relevant comparison pairings as generated by the Optosil® chewing test	191
4.2	95% CI plots for changes in mean MBP for relevant comparison pairings generated by the Prescale test	194
4.3	95% CI plots for changes in mean load generation across the arches for	

relevant comparison pairings generated by the Prescale test……196
4.4 95% CI plots for changes in mean OCA for the relevant comparison pairings generated by the Prescale test……198
4.5 95% CI plots for changes in mean OHIP-14 Sum score for the relevant comparison pairings……200
4.6 95% CI plots for changes in mean OHIP-14 Domain scores for the CRPD versus baseline comparison pairing……200
4.7 95% CI plots for changes in mean OHIP-14 Domain scores for the IRRPD versus baseline comparison pairing……204
4.8 95% CI plots for changes in mean OHIP-14 Domain scores for the IRRPD versus CRPD comparison pairing……206
4.9 95% CI plots for VAS questionnaire – IRRPD versus CRPD……207

LIST OF TABLES

Table	Title	Page
2.1	Prevalence of Kennedy Classes as reported in relevant literature	38
2.2	Clinical studies reporting the association of dental implants with mandibular KCI RPDs	63
2.3	Examples of documented survival rates of short implants	85
2.4	Contemporary reviews of short dental implants	88
2.5	Literature reporting on short implants placed in the posterior mandible	100
2.6	Materials used for chewing tests and number of chewing strokes employed	108
2.7	Test material sample amounts commonly used in chewing experiments (by number and/or weight)	112
2.8	Chewing side(s) options described in masticatory performance tests	114
2.9	Number of sieves used in masticatory performance tests	117
2.10	Single and multiple sieving methods - Advantages and disadvantages of each method	118
2.11	Sieving method (dry and wet) and chewing test materials used	120
2.12	Examples of drying methods employed in relevant sieving studies	121
2.13	Sieving times referenced in relevant literature	123
2.14	Available Prescale films and some relevant features	133
3.1	Sequencing and time-points for conducting of trial tests	174
4.1	Trial Subjects – Group designations and ages at enrolment	188
4.2	Subject details, arch configurations, implant sites, and Locator™ abutments	189
4.3	Paired T-test results for changes in mean $\log_2$ MPS for the relevant comparison pairings as generated by the Optosil® chewing test	192
4.4	Relative differences of mean MPS (back-transformed) within comparison pairings as generated by the Optosil® chewing test	192
4.5	Paired T-Test results for changes in mean MBP for relevant comparison pairings generated by the Prescale test	194
4.6	Paired T-test results for changes in mean load generation for relevant comparison pairings generated by the Prescale test	196

4.7 Paired T-test results for changes in mean OCA for relevant comparison pairings generated by the Prescale test……198
4.8 Paired T-test for changes in mean OHIP-14 Sum score for the relevant comparison pairings……200
4.9 Paired T-test for changes in mean OHIP-14 Domain scores for the CRPD versus baseline comparison pairing……203
4.10 Paired T-test for changes in mean OHIP-14 Domain scores for the IRRPD versus baseline comparison pairing……204
4.11 Paired T-test for changes in mean OHIP-14 Domain scores for the IRRPD versus CRPD comparison pairing……206
4.12 Paired T-test for VAS questionnaire – IRRPD versus CRPD……208
4.13 Testing for Order Effects and Treatment Order Interaction……209
4.14 Correlations between Objective and Subjective Measures……210
4.15 Total vertical bone loss (mm) between implant placement to final periapical radiograph (months)……212
4.16 Vertical bone loss (mm) between first abutment installation to final periapical radiograph - bone loss experienced during the period of loading (months) ……213

CHAPTER 1: INTRODUCTION

Loss of permanent teeth results in functional limitations and aesthetic compromise, potentially having an adverse effect on occlusal stability, food selection, nutrition and general health, and oral health-related quality of life (OHRQoL) [1-10]. A range of prosthetic treatment options have been described and applied in an attempt to mitigate these issues by restoring function and aesthetics to an acceptable level. The distal extension (or free end) pattern of tooth loss, characterised by lack of a suitable abutment tooth distal to the edentulous space, is one of the more challenging patterns to manage with a dental prosthesis. Prior to modern advances in the field of oral implantology, fixed prosthetic options necessitated a cantilever design with a tooth (or teeth) mesial to the edentulous space providing the necessary retention and support. Such dental prostheses are limited by the span-length of the cantilever, with recommendations that the number of abutment teeth should be increased whilst the number (span) of pontics decreased [11, 12]. In more recent times, dental implants have proven to offer a predictable and well-accepted treatment option for the fixed replacement of missing teeth [13-20]. Despite the many benefits offered by dental implants, they require surgical intervention(s) with the potential for surgical morbidity, time for healing (soft and hard tissue integration) prior to restoration, and an increase in the initial cost of treatment. Furthermore, certain anatomical considerations and systemic medical conditions can limit the application of the implant treatment option.

The conventional removable partial denture (CRPD) has historically been a commonly used treatment option for the management of missing teeth [21, 22]. Unlike tooth-bounded CRPDs that predominantly receive retention and support from natural teeth at each end of the edentulous space, distal extension CRPDs depend on teeth and soft tissues (fibromucosa) for support; these structures differ in their relative resiliencies and behaviour to loading [23, 24]. The distal extension CRPD has a tendency to rotate around a fulcrum line passing through an abutment tooth mesial to the saddle on each side of the arch. The literature reports that the acceptance of CRPDs for managing distal extension spaces, especially if anterior teeth are not included in the dental prosthesis (i.e. no aesthetic motivator for wearing the dental prosthesis), is generally low [22, 23, 25]. Reasons given for the low acceptance includes lack of denture comfort, stability, chewing ability, and food entrapment [26]. The anatomy of the mandible makes this situation more challenging to manage since the area of bone and soft tissues available

for support under the distal extension denture base is limited. Low acceptance and/or attempts to re-make such dental prostheses places into question the efficacy of this treatment option. It may be argued that poor acceptance of these dental prostheses indirectly lends support to the so-called 'Shortened Dental Arch' (SDA) concept, a concept which questions the need for replacing all missing posterior teeth (the SDA will be discussed further in section 2.5 of the Literature Review) [27].

Numerous authors have described the strategic use of dental implants to help improve the support and stability of the distal extension RPD [28-33]. Improved comfort, stability and function may address many of the concerns associated with the distal extension CRPD resulting in improved acceptance. The anatomy of the posterior mandible can preclude the use of standard-length implants, particularly if the height of the residual ridge above the inferior alveolar (mandibular) canal is limited and/or the undercut of the submandibular fossa is accentuated (what defines a standard length versus short length implant will be discussed in section 2.7 of this literature review). In such situations, the implant treatment plan will either require surgical management to re-establish the available bone height or the use of short implants. The evidence-level pertaining to the use of implants to assist the distal-extension CRPD is relatively low, comprising mostly of case series and case reports. Very few randomised controlled trials using objective and subjective measures to assess this treatment concept are available.

The overall purpose of this research is to contribute to the higher-level evidence-base for the treatment concept involving the strategic use of (short) dental implants in association with CRPDs for the prosthetic management of the bilateral distal extension situation in the mandible. This trial utilised short implants (4mm diameter and 6mm length – Astra Tech Osseospeed™, DENTSPLY Sirona, York PA, USA) and a resilient attachment mechanism (Locator™ attachment system – DENTSPLY Sirona/Zest Anchors LLC, Escondido CA, USA). This research was conducted as a clinical trial employing a within-subject crossover design. This clinical trial aimed to compare the performance of the cast-base tooth and tissue supported CRPD to that of the same CRPD incorporating implant support under each distal extension base. Since both denture designs was experienced and assessed by each respective subject, the subject served as a control. Each denture design was worn for a minimum of three months to ensure adequate adaptation. The order of which denture design a subject experienced first was randomly allocated. Data was also collected from each subject when not wearing the

lower dental prosthesis; this served as the baseline situation and, despite certain limitations that will be discussed later in this thesis, provided a basis upon which the assessment of both denture designs could be judged. Objective, subjective, and general clinical data was used as primary outcome measures to assess the effect of each denture design. The inclusion criteria employed were not overly rigorous; the aim was to reflect the situation that would be encountered in everyday general clinical practice. Furthermore, the general treatment flow was designed in such a way that it is simple and cost-effective, hence enabling most general dentists with some additional experience and training in the field of dental implantology to adopt this treatment protocol.

The objective measures were masticatory function through the use of a chewing test utilising a standardised synthetic material (Optosil® Comfort putty, Hareus Kulzer, Hanau, Germany), and a bite pressure test utilising pressure-sensitive film (Prescale, FujiFilm Holdings Corporation, Tokyo, Japan). The chewing test assessed how well each subject can comminute the Optosil® material, whilst the bite pressure test assessed the maximum bite pressure (MBP), load, and occlusal contact area (OCA) that can be generated when each denture design was worn. The subjective measures used to assess each denture design involved the Oral Health Impact Profile 14 (OHIP-14) and Visual Analogue Scale (VAS) questionnaires investigating RPD stability, retention, comfort, chewing ability, and overall satisfaction. The key clinical measures included implant survival, radiographic bone level changes, and any adverse impacts on existing natural teeth and associated oral structures (during the six-month active phase of the trial).

This research is presented as a traditional thesis. Following-on from this introduction, the literature review (chapter two) provides the background and context for this clinical trial. Chapter three documents a detailed methodology outlining all key aspects of the trial. Chapter four presents the results from the objective and subjective measures used to assess the performance of each denture design (i.e., Optosil® chewing test, Prescale tests, OHIP-14 questionnaire, and VAS questionnaires). Bone level changes and any clinical observations of interest are also presented in this chapter. Chapter five provides a detailed discussion of all of the findings, limitations, clinical recommendations, and recommendations for further research. Chapter six is the concluding chapter, bringing together all of the key findings of the clinical trial. The appendices will contain all relevant forms, tables, and general de-identified clinical data pertaining to each subject participating in the trial.

Aims of the Research:

- To assess if there is objective evidence demonstrating statistically significant improvement in masticatory performance when implants are used to provide support under mandibular distal extension RPDs.
- To assess if there is subjective evidence demonstrating statistically significant improvement in patient satisfaction when implants are used to provide support under mandibular distal extension RPDs.
- To provide greater insight into this treatment option and to guide clinicians in treatment planning for the mandibular KCI situation

Objectives of the Research:

- To compare the performance of each denture design relative to the baseline (no lower denture) situation.
- To compare the performance of each denture design from the time of insertion to the time of adaptation (i.e. minimum three month period).
- To assess the performance of short implants when used to support distal extension RPDs (in particular survival rates and bone level changes over the study period).
- To identify and report on what clinical aspects work well, and what aspects may require revision. Such findings will assist clinicians who are considering application of this treatment concept.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview

The principal purpose of this literature review is to provide a background and context to the clinical problem being investigated, the likely need for future management of this problem, and a basis as to how the methodology of this trial was developed. Although each section of the literature review can ostensibly be a thesis topic in itself, the aim of this review is to provide a relevant, yet succinct, overview of the relevant issues that will allow the reader to gain an appreciation of this body of research; essentially adding to the evidence-base supporting or contradicting the treatment option of using (short) dental implants to assist in the retention and support of KCI mandibular removable partial dentures.

Section 2.2 of this review will discuss changing population demographics such as population size, growth rates, life expectancies, and changing age profiles, which will undoubtedly have an impact on future dental treatment needs. Since this research is being conducted on an Australian cohort, a deeper analysis of these changes in relation to the Australian population will be presented. Section 2.3 will discuss the main causes of tooth loss and look at any changing trends in relation to these causes into the future. Changing patterns in tooth loss experience will be presented; this is of particular relevance to this research since a shift from edentulism to partial edentulism will result in a greater future demand for prosthetic rehabilitation using partial denture prostheses.

Section 2.4 will present a brief overview as to the relative prevalence of partial tooth loss patterns based on the Kennedy-Applegate classification of partial edentulism. The KCI pattern is amongst the most frequently encountered and is commonly acknowledged as the most challenging situation to manage with CRPDs. This section will discuss the issues pertaining to the KCI situation, including the clinical challenges and available treatment options. The lack of a distal abutment tooth (i.e., distal to each posterior edentulous space) necessitates denture support and retention to be received from tissues differing in their compressibility and hence behaviour to loading. This imparts biomechanical challenges that need to be overcome. Furthermore, there is debate as to the impact that CRPDs have on improving function, and the potential

adverse impact on the remaining natural teeth, soft tissues, and the overall stomatognathic system.

Section 2.5 will review the most obvious option of managing tooth loss, and that is to do nothing. Although this treatment option has been in existence ever since humans first started losing permanent teeth, it wasn't until the latter part of the twentieth century that this treatment option was investigated scientifically in order to validate its application. The available evidence suggests that not all missing posterior teeth require replacement. The occlusion appears to possess a level of redundancy whereby the loss of a given number of teeth can be overcome by adaptation to the new situation and that a dentition comprising of a 'second premolar-to-second premolar' occlusion can provide sufficient function and is conducive to a stable situation without risk of significant pathological changes.

Section 2.6 will provide an overview of the research already conducted on the use of dental implants to retain and support removable partial dentures. The key topics relating to this treatment option will be discussed, including the advantages and disadvantages of using implants, the positioning of implants in the edentulous space, implant lengths used, attachment method(s) used, impact on function (objective measures), and effect on patient satisfaction and OHRQoL. Section 2.7 will discuss the current understanding of the use of short dental implants. This is of relevance since the anatomy of the posterior mandible can often preclude the use of standard (longer) length implants unless advance bone augmentation procedures are used. These procedures carry surgical risks and add to the time and cost of treatment. Short implants, if proven to perform in a manner similar to standard-length implants, may offer a solution for many cases with reduced bone height in the posterior mandible.

The final three sections of this review (sections 2.8, 2.9, and 2.10) will discuss objective and subjective measures that have been used to assess masticatory performance, bite forces/pressures, and patient satisfaction. The discussion throughout these sections will provide the reader with an insight and justification as to the methodology used in this trial. Most of the measures used in this trial have their basis on precedence, however where necessary, some minor modifications have been made to make these tests more suited to the current trial.

2.2 Population demographics of relevance for future prosthodontic treatment need: Population size, growth rates, and age profiles

Identifying and interpreting changing trends in population demographics (i.e., population size, growth rates, and age distributions), together with changing patterns of tooth loss experience is of significance as it enables dental professionals and healthcare administrators to develop and employ evidence-based treatment protocols for the future needs of a defined population. Both the volume of treatment required (i.e., number of potential patients) and the nature of the treatment(s) required must be considered when determining treatment need. Healthcare policymakers can use this information to decide on the most efficient allocation of finite resources, hence ensuring that the population has access to the dental care required. Furthermore, Universities can use this information to better design and direct dental training programs such that graduating clinicians have the knowledge and skills necessary to manage the future needs of the ageing community [34]. The demographic characteristics of the population can be broadly assessed at global, regional, and/or local levels depending on how the population is defined. Since the relevant population for this body of research is the Australian population, the specifics relating to this population is of particular interest.

The world population first reached the milestone size of 1 billion around the year 1800. It took only a further 130 years for the global population to double in size, achieving 2 billion people in 1939. Population sizes of 3 billion were reached in 1959, 4 billion in 1974, and 5 billion in 1987 [35]. It is evident that the time required to achieve each subsequent billion in global population growth has been declining. The size of the global population in mid-2017 was estimated at 7.6 billion [36]. China is currently the most populous nation on earth (1.4 billion), followed by India (1.3 billion), the United States of America (324 million), and Indonesia (259 million). The global population is predicted to reach between 9.6 and 9.8 billion by 2050, at which time the population of India will exceed that of China and the population of Nigeria will overtake that of Indonesia [36-38]. The main reason accounting for the increase in projected global population for the latter part of this century is an increase in the projected population of Africa, explained mostly by high fertility levels (fertility rates above replacement levels) and to a lesser extent, a reduction in mortality [38].

For statistical convenience, the United Nations classifies countries into two broad categories – 'more developed' or 'less developed' - based on demographic and socio-

economic characteristics. Less developed regions include all of Africa, Asia (excluding Japan), Latin America and the Caribbean, and Oceania (excluding Australia and New Zealand). All other countries, including Japan, Australia, and New Zealand are classified as more developed [39]. In 2016, it was estimated that 16.9% of the global population resided in more developed countries, whilst 83.1% resided in less developed countries [37]. Population growth is not equally distributed around the world; regional differences are observed. In terms of absolute numbers, the populations of Africa and Asia are predicted to grow significantly between 2016 and 2050 (1.2 billion to 2.5 billion, and 4.4 billion to 5.3 billion respectively), whilst growth in North America (360 million to 445 million), South America (419 million to 494 million), and Australia (24.1 million to 41.3 million) will be more modest. Unlike other major regions, the population of Europe is predicted to contract over this period (from 740 million to 728 million) [37].

Even though the global population is continuing to grow in absolute numbers, the actual global population growth rate is declining. After reaching a peak of 2% in 1965, the global yearly population growth rate declined to 1.24% in 2007 and 1.10% in 2017, with predictions that this will continue to fall into the future, declining to less than 0.5% by 2050 [36, 40]. This observation is positive from the viewpoint that continually high population growth rates cannot be sustained into the future. The decline in the global population growth rate is largely a result of declining/lower fertility rates in more developed countries. In contrast to developed regions, the populations of poorer countries are increasing at unprecedented rates [40]. This poses a challenge for the global community since many countries have insufficient human, financial, and material resources necessary to ensure availability and access to necessary (oral-) health services [41].

Fertility rates and life expectancies are two variables that can explain the current and projected changes in population size, growth rates, and population age structures. These two variables may in fact, be closely dependent on each other. A decline in fertility rates is one of the main drivers contributing to declining population growth rates, especially in more developed nations [42]. As a result of increasing medical knowledge and advancements in medical technologies, greater provision of essential healthcare, better education, and healthier lifestyle habits, the average life expectancy of populations is increasing [39]. It is postulated that higher childhood survival rates in more developed nations (i.e., lower child mortality rates) has resulted in greater

confidence that children will survive into adulthood. As a result of this increased confidence of survival, parents no longer need to bear more children to ensure descendants in the long term [40]. Fertility rates in many developed nations have been declining, some to the point which is below that required for natural replacement. This may explain why the population of Europe is predicted to decline over the coming years and the rates of population growth in North America and Australia are declining.

As is the case with the global population, the Australian population is continuously growing in number. At the time of Federation (1901), the Australian population was estimated to be around 4 million [43]. The population grew to 6.97 million between Federation and World War II (WWII), with most of this growth being due to natural increase brought about by an improvement in survival rates with the birth rate overtaking the death rate [43, 44]. The Australian population at the end of WWII was 7.43 million [45]. Following WWII, the total fertility rate grew rapidly giving rise to the so-called 'baby boomer' generation (birth cohorts between 1946 and 1966). Post-war active overseas immigration also started to contribute significantly to population growth, and it is now the main driver of population growth of Australia [43, 44]. According to the Australian Bureau of Statistics (ABS), the estimated resident population of Australia on 2nd of January 2019 at 7.20pm was 25,207,386 people [46].

Given the range of variables that can influence population growth, projecting the size of the Australian population is a complex exercise. The main influential variables include fertility rates, mortality rates, and net overseas migration (NOM). The ABS applies a number of assumptions to each of these variables and as a result, develops a range of population projections. Three broad population projection series (series A, B, and C) are calculated based on different assumptions being applied to the variables. Using the 2012 Australian population size as a base (22.7 million), the ABS projects that the Australian population will reach between 36.8 million and 48.3 million in 2061, after which it will increase to between 42.4 million and 70.1 million in 2101 [47]. The projected range is significantly large, especially when projecting out to 2101. The growth rate of the Australian population for the year ending 31 December 2016 was 1.6%, equating to an increase of 552,100 people from 31 December 2015, with NOM and natural increase accounting for 56.0% and 40.9% respectively, of this growth. Inter-censal differences were used to explain the remaining 3.1% difference [48]. The average annual growth rate is expected to decline over the coming decades; the extent of this decline is difficult to predict since the variable of NOM can be adjusted on

political grounds and fertility rates are subject to both political and human behavioural influence.

The majority of the Australian population resides in urban areas and the major cities [43]. The most populous State of Australia is New South Wales (32.0%), followed in order by Victoria (25.6%), Queensland (20.0%), Western Australia (10.5%), South Australia (7.0%), and Tasmania (2.1%). The two Territories of Australia, the Australian Capital Territory (1.7%) and the Northern Territory (1.0%), are the least populous regions of Australia. As at 31 December 2016, Victoria enjoyed the highest growth in population over the previous year (2.4%), followed equally by New South Wales and Queensland with a growth rate of 1.5% over the previous corresponding period. All States/Territories of Australia demonstrated positive population growth [48]. In 2015, the total fertility rate (TFR) for Australia was 1.81 babies per woman [49]. This TFR is below the replacement level and has been so since 1976. A TFR of 2.1 is required to ensure replacement levels are achieved (i.e., for a woman to replace herself and partner). During the 2005 – 2010 period, approximately 48 per cent of the world's population resided in countries where the TFR was below replacement levels [50]. Australia's peak fertility rate was achieved in 1961 with 3.55 babies per woman [51]. The TFR has fluctuated over the past 16 years, having reached a low of 1.74 babies per woman in 2001 and achieving a thirty year high of 2.02 babies per woman in 2008 [49]. The population growth rate of Australia is being supported by NOM, since the TFR is below replacement levels.

Advances in medicine and socioeconomic development have resulted in improved survival rates (i.e. reduced mortality), particularly as a result of better management/prevention of infectious conditions and, to a lesser extent, non-communicable diseases [52]. Global life expectancy at birth has been increasing, with this trend projected to continue well into the future. The global life expectancy at birth for a child born during the period 2010 – 2015 is 70.8 years [36]. As is the case with population growth, the extent of improvement in life expectancy shows regional variations. The least developed countries have shown the greatest improvements in life expectancies in more recent years; however, they still lag the life expectancies seen in more developed countries. Children born in Africa during the 2010 – 2015 period can expect to live to 60.2 years, children born in Asia should reach 71.8 years, 74.6 years in Latin America and the Caribbean, 77.2 years in Europe, 77.9 years in Oceania, and 79.2 years in North America [36].

Life expectancy of Australians has increased significantly over the last century with Australia now enjoying one of the highest life expectancies of any county in the world [43, 53]. Compared to children born during the period 1881 – 1890, boys and girls born in Australia during the period 2013 – 2015 can expect to live some 33 and 34 years longer, respectively. The life expectancy for an Australian boy born during the 2013 – 2015 period is 80.4 years and that for a girl is 84.5 years. As more of life's stages are passed (i.e., birth, childhood, adolescence, etc.), the greater the likelihood of survival into later life, therefore life expectancies change during different stages of life [54]. Today's older Australians live generally healthier and longer lives than previous generations [55].

As a consequence of the population living longer and a reduction in fertility rates, the age profile of the population is changing [56]. This phenomenon has been referred to as 'population ageing', and is a notable demographic characteristic of most developed countries [36, 56]. The current lower population growth rates seen in many developed nations are a function of the historical higher growth rates that have subsequently fallen. For example, countries that 'developed' earlier in history (i.e., many European nations) experienced high population growth rates in the decades immediately following World War II (WWII), which have now dropped significantly. As these birth cohorts age, a shift is occurring in the population age profiles [39].

The mechanisms behind population ageing differs across countries, so a simple explanation to explain global population ageing is not available [57]. Some countries will experience ageing that is largely due to growth of the elderly population (i.e. increase in the number of persons passing into older age), whilst other countries may experience ageing due to a relative decline in the working-age (younger) population [58]. Globally, the population aged 60 years and over is growing more rapidly than the younger age groups. Europe has the greatest proportion of its' population aged 60 years and over (25% of the European population is aged 60 years and older). It is expected that all regions of the world, with Africa being the only exception, will have approximately a quarter of their populations aged 60 years and over by 2050 [36]. An ageing population presents both opportunities and challenges to society. Members of a healthy older population can add to the economic, social, cultural and family resources to a society [59]. However, an important consequence of population ageing is the rise in prevalence of chronic conditions, such as dementia, stroke, chronic obstructive

pulmonary disease, and diabetes; all conditions that have a strong association with age and requiring appropriate management [52]. Furthermore, ageing populations are likely to be associated with a shrinking workforce and increasing demand on health care, social care, and welfare [59].

As at June 30 2016, the median age of the Australian population was 37.3 years. This represents an increase of 3 years relative to the median age recorded in 2006, hence demonstrating that the population of Australia is ageing [56]. Tasmania has the oldest median age of all the Australian States/Territories and has demonstrated the largest increase in median age over the last 20 years. This observation is mostly explained by the net interstate migration of younger Tasmanians, presumably to seek further education and employment opportunities [56]. Between 1996 and 2016, the proportion of the Australian population aged between 15 and 64 years remained relatively stable (66.6% in 1996 and 65.9% in 2016). The proportion of the population aged 65 years and over increased from 12.0% to 15.2% during the same period. Furthermore, the proportion of the total population aged 85 years and over increased from 1.1% to 2.0% over the same 20-year period. The proportion of the younger population aged 15 years and younger decreased from 21.4% to 18.9% during this period. The 65 years of age and older age group is predicted to increase more rapidly over the coming decades as more birth cohorts of 'baby boomers' reach the age of 65 (as of 2016, only 5 of the 13 baby boomer cohorts had reached 65 years of age) [56].

Notwithstanding the decline seen in the annual population growth rate, the available information suggests that the Australian population is increasing in size and will continue to do so well into the second half of this century. With declining fertility rates and increased life expectancies, the age profile of the population is changing such that the proportion of persons aged 65 years and over will become more significant. Australia has both a growing and an ageing population, and when this is combined with the fact that people are retaining their natural teeth for longer (to be discussed in next section), it is clear that a significant need for dental care provision for an older population will exist for decades to come [34].

2.3 Causes of tooth loss and tooth loss experience: An overview

Loss of a permanent tooth is an irreversible phenomenon, often representing the culmination of the cumulative effects of oral disease(s) and the attempt(s) undertaken to manage these disease(s) over the lifetime of an individual. The ultimate decision to extract a tooth is complex and influenced by a range of factors including; the restorability of the tooth, the systemic health of the patient, general oral health, the strategic value of the tooth in terms of overall prosthetic rehabilitation, impact on aesthetics, impact on function (i.e. chewing ability, speech, etc.), patient motivation, access to appropriate dental care, financial considerations, and the experience and clinical judgement of the clinician [60-66].

Dental caries and periodontitis are the greatest oral health burdens and are the main causes of tooth loss around the world [67-73]. Ninety per cent of all tooth loss in Australia has been attributed to either dental caries or periodontal disease [74]. Both dental caries and (plaque-induced) periodontitis are infectious diseases with a multifactorial pathogenesis. Other causes of tooth loss include dental trauma, elective removal for orthodontic purposes, and incompletely erupted (impacted) teeth [63, 75]. Furthermore, socio-economic and lifestyle factors such as smoking, attitudes to dental care, and dental anxiety are also significant risk factors for tooth loss [76].

A thorough assessment of the prevalence, incidence, and changing trends in dental caries and periodontal disease globally, and even locally, is limited by broad study heterogeneity and methodological differences. Differences in the way these diseases are defined, thresholds and measures used to identify and categorise disease, and the quality of available data (evidence-levels) make comparisons across studies and over time difficult to undertake [72, 77, 78]. Despite these limitations, the available evidence suggests that dental caries has the greatest impact on tooth loss followed by periodontal disease [63, 79]. Dental caries affects both children and adults and remains a cause of tooth loss throughout life [72, 73, 80-85]. It has been reported that the caries rate over time in older people is at least as great as that seen in adolescents [80].

The distribution and severity of dental caries experience varies in different parts of the world and can even vary within regions or countries [69, 78]. Untreated dental caries in permanent teeth affected some 2.5 billion people worldwide in 2015 [86]. Industrialised countries have enjoyed a declining trend in caries experience over the

past twenty years with increased exposure to fluoride, changes in lifestyle and dietary habits, and better self-care practices contributing to this [69]. The trend of caries experience in developing countries however, which has historically been relatively low, is on the rise. Increasing consumption of sugars and inadequate preventive measures in developing countries can largely explain this observation [69]. A recent comprehensive literature review concluded that the global prevalence and severity of dentine carious lesions among 5- and 12-year olds has declined over the past forty years, with a lower prevalence detected among 12-year olds and among 35- to 44-year olds in high-income countries [72]. Data from 2010 indicated that untreated caries in permanent teeth peaked at 25-years of age, probably representing a delay in caries experience because of improved preventive practices in younger age groups. This change may also be due to lifestyle and health behaviour changes (i.e., cariogenic diet, sugar sweetened beverages, acidic drinks, alcohol, smoking, etc.) and stresses (including financial) [87, 88]. Interestingly, the same data from 2010 shows another peak in caries prevalence later in life (around 70 years of age) [78]. This second peak in later life may correspond with the onset of systemic health changes, progression of chronic periodontitis leading to gingival recession and clinical exposure of root surfaces, the administration of drugs that affect the quantity and/or quality of saliva, and/or a reduction in ability to practice adequate oral hygiene [89-91]. Older adults may also lose teeth as a longer-term consequence of prior dental caries, whereby previously treated teeth have experienced further damage rendering them no longer restorable.

The relative significance of caries and periodontal disease in tooth loss appear to be related. As younger adults are retaining more of their teeth as they age (i.e. in industrialised nations), these teeth will be exposed to the longer-term risk factors that contribute to chronic periodontitis. As a result, the relative importance of periodontal disease in tooth loss may be more significant in these populations [60]. Alternatively, the role of dental caries as the cause of tooth loss will appear more significant in a population with a higher prevalence of caries in adolescence and younger adults since extracted teeth will no longer have the opportunity of developing chronic periodontitis [63]. Molar teeth, especially first molar teeth, are usually the first teeth to be lost, probably because they are exposed to the oral environment the longest and are more challenging to treat (i.e. more complex endodontic morphology, and access challenges) [63, 92].

The DMFT index is an epidemiological tool used to assess the prevalence of dental caries and to gauge general population dental needs. DMFT refers to the mean measure of (D)ecayed, (M)issing, and (F)illed (T)eeth, with lower case letters being used when referencing the deciduous dentition (dmft). The index can be modified to DMFS if the level of analysis focuses on the number of tooth surfaces involved. The maximum DMFT possible for a permanent dentition is 28 (or 32 if the third molar teeth are included) [93]. DMFT describes lifetime caries experience (both treated and untreated caries) but does not convey the prevalence of untreated disease. It has been suggested that assessing the decayed component of the DMFT index is of more relevance to planners of healthcare services since treated disease does not cause 'burden' [78, 86]. Despite this limitation, the DMFT index is an often-used measure in oral epidemiology to assess changes in disease experience.

The dental health of children in Australia has been monitored from 1977, at which time the mean DMFT for 12-year-olds was 4.79 and the mean dmft for 6-year-olds was 3.13 [94]. By this time, the major centres of Canberra (1964), Hobart (1964), Perth (1968), Sydney (1968), Adelaide (1971), Darwin (1972), and Melbourne (1977) had introduced fluoridation of water supplies, resulting in over sixty per cent of the Australian population having access to fluoridated drinking water [95, 96]. The Queensland government has left the decision of whether or not to fluoridate public water supplies to individual councils. A marked decline in caries prevalence in Australia was observed in the subsequent decades, with the mean DMFT of 12-year-olds in 2010 being 1.34 (72% reduction from 1977) and the mean dmft of 6-year-olds being 2.58 (18% reduction from 1977). Encouraging as these declining trends are, there is more recent evidence indicating that these declining trends have plateaued (around the early 2000's) and have since started to increase. The mean DMFT for 12-year-olds was 0.95 in 2002 and then rising to 1.34 in 2010, and the mean dmft for 6-year-olds was 1.92 in 2002 and rising to 2.58 in 2010 [94]. This data indicates that there is an increase in the caries experience in both 6- and 12-year-olds; the majority of this disease appears to be concentrated in a small percentage, or subset, of the total population [95, 97].

Population-level epidemiological data for caries experience of the Australian adult population is not available; thereby, conclusive comments regarding changes in caries prevalence cannot be made. One published study investigated disease experience in a specific sample comprising of Australian army recruits monitored between 2002 and 2008. This study concluded that an increasing trend of disease experience was detected

over this period [98]. Recent evidence suggesting that there is a rise in caries experience in both children and adults highlights the need for continued vigilance and appropriate resource allocation towards preventive oral health measures. Based on data collected by the National Survey of Adult Oral Health (NSAOH) 2004-6 (latest available data), it was determined that the average DMFT scores for adults was higher for the older age groups (ranging from 3.17 for the 15- to 24-year-old group to 23.70 for those aged 65 years and over). Filled teeth (F) contributed most to the DMFT score for adults aged between 15 and 64 years, whilst missing teeth (M) contributed most in the 65 years and over age group. The proportion of people with untreated caries was highest for adults aged between 25 and 44 years of age (28.5%) and lowest for people aged 65 years and over (21.8%). Factors associated with caries experience and the relative differences in the DMFT measures included sex, location/region, insurance status, household income, and age [75, 94].

Unlike dental caries that affects children and adults, chronic periodontitis predominately affects adults, with disease severity being more profound in middle and older adulthood. It has been reported that severe periodontal disease is found in 15-20% of middle-aged adults (35- to 44-years of age) worldwide, and that most children and adolescents exhibit signs of gingivitis (often a precursor of periodontitis in susceptible individuals) [71, 99, 100]. The prevalence of severe periodontal disease varies by country and world region, but as discussed previously, differences in study methodologies does not allow for firm comparisons and conclusions to be made regarding trends in periodontal health [72, 86]. In 2010, it was reported that Oceania had the lowest prevalence of severe periodontitis (severe periodontitis defined by a Community Periodontal Index of Treatment Needs (CPITN) score of 4, clinical attachment loss greater than 6mm, or periodontal probing depth of more than 5mm), whilst the highest prevalence was reported for Southern Latin America [72].

It was estimated that 538 million people worldwide were affected by severe periodontal disease in 2015 [86]. The prevalence of periodontitis increases with increasing age [63]. In 2004-2006, the prevalence of moderate or severe periodontal disease in the Australian population was higher at older ages, varying from 2.7% for those aged between 15 to 24 years to 53.4% for those aged 65 years and over. Males demonstrated a higher prevalence of periodontal disease. Other factors associated with higher prevalence of periodontal disease included location/region, lack of insurance, eligibility for public dental care, and lower household income [75, 94].

Tooth loss as a measure is considered to be an effective marker of population health; it signifies past dental disease experience and the consequences of its treatment by dental extraction [70]. The epidemiology of tooth loss however is not yet fully understood [68]. This lack of understanding is largely due to the challenges of obtaining population-wide data, or even representative samples of the wider population, and the relatively low quality of available studies. Only a few countries worldwide have surveyed edentulism on a national scale, and even fewer have done so on several occasions that would enable changes in incidence of tooth loss to be analysed [101]. Much of the available research originates from developed countries and often involves convenience samples (i.e. elderly, aged-care residents, institutions, public-sector, military, etc.). Information relating to tooth loss experience from developing and poorer nations is limited; further research is required to provide a clearer global picture of tooth loss. Complicating the study of tooth loss, in particular incidence, is the lack of well-designed longitudinal studies examining this topic [76].

Accepting the significant limitations inherent in the available data, it is becoming apparent that the prevalence of severe tooth loss and edentulism is on the decline in developed countries, resulting in more people retaining more of their natural teeth into later life [68, 70, 76, 79, 92, 102]. A recent systematic review and meta-analysis assessing the global burden of severe tooth loss (as defined by having nine or fewer remaining teeth) reported geographic differences, and on a global basis, the age-standardised prevalence and incidence rate of total tooth loss in the entire population decreased by 45% between 1990 and 2010 [68]. Some countries demonstrated severe tooth loss significantly higher than the global mean (i.e., Brazil, Turkey, Iran, Mexico, and New Zealand), whilst other countries demonstrated severe tooth loss well below the global mean (i.e., China, Japan, Nigeria, Sri Lanka, and Sweden). The greatest fall in prevalence of severe tooth loss during the ten-year period of analysis was found in Slovenia, United Arab Emirates, Kuwait, Columbia, and Palestine. This declining trend in severe tooth loss was further supported by another review assessing the relevant European literature examining this issue [101]. Also acknowledging the limited data available, the authors of this review confirm that great differences in prevalence and incidence of tooth loss exists between countries, between different geographical regions within countries, and even between groups from various backgrounds. They identified only two nation-wide surveys (Sweden and United Kingdom) of suitable quality and repetition to enable the prevalence of edentulism to be projected for the next one to two

decades. Based on these two surveys, it was concluded that the complete denture market would decline by up to 50 to 60% over the next twenty years.

Edentulism used to be common in the Australian population. Today, edentulism is concentrated in disadvantaged groups such as the Indigenous population, the financially disadvantaged, and in the populations of rural and remote areas [70]. Edentulism in the Australian population aged 15 years and over has declined dramatically over the past 25 years as evidenced by a fall in prevalence from 14.4% in 1988 down to 6.4% in 2005. Furthermore, in 2013, the prevalence dropped even further to 4.4%, with the vast majority of edentulous being in the 65 years and over age group. Risk factors for tooth loss included sex (F>M), age (65 years +), location of residence (i.e., urban, rural, remote), lack of insurance, and lower household income. Between 1994 and 2013, the average number of missing teeth in dentate people aged 15 years and over dropped from 6.2 to 5.0 teeth per person. Consequently, dentate adults have a higher number of natural teeth than in the past and especially at older age [94, 103].

It is not unreasonable to assume that age is a major risk factor for tooth loss. Up until the middle of the twentieth century, a large proportion of the elderly population were edentulous; tooth loss and eventual edentulism were believed to be an inevitable consequence of ageing [104]. However, the assessment of prevalence of edentulism in different age cohorts has uncovered evidence to suggest that age in itself is not a significant risk factor for edentulism. A longitudinal study assessing four age cohorts (born pre-1915, 1915-1934, 1935-1954, and 1955-1964) and age-standardised to the 1979 resident population, found that the prevalence of edentulism at least halved between 1979 and 2002 among all ages, sexes, and States/Territories of Australia. Furthermore, there was no significant change in prevalence of edentulism in cohorts born after 1915, refuting the belief that the risk of edentulism increases with age. Instead, this data suggests that today's elderly had historically higher rates of extraction prior to the 1950's that have not been experienced by subsequent cohorts [70]. Since the introduction and deeper understanding of preventive dentistry, people now appreciate that natural teeth can be retained for life [104].

The global burden of oral conditions is now shifting from severe tooth loss toward severe periodontitis and untreated caries. A marked reduction in the prevalence of caries in developed regions may explain, in part, the reduced prevalence of severe tooth loss in these regions. A growing and ageing population, combined with a reduction in

prevalence of severe tooth loss, means that more people will be retaining more of their natural teeth into later life [68]. This has some important implications for oral health and the future demand for dental treatment. As teeth remain in the mouth longer, they will naturally be exposed to the (potential) risk factors associated with dental caries and/or chronic periodontitis. The risk status of an individual can change over time, particularly if there are changes to systemic health that may directly or indirectly affect the oral environment. The need and/or demand for prosthodontic care to manage partial edentulism will remain an important aspect of dentistry well into the future. To add further to the challenge of managing these situations, it is highly likely that partial edentulism will occur when patients are older, resulting in a substantial number of frail and functionally challenged patients attempting to adapt to partial dentures [92, 105].

Indigenous (Aboriginal) Australians experience significant disparities in oral health, with greater caries rates, higher level of untreated caries, more missing teeth, and higher rates of periodontal disease than the general population. This disparity is even worse in rural and remote areas [106, 107]. Clearly there is a need to remove these disparities, with prevention and early intervention being key. Nevertheless, if tooth loss has occurred, it is hoped that prosthetic treatment involving a removable dental prosthesis with a minimal number of strategically placed implants (if indicted) can make this treatment offering a reality for a broader section of the community. This is one of the key reasons for undertaking this body of research - to add to the evidence-base regarding this treatment option and to justify to governments the cost-benefit of using implants in certain situations.

2.4 The Mandibular Kennedy Class I (KCI) Situation: A Contemporary Review

65,535 different patterns (combinations) of partial edentulism can exist in a dental arch comprising of 16 teeth (Appendix 1). A number of classification systems have been proposed that aim to combine these patterns into categories sharing common features and treatment planning considerations, and as such, making order of this enormous number of different possible patterns of partial edentulism [108-113]. Furthermore, classification systems can assist with professional communications (i.e. between clinicians and the dental laboratory), the teaching of removable prosthodontics, and offer guidance in treatment planning [114, 115].

One of the more commonly used classification systems today has its basis on the original system proposed by Dr Edward Kennedy, of New York, in 1923 [116]. In its original form, the Kennedy system consisted of four 'Classes' (i.e. I to IV) that defined the topographical relationship of the edentulous space(s) and the natural abutment teeth [113]. The most distal edentulous space(s) of an arch defined the 'Class'. At the time of its inception, the KCI pattern of partial edentulism (characterised as a bilateral free-end arch or bilateral distal extension arch) was most prevalent in the population of interest for Kennedy. The designation of each subsequent 'Class' was based on decreasing prevalence. In 1954, Dr O.C. Applegate proposed two additional 'Classes' (V and VI) and applied eight rules to the original Kennedy system; the aim being to enable more situations to be described by the system and to help provide order over how the system should be applied [117]. This revised system is now referred to as the Kennedy-Applegate system and is in common use today [113, 114, 118].

Large scale epidemiological investigations recording the number of present and missing teeth and their respective locations in an arch would be required to gain a true picture of the relative prevalence of each Kennedy Class in a population. Such an exercise is logistically prohibitive; much of the current information relating to this topic is sourced from studies in the field of removable prosthodontics. Unfortunately, many of these studies do not employ randomisation in their sampling methods and are of limited scale, rather relying on the use of convenience samples (i.e., patients treated in a University or Hospital setting over a set period of time, reviewing the records of particular clinics or laboratories, etc.). The chronology of the data is of relevance since it is conceivable that disease experience and tooth loss patterns can change over time, thereby altering the

relative prevalence of each Kennedy Class in a population. Accepting the limitations inherent in the available data, it appears that the KCI and KCIII patterns of partial edentulism are most common, as summarised in Table 2.1.

Table 2.1. Prevalence of Kennedy Classes as reported in relevant literature.

Authors and year of publication	Country	Most common KCI - Mx	Most common KCI – Md	Other findings/comments of relevance (if any)
De-Souza et al. 2015 [119]	Brazil	KCIII	KCI	Majority KCI – 51 to 80 years of age. Majority KCIII – 31 to 50 years of age. More partial edentulous mandibles found.
Tansic et al. 2015 [120]	Serbia	KCI	KCI	Occlusal instability and chewing difficulty were the most significant symptoms found in treatment groups.
Vadavadagi et al. 2015 [121]	India	KCIII	KCIII	High overall prevalence of tooth loss. Community-based oral health programs recommended increasing awareness and reducing risk of tooth loss.
Bharathi et al. 2014 [122]	India	KCIII	KCIII	KCI was next common in both Mx and Md
Patel et al. 2014 [123]	India	KCIII	KCIII	More partial edentulous mandibles found.
Joshua and Olaide 2014 [124]	Nigeria	KCIII	KCIII	Aesthetics was the most important reason for demanding dentures by patients in this study.
Polychronakis et al. 2013 [125]	Greece	KCI	KCI	More partial edentulous mandibles found.
Sapkota et al. 2013 [126]	Nepal	KCIII	KCIII	More partial edentulous maxillae found.
Charyeva et al. 2012 [127]	Kazakhstan	KCIII	KCIII	
Avrampou et al. 2012 [128]	Greece	KCI	KCI	KCII was next most common in both arches.
Pellizzer et al. 2012	Brazil	KCIII	KCI	More partial edentulous

[129]				mandibles found.
Shinawi 2012 [130]	Saudi Arabia	KCIII	KCIII	
Pun et al. 2011 [131]	USA	KCIII	KCI	
Niarchou et al. 2011 [132]	Greece	KCI	KCI	
Al-Dwairi 2006 [133]	Jordan	KCIII	KCIII	
Sadig et al. 2002 [134]	Saudi Arabia	KCIII	KCIII	Younger patients had more KCIII; older patients had more distal extension RPDs (KCI and II).
Keyf 2001 [135]	Turkey	KCII	KCI	Mandibular RPDs are more common than maxillary RPDs.
Spratley 1988 [136]	Australia	KCV	KCV	More partially edentulous mandibles. KCV = bilateral bounded denture extension bases
Curtis et al. 1992 [137]	USA	KCI	KCI	Mandibular RPDs are more common than maxillary RPDs.

The defining characteristic of the KCI situation is the absence of a suitable abutment tooth distal to each bilateral distal edentulous space. Prior to the option of dental implants, rehabilitation of a free-end situation necessitated use of a dental prosthesis with a cantilever design. A cantilever is defined as a 'projected beam or member supported at one end' [138]; more specifically, the type of cantilever employed in restoring a free-end situation is defined as a Class I lever. A Class I lever acts as a force multiplier and demonstrates a tendency to rotate about the support structure (i.e., a mesial abutment tooth) when load is applied to the unsupported part of the beam [139]. The force acting on the support structure increases in proportion to the load and the distance that the load is applied from the mesial support structure (i.e., length of cantilever). Cantilevered dental prostheses impose biomechanical demands on the support structures as they attempt to resist this tendency for rotation. Unlike cantilevered fixed partial dentures (CFPDs) that receive most of their support from the mesial abutments, KCI CRPDs also receive support from the mucosa underlying the distal extension bases. However, the tendency for CRPDs to rotate around the fulcrum line passing through the most distal rests on each side of the arch is still present due to the greater compressibility of the mucosa relative to the abutment teeth (i.e. the mucosa supporting the denture extension base can be displaced much more than the intrusion of a normal abutment tooth) [140, 141]. Progressive changes to the underlying alveolar bone, such as loss of ridge height, will further exacerbate the tendency for rotation of the denture bases. There is some conjecture however, with the suggestion that the available evidence does not indicate that a reduction of torqueing forces transmitted to the abutment teeth is essential or necessary provided that satisfactory prosthodontic and oral conditions are established prior to and maintained after insertion of a CRPD [140].

Management options for the mandibular KCI situation can be discussed under the following headings: a) Shortened Dental Arch (SDA), b) CRPD, c) RPD and dental implant support, d) CFPD, and e) implant-supported fixed prostheses.

SDA

Key determinants of masticatory performance are the number of functional tooth units and the bite force [22]. Loss of posterior teeth will result in a reduction of functional occlusal units and the available chewing platform area. This will have a negative impact on objective masticatory function, as demonstrated by functional chewing tests [142-144]. Although the association between nutrition and systemic health is generally well accepted, the impact of moderate tooth loss and reduced objective masticatory function

on food selection and nutrition is inconclusive [145]. It appears that the impact on diet will be more significant as the severity of dental disability increases (i.e. edentulism followed by extreme SDA situations), thereby resulting in a more pressing need for prosthetic rehabilitation [146]. Based on reports assessing subjective chewing ability, a minimum of 20 'well-distributed' teeth can offer satisfactory, albeit slightly impaired, masticatory ability [147].

Comprehensive epidemiological and clinical investigations were carried out in The Netherlands from the late 1970's through to the 1990's to assess the impact of missing posterior teeth. Dr A. F. Käyser, a prominent researcher in this field over this time span, devised the term 'shortened dental arch (SDA)' to describe a dentition comprising of intact anterior and premolar segments with a reduced number of molar teeth. Cross-sectional and longitudinal follow-up studies have contributed valuable information in assessing the impact of the SDA on oral function, occlusal stability, periodontal health, craniomandibular disorders, comfort, and patient satisfaction [142, 147-162]. More contemporary research has added further to the evidence-base supporting the general conclusion that the SDA treatment concept is conducive to acceptable, yet sub-optimal, function and stomatognathic homeostasis [163-168].

The basis of the SDA treatment concept lies in the observation that an individual has an adaptive capacity (physiological range) allowing for adequate function to be maintained with an occlusion comprising of 'less than full' complement of teeth [169]. It appears that, in a symmetrical arch, the threshold of this adaptive capacity is in the vicinity of 20 well-distributed teeth (i.e. second premolar-to-second premolar occlusion or four functional occlusal units) [151]. Chewing function is severely impaired in subjects with extreme SDAs (i.e. 0 to 2 occluding premolars) [166]. By extension, the SDA treatment concept directs efforts to the maintenance and restoration of the strategic parts of the dentition, namely the anterior and premolar segments, and has been described as a 'problem-orientated' approach to treatment planning [160]. Treatment goals can be limited but still satisfy a patient's expectations and aspirations [159]. The SDA treatment concept supports the ultimate objective of dental care: the maintenance of a healthy functional dentition for life [160]. The other benefits of this treatment concept include; cost effectiveness, less interventions, and patient focus on maintenance of the existing dentition [149]. This treatment concept, however, should only be applied after assessment of the subjective needs and desires of the individual patient. It is not

inconceivable for a patient to have a desire to have molar units restored, provided that the remaining dentition is stable, and that financial cost of treatment is not a barrier.

CRPD

CRPDs are often selected because of their comparatively low cost and relative non-invasiveness [21]. Acrylic CRPDs depend predominantly on mucosal support and tend to sink into the tissues during loading. Such dental prostheses are damaging to the underlying tissues, show high failure rates, and should only be used in temporary or transitional manner [23, 170]. Metal-based dentures are more stable as they receive support from both teeth (i.e., via direct and indirect retainers) and the mucosa underlying the distal denture extension base; they are recommended for longer-term use. Despite the historical use of CRPDs as a treatment option for the KCI situation, the scientific evidence supporting this treatment option is somewhat inconclusive [22]. Issues of debate concerning the use of CRPDs include the effect on masticatory function, the impact on the remaining natural teeth and other oral structures, patient satisfaction and CRPD acceptance, the role of the CRPD in Combination Syndrome, and the use of dental implants with RPDs.

CRPD - Masticatory Function

A reduction of occlusal support length results in a lower capacity to select and break down food, hence the loss of molar and premolar teeth will result in a reduction of masticatory performance [171]. Any form of rehabilitation of missing posterior teeth (i.e., FPD or CRPD) that re-establishes the number of functional occlusal units will improve masticatory performance. However, the extent to which distal-extension CRPDs can re-establish or compensate for reduced masticatory performance relative to the SDA is unclear. A systematic review concluded that distal-extension CRPDs only partially compensated (50%) for the reduction in masticatory performance [172]. A study comparing the function of CRPDs and SDA (missing molars) concluded that no statistically significant difference could be detected between the groups and that a variety of factors besides occlusal force and occlusal contact area seems to affect the quality of mastication [173]. It has been reported that the distal extension dental prostheses in moderate shortened dental arches seem to have no positive effects on occlusion and temporomandibular function, and consequently, should be precluded in such situations [22, 163, 174]. Given the relatively low acceptance rate of the KCI mandibular RPD (to be discussed in a subsequent section), it is likely that any functional improvement is offset by the factor(s) contributing to the decision of an individual to

not wear the denture. This suggests that these individuals can function adequately with their SDA situation, thus further supporting the notion that the prescription of a CRPD is not warranted.

CRPD - Impact of CRPDs on Oral Structures

CRPDs impart both biological and biomechanical challenges to the remaining natural dentition and supporting structures. Literature evaluating the clinical use of CRPDs reports associations with dental caries, gingival inflammation, destructive periodontal disease, and tooth mobility [175-180]. Tissue changes at abutment teeth of mandibular KCI cases proved more frequent and severe than at abutment teeth of other denture classes [181]. CRPDs have been shown to accumulate biofilm (dental plaque), with the nature of this accumulated plaque reported to be more pathogenic in terms of dental caries and gingival inflammation [26, 182-185]. Further to the biological impact of plaque, the cantilever design of the distal extension bases and the tendency of the denture bases to rotate towards the more compressible mucosa upon loading places biomechanical stresses on the abutment teeth. A common reaction to such stresses is an increase in mobility of the abutment teeth, an observation that has been reported [186]. The severity and significance of this mobility however is questionable, since evidence exists showing that any change in tooth mobility is minimal and tends to stabilise shortly after issue of the denture and adaptation to the prosthesis [187-190]. The placement of a rest away from the distal denture extension base (i.e. a mesial rest on the abutment tooth) may also reduce tooth mobility by altering the direction of the rotational movement about the abutment tooth whilst also prohibiting the use of a clasp assembly that is potentially damaging [189]. Some studies have tried to investigate this latter issue further by determining if any particular direct retainer system was more favourable in terms of reducing this effect [191-193]. Although no single system has been widely accepted, stress-releasing systems such as the RPI system (mesial rest, distal guide plane, and gingival-approaching 'I' bar) are supported from the perspective of reducing the tendency for distal rotation of the distal abutment tooth [194]. A five-year longitudinal study however reported no significant differences between the RPI system and a system using a distal rest with a circumferential clasp on the periodontal health of the abutment tooth [195].

The challenge in determining the true effects of CRPDs on the remaining teeth and surrounding structures is the scarcity of long-term follow-up studies of sufficient

duration and sample size. More contemporary research, however, suggests that CRPDs in themselves may not be as detrimental to the remaining natural dentition as was originally thought [24, 187, 195-199]. Of particular interest are the findings reported in a 25-year follow-up study, largely focusing on mandibular KCI CRPDs, that found few lost teeth, few new carious lesions, a low number of endodontically treated teeth, and no apparent change in the periodontal conditions over this extended follow-up period [200]. The authors of this study emphasise the point that much of the literature presenting the adverse impact of CRPDs on existing teeth (dental caries and periodontal disease) were initiated in the 1950's and early 1960s. It was during the 1960s that our scientific knowledge of dental diseases developed such that the importance of preventive dentistry (i.e., plaque control and topical fluoride exposure) in the maintenance of oral health was realised and applied. As a consequence, more contemporary studies that place an emphasis on oral hygiene instruction and plaque control have reported only moderate or small adverse periodontal reactions and/or carious lesions in association with CRPD treatment, particularly when the CRPDs are carefully designed by employing biological design principles [177, 190, 200-202]. When caries does occur, the edentulous proximal side of the abutment teeth appear to be at greater risk [25]. Exposed cementum, as a consequence of gingival recession, can also be a risk for dental caries in association with CRPD use [189].

Achieving and maintaining stability of the distal extension bases is one of the most important factors in the long-term success of a mandibular distal-extension removable partial denture (KC I and KC II) [203]. Some studies have assessed the possible benefits of using a stress-breaker design that permits differential movement of the distal denture extension bases relative to the metal framework. However, this design may exacerbate the alveolar bone loss under the distal extension bases since more of the load will be borne by the mucosa rather than the abutment teeth. The reported complication rates for the stress-breaker design are higher than that of the rigid design and are not recommended [204, 205]. Extension base CRPDs are often poor-fitting, require more adjustments of the denture base, and tend to show lower survival percentages when compared to CRPDs with tooth-supported bases [23, 24]. Regular reviews enabling early identification of changes in denture base stability and performance of corrective measures may help improve long-term treatment outcomes.

Satisfaction and CRPD Acceptance

The few available long-term clinical studies evaluating the success and survival of CRPDs are limited by sample size and length of follow-up [23, 24]. Furthermore, the criteria used to define failure can vary between and even within studies, so interpretation of the results must bear this in mind. Most studies consider the remake of a denture (i.e. replacement denture) during follow-up or 'failure to wear' as criteria defining failure, whilst some studies also include abutment retreatment as a failure criterion [24]. The reported long-term success (or failure) rates of CRPDs is mixed. Some studies have reported high success rates over time, whilst other studies have reported high failure rates over a shorter time frame. Most of the failures occurred with the free-end denture extension base designs [21, 175, 176, 203, 205]. A survey from Adelaide reported that 25% of CRPDs were discarded in the first year and few survived more than 5 to 6 years. The authors of this study highlight that the subjects were not entered into a recall and maintenance programme [23]. A Japanese-based study reported a decreasing percentage of denture use from 90% at 15 months of insertion, 60% at 39 to 57 months of insertion, down to 40% at 63 months of insertion [25]. Most failures involve the KCI mandibular RPD [175, 203], although one study reported no statistically significant association between denture usage and the respective Kennedy classification [26]. Causes commonly given for non-use include breakage of dentures, poor fit, discomfort, chewing ability, food trapping, carious or lost abutment teeth, and pain associated with the dentures [26].

In stark contrast, a long-term longitudinal study reported that 65% ($^{13}/_{20}$) of the original CRPDs were still in function at the 25-year review. Although only 20 CRPDs (16 mandibular KCI, 1 mandibular KCII, and 3 maxillary KCI) were available for review at 25 years, the duration of follow-up is significant. The patients in this study attended an annual review and maintenance appointment during the first 10 years of follow-up. After the 10-year review, the patients were left to their own devices to arrange review and maintenance appointments with their own clinician [200]. Lower failure rates have also been reported in several studies of shorter duration (over 90% of dentures being worn at 2 years, and between 50% to 75% at 10 years) [24, 188, 189, 206]. A retrospective study of a Japanese population reported that 61% of the RPDs were still being worn at five years, with a higher percentage in the under 65-year age group (71% versus 37%). The authors suggest this may be due to younger patients placing a greater emphasis on aesthetics, function, and social activity, whilst older patients may have impaired oral motor functions and poorer ability to adapt to wearing CRPDs [21, 207].

Motivation for wearing CRPDs has been associated with the denture incorporating missing anterior teeth (i.e., aesthetic considerations), the patient having a low number of occluding pairs (not necessarily the absolute numbers of missing teeth), well-supported dental prosthesis (i.e. number of occlusal rests), and the denture treatment being initiated by the patient [170, 205, 208]. In an earlier referenced study with a high failure rate, 80% of CRPDs were made at the suggestion of the clinician. Improved aesthetics (by replacement of anterior teeth), impact on chewing and speech, adding dental units to the occlusion, retention and comfort of a mandibular CRPD, and ease of cleaning are factors recognised as being associated with general patient satisfaction with CRPDs [7, 209-212]. Non-compliance in CRPD use might be associated with a difference in priorities for treatment as viewed by the dentist and the patient; dentists tend to focus on physical function of teeth whereas patients focus on the social meaning of the mouth [208, 213].

Combination Syndrome

The term 'Combination Syndrome' or 'Kelly Syndrome' refers to a clinical situation that, in part, has been attributed to changes taking place underneath the distal extension bases in some patients presenting with a full upper denture opposing a mandibular KCI CRPD. Features of this so-called syndrome are: resorption of the upper anterior alveolar bone and replacement with hyperplastic tissues, over-eruption of the lower anterior teeth, down-growth of the maxillary tuberosities, (lower) distal residual ridge resorption, consequent changes in occlusion, and papillary hyperplasia of the palatal epithelium [214]. Several theories have been proposed linking these features, but regardless of the cause(s), changes in posterior support of the distal extension bases are an important observation.

Although these changes can often be observed in patients with a maxillary removable complete denture opposing a lower KCI CRPD, there is lack of conclusive epidemiological and clinical evidence to classify it as a true medical syndrome. It does not occur in all patients with this prosthetic configuration; most of the research relating to this topic is based on anecdotal observations and clinical experience rather than controlled studies [215-217]. Nevertheless, clinicians must be aware of these clinical features appearing in patients wearing a maxillary removable complete denture against a lower KCI CRPD. Periodic reviews will permit early detection and management of posterior residual ridge resorption and associated occlusal changes (i.e., through

denture reline/rebasing and occlusal corrections) thereby preventing or reducing the severity of these changes [214, 218]. The use of dental implants in the distal denture extension bases may be of benefit in these situations by helping stabilise the posterior occlusion and maintaining alveolar bone height [219].

Dental Implants and CRPDs

The use of dental implants with CRPDs has been reported in the literature, largely in case studies and case series. Only a few studies report on the objective benefits of using implants with RPDs. This topic will be discussed in further detail in section 2.6 of this literature review.

Cantilever FPD (CFPD)

Longitudinal studies report that CFPDs are better accepted by patients, conducive to less plaque accumulation, pose no greater risk of periodontal breakdown, may show lower incidence of dental caries, and have a lower need for dental and prosthetic follow-up treatment when compared to CRPDs in managing distal extension situations [11, 179, 220, 221]. CRPDs and FPDs are comparable in improving the chewing efficiency of patients with KCI and KCII partially edentulous conditions [222]. Further support for this treatment option is offered by authors who suggest that the evidence indicates CFPDs should be the first treatment option rather than distal extension removable partial dentures, and particularly so in elderly patients [221, 223].

Despite the benefits of the CFPD, it has a limited role in the management of extensive mandibular distal extension situations. The biomechanical loading imparted on abutment teeth by such dental prostheses is not favourable, particularly since higher loads are generated in the molar regions and intensified further by longer spans. The frequency of technical failures is directly related to the degree of cantilever extension, with the risk increasing with time in service and if the distal abutment tooth is non-vital [224, 225]. Therefore, the limited length of the distal cantilever restricts the usefulness of this dental prosthesis for managing moderate and extreme SDAs. The option of the CFPD may be useful when employed it in conjunction with the SDA concept whereby a single premolar needs to be replaced to re-establish a second premolar-to-second premolar occlusion and the use of an implant is not possible. Furthermore, these dental prostheses are at risk of both biological and technical complications, including dental caries, endodontic involvement, periodontal disease, fracture of the abutment teeth, de-bonding of the retainers, and fracture of the dental prosthesis [224, 225]. It is

recommended that two abutment teeth be used and that the distal cantilever be limited to one pontic [226, 227].

Implants in the posterior mandible

Dental implants have broadened the treatment options available for the replacement of lost teeth, including in the posterior mandible. Significant literature is available to support the long-term use of implants to support dental prostheses in the posterior mandible, with survival rates in excess of 90% over follow-up periods spanning 10 to 20 years [228-233]. Implants can be restored as either single units or used as abutments for the restoration of longer spans with FPDs. Anatomical limitations can sometimes complicate the placement of implants in the posterior mandible, however, more recent literature reports that short implants with modern surfaces, even as short as 4mm, can serve adequately to support dental prostheses in the posterior mandible. There is a growing body of literature reporting survival rates for short implants (< 10mm) of over 90% over 5 to 10 years [17, 234-236]. The use of short implants can broaden the number of patients suited to implant treatment without the need of more advanced and riskier surgical procedures (i.e., onlay grafting, nerve lateralisation, and distraction osteogenesis).

In situations where an entirely implant supported FPD is not possible, the option may exist for the FPD to be supported by both implant and a natural tooth. The splinting of a rigid implant to a natural tooth may be problematic due to biomechanical differential movement of the implant and tooth. Teeth show greater movement (in all directions) than implants, however, implants still possess some movement due to the elasticity of the surrounding bone. The superstructure itself also demonstrates a degree of movement (i.e. flexure of the metal in the FPD and movement of the abutment-to-implant interface). Provided the natural tooth used as an abutment does not demonstrate any clinical mobility, any tooth movement on loading can be accommodated by the movement of the implant and dental prosthesis [237].

Intrusion of the natural abutment tooth has been reported in FPDs rigidly connecting a natural tooth and an implant [238, 239]. The pathogenesis of this is likely multifactorial; with suggested causative factors including disuse atrophy, debris impaction, impaired rebound memory, and mechanical binding [240]. Despite these reports, extensive documentation exists supporting the rigid connection of implants to stable teeth [241, 242]. One author advises that the last tooth connected in the splint should not be

mobile and that terminal abutments in the splint should not have poor retention form [237]. Furthermore, lateral forces should be avoided in FPDs connecting an anterior tooth with posterior implant; anterior teeth demonstrate significant lateral movement that will be transferred to the implant, resulting in crestal overload and bone loss. Use of a natural tooth in the dental prosthesis should be avoided whenever possible. The tooth-to-implant FPD requires cementation, at least over the natural tooth, hence losing the advantage of easy retrievability. As is the case with conventional FPDs, the natural abutment tooth is still at risk of biological complications such as dental caries, endodontic involvement, and periodontal disease, all of which can compromise the prognosis of the FPD.

Numerous biological and biomechanical challenges are associated with the prosthetic rehabilitation of the KCI mandibular situation. Even though loss of posterior teeth will result in reduced masticatory performance, strong evidence supports the view that not all missing posterior teeth need replacement in order for individuals to adapt to and maintain acceptable function. Masticatory performance in situations of extensive SDA will benefit from prosthetic treatment. Implant-supported restorations are the preferred option in these situations; however, this may not always be possible. CFPD are of limited use in extensive SDA, whilst CRPDs offer an economical and relatively non-invasive treatment modality. Treatment with CRPDs must include a proper design, high standards of oral hygiene, and regular review and maintenance. The reported acceptance of the mandibular KCI RPD, especially if anterior teeth are not included in the dental prosthesis, is relatively low.

2.5 The Shortened Dental Arch (SDA) Concept

Prosthetic dentistry has traditionally focused on preserving a full complement of teeth, since this was deemed a prerequisite for the maintenance of a healthy masticatory system and satisfactory oral function [243]. The potential anatomical and functional consequences of tooth loss lend further support or justification for this 'morphologically-based' treatment philosophy of saving or replacing as many teeth as technically possible [160]. Teeth are a key component of the masticatory system and play a central role in the physiological process of mastication [148]. This process involves food being selected and positioned between opposing occlusal surfaces whereby the forces generated by the muscles of mastication can be imparted into the food. Molar teeth are specially adapted for chewing; loss of such posterior teeth will result in a reduction of the full potential of mastication [142, 244].

Since the posterior dentition consists of 20 teeth (assuming third molars are included for consideration), a range of posterior tooth loss patterns can exist. In terms of extremes, one situation will involve the loss of a single posterior tooth, whilst the other situation will see all posterior teeth missing (i.e., all premolar and all molar teeth). A fundamental problem in prosthetic dentistry is the decision on how many teeth should be saved or replaced in order to ensure satisfactory function, a phenomenon that seems to vary from individual to individual based on local and systemic factors [149, 150, 245]. Three particular measures have been used to assess the impact of tooth loss on oral function. The first measure is based simply on the number of missing teeth. The second measure is based on the number of remaining (or missing) occluding pairs or occlusal units, with an occlusal unit defined as a pair of opposing (i.e., antagonistic) teeth. This measure may be of more relevance, since occluding units are required for mastication. A pair of occluding premolar teeth equate to one occlusal unit, whilst a pair of occluding molar teeth are equivalent to two occlusal units. An occlusion with opposing arches each consisting of four functional premolars and four functional molars would account for 12 occlusal units [149]. An unopposed tooth is essentially a non-functional unit. The third measure is an extension of the previous measure by considering the occlusal contact area available for mastication [246].

Loss of a tooth (or teeth) does not always elicit active efforts for replacement. This has in fact been happening for a long time, but not as a formally framed treatment concept with supportive clinical evaluation [245]. To accept this as an evidence-based treatment

option, it is necessary to demonstrate through thorough clinical assessments that partial posterior edentulism allows for acceptable oral function and patient satisfaction without any deleterious pathological consequences. Occlusion can now be viewed from a physiological and functional basis rather than the traditional morphological (anatomical) approach [145]. A physiological and functional approach accepts that the stomatognathic system demonstrates a level of adaptability, such that it is possible for a variety of forms of occlusions to exist that are compatible with health and satisfactory oral function [145, 149]. In addition to adaptive capacity, the consumption of softer and more processed foods has further reduced the demands on occlusion. Acceptance of this philosophy therefore questions the need for rehabilitating partial edentulous situations back to 28 teeth [149]. There must be however, a 'minimum threshold' for the number of teeth below which oral function and health diminishes rapidly [247], signifying the point at which an individual's adaptive capacity is exceeded.

Chewing (masticatory performance) tests indicate that loss of molar teeth has a negative impact on objective chewing performance [142, 248, 249]. This is directly related to a reduction in number of functional occlusal units and associated reduction of available chewing platform area. The impact of this reduced objective masticatory performance on food selection appears inconclusive, and furthermore, the impact of any such changes on nutrition and general health is not clear [145]. It appears that only severe dental disability (i.e. extreme SDA situations) will have an influence on food selection [151, 249]. Based on reports of subjective chewing ability, a minimum of 20 'well-distributed' teeth can offer satisfactory, albeit slightly impaired, masticatory ability [147]. Both objective and subjective measures must be considered when assessing the impact of tooth loss on oral function.

During the period spanning the late 1970s through to the late 1990s, Käyser and fellow researchers from The Netherlands conducted comprehensive epidemiological and clinical investigations into the SDA treatment concept [142, 147-159, 161, 250, 251]. The SDA is a specific type of dentition with a reduced number of posterior teeth. Of particular focus were topics associating the SDA with oral function, occlusal stability, periodontal health, craniomandibular disorders, comfort, and patient satisfaction. Most of these studies were cross-sectional in nature, with some longitudinal studies also contributing valuable information. Further contemporary research has added to the evidence-base supporting the application of the SDA [164-168].

Occlusal Function

Based on his earlier works utilising both objective and subjective measures, Käyser concluded that sufficient adaptive capacity exists to maintain adequate oral function in SDAs when at least four occlusal units remain, preferably in a symmetrical position [142]. The turning point at which subjects started to complain about their masticatory function occurred when the number of occlusal units was less than four in symmetrically shortened SDAs and less than six in asymmetrically shortened SDAs. This suggests that the distribution of the occlusal units is an important consideration in determining treatment need on a subjective basis. This study identified two patterns of change of oral function in subjects with SDAs; a) oral functions that change slowly until four occlusal units remain after which they change rapidly, and b) oral functions that change progressively without a sudden change.

A review of the literature investigating SDAs and masticatory ability concluded that masticatory ability is generally sufficient as long as 20 or more 'well-distributed' teeth remain. Furthermore, the relationship between masticatory performance (an objective measure) and masticatory platform area is linear. Interestingly, the review concluded that only severe dental impairments will influence food selection [151]. Another study assessing subjective chewing ability and SDAs concluded that those subjects with intact premolar regions and at least one occluding pair of molars reported sufficient chewing ability. Subjects with three to four pairs of occluding premolars and asymmetric arches with a long side reported an impairment of chewing ability (especially for hard foods). Chewing function was reported to be severely impaired in subjects with extreme SDAs (i.e., zero to two occluding premolars) [166].

An interview-based study examining subjective experience of mastication in subjects with second premolar-to-second premolar occlusion (i.e. four occlusal units) reported that their chewing function, food perception, food selection and actual food consumption was hindered but within an acceptable degree [148]. Based on these studies, it appears that at least four occluding premolar units are required to ensure sufficient, yet sub-optimal, chewing function. Adding a molar occlusal unit will most likely improve function, however it is not clear if the degree of improvement justifies the effort (i.e. this may amount to overtreatment) [245].

Occlusal Stability

Loss of posterior teeth results in loss of posterior support and can potentially place the remaining teeth at risk of occlusal disturbances including tooth migration, change in the number of occlusal contacts between the anterior teeth, interdental spacing, occlusal tooth wear, changes in overbite, and changes in alveolar bone support. The term 'occlusal stability' has been used to consider these potential changes and is defined as the stability of the position of teeth in their spatial relationship in the occluding dental arches [164]. A controlled cross-sectional study reported more spacing for the SDA group relative to subjects with complete dental arches, particularly for those aged less than 40 years. However, the spacing recorded was not necessarily large and within values that also occurred in the control groups. There was a tendency for the lower teeth in the SDA group to show spacing. Other findings were that subjects with SDAs demonstrated more anterior contacts when occluding in intercuspal position, no significant differences in overbite, and no increase of wear as the number of teeth decrease. The general conclusion of this study was that migration of teeth does occur, but within an acceptable level [152]. Similar findings and conclusions have been supported by longitudinal clinical studies. They report that tooth migration and occlusal changes occur early after tooth loss, after which a new occlusal equilibrium is achieved. The occlusal changes are self-limiting and can provide long-term occlusal stability, although the risk to occlusal stability appears higher in extremely shortened dental arches [155, 156, 164, 165].

Temperomandibular disorders and Orofacial Pain

There is concern that loss of posterior support can cause mandibular overclosure, altered position of the condyles, and pathological changes of the temporomandibular joint (mechanical displacement theory) [167, 252, 253]. Furthermore, missing posterior teeth requires subjects to chew with anterior teeth and/or unilaterally which alters the loading dynamics of the TMJs. It is accepted that morphological changes do occur in the TMJ following the absence of the molar teeth [254-257]. Despite these reported changes, the relation between the absence of posterior support and the signs and symptoms of mandibular dysfunction is not conclusive [153, 258-260]. This issue was further investigated in a cross-sectional controlled study that compared SDAs (absence of molar support) and dentate subjects (control group) with respect to objective and subjective signs and symptoms of mandibular dysfunction (i.e., pain, TMJ noises, and mobility of the mandible). It was concluded that significant differences, with respect to signs and symptoms, were not found between the two groups. The presence of bilateral

premolar support seems to provide sufficient mandibular stability. The only exception was reported light or infrequent pain in or around the TMJ in SDA subjects less than 40 years of age [153]. The low prevalence of signs and symptoms associated with TMD was also proven in the adult population of Tanzania. Furthermore, it was suggested that only the complete absence of posterior occlusal support unilaterally or bilaterally appears to increase the risk for developing signs and symptoms associated with TMD [167]. A six-year follow-up study supported the findings of these cross-sectional studies, reporting that a SDA consisting of three to five occlusal units is not a risk factor for caniomandibular dysfunction [156].

Periodontal support

There is concern that the remaining teeth may receive greater loading after loss of posterior teeth. It has been reported that the bite force and periodontally borne load (i.e. averaged bite force divided by the normal root surface area) is greatest on the most posterior tooth in an arch [261]. Such loading could potentially injure the periodontal structures if the loads exceed the physiological adaptive capacity of these structures (i.e., trauma from occlusion). Trauma from occlusion can result in tooth mobility due to widening of the periodontal ligament (not attachment loss) and in itself is not an aetiological factor for plaque-induced periodontitis; however, it is not clear what role trauma from occlusion has on the progression of periodontal disease (i.e. it may possibly accelerate bone loss during active periodontitis) [262-264]. The adaptive capacity of these structures may be compromised by previous episodes of periodontal bone loss. The issue of the SDA and periodontal support has been investigated [154, 155]. Chronic periodontal disease has a chronological pathogenesis; what is seen clinically at a point in time represents the consequences of disease up to that point, yet the disease process itself could be in an inactive phase or even resolved. Therefore, cross-sectional studies limit the ability to project changes over time. Nevertheless, a controlled cross-sectional study concluded that subjects with SDA have more mobile teeth and lower alveolar bone scores than control subjects. Furthermore, the combination of increased loading and existing periodontal involvement appears to represent a potential risk factor for loss of teeth. Also highlighted was the fact that confounding variables, such as dental history and previous restorative treatments, can make interpretation of the results somewhat difficult and that longitudinal data would be necessary to confirm these conclusions [154]. Over a six-year follow-up period, it was concluded that the decrease in bone scores in the SDA group is the same as that in the complete dental arches (control) group. However, it was also reported that SDA with periodontally involved teeth show

continuing periodontal breakdown. It appears that the combination of existing periodontal disease and increased occlusal loading is a potential risk factor for further tooth loss [155]. Adequate oral hygiene and maintenance is essential in the SDA situation as to avoid any further deterioration of periodontal tissues and further tooth loss. If adequately maintained, any bone changes should be similar to that seen in completely dentate patients.

Aesthetics

The demand for replacement of missing teeth is related to the position of the missing teeth. From an aesthetic perspective, a SDA in the lower jaw does not appear to raise any appreciable problems. In the upper jaw, shortening of the arch until the second premolar might result in a negative but acceptable situation; however, loss of the first and/or second premolar teeth will often result in an aesthetic concern that acts as motivation for replacement [142]. Individuals appear to be more concerned about missing anterior teeth, and as a consequence, will show greater motivation in having anterior rather than posterior teeth replaced. Aesthetics is a more important motivator for tooth replacement than function. However, certain socio-demographic factors such as age and culture can change the subjective need for replacement of missing teeth [246].

Longitudinal studies

In addition to the findings of the six-year longitudinal follow-up study conducted at the School of Dentistry in Nijmegen, The Netherlands, as reported above [155, 156], some other longitudinal studies have added to our understanding of the SDA situation. A multi-centre randomised controlled SDA study investigating tooth loss over five years found that there were no significant differences in tooth loss between patients treated with SDA and those treated with SDA and CRPD. However, they noted that tooth loss was more frequent than expected and that more than 60% of tooth losses in the study jaw affected the posterior-most teeth, suggesting that these teeth might be at a particular risk in SDAs. There was no difference in tooth loss between the two study groups. This suggests that the presence of an CRPD will not have an adverse impact on tooth loss, hence the SDA versus CRPD treatment decision should be based on other factors [265]. An observational cohort study on SDAs assessing the clinical course over a period of 27 to 35 years reported that SDAs can last for 27 years and over and seems to be a relevant and cost-effective treatment approach. This study also investigated use of CRPDs in SDA situations and concluded that the clinical course in SDA plus CRPD is

unfavourable, especially when CRPD-related interventions are taken into account. However, similar to the previous mentioned study, no statistically significant difference in tooth loss (extractions) was identified between the two groups. The use of CRPDs was not recommended, although this recommendation appears to be made on a cost consideration basis rather than on concerns for increased risk of tooth loss [168].

Satisfaction and Comfort

It is recognised that patient satisfaction plays an important role in determining treatment outcome and treatment success. Patient satisfaction is largely a subjective measure that is influenced by many variables. Questionnaires and interviews are commonly used to evaluate patient satisfaction. Oral comfort is a composite measure that has been employed to gauge patient satisfaction with the SDA situation. Oral comfort has been defined as: a) absence of pain or discomfort of the stomatognathic system, b) satisfactory masticatory ability (i.e., normal eating habits without needing to change food selection or food preparation), and c) acceptable aesthetics. As with the other parameters assessed, it has been similarly concluded that SDA situations consisting of between three to five occlusal units appears to provide sufficient comfort. A small number of SDA patients may have aesthetic concerns if the second premolar or first molar teeth are missing [147]. As reported in a six-year follow-up study, oral comfort appears compatible with this type of SDA situation and over time [156].

The Oral Health Impact Profile (OHIP) and the short form version (OHIP-14) are validated questionnaires that are commonly used in studies to measure adverse impacts of oral conditions on daily life [247, 266-269]. A study comparing two national samples (UK and Australia) reported that age, the number of teeth, and cultural background are important variables that can influence OHRQoL. In this study, subjects in all populations and subpopulations with complete or almost complete natural teeth were associated with the best OHRQoL [247]. Younger SDA patients (30-49 years of age in Australia and less than 30 years of age in the UK) demonstrated the worst OHIP scores. When corrected for age, the independent effect of tooth loss resulted in worse scores in situations of fewer that 17 natural teeth in the UK and fewer than 21 teeth in Australia. This study also demonstrated that the impact of oral health problems on quality of life reduces with increasing age, which is independent from the effect of tooth loss; age and tooth loss are closely associated but have independent effects on OHRQoL. Based on these findings, dental rehabilitation should be of greater consideration in younger SDA patients and, when considering Australian subjects, when less than 21 teeth are present.

Although this study confirms that the number of remaining natural teeth plays a central role in determining subjective oral health, it does not discuss the distribution of the remaining/missing teeth. Additional studies support the findings that missing occlusal units are related to impairment of OHRQoL in subjects with SDA [10, 251, 270].

Dentist awareness and attitudes towards the SDA

Several studies have demonstrated a sizeable discrepancy between professionally assessed treatment need and subjective treatment demand, particularly in the elderly [271-274]. It has been postulated that this phenomenon is largely responsible for the low acceptance of the distal-extension CRPD, a likely consequence of lower subjective patient treatment demand relative to the professional's judgement of treatment need [149]. The attitude of dentists to the SDA concept is of importance, since this will influence when and how this treatment option is presented to patients. Research assessing dentist awareness and attitudes to the SDA concept and its application in clinical practice has been conducted in a number of countries. A questionnaire was completed by sixty-four staff members from the field of restorative dentistry at the Nijmegen School of Dentistry. General conclusions arising from this study were that most members of staff were aware of the SDA concept and contended that it has a useful place in clinical practice. However, they only applied this concept on a regular or at least occasional basis to less than 10% of the patients attending their practices, despite the fact that they judge the outcome of the SDA treatment concept to be generally satisfactory or at least sufficient [157].

Another questionnaire-based study, this time assessing the views of ninety-one consultants in restorative dentistry in the United Kingdom similarly concluded that the SDA is widely accepted but not widely practiced, even though this treatment concept was reported to offer acceptable outcomes in approximately 82% of cases [158]. Based on another survey of dentists in the United Kingdom, it was reported that the CRPD was the most popular treatment option among the different treatment options for managing the SDA [275]. In a study assessing the attitudes of dentists in Tanzania, 89% of dentists indicated that the SDA concept has a useful place in clinical practice. Despite this positive attitude, 89% of dentists also reported that they inserted free-end acrylic partial dentures in these cases [276]. Swedish general dentists have also reported a positive opinion toward the SDA concept with respect to oral function and oral comfort. Furthermore, Swedish private practitioners expressed fewer advantages in using the SDA concept compared to practitioners employed by the Public Dental Health Service in

terms of reduced risk of overtreatment, better patient economy, and the ability for older patients to keep their teeth [277]. This latter observation may have some basis in the fact that many public health systems work within a context of finite resources. One of the key advantages of the SDA concept lies in its cost effectiveness and suitability for public health care.

A study of 175 randomly selected rural and metropolitan dentists from Victoria, Australia, reported an awareness rate of the SDA concept of 61%. No significant difference of awareness was found between dentists in rural and metropolitan locations. The overall level of awareness is surprisingly low. This study concluded that most dentists (irrespective of whether they were originally unaware of the SDA concept) agreed that the SDA is a practical and useful treatment modality for older adults with limitations to complex restorative care. However, it was also emphasised that the application of the SDA concept varied considerably among dentists [278]. Despite awareness and understanding of the merits of the SDA, the frequency of application varies considerably.

The role of CRPDs in restoring SDAs was discussed in section 2.4 of this review. In summary, the role of the CRPD to manage SDAs is controversial. CRPDs may improve oral function, however, it is not clear if this improvement is significant enough to overcome some of the major issues with distal extension dental prostheses [213]. The wearing of CRPDs may exacerbate existing oral conditions unless adequate maintenance practices are followed and be uncomfortable to wear [187, 246, 279]. The success rates of lower CRPDs to manage SDAs are relatively low on the basis of low acceptance and wearing of the dental prostheses. Fixed options are often preferred, however CFPDs are limited by the extent of the cantilever, and implant-supported fixed partial dentures involve surgical intervention and higher initial costs.

The SDA treatment concept has been endorsed by a number of clinical studies as already discussed. This treatment concept assumes that an occlusion can adapt to a 'less than full' complement of teeth. It appears that the threshold of this adaptive capacity is in the vicinity of 20 'well-distributed' teeth (i.e., second premolar-to-second premolar occlusion or four functional occlusal units). Efforts should therefore be directed at maintaining as many natural teeth as possible and restoring the strategic parts of the dentition, namely the anterior and premolar segments. This form of management can be described as a 'problem-orientated' approach, and gives direction to the appropriate

allocation of finite resources [250]. Treatment goals can be limited but still satisfy a patient's expectations and aspirations [159]. The SDA treatment concept supports the ultimate objective of dental care which is the maintenance of a healthy functional dentition for life [160]. The other benefits of this treatment concept include; cost effectiveness, less interventions, and the ability for patients to focus on maintaining the existing dentition [149].

However, it is important to appreciate that the SDA treatment concept will result in sub-optimal function and some early occlusal changes. Loss of upper premolars may also have an aesthetic impact. Furthermore, a lot of the referenced literature in this section is derived from public sector dentistry with patient bias for positive results; limited (scarce) resources make the feasibility of restoring all missing posterior teeth in a population challenging. It is important that each individual be assessed on his or her own clinical situation and presented with the benefits and drawbacks of the SDA treatment concept. The success of treatment is not based solely on objective grounds. Only after thorough clinical assessment and in-depth discussions to uncover patient concerns can the appropriate treatment plan be developed, presented, and agreed upon. Based on the available evidence, the SDA treatment concept appears to be a sensible treatment option for SDA situations, however some patients may still benefit and/or seek replacement of molar teeth.

2.6 Association of dental implants with mandibular KCI removable partial dentures: A review of current concepts and clinical evidence

Absence of an abutment tooth at the distal of an edentulous space limits the treatment options available for managing the free-end situation. In more recent times implant therapy has increased the range of available options, however, use of implants is not always possible or feasible [280-283]. Due to simplicity and cost effectiveness (i.e., relative to implant therapy), the CRPD still remains a commonly used treatment option for the management of mandibular KCI situations [196, 284-288]. As discussed in section 2.5, the mandibular KCI CRPD is susceptible to a range of issues including lack of stability, discomfort, minimal retention, questionable impact on mastication, unaesthetic clasping, and relatively low acceptance [24, 33, 285, 286, 289-292]. Many of these issues have their basis on the fact that the free-end denture base derives support from multiple tissues that differ in compressibility and response to loading. Support for each denture base is derived from a natural tooth (at the mesial end of the edentulous space), soft tissues, and the underlying residual ridge [32, 281, 293, 294]. Mucosa is more resilient than the PDL of a healthy abutment tooth; a difference in compressibility of as much as 13:1 has been reported [295, 296]. Such a scenario results in the free-end denture bases compressing the underlying mucosa when vertically loaded. Since the mesial abutment teeth, via the periodontal ligament, do not move apically to the same amount as the mucosa compresses, the denture bases rotate about a fulcrum line. This fulcrum line passes through the most distal-positioned rest on the abutment tooth on each side of the arch according to lever-arm mechanics. The most distal rest may be located on the mesial aspect of the abutment tooth (e.g., RPI system). Despite incorporation of framework design features aimed at resisting this tendency for rotation, ongoing changes to the underlying ridges cannot totally eliminate this tendency [297].

The strategic use of implants in association with a CRPD is an approach that has been proposed to try and address the shortcomings of the CRPD [32, 105, 298-302]. The rationale for placing a single implant under each distal extension in the mandibular KCI situation includes:

- Improving the biomechanical behaviour of the RPD from a KCI situation (tooth- and tissue-supported) to that of a KCIII situation (tooth- and implant-supported) [303, 304]. The latter situation arises as a result of an additional firm support structure being situated under each distal-extension, thereby limiting the tissue-

ward movement (intrusion) of the denture bases and improving the stability of the dental prosthesis [293, 295, 305-308].

- More efficient distribution of masticatory forces along the CRPD and remaining teeth [280]. The improved support can result in higher bite force generation [306, 309, 310].
- Support from a distally placed implant will effectively reduce the length of the cantilever of the distal extension bases. This will reduce the tendency for rotation (lever movement) of the denture [311].
- Maintenance of the residual alveolar ridge through load-related stimulation of bone (via the implant) and a reduction of pressure exerted on the ridges by the denture bases [30, 282, 312-315].
- The use of attachment mechanisms to assist with denture retention, potentially eliminating the need for unaesthetic clasping [30, 280, 306, 312, 316].
- The extensions of the denture bases can be reduced since greater support will be provided by the implants and less support required from the soft tissues [289].
- The possibility of using narrower and/or shorter implants since loads applied to the denture can be shared between teeth, mucosa (and underling residual ridge), and implant; especially in situations when only vertical support is provided with freedom of action permitted in the horizontal plane [30]. The use of narrow and/or short implants will provide more opportunity to find suitable site(s) for implant placement.
- Offering a more cost-effective treatment option for partially edentulous patients that would benefit from the inclusion of implant therapy as part of their treatment plan [31, 32, 317].
- Improved patient satisfaction when compared to the previous clasp-retained CRPD [307].
- Because the dental prosthesis is removable, plaque control of the denture and fixed units (teeth and implants) is simplified [283].

The concept of associating dental implants with RPDs is not new, with literature dating back to the 1970's discussing this [318]. Most of the literature discussing this concept is of relatively low evidence levels, comprising largely of case reports and case series [30-32, 283, 291, 293, 298-300, 307, 312, 318-321]. There is little scientific evidence documenting the effect of IRRPDs on oral health [285]. The general consensus of this body of literature is:

- The stability and retention of the dental prosthesis (i.e., the biomechanics) is improved by associating dental implants with RPDs, eliminating many of the problems often associated with a tooth- and tissue-supported distal extension RPD [30-32, 286, 291, 293, 298, 307, 312, 320, 321].
- Stress-breaking (resilient) attachments can assist in evenly distributing the occlusal forces applied to the dental prosthesis to the alveolar ridge and implants [319].
- The implant associated RPD results in an improvement of function [291, 306, 312].
- The implant associated RPD results in increased patient satisfaction [33, 321, 322].
- The implant associated RPD results in increased comfort [30, 306, 312].
- The association of dental implants with RPDs is a suitable option for patients who cannot afford implant-supported fixed dental prostheses. It is a cost-effective treatment option [32, 291, 293, 307].
- Satisfactory aesthetic results can be achieved, particularly when clasping can be eliminated [30, 291, 312, 321].

In order to apply this treatment concept with greater confidence, it's important to obtain higher-level evidence in the form of well-designed clinical trials. Such studies should be of sufficient sample size, duration, and assess outcomes with both objective and subjective measures. Unfortunately, few documented clinical trials exist that examine this treatment option with the necessary vigour. Table 2.2 summarises some of the available studies comprising of clinical studies with at least 10 patients and specifically reporting on the association of implants with the mandibular KCI RPD.

Table 2.2. Clinical studies reporting the association of dental implants with mandibular KCI RPDs.

Year of Study	Type of Study	Patients & implants	Implant Position(s)	Implant Dimensions (width/length)	Implant Survival (& follow-up)	Dental Prosthesis Survival (& follow-up)	Abutment Type(s)	Main Outcomes
Threeburuth et al 2018[323]	RCT	30 patients 60 implants Ages: 64.1±5.56 years Age range 55-75 years	36 and 46 (i.e. first molar sites)	3mm X 10mm (Group 1) 3.75mm X 10mm (Group 2) PW Plus implants PWSE Co. Ltd. (Thailand)	Group 1 - 93.3% **success and survival rates** (12 months) Group 2 - 83.3% **success rate** (93.3% survival) (12 months)	Not disclosed	Equator Attachments: (patrix: low profile titanium abutment, matrix: stainless steel housing, and yellow retentive cap (0.6kg retentive force))	• Avg. radiographic bone loss (1 year) = 0.47 ± 0.42 mm (Group 1) and 1.03 ± 1.07mm (Group 2) • Bone loss significantly higher in Group 2 (wider diameter) • Patient satisfaction higher with IRRPDs than CRPDs (no significant difference between Group 1 and Group 2) • Use of mini implants to retain Md KCI RPDs can improve patient satisfaction significantly, to a similar degree to conventional dental implants. • Immediate-load mini implants can be used to retain Md KCI RPDs successfully, if high primary stability is achieved.
Payne et al 2017[324]	Multicentre prospective evaluation (3 centres)	48 patients (incl. 12 controls) 72 implants Age range across all centres: 46-85 years	First or second molar sites	Straumann RN tissue-level implants: 4.1mm diameter Lengths: 6mm (n = 34) 8mm (n = 17) 10mm (n = 21)	Overall implant survival after: 3 years = 100% 10 years = 92% (up to 10 year observation)	100% (after 10 years in New Zealand group) and 100% (after 3 years) in Netherlands and Columbia groups	Healing abutments (initially) then ball attachments (after 6 months) Patrix: retentive anchors (Straumann code: 048.439) Matrix: Dalla Bona-type gold matrices (Straumann code: 048.410)	• No early implant failures • 6 implants failures (5 patients) occurred between 5 and 10 years • Common issues: wrought wire clasp adjustment, loose healing abutments, need for matrix activation, clasp adjustments, puncture fractures or fracture of acrylic base in area of attachment, no issues with patrix (i.e., ball), minimal relines required • Maintenance events: 41 (NZ – over 10 years), 6 (Netherlands – over 3 years), and 14 (Columbia – over 3 years). • Mean crestal bone levels at baseline were 2.03 ± 0.71mm and after 3 years was 2.20 ± 0.81mm. • Majority of maintenance events during 1st year • Late implant failures and increased prosthodontics maintenance when an attachment system is used identifies the need for further research.
Jensen et al	Retrospective	23	Premolar (8	Not disclosed	No implant loss	3 dentures	Ball	• Mean change in marginal bone level of -0.9mm (SD

2017[288]	Study	patients	patients) Molar (15 patients)		in premolar group. 3 implants lost in molar group. Overall cumulative implant survival rate of 91.7% after 16 years.	were replaced (two at 5.5 years of function, and one at 7 years of function) Mean follow-up of 8 years (range: 3 to 16 years)	Locator™ Healing abutment	1.0mm) was observed over a mean follow-up period of 8 years – no significant difference between premolar and molar groups. • More biological complications with molar implants – peri-implant mucositis (also, lost implants were from molar region) • 65 % (15/23) had no technical complications during 8 years of observation. • In addition to replaced dentures (3), two were converted to overdentures, and one was not being worn (patient decided to function without ISRPD). • Patients were highly satisfied based on VAS scores.
Jensen et al 2016[325]	RCT – crossover design	30 patients 120 implants Mean Age 60.9 years Age Range 43.8-71.0	Premolar and molar	Straumann RN Width/length not disclosed	Not disclosed 14 months from implant placement to completion of observation period	Not disclosed	Low healing abutments and Matrix: Locator™ abutments Patrix: selected nylon cap Patrix: Specifics not provided Randomized crossover	• OHIP-NL49 values and mean wearing time were significantly more favourable for ISRPDs, regardless of implant position. • VAS scores for ISRPD's with molar implant support were higher than for premolar support. • 56.7% of subjects preferred molar implant support, 30% preferred premolar support, and 13.3% expressed no preference. • Patients with Md KCI situation opposed by F/- benefit from implant support to their Md dental prosthesis.
Campos et al 2015[326]	Prospective Clinical Trial	12 patients 24 implants Mean age 62.6±7,8 years	First molar	Neodent implants Diameters and lengths not disclosed	Not disclosed	Not disclosed Minimum of 8 months observation from time of insert of conventional RPD	Patrix: Ball abutment (BA; Neodent) Matrix: Capsule (but no further specifics provided)	• Improvement in all OHIP-49 domains after associating implants to the RPD. • The Md KCI ISRPD significantly improved OHRQoL.
Mahrous et al. 2015[327]	Comparative Clinical Study	20 patients Age range	First or Second molars	Pitt Easy V-TPS implants 3.75 X 10mm	Not disclosed	6, 12, and 18 months observation	Matrix: Locator™ abutment (n = 10)	• The Locator™ group recorded statistically significant lower bone loss than the Ball attachment group at the different intervals of the follow-up period (1.23mm for Locator™ and 2.177mm for ball attachments after 18

		30-60 years					Ball attachments (B&S) – specifics not provided (n = 10)	months). • The side of the ISRPD restored with the Locator™ abutment showed better effect on bone health around both the placed dental implant and main natural abutment as compared to using the Ball attachment.
Goncalves et al 2014[328]	Prospective Clinical Study – Within subject Crossover	12 patients Exact number of implants not disclosed Mean age 62.6±7.8 years	Premolar and molar sites	Diameters: 3.75 to 6mm Lengths: 7 to 13mm	Not disclosed	Not disclosed Minimum of 8 months observation from insert of conventional prosthesis	Healing abutments Patrix: Ball attachments (O-ring, Neodent) Matrix: no specifics provided	• Ball attachment placed in most distal implants, whilst other implants restored with healing abutments. • **This protocol differs in that it is a combination implant-retained and implant-supported dental prosthesis.** • Implant-retained and supported RPDs improve retention and stability, minimise rotational movements, and significantly increase patient satisfaction.
Goncalves et al 2013[310]	Paired Clinical Trial	12 patients 48 implants Mean age 62.6±7.8 years Age range 48-80 years	Premolar and molar sites	Titamax implants (Neodent) Dimensions not specified	Not disclosed	Not disclosed Minimum of 10 months observation from time of insert of conventional denture	Patrix: Ball abutments (O-ring, Neodent) Matrix: no specifics provided	• Comparison of conventional RPD, Implant-supported RPD, and then Implant-fixed dental prosthesis. • **2 implants placed per edentulous segment.** Only posterior implants loaded for Implant-supported dental prosthesis. • Maximum bite force generated by Implant-supported RPD is significantly greater than conventional RPD. • Implant-supported RPD significantly increases chewing capacity compared to conventional RPD. • Implant-fixed dental prosthesis is superior with these two measures.
Wismeijer et al 2013[329]	Prospective Multicentre Clinical Trial	44 patients (incl. 11 controls) 66 implants Mean Ages and	Second molar	Straumann implants Diameter: 4.1mm Lengths not disclosed	Not disclosed	Not disclosed 3 years observation	Patrix: Ball attachments Matrix: Dalla Bona original type	• Patients who were originally dissatisfied with existing RPD. • Patients with KCI Md IARPDs opposing a F/- will be more satisfied with distally placed Straumann implants having attachment systems placed for support and retention, compared to a simpler approach of leaving healing caps for support only. • In comparison to conventional RPDs, there is improvement in stability, subjective chewing ability and

		ranges: Control 71.0 (53-85 years) NZ group 63.3 years (42-46)* Columbia 54.8 (43-74 years) NL 57.8 (47-71 years)						overall patient satisfaction with Md IARPDs.
El Mekawy et al 2012[294]	Prospective Multicentre Clinical Trial	20 patients 40 implants Age range 35-45 years	Not disclosed	Diameter - 3.75 mm Length - 11.5 mm	95% cumulative success rate after 24 months.	Not disclosed 24 months observation	Healing Abutments – specific details not provided	• Intracoronal Md KCI RPDs. • 2 implant failures in the same patient. • Mean bone loss of 0.4 ± 0.24 mm at 24 months. • Within the limitations of the observation period and sample size, and from a peri-implant tissue health point of view, Md KCI ISRPDs can be a successful treatment modality for the rehabilitation of patients with Md bilateral posterior edentulism.
Elsyad and Habib 2011[330]	Retrospective Study	34 patients 68 implants Age range 44-61 years	First Molar	Diameters: 3.6mm, 4.2mm and 5.0mm Lengths: 8mm, 10mm, 11.5mm, and 13mm	Not disclosed	Not disclosed 5 year observation period	Healing abutment (Group 1) Patrix: Ball abutment Matrix: Gold smart matrix Dyna Dental Engineering (Group 2)	• Comparing radiographic changes between ISRPD and IRRPD Md partial overdentures (5 year review). • ISRPDs associated with reduced posterior mandibular ridge resorption than IRRPDs; mean ridge height reductions at the end of a 5-yr observation period were 0.15 and 1.03mm, respectively.

Avg. = average, CRPD = conventional removable partial denture, F/- = maxillary complete removable denture, IARPD = implant-assisted removable partial denture, IRRPD = implant-retained removable partial denture, ISRPD = implant-supported removable partial denture, KCI = Kennedy Class I, n = number, NL = The Netherlands, NZ = New Zealand, OHIP-49 = oral health impact profile (49 question version), OHIP-NL49 = oral health impact profile (Netherlands, 49 question version), OHRQoL = oral-health related quality of life, SD = standard deviation, VAS = visual analogue scale, * - the study reports age range of 42-46 years for the control group; however, must be an error since the mean age for this group is 63.3 years

Although the concept of associating dental implants with RPDs may appear straightforward, especially when converting an existing RPD to accommodate the implants, a number of variables and outcomes must be considered. These variables/outcomes include implant length and diameter, implant position within the distal extension space, implant survival/success when associated with an RPD, nature of the attachment between the implant and RPD (support only or support and retention), attachment types, prosthetic design/maintenance/complications, and clinical and patient subjective outcomes (i.e., effect on chewing function and patient satisfaction). Each of these topics will be discussed with reference to the studies summarised in Table 2.2. Some clinical studies were excluded from the Table 2.2 because they also focus on the maxillary situation and/or include other Kennedy Classes making extraction of the data specifically relating to the mandibular KCI situation problematic. Where appropriate, comments from these studies and other relevant literature are included to add depth to discussion.

Implant Length and Diameter

The identified clinical articles provide inconsistent information about the length(s) and diameter(s) of implants used, with few specifically addressing or discussing the rationale for size selection and the impact of these parameters on the treatment outcomes. A range of implant lengths is used (i.e., 6 to 13mm) mostly with diameters ranging from 3.75mm to 5mm. The rationale for selecting these dimensions is not discussed in any detail; it appears that the philosophy of using the longest and widest implant that is appropriate for the available bone volume is usually followed [322]. Only a few studies place some emphasis on implant diameter and/or length. A randomized clinical trial compared the outcomes between mandibular KCI CRPDs supported by immediate-placed mini-implants (3.5 mm diameter) and conventional-sized implants (3.75 mm diameter) of standard length (10mm). The survival and success rates after 12 months of follow-up was 93.3% for the 3mm diameter group. The success rate for the 3.75mm diameter implants after the same period of observation was 83.3% and the same survival rate of 93.3%. Furthermore, the 3mm diameter implants demonstrated significantly less radiographic bone loss than the 3.75mm implants and higher success and survival rates. The main conclusions of this study was that patient satisfaction was higher with IRRPDs than CRPDs (not influenced by implant diameter) and that immediate loaded mini implants can be used to retain mandibular KCI RPDs successfully provided that high primary stability is achieved [323]. A multicentre study that

included 6 mm length implants (n = 34) and used both implant support only (i.e. healing abutments) and implant support and retention (i.e. ball attachments) reported an implant survival rate of 100% after three years; this dropped to 92% after ten years with six failures occurring between years five and ten of follow-up [324]. Apart from these two studies, little additional information can be retrieved from the remaining studies in Table 2.2 specifically relating treatment outcomes to implant length and/or diameter.

One prospective clinical trial that was excluded from Table 2.2 because of the inclusion of KCII situations employed 4mm diameter and 6mm length implants. This study reported an implant survival rate of 97% after two years (one early implant failure from thirty implants placed) and only minor prosthetic complications most of which could be managed in a single visit. The study concluded that patients reported improved oral health following conversion of a CRPD to an ISRPD, and that the use of short implants is a treatment option that should be considered when treatment planning patients with distal-extension situations [285]. Additional studies, also excluded from Table 2.2 because of the inclusion of implants associated with other Kennedy Classes and/or upper arch, reported implant survival rates over 90% [33, 286, 308].

It has been proposed that the loading dynamics on implants associated with RPDs using resilient attachments is less demanding than that on implants supporting fixed restorations [281]. Studies involving CRPDs and implant-retained mandibular overdentures report that resilient (stress-breaking) attachments permit a degree of movement of the denture base with loading forces being resisted by the implant(s), abutment teeth, and the soft tissues underlying the distal extension bases [331-334]. Sharing of these forces reduces the overall load (stress) that needs to be resisted by any of these structures on their own. Furthermore, freedom of movement in the horizontal direction (i.e., when healing abutment is used solely as a vertical stop) will also reduce the demands on the implant. As a consequence, it may be possible for shorter and/or narrower implants to be successfully used with this treatment protocol [30, 309]. The possibility of using shorter and/or narrower implants in this treatment protocol has the potential of making this treatment option suitable for a larger proportion of the population (i.e., those patients with narrow and/or short distal ridges), with the benefits of making treatment simpler, less invasive, and obviating the need for complex, costly, and prolonged bone augmentation procedures. Despite the encouraging survival rates referenced in the previous paragraphs, it must be emphasised that only a limited

number of studies have reported on this and that more research is required to validate these treatment protocols.

Implant Position

Placing the implant as distal as possible in the edentulous space will offer the best biomechanical setting for supporting and stabilising the denture extension bases [289, 335]. Placing the implants in the sites previously occupied by the second molar teeth is commonly reported [286, 306, 336]. Such a scenario will ensure minimal cantilever extension and that the dental prosthesis behaves similar to a tooth bounded (KCIII) dental prosthesis. However, patient anatomy may not allow for the safe placement of an implant in the second molar region [295, 304, 335, 337]. One theoretical study concluded that the effect of implant support was not consistent but varied with the location of implant, with the lowest bending moments occurring when implants are placed in the second molar position (and hence eliminating the free-end segment of the base) [338]. An *in vitro* study employing piezoelectric force transducers and a unilateral distal extension model concluded that a more distally placed implant (second molar site) might be more effective for reducing damage to the abutment tooth or implant and the surrounding tissues [337].

There is some evidence, largely from *in vitro* studies employing FEA, suggesting that placement of implants in the first molar region may be advantageous in terms of improving the biomechanical behaviour of IARPDs whilst reducing maximum stress values at the peri-implant bone area, metal structure, implant, and remaining teeth [280, 303, 335]. The first molar region is also the region where maximum occlusal forces are exerted during maximum contraction of the jaw elevator musculature, and this may also make this site appropriate for implant support [339]. An FEA study using five hemi-arch models reported that an implant placed in the first molar region resulted in the lowest tendency for denture displacement, whilst an implant placed in the second premolar position demonstrated better relief with regard to demands on the abutment tooth; placing the implant closer to the abutment tooth positively (favourably) influenced the distribution of stresses on the support structures [295]. Although FEA provides valuable scientific information about stress distributions using mathematical modelling, it needs to be viewed within the context that it is based on numerous assumptions and is dependent on the accuracy of the input data; FEA studies have some inherent limitations in predicting actual biomechanical behaviour and this needs to be taken into account

when interpreting the results [280, 305, 340]. Three-dimensional FEA may provide superior information when compared to two-dimensional FEA, however, developing reliable three-dimensional models of the complex anatomical structures of the lower jaw requires use of tomography images with excellent resolution and the need for manipulation of the CT images through a series of specific software programs [341]. Despite certain limitations, information derived from suitably conducted two-dimensional FEA studies can still generate useful results and they do encourage further studies to be carried out in order to prove *in vivo* the results observed *in vitro* [281, 341].

It appears that a more mesial positioned implant (i.e., first or second premolar position) can still ensure appropriate support and retention to the dental prosthesis whilst being less detrimental to the health of the natural abutment teeth [282, 295, 304]. Even though a cantilever situation will still persist, a more mesial placed implant will still assist in reducing the overall length of cantilever of the distal-extension base relative to the CRPD situation. A more mesial positioned attachment system may also negate the need for unaesthetic clasping of canine and premolar teeth. A two-dimensional FEA study not only compared the outcomes of implants placed in the second premolar site versus implants placed in the second molar site, but it also took into account different ridge shapes in the sagittal plane. Four ridge shapes were described and assessed: horizontal, distally ascending, distally descending, and descending/ascending (concave). The conclusion of this analysis was that implant association benefited all ridge shapes, however the distally descending ridge situation benefited most by the association with implants (in terms of relieving supporting structures). Furthermore, it was concluded that the association of the implant in a more anterior site (i.e. second premolar) together with an ERA attachment (the attachment used in the study) and a distal guide plate (with no rest) was the most suitable situation regardless of ridge type [311].

Of the clinical studies referenced in Table 2.2, it can be seen that there is no one preferred site for implant placement. Some studies limit the placement to the first molar site [323, 326, 330], some to the second molar site [329], some to either first or second molar site [324, 327], and some studies describe placement of implants in both premolar and molar sites [288, 325]. A retrospective study reported significantly more biological complications with molar implants (i.e., peri-implant mucositis) than premolar implants over a mean follow-up period of eight years; the implants lost in this study were all from the molar region (three implant failures in total with one early

failure, one failure at three years of function, and another failure at six years of function). The cause given for late failures was peri-implantitis [288]. A randomised clinical trial employing a crossover design saw implants placed in both premolar and molar regions. Healing abutments and Locator™ abutments were used as support and retentive elements. These support and retentive elements were randomly placed in either the premolar or molar sites (e.g., healing abutments at premolar sites and Locator™ attachments at molar sites). After three months of adaptation and testing, this configuration was reversed (e.g., Locator™ attachments at premolar sites and healing abutment at molar sites). The opposing arch consisted of a conventional removable complete denture. Higher satisfaction and mean dental prosthesis wearing time was observed with the Locator™ attachment at either position, higher VAS scores were recorded for molar implant support, and 56.7% of subjects preferred molar support (compared with 30% for premolar support and 13.3% undecided) [325]. Based on the methodology of this study, it's highly likely that the denture base also received some degree of support from the healing abutment, so this may have also contributed to the overall improvement in performance of the dental prosthesis.

A crossover trial also looking at differences between a CRPD and an IRRPD designs, used a somewhat similar protocol in that implants were placed in both premolar and molar sites. Ball and O-ring attachments were used at the molar sites and healing abutments in the premolar sites. The main conclusions of this trial were that implant-retained and supported RPDs improve retention and stability, minimise rotational movements, and significantly increase patient satisfaction [328]. The protocol used in this study employed both support and retentive elements. The disadvantage of this protocol is that multiple implants were placed in each edentulous area, hence adding to the cost of treatment (although overall cost is likely to still be less than fixed implant-retained dental prostheses). An alternative study also described the placement of premolar and molar implants, however the premolar implants were not loaded during the trial of the IRRPD; the premolar implants were used to retain implant fixed dental prostheses as the trial was a within-subject comparison of CRPD, ISRPD, and implant fixed dental prosthesis [310].

Based on this discussion, it is clear that the optimal implant location along the distal extension space continues to be a source of debate; there is a paucity of evidence-based research concerning this issue [289, 303, 309]. Purely from a biomechanical perspective, fixed partial dentures are best supported with firm pillars supporting each

end of the beam. On the other hand, there is evidence that mesial placed implants may alter the loading dynamics such that less potentially destructive forces act through the mesial abutment teeth. The first molar position may therefore be a suitable compromise. The other advantage of the first molar position is that this will enable sufficient space to be available for the framework to surround the distal aspect of the implant attachment components and the acrylic required for the retention of the second molar denture tooth (author's comments based on clinical experience). Selection of an appropriate implant position is an important consideration in the treatment planning process; it must be kept in mind that a different type of dental prosthesis may be indicated or desired in the future (i.e. allowing for easy conversion to a complete overdenture or a fixed implant-supported dental prosthesis) [299, 308].

Implants should be orientated such that load is transferred axially through the implant (i.e. minimal offset) thereby reducing the amount of destructive non-axial forces [342, 343]. In a horizontal ridge, the axis of the implant will be perpendicular to the ridge and likely correspond with the long axis of the abutment tooth. In situations of ascending or descending ridges, there will be a discrepancy between the long axis of the natural abutment tooth and the orientation of the implant if it is placed perpendicular to the ridge. An *in vitro* study has looked at the effect of implant inclination relative to the long axis of the abutment tooth. It appears that some degree of inclination (up to 5 degrees) can be accepted without any obvious detriment, even though the parallel scenario is preferred [305]. Based on this information, it may be reasonable to suggest placing the long axis of the implant parallel with the angle bisecting that of the long axis of the natural abutment tooth and the line perpendicular to the ridge at the implant site. Furthermore, the axis of the contralateral implant must also be considered when managing the KCI situation, appreciating that a coincident path of insertion of the dental prosthesis must be established. A possible solution to manage angular discrepancies can be the use of angled abutments; in this scenario, implants are placed perpendicular to the ridge and the angled abutments positioned such that the abutment axis is parallel to the abutment tooth. However, very little clinical research is available to support this approach for the association of implants with RPD treatment option [344].

Nature of Attachment between Implant and RPD

Implants can be broadly associated with an RPD in one of two ways. In the first scenario, the implant simply acts as a vertical stop and does not actively attach itself to

the denture. The term 'implant-supported RPD' (ISRPD) is commonly used to describe this situation [286]. Healing abutments are often used to establish the vertical stop with the under-surface of the denture base being adjusted (or relined) to ensure close adaptation between the opposing surfaces. The polishing of healing abutments to create a dome shape in an attempt to achieve a single point contact with the denture base has been described [33]. The second scenario is one in which an attachment mechanism is used to support and retain the denture. A suitable abutment is inserted into the implant with the corresponding attachment mechanism incorporated into the denture base, often using an intra-oral direct pick-up technique [345]. The terms 'implant-assisted RPD' (IARPD) and 'implant-retained RPD' (IRRPD) are sometimes used to describe such situations [322, 324, 329]. Whilst also inherently providing vertical support to the dental prosthesis, the use of resilient 'stress-breaking' attachment mechanisms allows for some movement of the denture. This small amount of movement can assist with distributing loads more broadly and thereby reducing the amount of stress being resisted by the implant. Retentive attachments also impart horizontal and lateral support to the dental prosthesis and assist with the overall retention of the dental prosthesis. In some situations, the use of clasp arms may not be required. The term 'implant tooth-supported removable partial denture' (ITSRPD) has also been used, however it has been used in a situation in which retentive attachments were employed (this situation should more correctly be described as an implant tooth-retained removable partial denture) [308]. A study assessing the association of implants with double crown-retained mandibular removable dentures employed the term 'tooth-implant-retained partial dentures' (TIRPDs) to describe this situation [300].

Unfortunately, there are examples in the literature where the terms are used in a more general manner, and not necessarily follow the recommendations just made. For example, the term ISRPD is sometimes used in situations where a retentive attachment is used in place of a sole vertical stop (i.e., healing abutment) [285, 286]. This can create confusion when assessing the literature with regards to the performance of RPDs stabilised in only the vertical direction relative to the performance of RPDs stabilised in horizontal, lateral, and vertical directions. A reader must review the methodology sections of these studies to identify the type of abutments used and to determine the nature of the connection between the implants and the RPD. The term IRRPD will be used in this trial to describe the mandibular KCI RPD retained and supported by Locator™ abutments.

Attachment Types

Healing abutments and cover-screws can be used to establish vertical stops. The establishment of vertical stops prevents the denture bases from rotating and sinking into the tissues, hence resulting in a more stable dental prosthesis in the vertical direction [336]. This is a relatively simple treatment concept and can easily be used to modify an existing dental prosthesis to receive this support through a reline of the denture bases. The implications of converting a CRPD into an ISRPD or IRRPD in terms of denture design will be discussed further in the section 'Technical Complications, Maintenance, and Denture Design Considerations'.

The use of retention systems in the implant associated with RPD treatment option can improve patient satisfaction [282, 324]. Ball attachments, Locator™ attachments (Zest Anchors LLC, Escondido CA, USA), ERA (Easy Resilient Attachments), and (Preci) Clix attachments (Preat Corporation, Santa Maria CA, USA) have been used as to help retain mandibular KCI CRPDs. Each of these attachments varies in their design, but generally function by providing a mechanism creating retention through friction between the male and female components of the attachment mechanisms. All have been shown to be clinically effective for association with RPDs [346]. A study using two-dimensional FEA reported that the ERA attachment system loads part of the occlusal forces onto the alveolar ridge and decreases the stress on the abutment tooth. This study further concluded that in cases of reduced periodontal support of the abutment tooth (defined in this study as bone loss down to half the root length), it is preferable that a distal rest is avoided and that a distal guide plane be used to allow for individual movement of the abutment tooth and denture base [282].

Some studies have compared bone responses around 'implant-supported' and 'implant-retained' situations. A retrospective study comparing implant support (healing abutments) and implant retention (various attachment mechanisms) situations reported that no significant difference in bone loss was detected between the two groups [33]. Of the studies in Table 2.2 evaluating marginal/crestal bone loss, the following has been reported in terms of the upper extent of mean bone loss detected: 1.03 ± 1.07 mm (after one year) with use of equator attachments (i.e. IRRPD) [323], 2.20 ± 0.81mm (after three years) with use of ball attachments (i.e. IRRPD) [324], 0.9 mm (S.D. 1.0 mm) (mean follow-up period of eight years) with both healing abutments

and ball/Locator™ attachments (i.e. ISRPD and IRRPD) [288], and 2.177 mm (after 18 months) with ball attachment (i.e. IRRPD) [327]. It is generally accepted that early vertical loss of crestal (marginal) bone around implants can be quite variable, however ongoing bone loss after the first year of loading should be no more than 0.2mm/year in order for an implant to be classified as successful (amongst other success criteria) [347]. Of the abovementioned studies, the second and third studies report bone loss within the 0.2mm/year range; the first and fourth studies do not report 24-month data from initial loading.

A study reporting on the changes of residual ridge height rather than marginal/crestal bone levels found that after five years the residual ridge height reduced by 1.03 mm with the RPD supported by ball attachments (i.e. IRRPD) group and 0.15 mm for the RPD supported by healing abutments group [330]. A possible explanation for this latter observation is that the ball attachment is a resilient attachment (i.e., space present between the head of the ball and the attachment) that allows some vertical movement of the dental prosthesis. This vertical movement may result in the denture bases exerting some mild pressure on the underlying tissues, and hence contributing to the ongoing, albeit relatively small, amount of bone loss. A multicentre prospective evaluation reported that ball abutments (retentive anchors) on distal implants, as opposed to healing caps, significantly improved patient satisfaction for stability, chewing, and overall satisfaction [329]. A comparative clinical study compared the outcomes between ball attachments and Locator™ attachments. The study concluded that the side of the dental prosthesis restored with the Locator™ abutment showed better effect on bone health around both the placed dental implant and main natural abutment as compared to the ball attachment [327].

The loading dynamics of implants supporting removable dental prostheses is different to that for implant fixed restorations, so longer-term research is required to assess bone responses around the implants (and abutment teeth). An *in vitro* study employing photoelastic models compared CRPDs, ISRPDs (with healing abutment), and IRRPDs (with ball attachment/O-ring) in terms of retention of the dental prosthesis and stress distribution to the support structures. The implants were situated in the second molar sites and the first premolar teeth were the natural abutment teeth, and the study simulated 5-years of denture use (insertion/removal cycles). The study concluded that ISRPDs and IRRPDs decrease the load transmission to the first premolar and increased the transmission to the implant area. Additionally, the use of the ball attachment/O-ring

(IRRPD) improved load distribution between support teeth and implant when compared to the ISRPD, probably because the O-ring rubber partially absorbed the load [317].

Very little research has been reported on the initial retentive characteristics of IRRPDs with different resilient attachments and clasp designs [348]. Attachments for IRRPDs should provide enough retention to ensure adequate stability of the dental prosthesis whilst still allowing the patient to easily insert and remove the dental prosthesis [348]. As can be appreciated, individual variation exists as to what constitutes ease of dental prosthesis insertion and removal. One set of authors suggested that 300 to 750 grams of retention is acceptable for a conventional KCI RPD [349]. Another author suggested that an RPD should possess approximately 20 Newtons of force to secure it in place when sticky foods are chewed yet still enabling the patient to remove the RPD, with the clasps imparting retention of between 5 and 10 Newtons [350]. An *in vitro* assessment using O-ring and Locator™ attachment mechanisms supported in the first molar region found that both attachment types provided retention values above the 300 to 750 gram range. Another *in vitro* study assessing Locator™ attachments and hader bar yellow clips to retain overdentures reported that all attachment systems tested had retention values greater than 20 Newtons [351]. It was therefore concluded that unaesthetic claps were not necessary in KCI IRRPDs, and especially so when the Locator™ attachments were used [348]. The same authors cautioned that when the stability of the mandibular KCI IRRPD is at risk, the most predictable results could be achieved using a Locator™ attachment and infrabuldge clasp; Locator™ attachment and infrabuldge direct retainer demonstrated higher retentive values than those without a direct retainer.

Wear is a problem that impacts on all attachment systems and will influence the performance and longevity of the system [351]. The cause of this wear is the friction between two opposing surfaces during the insertion and removal of the dental prosthesis. Different types of attachments have demonstrated different wear behaviour and no correlation can easily be made between the type or material of the attachment and certain wear behaviour [352]. Much of the research investigating wear and retention characteristics of attachment systems is largely based on *in vitro* simulation tests (i.e., insertion/removal of attachment along the path of insertion over multiple cycles) [317, 352, 353]. An inherent shortcoming of *in vitro* testing of attachment systems relates to the relatively simple design of most tests, namely insertion and removal along a single path (i.e., path of insertion). In the clinical setting, attachments are also subject to other force vectors (i.e. functional or parafunctional loading) and a

more challenging environment (i.e. presence and composition of saliva, intraoral temperature, and variations in implant angulation) [354]. Therefore, *in vitro* results must be interpreted with caution and confirmed by clinical studies. The fact that maintenance events frequently occur during the first year of clinical use suggests that the behaviour of attachment systems differs clinically to that observed in the simulated *in vitro* setting [345, 352]. It has also been reported that there is increased demands for prosthetic maintenance when attachment systems are used [324].

The Locator™ attachment system a universal hinge attachment that can be used on appropriately prepared tooth roots, directly on implants, and on implant superstructures (i.e., bars). This resilient attachment system allows movements in both the vertical plane and the hinge axis; when the processing male nylon is replaced by the definitive male nylon, a space of 0.2 mm is created to allow for vertical resiliency and an 8 degree hinging in any direction [299]. It is manufactured by Zest Anchors (Escondido, Santa Maria CA, USA) and is available for a range of implant systems. The attachment system consists of a titanium abutment with a titanium nitride cap, and a 'male' nylon insert. A range of nylon inserts is available, allowing for different levels of retention to be achieved and to accommodate for differences in divergence between implants. The standard range of nylon inserts are designed for use in situations where the relative divergence between two implants is less than 20 degrees (i.e., 10 degrees divergence of each implant) and consists of three types of inserts; Blue (1.5 lbs. (680 grams) retention), Pink (3 lbs. (1361 grams) retention) and Clear (5 lbs. (2268 grams) retention). These nylon inserts function with dual retention functionality with inner stud retention and external retention. An extended range of inserts allows for up to 40 degrees of divergence between two implants (i.e., 20 degrees divergence of each implant) and consists of four inserts; White (0 lbs. (0 grams) retention), red (1 lbs. (454 grams) retention), Orange (2 lbs. (907 grams) retention), and Green (4 lbs. (1814 grams) retention). The extended range male nylons do not incorporate the internal stud retention [355].

The Locator™ attachment system has dual retention (external and internal retentive features), is self-aligning, does not require splinting, allows for pivoting of the male nylon within the denture cap, and has a low vertical profile; the Locator™ attachment saves a minimum of 1.68mm to 3.05mm of interocclusal space compared to other implant overdenture attachments [348, 355, 356]. The self-aligning feature simplifies insertion and removal of the dental prosthesis, whilst the low vertical profile makes this

system suitable for situations with reduced inter-occlusal clearance. The low profile also allows for more material (metal and acrylic) to be incorporated into the dental prosthesis that may assist with the strength and integrity of the dental prosthesis [324, 327]. The Locator™ attachment combines the best features of ball attachment, ERA attachment, and a cap attachment [357]. Locator™ attachments used for overdentures have been shown to provide significantly higher retentive forces compared to ball attachments and magnets when resisting vertical and oblique forces [351].

The Locator™ attachment system is not immune from wear and subsequent reduction in retention. An *in vitro* simulation study simulating approximately 2.3 years of denture use concluded that there was a decrease in the force at disengagement of all types of Locator™ nylon inserts tested (clear, blue, and pink), and at different rates over time. This change was most rapid over the first three months after which it stabilised after one year. However, after 2.3 years of simulated use the loss of retention of all three types of inserts was significant and ranged between 70.5% and 80.7% [352]. This same study also reported that greater retention was achieved when implants were slightly off-axis (5 degrees) relative to straight (0 degrees) or higher angulated (10 degrees) implants. Other potential problems associated with the Locator™ attachment system include plaque accumulation and food debris within the system, the need to periodically replace the nylons, and possibly more post-insertion aftercare than ball-type attachments (i.e., activation of retention) [358, 359]. Unfortunately, clinical reports of the long-term performance of the Locator™ attachment system in association with the mandibular KCI IRRPD are scarce. Most of the available research relating to the performance of attachment systems relates to implant support of complete arch overdentures (i.e., two to four attachments retaining a complete overdenture).

Technical Complications, Maintenance, and Denture Design Considerations

Few of the studies in Table 2.2 provide a detailed discussion on the technical and maintenance issues relating to the attachment mechanisms. The loosening and pitting of healing abutments has been reported for some ISRPD situations [33, 324]. The need to re-activate, re-tighten, or even change some of the retentive elements is not uncommon [324]. Fortunately, many of these adjustments are simple to do and not overly expensive. Other reported technical issues relate to the denture clasps (requiring tightening, fracture), rest rupture, and damage to denture teeth [308, 322, 324].

A further point of consideration when considering the association of implants with KCI RPDs is the change in loading dynamics of the dental prosthesis and the impact that this has on the stresses generated within the dental prosthesis. Acrylic and metal behave differently to loading; when an attachment system is incorporated into the acrylic, the load from the rigid implant is predominantly transferred into the acrylic which is weak in tension and has a low elastic modulus [360]. Furthermore, the acrylic is also connected to the rigid metal framework (i.e., it is fixed to two rigid structures). A potential destructive mismatch of strain distribution has been identified between the acrylic and the metal framework, which can be a potential weak spot and nidus for fracture [360, 361]. Lack of acrylic thickness around the attachment could be one reason contributing to the acrylic puncture fractures described in one of the clinical studies referenced in table 2.6 [324]. It is recommended that the IRRPD should be designed in such a way that the metal framework is situated along the neutral axis of the beam (i.e. the area of tension/compression) which is reported to be approximately 0.75mm from the tissue surface, the retentive mechanism should be directly associated with the framework, or at least a sufficient bulk of acrylic should surround the attachment mechanism [360]. Furthermore, the suggestion is made that a distal rest (rather than a mesial rest) on the natural abutment tooth may be more appropriate to provide support closer to the mesial end of the distal extension and to improve the stress distribution in the metal framework and acrylic resin denture base structures [361]. Since the biomechanics of the situation has changed from KCI to KCIII (elimination of the fulcrum line or shifting away from the natural abutment tooth), there is less concern for the potential distal tilting of the abutment tooth that is the rationale for employing a mesial rest for support of a conventional KCI RPDs. Based on this discussion, the conversion of an existing conventional RPD into an IRRPD could be considered to be a temporary measure [360]; a new dental prosthesis incorporating design features that consider the differences in biomechanics between the CRPD and the IRRPD may provide superior longer-term outcomes.

Based on the relevant literature summarised in Table 2.2 and other literature reporting on implant associated RPDs, it appears that these dental prostheses do have high survival rates over the short-to-medium term (i.e., based on catastrophic failures and/or need to remake a prosthesis). However, they do suffer from a range of more minor technical issues, most of which can be easily managed, and particularly so during the first year of function. Based on this, patients must be aware that the dental prosthesis

will require periodic review and maintenance, particularly of the attachment mechanisms that will be subject to wear and loosening.

Clinical and Patient Specific Outcomes

Clinical outcomes in terms of impact on remaining teeth and other oral structures are not well reported in the literature summarised in Table 2.2. The relatively short follow-up periods of many of these studies does not make reporting of such data overly relevant. Until such time that higher-level evidence becomes available, it may be appropriate to extrapolate the findings of existing studies reporting on longer-term outcomes with CRPDs. Both dental prosthesis types (CRPD and ISRPD/IRRPD) require sound biomechanical and biological design principles and appropriate oral hygiene measures. The main differences between the two scenarios are the potential for the implant-associated dental prosthesis to demonstrate a more stable posterior occlusion with less detrimental changes caused by ongoing residual alveolar ridge resorption, and the fact that the loading dynamics and demands on the natural abutment teeth will be altered. Some studies reporting on implant associated RPDs of longer duration indicate that this treatment concept is compatible with longer-term success [300, 302, 308, 322].

Patient satisfaction is a common outcome measure reported in the relevant literature. This information has been captured by questionnaires and visual analogue scales. Section 2.10 of this literature review will provide a summary as to the derivation and application of the Oral Health Impact profile (OHIP) and Visual Analogue Scales (VAS), both of which are instruments commonly used to assess patient satisfaction and quality of life. The general consensus of the relevant clinical literature is that implant association with RPDs for the management of mandibular KCI situations results in a more stable and comfortable dental prosthesis with an overall improvement in patient satisfaction (when compared to CRPDs). Interestingly, even with the reported improvement in satisfaction, there still appears to be a small proportion of patients who either don't wear the dental prosthesis or who have undergone subsequent conversion to other dental prostheses [288]. Research should be directed at trying to identify if factors such as the age of the patient, prior RPD experience, request for denture treatment (i.e. patient- or clinician-driven), and the number of occlusal units being replaced have an influence on patient satisfaction and likelihood to accept the dental prosthesis. Such information will prove useful in assisting patients and clinicians in deciding on the most appropriate treatment plan.

Based on the available evidence, the association of dental implants with a mandibular KCI RPD is a treatment option that can satisfactorily address many of the issues reported with the CRPD, at least in the short-to-medium term. It appears that denture stability, retention, and comfort are significantly improved, as is overall patient satisfaction. This option fills the gap between the spectrum of a tooth and tissue supported dental prosthesis and an entirely implant supported fixed dental prosthesis. It enjoys the advantages of being removable (for hygiene) and easily repairable, whilst also remaining retentive and stable during function. Some authors reinforce the importance of strict maintenance and follow-up protocols to ensure satisfactory results [29, 286, 308]. The need for fewer implants (relative to a conventional implant-retained fixed partial denture) and the possibility of using shorter and narrower implants may make this a relatively cost-effective option. The mandibular IARPD is a preferable treatment option for those patients with complaints/issues in wearing CRPDs [329]. However, it must be appreciated that very few long-term studies with sufficient sample size and robust study design are available assessing this treatment concept. More research is required to provide a higher-level evidence-base to determine the true benefit of implant association with RPDs (i.e., objective outcome measures) and the longer-term outcomes of this treatment option. In addition to the paucity of higher-level evidence to support this treatment option, another disadvantage of this option is the fact that the dental prosthesis is still removable; a fact that still concerns some patients [283, 299].

2.7 A contemporary review of the use of short dental implants with a focus on the posterior mandible

Use of dental implants to assist in the prosthetic rehabilitation of missing posterior teeth has been shown to be a predictable and well-accepted treatment modality [13-20]. A fundamental principle of implantology is the surgical positioning of an implant into a site of sufficient bone volume, with longer and wider implants traditionally being preferred. Longer and wider implants ensure maximum surface area is available for bone-to-implant contact (BIC) in order to achieve anchorage and transfer of applied loads into the surrounding bone, resulting in lower failure rates [362, 363]. Furthermore, longer implants ensure that a more favourable crown-to-implant ratio (CIR) can be achieved; an unfavourable CIR may be a factor that adversely impacts marginal bone stability and the biomechanical integrity of the implant hardware and associated dental prosthesis. The nature of the anatomy of the posterior jaws can sometimes present challenges to the safe placement of standard and longer length implants [364-370]. Of particular relevance is the presence of the maxillary sinus in the posterior maxilla, and the inferior alveolar canal, mental nerve, and submandibular fossa in the posterior mandible. The significance of this anatomy becomes even more pronounced in situations of advanced ridge resorption (i.e., as a consequence of long-term tooth loss and/or advanced periodontal disease). A radiographic study of 431 patients revealed that the placement of implants with a minimum length of 6mm in the posterior regions was possible in only 38% of maxillae and 50% of mandibles [371]. Adding to these anatomical challenges, the quality of bone in the posterior jaws (particularly maxilla) is often of sub-optimal (lower density) and the occlusal forces generated are higher than those generated in other parts of the mouth [17, 372, 373]. All of these factors can potentially affect the longevity of the implant treatment plan.

When insufficient bone height is available for the placement of standard-length implants (i.e., ≥ 10mm length implants), the surgeon must reconstruct the relevant bone dimensions prior to implant placement. Onlay grafts, distraction osteogenesis, osteotomy with interpositional grafts, sinus floor elevation, and nerve transposition are surgical techniques that have been described to manage such situations [362, 365, 374-378]. All of these procedures add time and cost to the implant treatment plan and cause short and potentially long-term surgical morbidity [374, 379, 380]. The use of short

implants may provide a useful option for managing situations that preclude the use of standard length implants [364]. Short implants offer a range of advantages including the avoidance of complex bone grafting procedures, faster treatment time, less cost, and an easier and safer surgical procedure thereby reducing the risk of serious surgical morbidity [362, 370, 379, 381]. A major disadvantage of shorter implants, particularly when compared to a longer implant of comparable diameter, is the reduction of surface area available for BIC and the greater stress that is applied to this interface (i.e. the same force being transferred over a smaller surface area) [365, 379]. It has been shown that the pull-out extraction force of longer implants (15mm) is greater than that of shorter implants (4- and 8-mm), even though the pull-out extraction force for the 4- and 8 mm length implants was not linearly related to the decrease in implant length (and hence surface area) when compared to 15mm-long implants [382]. This latter observation suggests that other geometric factors and bone properties (i.e., cortical versus cancellous bone) may contribute to these differences observed.

The length that demarcates a short implant from a standard length implant is not well described in the literature, with no apparent consensus on an accepted length to define this [364, 366]. An implant length of 10 mm is frequently referenced in the literature when referring to short implants; some authors include the 10 mm length [364, 383] whilst others only classify implants less than 10 mm as being short implants [17, 365, 366, 384]. 10 mm-long implants are now commonly considered to be standard length implants [365]. In the early 1990's, a minimum implant length of 13 mm in the maxilla and 10 mm in the mandible was recommended [383]. The basis for using 10 mm as a cut-off for defining short implants may have its basis on earlier views that 10 mm was the minimal implant length required for predictable success [362, 379]. Implant length is defined as the distance between the implant neck and the implant apex [365]. However, the implant length may not always be equal to the intra-bony length of the implant (i.e. the length of implant surrounded by bone) [365, 368]. The actual implant length embedded in bone can be influenced by implant type, placement position, and timing of abutment connection [365]. This variable adds to the complexity of analysing the performance of implants, since the actual surface area engaging bone may be less than the theoretical surface area available for a given implant type. The terms 'extra-' and 'ultra-' short have been used to describe implants with intra-bony length of less than 6 mm [384-386].

Based largely on finite element analyses (FEA), it appears that the magnitude and distribution of stress on the alveolar bone is greatest around the crest of an implant with little dependence on implant length; most of the stress concentration on a loaded implant takes place along the crestal 5 mm of the BIC interface [373, 387-390]. This hypothesis lends support to the concept of using shorter implants [369]. The crestal portion of an implant body is most involved in load bearing with much less stress being transferred by the apical portion and as such, implant length per se may not be a primary factor in distributing prosthetic loads to the bone-implant interface [374]. The crestal bone is able to adequately tolerate the relatively light momentary loads arising during mastication [388]. Based on this perspective, there does not appear to be any benefit from using a longer implant purely on the basis of dissipation of load. Nevertheless, longer implants are still advantageous in terms of primary and early implant stability whilst also reducing the significance of any minor crestal bone loss. Regarding this latter point, a loss of 2 mm of crestal bone height around a 14 mm length implant may be of minor clinical significance provided adequate soft tissue integration is present, whereas loss of the same amount of bone around a 6mm implant should be interpreted differently on clinical grounds since it represents loss of a third of the available supporting bone [374, 391]. This issue may also be of relevance over the long-term; crestal bone loss caused by bouts of peri-implantitis may be of more significance when involving short implants (i.e. this situation may still be manageable for a longer implant as increased implant length provides better chances of survival) [384].

Documented survival rates for short implants vary considerably. The literature can be categorised by two broad categories: documented survival rates below 85% and survival rates above 90%. Survival rates above 90% start approximating that expected of standard and longer-length implants. Table 2.3 provides examples of some of the available literature reporting on the survival rates of short implants.

Table 2.3 Examples of documented survival rates of short implants.

Survival Rates below 85%						
Author(s)	**Year**	**No. of Implants**	**Implant Length(s)**	**Implant Brand**	**Follow-up Period**	**Survival Rate**
Jemt T. and Lekholm U. [392]	1995	298	7mm	Branemark	5 years	74% (78 implants lost)
Minsk L., et al. [393]	1996	25	7mm to 9mm	Multiple systems	Up to 6 years	84% (4 implants lost)
Saadoun A.P. and Le Gall M.G. [394]	1996	115	8mm	Steri-Oss (multiple designs)	Up to 8 years	79.1% (24 implants lost)
De Bruyn H., et al. [395]	1999	9	7mm	Screw Vent	7 years	67% (3 implants lost)
Winkler S., Morris H.F., and Ochi S. [396]	2000	152	7- & 8mm	Multiple	3 years	80.9% (29 implants lost)
Naert I., et al. [19]	2002	1168	6-, 7-, 8-, and 8.5mm	Branemark	Up to 16 years	81.5% (for implants shorter than 10mm)
Weng D., et al. [20]	2003	97	7- & 8.5mm	3i (machined surface)	5 years	79.4% (20 implants failed)
Survival Rates above 90%						
Author(s)	**Year**	**No. of Implants**	**Implant Length(s)**	**Implant Brand**	**Follow-up Period**	**Survival Rate**
Higuchi K.W., et al. [397]	1995	109	7mm	Branemark	3 years	93.6% (7 implants failed)
Lekholm U., et al. [398]	1999	101	7mm	Branemark	10 years	94.1% (6 implants failed)
Van Steenberghe et al. [399]	2000	16	8- & 9mm	Astra Tech	2 years	100%
Testori T., et al. [400]	2001	31	7- & 8.5mm	3i (Osseotite)	4 years	96.8% (1 implant failed)
Tawil G. and Younan R. [401]	2003	116	6-, 7-, 8-, & 8.5mm	Branemark	12 to 92 months	93.1% (8 implants failed)
Misch C.E. et al. [234]	2006	745	7- & 9mm	Biohorizons	12 months to 6 years	98.9% (8 implants failed)

Despite the encouraging survival rates, there is hesitancy concerning the use of short implants and it still remains a topic of controversy [364, 365, 402]. A number of systematic reviews, some of which have attempted meta-analysis, have endeavoured to provide higher-level evidence on the general performance of short implants. Table 2.4 presents details of some relevant reviews together with a summary of key conclusions. Based on these studies, a number of insights into the performance of short implants have been provided. Of particular note is the chronology of the data (i.e. early experiences versus more contemporary research), the impact of implant surfaces and implant diameter on survival of short implants, differences in survival of short implants between maxilla and mandible, the timing of failures, and the impact of CIR on marginal bone levels and prosthetic complications.

Much of the controversy surrounding the use of short implants stems from early experiences with short implants, which generally demonstrated less reliability and inferior performance relative to the standard and longer implants of the time [18, 20, 391, 403-410]. Short implants have previously been avoided, especially in the posterior maxilla, and were generally thought to have poor prognosis [383, 411]. More contemporary research has provided support for the use of short implants. Cumulative survival rates for short implants in excess of 92% is commonly reported in more contemporary literature, with many examples of cumulative survival rates over 95% [365, 368, 402, 403, 412]. One systematic review that assessed 3046 short implants (defined by a length of 7 mm and less) concluded that survival rates of short implants has increased gradually over time with survival rates of 82.45% to 98.48% reported in literature sourced from 1991-1995, 80% to 95.5% in literature sourced from 1996-2000, and 98% to 100% in literature published between 2001 and 2011 [413].

It is important to recognise that assessing the literature reviewing the performance of short implants is difficult because of the heterogeneity of the methodologies used and the range of potential variables that can influence the performance of short implants. Systematic comparison of the literature is challenging, and it has been proposed that the performance of meta-analytical assessments of the data is difficult, if not impossible [365, 383, 384, 404, 414, 415]. One of the most common outcome measures used in the literature to compare the performance of implants is the implant survival rate. This is a relatively crude measure that simply indicates that the implant is still *in situ* at the time

of assessment. Implant success would be a more useful measure as this takes into account the clinical performance of the implant after being put into function [383]. Even though success rates offer a greater depth of analysis, most of the comparable data on short implants is based on survival rates. Because of the lack of a clear definition of what constitutes a short implant, caution must be applied when analysing pooled data. The reason for this is that short implants can include any length from 10 mm and below. However, there is a significant difference in length between a 5 mm implant and a 10 mm implant. Therefore, averaged or mean results based on a range of different short implant lengths can distort the actual survival rates of the different individual length short implants. Literature offering a breakdown of the outcomes for the individual implant lengths assessed therefore provides more valuable information.

Table 2.4. Contemporary reviews of short dental implants.

Author(s) & Year	No. of implants	Implant length(s)	Locations	Follow-up period	Survival Rates	Conclusions & Comments
Lemos C.A.A., et al. (2016) [375]	981 SI & 1650 St.I (2631 total)	≤ 8 mm (SI) versus > 8 mm (St.I)	Posterior Maxilla & Mandible	3 months to 12 years	96.1% SI (38 failed implants) 97.3% St.I (45 failed implants)	• SI showed marginal bone loss, prosthesis failures and complication rates similar to St.I. • SI can be considered predictable treatment for posterior jaws, especially if complementary surgical procedures are required for St.I. • However, SI with lengths <8mm (i.e., 4-7mm) should be used with caution because they present greater risk for implant failures when compared to St.I.
Goncalves T.M.S.V. et al. (2015) [385]	1260	< 10 mm in total length and ≤ 8 mm intra-bone length	Majority in posterior Maxilla & Mandible	1 to 10 years	96.1% (49 failed implants) Range: 85% at 5 years to 100% at 10 years	• The provision of SI in atrophic alveolar ridges appears to be a successful treatment option. • 61.2% (30 implants) were lost before loading versus 38.8% (19 implants) lost after loading. • The majority of selected articles were not able to establish a strict relation between the crown-to-implant ratio and marginal bone loss.
Mezzomo L.A. et al (2014) [370]	762	< 10 mm	Posterior Maxilla & Mandible	Mean: 44 ± 33.72 months	94.1%	• Single crowns supported by short implants in the maxilla have a better prognosis over installation in the mandible. • Increased crown-to-implant ratios did not influence marginal bone loss and cannot be associated with

						increased implant failure rates and the occurrence of technical complications.
Atieh M.A. et al. (2012) [402]	3573	≤ 8.5 mm	Posterior Maxilla & Mandible	1 to 7 years (average 3.9 years)	97.9% (5 year CSR for all SI)	• SI (defined as ≤ 8.5mm) demonstrated success rates comparable to those of longer implants, irrespective of design, surface, and width. • Use of SI for the treatment of partial edentulism may be considered as possible alternative to the use of longer implants, which require additional surgical procedures or involve safety concerns.
Karthikeyan I., et al. (2012) [413]	3046	≤ 7 mm	Maxilla & Mandible (sites not specified)	4 months to 7 years	82.45 - 98.48% (1991-1995) 80 – 95.5% (1996-2000) 98 – 100% (2001-2011)	• Survival rates of SI were found to increase gradually from 80% to 90%, with more recent articles reporting up to 100%. • Main causes for failure (1991-2000): small bone volumes, distal implants with excessive occlusal forces, maxilla, short and standard diameter implants. • Main causes for failures (2001-2011): soft bone, smooth machined implants, and osteoporotic bone. • When severe atrophy of the jaws is encountered, short and wide implants can be successfully placed.
Srinivasan M., et al. (2012) [384]	1828	< 8 mm	Maxilla & Mandible (sites not	3 months to 9 years	92.2% to 100%	• This structured review provides sufficient evidence of the predictability of treatment outcomes with microrough surface SIs (< 8mm) in the treatment of

			specified)			partially and fully edentulous arches. • Microrough surface implants with lengths in the range of 6 to 7.5mm appear to provide favourable survival rates. • Machined surface implants were excluded from this review
Annibali S., et al. (2012) [374]	6193	< 10 mm	Maxilla & Mandible (sites not specified)	1 month to 14 years (mean: 3.2 ± 1.7 years)	98.3% (103 implants failed)	• SI-supported prosthesis appears to be a valid option in the treatment of the atrophic jaw. • High survival rates and low incidence of biological complications are reported after mean follow-up of 3.2 ± 1.7 years. • Surgical technique, implant location, and type of edentulism and prosthetic restoration did not affect SI survival. • Rough-surfaced implants preferred. • More RCTs and prospective studies with longer follow-up times and sample-sizes necessary to validate current findings.
Sun H.L., et al. (2011) [365]	14722	≤ 10 mm	Maxilla and Mandible (sites not specified)	1 to 10 years (mean: 5.91 years)	95.5% (659 implants failed)	• No statistically significant difference between the failure rates of SI (<10mm) and St.I (10mm) implants. • Maxilla showed statistically significant higher failure rate than mandible. • Machined-surface implants showed statistically

						significant higher failure rates. • No statistically significant difference between one and two stage placement. • More failures before loading (66 versus 48).
Telleman G., et al. (2011) [379]	2611	< 10 mm	Maxilla and Mandible (site not specified)	1.6 to 8.1 years (mean: 3.7 years)	After 2 years: 93.1% - 5mm 97.4% - 6mm 97.6% - 7mm 98.4% - 8mm 98.8% - 8.5mm 98.0% - 9mm 98.6% - 9.5mm	• SI (i.e., <10mm) can be placed successfully in the partially edentulous patient. • Tendency towards an increasing survival rate per implant length. • Installation of SIs in the mandible has a better prognosis than in the maxilla. • Studies excluding smokers revealed higher implant survival rates than studies including heavy smokers (i.e., ≥ 15 cigarettes/day). • Surface topography and an augmentation procedure preceding implant installation apparently did not affect the failure rate of short implants.
Menchero-Cantalejo E., et al. (2011) [383]	7392	≤ 10 mm	Maxilla and Mandible (site not specified)		Avg. CSR for machine-surfaced implants was 92.5% Avg. CSR for rough-surfaced	• Rough-surfaced implants show greater stability than machined surface implants (which demonstrate a progressive downward trend over 6 years). • The majority of studies obtained a CSR similar to that of St.I. • The studies that record lower CSRs are 'later (older)'

					implants was 98.38%	studies that analyse implants with machined surfaces. • Rehabilitation with SIs is a reliable treatment. • Lack of consistency in study designs and presence of bias in all of the reviewed studies makes it difficult to analyse the data.
das Neves F.D., et al. (2006) [364]	16344	7-, 8.5-, & 10 mm	Maxilla and Mandible. Sites not specified.	0.4 to 14 years	95.2% (786 implants failed)	• 3.75mm X 7mm length implants demonstrated failure rate of 9.7% compared to 3.75mm X 10mm implants that showed a failure rate of 6.3%. • 54.5% of failures occurred before prosthesis connection. • Risk factors: shorter length, poor bone quality, narrower implants (4mm diameter appeared to minimise failure) • SIs (including 3.75mm X 7mm) can be considered to be an alternative to advanced bone augmentations, which raise costs, morbidity, and treatment time.

SI = Short Implant, St.I = Standard Implant, CSR = cumulative Survival Rate

When taking a closer look at the survival rates of individual implant lengths, the following survival rates has been reported: 6 mm (survival 95.9%, n = 660), 7 mm (survival 94.1%, n = 948), 7.5 mm (survival 100%, n = 66), 8 mm (survival 97.5%, n = 4,019), 8.5 mm (survival 96.8%, n = 1,215), 9 mm (survival 99.4%, n = 1,117), and 10 mm (survival 93.5%, n = 4,614) [365]. The mean follow-up period for this data was not stipulated, although the authors did advise that the implants were *in situ* from 1 to 10 years. Interestingly, the survival rate for the 10 mm implant is lower than that of the other lengths reported. This is in disagreement with other reports that conclude that there is a tendency towards an increasing survival rate per implant length, especially below 8 mm [379, 402]. This latter conclusion is further supported by another review that reported the following estimated survival rates after two years; 5 mm (93.1%, n = 12), 6 mm (97.4%, n = 57), 7 mm (97.6%, n = 521), 8 mm (98.4%, 1,295), 8.5 mm (98.8%, n = 420), 9 mm (98.0%, n = 238), and 9.5 mm (98.6%, n = 95) [379]. Based on these reviews, it appears that 5 mm and 6 mm short implants (i.e., the shorter implants analysed) do offer acceptable survival rates. Weaknesses of the current research are the relatively low number of the shorter implants being assessed (sample size) and the time in function. These results should be considered with some caution until such time that more data becomes available to enable a more robust comparison to be made between the outcomes of the different implant lengths.

Short implants with rough surfaces reportedly provide better outcomes than smooth surfaced implants [363, 365, 383, 403, 416]. Modification of implant surface micro-topographies appears to be an import development in the evolution of short implants by significantly increasing the implant surface area available for BIC, thereby lessening the stress applied to the bone-implant interface [365, 379, 417, 418]. Roughening of implant surfaces can be produced by either an additive process (i.e., titanium plasma spray, hydroxyapatite, etc.) or by a subtractive process (i.e., grit blasting, acid etching, etc.). By increasing the available surface area, there is an increase in the potential for BIC (i.e. higher bone-to-implant contact percentage), hence compensating for a reduction of implant length [383]. Treated surfaces are also more bioactive by promoting recruitment, adhesion, and proliferation of osteogenic and fibroblastic cells, and thereby facilitating more efficient and effective hard and soft tissue integration [419].

One review was not able to demonstrate a statistically significant difference between the survival rates of rough surfaced implants and smooth surfaced implants [379]. An explanation offered for this finding was the inadequate descriptions of surfaces in some studies, hence making it difficult to correctly categorise them. In addition to improved surfaces, a better understanding of bone physiology and the behaviour of different bone qualities, together with modifications in surgical protocols to accommodate for these differences, have been suggested as possible reasons contributing to improved outcomes.

The role of implant diameter of short implants has also been discussed in the literature [368, 369, 397, 398, 420-422]. Increasing the diameter of an implant is more effective for osseointegration by counteracting the loss of surface area caused by the reduction of implant length [422]. It has been calculated that the surface area of an implant, depending on the implant design, can increase from 30% to 200% for every mm increase in diameter [139]. It has also been reported that an increase in diameter results in a decrease in the maximum von Mises equivalent stress around the neck of the implant and that implant diameter is more important for stress distribution than length [366, 387, 423]. von Mises stresses are commonly reported in finite element analyses; summarising the overall stress at a point (i.e. combining all stress components into one value) [424, 425]. A number of studies, many using implants with diameters up to 6 mm, have demonstrated similar or improved survival rates relative to regular diameter implants [234, 397, 398, 408, 426-429]. Wider implants have been advocated for use in sites of poor bone quality, commonly seen in the posterior maxilla, since the wider implants offer greater surface area for BIC.

However, there does appear to be a limit as to how much the diameter can be increased beyond which implant failures rise. A number of studies using wider implants (i.e., ≥ 5 mm) have reported higher failure rates, some of which have reported failures to be more frequent in the mandible [229, 422, 430-433]. A likely explanation for the increase in failures relates to the fact that as implant diameter increases, less width of vascular trabecular bone surrounds the body of the implant. Bone loss may result as a consequence of the implant body encroaching the surrounding cortical bone. A minimum of 1 mm of bone thickness must surround the entire implant[434]. Any loss of this cortical bone can lead to exposure of the implant surface with consequent

biological complications. Furthermore, wider implants are sometimes used as 'rescue' implants and placed in sites of previous implant failure (i.e. there may be some underlying predisposition for implant failure in such patients), are often placed in compromised sites (i.e. posterior maxilla), employ a surgical protocol with the potential of adversely affecting local bone (i.e. overheating of bone, too high insertion torque, etc.), and thereby have an associated learning curve when modifications to usual surgical protocols are required [431, 435, 436]. As discussed, the reviewed literature suggests that wider implants up to 5 mm in diameter can achieve similar or improved survival rates relative to regular diameter implants. In more recent studies, no relationship has been found between wide-diameter implants and survival rates, possibly reflecting use of newer implant designs, better treatment planning, and adapted surgical techniques [368]. Nevertheless, caution may be recommended when using implants with diameters greater than 5 mm, and are probably best reserved for situations of poor bone quality with adequate bone width [364].

Another consideration relating to short implants is the effect of the CIR on the bone surrounding the implant. Short implants are often employed in situations of reduced alveolar height, hence necessitating longer (taller) crowns to achieve contact with the opposing dentition [386]. This results in a higher CIR which is unfavourable in terms of lever arm mechanics [383]. A lower CIR ensures that the lever arm effect, especially when off-axis forces are applied, are minimised. Based on conventional fixed prosthodontics principles (i.e., crown-to-root ratio), a higher CIR was thought to contribute to marginal bone loss and adversely affect the long-term prognosis of an implant [404, 437]. Despite the concentration of non-axial loads at the bone crest, the available clinical evidence suggests that there is no correlation between higher CIRs and marginal bone loss (i.e., in terms of biological complications)[375, 386, 438-440].

The CIR appears to be more relevant for prosthetic complications; however, the acceptable success rates of single crowns supported by short implants suggests that the complications are generally minor in nature [438, 441, 442]. One theory suggests that the micro-roughened implants allow for greater BIC which largely offsets the existence of inadequate CIRs [383]. The placement of a greater number of implants has also been advocated as a reasonable solution for offsetting an unfavourable CIR, since this can considerably decrease the stress placed on the bone surrounding the implants [383].

Splinting of crowns (when multiple teeth are being replaced) can also support the maintenance of marginal bone tissue by decreasing the crestal strain in the surrounding bone [375, 443, 444]. With improvements in the designs of implant-to-abutment connections, such as a change from short and flat external hex connections to deeper internal connections (including Morse taper connections) and the availability of wider-diameter implants with micro-textured surfaces, higher CIRs may be acceptable from a biomechanical view-point [366]. It is now reasonable to recommended that the crown-to-root ratio guidelines used to establish prognoses for natural teeth do not apply in the same manner to the single-tooth implant-supported restoration [440].

The literature indicates that short implants have a tendency to fail more commonly before loading, implying that the forces associated with implant loading and reduced BIC are not the primary determinants in the ultimate success or failure of short implants [364-366, 374, 397, 402, 415, 445]. A longitudinal review reporting a higher failure rate before loading (54.9%) calculated that the failure rate increased to 63.2% when the first year of loading was also considered [364]. The pre-loading phase and first year of loading appears to be a period of increased risk for failure of short implants. The benefit of early failures (prior to loading) is that the costs and time associated with the prosthetic phase of treatment can be minimised provided the dental prosthesis has not already been constructed. Even though pre-loading failures appear to be more common, some studies have reported increased failure rates after loading [17, 19, 446, 447]. Biomechanical (i.e., loading, parafunctions, etc.), biological (peri-implantitis), and/or host attributes (i.e., poor oral hygiene, smoking habits, etc.) are likely factors contributing to post-loading failures. One study reported that when late failures occurred, the prevalence was higher for machined-surface implants [374]. It could be that the machined-surface implants have been *in* situ for a longer period and have had more time to fail. Implant failure is a multifactorial phenomenon and can hardly be accounted for by a single factor; the risk of failure increases with more risk factors present [364]. It has been suggested that longer-term follow-up is required to further study these inconsistent findings [365].

It has been reported that the failure rates of short implants are higher in the (posterior) maxilla than the mandible, with inferior bone quality in the posterior maxilla believed to largely explain this observation [379]. Modifications in surgical technique to better

manage these situation (i.e., use of bone condensers, undersizing of the osteotomy, use of wider implants, etc.) and improvements in implant surfaces are believed to contribute to more recent improvements in the performance of short implants in the posterior maxilla. The prosthetic complication rates on dental prostheses supported by short implants are reported to be similar to that on longer implants, including the performance of single unit (non-splinted) crowns. A systematic review reported an overall cumulative survival rate of 96.1% (failure rate of 3.9%) for 1260 short implants placed in 687 patients, of which 77% of the dental prostheses were single crowns [385]. This finding is further supported by another review that reported a five-year cumulative survival rate of 98% for all short implants assessed, with 1,952 of these implants (55% of the implants reviewed) restored as single crowns [402]. This is encouraging, as the single unit posterior crown supported on a short implant would be one of the more demanding clinical situations for a dental prosthesis to withstand (i.e. short implant, higher loads, and unfavourable CIR).

No statistical difference in implant survival was found between implants placed in a single stage and those placed in two stages [365], hence it appears that surgical protocol may not play a key role in the prognosis of short implants. In contrast to this finding, a study assessing the use of short and wide implants (Bicon®, 6 mm X 5.7 mm) reported that a two-stage approach is associated with 80% less failures than a one-stage approach when using these implants and therefore recommends that a two-stage approach should be preferred when using short implants [442]. Although a one-stage approach has the benefit of reducing the need for an additional surgical intervention, a two-stage protocol may be a more prudent approach when using short implants and especially so in situations when optimal primary stability is difficult to achieve [448].

When evaluating the survival and success rates of short implants, it has been proposed that they should not necessarily be compared directly to the outcomes for standard and longer implants placed in native jawbone; rather, they should be compared against the outcomes of standard implants placed into augmented sites [374, 383]. The reason for this is that short implants offer an alternative treatment option to the accepted protocol of augmenting deficient sites prior to, or concurrently, with standard length implant placement. In this way, an informed decision can be made as to which of the two

approaches has the better chance of achieving a satisfactory treatment outcome in the simplest manner with least risk.

In order to establish a context for the performance of short implants, the literature reporting the outcomes of standard implants placed in grafted sites has been assessed. A comprehensive review conducted in 2009 assessed the implant survival rates in sites augmented with either onlay grafts, sinus floor elevations (via lateral approach), Le Forte I osteotomies with interpositional grafts, ridge splitting/expansion, or alveolar distraction osteogenesis [449]. Despite the challenges in interpreting the data in the available literature because of the heterogeneity in methodologies used and the associated variables involved, the following conclusions were presented: a) An overall survival rate of implants in maxillae and mandibles reconstructed with onlay grafts of 87% (range of 60% to 100%), with better results for implants placed in the mandible and when rough-surfaced implants were used, b) Survival rates ranging between 60% and 100% for implants placed into sites augmented with sinus floor elevation (lateral approach), with the majority of studies reporting values greater than 90% and superior outcomes when rough-surfaced implants were used, c) Survival rates ranging between 91% and 97.3% for sites managed with ridge splitting/expansion, d) Survival rates ranging between 88% and 100% for sites augmented via alveolar distraction osteogenesis, and e) Survival rates ranging between 66.7% and 95% for sites reconstructed with Le Forte I osteotomy and interpositional bone grafts.

Based on these outcomes, it can be generally concluded that these procedures offer relatively predictable outcomes. However, the results are less than that for implants placed into non-grafted sites, and it must be appreciated that there is a range of outcomes with a low side. Another comprehensive review concluded that short implants appear to be a better alternative to vertical bone grafting for resorbed mandibles and that complications, especially for vertical augmentation, are common [380]. A report of the European Workshop on Periodontology looking at advances in bone augmentation enabling dental implant placement reported a consensus view that bone augmentation can fail and that implants placed in these areas do not necessarily enjoy the high long-term survival rates of dental implants placed in pristine sites [450]. Therefore, if survival and success rates in the range of 90%+ can be reliably achieved with short implants, this could justify their use in place of advanced augmentation

procedures and placement of longer implants. Use of short implants satisfies the philosophy of employing procedures that are simple, less invasive, involve less risk of complications, and achieving treatment goals within the shortest timeframe [17, 364]. The ability to avoid additional complicated surgery has the added advantage of simplifying implant treatment and making it accessible to a higher number of patients and dentists [362, 366].

The discussion thus far has looked at the performance of short implants, with particular focus on the posterior jaws. Table 2.5 further assess literature that focus on the posterior mandible and summarises some of the key points identified in the relevant literature. As can be seen, the large majority of studies report survival rates well above 90% for short implants placed in the posterior mandible including many cases restored as single-unit crowns.

Table 2.5. Literature reporting on short implants placed in the posterior mandible.

Author(s) & Year of Publication	Short Implants in post. Md. (N)	Implant Length(s) (mm)	Implant Diameter(s) (mm)	Follow-up	Implant Outcomes	Conclusions/Comments
Block et al. 1996 [451]	80	8	Not reported in this paper	10 year CSRs (determined by life table analysis)	55% (45% failure rate)	• Placement of 8mm long HA-coated implants in the post. Md should be avoided, especially in molar locations. • Implants placed in the second molar location have greatest incidence of failure. • No implants were lost after 5 years in patients who were followed up for up to 10 years.
Griffin and Cheung 2004 [420]	78	8	6	Mean – 34.9 months (up to 68 months)	100% CSR	• For residual ridges with minimal height but adequate width, use of short and wide HA-coated implants may offer a simple and predictable treatment alternative in posterior areas.
Goene et al. 2005 [412]	242	7 & 8.5	3.75, 4, 5, & 6	Mean – 39.1 months	95.9% (10 failures)	• Micro-roughened implants - Osseotite • The performance of short implants with the Osseotite acid-etched surface was found equivalent to standard-length implants. • The restriction of the use of short-length implants is no longer warranted.
Fugazzotto 2008 [369]	722	6, 7, 8, & 9	6.5	Mean – 28.5 months in function (range: 61 to 73 months)	99.9% CSR	• TPS and SLA surfaces (Straumann) • Restored as single crowns
Grant et al. 2009 [381]	335	8	3.5, 4.3, 5, & 6	From stage I surgery to a	99% SR (4 failures, but 3 replaced and were	• Implant surface not reported.

				functional prosthesis for up to 2 years)	successful)	• Placement of short dental implants is a predictable treatment method for patients with decreased posterior mandibular bone height.
Sohn et al. 2010 [422]	81	5, 7, & 9	4.1 & 5	Mean: 55.8 months (range: 5 to 108 months)	98.8% (1 failure)	• Sintered porous-surfaced implants
Deporter et al. 2012 [236]	48	7 & 9 (incl. collar) or 6 & 8 intra-bony	Not specified other than brand (SPS – Endopore)	10 years of implant function	95.5% SR (2 failures)	• Press-fit, sintered, porous-surfaced implants • Short SPS implants offer an effective and predictable solution for partial edentulism in the posterior mandible provided that there is sufficient buccolingual alveolar ridge width and keratinized peri-implant mucosa.
Jiansheng et al. 2012 [452]	105	5.7, 6, & 8	5, 5.5, 6, & 7	Mean post-loading: 24 months (range: 12 to 56 months)	100% SR	• Micro-roughened (Friadent Plus) and HA-coated implants • Immediate placements. • All restored as single crowns. • Placement of short and wide implants in fresh extraction sockets may offer simple and predictable treatment alternative.
Pieri et al. 2012 [453]	61	6	4	2 years post-loading	96.8% SR (2 implants failed pre-loading)	• Osseospeed surface (Astra Tech) • Within the limitations of the short follow-up period, the use of 6mm-long implants is a predictable treatment method for patients with atrophic posterior mandibles and increased crown-to-implant rations.
Slotte et al. 2015 [454]	86	4	4.1	5 years	92.2% SR	• SLA active surface • Restorations splinted • Subject to limitations of the study,

						4mm-long titanium implants with SLA active surface can be safely and successfully used to support an FPD in severely resorbed posterior mandibles for at least 5 years, with healthy peri-implant conditions.
Al-Hashedi et al. 2016 [455]	40	6 & 8	3.5 & 4.5	12 months post-loading	100% SR	• Friadent Plus surface & Bicon (Integra-Ti™) • The provision of short implants to rehabilitate the partially edentulous mandibular ridge appears to be highly predictable and demonstrates an overall success rate of 100% at 12-months post-loading.
Villarinho et al. 2017 [456]	23	6	4.1	Mean post-loading: 45 ± 9 months (range: 16 to 57 months)	91.3% (2 implants lost)	• Single short implants in the posterior Md are a potential treatment option with high survival rates. • An increased crown-to-implant ratio was considered a risk factor for bone loss. • Higher failure probability (95%) in Md versus Mx.
Han et al. 2017 [457]	95	6	4	3 years post-loading	95.6% (4 failures)	• Osseospeed TX implants • Three-year data indicates the use of splinted 6mm-short implants is a viable treatment option in posterior regions with low marginal bone resorption. • Early loading after 6 weeks should be taken cautiously in patients with known risk factors.
Kim et al. [421] 2018	120	7 & 8	4, 4.5, 5, 6, & 7	Mean: 53.2 months	95.0% survival rate and 92.5% success rate	• Implantium Superline Implants (SLA surface).

						• Favourable clinical outcomes can be expected from single short implants in the posterior area.

CSR = cumulative survival rate, HA = hydroxyapatite, Md = mandibular, Mx = Maxillary, SR = survival rate, SLA = sandblasted/large grit/acid-etched, SPS = sintered porous surface, TPS = titanium plasma-sprayed

When assessing the ever-growing body of literature related to short implants, it is clear that a variety of outcomes have been reported. One review provided a very useful summary by categorising the relevant research, much of which has been discussed thus far, into one of four subgroups [368]: a) Studies that clearly show short implants fail more often than longer implants, b) Studies that show increased failure rates with short implants, however still providing adequate survival rates, c) Studies showing implant length has no significant difference on survival, and d) A group of articles, focusing specifically on short implants, showing similar outcomes to those of longer implants. As previously discussed, the poorer success rates (i.e. the first two categories), are generally based on earlier literature (i.e., 1990's/early 2000's), whilst the more contemporary research adds support to the use of short implants. A more recent review comparing the survival rates of short implants (defined as ≤8 mm) to that of standard-length implants (defined as > 8 mm) suggests that 8 mm implants can be considered 'standard implants' in clinical terms since their survival rates are similar to longer length implants. The authors did however, emphasise that caution should be employed when implants shorter than 8 mm (4- to 7-mm) are used in the posterior jaw because the survival rates are reduced significantly when compared to standard implants [375].

The final point in the previous paragraph is further supported by a recently published meta-analysis comparing the survival rates of short implants (≤ 6 mm length, n = 637) to that of standard implants (longer than 6 mm, n = 653) in posterior jaw areas. The reported survival rates of short implants ranged from 86.7% to 100% and that for standard implants ranged from 95% to 100%, with a follow-up of 1 to 5 years. The general conclusion from this analysis was that short implants, defined as having ≤ 6 mm length, were found to have higher variability and lower predictability in survival rates compared to longer implants (after periods of 1 to 5 years in function). The authors recommend that short implants should be carefully selected because they may present greater risk for failure compared to implants longer than 6 mm [458].

There is promising evidence that modern short dental implants can offer a simpler and safer alternative for managing posterior partial edentulism. In order to maximise the potential for favourable outcomes, it is important to ensure sound treatment planning and surgical principles are employed and that risk factors are appreciated (e.g. smoking, low bone density, and operator experience)[366]. Every effort should be made to

maximise BIC, minimise non-axial loading, minimise parafunctional habits/activities, and ensure that the implant and dental prosthesis can be well maintained. Based on the review of the literature, survival rates above 90% should be expected for short implants (6 mm to 10 mm lengths). Based on the available evidence, caution should be employed when using implants shorter than 6 mm as they may be at greater risk of failure. Further research with higher-level evidence, especially for implants ≤ 6 mm in length, should be performed to further investigate and support the use of short implants.

2.8 Objective Assessment of Masticatory Function: Chewing Tests Utilising Sieving Methodologies

Mastication is the process of chewing food in preparation for swallowing and digestion [138]. The key function of mastication is to comminute consumed foods into smaller particles, thereby increasing the total available surface area over which the digestive enzymes can effectively act and increase the bio-accessibility of the nutrients contained within food. [459-461]. In addition to the physical act of pulverising food, the mastication process also facilitates the lubrication of food with saliva and the formation of a bolus that is suitable for swallowing [462, 463]. From a functional perspective, prosthodontics is concerned with ensuring that a sufficient quantity and quality of functional tooth units are available to enable satisfactory mastication. Objectively assessing how a given occlusion functions offers an insight into the presence and extent of any masticatory limitations. Objective measures provide tangible information that can be observed and measured by a third party (i.e., such as a clinician and/or researcher). Subjective assessment of mastication and treatment outcomes is provided by the patient and as such cannot be directly observed by a third party. A number of instruments have been developed, largely questionnaire based, to try and quantify subjective measures including the perception of function and the impact of a patient's condition and/or treatment on his or her quality of life. The significance of subjective measures has gained greater importance in more recent times, stemming largely from the fact that relatively weak correlations have been reported between objective and subjective measures [464, 465]. Therefore, both objective and subjective measures provide important information that can be used to assist in making better-informed treatment planning decisions and to compare before and after treatment outcomes.

Masticatory performance is an example of an objective measure of mastication, with the particle size distribution of a chewed and recovered food sample being the most frequently employed measure for characterising this outcome [461, 463]. It is influenced by three broad variables: dental status (particularly occlusal contact area), strength of the muscles of mastication, and jaw movements [466]. Masticatory performance essentially defines the ability of an occlusion to comminute a test food over a given number of predetermined chewing cycles, usually under standardised testing

conditions [138]. This measure needs to be differentiated from another objective measure referred to as 'masticatory efficiency'; masticatory efficiency assesses the number of chewing cycles or time (i.e. effort) required to reduce a given test food to a certain particle size [138]. A 'chewing' test involves collection of the bolus after a predefined number of chewing strokes, with the observed granulometry characterising the effects of the dental and muscular apparatus on comminution of the sample. A 'mastication' test differs in that the bolus is collected at the swallowing threshold, with the granulometry observed reflecting a subject's ability to adapt his/her mastication to food texture [461].

Passing a material or food particles through a sieve or a series of sieves with predefined mesh (aperture) sizes offers a means whereby chewed and recovered test material can be separated into different particle sizes and then analysed [461]. In theory, a subject with a superior masticatory performance will achieve a smaller average particle size after comminution of a test material relative to that of a subject with an inferior masticatory performance. The physical sieving method is most commonly employed method used to process recovered test material(s) [467]. The sieving methodology is an evaluation method that is generally well accepted with proven validity and reliability and has been used as the 'gold standard' test for masticatory performance [462, 464, 468]. The validity of this method is supported by high correlations with masticatory determinants such as the number of missing teeth, changes in available occlusal area, and number of chewing strokes [469]. The use of a simple sieving method for the purpose of assessing mastication was described as early as 1901 [470] with fractional sieving, a modified version of the simple method that enables a more detailed particle size distribution to be established, being described as early as 1924 [471]. Even though the chewing test utilising a sieving methodology can yield very useful information, it is disadvantaged by the time and potential costs involved in running these tests (i.e. cost of automatic sieve shakers and multiple sieves), and the complexity of the process [462]. Because of these limitations, these tests are rarely used in the general clinical setting [464].

A broad range of variables are associated with chewing tests employing sieving methodologies, and they include the choice of test material (natural or artificial), amount of material chewed, chewing side(s) used, number of chewing cycles before

expectoration, number and size of sieves used (i.e., sieve aperture sizes), wet or dry sieving, and the nature and extent of sieve shaking (i.e., manual, automated, amplitude, duration, etc.). It is clear from the literature that there is no universally accepted standardisation of the methodologies used in chewing tests employing sieving. This limits the ability to compare results arising from masticatory performance tests using dissimilar methods; comparisons can only be made if both a standardised particle size analysis and a standardised test food are used [472]. These variables will now be reviewed.

Nature of the Chewing Test Material

Chewing test materials can be broadly categorised as either natural foods or artificial (i.e. synthetic) materials. Natural test foods are found in nature, or are processed from a natural food source, and are generally edible. Artificial test materials are not found in nature, at least not in the state in which they will be used during testing and are often created by mixing two or more substances together. Obtaining a universally accepted test material that is uniform in quality has been difficult and is an issue that remains unresolved [472]. Table 2.6 lists examples of test foods and materials used in masticatory performance tests together with the number of chewing cycles employed.

Table 2.6. Materials used for chewing tests and number of chewing strokes employed.

Test Food/Material	Number of Chewing Strokes
Natural	
Almonds (not specified)	5 [473, 474], 15 [474], 20 [475], urge to swallow [476]
Almonds (roasted/cooked)	5 [477]
Peanuts (not specified)	5, 10, 15 [467], 20 [244, 459, 478-499], 25 [467], 30 [467, 500], 35 [467]
Peanuts (roasted)	1-8, 10, 12, 14, 16, 18 [501], 20 [501, 502], 22, 24 [501], 40, 60 [502]
Carrots	30 [499], 40 [478, 490, 492, 497, 498, 503]
Rice	Urge to swallow [504]
Frito corn chips	15, 30 [505]

Decaffeinated coffee beans	5 [506]
Gelatine	15 [507]
Vegetable oils/fats/carnauba wax	5, 7, 10, 15, 20, 30 [464], 10 [508]
Lean ham	20 [509]
Artificial (Synthetic)	
Optosil	15 [510], 20 [460, 511-518], 40 [518], 60 [517, 518], 80 [518], 120 [517]
Optosil Comfort	15 [468], 20 [519, 520]
Optosil Plus	20 [521-525]
Optocal	15 [510, 526-529], 20 [171, 520, 530-533], 30 [528], 40 [530, 533-538]
Optocal Plus	15 [539-542], 20 [543-546], 60 [545], urge to swallow [541]
Optosoft	15 [547, 548], 30 [547]
Cuttersil	20 [549-554], 30 [466, 555]
Speedex	20, 30, 40 [556]
Agar hydrocolloid	10, 20 [557]
Hydrocolloid	5, 10, 15, 20, 25, 30, 35 [467], 20 [558]
Perfil	20 [520]
Zetaplus	20 [520], 60 [173]
Silaplast	60 [559]

The broad range of indicative test foods and materials that have been used in chewing studies again illustrates the challenge of standardisation and comparison between studies. Each material has advantages and disadvantages when used in chewing tests, differing in terms of textural and physical properties and behaviour to chewing. Familiarity is a major advantage of natural foods with subjects being accustomed in chewing them [459, 463, 472]. Such familiarity could favour a more habitual chewing action during the test procedure(s) [534]. Potential differences in consistencies within batches, between batches, and over-time are disadvantages of natural foods when employed as test materials. Seasonal and geographic variations coupled with difficulty in controlling the size of the natural test foods can result in unexpected differences that

lower their reliability as test materials [459, 464, 472]. The high prevalence of nut allergies in the general community may also limit the usefulness of peanuts in large-scale trials [560]. Advice from early research employing masticatory performance tests was that the test food/material selected should be one that is normally consumed and should offer the proper degree of difficulty, hence permitting a normal dentition to receive a high rating and a deficient dentition a poor rating [561].

In contrast to natural foods, artificial materials are less susceptible to issues of inconsistencies, provided the identical ingredients are used and a reproducible method is used when creating the test material samples. The use of artificial test materials offers the advantage of fulfilling the need for standardisation and reducing the variations in the force-deformation, fracture, and tear strength characteristics of the test material [459, 518]. Other documented advantages of artificial foods include their standardised hardness, anisotropy, resistance toward dilution in saliva, and storability [462]. Nevertheless, even artificial materials can potentially show variations in properties because of alterations or modifications made by the manufacturer to the individual ingredients over time. Some authors appear to appreciate the importance of this issue, providing detailed information about the version of test material utilised in the chewing test (i.e. year and details of manufacturer) [539]. A disadvantage of artificial materials is that patients are generally not accustomed to eating or swallowing them [562]. It has however, been shown that good correlation exists between the chewing of peanuts (i.e. natural food) and Optocal Plus® (artificial material) in terms of number of chewing cycles prior to swallowing [541].

The physical properties of a test material, and in particular its behaviour to chewing effort, will have an influence on the masticatory performance achieved. Debate exists as to the suitability of Optosil®, a commonly cited condensation silicone material, as a suitable test material for chewing tests. Although the force needed to crush Optosil® is much larger than that required for natural foods [563] (possibly affecting habitual chewing), it is within the physiological range of healthy subjects [564]. In contrast to young adults with natural dentitions, complete denture wearers have demonstrated a very poor ability to break down Optosil® [518]. An explanation given for this relates to the relative maximum bite forces that can be generated by complete denture wearers in comparison to the fracture strength of the material. As the maximum bite forces

generated reduce and start approaching the fracture strength of the test material, the likelihood exists for inferior comminution of the test material. Furthermore, if the maximum bite force generated falls below that of the fracture strength of the material, then no comminution can be expected. The relative differences between maximum bite force and fracture strength of the material appears to be an important consideration in assessing the suitability of a test material. The test material should possess high enough fracture strength to allow for differences between various occlusal states and treatment options to be observed (i.e., a soft material with low fracture strength may be sufficiently comminuted by a range of occlusions and hence masking inferior masticatory performance). Although relatively firm, the Optosil® family of materials have been shown to correlate favourably with masticatory variables such as the number of occlusal pairs and bite force, and as such, have been deemed suitable for use as chewing test materials [519].

A modified version of Optosil®, called Optocal, has been developed to address some of these potential concerns. It demonstrates better fragmentation in patients with severely compromised function. The basis of this material is Optosil® putty which is mixed with dental plaster, alginate, Vaseline®, toothpaste, and catalyst paste [526, 531]. Patients have judged the texture of Optocal to be comparable to that of cheese and boiled vegetables [526]. It has been suggested that Optocal may be preferred to Optosil® for assessing masticatory performance in complete denture wearers [563]. A disadvantage of Optocal relates to the number of individual ingredients involved and the potential variations that this could add to the manufacturing process. A heated version of Optosil®, called Optosoft, has also been described as a test material that is easier to chew [547]. Based on this information, it may be advisable to use a test material that is easier to chew than Optosil® when assessing masticatory performance of complete denture wearers, whereas Optosil® is suitable for dentate and partially dentate subjects (especially when a high degree of discrimination between treatments is being sought).

Other material properties can also impact masticatory performance. Gelatine is a material that is more elastic in nature than peanuts and requires greater chewing shearing activity to break it down. Peanuts are harder and more brittle in texture and behave differently when chewed [459]. In other words, the nature of the food affects its

ability to be reduced into particles [565]. As a consequence, studies using test foods with different properties and different behaviours to chewing pressures will produce different masticatory performance outcomes. Again, this highlights caution when comparing results of studies employing different test materials. Performing multiple chewing tests using test materials with different properties can provide a broader insight into the objective chewing ability of patients when evaluating the effect of prosthodontic treatment [459]. It appears that almonds, carrots, and peanuts are amongst the most commonly used natural foods in granulometry tests, whilst Optosil® (and Optosil-based) materials are the most commonly used artificial materials [461].

Amount of Test Material Used

The amount of test material used in masticatory performance tests is another variable that lacks standardisation. Peanuts and silicone are two of the more commonly used test materials. Table 2.7 provides information as to the sample amount of test materials commonly used in chewing experiments.

Table 2.7. Test material sample amounts commonly used in chewing experiments (by number and/or weight).

Material	Dimension/Shape/Volume	Amount
Peanut	Natural food – natural variation	Approx. 3 grams [244, 459, 467, 478-481, 483-489, 491, 493-497, 502, 541, 566-572]
Silicone	Cubes with 5.6mm edge length (volume: 3cm^3).	17 cubes [171, 468, 510, 512, 514-516, 518, 519, 526, 529, 530, 532-535, 537-545, 573-580]
Silicone	¾ pieces of a cylinder with 20mm diameter and 5mm height.	Approx. 2.5 grams [466, 513, 521-525, 546, 549-552, 554, 556, 581, 582]

There does not appear to be any particular rationale as to the amount of initial chewing test sample size and amount used in previous studies (either by number, weight, or

volume) other than it being an adequate amount that can be comfortably chewed and subsequently recovered for scientific analysis. When peanuts are used as the test food, it appears that masticatory performance is independent of the size of mouthful as long as the number of chewing cycles is kept constant [561].

It has been suggested that the edge size of a cube of material may have an influence on the masticatory performance observed. A pilot study reported that complete denture wearers had difficulty chewing a sample of Optosil® cubes with 8mm edge length and volume of $4cm^3$. Once changed to cubes of 5.6mm edge length ($3cm^3$ volume), patients could chew the material, although the particle size distribution was dominated by larger particles [563]. This latter observation most likely relates to the lower maximum bite forces that can be generated by complete denture wearers relative to the fracture strength of the Optosil® material as previously discussed.

Number of Chewing Cycles Prior to Expectoration of test sample

Table 2.6 provides examples of the number of chewing cycles employed prior to sample expectoration across various studies. It appears that the use of twenty chewing cycles is preferred in a large majority of studies reviewed. One study assessing the comminution of Optosil® and Optocal in both dentate subjects and denture wearers found that large differences in median particle size (MPS) between the two groups was established within twenty chewing strokes. The differences in MPS between Optosil® and Optocal within both groups also became largely apparent within twenty chewing strokes [563]. This same study further addresses the issue of number of chewing cycles by suggesting that in order to measure differences in masticatory performance, the length of the chewing sequence should be based on the type of dentition of the subjects under investigation as well as the physical characteristics of the test food.

In view of the findings that the differences in MPS were largely established within twenty chewing strokes, sequences of twenty chewing strokes may be sufficient when Optosil® and/or Optocal is used as the chewing test material in dentate and partially dentate subjects. For complete denture wearers, it does not seem necessary either to extend the chewing sequence beyond forty chewing strokes, although prolonging the chewing sequence to sixty chewing strokes for Optosil® may be preferred to allow for

inter-individual differences to develop completely. It is preferable to investigate masticatory performance through more detailed measurements using shorter chewing sequences [563].

A time-based chewing test using a ten second chewing interval rather than the number of chewing strokes has been described [583]. Most studies reviewed do not offer a detailed explanation as to the reasoning behind the selection of the number of chewing cycles employed. This decision may be based on precedence from previous studies, some of which have reported that twenty cycles enable adequate discrimination of masticatory performance. The information contained in Table 2.10 shows that chewing cycle protocols of twenty chewing strokes are often employed when peanuts or silicones are used as the chewing test material, while forty chewing strokes are often seen in studies using fresh/raw carrots as the test food.

Chewing Side(s) used

Three general options for chewing side have been described in previously reported masticatory performance tests. Examples of these options are documented in Table 2.8.

Table 2.8. Chewing side(s) options described in masticatory performance tests.

Chewing Side	Literature
Left or Right or Treatment side (as instructed by researcher/examiner)	[244, 466, 468, 473, 479, 480, 489, 494, 498, 555]
Preferred chewing side (as determined by the subject)	[459, 467, 482-485, 488, 492, 497, 501, 569, 571, 572]
Unrestricted or Habitual or Normal or Natural or Whole-Mouth chewing pattern (may involve unilateral or bilateral chewing)	[171, 173, 472, 486, 491, 493, 502, 510-512, 516, 519, 521, 523, 524, 526, 532-535, 537, 539, 545, 546, 549, 550, 552, 553, 570, 575, 581, 582, 584]

Permitting a subject to use his or her habitual chewing pattern, which often involves use of a preferred side, appears to be the more commonly used option. It has been suggested that masticatory performance tests employing unilateral chewing yield the

same results as swallowing threshold tests, which permit bilateral chewing [585]. This observation is further supported by another set of authors who report that a good approximation of masticatory performance of the whole mouth can be obtained by measuring the performance of the side that is preferred for mastication [561]. One study used a method whereby almonds were sealed in two thin latex bags. One bag (containing almonds) was chewed on the left side, after which the other bag (containing almonds) was chewed on the right side. The contents of each bag were then combined for subsequent processing and analysis [474]. Based on these observations, it appears that either (preferred) one-sided or bilateral chewing can yield similar outcomes. The decision on which method to use may be influenced by what the examiner is testing for.

Counting the Number of Chewing Strokes per Cycle

The methods employed in relation to this variable are difficult to determine from the descriptions in the available literature. Although many of the studies reviewed inform that the researcher(s) count the number of chewing cycles [472, 475, 511, 512, 519, 520, 523, 527, 532-534, 543, 544, 549, 550, 552, 573, 574, 577, 581], there is little mention as to whether the counting is verbal and audible to the subject. In addition to the number of chewing strokes visually monitored by the researcher(s), the use of video recording to verify the number of chewing strokes has also been reported [576].

Some study protocols provide subjects with an opportunity to chew the test material prior to the formal test in order to train or familiarise themselves with the texture of the material [516, 532, 554]. The formal chewing test commonly involves multiple chewing cycles and recovery sequences. The basis for this is two-fold: to reduce the impact of variations between individual chewing sequences, and to ensure that an adequate amount of test material can be recovered for appropriate analysis (i.e., by combining the recovered material from each chewing sequence). Examples of the number of chewing and recovery sequences used include: two [173, 485, 532, 545, 547], three [244, 459, 473, 480, 483, 489, 492, 494-498, 501, 503, 566, 568, 571, 586], five [511, 513, 521-525, 549-552, 554, 570, 581, 584], and seven [466, 555]. One method described involves the chewing test and sieving process being conducted twice, with the portion showing the least percentage loss between initial and final weights being used for subsequent analysis [576].

The incorporation of rest periods between successive chewing and recovery sequences has been proposed. This takes into account the potential of muscle fatigue occurring when performing repeated chewing cycles which could affect masticatory performance [553, 554, 584]. Rest periods of forty seconds [549, 550], and one minute [502, 548] between successive chewing cycles have been used, whilst one method provided an opportunity for the subject to rest between trials if he or she felt fatigue [552]. Very few of the articles reviewed discuss the issue of intra-test and inter-test reproducibility of the sieving methodology. However, it was concluded that stable measurements could be achieved when masticatory performance was measured on different occasions [467].

Number of Sieves Used and Sieve Aperture Sizes

One of two techniques can be employed when sieving recovered test material. The first technique uses only one sieve and is referred to as the single sieve technique. This technique simply determines the amount of test material that can pass through a single sieve (of a given aperture size) and is usually expressed as a percentage by weight. A commonly used sieve aperture size is the US standard number 10 sieve (2 mm sieve aperture size) and is often used in studies using peanuts as the chewing test material [478, 482, 485-487, 490, 491, 493, 495, 496, 572]. The US standard number 5 sieve (4 mm sieve aperture size) is also used in single sieve analyses, usually when carrots are used as the chewing test material [478, 490].

The second technique involves the use of multiple sieves of different aperture sizes, and is referred to as fractional sieving [481]. This technique is somewhat more involved, since the recovered material is progressively sieved through apertures of decreasing size (i.e., from wider/larger to narrower/smaller sieve openings). A recovered sample containing a greater proportion of small particles will result in more of the particles passing through the wider apertures and being retained on the sieves with narrower openings. There does not appear to be any standardisation in the literature as to the number of sieves used and the aperture sizes selected when using the multiple sieve technique. Table 2.9 references some examples of the different number of sieves used in chewing tests.

Table 2.9. Number of sieves used in masticatory performance tests.

Number of Sieves Used	References
1	[464, 473, 478, 482, 485-487, 489-491, 493, 495, 496, 500, 503-505, 508, 509, 587]
2	[477, 507, 557, 568, 588, 589]
4	[475, 506, 566, 567]
5	[173, 479, 584, 590]
6	[554]
7	[466, 511, 531, 549-553, 555, 556, 581, 591]
8	[244, 459, 474, 480, 483, 501, 513, 525, 530, 533, 536, 546, 559, 578, 582]
9	[510, 517, 529, 540, 542]
10	[171, 467, 468, 499, 511, 512, 514-516, 518-524, 527, 532, 534, 535, 537, 539, 541, 543-545, 563, 573-577, 592]
11	[548, 586, 593]
12	[502, 594]
14	[472]

The use of a stack of ten sieves is commonly found in the literature. With respect to apertures sizes, the largest size tends to correspond to the initial size of the test food being used, after which the sizes gradually become narrower. It is easier to match the size of a test material with standardised dimensions, such as a cube of Optosil® of known edge length. The 5.6 mm sieve aperture is commonly used as the first sieve (i.e., the largest sieve) with progressively smaller aperture-size sieves stacked below this [171, 501, 502, 510-513, 515, 516, 518-520, 525-527, 529-536, 539-545, 549-555, 559, 563, 575-578]. A progressive change in sieve aperture size corresponding to a ratio of $2^{1/2}$ is often used in the multiple sieving techniques [468, 472, 548, 586, 593]. A number of methods also discuss the use of a baseplate or collector at the bottom of the stack of sieves, providing an opportunity for all of the recovered material to be collected for analysis [475, 501, 510, 512, 516, 517]. Despite the additional work and time required

to perform fractional sieving, it does allow for a greater depth of analysis of the recovered sample.

An important study comparing the ability of single and multiple sieve methods to determine masticatory performance concluded that a single sieve method can provide reliable results if the sieve diameter used is close to the median particle size of the recovered samples from all of the subjects. However, if more detailed information about the masticatory performance and greater reliability is required, use of the multiple sieve method is recommended [594]. Advantages and disadvantages of the single and multiple sieve methods as presented in this referenced study are summarised in Table 2.10.

Table 2.10. Single and multiple sieving methods - Advantages and disadvantages of each method.

	Single Sieve Method	**Multiple Sieve Method**
Advantages	• Less effort and time (only one sieve required). • Simple data analysis (Masticatory Performance Index (MPI) = % weight passing through the sieve.	• Allows determination of a median particle size: this has a physical meaning and allows for comparisons. • Chance weight fluctuations cancelled out in the cumulative function used in the data analysis (i.e. low weight on one sieve may be compensated by relatively larger weight on the next sieve).
Disadvantages	• Reliability of the MPI deteriorates when the single sieve aperture deviates too much from the MPS (the MPI should not be outside 20-80% in order for reliable results). • Results susceptible to chance fluctuations.	• More effort, time, and equipment required. • Need to calculate a particle size distribution and a MPS. • If comminution is insufficient, the MPS approaches the initial size of the test food, and the '*b*' variable becomes theoretically infinite, making the analysis less tangible [595, 596].

When discussing granulometry, the particles are characterised by their Feret diameter [461, 597]. The Feret diameter (or Feret's diameter) is a measure of an object size along a specified direction, and in general, is defined as the distance between the two parallel planes restricting the object perpendicular to that direction. Theoretically, the smallest Feret diameter of a particle (mini Feret diameter) relative to the aperture size of the sieve mesh will determine whether a given particle will pass through this sieve; the actual passage of the particle through the sieve will also be dependent on the fact that the mini Feret diameter aspect of the particle must interact perpendicularly with the sieve.

Dry and Wet Sieving

Dry or wet sieving refers to the state of the recovered material during the sieving process. Dry sieving requires the recovered material to be suitably dried before undergoing the sieving process. Wet sieving allows the recovered sample to be sieved whilst still in a wet/hydrated state. In addition to this, water (or alternative liquid) can be used to help facilitate the wet sieving process. Many of the natural test foods tend to clump together when wet, so wet sieving of these samples is difficult. In an attempt to overcome this problem, chewed peanuts have been stored in detergent solution (50mL at a concentration of 0.03%) prior to the wet sieving process [493]. Dry sieving appears to be a more common approach. Table 2.11 outlines a number of studies that employ wet or dry sieving, and the test material used.

Table 2.11. Sieving method (dry and wet) and chewing test materials used.

Sieving Method	Test Material
Dry	Almonds [475]
	Roasted Peanuts [501, 502]
	Optosil [510-514]
	Speedex [511]
	Optocal [171, 510, 520, 526, 527, 530, 532, 535, 537]
	Optocal Plus [524, 539, 541, 543-546]
	Optosil Comfort [519, 520]
	Perfil [520]
	Zetaplus [173, 520]
	Gelatin [507]
	Optosil Plus [522, 523, 525]
	Cuttersil [466, 549, 550, 552-555]
	Silaplast [559]
	Decaffeinated Coffee Beans [506]
Wet	Peanuts [459, 467, 478-480, 483, 485-487, 491, 493, 500]
	Carrots [478]
	Agar Hydrocolloid [557]
	Optocal [533]
	Hydrocolloid [467]

When dry sieving is employed, the saliva, water, and any disinfectant solutions must be sufficiently removed from the sample with some form of drying process before the sieving process [512, 514, 556]. Some techniques involve drying the sample at room temperature [507, 535], whilst other methods described involve the use of ovens or desiccators that are set to various temperatures for differing lengths of time. If the material is wet sieved, the drying process takes place after the sieving process. This usually takes place prior to the weighing process in order to minimise the impact of hydration on the masticatory performance observed. Examples of drying techniques described in the relevant literature are listed in Table 2.12.

Table 2.12. Examples of drying methods employed in relevant sieving studies.

Temperature	Drying Time	References
130 ^{0}C	40 minutes	[475]
100 ^{0}C	3 hours	[572]
100 ^{0}C	1 hour	[485]
80 ^{0}C	25 minutes	[519, 523]
80 ^{0}C	24 hours	[487, 491, 493]
80 ^{0}C	25 minutes	[512, 515, 516, 519, 521, 523, 524, 575]
80 ^{0}C	1 hour	[466, 511, 549, 550, 552-556, 581]
80 ^{0}C	3 hours	[244, 459, 480, 483]
80 ^{0}C	24 hours	[491, 493]
60 ^{0}C	20 hours	[527]
60 ^{0}C	3 hours	[472, 533]
60 ^{0}C	24 hours	[479, 510, 526, 541]
54 ^{0}C	6 hours	[598]
37 ^{0}C	24 hours	[502]
Ambient air	3 hours	[500]
Room temperature	3 days	[543]
Room temperature	1 week	[171, 507, 535, 537, 538]
Freeze-dry technique (- 40 ^{0}C)	12 hours	[501]

Wet sieving allows the recovered sample to be directly sieved without the delay of a pre-sieving drying step, and hence making the process more efficient. If the material is to be weighed as part of the analysis, the efficiency of the process will be reduced because a post-sieving drying step will be required. It would be expected that hydrophobic materials, such as silicones, and materials that don't clump when hydrated are more suited to this type of sieving method.

One method used to avoid the effect of saliva on the test food is to place the sample material in a thin sealed latex bag. This still enables chewing of the material without contacting saliva. This method will ensure minimal loss of sample material during the

chewing and recovery steps of the process [474]. Despite the potential to interfere with the natural chewing process, it has been reported that bagged almonds demonstrate well-correlated MPSs with almonds chewed directly [599]. Similar high-level concordance was found between chewing bagged and unbagged silicone [546].

Mechanical Sieving – Duration and Settings

Sieving can be performed either manually or with the assistance of a mechanical sieve shaker or dental laboratory vibrator. Most contemporary studies employ the use of mechanical sieve shakers. Even though the use of mechanical mechanisms to assist with the sieving process is described in the literature, few papers provide a detailed description of the type of shaker used (i.e., make, model, and manufacturer), and the settings used. Examples of more detailed descriptions of the sieving mechanism used are: "use of a vibratory sieve shaker (AS200 digit; Retsch Technology GmbH) at 70Hz for 3 minutes" [502], and "vibrated simultaneously on a dry-type full automatic sonic sifter set at the possible maximum vibration for 5 minutes (ROBOT SHIFTER RPS-85, Seishin, Japan) and pulse interval set at 1 second" [501]. The settings of relevance include: the duration of sieving, the vertical movement of the shaker base (amplitude), the frequency, the speed of vertical movement of the shaker base, and any rotational movement of the shaker base (if rotation is possible). These parameters are of significance when attempts are made to replicate studies or to compare results of different studies. A variety of sieving times have been used with examples listed in Table 2.13. The complexity of sieving apparatus that is most appropriate is determined by the degree of accuracy and reproducibility being sought after.

Table 2.13. Sieving times referenced in relevant literature.

Sieving Time	Relevant References
60 seconds	[475, 513, 525, 546]
2 minutes	[466, 474, 479, 511, 521-524, 530, 533, 549, 550, 552-555, 581, 582]
3 minutes	[502, 506]
5 minutes	[501, 526, 527, 531, 584, 590]
10 minutes	[574, 577]
12 minutes	[468]
20 minutes	[171, 512, 514, 519, 532, 534, 535, 537, 539, 541, 543-545, 573, 576]

Analysis of Recovered Samples

The purpose of passing a recovered sample through a sieve (or series of sieves) is to separate the particles according to their dimension(s), and when multiple sieves are used, to determine a particle size distribution. Once the recovered sample has been sieved, the particles collected on the sieve(s) can be analysed by a variety of measures, including weight, volume, number of particles on each sieve, and image analysis of the particles. The following section briefly discusses some of the more commonly used analytical methods.

The Masticatory Performance Index (MPI)

This is a relatively simple form of analysis, essentially reporting the ratio of material (by weight) passing through the sieve to the total material recovered expressed as a percentage [475, 479, 485, 486, 491, 494, 496-498, 505, 509, 561, 596, 600]. Another method involves normalising the weight of the material that passes through the sieve to that of the weight of the original material prior to the chewing test [473]. One study calculated masticatory efficiency as the weight percentage of fractioned material that passed through a 5.6 mm mesh [171]; additional studies have assessed masticatory performance based on the amount of sieved test material passing through a number 10 US-standard sieve divided by the total weight of the recovered material [493, 494, 572].

Another method involves subtracting the MPS (as obtained by the sieving process) from the initial particle size, normalising it to the initial particle size, and then converting it to a percentage [536].

Index of Masticatory Efficiency (IME)

Some authors have used a double-sieve technique to calculate the IME and using this as a measure of masticatory performance. The IME is calculated using the empirical formula:

$$IME = 100[1- ((X+Y)/(2T-X))]$$

Where X and Y are the weights of the particles retained on the first (coarse fraction) and second (medium fraction) sieves respectively, and T is the total weight of masticated particles [479, 519].

Geometric Mean Diameter (GMD)

This measure is based on the weight of material retained on each sieve, with the GMD of the chewed particles calculated from the means of the weighted geometric means using Excel spread sheets [533]. The GMD represents the index of performance/chewing efficiency, with a lower value indicating better masticatory performance [533, 601].

Masticatory Performance determined by volume

Assessing the volume of particles remaining on each sieve, in contrast to weight, is another analytical technique that has been described. This analytical method usually involves the particles retained on the sieve being placed into a suitable centrifuge tube. After adequate centrifugation (i.e. 1,500 rpm for 3 minutes), the volume occupied by the particles is determined. The formula employed to assess masticatory performance using a single sieve technique and volume analysis of the recovered test material is [481, 482]:

$$\text{Masticatory Performance} = (F/(F+R)) \times 100$$

Where F is the volume of sedimentation of filtrate and R is the volume sedimentation of residue. Masticatory performance is calculated by dividing the volume of test material that passes through a given sieve with the total volume of test material recovered. This

fraction is then expressed as a percentage [476, 489, 490, 492, 497, 498, 503, 566-568, 571, 591, 602].

Masticatory Performance determined by numbers of particles retained on each sieve(s)

This measure has been described by the formula [557, 588, 589]:

$$\text{Masticatory Performance} = (B-A)/10$$

Where A represents the number of particles obtained after 10 strokes on a 1.40 mm sieve and B represents the number of particles obtained after 20 strokes on a 1.40 mm sieve.

Comminuting Ability Index (CAI)

Researchers evaluating the validity and reliability of a more contemporary method for evaluating masticatory function using discriminant analysis propose that the CAI (according to Kato et al. [603]) is an improved version of the sieving method proposed by Manly and Braley [561]. Put simply, the CAI assesses the distribution of comminuted test food remaining on a size 10 US standard sieve as measured by digital image analysis. The CAI was obtained by input of the size distribution into the formula determined from the discriminate analysis [464].

The use of weight, rather than volume and number of particles, appears to be the more commonly used measurement for the analytical methods used to assess masticatory performance. Another method for determining masticatory performance involves calculating the slope of the regression line where the x-axis represents the number of chewing strokes and the y-axis represents the number of masticated particles on each mesh [467]. Masticatory Performance has also been defined by the time it takes for a subject to chew one almond. The masticatory performance is calculated from the ratio of one over the time taken to chew an almond [587].

Fractional (multiple) Sieving

A frequently used method for analysing the recovered test material using the fractional (multiple) sieving method involves weighing of the particles retained on each sieve and then using mathematical modelling (cumulative function) to describe the particle distribution. The interpretation of the distribution can then be used to describe the 'quality' of mastication, with a particular reference to the MPS, also referred to as X_{50}. The mathematical function often used for this purpose is the Rosin-Rammler equation [171, 244, 459, 466, 468, 480, 483, 501, 502, 510-516, 519-527, 532, 534, 535, 539, 542-544, 549-555, 559, 563, 573-577, 581, 584, 594], and is defined by:

$$Q_W\text{-}(X) = 1 - 2^{-(X/X_{50})b}$$

Where:

- $Q_W\text{-}(X)$ is the fraction by weight of particles with a size smaller than X,
- X_{50} is the MPS by weight, and is the aperture size of a theoretical sieve through which 50% of the weight can pass,
- *b* is the variable which represents the size spread of the distribution (i.e., the so-called broadness variable). A higher broadness variable is reflective of a steeper slope that signifies a tighter distribution of the particle sizes (i.e., less variation from the smallest to the largest particles).

This equation enables determination of the amount of test material (by weight) that is less than size X. The X_{50} (MPS) can also be used to compare the masticatory performance between subjects and within subjects tested at different time points. The variables X_{50} and *b* can be determined by curve-fitting the data on the equation by using a least squares method. A more efficient and effective masticatory system will result in a greater degree of food comminution and smaller particle size distribution (i.e., larger relative proportion of smaller particles). A larger X_{50} value indicates a relatively inferior masticatory performance.

The theoretical MPS can also be determined graphically (graph method) by plotting the cumulative per cent weights from each trial (y-axis) against sieve aperture size in millimetres (x-axis). Finding the intersection point for 50% of the mass of the bolus along the Y-axis and then dropping a vertical line from the intersection to the X-axis

identifies the MPS [173]. The MPS values as calculated using the Rosin-Rammler equation and the graph method have been shown to be extremely close, suggesting that the two methods produce similar results. However, the Rosin-Rammler equation is more precise [584]. Using Optosil® as a standardised test material and describing the particle size distribution using the Rosin-Rammler function provides an opportunity to quantify the masticatory performance of an individual in a reproducible way [472]. A limitation of the Rosin-Rammler function is that it is less adequate in describing particle size distributions dominated by the presence of almost intact, equally-sized particles [518].

Optical Scanning Method

An optical scanning method has been developed that offers another tool for the analysis of recovered samples. Image analysis technologies are based on the transformation of three-dimensional food particles into two-dimensional figures [461]. One study comparing the particle size distribution of Optosil® obtained by an optical scanning method to that achieved through sieving, concluding that the optical scanning method is a valid, simple, and feasible method to determine masticatory performance [462]. A drawback of the optical scanning method relates to the fact that the third dimension needs to be estimated since the scanning process can only register two dimensions. The area, volume, and weight of the particles can only be determined once the third dimension has been estimated. Although this method shows promise and may be a feasible method for use in a clinical setting, the authors advise that further studies are required to test its ability to detect small changes in masticatory performance.

Other Methods Used for Determination of Masticatory Performance

A detailed description of other methods used to assess masticatory performance lies outside the scope of this literature review. For completeness however, some other methods discussed in the literature are summarised as follows:

- Colorimetric assay method; this technique assesses masticatory performance by measuring the amount (concentration) of dye released from particular test foods [604, 605].

- Food (or wax) mixing ability tests: this technique looks at a subject's ability to mix (via chewing) a range of substances such as two-coloured or colour changeable chewing gums [244, 459, 480, 483, 487, 510, 539, 569, 606-615].
- Glucose concentration tests: this technique analyses the concentration of glucose in solution containing chewed gummy jelly. The rationale behind this test is that the concentration of glucose in solution storing the chewed gummy jelly is directly correlated to the exposed surface area of chewed gummy jelly. A sample that is more highly comminuted will contain smaller particles, resulting in an increase in overall (exposed) surface area of the recovered sample and hence higher concentrations of glucose [459, 616-620].
- Use of 'biocapsules' containing beads of given composition. After chewing and recovery, the biocapsule contents are analysed using a spectrophotometer. The absorbance data obtained is transformed into dye concentrations using a mathematical equation. This information then forms the basis for assessing masticatory performance [621]. One study using fuchsin beads for evaluation of masticatory performance concluded that the reliability and validity were low because the fuchsin beads do not measure the grinding capacity of masticatory function (compared to silicone). Instead, this test food describes the crushing potential of teeth. Thus the two kinds of test foods (i.e. fuchsin beads and silicones) evaluate different properties of masticatory capacity [595].

The use of sieving as a method for processing recovered test material is well documented and still regarded as the 'gold' standard for assessing chewing or masticatory performance. Both natural foods and artificial materials have been used as test materials, with peanuts (natural) and condensation silicone (artificial) commonly used. Despite relatively wide use, it is apparent that there is a lack of standardisation of the sieving methodology, with much of this related to the numerous variables associated with the process. This lack of standardisation does not allow for direct comparisons between studies employing different methodologies. It has been suggested that the multiple (fractional) sieving technique is superior because a MPS can be determined which can be used as a measure to define and compare masticatory performance. It also appears that use of an artificial test food may help to reduce variations between samples, although one must be alert that even these materials can differ over time if a manufacturer makes modifications to the component compositions. There is merit in

recommending that a more standardised approach be agreed upon when using a sieving methodology to assess masticatory performance. Such an approach will enable results of studies assessing different clinical conditions and/or prosthodontic treatments to be more readily comparable.

2.9 Objective Assessment of Masticatory Function: Assessing bite pressure and occlusal contact area (OCA) with Prescale pressure-sensitive film

Biting (occlusal) force is defined as the force created by the dynamic action of the muscles during the physiological act of mastication [138]. Maximum bite force can be achieved when clenching in the intercuspal position at maximum effort, and is an objective static measure often used in the assessment of masticatory function [589]. Bite force has been said to contribute up to nearly 50% of the variation in chewing efficiency of adult subjects [622]. Since bite forces are the forces that are transferred into food for the purpose of breaking it down into smaller particles, it makes sense that this is a measure of interest when assessing masticatory function. Numerous methods have been used to measure bite force and/or pressure, including use of Piezo film, strain gauges, biting forks, bite force dynamometers, and stress paint [623, 624]. A wide range of maximum bite forces is reported in the literature, explained largely by differences in anatomical and physiological characteristics of patients [625]. As is the case with chewing experiments, comparing bite force data documented in studies employing differing equipment and methodologies is problematic. Many of the documented techniques used have limitations necessitating caution when interpreting the results [626].

Bite force (strain) gauge transducers are often customised for each subject, require use of complex equipment, assess stress at limited points on the surface being studied, and due to the thickness of the strain gauge, records the bite in an open position (i.e., often greater than 4 mm) [623, 624, 627-629]. Such open positions are unstable. Furthermore, subjects may be reluctant to bite maximally because of fear of tooth damage or pain [630]. Piezo film will only measure dynamic forces and cannot be applied for the assessment of static load applications [623]. The T-Scan system is convenient and simple but poor in regards to reproducibility and quantification [631]. Currently, no gold standard method for measuring occlusive force exists [632].

Prescale (Fuijilm Holdings Corporation, Tokyo, JAPAN) is a type of pressure transducer that that uses pressure-sensitive films to quantify contact pressure and contact area [623]. It is unique and differs to the other methods available for evaluating bite force in that it allows for the entire dental arch to be assessed in the one recording whilst

concurrently measuring the occlusal contact area [631, 633, 634]. Industrial needs to evaluate pressures between pressed surfaces provided the main impetus for development of the pressure-sensitive film by the Fuji Photo Film Company in 1977 [635-637]. Dental applications of this technology, such as measuring bite pressure and occlusal balance, was first described in 1978 (published in Japanese) [638]. In addition to the manual comparison of pressed films to calibrated colour scales to determine pressure outcomes, the Prescale system also involves a method whereby pressed films are optically scanned and analysed by a dedicated software program loaded onto a computer. This latter method increases the measurement accuracy of the system [639]. The Prescale system can measure the following parameters: maximum pressure (MPa), average pressure (MPa), pressed (occlusal contact) area (mm^2), load (bite force - N), and load centre position. Further to the numerous industrial applications of the Prescale system, it has more recently been used in a variety of medical research applications (i.e., forces applied during orotracheal intubation, measurement of plantar pressure, pressure distribution in the ankle joint, contact pressures at osteochondral donor sites in the knee, etc.) [640-646].

The general mechanism of action of Prescale involves the interaction between the active components of two film layers. The first layer (A-film) is randomly coated with microcapsules (2 to 25μm in diameter) that burst when pressure above a given threshold is applied to the film. Upon bursting, the released colourless agent (colour former) contacts and chemically reacts with the developer (colour generation agent) on the active surface of the second film (C-film) to generate a red colour. Because the nature of the microcapsules is adjusted to burst under different pressures, the distribution and intensity (darkness) of the red colour on the C film reveals the nature of the pressure occurring at the interface of the two contacting surfaces. The thinnest microcapsules with largest diameter break earlier (at lower pressures) whereas the thicker and smaller diameter microcapsules break at higher pressures [635, 647, 648]. The nature of the microcapsules on the A-film will determine the pressure rating of that film type (i.e., relative sizes of the microcapsules on the A-film). The functional formula between the applied pressure and the density of red colour is constant [633]. Figures 2.1 and 2.2 demonstrate the composition of typical Prescale films (both two-sheet and mono-sheet variants). Applied pressure that is below the lower pressure threshold for a given film-grade will not produce a red stain, whilst applied pressure above the upper

pressure threshold will produce a saturated stain [635, 649]. Table 2.14 shows some details of the eight different Prescale film types currently available. Each film type is designed to assess a different pressure range (entire range: 0.006 to 300 MPa). The C-film (containing the developer) is compatible with any of the A-films. Of particular note is the fact that some films comprise two separate sheets (i.e., two-sheet type), whilst some films comprise a single sheet that contains both the dye-forming microcapsules and the developing agent (mono-sheet type). The Prescale films designed for measuring medium pressure are available in both the Two-sheet and Mono-sheet variants.

Figure 2.1. Structure of mono-sheet type Prescale pressure-sensitive film (Source: Instruction Manual – Pressure Measurement Film PRESCALE, LLW. Fujifilm Holdings Corporation, Tokyo, Japan).

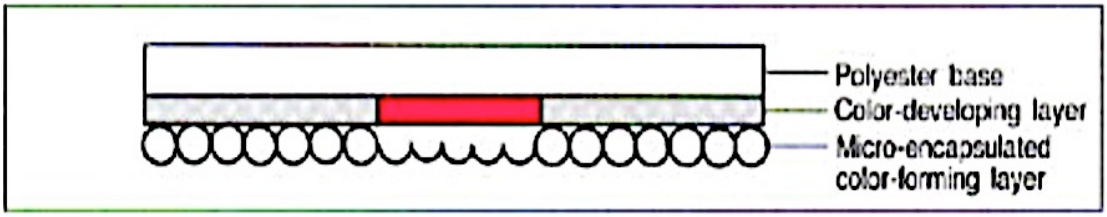


Figure 2.2. Structure of two-sheet type Prescale pressure-sensitive film (Source: Instruction Manual – Pressure Measurement Film PRESCALE, LLW. Fujifilm Holdings Corporation, Tokyo, Japan).

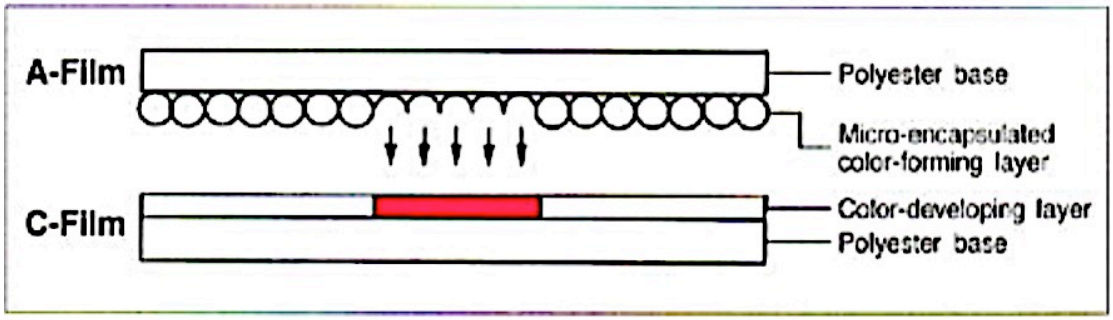


Table 2.14. Available Prescale films and some relevant features (Source: Operations Manual – Fujifilm Pressure distribution mapping system for PRESCALE FPD-8010E version 2.0. Fujifilm Holdings Corporation (2008), Tokyo, Japan).

Film type	Abbreviation	Pressure measurement range	Classification
For Extreme Low Pressure	4LW	0.05 – 0.2 MPa	Two-sheet type
For Ultra Super Low Pressure	LLLW	0.2 – 0.6 MPa	Two-sheet type
For Super Low Pressure	LLW	0.5 – 2.5 MPa	Two-sheet type
For Low Pressure	LW	2.5 – 10 MPa	Two-sheet type
For Medium Pressure	MW	10 – 50 MPa	Two-sheet type
For Medium Pressure	MS	10 – 50 MPa	Mono-sheet type
For High Pressure	HS	50 – 130 MPa	Mono-sheet type
For Super High Pressure	HHS	130 – 300 MPa	Mono-sheet type

The modern version of the Prescale software is referred to as the 'Fujifilm Pressure Distribution Mapping System for Prescale FPD-8010E'. The system requires a suitable optical scanner and a computer that serves as the processing engine. The FPD-8010E is a pressure image system that scans-in the pressurisation and converts it into pressure values. This essentially comprises the scanning process and the software management of the data. The functionality of the system can change over time in-line with software updates and newer versions. The FPD-8010E version enables automatic calibration of the system using a calibration sheet provided by the manufacturer. When scanning-in a pressed film, the software permits the following input variables to be customised/adjusted (source: Fujifilm Pressure Distribution Mapping System for Prescale FPD-8010E – Operations Manual, Fujifilm Holdings Corporation):

- Sample Name
- Examination date and time
- Measurement date and time
- Prescale film type
- Horizontal scanning count (for scanning of multiple films)

- Vertical scanning count (for scanning of multiple films)
- Examination temperature (^{0}C)
- Examination humidity (%)
- Resolution (mm)
- Pressure type – Continuous or Momentary

The manner in which the pressure is applied to the sheet will determine the selection of the 'pressure type' variable. 'Momentary' refers to situations where the time to reach the pressure is 5 seconds and then maintained for 5 seconds. 'Continuous' refers to situations where the time to reach the pressure is 2 minutes and then maintained for 2 minutes. The manufacturer provides two calibration charts for each film grade addressing each of the pressure types (Momentary and Continuous – See Figures 2.3 and 2.4). Furthermore, each chart has multiple calibration curves that compensate for different temperature and humidity conditions. When using the manual method, the colour on a pressed film is compared to the eight colour samples on the calibration chart (y-axis). The corresponding pressure is read off the x-axis of the chart. The other input of particular importance is the correct selection of the film-type being scanned. This will ensure correct analysis of the scanned data.

Figure 2.3. Standard continuous pressure chart for LLW Prescale pressure-sensitive film (Source: Instruction Manual – Pressure Measurement Film PRESCALE, LLW. Fujifilm Holdings Corporation, Tokyo, Japan).

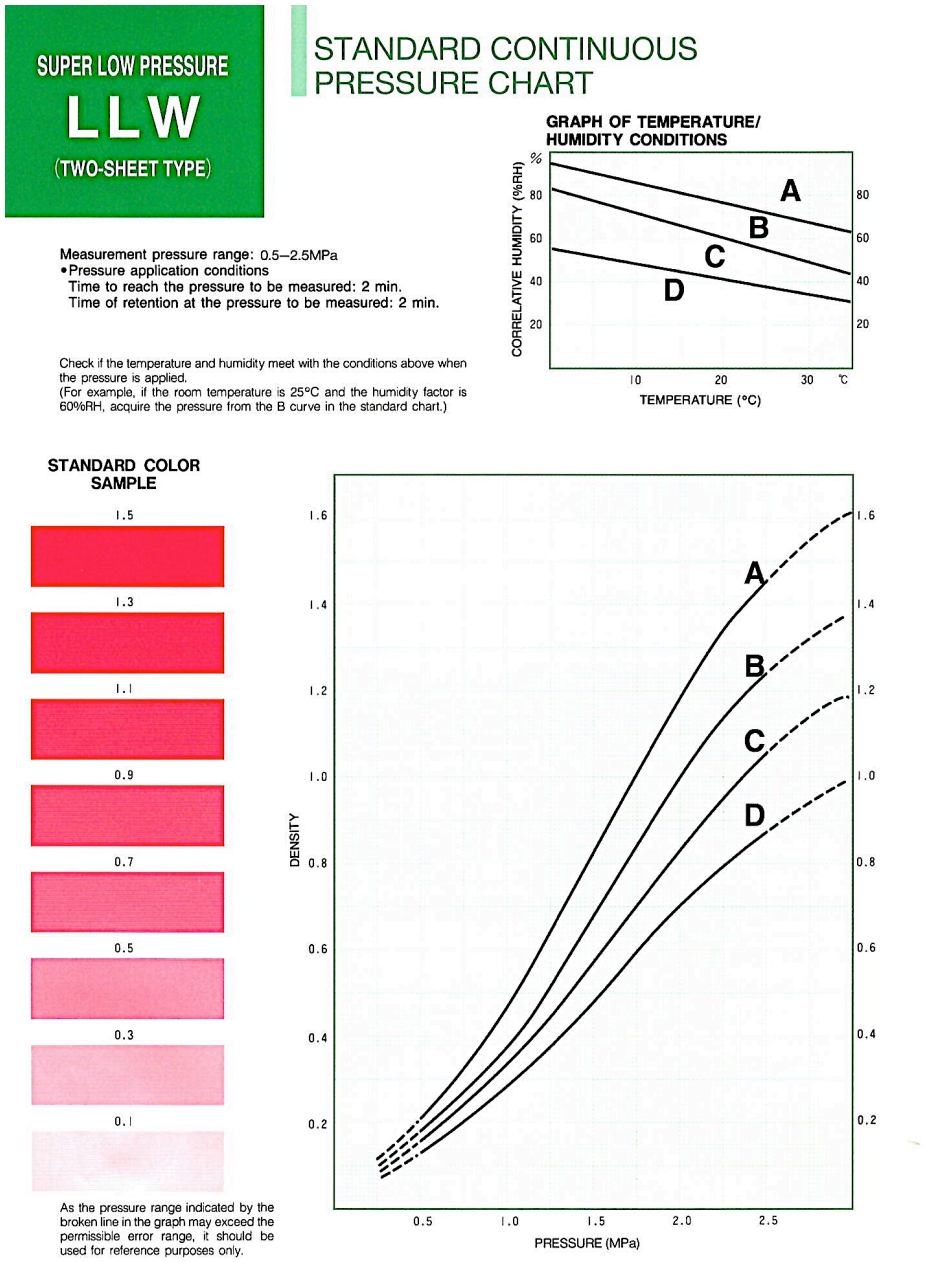
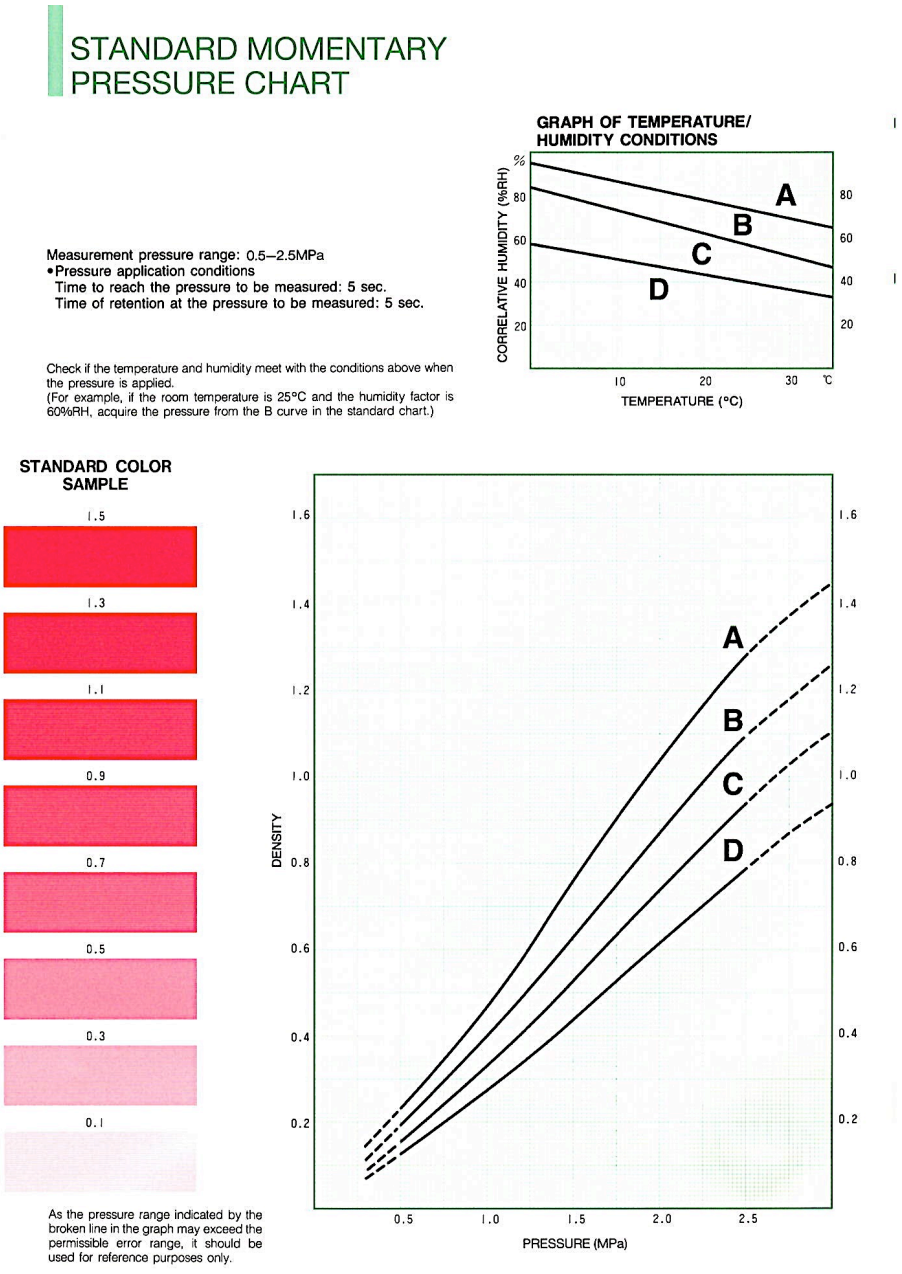


Figure 2.4 Standard momentary pressure chart for LLW Prescale pressure-sensitive film (Source: Instruction Manual – Pressure Measurement Film PRESCALE, LLW. Fujifilm Holdings Corporation, Tokyo, Japan).



Once the film has been scanned, the following measurements are displayed:

- **Prescale Film Effective Rate (%)**. This is the proportion of recorded pressure that lies within the detection range of the given film type. It is the red section of the total surface area (green refers to pressures below the detection range and yellow refers to pressures above the detection range).
- **Pressed Area (mm^2)** – The surface area on which all colours are generated.
- **Average Pressure (MPa)** – Average pressure of area on which all colour is generated.
- **Maximum Pressure (MPa)** – Maximum pressure of area on which all colour is generated.
- **Load (N)** – This is the load value of the area on which all colour is generated and is the product of pressed surface area and the average pressure.
- **Measured Area (mm^2)** – This displays the surface area of the area subject to processing by the FPD-8010E (the area specified and scanned with the scanner).

The software has many more features enabling enlargement and reduction, editing, and detailed interpretation and analysis of the scanned images. Because handling of the films can result in unwanted pressure applications (i.e., pressure that is not related to the area of interest), a method must be used to remove these stains. Two methods have been described to achieve this: a) the Erase method, and b) the Threshold method. The erase method consists of removing stained areas deemed by the investigator to be outside the perimeter of the pressure stain. An eraser tool in the image analysis software is available to achieve this function. The threshold method consists of setting coloured pixels to black or white depending on the degree of pigmentation (i.e., selecting pressures above or below a predetermined threshold). Most of the available literature discussing use of the Prescale system fails to mention which technique is employed [650].

The vast majority of dental-related literature referencing Prescale largely originating in Japan, uses a form of the product called Dental Prescale [651]. It is a modified version of Prescale, which makes it more practical and convenient for use in a dental context. The fact that a Japanese-owned company manufactures this product may explain the greater

awareness and documented use of this technology in Japan. Dental Prescale has been designed to objectively evaluate occlusal contact area (mm^2) and bite force (N) on each tooth in the intercuspal position [652]. The system is capable of simultaneously measuring these parameters for teeth separated by less than 100 μm and has potential for research in centric occlusion [631]. The film has a horseshoe shape design with a plastic handle at the anterior aspect. It is designed to detect a pressure range of between 3 to 120 MPa. A dedicated precalibrated scanner, called an Occluzer, is used to scan the pressed films. The most commonly used version of Dental Prescale is the 50 H type-R film and is used to assess pressure and occlusal contact area. The measurements of this system all have their basis on an elementary unit which is based on the mean bite pressure in a square measuring $0.25mm^2$ [653]. A type-W film (i.e. 30H-W) also exits; it measures pressure within the range of 3 and 13MPa and is covered with blue paraffin wax surface enabling the marking of occlusal contacts [654, 655]. Although the R-type film is more sensitive against occlusal pressure than other types, it is sometimes difficult to recognise the location of occlusal points in the dental arch because it shows no information about the dentition [655]. The type-W film would be useful in these situations. The Dental Prescale system has been used to investigate a range of dental topics including bite forces [624, 656-658], occlusal analysis with dentures [654, 659], implants [654], orthodontics [660], and orthognathic surgery [633, 636, 637, 657, 661].

Compared with traditional strain gauge transducers, Prescale has the advantage of being very thin and flexible [657]. The two-sheet type version, consisting of A- and C-films, has a reported thickness of 0.2 mm [623], whilst the mono-sheet film can be as thin as 0.1mm [625]. The thinness of these films makes them superior to other measuring systems because the pressure is measured very near the true intercuspal position (i.e. in the natural physiological position) over the entire dentition (in contact with the film) [626, 647, 658, 660, 662]. It also enables an immediate and observable force distribution pattern to be visualised and quantified. Unlike some other measuring systems, Prescale does not directly measure occlusal force; rather, it is calculated by multiplying the contact area by the pressure [173, 639]. Nevertheless, the pressure and contact area data used to calculate force is measured in the (near) intercuspal position. Therefore, these occlusal force measurements may be nearly correct values and more closely correlated with the occlusal condition than that measured with a bite force transducer [653, 657]. In addition to the thin and flexible nature of Prescale film and the ability to

measure pressure and contact area with minimal change to the occlusal vertical dimension, further advantages of the system includes the ability to store data obtained after scanning pressed films, the ability to examine many patients in a relatively short period of time, and the ability to use the scanned images to help explain to patients their condition and the impact of treatment [659]. Because of the irreversible bursting of microcapsules when subjected to pressures above the minimum threshold for a given film-type, Prescale films are single use.

The validity (accuracy) and reliability of Dental Prescale has been examined and reported on. Validity refers to the accuracy of the Prescale system (i.e., how close the recorded pressure/area is to the actual pressure/area) and reliability refers to the consistency of measure over time (i.e. test-retest reliability). Thin pressure-sensitive sheets have been extensively used to measure both forces and occlusal contact areas and are reported to represent the occlusal condition quite accurately [631, 633, 634, 636, 637, 654, 659, 663, 664]. A linear relationship between applied and measured loads, on both subjects and on dental casts, has been reported which lends support to the validity of Dental Prescale (50 H film was used) [665]. Another study has also reported a strong linear relationship between applied load and the readout load, hence supporting the view that Prescale is a trustworthy system for measuring occlusal forces [634]. One study reported that a reliable measurement will result if 95% of effective pressure is recorded (i.e. 95% of the pressure measured is within the detection range of the film type) [666]. The manufacturer of the Prescale system specifies limits of accuracy of between plus or minus 10% when their densitometer is used (at 23^0C and 65% relative humidity – Pressure Measurement Film Prescale instruction manual). The accuracy of the Prescale system is further supported by another study reporting measurement errors of 4% at 20-80M Pa and 7% at 100 MPa, concluding that the Dental Prescale system can measure the occlusal forces within the range of 20 to 80 N with high accuracy and with slightly less accuracy up to 100 N [667]. This information appears to support the 10% accuracy published by the manufacturer of Prescale.

A pilot study using Dental Prescale (50H R-type film) to assess the effect of orthodontic treatment on occlusal forces examined the reproducibility (i.e., reliability) of measurements. After calculating the coefficient of variation from multiple tests, the authors concluded that their study showed adequate reproducibility [668]. One study

investigated the standard error of the Dental Prescale method by examining 15 randomly selected Japanese subjects one month after their initial assessment. The reported systematic differences between the first and second measurements were 0.9 mm^2 in occlusal contact area, 1.5 MPa in average occlusal pressure, and 83.2 N in bite force. The contributions of errors to the total variance were 4.4% in occlusal contact area, 5.9% in average occlusal pressure, and 9.4% in bite force. According to the authors of this study, when the systematic differences and error variance are considered together, the results for bite force should be interpreted with care [669]. This conclusion differs from the numerous previously cited scientific papers that confirm the higher reliability of the system. Use of image techniques and sophisticated calibration can help improve the detail of analysis (i.e. using smaller sample-areas and pressure-increments) [635].

It has been stated that Prescale data is scientifically meaningful, conducive for the comparison of data obtained in large case studies (such as cohort studies) and has the advantage of portability for epidemiological and survey research [665, 669, 670]. It has been reported that the speed and duration of the strength of occlusion applied to the Prescale sheet does not influence any changes in its colour [663]. This point needs to be elaborated further, since it differs from the instructions pertaining to the use of the Prescale system (as provided by the manufacturer). The instructions advise that there are two methods for pressure application on the Prescale film. The 'momentary' application method requires a five second duration to reach the pressure to be measured and then held at this pressure for another five seconds. In the 'continuous' method, the time to reach the pressure to be measured is two minutes after which it is held at this pressure for another two minutes. The fact that two methods are available suggests that the pressures detected will show some differences depending on the method employed. This aspect of Prescale is a potential limitation of the system, since pressure applications outside of these parameters may not be convenient for any particular test [635].

Further points of contention relate to the effect of moisture, temperature, and humidity on the Prescale film. Some literature suggests that Prescale films may require protection against fluid damage that could potentially distort the colour intensity and thereby the pressures measured [623, 635]. It appears that the application of a

polyethylene terephthalate (PET) layer ensures that the films are safe and waterproof in the oral cavity, hence alleviating this as an issue [654, 671]. Nevertheless, some studies still employ methods that seal the films (i.e. a thin transparent plastic layer fused in all borders), thereby avoiding the potential of moisture affecting the recording and subsequent analysis [625]. This does however seem to be a point of contention with other authors stating that Prescale films are not influenced by intraoral moisture, humidity, and temperature change [653, 663]. Similar to the discussion above relating to the method of pressure application on the pressure outcomes, the calibrated pressure charts (and software) provided by the manufacturer indicates that humidity and temperature will also have an effect on the profile of the colour density to pressure relationship (see Figures 2.3 and 2.4). This is in disagreement with those authors advocating that pressure application (speed and duration), temperature, and humidity has no effect on the Prescale film. To minimise these issues when used in the mouth, it may be prudent to seal the films (i.e., with clear film, or thin snap-lock bag) to remove the impact of moisture and humidity. When using Prescale in research for comparative purposes (i.e., before and after treatment, or between different subjects and/or treatment options), it would be advisable to use a consistent technique with the same settings. The disadvantage of sealing the films is the slight increase in overall thickness of the sealed film and any errors that may be associated with material properties of the plastic (i.e. the plastic layers may have a 'cushioning affect' during occlusal contact and hence reduce the pressure transfer onto the film).

The Prescale system does have some additional limitations that need to be acknowledged. It has been reported that the colour of 'pressed' Prescale film fades with time and exposure to light which can be a potential source of error when using the Prescale system to assess bite pressure. The placement of transparent tape over the film after exposure to pressure is a technique that has been described to try and reduce the extent of this fading. A study examining the storage conditions of pressed pressure-sensitive Fuji film, in terms of light exposure and sealing with tape, concluded that for the best accuracy and reliability, the film should be digitised or analysed within eight hours of exposure to pressure [623]. The same authors suggested a further option for addressing this issue; the creation of calibration prints around the same time that the film is pressed. Since the calibration prints will fade at the same rate as the pressed films, they can be used for the future assessment of the pressed films and hence

ensuring more reliable results. Another set of authors further support this method by suggesting that as long as both the calibration and experimental stains are produced at approximately the same time, under similar conditions, and stored in a similar manner, the analytical technique introduces no new errors [649]. Prescale films can be sterilised with a standard ethylene oxide (ETO) gas process. However, calibration sheets that have also undergone the same process are required to ensure accurate interpretation of the pressed films [672]. Storage of pressed sheets in a lightproof box for at least 3 hours to stabilise the intensity of colour before scanning has also been described [654, 671].

Other potential limitations of Prescale relate to the deformation of its sensors and its thickness; the thickness of the film may interrupt movement into intercuspation [639]. As reported earlier, the films are however, sufficiently thin as to approximate the interscuspal position and especially so when comparing them to conventional bite forks and other transducers. Missing a small aspect of the occlusion is an issue if the film moves slightly during the closing phase [673]. Another potential limitation of the Prescale system is the presence of upper and lower pressure limits (thresholds) that can be detected. For instance, with the MS film (mono-sheet with pressure range of 10 to 50 MPa), pressures exceeding 50 MPa will be expressed as 50 MPa. In such situations, the mean pressure and total occlusal force would be underestimated [653]. Furthermore, one group of authors state that Fuji Prescale film measures area with relatively poor accuracy because an ink stain is only created for loads above a certain threshold, and therefore 'true' contact is not identified in regions transmitting loads below that threshold [642]. Based on this, it may be appreciated that the accuracy of the system is dependent on the percentage of pressure measurements recorded that lie within the detectable range (i.e., above the lower threshold and below the upper threshold). As reported earlier, one study advises that reliable readings can be achieved if greater than 95% of the measured pressure is within the detectable range (for the given film type). Stacking layers of films of different pressure sensitivities and loading them simultaneously can help improve the accuracy of the pressure and area assessments, however this will have the disadvantage of increasing the thickness of the sensor [674]. Another consideration relating to the issue of exceeding the maximum threshold of the Prescale system is that only 30 to 50% of maximum occlusal force is used in the chewing of foods [675]. If this view is accepted, then a small amount of pressure detected as being above the upper threshold, and hence resulting in an underestimation of bite force

by the Prescale system, may not have a significant practical impact on masticatory function. Higher maximum bite force does not necessarily mean better masticatory performance [676]. The measurement methods available for Prescale system also pose limitations. The manual method using calibrated pressure charts involves a level of subjective assessment of the pressed film and a small number of pressure increments (i.e., depending on the number of colour tabs on the y-axis of the pressure chart). The automatic method requires access to a scanner, necessary software, and a computer: all adding to the cost of this method. Use of the eraser method to remove stains outside the area of interest involves a degree of subjectivity on the part of the examiner, hence introducing another source of potential error. The Prescale films are single use, and only provide static loading measures [635].

Most studies utilising Dental Prescale have the subject seated in a relaxed position and looking forward. The Frankfort (Frankfurt) or Camper's plane is aligned such that it is parallel (horizontal) to the floor [651, 661, 670, 677]. The head is in an unsupported (unrestrained) position. The pressure-sensitive film is placed between the arches and the patient is asked to clench into the intercuspal position (centric occlusion)[173, 662, 670, 673, 677]. Most studies have the subject clench as hard as possible (i.e. maximum voluntary bite force) [661, 662, 670, 677, 678]. Slow closure to ensure correct positioning and prevent sliding of the sheet has also been described [648]. One methodology used instructed subjects to steadily increase the occlusal force over a period of 3 seconds until they reached the force required to chew a piece if bread (i.e. normal masticatory force)[673]. Various clenching times have been employed, including two seconds [679], three seconds [173, 613, 631, 651, 661, 670, 673, 677, 678], and five seconds [652, 660, 662, 680]. One study which used centric relation as the biting position, employed significantly longer closure times of five minutes, three minutes, and two minutes [625]. Most studies report multiple recordings for each situation, such as twice [613, 678], three times [589, 631, 652, 661, 677] and five times [648]. Multiple recordings are commonly averaged, with the average being used for statistical analysis. Various 'rest' periods have been used between multiple recordings with the aim being to minimise the effect of muscular fatigue. The rest times used vary, but thirty seconds and one minute are commonly reported.

Occlusal contact area and bite force are known variables that can affect masticatory performance; therefore, occlusal contact area and bite force measurements can provide an objective evaluation of the impact of prosthetic treatment on occlusal function [652, 681]. The Prescale system offers an accurate, reliable, simple, and quick method to objectively assess bite pressure (and force) and occlusal contact area. The key advantages of this system include the thinness of the films, allowing measurements to be taken at the near physiological position of maximum intercuspal position (i.e., centric occlusion), and the use of dedicated software enabling the detailed analysis of the digitised scanned pressed films.

2.10 SUBJECTIVE ASSESSMENT OF DENTAL TREATMENT AND THE ORAL CONDITION: USE OF THE ORAL HEALTH IMPACT PROFILE (OHIP) AND VISUAL ANALOGUE SCORE (VAS) QUESTIONNAIRES

The traditional focus of medicine and dentistry has been on the identification (diagnosis), eradication, and prevention of disease. In more recent times, a better understanding of the consequences of disease in terms of effect on function, comfort, and ability to perform everyday activities has gathered importance. The collective term 'social impact' is used to describe the effects of dysfunction, discomfort, and disability resulting from diseased states [682]. There is now an appreciation that health is a resource and not simply the absence of disease [683]. A range of benefits can be realised from having a better understanding the social impact of disease, including improvement in the priorities for care (i.e., formulating appropriate treatment plans), improved understanding of oral health-related behaviours (i.e., motivators for improving prevention and care-seeking behaviours), advocacy for oral health (i.e. emphasising the importance of oral health as part of general health), and improved evaluation of dental treatment. Early work in determining the social impact of disease focused on the population level. Work loss and days lost from school due to oral conditions are two measures that can illustrate the impact of oral disease on daily activities and the cost to society [682]. Information relating to the social impact of disease complements clinical findings, thereby providing a broader basis for assessing oral health at both individual and population levels [684].

Prior to the 1990's, there was a virtual absence of indices available to measure the social impacts of oral health [683]. Since then, a number of instruments have been developed to try and capture information relating to the social impacts of disease and how they impact on an individual's Quality of Life (QoL); the term Oral Health-Related Quality of Life (OHRQoL) is used when focusing more specifically on the impact of oral health on an individual's QoL. OHRQoL is a multidimensional construct that includes a subjective evaluation of the individual's oral health, functional well-being, emotional well-being, expectations and satisfaction with care, and sense of self [685]. Surveys and questionnaires of varying complexity have been developed in an attempt to capture the subjective impact of disease. Some of these instruments have looked at developing scales that are used to provide an index of the impact of oral disorders, and are

characterised by scores indicating their extent and severity [682]. The Sickness Impact Profile (SIP) is a useful questionnaire instrument designed to measure sickness-related behavioural dysfunction, providing a reliable generic index (outcome measure) in the evaluation of health care [686]. Differing to the SIP, the Geriatric (Generic) Oral Health Assessment Index (GOHAI) is a reliable and validated twelve-item questionnaire that focuses more specifically on oral conditions [687]. It can be regarded as an inventory that adds together a variety of patient-reported oral functional problems and assesses the psychosocial impacts associated with oral disease [688]. Another instrument that has been used is the Dental Impact Profile (DIP), comprising of twenty-five questions designed to measure how life quality has been affected by, detracted from, or enhanced by, oral health and oral structures. It is an entirely self-report instrument that can serve as an indicator of how important or salient teeth are to an individual or a population [689]. Because it also incorporates patient perceptions, the DIP provides even more information than a standard inventory [682]. The Dental Impact on Daily Living (DIDL) and the Oral Impacts on Daily Performances (OIDP) are instruments designed to measure both the frequency and severity of oral problems on functional and psychological well-being [690-692].

The Oral Health Impact Profile (OHIP) & short-form Oral Health Impact Profile (OHIP-14)

Attempts have been made to arrange functional disorders and their social consequences into a hierarchy of outcomes, rather than simply summing responses into a single inventory. Different outcomes are placed into a hierarchy according to whether they are entirely internal (such as a patient having an awareness of chewing difficulties) or related to interpersonal or social experiences (such as avoiding socialising). Individuals then attain a 'profile' of social impact across this hierarchy. This type of instrument is likely to be relevant for oral conditions, since many conditions have an internal impact (i.e. pain and functional limitations) as well as an impact on interpersonal and social behaviour. The Oral Health Impact Profile (OHIP) provides a scaled index that measures a person's perception of the social impact of oral disease on well-being (in terms of self-reported dysfunction, discomfort, and disability) [682, 683, 693]. The OHIP is one of the most comprehensive instruments available, and is designed to provide a measure that captures the various ways in which oral disorders compromise the well-being of people [694, 695]. All impacts measured by the OHIP questionnaire are conceptualised as

adverse outcomes; the instrument does not measure any positive aspects of oral health [693].

The OHIP was developed and evaluated by Slade and Spencer using a non-randomised collection of sixty-four participants sourced from private dental offices, a dental hospital primary care clinic, and a dental hospital prosthodontic clinic in Adelaide, South Australia [682]. Use of a non-randomised sample was justified on the basis that this group was more likely to have a range of oral diseases with consequent social impacts when compared to a randomised sample of the general population. The OHIP has it's basis on an original model of oral health proposed by Locker [696]. The OHIP consists of forty-nine questions that are divided into seven domains, with each domain assessing different impacts of oral diseases and conditions. The seven OHIP domains are: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap [683]. The hierarchy of the OHIP captures the outcomes that have an increasingly disruptive impact on people's lives [683].

Based on research involving the previously mentioned cohort of sixty-four patients from South Australia, forty-nine questions were identified as being relevant for the OHIP questionnaire [682]. For each of the questions, subjects are asked how frequently they had experienced the impact over a given time period [694]. The answer for each question was based on a 5-point Likert scale, with the following options: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, and 4 = very often [694]. A lower score indicates a more favourable response (i.e., better situation). The data recorded on the OHIP questionnaire (and OHIP-14 questionnaire) can be assessed on two levels; firstly, the impact for each domain (i.e. subscale) can be calculated by summing the responses for each question of that domain, and secondly, the responses of all questions can be added together to determine an overall level of impact [683]. The OHIP data can also be analysed by [683, 684, 695, 697]:

- Calculating the OHIP prevalence – defined as the percentage of subjects who reported one or more OHIP items with a 'fairly often' or 'very often' response.

- Calculating the OHIP simple count (i.e., OHIP-14 SC). This also measures the degree of prevalence and is assessed by counting the total number of impact items for each patient.
- Determining the OHIP sum (i.e., OHIP-14 sum), which is calculated as a simple non-weighted summation of impact scores after assigning the 5-point Likert scale values to each OHIP-14 item (as discussed previously).
- Some researchers have calculated and applied a series of weightings to the raw data, with the weightings reflective of lay judgements as to the relative severity of each OHIP question. This is referred to as the weighted-standardised method (i.e., OHIP-WS).

The OHIP questionnaire offers a reliable and valid instrument for the detailed measurement of the social impact of oral disorders, potentially assisting in better clinical decision-making and research [682, 697]. This is particularly the case in Australia, the USA, and Canada where the OHIP has been adopted in various epidemiological studies of elderly populations [267, 695, 698-702]. Epidemiological studies that have used the OHIP have found that missing teeth, untreated decay, periodontal attachment loss and barriers to dental care are associated with increasing levels of impact on well-being [683]. In other words, there is a positive correlation between clinical parameters of disease and the social impact determined by the OHIP. Despite this, there is some evidence suggesting that only a weak association exists between OHIP scores and clinical measures of oral disease [698, 700, 702]. This may not be overly surprising since, although significant, the reported correlations between objective and subjective measures of disease, oral status, function, and even quality of treatment are relatively weak [246, 697, 698, 703-706]. The correlation of some measures appear to be of more significance, with the number of missing functional pairs of teeth having more significance than the actual number of missing teeth [707, 708].

The original form of the OHIP applied weightings to each question in order to standardise the scores and take into account variations in impact arising from different events [682, 683]. For example, a severe toothache should be given a higher weighting than mild sensitivity arising from contact with hot or cold foods. The weightings were determined using Thurstone's method of paired comparisons based on the lay

judgements of the relative unpleasantness of each impact [682, 683]. It has been reported that employing weightings has the potential of increasing the validity and predictive ability of a scale; however, the use of weightings also adds complexity to the process and is more time consuming [684]. A study assessing the role of weightings and the OHIP-49 and OHIP-14 questionnaires concluded that weighting did not substantially improve the performance of the OHIP compared to other scoring methods in terms of identifying significant differences between groups [684]. This study also suggested that use of unweighted measures might be appropriate for clinical and other settings where the computation of weighted scores is not feasible. In another study, the discriminant, concurrent, and predictive validity of the weighted and unweighted OHIP scores of both the long- and short-form OHIP has been assessed with the conclusion that the use of weightings did not substantially improve the performance of OHIP compared to other scoring methods [683, 684].

A weaknesses or disadvantage of the OHIP-49 is the fact that it is a time consuming exercise to complete the survey [694]. One study reported that the average time to complete the OHIP-49 questionnaire, administered by an interviewer, was 17 minutes [682]. This may not be practical in a clinical setting and even in a research setting [683]. In an attempt to overcome limitations imposed by the number and availability of interviewers, the OHIP questionnaire can also be issued as a self-completed questionnaire. Furthermore, the detailed questionnaire may not be appropriate for some individuals (i.e. children, language issues, cognitive skills, etc.), and it needs to be borne-in-mind that the original questionnaire was in English language and for a specific population [682]. The OHIP and OHIP-14 questionnaires have subsequently been translated and adapted for a range of languages (i.e., Chinese, Korean, Japanese, Spanish, Portuguese, Dutch, etc.) maintaining reliability and validity, and demonstrating a reasonable degree of cross-cultural consistency [325, 326, 694, 709-714].

The time-consuming issue has been addressed by the development of a short form version of the OHIP, called OHIP-14. As the name suggests, the questionnaire comprises of fourteen questions. It also contains the same seven domains, however only two questions are included for each domain. This short-form version has shown good statistical properties and validity; the fourteen questions account for 94% of variation in total OHIP score and with high internal reliability [683]. Additional studies have also

reported that the reliability and validity of the short-form OHIP-14 is comparable to that of the long-form OHIP-49 [684, 715]. The OHIP-14 instrument may be useful for quantifying levels of impact on well-being in settings where only a limited number of questions can be administered. The OHIP-14 is a more user-friendly version of the questionnaire and more suitable for chair-side completion [694]. A shorter and simpler questionnaire meets the requirements proposed for health status questionnaires, including the demonstration of reliability, validity, precision, and in clinical settings, being simple and easy to use [716]. One set of authors suggested that different short form versions may need to be considered and applied according to the purpose of the investigation, the population to which it is applied, and the context in which it is being used [717]. OHIP and OHIP-14 have been used in numerous studies involving prosthodontics interventions (including dental implants) [199, 285, 301, 697, 711, 718, 719].

The Visual Analogue Scale (VAS)

The Visual Analogue Scale (VAS) is another instrument designed to capture subjective information and enabling the conversion of this information into quantitative data. VAS instruments have been used in medical and dental research to measure a variety of subjective phenomena, including anxiety [720-723], pain [724-729], nausea [730], fluorosis severity [731], salivary dysfunction [732], denture satisfaction [733-735], and prosthetics supported by implants [736-740]. The VAS instrument essentially involves a subject answering a question by placing a mark along a straight line (usually 100 mm in length), with the relative position of the mark indicating the response. Use of lines shorter than 100 mm have been reported to produce greater error/variance [741]. The lines may be orientated either vertically or horizontally with horizontal lines being reported as producing a more uniform distribution of responses [742]. Labels corresponding to the extremes of the responses for the question being measured anchor the ends of the line. The extreme left side of the horizontal line corresponds to the lowest value (i.e., 0, 0%, or very dissatisfied) whilst the extreme right side of the line corresponds to the highest value (i.e. 1, 100%, or very satisfied).

The respondent is encouraged to mark the line at the point that indicates his or her response (perception) relative to these extremes [743]. The response can be converted into quantitative data by measuring the mm distance of the marking from the left-hand

side of the line (i.e., from the 0 point). When using a unipolar scale, a larger measurement indicates a more positive response, which may or may not correspond to a better situation. For example, the left side of the line could be labelled 'no pain' and the right side could be labelled 'worse pain possible'. 'Worse pain possible' is obviously a more negative outcome, even though it produces a larger (more positive) measurement. A unipolar scale is characterised by the left anchor representing the absence of the phenomenon (i.e. no pain). A bipolar scale is one in which the 'normal' response is likely to occur around the mid-point of the line. This type of scale can be exemplified by a question that is designed to measure 'mood'. In this example, the left anchor label might be 'depression/depressed' and the right anchor label might be 'elation'. Bipolar versions of VAS are more difficult for subjects to understand [743].

The reliability (test-retest, methodological variables, and inter-rater) and validity (construct, discriminant, and criteria-related) of the VAS instrument has been reported [731, 743]. In spite of these reports, it has also been reported that due to a variety of constraints, evaluating the reliability and validity of the VAS remains unresolved and that difficulties may be encountered in validating VAS measuring complex subjective phenomena [744]. The assumption cannot be made that demonstrated validity under one circumstance ensures generalisability of the method to other applications [743]. Notwithstanding this, the VAS instrument has been successfully used in a range of studies with acceptable reliability and validity [739, 740, 745, 746]. A number of factors must be considered when assessing data obtained from the VAS instrument. Firstly, the 'meaning' of the measurement recorded must be established and a minimum 'cut-off' signifying a significant difference must be decided upon. Although the VAS instrument has been shown to predict experimental sensations, it is not clear if this relationship exists over the entire range of the VAS instrument (i.e., over the entire 100 mm length). Furthermore, there is uncertainty as to what a five mm difference in scores between subjects signifies, or whether a twenty mm difference at one point of the VAS line is comparable to a twenty mm difference at another part of the line [747]. The level of measurement issue is more crucial, however, when data are grouped for between-subject comparisons and parametric methods of analysis are applied [743]. Both parametric and nonparametric tests can be used to analyse the VAS data. It has been stated that within-subject comparisons are more sensitive and accurate than between-subject comparisons, with borderline areas existing where the choice of test may make a

difference in the conclusions made (i.e. parametric or nonparametric tests) [743, 748]. VAS data has also been reported as consistently violating the parametric assumption of constancy of measurement error [747].

Identifying significant differences between measurements recorded using the VAS instrument have been determined by a variety of methods including the setting of cut-off values (and comparing the measurements relative to the cut-off values), the predetermined setting of a minimum difference between two comparison points (i.e., a minimum detectable difference of 10 mm), or the statistical analysis of the difference in measurements between two comparison points. A study assessing the satisfaction levels of complete denture wearers concluded that upper cut-off values of 31, 47, and 36 mm, respectively, identified overall dissatisfaction, dissatisfaction with the maxillary denture, and dissatisfaction with the mandibular denture. The lower cut-off values of 79, 80, and 83 mm, respectively, identified overall satisfaction, satisfaction with the maxillary denture, and satisfaction with the mandibular denture [735]. A study designed to validate the VAS for anxiety concluded that it can be used effectively in the assessment of dental patients, using the values of 5.1 cm and 7.0 cm as cut-off values for anxiety and phobia, respectively [723]. A study assessing patient satisfaction with two designs of implant-supported removable overdentures set a VAS difference of 10 mm to represent a significant clinical difference [740].

The main strengths and advantages of the VAS instrument include [743, 744]:

- Is a convenient tool that can be rapidly administered.
- Is easy to use, for both researcher and subject.
- Is useful in a wide variety of clinical and research settings.
- Is able to measure a range of subjective phenomena.

The main limitations and weaknesses of the VAS instrument include:

- Subjects must have a minimum level of comprehension enabling understanding of the method and question(s) being asked (i.e., language, following instructions, eyesight, ability to place a mark on the VAS, etc.).

- The instrument relies on a subject's unique interpretation of the anchor labels, which will be influenced by a past experience(s).
- No established criteria to determine the degree of patient satisfaction from the actual values when the VAS is used in a clinical setting.
- The potential for inaccuracy in reproduction of the VAS instrument itself (i.e. accidental expansion or reduction during printing/copying that can distort the line length, measurement errors, etc.).
- The subject not placing the mark on the line itself.

The significance of subjective measures is gaining prominence in the assessment of treatment outcomes. The challenge is in the capture and quantification of this information, and in a research context, enabling relevant statistical analysis to be performed. A range of instruments have been designed and employed in this endeavour. The OHIP (both long- and short-forms) has been specifically designed to determine the impacts of oral conditions on a subject's quality of life (i.e., social impact). This questionnaire has been extensively used in dental research. The VAS is a simple tool that is easy to apply and use. The tool has also been extensively used in medical and dental research. The instrument is not without limitations; however, it does contribute useful information. A broader assessment of treatment needs, and outcomes can be achieved by combining information obtained from objective and subjective tests.

2.11 CONCLUSION

This literature review covers a wide range of topics that provide background and context to this clinical trial. The main points covered were:

- The size and age profile of the population, both globally and locally, are growing.
- The prevalence of edentulism is decreasing, with more people retaining more of their teeth longer.
- The prevalence of partial edentulism is increasing; the need for prosthodontic rehabilitation of partial edentulism will increase into the future.
- The SDA is a treatment concept that will have increased relevance into the future, especially in situations of scarce resources.
- CRPDs are still one of the most commonly employed treatment options for managing partial edentulism.
- The mandibular KCI RPD may be associated with a range of problems such as uneven denture support, inadequate retention, insufficient stability, discomfort, and damage to supporting tissues.
- The mandibular KCI RPD, especially if anterior teeth are not replaced by the dental prosthesis, have relatively poor patient acceptance.
- The strategic use of implants may help address some of the concerns relating to the KCI RPD, and hence improve the acceptance of this treatment option.
- The ability to use short implants may make this treatment option relevant to a larger proportion of the population.
- There is a need for further research in this field comprising of higher evidence-levels. The treatment concept of associating implants with RPDs to rehabilitate the KCI situation should be supported by both objective and subjective measures obtained through well-designed clinical trials.

This body of research aims to contribute objective and subjective outcome measures comparing the performance of CRPDs and IRRPDs for the management of mandibular KCI situations. The null hypothesis for this clinical trial is that the association of (short) dental implants to assist in the retention and stabilisation of a mandibular KCI CRPD will not significantly improve objective and subjective performance measures.

Chapter 3: MATERIALS AND METHODS

3.1 Rationales and general design of the clinical trial

This clinical trial was undertaken as a prospective within-subject crossover design whereby each subject had an opportunity to experience a lower partial denture with and without implant retention and support. The overall aim of this trial was to compare the objective and subjective performance of an implant retained and supported mandibular bilateral distal extension cast-base CRPD to that of the same denture when worn in a conventional manner relying on mesial abutment teeth and underlying soft tissues for denture retention and support. The anatomical changes that occur in the posterior mandible after tooth loss can often complicate the placement of standard-length implants. For this reason, the trial utilised short implants (6 mm length). The trial also assessed and reported on the general impact of removable partial dentures on the existing teeth and associated oral structures.

To address the issue of bias associated with the order of denture experience, the subjects enrolled in the trial were randomly allocated into one of two groups: Group A and Group B. Subjects allocated to Group A experienced the CRPD in the first instance, whilst subjects allocated to Group B initially experienced the IRRPD. After an adaptation period of at least three months, each denture design was tested using objective and subjective measures, after which the denture was converted to the alternate design. The details of how this was accomplished will be discussed further in the prosthodontic section of this methodology. In addition to the testing of each denture design, testing also took place on the situation without the lower dental prosthesis in place. These tests were termed 'baseline' tests and aimed to provide a basis upon which the performance of both denture designs could be compared. Testing was also performed at the time of lower denture insertion or conversion. These results were used to determine whether there was an improvement, deterioration, or no change in objective and subjective performance over the course of the adaptation period, although the significance of any changes will be considered further in the discussion section of this thesis.

The procedures and overall workflow of the clinical aspects of the trial were designed in such a way that the protocol could be practically applied by most general dentists with some experience in the field of prosthodontics.

3.2 Ethics considerations and trial registrations

The primary application for ethics approval for undertaking the clinical trial was made to The University of Melbourne (Health Sciences Human Ethics Sub-Committee). The approval details were:

- The University of Melbourne - Ethics ID: 1238413 (Issued on 26/10/2012)

Annual renewal and relevant amendment requests were submitted and approved over the duration of the trial.

Subsequent to this approval, an application for ethics approval was also submitted to DHSV. The approval details were:

- DHSV – Ethics approval number: 260 (issued 08/03/2013)

The trial was registered with The Australian New Zealand Clinical Trials Registry (ANZRCT) with number: 12612000893808.

3.3 Inclusion and exclusion criteria

Unlike many trials that impose numerous strict inclusion and exclusion criteria, the philosophy of this trial was to test this treatment protocol in a manner reflective of normal (general) clinical practice. Consequently, the exclusion criteria applied were not exhaustive.

Inclusion criteria:

- Subjects must be over 18 years of age.
- Subjects must be missing all lower molar teeth and at least one lower premolar tooth.
- All lower anterior teeth must present (lower canine to lower canine teeth) or restored with fixed dental prosthesis.
- Minimum bone height present permitting the safe placement of a 6mm length implant anywhere along the posterior segment (from first premolar through to second molar position). The minimum bone height required above the inferior alveolar canal was 8 mm, hence ensuring a 2 mm safety margin to the inferior alveolar canal.
- Bone width ≥ 6mm at the proposed implant site. This will permit placement of a 4 mm diameter implant without the need for horizontal bone augmentation.
- Subject has the capacity to provide informed consent.
- Subject must have reasonable command of the English language – subject has the ability to answer questionnaires (either written or verbally).
- Subject is able to attend periodic dental appointments and can tolerate minor oral surgical procedures in an outpatient setting.

Main exclusion criteria:

- Inadequate bone height and/or width in the posterior mandible for the placement of implants with 4 mm diameter and 6 mm length (without the need for planned bone augmentation procedures).
- Uncontrolled oral diseases (i.e., active caries and periodontal diseases).
- Pregnancy.
- Uncontrolled/poorly controlled metabolic disorders.
- Previous exposure to head and neck radiation.
- Use of drugs that affect bone turnover, such as bisphosphonates and denosumab (i.e., Prolia®)
- Severe parafunction (untreated).
- Unmotivated patients.

The criteria listed are intended to ensure that all subjects have an objective need for prosthetic treatment (i.e., less than twenty functional teeth) and that the implants can be surgically placed without the need for advanced augmentation techniques.

3.4 Trial venues/location and sourcing of subjects

The trial received ethics approval by the Health Sciences Ethics Sub-Committee (The University of Melbourne) and was conducted as part of a PhD program undertaken by the principal researcher at The University of Melbourne. The clinical aspects of the trial were conducted at The Royal Dental Hospital of Melbourne (RDHM), primarily in the specialist Fixed Prosthodontics and Oral Surgery (outpatient) departments. Dental Health Services Victoria (DHSV) is the Victorian public oral health agency that administers the RDHM and is the entity that granted permission for the trial to take place in the relevant clinics. The prosthetic laboratory work was carried-out by the DHSV Dental Laboratory and/or accredited outsourced entities.

Since the trial was conducted in the RDHM clinics, all subjects were required to have a valid Department of Human Services-issued Health-Care Card at the time of commencing the trial (i.e., eligibility for public dental care). Subjects were sourced from the RDHM (primary care, general dental, and teaching clinics), and selected metropolitan community-managed dental clinics. The only financial commitment from the research subjects was paying the DHSV capped co-payment fees for treatment provided at DHSV clinics (as would apply even if not participating in the clinical trial). The principal researcher was actively involved in informing relevant clinic heads and clinical staff about the objectives of the trial and the main applicable inclusion/exclusion criteria. Details of potentially suitable subjects were directed to the principal researcher who subsequently arranged information and screening appointments for these subjects.

3.5 Sample size considerations and randomisation process

Although the original intention was to recruit 30 subjects, 19 patients were eventually enrolled into the trial, of which 17 subjects completed the two phases of the trial (i.e., the wearing and comparing of both denture designs).

Randomisation process

After an initial 'information and screening appointment', subjects satisfying the necessary inclusion criteria (and not having any exclusions) were enrolled into the trial. Each subject was allocated a subject trial number based on the chronological order of this initial appointment. To address the potential impact that the ordering of treatment may have on the results, subjects were randomly allocated into one of two groups: Group A and Group B. Subjects in Group A experienced the conventional denture in the first instance, whilst subjects in Group B experienced the implant retained and supported denture in the first instance. Permuted block randomisation with block size 4 was used to randomly allocate each subject to the relevant Group. Mr Geoff Adams, a statistician employed at The Melbourne Dental School (The University of Melbourne), performed the randomisation process. Mr Adams had no direct involvement with the clinical trial. Each allocation was placed in a sealed envelope and a number placed on the outside of the envelope. The sealed envelopes were then made available to the principal researcher. Once a subject was enrolled into the trial, the relevant envelope corresponding to a subject's trial number was opened to reveal which of the two groups the subject had been allocated to.

Two of the nineteen subjects prematurely withdrew from the trial (i.e., before both denture designs were assessed). Subject number 8 unfortunately passed away from a late diagnosed illness during the second part of the comparison stage of the trial (i.e., following conversion to denture design 2) and subject number 12 decided to withdraw from the trial after implant placement but before construction of the dental prosthesis. As stipulated in the terms of the ethics approval, subjects have the right to withdraw from a clinical trial whenever they wish and without needing to offer a reason. Therefore, the trial will report on data collected from 17 subjects.

3.6 Screening processes and consents

During the screening stage of the trial, each subject was issued with a 'Plain Language Statement' (PLS) that provided an overall outline of the purpose, design, risks, and requirements of the trial (Appendix 2). A consent form acknowledging understanding of the PLS and agreeing to partake in the clinical trial also formed part of the PLS. A consent form granting permission for the taking of clinical photos was also issued to patients (Appendix 3). Subjects were given an opportunity to read these documents, including taking them home for further consideration, and to ask any questions that may have arisen from the information contained in the documents. Once the forms were signed, the subject was enrolled into the clinical trial.

The screening appointment(s) involved a discussion about the purpose, scope, design, and requirements/commitments of the trial. An extra- and intra-oral examination was conducted to ensure that the necessary inclusion criteria were met, and that any exclusion criteria were identified. Of particular interest was the pattern of tooth loss, the general condition of the remaining teeth and any existing dental prostheses (both upper and lower), and the presence of any untreated diseases. Because two-dimensional radiographs (i.e., OPG) have limitations when used to assess sites for implant suitability, the final step in accepting a subject into the trial required assessment of a Cone Beam CT (CBCT). For this reason, primary dental impressions were taken at this screening appointment to enable a radiographic stent to be constructed that would subsequently be worn during the taking of the CBCT. A second appointment was required in order to modify and try-in the radiographic stent after which the patient was referred to Melbourne Dental X-Ray (723 Swanston St, Carlton VIC 3053) for the CBCT. Consequently, the screening appointment phase was often conducted over two to three visits.

The primary dental impressions were poured-up in dental stone by technicians at the RDHM dental laboratory. A subsequent wax-up of the missing teeth (in their respective anatomical positions) was then used to design and create a clear acrylic stent. The stent was designed such that it sat passively over the existing natural teeth and remained stable during seating. The principal researcher adjusted the stent by drilling

longitudinal cylindrical channels through the middle of each relevant tooth, finishing just short of the base of the stent. The channels were then filled with radio-opaque gutta percha points with the occlusal end of each channel sealed with blue wax and hence avoiding extrusion of the gutta percha points. The stent was now able to be used as a radiographic stent and was worn during the CBCT exposure. The radio-opaque appearance of the gutta percha points assisted with the interpretation of the CBCT, principally with determining the bone volume available in the proposed implant sites (One Volume Viewer software, J. Morita MFG. Corp., Hyoto, JAPAN). For this trial, the 'ideal' implant site was deemed to be the distal half of the lower first molar, since this would allow for distal implant support whilst still ensuring enough space was available distal to the implant abutment for the cast framework and artificial second molar tooth and acrylic associated with the lower partial denture. If this site was not suitable, then the 'closest' most distal site was selected.

Figure 3.1. Mandibular radiographic stent (view from posterior). Note that it is tooth-supported and has been adjusted to incorporate gutta-perch points in the (distal) first molar position on each side. Red wax has been used to seal the channels containing the gutta percha.

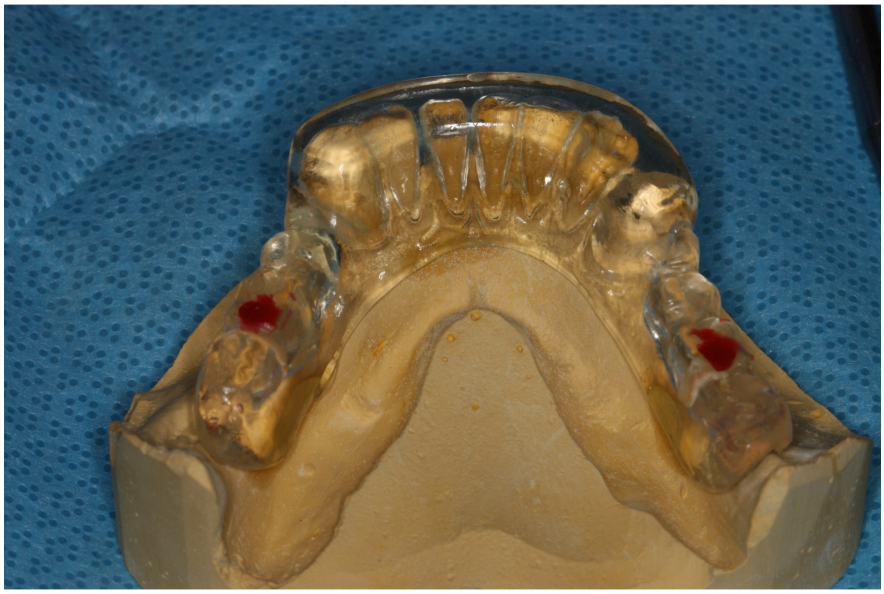
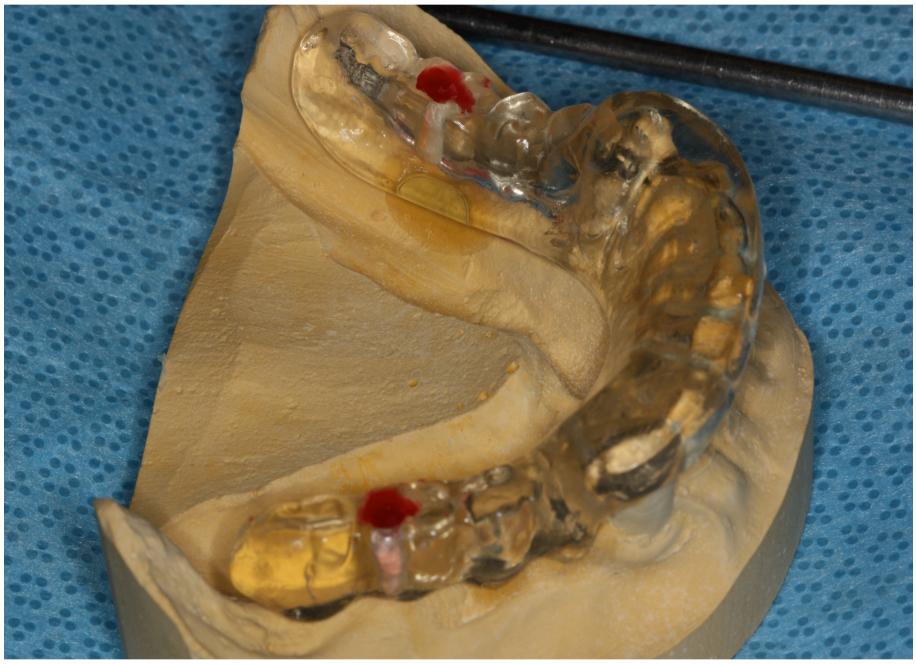


Figure 3.2. Mandibular radiographic stent (right lateral view). The gutta perch points can be seen in the (distal) first molar site.



3.7 General management of the upper dental arch

The recruiting of a suitable number of patients from the available patient pool proved to be a challenge. As a result of this, it was deemed impractical to try and limit inclusion of patients with a standardised upper arch situation (i.e., to only select subjects with full upper denture, or fully dentate in upper arch, etc.). Therefore, the objective was to ensure the upper arch was in a stable condition (control of active disease processes) and that all missing teeth, with the exception of third molars, were prosthetically replaced prior to construction of the lower dental prosthesis. This would enable a stable condition upon which the function of the lower denture could be assessed.

3.8 Preliminary prosthetic assessment

Prior to commencement of the surgical phase, the primary casts were articulated in order to assess the existing occlusion. A simple hinge articulator was used if the casts could not be manually held in a stable position with the aid of the maxillomandibular relationship record (i.e., when sufficient contacts of natural teeth were present). A dental surveyor was also used to assess the degree of available undercuts around the abutment teeth. This preliminary assessment was an important step as it assisted in determining the dimensions available for the denture components, the likely requirement for tooth preparations (i.e., rest seats, guide planes, etc.), and hence enabling consideration of appropriate denture designs. The findings of this step could also influence the ideal positioning of the implant relative to the overlying denture bases. For example, if the minimal occlusal clearance were insufficient in the second molar region for a denture tooth, then one option would be to limit restoration of the dental prosthesis to the first molar with the ideal implant placement being more mesial to that originally planned.

3.9 Surgical phase

The surgical placement of the implants in this study was performed in the Oral Surgery department (RDHM) in an outpatient setting. Both the principal researcher and a senior oral and maxillofacial surgery (OMFS) registrar assessed the CBCT scans of each subject for suitability of implant placement and the appropriate site of implant placement. The medical history of each subject was reviewed to re-confirm suitability for minor oral surgery. Once the decision was made that implants could be safely placed, the patient was scheduled for implant placement surgery.

The implants in this trial were placed by the principal researcher (3 patients) and by senior OMFS registrars rostered in the Oral Surgery implant outpatient clinic (14 patients). A consultant surgeon from the Oral Surgery department was present during the surgery performed by the principal researcher, whilst consultants were available for advice/assistance when the senior OMFS registrars placed the implants. Each surgeon

employed accepted surgical techniques. Antibiotics, either for surgical prophylaxis and/or postoperative therapeutic administration, were used at the discretion of the surgeon and only if there was a clinical or medical indication to do so. The objective of the first stage surgery was to expose the bone with a conservative flap design with extensions only limited to the point whereby adequate access and visibility could be attained. The most commonly used flap design was a 'H' flap. The implants used in this trial were the ASTRA Osseospeed™ TX with a 4 mm diameter and 6 mm length. DENTSPLY Implants (Mannheim, Germany) provided the implants according to a contract for the purpose of this clinical research.

Pre-operative chlorhexidine mouthrinse was used as a pre-surgical disinfectant. The radiographic stent (disinfected in chlorhexidine solution) was seated to assist with identification of the implant placement site. The surgical sites were anaesthetised using inferior alveolar nerve block and local infiltrations (Xylocaine – lignocaine with 1:80,000 adrenaline, DENTSPLY Sirona , York, PA, USA). After flap creation and reflection, the standard ASTRA implant system surgical protocol was followed for placement of 4 mm diameter and 6 mm length implants. The implants were placed such that the implant shoulder was at bone–level. Paralleling guide pins were used to try and ensure cross-arch parallelism of the implants, since parallel implants would assist with path of insertion of the dental prosthesis and minimise premature wearing of the prosthetic components. The distance from the distal surface of the mesial abutment tooth and the implant on each side of the arch was measured and documented; this distance is of importance when performing second stage surgery. Sterile saline irrigation was utilised at all times when the drills were used to create the implant osteotomy. 0 mm cover screws were placed into each implant and the flap margins re-approximated and held together by simple interrupted sutures (resorbable 4-0 vicryl, Johnson & Johnson, NJ, USA). Post-operative OPGs were taken in the RDHM radiology department. Post-operative review was conducted to ensure uneventful healing of the implant sites. The implants were allowed to integrate for a minimum of three months before stage-two surgery was performed for those subjects allocated to Group B.

Figure 3.3. Intra-operative photograph demonstrating the placement of dental implants together with cover screws. Note – 'H'- shaped flap and implants placed with shoulder at bone level.



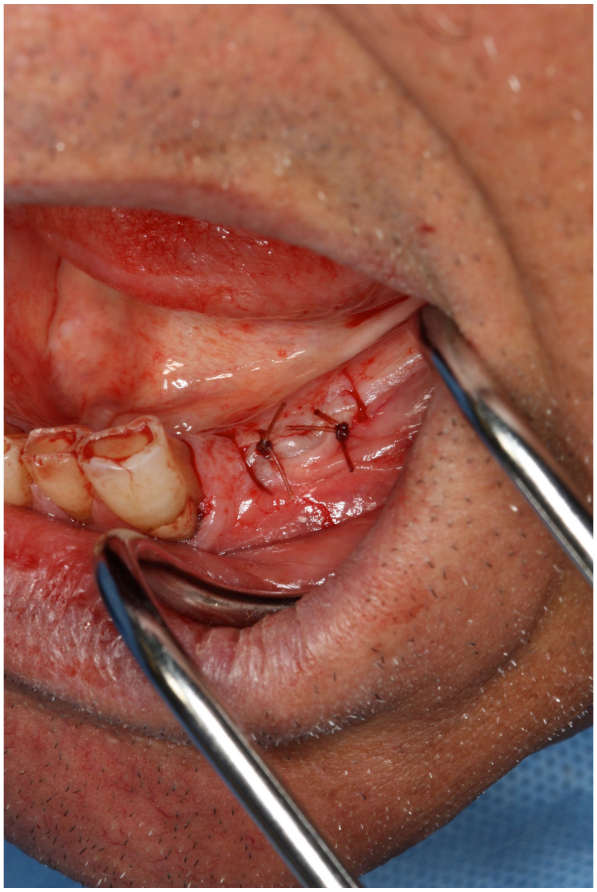


Figure 3.4. Closure of the 'H'-shaped flap with two simple-interrupted sutures

The principal researcher performed second stage surgery in the Fixed Prosthodontics department at RDHM. Each respective implant site was estimated from the distance measurement made during surgery and an assessment of the post-operative radiographs. The implant sites were anaesthetised with topical Xylocaine gel followed by infiltration anaesthesia (either 2% Xylocaine – lignocaine with 1:80000 adrenaline (DENTSPLY Sirona, York, PA, USA) or Septanest – 4% articaine hydrochloride with 1:100000 adrenaline (Septodont, Lancaster, PA, USA)). A small crestal incision was made over each implant site and a periodontal probe was used to feel for the cover screw. Once identified, the cover screw was removed using the ASTRA 0.05' hexagonal screwdriver. A Locator™ abutment (Zest Anchors LLC, Escondido, CA, USA) of appropriate height was placed into each implant using the Locator™ driver and tightened with a torque of 25 Ncm. If the gingival tissues provided resistance to abutment seating or demonstrated excessive blanching, a small incision was made perpendicular to the crestal incision, hence reducing the tissue resistance and allowing seating of the abutment. Sutures were rarely required as the insertion of the Locator™ abutment exerted adequate pressure on the wound margins to minimise post-operative haemorrhage.

3.10 Prosthetic phase

The lower partial denture was designed and fabricated prior to the performance of stage-two surgery. This phase involved inputs from both the clinician and the dental technician. Based on the assessment of the primary casts, a preliminary denture design was made. The preferred design employed currently accepted cast metal-based denture design features. Where possible, mesial occlusal rests were placed on premolar abutment teeth with gingival approaching clasps engaging the infra-bulge aspect of the buccal surfaces of these teeth. Cingulum rests were placed on the canines (to serve as indirect retainers), and if canines were also used as direct abutments, then gingival approaching clasps were utilised. The more commonly prescribed major connector was the lingual bar, however lingual plates were also used if deemed necessary. Guide planes were only utilised if the convexity of the distal surface of an abutment tooth was

accentuated and would thereby interfere with the path of insertion and/or adversely affect denture stability.

After completion of any necessary tooth preparations, a dental impression of the lower arch was made using an acrylic customised tray (two wax layers of spacing) and addition-cured polyvinylsiloxane (PVS) impression material (heavy body around the peripheries of the tray and low viscosity around the teeth and residual ridge) (Flexitime®, Kulzer GmbH, Hanau, Germany). In some instances, a monophase PVS material (Aquasil Monophase fast set, DENTSPLY Sirona, York PA, USA) was used as an alternative to the two-component technique. A dental impression of the upper arch was made in alginate. A maxillomandibular relationship record was taken with the patient in maximum intercuspal position. Depending on the number of existing natural teeth and reproducibility of the occlusion, this was achieved with the use of either bite registration material (3M ESPE Imprint™ 4 Bite VPS Bite Registration Material, St. Paul MN, USA), or use of laboratory constructed wax rims (more challenging occlusal situation employed acrylic-based wax rims).

The principal researcher assessed the secondary casts to ensure their suitability for continuing prosthetic work (i.e. no obvious distortions or air bubbles in critical sites, etc.). The casts were articulated on simple hinge articulators, and in a few instances, semi-articulated articulators were utilised (Whip Mix semi-adjustable articulator (Ref. HANAU 014309-000), Fort Collins, CO, USA). The distance of each implant from the distal surface of the respective abutment tooth was measured on the cast and marked lightly with a pencil in the mid crestal position. Using the same pencil, a circle of approximately 10 mm diameter (with the centre being the mid-crestal mark) was outlined on the cast. This is the area that would remain free of casting such that the Locator™ retentive componentry could be incorporated into the denture. The framework was designed to surround this recess where possible, hence extending around and behind the abutment. The typical framework therefore had a 'ring' pattern in the distal extension segment. The principal researcher completed a laboratory design instruction form for each denture. The key information conveyed on the form included: teeth to serve as abutments, presence and location of occlusal/cingulum rests, direction and type of clasps, design of the major connector (i.e., lingual bar/plate), location of dental implants and framework clearance, and denture extension bases. This form,

together with the articulated casts, was returned to the RDHM dental laboratory to continue with the laboratory work.

The RDHM dental laboratory outsourced all framework designs and manufacturing to a single commercial dental laboratory (Proslab Dental Laboratory, Canterbury VIC., Australia). The laboratory scanned the models and designed the framework using computer software. A senior technician assessed the scans and identified 0.3 mm undercuts around the abutment teeth, hence ensuring appropriate positioning of each clasp. The software-generated framework design images were emailed to the principal researcher for assessment and approval to proceed. Any concerns identified were communicated with the senior technician and necessary corrections/adjustments made. Following approval of the denture design, the laboratory utilised a 3-dimensional resin printer to print the framework pattern. This resin pattern was then invested and cast using conventional casting methods.

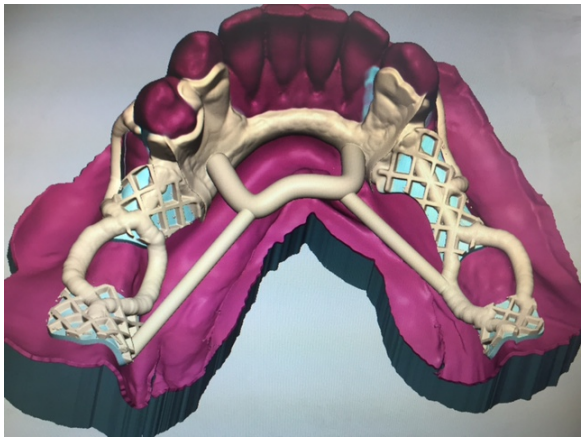


Figure 3.5. Denture design using Computer Assisted Design (CAD) software.

The framework was returned to the clinic for a framework try-in appointment. Once the fit, stability, and retention of the framework were confirmed, it was returned to the RDHM laboratory to continue with the denture-tooth set-up. Anatomical Portrait® teeth (DENTSPLY Sirona, York PA, USA) were used, with the tooth set-up following RDHM dental laboratory guidelines. The tooth set-up was carried-out either 'in-house' in the RDHM laboratory or outsourced to RDHM accredited dental laboratories. The RDHM laboratory and the principal researcher assessed all tooth set-ups prior to the try-in

appointment. The ultimate aim was to achieve a stable, bilaterally balanced, reproducible, and comfortable centric occlusion. The occlusion was assessed objectively with articulating paper and subjectively by asking the patient about their perceptions and comfort with the occlusion. The denture was then returned to the RDHM laboratory for processing.

The following sequence of events was dependent on the subject Group as follows:

Group A Subjects

Subjects allocated to Group A experienced the CRPD in the first instance. The subsequent step for these subjects was insertion of the lower denture. This involved confirming the fit, stability, and retention of the dental prosthesis. The occlusion was also checked to ensure it was within acceptable limits, stable, and comfortable. If the subject reported excessive pressure/discomfort/pain under one or both distal extensions, Fit Checker™ (GC Corporation, Tokyo, JAPAN) was applied to the under surface of the distal extensions to identify areas of increased pressure. The acrylic was relieved in any areas that identified heavy/increased pressure. Each subject was reviewed in the coming weeks to ensure comfort of the denture. In the rare instance that a subject could not attend a review appointment, he or she was advised to contact the principal researcher if there were any concerns that compromised wearing of the lower denture.

Group B Subjects

Subjects allocated to Group B experienced the IRRPD in the first instance. The basic process was similar to that for subjects in Group A, however, the procedure continued with stage-two surgery, placement of the Locator™ abutments, and intra-oral pick-up of the Locator™ retentive components into the lower denture. The acrylic present within the 'ring' recesses on the underside of each distal extension was removed using an acrylic bur inserted into a straight handpiece. This process continued until the denture could be fully seated with the abutments and retentive components in situ. In some instances, part of the metal framework was also trimmed/removed such that no obstructions were present, and the denture could be fully and passively seated. Furthermore, a channel was created on the lingual aspect on each side of the denture to

allow for injection of the chemically activated polymerisation acrylic that would secure the Locator™ retention cap into the denture.

Once the Locator™ abutments were securely fastened (25 Ncm torque), block-out rings were placed around the abutments after which a Locator™ retentive cap with the processing nylon sleeve was applied to each abutment. The purpose of the block-out rings was to minimise acrylic engaging the gingival portion of the abutments. The denture was re-seated to ensure full and passive seating. Any obstruction required further relief of the acrylic and/or metal framework until full passive seating was confirmed. At this point, the lingual channel on each side of the denture was checked intra-orally to ensure that the flowable acrylic would have access to the retention cap. A Monoject™ (Covidien, Dublin, Ireland) curved syringe was selected, and the tip cut with a pair of scissors some 5 mm from the end of the tip. This resulted in a smaller gauge at the tip (larger opening), allowing for easier flow of the thicker acrylic mixture. The syringe was tested to see if adequate access of the tip to the lingual channels could be achieved. The plunger was then removed from the syringe. The denture was removed at this point and petroleum jelly was applied to the non-*intaglio* surfaces of the denture, the intention being to avoid the acrylic from bonding to the 'outside' and tooth surfaces of the denture. The abutments (with seated retention caps) were dried and the denture re-inserted. Full and passive seating of the denture was visually re-confirmed.

Acrylic monomer (liquid) and polymer (powder) was mixed in a mixing cup until a smooth mixture of flowable consistency was achieved. This mixture was poured into the backend of the curved Monoject™ syringe and the plunger re-inserted to the back of the syringe. The syringe tip was placed into the lingual channel and the acrylic was pushed into the space surrounding the retention caps. The trapped air in the back of the syringe did not seem to interfere with the acrylic transfer (i.e., air between the acrylic and the plunger). This is probably due to the viscosity of the acrylic and the inability of the trapped air to pass through the material. The volume of acrylic inserted was greater than the available space, with some of the acrylic flowing under the denture surface (i.e., essentially performing a minor reline) and outside the lingual channel. Excess acrylic was removed with a cotton roll and a gentle flow of air with the triplex syringe was directed over the lingual channel. The denture was pressed firmly in position by the

principal researcher for approximately five minutes. After this, the patient was advised to close into maximum intercuspal position and to stay closed in this position until instructed to open. When necessary, the dental assistant would use suction to remove any excess saliva. Setting was confirmed when the acrylic block remaining in the Monoject™ syringe become hot-to-touch and set hard. The assumption was that the setting reaction would have already completed intra-orally since the oral environment is warmer that the clinic room temperature.

After setting of the acrylic, the denture was removed from the mouth. Once the denture was removed, the acrylic around the retention cap was inspected to identify any voids, and all excess acrylic was removed. An acrylic bur was used to help remove acrylic excesses and to ensure a smooth interface of the acrylic in the lingual channel with the surrounding acrylic. The denture-polishing lathe was then used to smoothen and polish the acrylic surfaces. The selection of which Locator™ nylon to use was made at this point. If the denture was 'very' retentive at this point simply with the processing (black) nylon, this was left in place. This was done so that the patient could adapt to the retention level and get used to inserting/removing the denture. The processing (black) nylons would then be changed at the review appointment. The decision of which colour nylon to use was subjective; a denture already regarded as being firm after retention cap pick-up tended to go with the blue nylons, whilst pink nylons (more retentive) were used when a denture was deemed to be less retentive. The subject was instructed on how to insert and remove the dental prosthesis, and the principal researcher observed this multiple times to ensure the subject was comfortable with these processes.

Objective and subjective tests were performed at this point to serve as a basis prior to adaptation to the new dental prosthesis.



Figure 3.6. Locator™ retention cap in situ. Note placement of white silicone spacer ring.



Figure 3.7. Access hole created for application of the chemically activated polymerisation acrylic. This will enable a direct pick-up of the Locator™ retention cap and incorporate into the denture base.

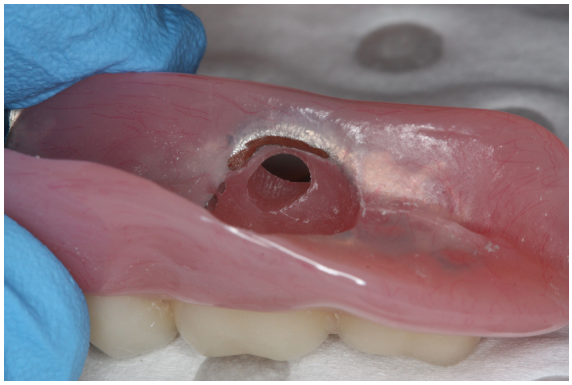


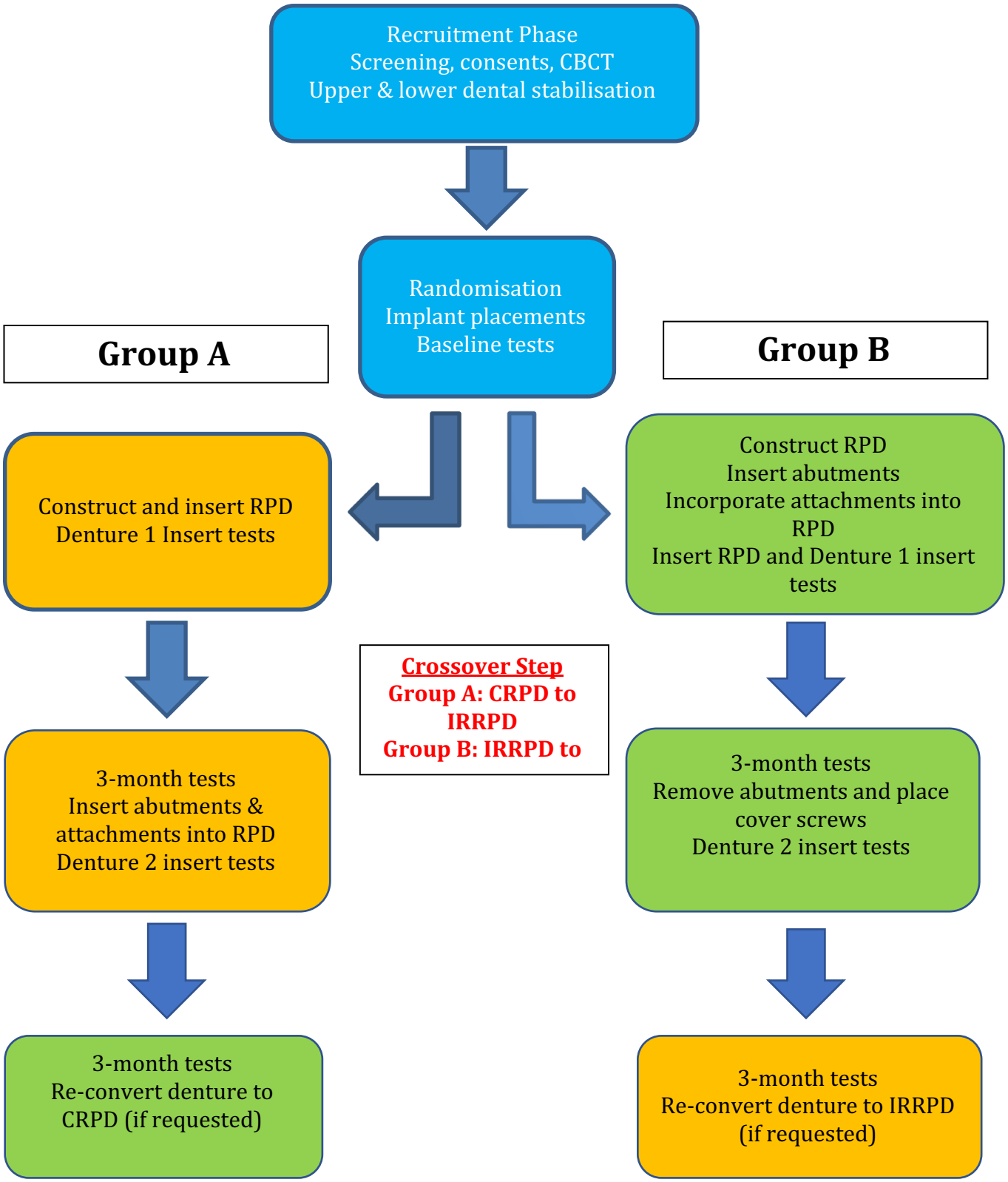
Figure 3.8. Relieving of denture extension base to ensure passive seating of denture over the LocatorTM retention cap. Note the access hole to allow injection of chemically activated polymerisation acrylic resin.

3.11 Sequencing and time-points of data collection

Table 3.1. Sequencing and time-points for conducting of trial tests.

Trial Time Point	Test	Activity
Baseline Prior to insert of Denture Design 1	• Charting • Optosil® Test • Prescale Test • OHIP-14 Questionnaire	Optosil® and Prescale Tests conducted without the lower dental prosthesis in the mouth
Denture Design 1 insert (or at nearest practical appointment time)	• Optosil® Test • Prescale Test • Group B – periapical radiographs of implants	Group A – CRPD Design Group B – Locator™ abutments engaged (IRRPD Design)
Review Denture Design 1 (min. 3 months function)	• Optosil® Test • Prescale Test • OHIP-14 Questionnaire • VAS Questionnaire • Group B – periapical radiographs of implants	
Denture Design 2 insert (or at nearest practical appointment time)	• Optosil® Test • Prescale Test • Group A – periapical radiographs of implants	Group A – Locator™ abutments engaged (IRRPD Design) Group B – Locator™ abutments removed (CRPD Design)
Review Denture Design 2 (min. 3 months function)	• Optosil® Test • Prescale Test • OHIP-14 Questionnaire • VAS Questionnaire • Group A – periapical radiographs of implants	
Reconversion of CRPD to IRRPD Design – Group B subjects	• Group B – periapical radiographs of implants	Group B – Locator™ abutments engaged (IRRPD Design)

Figure 3.9. Flow diagram depicting general trial design, time-points, data collection, and crossover



3.12 Denture design conversion (crossover) process

The crossover design necessitates a conversion of each denture. The conversion process for subjects in Group A was relatively straightforward. It essential involved the process outlined above for subjects in Group B (i.e., stage-two surgery, insertion of Locator™ abutments, adjustments to ensure passive and complete seating of the lower denture, and intra-oral pick-up of the Locator™ retention cap into the denture). The denture conversion for subjects in Group B involved removal of the Locator™ abutments and insertion of cover screws. The newly created 'dead-space' in the denture (i.e., the spaces occupied by the retention caps) were sealed with flowable resin composite applied to the inner recesses of the nylons. The denture was then reinserted and checked for comfort. In those subjects that reported ongoing discomfort, the nylon(s) was removed from the retention housing and some soft reline material (GC Reline™ Soft, GC Corporation, Tokyo, JAPAN) was applied to the denture pressing on this area. This tended to improve the situation. The denture retention was assessed, and the claps tightened if necessary. The occlusion was assessed with articulating paper and subjective feedback from the subject.

3.13 Objective test using Optosil® Comfort (Condensation Silicone) to assess Masticatory Performance

Unmodified Optosil® Comfort putty (Kulzer GmbH, Hanau, Germany) was used as the chewing test material to objectively assess how well a subject could comminute a firm material. Each subject was given an opportunity to chew on this material prior to the first recorded test in order to get an appreciation of the characteristics of the material. Fifteen cubes of approximately 6 mm edge length were fabricated, producing a total sample weight of approximately 3.4 gm. All samples were created during the afternoon of the day prior to the chewing test (which was conducted the following morning). This ensured a minimum of twelve hours for setting of the material. A putty-to-activator ratio of 20:1 was used to help standardise the test material as much as possible. Use of this ratio was based on previous *in vitro* laboratory testing investigating the material properties based on the instructions for use of the material provided by the

manufacturer. A scoop of putty was placed on a scale and weighed. The recorded putty weight was then divided by 20 in order to calculate the amount of activator required to achieve the correct putty-to-activator ratio. The scale used reported weight to two decimal places (Digitech Electronic Balance, Model: QM-7264, distributed by: Electus Distribution PTY., LTD., Rydalmere, Australia). Correct rounding was applied. The scale was then 'zeroed' and the correct amount of activator applied to the putty. The recorded weight on the scale needed to remain stable for at least five seconds to ensure the correct amount of activator was applied (activator was added/removed until the required weight was recorded). Non-latex gloves were worn by the principal examiner when manually kneading the putty and activator components until a well-mixed sample of material was formed (i.e., no sign of the red activator could be seen). The material was then rolled into a ball and placed onto a metal 'onion chopper' (Prepworks™ onion chopper, Progressive International Corp., Kent WA, USA) that had a metal grate with squares of 6 mm edge length.



Figure 3.10. Optosil® Comfort putty (Kulzer GmbH, Hanau, Germany).

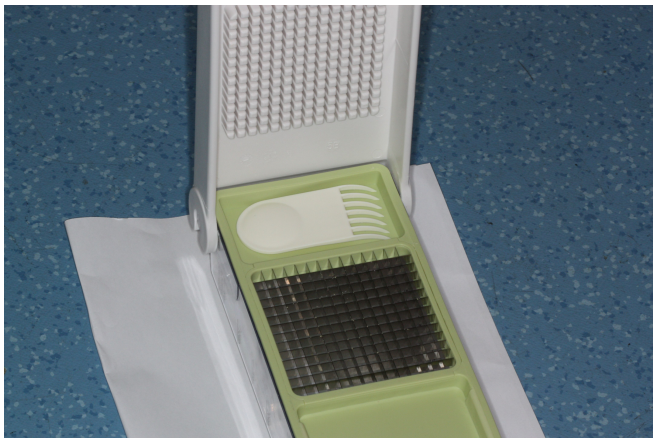


Figure 3.11. Prepworks™ onion chopper (Progressive International Corp., Kent WA, USA).

The lid of the 'onion chopper' was then closed forcing the material to pass through the grate. The material then took the form of elongated rods with a 6 mm by 6 mm square face. Using a measurement guide made on a piece of paper, the principal examiner manually created the third dimension of the cube. A horizontal straight line was drawn on a piece of paper and a ruler used to measure two points along this line 6mm apart. Two vertical lines were then drawn at these points perpendicular to the horizontal line. These three lines provided a guide for establishing the third dimension of the cube. With the long edge of the square rod placed parallel to the horizontal line, a number 15-scalpel blade was used to make two perpendicular cuts at each end of the square rod (corresponding to the two vertical lines on the paper). The end result was a cube with edge length of approximately 6 mm. Each cube had a small degree of variation due to the manual component of the production process, however the ultimate aim was that each cube possessed a minimum dimension preventing any undamaged (i.e. unchewed) material from passing through the largest sieve to be used during the processing of the recovered chewed sample (5.6 mm square aperture).

The fifteen cubes was weighed (to four decimal places) just prior to the chewing test appointment (Precisa, Model: XT120A, Precisa Gravimetrics AG, Dietikon, Switzerland). The cubes were then soaked in chlorhexidine solution (Colgate® Savacol® – alchohol free, Colgate-Palmolive, New York, USA) for a minimum of five minutes prior to the chewing test. Sitting in a stable upright position, each subject was instructed to chew five Optosil® cubes, using his or her 'normal' chewing pattern and as hard as they could without discomfort or pain, for twenty chewing strokes. The principal researcher observed the chewing strokes and provided a quiet count that was audible to the subject. The subject was also advised to keep count of the chewing strokes. Once twenty chewing strokes were completed, the subject was instructed to expectorate the contents of their mouth into a square container. The subject was also instructed to rinse with a mouthful of water and to expectorate this into the container, hence helping to recover more of the chewed particles. This process was carried-out another two times such that all fifteen cubes were chewed. A minimum of one minute elapsed before each subsequent chewing cycle. Following the final chewing cycle and expectoration, the patient was reclined, and the principal researcher inspected the mouth to identify and retrieve any remaining Optosil® particles. All removable dental prostheses were also

removed to check if any particles were present under the denture base(s). Approximately 100 mL of chlorhexidine solution was placed into the final collected sample to help disinfect the solution as much as practical before the sieving process.

A drying oven containing desiccation beads was pre-heated to 65 degrees Celsius. This was done to remove any residual moisture in the oven. Whilst the oven was being pre-heated, the sample was processed through a stack of nine sieves. The sieving was performed using a wet sieving technique with a specialised mechanical sieve shaker (Retsch Vibratory Sieve Shaker Model: AS 200 control, Retsch GmbH, Haan, Germany). The apertures of the square sieves used in descending order were: 5.6mm, 4mm, 2.8mm, 2 mm, 1.4 mm, 1 mm, 0.71 mm, 0.5 mm, and 0.355 mm. The settings of the sieve shaker were: 5-minutes of constant sieving with amplitude = 3 mm. Each processing cycle used the same water setting, with the tap controlling the water flow set to the fully open position. At completion of the 5-minute sieving cycle, the base of each sieve was 'blot-dried' from the under-surface with an absorbent towelling to remove as much residual water as possible. Care was taken to identify any particles that had collected on the under-surface to the sieve; with any identified particles being placed on the next sieve. The underside of the lid of the sieve shaker was also examined since some material was occasionally retained on this surface.

The temperature of the pre-heated oven was now reduced from 65 degrees Celsius to 40 degrees Celsius. The sieve stack was then transported to the oven and left overnight at 40 degrees Celsius (minimum of 20 hours) to ensure that as much moisture as possible was removed from the sample prior to weighing. Due to the dimension of the sieve stack (taller than the oven opening), it was necessary that any material present on the 5.6mm stack was placed in a small heat resistant container and placed next to the sieve stack in the oven. The 5.6 mm sieve would then be placed back onto the sieve stack when it was removed from the oven on the following morning. The material in the container was then poured onto the 5.6 mm stack to assess if any material would drop through (i.e., as a result of any dimensional change as a result of the removal of moisture).

The sieve stack was tapped up and down several times to loosen any material and to give an opportunity for any material to drop through to the next sieve in the event there

was some minor dimensional changes after moisture was removed from the material. The contents captured on each sieve were placed onto an open manila folder for collection. A soft bristled toothbrush was used to release any material that remained on the sieve. An empty plastic specimen collector jar was placed on the scientific balance and weighed. The setting was then zeroed, after which the contents on the manila folder were carefully transferred to the jar. The jar with contents was then weighed. Given that the balance was zeroed with the jar on the balance, the reading on the balance corresponded to the weight of the material present in the jar. The weight reading on the balance needed to remain stable for five seconds before it was recorded. The contents of the jar were then transferred to a small snap-lock bag, appropriately labelled and then stored. This process was sequentially performed for each sieve. The form used for data input included the following information: Date of sample preparation, Date of sieving, Date of weighing, Putty weight, Activator weight, Putty-to-Activator ratio, pre-test sample weight, weight of material on each sieve, cumulative weight, total cumulative weight, and percentage of recovered material (i.e., total cumulative weight divided by the pre-test sample weight). For the purpose of data analysis, the weight of material on each sieve was referenced to the total weight of material recovered using the formula: weight on sieve/total weight of recovered sample. This was done to reduce the impact of different sample starting (initial) weights and incomplete sample recovery.



Figure 3.12. Example of sieves used to create the sieve stack through which the recovered chewing test material was sieved. Each sieve has a mesh of different aperture size.

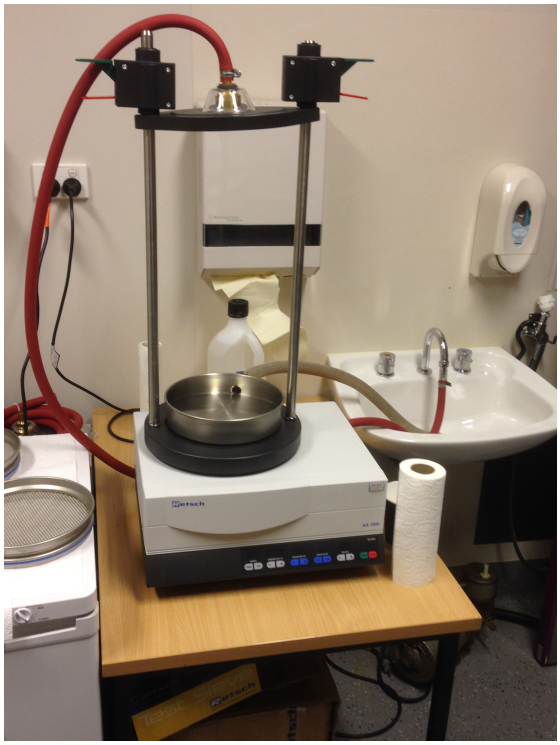


Figure 3.13. Retsch Vibratory Sieve Shaker Model: AS 200 control (Retsch GmbH, Haan, Germany).

The data obtained was used to determine a particle size distribution. Of particular interest was the MPS, which signified the theoretical sieve size that half of the recovered material would pass. This figure was used to compare the outcomes of the Optosil chewing test.

3.14 Objective test using Prescale pressure sensitive film to assess Masticatory Performance (maximum bite pressure, Load, and Occlusal Contact Area)

Prescale pressure sensitive film (Fujifilm Holdings Corporation, Tokyo, JAPAN) was used to assess changes in bite pressures generated by each denture design. A variety of Prescale films are available which cover a different portion of the pressure range. Because of the heterogeneity of the subjects enrolled in the trial (i.e., ranging from fully dentate upper arches through to removable complete denture upper arches), it was decided to use a range of films to help best ensure that the pressures generated could be recorded. The three films selected were: MS (Medium Pressure), LW (Low Pressure), and LLW (Super Low Pressure). The films used in this trial were purchased in the form of rolls. To prepare the films for use in the trial, a guillotine was used to carefully slice

the rolls into films of approximate dimension of 7.8 mm X 7.2 mm. This dimension ensured that all teeth would be recorded on the film and that they can be enclosed in a small snap-lock bag. The MS film was a single sheet, whereas the LW and LLW films comprised two sheets. All sheets were placed with the lustrous surface facing the lower arch. The top right corner of the MS film was nipped with a pair of scissors, hence helping to orientate the film during film placement in the mouth and scanning of the films. The back surface (i.e., facing upper arch) of top right corner of the C-film of the LW film was marked with a single dot by a black marker and the top right corner of C-film of the LLW film was marked with two small dots by a black marker. This ensured identification of which film was being used and to help with orientation of the films. For the two-sheet films to work (i.e., LW and LLW sheets), the rough (matte) surfaces must be placed against each other. The three film types were correctly orientated and placed in a small snap-lock bag (75 mm X 100 mm) to ensure the films remained free of contamination from saliva and other contaminants. Three lots of these film packets were made for each test, with each packet numbered from one to three (i.e., the order of use during the test).

Subjects were advised to sit upright and place their head into the headrest such that the head was in a stable position and the occlusal plane was parallel with the floor. The film packet was inserted into the mouth with the dots orientated on the right side (i.e., quadrant 1). The aim was to place the film in an appropriate position that would allow for all teeth to contact the film on closing. The subject was instructed to close into his/her normal bite (i.e., centric occlusion) and to gradually increase his/her bite force until they felt they were achieving their maximum bite force without discomfort or pain. The subject was advised to give the principal researcher a sign that this point has been reached (i.e., a thumbs-up gesture) and to hold this pressure for a slow count of five seconds (which was sounded by the principal researcher). This five-second count was required to ensure sufficient pressure was maintained on the film to optimise dye release and stain development. After the count of five, the subject was instructed to open his/her mouth and the film packet was removed. This was performed two more times (new film packets inserted) with a minimum one-minute break between subsequent bites.

The films were subsequently scanned after the subject was dismissed from the clinic. A scanner (Epson Perfection V330 Photo scanner, Seiko Epson Corp., Nagano, Japan) was used to scan the films and the Prescale Pressure Distribution Mapping System FPD-8010E software (Fujifilm Holdings Corporation, Tokyo, JAPAN) was used to analyse the scanned image. When scanning, the lustrous surface of each film was placed towards the scanning plate with the cut and marked corners placed on the front right side of the scanner. Each film was scanned separately. The software allows the following inputs to be entered for each scan: examination date and time, record date and time, scan name, film type, temperature, humidity, resolution, and type of pressure application (continuous or momentary). The inputs used in this trial were: temperature = 35 degrees Celsius, humidity = 65%, resolution = 0.125mm, and pressure application = momentary.

The detectable pressure range for each film type is as follows:

- MS film – 10MPa to 50MPa (Medium Pressure)
- LW film – 2.5MPa to 10MPa (Low Pressure)
- LLW film – 0.5 - 2.5MPa (Super Low Pressure)

The documented accuracy for these films is ± 10% or less (measured at 23 degrees Celsius and 65% relative humidity [749].

The Prescale software has a manual function that enables partial removal/erasing of pressure marks on the scan (erase method). This partial erasing function was used to remove as many of these marks as possible. There was a subjective element to this activity, however most of the marks removed were green in colour which indicates the marks were below the pressure recording threshold for the given film type. Furthermore, if there was any doubt as to whether a marking belonged to the occlusion, the mark(s) was retained. Once all of the perceived non-occlusion related marks were removed, the measurement table was generated. The measurement table provided the following data: Pressure effective rate (%), pressed area (mm^2), average pressure (MPa), maximum pressure (MPa), load (N), and measured area (mm^2). For each bite, the data from the edited scans were added together to calculate the pressed area, average pressure, and load. The data from each of the three bite samples for each respective film

type was then averaged. This was undertaken to try and smooth any variations between the three bite tests. The data of particular interest is the load measurement, whilst the pressure effective rate (%) provides a measure as to how much of the pressure recorded on the film lies within the detection range of that particular film type.

The MS films were used to measure MBP. The LW films were used to measure the load, and the LLW films were used to measure OCA. This was based on the detectable pressure ranges for each film type and the relationship of these pressure ranges to the measures of interest.

3.15 Subjective test utilising the OHIP-14 questionnaire to assess each denture design in terms of patient satisfaction.

The OHIP-14 questionnaire was used to record the subjective assessment of the baseline situation and following adaptation to each denture design. This OHIP-14 questionnaire in denture wearers has previously been used at RDHM and subsequently published [697]. The OHIP-14 questionnaire can be seen in Appendix 4.

Subjects were issued the questionnaire on three occasions during the trial: prior to delivery of the lower denture, following adaptation to denture design one, and following adaptation to denture design two. The questionnaire forms were given to each subject to read through and complete. Subjects were reassured the principal researcher would answer any questions/concerns relating to the questions. In the event that a subject had difficulty reading the questionnaire, the principal researcher was available to read-out the question and where a rating was required, the rating scale was explained to the patient. The principal researcher was conscious of minimising any 'leading' of the subject with regards to the ratings given.

The ratings of the OHIP-14 instrument were converted to quantitative data by assigning a numerical value to each rating. The following assignments were made: Never = 0, Hardly Ever = 1, Occasionally = 2, Fairly Often = 3, and Very Often = 4. The OHIP-14 data was analysed in two ways: OHIP-14 Sum and OHIP-14 Domain. OHIP-14 Sum for each subject (at each testing point) was calculated by adding the numerical rating for each of

the 14 questions. OHIP-14 Domain was calculated by adding the numerical ratings for the two questions making up each respective domain. The OHIP-14 instrument consists of seven domains, namely: Functional Limitation (questions 1 and 2), Physical Pain (questions 3 and 4), Psychological Discomfort (questions 5 and 6), Physical Disability (questions 7 and 8), Psychological Disability (9 and 10), Social Disability (questions 11 and 12), and Handicap (questions 13 and 14). In this analysis, a lower OHIP-14 score (Sum or Domain) signified a more satisfactory situation. The total score for each subject was calculated (OHIP-14 Sum) and then means calculated for each group. These means were used for the paired t-tests. With respect to OHIP-14 (Domain), the score for each Domain for each subject was calculated. Means were then calculated for each Domain for each group. These means were used for the paired t-tests.

3.16 Subjective test utilising a Visual Analogue Scale (VAS) questionnaire to assess each denture design in terms of patient satisfaction

The VAS is another tool available to assess the subjective performance of each denture design (Appendix 5). This tool was employed after adaptation to each denture design. The VAS used in this study consisted of five questions assessing the following variables: comfort, chewing ability, retention, stability, and overall satisfaction. A 10 cm (100 mm) horizontal line was located beneath each question with the term 'Not at all satisfied' situated to the left of the line and the term 'Totally satisfied' situated to the right of the line. The scale was explained to each subject; such that the extreme left of the line effectively signified 0% satisfaction and that the extreme right end of the line signified 100% satisfaction. Each subject was instructed to read the question and place a mark along the line that corresponded to his or her perception regarding the relevant variable.

The principal researcher used a plastic (clear) measuring ruler with mm gradations. The zero point of the ruler was placed at the extreme left point of the line and a measurement was made as to where the mark intersected the horizontal line. In the event that a mark missed intersecting the horizontal line, a perpendicular line was

drawn from the mid-point of the mark (or from the point of intersection if an 'X' was used as the mark) down to the horizontal line. This point of intersection was used for the purpose of measurement. Higher measurement values signified a greater level of satisfaction of the variable in question. The VAS was not used during the assessment of the baseline situation since the baseline situation did not include the lower denture.

3.17 Clinical data collection

Dental and periodontal chartings were conducted before insertion of the lower dental prosthesis (baseline) and following the wearing of the second denture design (i.e., after a minimum period of six months). Periapical radiographs of each implant were taken at the times of first abutment insertion and at the conclusion of the adaptation period of the second denture. Radiographers in the radiology department of RDHM took the periapical radiographs. The x-ray prescription form requested that the paralleling technique be used, thus enabling better comparison of radiographs taken at different time-points. Of particular interest were any significant changes in mesial and distal bone levels around the implants (relative to the implant shoulder), caries levels, and periodontal probing depths.

The periapical radiographs were correctly orientated on a horizontal x-ray viewing light box. A magnification glass with 2X and 4X magnifications was used to better visualise the radiographs (Foldable Magnifier with 110 mm lens size, Cat. No. QM3503, Jaycar (distributor), Rydalmere, Australia), and an electronic calliper was used to measure the distance between the shoulder of the implant and the first bone-to-implant contact (on both mesial and distal sides) (Budget 150 mm Digital Vernier Calipers – 0.01 mm resolution, Cat. No. TD2082, Jaycar(distributor), Rydalmere, Australia). The potential for some dimensional distortion was considered and as such a distortion factor was calculated and applied wherever necessary. Since the width of the implants used in this trial was known (i.e., 4 mm), this measure was compared to that recorded on the periapical radiograph. The distortion factor was calculated by dividing the width of the implant platform as measured on the periapical radiograph (mm) divided by 4 mm (known diameter). This distortion factor was then applied to any measurements recorded from a given radiograph. Measurements were taken at the time of first

abutment insertion, and at the end of the comparison phase. The shoulder of the implant platform served as the reference point.

3.18 Statistics

Paired t-tests were used to assess for treatment effects over time and to compare between treatments. Differences were summarised with means, standard deviations, and 95% confidence intervals. Where normality assumptions of t-tests were not met for raw data, a log transformation was performed before statistical testing, with the results subsequently summarised on the back-transformed scale. Treatment order effects were assessed using an ANOVA model, with treatment and order interaction included in the model. Where multiple time points were available for a given outcome, the three-month to baseline change was used to assess order effects. All analyses were performed in Minitab version 18 (Minitab, LLC, State College PA, USA) with the expert assistance of Dr Sandy Clark-Errey and Ms Sue Finch (Statistical Consulting Centre, The University of Melbourne).

Appendix 6 illustrates some of the steps (methods) with photographs (subjects BP and JK).

Chapter 4 - Results

4.1 Sample Characteristics

Nineteen subjects were initially enrolled into the clinical trial. Of the nineteen subjects enrolled, seventeen completed the comparison phase of the trial, which involved the wearing of each denture type for a minimum three-month adaptation period and then the performance of relevant tests. Two subjects withdrew from the trial before completion of the comparison phase; subject number 8 (from Group A) passed away during trial (suspected late diagnosed malignancy not related to trial interventions) and subject number 12 (from Group A) who informed the research group that she no longer wanted to participate in the trial, even after having undergone surgical placement of the two implants (but before denture construction). This signifies a dropout rate of 10.5%.

4.2 Subject Data – Age Profile, Sex Breakdown, and Group Designation

Table 4.1. Trial Subjects – Group designations and ages at enrolment.

	N	N Male	N Female	Mean age (Years)	Mean age Males (Years)	Mean age Females (Years)
Group A	7	4	3	53.5	55.1	51.4
Group B	10	4	6	58.1	61.8	55.7
Total	17*	8	9	56.2	58.4	54.2

* 19 subjects were originally enrolled into the trial; two subjects withdrew from the trial after implant placements (both from group A).

4.3 Subject details, arch configurations, implant sites, and Locator™ abutments

Table 4.2 Subject details, arch configurations, implant sites, and Locator™ abutments.

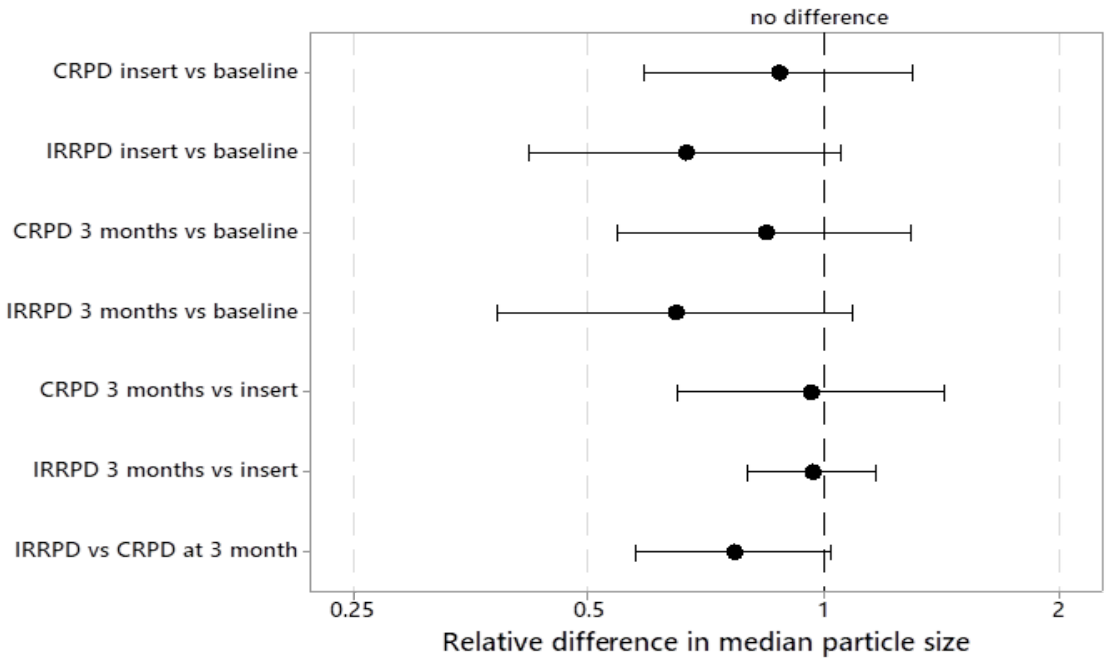
SUBJECT ID	GROUP	DATE OF BIRTH	AGE AT ENTRY (YEARS)	SEX	UPPER ARCH CONFIG.	LOWER ARCH CONFIG. (Teeth Present)	IMPLANT SITES		Locator™ HEIGHTS		Locator™ NYLONS USED
							Q3	Q4	Q3	Q4	
1	A	29/05/1940	73y, 11m, 21d	M	FD	35 to 44	37(M)	47(M)	2mm	2mm	Blue
2	B	09/02/1946	68y, 8m	F	IRFD	34 to 43	36	45	2mm	2mm	Pink
3	A	02/10/1984	30y, 7d	M	D	34 to 43	36	46	3mm	3mm	Pink
4	B	11/11/1946	67y, 11m, 3d	F	D	38 to 36, 34, and 33 to 45	36	46	3mm	3mm	Blue
5	A	04/10/1964	50y, 1m, 9d	F	CRPD	35, and 33 to 44	37(M)	47(M)	3mm	2mm	Pink
6	B	09/11/1960	54y, 1m, 2d	F	CRPD	33 to 45	36	47(M)	2mm	2mm	Pink
7	B	23/11/1950	64y, 3m, 2d	M	CRPD	34 to 33	36	46	2mm	3mm	Pink
9	B	19/06/1966	48y, 11m, 22d	F	IRRPD	35 to 44	36	46	3mm	3mm	Pink
10	A	22/02/1967	48y, 5m, 23d	F	CRPD	35 to 44	37(M)	47(M)	3mm	3mm	Blue
11	B	30/12/1981	33y, 7m, 22d	F	D	35 to 44	36	46	2mm	3mm	Blue
13	A	15/10/1936	79y, 1m, 12d	M	D	33 to 43	36	44	2mm	3mm	Pink
14	B	28/09/1955	60y, 2m, 6d	F	D	33 to 44	36	47(M)	3mm	3mm	Blue
15	A	07/01/1961	55y, 4m, 3d	F	RPD (Flexible)	34 to 44	35	46	3mm	3mm	Blue
16	B	02/06/1941	75y, 1m, 11d	M	CRPD	33 to 43	36	46	3mm	3mm	Pink
17	A	03/08/1979	36y, 11m, 16d	M	CRPD	34 to 44	36	46	2mm	3mm	Blue
18	B	29/08/1948	67y, 11m, 12d	M	D	34 to 43	36	45	2mm	2mm	Pink
19	B	25/03/1977	39y, 5m, 6d	M	CRPD	35 to 44	37(M)	46	4mm	2mm	Blue

Note: Subjects 8 and 12 were withdrawn from the trial after implant placements (17 subjects completed the trial).
M = Male, F = Female, FD = Full Removable Denture, IRFD = Implant Retained Full Denture, D = Dentate, CRPD = Conventional Removable Partial Denture, RPD (Flexible) = Flexible Acrylic Removable Partial Denture (no metal base), (M) = Mesial side

The majority of Locator™ abutments placed had gingival heights of either 2mm (n = 14, 41.1%) or 3mm (n = 19, 55.9%). One of the thirty-four abutments placed had a 4mm gingival height (subject number 19, implant site 36). In the majority of cases, the decision was made to change to more retentive nylons on the day of denture insertion. In a limited number of cases, the processing (black) nylons were initially retained until subjects become familiar with inserting and removing the denture. This was decided on after assessing the retentiveness of the denture and the subjects' ability to remove and insert the dental prosthesis. These nylons were subsequently changed to suitable retentive nylons at the next review visit. The blue (extra-light retention) and pink (light retention) Locator™ nylons were the most commonly used nylons.

4.4 Masticatory performance test using Optosil® Comfort putty

Figure 4.1. 95% Confidence interval (C.I.) plots for changes in mean Median Particle Size (MPS) for the relevant comparison pairings as generated by the Optosil® chewing test.



CRPD insert vs baseline – difference in results obtained at time of insertion of the CRPD and the baseline situation (i.e., when lower denture was not in situ).

IRRPD insert vs baseline – difference in results obtained at time of insertion of the IRRPD and the baseline situation.

CRPD 3 months vs baseline – difference in results obtained at the end of the 3-month adaptation period for the CRPD and the baseline situation.

IRRPD 3 months vs baseline – difference in results obtained at the end of the 3-month adaptation period for the IRRPD and the baseline situation.

CRPD 3 months vs insert – difference in results obtained at the end of the 3-month adaptation period for the CRPD and at the time of insertion of the CRPD.

IRRPD 3 months vs insert – difference in results obtained at the end of the 3-month adaptation period for the IRRPD and at the time of insertion of the IRRPD.

IRRPD vs CRPD at 3 month – difference in results obtained at the end of the 3-month adaptation period for the IRRPD and at the end of the 3-month adaptation period for the CRPD.

Table 4.3. Paired T-test results for changes in mean log_2 MPS for the relevant comparison pairings as generated by the Optosil® chewing test.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
CRPD insert vs baseline	-0.20	1.11	(-0.77, 0.38)	-0.72	0.479
IRRPD insert vs baseline	-0.59	1.29	(-1.25, 0.08)	-1.88	0.079
CRPD (3mths) vs baseline	-0.25	1.21	(-0.87, 0.37)	-0.86	0.405
IRRPD (3mths) vs baseline	-0.63	1.47	(-1.39, 0.12)	-1.78	0.093
CRPD (3mths) vs CRPD insert	-0.06	1.10	(-0.62, 0.51)	-0.21	0.837
IRRPD (3mths) vs IRRPD insert	-0.05	0.53	(-0.32, 0.22)	-0.38	0.709
IRRPD (3mths) vs CRPD (3mths)	-0.38	0.81	(-0.80, 0.03)	-1.97	0.067

Note: The results for the chewing tests are transformed using the log_2 scale to correct for skewness observed in the raw data, and the results in Table 4.3 are presented on this scale. The results in Table 4.4 have been backtransformed and should be interpreted as relative or proportional differences. For example, it is estimated that the mean MPS is 23% smaller for the IRRPD compared to CRPD at three months (see Table 4.4).

Table 4.4. Relative differences of mean MPS (backtransformed) within comparison pairings as generated by the Optosil® chewing test.

	Estimation for Paired Relative difference	
Test Pair	**Mean**	**95% C.I.**
CRPD insert vs baseline	0.87	(0.59, 1.30)
IRRPD insert vs baseline	0.67	(0.42, 1.05)
CRPD (3mths) vs baseline	0.84	(0.55, 1.29)
IRRPD (3mths) vs baseline	0.64	(0.38, 1.09)
CRPD (3mths) vs CRPD insert	0.96	(0.65, 1.42)
IRRPD (3mths) vs IRRPD insert	0.97	(0.80, 1.17)
IRRPD (3mths) vs CRPD (3mths)	0.77	(0.58, 1.02)

The Optosil® chewing test generated the following results:

- As seen in the 95% C.I. plots, all comparison pairings demonstrated a reduction in mean MPS as observed by a shift of each respective mean to the left of the zero-difference line. Such a shift is in favour of the first listed item in the comparison pairing title.
- No statistically significant reductions were observed in mean MPS for any of the comparison pairings (i.e., at the five per cent level of statistical significance ($p < 0.05$)).
- A strong positive trend in reduction of mean MPS was seen for each of the following three pairings; a) the IRRPD after adaptation versus CRPD after adaptation ($p = 0.067$), b) the IRRPD insert versus baseline situation ($p = 0.079$), and IRRPD after adaptation versus baseline situation ($p = 0.093$).
- The mean MPS of the IRRPD after adaptation was lower than that for the CRPD after adaptation, although not significant at the five per cent level ($p = 0.067$). This suggests that the IRRPD may favour better chewing function when compared to the CRPD because smaller particles would be expected after chewing with the IRRPD.
- Little improvement in masticatory performance, as demonstrated by a modest reduction in relative differences of mean MPS, was seen over the adaptation period for either denture type (4% for CRPD and 3% for IRRPD). This suggests that there is limited potential for improvement of chewing function between insertion of the dental prosthesis and the three-month adaptation period, with the functional benefit of each denture type being realised soon after insertion.
- Since no significant differences were detected relative to the baseline situation for either denture type, there appears to be support for the SDA situation on the basis of the Optosil® chewing test as employed in this trial.
- A larger sample size may better assess the function of the IRRPD design, since it showed the strongest trend towards achieving significance.

4.5 Masticatory performance test using Prescale pressure sensitive film - Maximum Bite Pressure (MBP)

Figure 4.2. 95% C.I. plots for changes in mean MBP for relevant comparison pairings generated by the Prescale test.

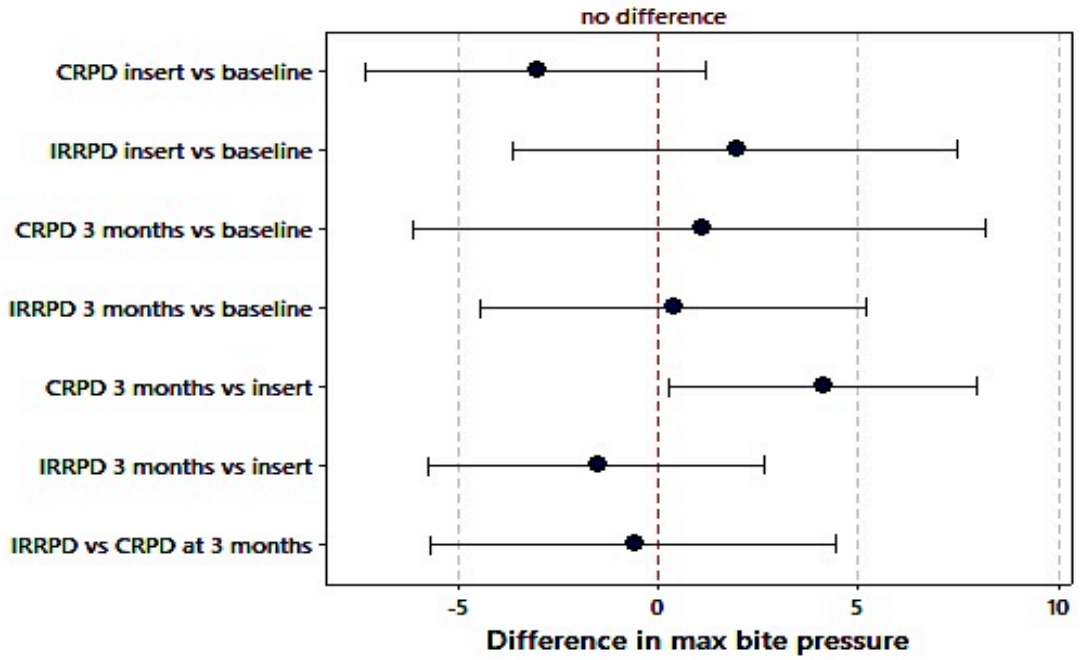


Table 4.5. Paired T-Test results for changes in mean MBP for relevant comparison pairings generated by the Prescale test.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
CRPD insert vs baseline	-3.09	8.32	(-7.37, 1.19)	-1.53	0.146
IRRPD insert vs baseline	1.91	10.85	(-3.66, 7.49)	0.73	0.477
CRPD (3mths) vs baseline	1.01	13.92	(-6.15, 8.17)	0.30	0.769
IRRPD (3mths) vs baseline	0.35	9.41	(-4.49, 5.18)	0.15	0.880
CRPD (3mths) vs CRPD insert	4.10	7.46	(0.26, 7.93)	2.26	**0.038**
IRRPD (3mths) vs IRRPD insert	-1.56	8.20	(-5.78, 2.65)	-0.79	0.443
IRRPD (3mths) vs CRPD (3mths)	-0.66	9.89	(-5.74, 4.42)	-0.28	0.786

The results generated by the Prescale test for MBP include:

- The only comparison pairing to achieve significance ($p = 0.038$) was the CRPD over the adaptation period (between insert and three-months).
- Both denture types demonstrated a small increase in mean MBP relative to the baseline situation, but not at a level achieving significance.
- No significant differences were detected in any of the other comparison pairings, suggesting that the presence of the dental prosthesis has minimal impact on MBP generation.
- A reduction in mean MBP was observed for the following three comparison pairings: a) CRPD insert and baseline, b) IRRPD after adaptation versus IRRPD insert, and c) the IRRPD and CRPD after adaptation pairing (albeit none were of significance at $p < 0.05$ levels).
- As was the case with the Optosil® chewing test, the MBP test suggests that presence of either dental prosthesis type has no significant impact on the baseline (SDA) situation.

4.6 Masticatory performance test using Prescale pressure sensitive film – Load

Figure 4.3. 95% C.I. plots for changes in mean load generation across the arches for relevant comparison pairings generated by the Prescale test.

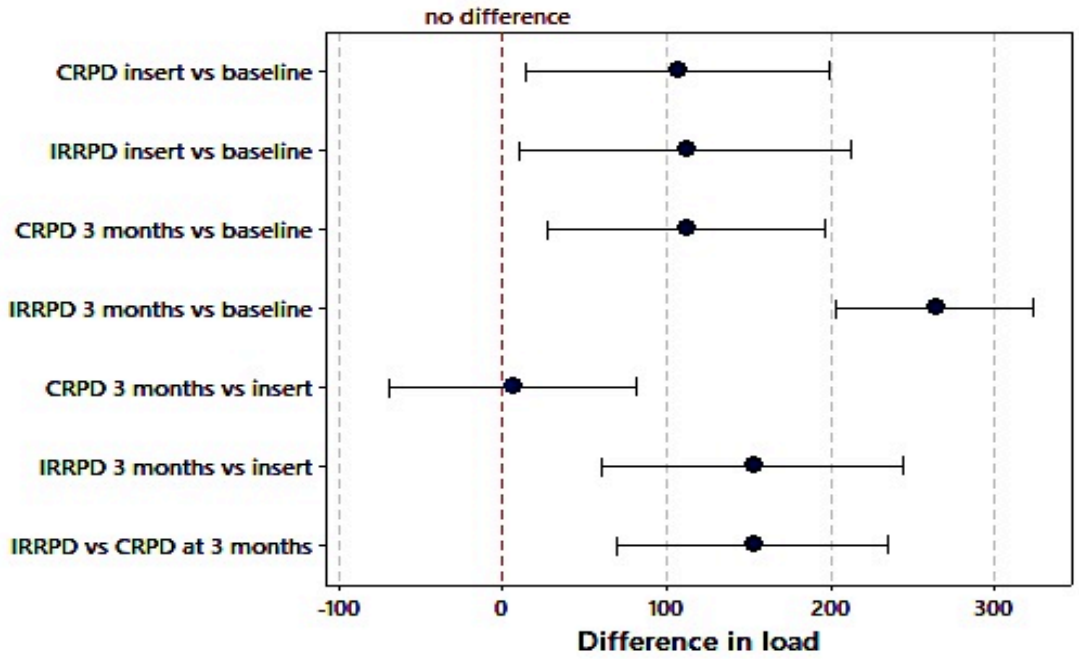


Table 4.6 Paired T-test results for changes in mean load generation for relevant comparison pairings generated by the Prescale test.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
CRPD insert vs baseline	106.1	180.5	(13.2, 198.9)	2.42	**0.028**
IRRPD insert vs baseline	111.1	197.5	(9.5, 212.6)	2.32	**0.034**
CRPD (3mths) vs baseline	111.2	164.3	(26.7, 195.7)	2.79	**0.013**
IRRPD (3mths) vs baseline	263.2	116.6	(203.2, 323.1)	9.30	**<0.001**
CRPD (3mths) vs CRPD insert	5.1	146.6	(-70.2, 80.5)	0.14	0.887
IRRPD (3mths) vs IRRPD insert	152.1	180.0	(59.6, 244.7)	3.48	**0.003**
IRRPD (3mths) vs CRPD (3mths)	152.0	160.9	(69.3, 234.8)	3.89	**0.001**

The results generated by the Prescale test for load show:

- All comparison pairings, with the exception of CRPD after adaptation versus CRPD insert, demonstrated statistically significant increases in mean load generation (at $p < 0.05$ levels).
- The greatest increase in mean load generation is seen in the IRRPD after adaptation versus baseline situation ($p < 0.001$).
- The IRRPD after adaptation demonstrated significantly greater load generation when compared to the CRPD after adaptation situation ($p = 0.001$). This finding is consistent with the trend seen for the same comparison pairing using the Optosil® chewing test.
- The only comparison pairing not showing a significant increase in mean load generation is the CRPD after adaptation versus CRPD insert situation, suggesting minimal improvement during the adaptation period. This is opposite to the findings of the MBP test, which demonstrated a significant improvement for this comparison pairing.
- Unlike the CRPD situation, significant improvement in mean load generation was seen in the IRRPD after adaptation versus IRRPD insert comparison pairing ($p = 0.003$), suggesting greater potential for improvement in this measure during the adaptation period. This finding differs to that seen in the Optosil® chewing test, which demonstrated little improvement over the three-month adaptation period (for either denture type).
- All comparison pairings relative to baseline demonstrated a significant improvement in mean load generation. Hence, based on mean load generation, the presence of either denture types significantly improves the baseline (SDA) situation.

4.7 Masticatory performance test using Prescale pressure sensitive film – Occlusal Contact Area (OCA)

Figure 4.4. 95% C.I. plots for changes in mean OCA for the relevant comparison pairings generated by the Prescale test.

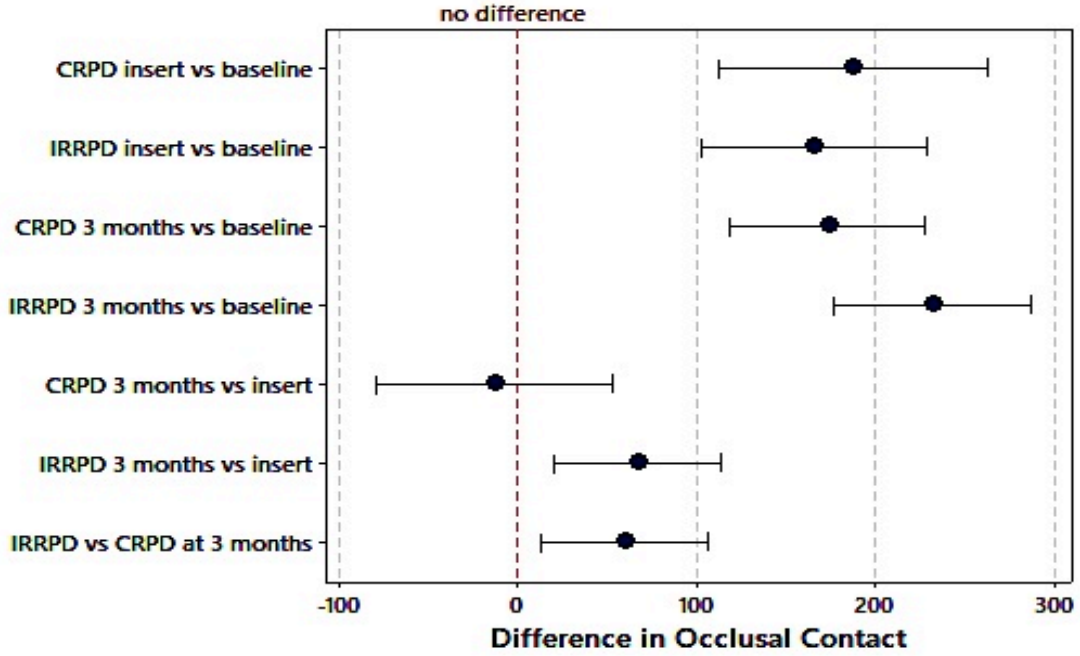


Table 4.7. Paired T-test results for changes in mean OCA for relevant comparison pairings generated by the Prescale test.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
CRPD insert vs baseline	187.2	146.9	(111.7, 262.7)	5.26	**<0.001**
IRRPD insert vs baseline	165.4	123.2	(102.0, 228.7)	5.54	**<0.001**
CRPD (3mths) vs baseline	172.9	105.9	(118.5, 227.4)	6.73	**<0.001**
IRRPD (3mths) vs baseline	232.3	107.4	(177.0, 287.5)	8.91	**<0.001**
CRPD (3mths) vs CRPD insert	-14.3	128.8	(-80.5, 51.9)	-0.46	0.654
IRRPD (3mths) vs IRRPD insert	66.9	91.2	(20.0, 113.8)	3.02	**0.008**
IRRPD (3mths) vs CRPD (3mths)	59.3	90.9	(12.6, 106.1)	2.69	**0.016**

The results generated by the Prescale test for OCA include:

- All comparison pairings, with the exception of the CRPD after adaptation versus CRPD insert, demonstrated a significant increase in mean OCA. These results are similar to those observed for the mean load tests.
- The IRRPD demonstrated a significant increase in mean OCA over the adaptation period ($p = 0.008$), whereas this was not observed for the CRPD. These results are consistent with the load generation test but differs to the result of the Optosil® chewing test.
- After adaptation for each denture type, the IRRPD demonstrated significantly greater mean OCA compared to the CRPD ($p = 0.016$). This is consistent with the load generation test and the positive trend observed in the Optosil® chewing test but differing to the result observed in the MBP test.
- Both denture types demonstrated a significant increase in mean OCA relative to the baseline (SDA) situation ($p < 0.001$ for both CRPD and IRRPD); hence presence of either denture type will improve the SDA situation on the basis of mean OCA improvement.

4.8 Subjective assessment using the OHIP – 14 questionnaire (Sum)

Fig. 4.5. 95% C.I. plots for changes in mean OHIP-14 Sum score for the relevant comparison pairings.

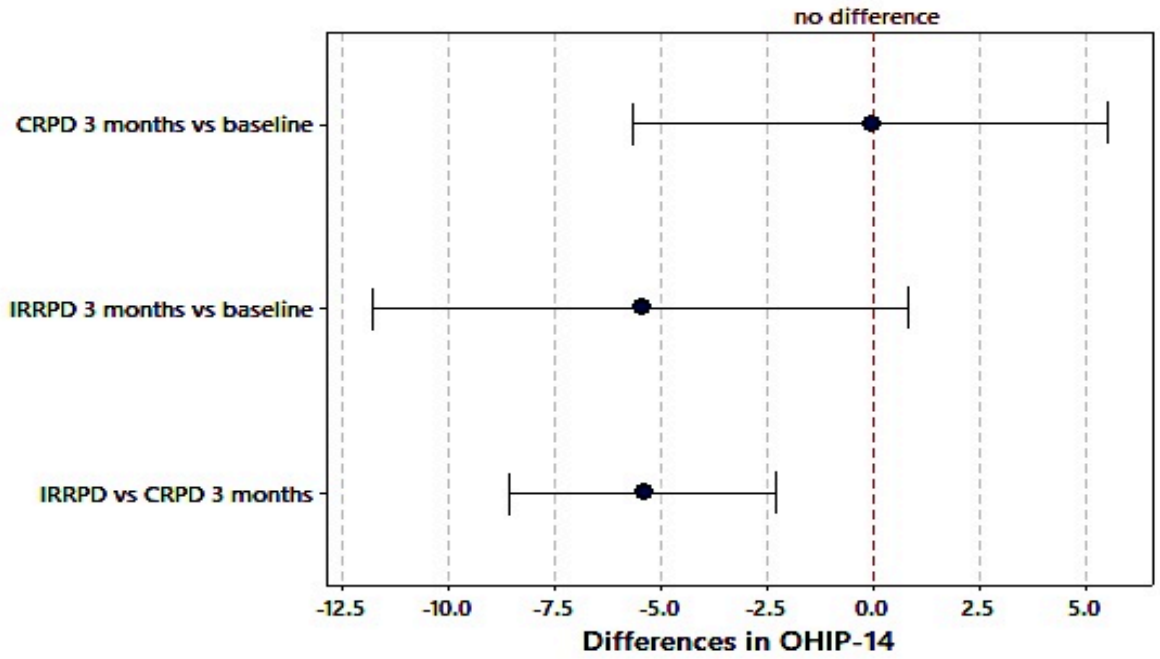


Table. 4.8. Paired T-test for changes in mean OHIP-14 Sum score for the relevant comparison pairings.

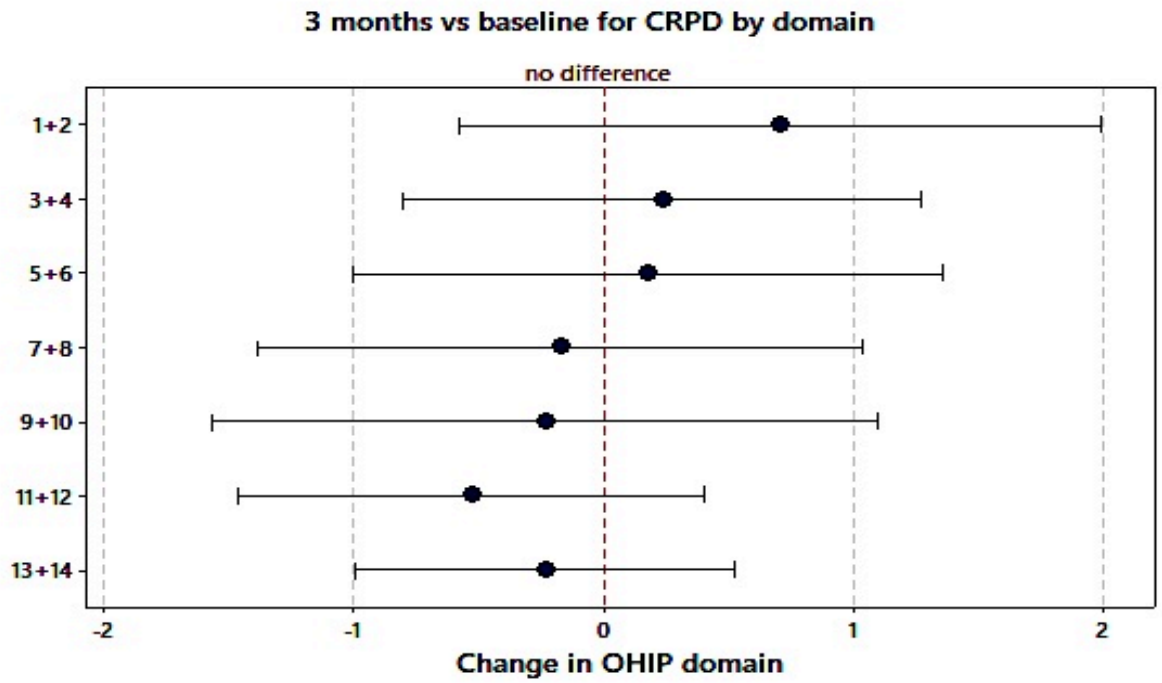
	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
CRPD (3mths) vs baseline	-0.06	10.90	(-5.66, 5.55)	-0.02	0.983
IRRPD (3mths) vs baseline	-5.47	12.30	(-11.79, 0.85)	-1.83	0.085
IRRPD (3mths) vs CRPD (3mths)	-5.41	6.12	(-8.56, -2.26)	-3.64	**0.002**

The results of the OHIP-14 Sum questionnaire include:

- Minimal improvement was observed in OHIP-14 Sum score for the CRPD after adaptation versus baseline situation.
- Although a strong positive trend (i.e., reduction) of mean OHIP-14 Sum score for the IRRPD after adaptation versus baseline situation was observed, it was not significant at the five per cent level.
- The IRRPD after adaptation demonstrated a significantly better OHIP-14 Sum score relative to the CRPD after adaptation situation ($p = 0.002$), suggesting that the IRRPD has a greater (positive) impact on a subjects' OHRQoL.
- The failure of either denture type to achieve significance relative to the baseline situation suggests that presence of either denture type does not improve the baseline (SDA) situation, albeit the IRRPD shows a much stronger tendency towards achieving significance.

4.9 Subjective assessment using the OHIP-14 questionnaire (by domain) – CRPD vs Baseline

Fig. 4.6. 95% C.I. plots for changes in mean OHIP-14 Domain scores for the CRPD versus baseline comparison pairing.



1 + 2 = Functional Limitation domain

3 + 4 = Physical Pain domain

5 + 6 = Psychological Discomfort domain

7 + 8 = Physical Disability domain

9 + 10 = Psychological Disability domain

11 + 12 = Social Disability domain

13 + 14 = Handicap domain

Table 4.9. Paired T-test for changes in mean OHIP-14 Domain scores for the CRPD versus baseline comparison pairing.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
Functional Limitation (1 + 2)	0.71	2.49	(-0.58, 1.99)	1.17	0.260
Physical Pain (3 + 4)	0.24	2.02	(-0.80, 1.27)	0.48	0.637
Psychological Discomfort (5 + 6)	0.18	2.30	(-1.01, 1.36)	0.32	0.756
Physical Disability (7 + 8)	-0.18	2.35	(-1.39, 1.03)	-0.31	0.761
Psychological Disability (9 + 10)	-0.24	2.59	(-1.57, 1.10)	-0.38	0.713
Social Disability (11 + 12)	-0.53	1.81	(-1.46, 0.40)	-1.21	0.245
Handicap (13 +14)	-0.24	1.48	(-1.00, 0.53)	-0.66	0.522

The results of the OHIP-14 Domain scores for the CRPD versus baseline comparison pairing include:

- No significant changes were observed for any of the seven OHIP domains between the CRPD after adaptation and the baseline situation.
- The mean scores for the functional limitation, physical pain, and psychological discomfort domains demonstrated a positive shift, suggesting a worsening of these domains (although not at the five per cent level of statistical significance).
- The mean scores for the remaining four domains demonstrated a negative shift, suggesting an improvement in these domains, although again, not at the five per cent level of statistical significance.

4.10 Subjective assessment using the OHIP-14 questionnaire (by domain) – IRRPD vs Baseline

Fig. 4.7. 95% C.I. plots for changes in mean OHIP-14 Domain scores for the IRRPD versus baseline comparison pairing.

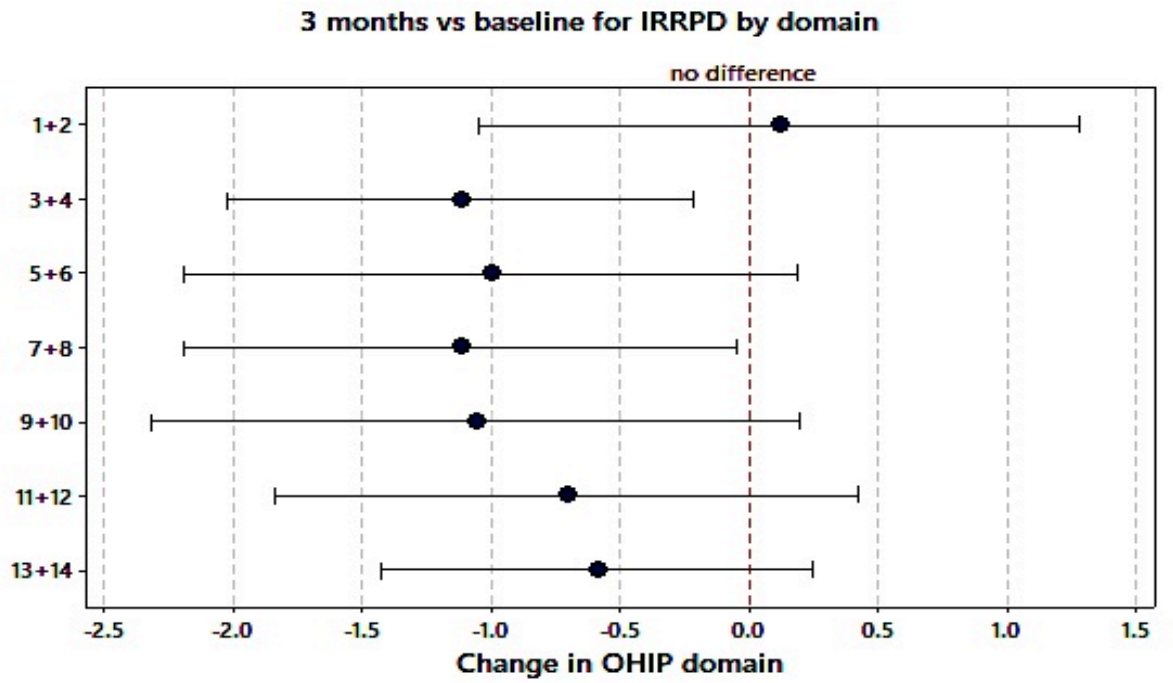


Table 4.10 Paired T-test for changes in mean OHIP-14 Domain scores for the IRRPD versus baseline comparison pairing.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
Functional Limitation (1 + 2)	0.12	2.26	(-1.05, 1.28)	0.21	0.833
Physical Pain (3 + 4)	-1.12	1.76	(-2.02, -0.21)	-2.61	**0.019**
Psychological Discomfort (5 + 6)	-1.00	2.32	(-2.19, 0.19)	-1.78	0.094
Physical Disability (7 + 8)	-1.12	2.09	(-2.19, -0.04)	-2.21	**0.042**
Psychological Disability (9 + 10)	-1.06	2.44	(-2.31, 0.19)	-1.79	0.092
Social Disability (11 + 12)	-0.71	2.20	(-1.84, 0.43)	-1.32	0.205
Handicap (13 +14)	-0.59	1.62	(-1.42, 0.25)	-1.49	0.154

The results of the OHIP-14 Domain scores for the IRRPD versus baseline comparison pairing include:

- The 'physical pain' and 'physical disability' domains demonstrated significant improvements (i.e. lower mean OHIP Domain scores) for the IRRPD after adaptation versus baseline comparison pairing ($p = 0.019$ and $p = 0.042$ respectively).
- All other domains, with the exception of 'functional limitation', demonstrated an improvement (i.e. reduction) in mean OHIP Domain scores, however none of these improvements were statistically significant at the five per cent level.
- Strong favourable trends were observed with the 'psychological discomfort', 'psychological disability', 'social disability', and 'handicap' domains, however none achieved significance.
- These results suggest that wearing an IRRPD does help improve the SDA situation.

4.11 Subjective assessment using the OHIP-14 questionnaire (by domain) – IRRPD vs CRPD

Fig. 4.8. 95% C.I. plots for changes in mean OHIP-14 Domain scores for the IRRPD versus CRPD comparison pairing.

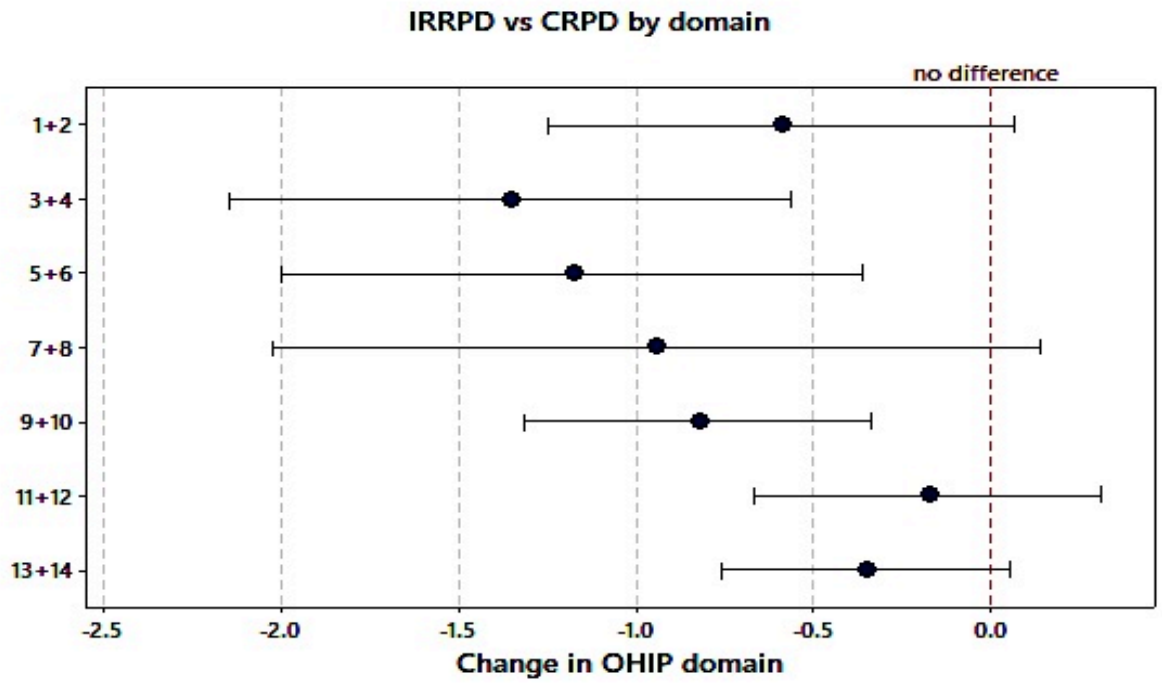


Table 4.11. Paired T-test for changes in mean OHIP-14 Domain scores for the IRRPD versus CRPD comparison pairing.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
Functional Limitation (1 + 2)	-0.59	1.28	(-1.25, 0.07)	-1.90	0.076
Physical Pain (3 + 4)	-1.35	1.54	(-2.14, 0.56)	-3.63	**0.002**
Psychological Discomfort (5 + 6)	-1.18	1.59	(-1.99, -0.36)	-3.05	**0.008**
Physical Disability (7 + 8)	-0.94	2.11	(-2.02, 0.14)	-1.84	0.084
Psychological Disability (9 + 10)	-0.82	0.95	(-1.31, -0.34)	-3.57	**0.003**
Social Disability (11 + 12)	-0.18	0.95	(-0.67, 0.31)	-0.77	0.455
Handicap (13 +14)	-0.35	0.79	(-0.76, 0.05)	-1.85	0.083

The results of the OHIP-14 Domain scores for the IRRPD versus IRRPD comparison pairing include:

- The IRRPD demonstrated statistically significant improvements with respect to the 'physical pain' (p = 0.002), 'psychological discomfort' (p = 0.008), and 'psychological disability' (p = 0.003) when compared to the CRPD situation.
- All other domains demonstrated an improvement in mean OHIP Domain scores, however not achieving statistical significance at the five per cent level.

4.12 Subjective assessment using Visual Analogue Scales (VAS) – IRRPD vs CRPD

Fig. 4.9. 95% C.I. plots for VAS questionnaire – Direct comparison of IRRPD and CRPD results after 3-months adaptation.

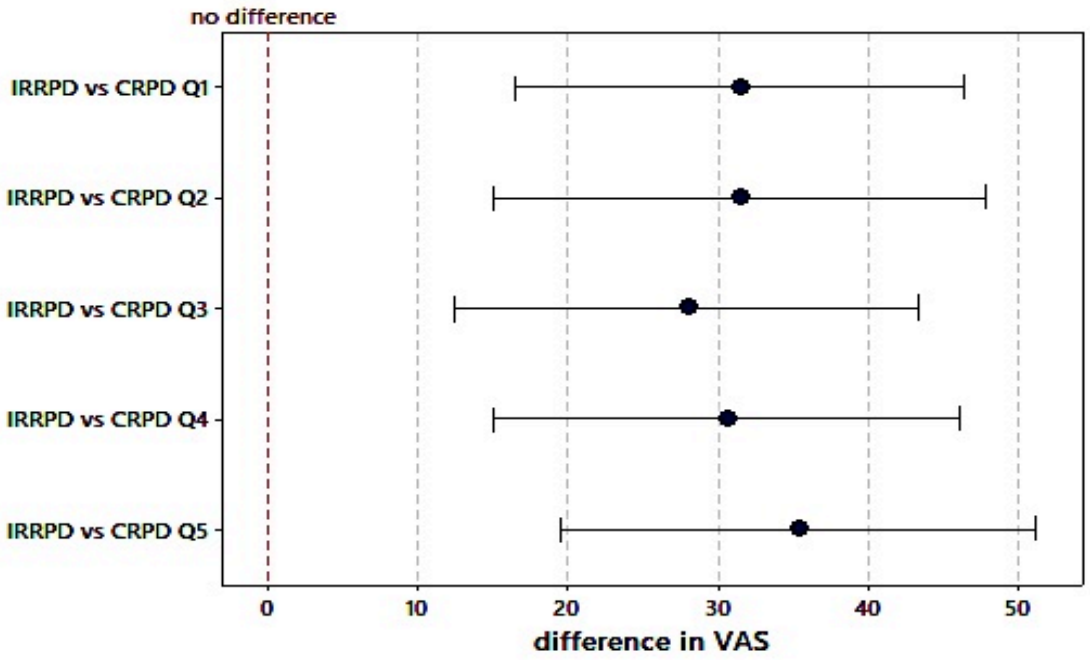


Table 4.12. Paired T-test for VAS questionnaire – IRRPD versus CRPD after 3-months adaptation.

	Estimation for Paired Difference			Test	
Test Pair	**Mean**	**Standard Deviation**	**95% C.I.**	**T-Value**	**P-Value**
Question 1 – Comfort	31.41	29.03	(16.49, 46.34)	4.46	**<0.001**
Question 2 – Chewing Ability	31.47	31.88	(15.08, 47.86)	4.07	**0.001**
Question 3 – Retention	27.94	30.01	(12.51, 43.37)	3.84	**0.001**
Question 4 – Stability	30.59	30.21	(15.05, 46.12)	4.17	**0.001**
Question 5 – Satisfaction	35.35	30.83	(19.50, 51.20)	4.73	**<0.001**

The results of the VAS questionnaire for the IRRPD versus CRPD comparison pairing (after three-month adaptation of each denture) include:

- The IRRPD resulted in significantly higher (better) mean scores than the CRPD for all questions of the VAS questionnaire ($p < 0.001$ for questions 1 and 5, and $p = 0.001$ for questions 2, 3, and 4).
- Subjects were significantly more satisfied with the IRRPD than the CRPD ($p < 0.001$).
- Question 5 (satisfaction) demonstrated the largest mean difference between the IRRPD and CRPD.

4.13 Testing order effects

Tests were conducted to assess for any significant order effects (Table 4.13). These tests looked for differences between baseline and three-month outcomes (where more than one time-point was available). With the exception of question 2 of the VAS questionnaire, it was determined that there were no statistically significant order effects (Group A versus Group B) and nor were the treatment differences dependent on the order (i.e., no order and treatment interaction). The results for question 2 of the VAS had a significant order by treatment interaction ($P = 0.031$). This suggests that if the CRPD was the first dental prosthesis to be experienced, then the question 2 VAS score will be higher on

average than if the CRPD was second. For the IRRPD, the order does not matter as much; the mean score was consistently higher.

Table 4.13. Testing for Order Effects and Treatment Order Interaction.

	Order		**Treatment Order Interaction**	
Outcome	**F-value**	**P-value**	**F-value**	**P-value**
MPS (baseline to 3 months)	1.49	0.231	1.60	0.216
MBP (baseline to 3 months)	2.71	0.110	0.11	0.747
Load (baseline to 3 months)	0.97	0.332	0.72	0.402
OCA (baseline to 3 months)	0.56	0.462	0.03	0.866
OHIP-14 (baseline to 3 months)	0.98	0.331	0.10	0.749
VAS 1 (3 months)	2.98	0.095	1.11	0.301
VAS 2 (3 months)	5.09	**0.031**	5.15	**0.031**
VAS 3 (3 months)	2.17	0.151	1.31	0.261
VAS 4 (3 months)	1.57	0.220	2.04	0.164
VAS 5 (3 months)	3.67	0.065	2.91	0.098

4.14 Correlations between Objective and Subjective Measures

Table 4.14. Correlations between objective and Subjective measures.

		Comparison Pairings		
	Test	**CRPD (3-mths) vs Baseline**	**IRRPD (3-mths) vs Baseline**	**IRRPD vs CRPD (3-mths)**
Objective Measures	**Optosil®**	+	+	+
	MBP	+	+	–
	Load	++	++	++
	OCA	++	++	++
Subjective Measures	**OHIP-14 (SUM)**	+	+	++
	OHIP-14 (Domain) Functional Limitation	–	–	+
	OHIP-14 (Domain) Physical Pain	–	++	++
	OHIP-14 (Domain) Psych. Discomfort	–	+	++
	OHIP-14 (Domain) Physical Disability	+	++	+
	OHIP-14 (Domain) Psych. Disability	+	+	++
	OHIP-14 (Domain) Social Disability	+	+	+
	OHIP-14 (Domain) Handicap	+	+	+
	VAS – all questions	**N/A**	**N/A**	++

Key:

++ = A significant improvement of the first item of the comparison pairing

\+ = A non-significant improvement of the first item of the comparison pairing

−− = A significant improvement of the second item of the comparison pairing

− = A non-significant improvement of the second item of the comparison pairing

N/A = Not Applicable

CRPD (3-months) vs Baseline

- All of the objective measures are positively correlated in favour of the CRPD (3-months) situation; however, only Load and OCA measures demonstrated statistical significance in favour of the CRPD (3-months) situation.
- Correlations between subjective measures is mixed. OHIP-14 (SUM), OHIP-14 (Domain) Physical Disability, Psychological Disability, Social Disability, and Handicap are positively correlated in favour of the CRPD (3-months), but none of these measures achieved statistical significance.
- OHIP-14 (Domain) Functional Limitation, Physical Pain, and Psychological Discomfort are negatively correlated to all other measure. None of these measures achieved statistical significance.
- It appears overall that there is a positive correlation between the objective and subjective measures, but is weakened by the fact that three of the OHIP-14 (Domain) measures demonstrate a negative correlation, and with few of the measures achieving statistical significance (i.e. only Load and OCA).

IRRPD (3-months) vs Baseline

- All objective measures are positively correlated in favour of the IRRPD (3-months) situation, mirroring that of the CRPD (3-months) situation.
- OHIP-14 (Domain) Functional Limitation is the only measure that is negatively correlated to all other measures, which are all in favour of the IRRPD (3-months) situation. The OHIP-14 (Domain) Physical Pain and Physical Discomfort measures (positive correlation) achieved statistical significance, whilst the OHIP-14 (Domain) Functional Limitation measure (negative correlation) did not achieve statistical significance.
- The IRRPD (3-months) vs Baseline comparison pairing shows a stronger positive correlation between objective and subjective measures (in favour of the IRRPD (3-months)) when compared to the CRRPD (3-months) vs Baseline comparison pairing.

IRRPD (3-months) vs CRPD (3-months)

- MBP is the only measure that is negatively correlated to all other measures, which are all in favour of the IRRPD (3-months) situation. The MBP measure was not statistically significant.
- Load, OCA, OHIP-14 (SUM), OHIP-14 (Domain) Physical Pain, Psychological Discomfort, Psychological Disability, and VAS (all questions) measures achieved statistical significance.
- This comparison pairing demonstrated the strongest positive correlation between the subjective measures (which also included the VAS (all questions)), and weakest positive correlation between the objective measures (i.e., due to the MBP result).
- There is a moderate positive correlation between objective and subjective measures, which strengthens if the MBP result is excluded.

4.15 Radiographic bone levels around implants (mesial and distal)

Table 4.15. Total vertical bone loss (mm) between implant placement to final periapical radiograph (months).

	Consolidated (n=32)	Group A (n=13)	Group B (n=19)	Consolidated* (n=34)	Group A* (n=14)	Group B* (n=20)
Mesial	- 1.25	-1.08	-1.36	-1.53	-1.44	-1.59
Distal	-0.86	-0.79	-0.90	-1.16	-1.17	-1.16
Mean Time	26.5	30.1	24.1	26.1	29.5	23.8

* These results include consideration of the two implants that failed after objective and subjective tests but before final periapical radiographs were obtained. The assumption here is that these two implants experienced maximum vertical bone loss (i.e., 6 mm on both mesial and distal aspects).

Table 4.16. Vertical bone loss (mm) between first abutment installation to final periapical radiograph - bone loss experienced during the period of loading (months).

	Consolidated (n=32)	Group A (n=13)	Group B (n=19)	Consolidated* (n=34)	Group A* (n=14)	Group B* (n=20)
Mesial	-0.51	-0.01	-0.85	-0.83	-0.44	-1.11
Distal	-0.46	-0.19	-0.65	-0.79	-0.60	-0.92
Mean time	13.6	10.6	15.6	13.5	10.6	15.5

Notes: Subject 3 - Radiographs for 1st abutment placement taken on 13/02/2017 (actual abutment placement was on 16/01/2017). Subject 5 - Radiographs for 1st abutment placement taken on 23/08/2016 (actual abutment placement was 22/08/2016). Final radiographs for subjects 2, 3, 10, and 16 were taken at a subsequent appointment to the objective and subjective test appointment due to misplacement of original radiographs before the researcher attended the radiology department for collection (subject 10) or time limitations/subject availability.

4.16 Clinical findings of relevance

Dental and periodontal chartings were conducted before insertion of the first denture and at the completion of the three-month adaptation period for the second denture type. Apart from some minor dental issues that related to the situation before insertion of the first denture (i.e., pre-existing periodontal attachment loss), minimal adverse changes were noted over the course of the trial. Very few of the periodontal probing depths around the lower teeth differed by more than 1 to 2 mm between the two chartings with signs of localised gingivitis being an occasional finding as evidenced by minor bleeding points arising within 30 seconds of probing. Given the short time frame of review, the clinical findings recorded were not unexpected. Only one tooth was lost during the trial, and this occurred in subject number 16 who lost tooth 41 due to mobility and discomfort. Extraction of this tooth occurred just before completion of the second denture adaptation period (i.e., approximately six months of denture wearing in total).

This tooth had pre-existing extensive bone loss and a guarded prognosis before denture insertion. More unexpected was fracture of the 31 crown in the same patient. This occurred around the time when converting the dentures (i.e., after approximately three-months of denture wearing). The prosthodontic postgraduate student who initially managed this patient carefully assessed the tooth (it had previous RCT); it was decided to retain the root and simply add a denture tooth to the denture.

Minimal prosthetic complications were noted during the trial period. Subject 9 experienced two minor prosthetic issues during the trial period. This subject had a KCI upper and lower configuration, with both arches managed by an IRRPD. She experienced a minor acrylic fracture of the upper IRRPD (right denture extension base) and a minor acrylic fracture of the lower IRRPD (left denture extension base). Both fractures were satisfactorily repaired in the laboratory. This subject also experienced fracture of the lower left clasp at the final reconversion appointment. The denture proved to be sufficiently retentive without the clasp, so the decision was made to continue with the denture without repair. Some of the subjects from Group B required multiple adjustments and even minor reline procedures to ensure denture comfort soon after the conversion from IRRPD design to the CRPD design. Subjects from Group A did not experience this issue, other than some minor adjustments early after denture insertion.

CHAPTER 5: DISCUSSION

The first part of this discussion will provide an interpretation of the results derived from the objective and subjective tests comparing the performance of the CRPD and IRRPD. Points of relevance relating to the tests and methods used will be presented where appropriate. Despite the short duration of the clinical phase of the trial, comments will be made regarding the bone (radiographic), clinical, and prosthodontic observations made throughout the trial period. The discussion will also highlight clinical challenges encountered using the described clinical protocol; the intention being to assist clinicians in avoiding or managing such challenges if they so chose to use this treatment protocol. The next part of the discussion will consider the strengths and weaknesses of the within-subject crossover trial design and derivation of the sample size. The limitations of this clinical trial will also be considered. The final part of this discussion will propose a decision rubric on the management of mandibular KCI situations with removable dental prostheses and offer advice on the clinical application of this treatment protocol.

Optosil® Masticatory Performance (Chewing) test

A recovered particle size distribution comprising a smaller MPS indicates superior masticatory performance since the sample has been comminuted into smaller particles. The MPS is the size of a theoretical sieve aperture whereby 50% of the recovered particles (by weight) remain on the sieve with the remaining 50% (by weight) passing through the sieve. When comparing the changes in mean MPS observed for the two denture types at insertion relative to the baseline situation, the IRRPD demonstrated a greater reduction than the CRPD; 33% reduction in mean MPS for the IRRPD compared to 13% reduction in mean MPS for the CRPD. Both situations did not achieve significance at $p < 0.05$ levels. The IRRPD demonstrated a stronger trend towards significance, as seen in the 95% CI plot (Figure 4.1). The three-month versus baseline results revealed an improvement in mean MPS for both situations with a 36% reduction for the IRRPD and a 16% reduction for the CRPD (Table 4.4). Both situations also failed to achieve significance at $p < 0.05$ levels. The differences between the insertion versus baseline situation and the three-months versus baseline situation, for both denture types, showed a reduction in mean MPS of 3% *(note: the reduction in mean MPS for the CRPD between insertion and three-months is shown as 4% (0.96) in Table 4.4, however the*

difference between the individual calculations for CRPD insert versus baseline and CRPD three-months versus baseline is 3% (i.e. 0.87 – 0.84); this 1% difference is due to rounding and is negligible).

Failure of either denture type relative to the baseline situation to achieve a significant reduction in mean MPS, both at insertion and after three-months, is an unexpected result given that the addition of functional occlusal units increases the overall occlusal support length and surface area available for comminution [169, 171, 622]. Missing posterior teeth therefore reduces the available functional occlusal surface area available for the application of forces required to comminute the chewing test material. The hypothesis is that the wearing of a dental prosthesis will re-establish much of the occlusal surface area available for comminution and provide the potential for improvement (i.e. reduction) in mean MPS. The results observed in this trial are consistent with the literature reporting that the distal extension CRPD only partially compensates for reduced masticatory performance and that such dentures in moderate SDAs, such as when three to five occlusal units persist, seem to have little positive effects on function [22, 163, 172, 174, 213, 750, 751]. The results of the Optosil® chewing test agree with the literature supporting the SDA concept and the treatment focus on maintaining a second premolar-to-second premolar occlusion, since the wearing of a lower CRDP does not appear to significantly improve masticatory performance much beyond the SDA situation [169, 173, 213]. Functional improvements are however reported for extreme SDAs in the lower jaw [752].

Failure to achieve significance at dental prosthesis insert may also be partly explained by the fact that a subject has not yet had the opportunity to adapt to the new situation and is continuing to use chewing patterns similar to when the dental prosthesis is not *in situ*. It's highly likely that the chewing and bite tests at this early stage were performed using established pre-programmed chewing patterns with a preference to occlude on the remaining natural dentition. It has been suggested that the texture of the chewing material may also influence chewing patterns and even denture adaptation [571]; one particular study looked at masticatory performance using gelatine and almonds as test materials. It reported that subjects used more of the natural front teeth to comminute the harder almonds, whilst more of the posterior teeth were used to comminute the softer gelatine [752]. The author did however add that the differences in methodologies

used to assess masticatory performance (i.e., sieving for almonds and dye concentration for gelatine) might have contributed to some of the observed differences. Nevertheless, subjects in this clinical trial may have preferentially used the remaining natural teeth in an attempt to better comminute the harder Optosil® material right from the outset and throughout the duration of the trial, thereby not achieving any significant improvements beyond the baseline situation.

The results for the IRRPD relative to baseline show a greater reduction in mean MPS as compared to the CRPD, and a stronger tendency towards significance. An improved (i.e., reduced) mean MPS with the IRRPD is not unexpected since this dental prosthesis possesses a more stable posterior occlusion. The improvement observed was not enough to reach significance at $p < 0.05$ levels. Even after a three-month period of adaptation, the results of this test indicate that any improvement in function over this period was not significant. This could be due to a number of reasons including subjects still not having fully adapted to the dental prosthesis design even after three months, subjects still preferring to chew on their natural anterior teeth and not realising the full potential of functioning with the dental prosthesis, the likelihood that the dental prosthesis offers no functional benefit as compared to not wearing the denture at all, and/or inherent features of the methodology used.

The evidence discussing the issue of oral adaptation, especially for CRPDs, is limited [169]. The literature reporting on adaptation, largely based on the experience of complete denture wearers, is mixed with regards to how quickly subjects adapt to dentures. Some studies report that adaptation occurs early after denture insertion [169, 753, 754], whilst others advise that adaptation occurs over time, sometimes even up to a year [571]. The results of this clinical trial suggest that most of the functional benefit of wearing the dental prosthesis is realised at the time of insertion and that functional improvement over the three-month adaptation period is modest at best. However, it must be appreciated that adaptation with the KCI CRPD is complex and influenced by a range of factors, which include prosthetic factors (i.e. stability, support, retention) [755], physiological factors (i.e. proprioception, texture perception, muscular function) [756], and anatomical factors (i.e. number of remaining natural teeth) [619]. In fact, very little is known about how subjects adapt their oral function to the establishment of new oral environments [757, 758]. As a consequence of the range of variables and the complex

interplay between them, including the textural properties of the test material, every individual will vary in the extent and rate of adaptation after insertion of a new dental prosthesis.

Comparison of the adapted results for the IRRPD and CRPD situations is the most important measure in this trial since it provides the greatest insight into the relative performance of each dental prosthesis type. The IRRPD resulted in a 23% smaller mean MPS as compared to the CRPD. The IRRPD and CRPD adapted comparison pairing was the closest of all pairings to achieve significance ($p = 0.072$), suggesting that there is a strong trend in favour of the IRRPD. It is possible that a larger sample size may have further confirmed this trend, resulting in a significant finding. Further research is required to substantiate this proposition.

Whether adaptation occurs early or develops gradually after dental prosthesis insertion, it is assumed that sufficient adaptation has taken place over three-months. Tests at the three-month time-point will better reflect the true functional potential of wearing the dental prosthesis as compared to the insert tests. Numerous studies assessing prosthodontic interventions have employed a predetermined adaptation period, with two- [326, 328, 737, 738, 759-761] and three-months [285, 325, 711, 733, 734, 736, 740, 762, 763] commonly used before testing the performance or outcome(s) of treatment. The original design of this trial was to employ a six-month adaptation period for each dental prosthesis design in order to further ensure adaptation had taken place, however based on precedence and the desire to minimise inconvenience to the subjects enrolled in the trial (and risk of dropout), an adaptation period of three months was deemed sufficient.

Chewing is the physiological act whereby functionally opposed teeth comminute food into smaller particles and moistened by saliva to form a bolus in preparation for swallowing [148, 463]. A chewing test using Optosil® as a test material is relevant because it attempts to quantify functional performance under various conditions such as baseline (without the dental prosthesis present) and when the dental prosthesis is *in situ*. As presented in the literature review of this thesis, the use of Optosil® (and variants) is an accepted test material for use in masticatory performance tests. A key advantage of Optosil® for use as a test material is that samples can be standardised

based on the relative amounts of ingredients used during manufacture and the dimensions produced [459, 518, 764]. The use of the Optosil® chewing test is a reliable test; highly reproducible results achieved in dentate subjects is evidence of this [519].

The instructions provided to each subject was to chew the test sample as hard as he/she could using a normal (habitual) chewing pattern, without discomfort, in order to breakdown the Optosil® cubes as best they could. No specific instructions were given regarding what side(s) of the mouth to use. Although there is potential for variations in bite forces generated at different time points, literature reporting on the assessment of bite force measurements between separate sessions concluded that the variability of maximum bite force is very small when measured in the same position on different occasions (i.e. tested weekly over three consecutive weeks) [765]. This suggests that the degree of intra-subject variability in chewing tests may be low, since bite force is an important variable contributing to chewing function. Other research groups have also assessed and demonstrated the reproducibility of masticatory performance tests using Optosil® Comfort (and variants) over various time points spanning several weeks [472, 518, 519, 525]. Based on this information, it can be concluded that the Optosil® chewing test is a valid test over time.

Each time-point assessment in this trial comprised of three separate chewing test cycles; each test cycle involved the chewing of five Optosil® Comfort cubes using 20 chewing strokes with a minimum 90 second interval between test cycles. The recovered material from each test cycle was combined and represented the overall sample to be sieved and weighed for the given time-point. The fact that three separate test cycles were combined for each time-point test may have helped further reduce the impact of any potential variability between testing at different time-points. Furthermore, the Optosil® test was not the only objective test used in this trial. MBP, load, and OCA provided additional objective measures for assessing the functional performance of each intervention and hence improving the overall validity of the objective findings.

Optosil® in its unmodified form can be a challenging material to break down, especially for complete denture wearers [518]. Because of the heterogeneity of the subjects enrolled in this trial in terms of the state of the upper arches and number of missing lower teeth, it was decided that a more 'challenging-to-chew' material would provide

greater discrimination between the interventions being assessed. A material that was easier to comminute may not provide the necessary degree of discrimination between the interventions. It must be appreciated that test materials of differing textural properties will produce different particle size distributions. Natural foods are sometimes preferred on the basis that subjects have familiarity chewing and swallowing these foods [764]. Future research may also include variety of chewing test materials with different properties, thereby providing a deeper insight into denture performance. In hindsight, selection of a slightly 'easier-to-chew' version of Optosil® may have been useful since most particle size distributions retrieved were skewed towards the first half of the sieve stack (i.e. sieves with aperture sizes: 5.6mm, 4mm, 2.8mm, and 2mm). To accommodate for the spread of data, the calculations were adjusted using the base log2 resulting in a more linear spread of the data. Provided all calculations incorporated the base log2, mathematical modelling enabled a median particle size to be calculated that could be used for comparison and statistical analysis. The data was then backtransformed enabling relative or proportional differences to be identified between the comparison pairings. It must again be emphasised that the conclusions arising from this chewing test can only be based on the test material used and methodology employed.

The decision to use wet sieving in this trial was made on the basis that Optosil® can be sieved in a wet state as compared to materials that tend to bind together when wet. After sieving, the sieve stack was placed in an oven and dried at 40 degrees C overnight (minimum of 20 hours) to remove any residual moisture. It was noted that some of the particles underwent small dimensional changes during this drying process, and so it was important that the sieve stack was tapped (up and down motion) about a dozen times to ensure loosening of the particles on the sieve meshes and an opportunity for such particles to progress through to the next sieve if indeed the dimensional change permitted this. Alternatively, the recovered chewing material could have been dried first and then sieved at a later time. In this trial, it was more convenient to complete the sieving soon after recovery of the sample with measurements being recorded the following day. Future research can consider either approach. The important aspect is that a consistent methodology is used within a trial. Such consistency will minimise any internal reliability concerns. Comparison of results between trials must take into

account the nature of the test material used, the chewing and sample collection protocols, and the sieving technique employed.

Objective tests using Pressure-Sensitive Film - PRESCALE

The 95% CI plots displaying differences in mean MBP for the various comparison pairings demonstrated mixed results (Figure 4.2). A shift of the mean to the right of the zero (no difference) line indicates an increase in MBP. Of all the comparison pairings, only the CRPD after adaptation versus the CRPD at insert demonstrated a significant increase ($p = 0.038$), thereby confirming a significant improvement in MBP over the three-month adaptation period. Three comparison pairings showed a reduction in MBP, namely: CRPD insert versus baseline, IRRPD after adaptation versus baseline, and IRRPD after adaptation versus CRPD after adaptation. These reductions were not significant at $p < 0.05$ levels, but interesting nonetheless since a decrease was observed.

MBP is a point measure(s) that can occur anywhere throughout the occlusion. This can occur in the anterior segments involving natural teeth, along the distal extension(s) of the denture, or in both locations. It is possible that high pressures can be generated in the baseline situation since contact is taking place between natural teeth. A significant increase in MBP will only be seen if the presence of the dental prosthesis results in significantly greater pressure being registered in the distal extension segment relative to the baseline situation. This may not always be possible to achieve, and reasons for this can include:

- Subjects not having fully adapted to the dental prosthesis at three-months
- Despite the presence of the dental prosthesis, subjects still preferring to bite more on natural anterior teeth
- The compressibility of the soft tissues under the distal extension bases causing the dentures to rotate posteriorly in a tissue-ward direction during clenching, resulting in greater contact on the natural anterior teeth (for the CRPD situation)
- The resiliency of the Locator™ attachment system may allow for some sinking of the distal extension bases during maximum voluntary clenching, hence resulting in greater contact on the natural anterior teeth (for the IRRPD situation)
- The limitations of using articulating paper and subjective patient feedback to assess for bilateral stable and balanced occlusion in maximum intercuspal

position at dental prosthesis insertion (was not assessed at maximum voluntary clenching)

- The potential for sensory feedback mechanisms to modulate neuromuscular coordination of the masticatory muscles after dental prosthesis (and implant) insertion

Any of these listed reasons, either individually or in various combinations, may help explain why no significant differences were observed for either denture type relative to the baseline situation. Since MBP is a point measure(s), it's not inconceivable that the presence of a dental prosthesis may only have a modest impact on this measure, especially if a greater proportion of contact is still taking place on the remaining anterior natural teeth which typically display smaller areas of contact (i.e., Pressure = Force/Area). Load on the other hand, as assessed in this study, associates bite pressures with occlusal contact area over the entire arch. This measure would therefore provide a greater insight into the potential impact of each denture design on masticatory function, and this will be discussed shortly.

Research investigating the SDA reports that patients with missing posterior teeth have more anterior teeth in occlusal contact in the intercuspal position in comparison to controls with complete dental arches [164]. The authors of this research rationalised that this may be a mechanism supporting the premolars to withstand occlusal forces, effectively acting as a physiological protective mechanism. Any compromise in the stability of the posterior occlusion necessitates a shift of the occlusion to the anterior region, hence resembling the baseline (SDA) situation. Two clinical variables can affect the stability of the posterior occlusion at the time of dental prosthesis insert. Firstly, the occlusion established in the trial was determined by use of conventional articulating paper and the subjective assessment provided by the subject when occluding in the intercuspal position (not at maximum voluntary clenching). The goal was to ensure that uniform articulator paper markings could be observed on all natural and denture teeth across the arches (i.e., distribution, size, and intensity). Literature exists however suggesting that the use of articulating paper may be problematic since no direct relationship has been established between the area of articulating paper markings and applied load [766]. This fact can cause the operator to misinterpret markings with regards to the amount of occlusal pressure being registered, resulting in either over- or

under- adjustment of the occlusion. A relative over-adjustment of the occlusion (i.e., removal of more denture tooth material) can result in an occlusion that favours for more anterior tooth contact, especially when the subject performs maximum voluntary clenching. Secondly, the resilient nature of the tissues supporting the denture bases may have an influence on the bite pressure recordings. Maximum clenching will result in a tissue-wards movement of the distal denture extension bases and hence greater potential for increased anterior tooth contact to occur. Even though the IRRPD would be less susceptible to this phenomenon, the Locator™ attachment system still permits a degree of resiliency that can result in some tissue ward (vertical) movement of the attachment system [299].

Interpretation of the results relating to the IRRPD and MBP is more challenging. As reported, a more stable posterior occlusion with a firm support element results in increased bite forces [306]. However, this was not observed in this trial. A possible explanation for the observations involving the IRRPD is that a more stable and 'firmer' posterior occlusion favours improved discriminatory proprioception provided by the remaining opposing natural dentition in those subjects with remaining natural upper premolar and molar teeth. In the CRPD situation, compression of the underlying soft tissues by the denture bases can delay or reduce the discriminatory proprioceptive feedback provided by the opposing natural teeth, and as such; greater biting forces are generated before inhibitory outputs are generated. Further to this, research has suggested that even with loss of PDL associated proprioception, the presence and loading of implants may still be associated with some form of proprioception; it has been reported that loading of implants in the mandible elicits a response that can be observed in the inferior alveolar nerve [767, 768]. The exact mechanisms responsible for this phenomenon are not entirely clear, but may include the presence of residual axonal elements in the peri-implant region [769].

The term 'osseoperception' has been used to describe mechanoreception in the absence of functional periodontal mechanoreception, with such inputs being derived from TMJ, muscle, cutaneous, mucosal, and periosteal mechanoreceptors. These inputs provide the mechanosensory information for oral kinaesthetic sensibility in relation to jaw function and the contacts of artificial teeth [770-772]. It appears that some peripheral feedback pathways can be restored when using osseointegrated implants and as such,

implant-mediated sensory-motor control may have important clinical implications [773, 774]. This situation differs to that of conventional complete dentures in which it appears that not enough sensory information is generated to restore the necessary feedback pathways for motor function [774]. The frequency of implant overload is generally low, and with appropriate treatment planning, overload is almost always preventable [775]. It has also been reported that patients can adapt well to implant-supported dental prostheses, enabling the performance of habitual masticatory functions. However, non-habitual functions such as maximal occluding force and chewing of hard foods, reveals less coordinated muscle activity in implant patients [776, 777]. Given that implants may be associated with some form of proprioception enabling coordinated jaw muscle activity (for habitual masticatory functions), and that overload of implants is not overly common, a protective feedback mechanism may exist that prevents overloading of the dentition, support structures, and implants. A reduction of maximal occlusal force has been reported in subjects with fixed dental prostheses supported by implants relative to dentate subjects [778]. This theory merits further research; at present, detailed investigations are lacking of the possible sensorimotor cortical adaptive processes that may be associated with loss of teeth in the first place, or with the replacement therapies [779].

The fact that a subject had not yet adapted to the IRRPD at insert could explain why a reduction in MBP was observed over the adaptation period, since the subject had 'learned' to use the dental prosthesis and to better control chewing forces over this period. The reduction in MBP between baseline and the CRPD insert is not as easy to explain; it may be that the presence of the CRPD at insert reduced the amount of contact on the anterior teeth and therefore a reduction in MBP. The CRPD after adaptation versus CRPD insert showed a significant increase in MBP, suggesting that the patient had either adapted better to the dental prosthesis over this period or is biting harder on the dental prosthesis as a result of inferior inhibitory feedback inputs as already discussed. The significant improvement in MBP for the CRPD differs to the results of the Optosil® chewing test that demonstrated no significant improvement during the adaptation period.

The Load (N) value for a given Prescale scan film is the load value of the area on which colour is generated and represents the product of the pressurised surface area and the

average pressure (Fujifilm pressure distribution mapping system for Prescale: FPD-8010E Ver. 2.0 – Operations Manual, Fujifilm Holdings Corporation © 2008). The ability to register the load over the entire arch is an advantage of the Prescale method [626, 647, 658]. A higher load value suggests that more force can be imparted into the food being comminuted across the arches. Even though the load measurement includes a contribution from the non-denture-related aspects of the occlusion, the fact that no significant changes were made to the occlusion during the trial period implies that the differences observed could be largely attributed to the differences in the denture types tested.

The 95% CI plots for the load comparison pairings (Figure 4.3) demonstrates significant differences ($p < 0.05$) for all comparative pairings with the exception of the CPRD after adaptation versus CPRD insert pairing ($p = 0.887$). This latter observation indicates that minimal change occurred in load generation over the three-month adaptation period for the CRPD situation, agreeing with the results of the Optosil® chewing test but differing to the MBP results. A significant increase in load was observed for the IRRPD after adaptation versus IRRPD insert pairing ($p = 0.003$). This observation indicates that greater potential exists for functional improvement, on the basis of load generation, as subjects become more accustomed to functioning with implant support under the distal extension bases.

The more stable posterior occlusion of the IRRPD enables greater force to be directed towards the occlusion as compared to the CRPD situation where the compressibility of the underlying mucosa and the rotational tendencies of the distal extension bases causes the denture bases to sink into the tissues. This rotational and sinking tendency results in some force dissipation and reduces the potential for occlusal load generation (i.e., some energy is directed to compressing the soft tissues rather than being imparted into the food) [293, 295, 305-308]. The application of pressure onto the underlying soft tissues and abutment teeth as a consequence of the rotation tendencies of the CRPD bases may be one reason contributing to the limited potential for any further increase in load generation as compared to the insert situation; the sinking of the distal extension bases favours re-establishment of anterior tooth contact and hence approximating the baseline situation. The vertical support offered by the implants minimises these issues thereby enabling a subject to train him- or her-self to increase occlusal loading over the

adaptation period. These results are consistent with other literature that report improved function with implant supported/retained dental prostheses [291, 306, 310, 312]. The significant increase in mean load generation observed for the IRRPD relative to the CRPD after adaptation differs to the results observed for the MBP test, where no significant difference (and even a slight decrease) was seen for the IRRPD. Observing a reduction of MBP and an increase in overall load during the same test may be counterintuitive. This must be viewed in the context that MBP is a point measure, whereas load is the sum of pressure over the entire occlusion. Therefore, it can be possible to observe these results during the same test for a given individual.

The most significant increase in load was seen with the IRRPD after adaptation versus baseline pairing ($p < 0.001$). This result is not unexpected since this comparison pairing represents the extreme in anatomical and functional change from a 'no dental prosthesis' situation to a situation where the missing posterior units are restored by a dental prosthesis stabilised and retained by firm support structures. When comparing the results for both denture types after adaptation, it can be seen that the IRRPD situation generates significantly greater load than the CRPD ($p = 0.001$). This result is consistent with other clinical and *in vitro* studies reporting that implants associated with distal extension CRPDs improves denture support, stability, and overall biomechanical behaviour of the IRRPD [303, 304, 328, 329].

Even though minimal actual tooth-to-tooth contact occurs during chewing, OCA is still an important consideration in assessing masticatory potential [780, 781]. One of the justifications for prosthetic rehabilitation of missing posterior teeth is to increase the occlusal contact area (length) available for mastication since reduced contact has been associated with decreased masticatory performance [171, 782]. The OCA information provided by the Prescale method provides a static measure of the contact between the upper and lower dentition. Any differences in OCA seen between the IRRPD and CRPD may be related to the nature of support provided to the distal extension bases. By compressing the underlying mucosa during loading, some of the occlusal pressure applied to the distal extensions of the CRPD is directed away from the occlusal surfaces of the denture teeth, thereby reducing the potential for contact between the denture teeth and the opposing arch. Furthermore, sinking of the distal extension bases may

result in greater contact being borne by the natural anterior teeth, which generally show smaller areas of contact relative to the wider posterior teeth.

The 95% CI plots for the mean OCA comparison pairings (Figure 4.4) shows that all pairings, with the exception of the CRPD after adaptation versus CRPD insert pairing ($p = 0.654$), were significant at $p < 0.05$ levels. These results are similar to those assessing load, which also showed no significant difference between the CRPD after adaptation versus CRPD insert but differing to the MBP results. Observing significant differences with the baseline comparison pairings is not unexpected since the presence of the dental prosthesis inherently increases the surface area available for contact; the purpose of the dental prostheses was to increase the number of functional occluding pairs and hence contribute to the overall contact between the opposing dentition. Interestingly, there was a small shift of the mean OCA to the left of the no difference line for the CRPD after adaptation versus CRPD insert comparison pairing. The IRRPD after adaptation demonstrated a significant increase in mean OCA when compared to the CRPD after adaptation ($p = 0.016$).

Forces applied to food via the teeth are responsible for the comminution of food. Therefore, the Prescale bite pressure test is a relevant measure that can be used to objectively assess an important variable contributing to masticatory function. The Prescale method enjoys a number of advantages, particularly with the 'thinness' of the films enabling bite pressures to be registered at near physiological position and the ability to measure bite pressure across the entire arch (multiple positions) [626, 647, 657, 660, 662]. However, it needs to be kept in mind that this method measures bite pressure in a static position, and therefore may not be truly reflective of the pressures that are generated during physiological activity. A potential disadvantage of the Prescale technique, as encountered in this trial, is for the films to shift and bend during closure, sometimes resulting in very small parts of the occlusion to be missed if the films have moved a sufficient amount, a situation compounded if a subject has a wide arch. Fortunately, this was not a common problem and furthermore, each bite test involved three separate bite recordings. The scanned results of each of the three bite recordings were averaged, hence further reducing the impact of an individual bite recording missing a small portion of the occlusion. The Prescale method also requires use of software, a scanner and PC, and the need for a researcher to subjectively remove

pressure markings from the scanned image that appear to not be directly related to the occlusion (i.e. noise and pressure due to handling and/or bending of the films).

Three separate film types were concurrently used in each bite recording in order to broaden the overall detectable pressure range. Together with the plastic snap-lock bag used to protect the films from moisture and to facilitate infection control, the use of multiple films increased the overall thickness of the recording apparatus, but still less than traditional methods using bite forks or gauges. Previous research using Prescale is largely reported by Japanese research groups (see literature review section 2.9), with the horseshoe shaped Dental Prescale being the most commonly used version of Prescale. This version has a broader pressure range than the individual film types used in this trial and comes in a horseshoe shape. The Dental Prescale version permits a single film to be used rather than stacking of multiple sheets, and the horseshoe shape may help minimise the shifting and bending of the films during closure. This version unfortunately was not available in Australia at the time of devising this research project, hence explaining why multiple Prescale pressure-sensitive films were used in this trial (i.e., they are available in Australia). Each Prescale film type has a pressure range with a given minimum and maximum pressure. Any pressures registered below this range appear as green, and any pressures above the maximum appear as yellow. The aim is to have most of the applied pressure within the detectable range (red colour – this represents the Prescale Film Effective Rate); otherwise, there is a risk of over- or under-estimating the actual pressure. This observation can assist in determining the most appropriate film-type(s) to use.

Another limitation of the Prescale method as employed in this trial is the difficulty in precisely locating the area(s) of MBP. This trial simply reports the MBP detected on the scanned image as calculated by the Prescale software. The scan images produced by the software can help identify approximate locations of applied pressure, such as anterior, posterior, left, and right, but it cannot accurately relate these areas to individual teeth. Being able to relate pressure to individual teeth would be useful, as this can allow identification of any shift in position of the MBP area(s). Future research should therefore use a method whereby the scans can be related accurately to the occlusion. This could take the form of digitally scanning dental casts and then superimposing the Prescale scan image to the cast image [647]. In this way, it would be possible to more

accurately relate pressure markings to the actual tooth/teeth and further support or refute some of the ideas presented in this discussion.

An inherent limitation of the Prescale method was the need to subjectively remove parts of the scan that were deemed not directly related to the occlusion. Due to the sensitivity of the films, handling and other actions (i.e., bending of films) can easily cause non-occlusal-related pressures to appear on the resultant scan images. Most of the pressure markings removed by the eraser software function were clearly not associated with the occlusion, however a reasonable amount of 'scatter' in closer proximity to the occlusion was also removed; almost all of this 'scatter' was coloured green, indicating that these pressure markings were below the minimum threshold for the pressure range of the particular Prescale film. Therefore, the removal of these markings was unlikely to have had a significant impact on the calculations of relevance. The same researcher inspected and edited all scans, ensuring that variation between different researchers/operators was minimised. The pre- and post-edited scans were re-assessed and compared to each other to ensure that no relevant contact areas were accidentally or erroneously removed during the editing stage. If there was any doubt the source of the markings, the decision was to err on the side of retaining the markings.

After taking into consideration the limitations presented, the following can be summarised with respect to the objective impact of implant association with the mandibular KCI RPD:

- There is no significant difference in masticatory performance between the IRRPD and the CRPD after three-months adaptation as assessed by a chewing test using Optosil® Comfort putty as the chewing test material.
- Although not significant, there is a tendency for the IRRPD to demonstrate smaller mean MPS of the recovered chewing test sample. Future trials using larger sample sizes may help further support this trend.
- There is no significant difference in mean MBP between an IRRPD and CRPD after adaptation as assessed by a Prescale test. In fact, the IRRPD demonstrates a slightly lower mean MBP. This latter observation possibly arises from an improvement of muscular control (i.e., finer control of force generation by the

masticatory muscles responsible for mandibular closure) and/or a protective phenomenon aimed at minimising overload of the implants.

- The only result of significance with regards to mean MBP was the CRPD after adaptation versus CRPD insert comparison pairing. This indicates a greater potential for increasing MBP over the adaptation period for the CRPD.
- Mean load generation across the arches was significantly greater for the IRRPD than the CRPD after three-months as measured by a Prescale test.
- OCA was significantly greater for the IRRPD than the CRPD after three-months as measured by a Prescale test.
- The CRPD demonstrated no significant improvements in load and OCA over the adaptation period.
- The results of the objective tests conducted in this trial are inconclusive (i.e. mixed) in terms of the functional impact of implant association with the mandibular KCI RPD. There is a trend indicating improved masticatory performance with the IRRPD as demonstrated by a reduction in the mean MPS, (albeit not significant at $p < 0.05$ levels), and significant increases in load and OCA when compared to the CRPD situation after adaptation. There is no significant difference in mean MBP between the IRRPD and CRPD.
- These results must be viewed within the context of the sample size, nature of test material used, and the methodologies described. Further research using test materials of differing properties, improved standardisation of subjects, larger sample size, and longer follow-up will yield a deeper insight as to the objective impact of implant association with RPDs.

Subjective tests using OHIP-14

The subjective assessments performed in this trial employed the short form Oral Health Impact Profile (OHIP-14) and a Visual Analogue Scale (VAS). The OHIP-14 results were reported in two ways, namely: a) OHIP-14 Sum, and b) OHIP-14 Domain. The OHIP-14 Sum added all outcomes of the fourteen questions to determine an overall OHIP score. The OHIP-14 Domain added the outcomes of the two questions comprising each of the seven OHIP Domains. The OHIP-14 questionnaires were completed at baseline, and after the three-month adaptation period for each denture type. There was no reason to

complete the OHIP-14 questionnaire at the insert visit of each denture type since the subject would not have had an opportunity to assess the impact of treatment.

Each OHIP question has five answer options ranging from a score of zero to a score of four (i.e.: 0, 1, 2, 3, and 4). A lower score represents a more favourable (better) situation in terms of impact on oral health and satisfaction. A shift of a mean to the left of the zero-difference line on the 95% CI plots for OHIP-14 signifies an improvement in the OHIP-14 measure (i.e., a reduction in OHIP-14 Sum score). Of the three plots shown in figure 4.5, it is evident that the IRRPD versus CRPD after adaptation is the only comparison pairing demonstrating a significant difference at $p < 0.05$ levels. This conveys that the IRRPD has a significantly greater (more favourable) impact on oral health and satisfaction. This finding suggests that if a lower dental prosthesis is to be constructed, the IRRPD design will have a greater favourable impact on OHRQoL and patient satisfaction when compared to the CRPD, and is consistent with the available literature reporting improved patient satisfaction when implants are used to assist in the retention and/or support of KCI RPDs [288, 323, 325, 326, 328, 329].

It is interesting to note that neither of the denture types demonstrated a significant improvement in OHIP-14 Sum relative to the baseline situation. The IRRPD result was much closer to achieving significance than the CRPD ($p < 0.085$ for IRRPD, $p < 0.983$ for CRPD), and showed a larger favourable shift of the mean. As was the case with some of the objective findings of this trial, this measure closely approached but failed to achieve statistical significance; again, a larger sample size may have served to better establish or refute these findings. Based on these findings, the key question that needs answering is whether or not treatment with either denture type will significantly improve the condition relative to the baseline SDA situation. These findings appear to support some of the classic literature suggesting that the SDA is a suitable treatment option for the management of missing posterior teeth (refer to sections 2.4 and 2.5 of the literature review of this thesis).

When assessing the impact of treatment on the various domains compromising the OHIP instrument, it can be seen that the CRPD at three-months relative to baseline has no significant impact on any of the seven domains (see Figure 4.6). In fact, there is a shift to the right of the no difference line for the means of the 'functional limitation', 'physical

pain', and 'psychological discomfort' domains, signifying a worsening of these domains after CRPD treatment. Minimal improvement in function and adverse impacts in these particular domains may explain why acceptance of this type of dental prosthesis is reported to be relatively poor and provides further support to the existing literature reporting on the low acceptance of the mandibular KCI RPD [23, 25, 26, 213, 750]. The IRRPD at three-months relative to baseline shows a significant improvement in the 'physical pain', and 'physical disability' domains. Apart from the 'functional limitation' domain, all of the other domains demonstrate a clear shift of the means to the left of the zero-difference line (see Figure 4.7) signifying improvement, albeit not significant at $p < 0.05$ levels. The only domain demonstrating deterioration for the IRRPD was the 'functional limitation' domain, as evidenced by a slight shift of the mean to the right of the zero-difference line, but not achieving a level of significance. This observation is interesting since one of the documented justifications for use of the IRRPD is improved function; this was not supported by this subjective assessment method.

The most striking results can be seen in the 95% CI plots comparing the two denture designs after adaptation (Figure 4.8). All domains demonstrated a shift of means to the left of the zero-difference line. The shifts were significant for the 'physical pain', 'psychological discomfort', and 'psychological disability' domains. The other shifts of means were not significant, however trending towards significance. These results generally support the acceptance of the IRRPD relative to the CRPD in terms of impact on OHRQoL and satisfaction. The significant improvements observed in the 'physical pain' and 'psychological discomfort' domains may contribute strongly to the overall support for the IRRPD design, and thereby improving the acceptance this treatment option. This is consistent with the literature reporting on patient preference for the IRRPD, particularly on the grounds of improved comfort, chewing, retention, and stability [306].

Subjective tests using VAS

The VAS instrument provided a second method for assessing the subjective impact of each denture type. Four of the questions were designed to assess specific aspects of the prosthetic intervention whilst the final question was designed to assess the overall satisfaction with each dental prosthesis type. As was the case with the OHIP-14

questionnaire, the preferred method for completing the VAS questionnaire was for each subject to do so under his or her own volition. When necessary, the principal researcher assisted the subject by reading out the question and the anchor terms situated on each side of the 10cm horizontal response line. The researcher was conscious of not leading the subject with the answer, as this would potentially impact the outcomes. The VAS questionnaire relating to each denture type was administered after the three-month adaptation period for each denture design. Since most patients had no pre-existing lower partial denture, there was no reason to administer this questionnaire at baseline. There was also no need to administer the VAS at the insertion of each denture design.

The 95% CI plots for the VAS of the IRRPD versus CRPD after adaptation comparison pairing (Figure 4.9) demonstrated that the IRRPD was significantly superior to the CRPD for all questions ($p < 0.05$). The all-important question regarding overall satisfaction (question 5) demonstrated the largest shift of mean to the right side of the zero-difference line. These results strongly support the IRRPD over the CRPD in terms of patient satisfaction.

In summarising the subjective findings of this clinical trial, the IRRPD was more conducive in improving patient satisfaction when compared to the CRPD. This is consistent with the available literature reporting on this treatment concept (refer to section 2.6 of the literature review of this thesis). However, the OHIP-14 instrument also suggests that any improvement in satisfaction between each respective denture type and the baseline (SDA) situation was not significant, even though the IRRPD was much closer to achieving significance.

When assessing the correlation between objective and subjective measures, the IRRPD (3-months) vs CRPD (3-months) comparison pairing demonstrated the strongest positive correlation. For this comparison pairing, seven of the measures achieved statistical significance favouring the IRRPD over the CRPD (two objective and five subjective). The only negative (yet non-significant) measure for this comparison pairing was seen for MBP. For the IRRPD (3-months) vs Baseline comparison pairing, four of the measures achieved statistical significance in favour the IRRPD (2 objective and 2 subjective – note: VAS (all questions) was not performed for the baseline comparison pairings). The weakest correlation between objective and subjective measures was seen

in the CRPD (3-months) vs Baseline comparison pairing; only two objective measures achieved significance with no subjective measures achieving significance.

When combining the objective and subjective outcomes of this trial, there appears to be support for the IRRPD over the CRPD, however the strength of this support is not overwhelming relative to the SDA situation. The Optosil® chewing test suggests improved function for the IRRPD, but not reaching significance at $p < 0.05$ levels. Load and OAC are significantly improved for the IRRPD when using the Prescale test whilst MBP is similar for both designs. Subjects were more satisfied with the IRRPD design; however, the OHIP-14 Sum results did not reveal a significant improvement for either of the denture designs relative to the baseline situation. It may be interpreted that the SDA treatment option, particularly if some functional premolar and/or molar pairs are present, remains a suitable treatment option and especially so within a context of scarce resources (i.e., financial and workforce limitations).

Radiographic Observations of Mesial and Distal Bone Changes

Early loss of marginal crestal bone around an implant is a common observation with multifactorial causation that is not fully understood [783]. Factors contributing to this bone loss may include surgical factors (i.e. trauma from surgery, heat, pressure, primary stability, etc.), patient factors (i.e. bone quality and quantity, general health, medications, foreign body reaction, smoking, etc.), and implant factors (i.e. implant dimensions and/or shape/design, surface structure and chemistry, and nature and location of the implant-to-abutment connection) [784-789]. The nature of loading of the crestal bone may also play a role in the crestal bone loss since crestal bone is sensitive to shear forces [790].

The loss of marginal crestal bone is discussed in terms of early (initial) bone loss and longer-term bone loss [786, 791]. Early bone loss refers to loss of bone occurring from the time of surgical implant placement up to the end of the first year of loading [789]. Longer-term bone loss is that which occurs after this period. Early bone loss is a recognised phenomenon; early research and clinical experience has identified a range of bone loss [792-795]. It has been suggested that 1.5 to 2mm of crestal bone loss could be expected after the first year of loading [792, 796, 797]. One set of criteria proposed to assess implant success uses 1.5 mm of marginal bone loss after the first year of loading

as the upper limit for establishing implant success [796]. Loss of marginal bone down to the first thread with a saucer-shaped pattern was a common observation with the classical Branemark (and similar) implants with smooth surfaces [313, 792, 798]. The term 'bone remodelling' has been used to describe this expected early marginal bone loss [784, 787, 793]. Generalisations about expected bone loss must be considered with caution however, since this phenomenon could be impacted by the features of a given implant system (i.e., nature of implant-abutment connections, implant designs, and implant surfaces, etc.). Loss of no more than 0.2mm of marginal bone (for two-piece implants) over each subsequent year following the first year of loading indicates a stable situation and is regarded as a successful outcome over the longer-term [347, 796]. Loss of bone greater than 0.2mm per year is not considered normal (i.e. considered a complication), and most likely has an inflammatory and/or occlusal overload component [784, 785].

This study confirmed average vertical crestal bone loss of 1.25 mm on the mesial aspect of the implants and 0.86 mm on the distal aspect of the implants from the time of surgical placement to the time of final periapical radiograph (average timespan from surgery being 26.6 months). The amount of bone loss from the time of first abutment placement to the time of final periapical radiograph, representing the period of loading, was 0.51 mm for the mesial aspect of the implants and 0.46 mm for the distal aspect of the implants (average timespan of loading was 13.6 months). These results fall well within the range of expected bone loss during the first year of loading as discussed in the previous paragraph. When looking more specifically at each of the two groups, the results for group A showed total mean vertical crestal bone loss between time of surgery and final periapical radiograph of 1.08 mm on the mesial aspect of the implants and 0.79 mm on the distal aspect of the implants (average timeframe of 30.2 months). The amount of mean vertical crestal bone loss between the time of first abutment placement and final periapical radiograph was 0.01 mm for the mesial aspect of the implants and 0.19 mm for the distal aspect of the implants (average timeframe of loading of 10.6 months). The results for group B showed total mean vertical crestal bone loss from the time of surgery to the final periapical radiograph of 1.36 mm on the mesial aspect of the implants and 0.90 mm on the distal aspect of the implants (average timeframe of 24.1 months). The amount of mean vertical crestal bone loss from the time of first abutment placement and the time of the final periapical radiograph was 0.85 mm on the mesial

aspect of the implants and 0.65 mm on the distal aspect of the implants (average timeframe of loading of 15.2 months).

Two implants failed prior to loading and were successfully replaced. Two additional implants failed prior to the taking of the final periapical radiograph, but fortunately not before recording of the final objective and subjective tests. This represents a survival rate of 94.1% on the basis that 34 implants were integrated during the comparison phase of the trial (the two implants that failed prior to loading were not included in these figures since they were successfully replaced). The first post-loading implant failure occurred in subject 15 (Group A) who presented with a mobile implant in site 35. A periapical radiograph was not taken on the day of final testing due to time constraints, with the decision made to take the periapical radiographs at a subsequent appointment. The patient presented with this complication a few weeks later before the subsequent scheduled appointment. This is why a final periapical radiograph was not available for this patient for site 35, and so this implant was not included in the radiographic calculations. When reviewing the case notes, it was identified that this implant had a minor bony dehiscence at the time of surgery that was augmented with autogenous bone chips and BondBone™ (biphasic calcium sulphate, MIS Corporation). This information suggests that this implant may have been at higher risk of failure.

The second implant failure occurred in subject 19 (Group B). The implant in site 46 failed after final testing but before the taking of the final periapical radiograph. It actually failed when re-inserting the Locator™ abutment, after which a periapical radiograph was to be taken. When torque of 25 Ncm was applied, loss of integration was detected. Interestingly, this subject experienced early failure of the implant placed on the contralateral side (a replacement implant was successfully placed). This subject had a history of smoking. Smoking, together with a history of previous early implant failure, suggests this subject had a higher risk of implant failure. This implant was not included in the radiographic assessment because a final periapical radiograph was not available. If these two implants were to be included in the bone level calculations, and assuming an extreme amount of bone loss for each implant (6 mm), the results still indicate that the total amount of bone loss experienced was within the normal range if 2mm is considered the upper limit, or just above normal if 1.5 mm is regarded as the

upper limit (i.e. the measurements outside the 1.5mm upper limit were the consolidated mean mesial bone loss of 1.53 mm and the Group B mean mesial bone loss of 1.59 mm).

Bone loss prior to loading is most likely associated with surgical trauma and patient-related factors [784, 786, 799]. Occlusal load and biologic width are factors that become relevant once the abutment is connected to the implant [784]. More recent research has suggested that the amount of early crestal bone loss can be reduced by modifying some of the implant characteristics such as roughened implant surfaces, micro-threads, conical implant-to-abutment connections (reducing the size of the microgap and/or transferring functional loading deeper into the bone), and platform switching (shifting the microgap further away from the marginal bone) [784, 785, 799-803]. Studies including implants that incorporate many of these features report significantly lower amounts of early marginal bone loss when compared to classic implant designs [787, 791, 802, 804, 805]. The ASTRA TECH Osseospeed™ implant system, as used in this trial, incorporates many of these features.

The ASTRA TECH implant system has been in use with the Osseospeed™ surface since 2004 with the manufacturer providing a comprehensive reference list documenting high success rates; the manufacturer concludes that based on more than 9000 patients followed prospectively for up to sixteen years, the implant system shows safe, consistent and predictable results in terms of high implant survival rates and well-maintained marginal bone [806]. The manufacturer references a meta-analysis which included 94 publications (prospective data from > 4000 patients with > 8000 OsseoSpeed implants), reporting mean marginal bone loss of 0.3 mm after five and ten years of follow-up [806, 807]. Diminishing of the gap between the original bone and implant during healing with a subsequent increase in bone-to-implant contact in a coronal direction is offered as an explanation for the marginal bone stability observed [808]. Although the vertical crestal bone loss observed in this clinical trial was consistent with the general literature reporting on this topic, the amount of bone loss for the consolidated results was higher than the 0.3 mm reported by the previously discussed meta-analysis (the reference point being the shoulder of the implant and baseline being the time of prosthetic connection). When assessing the individual groups, it can be seen that the post-loading mean bone loss for Group A comfortably falls within this range (i.e. post-loading mean bone loss < 0.3 mm for both mesial and distal sides), whilst the mean bone loss for

Group B falls outside this range (0.85 mm on the mesial side and 0.65 mm on the distal side). When adding the two failed implants into the results, and assuming extreme bone loss of 6 mm for these implants, the results worsen (consolidated post-loading mean bone loss of 0.83 mm on the mesial side and 0.79 mm on the distal side; post-loading mean bone loss for Group A: 0.44 mm on the mesial side and 0.60 mm on the distal side; post-loading mean bone loss for Group B: 1.11 mm on the mesial side and 0.92 mm on the distal side). All these measurements are above the 0.3 mm reported by the previously mentioned meta-analysis.

By nature of the crossover design of this trial, subjects of Group B underwent the additional steps of abutment removal and reinsertion. This differed to the experience of subjects in Group A that had the abutments installed once and not removed again throughout the trial. This additional removal and reinsertion step experienced by subjects in Group B undoubtedly caused some minor trauma and irritation to the peri-implant tissues and may explain why more negative bone responses were observed. The overall vertical bone loss was still less than 1.5 mm of early bone loss described as normal in the literature [796, 807, 809, 810]. Longer-term follow-up of all subjects would be required to confirm if any ongoing vertical bone loss after the first year of loading satisfies the 0.2 mm per year upper limit suggested for ongoing implant success [796].

The early marginal bone loss observed in this trial most likely has a surgical trauma component since much of the bone loss occurred prior to connection of the abutment, however the quality of bone in an atrophied posterior mandible and the shape of the ridge at the site of implant placement may also contribute. The amount of cancellous bone underneath the cortical bone influences the reparative potential around an implant [784]. A correlation between marginal bone loss and the proportion of cortical bone around Branemark® implants in the posterior part of the mandible has been reported [811]. The crestal cortical bone thickness has been shown to be greatest in the posterior mandible [812-814], and with reduced bone height, the relative proportion of cortical bone to cancellous bone will increase. Short implants placed in the posterior mandible will be surrounded by a greater proportion of cortical bone, which by nature is more sensitive to surgical trauma and shear loading forces, and this may be a factor contributing to the early bone loss observed in this trial [790, 815]. The significance of

this bone loss is accentuated around shorter implants. Another contributing factor to bone loss relates to the shape of the ridge in the proposed implant site. Due to the limited bone height available, flattening of the ridge is not always possible. Flattening of the ridge can ensure adequate bone thickness is available around the implant platform. In situations where this flattening is not possible, a thinner layer of cortical bone may surround the implant platform after placement. Thin cortical bone can be susceptible to early loss, hence also contributing to the early bone loss pattern observed [789, 816]. Due to the nature of the bone in the posterior mandible, and the disproportionate impact of even modest bone loss around short implants, short implants must be used with caution in this region, and especially so if the ridge shape limits the amount of crestal bone surrounding the implant platform.

The implants were surgically placed by a number of surgeons of moderate clinical experience (senior oral and maxillofacial surgery registrars and the principal researcher) under supervision of consultant surgeons. The fact that multiple surgeons placed the implants adds another variable to the surgical phase of the trial. However, this is an interesting variable to include in a trial because in a 'real-world' setting, implants are placed by clinicians of different experience-levels and using their own preferred surgical techniques/protocols. Trials assessing implants placed by a limited number of highly experienced surgeons in a very controlled protocol may offer an insight into the theoretical survival and success rates of implants, but unlikely to be achievable in the broader clinical setting. The literature reports that implant success is related to surgical implant experience (i.e., often measured by the number of implants placed) [817-819]. The observation of the early bone levels assessed in this trial is therefore encouraging when viewed in this context.

The reference point for all of the radiographic measurements made in this trial was the platform shoulder of the implant. Periapical radiographs were not available at the time of implant placement; however, the surgical protocol was to place the implant platform at bone level. As the implants were placed using open flap surgery, direct vision ensured this was achieved. All subsequent measurements recording bone level changes were related to the platform level. Periapical radiographs are commonly used to assess bone levels around implants; however, they are limited by the fact that they only provide two-dimensional information. Conventional periapical radiographs allow

assessment of radiographic bone level changes at the mesial and distal aspects of an implant, but minimal information is provided regarding the state of the bone on the buccal/labial and palatal/lingual aspects. [787, 793]. A more comprehensive assessment of these sites can only be achieved with three-dimensional imaging, deep probing, or gaining surgical access for direct measurement; all activities outside the scope of this trial. Use of periapical radiographs is a standard technique used to evaluate interproximal bone levels [808, 820, 821].

A limitation associated with assessing bone level changes on sequential periapical radiographs relates to the standardisation of the periapical radiographs [793]. Radiographers of the Radiology Department at the RDHM took all periapical radiographs in this trial; all of the radiology request forms included clear instructions to employ the paralleling technique. The assumption is that this was carried out. In order to correct for any errors, a magnification factor was calculated by comparing the width of the implant platform (as measured on the film) to the actual known width of the implant platform (i.e., 4.0mm). If a difference between these two measurements was detected, a magnification factor was calculated and applied to the measured length (i.e., vertical distance from platform to first bone contact) to determine the actual extent of bone loss. A small number of baseline periapical radiographs were not available (immediately after surgery) since the prescription and taking of periapical radiographs was dependant on the timing of surgery and subsequent operating hours of the RDHM Radiology department. As previously discussed, the position of the implant shoulder was used as a baseline reference point since the surgical protocol was to place the implant shoulder at bone level [793]. Many studies do not use surgical placement as the baseline situation; rather, bone levels at the time of implant uncovery is used as the baseline measure. This trial can only comment on early marginal bone loss since the follow-up period is not long enough to observe ongoing bone behaviour.

Clinical and Prosthodontic Observations and Considerations

The clinical health of the remaining natural teeth and associated soft tissues remained stable and unremarkable throughout the trial; the main finding was mild gingivitis as determined by delayed bleeding on probing in limited sites. Periodontal probing depths

remained stable between baseline and final examination (rarely was a difference of more than 1 mm in periodontal probing depth observed). These observations are not surprising given the relative short duration of the trial and the fact that the remaining natural dentition was stabilised prior to delivery of the lower dental prosthesis. Subject 16 suffered a crown fracture of a previously root treated lower anterior tooth (tooth 31). It was decided to keep the root *in situ* and simply add an acrylic tooth to the existing denture. The patient was satisfied with this outcome. The same subject had tooth 41 extracted due to mobility and discomfort towards the latter part of the trial. This tooth had a guarded prognosis at the commencement of the trial, and it was not entirely surprising that this complication arose. The tooth was subsequently removed, and a replacement tooth added to the lower denture. No other teeth were lost from any of the other subjects during the trial.

One subject (subject 9) suffered two prosthetic complications during the trial. This particular subject had an upper IRRPD opposing a lower IRRPD and a heavy bite (reduced inter-occlusal clearance and wear facets on the anterior teeth). She experienced minor acrylic fractures of her upper IRRPD (right side) and lower IRRPD (left side); the laboratory easily repaired both fractures. A heavy (deep) occlusion combined with opposing implant-supported dental prostheses contributed to these complications. No other prosthetic complications requiring laboratory repair occurred during the trial. It has been reported that the majority of maintenance events occurs during the first year [324]. Although it is acknowledged that the presence of RPDs can have an adverse impact on the health of the remaining natural dentition because of plaque accumulation, it is also reported that a well-designed dental prosthesis with meticulous oral hygiene and maintenance can result in successful long-term treatment with CRPDs [177, 190, 200-202]. This clinical trial cannot add much to this discussion given the short follow-up.

Due to the crossover design of the trial, the denture included clasp arm support. It has been suggested that clasp arm support can be avoided in IRRPDs (see section 2.6 of the literature review). This was not tested in this trial. Another interesting area of research would be to compare the function and performance of IRRPDs with and without clasp arm retention. The role and significance of the clasp arms may be related to the position of the implants relative to the distal abutment tooth on each side of the arch and the

degree of retention provided by the Locator™ attachment system. Removing anterior clasp arms has aesthetic benefits and can contribute to greater acceptance of the removable dental prosthesis [30, 306, 312, 316]. If the IRRPD was deemed to be very retentive at the time of intra-oral pick-up of the Locator™ retention caps, the black processing nylons were retained for a short period. This allowed the subject to use the IRRPD (with the Locator™ black processing nylons) for the first few weeks in order to familiarise him-/her-self with inserting, removing, and handling the dental prosthesis. After this time, the black processing nylons were replaced with suitable retentive nylons.

Most Locator™ abutments (and hence implants) in this trial were situated in the first molar or mesial half of the second molar sites. Due to anatomical restrictions, three abutments were placed in the premolar regions (Subject 2 – Q4, Subject 13 – Q4, and Subject 15 – Q3). Subject 18 also had an implant placed in a premolar region; this was decided upon after discussion with the subjects' pre-test restorative dentist (prosthodontic post-graduate student) who wanted to keep the possibility of a future fixed dental prosthesis as an option. The premolar site was deemed more appropriate for this subject (in Q4). These abutments still served to provide adequate support and retention of the distal extension bases, and there was no suggestion that this positioning affected function or satisfaction. As presented in the literature review (section 2.6.2), a number of studies have reported on the positioning of abutments in premolar, first molar, and second molar positions. No site appears to offer a significant advantage. Purely from a biomechanical perspective, abutments positioned in the second molar site will most effectively support a beam (minimal cantilever). The first molar site however corresponds to support being provided under the area of maximum bite force generation, whilst also ensuring enough space is available distal to the abutment for cast-metal framework and acrylic [339]. Abutments located in the premolar sites may be beneficial to the adjacent abutment teeth [295]. Placing implants in the first molar site, or as distal as practical in the premolar region subject to anatomical constraints may therefore be advisable. One must also consider the most appropriate implant sites with respect to the potential of converting the IRRPD to a fixed prosthetic solution in the future.

All subjects in this study preferred the IRRPD. Nevertheless, this did not always equate to all subjects wanting to continue longer-term with the IRRPD. Two of the younger subjects in the trial were keen to explore fixed options after the crossover phase was completed. In fact, subject 11 (Group B) expressed a preference not to have the Locator™ abutments reinserted because she wanted to progress to a fixed alternative. Subject 3 (Group A) misplaced his denture after completion of the trial, and rather than have a new denture made, wanted to explore fixed options. Although more satisfied with the IRRPD, Subject 14 (Group B) continued to express concerns with adapting to the 'feeling' of the major connector (lingual bar), and as a result, this impacted the amount of time she wore the dental prosthesis. This subject had pre-conceived concerns about tolerating a removable denture even before the trial commenced; hence there was probably a psychological element to her attitude towards the RPD prosthesis regardless of implant association. It may be that patients with prior negative experience(s) with wearing CRPDs will benefit more from converting to the IRRPD design as compared to patients already tolerating a CRPD or with no prior denture experience at all. Younger patients appear to favour fixed restorative options. These are points of consideration when treatment planning and discussing treatment options with patients.

One of the main differences between the CRPD and IRRPD is the surgical placement of two implants and incorporation of attachment mechanisms for the IRRPD. This will significantly increase the cost of the IRRPD design in the initial stages. Not taking into account any significant or catastrophic complications during the life of the dental prosthesis, such as implant failure and/or irreparable dental prosthesis fracture, much of the ongoing maintenance for the IRRPD will involve denture hygiene, assessing denture retention, and the changing of Locator™ nylon inserts when required. The CRPD design will likely require more frequent relining than the IRRPD design over a comparable lifetime and adjustment of clasps and management of any sore spots. The longer-term cost/benefit differential between the two designs will need to compare the frequency and expense of changing the Locator™ nylon inserts for the IRRPD versus the frequency of relines and clasp and denture adjustments for the CRPD design, and the relative differences in acceptance and wearing of each dental prosthesis. For example, failure to wear the CRPD on a regular basis (i.e., low acceptance) or a need to re-make a CRPD more often may prove more costly over the long-term despite the higher initial

costs of the IRRPD. Nonetheless, both designs can be susceptible to complications such as fractured/lost denture teeth, metal base fractures, acrylic fractures, loosening/breakage of clasps, and breakage of other denture components.

The IRRPD is susceptible to issues involving the attachment mechanism, with fractures involving the acrylic surrounding the retention components having been reported [324]. It must be appreciated that an implant-retained dental prosthesis will lack the 'suspension' provided by a periodontal ligament of a natural abutment tooth and the underlying mucosa. The resilience of the Locator™ nylon will allow for some movement of the dental prosthesis, up to 0.2mm in the vertical direction and 8 degrees hinging in any direction, as a result of the size differences between the taller black processing patrix and the nylon retention inserts [299, 822]. Nevertheless, such movement may not fully compensate for that offered by the periodontal ligament and mucosa, and as such, the occlusion between upper and lower implant-retained dental prosthesis may result in the dental prostheses encountering destructive forces during function; such forces could place the dental prostheses at risk of fracture and other stress-related complications as seen in subject 9. These fractures were successfully repaired in the laboratory; however, care must be exercised when such scenarios present themselves.

Due to the requirement of the crossover design, subjects in Group B required a minor additional intervention at the completion of the final adaptation period if they wanted to convert back to the IRRPD (i.e., a minor implant uncovery procedure to reinsert the Locator™ abutments). Only one subject (subject 18 – Group B) expressed concern with the CRPD to the point that he wanted re-conversion back to the IRRPD prior to the three-month adaptation period for the CRPD. This subject was nursed along with a number of adjustment appointments, including addition of a soft liner over the implant sites, after which it was decided to reconvert at around the two-and-a-half-month adaptation point. Other than this example, no other subject from Group B expressed deep concerns requiring premature reconversion. Additional subjects from Group B reported early discomfort following the conversion phase from IRRPD to CRPD. This was due to compression of the soft tissues previously surrounding the Locator™ abutments by the distal extensions of the CRPD. Most situations were managed by minor denture base adjustments; as with subject 18, subjects 9 also had a temporary soft reline material placed on the denture bases over the areas of tenderness. Subject 9

expressed difficulty in chewing on the day of conversion from the IRRPD to the CRPD. The CRPD insert tests for subject 9 were retaken at a subsequent visit after a soft reline over the implant sites. This situation was more comfortable for the subject and more likely that reliable chewing results were recorded. The conversion step for subject in Group B must be acknowledged as a limitation of the crossover design of this study. A parallel design would address this issue, however as discussed, a parallel design would require more subjects and incur greater costs.

This clinical trial was undertaken to contribute to our understanding of the treatment option of using RPDs in an association with implants for managing the challenging mandibular KCI situation. The treatment protocol was designed in a manner to keep the procedure as simple as possible, enabling most experienced general practitioners to provide this treatment whilst minimising the overall biological and financial costs of the procedure. The protocols used also endeavoured to reflect how this treatment philosophy and protocol could be provided in a 'real-world' setting, by not using overly restrictive exclusion/inclusion criteria and not dictating strict treatment protocols. Furthermore, providing a cost-effective treatment protocol, relative to fixed implant restorations or poorly accepted removable dental prostheses, has relevance for both public (i.e., government funded) and private practice settings. The implant placements were undertaken in the outpatient Oral Surgery Department at the RDHM by senior registrars and the principal researcher employing accepted surgical protocols as routinely used in the department. Antibiotics were not routinely prescribed unless deemed necessary by the surgeon since evidence does not conclusively support the use of antibiotics for simple implant surgery in healthy patients, whilst overuse of antibiotics poses other issues [823]. Furthermore, the prosthetic phase of treatment was also kept simple; face-bow transfers and semi-adjustable articulators were not used unless there was a significant change to the occlusal vertical dimension and/or maxillomandibular relationship required. All laboratory work was referred to and provided by the Laboratory Department of the RDHM and its approved contractors.

A challenging aspect of the surgical phase of the trial was the placement of implants in the correct 3-dimensional position. Although it is claimed the Locator™ system permits up to 40 degrees of variation in angulation between two implants (by using the extended range nylons), the aim is to minimise any angulation discrepancies between

Locator™ abutments and also the path of insertion of the dental prosthesis. Achieving cross-arch parallelism in the mesio-distal and bucco-lingual planes and parallelism with the distal abutment teeth was challenging, even with the use of paralleling guide pins. Use of treatment planning software to design a surgical guide is an option available for ensuring the correct three-dimensional placement of the implants, however this will add to the overall cost of this treatment protocol (i.e., requiring access to appropriate treatment-planning software and a manufacturing platform). An experienced clinician may be able to employ this protocol on the basis of an OPG and clinical assessment. If this assessment confirms that implants can be placed with sufficient dimensional clearance from any vital structures, a tomographic scan may not be required; hence providing another way of enhancing the cost effectiveness of this treatment protocol.

Trial Design and Sample Size Considerations

High-quality randomised controlled clinical trials are regarded as the gold standard for assessing the safety and efficacy of therapeutic interventions, and providing the evidence-base for appropriate treatment planning [824, 825]. These trials can be structured with parallel arms (i.e., control arm and intervention arms) or as within-subject crossover trials. Each of these trial designs has advantages and limitations. In trials using parallel arms, each arm is exposed to a single intervention (or no intervention – control arm), with the mean results of each arm used to identify any significant differences in outcomes. Each arm must consist of a randomly selected minimum sample size that will enable valid statistical analysis and conclusions to be made. Appropriate standardisation is also recommended as to minimise the impact of cofounding variables from influencing the outcomes being assessed. A key advantage of the within-subject crossover design is that the same subject experiences all interventions and as such, serves as his- or her-own control [826, 827]. The sequence of intervention is randomly allocated and is usually separated by an appropriate washout period. In this way, any potential bias caused by unmeasured cofounding variables can be addressed since these variables are consistent for each subject and are present during all interventions. This eliminates between-subject variability and allows for between and within group comparisons to be made [824, 828]. This is one reason why within-subject crossover studies can have smaller sample sizes yet still be able to obtain powerful estimates of treatment effect [826, 829]. Another advantage of this study

design is the potential reduction in costs since fewer overall subjects are required (and hence fewer implants and fewer dental prostheses in this particular trial) [830]. In this trial, each subject required only one dental prosthesis that could be modified between CRPD and IRRPD designs, whereas in a parallel-arm research design, subjects of both arms would require a dental prosthesis. Furthermore, the number of implants and related components would be greater for the parallel design if the IRRPD arm required a sample size greater than seventeen subjects included in this trial.

A number of limitations must be acknowledged and accepted when reviewing the within-subject crossover trial design and the endeavour of determining the true effect of an intervention(s). The benefit of requiring fewer subjects relative to a parallel-arm trial is offset by the fact that subjects in a within-subject crossover trial must undergo multiple interventions, conform to a longer and/or more onerous treatment and recall regimes (i.e. more appointments and more tests), and as a consequence, there is risk of subject dropout before all interventions are assessed [829, 831]. The within-subject crossover design can only be used if the condition being investigated is chronic and stable, and is not suitable if a period effect exists; a period effect is said to exist if the condition being investigated improves or deteriorates through the passage of time regardless of intervention [829]. Another limitation relates to the potential of a carry-over or spill over effect [830]. This occurs when the impact of the first intervention influences the impact of the second intervention; hence the order of interventions can potentially influence the outcomes [829]. This may be more of an issue when assessing interventions that continue to take effect even after cessation of the intervention, such as the administration of drugs with long half-lives. Application of a suitable washout period can help minimise the spill over effect. A washout period is essentially a period of time between interventions that allows the impact of the first intervention to dissipate.

The spill over effect for this clinical trial is interesting to assess. In the first instance, the morphological (i.e., anatomical) situation reverts to the baseline situation the moment the lower denture is removed from the mouth. In this way, there is no spill over effect when viewing the situation from an anatomical perspective. However, it would be reasonable to expect that some time would be required for the subject to 're-adapt' to the true baseline situation from a functional perspective. Due to practicality reasons

(i.e., time limitations and subject convenience), the crossover was performed with minimal washout period. Therefore, the results obtained at the denture insert time-points must be interpreted with some caution since the early function of the newly inserted denture may be influenced by prior experience, as has previously been discussed. Again, due to practicality reasons, the first denture insert may have also occurred before a full three-month adaptation period was completed for establishment of the baseline situation. Despite these limitations, the results are still valid and of interest since in 'real world' clinical scenarios, patients are rarely subjected to wait many months before treatment and dental prosthesis delivery solely for the purpose of adaptation. The most important objective of this trial was to compare the performance of the CRPD and the IRRPD after three-month adaptation periods; the trial design ensured that this situation was met.

Another important consideration with the within-subject crossover design is the order effect. It is conceivable that the result of one of the interventions may be influenced by experience from the other intervention on psychological grounds (i.e. psychological carry-over effects) [738]. For example, subjects in Group A of this clinical trial could initially over-estimate the subjective view of the CRPD because they have yet not experienced the IRRPD. The results provided for the CRPD may be seen differently in light of experience with the IRRPD. Alternatively, subjects in Group B may underestimate the subjective experience with the CRPD since it was assessed after having experienced the IRRPD in the first instance. These scenarios are only valid if the IRRPD produces a superior subjective experience (which may not necessarily be the case). To mitigate the order effect, two groups were established such that subjects in Group A experienced the CRPD first whilst subjects in Group B experienced the IRRPD first. Subjects were randomly allocated into one of these two Groups. The test used to determine significance in this trial was based on the use of paired T-tests. All results obtained in this trial were tested for order effect. Testing showed that no significant ordering effect was detectable, with the exception of question 2 of the VAS questionnaire. This means that for question 2 (Chewing Ability), if the CRPD was the first dental prosthesis to be experienced, the question 2 VAS score will be higher on average than if the CRPD was second; for the IRRPD, the order did not matter as much since the mean score was consistently higher. This over-estimation of chewing function for the CRPD (by subjects in Group A) further supports the evidence that the IRRPD may

be superior in terms of chewing function. Apart from this, statistical analysis of all other tests indicates that the sequence in which each denture design was experienced did not influence the outcomes. This is a reassuring result, as intuitively there could be concern that subjects may under- or over- estimate the impact of an intervention subject to prior experience.

Determining the sample size for this trial was not a simple exercise, with the eventual number arrived at being one more of convenience and within the range of sample sizes used in similar prosthodontic-related clinical trials (i.e., based on precedence). Using previous studies to assist in calculating an appropriate sample size (i.e., based on power and effect size calculations) was not possible since multiple outcome measures were being assessed in this trial; no studies were found using the same combination of outcome measures used in this trial. Nevertheless, a number of studies assessing prosthodontic interventions have reported on sample size calculations, with examples including:

- "Sample size was based on clinical findings of other crossover studies (van Kampen et al 2002, van der Bilt et al 2010) that demonstrate a significant difference in masticatory function between three types of mandibular implant-supported dental prostheses." (Crossover study, n = 18) [762].
- "A minimum of 9 participants was needed to detect a difference (power of 80% and an error probability of 5%). In view of the withdrawal rate of 25%, the final sample was established at 12 volunteers." (Prospective trial – no crossover, n = 12) [328].
- "A sample size test based on a previous study (Slade *et al.* 2004) indicated that 10 volunteers would be enough to detect a 10-point difference in the Oral Health Impact Profile (OHIP) questionnaire (power of 80% and an error probability of 5%). Therefore, the study sample consisted of 12 volunteers." (Prospective trial – no crossover, n = 12) [326].
- "We calculated the sample size for standard statistical criteria ($\alpha = 0.05$, $\beta = 0.20$) and an effect size of 10mm, using the mean and variance of scores of general satisfaction of mandibular long-bar overdentures on a 100-mm Visual Analogue Scale (VAS) taken from de Grandmont *et al* 1994." (Crossover trial, n = 16) [761].

- "The sample size was calculated using standard statistical criteria (α = 0.05, β = 0.20) for an effect magnitude of 10mm on a 100mm Visual Analogue Scale (VAS), based on previous work (de Grandmont *et al.* 1994), and 2 patients were added to compensate for dropouts." (Crossover trial, n = 16) [737].

Based on these studies, it is reasonable to conclude that a sample size of between 10 and 18 was appropriate for this type of trial; especially given it was a crossover trial. The original aim was to achieve 30 subjects, but due to a number of challenges, 19 subjects were eventually enrolled into the trial within the available timeframe. A recent study assessing randomised clinical trials in dentistry conducted over the years 1955-2013 reported that withdrawals/dropouts were reported in the vast majority (89.4%, n = 483) of trials, with withdrawal/dropout rates being acceptable (less than or equal to 20%) in 73.1% (n = 395) of the trials [832]. Even taking into account a potential dropout/withdrawal rate of up to 20%, this would ensure that at least 15 subjects would complete the trial (15.2 represents a 20% withdrawal rate from the original 19 enrolled subjects). 17 subjects actually completed this trial (withdrawal rate of 10.5%). This withdrawal rate was acceptable when taken in context of the withdrawal rates reported from other randomised clinical trials in dentistry.

In an ideal study design, all subjects would have a similar pattern of tooth loss on the lower arch and a similar upper arch configuration, thereby minimising the impact of any cofounding variables on intervention outcomes. As previously discussed, fortunately the within-subject crossover design helps mitigate much of this concern since each subject serves as his- or her-own control. Nevertheless, it would have been beneficial to have a standardised upper arch (i.e., all subjects with full upper denture or all fully dentate/fixed) and with the same number and pattern of missing teeth in the lower arch. This was not possible for practical reasons; the trial was conducted predominantly by a single researcher in a single location and only having access to patients eligible for care at RDHM and limited public clinics. Identification of potential subjects was largely dependent on clinical staff from the relevant clinics advising the principal researcher of potentially suitable subjects. Furthermore, time-line limitations placed a finite period available for recruitment. As the aim of this trial was to assess a treatment option that could be applied broadly in general dental practice, it was decided that there was merit

in accepting a broader range of subjects by relaxing strict exclusion criteria. Use of strict inclusion and exclusion criteria usually under-represent vulnerable patient groups and only provide results of average patients [824]. For instance, patients seen in general practice may smoke or have evidence of parafunction. Many studies exclude such patients; however, the inclusion of such patients will generate outcomes that more closely reflect how the treatment would perform in everyday general practice. Provided a subject did not have a systemic health condition posing a significant risk of complications from outpatient oral surgery or uncontrolled disease(s)/conditions (i.e., active caries, active periodontal disease, or TMJ pain), he/she was not excluded from the trial. Blinding could not be employed in this trial since it was obvious to both the researcher and subject as to which denture type was being worn and tested.

A variable of interest that could not be assessed in detail in this trial is the impact of treatment in subjects missing all lower posterior teeth (i.e., extreme SDA); it may be hypothesised that the impact of treatment is dependent on the number of teeth being replaced by the dental prosthesis. Increasing the sample size to include a suitable number of SDAs ranging from minimal to extreme would be a useful recommendation for future trials. This will help identify the point where use of a RPD (either CRPD or IRRPD) is likely to have a significant impact on masticatory function.

In an ideal setting, each subject would experience a three-month adaptation period between stabilisation of the remaining dentition (if required) and the baseline tests. This was not always possible because of time-line limitations and the inconvenience caused to the participants (i.e., delay in treatment solely for the purpose of performing baseline tests). This scenario means that some subjects underwent baseline tests without necessarily having fully adapted to their new baseline situation and as such, some of these baseline results may have underestimated their actual functional potential. Performing baseline tests at another time-point would not have been practical either, since this too would not have provided a true representation of the baseline situation. The main focus of this trial was to compare the three-month results for each dental prosthesis type.

Unforseen delays occurred throughout the trial period, largely as a result of technical and procedural challenges associated with a prosthodontic-related clinical trial and the

management of subject compliance. This partly explains why some of the mean time frames shown in tables 4.14 and 4.15 are greater than expected. The overall timeline for subject 2 (Group A) was significantly extended because of challenges encountered in stabilising her upper dental prosthesis. Although the subject had a new maxillary removable complete denture inserted that initially seemed to be functioning adequately prior to baseline testing, it became apparent after lower implant placement and denture construction that she was having increasing difficulties functioning with the upper denture. Despite multiple adjustments, relines, and even a new upper denture, the subject could not function adequately. After multiple consultations and assessments with specialist prosthodontists (trial supervisors), it was decided to include implants to assist with retention and support of the upper denture. This step increased the overall time frame for this patient. To further prevent delays, it was necessary to perform base-line functional tests at a later stage during the trial (i.e., without lower denture in place) for this particular subject. Subject 13 experienced a framework fracture of the lower dental prosthesis during the denture conversion stage. Under magnification, porosities were identified within the casting at the fracture site. Therefore, it was determined that this fracture was largely a technical issue with the casting. A new dental prosthesis was constructed, including a greater bulk of metal at the site of fracture, and this subject re-commenced the trial at the beginning of the first denture design insert stage. Subject 14 consistently complained of tongue biting when wearing the lower denture. There was minimal improvement after multiple adjustments. It was decided to re-set the lower occlusion, which seemed to improve the situation. This subject recommenced the trial at the first denture design insert stage after re-setting of the lower denture teeth.

An important issue arose with subject 10 who required her framework to be re-designed after completion of the first stage of the trial. It was identified that the position of one of the recesses in the cast metal framework for the Locator™ retention cap was in the incorrect position, so much so that adjustments could not rectify this problem; therefore, it was decided to redesign the framework. This subject recommenced the trial at the first denture design insert stage. This error demonstrates the importance of re-confirming the design of the framework with the available information in order to accurately match the implant position and is an important learning regarding this treatment concept. Extra vigilance will ensure that the future incorporation of the Locator™ cap can be an efficient process. Furthermore, a number of other subjects

required some adjustments of the framework to ensure passive accommodation of the Locator™ retention caps. Even when the recesses are in the correct location, the angulation of the Locator™ abutments (which is dependent on implant inclination) can sometimes cause the Locator™ retention cap to make contact with the cast metal framework if the diameter of the recess is insufficient. Adjustments can be time-consuming and potentially weaken the integrity of the framework. This is an important consideration and a point of caution for clinicians employing this treatment concept.

A useful learning during the trial was to take direct measurements during implant placement surgery. Direct measurement of the distance between the distal edge of the abutment tooth and the implant position can be recorded at the time of implant placement surgery, thereby assisting with the precision of stage two surgery and design of the denture framework. In the pilot protocol, which was used for the first three subjects, an open-tray implant-level dental impression was taken prior to the denture design stage. This provided a very accurate way of identifying the implant locations and inclinations, however it did involve an additional invasive procedure and added to the complexity of the procedure. Employing a simpler and more efficient technique with less surgical intervention was appealing, and so it was decided that the implant location could be identified in a less invasive manner without an additional surgical intervention. If the decision is made from the outset that an IRRPD is to be the dental prosthesis of choice, it makes sense for the framework design stage to take place after implant uncovery and seating of the Locator™ abutments. Subject 3 proved difficult to contact towards the end of the second denture design stage, hence resulting in delays in obtaining the second denture design final results. Subject 11 lost her denture during the trial. It was necessary to make a new denture and recommence the trial at the first denture design insert stage.

Decision Rubric for Treatment Planning and Future Recommendations

Based on the results and experiences gained from this clinical trial, the following questions and decision rubric can be considered when treatment planning for the mandibular KCI situation:

- How is the patient currently functioning with the SDA situation and is he/she satisfied with the existing situation? If acceptable, then the crucial question to consider is whether or not a lower dental prosthesis is even required (i.e., accept the SDA treatment concept). A lower dental prosthesis is probably not necessary if a second premolar-to-second premolar occlusion is present with acceptable function and patient satisfaction.
- If function and/or satisfaction are not acceptable and/or if there are indications to suggest that prosthetic replacement of missing teeth would be beneficial, then the CRPD and IRRPD can be considered amongst the available treatment options.
- Is the patient currently using a CRPD, or will this be the first dental prosthesis? If the patient currently has a lower dental prosthesis, is it satisfactory and is the patient functioning well and satisfied? A new dental prosthesis may not be indicated at this time.
- If function and/or satisfaction with the existing CRPD is unsatisfactory and the CRPD design or condition is not acceptable, then consider a new CRPD but treatment plan it in a way that the CRPD can be easily converted to an IRRPD design at a future date (if required).
- If function and/or satisfaction with the existing CRPD are unsatisfactory yet the CRPD design and condition is acceptable, then consider the IRRPD option.
- If the patient has never worn a lower dental prosthesis, consider a CRPD but treatment plan it in a way that the CRPD can be easily converted to an IRRPD design at a future date. An IRRPD design may be preferred for younger patients if a fixed option is not possible.

When treatment planning for these scenarios, a pre-treatment CBCT scan should be taken to assess the bone volume and quality in the posterior mandible and to determine potential suitable implant sites. This information can be used to help in designing the cast metal framework; the framework should be designed to incorporate a circular recess in each denture extension base in the approximate location of (potential) future implant placement. The recess should be large enough to house a Locator™ retention cap and provide some clearance for acrylic. The recesses will be filled with acrylic in the CRPD design. If and when a retrofitting procedure is undertaken, the acrylic can be removed from each recess, thereby providing the space necessary for the Locator™ retention cap to be incorporated into the denture using an intra-oral pick-up technique.

The CRPD can also be used as a type of surgical guide to assist the surgeon in identifying the correct location for implant placement. If the decision is made from the outset to provide an IRRPD design, the framework of the definitive dental prosthesis can incorporate distal rest seats on the abutment teeth (together with or in place of mesial rests) and be designed after placement of the Locator™ abutments. This will provide the most accurate way of designing the framework to ensure ideal positioning of the circular recesses to accommodate the Locator™ retention caps.

The overarching principle of treatment planning is to consider all available and relevant information in order to arrive at an evidence-based treatment option(s) with the health and well-being of the patient at the centre of all decisions made. It's clear there is no absolute recommendation for the management of free-end partially edentulous arches [833]. The SDA concept may be a satisfactory option from resource and financial perspectives but is not suitable as a 'one size fits all' option. Each patient must be treated as an individual and assessed and managed according to their clinical and psychological needs, such as his or her perception of chewing ability [834]. The results of this clinical trial, although supportive of the SDA, still suggest that the IRRPD can offer advantages when compared to the CRPD if indeed prosthetic rehabilitation of missing lower posterior teeth is indicated.

A stepwise treatment planning approach appears sensible; if a dental prosthesis is to be provided, it can be recommended that it is designed in a manner that the CRPD can be easily converted to an IRRPD. From the outset, the design of the framework should incorporate adequate clearance in and around prospective implant sites, which in a ridge of sufficient bone height should correspond to the site of the missing lower first molar tooth. More mesial sites can be considered if bone height is compromised at the first molar site. This treatment approach enables the patient to experience the CRPD option, allowing assessment of function, impacts on OHRQoL and overall satisfaction after a suitable adaptation period. Only those patients experiencing significant challenges with the CRPD can then progress to the IRRPD option. Such an approach will optimise treatment in a cost-effective manner and offer significant benefits to funders of dental care (i.e., governments, insurance companies, charitable organisations, etc.) since not all patients will progress to the IRRPD. Such an approach will also hopefully increase overall acceptance of the chosen dental prosthesis.

Chapter 6 - Conclusion

The strategic association of a dental implant under each distal extension base of a mandibular KCI RPD improves function and patient satisfaction. However, the degree of functional improvement is varied with the results of the Optosil® chewing tests demonstrating a strong trend towards improvement but failing to achieve significance, whilst load and OCA results are significantly better for the IRRPD. The MBP results are similar for both designs. These results are also true for each denture designs relative to the baseline situation. Subjects were more satisfied with the IRRPD in comparison to the CRPD, with significant improvements reported for the OHIP domains of 'physical pain', 'psychological discomfort' and 'psychological disability'. Very little improvement in satisfaction was detected between the baseline situation and use of a CRPD, whilst the IRRPD demonstrated a strong trend towards improved satisfaction but failing to achieve significance. The failure to achieve significance relative to the baseline (SDA) situation suggests that the SDA treatment option must be a strong consideration when treatment planning for missing lower posterior teeth.

The strongest positive correlations between objective and subjective measures were observed for the IRRPD (3-months) verses CRPD (3-months) results. Seven of the twelve measurements for this comparison pairing were significantly in favour of the IRRPD (3-months), five were in favour of the IRRPD (3-months) although not achieving a level of significance, and one measure (MBF) was non-significantly in favour of the CRPD (3-months) situation (i.e. negatively correlated to all other measures). There was a more moderate positive relationship between the objective and subjective measures for the IRRPD (3-months) versus Baseline situation comparison pairing; four measures were significantly in favour of the IRRPD (3-months), seven measures were non-significantly in favour of the IRRPD (3-months), and one measure was non-significantly in favour of the Baseline situation. The weakest positive correlation between objective and subjective measures was observed for the CRPD (3-months) versus Baseline situation comparison pairing. Two of the objective measures were significantly in favour of the CRPD (3-month), whilst no other measurements achieved significance. Three of the eight subjective measures demonstrated a tendency favouring the Baseline situation.

Two implants failed during the preloading phase with replacement implants successfully placed. Two implants failed at the end of the trial period. This represents a survival rate of 94% of the loaded implants during this trial. Short implants can be used with caution in the posterior mandible; early bone loss in the posterior mandible was towards the upper limit of the normal range. Even a small amount of vertical bone loss around a short implant will have a disproportionate impact when compared to an equivalent amount of bone loss around longer implants. The LocatorTM retention system provided adequate support and retention to the IRRPD with minimal maintenance and complications throughout the trial. Prosthetic complications were uncommon; the main complication was acrylic fractures in one subject who had an IRRPD occluding against another IRRPD. All patients preferred the IRRPD, but not all were willing to persist with this option. Some of the younger subjects expressed a desire to explore fixed restorative options.

The outcomes of this trial confirm that the IRRPD is superior to the CRPD in a head-to-head comparison in terms of function and patient satisfaction. This conclusion is consistent with *in vitro* and clinical literature reporting on the advantages of implant association with RPDs. This trial also provides greater insight into the issue of managing the mandibular KCI situation. Interestingly, the improvements in function and satisfaction for either denture type over the baseline (SDA) situation was not significant for some of the tests, in particular the Optosil® chewing test and the OHIP-14 Sum questionnaire. The results for the IRRPD did however, show a strong tendency towards significance. These observations are important since it reinforces the need to consider the SDA treatment concept and the IRRPD when treatment planning for the mandibular KCI situation.

Based on this trial, a staged treatment planning process may be advocated. The first stage of the process involves deciding whether a dental prosthesis is actually required; a decision arrived at after considering observed function and reported functional and satisfaction measures. The next stage of the process, if required, is to the provision of a high-quality CRPD that is designed in such a way that will permit implant association in the future. The final stage of the process would be to place implants and associate these implants to the denture (if an IRRPD is required). Situations in which existing satisfactory CRPDs have not been well accepted may benefit from progressing directly to

the final stage. Such a staged treatment planning process will ensure patients receive appropriate treatment in a conservative and cost-effective manner. Some patients will accept and function to an acceptable level with the CRPD, hence avoiding the need to progress to implant placement with associated clinical and component costs. This will have positive benefits for public sector planning and in situations of scare resources and financial limitations. Beyond the CRPD/IRRPD treatment options, multiple implants could be placed in each edentulous span to facilitate long-span fixed restorative options. Such treatment is more complex in terms of additional surgical interventions, clinical, componentry, and laboratory costs.

Prior to acceptance of modern implantology, the mainstay treatment options for the mandibular KCI situation entailed either no treatment or the provision of a CRPD; fixed options were limited. As discussed throughout this thesis, the acceptance of the KCI mandibular CRPD is amongst the lowest of the Kennedy classes. Numerous studies have reported on the potential benefits of associating dental implants with the distal extension bases of the KCI CRPD. However, the evidence level supporting this is relatively low, with few randomised controlled clinical trials of sufficient quality identified. This research was undertaken to add to the scientific evidence base for some of the options available for the management of the mandibular KCI situation. This trial was conducted as a within subject crossover design which offered a range of benefits, including utilising a smaller sample size, enabling each subject to serve as his- or her-own control, and reduction of costs and resource commitments. The potential limitations of this study design included the possibility of an order effect (which was tested for), and the need for subjects of group B to have abutments removed with the denture reinserted onto irritated tissues, and the need for re-conversion when the trial was completed. The first issue caused some minor discomfort, whilst the added surgical interventions irritated the peri-implant tissues. Bone level results showed that implants of group B subjects experienced more bone loss than in subjects of group A, an observation that may have some relation to these added interventions.

The trial was limited in terms of sample size, the availability of suitable patients within the available recruitment time frame, and the resulting heterogeneity of patients in terms of demographics, medical history (including smoking history), upper arch situation and lower arch configuration. The chewing test results are relevant for the

chewing test material used. Optosil® is an artificial material that proved to be challenging to chew, as evidenced by the skewed particle size distributions towards the larger sieve sizes. Other limitations encountered in this trial included the delays caused by the requirement of managing the upper arch and remaining lower teeth prior to commencing the trial, availability of surgical and laboratory turn-around times, and subject availability to attend planned appointments.

A number of recommendations can be made to assist clinicians who are seeking to conduct further research on this topic. Utilising a larger sample size which also includes a range of SDA situations (i.e., from extreme SDA to minimal SDA) may help identify a point where provision of a CRPD/IRRPD will likely result in significant improvement. This trial was conducted as a crossover study; future trials may be conducted using a parallel arm design and in multiple centres (multicentre study). If using a parallel arm design, greater consideration will need to be given to standardising the upper arch situation. Chewing test materials of differing textural properties can also be considered, as can dynamic techniques that observe changes during occlusal function (e.g., Tekscan, (Tekscan Inc., South Boston MA, USA) which detects pressure/force changes during function). Further research about the short and long-term performance of short implants in the posterior mandible will also add to the evidence supporting their use in this treatment concept. A clinical comparison of outcomes with implants placed in different sites (i.e., premolar, first molar, and second molar sites) may also offer greater insights into the most appropriate placement location. Studies assessing the impact of removing cast clasp arms will be of interest, since evidence supporting the avoidance of clasp arms may improve the appearance and acceptance of the IRRPD.

This body of work has contributed greater insights into the management of the mandibular KCI situation, and in particular, the comparison of the CRPD and IRRPD treatment options. The general outcomes indicate that the IRRPD is superior in terms of function and satisfaction. A staged treatment planning protocol has been proposed, with consideration of the SDA in the first instance. If a dental prosthesis is indicated, the CRPD should be designed using implant treatment planning principles; the metal framework can be designed in a way that will enable implant association in the future if deemed necessary. A staged treatment planning process aims to provide a less invasive and more efficient way of managing the mandibular KCI situation. Patients with

historical issues in accepting CRPDs or younger patients may benefit from progressing directly to the IRRPD (if fixed options are not possible), although this can still be achieved by following the staged approach.

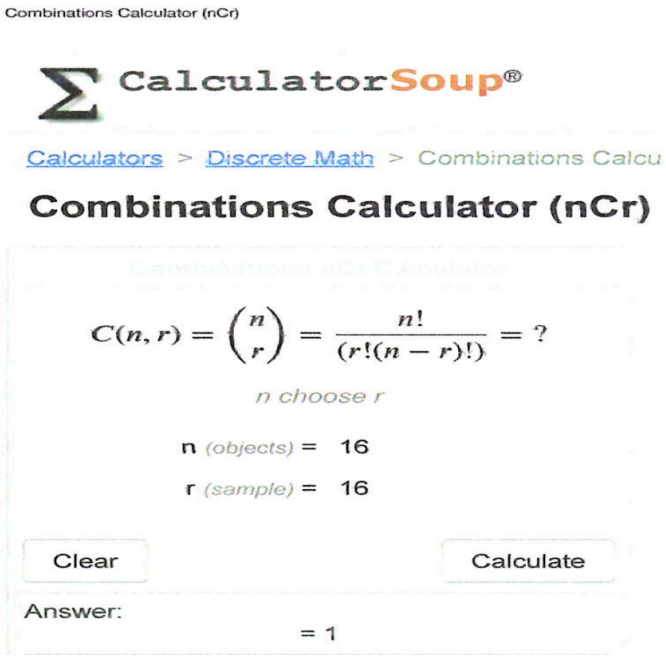
Summary of conclusions:

- When compared head-to-head, the IRRPD was superior to the CRPD in terms of function and impact on OHRQoL and patient satisfaction.
- However, relative to the baseline (SDA) situation, a number of tests failed to achieve significance in favour of either the IRRPD or CRPD.
- The SDA concept should be considered in treatment planning discussions for mild-to-moderate mandibular KCI situations.
- Even though all subjects preferred the IRRPD, this did not always equate to all subjects wanting to continue longer-term with the IRRPD. Some subjects expressed a desire to explore fixed restorative options in the future.
- A staged treatment planning approach can be advocated whereby the dental prosthesis is designed in a manner allowing for future modification. In the event sufficient evidence arises suggesting difficulties in adapting to the CRPD situation (in terms of function and/or OHRQoL and patient satisfaction), implants can be associated to the dental prosthesis.
- Short dental implants were able to support the IRRPD and demonstrated bone responses within normal limits during the trial period.
- Prosthetic complications were few and minor in nature during the trial period.
- Clinical parameters remained stable during the trial period.
- The latter three findings should be viewed with caution due to the short follow-up of this trial.
- Future randomised clinical trials of more standardised and larger sample sizes with longer follow-up time will help to further substantiate the findings of this trial.

The null hypothesis can be partly rejected on the basis that the IRRPD was superior to the CRPD for most objective and subjective measures. However, failure to achieve significance for the Optosil® chewing test, albeit very close, suggests caution with this

rejection. The failure to show clear significant superiority of either denture type to the baseline (SDA) situation also prevents total rejection of the null hypothesis.

Appendix 1



Number of teeth present in arch	Number of combinations
16	1
15	16
14	120
13	560
12	1820
11	4368
10	8008
9	11440
8	12870
7	11440
6	8008
5	4368
4	1820
3	560
2	120
1	16
0	1
Total	**65536**

https://www.calculatorsoup.com/calculators/discretemathematics/combinations.php

Appendix 2 – Plain Language Statement and Trial Consent Form

Within subject crossover prospective clinical study:

Replacing missing back lower teeth with a removable plate that is held in place by dental implants

Introduction

You are being invited to take part in a research project. Taking part in this project is entirely voluntary and your decision. Before you make your decision to join the study, it is important for you to understand why the research is being done and what it will involve. Please take as much time as you need to read the following information carefully and discuss it with friends, relatives and your dentist if you wish. The study has been approved by Human Research Ethics Committees at The University of Melbourne and The Royal Dental Hospital of Melbourne (RDHM).

What is the reason for doing the study?

The reason for doing this study is to see if a removable partial plate held in place with short dental implants can provide a comfortable and useful option for replacing you missing lower back teeth. A dental implant is an artificial tooth root, which is surgically placed into the jawbone, to hold a tooth or plate in place.

What will happen in the study?

You will be treated as a patient of the RDHM Implant and Prosthodontic clinics. During the project, you will receive and wear a removable plate to replace your missing lower back teeth. When you join the project, you will have two short dental implants placed in your lower jaw (one on each side) under local anaesthetic. You will then be allocated into one of two groups. Each group will experience a plate that is held in place by teeth only, and then a plate that is held in place by teeth and dental implants. The order of which plate design you experience first will be randomly assigned. Each plate will be used for a minimum of 6 months. During the project, a number of simple tests will be conducted, such as chewing tests and bite force tests, to test the usefulness of the two plate designs. You will also be asked to complete some simple questionnaires about the comfort and performance of the plates. At the end of the study, you will choose which plate design you want to keep.

Why are you asked to take part in the study and what are the possible benefits to me?

You have been asked to take part because your dentist believes that you will benefit from the replacement of your missing lower back teeth with a removable plate. You will have the opportunity of trying and comparing two removable plate designs, one of which will involve the use of short dental implants. You will then be able to choose and continue with the plate design that you like best.

What will l need to do during the study (and will l need to change my usual dental care)?

We expect you to follow our home care instructions for your new removable plate and to come on time for your booked appointments. During the study, you will undergo some simple tests (i.e. chewing and biting tests) to assess the performance of the plates. You will also be asked to complete some basic questionnaires about the performance of each plate and how happy you are with each of them. Taking part in the study will not affect your usual dental care with your regular dentist.

Will there be additional costs for taking part in the study?

No. The overall cost to the patient will be no different to that when having a normal removable plate made in the RDHM clinics.

What are the possible risks of taking part in this study?

The risks associated with this project are the same as the risks associated with normal implant treatment.

The general risks involved in any type of dental implant treatment include:

- Discomfort and swelling that may necessitate several days of home recuperation following the implant placement surgery.
- Bleeding after the surgery, which in a few instances may require additional treatment.
- Infection after the surgery, which in a few instances may require additional treatment.
- Stretching of the corners of the mouth that could result in some cracking and bruising.
- Breakage of the jawbone.
- Injury to the adjacent nerves resulting in temporary or permanent numbness in the region of sensory distribution. This is more of a risk if the nerves are very close to the site of implant surgery.
- Bruising of the chin, neck, and other tissues in the area where the surgery will be performed.

These risks will be discussed with you by your dentist prior to enrolment in this study. In general, the above risks are relatively rare, and if they do occur, are often temporary and mild in nature.

Do l have to take part in this study?

It is your decision whether or not to take part. If you decide to enrol, you can still withdraw at any time, without giving a reason. If you decide not to take part, or decide later to withdraw, it will not affect the care you would receive at The Royal Dental Hospital of Melbourne or elsewhere.

Who will see my study records?

All research records will be securely stored at The University of Melbourne for a minimum of 15 years and then destroyed. No information will be revealed about your participation in this project, without your permission. The findings from this study may be published; however, the information will be presented in reports in a way that will not allow any individual to be identified by the readers.

To satisfy their legal responsibilities, the investigators and authorized monitors from the sponsors of the study, and The University of Melbourne's Human Research Ethics Committee, will have access to study related information.

What are my rights if something goes wrong?

In the event that you suffer a physical injury or complication that is related to the project, you should notify Dental Health Services Victoria, the principal researcher, and the Clinical Trial Unit at the Melbourne Dental School on (03) 9341 1582. Any unexpected health-related events should be promptly reported to project staff so that any appropriate action can be taken and details of the event recorded. If any participants have concerns about the conduct of this research project, they can contact the Manager, Human Research Ethics, The University of Melbourne: Ph.: (03) 8344 2073; fax: (03) 9347 6739.

Contact for questions?

If you have any questions or problems at any time during this study, you may contact the principal researcher, Dr George Alexopoulos, on 0401198474. In addition, if you would like to speak to someone NOT involved in the study about how the study is being conducted, or about your rights as a study participant, you may call, Human Research Ethics Committee at The University of Melbourne on (03) 8344 2073.

About the investigators (Researchers)

The study will be conducted by a post-graduate student researcher who is a qualified dentist. This study will form a major component of the PhD research project being undertaken by the researcher (at the Melbourne Dental School - The University of Melbourne). The student researcher will be under direct supervision from staff researchers of The University of Melbourne.

- Dr George Alexopoulos (Principal Researcher)
  Ph: 0401198474 Email: georgeca@student.unimelb.edu.au
- Associate Professor Roy Judge (Supervisor)
  Ph: (03) 9341 1531 Email: roybj@unimelb.edu.au
- Associate Professor Menaka Abuzar (Supervisor)
  Ph: (03) 9341 1495 Email: maabuzar@unimelb.edu.au
- Associate Professor Joseph Palamara (Supervisor)
  Ph: (03) 9341 1532 Email: Palamara@unimelb.edu.au

Informed Consent Form

Participant
I have read, or have had read to me, and l understand the Information Brochure.

I have been given the chance to ask questions and discuss my participation in the study. I freely and voluntarily chose to be in this research project.

I will be given a copy of the Information Brochure and signed Consent Form to keep.

I agree that:

- The possible effects of this research and procedures have been explained to me to my satisfaction.
- The overall treatment l will receive will provide me with a solution for managing my missing lower back teeth. The two options used in this study are based on conventional removable partial dentures, with one of the options having support provided by dental implants. The treatment will require a minimum of 14 visits over a three-year period (this includes annual reviews).
- My dentist will collect information regarding procedures and my visits via clinical examinations, simple tests, and completion of questionnaires. Radiographs (x-rays) will be taken during some visits (in-line with standard practice for implant dentistry).
- The involvement in the project is voluntary and l am free to withdraw at any time, and free to withdraw any unprocessed identifiable data previously supplied without explanation or prejudice.
- The study is for the purpose of research and treatment.
- The confidentiality of any information provided by me will be safeguarded subject to any legal requirements.

My full name: _____

Signature: _____

Date: _____ / _____ / 20 _____

Investigators: Dr George Alexopoulos, A/Prof. Roy Judge, A/Prof Menaka Abuzar, and A/Prof Joseph Palamara

Subject Number: Subject Initials:

Clinical Trials Unit Melbourne Dental School, Faculty of Medicine, Dentistry, and Health Sciences, The University of Melbourne, Victoria 3010, Australia

Appendix 3 – Consent Form For Photography

dental health services victoria

UR Number: _____

Surname: _____

Given Name: _____

DOB: _____

AFFIX PATIENT LABEL HERE

Consent to Photography

Patient's Name: _____

Guardian's Name (If applicable): _____

Use of photographic images

Dental Health Services Victoria (DHSV) may need to take photographs of patients to assist in treatment. Other reasons for wishing to take photographs of patients are to facilitate teaching or dental research. Your dental clinician will explain the need for photographs. All photographs are taken with DHSV cameras and securely stored on the DHSV computer system. Your privacy, as with all medical and dental records is maintained at all times

---

CONSENT

I consent to my photograph being taken for the purposes explained to me by my dental clinician and I understand how and where my photographs / images will be used.

I acknowledge that (please tick):

- ☑ I have been informed that the confidentiality of my personal and health information will be safeguarded.
- ☑ Photographs / images may be used for treatment planning for a course of dental care and will be stored as a part of my dental record.
- ☑ I have been informed that I am free to withdraw my consent or my agreement to have photographs taken, and that this will not prejudice any ongoing treatment

I give my permission for (please tick):

Yes	No	
☑	☐	A representative of DHSV or University of Melbourne Dental Student to take the photographs.
☑	☐	Photographs / images to be used for teaching purposes (including lectures).
☑	☐	Photographs / images to be used in case presentations and case log books for students requiring this information for examination purposes. .
☑	☐	Photographs / images to be used for research. Only research that has been approved by either the University of Melbourne or DHSV Ethics Committee will be able to use the photographs / images.

I _____ have read this form and understand how my (or my child's) images will be used and disclosed.

Signed: X _____ **Full Name:** _____ (Please Print)

Relationship to Patient: _____ **Date:** ___/___/___

Oral Health for Better Health www.dhsv.org.au

ABN: 55 284 581 977

Appendix 4 – OHIP-14 Questionnaire

The OHIP-14 (modified for denture wearers) questionnaire

The following part of the questionnaire aims to assess the impact of dental problems on your quality of life **during the past 6 months**. Please indicate the frequency of symptoms and difficulties experienced **by placing a tick in the appropriate box**.

During the last 6 months,	**Never**	**Hardly ever**	**Occasionally**	**Fairly often**	**Very often**
1. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?					
2. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures					
3. Have you had a painful aching in your mouth?					
4. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?					
5. Have you been self-conscious because of your teeth, mouth or dentures?					
6. Have you felt tense because of problems with your teeth, mouth or dentures?					
7. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?					
8. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?					
9. Have you found it difficult to relax because of problems with your teeth, mouth or dentures?					

10. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?					
11. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?					
12. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?					
13. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?					
14. Have you been totally unable to function because of problems with your teeth, mouth or dentures?					

Thank you for your participation

Appendix 5 – Visual Analogue Scale Questionnaire

QUESTIONNAIRE – Comfort/Chewing/Retention/Stability

Date: **Test situation: BL / D1 / D2 / R1 / R2**

Subject:

Please place a cross (X) along the line based on your perception of each variable.

In general, are you satisfied with the **comfort** of your lower denture?

Not at all satisfied _____ Totally satisfied

In general, are you satisfied with your **chewing ability** using your lower denture?

Not at all satisfied _____ Totally satisfied

In general, are you satisfied with the **retention** of your lower denture?

Not at all satisfied _____ Totally satisfied

In general, are you satisfied with the **stability** of your lower denture?

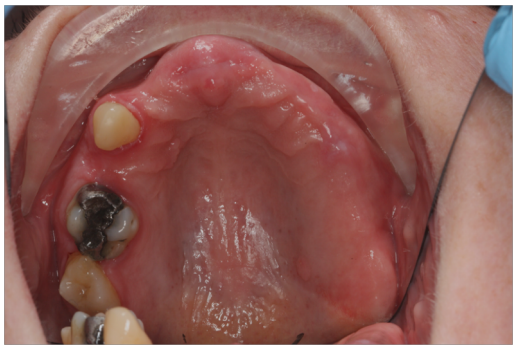
Not at all satisfied _____ Totally satisfied

In general, are you satisfied with your lower denture?

Not at all satisfied _____ Totally satisfied

APPENDIX 6 – Photographs Illustrating Methods

Subject BP



Occlusal view – upper arch



Occlusal view – lower arch



Occlusal view – upper arch with new P/- inserted



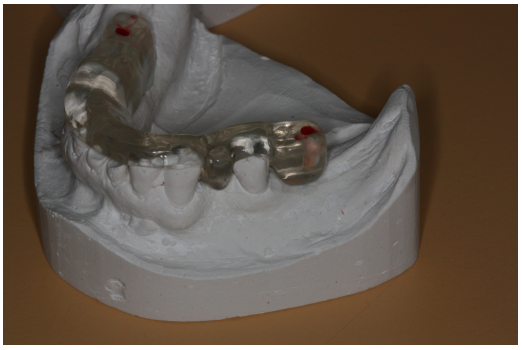
Left lateral view with new P/- inserted



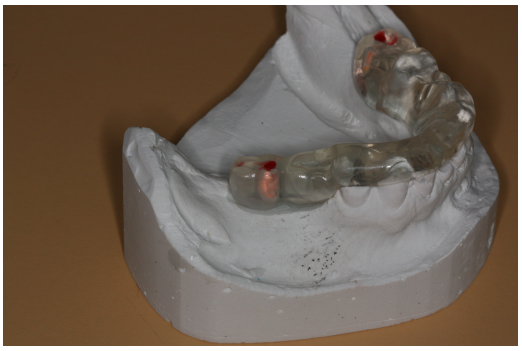
Frontal view with new P/- inserted



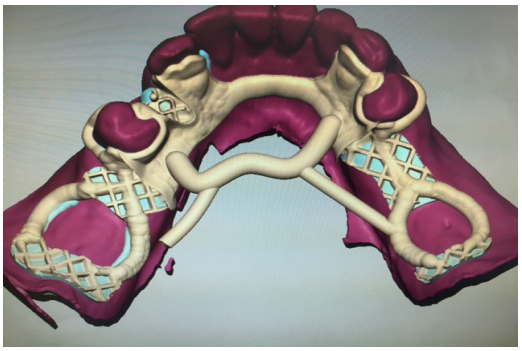
Lower cast with seated radiographic/surgical stent



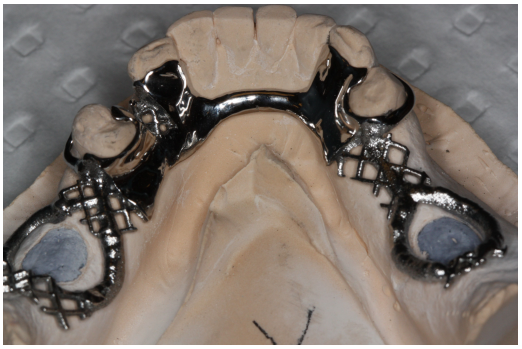
Lower cast with seated radiographic/surgical stent – left aspect. Note: radiopaque gutta percha inserted into first molar site with red wax sealing the chamber.



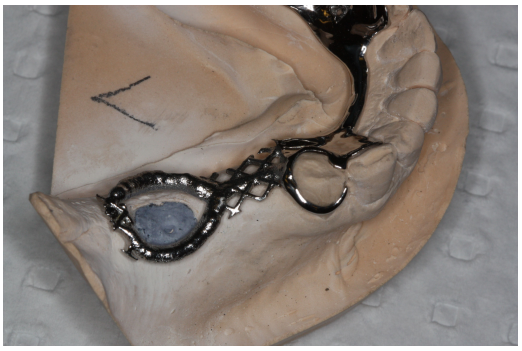
Lower cast with seated radiographic/surgical stent – left aspect. Note: radiopaque gutta percha inserted into first molar site with red wax sealing the chamber.



Framework - Computer Assisted Design



Cast-metal framework seated on cast



Cast-metal framework seated on cast – right lateral aspect. Note ring clearance for future Locator™ retention cap



Cast-metal framework seated on cast – right lateral aspect. Note ring clearance for future Locator™ retention cap



Occlusal view of the final mandibular removable partial denture



Tissue-aspect view of the final mandibular removable partial denture



Occlusal view – final mandibular removable partial denture



Frontal view with new mandibular removable partial denture inserted



Lower arch demonstrating dental implant locations



Tissue-aspect of -/P with acrylic removed in areas where Locator™ retention caps will be inserted



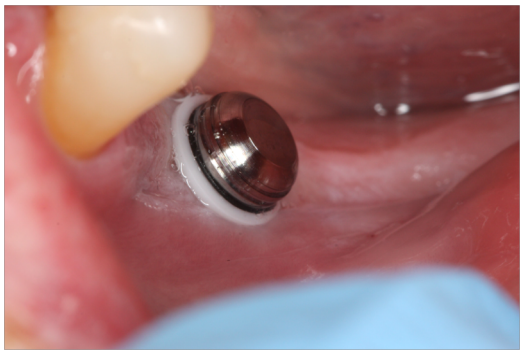
Access hole for flowable acrylic (for intra-oral pick-up of Locator™ retention cap) – left side



Access hole for flowable acrylic (for intra-oral pick-up of Locator™ retention cap) – right side



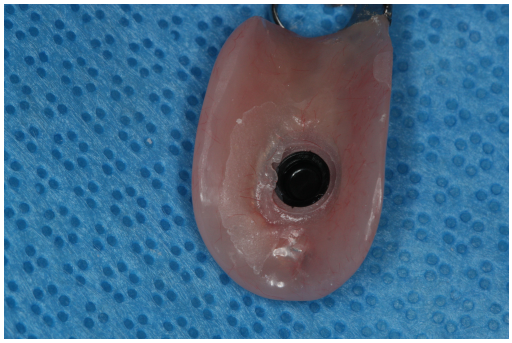
Locator™ retention cap seated on abutment – right side. Note the white spacer ring



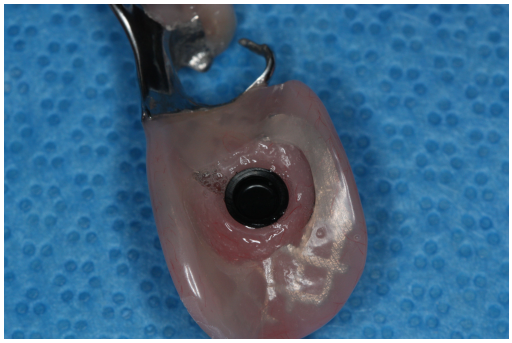
Locator™ retention cap seated on abutment – left side. Note the white spacer ring



Locator™ retention caps incorporated into denture. Black processing nylons still present



Locator™ retention cap incorporated into denture. Black processing nylon still present. Right aspect



Locator™ retention cap incorporated into denture. Black processing nylon still present. Left aspect



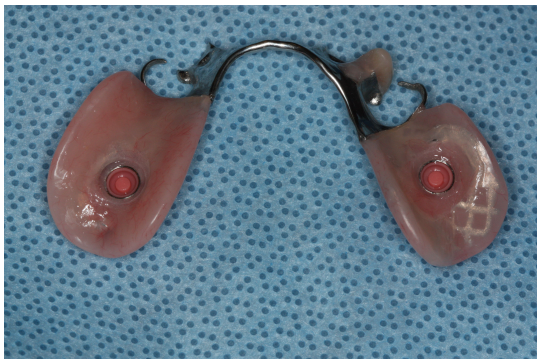
Locator™ retention cap incorporated into denture. Acrylic has closed the access hole. Left aspect



Locator™ retention cap incorporated into denture. Acrylic has closed the access hole. Right aspect



Tissue-aspect with Locator™ caps incorporated. Black processing nylons still present. Excess acrylic removed and polished



Tissue-aspect with Locator™ caps incorporated. Black processing nylons replaced with pink Locator™ retentive nylons

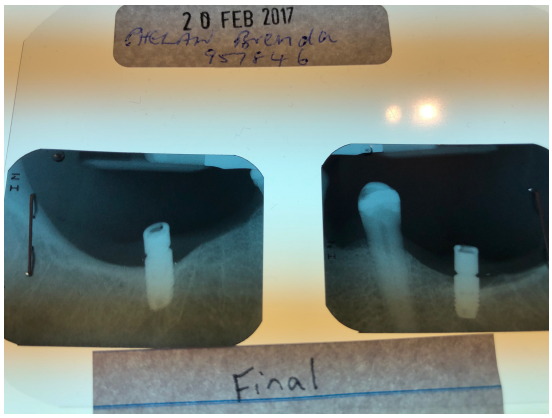


Photo of periapical radiographs showing implants with Locator™ abutments placed

Subject JK



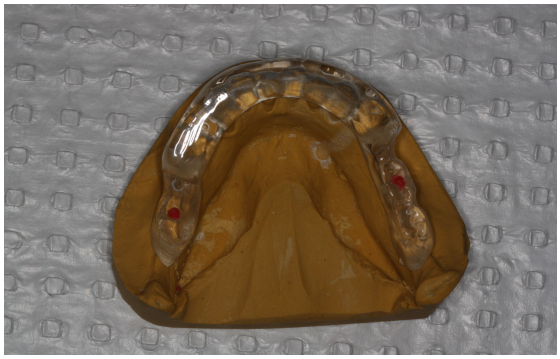
Occlusal view of upper arch – tooth 16 restored by implant (after external sinus elevation procedure)



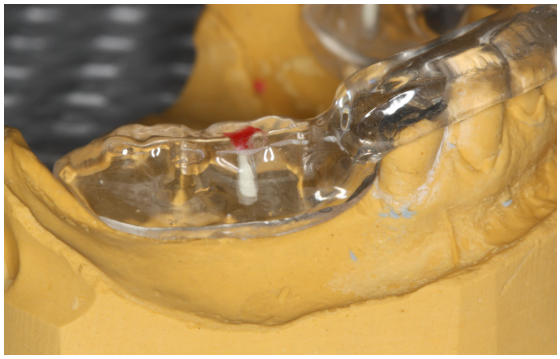
Occlusal view of lower arch – note: tooth 35 was extracted prior to lower denture construction to advance attachment loss and mobility



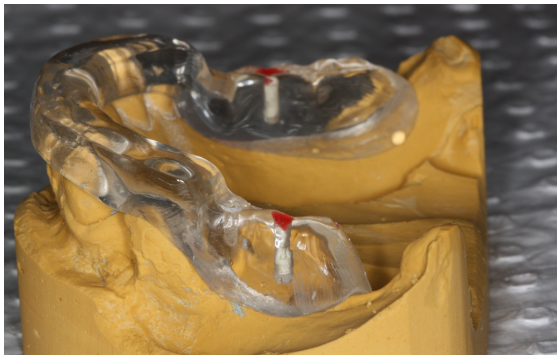
Frontal view on smile. The patient has a history of multiple restorations to upper dentition, including implants and fixed partial dentures.



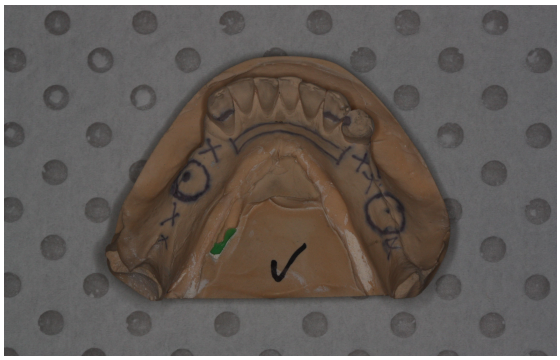
Radiographic stent/surgical guide – note the red wax covering the sites filled with radiopaque gutta percha. These sites correspond to the lower first molar positions



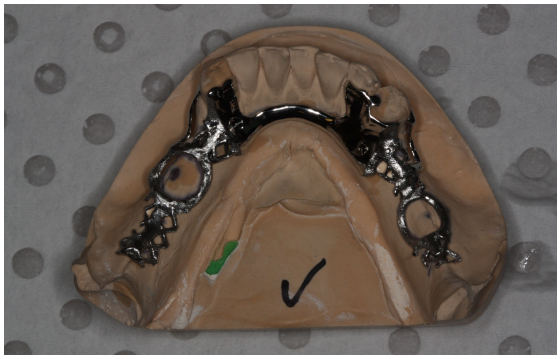
Gutta percha placed in site 46



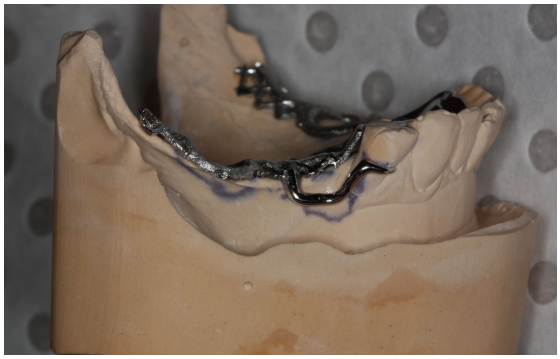
Another aspect of the radiographic/surgical stent



Lower cast with markings indicating the approximate implant positions



Cast metal framework sitting on the master cast. Note the rings present to allow accommodation of the Locator™ retention mechanism



Cast metal framework sitting on the master cast – right aspect



Cast metal framework sitting on the master cast – left aspect



Cast metal framework *in situ* – right aspect



Cast metal framework *in situ* – left aspect



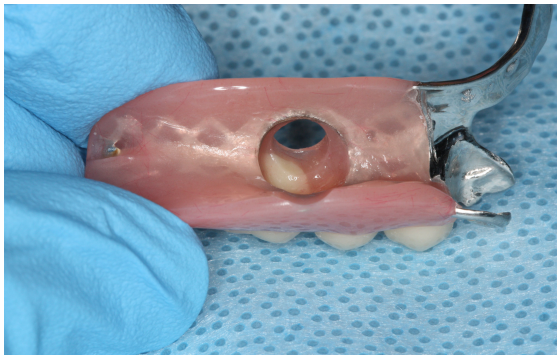
Periapical radiographs of implants with Locator™ abutments



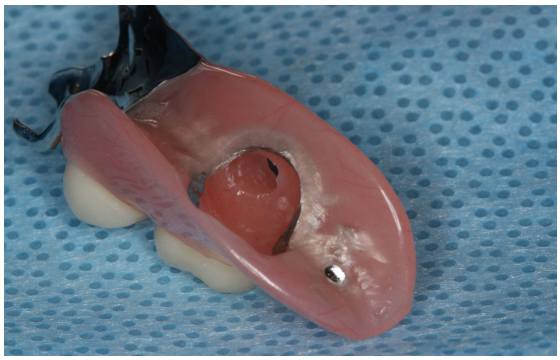
Access channel - providing avenue for flowable acrylic to be inserted into denture to enable intra-oral pick-up of the Locator™ retention cap (left side)



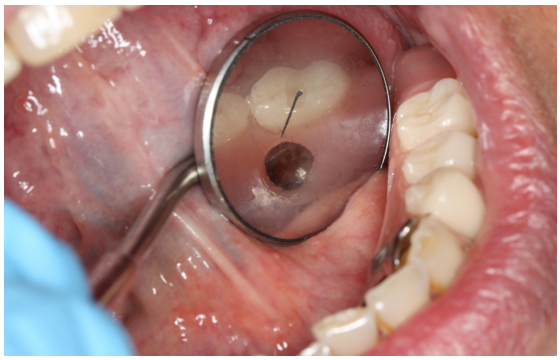
Access channel - providing avenue for flowable acrylic to be inserted into denture to enable intra-oral pick-up of the Locator™ retention cap (right side)



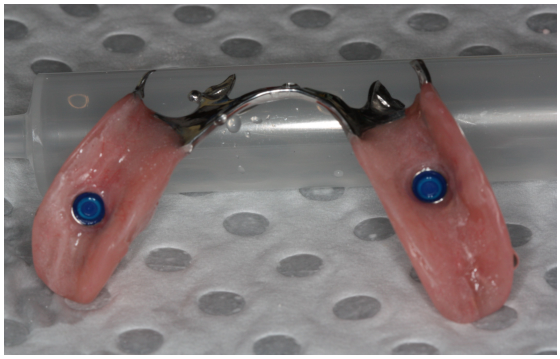
Access channel - providing avenue for flowable acrylic to be inserted into denture to enable intra-oral pick-up of the Locator™ retention cap (left side) – view from underside



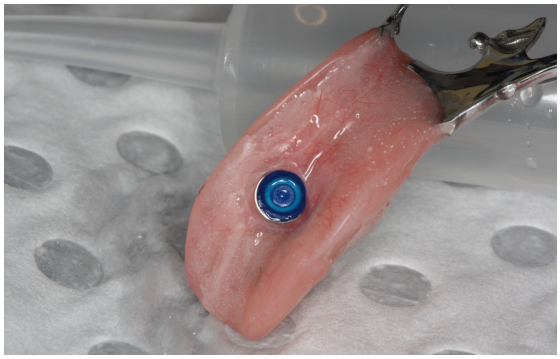
Access channel - providing avenue for flowable acrylic to be inserted into denture to enable intra-oral pick-up of the Locator™ retention cap (right side) – view from underside



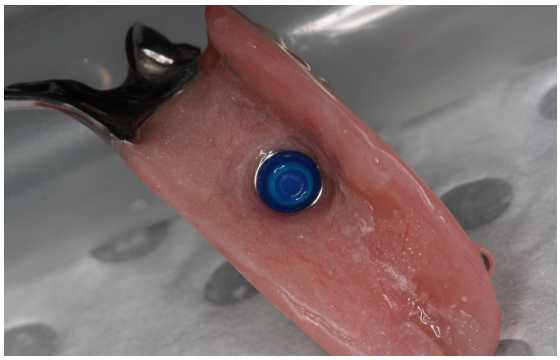
Mandibular removable partial denture seated – top of Locator™ retention cap can be seen through access channel



Underside of denture after pick-up of Locator™ retention caps (with chemically activated polymerisation acrylic). The blue Locator™ nylons have been selected for this subject



Underside of denture after pick-up of Locator™ retention caps (with chemically activated polymerisation acrylic) – right side. The blue Locator™ nylons have been selected for this subject



Underside of denture after pick-up of Locator™ retention caps (with chemically activated polymerisation acrylic) – left side. The blue Locator™ nylons have been selected for this subject



Mandibular removable partial denture *in situ*



Mandibular removable partial denture *in situ* – left side



Mandibular removable partial denture *in situ* – right side

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