

Proximal Femoral Osteotomy in Children and Adolescents with Cerebral Palsy

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**In the midst of hate,
I found there was, within me,
an invincible love.**

**In the midst of tears,
I found there was, within me,
an invincible smile.**

**In the midst of chaos,
I found there was, within me,
an invincible calm.**

**I realised, through it all,
that... In the midst of winter,
I found there was, within me,
An invincible summer.**

**For it says that no matter how hard
the world pushes against me, within me,
there is something stronger - something better,
pushing right back.**

Albert Camus.

ABSTRACT

Background

Cerebral Palsy (CP) is the most common cause of physical disability affecting children in developed countries. Approximately one third of children with CP may develop hip displacement. Non-ambulant children at Gross Motor Function Classification System (GMFCS) levels IV and V are at highest risk. Without early detection through surveillance programs, hip displacement can progress to hip dislocation, which is frequently painful and negatively impacts health-related quality of life (HRQoL). Injections of Botulinum Neurotoxin A (BoNT-A) have no role, and soft tissue surgery has a limited role in preventing hip displacement in non-ambulant children with CP. Bony hip reconstruction surgery such as a proximal femoral osteotomy (PFO) is effective in stabilising the hip and HRQoL. PFOs include Femoral Derotation Osteotomies (FDO) which aim to improve the gait of an ambulant child (GMFCS I-III), and Varus Derotation Osteotomies (VDRO) which aim to contain the hips in non-ambulant children (GMFCS IV-V). However, PFOs can carry high risks, especially in children with medical co-morbidities such as respiratory disease, nutritional deficiencies, hypertonia and osteopenia.

Aim

This thesis involved a series of three studies, which aimed to expand our knowledge of the trainee learning curve, outcomes and adverse events relating to PFO in children and adolescents with CP.

Method and Results

A new implant combining locking and cannulated technology (Locking Cannulated Blade Plate, LCBP) was recently developed for use in PFO. A pilot study was performed on the first 25 patients who had surgery with the LCBP, at the Royal Children's Hospital (RCH), Melbourne. This study established safety for use in children as young as three, with weights as low as eleven kilograms. A further prospective, parallel cohort study of 90 consecutive children with CP

was conducted to compare the LCBP against with existing non-cannulated, non-locking implant (Angled Blade Plate, ABP). Technical and radiological outcomes of surgery were similar between implants. However, the surgical technique was reported by trainees to be easier when using the LCBP, with less technical errors. Approximately 60 percent of the children experienced minor adverse events including: constipation, inadequate pain control, and respiratory compromise. However, a CP specific tool was not available to classify the severity of events. Study three was performed to clarify the Modified Clavien-Dindo (MCD) system for lower limb surgery in children with CP and test its' reliability for classifying adverse events. Very good reliability was demonstrated amongst members within a multidisciplinary team.

Conclusion

Novel findings from these studies may help improve the safety and efficacy of the management of hip displacement in children with CP. Further research should address the long-term outcomes of PFO in children with CP, evaluate the validity of the MCD for children in CP and determine if the MCD can be embedded in the electronic medical records (EMR) as a routine tool for audit and clinical research.

STATEMENT OF AUTHENTICATION

The complete manuscript and publications presented for this Master of Philosophy is an original work, with the exception of references acknowledged within the text. Copyright to incorporate figures and tables from previously published work by other authors has been approved, and details can be found in Preface: List of Third Party Copyrights.

I hereby declare that material from this major thesis has not been submitted for another degree at the University of Melbourne, nor any other institution.



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DECLARATION OF CONTRIBUTIONS

Contributors: Dr Leena Zhou^{1,2} (MPhil candidate, First author), Prof H. Kerr Graham^{1,2,3} (Primary supervisor, Professor of Surgery, Consultant Orthopaedic Surgeon, Co-Author), Mr Abhay Khot^{1,2} (Secondary supervisor, Consultant Orthopaedic Surgeon, Co-Author), Dr Kate Willoughby^{1,2,3} (MPhil Advisory Committee Member, Senior Physiotherapist, Co-Author), Mr Mark Camp² (Orthopaedic Fellow, Co-Author), Mr Abhay Gahukamble² (Orthopaedic Fellow, Co-Author), Dr Charles Gallagher² (Research Fellow, Co-Author), Ms Pam Thomason⁴ (Senior Physiotherapist, Co-Author), Ms Mela Harambasic² (Senior Nurse, Co-Author), Dr Natalie Strobel⁵ (Statistician, Co-Author), A/Prof Susan Donath⁶ (Statistician, Co-Author), Ms Charlotte Molesworth⁶ (Statistician, Co-Author)

Prof Graham identified three key research knowledge gaps requiring further investigation and review. Under the supervision of Prof Graham and Mr Khot, I conducted a literature search on each area of interest. Relevant articles were identified and critically appraised. These articles were also used as a framework for my thesis literature review. I wrote the full manuscript for this major thesis and edits were suggested by Prof Graham and Mr Khot. In accordance with the University of Melbourne policy, this thesis manuscript contains less words than the maximum word limit decreed by the Research Higher Degrees Committee.

The background, aims, hypotheses and methods for all three projects were developed with supervisory academic support. Data for the first two research projects was prospectively collected by Prof Graham and given to me in de-identified format, in concordance with the requirements of the Royal Children's Hospital (RCH) Ethics & Governance Board. Reliability testing for the third research project was performed in combination with my co-authors. Statistical analyses for all three projects were performed in part, by myself, and in part, by statisticians from the University of Western Australia and the Clinical Epidemiology & Biostatistics Unit (CEBU) at the Murdoch Children's Research

Institute (MCRI). I analysed, interpreted, and discussed the findings of our results with the assistance of the statisticians and my supervisors. I wrote the manuscript for each research project and my co-authors contributed to its' critical review prior to journal publication. The proportion of each project that I claim to be my own original work is listed in the *Declaration of Thesis with Publication Form*.



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I dedicate my thesis to you.

PUBLICATIONS AND PRESENTATIONS DURING CANDIDATURE

Publications

Zhou L, Camp M, Gahukamble A, Khot A, Graham HK. *Cannulated, locking blade plates for proximal femoral osteotomy in children and adolescents*. Journal of Children's Orthopaedics. 2015;9:121-127.

Zhou L, Camp M, Gahukamble A, Willoughby K, Harambasic M, Molesworth C, Khot A, Graham HK. *Proximal femoral osteotomy in children with cerebral palsy: the perspective of the trainee*. Journal of Children's Orthopaedics. 2017;11:6-14.

Zhou L, Willoughby K, Strobel N, Thomason P, Gallagher C, Harambasic M, Khot A, Graham HK. *Classifying Adverse Events Following Lower Limb Orthopaedic Surgery in Children with Cerebral Palsy: Reliability of the Modified Clavien-Dindo System*. Journal of Pediatric Orthopaedics. 2018;38(10):e604-e609.

Published Abstracts

Zhou L, Camp M, Gahukamble A, Khot A, Graham HK. *Cannulated, locking blade plates for proximal femoral osteotomy in children and adolescents*. Journal of Children's Orthopaedics. 2015;9:121-127.

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Presentations

Zhou L, Camp M, Gahukamble A, Khot A, Graham HK. *Cannulated Fixed Angle Locking Blade Plates for Proximal Femoral Osteotomy in Children and Adolescents: Preliminary Experience*. Australian Orthopaedic Association 74th Annual Scientific Meeting, Melbourne, 12-16 October 2014.

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Zhou L. *Proximal Femoral Osteotomy in Children and Adolescents with Cerebral Palsy*. University of Melbourne Completion Seminar. Ella Latham Auditorium, the Royal Children's Hospital, Melbourne, 30 June 2017.

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LIST OF ABBREVIATIONS

A

AACPDM	American Academy of Cerebral Palsy and Developmental Medicine
ABP	Angled Blade Plate
ADR	Acetabular Depth Ratio
AE	Adverse Event
AI	Acetabular Index

B

BoNT-A	Botulinum Neurotoxin A
--------	------------------------

C

CCI	Comprehensive Complication Index
CEBU	Clinical Epidemiology & Biostatistics Unit
CFCS	Communication Function Classification System
CP	Cerebral Palsy
CPCHILD™	Caregiver Priorities & Child Health Index of Life with Disabilities
CT	Computed Tomography

D

DDH	Developmental Dysplasia of the Hip
-----	------------------------------------

E

EMR	Electronic Medical Records
EUA	Examination Under Anaesthesia

F

FDO	Femoral Derotation Osteotomy
FNA	Femoral Neck Anteversion

G

GMFCS	Gross Motor Function Classification System
GMFCS-ER	Gross Motor Function Classification System – Expanded & Revised

H

HO	Heterotopic Ossification
----	--------------------------

HRQoL	Health-Related Quality of Life
I	
ICU	Intensive Care Unit
L	
LCBP	Locking Cannulated Blade Plate
LCP	Locking Compression Plate
M	
MACS	Manual Ability Classification System
MAE	Medical Adverse Event
MCD	Modified Clavien-Dindo System
MCDS	Modified Clavien-Dindo-Sink System
MCPHCS	Melbourne Cerebral Palsy Hip Classification Scale
MCRI	Murdoch Children's Research Institute
MP	Migration Percentage
MPHIL	Master of Philosophy
N	
NSA	Neck Shaft Angle (Femur)
P	
PEG	Percutaneous Endoscopic Gastrotomy
PFO	Proximal Femoral Osteotomy
PO	Pelvic Osteotomy
R	
RCH	The Royal Children's Hospital
RCT	Randomised Controlled Trial(s)
S	
SAE	Surgical Adverse Event
SCFE	Slipped Capital Femoral Epiphysis
STR	Soft Tissue Release
U	
UOM	University of Melbourne
V	
VDRO	Varus Derotation Osteotomy
W	
WHO	World Health Organisation

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Citation: Hau R, Dickens DRV, Nattrass GR, et al. Which Implant for Proximal Femoral Osteotomy in Children? A Comparison of the AO (ASIF) 90° Fixed-Angle Blade Plate and the Richards Intermediate Hip Screw. J Pediatr Orthop. 2000;20(3):336-43. **Permissions granted by Lippincott Williams & Wilkins Rightslink on 05 Nov 2018.**

Figure 20: Anteroposterior radiograph of a left proximal femoral osteotomy, internally fixed with a locking cannulated blade plate. Image obtained from Grant 1990..... 41

Citation: Grant AD, Lehman WB, Strongwater AM, et al. Cannulated Blade Plate for Proximal Femoral Varus Osteotomy. Clin Orthop Relat Res. 1990;259:111-3. **Permissions granted by Lippincott Williams & Wilkins Rightslink on 05 Nov 2018.**

Table 1: Table obtained from DiFazio et al 2016 describing the incidence and type of adverse event observed in children with cerebral palsy (CP) and typically developing children (non-CP). (CP, cerebral palsy; GI, gastrointestinal)..... 44

Citation: DiFazio R, Vessey JA, Miller P, et al. Postoperative Complications After Hip Surgery in Patients With Cerebral Palsy: A Retrospective Matched Cohort Study. J Pediatr Orthop. 2016;36(1):56-62. **Permissions granted by Lippincott Williams & Wilkins Rightslink on 05 Nov 2018.**

Table 2: Table obtained from Clavien & Dindo describing the Clavien-Dindo Classification of Surgical Complications..... 46

Citation: Dindo D, Demartines N, Clavien PA. Classification of Surgical Complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004;240(2):205-13. **Permissions granted by Lippincott Williams & Wilkins Rightslink on 05 Nov 2018.**

Table 3: Table obtained from Sink et al describing the Modified Clavien-Dindo System for hip preservation surgery..... 47

Citation: Sink EL, Leunig M, Zaltz I, et al. Reliability of a complication classification system for orthopaedic surgery. Clin Orthop Relat Res. 2012;470(8):2220-6. **Permissions granted by Lippincott Williams & Wilkins Rightslink on 05 Nov 2018.**

Complete publication of Study One Journal Article..... 53

Citation: Zhou L, Camp M, Gahukamble A, et al. Cannulated, locking blade plates for proximal femoral osteotomy in children and adolescents. J Child Orthop. 2015;9:121-127. **Permissions granted by the Editor of the Journal of Children's Orthopaedics on 29 Nov 2017.**

Complete publication of Study Two Journal Article..... 63

Citation: Zhou L, Camp M, Gahukamble A, et al. Proximal femoral osteotomy in children with cerebral palsy: the perspective of the trainee. J Child Orthop. 2017;11:6-14. **Permissions granted by the Editor of the Journal of Children's Orthopaedics on 29 Nov 2017.**

Complete publication of Study Three Journal Article..... 75

Citation: Zhou L, Willoughby K, Strobel N, et al. Classifying Adverse Events Following Lower Limb Orthopaedic Surgery in Children with Cerebral Palsy: Reliability of the Modified Clavien-Dindo System. J Pediatr Orthop. 2018;38(10):e604-e609. **Permissions granted by Lippincott Williams & Wilkins Rightslink on 11 Oct 2018.**

I. INTRODUCTION

In this thesis, I investigated the challenges of proximal femoral osteotomy (PFO) in children and adolescents with cerebral palsy (CP) at the Royal Children's Hospital (RCH) in Melbourne.

Approximately 35 percent of children with CP will develop hip displacement. Without early detection through surveillance programs, displacement can progress to painful hip dislocation. This adversely affects health related quality of life (HRQoL) as demonstrated by the Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD™) scores (1). Non-operative interventions such as: Botulinum Neurotoxin A (BoNT-A) injections and abduction bracing, have no role in preventing hip displacement in non-ambulant children. Preventive soft tissue procedures such as adductor releases, remain the first line treatment for hips 'at risk'. However, adductor surgery has a high failure rate in children with CP, especially in those who are non-ambulant (2).

In an effort to improve the stability of the hips and prevent progressive dysplasia, dislocation and long-term sequelae such as painful arthritis, it has been proposed that younger children should be offered bony reconstructive surgery, if and when soft tissue surgery fails. Bony reconstructive surgery may include a proximal femoral osteotomy (PFO) such as a Varus Derotation Osteotomy (VDRO) and a Pelvic Osteotomy (PO), when indicated. The impact and consequences of major surgery in younger children with CP are still being researched. The information obtained from the studies conducted for this thesis are intended to improve the pre-operative counselling of surgical risks for families, and aid orthopaedic surgeons to choose the appropriate implant when working with trainees. It will also provide a basis for sample size calculations in future clinical trials to ultimately develop a step-wise, age-appropriate approach to the management of hip displacement in CP according to GMFCS level.

Section *II. Literature Review*, will explore the key concepts in further detail. This will include a review of the epidemiology and functional classification systems

associated with CP, as well as options used for managing hip displacement using currently available literature. The knowledge gaps identified within this literature review will lay the foundation for the thesis aims and hypothesis, and the development of three relevant research projects. Each publication will describe the specific aims, hypotheses, methodology, results, and discuss the strengths and weaknesses. A subsequent summary and bridge to each publication will link Sections IV, V and VI respectively. A combined discussion of the key findings from all research projects, their clinical impacts and future directions will be reported in Section VII. Discussion.

II. LITERATURE REVIEW

This literature review provides an overview of cerebral palsy (CP) and definitions of CP classification systems, with reference to data obtained from population based CP registries worldwide. The link between CP and hip displacement will also be explored. Particular attention will be focused on proximal femoral osteotomies (PFO) such as Varus Derotation Osteotomy (VDRO) as a treatment for hip displacement in CP. Surgical implants used for PFO, as well as the efficacy and safety profile of PFOs in children with CP will be reviewed.

A number of knowledge gaps are identified in this review, providing a research platform to investigate the utility of proximal femoral osteotomies in children and adolescents with CP.

1 CEREBRAL PALSY

Cerebral palsy (CP) is the most common cause of physical disability affecting children in developed countries, including Australia. CP affects approximately 1 in 500 neonates (3) and describes a group of children who acquire a non-progressive brain lesion before, during, or early after birth. The lesion affects the musculoskeletal system, causing a progressive disorder of movement and posture (4).

There is currently no cure for CP. Research efforts are therefore focused on management strategies that aim to maximise a child's function and participation in activities, and minimise morbidity from factors such as hip dislocation, scoliosis and feeding difficulties (5).

1.1 Definition

The first description of CP was documented in 1861 by an English orthopaedic surgeon, William J. Little (6). He recognised an association between difficult or premature births and asphyxia, leading to childhood mental and physical deformities. Further important contributions were made by Sigmund Freud and Sir William Osler in the late nineteenth century (7, 8).

Several attempts to define CP were made in the twentieth century, as the understanding of the condition broadened. Although Little's link between birthing difficulties and deformity was accepted, it was recognised that there were other triggers that could lead to CP in the prenatal and postnatal periods. In 1959, Mac Keith and Polani suggested CP as: *'a persisting but not unchanging disorder of movement and posture, appearing in the early years of life and due to a non-progressive disorder of the brain, the result of interference during its development'* (9). In 1964, Bax and colleagues from an international working group defined CP as: *'a persisting but not unchanging disorder of movement and posture due to a defect or lesion of the immature brain'* (10). This classical definition of CP was used until the early twenty-first century, but failed to acknowledge the heterogeneity of disorders encompassed by the

umbrella-term ‘cerebral palsy’ and other sensory, cognitive and behavioural manifestations that affect individuals with CP. This was further limited by the inability to identify a specific cause for CP, and the absence of genetic, haematologic, immunologic or metabolic means to test for CP.

In 2006, the executive committee of the American Academy for Cerebral Palsy and Developmental Medicine (AACPDM) led by Peter Rosenbaum, endeavoured to address these previous deficiencies. The revised and currently accepted definition is:

‘Cerebral palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behaviour, by epilepsy, and by secondary musculoskeletal problems.’ (4)

1.2 Epidemiology

A meta-analysis conducted on birth cohorts from 1985 to 2004 in Australia, Canada, United Kingdom, Europe, the United States, China and Kenya, estimated the prevalence of CP to be 2.1 per 1000 live births (11). However, more recent studies have demonstrated that prevalence rates may be even higher, affecting over 3 per 1000 live births in the United States (12), Taiwan (13) and Egypt (14).

The increasing prevalence in the late twentieth century appears to reflect the increasing survival of very premature infants, the effects of which are stabilising (15) and can be demonstrated by data from population-based registries in Australia and Europe. In Australia’s 2016 report, prevalence dropped from 2-2.5 per 1000 live births down to 1.4-2.1 per 1000 live births in the 2007-2009 period (16). Similarly, European registries demonstrated a fall from 1.9 per 1000 live births in 1980, to 1.77 per 1000 live births in 2003 (17).

Contrasts in the prevalence of CP between countries may represent the demographic variation between population groups and the heterogeneous nature of data collection between cohort studies, epidemiological studies of CP and formal CP registers (18).

1.3 Classifying Cerebral Palsy

CP can be classified according to topographic distribution, motor type, and functional severity. Clinicians have historically utilised limb topography to map out the affected limbs of an individual with CP (Figure 1) (19).

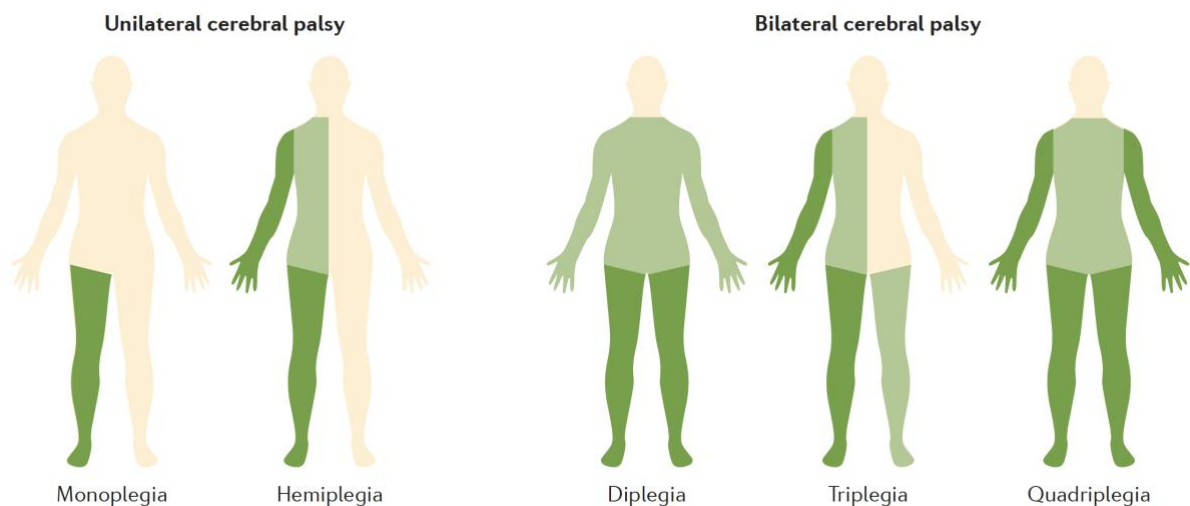


Figure 1 | Topographical description in cerebral palsy: unilateral and bilateral cerebral palsy. (5) Copyright permissions to reuse material granted.

Another method involves the identification of the motor type or movement disorder displayed by an individual with CP (20, 21). There are two principal movement disorders. The most common is spasticity, where: *'resistance to externally imposed movement increases with increasing speed of stretch and varies with the direction of joint movement, and/or rises rapidly above a threshold speed or joint angle'* (21). The other is dystonia, where muscle contractions are intermittent or sustained, causing abnormal and repetitive movements or postures (21). Although these descriptions are helpful, the functional capacity of an individual with CP cannot be determined by the use of topographical distribution nor motor type alone.

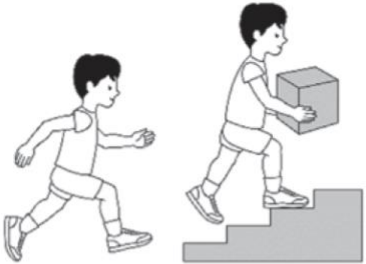
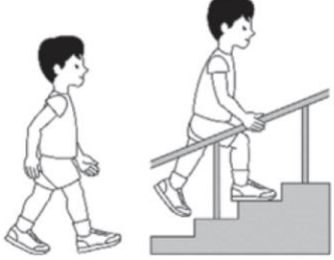
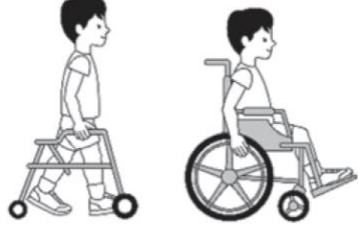
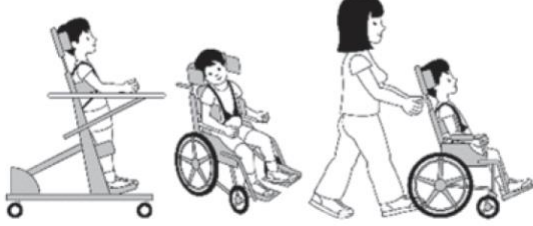
The Gross Motor Function Classification System (GMFCS), Manual Ability Classification System (MACS) and Communication Function Classification System (CFCS) are the three key systems that currently classify CP according to level of function, with general stability over time (22). The use of these systems are prognostic indicators that enable clinicians to inform individuals with CP, families, and care givers, of the likely interventions and assistive devices required in future. Furthermore, clinicians are able to report findings through research in a standard manner.

1.4 Gross Motor Function Classification System (GMFCS)

The GMFCS was initially described by Palisano and colleagues in 1997 (23). It is a simple five-grade ordinal system that is used to classify children up to the age of 12 years according to their gross motor abilities and limitations. GMFCS levels I, II and III describe children who ambulate with or without assistive devices. GMFCS levels IV and V described children who are non-ambulant.

Illustrations by Graham and Reid were developed to accompany the GMFCS descriptors (Figure 2). The combination of the GMFCS and illustrations has enabled families and clinicians to hold conversations regarding a child's current gross motor function and the likely equipment or mobility devices that the child may require in future (24).

The GMFCS is widely validated, and a more recent expanded and revised (GMFCS-ER) version has since been published to include children up to the age of 18 (25), along with revised illustrations (Figure 2). The GMFCS is generally stable over time, which is important for realistic goal-setting and in counselling families (26).

	GMFCS Level I Children walk at home, school, outdoors and in the community. They can climb stairs without the use of a railing. Children perform gross motor skills such as running and jumping, but speed, balance and coordination are limited.
	GMFCS Level II Children walk in most settings and climb stairs holding onto a railing. They may experience difficulty walking long distances and balancing on uneven terrain, inclines, in crowded areas or confined spaces. Children may walk with physical assistance, a hand-held mobility device or used wheeled mobility over long distances. Children have only minimal ability to perform gross motor skills such as running and jumping.
	GMFCS Level III Children walk using a hand-held mobility device in most indoor settings. They may climb stairs holding onto a railing with supervision or assistance. Children use wheeled mobility when traveling long distances and may self-propel for shorter distances.
	GMFCS Level IV Children use methods of mobility that require physical assistance or powered mobility in most settings. They may walk for short distances at home with physical assistance or use powered mobility or a body support walker when positioned. At school, outdoors and in the community children are transported in a manual wheelchair or use powered mobility.
	GMFCS Level V Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control leg and arm movements.

GMFCS descriptors: Palisano et al. (1997) Dev Med Child Neurol 39:214-23
CanChild: www.canchild.ca

Illustrations Version 2 © Bill Reid, Kate Willoughby, Adrienne Harvey and Kerr Graham,
The Royal Children's Hospital Melbourne ERC151050

Figure 2 | Expanded and revised Gross Motor Function Classification System (GMFCS-ER) for children from their 6-12th birthday: descriptors and illustrations (24, 25, 27).

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1.5 Manual Ability Classification System (MACS)

MACS (Figure 3) is a reliable and valid grading system to describe how children with CP between the ages of 4 and 18 years, use their hands when handling objects in daily activities (28, 29). Like the GMFCS, it utilises a five-grade ordinal system. An increase in MACS suggests decreased bimanual hand function (Figure 3). The combined use of MACS and GMFCS level in children with CP is useful when discussing expectations and setting goals for the development of functional skills with families and care givers (30).

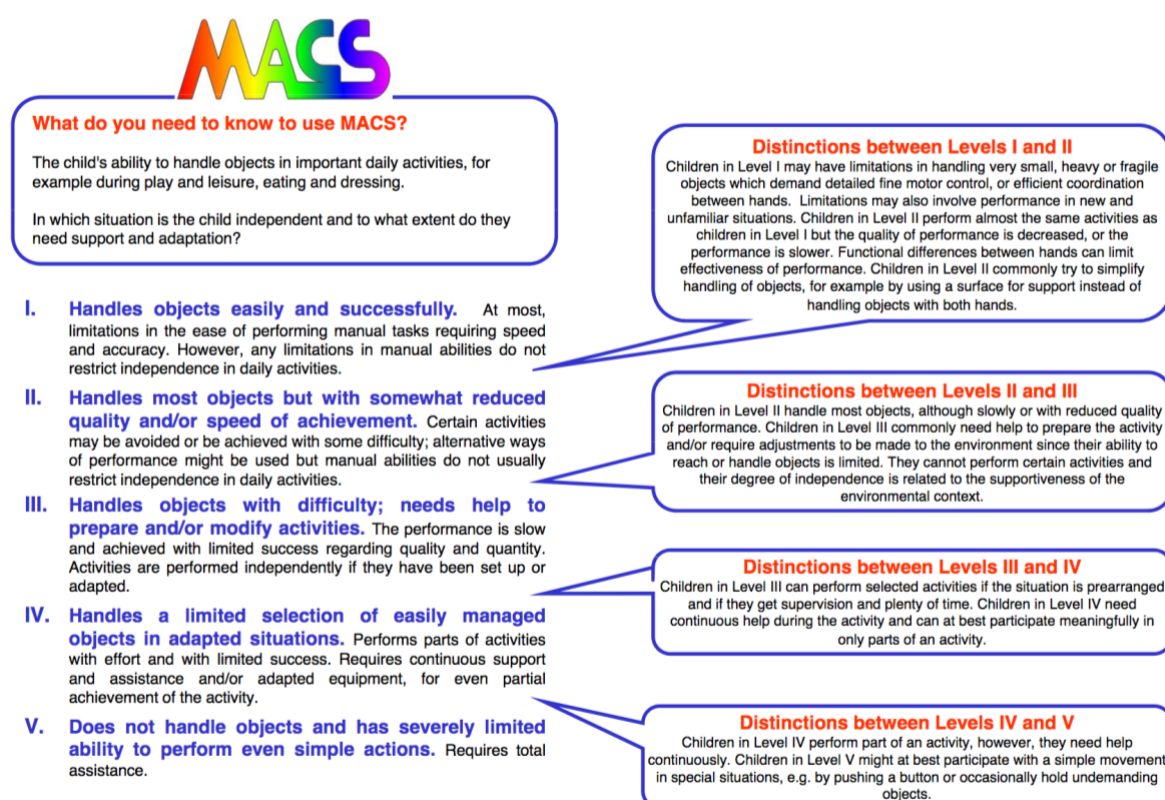


Figure 3 | Manual Ability Classification System (MACS) for children from their 4-18th birthday: descriptors (28). Copyright permissions to reuse material granted.

Eliasson and colleagues subsequently developed Mini-MACS for children aged between 1 and 4 years, demonstrating good interrater reliability amongst parents and therapists (31).

1.6 Communication Function Classification System (CFCS)

The CFCS (Figure 4) was created in 2011 to determine the communication ability of an individual with CP (32). Sender skills, receiver skills, pace of

communication, degree of familiarity with the communication partners, age-appropriateness, and use of augmentative and alternative communication were important factors considered during its' development (32). Similar to GMFCS and MACS, the CFCS is a five-grade ordinal system where increasing grade suggests decreased level of communication ability (Figure 4).

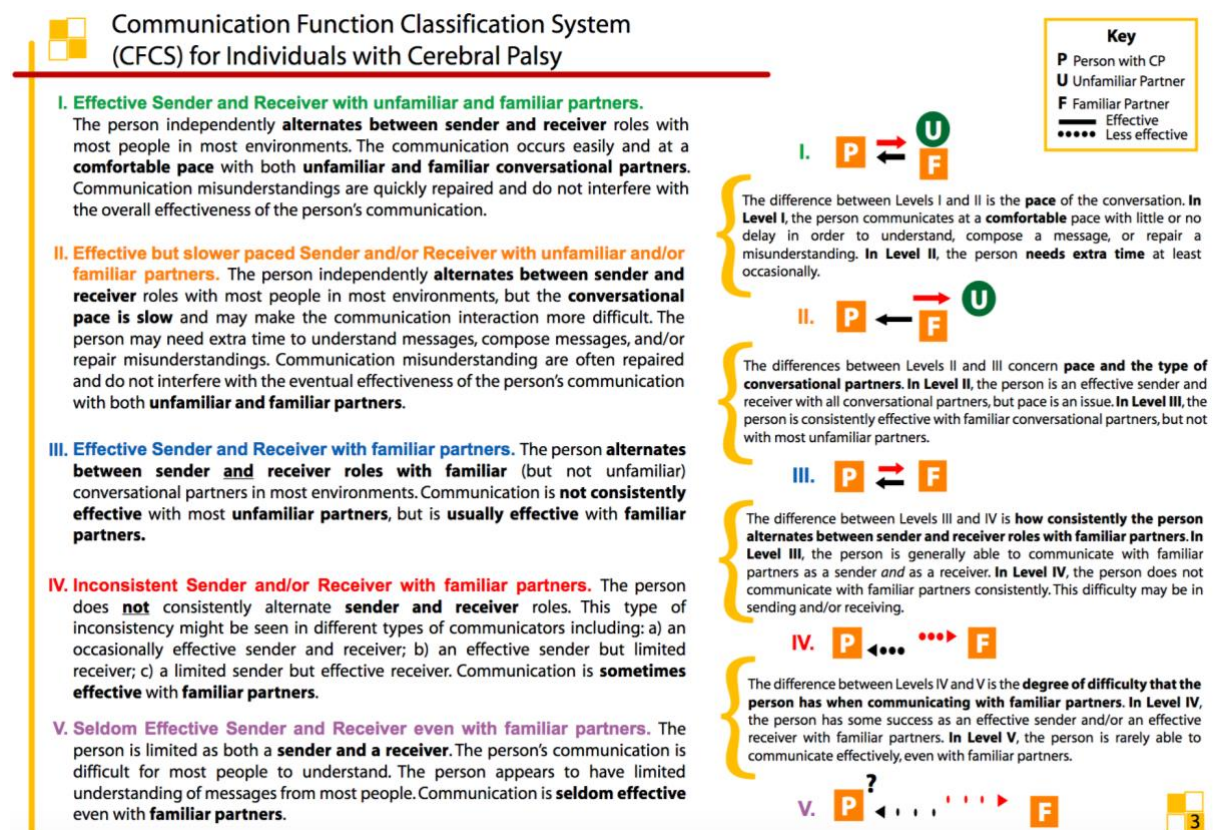


Figure 4 | Communication Function Classification System (CFCS): descriptors (32).

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The CFCS may be the most important classification tool for individuals with CP. An individual's ability to communicate discomfort or pain in association with musculoskeletal deformities such as hip displacement, as well as a family member's ability to perceive and relay the discomfort to a clinician, will likely implicate future clinical assessment and management protocols (27).

2 HIP DYSPLASIA

Hip dysplasia is the second most common musculoskeletal issue after equinus for individuals with CP. Approximately 35 percent of all children with CP will develop hip displacement, and this increases with functional severity, as determined by GMFCS (33). Hip displacement initially occurs silently but becomes symptomatic with age, along with the concurrent development of fixed deformities, articular cartilage damage, inflammatory mediator sensitisation and eventually, degenerative arthritis (34, 35). In the absence of careful hip surveillance (33, 36-40), displacement can lead to painful hip dislocation (41) in adolescence and early adulthood. Simple activities such as standing, comfortable sitting, or maintaining perineal hygiene may become burdensome or intolerable, with significant effects on health related quality of life (HRQoL) (1, 42).

2.1 Definition

Hip displacement refers to the spectrum of dysplasia, displacement, subluxation and eventual dislocation of the femoral head from the acetabulum. The presentation of hip displacement in children with CP differs from developmental dysplasia of the hip (DDH) observed in typically developing children (3). In children with CP, the hip is normal at birth. Abnormal forces transmitted through the CP hip cause a mismatch of the femoral head and acetabulum, resulting in progressive dysplasia and eventual arthritis with time (43).

Historically, physicians believed that increased spasticity and development of fixed contractures of the hip adductors, flexors, and medial hamstrings, and converse abductor insufficiencies were the primary drivers of hip displacement (Figure 5) (35, 44). In this view, the contracted muscles were felt to pull the proximal femur into adduction, flexion and internal rotation, driving the femoral head out of the joint (35). Furthermore, they were felt to contribute to deformation of the proximal femur by increasing femoral neck anteversion (FNA) (Figure 6), coxa valga as measured by neck shaft angle (NSA) (Figure 7, 8) (45, 46), and acetabular dysplasia (44, 47, 48). However, this theory failed to

explain why hip displacement occurred in all forms of CP motor types, regardless of the presence or absence of muscle contractures (33).

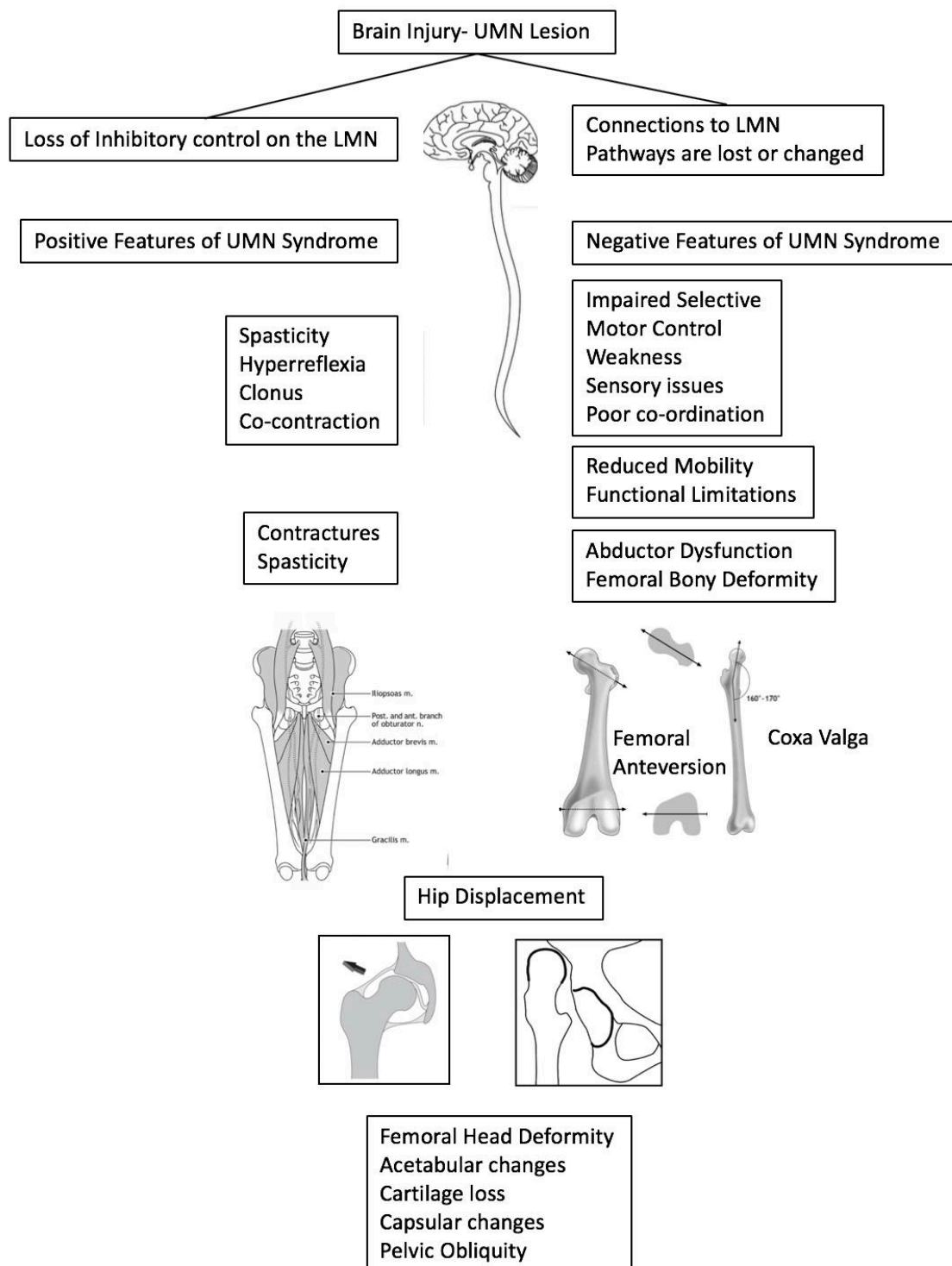


FIGURE 5 | Summary of the neuronal pathways contributing to hip pathology in cerebral palsy. Adapted with acknowledgements to A Khot, J Howard and HK Graham.

More recent evidence supports functional severity according to GMFCS level to be the largest predictive factor for hip displacement (5, 33, 46), and will be explored in further detail in Section [2.3 Links with GMFCS](#).

2.2 Pathoanatomy of Hip Dysplasia

2.2.1 Proximal Femoral Dysplasia

Important factors relating to proximal femoral geometry and hip subluxation or dislocation in CP include: increased femoral neck anteversion (FNA), coxa valga as measured by neck shaft angle (NSA), and horizontal or lateral tilt of the proximal femoral physis (44, 49).

Femoral neck anteversion (FNA) refers to the degree of anterior torsion found within the long axis of the femoral neck, in relation to the distal bicondylar femoral axis (Figure 6) (46, 50). In typically developing children, FNA is between 35-45° at birth and decreases to 10-15° at skeletal maturity (51) with the application of normal joint forces when standing and walking (44, 46). However, the decrease in FNA from birth is either absent or diminished in children with CP, and correlates with functional severity (46, 52, 53). In a large population-based study of 292 children with CP, Robin and colleagues associated changes in proximal femoral geometry according to GMFCS level (46). FNA was found to be 30° for GMFCS I, 36° for GMFCS II, 40° for GMFCS III, and 40° for GMFCS IV to V children (Figure 13) (46). It has been suggested that the corresponding FNA values seen in non-ambulant children (GMFCS IV-V) to FNA values at birth, reflect the absence of normal joint forces that accompany ambulation. However, the underlying cause for persisting increased FNA values in ambulant children (GMFCS I-III) is still being examined. A delay in reaching independent walking, in addition to mechanical load imbalances between octahedral shear stress (deviatoric stress) and hydrostatic stress (dilatational stress) within the proximal femur (54), may decrease the remodelling potential of femoral anteversion in CP hips compared to those of typically developing children.

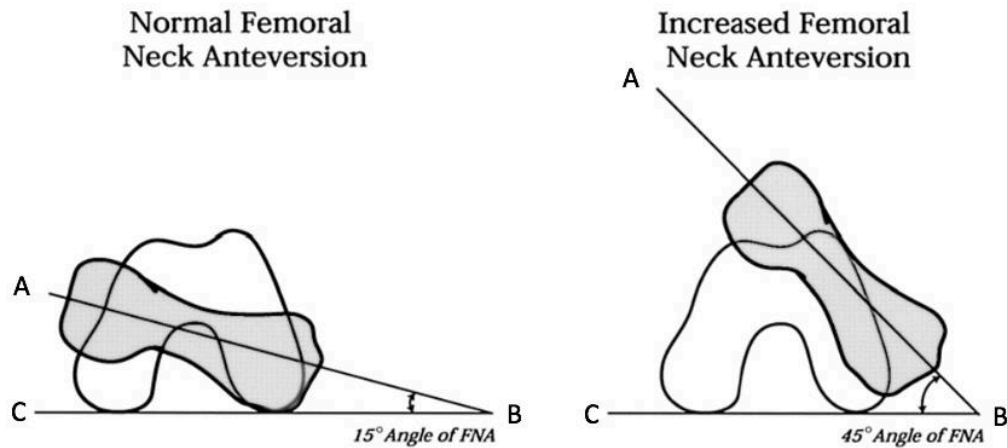


Figure 6 | Image from Cibulka 2004, describing FNA (50). FNA is defined as the angle between the distal bicondylar femoral axis (point B to point C) and the long axis of the femoral neck (point B to point A) (55-57). (FNA, Femoral Neck Anteversion) Copyright permissions to reuse material granted.

Coxa valga is a proximal femoral deformity that occurs when the femoral neck shaft angle (NSA) (Figure 7, 8) is greater than the normal range. In typically developing children, the NSA is 135° - 140° at birth and decreases to around 125° at skeletal maturity (52). In children with CP, a lack of weight-bearing and abductor insufficiency is thought to alter the compressive forces within the hip joint (58), causing abnormal lateral tilt of the proximal femoral physis and propagating a coxa valga deformity (59). The severity of coxa valga is linked to functional severity (60) as determined by GMFCS (46). In Robin and colleagues study of proximal femoral geometry, NSA increased from 136° in GMFCS I, 141° in GMFCS II, 149° in GMFCS III, 155° in GMFCS IV, and 163° in GMFCS V children with CP (Figure 13) (46).

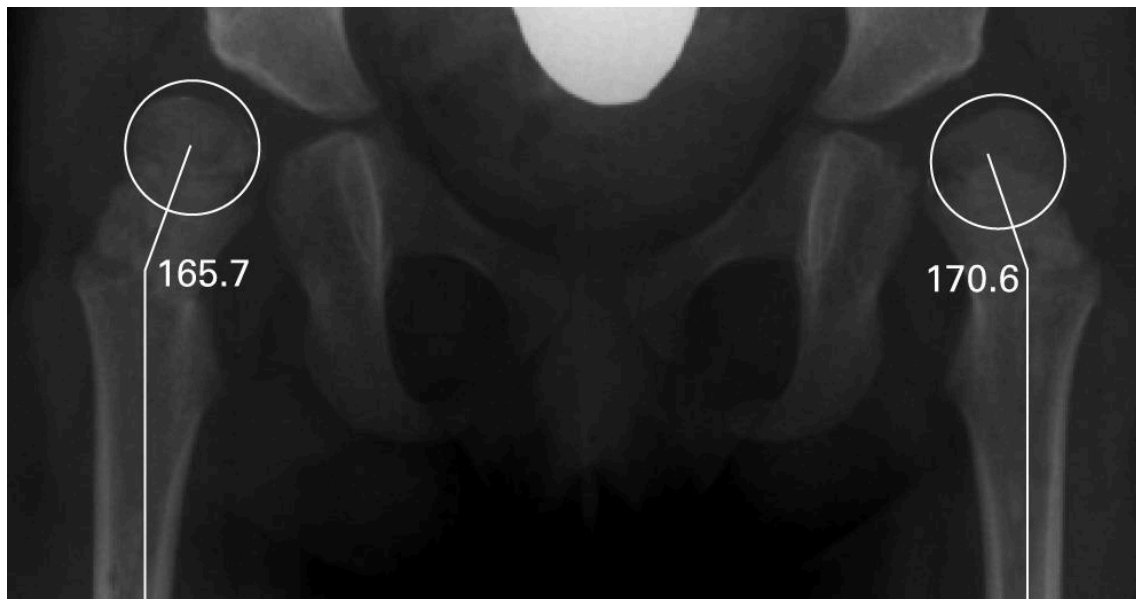


Figure 7 | Anteroposterior pelvis radiograph with neutral hip rotation, obtained from Robin et al 2008, demonstrating the apparent NSA which is falsely elevated (46). The true NSA cannot be measured on this view due to concomitant FNA. (NSA, Neck Shaft Angle; FNA, Femoral Neck Anteversion) Copyright permissions to reuse material granted.



Figure 8 | Anteroposterior pelvis radiograph with internal hip rotation, obtained from Robin et al 2008, demonstrating true NSA (46). NSA is the angle between the long axis of the femoral shaft and the long axis of the femoral neck, when the FNA is neutralised to 0° rotation (45). (NSA, Neck Shaft Angle; FNA, Femoral Neck Anteversion) Copyright permissions to reuse material granted.

In 1980, Reimers described the migration percentage (MP) in his published thesis: *'The Stability of the Hip in Children'* (61), which investigated radiographic outcomes of the hip in CP following soft tissue surgery. The MP measures the

proportion of femoral head that is uncovered by the acetabulum (Figure 9). It is a valid and reliable radiographic tool (62-65) used to quantify the severity of hip displacement. MP can be measured on a neutral anteroposterior pelvic radiograph. A horizontal Hilgenreiner (66) and perpendicular Perkins line (67) is drawn on the radiograph. MP is calculated as the percentage of ossified femoral head that is lateral to Perkins line (Figure 8). In children with CP, the MP increases by 2-5 % per year until it reaches approximately 50%. At this point, displacement may occur rapidly with progressive bony deformity and degenerative arthritis (49, 68). A MP of 30 to 60% leads to a 25% risk of progressive hip displacement (69).

There is a linear relationship between MP and GMFCS (33), and a corresponding link to FNA and NSA (46, 59). This will be discussed in Section 2.3 Links with GMFCS. FNA, NSA and MP are valid and reliable tools for measuring hip displacement in children with CP (70).

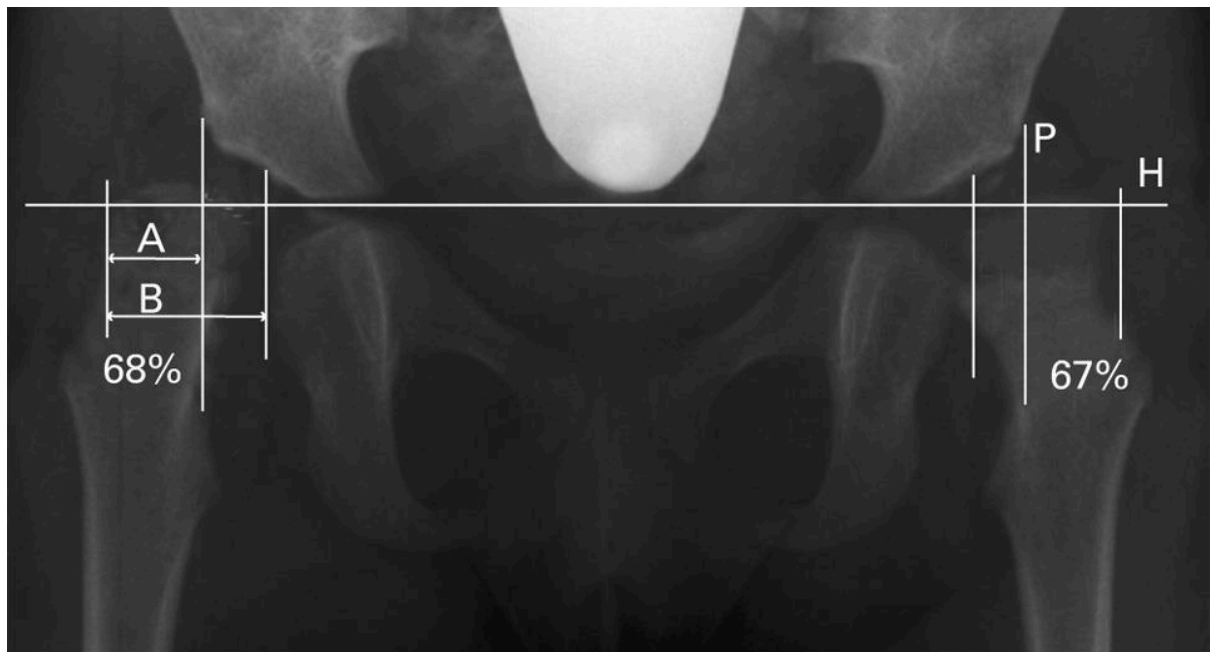


Figure 9 | Neutral anteroposterior pelvis radiograph obtained from Robin et al 2008 (46) demonstrating migration percentage (MP) = $A/B \times 100$. (H, Hilgenreiner line; P, Perkins line; A, proportion of femoral head lateral to Perkins line; B, total width of the femoral head). Copyright permissions to reuse material granted.

Femoral head dysplasia is also associated with longstanding or severe hip subluxation or dislocation (71). It is thought that constant lateral pressure from the hip capsule and the gluteal muscles causes a lateral femoral head groove and concavity (71, 72). Furthermore, a posterior acetabular rim impingement on the anterolateral femoral head can cause a wedge defect (71, 72). Hip surveillance programs to detect early hip displacement before these degenerative changes occur is paramount (33, 36-40), to prevent the need for salvage procedures and their associated inferior clinical outcomes (73).

2.2.2 Acetabular Dysplasia

Acetabular dysplasia in CP is thought to occur along the same path of femoral head migration and subluxation. Increased coxa valga and lateral tilt of the proximal femoral physis may contribute to the progression of dysplasia by shifting joint forces through the lateral aspect of the acetabulum (59) and delay or prevent ossification of the lateral acetabular cartilage (74). These abnormal joint forces, which are up to six times that of typically developing children (75, 76), may cause 'de-roofing' of the femoral head and subsequent dislocation (46, 59, 60, 77) with radiological evidence of a 'gothic arch' (63, 78, 79). Acetabular dysplasia manifests as increased acetabular inclination and can be measured radiologically by the acetabular index (AI) (Figure 10) (80). In younger children, AI can be overestimated if the lateral acetabular cartilage is not ossified, and an arthrogram or MRI is not performed. Acetabular dysplasia may also cause a shallow acetabulum. This can be measured by the Acetabular Depth Ratio (ADR) (Figure 10) with good reliability (81).

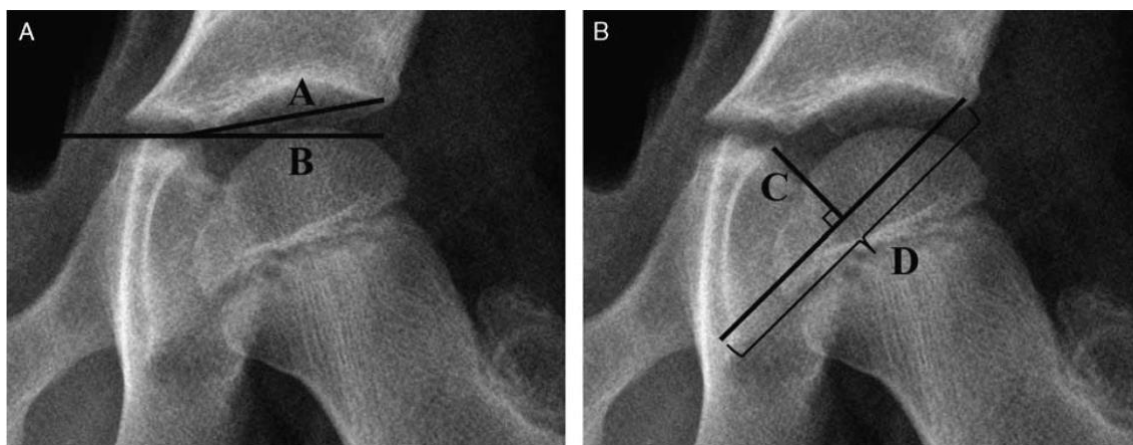


Figure 10 | Anteroposterior radiograph of a left hip obtained from Novais et al 2018 (81).

A. Acetabular Index (AI), defined as the angle between Line A (lateral aspect of the sourcil to the lateral portion of the superior acetabular roof) and Line B (Hilgenreiner line; a horizontal line connecting the inferior margins of the ilia at the triradiate cartilage).

B. Acetabular Depth Ratio (ADR), defined as Line C (acetabular depth) / Line D (acetabular width) x 100. Acetabular depth = perpendicular distance between the halfway point of the acetabular width and the roof of the acetabulum. Acetabular width = distance between the lateral margin of the sourcil and the most inferior aspect of the acetabular teardrop. *Copyright permissions to reuse material granted.*

The location of acetabular dysplasia is classically postero-superior (49, 82), but has also been observed anteriorly, superiorly and globally, depending on the direction of migration (76, 83-85). Using 3D computed tomography (CT), Chung and colleagues identified that acetabular deficiencies were primarily posterior and progressed to global involvement (shallow acetabulum) when the hip became dislocated (86). This correlates with their previous study which demonstrated an inverse relationship between acetabular volume (depth) and migration percentage (MP) (84). As the MP increased, acetabular volume decreased from 14.2ml (no displacement) to 3.4ml (dislocation) (84).

Chung and colleagues' most recent case control study of 176 children with CP and 55 typically developing children (mean age 9 years 5 months) demonstrated that increasing MP and increasing GMFCS were independent risk factors for acetabular dysplasia (86). Similar findings were made by Gose and colleagues in 75 younger children with bilateral spastic CP (mean age 5 years 5 months), with non-ambulant children (GMFCS IV-V) being the worst affected.

The acetabulum may remodel if abnormal proximal femoral forces are addressed early, before the onset of severe acetabular dysplasia (76). In 1977, Eilert and colleagues observed acetabular remodelling in nine of ten children under the age of 8, following varus derotation osteotomy (VDRO) of the femur (87). However only two of five children over the age of 8 remodelled (87). More recently, Shore and colleagues demonstrated that children under the age of 6 years experienced the greatest benefits of acetabular remodelling following isolated VDRO (88). AI decreased by approximately 1° per year in those under

the age of 6, whereas the AI in children over 6 years only decreased by 0.6° per year (88). ADR has also been shown to improve in a study by Chang and colleagues involving 87 children (average age 4 years and 7 months) with CP who underwent bilateral VDRO (89). GMFCS and NSA were the strongest predictors for improvements in ADR. Decreased NSA intraoperatively was associated with increased ADR postoperatively. Ambulant children (GMFCS I-III) had an increased ADR compared to non-ambulant children (GMFCS IV-V) during follow up. However, positive acetabular remodelling was observed in all children. Given that the progression of hip dysplasia is more rapid in non-ambulant children, earlier VDRO has been recommended by the authors to maximise the potential remodelling benefits (89).

2.2.3 Classifying Hip Dysplasia

Until the early 2000's, there was a lack of consensus in the reporting of proximal femoral and acetabular dysplasia according to severity. In response to this, Robin and colleagues published a valid, radiographic classification for hips in skeletally mature individuals for CP (79) (Figure 11), utilising the experience from previous publications (33, 58, 90, 91) and radiological review of 268 hips from their own institution. This classification is otherwise known as the Melbourne Cerebral Palsy Hip Classification Scale (MCPHCS) (79) (Figure 11) . It is reliable (92) and has standardised the reporting of hip dysplasia in research worldwide.

The Melbourne Cerebral Palsy Hip Classification Scale (Expanded and Revised)

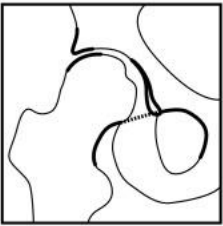
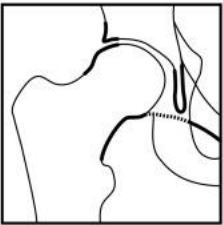
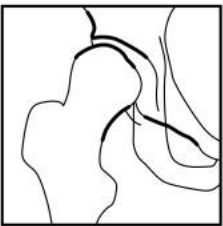
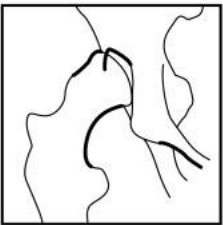
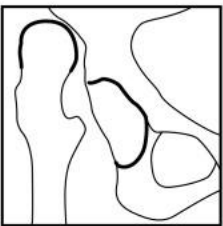
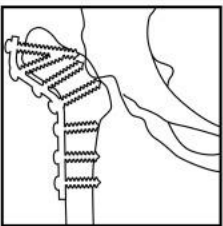
		Grade 1: Normal Hip – Migration Percentage <10% - Shenton's arch intact - Femoral head round (within 2mm using Mose circles) - Acetabulum – normal acetabular development with a normal horizontal sourcil, an everted lateral margin and normal tear drop development - Pelvic obliquity <5° - No degenerative change, no pain
		Grade 2: Near Normal Hip – Migration Percentage ≥10% ≤15% - Shenton's arch intact - Femoral head round or almost round - Acetabulum – normal or near normal development - Pelvic obliquity <5° - Low risk of degenerative change, usually pain free
		Grade 3: Dysplastic Hip – Migration Percentage >15% ≤30% - Shenton's arch intact or broken by ≤5mm - Femoral head round or mildly flattened - Acetabulum normal or mildly dysplastic including blunting of the acetabular margin and a widened tear drop - Pelvic obliquity <10° - Low risk of degenerative change, occasionally mild pain
		Grade 4: Dysplasia With Mild Subluxation – Migration Percentage >30% <60% - Shenton's arch broken by >5mm - Femoral head some flattening – Appendix 1 - Acetabulum dysplastic – Appendix 2 - Pelvic obliquity variable – Appendix 3 - Risk of degenerative change, pain variable
		Grade 5: Moderate to Severe Subluxation – Migration Percentage ≥60% <100% - Shenton's arch broken by >10mm - Femoral head variable deformity – Appendix 1 - Acetabulum variable deformity – Appendix 2 - Pelvic obliquity variable – Appendix 3 - Degenerative change frequent, pain frequent
		Grade 6: Dislocated Hip – Migration Percentage ≥100% - Shenton's arch completely disrupted - Femoral head variable deformity – Appendix 1 - Acetabulum variable deformity – Appendix 2 - Pelvic obliquity variable – Appendix 3 - Degenerative change frequent, pain frequent
		Grade 7: Salvage Surgery - Valgus osteotomy - Arthrodesis - Excision arthroplasty (Castle) ± valgus osteotomy (McHale) - Replacement arthroplasty - Pain relief following salvage surgery: variable

FIGURE 11 | The Melbourne Cerebral Palsy Hip Classification Scale (MCPHCS) expanded and revised (79). Copyright permissions to reuse material granted.

2.3 Links with GMFCS

Population based cohort studies have shown that approximately one-third of children with CP will develop hip displacement (33, 38, 93, 94). In a landmark study, Soo and colleagues challenged the historical beliefs of spasticity as the primary drivers of hip displacement. They were able to demonstrate a linear relationship between the risk of hip displacement (MP > 30%) in children with CP and GMFCS level (33). In their study cohort of 279 children with spastic CP, hip displacement was observed in: 0% GMFCS I, 15.1% GMFCS II, 41.3% GMFCS III, 69.2% GMFCS IV, and 89.7% GMFCS V children (33) (Figure 12).

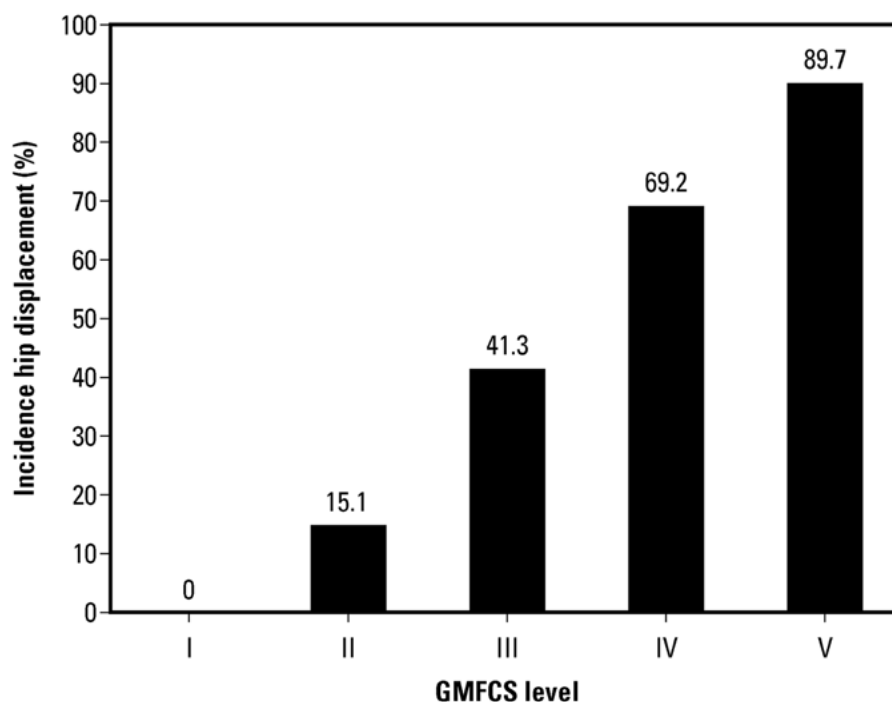


FIGURE 12 | Figure obtained from Soo et al 2006 (33) demonstrating the incidence of hip displacement (MP > 30%) according to GMFCS level. (MP, Migration Percentage; GMFCS, Gross Motor Function Classification System) *Copyright permissions to reuse material granted.*

Robin and colleagues furthered these findings, and correlated the abnormal geometry of the proximal femur in children with CP with GMFCS (46, 95). FNA, NSA and MP were measured in 292 children with CP of all GMFCS levels. Findings demonstrated that an increasing FNA, NSA and MP corresponded to an increasing GMFCS level (Figure 13).

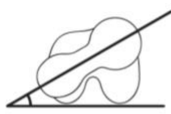
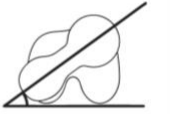
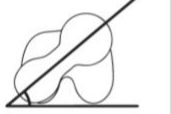
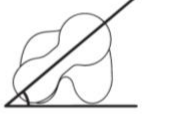
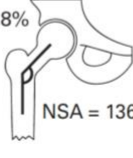
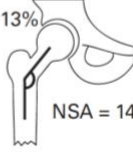
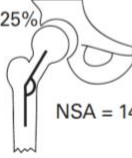
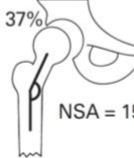
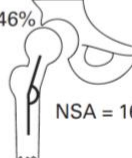
	GMFCS I	GMFCS II	GMFCS III	GMFCS IV	GMFCS V
FNA	 FNA = 30°	 FNA = 36°	 FNA = 40°	 FNA = 40°	 FNA = 40°
NSA + MP	 MP = 8% NSA = 136°	 MP = 13% NSA = 141°	 MP = 25% NSA = 149°	 MP = 37% NSA = 155°	 MP = 46% NSA = 163°

FIGURE 13 | Figure obtained from Robin et al 2008 (46) showing FNA, NSA and MP according to GMFCS Level. (FNA, Femoral Neck Anteversion; NSA, Neck Shaft Angle; MP, Migration Percentage) Copyright permissions to reuse material granted.

Correlation of these findings with GMFCS has led to a change in thinking. Delayed or absent ambulation and persistently reduced activity in hip abductor function may be the primary drivers of abnormal proximal femoral geometry and hip displacement (5, 46, 60).

These combined findings have facilitated the development of national hip surveillance guidelines (96), enabling clinicians to monitor children with ‘hips at risk’ and provide timely orthopaedic referrals to prevent the progression of hip displacement through surgical intervention.

2.4 Quality of Life

Quality of life, defined by the World Health Organisation (WHO) as ‘*the individual’s perception of their position in life in the context of the culture and value systems in which they live*’ (97), is a crucial outcome to assess in children with developmental disabilities (1). However, measures of health related quality of life (HRQoL) are subjective and self-reported (5), which makes outcome reporting of HRQoL difficult to interpret in the CP. This led to the development of the Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD™) questionnaire in 2006 (1). CPOCHILD™ is a reliable and valid outcome tool to measure disease-specific health status and well-being from the caregiver’s perspective on issues related to comfort, well-being, health status

and ease of care for children with severe developmental disabilities (GMFCS IV or V) (1).

Pain is strongly associated with reduced HRQoL and reduced participation (5). At all ages, pain in individuals with CP is more prevalent than in the general population (98-100), and should be alleviated where possible (5). Surgeons perform interventions about the hip to prevent painful hip dislocation in children with CP (101). However, only recently has the effect of reconstructive hip surgery in non-ambulant children with CP and HRQoL been studied using the CPCHILD™ questionnaire (42). In this study by DiFazio and colleagues, it was noted that increasing migration percentage (MP) preoperatively, negatively correlated with CPCHILD™ scores (42). However, significant improvements in scores were observed from six weeks after surgery. They were related to changes in MP following VDRO but not the changes in acetabular index (AI) following a pelvic osteotomy (42). All domains within the CPCHILD™ questionnaire improved, with the exception for the communication and social interaction domain. The greatest improvements were seen in the comfort and emotions domain (42).

Treatments are therefore targeted to address fixed deformities about the hip before painful progression of hip displacement, dislocation, or degenerative arthritis occurs (102). The principle aim of CP hip surgical treatment is to achieve a painless, enlocated hip with a flexible range of motion and morphology that is adequate for the functional demands of the individual with CP (49, 103), and will secondarily improve HRQoL (1, 42, 101) (Figure 14). Treatment options can be considered as: non-operative, preventive, reconstructive and salvage (35, 49) .

Decision Matrix

AGE	Surveillance and skeletal maturity				
	0	5	10	15	20
GMFCS					

FIGURE 14 | Decision matrix used to determine the treatments required to manage hip dysplasia for a child with cerebral palsy. Adapted with acknowledgements to A Khot, J Howard and HK Graham.

3 NON-OPERATIVE INTERVENTIONS FOR HIP DISPLACEMENT

Non-operative interventions have been trialled to reduce or prevent the progression of hip displacement and are still widely practiced (5). These have included postural sleeping systems, seating modifications, standing programs, abduction bracing, and intramuscular injections of neurolytic agents including phenol and Botulinum Neurotoxin A (BoNT-A) (35, 104).

Standing programs for non-ambulant children have a theoretical potential to encourage hip development, maintain posture, prevent contractures of the lower limb and improve bone, cardiorespiratory and digestive health (105, 106). However, the effect of standing programs and hip stability is inconclusive (107). There is limited evidence to support the use of other postural control systems for hip stability in children with CP (108-111).

Hip abduction bracing has a limited role in maintaining improved range of hip abduction after adductor surgery. Current evidence to support abduction bracing is difficult to assess in the setting of weak study design and implementation (109, 111). Bracing appears to be poorly tolerated and is not effective in non-ambulant children with severe adductor spasticity, who are at highest risk for hip displacement.

BoNT-A is a potent neurotoxin produced by the bacteria *Clostridium botulinum* under anaerobic conditions. It causes a dose-dependent chemodenervation of a muscle with approximately 3-month effect (19). Injections of BoNT-A reduce spasticity in the hip adductor muscles (112-115) and may contribute to pain relief for severe hip pain from hip displacement or dislocation (116). However, a three-year randomised controlled trial (RCT) of 90 children with CP and 'hips at risk' (MP 10-40%) demonstrated that BoNT-A to the adductors and hamstrings in combination with a hip abduction brace, did not reduce the risk of hip displacement (115). Willoughby and colleagues conducted a further long-term follow up of 46 children who were enrolled in the initial RCT to skeletal maturity

(117). Findings from the long-term study demonstrated no differences in pain, hip morphology, nor the need for either preventive or bony reconstructive surgery between treatment and control groups (117). This confirmed the hypothesis that BoNT-A and abduction bracing can make meaningful changes to children's spasticity, but no effective changes to the prevention of progressive hip displacement in children with CP.

4 ADDUCTOR SURGERY FOR HIP DISPLACEMENT

Preventive surgery refers to surgical interventions that are aimed to prevent progressive hip displacement (MP > 30%) in younger children with 'hips at risk' (90, 118). Adductor surgery is one such form of preventive surgery. This usually involves the lengthening of hip adductors, with the occasional addition of hip flexor lengthening and phenolisation or neurectomy to the anterior branch of the obturator nerve (119-122).

However, the timing and indication for the procedure, the specific muscles requiring release, and post-operative management are controversial (123). The variability of the treatment protocols employed by individual institutions for a heterogeneous population of children with CP have led to uncertainty regarding the success of adductor surgery for prevention of hip displacement (124).

A systematic review of hip adductor releases for hip subluxation in children with CP demonstrated that a preoperative MP of less than 30 to 40% was associated with successful outcomes for 75 to 90% of hips (124). However, 75 to 77% of hips remained subluxated or dislocated if the preoperative MP was over 40 to 50% (124). In another long-term study of children with spastic CP, it was noted that children who were able to walk pre-operatively had a better outcome from adductor surgery (123). Neither the pre-operative MP nor age at surgery affected the post-operative outcome (123).

The link between walking ability as described by GMFCS, and success of adductor surgery was formally made in 2012 (2). Shore and colleagues performed a retrospective review on 330 children who underwent adductor surgery at a single tertiary centre with a minimum two-year follow up. The authors demonstrated that the success of adductor surgery for primarily preventing progression of hip displacement had an inverse relationship to GMFCS level (2). GMFCS level II children had a 94% success rate, whereas GMFCS level V children only had a 14% success rate and required bony reconstructive surgery (2).

Until this publication, bony reconstructive surgery such as Varus Derotation Osteotomy (VDRO) was offered as a second line treatment, if and when adductor surgery failed. But in the face of a paradox where non-ambulant children who need the benefits of adductor surgery most, benefit the least (2), research efforts have been directed toward offering primary bony reconstructive surgery to younger children when needed.

5 PROXIMAL FEMORAL OSTEOTOMY FOR HIP DISPLACEMENT

Proximal femoral osteotomy (PFO) was first described by Friedrich Pauwels for adult hip arthritis. PFOs were intended to relieve excessive joint pressure that could cause the destruction of articular cartilage and lead to osteoarthritis (125). He expressed the biomechanics of the hip in two-dimensions (coronal and sagittal) and this was expanded to a three-dimensional concept (coronal, sagittal and axial) by Renato Bombelli (126). The original concept of the PFO in adults has been translated for use in children and adolescents, and it is now the most common major reconstructive surgery about the hip in this age group (127).

5.1 Indications for Surgery

In children and adolescents, PFOs can be performed for two main issues. Abnormal gait patterns such as excessive in-toeing, can be corrected with a Femoral Derotation Osteotomy (FDO) (128-130). As the name suggests, this surgery entails an osteotomy that derotates the femur on a coronal and sagittal plane to achieve a gait with improved or normal biomechanics. PFOs are also used for the treatment of hip displacement with a Varus Derotation shortening Osteotomy (VDRO) (Figure 15) (131, 132).

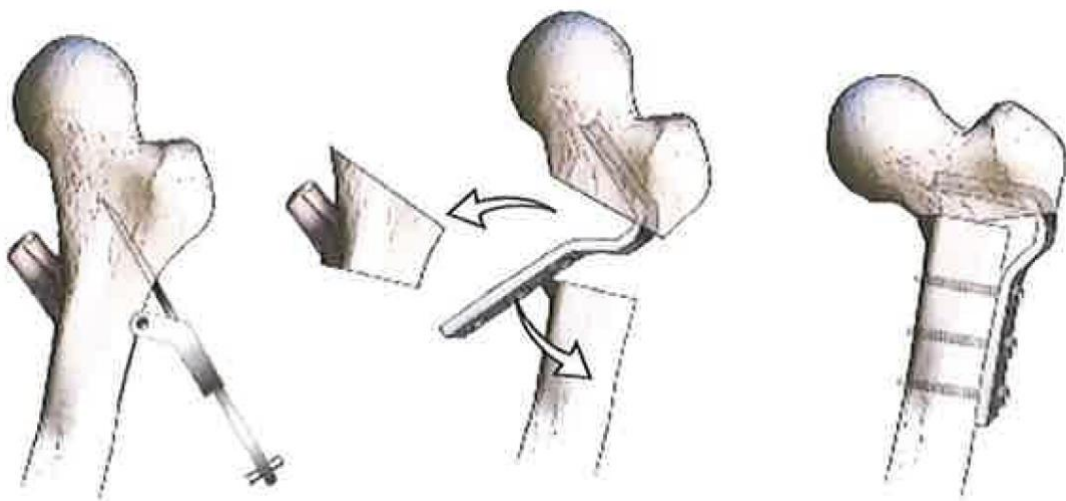


Figure 15 | Illustration from Graham 2014 (3) demonstrating VDRO as a reconstructive

option for moderate hip displacement in non-ambulatory children with cerebral palsy. (VDRO, Varus Derotation Osteotomy). *Copyright permissions to reuse material granted.*

5.1.1. PFO in Ambulant children with Cerebral Palsy

The use of a Femoral Derotation Osteotomy (FDO) for ambulant children (GMFCS I to III) with spastic diplegia is well described (128-130, 133, 134) and correction of an internally rotated gait through FDO can be successfully maintained beyond puberty (129). FDO is frequently combined with other procedures as part of a single-event multi-level surgery (SEMLS). A landmark randomised controlled trial (RCT) by Thomason and colleagues demonstrated that SEMLS improved gait biomechanics after 12 months, and clinically significant improvements in gross motor function and quality of life were seen after 24 months (134). Recently published long-term results affirmed the effectiveness of SEMLS, with the maintenance of improved gait biomechanics in 76.6% of ambulatory children with spastic diplegic CP (128).

5.1.2. PFO in Non-Ambulant children with Cerebral Palsy

A step-wise approach to hip subluxation (MP > 50%) or dislocation is frequently adopted in non-ambulant children with CP (GMFCS IV and V) (135). Since adductor surgery is not predictable in isolation (2), **i)** soft tissue surgery combined with **ii)** Varus Derotation Osteotomy (VDRO) has been recommended as the primary reconstructive option for these children (132, 135). A **iii)** Pelvic Osteotomy (PO) (136, 137) can be utilised as a secondary option if hip dysplasia or displacement persists following the primary procedure (49, 103). **iv)** Salvage procedures such as a valgus osteotomy, arthrodesis, excisional arthroplasty, or joint arthroplasty (79) are reserved for painful, dislocated hips (Figure 16). However, salvage procedures have inferior clinical outcomes when compared to reconstructive procedures (73). Salvage procedures are unpredictable with respect to their ability to relieve pain and have a high risk of post-operative complications and revision surgery (102). Hip surveillance programs (39, 90) are therefore paramount in identifying and treating hip dysplasia before displacement progresses and pain occurs (73, 138).

The effects of VDRO to re-orient the femoral neck and correct excessive anteversion (103) from several mid- to long-term studies have demonstrated positive results (47, 87, 131, 132, 139-143) with improvements in HRQoL (42). Ambulatory status and pre-operative migration percentage are significant determinants for post-operative success (47, 132). Non-ambulatory children with CP who have primarily unilateral involvement, may develop contralateral hip subluxation following unilateral reconstructions (47, 62, 144, 145). Shukla and colleagues reviewed 35 non-ambulant children with CP who underwent unilateral hip reconstruction. Contralateral hip subluxation developed in 10 (28%) children, and ipsilateral hip failure was seen in 12 (34%) children. Predictors of failures included: a lack of contralateral hip soft tissue release (STR), reversal of pelvic obliquity angle and contralateral MP over 25% in children under the age of 8 (144). In 2012, Park and colleagues created a decision-tree model, which favoured performing a prophylactic VDRO on the contralateral stable hip in non-ambulant children with CP under the age of 10 years, rather than observing the contralateral hip until subluxation became present. This was on the basis that children would have improved pain, as measured by HRQoL focused on hip pain using the time trade-off technique (146). It would also decrease the need for an extensive hip reconstructive surgery (e.g. STR, VDRO and PO combined) associated with delayed intervention and its' increased risks of post-operative complications (147). As such, bilateral VDROs are recommended in the majority of non-ambulatory children with CP (103) (Figure 16).

Surveillance and Management of Hip Displacement in Cerebral Palsy (GMFCS IV and V)

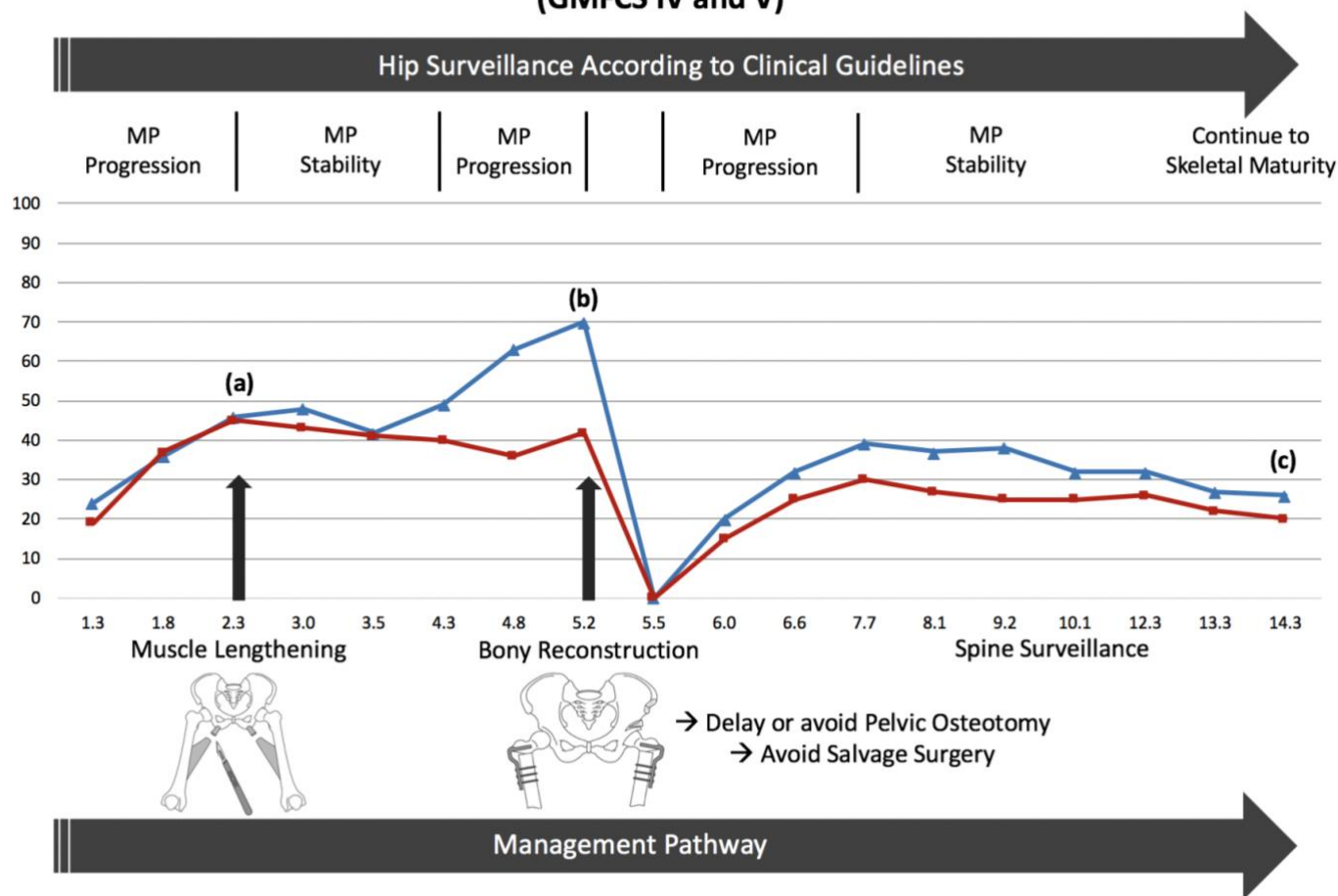


FIGURE 16 | By following hip surveillance guidelines, hip dysplasia in non-ambulant children with cerebral palsy can be treated earlier, potentially avoiding the need for more extensive hip reconstructive surgery or salvage surgery. Adapted with acknowledgements to A Khot, J Howard and HK Graham.

The effect of performing VDRO in younger children remains controversial (47, 89, 132). In an average 5 year follow up of 65 children who underwent 79 VDROs, Noonan et al demonstrated that hips of children under the age of 6 years were less likely to re-subluxate or dislocate than children over 6 years (47). Conversely, Shore et al demonstrated that children under the age of 6 years were more likely to require further surgery for re-subluxation or dislocation in a cohort of 320 children and 467 hips (132). There is emerging evidence to suggest that performing VDRO in children under the age of 6 years may have a bimodal effect on hip development. Studies have shown that early VDRO may improve or even reverse acetabular dysplasia (87-89), which may alleviate the need for pelvic osteotomy. However, rebound coxa valga of the proximal femur may occur (88). There are technical difficulties associated with operating on younger children with smaller bones which also need to be considered. This is further surmounted by issues such as osteopenia and poor nutrition. Experienced surgeons who perform over five VDROs per year are likely to improve the success of these difficult surgeries (132).

5.1.3. PFO in Other Conditions

Proximal femoral osteotomies have been used for a number of other conditions relating to the hip in childhood. These have included treatment for congenital conditions such as developmental dysplasia of the hip (DDH) (127, 148-157) and congenital coxa vara (153, 158-163), acquired conditions such as Legg-Calve-Perthes' disease (148, 164-166) and slipped capital femoral epiphysis (SCFE) (167-169), deformity following infection or traumatic injury (153, 170-173) as well as other neuromuscular conditions including spina bifida (148, 174) with good outcomes.

5.2 Surgical Implants used for Proximal Femoral Osteotomy

There have been several described methods used to maintain the position of a proximal femoral osteotomy. These have previously included external fixation, a combination of internal and external fixation, and in the current era, internal fixation alone (173).

Surgical implants used for proximal femoral osteotomy need to be diverse. Implants should be able to accommodate children with ages from 12 months to skeletal maturity, and cater for a range of body weights from 10 kilograms to more than 120 kilograms. A variety of implants have been used for fixation of PFOs in the last century (173) and have evolved with time.

The use of a hip spica following proximal femoral osteotomy was historically used for stability and to prevent loss of fixation (87, 148). However, in medically frail children with osteopenic or osteoporotic bone, the high risks of: fracture, pressure sores, skin breakdown, soiling and general inconvenience, far outweigh its' benefits (175, 176). Whilst the primary technical goal is to ensure stable fixation, the evolving management through multidisciplinary care for children with CP (27) and device technology for PFO fixation has encouraged a trend for immediate post-operative mobilisation with the use of analgesic and anti-spasmodic adjuncts, in order to avoid cast-related complications (140, 177-179).

5.2.1 Historical implants: Two Part Devices

The Coventry lag screw and plate was initially developed by Raymond Brigden, for Mr J.H. Penrose at Warwickshire Hospital in Coventry, England (173). This implant incorporated a cannulated screw with an outer threaded hexagonal head that fitted onto a hexagonal self-locking nut. The lag screw was attached to a stainless-steel plate. The plate could be bent intra-operatively and contoured to the osteotomy site (Figure 17) (173).

Canale utilised this implant for proximal femoral osteotomy in a study of 30 children and 38 hips for a variety of conditions (173). The post-operative results of 31 hips was considered satisfactory. The remaining seven (18.4%) were unsatisfactory. Of these seven unsatisfactory hips, three osteotomies were performed in children CP where there was one case of osteotomy non-union and two cases of screw prominence requiring removal of metalware. In the remaining four unsatisfactory results, there were two prosthetic fractures in the setting of a valgus osteotomy, one periprosthetic fracture distal to the plate, and one malunion (173). All patients in the study cohort required a hip spica cast

post-operatively for 7 to 30 weeks. Cast-related complications were not discussed (173). Unpublished data from a colleague of Canale's at Gillette Children's Hospital experienced 15 significant complications in their group of 13 children with CP (173). These included six protrusions of the fixation device and four significant losses of fixation. There were five cast-related complications including three cast pressure sores and two distal femur fractures following spica removal. It was felt that the complication rate was unacceptably high, and that other surgical devices should be considered (173).

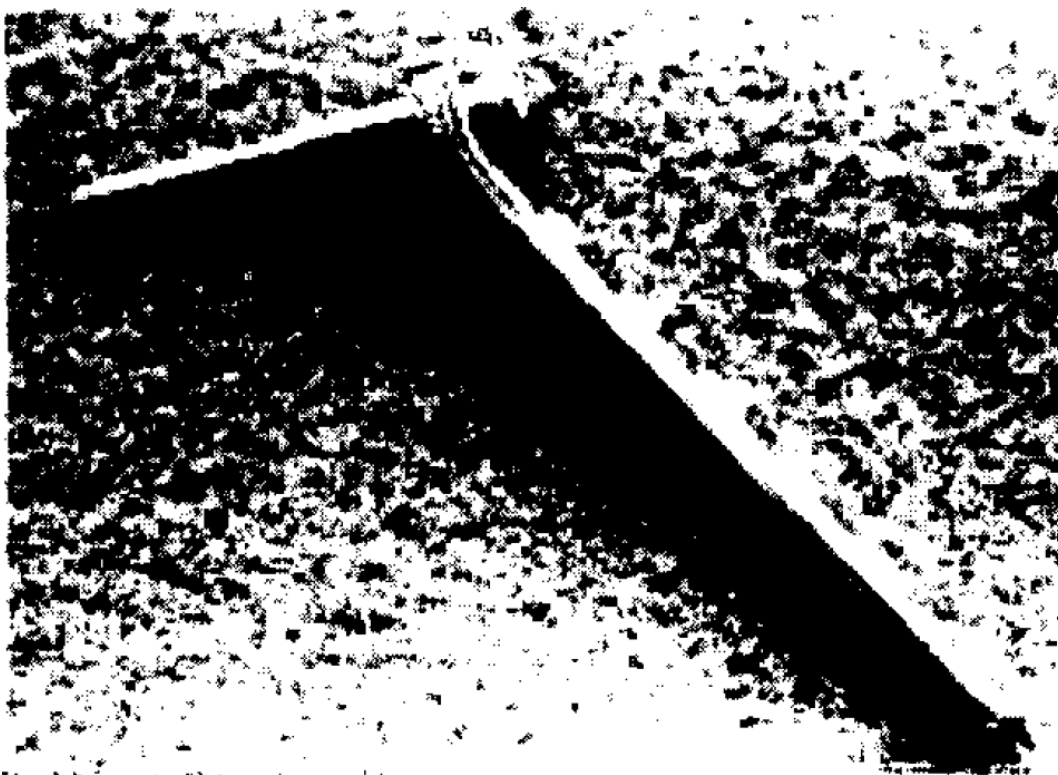


Figure 17 | Black and white photograph of the Coventry screw and plate implant obtained from Canale 1983 (173). Copyright permissions to reuse material granted.

In 2000, Hau and colleagues reviewed the short term clinical and radiological outcomes of PFOs using the Richards intermediate hip screw in 56 hips of 44 patients. This was another two-part device with sliding screw technology, largely derived from fixation devices used for adult neck of femur fractures (Figure 18) (178). Findings demonstrated no technical errors involving penetration of the femoral calcar. However, there were two technical errors involving malrotation

at the osteotomy site and one loss of fixation requiring revision surgery (178). Other reported complications included one case of trochanteric bursitis requiring removal of implant, and a case of painful non-union requiring revision to an angled blade plate. Although the authors concluded that the hip screw device was acceptable for use in PFOs, the inability to medialise the femoral shaft following varus correction was a short fall of the device (178). Furthermore, 27 patients (61%) required hip spica immobilisation for approximately six weeks (range 3-8 weeks) due to unstable fixation (178). A subsequent study from the institution modified the technique to increase the stability of fixation, by adding an anti-rotation screw through the proximal slot of the side plate (180). This decreased the need for a spica to 16% (2 of 12 patients) (180). One of the two patients who required a spica developed a sacral decubitus ulcer that was managed with dressings.

Findings from another study of 81 hips in 72 children demonstrated good results, with only four reported complications (181). Two children experienced superficial wound infections managed with antibiotics. One child developed a wound haematoma requiring evacuation in theatre, and one further child required revision to an angled blade plate after the screw cut out two weeks post-operatively (181). 16% of children with CP and 96% of children with DDH required post-operative hip spicas, but no cast-related complications were disclosed (181). A recent large cohort, retrospective study demonstrated a lower incidence of implant-related fractures from the Richard's intermediate hip screw (1.6% of 254 children) compared to the fixed angled blade plate (2.9% of 480 children), although this was not statistically significant (182). The use of an anti-rotation screw or post-operative hip spica were not documented (182).

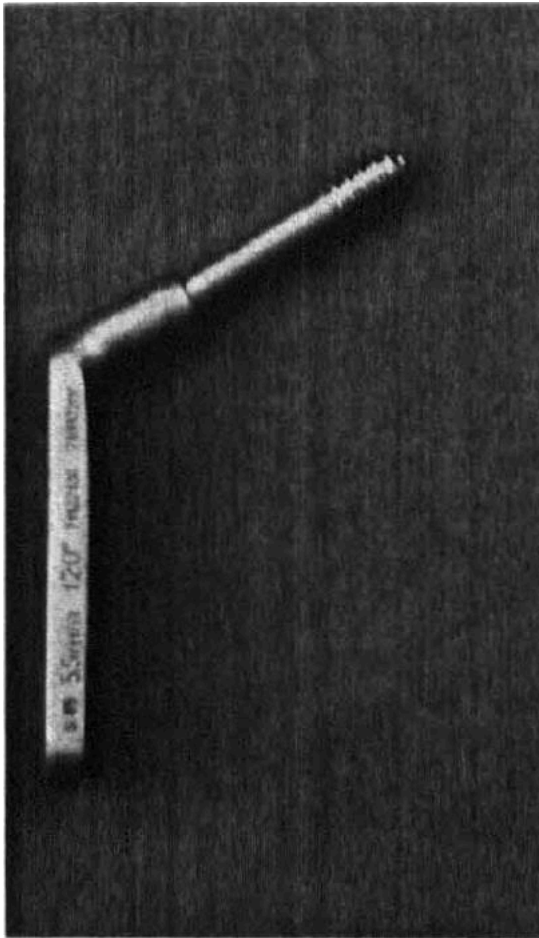


Figure 18 | Black and white photograph of the Richards intermediate hip screw obtained from Hau et al 2000 (178). Copyright permissions to reuse material granted.

5.2.2. Fixed Angled Blade Plates

The use of non-cannulated, non-locking devices such as the fixed Angled Blade Plate (ABP) have been described since the late 1970s (148, 183). The ABP is a stable single-piece device with femoral shaft screw holes, and allows medialisation of the femoral shaft during Varus Derotation Osteotomies (VDRO) (Figure 19).

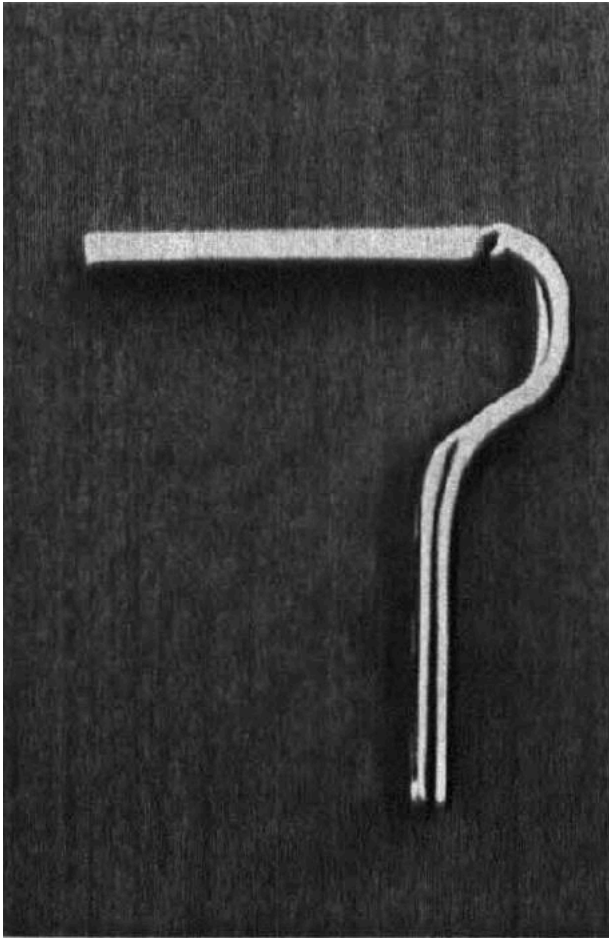


Figure 19 | Black and white photograph of the AO-fixed Angle Blade Plate obtained from Hau et al 2000 (178).

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In 1980, Root presented a series of 100 osteotomies that underwent fixation with a fixed angled blade plate. All except one osteotomy healed within eight weeks (148). Limited adverse events were documented, likely due to the retrospective nature of the study. This included a deep infection requiring removal of metalware and application of a hip spica, avascular necrosis of one femoral head but a result of an osteotomy error rather than the implant, and four cases of heterotopic ossification (148). All osteotomies required post-operative hip spicas for three weeks. There was no documentation of cast-related complications (148).

Beauchesne and colleagues reviewed the ABP with more vigour in a cohort of 157 hips in 101 children with a variety of diagnoses. Immediate post-operative mobilisation was encouraged without the need for a hip spica in all but three patients. A total of fourteen post-operative complications were reported, with the vast majority of these involving children with CP (177). There were two deep

wound infections requiring debridement, two superficial wound infections requiring outpatient care, one lateral wound breakdown due to bone prominence and five proximal femur fractures. Two osteotomies had failure of initial fixation which required revision surgical fixation. It was felt that the choice of blade plate was too small in both cases, leading to unstable fixation. Of the three children requiring post-operative hip spicas, there were two cast-related fractures following removal of spica (177).

The use of the ABP was more recently evaluated by Hau (178). 88 patients who underwent 108 hip osteotomies were reviewed. Reported adverse events included two common peroneal palsies, three superficial wound infections, two deep infections, two femoral fractures, and one skin breakdown causing exposure of the blade plate. Only 15% of the cohort required hip spica application. Cast-related adverse events were not reported (178).

Good results have been reported for PFO utilising an ABP without a post-operative hip spica (140, 176, 179). Positive effects can also be obtained from early weight-bearing. Improvements in post-operative pain, initiation of early standing, and earlier return to baseline walking have been demonstrated (179).

Despite the inconsistencies with adverse event reporting, the superior biomechanics and lower rates of adverse events has led fixed angle blade plates to be widely used and is considered the 'gold standard' implant to this day.

5.2.3. Locking Cannulated Implants

Recent developments in fracture fixation have incorporated locking screws to improve the biomechanical construct of surgical devices (184). This technology has been introduced to devices used for PFOs in children.

In 2010, Rutz compared the ABP with a paediatric locking compression hip plate (LCP) (185). The advantage of inserting screws within the proximal fragment was theorised to improve angular stability (186, 187), grip and decrease loss of fixation. Technical outcomes were similar between groups

(185) and approximately two-thirds of the total cohort required hip spica application. However, the use of the LCP was weighed down by longer operative time and more blood loss due to the increased technical demands of using the compression plate. Furthermore, bone healing was delayed at 6 weeks with the LCP when compared to the conventional ABP, resulting in a subsequent delay in plate removal (185). Similar findings were demonstrated in another study of 30 hips in 22 patients (188).

There may be an increased risk of fracture associated with the LCP compared to the ABP (189). It has been theorised that the strength of fixation obtained from the LCP may cause a stress-shielding effect on osteopenic bone in children with CP (189). Removing the plate twelve months or later from the index surgery may also be difficult (190). Stripping of screw heads, cold welding of the screw to plate, retained metalware and secondary intraoperative fractures have been described (190).

There has been growing interest in the utilisation of a locking cannulated blade plate (LCBP) that is able to incorporate the strengths of the traditional ABP with the strengths of new trauma technology (Figure 20). A description of this form of surgical device was first described by Alfred Grant in 1990 (191), but has only recently become commercially available in a variety of sizes for children and adolescents. The addition of a cannulated component enables the blade plate to slide directly over the guidewire, ensuring that the desired line of plate insertion can be performed with more accuracy and ease (191). The technical outcomes and the safety profile of the LCBP for use in proximal femoral osteotomies have not yet been assessed, and should be compared to the existing gold standard ABP device.

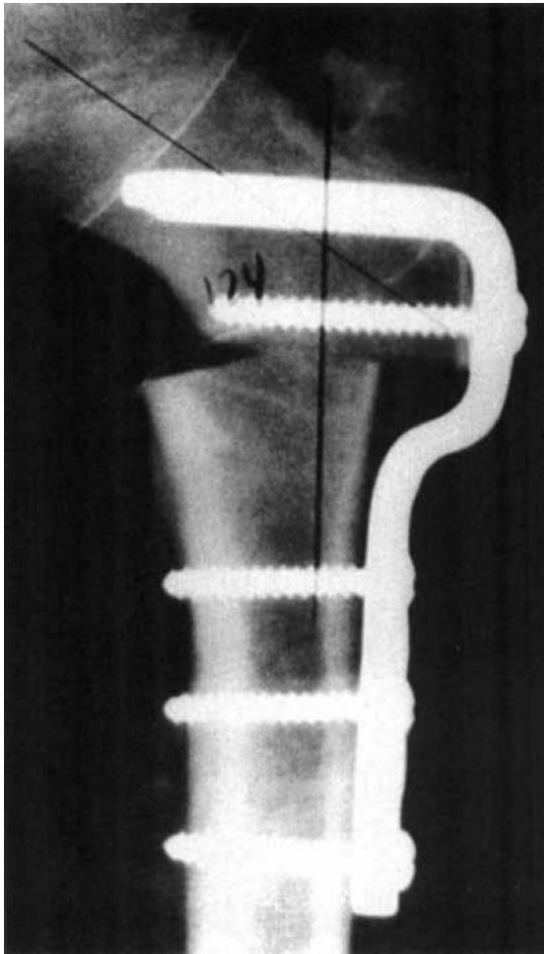


Figure 20 | Anteroposterior radiograph of a left proximal femoral osteotomy, internally fixed with a locking cannulated blade plate. Image obtained from Grant 1990 (191).

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6 ADVERSE EVENTS ASSOCIATED WITH SURGERY FOR HIP DISPLACEMENT

Documentation of post-operative adverse events (AE) experienced by children with CP following lower limb surgery for hip displacement is limited (175, 192). There are several contributing factors. Surgeons have historically reported short-term AEs with longer-term treatment outcomes that do not involve patients' perceptions (137, 140, 193, 194). Reported outcomes are often not standardised, and therefore not reproducible, which hinders evaluation (195). It is suspected that the retrospective nature of many studies decreases the true incidence of reported medical and surgical adverse events. Despite calls for surgical research to be more rigorous (196, 197), the overall frequency of high-quality research with RCTs has been consistently low. Ergina and colleagues identified potential challenges that limited evaluation of surgical procedures, including: the operative complexity, surgeon-related factors, and the broad range of measured outcomes (195). The group urged that although difficult, surgical evaluation is achievable and necessary (195).

6.1 Adverse Events in Cerebral Palsy

Children with CP are more likely to have concomitant medical issues that may contribute to their post-operative risk of developing an adverse event following surgery (192). Issues such as pre-existing respiratory disease, nutritional issues and seizures need to be considered (27). The most common cause of mortality for adolescents at GMFCS IV and V is chronic lung disease (27).

6.1.1. Medical Adverse Events

Medical adverse events are poorly described in the literature. In a retrospective evaluation of complications following osteotomies in severe CP, Stasilekis reported a 25% incidence of complications. Medical adverse events (MAE) were not separated from surgical adverse events (SAE). Five patients were noted to have decubitus ulcers at the time of cast removal, and were managed with outpatient wound care. There were no reports of other MAEs such as chest

infections and anaemia requiring transfusion. The presence of a tracheostomy or gastrostomy significantly increased a child's risk of a post-operative complication (194).

This is further evidenced by Miller and colleagues, who only reported MAEs involving one pneumonia, one pneumothorax and one urinary tract infection (UTI), in the outcomes of 51 children following PFO and pelvic osteotomies (140). More recently, a long-term retrospective follow up of 168 hip reconstructions in 121 patients demonstrated a MAE incidence of 29.8% (131). Sixteen (13.2%) developed chest infections, two (1.7%) developed an aspiration, twelve (9.9%) had decubitus ulceration involving the heel or coccyx, three (2.5%) had a deteriorating seizure disorder and three (2.5%) had a UTI (131).

In 2016, DiFazio and colleagues published a landmark paper describing the frequency and differences between adverse events observed in children with CP compared to typically developing children (192) following hip reconstructive surgery. A retrospective matched cohort study of 110 children was utilised. Children with CP (65%) experienced twice as many adverse events compared to typically developing children (36%), and were 82% more likely to develop an AE. The majority of AEs described in the CP group were medically-related and were relatively minor. These included skin breakdown from immobilisation devices, issues with feeding or constipation, respiratory infections, poor bone healing, exacerbation of seizure disorder and uncontrolled pain (Table 1) (192). Conversely, typically developing children were more likely to develop surgically related AEs, such as a post-operative neuropraxia or delayed union (Table 1) (192).

	CP (n = 53)	Non-CP (n = 22)	P
Orthopaedic complications	9 (17)	13 (59)	< 0.001
Bony healing	5	4	
Fracture	1	0	
Subcutaneous hematoma	0	3	
Sciatic or femoral neuropraxia	0	4	
Heterotopic ossification	3	2	0.10
Skin complications	23 (43)	5 (23)	
Sacral decubitus ulcer	2	0	
Epidural site	1	0	
Immobilization device	16	4	
Surgical site	4	1	0.08
Surgical site infection	0	0	
GI complication	7 (13)	0 (0)	
Feeding issue	4	0	
Constipation	3	0	
Urinary complication	4 (8)	1 (5)	0.78
Urinary retention	1	1	
Urinary tract infection	3	0	
Respiratory complication	4 (8)	0 (0)	0.27
Seizures	2 (4)	0 (0)	—
Pain symptomology	2 (4)	3 (14)	0.13
Other complications	2 (4)	0 (0)	—

Table 1 | Table obtained from DiFazio et al 2016 (192) describing the incidence and type of adverse event observed in children with cerebral palsy (CP) and typically developing children (non-CP). (CP, cerebral palsy; GI, gastrointestinal). Copyright permissions to reuse material granted.

6.1.2. Surgical Adverse Events associated with PFO

Surgical adverse events (SAE) are usually better described in the literature, with a variable incidence of 10 to 45% depending on institution (131, 137, 142, 145). In McNerney's study of 75 children with CP who underwent single-stage correction of hip dysplasia with combined proximal femoral and acetabular osteotomies, 44 SAEs were described in 33 children (137). Avascular necrosis (AVN) of the femoral head was noted in eight hips. Three of these developed subsequent coxa vara, and one child died from a respiratory arrest during a valgus osteotomy. There were two deep infections requiring operative debridement, and one superficial infection requiring outpatient wound care. Seven hips developed heterotopic ossification (HO) and did not require further surgical intervention (137). Of note, this publication did not report any medical adverse events (137).

Similarly, a long-term retrospective study of 19 children with CP reported surgical adverse events only (142). Five SAEs were seen in four hips. These included one dislocation, one subluxation, one coxa vara with adduction deformity, one subtrochanteric fracture and one infection. Management of these

adverse events were not documented (142). Another recent publication demonstrated a 10.5% incidence of surgical adverse events (131). Of the 168 hips treated with PFOs, there was one case of septic arthritis requiring surgical debridement, three distal femur fractures requiring surgical fixation, one hip requiring revision due to excessive rotation, one case of acetabular necrosis which resolved conservatively, and one case of HO. Interestingly, the two hips that required revision hip reconstruction following recurrent dislocation were also considered as a complication (131), rather than a surgical failure (132).

6.2 Classification for Adverse Events

There is no standardised method to report adverse events for children with CP following lower limb surgery. The retrospective nature of many studies, heterogeneity of the studied children with CP, variability in surgical technique and likely under-reporting of adverse events by authors further compounds this issue.

6.2.1. General Surgery

In 1992, Pierre-Alain Clavien recognised that a: *'lack of uniform reporting of negative outcomes make interpretation of surgical literature difficult'* (198). He differentiated the meaning of a complication from negative outcomes such as a sequelae or a failure of surgical therapy. Clavien proposed a four-grade classification system to assess complications following cholecystectomy. This classification would provide institutions a way to compare results, perform meta-analysis, identify objective pre-operative risk factors and establish pre-operative prognostic scores (198). It was suggested that grade I events were alterations from the ideal post-operative course that only required bedside intervention but did not prolong hospital stay, was not life-threatening and did not cause a lasting disability. Grade II events were potentially life-threatening but without residual disability. Grade II events were divided into a) treatment without invasive procedures and b) treatment with invasive procedures. Grade III events caused residual disability, including organ resection or persistence of life-threatening conditions. Grade IV events resulted in death (198).

In 2004, Clavien expanded the system to five grades with his colleague, Daniel Dindo, for wider dissemination in general surgery (Table 2) (199). This Clavien-Dindo (CD) System was determined by the treatment required to manage the complication and the outcome of the complication. Clinical examples of complications by body system were created for each grade (199).

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix “d”	If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix “d” (for “disability”) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.

Table 2 | Table obtained from Clavien & Dindo (199) describing the Clavien-Dindo Classification of Surgical Complications. (CNS, central nervous system; IC, intermediate care; ICU, intensive care unit). Copyright permissions to reuse material granted.

The CD is now a widely accepted, valid and reliable tool (199, 200). It is perceived similarly by patients, nurses and physicians, and has been suggested for use as part of the shared or informed decision making process (201).

The current CD system is used for grading single adverse events (201) and it is unclear how the system could be applied if there are multiple adverse events experienced by an individual (201). The authors previously recommended that only the most severe AE should be graded in the setting of multiple AEs (202). However, ignoring events of lesser severity would fail to represent the true overall morbidity burden of a procedure (202). Slankamenac and Clavien therefore created the comprehensive complication index (CCI), which is a mathematical formula, aimed to rank the weighted severity of multiple complications from 0 to 100 in a single patient (202). The CCI has been

validated (202), but reliability testing has not yet been performed. The CCI has not been utilised in orthopaedic literature to date.

6.2.2. The Clavien-Dindo System and Orthopaedic Surgery

In 2011, Sink and colleagues were the first to implement the CD system for reporting adverse events in hip preservation surgery (203). However, Sink recognised that the classification needed to be tailored prior to use in orthopaedic surgery. For example, Sink clarified that a Grade IV adverse event caused a long-term orthopaedic disability or was life-threatening, including a permanent nerve injury, pulmonary embolus, osteonecrosis, or admission to the intensive care unit (ICU) (203) (Table 3). Sink published a subsequent study, to determine the reliability of the modified Clavien-Dindo (MCD) in hip preservation surgery. The overall Fleiss kappa (κ) value for inter-rater reliability was 0.887, and Cohen's kappa value for intra-rater reliability was 0.891 (204).

Grade	Definition	Specific complications
I	A complication that requires no treatment and has no clinical relevance; there is no deviation from routine followup during the postoperative period; allowed therapeutic regimens include: antiemetics, antipyretics, analgesics, diuretics, electrolytes, antibiotics, and physiotherapy	Asymptomatic Grade I or II heterotopic ossification; postoperative fever, nausea, constipation, minor UTI; wound problem not requiring a change in postoperative care
II	A deviation from the normal postoperative course (including unplanned clinic visits) that requires outpatient treatment: either pharmacologic or close monitoring as an outpatient	Superficial wound infection (additional clinic visits); transient neurapraxia from positioning or surgical retraction that resolves under close observation; nerve palsy requiring bracing and close observation (complete resolution); trochanteric delayed union
III	A complication that is treatable but requires surgical, endoscopic, or radiographic interventions or an unplanned hospital admission	Trochanteric nonunion; fracture; deep infection; surgical hematoma; clinically significant heterotopic ossification that requires surgical excision; deep vein thrombosis (admission and anticoagulation)
IV	A complication that is life threatening, requires ICU admission, or is not treatable with potential for permanent disability; a complication that requires organ resection (THA)	Osteonecrosis; permanent nerve injury; major vascular injury; pulmonary embolism; CNS complications; organ dysfunction
V	Death	

Table 3 | Table obtained from Sink et al (204) describing the Modified Clavien-Dindo System for hip preservation surgery. (CNS, central nervous system; ICU, intensive care unit; UTI, urinary tract infection). Copyright permissions to reuse material granted.

Over time, Sink's 2012 adapted MCD system has been utilised in publications involving children with CP who underwent lower limb surgery (128, 175, 192). However, it is not yet known whether the MCD is reliable for grading the unique adverse events experienced by these children (192).

Most recently in October 2018, colleagues from the same group at the Hospital for Special Surgery produced another publication, aiming to broaden the application of the MCD-Sink (MCDS) system to all sub-types of paediatric orthopaedic surgery (205). A slight alteration was made to Grade IV events, differentiating complications that were life threatening but did not have long-term disability (IVa) and those that did (IVb). 22 paediatric orthopaedic surgeons rated 48 complications, demonstrating very good inter-rater and near perfect intra-rater reliability. This new system is still yet to be validated and more widely accepted in the literature (205).

7 CONCLUSIONS OF LITERATURE REVIEW: IDENTIFIED INFORMATION GAPS

A comprehensive review of the literature has identified several information gaps.

It remains unclear whether proximal femoral osteotomies can be performed safely in younger children with CP. The locking cannulated blade plate (LCBP) is available in a range of sizes that is tailored for use in younger children with small bones. However, the safety profile and technical outcomes of the LCBP for proximal femoral osteotomies is unknown. The potential benefits of using the LCBP to train orthopaedic registrars and fellows also requires further assessment.

It is unknown whether younger children will tolerate proximal femoral osteotomies with an acceptable surgical risk profile. Accurate, prospective recording of all adverse events will be required. Reliability of the Modified Clavien-Dindo (MCD) system for reporting the adverse events observed in children with CP following proximal femoral osteotomy will also need to be addressed, to meaningfully interpret the severity of adverse events experienced by children with CP in a standardised manner.

Finally, the success in performing a single-stage hip reconstructive surgery to maintain satisfactory hip stability and reduction until skeletal maturity is uncertain. A large cohort, long-term prospective study will be required. However, the evaluation of this final question is currently beyond the scope of this thesis and will require future exploration.

III. AIMS & HYPOTHESIS

The specific aims and hypotheses of each study have been published, and are available in Sections IV, V and VI respectively.

1 AIMS

This thesis aimed to assess the safety of PFOs in children and adolescents with cerebral palsy, in a series of three studies.

1. Can proximal femoral osteotomies be performed safely using the new LCBP implant?
 - a. Is there a difference in outcome comparing the gold standard ABP to the LCBP implant?
 - b. Is the technique in using the LCBP compared to the ABP implant easier to teach to orthopaedic surgery trainees?
2. Can proximal femoral osteotomies be performed in younger children with cerebral palsy?
 - a. Will younger children with feeding and medical issues tolerate such a major operation with an acceptable risk versus benefit?
3. Are there additional unknown adverse events with PFOs that will require careful counselling with families prior to the operation?
 - a. How can these adverse events be classified? Is the Modified Clavien-Dindo System (204) a reliable classification tool for lower limb surgery adverse events in children with cerebral palsy?

2 HYPOTHESES

Using the current evidence highlighted in Section *II. Literature Review*, it was hypothesised that:

1. Proximal femoral osteotomies could be safely performed using the new LCBP implant.
 - a. Post-operative surgical outcomes between the ABP and LCBP implant would be similar.
 - b. The cannulated technology within the LCBP implant would provide orthopaedic surgery trainees an easier learning curve, with less technical error, when performing proximal femoral osteotomies.
2. Proximal femoral osteotomies could be performed in younger children with cerebral palsy.
 - a. A thorough, holistic approach to preoperative surgical planning and medical optimisation would be required with multidisciplinary involvement, to ensure successful risk minimisation.
3. More frequent minor adverse events were anticipated due to the prospective nature of data recording. The incidence of major adverse events would be similar to current published literature.
 - a. The Modified Clavien-Dindo System would be a reliable tool for grading the severity of adverse events observed in lower limb surgery for children and adolescents with CP.

IV. STUDY ONE

1 PUBLISHED PAPER

Cannulated, Locking Blade Plates for Proximal Femoral Osteotomy in Children and Adolescents.

- A Pilot Study on Patient Safety and Implant Efficacy

Published by the Journal of Children's Orthopaedics in March 2015.

Cannulated, locking blade plates for proximal femoral osteotomy in children and adolescents

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Abstract

Background Proximal femoral osteotomy is the most common major reconstructive surgery in the region of the hip joint in children and adolescents. Given that it may be required across a wide range of ages and indications, appropriate instrumentation is necessary to ensure a technically satisfactory result. Recent developments in fixation include cannulation of the blade plate and locking screw technology.

Methods We conducted a prospective audit of our first 25 patients who had a unilateral or bilateral proximal femoral osteotomy using a recently available system which combines cannulation and locking plate technology. The principal outcome measures were the radiographic position of the osteotomy at the time of union and surgical adverse events.

Results Forty-five proximal femoral osteotomies were performed in 25 patients, mean age 8 years (range 3–17 years), for a variety of indications, the most common of which was hip subluxation in children with cerebral palsy. All osteotomies were soundly united by 6 weeks in children and by 3 months in adolescents, in the position achieved intra-operatively. There were no revision procedures and the technical goals of surgery were achieved in all patients. There was one adverse event, a low-grade peri-

prosthetic infection, diagnosed at the time of implant removal.

Conclusions In this prospective audit of our first 25 patients, the new system performed well across a wide range of ages, body weights and surgical indications. Further comparative studies will be required to determine whether it offers additional advantages over more traditional systems.

Keywords Proximal femoral osteotomy · Cannulated blade plate · Locking screw fixation

Background

Proximal femoral osteotomy (PFO) is the most common major reconstructive surgery in the region of the hip in children and adolescents [1]. The indications are wide and include developmental dysplasia of the hip (DDH), containment in Perthes' disease, realignment of the proximal femur following slipped capital femoral epiphysis and stabilisation of the hip in a wide range of neuromuscular diseases, the most common of which is cerebral palsy (CP) [2–5]. Implants for proximal femoral osteotomy may be required for internal fixation from approximately the age of 12 months to skeletal maturity and across a range of body weights, typically ranging from 10 kg to more than 120 kg. Historically, two-part devices were first used in proximal femoral osteotomy in children, derived from devices used for the fixation of proximal femoral fractures in adults [6]. With time, fixed-angle blade plates became the most widely used implant because of their sound biomechanical basis supported by several large retrospective studies showing excellent results [7, 8].

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Recent developments in fracture fixation, incorporating locking screws to improve the biomechanical construct, have been introduced to implants for internal fixation in proximal femoral osteotomy [9–11]. A second significant innovation was the development of a one-piece cannulated blade plate, which can be inserted over a guide wire [12]. The guide wire is inserted in the desired position in the proximal femur. The seating chisel is passed over the guide wire to cut the track for the blade plate, which is also inserted over the guide wire. This differs from classical PFO with AO blade plate fixation, in which a guide wire is inserted in the proximal femur and the insertion of the seating chisel and implant is referenced from the position and direction of this wire, but not passed directly over the guide wire [7, 8]. The cannulated blade plate concept was described by Grant and colleagues in 1990 but has only become widely available commercially in recent years [12, 13]. In 2013, Poul and colleagues reported more precise correction of proximal femoral deformities in a study in which the Cannulated Paediatric Osteotomy System (CAPOS) was compared to the conventional angled blade plate (Synthes) [13].

Approximately 160 proximal femoral osteotomies per annum are performed at our tertiary-level paediatric hospital. The safety and efficacy of this procedure is therefore very important in our overall service. It is also important for us to be able to teach this surgery to our surgical registrars and fellows. We hypothesised that this new system would offer significant advantages over existing systems, including more stable fixation and an easier and safer learning curve for trainees. We decided to introduce the implant in a controlled fashion and prospectively audit our first 25 patients. Our study goals were limited to short-term, technical outcomes of the PFO. Given the diverse diagnoses, clinical and functional outcomes would require long-term follow-up of larger, homogeneous subgroups.

An Excel (Microsoft) spreadsheet was devised to include demographic details, diagnosis, surgical indications, surgical planning, operation report, the implant used, pre- and post-operative radiographic data and surgical adverse events. No outside funding was received in relation to this study. The study was conducted under the audit provisions of the hospital's research and ethics committee.

Materials and methods

This was a prospective cohort study, with consecutive enrolment of all children and adolescents who had a PFO with the PediLoc[®] Locking Cannulated Blade Plate System (OrthoPediatrics), between April 1, 2013 and July 31, 2014 (Table 1). Patient data was entered on an Excel spreadsheet from the patient's electronic scanned medical record

(ESMR), and operation reports and radiological data from the Patient Archiving and Communication System (PACS). Pre-operative radiographs were reviewed on Synapse (Fujifilm, PACS) and a number of radiographic parameters measured, relevant to the underlying diagnosis. These included migration percentage (MP), neck shaft angle (NSA) and trochanteric height. Neck shaft angle was measured from an AP radiograph with the hips internally rotated by an amount equal to the estimated femoral neck anteversion (FNA), usually about 40° [14]. FNA was measured by the trochanteric prominence test (TPAT) and confirmed by computed tomography in selected patients [15]. Ambulant children with CP had three-dimensional gait analysis to plan single event, multilevel surgery (SEMLS) [16, 17].

Sequential radiographs were obtained before discharge from hospital and at 3, 6 and 12 weeks after surgery. For the purposes of this study, bony union was defined as the presence of bridging callus across >75 % of the osteotomy surface as well as external, medial bridging callus. The time to union was noted and the position of the implants studied on PACS at each interval, specifically looking for signs of union and any change in position of the implant or osteotomy. Technical outcomes of the surgery including femoral head cover (MP) and change in neck shaft angle were also observed. Changes in MP and NSA in the non-ambulant CP [gross motor function classification system (GMFCS) IV and V] subgroup were compared using paired *t* tests with *P* < 0.05.

Surgical technique

PFOs were performed under general anaesthesia, peri-operative intravenous antibiotics and insertion of an epidural catheter and bladder catheter when considered appropriate [16, 18]. The patient was placed supine on a radiolucent operating table. The lower limbs were prepared and draped free and a preliminary fluoroscopic examination was performed to confirm adequate range of motion, that any subluxation of the femoral head was reducible and that the goals of surgery were technically feasible [18]. The need for additional soft tissue releases and bony procedures was also assessed, including adductor and psoas releases, open reduction of the hip and pelvic osteotomy [16–19]. Biplanar fluoroscopy was used throughout the procedure with the C-arm in a fixed position over the operated hip. The lateral radiographs were obtained by moving the operated limb into a flexed, abducted position [19].

The proximal femur was exposed subperiosteally with careful retraction of the vastus lateralis to preserve its nerve and blood supply. A suitable entry for the insertion of the guide wire was marked using a combination of analysis of the surgical goals, the likely implant to be used and the patient's specific anatomy. For the most common

Table 1 Diagnosis, surgical indication, operative procedure and outcome of 25 patients with proximal femoral osteotomy and cannulated locking blade plate fixation

ID	Diagnosis	GMFCS level	Indication	Operation	Outcome
1	CP	V	Subluxation	Bilateral VDRO	S
2	CP	V	Subluxation	Bilateral VDRO	S
3	CP	V	Subluxation	Bilateral VDRO	S
4	CP	V	Subluxation	Bilateral VDRO	S
5	NM	IV	Windswept hips	Bilateral VDRO	S
6	CP	II	SEMLS	Bilateral FDO	Infection
7	CP	V	Subluxation	Bilateral VDRO	S
8	CP	V	Subluxation	Bilateral VDRO	S
9	CP	V	Subluxation	Bilateral VDRO	S
10	CP	II	SEMLS	Bilateral FDO	S
11	LCP	TD	Coxa vara	Right valgus PFO	S
12	CP	V	Dislocation	Bilateral VDRO	S
13	CP	IV	Subluxation	Bilateral VDRO	S
14	CP	V	Subluxation	Bilateral VDRO	S
15	Metabolic	V	Fracture	Left hip fracture ORIF	S
16	NM	V	Subluxation	Bilateral VDRO	S
17	CP	III	SEMLS	Bilateral FDO	S
18	CP	IV	Subluxation	Bilateral VDRO	S
19	CP	IV	Subluxation	Bilateral VDRO	S
20	CP	II	SEMLS	Bilateral FDO	S
21	DDH	TD	Subluxation	Left VDRO	S
22	LCP	TD	Containment	Right VDREO	S
23	DDH	TD	Dislocation	OR/left VDRO	Unknown
24	Metabolic	IV	Subluxation	Bilateral VDRO	S
25	CP	II	SEMLS	Bilateral FDO	S

CP cerebral palsy, NM neuromuscular, LCP Legg–Calvé–Perthes disease, DDH developmental dysplasia of the hip, GMFCS gross motor function classification system, TD typically developing, VDRO varus derotation osteotomy, FDO femoral derotation osteotomy, PFO proximal femoral osteotomy, OR open reduction, ORIF open reduction internal fixation, VDREO varus derotation extension osteotomy, S satisfactory: defined as no change in the position of the implant between the time of surgery and latest follow-up, union within 6 weeks in children and 12 weeks in adolescents, and all technical goals of surgery achieved

procedure (varus derotation osteotomy in CP) the goal was a NSA of 100° and complete containment of the femoral head. The guide wire was inserted into the centre of the femoral neck on both AP and lateral radiographic projections and a 100° plate of the appropriate width and length was selected. Selection of the blade width was aided by passing a seating chisel over the guide wire and, in the flexed-abducted view, checking fluoroscopically that the chisel (and plate) would be able to cross the isthmus of the neck without risk of penetration or fracture. The appropriate seating chisel was used to cut a track for the selected blade plate; the seating chisel and blade plate were matched. Attention was given to cutting the track collinear with the guide wire to avoid inadvertent advancement or removal of the guide wire. The seating chisel was then backed out slightly but left in situ [12]. The appropriate osteotomy was then marked and performed using an

oscillating saw with the appropriate spacing device to make sure that the cut was at an appropriate distance from the seating chisel. The first cut was made parallel to the seating chisel. Depending on the correction desired, the second cut was made on the distal fragment to improve the reduction of the osteotomy and coaptation of the fragments [18, 19]. If there was a significant medial offset, then a third cut was made on the lateral surface of the proximal fragment to recess the plate against the femur. This had the added advantages of increasing proximal stability and preventing implant prominence and soft tissue irritation. The osteotomy surfaces were coapted to check for the fit. The seating chisel was removed and the blade plate inserted over the guide wire. A reduction clamp was then used to finalise the position of the implant with respect to both parts of the proximal femur. Preliminary fixation was performed using a non-locking screw to achieve

compression at the osteotomy site. Fixation was then completed using the requisite number of locking and non-locking screws (Fig. 1). The position of the implant was

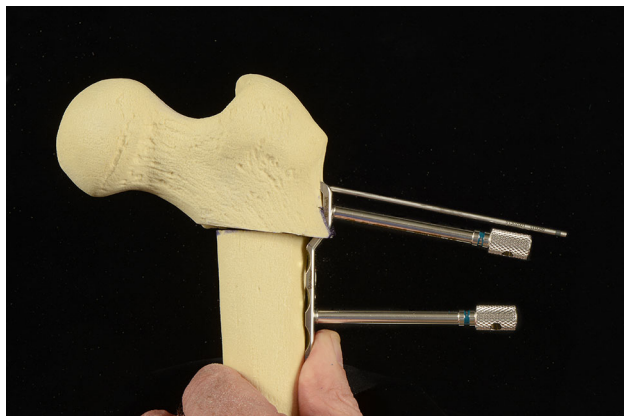


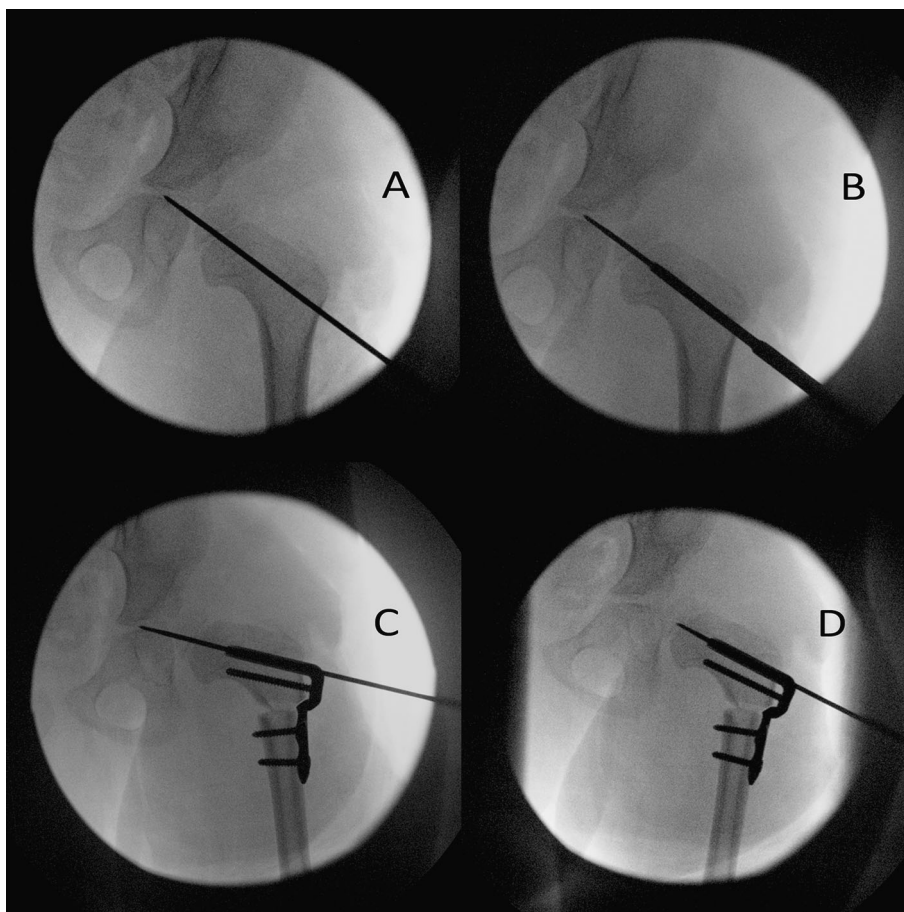
Fig. 1 Cannulated locking blade plate fixation in a sawbone model of VDRO of the proximal femur. Note that the blade plate has been inserted over the guide wire. Two locking towers are in position, in the first screwhole (which is inserted into the proximal metaphysis) and the third screwhole (which is inserted into the diaphysis). The remaining screwholes, the second and fourth, are for non-locking screws and offer the opportunity for compression prior to the insertion of the locking screws

recorded in both AP and lateral fluoroscopic projections. The hip was put through a range of motion to ensure that fixation was stable. The fluoroscopic images were also scrutinised to determine whether the goals of surgery had been achieved: e.g., femoral head cover. The stability of fixation was assessed and this determined the need for hip spica casting, restricted weight-bearing or immediate mobilisation (Fig. 2). The guide wire was removed and, following irrigation, the incision was closed in layers. Routine post-operative care was provided with formal imaging of the osteotomy prior to discharge from hospital. Immediate range of motion, physiotherapy and full weight-bearing as tolerated was encouraged in all patients apart from one 3-year-old girl with DDH who had a revision open reduction and capsulorrhaphy.

All patients were followed closely after surgery to monitor healing, function and surgical adverse events (SAEs). SAEs were classified according to the modified Clavien–Dindo system [20].

Descriptive statistics were obtained from Excel, including means and standard deviations (SDs). Statistical analyses were performed using Stata Statistical Software, release 13 (StataCorp, College Station, Texas, USA).

Fig. 2 Four fluoroscopic images showing the sequence of fixation using the cannulated locking blade plate. **a** Revision anterolateral open reduction has been performed for left DDH. The guide wire has been inserted close to the centre of the proximal femoral metaphysis and advanced across the proximal femoral growth plate and into the triradiate cartilage to stabilise the open reduction. NB: This is not a standard step. **b** The seating chisel has been advanced across the guide wire. **c** The 90° toddler plate has been bent to change the NSA to 100°. The osteotomy and shortening have been performed and the blade plate has been inserted and fixation screws placed. **d** The guide wire has been partially removed to check the stability of the open reduction and the stability of the VDRO. Following this, the guide wire was removed and a hip spica cast applied, the only hip spica in the series



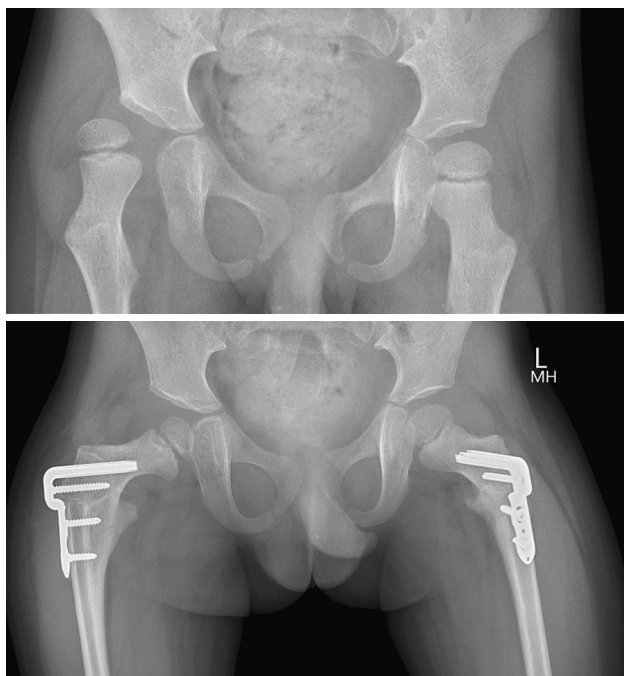


Fig. 3 Right hip dislocation in a 5-year-old boy with severe cerebral palsy and poor nutritional status, weighing 12 kg. The right hip was already painful. Bilateral VDROs with the infant plate showing containment of both hips, sound bony union with no loss of position and no requirement for a hip spica cast

Results

Between April 1, 2013 and July 31, 2014, 45 proximal femoral osteotomies were performed in 25 children and adolescents. The majority of PFOs were performed by registrars and fellows, under the supervision of the senior authors. There were 13 boys and 12 girls with a mean age of 7 years and 9 months (range of 3–17 years) and a mean weight of 22.7 kg (range 11–66 kg).

Mean follow-up was 9 months (SD range 4–20 months). All children were followed to bony union apart from one girl with DDH who moved to another state, within 4 weeks of surgery, whilst in hip spica cast.

Seventeen children had cerebral palsy, two had other neuromuscular diseases, two had DDH, two had metabolic disease and two had Perthes' disease. Five ambulant children with CP had bilateral external rotation PFOs to improve gait, 15 children with CP/other neuromuscular and metabolic disorders had bilateral varus derotation osteotomies (VDROs) for hip subluxation, two girls with DDH had unilateral VDROs, one boy with Perthes' disease had unilateral VDRO for containment and another boy with Perthes' disease had valgus osteotomy for coxa vara. One child with a metabolic disorder had fixation of an insufficiency fracture. In the CP/neuromuscular group who had bilateral VDROs for hip subluxation (Fig. 3), the mean MP

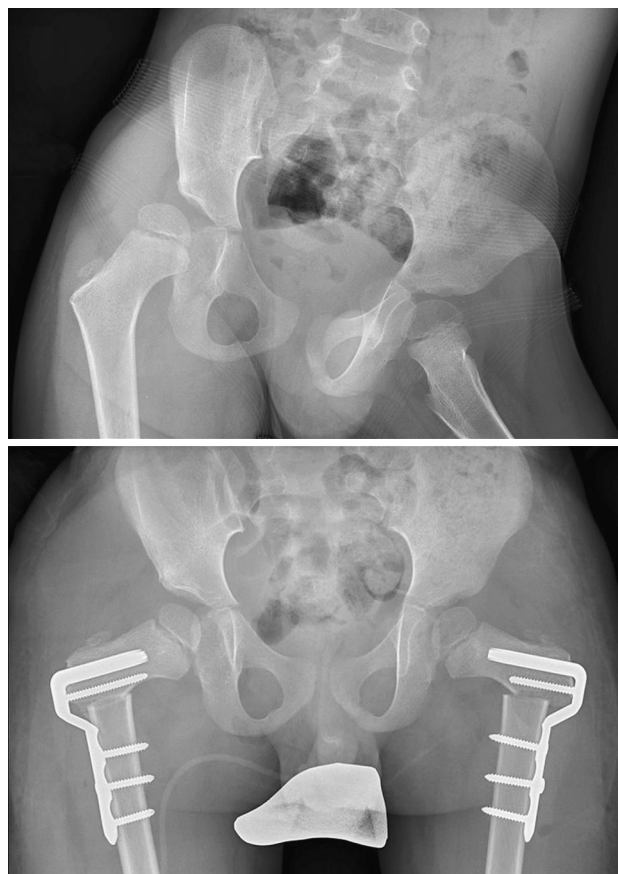


Fig. 4 Windswept hips in a 7-year-old boy with a neuromuscular disease. A left hip abduction contracture and right hip adduction contracture were released and combined with bilateral VDROs using 40 mm, 90° child plates. Both hips are contained and the pelvis has been levelled. This is the simplest type of osteotomy because the guide wire, chisel and blade plate are placed centrally in the proximal metaphysis

pre-operatively was 48 % (SD 24 %) and post-operatively was 11 % (SD 13 %). The mean NSA was 155° (SD 9.6°) and the mean post-operative NSA was 112° (SD 9°). These changes were significant at $P < 0.001$. The ambulant CP group had satisfactory correction of internal rotation gait clinically, which was confirmed on gait analysis in the first two patients who have had follow-up gait analysis (Figs. 4, 5).

In the two girls with DDH, one achieved correction of long leg dysplasia by a PFO which included 30° derotation, 10° varus and 1 cm of shortening. In the other girl, VDRO was used to stabilise a revision open reduction with varus of 20°, derotation of 40° and shortening of 1 cm (Fig. 2).

The boy with Perthes' disease had satisfactory containment following varus of 15°, extension of 15° and external rotation of 20°. The second boy with Perthes' disease had satisfactory correction of iatrogenic coxa vara by valgus PFO of 30°. His mean pre-operative NSA of 94° was corrected to 134° post-operatively. (Fig. 6).

There were no delayed unions, mal-unions or loss of position. There were no revision procedures for implant-related complications. One boy with neuromuscular disease and impaired immunity had a low-grade *Staphylococcus epidermidis* infection. The infection was asymptomatic and was only recognised at the time of routine plate removal by the culture of a small amount of fluid which was present around the blade of the implant. The infection was

eradicated following removal of the implant and antibiotics. This was a Grade III complication, according to the modified Clavien–Dindo system [20].

Discussion

Proximal femoral osteotomy is an important reconstructive option in the management of a wide range of hip pathology in children and adolescents [1–8]. The implants for this procedure have paralleled advances in implant technology for fixation of proximal femoral fractures and osteotomies in adults [6–11]. More recently, developments in cannulated device technology along with locking plate technology have been combined into a new system, which appears to have the versatility to cover the full range of reconstructive requirements from birth to skeletal maturity in children's orthopaedics [12]. The principles and surgical approach are built solidly on the foundations of previous technology and require only minor modifications. We conducted an audit of our first 25 patients to determine the complication rate during the learning curve as well as the ability of established and trainee surgeons to learn how to use the new system. Technically, the system performed faultlessly with no loss or change of position between the insertion of implants and bony union at 6–12 weeks after surgery. The stability of fixation was felt to be adequate, even in younger children with CP who had hypertonia, nutritional impairment and osteopenia [19]. Apart from one girl with an open reduction of DDH, hip spicas were not

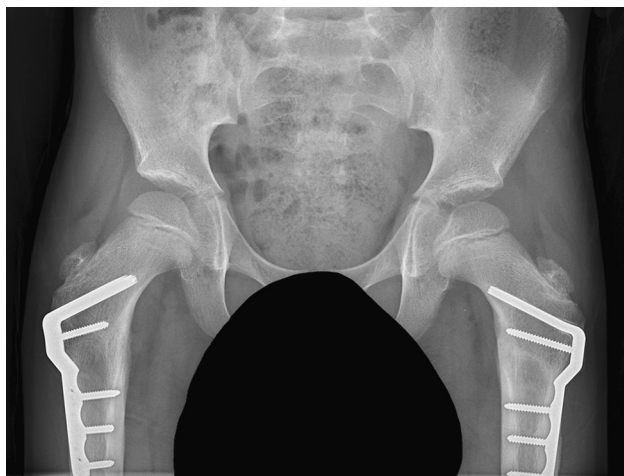
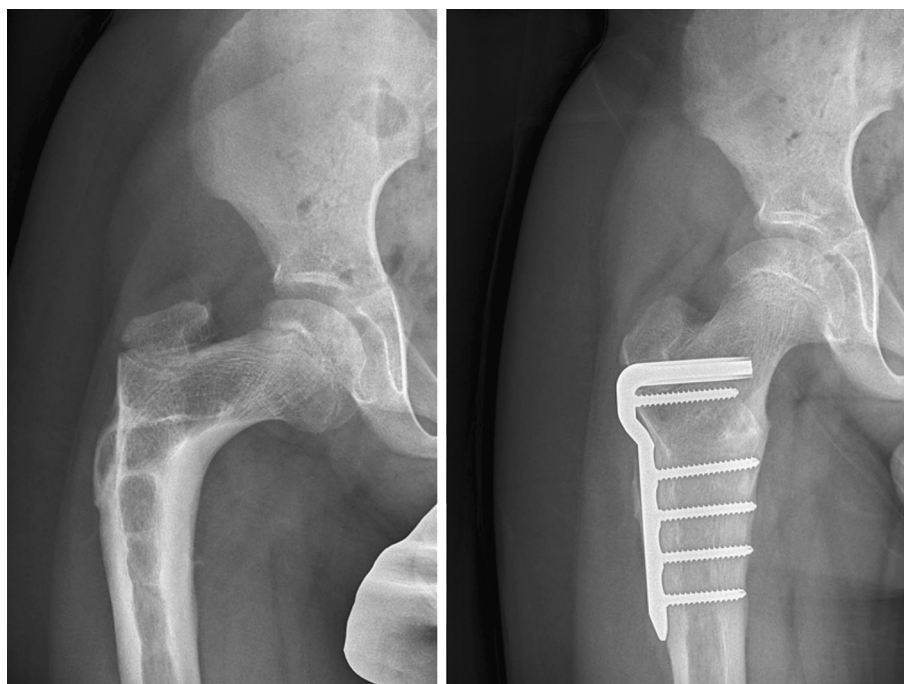


Fig. 5 Bilateral FDOs with the 100° cannulated locking blade plate, in a 10-year old boy with cerebral palsy, GMFCS level II, undergoing SEMLS. The goal was a 40° external rotation correction on both sides with no change in NSA. Note the position of the tip of the blade in the strong bone of the calcar and inferior femoral neck. The patient mobilised full weight-bearing within a week of surgery and had excellent correction of internal rotation gait

Fig. 6 Iatrogenic coxa vara in a 10-year-old boy previously treated by VDRO for Perthes' disease. He presented with fatigue pain and limping due to abductor insufficiency. The preoperative NSA was 94°. A valgus proximal femoral osteotomy was formed with a 90° plate and the NSA was restored to 132°, with correction of limb length discrepancy and the abductor insufficiency. A pelvic osteotomy will be required in due course



used. No restrictions were placed on mobility or weight-bearing, which was a major advantage for early rehabilitation after SEMLS [16]. Despite this immediate mobilisation policy, there were no changes in implant position, and the technical goals of all procedures were achieved. This zero revision rate compares favourably with both older and newer systems such as the Richards intermediate hip screw, the AO blade plate and the Pediatric LCP Plate [7, 8, 10, 11]. In addition, older systems were more likely to be followed by hip spica casting, which has high costs in terms of time and materials, is inconvenient for families and is associated with significant morbidity [8, 10, 17, 18, 21, 22]. The LCP system also employs a locking screw technology but there are significant restrictions on the choice of NSA, given that most commercial systems have only two side-plate angles for varus correction [11, 12]. In addition, delayed union seems to be a problem with the LCP system, where the fixation system seems to be too rigid for some paediatric indications [10, 11].

The limitations of our study include the wide range of ages and indications, the concentration on purely technical and not functional outcomes and the small number of patients and osteotomies. Future studies will include comparison of this device with existing technology. In addition, a detailed study of attitudes and comfort levels from trainees at different levels will be conducted again in comparison with existing non-cannulated, non-locking technology.

Conflict of interest There are no conflicts of interest directly related to this manuscript.

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2 SUMMARY AND BRIDGE

The locking cannulated blade plate (LCBP) was introduced as an alternative to the existing 'gold standard' fixed Angle Blade Plate (ABP). The cannulated component is familiar to many surgeons and trainees in a trauma setting (191). It was theorised to improve the technical accuracy of blade plate insertion when performing proximal femoral osteotomy (PFO). The addition of a locking component was aimed to provide better biomechanical fixation (184, 185, 188), which is particularly relevant in children with cerebral palsy (CP) who suffer from osteopenia.

Caution should be exercised when a new implant is introduced, especially in the setting of a current gold standard implant with proven safety and efficacy. This was the basis of Study I, which explored the utility and safety of the LCBP for use in PFOs for children with a wide range of age groups and indications. Results demonstrated that the LCBP was versatile, and short-term technical outcomes were achieved. This included union of the osteotomy site, without loss of fixation or position.

In summary, this pilot study confirmed that the LCBP could be used safely for PFO. However, it did not address whether the LCBP would be a better implant choice for PFOs over the ABP and more specifically, for children with CP. Many children with CP suffer from concomitant medical issues. These may include: increased skin pressure risk with limited activity, poor nutrition which may require percutaneous endoscopic gastrostomy (PEG) feeding, as well as frequent respiratory and urinary tract infections (192). Careful pre-operative multidisciplinary planning, with the provision of safe and efficient surgery, are vital for minimising post-operative adverse events in a high-risk group.

The Royal Children's Hospital (RCH) in Melbourne, Australia, is a tertiary teaching institution. Orthopaedic surgeons at the RCH perform over 150 proximal femoral osteotomies each year on children with CP. The majority of these are performed by orthopaedic registrars and fellows under consultant

supervision during their training. The choice of implant has the potential to decrease the steepness of their trainee learning curve and may improve patient outcomes.

This led to the development of Study II which aimed to prospectively compare the gold standard ABP to the LCBP when trainees performed PFOs in a cohort of children with CP. The completion of a trainee questionnaire was planned to identify their ease of use of both implants. More specifically, each technical step of the operation, stability of fixation, and post-operative weightbearing status would be assessed immediately following a PFO to reduce recall bias. Intended follow up would be over 18 months, to enable a review of longer term radiographic and clinical patient outcomes. Unforeseen medical and surgical adverse events following PFO in the immediate post-operative period, as well as implant removal at 12 to 24 months, would be prospectively documented.

The potential impact of the findings from Study II would be two-fold: to identify an implant choice for trainees when learning to perform a PFO, and to identify if the radiographic and technical outcomes of the LCBP compared with the ABP.

V. STUDY TWO

1 PUBLISHED PAPER

Proximal Femoral Osteotomy in Children with Cerebral Palsy: The Perspective of the Trainee.

- *A Study on Trainee Safety and Learning Curve*

Published by the Journal of Children's Orthopaedics in February 2017.

Proximal femoral osteotomy in children with cerebral palsy: the perspective of the trainee

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Abstract

Background There are a range of implants for fixation of proximal femoral osteotomies (PFOs) in children. We investigated the training experiences and preferences of orthopaedic residents and fellows who were learning PFO, using a fixed angled blade plate (ABP) or a locking, cannulated blade plate (LCBP). We also studied short-term technical and radiographic outcomes.

Methods This was a prospective, parallel-group, cohort study of 90 consecutive children and adolescents with cerebral palsy who underwent bilateral PFOs with ABP or LCBP. Surgical trainees completed a questionnaire to document the ease or difficulty of each operative step.

Results There were 48 boys and 42 girls, with a mean age of eight years and a mean follow-up of 25 months. Trainees preferred the LCBP system for: insertion of the guidewire, the seating chisel and the blade plate, as well as overall technical ease of use ($p < 0.001$). Radiographic outcomes were similar with no between-group differences for migration percentage ($p = 0.996$) or neck shaft angle ($p = 0.849$), but there was a higher prevalence of technical errors in the ABP group.

Conclusions Trainee surgeons expressed a preference for LCBPs when learning PFO in children with cerebral palsy. Radiographic outcomes were similar in both groups, with close attending surgeon supervision.

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Keywords: surgical training; proximal femoral osteotomy; cerebral palsy; angled blade plate; cannulated blade plate; locking screw fixation

Introduction

Proximal femoral osteotomy (PFO) is the most common major reconstructive surgery about the hip in children and adolescents.¹ There are many indications, the most common of which are to provide hip containment or correct internal hip rotation gait in children with cerebral palsy.²⁻⁵ In our tertiary level paediatric teaching hospital, approximately 150 PFOs are performed each year. Residents and fellows who are training in orthopaedic surgery conduct many of these, under the supervision of an attending surgeon.

PFOs have frequently been performed with fixed angled blade plates (ABP) with several studies reporting good results.^{6,7} The technique can be difficult to teach and the learning curve may be steep. A recent innovation in implant design is cannulation of the blade plate and locking screw technology for which limited reports exist in the literature.^{1,8-10} Results from one small study demonstrated that the locking, cannulated blade plate (LCBP) provided good fixation, stability of the osteotomy and predictable union, with few adverse events, in children with a wide range of diagnoses and indications.¹ In comparison with conventional ABPs, the LCBP system allows for both the seating chisel and blade plate to be inserted over a guidewire into the femoral neck. This may result in more precise technique with greater intra-operative control and decreased margin for error.^{1,8} In addition, most trainees in orthopaedic surgery are familiar with referencing internal fixation over a guidewire and with the use of locking screws. Alternative systems, which involve multiple points of fixation in the proximal femur with locking screws, include the paediatric locking compression

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plate (LCP). The LCP system offers increased stability in osteoporotic bone.¹¹ The disadvantages include delayed union, increased operative time and increased blood loss, in comparison with the ABP.¹¹ It is therefore important for new implants and new technology to be compared with existing gold standards.

The aims of our study were:

1. To investigate trainee preferences and opinions on the use of the LCBP and ABP systems.
2. To compare the radiographic and technical outcomes of both systems.

Patients and Methods

This was a prospective, parallel-group, consecutive cohort study of children and adolescents with cerebral palsy who were scheduled for bilateral PFOs between 1 April 2013 and 31 December 2014 at a tertiary paediatric hospital (Fig. 1). Internal fixation was achieved with either the PediLoc Locking Cannulated Blade Plate System (Ortho-Pediatrics) or the Angled Blade Plate System (Synthes). The choice of implant was at the discretion of the attending surgeon. A randomised clinical trial was the preferred study design, but the attending surgeons lacked equipoise in their implant preference and choices.

Inclusion criteria were children with a diagnosis of cerebral palsy and registration on the Statewide Cerebral Palsy Register, bilateral PFOs performed by orthopaedic residents or fellows, supervised by one of three attending surgeons. Children at all levels of the Gross Motor Function Classification System (GMFCS) were included. Bilateral

PFOs were performed in the context of Single Event Multilevel Surgery (SEMLS) for gait correction (Fig. 2), as well as containment PFOs for non-ambulant children with hip displacement.²⁻⁵ Bilateral medial hip muscle releases were allowed in hip containment procedures as were the typical muscle-tendon procedures utilised in SEMLS.^{12,13} Children with diagnoses other than cerebral palsy were excluded, as were children who had unilateral surgery, pelvic osteotomy or surgery performed entirely by attending surgeons.

Procedure

Patient demographics including age at surgery, sex, weight, GMFCS level and medical co-morbidities, including the need for feeding tubes and medications for epilepsy, were entered on an Excel spreadsheet from the patient's electronic scanned medical record (ESMR).^{14,15} Pre-operative radiographs were viewed on the Patient Archiving and Communication System (PACS) (Synapse, Fujifilm), which were then compared with sequential radiographs obtained at three, six and 12 weeks and at six and 12 months following surgery and yearly thereafter. Migration percentage (MP) and neck shaft angle (NSA) were measured according to a standardised method with good reliability.^{16,17} Time to union was assessed and defined as the presence of bridging callus across more than 75% of the width of the bone at the level of the osteotomy surface, as well as external, medial bridging callus.¹

Femoral derotation osteotomies (FDOs) for gait correction surgery were performed to correct internal hip rotation and intoed gait (Figs 2 to 4). The aim was to correct excessive femoral neck anteversion, by a single oblique

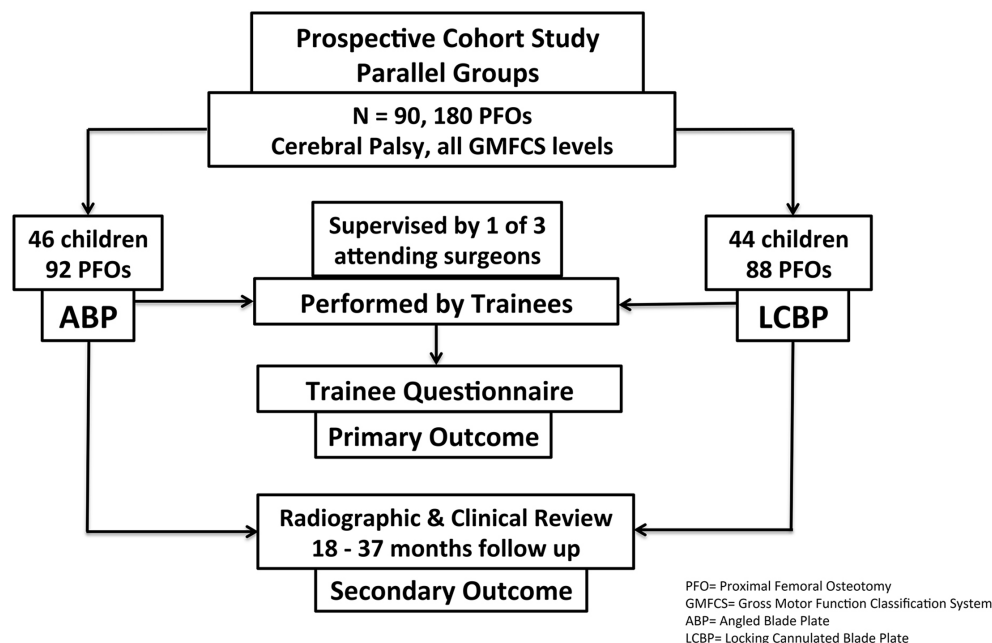


Fig. 1 Study design flow chart.

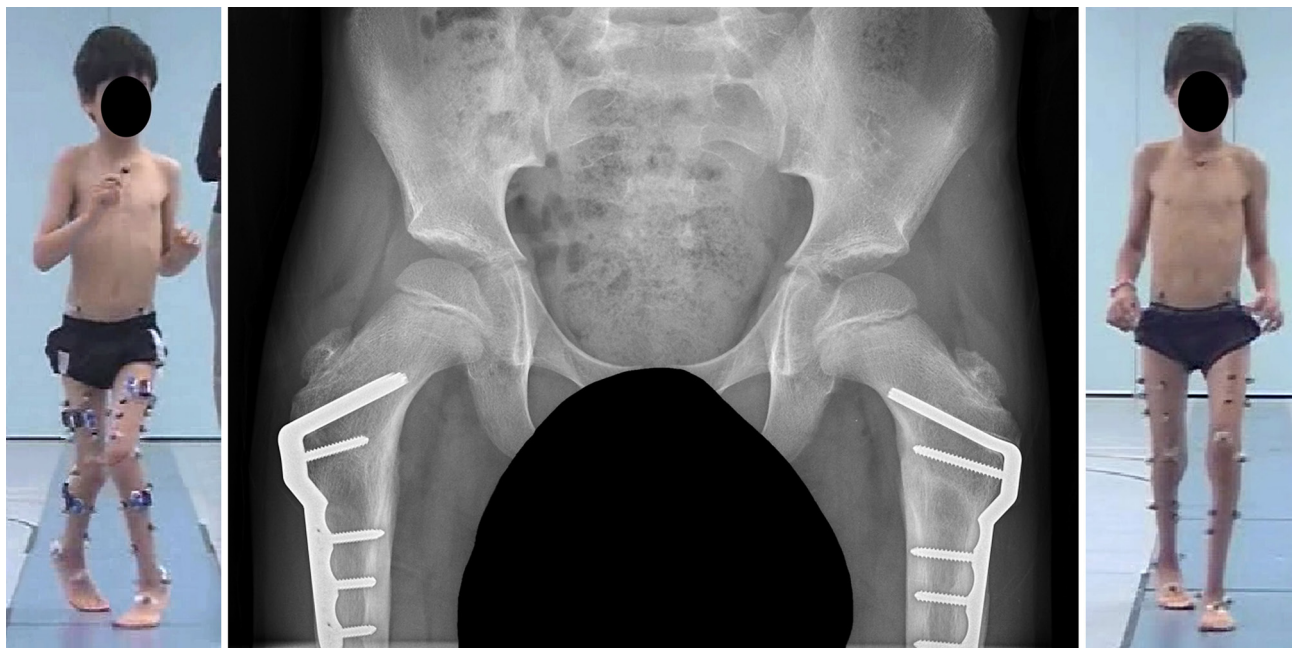


Fig. 2 Bilateral femoral derotation osteotomies (FDOs) with the 100° cannulated locking blade plate, in a ten-year-old boy with cerebral palsy, GMFCS level II, undergoing Single Event Multilevel Surgery (SEMLS). The operative aim was a 40° external rotation correction bilaterally without altering the neck shaft angle. Note the position of the tip of the blade in the solid bone of the calcar and inferior femoral neck. The patient mobilised full weight-bearing within one week of surgery with correction of internal rotation gait.



Fig. 3 Bilateral hip subluxation (right greater than left) in a nine-year-old girl, GMFCS III prior to Single Event Multilevel Surgery (SEMLS). There was coxa valga and increased femoral neck anteversion of 40° bilaterally. This resulted in hip displacement and intoed gait.

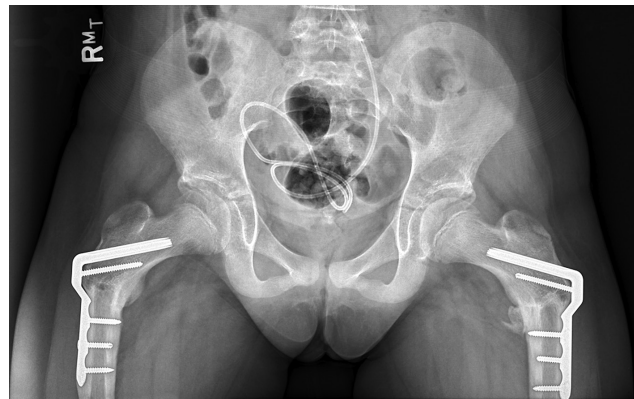


Fig. 4 Following bilateral V드로Os, including bilateral distal hamstring lengthening, bilateral Strayer gastrocnemius recessions. The hips are now well contained and there has been extensive acetabular remodelling. Correction of both hip dysplasia and intoed gait was achieved.

osteotomy in the intertrochanteric region, to between 5° and 10°. Varus derotation osteotomies (VDROs) for hip displacement surgery were undertaken to correct excessive valgus and anteversion in the proximal femur, hip subluxation and to prevent dislocation (Figs 5 and 6). In some children, it was necessary to correct intoed gait and hip displacement simultaneously (Figs 3 and 4). The indications and techniques for both types of osteotomy have been previously described.^{18,19} The range of hip abduction was assessed before PFO and adductor lengthening was

performed, following published protocols.^{12,18} Osteotomies were performed in children at GMFCS IV and V, in a supine position.¹⁸ Ambulant children had a full biomechanical assessment, including three-dimensional gait analysis and axial imaging prior to surgery, and underwent gait correction surgery in a prone position.^{18,19} The indication and techniques for the SEMLS procedures have been previously published.^{13,18} Intra-operative fluoroscopy was used in both groups and selected images were saved in PACS for subsequent analysis.



Fig. 5 Bilateral hip displacement, in an eight-year-old girl, GMFCS level IV, who missed out on hip surveillance and presented with hip pain and restricted abduction. Note the femoral head deformity and severe acetabular dysplasia.



Fig. 6 At 18 months after bilateral varus derotation osteotomies (VDROs) with angled blade plate (ABP) fixation, the hips are well contained; some remodelling of both the femoral head and the acetabulae has occurred, and the lateral acetabular epiphysis has appeared on both sides. However, there was penetration of the calcar in the left hip with type 3 avascular necrosis (AVN) changes in the femoral head, the significance of which will not be apparent until long-term follow-up. Penetration of the calcar may be a risk factor for AVN.

The degree of assistance provided to the trainee during surgery was at the discretion of the attending surgeon in the interests of patient safety and was not recorded. Following every operation, trainees were asked to complete a custom-designed questionnaire for each hip. Eight questions were asked using nine-point Likert scales. Five questions addressed sequential steps in the operation, with question 6 addressing the technical 'overall ease or difficulty' of the operation. Questions 1 to 6 were anchored at 1 (very easy) and 9 (extremely difficult).

Question 7 addressed the operating surgeon's assessment of the stability of fixation with 1 (very stable) and 9 (extremely unstable). Question 8 reviewed weight-bearing status at 1 (no restrictions) and 7 (six weeks in a hip spica) (Appendix 1).

Technical outcomes included the position of the implant in the proximal femur and stability of fixation. The angulation between the guidewire and blade plate was measured in hips where the ABP was used, in anteroposterior (AP) and lateral projections, from saved fluoroscopic images in PACS (Figs 7 and 8). Operating time was measured as the time required for bilateral PFOs. Anaesthetic time, surgical time for concomitant procedures and time required for cast application in the SEMLS group were excluded.

Adverse events were collected prospectively and reported using a modified Clavien-Dindo (MCD) classification reported by Sink et al.^{20,21} Clinical and radiographic follow-up was conducted at three and six weeks after surgery, then at six and 12 months after surgery, and yearly thereafter. Patients who defaulted on follow-up appointments were contacted by the clinical nurse co-ordinator and rebooked to the next available clinic.

Avascular necrosis (AVN) was graded according to the criteria designed by Kruczynski et al.^{22,23} Removal of implants was advised in all patients after 12 to 24 months.

Statistical analysis

Parametric data were reported for group comparisons using means, standard deviations, range and t-tests. Non-parametric data were reported as medians and interquartile ranges (IQR) with rank sum tests to assess group differences. Dichotomised results for the trainee questionnaire were reported with p-values from Fisher's exact tests ($p < 0.05$ was considered statistically significant). All calculations were performed in Stata version 12.1 (StataCorp., College Station, Texas).

Results

Between 1 April 2013 and 31 December 2014, 180 PFOs were performed in 90 children and adolescents with a diagnosis of cerebral palsy and registration on the State-wide Cerebral Palsy Register. There were 46 children in the ABP group and 44 in the LCBP group, 48 boys and 42 girls, with a mean age of 7 years 11 months (4 years 3 months to 13 years 9 months), and a mean weight of 25.8 kg (12 to 58). The minimum follow-up was 21 months (mean 28 months; 21 to 40), with no loss to follow-up.

The osteotomies were performed by eight trainees in orthopaedic surgery. Four were undertaking fellowships in paediatric orthopaedics and four were orthopaedic residents.

Age, gender, weight, GMFCS level and radiographic parameters (MP, NSA) were comparable at baseline between the two groups (Table 1). The mean PFO surgical time in the LCBP group was 71 minutes (SD 13.7; 45 to 97)

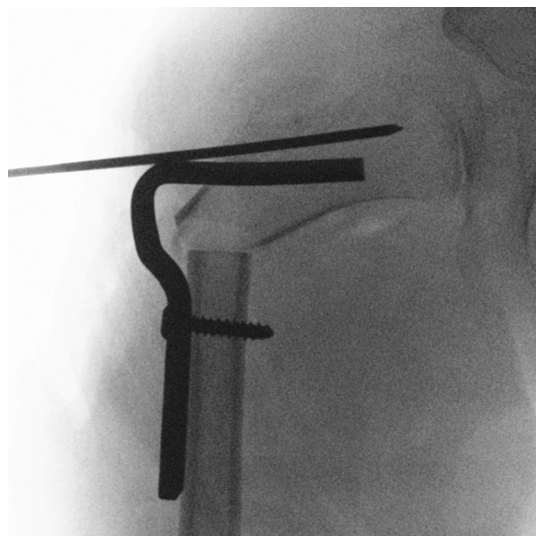


Fig. 7 When using the angled blade plate (ABP) system, the guidewire and blade may not be parallel in the frontal plane. The seating chisel and the implant are inserted distal to the guidewire, in the femoral neck. The space available between the trochanteric apophysis and the calcar is limited.

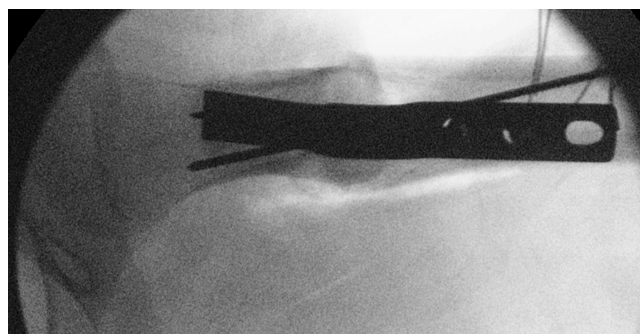


Fig. 8 In this hip, surgery proceeded after several failed attempts at placing the guidewire in a central position. Insertion of the blade plate was attempted in a more central position in the femoral neck. However, anterior angulation occurred with a 17° angulation between the angled blade plate (ABP) and the guidewire. The anterior cortex of the femoral neck was at risk of penetration by the ABP.

Table 1. Baseline demographic and radiographic parameters.

	LCBP n = 44 children (88 hips)	ABP n = 46 children (92 hips)	p
Age, years:months	7:11 (4:3 to 13:0)	8:1 (4:3 to 13:9)	0.684*
Gender, n (%)			
Male	23 (52)	25 (54)	
Female	21 (48)	21 (46)	0.844†
Weight, kg	25.5 (12 to 49)	26.2 (13 to 58)	0.741*
GMFCS, n (%)			
I	0 (0)	1 (2)	
II	11 (25)	11 (24)	
III	5 (11)	7 (15)	
IV	8 (18)	13 (28)	
V	20 (45)	14 (30)	0.471†
Follow-up time (mths)	28.3 (21 to 40)	28.1 (20 to 39)	
Migration percentage (%)	43.2 (12 to 100)	38.2 (8 to 100)	0.138*
Neck-shaft angle (°)	155.6 (138 to 175)	155.0 (135 to 179)	0.690*

Values are mean (range) unless otherwise noted

*t-test

†Chi-squared test

ABP, angled blade plate; GMFCS, Gross Motor Function Classification System; LCBP, locking cannulated blade plate

in comparison with 76 minutes (SD 18.1; 50 to 125) for the ABP. This difference was not significant ($p = 0.137$). The mean number of procedures performed during SEMLS was 7.4 (SD 2.1; 4 to 12) in the ABP group and 7.3 (SD 2.0; 5 to 12) in the LCBP group.

Technical outcomes

Both systems achieved the planned changes in containment and proximal femoral geometry according to MP and NSA (Table 2). In the ABP group, the mean angulation between guidewire placement and blade plate was 6° in both the coronal (SD 4.67, 95% confidence interval (CI) 5.21 to 7.11) and lateral planes (SD 5.25, 95% CI 5.00 to 7.15). However, the range was much wider – between 0° and 21° in the coronal plane, and between 0° and 23° in the lateral plane (Figs 7 and 8).

Trainee preferences

The questionnaire responses demonstrated floor effects with a majority of scores at the lower end of the Likert scales for both systems. Due to the skewed nature of these responses, results were dichotomised into 'easier' (Likert scale 1 and 2) and 'more difficult' (Likert scale 3 to 9), and then re-analysed (Table 3).

Table 2. Radiographic measurements comparing the locking, cannulated blade plate (LCBP) and angled blade plate (ABP) groups.

	LCBP (n = 44)			ABP (n = 46)		
	Pre-operative	Post-operative	Difference	Pre-operative	Post-operative	Difference
Migration percentage (%)	43.2 (12 to 100)	10.1 (0 to 55)	33.1 (1 to 100)*	38.2 (8 to 100)	5.1 (0 to 26)	33.1 (3 to 78)*
Neck shaft angle (°)	155.6 (138 to 175)	119.9 (92 to 155)	35.8 (2 to 77)*	155.0 (135 to 179)	119.8 (93 to 142)	35.1 (2 to 76)*

All values are mean (range)

*Differences reached statistical significance

Trainees reported that guidewire insertion was easier in the LCBP group (78%) compared with the ABP group (51%) ($p < 0.001$). Insertion of the seating chisel and the blade plate was also significantly easier in the LCBP group. The score for overall technical ease/difficulty also favoured the LCBP system ($p < 0.001$) (Table 3). No between-group differences were found for scores relating to performing the osteotomy cuts or reduction of the osteotomy.

Adverse events

Minor medical adverse events (MAEs, MCD I and II) occurred in just over half of the patients in both groups. The most common AEs were constipation, respiratory infections, skin irritation from casts or splints and problems with epidural infusions or morphine infusions, leading to incomplete pain and spasm control. All MAEs resolved with appropriate treatment.

There were four Grade III AEs requiring an unplanned return to the operating theatre. Two children had replacement of a poorly functioning epidural, one had injections of Botox to the hamstrings and adductor muscles for post-operative spasms and one required bladder catheterisation for acute retention. There were three Grade IV AEs. Two children (GMFCS V) had unplanned admissions to ICU for post-operative pneumonia and recovered fully. One child in the ABP group had an acute

unilateral, post-operative dislocation. He had revision surgery with a San Diego pelvic osteotomy and hip spica casting.

In the ABP group, Grade I AVN was noted in six hips in four patients, Grade III AVN in one hip in one child and Grade V AVN in the patient who sustained the post-operative dislocation and revision surgery. In the LCBP group, six hips in three patients had Grade 1 AVN with no higher grade AVN. Seven children had mild asymptomatic, bilateral heterotopic ossification (MCD Grade II, four in ABP group and three in LCBP group).

Seven hips in four children had penetration of the calcar by the tip of the blade plate which was partial in six and complete in one. All were in the ABP group (three MCD II, one MCD IV). In the patient with complete penetration of the anterior femoral neck, the lateral fluoroscopic images were of poor quality. The error was not realised until post-operative radiographs were obtained. The AP radiograph was not conclusive (Fig. 9) and it was seen only on a cross-table lateral view (Fig. 10). The blade plate had not followed the track cut by the seating chisel. The patient was a 14-year-old boy weighing 52 kg with severe intellectual disability and could not reliably remain on protected weight-bearing. His parents refused revision surgery and the patient was managed by non-weight-bearing for six weeks until union was achieved, under inpatient supervision.

Table 3. Results of the trainee questionnaire with scores for each question dichotomised to two ranges.

Question	LCBP n = 88 hips	ABP n = 92 hips	p
1. Guidewire insertion			
Easier	69 (78%)	47 (51%)	< 0.001
More difficult	19 (22%)	45 (49%)	
2. Seating chisel			
Easier	88 (100%)	44 (48%)	< 0.001
More difficult	0 (0%)	48 (52%)	
3. Osteotomy cuts			
Easier	47 (53%)	59 (64%)	0.144
More difficult	41 (47%)	33 (36%)	
4. Insertion of blade plate			
Easier	87 (99%)	35 (38%)	< 0.001
More difficult	1 (1%)	57 (62%)	
5. Reduction of osteotomy			
Easier	59 (67%)	63 (68%)	0.837
More difficult	29 (33%)	29 (32%)	
6. Overall score			
Easier	76 (86%)	34 (37%)	< 0.001
More difficult	12 (14%)	58 (63%)	
7. Stability of fixation			
More stable	86 (98%)	88 (96%)	0.438
Less stable	2 (2%)	4 (4%)	
8. Weight-bearing status			
Earlier (< 3 weeks)	88 (100%)	90 (98%)	0.164
Later (≥ 3 weeks)	0 (0%)	2 (2%)	

Easier score, 1 to 2; More difficult, score 3 to 9; More stable, score 1 to 2; Less stable, score 3 to 9; Earlier score, 1 to 3; Later score, 4 to 7

LCBP, locking cannulated blade plate; ABP, angled blade plate



Fig. 9 Right proximal femoral osteotomy with an angled blade plate (ABP) in a 14-year-old boy, GMFCS level II, as part of Single Event Multilevel Surgery. Fluoroscopic images were of poor quality because of limited hip abduction. The post-operative anteroposterior radiograph showed what seemed to be a satisfactory position and stable fixation.

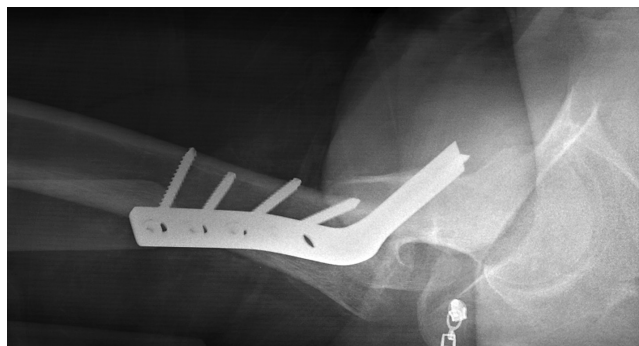


Fig. 10 When a cross-table lateral radiograph was obtained, complete penetration of the anterior femoral neck by the angled blade plate (ABP) was noted and the fixation was considered to be unstable. Non-weight-bearing was required for the next six weeks until union occurred.



Fig. 11 With the locking cannulated blade plate (LCBP) system, both the seating chisel and the implant are inserted over the guidewire. There can be no angulation between the seating chisel, or the LCBP, and the guidewire.

Discussion

A recent large study reported a 37% failure rate following bilateral VDROs in children with CP and found that this was related to surgeon volume as well as GMFCS level.³ Even in high-volume tertiary centres, failures occur and surgeon experience and volume are important.^{4-6,9,10} The challenge of teaching PFO is self-evident. Attending surgeons have to balance the competing demands of teaching surgery, patient safety and ensuring good clinical outcomes.

In this study, trainees reported that the cannulated system was easier to use in four of six domains.^{1,9} Guidewire placement with the LCBP system is the most important step in PFO. The seating chisel and implant are passed directly over the wire (Figs 11 and 12), which thereby dictates the final blade plate position. This con-



Fig. 12 The position of the locking cannulated blade plate (LCBP) over the guidewire is almost central, in the femoral neck, in the lateral projection. There can be no angulation between the LCBP and the guidewire.

trasts with the ABP system in which guidewire placement serves only as a reference plane for the insertion of the seating chisel and implant (Figs 7 and 8).^{6,7} Deviation of the blade plate angle from the direction of the guidewire with the ABP introduces an uncontrolled variable, which has not been previously reported. Experienced surgeons are usually able to manage this angulation. After several guidewire placements, some surgeons may choose to accept a position which is less than perfect and to make a correction by altering the angle of the seating chisel to the guidewire (Figs 7 and 8). Trainees dislike this variability because it is unpredictable and makes it difficult to ensure that the pre-operative plan is correctly executed. These problems were not encountered with the cannulated system.

It may seem counterintuitive that trainees would rate insertion of the guidewire as easier in the LCBP system. Trainees expressed the view that insertion of the guidewire in the LCBP system could be identified precisely during pre-operative planning and the operative plan executed with precision. In contrast, the insertion of the guidewire in the ABP system is close to, but not in the same position as, the line of the seating chisel and the implant, necessitating an adjustment in pre-operative planning.

Experienced surgeons using the ABP system can usually avoid deviating from the track cut by the chisel during insertion of the blade plate.^{6,7} Trainees are more prone to losing the track cut by the seating chisel and require high levels of concentration and supervision to ensure that the blade plate is inserted in the correct position, without cutting a false passage and penetrating the femoral neck or calcar (Fig. 10), which may result in intra-operative fracture and unstable fixation.^{6,7} Any variability in the final

position of the blade plate will alter the desired correction, which will lead to a difference between planned correction and actual correction.

The floor effects in the trainee questionnaire was an unexpected finding. Close supervision from experienced surgeons allowed trainees to perform PFO in a controlled environment, conducive to patient safety and good outcomes. Trainees expressed the opinion that insertion of the guidewire, seating chisel, blade plate and the overall ease or difficulty of the procedure was easier with the LCBP system than the ABP system. Not surprisingly, no difference was expressed for the performance of the osteotomy cuts or the reduction of the osteotomy. These questions were included to look for evidence of systematic bias.

Although we did not record the time for individual operative steps, the trainee's impression was that the extra time required to insert the guidewire in exactly the right position in the LCBP group was recouped by the subsequent speed and certainty of insertion of the seating chisel and blade plate. In contrast, placing the seating chisel below the guidewire and in the proximal femoral metaphysis in the ABP system increased the risk of both calcar and femoral neck penetration. Penetration of the femoral neck resulted in unstable fixation in one hip and was associated with Grade III AVN in another hip (Fig. 10).

There was no difference in overall operating time for bilateral PFOs with the two systems. This is in contrast to a previous study in which the LCP hip plate and the ABP were compared.¹¹

Implant systems, which make surgery more reliable, predictable and comfortable for trainees may offer significant advantages in terms of improved outcomes and lower revision rates.¹

There was also no difference in the stability of fixation or in weight-bearing status. In this low-demand group, both implants were considered to be equally stable, allowing early weight-bearing, with no restrictions and no casts. There was no loss of position or revision surgery related to implant loss of position, implant breakage, delayed union or nonunion. This is in contrast to a previous study in which the ABP system was compared with the LCP system.¹¹ The rate of radiological consolidation at six weeks post-operatively with the LCP was lower than with the ABP with equivalent healing at three months.¹¹

The strengths of our study included the prospective nature of the study, the large number of patients in both groups, standardisation of the operative procedures and follow-up, and the small number of supervising surgeons and trainees. Study limitations included lack of randomisation due to lack of equipoise and short-term follow-up. The questionnaire was designed for this study and has not been tested for validity or reliability. The reported

outcomes were in technical domains and AEs, and did not include long-term clinical or functional outcomes.

Based on the findings of this study, both the ABP and LCBP systems are safe and effective for internal fixation of PFOs. However, the LCBP system may help trainee surgeons negotiate the learning curve with more confidence, fewer technical errors and improved outcomes. Finally, when choosing an implant for PFO in children, the difficulty of implant removal must be carefully considered. Removal of the titanium LCP has been associated with a high prevalence of fractures and retained hardware in children with CP.²⁴ In contrast, removal of both the stainless steel ABP and LCBP in this study has been easily achieved, without significant morbidity. Specifically, there have been no cases of cold welding of locking screws to the plate, no peri-operative fractures and no retained hardware.

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COMPLIANCE WITH ETHICAL STANDARDS

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OA LICENCE TEXT

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ETHICAL STATEMENT

Ethical approval was granted by the hospital's Human Research Ethics Committee, Number: 35213A.

ICMJE CONFLICT OF INTEREST STATEMENT

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2 SUMMARY AND BRIDGE

Study II compared the utility of the LCBP and ABP in PFOs performed by trainees in a prospective cohort, parallel group study with 90 consecutive children who underwent bilateral VDROs. The decision to perform bilateral VDROs without additional procedures such as pelvic osteotomy, were based around the current evidence discussed in Section *II. Literature Review*. Studies have demonstrated that VDRO in younger children may improve or even reverse acetabular dysplasia (87-89), and therefore reduce the need for a pelvic osteotomy. Bilateral reconstructions may improve pain-related health related quality of life outcomes (147) by decreasing the risk of ipsilateral surgical failure or contralateral hip subluxation in a previously stable hip (144) and thereby preventing the need for a more extensive, higher risk, hip reconstructive surgery at a later age (147).

A randomised controlled trial study design was preferred, but there was a lack of equipoise in consultant surgeon implant preferences. Results demonstrated that both the ABP and LCBP were equally safe and effective for internal fixation of proximal femoral osteotomies with similar radiographic and technical outcomes. However, the LCBP appeared to aid trainee surgeons to negotiate the learning curve with more confidence and fewer technical errors.

Careful prospective documentation of post-operative adverse events revealed a significant number of minor medical adverse events (MAE), involving 50% of children in the LCBP group and 61% in the ABP group. The most commonly reported adverse events included constipation, inadequate pain management from malfunctioning epidural or morphine infusions, skin irritation from casts of splints, and respiratory infections. These events were related to worse GMFCS level rather than the implant that was used. The high numbers of MAEs observed in Study II were nearly double that of a previously published retrospective study of a similar cohort in children with CP (131).

The Modified Clavien Dindo (MCD) classification system was used to grade the severity of adverse events observed in Study II. The MCD is a reliable and valid system that was initially developed for general surgery (198-201), and later adapted by Sink & colleagues for hip preservation surgery in 2012 (204). However, the profile of adverse events observed in children with CP is different to that of typically developing children (192), and little is known about the reliability of reporting adverse events in complex neurological conditions such as CP.

This led to the development of Study III, which wished to identify a reliable classification system that would enable standardised reporting of AEs in the literature. The MCD was a useful system but required further clarifications to better reflect the unique adverse event profile observed in children with CP. Study III aimed to determine the reliability of the MCD for grading adverse events in CP, and to establish the MCD as a tool that could be easily used by medical and allied health professionals as well as be recognised and understood by individuals with CP and their families.

VI. STUDY THREE

1 PUBLISHED PAPER

Classifying Adverse Events following Lower Limb Orthopaedic Surgery in Children with Cerebral Palsy: Reliability of the Modified Clavien-Dindo System.

- A Study on Patient Safety and Complications

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Classifying Adverse Events Following Lower Limb Orthopaedic Surgery in Children With Cerebral Palsy: Reliability of the Modified Clavien-Dindo System

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Background: The modified Clavien-Dindo (MCD) system is a reliable tool for classifying adverse events (AEs) in hip preservation surgery and has since been utilized in studies involving lower limb surgery for ambulant and nonambulant children with cerebral palsy (CP). However, the profile of AEs recorded in children with CP compared with typically developing children is different, and the reliability of the MCD in CP is unknown. This study aimed to evaluate the interrater and intrarater reliability of the MCD system for classifying AEs following lower limb surgery in children with CP. **Methods:** Eighteen raters were invited to participate, including clinicians from surgical, nursing, and physical therapy professions, and individuals with CP. Following a MCD familiarization session, participants rated 40 clinical scenarios on 2 occasions, 2 weeks apart. Fleiss' κ statistics were used to calculate interrater and intrarater reliability.

Results: The overall Fleiss' κ value for interrater reliability in the first rating was 0.70 (95% confidence interval, 0.61-0.80), and increased to 0.75 (95% confidence interval, 0.66-0.84) in the second rating. The average Fleiss' κ value for intrarater reliability was 0.78 (range, 0.48 to 1.00). Grading of more severe AEs (MCD III to V) achieved near perfect agreement (κ , 0.87 to 1.00). There was a lower level of agreement for minor AEs (MCD I-II) (κ , 0.53 to 0.55). A κ score of 0 to 0.2 was deemed as poor, 0.21 to 0.4 as fair, 0.41 to 0.6 as good, 0.61 to 0.8 as very good, and 0.81 to 1.0 as almost perfect agreement.

Conclusions: The MCD System demonstrates a very good interrater and intrarater reliability following lower limb surgery in children with CP. The MCD can be used by clinicians from different health care professions with a high level of reliability. The MCD may improve standardization of AE recording with a view to accurate audits and improved clarity in outcome studies for CP.

Level of Evidence: Level II—diagnostic.

Key Words: cerebral palsy, lower limb, orthopaedic surgery, adverse event, complication, modified Clavien-Dindo

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Reporting surgical adverse events (AEs) is a critical component of surgical outcome studies but does not always receive adequate methodological rigor. Just over 20 years ago, the editor of the *Lancet* identified poor study design and lack of standardization in the reporting of safety and outcomes relevant to patients, as areas of major concern in surgical literature.¹

In an effort to address this, Clavien and Dindo developed a valid and reliable classification system for AEs in general surgery,^{2–4} which is perceived similarly by patients, nurses, and physicians.⁵ In its first orthopaedic application, Sink et al⁶ modified the Clavien-Dindo system (MCD) for hip preservation surgery and showed good interrater and intrarater reliability. Until now, there has been no standardized system for reporting the severity of AEs in orthopaedic surgery and little is known about the reliability of reporting AEs in complex neurological conditions, such as cerebral palsy (CP).^{6,7}

A retrospective matched cohort study by DiFazio et al⁸ utilized the MCD for reporting postoperative complications after hip surgery in nonambulant children with CP compared with children without CP. The study showed that children with CP had more frequent AEs than children without CP, and had a different profile of AEs.⁸ In children without CP, surgical AEs such as delayed union, wound hematomas and neuropraxias were the most common complications. In children with CP, skin complications were frequent as were medical AEs including gastrointestinal and respiratory complications.⁸ Most recently, Dreher et al⁹ utilized the MCD in a long-term multicenter retrospective study, reporting the outcomes of surgery to improve gait in ambulant children with CP. Nearly half of the children suffered from an AE, most of which were self-limiting. The use of the MCD as a formal tool to report surgical AEs was commended by Theologis,¹⁰ in a commentary for the study by Dreher et al.⁹

We have also found the MCD by Sink et al⁶ to be useful for reporting AEs following orthopaedic surgery in children with CP. Given that the AE profiles of children with CP and typically developing children are very different, further minor modifications and clarifications appropriate for use in children with CP were considered to be required,⁸ along with evaluating the reliability of this modified MCD for use in children with CP.

The aim of the study was to evaluate the interrater and intrarater reliability of the MCD of AEs for use in CP after lower limb orthopaedic surgery, and to determine if the MCD was a tool that could be easily used by medical and health professionals in a multidisciplinary setting, and be understood and acceptable to individuals with CP and their families.

METHODS

Developing a MCD System for CP

The MCD is a 5-grade ordinal system (Table 1), with grading determined by the treatment required to manage the AE and any associated long-term morbidity. We based our MCD on modifications made by Sink et al⁶ to the CD, in combination with the profile of AEs experienced by children with CP after orthopaedic surgery in recently reported studies.^{7,8} Using information from these studies, we made several customizations to the MCD to increase its applicability to children with CP (Table 1, Appendix 1, Supplemental Digital Content 1, <http://links.lww.com/BPO/A170>).

Participants

We identified and invited 18 multidisciplinary members who worked closely within a team and were willing to participate in the ratings of 40 clinical scenarios related to children with CP who had undergone orthopaedic surgery at a single tertiary pediatric center. The panel of raters comprised of the following:

- Eight orthopaedic surgeons (3 attendings with fellowship training in pediatric orthopaedics, 3 clinical fellows in pediatric orthopaedics, and 2 research fellows).
- Five senior physical therapists who were working in a gait laboratory or hip surveillance service.
- Two senior clinical nurse coordinators, with both ward and outpatient experience.
- Three young adults with CP who had previously experienced orthopaedic surgery and who were currently working in the medical field.

TABLE 1. Summary of Definitions of Each Grade of the Modified Clavien-Dindo System, Modified for Children With Cerebral Palsy, including examples for each grade

Grade	Definition	Specific Complications
I	A complication that is managed with minor modifications to routine postoperative care, but does not require new treatment. Allowed treatments include: adjustment of precharted medications, physical therapy, nursing, and orthotic care	Increased aperients for constipation, dose adjustment of analgesics, and antispasmodics for increased pain or muscle spasm; increased observation for skin redness without breakdown; increased chest physical therapy for basal atelectasis
II	A deviation from the normal postoperative course, including new medications, additional nursing or physical therapy regimens. Unplanned clinic visits for additional monitoring are also included	New aperients for unresolved constipation; new analgesic infusions, or epidural catheter adjustments for pain; skin breakdown requiring dressings; major brace adjustments by an orthotist; new antibiotic prescription for chest or UTI; blood transfusion for anemia
III	A complication that is treatable but requires surgical, endoscopic, or radiographic interventions or an unplanned hospital admission	Manual fecal disimpaction under GA; repositioning of epidural catheters under GA; Botulinum toxin-A injections for uncontrolled spasm; surgical debridement for wound breakdown or drainage of an abscess; bronchoscopy for evacuation of mucous plug
IV	A complication that is life threatening, requiring an ICU admission, or is not treatable with potential for permanent disability; a complication that requires organ resection (arthroplasty)	Unplanned ICU admission, for example, intubation, tracheostomy, or mechanical ventilation for severe respiratory compromise; long-term analgesia for chronic pain; long-term antimicrobial therapy for suppression of chronic infection which cannot be eradicated; arthroplasty for AVN of the femoral head ¹¹
V	Death	Death within 3 months of surgery, that can in any way be linked to the index surgery. Examples: multiorgan failure, sepsis, pulmonary embolism

See Appendix 1 (Supplemental Digital Content 1, <http://links.lww.com/BPO/A170>) for further detail.

Modified from Sink et al.⁶

AVN indicates avascular necrosis; GA, general anesthesia; ICU, intensive care unit; UTI, urinary tract infection.

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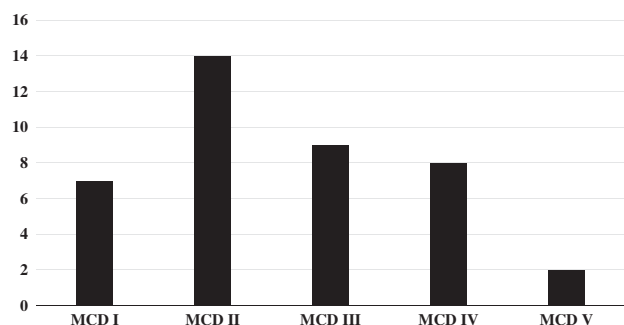


FIGURE 1. Distribution of graded MCD adverse events used for clinical scenario ratings. MCD indicates modified Clavien-Dindo system.

Reliability Ratings

We drew upon the experience of Sink et al⁶ to determine the number of clinical scenarios required for the study. Forty clinical scenarios were created from complications recorded over a 20-year period in our tertiary center, which provides surgical care for a large population of children with CP. Scenarios were aimed to reflect a combination of recently published AEs.⁷⁻⁹ Each scenario was based on a specific patient and real clinical events with a minimum 2-year follow-up to be certain about long-term outcomes. Information included age, sex, Gross Motor Function Classification System level, clinical and operative information, details about the AE, management of the AE, and long-term outcome. Clinical photographs or radiographs, which had been archived from the time of the AE, were used to illustrate each scenario. The clinical scenarios were presented in PowerPoint (Appendix 2, Supplemental Digital Content 2, <http://links.lww.com/BPO/A171>). All MCD grades were represented across the scenarios, but they did not reflect the frequency of MCD grades from previous studies (Fig. 1).^{7,8} Patient data was deidentified and institutional privacy regulations observed.

Immediately before the first rating, a meeting was held with all raters to provide orientation to the MCD. All raters were presented with material to familiarize them with the MCD for CP, including a detailed description

of the study purpose and the MCD (Appendix 3, Supplemental Digital Content 3, <http://links.lww.com/BPO/A172>). Four example scenarios were provided for each MCD grade and discussed. Using skin-related AEs as a specific example, a priori discussion with raters agreed on the following:

- Grade I—skin redness or irritation from a cast or splint which is resolved by a simple adjustment.
- Grade II—a partial thickness skin breakdown which required outpatient dressings.
- Grade III—the presence of a full thickness ulcer, requiring surgical debridement, skin grafting, or a skin flap, under general anesthesia.

The first ratings were completed following the familiarization meeting. The second rating was conducted 2 weeks later, with prior randomization of the scenario presentation order. Raters recorded their responses on a standard form and responses were then collated and transcribed onto an Excel spreadsheet. Each rating was identified by the rater's profession and rating occasion, (eg, PTR1 = physical therapist rating 1), but individuals were not identified.

Statistical Analyses

The data was analyzed with statistical support provided external to our institution. Fleiss' κ statistics with 95% confidence intervals (CI) were used to determine the level of agreement (interrater reliability) between (Tables 2 and 3)

- All raters, across all MCD grades.
- Professional group across all MCD grades.

Fleiss' κ statistics with 95% CI were also used to describe the intrarater reliability for each rater (Table 4). The preference to use Fleiss' κ over weighted κ were 2-fold: to eliminate the risk of falsely inflating our results, and to increase result reproducibility.

A κ score of 0 to 0.2 was deemed as poor, 0.21 to 0.4 as fair, 0.41 to 0.6 as good, 0.61 to 0.8 as very good, and 0.81 to 1.0 as almost perfect agreement.^{12,13} All calculations were performed in Stata version 14.1 (StataCorp, College Station, TX).

TABLE 2. Fleiss' κ for Interrater Reliability of the Modified Clavien-Dindo System for Children With Cerebral Palsy

	First and Second Rating		First Rating		Second Rating	
	κ (95% CI)	Total Ratings (n)	κ (95% CI)	Total Ratings (n)	κ (95% CI)	Total Ratings (n)
Overall interrater agreement						
Overall agreement	0.73 (0.64-0.82)	1440	0.70 (0.61-0.80)	720	0.75 (0.66-0.84)	720
Overall agreement by professional group						
Attending surgeon	0.86 (0.78-0.94)	240	0.93 (0.86-1.00)	120	0.78 (0.65-0.91)	120
Orthopaedic clinical fellow	0.81 (0.71-0.91)	240	0.76 (0.63-0.89)	120	0.85 (0.74-0.96)	120
Orthopaedic nurse	0.75 (0.62-0.87)	160	0.77 (0.61-0.93)	80	0.71 (0.53-0.89)	80
Orthopaedic research fellow	0.77 (0.66-0.88)	160	0.64 (0.45-0.84)	80	0.90 (0.79-1.00)	80
Individual with cerebral palsy	0.73 (0.62-0.84)	240	0.76 (0.63-0.89)	120	0.64 (0.49-0.79)	120
Physical therapist	0.68 (0.57-0.78)	400	0.59 (0.47-0.72)	200	0.76 (0.65-0.87)	200

Fleiss' κ statistics are reported for overall interrater agreement, and by professional group (surgeons, physical therapists, nursing staff, and individuals with cerebral palsy).

CI indicates confidence interval.

TABLE 3. Fleiss' κ for Interrater Reliability Within Each Modified Clavien-Dindo System Grade Among All Raters

MCD Grade	First and Second Rating		
	κ	First Rating	Second Rating
I	0.55	0.52	0.57
II	0.53	0.47	0.58
III	0.87	0.84	0.90
IV	0.96	0.97	0.95
V	1.00	1.00	1.00

Fleiss' κ statistics are reported for interrater agreement for each MCD grade, among all raters.

MCD indicates modified Clavien-Dindo system.

RESULTS

Rating 1 Interrater Reliability

The overall agreement for all raters on all MCD grades was very good (κ , 0.70; 95% CI, 0.61-0.80) (Table 2). The overall agreement varied among professional groups, ranging from κ 0.59 to 0.93. A difference in scores was noted between MCD I and II, compared with agreement among the other grades (Table 3). Overall agreement for MCD I and II was good (κ : 0.52, 0.47, respectively). Grading of MCD III, IV, and V AEs were near perfect (κ : 0.84, 0.97, 1.00, respectively).

Rating 2 Interrater Reliability

Reliability increased at rating 2, with very good overall agreement on MCD grades (κ , 0.75; 95% CI, 0.66-0.84)

TABLE 4. Fleiss' κ for Intrarater Reliability of the Modified Clavien-Dindo System for Children With Cerebral Palsy

Subcategory	Observed	Expected	
Intrarater Agreement	Agreement (%)	Agreement (%)	κ (95% CI)
Attending surgeon			
Rater 1	100.0	24.6	1.00 (1.00-1.00)
Rater 2	90.0	22.9	0.87 (0.74-1.00)
Rater 3	85.0	26.3	0.80 (0.64-0.95)
Orthopaedic clinical fellow			
Rater 1	92.5	22.9	0.90 (0.79-1.00)
Rater 2	85.0	23.1	0.80 (0.65-0.96)
Rater 3	77.5	23.1	0.71 (0.53-0.89)
Orthopaedic nurse			
Rater 1	85.0	24.4	0.80 (0.65-0.96)
Rater 2	75.0	22.8	0.67 (0.49-0.86)
Orthopaedic research fellow			
Rater 1	82.5	23.1	0.77 (0.61-0.94)
Rater 2	87.5	24.2	0.84 (0.69-0.98)
Individual with cerebral palsy			
Rater 1	92.5	23.6	0.90 (0.79-1.00)
Rater 2	70.0	22.8	0.61 (0.42-0.81)
Rater 3	95.0	23.9	0.93 (0.84-1.00)
Physical therapist			
Rater 1	82.5	22.8	0.77 (0.61-0.93)
Rater 2	85.0	24.6	0.80 (0.65-0.96)
Rater 3	60.0	23.2	0.48 (0.27-0.69)
Rater 4	67.5	22.8	0.58 (0.37-0.78)
Rater 5	85.0	23.8	0.80 (0.65-0.96)

Fleiss' κ statistics are reported for intrarater agreement for each rater.
CI indicates confidence interval.

(Table 2). Grading of MCD I and II AEs slightly improved but remained good (κ : 0.57, 0.58, respectively) (Table 3). Grading of MCD III, IV, and V AEs were once again near perfect (κ : 0.90, 0.95, 1.00, respectively).

Intrarater Reliability

Overall intrarater reliability among raters was very good (average κ , 0.78). The highest level of agreement was seen among attending surgeons (κ , 0.80 to 1.00), orthopaedic clinical fellows (κ 0.71 to 0.90), and individuals with CP (κ , 0.61 to 0.93) (Table 4). The lowest level of agreement was observed among physical therapists (κ , 0.48 to 0.80).

DISCUSSION

Preventing surgical AEs is critically important to providing high-quality clinical care, minimizing harm, maximizing function, and containing health care costs.^{8,14,15} Historically, surgeons have reported short-term complications and longer term treatment outcomes that do not involve patients' perceptions¹⁶⁻¹⁹ and is hindered by a lack of standardization and reproducibility.²⁰ A classification system that is valid, reliable, and easy to use may permit transparent standardized reporting of AEs, improve the accuracy of audits, and lead to more objective understanding and comparison of surgical outcome studies in the literature. Use of such systems can promote early recognition of events that deviate from the normal postoperative course, to prevent a cascade effect that could cause permanent morbidity or mortality. Clear documentation and collection of data related to complications will also add information on the associated risks of surgery, guiding the shared or informed decision-making process with parents, caregivers, and young people with CP.^{7,8}

This study shows a very good interrater and intrarater reliability of the MCD for lower limb surgery in children with CP. The system has good face validity and we have shown that it can be used reliably in a multidisciplinary team environment by surgeons, allied health and nursing professionals. Our data shows that a high level of agreement was consistent among orthopaedic attending surgeons and clinical fellows, which could reflect their experience and expertise in recognizing and managing AEs.

Raters had lower agreement with MCD grades I and II overall, and this may indicate some uncertainty in distinguishing typical postoperative sequelae from minor AEs. Subtle differences exist between a treatment considered "preexisting" compared with the addition of new treatment. We think that agreement between MCD grades I and II could be improved by a priori discussion, and the development of more detailed guidelines are now included in Appendix 1 (Supplemental Digital Content 1, <http://links.lww.com/BPO/A170>).

Near perfect agreement was achieved among MCD grades III, IV, and V, irrespective of professional background. This suggests that grading by treatments required to address the AE was clearly understood, and that the outcome worsened with increasing MCD grade.

Children who are most in need of major reconstructive lower limb surgery^{21–23} are often the most medically frail.^{8,18} MCD grades I and II events occurred in up to 60% of children in a recent prospective cohort study of hip surgery in nonambulant children with CP.⁷ The most common complications were constipation, cast-related or splint-related skin irritation, inadequate pain and spasm control from malfunctioning epidural or morphine infusions, and respiratory infections. Most were self-limiting or resolved with simple medical treatment.⁷ However, some children had multiple AEs and in other children, minor AEs escalated to more serious events. For example, children functioning at Gross Motor Function Classification System V have a high prevalence of preexisting respiratory disease. Attempts to manage postoperative pain and spasm with narcotic infusions and diazepam can lead to respiratory depression and pneumonia, which may require an intensive care unit admission and mechanical ventilation.^{7,8} DiFazio et al⁸ reported similar findings, in which 65% of children with CP suffered from postoperative AEs at a rate nearly twice that of typically developing children. This contrasts with a 10.5% surgical and a 29.8% medical AE reported in a large, retrospective cohort study of 168 hip reconstructions involving 121 children with CP.²² Constipation and inadequate analgesia were not reported, which may be due to the retrospective nature of the study.²²

The difference between the reported rates of AEs in outcome studies of children with CP suggests that underreporting of AEs exists in the literature. This is an important issue that requires addressing. Surgeons readily accept that wound infections, hardware failure, or nonunion are surgical AEs that should be reported.^{6,8} As physicians who operate, surgeons should also take responsibility for reporting, preventing, and ameliorating “medical” AEs. If the child was not subjected to general anesthesia and the operation, the exacerbation of constipation, pain, hypertonia, aspiration, and chest infection would not have occurred. Medical and surgical AEs should be “owned,” prevented, and managed by all members of the clinical team. This is the principal reason that we involved all members of our multidisciplinary team in assessing the reliability of the MCD for CP, as well as the perspective of individuals with CP. We strongly encourage a proactive system of prospective documentation, to improve the transparency of recognizing and reporting events.

The key strengths of our study include the inclusion of participants from medical, nursing, and allied health professions, and of individuals with CP whom have experienced orthopaedic surgery. The diversity of our raters aimed to model holistic care provided by a multidisciplinary team, and included the perceptions of AEs in individuals with CP.

This study is the first to examine the reliability of the MCD in children with CP, and it has some limitations. First, raters were inexperienced in using the MCD, resulting in less than perfect agreement. Second, this study highlights the difficulty of distinguishing the severity of minor AEs (MCD I and II), with little comparative data in

existing literature. With increasing utilization of this system in time, it is felt that reliability in grading minor AEs will also continue to improve, shown by the increased observed agreement from rating 1 to rating 2. Future reporting of all minor AEs should be encouraged in the literature to characterize the true frequency of events, identify risk factors and develop strategies for prevention in the postoperative period. Third, many of our complex care children experience more than 1 AE. The MCD system currently has no guidance on how to rate or summarize the effects of multiple complications.

In conclusion, this study has shown that the MCD is a system that can be utilized reliably for grading AEs in CP, following hip and lower limb surgery. The MCD is a useful tool that is easily understood and can be explained to any member of the multidisciplinary team. Future research will be directed on developing a system for grading multiple AEs and testing the validity of the MCD in lower limb surgery for CP in a real time, prospective clinical trial. We recommend the use of the MCD until there is consensus for a gold standard system in AE reporting.

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2 SUMMARY

Study III highlighted the systemic under-reporting of adverse events in the literature, and the importance of recognising AEs early in CP for improved patient safety. Even though the majority of adverse events seen in children with CP were minor, minor events could easily escalate to more serious events without early recognition and management. For example, opiate infusions are commonly prescribed to children with CP for pain management following VDRO. However, opiate use can cause respiratory depression that may lead to a pneumonia (MCD II). If the pneumonia is refractory to antibiotics and chest physiotherapy on the ward, intensive care may be required for assisted ventilation (MCD IV) until clinical improvement is observed.

Study III was able to address this by utilising a further adapted MCD system to standardise the reporting of AEs following lower limb surgery for CP. In summary, very good inter-rater and intra-rater reliability of the MCD was demonstrated for lower limb surgery in children with CP. Furthermore, the MCD could be used in a multidisciplinary team environment and by individuals with CP who had personal experience of lower limb surgery and were working in the medical field.

The use of the MCD to describe adverse events in a standardised manner was commended by Theologis (206), in a long-term SEMLS study for ambulant children with CP that was published by Dreher and colleagues (128). More recently, the Neuro-Orthopaedic journal club conducted at the American Academy of Cerebral Palsy and Developmental Medicine (AACPDM) Annual Meeting in October 2018 applauded the publication of Study III. The journal club ranked Study III as the *most* important article published in the last twelve months. It encouraged esteemed international members of the AACPDM to promote a culture of active prospective documentation of AEs, and to openly report AEs in the literature by using the MCD system.

It is felt that increased reporting of AEs and information sharing will enable multidisciplinary teams involved in the care of children with CP to: quantify risks of adverse events more accurately, inform parents of these risks during the shared decision-making pathway, as well as identify and manage minor adverse events early to improve patient outcomes.

VII. DISCUSSION

1 FUTURE DIRECTIONS

PFOs have now been shown to be safely performed in children with CP with ages as young as 3 years. However, it is still unknown whether the lasting effects of a single-event, bony reconstructive surgery can satisfactorily prevent the progression of hip displacement until adulthood. Future research efforts using a large cohort prospective cohort study to skeletal maturity will be required to address this question. This form of study will also enable further auditing of the surgical devices used for PFO. This will determine if a gold standard device is present, and identify any unforeseen issues that are not currently apparent with the LCBP beyond the 18-month post-operative period. An observational study could also be included, to determine the risk of perioperative fracture or retained metalware at the time of implant removal.

The MCD system is reliable for grading adverse events in children with CP following lower limb surgery. A prospective clinical trial will now be required to test the validity of the MCD system. The MCD system is also unable to summarise the effects of multiple adverse events. Future studies will therefore, focus on reviewing systems such as the comprehensive complication index (CCI) for grading multiple AEs in CP and determine if the MCD can be embedded in the electronic medical records (EMR) as a routine tool for audit and clinical research.

2 CONCLUSION

The three studies within this thesis explored the importance and contribution of implant choice, training, and adverse events relating to PFO in children with CP. A systematic review of the literature found little published evidence in the safety and use of a locking cannulated blade plate for PFOs. Likewise, the choice of implant contributing to an improved trainee learning curve when performing PFOs has not yet been explored. During this study, the prospective detection of increased minor adverse events led to an examination of adverse event reporting in the literature. A standardised or reliable classification tool for reporting adverse events following lower limb surgery in children with CP was not found.

Controlled auditing of the LCBP since its introduction to the Royal Children's Hospital, enabled careful review of the implant's technical performance and safety profile. The use of a prospective, parallel group cohort allowed comparison of the LCBP to the gold standard ABP, and encouraged the evaluation of trainee implant preferences during their PFO learning curve. The review and application of an existing classification system to report adverse events in the second study, provided a basis for the development of the first known reliable system to report adverse events following lower limb surgery in CP.

In summary, and to answer the research questions posed at the opening of this thesis:

Proximal femoral osteotomies, using the new LCBP implant, can be safely performed for a variety of indications, with acceptable post-operative outcomes in younger children. The technical and radiological outcomes of the LCBP are comparable to the existing ABP when PFOs are performed in children with CP. The technique in using the LCBP compared to the ABP implant is easier to teach to orthopaedic surgery trainees. Trainees have expressed a preference for the LCBP to aid their learning curve and intra-operative technical precision.

There is a high probability of medical adverse events experienced by children with CP following PFOs. The majority of adverse events are minor, and mainly relate to uncontrolled pain, constipation, skin issues and chest infections. The Modified Clavien-Dindo System clarified reporting adverse events in children with CP following lower limb surgery, and was found to be a reliable classification tool that can be used by members of a multidisciplinary team caring for individuals with CP.

The knowledge obtained from performing the studies in this thesis adds to the growing literature investigating the benefits and risks of offering a single-event, bony hip reconstructive surgery to children with CP. When combined with future research endeavours, I believe this information will aid in the orthopaedic management of children with CP and ultimately translate to an improvement in their quality of life.

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VIII. APPENDIX

1 STUDY TWO – APPENDIX 1 (IN PUBLISHED PAPER)

Proximal Femoral Osteotomy in Children with Cerebral Palsy: The Perspective of the Trainee.

- A Study on Trainee Safety and Learning Curve

Published by the Journal of Children's Orthopaedics in February 2017.

Appendix 1: Proximal Femoral Osteotomy (PFO) Questionnaire

Question No 1: Insertion of Guide Wire

1 2 3 4 5 6 7 8 9

Very easy

Extremely difficult

Question No 2: Insertion of Seating Chisel

1 2 3 4 5 6 7 8 9

Very easy

Extremely difficult

Question No 3: Osteotomy Cuts

1 2 3 4 5 6 7 8 9

Very easy

Extremely difficult

Question No 4: Insertion of Blade Plate

1 2 3 4 5 6 7 8 9

Very easy

Extremely difficult

Question No 5: Reduction of osteotomy

1 2 3 4 5 6 7 8 9

Very easy

Extremely difficult

**Question No 6: Overall technical ease or difficulty of the procedure with reference
to questions 1-5 above**

1 2 3 4 5 6 7 8 9

Very easy

Extremely difficult

Question No 7: Stability of Fixation

1 2 3 4 5 6 7 8 9

Very stable

Extremely unstable

Question No 8: Weight Bearing Status

No restrictions 1 week 2 weeks 3 weeks 4 weeks 5 weeks 6 weeks in a hip spica

2 STUDY THREE – APPENDIX 1 (IN PUBLISHED PAPER)

Classifying Adverse Events following Lower Limb Orthopaedic Surgery in Children with Cerebral Palsy: Reliability of the Modified Clavien-Dindo System.

- A Study on Patient Safety and Complications

Published by the Journal of Paediatric Orthopaedics in November 2018.

Appendix 1: Modified Clavien-Dindo System for Children with Cerebral Palsy

Grade	Definition	Specific Complications	Treatment Required	Outcome
I	A complication that requires no new treatments apart from those planned and charted. There is no deviation from routine follow up during the post-operative period.	Constipation; post-operative pain, muscle spasm; fever, nausea; wound problems not requiring a change in post-operative care, skin redness from a cast or splint without skin breakdown; basal atelectasis; asymptomatic Grade I or II HO, Grade 1 femoral head AVN.	Minor adjustment of <i>pre-existing</i> treatments. Examples: increased observation; dose adjustments of pre-charted oral medications or infusions including aperients, analgesics, antispasmodics, antipyretics, antiemetics, antibiotics (not <i>new</i> medications); minor adjustment of a splint or brace by an orthotist routinely visiting the ward or clinic; increased frequency of chest physical therapy.	Full recovery, following more of the <i>same</i> medical or nursing treatment
II	A deviation from the normal post-operative course, including new medications, additional nursing or physical therapy regimens. Unplanned clinic visits for additional monitoring are also included.	Enemas for constipation; significant pain requiring introduction of new analgesics; new medications to treat muscular spasms, spasticity or dystonia; pressure sores from casts or splints, superficial wound infection requiring additional clinic visits, antibiotics and/or dressings; chest infection requiring antibiotics; transient neuropraxia from positioning or surgical retraction that resolves under close observation; transient nerve palsy requiring bracing and observation; delayed union requiring increased observation; anaemia requiring iron or blood transfusion.	<i>New</i> non-operative inpatient or outpatient treatment. Examples: new aperients; new pain medications (e.g. Ketamine or Morphine infusions, Clonidine, Gabapentin, Baclofen), adjustment of epidural catheter position; cast removal for paresthesia or inability to move toes on the ward or clinic (not routine cast split in operating theatre), complete cast change, major adjustment or replacement of a brace or splint by an orthotist; blood transfusion for anaemia, new antibiotic prescription for UTI or chest infection.	Full recovery, following <i>new</i> medical treatment, non-medical treatment or observation.
III	A complication that is treatable but requires	Manual evacuation for faecal impaction under GA; unplanned epidural for pain	Treatment requiring <i>unplanned</i> GA and/or surgical intervention.	Full recovery, following treatment

	surgical, endoscopic, or radiographic interventions or an unplanned hospital admission.	or Botulinum toxin-A injections for increased spasticity; change of cast under GA; Deep infection requiring drainage; surgical haematoma requiring evacuation; compartment syndrome or neurovascular injury requiring surgical treatment; endoscopy for gastric bleeding; significant HO requiring excision	Examples: manual faecal disimpaction under GA; re-positioning of epidural catheters; Botulinum toxin-A injections; bronchoscopy for mucus plug evacuation; urinary catheter insertion; fasciotomies; abscess or haematoma evacuation; revision surgical fixation	or surgical intervention under GA. No long-term sequelae.
IV	A complication that is life threatening, requiring an ICU admission, or is not treatable with potential for permanent disability; a complication that requires organ resection.	Organ dysfunction; Bowel obstruction or perforation requiring ICU; severe respiratory disease (e.g. aspiration pneumonia) requiring ICU, intubation, bronchoscopy or tracheostomy; pulmonary embolism requiring ICU; permanent nerve injury; ischaemic contracture; major vascular injury; CNS complications (e.g. encephalopathy after hypoxic episode, prolonged seizures or a blocked shunt); severe femoral head AVN	Life threatening. Examples: <i>unplanned</i> ICU admission, tracheostomy, prolonged hospitalisation for haemodynamic or respiratory support Permanent organ damage or disability. Examples: bowel perforation requiring resection and stomal therapy, long-term analgesia for CRPS type II; contracture release; long-term antibiotic for chronic infection which cannot be eradicated; arthroplasty for femoral head AVN ²³	Life threatening with or without full recovery OR Permanent disability, chronic pain, or deterioration in GMFCS level
V	Death within three months of surgery, that can in any way be linked to the index surgery	Organ failure; sepsis; recurrent respiratory disease; pulmonary embolism	Exclusions: Death following an event that cannot be plausibly linked to surgery e.g. motor vehicle accident Independent verification by a colleague is advised	

In this Appendix, we provide a significantly greater amount of information than that in Table 1. The Appendix gives a definition for each Grade, examples of the complications, examples of the treatment required and the anticipated outcomes. This information may be helpful to researchers who wish to use the modified Clavien-Dindo System for audit, research or clinical outcome studies. HO, heterotopic ossification; AVN, avascular necrosis; UTI, urinary tract infection; GA, general anaesthesia; ICU, intensive care unit; CNS, central nervous system; CRPS, chronic regional pain syndrome; GMFCS, Gross Motor Function Classification System

3 STUDY THREE – APPENDIX 2 (IN PUBLISHED PAPER)

A sample of clinical scenarios that were presented in Powerpoint format for inter and intrarater grading of MCD events in:

Classifying Adverse Events following Lower Limb Orthopaedic Surgery in Children with Cerebral Palsy: Reliability of the Modified Clavien-Dindo System.

- A Study on Patient Safety and Complications

Published by the Journal of Paediatric Orthopaedics in November 2018.

1. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Boy, 6 years, GMFCS IV Day 1 post VDROs
2. Problem: increased pain and spasm. Patient has diazepam charted, epidural and morphine infusion running
3. Treatment: Bolus of diazepam+ increase in doses to follow, epidural rate increased, bolus of morphine
4. Outcome: pain relieved, no delay in discharge

2. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 11 year old girl, Type IV hemiplegia, GMFCS II, Unilateral SEMLS
2. Problem: Skin red under Knee Immobilizer splint, from contact with metal bar
3. Treatment: Adjusted on ward by Orthotist
4. Outcome: No skin breakdown, full recovery

3. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Boy aged 8 years, GMFCS IV, dystonia.
Day 21 after VDROs, spica removed because of pain and smell
2. Problem: Pressure sores, partial and full thickness
3. Treatment: admit, bd dressings
4. Nurse prone, air mattress
5. Split Skin Grafts required, under GA
6. Outcome: full recovery

4. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 5 year old girl, GMFCS V, day 1 post bilateral adductor releases and VDROs
2. Problem: vomiting, x3 episodes, in succession
3. Treatment: anti-emetics given, per charted post-op plan, by anesthetics
4. Outcome: complete resolution

5. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 14 years, boy, GMFCS V
2. Post extensive, revision adductor release
3. Problem: pain and redness over medial aspect, left knee, in abduction brace.
4. Treatment: Brace adjusted on ward, by Orthotist
5. Outcome: No skin breakdown
6. Full recovery, discharge not delayed

6. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Boy aged 11 years, GMFCS V+PEG, Day 3 post Bilateral VDROs+ Unilateral Dega
2. Symptoms: Fever, increased respiratory rate
3. Problem: aspiration and chest infection
4. Treatment: Unplanned admission to ICU.
5. Intubated for 3 days; IV antibiotics, CPAP, chest Physiotherapy
6. Outcome: Full recovery, delayed discharge

7. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Boy aged 9, WGH Type IV hemiplegia and cavovarus foot deformity
2. Day 23 post Tib post Lengthening and Plantar Fascia Release
3. Problem: stitch abscess, noted at cast change
4. Treatment: remove suture in clinic, dressing
5. Outcome: Full recovery

8. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 12 year old girl, GMFCS II, day 1 post SEMLS
2. Problem: cough and stridor, considered to be secondary to prolonged intubation
3. Treatment: observation
4. Outcome: complete resolution

9. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Boy aged 8 years, GMFCS V, 11 weeks after VDROs
2. Problem: Skin breakdown over great trochanter, pressure from wheelchair.
3. Treatment: Taken to operating theatre, plates removed early, skin healed with dressings
4. Outcome: No permanent sequelae, full recovery Hips enlocated, no osteomyelitis

10. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Girl age 12 years, GMFCS II
2. Day 2 post SEMLS, VDROs, Semi T, bilateral foot reconstruction + SMOs in BK casts
3. Problem: pain, can't feel toes
4. Treatment: cast split in ward, 2 hours after Sx
5. Outcome: pain relieved, sensation returned
6. Recovery full

11. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Boy 14 years, GMFCS III, severe crouch gait
2. Day 1 post SEMLS, SEO and PTS
3. Problem: can't feel toes, no movements
4. Treatment: Return to theatre, LL casts removed, knees flexed
5. Outcome: pain relieved, incomplete return of sensation and mild persistent weakness
6. Recovery: Incomplete recovery of sensation and movements at 12 month follow up.

12. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Girl aged 9 years, GMFCS II, Day 7 post SEMLS, Semi T transfers and Supramalleolar Osteotomies (SMOs), distal tibiae, T plate fixation.
2. Problem: Post op x ray showed 1 screw across growth plate
3. Treatment: return to theatre on Day 3, screw changed to shorter screw, different angle
4. Outcome: healed, no growth arrest, full recovery

13. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 9 year old boy, GMFCS V; Day 4 post bilateral VDROs, left Dega
2. Problem: pneumonia, low PO2 despite antibiotics, chest physiotherapy etc.
3. No ICU bed booked
4. Treatment: Unplanned admission to ICU, tracheostomy, prolonged hospitalisation
5. Outcome: full recovery

14. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 11 year old girl, GMFCS II, Day 2 post SEMLS
2. Problem: Unilateral block from epidural. Effective on left side. Severe pain right hip.
3. Treatment: Reviewed by Children's Pain Management Service (CPMS). Morphine and Ketamine infusions started
4. Outcome: Adequate pain relief not achieved until day 4. Then full recovery

15. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: Girl, age 7 years, GMFCS V, PEG fed. Day 5 after bilateral adductor releases.
2. Progressive increase in abdominal pain and distension.
3. Problem: Acute obstruction, surgical consult
4. Treatment: laparotomy, to free adhesions around PEG
5. Outcome: full recovery, after 2 weeks in hospital

16. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 8 year old boy, day 2 post bilateral VDROs and bilateral Degas
2. Problem: low PO₂, tachycardia, hypotensive, aspiration and lung consolidation
3. Treatment: transferred to ICU, ventilated
4. Outcome: parents requested withdrawal of ventilation Day 6. Died in ICU Day 7

17. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 11 year old girl, GMFCS III, Day 5 post SEMLS, foot reconstruction, BK casts
2. Problem: pain over outer ankle
3. Treatment: cast windowed in ward, cast sore noted, patient too upset to co-operate with full evaluation. Returned to operating theatre. Skin red, minor skin loss, dressed and new padded cast, under GA
4. Outcome: full recovery

18. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 8 year old girl, GMFCS V, day 2 post bilateral VDROs
2. Problem: low PO₂, over sedation with diazepam
3. Treatment: Oxygen via nasal prongs, 2 doses of diazepam omitted
4. Outcome: Resolution within 24 hours

19. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 8 year old girl, GMFCS II, SEMLS with bilateral proximal femoral osteotomies.
2. Problem: Grade 3 AVN left hip
3. Noted at 12 month follow up,
4. Mild hip pain and stiffness
5. Treatment: removal of blade plate, observation
6. Outcome: some improvement after plate removal; still has pain with prolonged activity
7. Perthes' like changes, at 24 months, with extensive healing and remodelling

20. Grade This Adverse Event

Treatment and Outcome = Grade

1. Patient: 8 year old boy, Type II Hemiplegia,
2. Vulpius, Botox and casting for equinus gait
3. Problem: Returned to clinic at 1 week with heel pain
4. Treatment: Change of cast, heel red, new cast more padding
5. Outcome: Full recovery, no skin breakdown

4 STUDY THREE – APPENDIX 3 (IN PUBLISHED PAPER)

An in-house MCD familiarisation session, incorporating the study purpose and the MCD grading system for CP, was presented in Powerpoint format to all raters prior to ratings in:

Classifying Adverse Events following Lower Limb Orthopaedic Surgery in Children with Cerebral Palsy: Reliability of the Modified Clavien-Dindo System.

- A Study on Patient Safety and Complications

Published by the Journal of Paediatric Orthopaedics in November 2018.

Why we need a Classification System?

There is no accepted “gold standard”

Adverse events happen: 0%-60%

Existing systems are opaque and subjective

“Mild, moderate, severe “

Classification systems should be valid, reliable
and easy to use

It would be a bonus if Nurses, Physiotherapists,
Surgeons and persons with CP could agree

Modified Clavien Dindo (MCD)

Defined by the treatment needed.

Grade 1: MORE OF SAME eg increased observation, more of same medications, (not new medications) increase infusions eg morphine bolus, more of same chest Physio. Minor adjustment of a splint or brace by an orthotist routinely visiting the ward or clinic.

Grade 2: NEW MEDICAL/NON-OPERATIVE/WARD/ OP TREATMENT: NEW prescription for antibiotics, new/additional pain meds, adjust the epidural catheter position. Split cast for numbness or inability to move toes, in ward, not a routine split in operating theatre. Complete cast change. Major adjustment or replacement of a brace or splint by an orthotist.

Modified Clavien Dindo (MCD)

Defined by the treatment needed.

Grade 3: SURGICAL TREATMENT or TREATMENT WHICH REQUIRES A GA OR TRIP TO THEATRE- WHICH WAS NOT PLANNED Unplanned general anesthetic/return to operating theatre even if there is no operation. Re-site epidural, insert urinary catheter or IV line, adjust fixation, change cast for ? Compartment syndrome, inject Botox for spasms. Remove drain from incision. Drain abscess, release haematoma

Grade 4: LIFE THREATENING OR ORGAN DAMAGE. Unplanned admission to ICU with or without full recovery. Tracheostomy. Organ damage. Grades 2-5 AVN hip, renal failure, liver failure. Permanent nerve injury. Ischaemic contracture. Chronic Regional Pain Syndrome (CRPS) at > 12 months

Modified Clavien Dindo (MCD)

Defined by the outcome

Grade 1: FULL RECOVERY, after more of same

Grade 2: FULL RECOVERY, after new medical treatment

Grade 3: FULL RECOVERY, after treatment/surgery under GA

Grade 4: LIFE THREATENING Can be full recovery eg severe pneumonia, ICU tracheostomy, prolonged hospitalisation, then slow/full recovery.

PERMANENT DISABILITY Most have permanent disability AVN, nerve injury, neuroma and chronic regional pain syndrome, compartment syndrome with ischaemic contractures, deep infection with chronic osteomyelitis which can not be eradicated.

Grade 5: Death: within 3 months of surgery

Modified Clavien Dindo Grade 1

Grade I: A complication that requires no additional treatment and has no long term clinical relevance; there is no deviation from routine follow-up during the postoperative period; allowed therapeutic regimens include: epidural infusions, analgesics IV, PEG or oral analgesics, antispasmodics (diazepam), laxatives, anti-emetics, antipyretics, antibiotics, and physiotherapy

EXAMPLES: postoperative pain and spasms, fever, nausea, constipation, wound problem not requiring a change in postoperative care.
Asymptomatic Grade I or II heterotopic ossification; Grade 1 AVN. Skin redness from a cast or splint without skin breakdown.

Rx=MORE OF SAME eg increased observation, more of same medications, (not new medications) increase infusions eg morphine bolus, more of same chest Physio. Adjust cast or splint in ward or clinic.

OUTCOME: Full recovery

Modified Clavien Dindo Grade 2

Grade 2: A deviation from the normal postoperative course that requires ward treatment, outpatient treatment: either pharmacologic or close monitoring as an outpatient

EXAMPLES: Significant pain, increased muscle spasms requiring new/additional epidural boluses or new dugs, Ketamine or Morphine infusions, Clonidine, Gabapentin, Baclofen etc. New drugs for spasticity or dystonia. Enemas for constipation. Superficial wound infection (additional clinic visits/antibiotics/dressings); transient neurapraxia from positioning or surgical retraction that resolves under close observation; nerve palsy requiring bracing and close observation (complete resolution); delayed union requiring increased observation. Anaemia. Pressure sores from casts or splints.

Rx=OBSERVATION, MEDICAL TREATMENT: pain meds, tone meds, antibiotics, dressings, blood transfusion, TPN, feeding tube. Pressure sores requiring dressings, complete (unplanned) change of cast or splint. Excludes planned change of plater casts at 3 weeks to fabricate AFOs.

OUTCOME: Full Recovery

Modified Clavien Dindo Grade 3

Grade 3: A complication that is treatable but requires surgical, endoscopic, or radiographic interventions. Unplanned GA, return to operating theatre or an unplanned hospital admission.

EXAMPLES: Deep infection (drainage); surgical hematoma (evacuation); compartment syndrome or neurovascular injury requiring surgical treatment or change of cast under GA, manual evacuation for faecal impaction under GA, unplanned Botox injections for increased spasticity, tracheostomy, endoscopy for bleeding from the gut, clinically significant heterotopic ossification that requires surgical excision; deep vein thrombosis/pulmonary embolism (admission and anticoagulation)

Rx=Drain abscess, evacuate haematoma, fasciotomy, nerve decompression, endoscopy

OUTCOME: Full recovery

Modified Clavien Dindo: Grade 4

Grade 4: A complication that is life threatening, requires ICU admission, or is not treatable with potential for permanent disability; a complication that requires organ resection eg excision of femoral head for AVN

EXAMPLES: Severe respiratory disease eg aspiration pneumonia, requiring ICU, intubation, bronchoscopy, tracheostomy.

Permanent nerve injury; major vascular injury; pulmonary embolism; CNS complications eg encephalopathy after hypoxic episode, prolonged seizures or a blocked shunt; organ dysfunction, AVN
Grades 2-5

Rx= UNPLANNED ICU admission, nerve grafting, THA or femoral head excision for AVN

OUTCOME: Usually some degree of permanent disability, chronic pain
Sometimes a deterioration in GMFCS Level,

Modified Clavien Dindo: Grade 5

Grade 5: Death, within 3 months of surgery, that can in any way be linked to the index surgery

Eg recurrent respiratory disease, sepsis, organ failure, Pulmonary Embolism.

Death following an event that can not plausibly be linked to surgery eg a MVA is excluded

Independent verification by a colleague, is advised

Modified Clavien Dindo (MCD)

Grade 1: common examples in CP

Gut: constipation, nausea, vomiting, Usual meds

Pain, spasms, increased spasticity or dystonia

Skin: inflamed from cast, splint, dressing, rash

Chest: Hypoxia O2 sats low, fever, cough

Incisions: bleeding, inflammation

Cast: feels tight but does not need changed or split

IDC: irritation from catheter

Seizures, tingling, temporary alteration in sensation
or movement

Modified Clavien Dindo (MCD)

Grade 2: common examples in CP

Gut: severe constipation: more/new laxatives or enemas

Pain, spasms, increased spasticity or dystonia: adjust epidural position, new meds, new infusion

Skin: split or change cast (in ward, no GA), adjust splint

Nerves (motor and sensory): Remove pressure from nerves by flexing knee, splitting cast, removing cast or splint: full recovery

Chest: Chest physio, IV antis CPAP

Incisions: change dressing, pressure bandage, antis for superficial wound infection

Transfusion for anaemia and low blood pressure/low output

Order air mattress, new dressings

IDC: antis for UTI, catheterize for acute retention in Ward

Modified Clavien Dindo (MCD)

Grade 3: common examples in CP

Gut: GA for manual dis-impaction, faecal impaction,

Pain: GA for a new epidural, Botox/cast for spasms

Skin: change cast GA, debride or skin graft a pressure sore

Chest: Bronchoscopy, bronchial lavage GA,

Incisions: drain haematoma or pus in theatre, change hardware or remove hardware early, apply hip spica: full recovery

Retention: catheterize under GA, cystoscopy for haematuria

Fasciotomy for compartment syndrome, in time for full recovery of muscle and nerves

Surgical decompression of nerves: full recovery

Endoscopy or surgery for bleeding ulcer, bowel obstruction,

Modified Clavien Dindo (MCD)

Grade 4: common examples in CP

Unplanned ICU for chest/pneumonia or organ failure; ventilation

Pancreatitis, bowel obstruction with permanent disability

Chronic osteomyelitis, especially around an implant

Permanent nerve injury, compartment syndrome with contracture

Avascular necrosis hip: Grades 2-5

Growth arrest with limb shortening or angular deformity

Modified Clavien Dindo (MCD)

Grade 5: common examples in CP

Death, within 3 months of surgery

From any reason that might be causally linked to surgery. Relapse in respiratory disease, organ failure, pulmonary embolism, exacerbation of seizures.