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Title Page

Three-Dimensional Printing in Oral and Maxillofacial Surgery: Current Landscape and Future Directions

Running title: 3D printing in oral and maxillofacial surgery

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Abstract

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Three-dimensional (3D) printing technology continues to develop at a rapid pace, with the potential to revolutionise multiple industries and fields including medicine. Oral and maxillofacial surgeons are particularly well placed to advance and integrate this technology into practice. This review provides a summary of 3D printing and discusses the current and future applications of this technology in oral and maxillofacial surgery, including the production of surgical planning models, training tools, cutting guides and personalised implants. While early research is promising, there still remains a paucity of large scale, well controlled clinical studies supporting the use of 3D printing technologies for many of these applications. There are also a number of other technical and regulatory challenges which will need to be addressed as this technology is taken up more widely.

Keywords

3D printing, 3D printed medical device, personalised implant, personalised surgery

Introduction

Three-dimensional (3D) printing technology, also known as additive manufacturing or rapid prototyping, refers to the process of constructing an object from a 3D digital model by successively adding material in layers. Since the introduction of 3D printing in the 1980's, applications for this technology have grown to include the automotive,¹ aerospace² and consumer goods industries³ as well as the medical and dental sciences.⁴ Innovations in medical 3D printing have attracted significant attention, especially within oral and maxillofacial surgery,⁵ due to the ability to digitally recreate highly precise complex bony anatomy and produce patient-specific medical devices in a timely and cost-efficient manner.⁶ ⁷ The objective of this review is to summarise 3D printing science and explore current and emerging applications of this technology in contemporary oral and maxillofacial surgery practice.

Overview of the 3D Printing Processes

Secure transfer, processing, and digital reconstruction of anatomic scans are the first steps in the process of 3D printing. Whilst this usually takes the form of a fine-slice computed tomogram (CT) due to superior hard tissue contrast and spatial resolution, magnetic resonance imaging (MRI) has been shown to be useful for virtual surgical planning in situations where ionising radiation may be contraindicated.^{8,9} More recently, cone-beam

computed tomography (CBCT) has gained popularity in the diagnosis and management of conditions involving bone or teeth, due to good hard tissue image quality and lower radiation dose compared with conventional CT imaging.¹⁰ Resulting imaging data is reconstructed in two-dimensional (2D) grey scale images that are usually saved in Digital Imaging and Communications in Medicine (DICOM) file format. Anatomical tissues are delineated by digital image segmentation, and a virtual 3D surface model is generated, usually in the format of a Standard Tessellation Language (STL) file. Accurate imaging and reconstruction of teeth can be difficult via these modalities, partly due to image resolution but also the different radiodensities of enamel, dentine, restorative material and orthodontic brackets. While modified imaging protocols have been developed,¹¹ it is still commonplace to reimagine the dentition using digital scanners, either intraorally or from dental casts and integrate these into the 3D STL reconstruction.¹² 3D reconstructions can then be used to design medical devices using specialised proprietary computer-aided design (CAD) software. Depending on the application, the oral and maxillofacial surgeon may be involved at this stage of design. The final model is exported to the printer, usually as an STL file, in order to generate a G-code which contains specific commands for printing. Depending on the application and material to be used, different 3D printing techniques can be utilised. The printed object will then usually undergo further post-printing processing, which can include removal of support structures, heat treatment, polishing and finishing, all of which can add significant time and cost to overall workflow. The final product may then undergo sterilisation depending on its planned use (Figure 1).

3D Printing Techniques and Materials

The most common 3D printing techniques employed in medicine are stereolithography, fused deposition modelling, powder bed fusion processes, and inkjet printing processes¹³ (Figure 2). Available materials vary depending on the technique chosen (Table 1).

Stereolithography

Stereolithography is the earliest 3D printing technology described in medicine.¹⁴ Liquid photopolymer in a tank is cured using UV laser, and as the build platform descends, the next layer is then cured. The main advantage of stereolithography is very high resolution, with smooth surface finishes, while the main disadvantages are that the process is slow, material choice is limited, and supporting structures must be manually removed post production.¹⁵

Fused Deposition Modelling

In fused deposition modelling, a continuous filament of thermoplastic polymer is heated to reach a semi-liquid state and then extruded in single plane. The build platform descends, and a new layer is deposited on top of the previous layer. Filaments fuse together and solidify at room temperature. The main advantages of fused deposition modelling are low start-up and production costs and high speed of production, while the main disadvantages include weak mechanical properties, a layer-by-layer appearance and retained support structures requiring removal.¹⁶

Powder Bed Processes

Thin layers of fine powders of thermoplastic, metal, glass or ceramic are fused together in powder bed fusion processes using high power laser beams, which move in a single plane. As the build platform descends, a new layer of powder is applied, and the layer-by-layer fusion process continues. Selective laser sintering is a variation of this process, where, powders are not fully melted, but instead heated sufficiently to allow individual grains to fuse. This can result in a porous material, or one that contains large numbers of microvoids.¹⁷ In selective laser melting (SLM), powders are fully melted and fused together resulting in higher density materials and mechanical properties similar to the billet material.¹⁸ Electron beam melting is similar to SLM except a high-powered electron beam is used to fuse powders under vacuum conditions.¹⁹ Compared with other 3D printing techniques, powder bed processes have superior mechanical properties, making them most suitable for constructing maxillofacial and other biomedical implants.²⁰ The main disadvantages of powder bed techniques are that the process is slow, costly and usually requires large scale commercial equipment prohibiting its use for many smaller healthcare institutions.¹⁶

Inkjet Printing Processes

The two primary inkjet printing processes are binder jet printing and material jetting. Binder jet printing is similar to powder bed fusion; however, rather than a high-powered laser or electron beam fusing powders directly, a printer head ejects a binder, joining powders together. The build platform descends, a new layer of powder is applied, and the process continues. A wide range of materials, including metals, can be used and support structures are not required. The major disadvantages include poor mechanical properties compared powder bed technologies, making it less suitable for building implantable medical devices.²¹ In material jetting, a printer head, moving in a single plane, sprays a photopolymer in layers, which is simultaneously cured by a UV lamp. The build platform gradually descends, as

layers are deposited one on top of the other. Supporting gels can simultaneously be printed for removal post-production. Material jetting can use different materials for different parts of the object. Major disadvantages include high cost and a limited range of photopolymerisable materials available.²²

3D Printing in Oral and Maxillofacial Surgery

Surgical Planning and Reference

3D printing in maxillofacial surgery was popularised in the 1990's, primarily for printing of anatomical biomodels to assist in surgical planning of patients with severe craniomaxillofacial deformities.²³ The use of biomodels has since spread to other domains of oral and maxillofacial surgery, including orthognathic surgery,²⁴ head and neck oncology,²⁵ and complex maxillofacial trauma.²⁶ Both hard and soft tissue modelling is possible, with the ability to colourise pathology or other structures of interest (Figure 3).²⁷ 3D printed models can be used to enhance the interpretation of volumetric image data, optimise surgical planning, as a reference during surgery, and for presurgical adaptation of hardware.²⁸ Importantly, 3D printed models are also highly accessible, as they are generally not subject to medical device regulation. High level evidence for the use of 3D printed models is scarce, in part due to the tendency for most centres to reserve 3D printing for highly complex cases only. One randomised controlled trial used 3D models to preoperatively simulate surgery in patients with head and neck tumours. The authors demonstrated reduced surgical time, reduced donor site morbidity and improved patient reported cosmesis, compared with standard preoperative planning.²² Questionnaire based studies in surgeons using 3D models to plan craniomaxillofacial surgery have reported similar benefits subjectively.^{29, 30}

Today surgical planning is increasingly being completed digitally via virtual surgical planning (VSP) technologies. VSP shares many of the benefits of 3D printed models including detailed visualisation of the craniomaxillofacial complex and the ability to simulate surgeries preoperatively, however VSP is much more accessible and often more versatile compared to 3D printing, and avoids the cost and time associated with 3D printed models.³¹ As VSP technologies continue to be taken up by oral and maxillofacial surgeons, it is likely that 3D printed models for planning or surgical reference will become less common.

Custom Surgical Guides

Custom surgical guides are employed frequently across multiple surgical specialties to allow for more accurate surgical resections, osteotomies or implant placement, and to reduce surgical time.⁵ Benefits of 3D printing surgical guides include better integration with virtual

surgical planning protocols, improved versatility and lower production cost compared with conventional fabrication processes.³² Two randomised controlled trials have shown increased accuracy of dental implant placement and improved clinical outcomes using 3D printed guides compared to unguided surgery, with other additional advantages including avoidance of raising a mucoperiosteal flap, and the possibility of immediate implant loading using a prefabricated fixed prosthesis based on planned implant position.^{33, 34}

3D printed occlusal splints and cutting guides are also used widely in orthognathic surgery. A number of small retrospective cohort studies have shown that the use of 3D printed occlusal splints achieves similar surgical accuracy compared to facebow and model surgery, with a possible additional benefit in cases with a high degree of left-right asymmetry or an unstable condylar position.^{35, 36} Despite increased uptake, there remains a paucity of high-quality evidence investigating the efficacy of cutting guides in orthognathic surgery, with most publications either presenting surgical protocols or a case reports.³⁷⁻⁴² One recent randomised trial of 21 patients demonstrated improved accuracy and reduced surgical time for bimaxillary orthognathic surgery using virtual surgical planning, 3D printed splints and prebending bone plates compared with conventional treatment.⁴³ Multiple prospective cohort studies have supported these findings.^{44, 45} Another randomised, split-mouth trial showed improved neurosensory function associated with 3D printed cutting guides compared with unguided surgery in bilateral sagittal split ramus osteotomies, however this study was limited by a small sample size and short follow-up period.⁴⁶

Surgical cutting guides are also used for bone grafts in reconstructive surgery of the maxillofacial complex. One common application is for segmental mandibular reconstructions with vascularised free flaps following severe trauma or after resection of pathology. In these cases, cutting guides can be used for both maxillofacial and donor site osteotomies (Figure 4). In oral and maxillofacial surgery, free fibula flap reconstructions are the most common and well researched, with one small randomised controlled trial and a number cohort and case control studies showing that use of 3D printed cutting guides for maxillofacial reconstruction results in reduced ischemic time, reduced surgical time and improved surgical accuracy.⁴⁷⁻⁵⁵ A randomised controlled trial of 20 patients found similar benefits using 3D printed cutting guides in vascularised iliac crest graft mandibular reconstructions.⁵⁶

Virtual treatment planning and 3D printed cutting guides have been widely used in calvarial vault remodelling for craniosynostosis. In these cases, templates and cutting guides based on idealised craniofacial morphology can be 3D printed preoperatively instead of relying on the surgeon's subjective perception of normal morphology intraoperatively. A number of retrospective case-control studies have shown that the use of 3D printed templates for calvarial reconstruction results in improved post-operative outcomes and shorter surgical times.^{57, 58} Further larger scale, prospective studies would help validate the benefits of 3D printed surgical guides in this context.

Personalised Implants and Prostheses

Personalised medical implants may be patient-specific whereby they are custom made for sole use in a particular patient, or patient-matched whereby an implant is matched to a patient's anatomy within a specified design envelope. This distinction is highly relevant to the regulatory and legal requirements of medical devices in different jurisdictions. In the UK, under the European Medical Device Regulations,⁵⁹ patient-matched implants, which are typically mass produced, are subject to a higher level of regulation, requiring manufacturers to have a formal quality management system and certification mark. This review refers to patient-specific and patient-matched implants together as "personalised implants".

Personalised implants are being used across oral and maxillofacial surgery to improve surgical outcomes for routine surgeries but also to treat complex conditions which would be otherwise unamenable to conventional therapies. Titanium remains the metal of choice for 3D printing maxillofacial implants and has wide regulatory approval. It has the advantages of high strength, good biocompatibility, and the potential for osteointegration.⁶⁰ To date, the main non-resorbable polymers used in maxillofacial implants are high molecular weight polyethylene and polyether ether ketone (PEEK), which are chosen due to similar strength and elasticity to bone.⁶¹ The manufacture of PEEK implants has been previously limited mainly to subtractive manufacturing processes. More recently PEEK 3D printing has allowed construction of more complex geometry, with hollow or lightweight biomimicking designs that cannot be manufactured using alternative technologies.⁶² A disadvantage of both polyethylene and PEEK is that they have potentially higher rates of infection and foreign body reaction compared with titanium.⁶³ A limited number of resorbable implant materials are also available such as poly D, L-lactic acid (PDLA) and poly lactic-co-glycolic acid (PLGA) which are typically reserved for paediatric patients.⁶⁴ Achieving approval for other new materials remains a major regulatory challenge.

Surgical plates and screws are used to stabilise bone segments in oral and maxillofacial surgery. Conventionally, surgical plates are mass-produced and require manual manipulation in order to match bony anatomy intraoperatively. This can be time consuming, especially for inexperienced surgeons.⁶⁵ Repeat bending of surgical plates can alter the mechanical properties resulting in an increased risk of complications, such as plate fracture.⁶⁶ 3D printed, personalised surgical plates and screws attempt to address these issues (Figure 5). A number of small, retrospective studies have shown personalised 3D printed surgical plates to significantly reduce total surgical time and improve surgical accuracy in head and neck cancer surgery and orthognathic surgery.⁶⁷⁻⁷⁰

In oral and maxillofacial surgery, personalised reconstructive implants have been used to successfully restore form and function in cases that may not otherwise be amenable to conventional treatment. Benefits of personalised reconstructive implants in these cases include improved surgical accuracy, improved cosmesis, the ability to restore large and geometrically complex anatomical defects, reduction in operative times and the ability to perform resection and reconstruction in one step.^{61, 71} Currently, evidence is limited to proof-of-concept studies and case reports. Some common applications of personalised implants include cranioplasty and restoration of large maxillary, mandibular and zygomatic defects.⁷²⁻

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Orbital wall reconstructions have conventionally been managed by intraoperative shaping of autologous bone grafts or by manual manipulation of stock implants. Especially in large defects or in revision surgery, this can be difficult because of the complex 3D anatomy of the orbit and because slight malpositioning of the graft or mesh can result in enophthalmos or other complications.⁷⁹ Prebending stock implants preoperatively using 3D printed models has already been shown to improve postoperative outcomes and reduce total surgical time in a several cohort studies,^{79, 80} however evidence for personalised 3D printed orbital implants (Figure 6) remains limited. One small randomised controlled trial demonstrated reduced postoperative enophthalmos associated with 3D printed titanium mesh compared with intraoperative manipulation of stock mesh, however this study was limited by a small sample size.⁸¹ Larger scale studies are required to support these findings and outline a future role for 3D printing technology in orbital reconstruction.

Until recently, a major shortcoming of TMJ replacement surgery has been the limitations of stock TMJ components, which may not conform well to the wide range of jaw morphologies and hard tissue pathologies that patients requiring TMJ replacement may present with.

Advancements in 3D manufacturing technology have facilitated the development of personalised TMJ implants (Figure 7) which are more anatomically acceptable, especially in cases of severely degenerated or distorted mandibular condyles or in cases of significant skeletal malocclusion.⁸²⁻⁸⁴ Preliminary outcomes for 3D printed TMJ implants are promising^{84, 85} with further larger scale, comparative studies required in order to support their use over alternative technologies.

While endosseous dental implants provide a highly predictable solution for prosthetic rehabilitation in cases of partial or total edentulism,⁸⁶⁻⁸⁹ bone volume and quality can limit their application.⁹⁰⁻⁹² An emerging role for 3D printing is in the fabrication of personalised subperiosteal implants for prosthetic rehabilitation in these cases (Figure 8). Subperiosteal implants were popular from the 1940's to the 1980s,⁹³ however suffered from a number of major shortcomings, including a relatively morbid impression stage requiring extensive surgical skeletisation, and complex laboratory construction. 3D printed subperiosteal implants allow for single step prosthetic rehabilitation, without the need for complex adjunctive bone augmentation procedures which may otherwise be required.⁹² A limited number of outcome studies have been published on 3D printed subperiosteal implants, reporting failure rates of 0-2.1% per year.^{94, 95} However, these are limited by small, highly selective samples and short follow up periods. Larger prospective studies with longer follow up periods are required prior to wider uptake.

A recurring limitation to current research in 3D printed maxillofacial implants is the absence of large-scale clinical trials, which are difficult or impossible to conduct for many highly bespoke devices. An emerging solution is through the use of personalised musculoskeletal models and simulations, which can be used for evaluating the functional performance of an implant prior to printing and implantation. In oral and maxillofacial surgery, this is particularly important for implants that are subject to masticatory forces and are subsequently at high risk of mechanical failure.⁹⁶ Musculoskeletal models can be used to simulate muscle and joint loading on a subject-specific basis in order to evaluate the load-response of the implant and assess the effect of different design parameters, including implant size, shape and material properties. They also facilitate assessment of the influence of implant malposition,

screw fixation and other surgical variables on implant function and device longevity.⁸³ In the future, these processes may give clinicians more confidence in the safety and efficacy of personalised implants and eventually form part of the regulatory approval process for these devices.

Education and Training

3D printed models and devices can be used to teach anatomy and for practicing procedures on patient-specific replications with a high degree of anatomical and structural fidelity consistent with live tissue and important disease processes. As a tool for anatomy education, 3D printed models have the advantage of being cheaper than cadaveric material, show anatomical variation and are not subject to legal barriers relating to transportation, importation and licensing, making them an attractive option for medical educators. One randomised controlled trial showed improved learning efficiency using 3D printed skulls compared with cadaveric skulls and atlases in a cohort of medical students.⁹⁷

3D printed models are also being used for procedural training across a range of oral and maxillofacial surgery procedures, including third molar surgery, maxillary sinus lifts, mandibular reconstructions, skull base surgery, craniofacial surgery and facial trauma⁹⁸⁻¹⁰³ with many more applications feasible. Of the handful of studies directly comparing 3D printed models of head and neck structures to corresponding cadaveric and animal specimens, all report realistic mechanical and handling properties.¹⁰⁴⁻¹⁰⁷ Other advantages of 3D printed models compared with existing simulation technologies include lower cost and greater customisability.¹⁰⁵ Currently, 3D printed models for surgical training in oral and maxillofacial surgery have mainly focussed on replicating bone, with polycarbonate materials probably representing the best compromise between anatomical and mechanical accuracy, visual and surface appearance and production cost.¹⁰⁴

Tissue Engineering and 3D Bioprinting

An emerging application for 3D printing is in tissue engineering and regeneration, with the goal of developing personalised, living tissue constructs for reconstructive surgery, without the donor site morbidity associated with autogenous tissue grafts. The technical aspects of 3D printing biological tissues is outside the scope of this review and have been described in detail previously.¹⁰⁸⁻¹¹¹ Briefly, there are two main methods commonly employed: printing acellular scaffolds which are later seeded with cells prior to implantation, or printing living tissue with spatial control of the functional components, the latter termed “3D bioprinting”.¹¹²

Early studies using 3D printed bone scaffolds for treating calvarial, mandibular and maxillary bone defects in animal models, suggest improved angiogenesis, bony ingrowth and bone regeneration compared to non-biological controls.¹¹³⁻¹¹⁶ These findings have also been replicated using direct, in-situ, bioprinting techniques.¹¹⁷ 3D printing other tissue types such as skin¹¹⁸⁻¹²² and cartilage¹²³⁻¹²⁶, similarly show promise, however research in this field is still in the preclinical phase.

Conclusion

There is now a wide range of applications for 3D printing in oral and maxillofacial surgery including in the production of surgical planning models, training tools, cutting guides and personalised implants. As useability and accessibility increase, it is likely that oral and maxillofacial surgeons will engage more with these technologies. Current technical challenges include increasing the quantity and diversity of materials available, which to date have been limited by the need to use proprietary materials from the printer manufacturer, and challenges in gaining regulatory approval for the use of new biocompatible materials.¹²⁷ Also, advancements in post-printing processing, especially in the removal of support structures, will assist in speeding up the manufacturing process.¹²⁸ In oral and maxillofacial surgery, there remains a paucity of high quality, well controlled studies demonstrating the benefits of 3D printing techniques over conventional therapies. This may be offset in some ways through patient-specific musculoskeletal modelling and simulations, which are becoming increasingly advanced and computationally efficient. Simultaneously, a number of past and current applications for 3D printing, for example 3D models for preoperative planning, may become less common, as they are superseded by other emerging technologies such as virtual treatment planning and virtual reality simulations. Regulatory bodies must continue to balance advancement and access of 3D printing technologies for personalised surgery with the need to protect the public from bespoke devices without adequate testing or evaluation.

Conflict of interests

The senior author (G.D.) holds shares in OMX Solutions Pty Ltd.

Co-authors (S.F. and N.W.) are employed by OMX Solutions Pty Ltd.

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Figure Captions

Figure 1: Typical workflow for the production of a 3D printed medical device in oral and maxillofacial surgery

Figure 2: Main 3D printing techniques including (A) fused deposition modelling, (B) powered bed fusion, (C) stereolithography and (D) material jetting.

Figure 3: A composite 3D printed mandible showing the inferior alveolar nerve (coloured).

Figure 4: Surgical cutting guides for mandibular reconstruction showing (A) preoperative mandible model with a large right sided ameloblastoma (colourised), (B) preoperative fibula with 3D printed cutting guide in place and (C) planned postoperative mandibular reconstruction.

Figure 5: 3D printed titanium plates for bimaxillary advancement on a 3D printed model.

Figure 6: Personalised 3D printed titanium implant for orbital floor reconstruction following blowout fracture.

Figure 7: Personalised 3D printed TMJ implant showing (A) preoperative STL reconstruction and (B) postoperative radiograph.

Figure 8: Subperiosteal implant for prosthetic rehabilitation of an atrophic maxilla showing (A) implant and prosthesis on a 3D printed model and (B) post-operative radiograph.

Figure 1

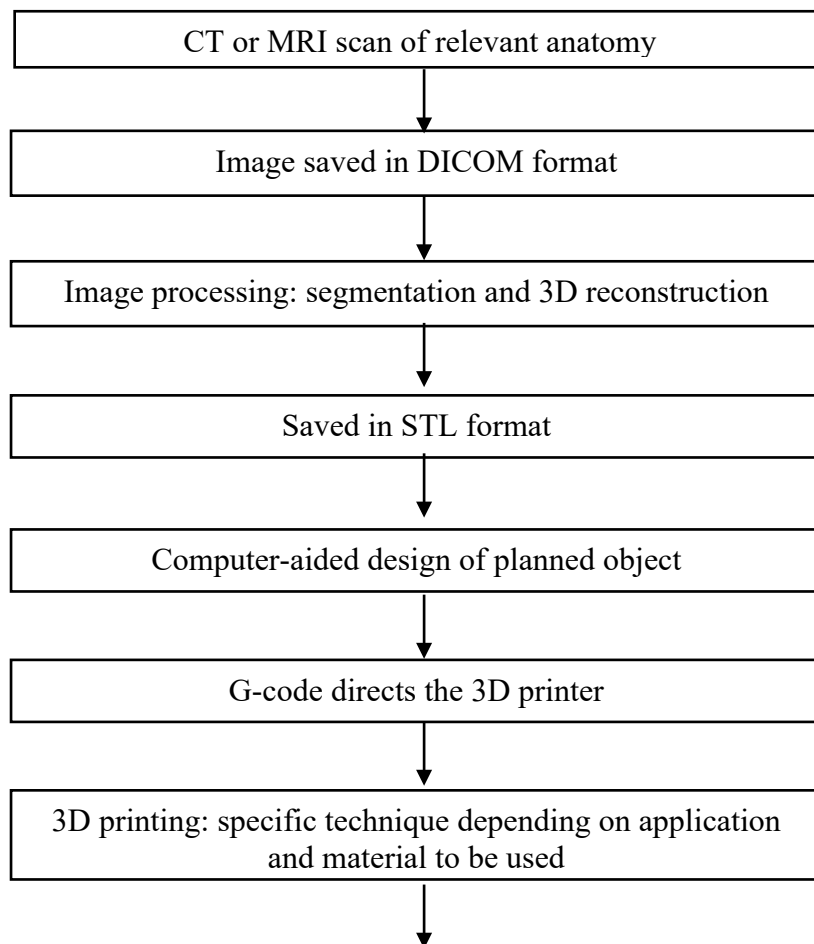


Figure 2

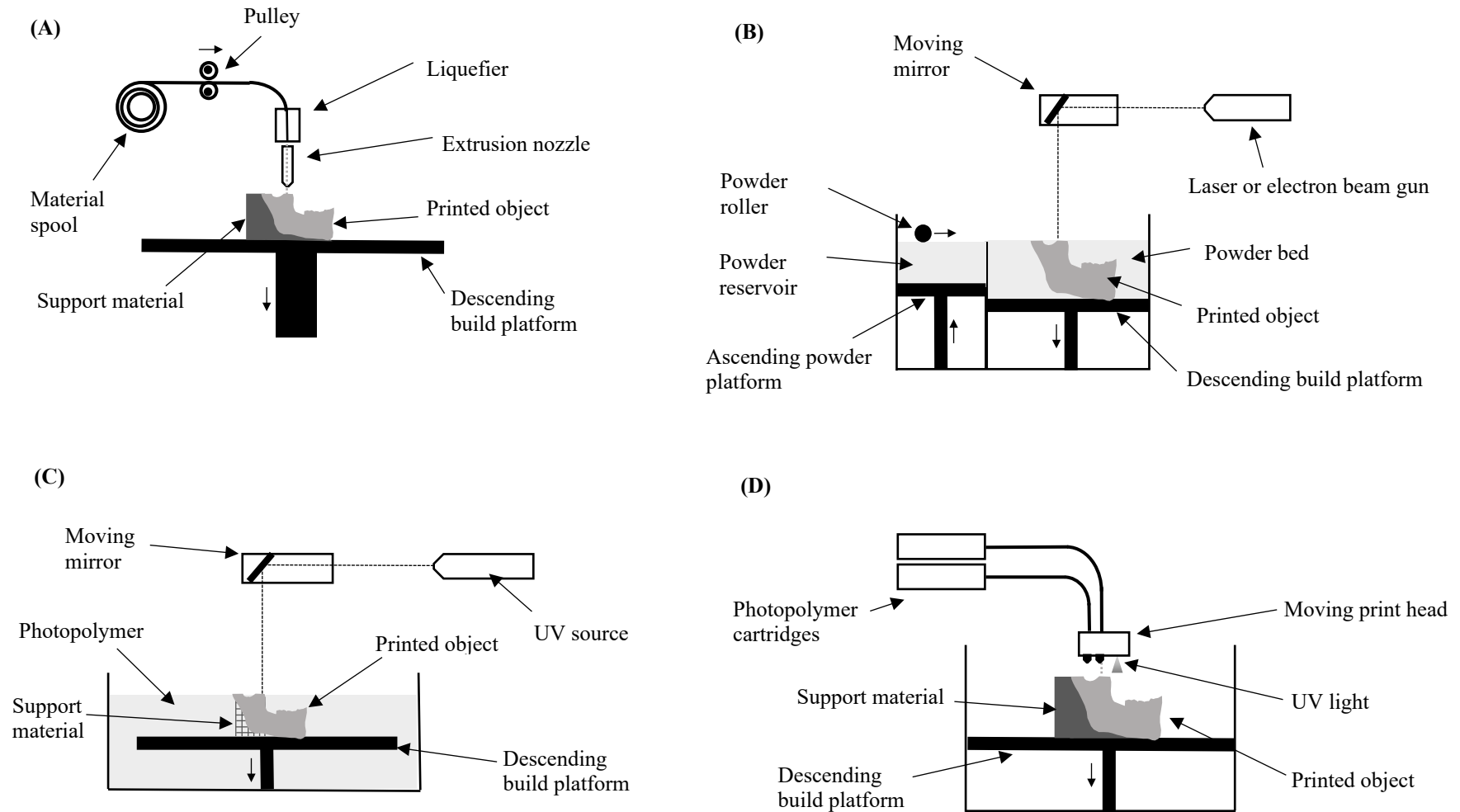


Figure 3

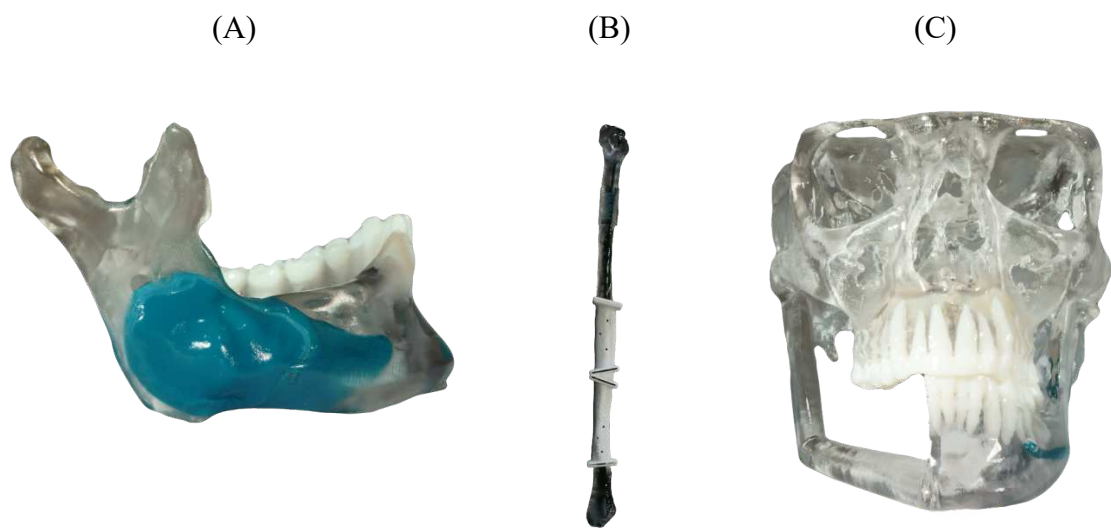


Figure 4

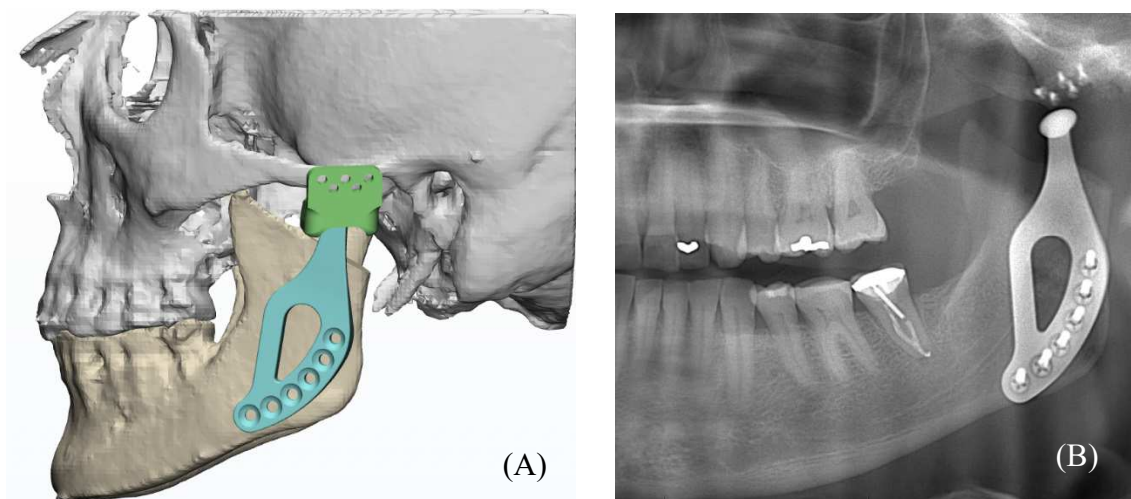
Figure 5



Figure 6



Figure 7



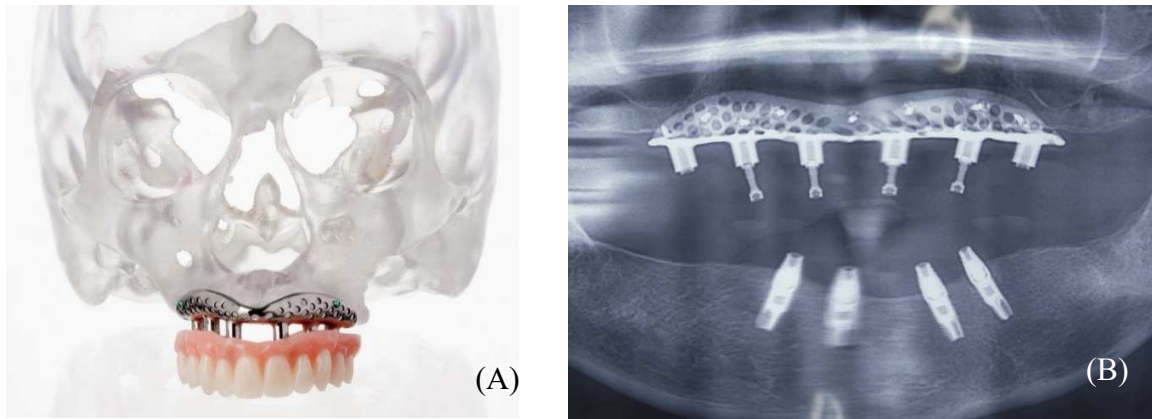


Figure 8

Table 1

Materials available for each 3D printing technique

	Polymers	Metals		Ceramics
		Pure	Alloys	
Fused deposition modelling (FDM)	◆			
Powder bed fusion processes				
Selective laser sintering	◆	◆	◆	◆
Selective laser melting		◆		
Electron beam melting		◆		
Stereolithography	◆			
Inkjet processes				
Binder jetting	◆		◆	◆