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Measuring outcomes after lower limb surgery in children with cerebral palsy

Nichola Carolyn Wilson

A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy in Surgery, The University of Auckland, 2015

Abstract

Cerebral palsy (CP) is the most common physical disability affecting children, with an incidence of 2–2.5 per 1,000 live births. Children with CP frequently undergo orthopaedic surgery as part of their care, with reported improvements in gait pattern as measured by three-dimensional gait analysis (3DGA). However, evidence is lacking on the impact of this surgery on the child's activity and participation in the community. The programme of research presented in this thesis aims to further the knowledge on outcome measures in these domains for lower limb orthopaedic surgery in children with CP.

In the initial study, a mapping review of 229 papers published in the period 1990–2011 was carried out to identify the breadth of outcome measures used to report the results of lower limb orthopaedic surgery in children with CP. The review found that the majority of the studies reported only on changes in impairment of body structure and function, with the most commonly reported measures being clinical examination, 3DGA, and gait velocity. Only 9% of reported outcomes reflected activity and participation, an example of which is the Functional Mobility Scale (FMS). To further investigate this gap in the literature, the following three studies explored whether impairment-based measures can accurately reflect all aspects of free-living walking activity seen in children with CP and thus could, or should, be the only measures of outcome after surgery. Firstly, the relationship between community mobility measured by the FMS and an impairment-based measure of walking capacity, the six-minute walk test, was analysed. Only 20%–27% of the variance of the FMS was accounted for by variation in the six-minute walk test, suggesting that factors other than walking capacity significantly influence a child's choice of mobility across different distances, e.g., wheelchair versus crutches. Daily step count as measured by the StepWatch™ activity monitor had a moderate level of association with the Gait Deviation Index, derived from 3DGA, and is calculated as a single representative score of gait deviation from normalcy (Spearman's $\rho=0.58$). However, significant variations in levels of daily step activity were noted for any single Gait Deviation Index score. Capturing the intensity of walking activity using cadence bands showed that most steps captured by the activity monitor were incidental; our group of children with CP walked only 50.5 minutes per day at faster than a slow walking pace (>59 steps/minute) and only 3.3 minutes faster than a brisk pace (>120 steps/minute). Achieving an increase in moderate to high intensity activity or a decrease in sedentary behaviour may be a better outcome measure following surgery than a change in daily step count and would have potential long-term health benefits for the child.

The final study investigated the feasibility of including measures of activity and participation in the assessment of outcomes at three and six months post lower limb orthopaedic surgery. The Gait Deviation Index was improved at three months, but walking activity in the community decreased by 42% and had not returned to baseline at six months. Surgery led to restriction in diversity and intensity of activities, but did not change enjoyment of these activities over the six-month study period. Data ascertainment of activity and participation measures was lower than for impairment of body structure and function, especially for those measures perceived by parents as different to usual care.

In conclusion, measuring outcomes following lower limb orthopaedic surgery in the activity and participation domains has not been common but is increasing. Impairment-based measures have only moderate relationships with activity levels and cannot reflect all aspects of a child's walking activity. However, families comply better with impairment-based measures because these are seen as standard of care. Making activity and participation outcome measures part of standard care would increase their use in outcome studies and provide valuable information for the future.

For George, Oliver and Charlotte

Acknowledgements

Contents

Tables

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Abbreviations

3DGA	Three-dimensional gait analysis
1MWT	One-minute walk test
6MWT	Six-minute walk test
ADHD	Attention deficit disorder with hyperactivity
ASK	Activities Scale for Kids
CAPE	Children's Assessment of Participation and Enjoyment
CFCS	Communication Function Classification System
CHQ	Child Health Questionnaire
CP	Cerebral palsy
FIM	Functional Independence Measure for Children
FMS	Functional Mobility Scale
GDI	Gait Deviation Index
Gillette FAQ	Gillette Functional Assessment Questionnaire
GGI	Gillette Gait Index
GMFCS	Gross Motor Function Classification System
GMFM	Gross Motor Function Measure
GPS	Gait Profile Score
HAT	Hypertonia Assessment Tool
ICF	International Classification of Functioning, Disability and Health
ICF-CY	International Classification of Functioning, Disability and Health for Children and Youth
LED	Light emitting diode
MACS	Manual Ability Classification System
MRI	Magnetic resonance imaging
NCW	Nichola Carolyn Wilson
PAI	Peak Activity Index
PEDI	Pediatric Evaluation of Disability Inventory
PODCI	Pediatric Outcome Data Collection Instrument
SCPE	Surveillance of Cerebral Palsy in Europe
WS	Walking speed

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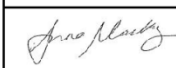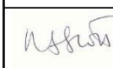
CO-AUTHORS

Name	Nature of Contribution
Dr Jimmy Chong	study design, data collection, manuscript preparation
Dr Anna Mackey	study concept and design, manuscript preparation
Professor N Susan Stott	study concept and design, manuscript preparation, management of reviewers comments

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The undersigned hereby certify that:

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- in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

Name	Signature	Date
Jimmy Chong		1/07/2015
Anna Mackey		15/07/2015
Susan Stott		15/07/2015

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Chapter 4. How does the Functional Mobility Scale relate to capacity-based measures of walking ability in children and youth with cerebral palsy?	
Nature of contribution by PhD candidate	study concept and design, data collection, data analysis, manuscript preparation and submission, management of reviewers comments and rebuttals
Extent of contribution by PhD candidate (%)	95%

CO-AUTHORS

Name	Nature of Contribution
Dr Anna Mackey	study design, review of manuscript
Professor N Susan Stott	study concept and design, manuscript preparation, management of reviewers comments

Certification by Co-Authors

The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and
- in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

Name	Signature	Date
Anna Mackey	*Anna Mackey*	15/07/2015
Susan Stott	*N Stott*	15/07/2015

Last updated: 25 March 2013

Graduate Centre
ClockTower – East Wing
22 Princes Street, Auckland
Phone: +64 9 373 7599 ext 81321
Fax: +64 9 373 7610
Email: postgraduate@auckland.ac.nz
www.postgrad.auckland.ac.nz

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Chapter 5: Variability of Total Step Activity in Children with Cerebral Palsy –Influence of Definition of a Day on participant retention within the study

Nature of contribution by PhD candidate	study concept and design, data collection, data analysis, manuscript preparation
Extent of contribution by PhD candidate (%)	85%

CO-AUTHORS

Name	Nature of Contribution
Dr Suzie Mudge	study design, review of manuscript
Professor N Susan Stott	study design, manuscript preparation

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- in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

Name	Signature	Date
Suzie Mudge		14/07/2015
Susan Stott		15/07/2015

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Chapter 6. Measuring intensity of walking activity in children with cerebral palsy	
Nature of contribution by PhD candidate	study concept and design, data collection, data analysis, manuscript preparation
Extent of contribution by PhD candidate (%)	90%

CO-AUTHORS

Name	Nature of Contribution
Professor n Susan Stott	study design, manuscript preparation

Certification by Co-Authors

The undersigned hereby certify that:

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- in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

Name	Signature	Date
Susan Stott		15/07/2015

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Chapter 7. Gait deviation index correlates with daily step activity in children with cerebral palsy

Nature of contribution by PhD candidate	study concept and design, data collection, data analysis, manuscript preparation and submission, management of reviewers comments and rebuttals
Extent of contribution by PhD candidate (%)	90%
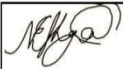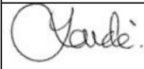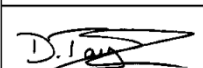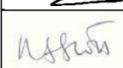
CO-AUTHORS

Name	Nature of Contribution
Dr Nada Signal	data analysis, review manuscript
Yanto Naude	data collection, data analysis, review of manuscript
Dr Densie Taylor	data analysis, review of manuscript
Professor N Susan Stott	study design, manuscript preparation, management of reviewers comments

Certification by Co-Authors

The undersigned hereby certify that:
- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and
- in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

Name	Signature	Date
Nada Signal		15/07/2015
Yanto Naude		16/07/2015
Denise Taylor		16/07/2015
Susan Stott		15/07/2015

Last updated: 25 March 2013

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Graduate Centre
ClockTower – East Wing
22 Princes Street, Auckland
Phone: +64 9 373 7599 ext 81321
Fax: +64 9 373 7610
Email: postgraduate@auckland.ac.nz
www.postgrad.auckland.ac.nz

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Please indicate the chapter/section/pages of this thesis that are extracted from a co-authored work and give the title and publication details or details of submission of the co-authored work.

Chapter 8. A pilot study of the short term impact of lower limb orthopaedic surgery on children with cerebral palsy across the international Classification of Functioning, Disability and Health. Unpublished manuscript

Nature of contribution by PhD candidate	study concept and design, data collection, data analysis, manuscript preparation
Extent of contribution ·by PhD candidate (%)	90%
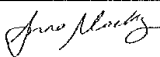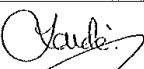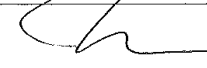
CO-AUTHORS

Name	Nature of Contribution
Dr Anna Mackey	data collection, review of manuscript
Yanto Naude	data collection, data analysis, review of manuscript
Dr Jason Donovan	study concept and design, review of manuscript
Professor N Susan Stott	study concept and design, review of manuscript

Certification by Co-Authors

The undersigned hereby certify that:

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ᴠ in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

Name	Signature	Date
Anna Mackey		15/07/2015
Yanto Naude		16/07/2015
Jason Donovan		30/07/2015
Susan Stott		15/07/2015

Chapter 1 Introduction

1.1 Cerebral palsy

Cerebral palsy (CP) is a term used to describe a heterogeneous group of individuals with permanent motor impairment from non-progressive injury to the developing brain. This impairment ranges from a mild deficit to more severe involvement requiring mobilisation in an attendant-propelled wheelchair. CP is the most common cause of movement disorder in children, with an incidence of 2–2.5 per 1,000 live births.[1]

Definition of cerebral palsy

Defining CP has been a challenge ever since its initial description by William Little in 1861.[2] At that time it was called "cerebral paresis" and often referred to as Little's disease.[3,4] Little believed that the condition was due to prematurity and birth asphyxia.[3] This description led to the long-held belief that birth asphyxia was the primary cause of CP.[5,6] Many other pre-eminent physicians have also written about the condition, including Sir William Osler and Sigmund Freud. Sigmund Freud noted that it was difficult to determine if the motor problems were related to birth injury or a predisposing factor[3], but there was little recognition of this alternative viewpoint[6].

In 1957, an informal group known as the "Little Club" was formed by Dr MacKeith and Professor Polani, who felt that the terminology of CP needed rethinking.[7] They published their definition as:

> A permanent 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.[8]

Since then, a more widely accepted definition was agreed upon at the International Workshop on Definition and Classification of Cerebral Palsy[9], held in Bethesda, MD, USA, in 2004. This group defined CP as:

> 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.[9,10]

For the orthopaedic surgeon, the above definition was the first to recognise the significance of musculoskeletal problems, but this was only included after the writing group was asked to

reconsider their definition.[11] The challenge of diagnosis and classification of CP contributes to the difficulty in measuring outcomes of orthopaedic surgery. There is wide variation in movement and posture disorder with CP and in accompanying disturbances in affected children. This heterogeneity is a significant confounder with regard to outcomes following surgery, and raises problems when relating the results of studies to individual patients.

Incidence and aetiology

Despite 40 years of clinical improvements in obstetric and neonatal care, the prevalence of CP remains at about 2.0–2.5 per 1,000 live births[1], and may even be increasing according to recent data[12,13]. CP remains one of the most common causes of physical disability in childhood,[14,15] and is the most common diagnosis on admission after trauma in most paediatric orthopaedic units.[16]

Whilst the current consensus is that CP is defined by clinical description, for which there is no definitive test,[1,17] the aetiology continues to be investigated.[18] It was thought initially that most cases were due to obstetric difficulties; however, in the developed world, it is suggested that, in the majority of affected children, CP results from aetiologies that culminate in a brain lesion or abnormal development of the brain prenatally.[1] Over 80% of children with CP have an abnormal magnetic resonance imaging (MRI) scan,[19] with the majority of the brain abnormalities occurring in utero. The frequency with which structural brain abnormalities has been found in children with CP has led to some calling for a name change to "early acquired brain injury".[20]

Research looking at the genetic basis of CP is also evolving. It is known that many malformations of the brain have a genetic basis.[21] Considerable heterogeneity has been found in studies looking at the potential genetic causes of CP.[22] A recent paper using whole-exome sequencing found a potential disease-causing gene in 14% of cases.[22] It is also important to remember that many neurogenetic disorders that masquerade as CP are now more easily diagnosed with improved imaging and diagnostic tests.[23]

However, although the number of specific causes of CP is increasing, the definition remains a clinical description. Stanley et al have argued that if the clinical criteria are met, a diagnosis of CP should not be excluded on the grounds of aetiology or pathology.[1] Having a consistent definition of CP is particularly important to be able to measure trends and requires collaboration between CP registries.[18]

Classification

Motor impairment in children with CP can be classified according to anatomical distribution, motor type, or functional limitation. Historically, CP has been defined by topography. Sir William Osler classified his case series of 151 patients in 1889, using the terms infantile hemiplegia, bilateral spastic hemiplegia, and spastic paraplegia.[3] However, topography would now be described using the terms spastic quadriplegia or tetraplegia (involvement of all four limbs), spastic diplegia (where the lower limbs are predominantly involved), or spastic hemiplegia or monoplegia (where one side of the body or a single limb in predominantly affected).[15]

When using motor type to classify children with CP, spastic CP is the most common presentation and accounts for 65%–98% of cases, depending on the CP register used[24,25] (see Figure 1-1). Spasticity is defined as velocity-dependent resistance, which increases with increasing speed of passive movement.[26] Other rarer types of tonal change include dyskinesia (dystonia or athetosis) and ataxia, and these can overlap.[24,27]
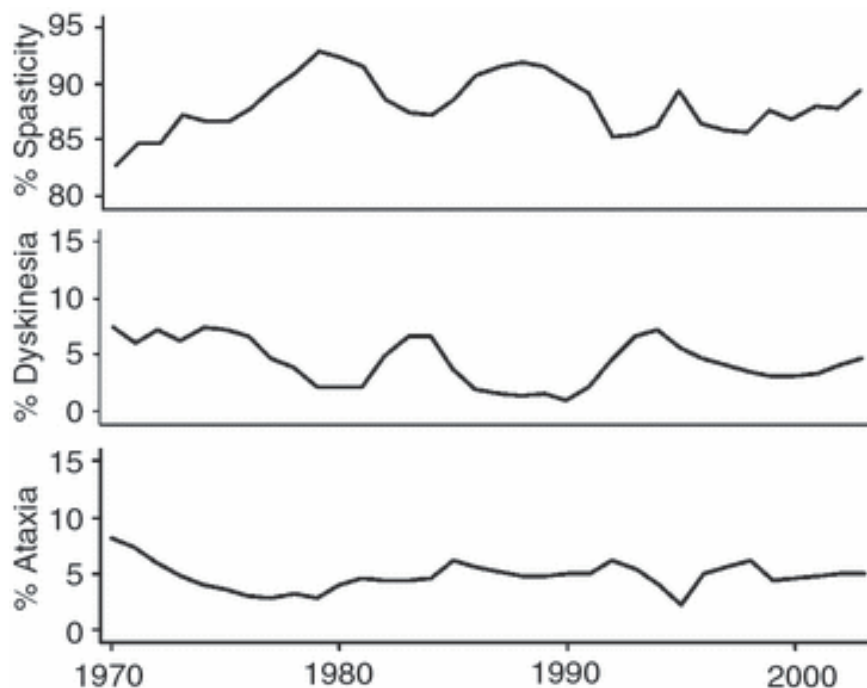
Figure 1-1 Proportion of individuals with cerebral palsy of each motor type over time (3-year moving averages), 1970 to 2003.Reproduced from Reid et al, with permission from *Developmental Medicine and Child Neurology.* 2011;53(3):233–238.[24]

Whilst classifications based on anatomical involvement and motor type have been widely used, these have been shown to have a poor level of interobserver agreement.[25,28] As outlined in the previous paragraph, there is a wide variation in the reported motor type, and this is in part thought to be due to use of multiple categories and definitions.[24]

The Surveillance of Cerebral Palsy in Europe (SCPE) is a more recent classification system designed to assist researchers and CP register designers to classify CP in a more uniform manner.[29,30] The SCPE utilises a decision tree to aid classification, and uses the simplified topographical description of unilateral or bilateral involvement. Interrater reliability for classification of motor type and distribution of CP has been shown to be good.[31,32] Whilst the SCPE has been a step forward, limitations have been identified, including the lack of clarity around timing of the brain injury, which syndromes are excluded[33], and the fact that the function of the individual patient is not included. These limitations have led experts in the field to highlight the importance of also using a functional classification.[34] There are now three commonly used functional classification systems, i.e., the Gross Motor Function Classification System (GMFCS), the Manual Ability Classification System (MACS), and the Communication Function Classification System (CFCS). Each of these classification systems focuses on a different type of impairment (see Table 1-1).

The GMFCS was the first to be introduced in 1997, and addressed the need for a standardised system to measure motor impairment in children with CP;[35] it has had widespread uptake internationally and is used by a broad range of health professionals.[36] The GMFCS classifies children into one of five levels according to their usual functional ability, with those having GMFCS level V being the most severely affected (see Table 1-1).

The GMFCS has been shown to be valid[37,38] and reliable[31,32,35,39-41], with excellent long-term stability once children have reached the age of 6 years.[42] Utilisation of the GMFCS in research has enabled subgroup analysis, allowing clinicians to target surveillance and treatment in the most appropriate manner.[36] For example, in orthopaedics, the GMFCS level has been shown to predict risk for hip subluxation[43-45], scoliosis[46], outcome of foot surgery[47], and outcome of adductor surgery to prevent hip subluxation[48]. The GMFCS has also had an impact in clinical practice by assisting in prediction of likely functional ability in the future and helping children and their families to set realistic goals.[36,49]

Table 1-1 Summary of the Gross Motor Function Classification System, Manual Ability Classification System, and Communication Function Classification System

Level	GMFCS	MACS	CFCS
I	Walks without limitation; speed, balance and coordination are limited	Handles objects easily and successfully; at most, limitations in performing manual tasks requiring speed and accuracy	Sends and receives with familiar and unfamiliar partners effectively and efficiently
II	Walks with limitation, especially over long distances, on uneven terrain and inclines, and in crowded or confined spaces	Handles most objects but with somewhat reduced quality and/or speed; may avoid some tasks	Effective but slower paced sender and/or receiver with unfamiliar and/or familiar partners
III	Walks using a handheld mobility device when indoors; uses wheeled mobility when travelling long distances	Handles objects with difficulty, needs help to prepare and/or modify activities	Effective sender and receiver with familiar partners
IV	Self-mobility with limitations; may use powered mobility	Handles a limited selection of easily manageable objects in adapted situations, requires continuous support	Inconsistent sender and/or receiver with familiar partners
V	Transported in manual wheelchair in all settings	Does not handle objects and has severely limited ability to perform even simple actions; requires total assistance	Seldom effective sender and receiver even with familiar partners

Abbreviations: GMFCS, Gross Motor Function Classification System; MACS, Manual Ability Classification System; CFCS, Communication Function Classification System

Reported in 2006, the MACS aimed to classify how children aged 4–18 years use both hands in daily activities in their personal space and to broaden the functional perspective of CP beyond just gross motor issues.[50] Like the GMFCS, the MACS classifies children into one of five levels. Children who are MACS level I handle objects easily and successfully, with any limitations in manual ability not restricting independence in daily activities, whereas those with MACS level V do not handle objects, have severely limited ability to perform even simple actions, and require total assistance (see Table 1-1). The MACS has been shown to have good interrater reliability[31,50,51], to be stable over time[52,53], and to have predictive value[52]. The MACS is not as widely used as the GMFCS, but provides useful information to aid communication with families, other clinicians, and policy makers, as well as for research analyses. For example, the MACS has been used to investigate computer cursor control in adolescents with CP.[54] Studies looking at the relationship between the MACS and the GMFCS have found that manual ability may not be congruent with mobility, particularly in children with hemiplegia[55], highlighting the importance of having separate classification systems.

Finally, the CFCS was published in 2011 to address the lack of a classification system for functional communication in children with CP.[56] Analogous to the GMFCS and MACS, the CFCS utilizes a five-level ordinal scale of I–V, and has good interrater reliability (see Table 1-1).[31,56] One of the key features of the CFCS classification system is its inclusion of the term "effective communication", which is not restricted to verbal communication but can include manual signs, pictures, communication boards, communication books, and talking devices. The CFCS further acknowledges that communication involves two parties and can be influenced by whether the communication is with a familiar partner (someone who knows the person with CP and can use their shared experiences when communicating) or with an unfamiliar partner (i.e., a stranger or acquaintance).[56]

Alongside the work on functional classification, there has been renewed interest in classifying the underlying brain injury using MRI, given that this may predict and correlate with the individual's level of functional impairment. MRI has been recommended by the American Academy of Neurology for use in children suspected to have CP if the aetiology has not been established by perinatal imaging, for example[19]; in that review, it was found that on average 89% (range 68%–100%) of MRI scans showed an abnormality and were helpful in determining whether the injury was prenatal, perinatal, or postnatal in onset.

In the preterm infant, perinatal white matter injury and germinal matrix haemorrhage represent the most common forms of brain injury[23,57], whereas in the term infant, the most common perinatal

brain injuries are hypoxic-ischaemic encephalopathy and perinatal stroke.[23] Neuroimaging findings are associated with patterns of CP, with perinatal white matter injury often associated with spastic diplegia, unilateral CP with cerebrovascular events, and dyskinetic CP with deep grey matter injury (e.g., the basal ganglia and thalamus).[23,57-59]

Economic burden

CP is a condition that impacts significantly on the health care budget. A 2007 Australian study on the economic impact of CP found that "…CP has a higher disability burden than being blind, deaf, having severe asthma or diabetes. It is also more disabling than having heart failure, localized cancer or the most severe forms of Attention Deficit disorder with Hyperactivity (ADHD)"[14]. In that study, the financial cost of CP was estimated at AUS$43,431 per annum per person with CP, and when the value of lost well-being was included, the cost increased to over $115,000 per annum per person with CP.[14] In 2003, the average lifetime cost for a person with CP was estimated at $921,000 USD.[60] Although the total number of people with CP in New Zealand is not known, based on overseas incidence, the number of adults with CP is likely to be in excess of 5,000, giving combined direct and indirect annual costs of $217 million. These costs do not include an estimate of the cost with respect to "quality of life" for children and families affected by CP.

1.2   Orthopaedic interventions in cerebral palsy

To date, there are no early universal treatments to reverse the brain injury leading to CP, although several modalities are in trial phase for specific causes of CP, e.g., use of a cooling cap, stem cell therapy, and melatonin.[61-65] Therefore, for many children, clinical management is focused on managing spasticity and on later orthopaedic surgery guided by three-dimensional gait analysis (3DGA) to correct the secondary muscle contractures and bone deformities that occur in the growing skeleton as a consequence of spasticity and muscle weakness. Orthopaedic surgery for CP remains complex and resource-intensive, is a significant investment for the patient, family, and health care system, and involves extensive rehabilitation.

Historically, orthopaedic surgery to correct the secondary musculoskeletal deformities associated with CP was performed in a staged manner to address one deformity at a time.[66] For many children, this meant surgery every couple of years, a practice referred to as "birthday syndrome". In the 1980s, there was evolving evidence indicating a shift in practice to multiple surgeries performed in one sitting.[67,68] This is now commonly referred to as single-event multilevel surgery.[69-81]

Multilevel surgery is most commonly based on the findings of 3DGA. Three-dimensional gait analysis provides objective and reliable measures of joint angle parameters in gait and temporospatial data that can be compared with age-matched norms.[82,83] From 3DGA data, global scores such as the Gillette Gait Index (GGI), Gait Deviation Index (GDI), and Gait Profile Score (GPS) can be calculated to assess the degree of deviation of gait from normal.[84-86]

Three-dimensional gait analysis also provides measures of joint angle parameters in gait, which need to be interpreted by the clinician and a decision made regarding the surgical plan. Several studies have shown variability in the surgical prescription based on the same gait data.[87,88] This would not be unexpected, given similar findings in other areas of orthopaedics where an investigation such as MRI will lead to different surgical treatment depending on the orthopaedic surgeon. However, unlike other areas of orthopaedics, the heterogeneity of this patient group and the variable response to surgery mean that there is disagreement as to the "correct" or "best" interpretation of the data, even among experts.[89,90]

Therefore, despite surgical outcomes being guided by gait analysis for at least 20 years, there is still controversy with regard to what type of surgery should be undertaken and how best to measure outcomes following surgery. One of the largest randomised controlled trials in orthopaedic surgery for CP recruited 19 children (eleven in the surgery arm) and used the GPS and GGI, both derived from gait analysis data, as the primary outcome measures.[81] While the GPS and GGI were shown to improve in the surgery arm of the trial, these measures are not necessarily the outcomes of interest or of importance to the child/family. Further, there is little information as to how reliably gait analysis data can be used as a surrogate outcome measure to reflect changes in daily walking activity.

The natural history of CP also has implications for assessing the outcome of orthopaedic surgery.[90] Longitudinal studies using the Gross Motor Function Measure (GMFM-66), a validated measure of gross motor function in children with CP, have shown that gross motor function improves in children with CP up until the age of 6–7 years, when it reaches a plateau of function that depends on the GMFCS level (Figure 1-2).[49,91] In children with GMFCS level I or II, this plateau will usually remain stable, but will decline in those with a GMFCS level of III, IV, or V.[91] There is some evidence that improvement in management of spasticity with Botulinum toxin type A, selective dorsal rhizotomy, and intrathecal baclofen reduces the need for orthopaedic surgery on a population basis.[92]
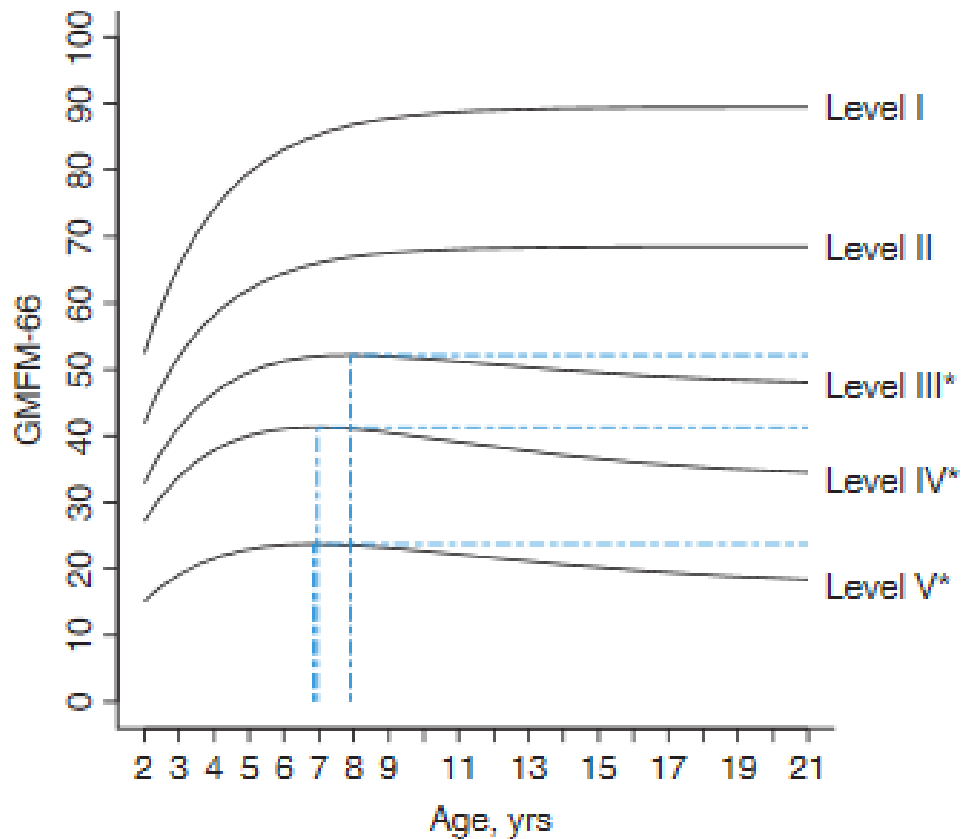
Figure 1-2 Predicted GMFM-66 motor scores as a function of age by Gross Motor Function Classification System level.**Abbreviation:** GMFM, Gross Motor Function Measure. Reproduced from Hanna et al, with permission from *Developmental Medicine and Child Neurology*. 2009;51(4):295–302.[91]

1.3 Why measure outcomes?

Since the increasing prominence of evidence-based medicine in the 1980s and 1990s as popularised by Sackett, there has been a move away from expert opinion to systematic research based on the best available evidence.[93]

Outcomes are measured for a number of goals, with the primary one being that of improving the care of the patient. Outcome tools are designed for a number of purposes and are selected to answer the question posed.[94]

A better understanding of outcome measures is important for several reasons:

- In an environment of budget restrictions, expensive interventions need clear justification of both clinical and economic benefit
- These measures can lead to improvement in standards of care, resulting in better quality of life for children and their families

- There is increasing evidence that patients, families, and treating clinicians want outcomes assessing surgical intervention to move beyond the clinic and reflect the "real world".[93,95]

The work by Vargus-Adams[95], looking at what outcomes following surgery are important to patients and their families, has shown that at times they are similar to those of clinicians but more frequently centre on how the intervention will change what the child can do in the community. The finding that children and their families are interested in community function is reflected in the World Health Organisation change from the International Classification of Diseases to the International Classification of Functioning, Disability and Health (ICF).

Properties of a good outcome measure

A good outcome measure should be valid, reliable, repeatable, and responsive to change.[93,94,96] Validity means that the tool measures what it is supposed measure. There are two broad measures of validity: external validity, i.e., the ability to apply the findings of the study to other people and situations, and internal validity, i.e., the confidence that can be placed in bias being minimised.[97] Internal validity has the subcategories of content validity, criterion-related validity, and construct validity. Reliability is the degree to which a test or measure produces similar results each time it is used; if reliability is high, measurement errors are small in comparison with the true differences between subjects.[98] Repeatability of a measurement refers to the variation in repeat measures made on the same subject under the same conditions.[98] Responsiveness is defined as the ability of an outcome measure to detect true change accurately over time.[99]

As well as the outcome measure having good psychometric properties, there are also a number of practical issues to consider. These include ease of administration, whether the measure is publically available or has licensing fees, respondent burden, ease of scoring, interpretability of results, whether it is developmentally appropriate, and if there is a companion proxy version for children who cannot complete the measure themselves.[100]

1.3.1 What should be measured?

The International Classification of Functioning, Disability and Health was developed in 2001 by the World Health Organisation and focuses on a shift away from negative language to more positive language reflecting what a person can do. The ICF classification contains two main subdivisions: Part 1, which includes functions and disability, including the components of body function and structure, and activity and participation; and Part 2, which includes contextual factors, including components of environmental factors and personal factors. The components of the ICF interact with each other so that if one component is affected, another may be modified (Figure 1-3). If body function and structure are affected, this is referred to as impairment, and if activities and participation are reduced, it is known as restriction. It is important to remember that the ICF applies to all people, not only those with disabilities, and has universal application.[101]
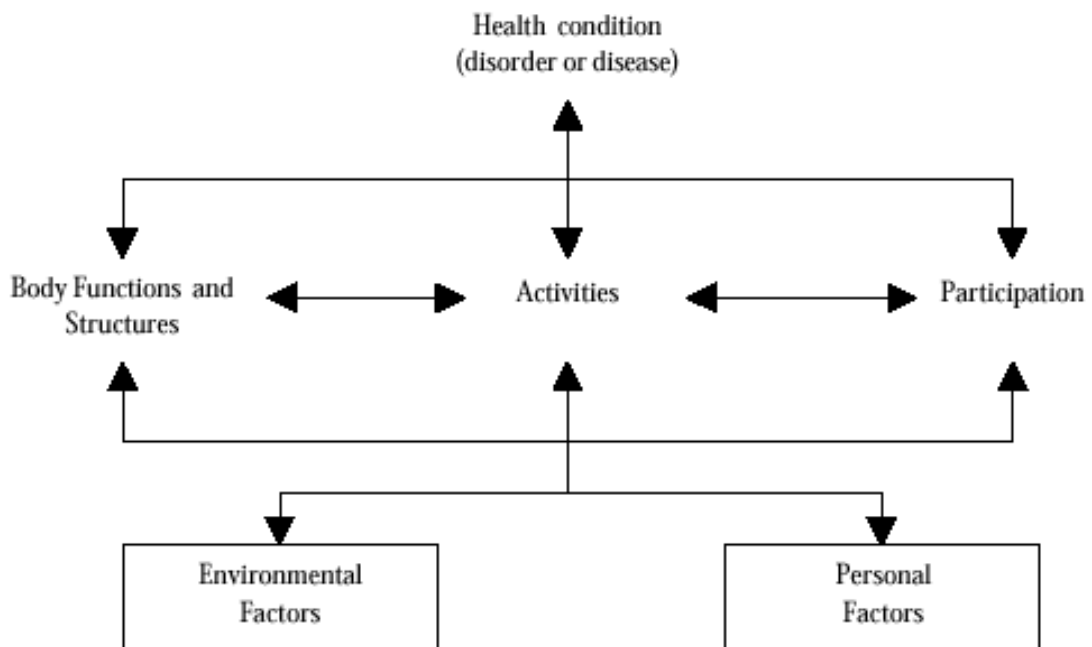
Figure 1-3 Interactions between components of the International Classification of Functioning, Disability and Health. Reproduced with permission from the World Health Organisation.[102]

The International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY) was published in 2007.[101] The ICF-CY covers the age range from birth to 18 years and expands the coverage of the original ICF to include body function and structure, activities, participation, and environment specific to infants, toddlers, children, and adolescents.[101] The parts and components of the ICF-CY are the same as those of the ICF.

Following the introduction of the ICF, there has been a move in the treatment of CP towards optimising activity and participation rather than improving body structure and function.[103,104] The change in focus to activity and participation aligns with the finding that families are wanting information about how interventions will change their child beyond the body structure and function level in terms of "How will it change what my child can do".

Along with the concepts of activity and participation are those of capacity, i.e., what a child can do in a safe and protected environment such as a laboratory, and performance, i.e., what a child does in actual life situations. The gap between these two measures may reflect environmental factors or differences in opportunities. The environmental factors or differences in opportunities would not necessarily be changed by an intervention such as lower limb orthopaedic surgery, but are important when looking at outcomes and giving realistic expectations to families.

It is important to note that the functional classification systems previously described in this chapter (GMFCS, MACS, and CFCS) look at usual activity or "performance" rather than capacity or what the children can achieve in an optimal clinical environment.[34]

1.4   How to measure outcomes of lower limb surgery

To evaluate the results of surgery, valid, reliable, repeatable, and responsive outcome measures are needed. These measures need to address the question that is being asked, which may be different for the clinician and for the patient and family. The ICF has provided a framework for assessment of outcome measures by accommodating the need to include relevant measures from across all components of function. Multiple outcome measures are available to measure different outcomes in children with CP and span the domains of the ICF; however, it was not clear from an initial literature review whether these measures were used in reported clinical and research studies. This gap is addressed by the work in Chapter 3. The following section provides an overview of more commonly reported outcome measures in CP, which are discussed under the most applicable domain heading (see Figure 1-4). It should be remembered that some of the outcome measures include components that are assessed by different parts of the ICF. Activity and participation are considered together because many outcome measures assess both of these parameters[105] and lack of a clear definition of activity and participation can make them difficult to separate.[106]
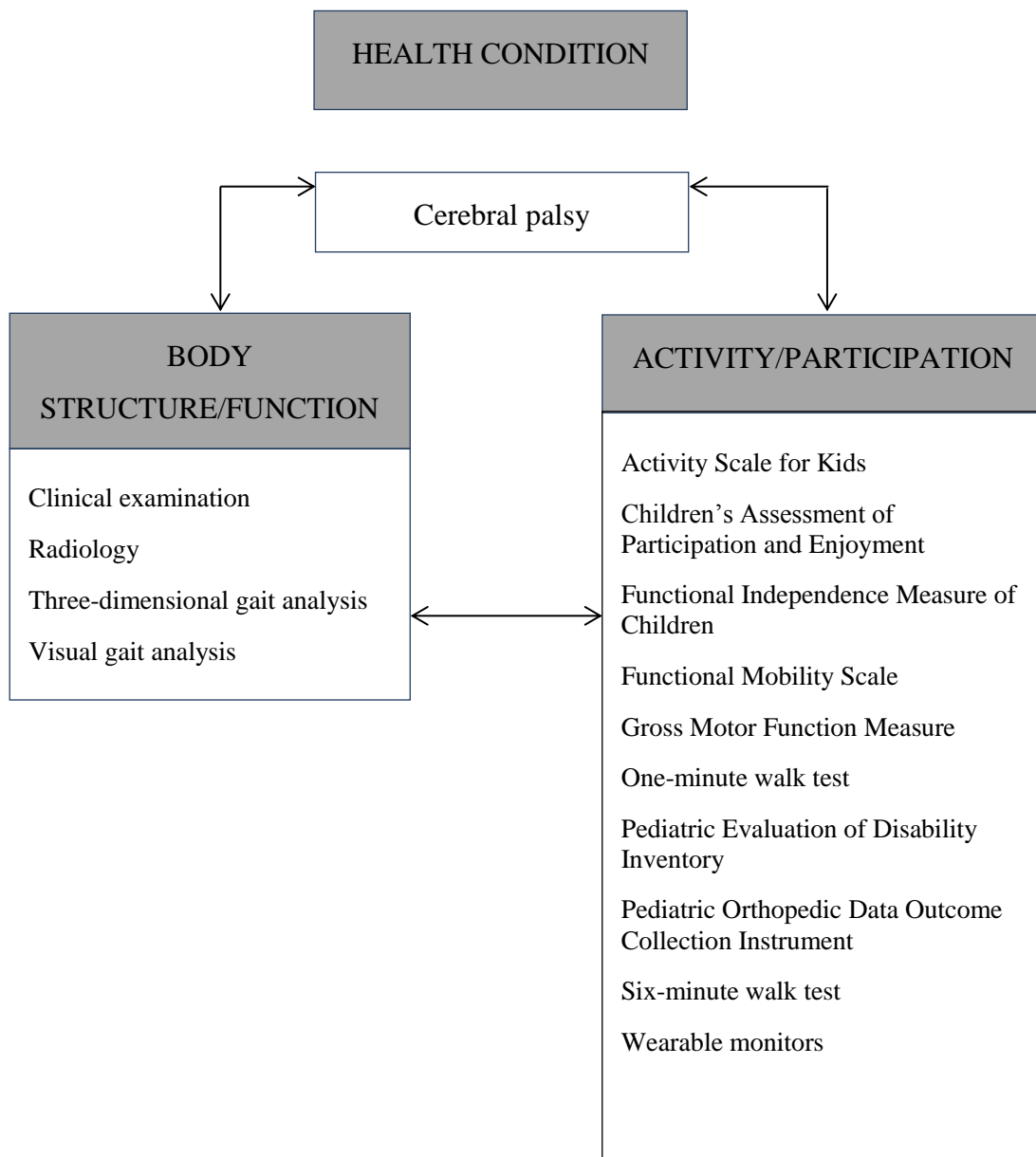
Figure 1-4 Outcome measures within the framework of the International Classification of Functioning, Disability and Health.

1.4.1 Functioning and disability

Traditionally, measures in the functioning and disability component of the ICF have looked predominantly at the body function and structure domain. The ICF defines body functions as physiological functions and body structures as anatomical parts of the body, such as organs, limbs, and their components. In CP, the primary injury to the brain results in movement disorders, such as spasticity, which then have secondary effects on body function, such as changes in muscle length, and body structure, such as bony torsional abnormalities.[16]

Body function and structure

Clinical examination

Clinical examination, in particular for range of motion and tone, has been used to assess outcomes after interventions in CP. However, these measures have poor reliability.[107-114] In children with CP, measurement errors of over 10 degrees have been documented when range of motion is measured by a goniometer,[107-109] with the finding that a change of 15–20 degrees is required for there to be a true change in range of motion between measurement sessions.[110] Correlations between passive range of motion and gait kinematics are fair to weak in children with CP.[115] Further, the validity of passive range of motion measures compared with the predicted Gross Motor Function Measure (GMFM) is also poor.[115]

Assessment of the level of muscle tone in children with CP has focussed primarily on spasticity. Spasticity is defined as a velocity-dependent stretch reflex leading to an increase in muscle tone in a manner that is approximately linear to the increase in velocity of stretch.[116] Spasticity can be measured by the Modified Ashworth Scale[117], Modified Tardieu Scale[118], or the Australian Spasticity Assessment Scale. The Modified Ashworth Scale and Modified Tardieu Scale have been criticised for their low reliability and poor validity.[111-114] The Australian Spasticity Assessment Scale is now used by the Australian CP register and was published in 2016.[119] Each scale has a slightly different definition for each grade (see Table 1-2).

Table 1-2: Definitions of Modified Ashworth Scale, Modified Tardieu Scale and Australian Spasticity Assessment Scale

Grade	Modified Ashworth Scale	Modified Tardieu Scale	Australian Spasticity Assessment Scale
0	No increase in muscle tone.	No resistance throughout the course of passive movement.	No catch on RPM.
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.	Slight resistance throughout the course of passive movement, with no clear catch at precise angle.	Catch occurs on RPM followed by release. There is no resistance to RPM throughout rest of range.
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM.	N/A	N/A
2	More marked increase in muscle tone through most of the ROM, but affected part(s) move easily.	Clear catch at precise angle, interrupting passive movement, followed by release.	Catch occurs in second half of available range (after halfway point) during RPM and is followed by resistance throughout the remaining range.
3	Considerable increase in muscle tone, passive movement difficult.	Fatigable clonus (<10s when maintaining pressure) occurring at precise angle.	Catch occurs in first half of available range (up to and including halfway point) during RPM and is followed by resistance throughout remaining range.
4	Affected part(s) rigid in flexion or extension.	Infatigable clonus (>10s when maintaining pressure) occurring at precise angle.	When attempting RPM, the body part appears fixed but moves on slow passive movement. Contracture is recorded separately.

Abbreviations: ROM, range of motion; RPM, rapid passive movement; s, seconds.

The other frequent movement disorder found in CP is dystonia, characterised by sustained or intermittent muscle contractions or co-contractions causing abnormal and repetitive movements.[116] Spasticity and dystonia can be identified by the Hypertonia Assessment Tool (HAT).[120] The HAT is a seven-item clinical assessment tool that has been shown to be good for measuring spasticity but only fair to moderate for assessing dystonia.[120] Figure 1-5 shows the scoring chart for the HAT tool. The designers of this tool note that further work needs to be done to improve the test when used for detecting dystonia. Manually controlled instrumented measures of spasticity are being developed, but are not commonly used in the clinical setting at present.[114]

HYPERTONIA ASSESSMENT TOOL (HAT) - SCORING CHART

Name:_____ Chart/File #:_____

Clinical Diagnosis:_____ Date of Birth: _____

Limb Assessed: Gender: ☐ Male   ☐ Female

  ☐ Arm   ☐ Left   ☐ Right   HAT Assessor:_____

  ☐ Leg   ☐ Left   ☐ Right   Date of Assessment: _____

HYPERTONIA ASSESSMENT TOOL (HAT)

HAT ITEM	SCORING GUIDELINES (0=negative or 1=positive)	SCORE 0=negative 1=positive (circle score)	TYPE OF HYPERTONIA
1. Increased involuntary movements/postures of the designated limb with tactile stimulus of another body part	0= No involuntary movements or postures observed	0	DYSTONIA
	1= Involuntary movements or postures observed	1	
2. Increased involuntary movements/postures with purposeful movements of another body part	0= No involuntary movements or postures observed	0	DYSTONIA
	1= Involuntary movements or postures observed	1	
3. Velocity dependent resistance to stretch	0= No increased resistance noticed during fast stretch compared to slow stretch	0	SPASTICITY
	1= Increased resistance noticed during fast stretch compared to slow stretch	1	
4. Presence of a spastic catch	0= No spastic catch noted	0	SPASTICITY
	1= Spastic catch noted	1	
5. Equal resistance to passive stretch during bi-directional movement of a joint	0= Equal resistance not noted with bi-directional movement	0	RIGIDITY
	1= Equal resistance noted with bi-directional movement	1	
6. Increased tone with movement of another body part	0= No increased tone noted with purposeful movement	0	DYSTONIA
	1= Greater tone noted with purposeful movement	1	
7. Maintenance of limb position after passive movement	0= Limb returns (partially or fully) to original position	0	RIGIDITY
	1= Limb remains in final position of stretch	1	

SUMMARY SCORE – HAT DIAGNOSIS

			Check box:
DYSTONIA	→	Positive score (1) on at least one of the Items #1, 2, or 6	☐ Yes ☐ No
SPASTICITY	→	Positive score (1) on either one or both of the Items #3 or 4	☐ Yes ☐ No
RIGIDITY	→	Positive score (1) on either one or both of the Items #5 or 7	☐ Yes ☐ No
MIXED TONE	→	Presence of 1 or more subgroups (e.g. dystonia, spasticity, rigidity)	☐ Yes ☐ No

HAT DIAGNOSIS:
(Fill in all that apply) _____

Figure 1-5 Hypertonia Assessment Tool scoring chart. Reproduced with permission from Professor D Fehlings. Abbreviation: HAT, Hypertonia Assessment Tool

Visual gait analysis

Standardised observational gait scores have been used before and after surgery as an inexpensive method for assessing gait. These include the Physician Rating Scale[121] and the Edinburgh Visual

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Gait Score.[122] The primary difference between these two observational gait scores is that the Physician Rating Scale only assesses the sagittal plane (see Table 1-3) while the Edinburgh Visual Gait Score evaluates gait in both the coronal and sagittal planes (see Figure 1-6). The Edinburgh Visual Gait Score has good intraobserver reliability and poor interobserver reliability, but its reliability is higher when used by more experienced observers.[123]

Table 1-3: Physician Rating Scale for gait analysis.

Dynamic function (ROM)		Score
Crouch	Severe (>20 hip, knee, ankle)	0
	Moderate (5–20 hip, knee, ankle)	1
	Mild (<5 hip, knee, ankle)	2
	None	3
Equinus foot	Constant (fixed contracture)	0
	Constant (dynamic contracture)	1
	Occasional heel contact	2
	Heel-to-toe gait	3
Hindfoot	Varus at foot strike	0
	Valgus at foot strike	1
	Occasionally neutral at foot strike	2
	Neutral at foot strike	3
Knee	Recurvatum >5	0
	Recurvatum 0–5	1
	Neutral (no recurvatum)	2
Speed of gait	Only slow	0
	Variable (slow-fast)	1
Gait	Toe-to-toe	0
	Occasional heel-to-toe	1
	Heel-to-toe	2
Total		

Abbreviations: PRS, Physician Rating Scale; ROM, range of motion. Reproduced from Read et al, with permission from *Journal of Pediatric Orthopedics.* 1993;13(3):489–495.[121]

	Stance				
	Flexion		Normal		Extension
Foot	2	1	0	1	2
1. Initial contact			Heel contact	Flatfoot contact	Toe contact
2. Heel lift	No forefoot contact	Delayed	Normal	Early	No heel contact
3. Max ankle dorsiflexion	Excessive dorsiflxn (>40° df)	Increased dorsiflxn (26°–40° df)	Normal dorsiflxn (5°–25° df)	Reduced dorsiflxn (10° pl–4° df)	Marked plantarflxn (>10° pl)
4. Hindfoot varus/ valgus	Severe valgus	Mod valgus	Neutral/slight valgus	Mild varus	Severe varus
5. Foot rotation	Marked extn >KPA (by >40°)	Mod ext >KPA (by 21°–40°)	SI more extn than KPA (by 0°–20°)	Mod int >KPA (by 1°–25°)	Marked int >KPA (by >25°)
Knee					
8. Knee progression angle	External, part knee cap visible	External, all knee cap visible	Neutral, knee cap midline	Internal, all knee cap visible	Internal, part knee cap visible
9. Peak extn stance	Severe flexn (>25°)	Mod flexn (16°–25°)	Normal (0°–15° flexn)	Mod hyperextn (1°–10°)	Severe hyperextn (>10°)
Hip					
12. Peak extn stance	Severe flexn (>15°)	Mod flexn (1°–15° flxn)	Normal (0°–20° extn)	Mod hyperextn (21°–35° extn)	Marked hyperextn (>35°)
Pelvis					
14. Obliquity at mid stance	Marked down (>10°)	Mod down (1°–10°)	Normal obliquity (0°–5° up)	Mod up (6°–15°)	Marked up (>15°)
15. Rotation at mid stance	Marked retraction (>15°)	Mod retraction (6°–15°)	Normal (5° retr–10° pro)	Mod protraction (11°–20°)	Severe protraction (>20°)
Trunk					
16. Peak sagittal position	Marked forward	Mod forward lean	Normal upright	Mod backward lean	N/A
17. Max lateral shift	Marked	Mod	Normal	Reduced	N/A

Figure 1-6: Edinburgh Visual Gait Score chart. Reproduced from Read et al, with permission from *Journal of Pediatric Orthopedics*. 2003;23(3):296–301.[122]

Radiology

Use of radiology in the assessment of outcomes is not uncommon, particularly in foot and ankle surgery and hip surgery. A standardised method of performing radiographic investigations assists in accuracy of measurement, which improves the utility of these measures.[124] Radiographic parameters on standing foot anteroposterior and lateral radiographs have been reported to be clinically relevant in terms of reliability, discriminant validity, and convergent validity[125], and have been used in children with CP.[126]

Three-dimensional gait analysis

Three-dimensional gait analysis is frequently used as part of the preoperative assessment for children with CP[81,127,128], and is an objective method for determining their gait characteristics. A systematic review by McGinley et al found that most studies reported less than 5 degrees of error for gait analysis, with the exception of hip and knee rotation.[83]

In this programme of advanced research, a standard procedure was used in all patients who underwent 3DGA. The 3DGA was obtained using the nine-camera Qualisys Oqus system (C-Motion, Inc., Germantown, MD, USA) and processed using Qualisys Track Manager and Visual 3D software. After collection of anthropometric measurements (height and weight), markers were placed directly on points of reference on the skin, as described in Davis et al,[129] for evaluation of the kinematics of each body segment and the kinetics of each joint. After placement of the markers, the participants completed practice trials as necessary to familiarise themselves with walking in the laboratory. The participants were instructed to walk at a self-selected pace along the walkway (8 m in length) in the gait laboratory. After familiarisation, at least five trials were performed.

The information obtained from 3DGA is complex and requires skill to interpret. Therefore, a number of tools have been developed that derive a single representative score of gait pathology from 3DGA data.[130] These include the GGI, GDI, and GPS. The GGI was the first of these three indices to be developed and was published in 2000.[84] The GDI was then developed to address the shortcomings of the GGI.[131] The GDI uses a smaller number of parameters than the GGI (see Table 1-4) and is transformed and scaled so that the average score for a typically developing group is 100 with a standard deviation of 10. The advantages of this index over the GGI are that it is easy to interpret, it has an inherent filter, and it is normally distributed so allows parametric statistical testing.[131] The GDI has been widely adopted and used in a number of papers looking at the outcomes of lower limb orthopaedic surgery.[132-141] The GPS is another index and was published in

2009.[85] It uses the same indices as the GDI (see Table 1-4) but is calculated as the root mean square difference between data from subjects and the mean from an able-bodied control dataset.[131] Unlike the GDI, degrees are the unit of measurement used for the GPS, and a lower GPS is a more normal gait. The GDI and GPS have been shown to be highly correlated.[85] Work looking at the sensitivity of the GGI, GDI and GPS in paediatric populations has shown the GDI and GPS to be the most sensitive for assessing treatment or comparison with control populations.[131]

Table 1-4 Parameters included in the gait indices.

GGI	GDI	GPS
Time of toe-off	Pelvic obliquity	Pelvic obliquity
Walking speed	Pelvic tilt	Pelvic tilt
Cadence	Pelvic rotation	Pelvic rotation
Mean pelvic tilt	Hip ab/adduction	Hip ab/adduction
Range of pelvic tilt	Hip flexion/extension	Hip flexion/extension
Mean pelvic rotation	Hip rotations	Hip rotations
Minimum hip flexion	Knee flexion/extension	Knee flexion/extension
Peak abduction in swing	Ankle dorsiflexion/plantar flexion	Ankle dorsiflexion/plantar flexion
Mean hip rotation in stance	Foot progression angle	Foot progression angle
Knee flexion at initial contact		
Time of peak knee flexion		
Range of knee flexion		
Peak dorsiflexion in stance		
Peak dorsiflexion in swing		
Mean foot progression angle		

Reproduced from Danino et al, with permission from *Journal of Pediatric Orthopedics*. 2016;36(3):294–298.[142]

In this research programme, the GDI was used as the single representative score of gait pathology from 3DGA data. The GDI was chosen because its' use is well established in the literature. The control dataset for the GDI in our laboratory comprised 50 children. The GDI has concurrent validity with measures of motor performance in children with CP, including the Gillette Functional Assessment Questionnaire (FAQ)[86] and the Gross Motor Function Measure[143]. Excellent interrater reliability and acceptable agreement has been demonstrated for the GDI.[144]

Activity and participation

The ICF defines activity as the execution of a task or action and participation as involvement in a real-life situation. There has been debate in the literature with regard to how to differentiate activity and participation, with some authors criticising the ICF for its lack of a clear definition.[106] Both activity and participation are included in many outcome measures[105] and are frequently discussed together in the literature.[105,145,146]

It should also be remembered that activity as defined by the ICF is different from "physical activity". The most widely cited definition of physical activity was that published by Caspersen and colleagues in 1985[147], i.e., "any bodily movements produced by skeletal muscles that result in energy expenditure".[148] Whilst physical activity is a subset of activity[149], "physical activity" in the form of exercise (a planned physical activity with bodily movements that are structured and repetitive and performed for the purpose of improving or maintaining physical health) may also fit under the ICF definition of participation.

There are many ways of measuring activity and participation in children, including self-report questionnaires, parent-report questionnaires, direct observation, and wearable monitors.[150] The following section discusses outcome measures that are currently in use under these headings.

Self-report tools

Activity and participation can be measured with self-report tools. As defined by the ICF, participation includes not only participating socially, but also basic activities such as eating, toileting, and getting about.[151] Direct observation by a researcher is not usually feasible, so self-report is the most common method of obtaining information. Self-report tools include global questionnaires, short-term recall questionnaires, quantitative history recall questionnaires, physical activity logs, and physical activity diaries.[152] The concern with all these methods relates to the accuracy of recall and reporting bias, which have been documented by many groups.[152-154] Children are less time-conscious than adults, and tend to engage in sporadic bouts of physical activity with varied intensity rather than the consistent patterns often seen in adults, making recall of intensity, duration, and frequency difficult.[154] They also may feel compelled to respond in a socially desirable fashion, so the validity of these measures can be poor, and children will often overreport.[154]

Children with CP tend to self-report higher scores than those recorded on parent-report forms.[94] This is in contrast with typically developing children, who tend to report the same scores as their parents.[155,156]

A number of self-report tools have been used in children with CP. These include the Gillette FAQ, Child Health Questionnaire (CHQ), Pediatric Outcome Data Collection Instrument (PODCI), Functional Independence Measure for Children (FIM), ABILOCO-Kids, Pediatric Evaluation of Disability Inventory (PEDI), Activities Scale for Kids (ASK), and Children's Assessment of Participation and Enjoyment (CAPE). Table 1-5 summarises the features of these outcome measures and their clinical utility. Two of these self-report measures of activity and participation, i.e., ASK and CAPE, are used in this thesis and are discussed more fully in the following paragraphs.

Table 1-5 Features of self-report outcome measures

Outcome measure	Target population	Activity or participation	Aspect of activity measured	Time taken to complete
Gillette FAQ	Participants with walking disabilities, age unclear	Activity and participation	Mobility	10 min
CHQ	Generic, all participants 5–18 years	Activity and participation	HRQOL with physical function subset	30 min
PODCI	Participants with orthopaedic problems, 0–18 years	Activity and participation	HRQOL with physical function subset	30 min
WeeFIM	Participants with developmental disabilities, 0–7.5 years	Activity and participation	Self-care, mobility and cognition	20 min
PEDI	Participants with disabilities, 0.5–7.5 years	Activity and participation	Self-care, mobility and social function	45–60 min
ASK	Participants with musculoskeletal disorders, 5–15 years	Activity and participation	Self-care, play, mobility	10 min
CAPE	Participants with developmental disabilities, 6–21 years	Activity and participation	Everyday activities outside of classroom	30–45 min

Abbreviations: FAQ, Functional Assessment Questionnaire; CHQ, Child Health Questionnaire; PODCI, Pediatric Outcome Data Collection Instrument; FIM, Functional Independence Measure for Children; PEDI, Pediatric Evaluation of Disability Inventory; ASK, Activities Scale for Kids; CAPE, Children's Assessment of Participation and Enjoyment; HRQOL, health-related quality of life

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The ASK is a child self-report measure of frequency of participation in relation to physical function, and was first published by Young et al in 2000.[157] It contains 30 items that are aggregated into a summary score. The ASK asks questions around seven subdomains including: personal care (three items), dressing (four items), other skills (four items), locomotion (seven items), play (two items), standing skills (five items), and transfers (five items). There are two versions of the ASK: the performance version that measures what the child "did do" during the previous week; and the capability version that measures what the child "could do" during the previous week. It is designed for children aged 5–15 years and is not specific to the CP population. The ASK has been shown to have excellent internal consistency, test-retest reliability, and intrarater and interrater reliability in children with CP.[158] The ASK takes about 10 minutes to complete.

The CAPE is a 55-item questionnaire designed to examine how children and youth participate in everyday activities outside of their school classes. It looks at dimensions of participation including: diversity (number of activities done), intensity (frequency of participation measured as a function of the number of possible activities within a category), and enjoyment of activities. It has been designed for children aged 6–21 years with disabilities. Reliability and validity have been established for the CAPE,[158] but its responsiveness following interventions is not known. The CAPE takes approximately 30–45 minutes to complete depending on the number of activities the child does.

Parent-report tools

Many children with CP are unable to complete self-report tools measuring activity and participation. Parent-report tools are thus often used as a surrogate. Two examples of a parent-report tool are the ABILOCO-Kids and the Functional Mobility Scale (FMS), the features of which are outlined in Table 1-6.

Table 1-6 Features of parent-report outcome measures

Outcome measure	Target population	Activity or participation	Aspect of activity measured	Time taken to complete
ABILOCO-Kids	Participants with CP, 4–18 years	Activity	Mobility	5 min
FMS	Participants with CP, 6–18 years	Activity	Mobility	5 min

Abbreviations: CP, cerebral palsy; FMS, Functional Mobility Scale

The most frequently used in the orthopaedic outpatient clinic setting is the Functional Mobility Scale (FMS),[159] which scores children over three distances: 5 m (to represent mobility in the home), 50 m (at school), and 500 m (at the shopping mall). The child is then assigned to one of six ordinal levels from 6 (independent on all surfaces) to 1 (uses wheelchair), as shown in Figure 1-7. Good interrater reliability, validity, and responsiveness have been reported.[72,159-162]

The FMS was designed to be rated by either a physician or a therapist. Work has been done to validate the FMS, with good interrater reliability (mean intraclass correlation coefficients 0.94–0.95) found between community-based physiotherapists, hospital-based physiotherapists, and orthopaedic surgeons.[160] Further work has looked at parental reports of mobility versus direct observation of mobility at home and at school, and found substantial agreement, with a trend towards better agreement at longer distances;[163] these authors emphasised that the FMS was intended to measure performance rather than capability but that parents may be keen to emphasise their child's best ability and therefore report capability.[163]

The FMS has been validated against the PODCI, CHQ, and Uptimer;[159,161] however, its relationship with measures of capacity is not known. This identified gap in the literature was investigated in our research programme and the findings are presented in Chapter 4. The FMS is used routinely in clinical practice at our centre and in others around the world because it is simple and quick to administer as well as being a well validated outcome measure.

Rating 6

Independent on all surfaces:

Does not use any walking aids or need any help from another person when walking over all surfaces including uneven ground, curbs etc. and in a crowded environment.

Rating 5

Independent on level surfaces:

Does not use walking aids or need help from another person.* Requires a rail for stairs.

*If uses furniture, walls, fences, shop fronts for support, please use 4 as the appropriate description.

Rating 4

Uses sticks (one or two):

Without help from another person.

Walking distance	Rating: select the number (from 1–6) which best describes current function
5 metres (yards)	
50 metres (yards)	
500 metres (yards)	

Rating 3

Uses crutches:

Without help from another person.

Rating 2

Uses a walker or frame:

Without help from another person.

Rating 1

Uses wheelchair:

May stand for transfers, may do some stepping supported by another person or using a walker/frame.

Rating C

Crawling:

Child crawls for mobility at home (5m).

Rating N

N = does not apply:

For example child does not complete the distance (500 m).

Figure 1-7 Functional Mobility Scale. Approval to use this graphic was obtained from Professor H Kerr Graham and the *Journal of Pediatric Orthopedics*.[159]

Direct observation

Many measures of activity are undertaken using direct observation, usually within the clinic environment. These include the GMFM, the one-minute walk test (1MWT), and the six-minute walk test (6MWT). Table 1-7 outlines the features of these outcome measures.

Table 1-7 Features of direct observation outcome measures

Outcome measure	Target population	Activity or participation	Aspect of activity measured	Time taken to complete
GMFM	Participants with CP, 4–18 years	Activity	Mobility	10 min
1MWT	Generic, all ages	Activity	Mobility	1 min
6MWT	Generic, all ages	Activity	Mobility	6 min

Abbreviations: GMFM, Gross Motor Function Measure; 1MWT, one-minute walk test; 6MWT, six-minute walk test

First published in 1989,[164] the GMFM is a widely reported measure of function that can be used to assess children with CP over time. As well as the original GMFM, now known as the GMFM-88, the GMFM-66[165] is also used. The GMFM-66 has been shown to be a valid tool for measuring motor function in children with CP.[164] The GMFM-66 D (standing) and E (dynamic function, i.e., walking, running, and jumping) are often used in intervention studies, with dimension E having been demonstrated to be able to discriminate GMFCS levels well.[94] The GMFM-66 takes about 45 minutes to complete.

The 1MWT was introduced in CP because some children had difficulty completing longer distance tasks. The developers proposed that it "... would be a greater discriminator of their functional ability for dynamic balance, muscle performance, and endurance than that recorded at self-selected speed",[166] and it has also been shown to be a reliable measure of functional ability in children with CP.[166,167]

The 6MWT was developed by Balke in 1963 as an measure of observed functional capacity.[168] Since then, the 6MWT has been used in many adult and paediatric populations.[169-173] It is undertaken in the clinic by asking the child to walk at a self-selected speed and allowing for rest periods over the six minutes according to standardised guidelines.[174] The 6MWT has been shown to be a reliable and valid measure for assessing functional ability in children with CP.[172,175-178] Work has been done demonstrating that the 6MWT is also a good surrogate measure of peak oxygen uptake relative to laboratory-based cycle ergometry testing in children with CP.[179] The 6MWT has been used in many clinical studies involving children with CP.[172,180-183] It has also been shown to be sensitive to change, with 40 m reflecting a real difference in adults with CP.[171]

Wearable monitors

Wearable monitors include: pedometers, which record the number of steps in a vertical plane); accelerometers, which detect motion in one, two or three directions (uniaxial, biaxial and triaxial monitors); and multisensory activity monitors, which can integrate multiple sensors. Pedometers are worn at the waist and use a pendulum-type mechanism to detect steps. The accuracy of pedometers has been shown to be lower than that of the accelerometer-based step count in both normal and obese children,[184] and pedometers are not recommended for children with CP. Accelerometers use varying technology; for example, the Actigraph is a triaxial digital accelerometer that generates an electrical signal proportional to the force acting on it along three axes.[185]

The Actigraph uses a piezoelectric acceleration sensor that filters and converts the signals produced from the sensor in samples collected at a preset frequency in Hertz.[186] Activity "counts" are converted from the accelerations over a given user-specified sampling interval known as an "epoch".[186] The conversion of counts per given time epoch into time spent in various physical activity levels has been the focus of much research and debate.[186-189] Work done in children with CP published in 2011 looked at whether intensity-related Actigraph cut-points developed for typically developing youth were valid for use in this group.[190] This study included 30 children and adolescents with CP and found Actigraph monitoring to be valid in these children and able to differentiate slow, comfortable and brisk walking. The cut-points published by Everson et al for typically developing children have been found to be suitable for use in children and adolescents with CP.[191]

However the Actigraph does not provide a total number of steps per day. The step is the most frequent unit of physical activity and would fit, depending on circumstances, in both the activity and participation components of the ICF. For this reason, the StepWatch was chosen for this programme of advanced research in 2011. Since that time, a number of articles have been published that utilise the Actigraph in the CP population.[183,192-198]

In 2015, O'Neil et al[199] published a study evaluating the inter-instrument reliability and concurrent validity of the Actigraph, StepWatch and SenseWear armband monitor. The Actigraph and StepWatch had the best inter-instrument reliability and good concurrent validity when compared with VO_2 output, with the authors concluding that all three monitors provide valid and reliable measurement of the intensity of physical activity among youth with CP.

The StepWatch is a custom biaxial accelerometer under microprocessor control. It is small (70×50×20 mm; 38 g), waterproof, and self-contained (Figure 1-8), and is worn around the ankle. The monitor provides no feedback to the wearer. The StepWatch is calibrated to each patient by specifying their height and gait during programming. The appropriateness of the settings can be manually verified by watching a test internal LED light on the monitor blink every time a step is detected and/or by a formal accuracy trial that compares observer counts with monitor counts. The StepWatch monitor is calibrated and downloaded using a standard computer via a docking station that plugs into a USB port.

Figure 1-8 StepWatch activity monitor.

The accuracy of step detection is excellent for both unimpaired gait and gait patterns that have previously been difficult to monitor accurately, such as geriatric shuffling, hemiplegic gait, and spastic gait. For typically developing children, the StepWatch has been demonstrated to have high accuracy when compared with manual step counting for both walking and running.[200]

Accuracy has also been demonstrated in children with CP,[201] as well as the relationship between total daily step count and GMFCS level.[201] Whilst the accuracy of the StepWatch activity monitor is established, Goodgold's commentary on the work done using this monitor noted that it is important to determine whether differences in ambulatory performance are real differences and not just variations in monitor use.[202] Goodgold highlighted non-adherence as an important issue and one that needed to be explored further.

Another influence on accuracy is the definition of a day. Table 1-8 shows the variation in definition of a day used to analyse the data. How varying this definition and its effects on repeatability of the

data and retention of study participants has not been studied before in children with CP, but in typically developing children, increased stringency of the definition of a day preferentially favours more active children. The StepWatch activity monitor has a number of inputs, including strides (doubled to assess total step count), sustained activity measures (Max 1, Max 5, Max 20, Max 30, and Max 60), and the Peak Activity Index (PAI). Max 1, Max 5, Max 20, Max 30, and Max 60 are derived by scanning the day's total data with a "window" of the designated width (1, 5, 20, 30, or 60 minutes) and identifying the continuous interval of that duration containing the highest number of recorded steps. The number of recorded steps is then divided by the duration of the time interval to give the best performance in steps/minute over that continuous time period in one day. In contrast, the PAI is a non-continuous measure calculated from the average step rate of the highest 30 minutes of the included time in a day, regardless of when they occurred. The most frequently reported outcome measure is total step count, as shown in Table 1-8. Very little has been published on Max 1 and PAI; however, these have been reported as indicators of best ambulatory effort for typically developing children in the free-living environment.[203]

The StepWatch can also measure cadence bands. Cadence bands have been proposed as a measure of activity intensity and used in typically developing adults and children.[203,204] The eight cadence bands are: no activity (0 steps); incidental movement (1–19 steps/minute); sporadic movement (20–39 steps/minute); purposeful steps (40–59 steps/minute); slow walking (60–79 steps/minute); medium walking (80–99 steps/minute); brisk walking (100–119 steps/minute); and all faster ambulatory activities (≥120 steps/minute). These eight cadence bands have not been investigated in children with CP, and this was identified as another gap in the literature.

As previously discussed in this chapter, 3DGA is frequently used in children with CP. How data generated from the 3DGA relate to StepWatch activity monitor outputs is not known. This programme of research investigated how the GDI relates to total daily step count and intensity of activity. The StepWatch activity monitor has only been used to investigate the outcomes following an intervention.[205,206] It has not been used to assess the outcomes of lower limb orthopaedic surgery; this is explored as novel work in the final chapter of this thesis.

Thus, several gaps have been identified in the current literature regarding use of the StepWatch activity monitor in children with CP: influence of definition of a day on both repeatability and adherence or retention of participants; use of other StepWatch activity monitor outputs; intensity of activity using cadence bands; relationship between StepWatch activity monitor outputs and 3DGA data; and responsiveness of StepWatch activity monitor outputs following lower limb orthopaedic

surgery. These gaps in the literature are addressed in this programme of research in Chapters 4, 5, 6, 7, and 8.

Table 1-8 Publications using the StepWatch activity monitor in children with cerebral palsy

Reference	Study purpose	Number of children and GMFCS levels	Researcher's definition of a day	StepWatch output used
Van Wely et al[205] 2014	Primary outcome measure in the Learn 2 Move 7–12 physical activity stimulation program	49 CP (I, 28; II, 12; III, 9)	Total recording time of the StepWatch was allowed to deviate a maximum of 3 hours from the total "awake" time as mentioned in the diary or a minimum of 10 hours of StepWatch wearing time per day	Strides per day Minutes per days spent inactive, medium to high stride rate (15–30) and high stride rate (>30)
Bjornson et al[207] 2014	Examine relationship between walking performance and participation in mobility-related habits of daily life	128 CP (I, 44; II, 54; III, 30)	Noncompliance defined as more than 3 hours of inadequate monitoring or unexplained lack of stride counts during waking hours (0600–2200)	Strides per day Number of total strides per day at >30 strides per minute
Balemans et al[208] 2014	Compare daily stride rate activity, daily exercise intensity, and heart rate intensity	43 CP (I, 23; II, 12; III, 8) 27 TD	Days excluded if i) >3 hours of data missing within time interval of being awake; ii) a day had <10 hours (week day) or <8 hours (weekend) of registration time	Intensity (inactive, 1–15 strides/minute; 16–30 strides/minute; 31–60 strides/minute; and >60 strides/minute)
Van Wely et al[209] 2014	Compare walking activity of children with and without CP between The Netherlands and USA	134 CP (I, 64; II, 49: III, 21)	Minimum 10 hours of wearing for school days and 8 hours for weekend days	Daily number of strides Intensity (inactive, low [0–15 strides], moderate [16–30 strides], high 31–60 strides])
Bjornson et al[210] 2014	Describe daily walking stride patterns	209 CP (I, 75; II, 84; III, 50) 368 TD	Valid SW monitoring data was defined as days with less than three hours of inadequate monitoring or no stride counts that was unexplained	Inactive time Peak stride rate/minute Number of strides (low/moderate/high) Time (low/moderate/high)
Ishikawa et al[211]	Identify sources of	201 CP (I, 75; II,	Days where number of steps was <100	Step count

Reference	Study purpose	Number of children and GMFCS levels	Researcher's definition of a day	StepWatch output used
2012	variance in step counts and to examine number of days to obtain stable measure of habitual ambulatory activity	78; III, 48)	considered outliers and treated as missing values; where 2 days of the week were missing, an individual information-centred approach was applied to replace missing values; 8 participants with ≥3 days of values were excluded from analysis	
Christy et al[206] 2012	Determine the effect of intense physical activity	17 CP (I, 3; II, 3; III, 11)	Does not give definition of non-compliance	Daily step activity Percent time child active Percent time at moderate/high levels
Van Wely et al[212] 2012	Assess ambulatory activity levels	62 CP (I, 37; II, 16; III, 9)	Data not used if there was >3 hours of missing data compared with activity diary	
Stevens et al[213] 2010	Influence of age on step activity patterns in children with CP and TD	27 CP (I, 21; II, 6) 27 TD	Does not give definition of non-compliance	Daily step activity Percent daily inactive time Percent time spent low/medium/high intensity
Bjornson et al[214] 2011	Describe walking activity patterns in TD and compare with youth with CP and arthrogryposis	CP 81 (I, 31; II, 30; III, 20) 428 TD	Non-compliance defined as days with >3 hours of inadequate monitoring or no stride counts during waking hours (0600–2200) which were unexplained	Used strides during one-minute epochs, then data for each were tabulated and minutes spent at each stride rate were calculated
Van Wely et al[215] 2010	Learn to Move 7–12 years RCT	Designed 50 children	Paper on study design rather than analysis of data	
Bjornson et al[216] 2008	Compare influence of functional level and ambulatory and physical activity performance on self-reported health	81 CP (I, 31; II, 30; III, 20) 30 TD	Data not used if >3 hours of inadequate monitoring during waking hours (0600–2200)	Steps/day

Reference	Study purpose	Number of children and GMFCS levels	Researcher's definition of a day	StepWatch output used
				status, quality of life
Bjornson et al[201] 2007	Assess ambulatory activity levels		Data not used if >3 hours of inadequate monitoring during waking hours (0600–2200)	Average daily step count Percentage of all time active Ratio of medium to low activity levels Percent time at high activity levels

Abbreviations: CP, cerebral palsy; GMFCS, Gross Motor Function Classification System; RCT, randomised controlled trial; TD, typically developing

1.4.2 Contextual factors

Environmental factors

Environmental factors make up the physical, social, and attitudinal environment in which people live.[101] They are not within a person's control, i.e., family, work, government agencies, laws, and cultural beliefs. These can have a positive or negative influence on the individual's body function or structure, capacity to execute a task, or perform as a member of society.

Environmental factors are generally not defined or included in analysis when looking at the outcome of interventions.

Personal factors

Within the ICF framework, personal factors include age, gender, race, educational level, and coping styles, and are not specifically coded in the ICF due to their wide variability among cultures.[101] Many of these would be routinely collected as part of demographics in a clinical study, but others are not well studied.

1.5   Summary

This review of the literature has highlighted the complexity of CP, its heterogeneity, and the difficulties in its diagnosis and treatment. It also highlights a number of gaps in the literature which this programme of research undertook to address, and the findings are reported in the next seven chapters.

Chapter 2 Thesis aims and structure

2.1   Thesis aims

The overall aim of this thesis is to further the knowledge on outcome measures for lower limb orthopaedic surgery in children with cerebral palsy (CP) in the context of the International Classification of Functioning, Disability and Health (ICF). The relationship between three different perspectives is examined: (1) standard laboratory and clinical assessments of gait; (2) child/parent reports of walking ability and functional activity/participation; and (3) objectively monitored walking activity in the child's usual environment.

This programme of research provides novel and important information on measuring outcomes following lower limb orthopaedic surgery.

2.2   Thesis structure

This thesis has been written in accordance with the 2011 University of Auckland PhD statute regulations to include published work and formatted as the style outlined in the guidelines for including Publication in a Thesis approved by the Board of Graduate Studies, March 2013. As required, the publications and manuscripts have been presented in a consistent format, citation style, and type face. The pages, tables, and figures have been numbered consecutively throughout the thesis to aid the reader. By using publications and manuscripts in this thesis, there is repetition in the introductions of these as they have been written to try and address similar problems. Permission has been obtained from the relevant journals to allow the articles to be included in this thesis.

> **Chapter 1:** Provides an introduction to the field.

> **Chapter 2:** Provides an outline of the thesis aims and structure.

> **Chapter 3**: Describes the methods and results of a mapping review to establish the current outcome measures used for assessing lower limb orthopaedic surgery.

> **Chapter 4**: Describes the methods and results of a validation of the Functional Mobility Scale as an outcome measure for children with cerebral palsy that is reflective of capacity.

Chapter 5: Describes the methods and results of a study looking at the repeatability of total step count recorded on the StepWatch™ activity monitor and its potential usefulness in clinical studies.

Chapter 6: Describes the methods and results of a study looking at activity, capacity, and cadence using alternative output measures from the StepWatch activity monitor.

Chapter 7: Describes the methods and results of a clinical study looking at how a multivariate measure derived from gait analysis data relates to measures of community activity.

Chapter 8: Describes the methods and results of a clinical study looking at outcome measures from across the ICF in children having lower limb orthopaedic surgery to assess their short-term recovery.

Chapter 9: Is a synthesis of the thesis presenting the key findings and discusses the implications of this work.

Chapters 3–9 take the format of a brief preface placing the publication or manuscript in context, then the results in the form of a publication or a manuscript for submission, followed by a commentary providing evaluation of the work and its impact on the field (as appropriate).

Chapter 3 Reported outcomes of lower limb orthopaedic surgery in children and adolescents with cerebral palsy: a mapping review

3.1 Preface

Chapter 3 describes the methods and results of a mapping review undertaken in 2011 to establish the current outcome measures used for assessing lower limb orthopaedic surgery. The need to shift our focus from disability to well-being and function in society when looking at the outcomes of paediatric orthopaedic surgery has been identified for some time.[16] The introduction of the International Classification of Functioning, Disability and Health and the International Classification of Functioning, Disability and Health for Children and Youth has been instrumental in this change in thinking, with much discussion in the literature about the need to focus more on how a child functions in the community. However, it is unknown how the introduction of the International Classification of Functioning, Disability and Health has influenced outcome measures used in the published studies looking at the results of lower limb orthopaedic surgery in children and youth with cerebral palsy. This identified gap in the literature was addressed by performing a mapping review. A mapping review is defined as a review that maps out and categorises existing literature to identify gaps in the research literature and differs from a systematic review in that it does not aim for an exhaustive search of the literature.[217]

The following section contains a reformatted reproduction of the article "Reported outcomes of lower limb orthopaedic surgery in children and adolescents with cerebral palsy: a mapping review" published in *Developmental Medicine and Child Neurology*, Volume 56, Issue 9, pages 808–814, September 2014. *Developmental Medicine and Child Neurology* is the official journal of the American Academy of Cerebral Palsy and Developmental Medicine and the British Paediatric Neurology Association, and covers research in the field of paediatric neurology and neurodisability. Permission has been obtained from the journal to include this work in the thesis.

This work was also presented as a podcast for *Developmental Medicine and Child Neurology* (http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1469-8749/homepage/podcasts.htm).[218]

Following the mapping review, an updated review of the literature reporting outcomes of lower limb orthopaedic surgery in children and adolescents with cerebral palsy is presented. This review is for the period January 2012 to December 2016.

3.2 Reported outcomes of lower limb orthopaedic surgery in children and adolescents with cerebral palsy: a mapping review

Nichola C Wilson[1,2], Jimmy Chong[1], Anna H Mackey[2], and N Susan Stott[1,2]
[1]Department of Surgery, Faculty of Medical and Health Sciences, The University of Auckland;
[2]Paediatric Orthopaedic Department, Starship Children's Hospital, Auckland City Hospital

Funding:

3.2.1 Abstract

Aim: Lower limb surgery is often performed in ambulatory children with cerebral palsy to improve their walking ability. This mapping review reports on outcome measures used in the published literature to assess surgical results, determine range and frequency of their use, and map each measure to the International Classification of Functioning, Disability and Health.

Methods: A mapped review of the literature published between 1990 and 2011 was carried out to identify papers reporting the outcomes of lower limb orthopaedic surgery in ambulatory children with cerebral palsy and aged 0–20 years.

Results: A total of 229 published papers met the inclusion criteria. Thirty-two outcome measures with known psychometric properties were reported in the 229 papers. Twenty measures

assessed impairments in body structure and function and were used in 91% of studies. Ten measures assessed restrictions in activity and participation and were used in 9% of papers. Two measures assessed quality of life. Since 1997, 29% of papers have used the Gross Motor Function Classification System to describe participants.

Interpretation: The body of literature evaluating outcomes of lower limb orthopaedic surgery in cerebral palsy is small but increasing. There is a need to develop a suite of outcome measures to understand better the effectiveness of surgery across the International Classification of Functioning, Disability and Health, including activity and participation.

3.2.2   Introduction

Cerebral palsy (CP) is the most common cause of physical disability in childhood, with an overall prevalence worldwide of 2.11 per 1,000 live births.[219] Many children with CP undergo lower limb orthopaedic surgery between the ages of 6 years and 20 years to address secondary muscle contractures and bone deformities, with the aim of improving or maintaining mobility. This surgery is frequently complex and resource-intensive, representing a significant investment for the patient, family, and health care system, and necessitating extensive rehabilitation. Therefore, it is important for both surgeons and parents to understand fully the outcomes of specific interventions.

Published studies of lower limb surgery in children with CP have utilised a wide range of outcome measures in an attempt to understand better the effectiveness of the surgical procedure for the child.[220,221] The psychometric properties and responsiveness to change of these outcome measures are important[220,221] and have been reviewed recently by several groups[70,105,158]. However, clinicians and researchers also need to consider what information they require from the outcome measure. After surgery, this may include measures of technical accuracy, as well as measures focused on functional gains for the patient. For some surgical interventions, the level of technical achievement may parallel the functional gains; for example, the position of an ankle for arthrodesis relates to functional outcome.[222] For other interventions, the level of association between technical outcomes and functional outcomes is lower[223,224] or unknown.[220]

The last two decades have seen advances in both the definition of CP and the assessment of outcomes after different interventions. The Gross Motor Function Classification System (GMFCS) and the Functional Mobility Scale have been developed and refined to better define lower limb functional ability,[35,38,159] while the 2001 International Classification of Functioning, Disability and Health (ICF)[102] has provided a conceptual framework to assess the effects of a health condition on

human functioning through its definitions of "impairment of body structure and function", "activity limitation", and "participation restriction".[225] Generic and condition-specific instruments that reflect activity and participation are increasingly available for use in children with CP,[90,221,226] with studies confirming that these outcomes align well with the goals of people with CP and their families[226,227].

However, it is not clear whether these advances are reflected in the published literature on outcomes of orthopaedic surgery in children with CP. Therefore, the goal of this review was to identify and quantify the outcome measures used to assess lower limb orthopaedic surgery in children with CP over the last two decades (1990–2011). We chose to use a mapping review methodology to itemise and categorise research outcomes existing in the literature and to identify gaps. Unlike systematic reviews, mapping reviews do not include a formal quality assessment and do not aim for an exhaustive, all-encompassing searching of the literature.[217] The specific aims were: (1) to determine the range and frequency of outcome measures used in the published literature to evaluate lower limb orthopaedic surgery in children and adolescents with CP; (2) to map each measure to the current ICF model to determine where there are gaps in the current use of tools; and (3) to examine whether the outcome measures used in the published literature have changed significantly between the periods before and after introduction of the ICF.

3.2.3   Methods

The search for relevant literature was performed in November 2011 by one investigator (NCW) who searched six different electronic databases: MEDLINE, MEDLINE in process, PubMed EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials. Key search terms included: "cerebral palsy" AND "surgical procedures" OR "surgery" OR "operative". Reference lists of review articles and key papers were also checked manually for relevant articles.

After removal of duplicate records, two investigators independently (NCW, JC) screened all titles and abstracts for potentially relevant articles. Articles were included if both reviewers agreed that they should be included. If there was disagreement, the abstract was reviewed with a third author (NSS), with the final decision being made by consensus between the three authors. Included abstracts were then obtained in full-text versions for review by the two investigators.

The selection criteria used for the studies were as follows: (1) publication in English between 1990 and 2011 in a peer-reviewed journal; (2) primary study reporting one or more outcome measures that assessed the results of lower limb surgery in CP; and (3) inclusion of ambulatory patients with CP and aged 0–20 years.

For the purpose of this review, lower limb surgery was defined as all surgeries focusing on alignment or gait improvement in the lower limb. Papers that reported surgery carried out only for hip dysplasia were excluded. Studies that included both children with CP and individuals with typical development were included only if the data for each group of children could be analysed separately.

Each article was read independently by two investigators (NCW, JC). The study aim, demographic data for study participants, study design, and outcome measures used were recorded using a standardised data extraction sheet (Microsoft Excel Mac OS X 2008, Microsoft Corporation, Redmond, WA, USA). The goal of data extraction was to identify all possible outcome measures reported within the paper rather than to report the quality of the evidence for a particular intervention. We therefore used a broad definition for a research outcome measure, requiring only that measures had to have been developed to assess change in an outcome of interest and had at least one published paper on its psychometric properties. This requirement was met by checking the reference list and also performing a separate search using the name of the outcome measure. Measures for which we could not identify any published psychometric properties were deemed to be anecdotal reports and were excluded from further review. The breadth of content for each of the identified outcome measures was then classified with reference to the ICF domains.[102]

Significance testing was conducted to test for differences between the pre-2001 and post-2001 time periods. The χ^2 P-value (Fisher's Exact test) was calculated using GraphPad InStat 3.0 (GraphPad Software Inc., San Diego, CA, USA).

3.2.4 Results

After removal of duplicates and exclusion of articles on the basis of title alone, 540 papers were appraised using the inclusion criteria and review processes. In total, 229 published papers were finally included in the mapping analysis (see Table S1, online supporting information). The excluded articles can be found in Table S2 in the online supporting information. Only 62 of the 229 papers identified in the search were published during the first half of the time period covered in the review (i.e., before 2001). The remaining 167 papers had been published on or after January 1, 2001 (Figure 3-1).
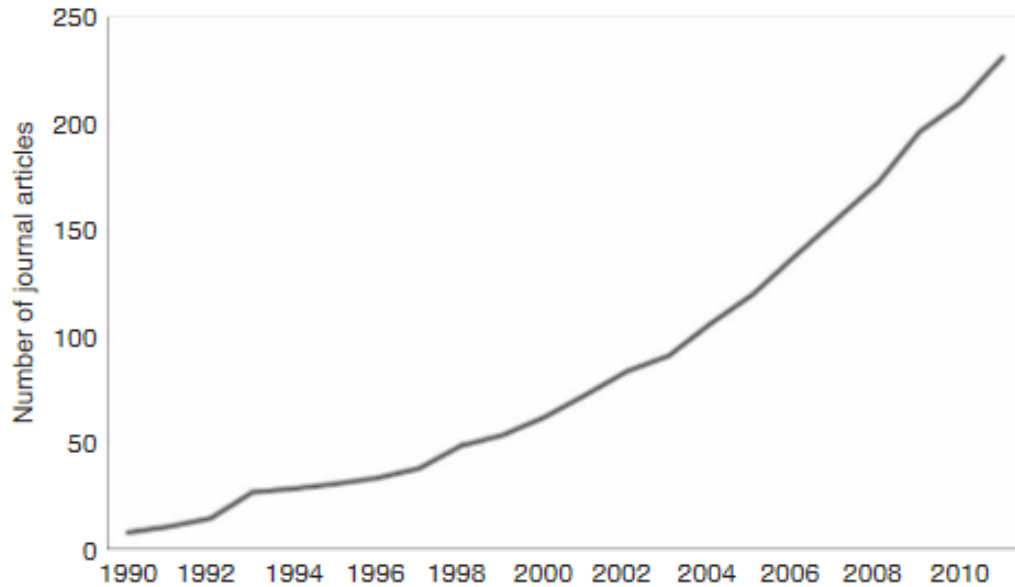
Figure 3-1 Cumulative number of articles published by year.

Study design

The majority of the reported studies had a retrospective design, reviewing patient data collected either retrospectively (n=73) or prospectively (n=111). There were three randomised trials, published in 1996, 2010, and 2011.[81,228,229] The 229 reported studies addressed a heterogeneous mix of surgical procedures in the lower limb, including bony surgery, soft tissue surgery, and combinations of bony and soft tissue surgery. Many of the papers reported on the results of specific lower limb surgery but included patients who had also had other lower limb surgeries at the same time. These other surgeries were not clearly defined, meaning that it was not possible to ascertain if single-event multilevel surgery had been performed as defined by McGinley et al.[70]

Study participants

The majority of the reported studies (n=204, 89%) included only individuals with CP, with a median of 25 participants per study (range 2–1,039). The other 25 studies had a median of eleven participants with CP (range 2–18). The proportion of papers reporting studies that only included participants with CP has not changed markedly over time, being 79% of all studies published before 2001 (n=49) and 93% of all studies published after 2001 (n=155).

Before publication of the GMFCS in 1997,[35] topography was the method most commonly used to describe the CP population in a study (32 of 38 papers, 84%). The GMFCS was first used to describe participants in papers looking at the outcomes of lower limb orthopaedic surgery in children with CP in 2003.[230] From 2003 to 2011, there was an increase in use of the GMFCS to 37% in the published articles (54 of 145 papers).

Range and frequency of outcome measures

Forty-seven different measures used to assess outcome were identified from the 229 studies. Thirty-two of these measures met the definition of an outcome measure and had at least one published paper outlining their psychometric properties. These 32 measures were included in the review and are presented in Tables 1 and 2 classified by their ICF domain and ranked by frequency of use. A representative reference is given for each measure.

A further 14 measures met the definition of an outcome measure but did not have published psychometric properties. They had been used in 68 studies, and included ten author-devised, non-validated questionnaires covering topics such as satisfaction with surgery, cosmesis, activity levels, footwear, personal hygiene, and deformity. These 14 measures were excluded from further analysis because they did not have any published psychometric properties.

The final measure excluded from further review was the GMFCS, a classification system for CP based on functional ability. This was incorrectly used as an outcome measure in 12 of the 229 studies.

Table 3-1 Most frequently used outcome measures according to International Classification of Functioning, Disability and Health domains

Outcome measure (representative reference)	Papers (n)			
	Total (n=229)	Before 2001 (n=62)	2001 onwards (n=167)	*P*-value
Measures of body structure and function				
Clinical examination[231]	159 (69%)	50 (81%)	109 (65%)	0.0249
Gait analysis (kinematics ± kinetics)[232]	134 (59%)	24 (39%)	110 (66%)	0.0003
Gait velocity[233]	75 (33%)	15 (24%)	60 (36%)	0.1133
Radiology[234]	61 (27%)	20 (32%)	41 (25%)	0.2441
Type of walking device[235]	29 (13%)	14 (22%)	15 (9%)	0.0122
Surface EMG[236]	19 (8%)	8 (13%)	11 (7%)	0.1745
Presence of pain[237]	12 (5%)	4 (6%)	8 (5%)	0.7389
Measures of activity and participation				
GMFM[238]*	16 (7%)	1 (2%)	15 (9%)	0.0762
Gillette FAQ[239]*	11 (5%)	0	11 (7%)	0.0385

Note: *Used as a condition-specific measure of activity and participation. **Abbreviations:** EMG, electromyography; GMFM, Gross Motor Function Measure; Gillette FAQ, Gillette Functional Assessment Questionnaire.

Table 3-2 Least frequently used outcome measures according to International Classification of Functioning, Disability and Health domains

Outcome measure (representative reference)	Total n=229	Pre 2001 n=62	2001 onwards n=167
Measures of body structure and function			
Gait Deviation Index[240]	9	0	9
Gillette Gait Index[241]	9	0	0
Foot pressure data[242]	6	1	5
Physiological Cost Index[238]	4	1	3
Energy cost of walking/oxygen consumption[243]	6	0	6
Biomechanical model[244]	3	1	2
Normalcy Index[245]	3	0	3
Physician Rating Scale[246]	2	0	2
Gait Profile Score[81]	2	0	2
Hip Flexor Index[247]	2	0	2
Observation gait[248]	2	0	2
Vertical plantar pressure[249]	1	0	1
Selective Control Assessment of Lower Extremity[250]	1	0	1
Measures of activity and participation			
Functional Mobility Scale [a, 251]	9	0	9
Pediatric Outcomes Data Collection Instrument[b, 252]	8	0	8
Functional Independence Measure for Children[b, 253]	3	1	2
Positional Activity Logger[b, 81]	1	0	1
Pediatric Evaluation of Disability Inventory [b, 254]	1	0	1
Gillette Functional Assessment Questionnaire (22-item skill set)[a, 245]	1	0	1
Modified Goal Attainment Scale[a, 227]	1	0	1
Gross Motor Performance Measure[a, 254]	1	0	1
Quality of life measures that include both ICF domains			
Child Health Questionnaire[81]	2	0	2
Pediatric Quality of Life Inventory [252]	1	0	1

Notes: [a] used as condition-specific measures of activity and participation; [b] generic measures of activity and participation.

Measures of impairment of body structure and function

Twenty measures reflecting impairment of body structure and function were used 537 times and made up 91% of the total reported outcomes. The most commonly used measures of impairment of body structure and function were clinical examination (n=159), e.g., muscle strength, tone, or passive range of motion, and three-dimensional gait analysis (n=134). Before 2001, ten measures of impairment were used, compared with 20 after 2001. The comparison between use pre-2001 and post-2001 is shown in Table 3-1, with analysis for each outcome measure by Fisher's Exact test. Clinical examination and description of walking devices were the only impairment measures for which use decreased proportionally from the pre-2001 to post-2001 time periods (P=0.0243 and P=0.0120, respectively). Gait analysis was the only impairment measure for which use increased from pre-2001 to post-2001 (P=0.0005).

Measures of activity and participation

Ten outcome measures assessing the activity and participation domain were used 52 times and made up only 9% of the total usage. In 16 papers, the Gross Motor Function Measure was used to measure the restriction of activity and participation. There was a fairly even distribution between those used as condition-specific measures (n=6) and generic outcome measures (n=4), as shown in Table 3-1 and Table 3-2. Before the introduction of the ICF in 2001, only two measures were reported in the activity and participation domain, i.e., the Gross Motor Function Measure and the Functional Independence Measure for Children.

Measures of quality of life

Two measures were used in three papers to assess health-related quality of life, i.e., the Child Health Questionnaire and the Pediatric Quality of Life Inventory. Both of these measures were first used after 2001.

3.2.5   Discussion

This mapping review assesses the types of measures used for papers reporting outcomes of lower limb surgery in children with CP, and was performed in the decades before and after the introduction of the ICF to observe changes in the use of domain-specific instruments. The results show an increasing body of published literature looking at the outcomes of lower limb orthopaedic surgery in children with CP. Although papers identified in this review reported a wide range of

outcome measures, most measures assessed impairment in body function and structure as defined by the ICF. Many of the papers did not clearly identify type of CP in their study participants and few have used the GMFCS since its introduction in 1997. Outcome measures mapping to the activity and participation domain of the ICF made up only 9% of the total usage, with less than half of these measures being condition-specific for CP.

The definition and classification of CP has been a challenge since the condition was first reported by Sir William Little in 1861.[2] Type of CP has traditionally been defined by changes in tone and by the anatomical distribution. However, reliability studies have shown only poor to moderate interobserver agreement between experts, at a level that is insufficient for accurate classification.[28] In 1997, Palisano et al[35] published their work on the GMFCS, including its high content validity and interrater reliability. The GMFCS is now widely accepted by the paediatric community as a method for reliably classifying functional ability of the lower limb in children with CP.[255] From the results of this mapping review, it seems that it has taken longer for the GMFCS to be incorporated into orthopaedic surgical practice, with only a limited number of papers using it as a classification tool. A surprising number of authors also chose to use the GMFCS as an outcome measure rather than as a tool to classify patients. This is despite the developers' original paper describing it as a classification system.[35] The GMFCS is an important predictor of the risk of scoliosis and hip dysplasia in CP[45,46,256], and may be linked to the success of some surgeries, reduction in muscle strength, and changes in range of motion over time[47,257,258]. Given the importance of the GMFCS for many surgical outcomes, we believe that its use to classify study participants should become a requirement for publication of orthopaedic outcomes of lower limb surgery.

Outcome measures reflecting impairment in body function and structure were the measures most commonly used to assess the outcomes of lower limb orthopaedic surgery. There is a wide range of measures within this domain, from clinical examination (such as passive range of motion), three-dimensional gait analysis, through to radiology. The frequency of use of these measures probably reflects their use in everyday clinical practice, with such measures often recorded in clinical records and thus accessible retrospectively. Some studies also included unique, sometimes anecdotal, measures of outcome, such as author-developed questionnaires, to explore other aspects of impairment in body structure and function, e.g., ability to use different types of footwear, the appearance of the foot, and difficulties with hygiene, despite lack of published evidence of validity and reliability.[259,260] Use of these non-standardised measures may reflect the paucity of standardised tools available in the literature to assess these outcomes, which are often of interest to the patient, family, and surgeon.[78]

The ICF emphasises "activity" and "participation"; however, we found that this emphasis was not reflected in the measures chosen for the studies reviewed in this paper. This finding is similar to the choice of outcome measures reported in studies of other health interventions in CP, such as aquatic exercise programmes, aerobic exercise interventions, physical therapy, and Botulinum toxin type A.[261-264] Whilst participation can be defined as an individual's involvement in life situations,[102] it can be difficult to operationalise at a research level, given that participation is influenced by both environmental and personal factors.[265] The construct of participation is multidimensional and, as yet, there is no one measurement tool specific for children with CP that can capture all aspects of participation across different environmental contexts.[266]

There is some controversy in the orthopaedic literature as to whether changes in activity and participation can, or should, be measured after orthopaedic surgery.[128] Thomason et al[128] have stated that "Orthopaedic surgeons have one simple but important tool to bring to the table, and that is correction of fixed musculoskeletal deformities. This is the domain in which our contributions and outcomes should be assessed". However, whilst surgery addresses impairments in body structure and function, families and children often desire outcomes in the activity and participation domain.[226] Given the natural history of CP, which can be one of deterioration in musculoskeletal function in later childhood and adolescence, some authors argue that surgery is mainly for maintenance of functional abilities, not improvement.[90] Nevertheless, information on what is reasonable to expect after surgery is still important for families. Measures that are appropriate, valid, and sensitive to change should be sought, and if necessary developed, to better understand the effect of surgery in multiple domains.

There are several clinical implications of this mapping review. First, the low usage of the GMFCS or another validated tool for classification of study participants makes it difficult for the practicing clinician to determine the extent to which their results can be generalised to their patient population. Second, while there is an increasing body of literature looking at the outcomes of lower limb orthopaedic surgery, few outcome measures are used consistently across the papers, making comparison of results difficult. A combination of the Gross Motor Function Measure and/or the Pediatric Evaluation of Disability Inventory, plus the Pediatric Outcomes Data Collection Instrument and the Cerebral Palsy Quality of Life questionnaire, has been suggested to cover most components of the ICF, and would seem to be a good start towards capturing the effect of surgical intervention on the functional profile of a child with CP before and after surgery.[145] However, measures that judge achievement of surgical goals also need to be part of the assessment, and it should be ensured that other outcomes of importance to the patient and family are included.

This study has several limitations. First, we included only articles published after 1990. This was done so that the outcome measures used most frequently in the recent literature would be represented. Second, our review included only English language literature, resulting in exclusion of 62 articles that may have reported different outcome measures. In addition, our review included only studies with outcome measures for which at least one published paper on psychometric properties was available. This meant that 14 outcome measures were excluded. Finally, the content of measures such as the Gillette Functional Assessment Questionnaire and Pediatric Outcomes Data Collection Instrument incorporate questions that map to different constructs in the ICF framework, leading to blurring of the boundary between the definition of function and that of activity.[267] Thus, for example, the self-reported Gillette Functional Assessment Questionnaire is used by some centres as a validated functional outcome measure, but can also be an indicator of activity.

In conclusion, there is an increasingly large body of literature looking at the outcomes of lower limb orthopaedic surgery in CP. However, the results of the studies and their clinical applicability are limited by the infrequent use of a standardised classification system for CP. In our opinion, universal use of the GMFCS would improve the quality of studies reporting outcomes of lower limb orthopaedic surgery. The body structure and function domain of the ICF is well reflected in current studies, but there is only limited assessment of the impact of surgery on the activity and participation domain. Future directions should include trying to gain some uniformity and consensus in the field as to which measures should be used in this heterogeneous patient population, with variable surgical prescriptions to achieve uniformity across studies. We suggest that in order to understand the full impact of lower limb orthopaedic surgery, a suite of outcome measures across the ICF may be needed, including the domain of activity and participation, which reflects outcomes relevant to the patient, family, and surgeon.

3.2.6   Supporting information

The following additional material may be found in the appendices or online at:

(http://onlinelibrary.wiley.com/doi/10.1111/dmcn.12431/suppinfo)

Table S1 showing included articles.

Table S2 showing excluded articles by reason.

3.3 Updated review of reported outcomes of lower limb orthopaedic surgery in children and adolescents: January 2012 to December 2015

To place the mapping review in the context of the literature published during the time the research that underpins this thesis was performed, a further review of the literature was carried out, looking at the time period from January 2012 to December 2015. The literature review was carried out in May 2016. The electronic databases MEDLINE, PubMed, EMBASE, CINAHL and the Cochrane Central Register of Controlled Trials were searched using the terms: "cerebral palsy" AND "surgical procedures" OR "surgery" OR "operative". All paper titles and abstracts were screened for potentially relevant articles. The criteria used were the same as for the mapping review: (1) publication in English between 1990 and 2011 in a peer-reviewed journal; (2) a primary study reporting one or more outcome measures for assessment of the results of lower limb surgery in cerebral palsy (CP); and (3) inclusion of ambulatory patients aged 0–20 years with CP. After removal of duplicates and exclusion of articles on the basis of title and abstract alone, 101 full text articles were reviewed. In total, 81 papers were finally included in the review (Appendices, Table S3). Figure 3-2 shows Figure 3-1 from the mapping review with the additional articles by year added.
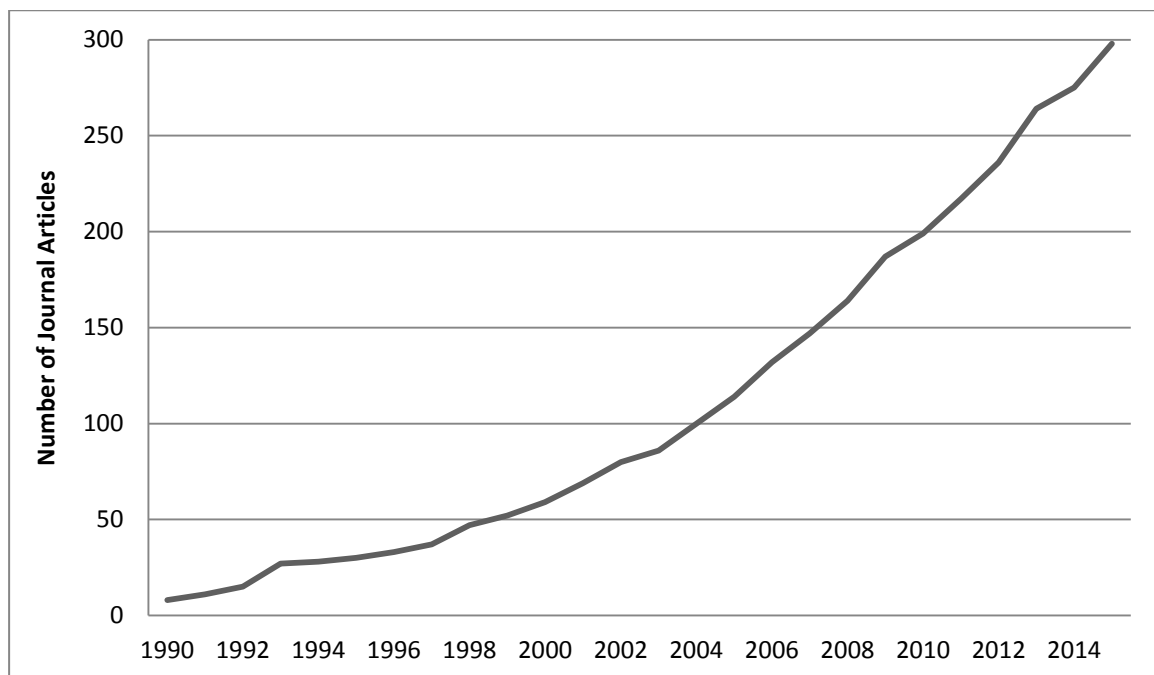
Figure 3-2: Cumulative number of articles published by year

Study design

The majority of studies published during the period 2012–2016 were retrospective in design (n=66). Three were randomised controlled trials, two of which analysed randomisation of surgeons receiving gait analysis data prior to surgery rather than randomising children to different surgical interventions. The first report included all children in the main study (n=156)[135] and the second was a subgroup analysis looking at 45 of the children who showed excessive internal rotation of the hip.[268] The purpose of the other randomised controlled trial was to establish whether the results of single-event multilevel surgery without distal rectus femoris transfer are similar to those of a conventional single-event multilevel approach that includes distal rectus femoris transfer.[269]

The majority of the reported studies (n=79, 96%) included only individuals with CP. The proportion of papers reporting studies that only included participants with CP has increased since the mapping review when 86% of all studies included only individuals with CP.

The GMFCS was used to describe participants in the majority of studies (n=67, 83%) which is a marked increase when compared with the papers published from 1997 when the GMFCS was first reported.

Range and frequency of outcome measures

Nineteen of the measures identified met the definition of an outcome measure and had at least one published paper outlining their psychometric properties. These 19 measures are included in the present review and are presented in Table 3-3 classified by their ICF domain and ranked by frequency of use.

Table 3-3 Outcome measures used according to the International Classification of Functioning, Disability and Health domains

Outcome measure	Total papers (n=81)
Measures of body structure and function	
Gait analysis (kinematics ± kinetics)	58
Clinical examination	49
Gait velocity	20
Radiology	16
Gait Deviation Index	11
Gillette Gait Index	11
Gait Profile Score	9
Foot pressure data	2
Presence of pain	2
Surface electromyography	1
Timed Up and Go	1
Total mechanical work	1
Measures of activity and participation	
Gross Motor Function Measure	7
Functional Mobility Scale	7
Gillette Functional Assessment Questionnaire	2
Pediatric Outcomes Data Collection Instrument	2
Pediatric Evaluation of Disability Inventory[b]	1
Functional Independence Measure for Children[b]	1
Quality of life measures including both ICF domains	
Cerebral Palsy Quality of Life for Children	1

Notes: [a]used as condition-specific measures of activity and participation; [b]generic measures of activity and participation.

The number of outcome measures identified represents a significant decrease from the 32 in the mapping review. The measures that were not used in the literature from January 2012 to December 2015 are listed in Table 3-4.

Table 3-4 Outcome measures not used in the literature between January 2012 and December 2015

Outcome measure
Measures of body structure and function
Type of walking device
Physiological Cost Index
Energy cost of walking/oxygen consumption
Biomechanical model
Normalcy Index
Physician Rating Scale
Hip Flexor Index
Observation gait
Vertical plantar pressure
Selective Control Assessment of the Lower Extremity
Measures of activity and participation
Positional Activity Logger[b]
Modified Goal Attainment Scale[a]
Gross Motor Performance Measure[a]
Quality of life measures including both ICF domains
Child Health Questionnaire
Pediatric Quality of Life Inventory

Measures of impairment of body structure and function

Twelve measures reflecting impairment of body structure and function were used 181 times and made up 90% of the total reported outcomes. The most commonly used measures of impairment of body structure and function were three-dimensional gait analysis (n=58) and clinical examination (n=49), e.g., muscle strength, tone, or passive range of motion.

Measures of activity and participation

Six outcome measures assessing the activity and participation domain were used 20 times and made up only 10% of the total usage. In seven papers each, the Gross Motor Function Measure and the Functional Mobility Scale were used to measure restriction of activity and participation. There was

an even distribution for use of these instruments as condition-specific measures (n=3) and generic outcome measures (n=3), as shown in Table 3-3.

Measures of quality of life

Health-related quality of life was measured in one paper only, and used the Cerebral Palsy Quality of Life for Children questionnaire.

Review of the literature published since the mapping review showed no change in the number of papers that are retrospective in nature and that the majority of outcome measures used looked at the body structure and function domain of the ICF. Interestingly, during the period covered by the literature review, there was a decrease in the diversity of measures used. This may reflect the fact that the review period was four years rather than 20 years which was chosen to look at ten years prior to and after the introduction of the ICF.

3.4   Commentary

The paper entitled "Reported outcomes of lower limb orthopaedic surgery in children and adolescents with CP: a mapping review" has contributed novel work concerning the changes in measures used to assess the outcomes of lower limb orthopaedic surgery for children with CP following introduction of the ICF. It documents that the body of literature looking at the outcomes of lower limb orthopaedic surgery has increased from eight to 18 papers from 1990 to 2011. During the same period, the number of outcome measures used increased from six to 21.

Defining the outcome measures and their frequency of use in lower limb orthopaedic surgery has also added to the broader body of literature assessing how to measure outcomes in children with CP. In comparison with results from the physical therapy literature, relatively few outcome measures were used in the orthopaedic literature. Thirty-two outcome measures were identified in our research, compared with 53 in a systematic review of the effectiveness of physical therapy interventions reported by Anttila et al[261]. In their review, it was found that only eight of the 53 outcome measures were used in more than one trial. In contrast, we found nine outcome measures that had been used more than ten times. Having outcome measures that are used commonly in an area of clinical research allows comparison of papers and their inclusion in meta-analysis.

An interesting finding of this study was the low rate of uptake of the GMFCS in the orthopaedic literature to classify children at a functional level. This is in contrast with the uptake seen in the

physiotherapy and paediatric communities.[255] Our recommendation is that the GMFCS should be included in all studies relating to children with CP; this is not novel, and has been suggested for at least 10 years.[270] The present study did not address the reasons for resistance to change, but this finding is in line with the statement that it takes on average 17 years for research evidence to reach clinical practice.[271]

Since the publication of our paper entitled "Reported outcomes of lower limb orthopaedic surgery in children and adolescents with CP: a mapping review", Mandaleson et al[272] have published their work looking at utilisation of the GMFCS by orthopaedic surgeons from 2005 to 2011. Their study had broader inclusion criteria, including lower limb surgery, spine surgery, and gait studies. However, they conducted a narrower search, looking at only three journals, i.e., *Journal of Pediatric Orthopedics*, *Journal of Bone and Joint Surgery*, and *Developmental Medicine and Child Neurology*. They found that 68% of their included papers used the GMFCS, with an improvement in utilisation from 13% to 80% over the seven-year study period. This is higher than our finding of 37% for papers from 2003 to 2011. This difference may be because we included studies published since 2003, as this was the first time that the GMFCS was used in a paper describing the outcomes of lower limb orthopaedic surgery, and also because we included a more diverse range of journals. However, Mandaleson et al[272] support our stance that the GMFCS should be used in all published studies investigating the results of lower limb orthopaedic surgery. The updated literature review looking at the period from January 2012 to December 2015 demonstrated an increase in use of the GMFCS, which was reported on in 87% of the papers.

Eighty percent of the papers identified in the mapping review were retrospective in nature and could be graded as level III or IV evidence.[273] A high percentage of studies graded level III or IV is seen across the orthopaedic literature in general. A study published in 2005, looking at nine different orthopaedic journals, found that 68% of papers were level III or IV evidence.[273] However, in the *Journal of Pediatric Orthopedics*, 75% of the articles were level III or IV. Since then, many journals have moved to preferentially publishing prospective studies, and require authors to complete the CONSORT statement or confirm that they have met the STROBE guidelines at the time of submission. However, despite this, the updated literature review showed that the number of retrospective papers remained the same (at 80%) from January 2012 to December 2015.

Three papers published during the mapping review period were randomised controlled trials, the most recent of which reported on a study of single-event multilevel surgery and was published in 2011.[81] This study enrolled 19 children with spastic diplegic CP who functioned at GMFCS levels

II or III. The aim of the study was to evaluate the outcome of single-event multilevel surgery across multiple ICF domains. Figure 3-3 (reproduced with permission from the authors of the paper) shows the outcome measures used according to ICF domain.[81] The key finding from this study was that improvements in gait, as determined by the GPS and GGI, were seen at 12 months following surgery, while improvements in other domains, including gross motor function and quality of life, were not observed until 12 months after surgery.

The other two randomised controlled trials investigated calf surgery. In 1996, Camacho et al looked at the outcome of tendo-achilles lengthening alone versus tendo-achilles lengthening combined with neurectomy of the gastrocnemius muscle in the treatment of equinus deformity of the foot associated with clonus in children with CP.[228] Twelve children, including nine with bilateral CP, were included in this study and randomly assigned to a treatment group. The authors followed up this group of children at six months and five years following surgery using clinical examination. The key finding was that the neurectomy group had greater subsidence of the clonus and none of the children had recurrence of their equinus deformity. The other randomised controlled trial, published by Jaddue et al in 2010, looked at open vs percutaneous tendo-achilles lengthening in children with spastic CP and equinus deformity of the foot. Eighteen ambulatory children with spastic diplegia were included but not described by GMFCS level. The assessments used in that study were clinical examination, assistive devices needed, and non-validated scores of parental satisfaction. The children were followed for a mean of 11 months. The key findings of this study were that the percutaneous tendo-achilles lengthening group achieved better active dorsiflexion and plantar flexion, with greater parent satisfaction and a lower complication rate.[229] Interestingly, both of the above-mentioned papers focused on tendo-achilles lengthening, a surgical technique now associated with development of crouch in children with bilateral CP.[246,274-276]
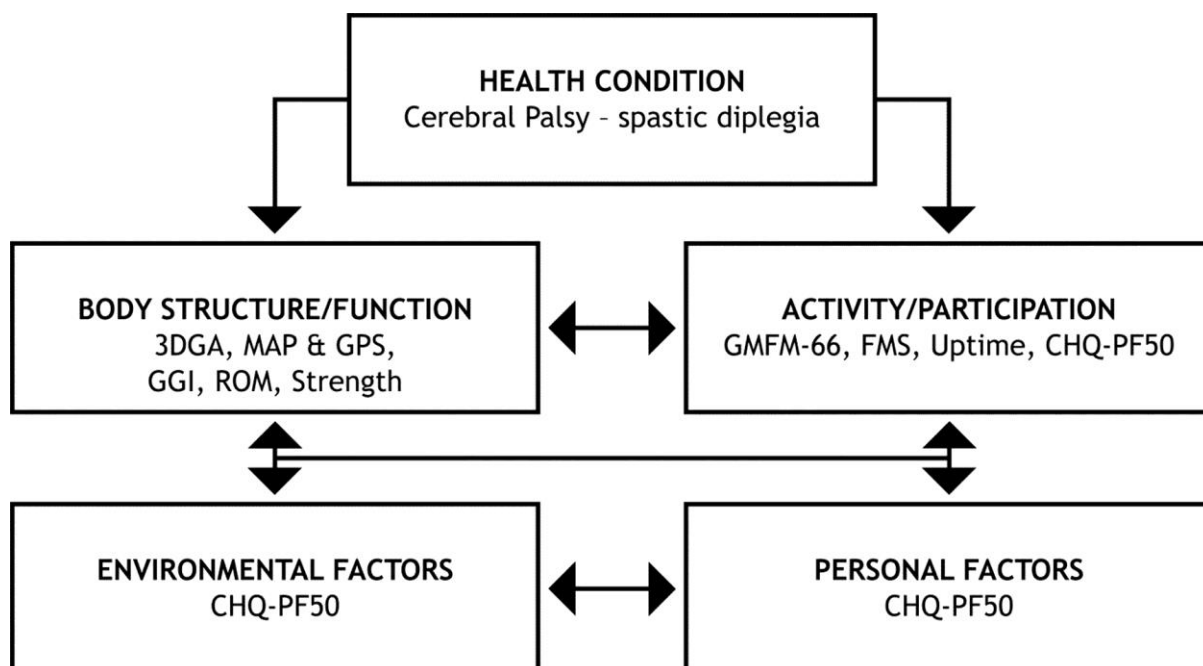
Figure 3-3 Outcome measures used according to the International Classification of Functioning, Disability and Health. Abbreviations: 3DGQ, three-dimensional gait analysis; MAP, Movement Analysis Profile; GPS, Gait Profile Score; GGI, Gillette Gait Index; ROM, range of motion; GMFM-66, Gross Motor Function Measure-66; FMS, Functional Mobility Scale; CHQ-PF50, Child Health Questionnaire-Parent Form 50.

An increase in use of three-dimensional gait analysis as an outcome measure between prior to 2001 and after 2001 was shown in the mapping review, and continued during the period of the updated review. This increase has also led to the development of multivariate outcome measures derived from kinematic data in an effort to simplify interpretation of the study data. The Gait Deviation Index, Gillette Gait Index and Gait Profile Score are the most commonly reported of these outcome measures. In the final study of this research programme, the Gait Deviation Index was used as a measure to look at short-term outcomes of lower limb orthopaedic surgery and the feasibility of activity and participation measures.

The additional data in the updated mapping review presented in Section 3.3 is consistent with the findings of the original published mapping review, i.e., the majority of the papers are retrospective in design and use outcome measures from the body structure and function domain.

In summary, this chapter provides evidence for research groups and publishers concerning deficiencies in current practice and underscores the need for prospective research on lower limb orthopaedic surgery in children with CP using a range of measures across the ICF. Whilst some groups have proposed a suite of measures, these need to be trialled in children undergoing lower

limb orthopaedic surgery to ensure that they are responsive to change and do not add undue burden for study participants.

Chapter 4 How does the Functional Mobility Scale relate to capacity-based measures?

4.1 Preface

The results of the mapping review of the current orthopaedic literature highlighted the fact that measures of activity and participation are used infrequently. We also found that the Functional Mobility Scale (FMS), published in 2004,[159] was one of the most commonly used measures of activity and participation.[277] The FMS rates the usual walking ability of the child according to the need for assistive devices over three different distances: 5 m (mobility in the home), 50 m (at school), and 500 m (at the shopping mall). There are six ordinal levels, from 6 (independent on all surfaces) to 1 (uses wheelchair), as shown in Figure 1-7. The target age group for this measure is 6 years to skeletal maturity. The group that designed the FMS excluded younger age groups because they felt that changes in functional mobility in these children were more likely to be due to developmental changes.[159]

The FMS has good concurrent and content validity when tested against the Pediatric Outcome Data Collection Instrument, Child Health Questionnaire, and Uptimer.[159,161] It has also been demonstrated to be sensitive to change following surgery.[72,159,162]

The relationship of the FMS to measures of capacity or to how a child walks in an optimised clinical environment is not known. The following section contains a reformatted version of an article entitled "How does the Functional Mobility Scale relate to capacity-based measures of walking ability in children and youth with cerebral palsy" published in *Physical & Occupational Therapy in Pediatrics*, Volume 34, Issue 2, pages 185–196, May 2014. This journal covers research in the field of developmental and physical rehabilitation of infants, children, and youth. This paper provides novel work looking at how the FMS relates to the six-minute walking test (6MWT) and walking speed (WS). Permission has been obtained from the journal to include this work in this thesis.

4.2 How does the Functional Mobility Scale relate to capacity-based measures of walking ability in children and youth with cerebral palsy?

ORIGINAL RESEARCH

How Does the Functional Mobility Scale Relate to Capacity-Based Measures of Walking Ability in Children and Youth with Cerebral Palsy?

Nichola C Wilson,[1,2] Anna H Mackey,[2] and N Susan Stott[1,2]

[1]Department of Surgery, Faculty of Medical and Health Sciences, The University of Auckland; [2]Paediatric Orthopaedic Department, Starship Children's Hospital, Auckland City Hospital

Funding

4.2.1 Abstract

This study examined the relationship between walking performance rated on the Functional Mobility Scale (FMS) and measures of walking capacity in children with cerebral palsy (CP). A total of 143 participants with spastic CP (Gross Motor Function Classification System levels I–III) were rated on the FMS and underwent assessment of self-selected WS, fast one-minute walk test, and six-minute walk test (6MWT). For each FMS distance, children rated 6 had significantly better 6MWT than children rated 5; children rated FMS 2, 3, or 4 had lower walking capacity scores but were not clearly distinguishable from each other. The 6MWT was an independent predictor of

variation in FMS score, accounting for 20%–27% of the variance across the three FMS distances. While walking capacity impacts on the mobility of children with CP in the community setting, much of the variance remains unexplained, suggesting that other factors also play an important role.

4.2.2   Introduction

The Functional Mobility Scale (FMS) is a six-level scale that describes the level of assistance required by children with cerebral palsy (CP) when walking in the community setting.[159] The rater is asked to score the usual walking ability of the child according to the need for assistive devices over three different distances chosen to represent mobility inside the home (5 m), at school (50 m), and at the shopping mall (500 m).[159] The developers of the FMS have established their own interrater reliability (mean intraclass correlation coefficients 0.94–0.95)[160] and demonstrated good concurrent and construct validity in children and youth with CP.[159-161,163] Studies using the FMS as an outcome measure in children aged 4–18 years have shown that FMS scores are sensitive to change following multilevel surgery.[159-161,163]

The FMS captures walking performance in a child's usual environment, i.e., what a child "does do". Other commonly used measures of walking ability in the older child with CP are capacity-based and capture what the child "can do" in an optimised clinical environment. Examples of capacity-based tests include gait laboratory walking speed (WS), with its component parameters of stride length and cadence, and timed walk tests, such as the six-minute walk test (6MWT) and one-minute walk test (1MWT).[166,167,175,176] Timed walk tests are performed over different periods of time, and are increasingly being used to assess function in adults and children with CP. The 6MWT assesses submaximal endurance over a six-minute time period and has been shown by two groups to be a reliable measure in children with CP.[175,176] Given that some children with CP struggle to complete a 6MWT, a rapid 1MWT has been introduced. This is proposed to better assess "dynamic balance, muscle performance, and endurance than that recorded at a self-selected speed"[166] and has also been shown to be a reliable measure in children with CP.[166,167] Both the 1MWT and 6MWT are now being used as proxy measures of walking performance in clinical intervention trials involving children with CP.[172]

As in other clinical areas, the relationship between these proxy measures (1MWT and 6MWT) of walking performance and true walking performance in the community is not yet known.[128] This makes it difficult to inform children and their families of the likely outcome of a proposed intervention in terms of the effects on day-to-day mobility, rather than how we expect the mobility of the child to change in a clinical or gait laboratory setting. It is the former outcome, i.e., "mobility

in the community", that is reported to be of more importance to families and children because it impacts on the child's participation and integration in the community and thus their quality of life.[221]

To determine accurately the effect of various lower limb interventions on children with CP, it is important to quantify mobility in terms of both capacity and performance and to understand better the relationship between the two types of measures. Thus, the goal of this study was to examine the strength of the relationship between FMS scores and capacity-based measures of walking ability (self-selected WS, 1MWT, and 6MWT) in children and youth with CP and Gross Motor Function Classification System (GMFCS) level I–III.

4.2.3 Methods

Participants

This study was a retrospective analysis of prospectively collected clinical data, using a convenience sample of children referred to our institution for three-dimensional gait analysis (3DGA). Review of the data for the purposes of this study was approved by the Auckland District Health Board Institutional Review Board. The inclusion criteria for the study were: age 5–20 years; a diagnosis of spastic CP; GMFCS level I–III; and having undergone 3DGA as part of clinical care between November 2007 and December 2011. The exclusion criterion was absence of one or more of the datasets for self-selected WS, 1MWT, and 6MWT. In total, 143 of 303 datasets fitted the inclusion and exclusion criteria.

Procedure

All children undergoing 3DGA at our institution have parent-reported FMS scores recorded for three distances: 5 m (at home), 50 m (at school), and 500 m (at the shopping mall). On the day prior to gait analysis, all children perform both a 1MWT and a 6MWT. These tests are administered by a therapy assistant trained in use of the standardised protocols for these tests. The 1MWT is performed from a standing start, and the child is instructed to complete as many laps of a 25 m circuit as possible by walking as fast as they are able without running. The 6MWT is administered according to American Thoracic Society guidelines, except that the course is a 25 m circuit rather than a 30 m corridor course.[174] The 3DGA is performed using a nine-camera (120 Hz) Qualisys ProReflex 240 system (Qualisys Medical AB, Gothenburg, Sweden), with data captured during the middle 4 m of a level 8 m walkway; self-selected WS is calculated from these data.

Data and statistical analysis

Data analyses were undertaken using JMP 8.0 (SAS Inc., Cary, NC, USA), StatsDirect 2.7.8 (StatsDirect Ltd, Cheshire, UK), and GraphPad InStat 3.0 (GraphPad Software Inc, San Diego, CA, USA) software. Kruskal-Wallis tests were used to investigate differences between FMS scores in WS, 1MWT, and 6MWT for FMS 5, FMS 50, and FMS 500. Post hoc analyses were performed using Dunn's multiple comparison test and the discussion focused on comparisons between adjacent FMS scores.

A multivariate ordinal logistic regression model using JMP 8.0 software was used to investigate the association of FMS 5, FMS 50, and FMS 500 scores with capacity measures. Only variables with $P<0.05$ in the univariate analysis were included in the multivariate model. The results from logistic models are described by r^2.

4.2.4   Results

Table 4-1 shows the demographics of the included patients and categorises their functional abilities. There were 80 males and 63 females, with an average age of 10.6±3.2 years. The majority of children and youth functioned at GMFCS level II (n=75). The wide range of distances achieved on the 1MWT (median distance 80 m, range 14.9–143.0 m) and on the 6MWT (median 450 m, range 75.0–698.0 m) reflected the wide range of walking abilities within the group. Table 4-2 further itemises the median scores and ranges for 1MWT, 6MWT, and barefoot WS, and reports these.

Table 4-1 Median scores and ranges for one-minute and six-minute walk tests and walking speed

		All data n=143	GMFCS I n=44	GMFCS II n=75	GMFCS III n=24
Type of CP	Unilateral	44	29	15	0
	Bilateral	99	15	60	24
Gender	Male: Female	80:63	25:19	38:37	17:7
Age (years)		10.0 (5–20)	10.0 (5–17)	11.0 (6–20)	9.5 (5–18)
1MWT (m)	Median	80.0	95.0	80.0	57.7
	Range	(14.9–143)	(30–143)	(26.5–114.5)	(14.9–77.3)
6MWT (m)	Median	450	505.4	434.9	300
	Range	(75–698.0)	(274–698)	(275–638.5)	(75–445)
Walking speed (m/sec)	Median	1.03	1.13	1.01	0.61
	Range	(0.2–1.43)	(0.77–1.41)	(0.4–1.43)	(0.2–1.22)

Abbreviations: 1MWT, one-minute walk test; 6MWT, six-minute walk test; WS, walking speed; CP, cerebral palsy; GMFCS, Gross Motor Function Classification System.

Table 4-2 Functional Mobility Scale scores versus walking capacity measures

	Datasets (n)	GMFCS levels I	II	III	1MWT (m) Median (range)	6MWT (m) Median (range)	WS (m/sec) Median (range)
FMS 5 scores							
6	n=92	40	52		90 (30–143)	482.2 (287–698)	1.09 (0.66–1.43)
5	n=34	4	22	8	68[a] (26.5–112.7)	380.2[a] (200–543.4)	0.99[b] (0.42–1.37)
4	n=6		1	5	51.2[d] (25–73)	301.1[d] (179–406)	0.54[d] (0.26–1.02)
3	n=3			3	64 (62.7–75)	300 (300–361)	0.71 (0.68–0.76)
2	n=6			6	35.0[c] (14.9–60.2)	163.3[c] (75.0–445)	0.58[c] (0.41–0.76)
1	n=0						
C	n=2			2	36.6 (29.3, 43.8)	191.75 (148, 235.5)	0.42 (0.2, 0.63)

	Datasets (n)	GMFCS levels			1MWT (m)	6MWT (m)	WS (m/sec)
		I	II	III	Median (range)	Median (range)	Median (range)
FMS 50 scores							
6	n=65	36	29		90.3 (30–143)	489 (287–698)	1.1 (0.66–1.41)
5	n=49	8	40	1	80.7 (26.5–120.8)	434.9[b] (274-559.8)	1.02 (0.46–1.43)
4	n=8		5	3	68[f] (29.3–90.4)	373.4[f] (148–543.4)	0.65[g] (0.2–1.1)
3	n=4		1	3	57.8 (25–64)	312.5 (179.0–335)	0.77 (0.26–1.02)
2	n=16			16	57.8[c, e] (14.9–77.3)	297.3[b, e] (75–445)	0.63[c, e] (0.41–1.22)
1	n=1			1	43.8	235.5	0.63
FMS 500 scores							
6	n=41	28	13		97.0 (30–143)	516.0 (337–675)	1.13 (0.85–1.4)
5	n=54	16	38		89.3 (50–120.8)	450[b] (274–698)	1.03 (0.64–1.38)
4	n=12		12		78.4 (44-96.9)	452.3 (327–559.8)	1.08 (0.72–1.43)
3	n=3		1	3	64 (60–76.8)	335[j] (300–387.9)	0.98 (0.68–1.02)
2	n=4		1	3	53.3[e] (39.1–64.3)	301.1 (280–324.2)	0.58[k] (0.44–0.79)
1	n=29		10	19	60.2[h, i] (14.9–88.5)	300.0[h, i] (75–475)	0.65[h, i] (0.2–1.22)

Notes: [a]level 5 significantly less than level 6, $P<0.001$; [b]level 5 significantly less than level 6, $P<0.01$; [c]level 2 significantly less than level 6, $P<0.001$; [d]level 4 significantly less than level 6, $P<0.001$; [e]level 2 significantly less than level 5, $P<0.01$; [f]level 4 is significantly less than level 6, $P<0.05$; [g]level 4 significantly less than level 6, $P<0.01$; [h]level 1 significantly less than level 5, $P<0.001$; [i]level 1 significantly less than level 6, $P<0.001$; [j]level 3 significantly less than level 6, $P<0.05$; [k]level 2 significantly less than level 6, $P<0.01$.

Abbreviations: FMS, Functional Mobility Scale; GMFCS, Gross Motor Function Classification System; 1MWT, one-minute walk test; 6MWT, six-minute walk test; WS, walking speed; C, crawl.

FMS 5 scores

Over short distances, most participants were independent on all surfaces (n=92), reflecting the relatively few children functioning at GMFCS level III in the study sample. There were significant differences between reported FMS levels for WS ($P<0.0001$), 1MWT ($P<0.0001$), and 6MWT ($P<0.0001$). Post hoc analyses showed significant differences between levels 6 and 5 for WS (1.09 m/sec versus 0.99 m/sec, $P<0.01$), 1MWT (90 m versus 68 m, $P<0.001$), and 6MWT (482.2 m

versus 380.2 m, *P*<0.001). No significant differences were found between adjacent FMS scores for other comparisons.

FMS 50 scores

Over intermediate distances (50 m), the majority of participants were reported to be independent on all surfaces (n=65) or independent on even surfaces (n=49). There were significant differences between reported FMS scores for WS (*P*<0.0001), 1MWT (*P*<0.0001), and 6MWT (*P*<0.0001). Post hoc analyses showed significant differences between levels 6 and 5 for 6MWT (489.0 m versus 434.9 m, *P*<0.01) but not for WS or 1MWT. No significant differences were found between adjacent FMS scores for other comparisons.

FMS 500 scores

Over longer distances (500 m), most participants were either independent on all surfaces (n=41), independent on even surfaces (n=54), or used a wheelchair (n=30). There were significant differences between reported FMS scores for WS (*P*<0.0001), 1MWT (*P*<0.0001), and 6MWT (*P*<0.0001). Post hoc analyses showed significant differences between levels 6 and 5 for 6MWT but not for WS or 1MWT. No significant differences were found between adjacent FMS scores for other comparisons.

Patients with bilateral CP tended to have lower walking capacity measures than patients with unilateral CP (group medians: 1MWT, 75 m versus 93 m; 6MWT 404 m versus 502 m; and WS 1.0 m/sec versus 1.1 m/sec; all *P*<0.001, nonparametric analysis of variance). Age and gender were not significantly correlated with any of the capacity measures.

A stepwise selection of independent variables in a multivariate logistic procedure demonstrated that 6MWT, barefoot WS, and CP topography had an independent predictive effect (Table 4-3). The 6MWT is a major independent predictor in the model for each FMS distance, with WS a minor contributor to the predictive value. Topography of CP contributed to the predictive value at FMS 50 and FMS 500 but not at FMS 5. Age and gender were variables with *P*<0.05 in the univariate analyses and were not included in the modelling. The 1MWT was excluded due to its high correlation with the 6MWT.

Table 4-3 Multiple ordinal logistic regression analysis

	FMS 5			FMS 50			FMS 500		
	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3	Step 1	Step 2	Step 3
R^2	0.27	0.32	Not additional	0.20	0.22	0.24	0.22	0.26	0.28
6MWT	$P<0.001$	$P<0.001$		$P<0.0001$	$P<0.0001$	$P<0.001$	$P<0.0001$	$P<0.0001$	$P<0.0001$
WS		$P<0.001$			$P=0.01$	$P=0.0064$		$P<0.0001$	$P=0.008$
Unilateral versus bilateral						$P=0.04$			$P<0.001$

Notes: Step 1, 6MWT; Step 2, 6MWT and WS; Step 3, 6MWT, WS and unilateral versus bilateral. **Abbreviations:** FMS, Functional Mobility Scale; 1MWT, one-minute walk test; 6MWT, six-minute walk test; WS, walking speed.

4.2.5 Discussion

The FMS was developed to reflect the child's and/or parental view of their walking performance in the community and to capture different methods of mobility over different distances. This study found that the 6MWT was the major predictor of FMS scores across the three FMS distances, predicting between 20% and 27% of the variance, with WS contributing a further 5% to the variance at FMS 5 m. Subgroup analyses showed that measures of walking capacity (6MWT) clearly discriminated between parent-reported FMS scores of 5 versus 6 for independently ambulatory children at all three FMS distances. Children rated as 1, 2, 3, or 4 at different FMS distances, (i.e., those using an aid to mobility or a wheelchair) had generally lower walking capacity measures when compared with independently ambulatory children, but there was no clear linear relationship between walking capacity measures and FMS scores for the latter group of children.

In typically developing children, gross motor capacity (e.g., ability to sit, stand, run, and jump) has increased by the age of 5–6 years to the point where walking performance in the community becomes dissociated from gross motor capacity and is more influenced by environmental factors and personal choice.[278] For example, a child of 7 years may travel the distance from home to school by walking, riding a bike, or catching a bus, with their choice of mobility being influenced by their peers, their parents, and external factors such as availability of a bus. In contrast, our study shows that for older children with CP, their mobility choices/walking performance in the community setting continues to be influenced by their walking "capacity" or endurance, as reflected by their 6MWT walk distances. This finding is consistent with previous studies using two parent-report questionnaires, i.e., the ten-item, Rasch-analysed ABILOCO and the Gillette Functional Assessment Questionnaire (FAQ) walking scale, both of which rate community ambulation in children.[172,279] Scores on the ABILOCO have a moderate to strong correlation with distances walked on both the 1MWT and the 6MWT, with the strongest relationship found for children who are GMFCS level II, in whom parent-reported ABILOCO scores predict 33% of variance in the 1MWT.[172]

It is perhaps not unexpected that walking capacity would continue to influence the walking performance of children with CP in the community setting, given their known significant gait impairments, which include varying combinations of muscle weakness, altered tone, and reduced motor control. Nevertheless, in this study, up to 80% of the variance in walking

performance remained unexplained by walking capacity, suggesting that there must be significant environmental and personal factors that influence the walking performance of children with CP.

Oeffinger et al reported that parents perceive weakness and lack of balance as the key factors affecting their child's walking ability, and raised concern about safety and pain as limiting factors.[267] While intrinsic factors such as muscle weakness might be expected to directly influence both walking capacity and walking performance, other factors such as perception of lack of safety may not impact on walking capacity in the "safe" clinical environment but are likely to negatively influence a child's walking performance in the non-optimised and "less safe" community environment. Therapists should have strategies to proactively and openly address these hidden concerns with children and families, as addressing these concerns represents a practical way to enhance walking performance in the community without requiring an improvement in walking capacity.

For older children with CP, their personal views also influence walking performance and need to be taken into account by the treating clinician. Work by Palisano et al looking at mobility in adolescents with CP found that, while some youth expressed the desire to walk better and more often, most selected methods of mobility that they perceived as most effective for particular situations rather than being preoccupied with the need to walk.[280] Thus, although being capable of walking in the community environment, youth chose methods of mobility that were faster and more efficient.

Smits et al have argued that capacity, capability, and performance should be seen as three separate constructs within the activity domain of the International Classification of Functioning, Disability and Health, reflecting innate ability to perform a task in an optimised environment (capacity), what activities individuals are capable of doing in the non-optimised environment that is everyday life (capability), and what they actually do (performance).[278] Few scales address more than one concept, but the Activities Scale for Kids (ASK) has shown that children with musculoskeletal disorders rate their own capability and performance differently, with an 18% greater score on judged capability to perform standard motor tasks such as dressing themselves.[281] Similarly, children with hemiplegic CP have a median ASK performance (ASK-p) score of 86.7, which is significantly lower than their median ASK capability (ASK-c) score of 93.4.[282]

Thus, if clinicians or researchers wish to assess the walking ability of a child with CP in a comprehensive manner, they need to use a suite of outcome measurement tools targeted at these separate constructs within the activity domain of the International Classification of Functioning, Disability and Health rather than use a single measure. As an example, these tools could include measures of capacity such as self-selected WS or the 6MWT, a measure of capability such as the ASK-c, and a measure of performance such as the ASK-p, complemented by the FMS or Gillette FAQ walking scale. The results of these tests would then pave the way for clinicians to explore more carefully the factors influencing decisions around walking in the community to identify potentially modifiable factors.

The FMS has been used as an outcome measure following single-event multilevel surgery to document change in functional mobility following surgery. After such surgery, the level of assistance required for mobilisation often increases, with a return to baseline by 12 months and reported functional gains by 24 months, along with an increase in FMS scores.[81,251] This is in contrast with the GMFCS, which remains stable in the majority of children following single-event multilevel surgery,[69,251] suggesting that it should not be used as an outcome measure[283]. How FMS scores relate to capacity-based walk tests provides further insight into how postoperative changes in these scores might be interpreted. For example, a group change from a preoperative score at FMS 50 of 5 (independent over level surfaces) to a score of 2 (uses a walking frame) at three months postoperatively could be viewed as reflecting a significant decrease in walking capacity, given that, at FMS 50, the median 6MWT for score 5 is 434.9 m compared with 297.3 m for score 2. This change would be clinically important, given that 40 m has been shown to be a true change in 6MWT in this patient group.[175]

Conversely, a group change from 1 (using a wheelchair) to 2 (using a walking frame) at FMS 500 m (median 6MWT of 300.0 m versus 301.1 m) at one year seems less likely to reflect a true change in walking capacity, but hypothetically could reflect differences in personal choices or ability to negotiate the community environment, leading to a change in capability and thus performance. This study suggests that, as a clinical tool, the FMS is able to provide valuable information for children and their parents regarding their day-to-day functioning in different environments following surgery. Further work needs to be done to look at how performance, as measured by the FMS, changes after interventions other than surgery.

Scores on the FMS may also be a way for clinicians to further discriminate children within GMFCS levels I or II[284], who make up a significant fraction of the total group of children with CP[285]. From the data in Table 2, it appears that children classified as GMFCS level II who have an FMS 5 score of 6 have significantly better walking capacity (as measured by the 1MWT, 6MWT, and WS) than those children, also GMFCS level II, who have an FMS 5 score of 5. In theory, these two groups of children could respond differently to interventions designed to enhance walking performance and should probably be clearly delineated by FMS scores in any study sample. Similar statements could be made for children who function at GMFCS level I and who appear evenly split between FMS scores of 5 and 6 at FMS 500. Overall, FMS 5 scores may be best for subgrouping children who are GMFCS level II, while FMS 500 scores would be better used to further classify children who function at GMFCS level I.

There are several limitations to this study. First, the participants represented a convenience sample and were not evenly distributed across the FMS levels, which may have reduced our ability to detect differences between walking capacity measures for FMS 2, 3, and 4 scores. This lack of variance and the potential ceiling effect of the FMS may also attenuate the correlation between the FMS and 6MWT. The population-based cross-sectional study by Rodby-Bousquet and Hagglund also found a low number of children at FMS levels 2, 3, and 4, with walking aids used by 4%−8% at the three FMS distances.[286] This suggests that an oversampling technique would be required to obtain even numbers in each FMS category. Second, the FMS scores were reported by parents and not verified by independent observation. However, previous work has demonstrated good construct validity for the FMS, with parent reports comparing well with direct observations by paediatric physiotherapists.[163]

In conclusion, walking capacity is an important contributor to variance in parent-reported FMS scores for children with CP and is not moderated by age, gender, or limb involvement. FMS scores of 5 and 6 could be clearly discriminated by the 6MWT, while lower FMS scores (2 to 4) are less clearly separated by the 6MWT. The small subject numbers in the study limit the conclusions that can be drawn, but suggest that higher FMS scores reflect walking capacity, while lower FMS scores (indicating choice of sticks, walking frame, or wheelchair for a specific distance) could be more reflective of variations in personal choice or environmental factors rather than walking capacity. The variation in FMS scores within a single GMFCS

level provides a potential way to further refine the classification of functional abilities in children with CP.

4.3 Commentary

Following publication of this paper, the FMS has continued to be recommended in review articles[287-289], used to assess the outcomes of lower limb orthopaedic surgery[290-292], and for other interventions in children with CP[293]. It is likely that its ease of use and ability to be scored by a range of clinicians or a parent make it an outcome measure that is valuable in standard care of the patient.

The FMS is used as a measure of performance[288] and is useful when consenting children and their families for surgery because it helps to inform them of a likely change in functional mobility following surgery. The main finding in our study was that the 6MWT predicted only 20%–27% of the variance in walking performance as measured by the FMS, indicating that 80% of walking performance in the community was predicted by factors other than walking capacity. This has implications for interventions aiming to make changes at the body structure and function domain level, as it is likely that environmental and personal factors will strongly influence whether there will be an improvement in activity and participation.

Chapter 5 Variability of total step activity in children with cerebral palsy – influence of definition of a day on participant retention within the study

5.1 Preface

From the findings of the literature review in Chapter 3, it is apparent that the majority of studies reporting outcomes of lower limb orthopaedic surgery look at body structure and function measures such as three-dimensional gait analysis. Therefore, it was necessary to investigate this in children with cerebral palsy (CP) to better understand the relationship between three-dimensional gait analysis and usual level of community ambulation.

To measure activity in the community, we chose the StepWatch™ activity monitor (Figure 1-8). As described in Chapter 1, this monitor is a sealed waterproof, microprocessor-controlled device that uses a combination of acceleration, position, and timing to detect steps. It has been used extensively in a number of populations, including adults with multiple sclerosis, diabetes, leprosy, chronic obstructive pulmonary disease, Parkinson's disease, chronic stroke, or incomplete spinal cord injury, and in both typically developing children and those with CP. The accuracy of the StepWatch activity monitor in children was established by Song et al, who demonstrated its accuracy for walking and running.[200] The StepWatch activity monitor has been used in CP by a number of research groups.[205,208,209]

The most commonly used output measure is that of total step count, with normative values available for both typically developing children[200] and children with CP[201]. However, the StepWatch activity monitor has many other outputs, which can be either continuous or non-continuous. These other variables are of interest because they may be more sensitive measures of capacity.

This chapter includes the first of two manuscripts presented in this thesis looking at the StepWatch activity monitor and its use in children with CP. This manuscript has been published in *BMC Research Notes (2016 Aug 20;9:411).*

5.2 Variability of total step activity in children with cerebral palsy – influence of definition of a day on participant retention within the study

Nichola C Wilson,[1,2] Suzie Mudge,[3] N Susan Stott[1,2]

[1]Department of Surgery, Faculty of Medical and Health Sciences, The University of Auckland ; [2]Paediatric Orthopaedic Department, Starship Children's Hospital, Auckland City Hospital; [3]School of Rehabilitation and Occupation Studies, Auckland University of Technology

5.2.1 Abstract

Background: Activity monitoring is important for establishing accurate daily physical activity levels in children with cerebral palsy (CP). However, few studies have addressed issues around inclusion or exclusion of step count data; in particular, how a valid day should be defined and what impact different durations of monitoring have on retention of participants in a trial. This study assessed how different "valid day" definitions influenced inclusion of participant data in final analyses and subsequent variability of the data.

Findings: Sixty-nine children with CP were fitted with a StepWatch activity monitor and instructed to wear the device for a week. The data analysis used two broad definitions of a day, based on either number of steps during a 24-hour monitoring period or the number of hours of activity recorded during a 24-hour monitoring period. Eight children either did not use the monitor at all or used it for only one day. The remaining 61 children provided two valid days of monitoring, defined as >100 recorded steps per 24-hour period, and 55 (90%) completed two valid days of monitoring with ≥10 hours of recorded activity per 24-hour period. Performance variability in the daily step count was lower across two days of monitoring when a valid day was defined as ≥10 hours of recorded activity per 24-hour period (intraclass correlation coefficient [ICC] 0.765) and higher when the definition was >100 recorded steps per 24-hour period (ICC 0.62). Only 46 participants (75%) completed

five days of monitoring with >100 recorded steps per 24-hour period and only 23 (38%) achieved five days of monitoring with ≥10 hours of recorded activity per 24-hour period. Datasets for participants who functioned at GMFCS level II were differentially excluded when the criteria for inclusion in the final analysis was five valid days of ≥10 hours of recorded activity per 24-hour period, leaving datasets available for only 8 of the 32 study participants.

Conclusion: We conclude that changes in definition of a valid day have a significant impact on both inclusion of participant data in the final analysis and measured variability in the total step count.

5.2.2 Introduction

Cerebral palsy is the most common cause of physical disability in childhood, with a prevalence of 2.11/1000 live births.[219] Children with CP have impaired gross motor function that contributes to reduced activity levels when compared with their typically developing peers.[158,201,294] The functional ability of children with CP can be classified by the Gross Motor Function Classification System (GMFCS), a valid and reliable 5-level system that classifies the gross motor function of these children from I (least involved) to V (most severely involved).[35,38,295] Ambulatory children with CP who function at GMFCS levels I, II or III have levels of walking activity that are 20%–60% that of their typically developing peers, with an average daily step count of 8440 (range 7478–9498) steps.[201]

Physical activity in childhood is increasingly being recognised as important for children with CP to maintain optimum health throughout their lifespan.[150,294,296-298] Therefore, there is increased interest in using activity monitors in these children to understand how different interventions in the lower limb might impact on intensity and amount of walking activity in the community. Accelerometers are the device of choice in the neurology population because they are more reliable for step detection than pedometers and can capture a wider range of information, including duration of activity, step rate, and intensity of activity.[299] The StepWatch activity monitor is one such device, and is a sealed, waterproof, microprocessor-controlled monitor that uses a combination of acceleration, position, and timing to detect steps. The StepWatch activity monitor has been used to quantitate daily activity levels in

children with CP and in adults with neurological disorders, to assess activity-related changes after an intervention,[206] and as an outcome measure in small clinical trials.[300]

The reported accuracy of step detection by the StepWatch activity monitor is 99% when compared with "manual counting" in both non-disabled adults[301] and children with CP.[201] This accuracy includes both indoor and controlled outdoor settings.[301] Further, the StepWatch activity monitor has been shown to be more accurate than other accelerometers for detection of steps in the presence of a slow or shuffling gait or during use of a rollator.[185,302,303] As such, the StepWatch is regarded as one of the most accurate accelerometers in the neurology population and has been used as a criterion standard against which other monitors are compared.[304] However, the majority of studies test the variability in measurement of step activity in a researcher-controlled environment and in comparison with a gold standard. Any variation in step detection can then be attributed to the device, not the participant.

In the free-living natural environment, variability in monitored step activity from day to day is a consequence of not only measurement error in the device but also the variation that occurs as a result of interaction between the individual's choices and behaviour and the environment. In addition, participants may inadvertently confound data collection by removing a monitor during specific activities or putting the monitor on incorrectly for periods of time, potentially changing the sensitivity of step detection. All of these factors combined lead to what has been termed "performance variability" in the free-living environment.[193] Researchers cannot usually influence how and when the monitor is worn in the community, but can influence the final dataset depending on the way they analyse the raw step activity data, which requires decisions about whether to include or exclude certain 24-hour periods of monitoring when there appears to be very low step activity or reduced hours of activity.[305]

Not all studies clearly report their decision-making with regard to the inclusion/exclusion of patient data from the final analysis and others adopt differing approaches to dealing with datasets when the monitor has recorded lengthy time periods of non-activity. For example, early studies using the StepWatch defined data collection to be valid when the monitor had recorded at least eight hours of clearly defined step activity over a 24-hour period[200] or when there was less than 3 hours of "inadequate" monitoring during the daytime hours of 6 am to 10 pm. Inadequate monitoring was defined as wearing the monitor upside down, not wearing the monitor at all, or wearing the monitor incorrectly on the ankle (i.e., not in the correct

plane).[201] Other studies have defined a day of monitoring as 10 hours of continuous recorded step activity during a 24-hour monitoring period;[208,209,306,307] however, one study included data in the analysis if more than 100 steps was recorded during the 24-hour monitoring period.[308]

In children with CP, Ishikawa et al have argued for extended periods of activity monitoring, with variation in length of monitoring based on GMFCS levels. These authors defined an acceptable G coefficient as >0.8 (similar to an ICC of >0.8). Their reported minimum number of days taken to achieve a G coefficient of >0.8 for total daily step count in children aged 6–14 years was six for GMFCS I, five for GMFCS II, and four for GMFCS III.[211] However, such prolonged periods of monitoring have the potential to adversely affect subject compliance in a study, particularly in the disabled population.

We are interested in identifying a form of activity monitoring that can be used to assess primary study endpoints after surgical intervention in children with CP. Therefore, the primary goal of this study was to determine how different definitions of valid data collection over a 24-hour period might contribute to exclusion of participant data and whether any bias would be introduced into the results by changing the definition of a valid day. A secondary goal was to determine the performance variability of measures of total step count over a two-day period of monitoring in the free-living environment, using two common definitions of a valid day from in the literature.

5.2.3   Methods and design

Participants

The data for this study were collected as part of two studies, both approved by the Northern X Regional Ethics Committee and the ADHB Research Office and conducted over a period of 3.5 years. Inclusion criteria were CP in childhood, GMFCS level I–III, age 6–18 years, and attendance at our service for clinically indicated three-dimensional gait analysis (3DGA). Exclusion criteria were significant illness (such as a major cardiac or respiratory disorder), injury or surgery within the previous 6 months that may impact usual activity levels in the community or planned treatment following 3DGA that precluded wearing of the monitor for a week.

The children were recruited when they attended a hospital clinic for their 3DGA assessment. Written consent was obtained from each child's parent or guardian along with assent from the child.

A StepWatch activity monitor (Orthocare Innovations, Mountlake Terrace, WA, USA) was fitted to the less impaired lower limb using the strap according to the manufacturer's instructions. The monitor was then calibrated in clinic to each participant's walking pattern. An accuracy check was performed by asking the child to walk at varying speeds in the clinic and manually correlating the triggered flashes from the internal LED light with the steps taken. Accurate calibration of the monitor was established when correlation with manual counting was greater than 95% for all participants. All participants were given verbal and written instructions to wear the monitor for a continuous 7-day period, removing it only for sleeping, swimming, bathing and showering. Data from the monitors were downloaded after being returned to the principal investigator by mail. Data collection occurred throughout the year of the study, with exclusion of school holidays.

Data analysis

Previous work using the StepWatch activity monitor has found that both typically developing children and children with CP have lower and more varied activity levels on weekend days, possibly as the result of a less structured environment.[200,212] We thus chose to analyse data only for the five week days collected during the seven consecutive days of monitoring. The StepWatch activity monitor captures the step activity of a single leg, so the step counts were doubled to obtain the overall step count.

In the first part of the data analysis, we applied increasingly stringent definitions of a valid day to the patient datasets and determined the number of participant datasets consequently excluded from the final analysis. The criteria used were based on either a required minimum number of recorded steps in a 24-hour monitoring period (starting at >100 steps and then 1,000 steps, increased in increments of 1,000 steps) or a minimum number of hours of recorded activity in a 24-hour monitoring period (increased in intervals of 30 minutes).

In the second part of the data analysis, we assessed the performance variability of measures of total step count in the free-living natural environment. To assess how different definitions of a "valid day" affected performance variability, we used two following definitions commonly found in the literature to determine inclusion or exclusion of data from the analysis: (1) when the monitor had recorded at least 100 steps over a 24-hour period of monitoring; and (2) when the monitor had recorded at least 10 hours of activity during waking hours with less than two hours of no recorded activity (120 minutes of consecutive zero counts) over a 24-hour period of monitoring.

Bland and Altman analyses were used to quantitate the performance variability between day 1 and day 2.[309] Intraclass correlation coefficients were calculated with SPSS Statistics version 21 software (SPSS Inc., Armonk, NY, USA) using the two-way random absolute agreement model to determine the variability in measures of total step count between day 1 and day 2, using the two above definitions for a valid day.

5.2.4 Results

Table 5-1 presents the demographic data for all participants (n=69) including gender, GMFCS level, and sidedness of CP. The participant inclusions and exclusions that resulted from variations in (1) the definition of a "valid day" and (2) the number of valid days of consecutive monitoring required for the final data analysis are shown in Figure 5-1. Seven of the initially recruited 69 children had no recorded activity data at all and were excluded from the study. The reasons for the lack of recorded data were: no longer wanting to wear the monitor after enrolment in the study (n=2), the monitor was lost (n=4); and not wanting to repeat the assessment when no recorded activity was found on the returned monitor (presumed to have been worn upside down; n=1). Of the remaining 62 participants with StepWatch data, one participant had only one day of recorded activity. For the remaining 61 participants, all had 2 or more days with >100 recorded steps in a 24-hour period, but only 55 children had 2 or more valid days with ≥10 hours of recorded activity in a 24-hour period.

Table 5-1 Patient demographics

Participants (n)	All participants recruited into study (n = 69)	All participants with recorded activity data (n=62)	Valid day defined as >100 steps recorded activity over a 24-hour period (number of participants with valid days of monitoring)			Valid day defined as ≥10 hours of recorded activity per 24-hour period (number of participants with valid days of monitoring)		
			Two or more valid days (n = 61)	Two to four valid days (n = 15)	Five valid days (n = 46)	Two or more valid days (n = 55)	Two to four valid days (n = 32)	Five valid days (n = 23)
Age, years median (range)	11 (6 – 18)	10 (6 – 16)	10 (6 – 16)	11 (6 – 16)	10 (6 – 16)	11 (6 – 16)	12 (6 – 16)	10 (7 – 13)
Male: Female	33: 36	31: 31	31: 30	7: 8	24: 22	29: 26	17: 5	12 : 11
GMFCS I;II;III	27; 37; 10	19; 35; 8	18; 35; 8	7; 7; 1	11; 28; 7	16; 32; 7	6; 24; 2	10; 8; 5
Bilateral: Unilateral	38: 31	36: 26	36: 25	7: 8	29: 17	32: 23	20: 12	12: 11

Figure 5-2A and 5-2B show the percentage of participant datasets retained in the study analysis as the requirements for data inclusion are changed. If ≥600 minutes of recorded activity per 24-hour period (with no less than 2 consecutive hours of no recorded activity) was defined as a valid day and the required number of valid days is either two or three 24-hour periods, then 55 (90%) and 47 (77%) of the participant datasets were eligible for inclusion in the final analysis (Figure 5-2A). However, if the same criterion for dataset inclusion was applied and the required number of valid days was extended up to five 24-hour periods, then only 23 (38%) of the participant datasets met the criteria for inclusion in the final analysis. If the required length of recorded activity was extended up to ≥720 minutes of recorded activity per 24-hour period (with no less than 2 consecutive hours of no recorded activity), then the numbers of participants who achieved this wear time for two or three 24-hour periods over the week decreased to 37 (61%) and 24 (39%), respectively. Conversely, if the required wear time is reduced to 480 minutes (8 hours) per 24-hour period and the total wear period is either two or three 24-hour periods, then 59 (97%) and 55 (90%) participant datasets would meet the criteria for inclusion.

If the criterion for dataset inclusion in the final analysis was the number of recorded steps per 24-hour period, then only a small number of participant datasets were excluded when the number of steps required per 24-hour period was >100 steps. The number of participants who achieved this wear time for two or three 24-hour periods over the week was 61 (100%) and 59 (97%), respectively. Increasing the required wear time to five 24-hour periods reduced the number of participant datasets meeting the criteria for inclusion in the final analysis to 46 (75%). If the required number of recorded steps was increased to >1,000 steps over a 24-hour period, then the numbers of participants who achieved this wear time for two or three 24-hour periods over the week were not dissimilar at 61 (100 %) and 57 (95%), respectively. However, there was a progressive loss of participant datasets from the analysis as the number of steps per 24-hour period increased above 3,000 steps, (Figure 5-2B).

The demographics of the retained participants, including age and gender distribution and sidedness of CP did not change significantly between two and five valid days of monitoring for either "day" definition, suggesting that changes in duration of monitoring and "valid day" definitions did not differentially affect retention of participant subgroups within the final analysis. However, the more stringent criterion for definition of a day, i.e., ≥10 hours of recorded activity per 24-hour period, led to a significant loss of children who functioned at

GMFCS level II, with a drop from 32 participants to 8 (a 75% decrease) between two and five valid days of monitoring. This was significantly different from the retention rate of participants who functioned at GMFCS level II when the definition of a "valid day" was >100 recorded steps over a 24-hour period, with 28 of 35 participants being retained in the study (a 20% decrease; $p < 0.012$, Fisher's Exact test).

Overall, there was less variability in measurements of total step count between day 1 and day 2 when a valid day was described as ≥ 10 hours of recorded activity per 24-hour period. Using this criterion for a valid day of monitoring, the ICC was 0.765 and the 95% limits of agreement between the measures for two valid days were -6154 steps to 4797 steps, with a bias between day 1 and day 2 of -673 steps. Conversely, measurements of total step count between day 1 and day 2 were more variable when a valid day was defined as >100 steps per 24-hour period; the ICC was 0.62 and the 95% limits of agreement between total step count for day 1 and day 2 were wider at -9055 steps to 5782 steps, with a bias between day 1 and day 2 of 1636 steps. These data are shown graphically in Figure 3-3A and 5-3B. Table 5-2 shows the results of the Spearman-Brown prophecy formula, and the number of days of activity monitoring predicted to achieve ICCs of 0.7, 0.8 and 0.9, respectively.
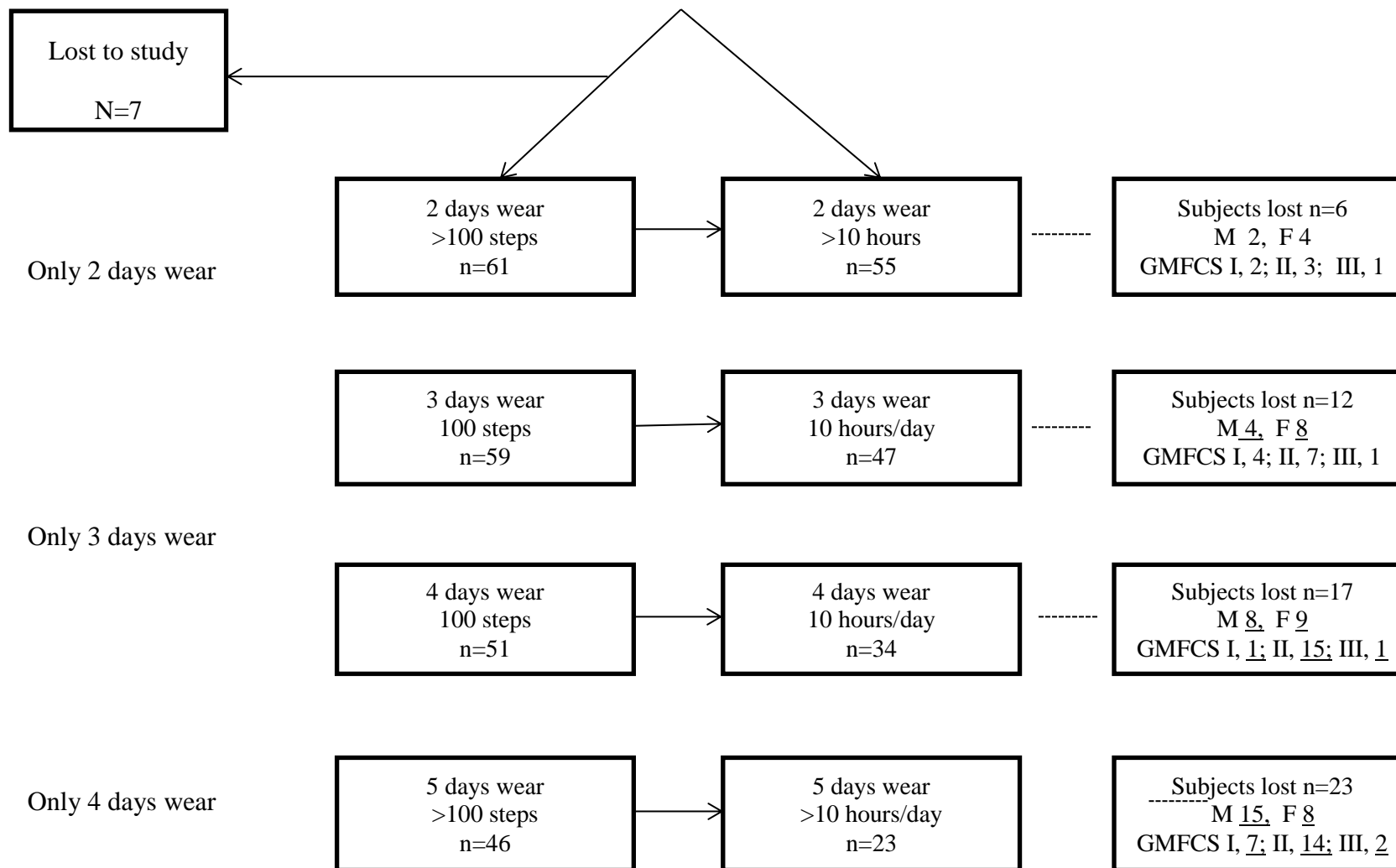
Figure 5-1 Flow diagram for 69 study participants. **Abbreviations:** M, male; F, female; GMFCS, Gross Motor Function Classification System

A
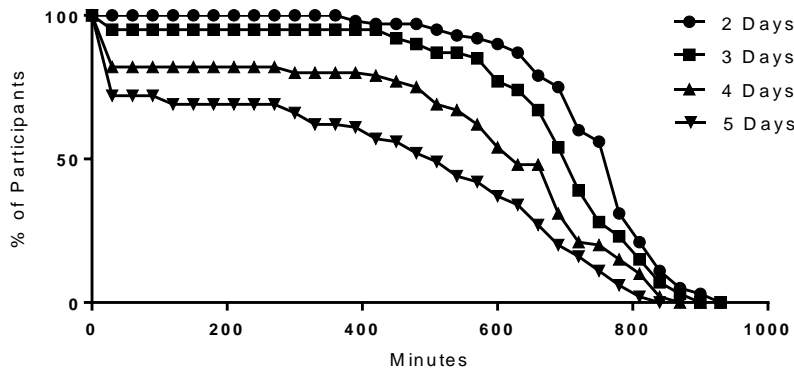
B
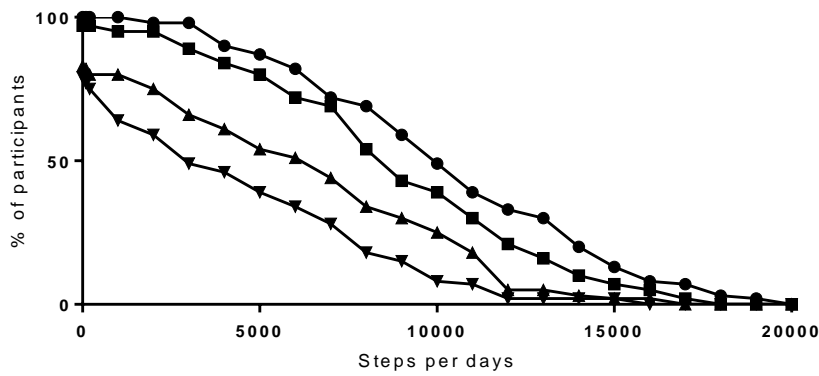
Figure 5-2 Variation in the percentage of participant datasets eligible for inclusion in final analysis. A: By minimum wear time per 24 hour period and the required number of days of monitoring B: By number of recorded steps per 24 hour monitoring period and the required number of days of monitoring;

A
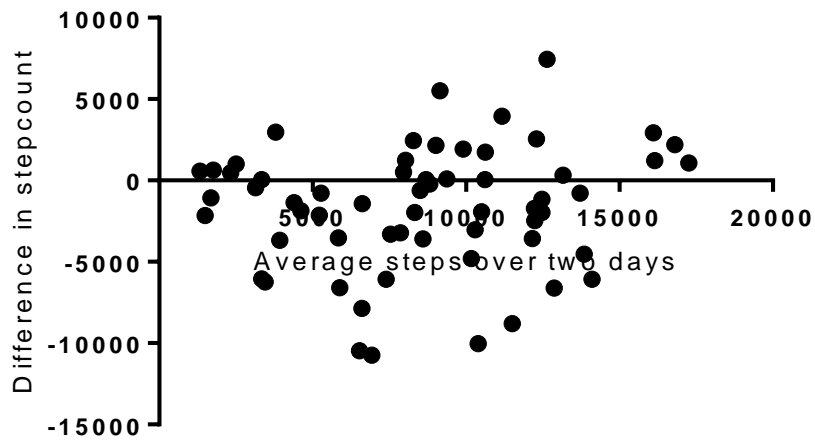
B
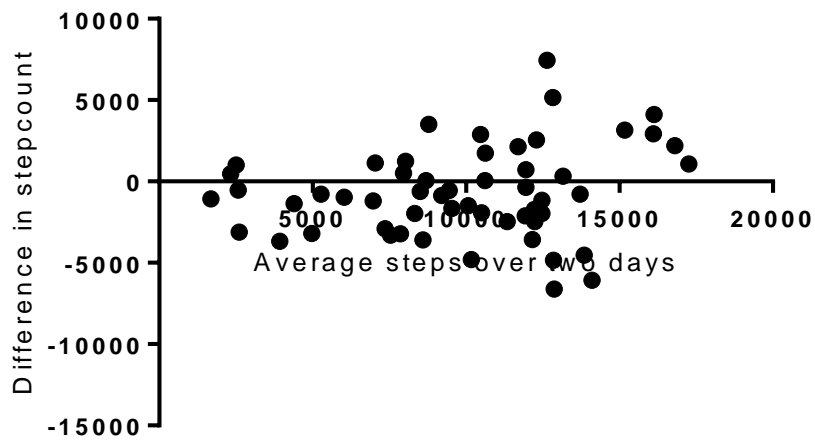
Figure 5-3 Bland Altman Plots A: For two days data with >100 steps per 24 hour period B: For two days data >10 hours per 24-hour period.

Table 5-2 Performance variability of activity monitoring in the free-living environment

	Number of children	Variability of two days of monitoring (ICC)	Predicted number of days of monitoring required to achieve an ICC of:		
			0.7	0.8	0.9
>100 steps per 24-hour period	61	0.620	2.8 days	4.9 days	11 days
≥10 hours per 24 hour period	55	0.765	1.4 days	2.5 days	5.5 days

Abbreviation: ICC, intraclass correlation coefficient

5.2.5 Discussion

The StepWatch activity monitor is widely used for assessment of activity levels in a number of populations, with total step count being the most frequently reported outcome. Monitoring is often for extended periods to capture different types of activity; however, longer periods of monitoring place an increasing burden on study participants. In this study, using a convenience sample of children with CP, we found that many children do not achieve five full days of monitoring, regardless of how a valid day is defined. However, changes in the definition of a valid day made substantive differences to the numbers of participant datasets that were retained or excluded from the final analysis. A low stringency criterion (>100 recorded steps per 24-hour period) led to retention of more participant datasets across all monitoring durations but had lower ICCs and more variability in step count between day 1 and day 2.   When a valid day was defined as ≥10 hours of recorded step activity within a 24-hour monitoring period, two complete days of monitoring led to an ICC of 0.765 and less variability in total step count measures. However, extending the numbers of valid days required to five consecutive days of ≥10 hours of activity monitoring per 24-hour period led to a 50% drop in the numbers of participants with valid datasets, with a disproportionate number of children functioning at GMFCS level II being excluded from the analysis.

Our finding that many participants did not achieve five valid days of monitor-recorded activity is not restricted to children with disabilities. In a large field-based, longitudinal study, Mattocks et al required 7159 children aged 11 years to wear an Actigraph monitor for seven days; however, only 36% wore the monitor for the full seven days and 56% wore it for between three and six valid days.[310] Whether incomplete accelerometer data are included or excluded from the final analysis has some potential to increase selection bias, as it likely reflects differences in how subgroups of participants comply with study requirements. For example, Toftager et al found that as the non-wear time of the monitor became shorter, more overweight and older adolescents were excluded.[311] In our study, children with CP GMFCS level II were significantly more likely to be excluded as the criteria for study inclusion became more stringent. Children with CP GMFCS level II walk without walking aides, although have difficulty with stairs and activities on uneven ground. We are not certain why this group of children were differentially excluded, but it is well known that children with CP can have associated behavioural and cognitive impairments as well as other medical conditions. These would potentially impact on study compliance.[312] Information on other impairments and comorbidities was not available in this study, but these factors influence on participant compliance with a study is worthy of further investigation.

We found in this study that monitoring for two consecutive days at ≥10 hours per 24-hour period produced ICCs of 0.765, with the Spearman-Brown prophecy formula predicting that 2.5 days of monitoring would be required to achieve an ICC of 0.8. A lower stringency criterion for dataset inclusion led to lower ICCs of 0.62. This finding is consistent with work by Rich et al[313] who suggested that data from children with 2 days of accelerometer monitoring lasting >10 hours is sufficient in the typically developing population, achieving a reliability coefficient >0.8 calculated using the Spearman-Brown formula. In their study, shorter periods of daily monitoring (<10 hours) necessitated more days of monitoring to achieve the same ICC. Addition of a weekend day did not alter the ICCs and was deemed not necessary.

Despite the ICC being 0.765 for the more stringent definition of a valid day, Bland Altman analysis identified significant performance variability over two days of monitoring, with 95% of repeated observations of total step counts expected to be within -6154 to 4797 steps of the first measure. The mean daily step count for those 55 participants was only 9870 steps, meaning that a very substantive change in daily total step count would be needed to demonstrate efficacy of an intervention in a randomised trial. In practical terms, positive changes of less than this amount would be blurred by the background variability. Therefore, it is unlikely that total step count would be a useful measure in a small study due to the variability introduced by both personal and environmental factors.

Bland Altman analyses do not determine the cause of variation or determine which outcome measure is more accurate. The variability detected in total step count on a daily basis was likely a consequence of variation in participant activity levels during the school week coupled with missing data due to wearing the monitor incorrectly or removing it and some degree of variation in sensitivity of step detection by the measurement device. A large study of 209 children with CP by Ishikawa et al suggested that between a third and a half of the variance in total step count recorded by the StepWatch activity monitor was related to the functional ability of the wearer and another third to half due to unquantifiable factors.[211] Only a small percentage of the variation was attributable to the day of the week of measurement. This raises the question whether it is better to include all days with recorded activity and accept the wide variation from day or day or include only those datasets with longer periods of activity monitoring. The decision made in this regard would depend on the goal of the study, but needs to be explicit in the study design. Certainly our data suggest that it becomes increasingly difficult to achieve complete datasets for all participants as the stringency of the criterion for dataset inclusion increases.

There were several limitations to this study. First, the number of participants was small, which may limit the generalizability of the results. Second, activity levels could have been underreported for several reasons, e.g, the monitor could not be worn when swimming, which is a frequent leisure activity for adolescents with CP, and underreporting of physical activity such as swimming has been reported.[294] Further, school-aged children in New Zealand often remove footwear in the classroom so it is possible that the monitor was removed at intervals throughout the day, leading to underreporting of physical activity.

Conclusions

In conclusion, how a valid day is defined has a significant impact on the size of the sample and which individual datasets can be retained in the study analysis. Researchers need to balance the variability of the data collected by the StepWatch activity monitor against the potential burden to participants and the need to retain sufficient participants within a research study to achieve an adequate sample size. The variability in total step count from day to day is significant in this group of children, which makes it difficult to use the StepWatch activity monitor as a primary outcome measure in a small intervention trial. Researchers need to consider this variability when designing research studies to ensure they are appropriately powered.

5.3 Commentary

The work described in this paper looked at total daily step count output from the StepWatch activity monitor. Walking is the most common form of exercise for both adults and children.[314-316] The stepping that makes up walking is a movement that everyone understands, so inherently seems a good outcome by which to measure activity levels. Our finding of large variability in total daily step count between days and subjects has also been reported by others.[201] However, this paper highlights the increasing loss of participants as the requirements for the number of hours the monitor needed to be worn increased. This loss of participants was higher in children functioning at GMFCS level II and the reason for this is not known. One suggestion is that children who are GMFCS level II have greater behavioural and cognitive impairments than children who function at GMFCS I, meaning that they required greater parental involvement to be able to complete the study. These additional difficulties also place a higher burden on day-to-day life, making it more challenging to participate in research. Goodgold,[202] when commenting on the work done using the StepWatch activity monitor, raised the concern that parents may forget to remind their child to wear the monitor, and children may refuse to wear it when family life is busy during the school year.

While GMFCS level III children have the highest likelihood of additional behavioural, cognitive, or other medical difficulties, this group in our study made up only a small number of children with CP, and it may be that the parents of these children are already involved in many aspects of caring for their child at home, and at school they may have additional teacher aide or physiotherapy support for assistance with use of the activity monitor. The disproportionate loss of children in GMFCS level II has important implications for study design and reducing bias.

As well as recruitment issues, the method used to analyse the data is a potential source of bias in studies of physical activity. Trying to define a "day" is complex, and risks both loss of participants and inclusion of non-representative days, both of which are sources of bias. In this study, we chose to exclude data for days when the monitor was only worn for part of the day. The alternative is an imputation strategy where methods are used to estimate the data for non-complete days, providing a pseudo-complete dataset in which the individual will either have observed or imputed data for all days that are used in the analysis.[317] However, for imputation to be most effective, the proportion of missing data needs to be small, there needs to be a high correlation between activity levels of the subjects between days, and longer periods of complete monitoring are better. These criteria requirements of low variation in activity levels between days and long periods of complete monitoring were not met in our study.

In clinical research, investigators are often trying to assess what is a true change beyond random error; this is also known as the minimal detectable change (MDC). Using the equation: $MDC = 1.96 \times (SD \times [\text{square root } (1 - ICC)]) \times \text{square root of } 2$, the MDC in this study for children with CP who wore the monitor for more than 10 hours with less than 2 hours of non wear time was 2,692 steps.

Since the design and implementation of this research study, another group has published a number of papers looking at the reliability and validity of an alternative objective measure of physical activity, i.e., the ActiGraph GT3X accelerometer.[183,193,318] This differs from the StepWatch activity monitor in that it is worn on the waist rather than at the ankle, assesses the intensity of activity using "activity counts", and can determine anatomical position (i.e., lying down, sitting, and standing).[319] An advantage of the ActiGraph device is that it can be used in non-ambulatory children with CP (GMFCS levels IV and V), but it does not detect activity on cycling[320]. Also, the ActiGraph GTX3 accelerometer does not have all of the additional outputs present in the StepWatch activity monitor analysis algorithms. These additional output measures of maximum number of steps in one minute (Max 1), Peak Activity Index, and cadence bands are investigated further in Chapter 6.

Chapter 6 Measuring intensity of walking activity in children with cerebral palsy

6.1 Preface

The preceding chapter described the repeatability of total step count using the StepWatch™ activity monitor. The logical next step was to look at the other available outputs from this monitor. These include both continuous and non-continuous outputs as well as intensity of activity.

As discussed in Chapter 1 the StepWatch™ activity monitor has continuous output measures that include strides (doubled to assess total step count) and sustained activity measures (Max 1, Max 5, Max 20, Max 30, and Max 60). Max 1, Max 5, Max 20, Max 30, and Max 60 are derived by scanning the day's total data with a "window" of the designated width (1, 5, 20, 30, or 60 minutes) and identifying the continuous interval of the duration containing the highest number of recorded steps. The number of recorded steps is then divided by the duration of the time interval to give the best performance in steps/minute over that continuous time period in one day. The non-continuous measure is the Peak Activity Index (PAI), which is calculated from the average step rate of the highest 30 minutes of the included time in a day, regardless of when they occurred.

The StepWatch activity monitor can also measure intensity by using cadence bands. Using the proprietary software, low, medium, and high intensity bands can be set by the user. Various definitions have been used by groups using the StepWatch. Eight cadence bands as a measure of activity intensity have been proposed, and have been used in typically developing adults and children.[203,204] These are: no activity (0 steps); incidental movement (1–19 steps/minute); sporadic movement (20–39 steps/minute); purposeful steps (40–59 steps/minute); slow walking (60–79 steps/minute); medium walking (80–99 steps/minute); brisk walking (100–119 steps/minute); and all faster ambulatory activities (≥120 steps/minute). These eight cadence bands provide a meaningful description as to what the steps mean.

We chose to focus on the Max 1, PAI, and the eight intensity bands, given that these had previously been reported on in the literature. Max 1 and PAI have been described as reflecting best ambulatory performance under natural free-living conditions[321], and intensity bands have been used as a surrogate for energy expenditure in adults.[321]

For this programme of research, a study was planned that involved use of an activity monitor as a primary endpoint after surgical intervention in children with CP. Studies using the StepWatch had focussed on the step count. Further work needs to be done using further outputs from the StepWatch activity monitor, including intensity of activity. The remainder of this chapter is from a manuscript reporting the intensity of activity in children with CP that has been prepared for publication.

6.2 Manuscript: Measuring intensity of walking activity in children with cerebral palsy

Nichola C Wilson,[1,2] N Susan Stott[1,2]

[1]Department of Surgery, Faculty of Medical and Health Sciences, The University of Auckland; [2]Paediatric Orthopaedic Department, Starship Children's Hospital, Auckland City Hospital

6.2.1 Abstract

Aim: The purpose of this study was to assess the intensity of walking activity in ambulatory children with cerebral palsy (CP).

Methods: We recruited a convenience sample of 55 children with CP (29 male; median age 11 [range 6–16] years; 32 with bilateral CP; Gross Motor Function Classification System [GMFCS] levels I [n=16], II [n=32], or III [n=7]) who underwent activity monitoring concurrent with three-dimensional gait analysis.

Results: Max 1 (peak cadence over one minute/leg) and Peak Activity Index (PAI; peak cadence over 30 non-consecutive minutes/leg) had acceptable repeatability, with intraclass correlation coefficients of 0.72 and 0.75, respectively, and a strong level of association with the six-minute walking test ($r=0.62$ and $r=0.61$). Average Max 1 measured 64 at GMFCS level I, 59 at GMFCS II, and 45 at GMFCS III ($P<0.0001$). Average PAI measured 52 at GMFCS level I, 45 at GMFCS II, and 32 at GMFCS III ($P=0.0001$). Accumulated minutes per day spent at >59 steps/minute (i.e.,

slow, medium, or brisk walking pace) varied between the GMFCS levels, with 68.7 minutes accumulated at level I, 48.2 minutes at level II, and 18.7 minutes at level III.

Interpretation: StepWatch outputs, i.e., Max 1 and PAI, have acceptable repeatability and clearly differentiate GMFCS levels. Many children with CP spend less than an hour a day at a walking pace at or above slow walking.

6.2.2   Introduction

Physical activity in childhood is important to maintain optimum health throughout the lifespan.[150,294,296-298] Acquired physical disability in childhood can lead to significantly reduced levels of habitual physical activity, with secondary consequences in adulthood, such as osteoporosis and increased fracture risk[322]. Cerebral palsy (CP) is the commonest cause of physical disability in childhood, with a reported rate of 2–3 per 1,000 live births.[58] The functional ability of children with CP is classified by the Gross Motor Function Classification System (GMFCS), a valid and reliable five-level system that classifies gross motor function of children from I (least involvement) to V (most severe involvement).[35,38,295] Between half and two thirds of children with CP function at GMFCS levels I–III, i.e., ambulatory with or without walking aids.[323] However, these children have reduced physical activity when compared with their typically developing peers, with a reduction in daily walking activity of up to 60%.[158,201,294]

Daily activity levels can be measured in a number of ways, with most methods relying either on self-reported activity, e.g., activity diary or questionnaire, or some form of objective monitoring, e.g., pedometer or accelerometer device.[324,325] Activity diaries have been shown to be relatively inaccurate in children, requiring proxy reporting.[153] Pedometers are cheap and easy to use in population-based studies, but can be inaccurate in subjects with neurological gait disorders, due to variations in gait patterns and pelvic motion.[326] In children with CP, the StepWatch activity monitor has been demonstrated to accurately detect single steps[201] when compared with manual counting, and has been used to define normative values for total daily step count relative to the GMFCS.[201] Extended monitoring with the StepWatch shows variation in total step count from day to day in children with CP, with more repeatable activity across school days and lower, more variable activity at the weekend, likely due to both environmental influences and personal choice.[200,212,327]

Although daily total step count is easy to measure, it is not a good measure of the intensity of walking activity undertaken in a day. An alternative method is use of cadence bands to define the intensity of ambulatory activity. Tudor-Locke et al have defined eight incremental cadence bands

to describe free-living ambulatory behaviour and shown that the time an individual spends daily in the different cadence bands predicts 39%–73% of his or her variability in total energy expenditure and 30%–63% of his or her variability in physical activity energy expenditure.[321] These eight bands are: no activity (0 steps); incidental movement (1–19 steps/minute); sporadic movement (20–39 steps/minute); purposeful steps (40–59 steps/minute); slow walking (60–79 steps/minute); medium walking (80–99 steps/minute); brisk walking (100–119 steps/minute); and all faster ambulatory activities ($\geq$120 steps/minute).

In children with CP, mean heart rate reserve (an indicator of the relative stress placed on the cardiovascular system during physical activity) is linearly correlated with stride rate levels, suggesting that cadence bands would be an appropriate measure for estimating the intensity of walking activity in this group of children.[208] The StepWatch activity monitor can be programmed to report broad bands of intensity of walking activity.[200,201] However, the current literature for children with CP does not align with the cadence bands defined by Tudor-Locke et al, and is complicated by different definitions of low, moderate, and high stride rate. Earlier studies have defined "low activity" as $\leq$15 steps/minute, "medium activity" as 16–40 steps/minute, and "high activity" as >40 steps/minute.[200] However, more recent studies have defined "low stride rate" as 1–30 steps/minute, "moderate stride rate" as 30–60 steps/minute, and "high stride rate" as >60 steps/minute.[207,210] Of note, these definitions apply only to one leg, and need to be doubled for comparison with the definitions used in the work by Tudor-Locke et al.[321]

There are also other StepWatch outputs that measure high intensity activity over short periods of time.[328] These outputs include sustained activity measures (Max 1, Max 5, Max 20, Max 30, and Max 60) and the Peak Activity Index (PAI). Max 1, Max 5, Max 20, Max 30, and Max 60 are derived by scanning the day's total data with a "window" of the designated width (1, 5, 20, 30, or 60 minutes) and identifying the continuous interval of the duration containing the highest number of recorded steps. The number of recorded steps is then divided by the duration of the time interval to give the best performance in steps/minute over that continuous time period in one day. In contrast, the PAI is a non-continuous measure calculated from the average step rate of the highest 30 minutes of the included time in a day, regardless of when these minutes occurred.

Of these six outputs, only Max 1 and PAI have been extensively reported on in typically developing children, being categorised as peak cadence indicators or an indication of best ambulatory effort in the free-living environment.[203] The present study was thus performed to obtain further insight into the intensity of activity in children with CP and the usefulness of Max 1 and PAI in this population. We are presently in the process of designing a study to investigate whether these parameters could

serve as primary endpoints after surgical intervention in children with CP. The aims were: to determine the repeatability of Max 1 and PAI in children with CP; to test how well these output measures reflect an established clinic-based assessment of walking capacity, i.e., the six-minute walk test (6MWT); to determine the strength of association with GMFCS level in our cohort; and to provide some pilot data on cadence bands for this group of patients.

6.2.3 Methods

Participants

The data for this study were collected as part of two studies, both approved by the Northern X Regional Ethics Committee and the Auckland District Health Board Research Office. The total daily step count data from these studies have been published previously.[329] Children were recruited when they attended for clinically indicated three-dimensional gait analysis (3DGA). Inclusion criteria were GMFCS level I, II, or III and age 6–18 years. Exclusion criteria were significant illness, injury, or surgery within the last 6 months that could have impacted usual activity levels in the community, inability to complete 3DGA, and treatment planned following 3DGA that would not allow wearing of the monitor for a week. Written consent was obtained from each child's parent or guardian and assent was obtained from the child.

Procedure

On the day prior to gait analysis, all children carried out the 6MWT and a GMFCS level was assigned by an experienced rater. The 6MWT was administered according to American Thoracic Society guidelines except that the course was a 25 m circuit rather than a 30 m corridor course.[174]

A StepWatch activity monitor (Orthocare Innovations, Mountlake Terrace, WA, USA) was fitted to the less impaired lower limb using the strap, according to the manufacturer's instructions. The monitor was then calibrated in clinic to the walking pattern of each subject. An accuracy check was performed by asking the child to walk at varying speeds in the clinic and manually correlating the triggered flashes from the internal LED light to the steps taken. The accuracy of calibration of the monitor to manual counting was greater than 95% for all subjects. All participants were given verbal and written instructions to wear the monitor for a continuous seven-day period, removing it only for sleeping, swimming, bathing, and showering. Data from the monitors were downloaded using the docking stations and analysed using proprietary software after being returned to the principal investigator (NCW) by mail. Data collection occurred throughout the year, with the exclusion of school holidays.

Data analysis

Previous work using the StepWatch activity monitor has found that both typically developing children and children with CP have lower and more varied activity levels on weekend days, possibly because of a less structured environment.[200,212] For the purposes of this study, we used the first two valid days of activity monitoring of the five week days collected during seven consecutive days of StepWatch monitoring. A valid day was defined as a day in which the monitor had been worn for at least 10 consecutive hours with less than two hours of no recorded activity. Max 1 and PAI were calculated for each day of monitoring using algorithms built into the proprietary StepWatch software. These datum points were then averaged for each participant to produce a mean Max 1 and a mean PAI for two days of consecutive monitoring. Box and whisker plots were used to show the distribution for these measures at each GMFCS level.

The within-subject standard deviation (s_w) and repeatability between the first and second days of valid data were calculated as described by Bland and Altman (1996) to define the measurement error for the group.[309] Repeatability is defined as the difference between two duplicate measurements for the same subject, and is expected to be less than $2.77 \times s_w$ for 95% of pairs of observations. Intraclass correlation coefficients (ICCs) were also calculated using the two-way random, absolute agreement model. These analyses were performed using IBM SPSS Statistics version 21 (SPSS Inc., Armonk, NY, USA).

Cadence bands were extracted from the data and organised into incremental bands of 20 steps/minute (1–19, 20–39, 40–59, 60–79, 80–99, 100–119, and ≥120 steps/day). These increments were based on doubling of the data collected for one leg and represented the average of two days of data for each participant. The amount of time spent in each band and the steps accumulated within each cadence band per day were also computed.

Statistical analysis

A generalised linear mixed model with repeated measures (distribution, normal; link function, identity), adjusted by age and gender was performed using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA) to explore the relationship between GMFCS level, mean Max 1, and PAI.

6.2.4   Results

Table 6-1 presents the demographic data for all subjects recruited into the study (n=69), including gender, GMFCS level, and sidedness of CP. Seven of the initial 69 children had no StepWatch data recorded on their activity monitors and were lost to the study.   Of the remaining 62 participants, seven were excluded from analysis because their monitors did not have at least two week days with

monitoring of at least 10 consecutive hours and less than two hours of no recorded activity. This left 55 subjects with two days of satisfactory data collection. The mean activity monitor wear time by these 55 subjects ranged from 639 minutes to 883 minutes (i.e., 10 hours and 39 minutes to 14 hours and 43 minutes per day, respectively). There was no significant difference in mean wear time according to days, gender, or GMFCS level.

Table 6-1 Demographic data for study participants

	All participants (n=69)	**2 days >10 hours (n=55)**
Age, years	11 (6–18)	11 (6–16)
Male: Female	33: 36	29: 26
GMFCS level	I, n=27; II, n= 37; III, n=10	I, n=16; II, n=32; III, n=7
Bilateral: Unilateral	38: 31	32: 23
Monitor wear time (minutes/day)	N/A	745 (639–883)

Abbreviations: GMFCS, Gross Motor Function Classification System; N/A, not available

Figure 6.1 shows box and whisker plots for average Max 1 and PAI values by GMFCS level over two days of monitoring. The median average Max 1 across the two days of monitoring was 64 (range 56–74) for children who functioned at GMFCS level I, 59 (range 29–78) for children who functioned at GMFCS level II, and 49 (range 30–62) for children who functioned at GMFCS level III. Overall, 13 of 16 children (81%) who functioned at GMFCS level I had a Max 1 of >60 steps/minute, as did 14 of 32 children (44%) who functioned at GMFCS level II. Only one of seven children who functioned at GMFCS level III achieved this intensity of activity over one minute. The median average PAI across the two days of monitoring was 52 (range 33–61) for children who functioned at GMFCS level I, 47 (range 14–62) for children who functioned at GMFCS level II, and 32 (range 18–54) for children who functioned at GMFCS level III. It should be noted that both Max 1 and PAI are derived from single leg data and needed to be doubled to determine steps taken per minute by both legs.

The generalised linear mixed model with repeated measures, adjusted by age and gender, showed that the effect of GMFCS level was significant for both Max 1 and PAI ($P<0.001$). There was no interaction between GMFCS and day of monitoring ($P=0.45$). Analysis of the Max 1 data showed significant group differences according to GMFCS level ($P<0.0001$). The mean Max 1 was significantly higher for GMFCS level II versus level III (58.9 versus 45.4, respectively, $P=0.0005$,

difference 13.5) and for GMFCS level I versus level III (64.2 versus 45.4, *P*<0.0001, difference 18.8), with a trend towards significance for GMFCS level I versus level II (64.2 versus 58.9, *P*>0.0520, difference 5.3). Analysis of the PAI data also showed significant group differences between GMFCS levels (*P*=0.0001). Mean PAI was significantly higher for GMFCS level I versus level II (51.6 versus 44.9, respectively, *P*=0.03, difference 6.7), GMFCS level II versus level III (44.9 versus 31.1, *P*=0.0013, difference 13.8), and GMFCS level I versus level III (51.6 versus 31.1, *P*<0.0001, difference 20.5).

Repeatability statistics comparing the first day and second day of monitoring showed that Max 1 had a mean value of 58, with an estimated within-subject standard deviation of 6.0 and a repeatability of 16.6. This suggests that 95% of repeat measures of Max 1 would fall within 16.5 steps/minute of the first measure. PAI had a mean value of 45, with an estimated within-subject standard deviation of 6.3 and a repeatability of 17.4, suggesting that 95% of repeat measures would fall within 17.5 steps/minute of the first measure. The ICCs were >0.7 for two days of monitoring for both Max 1 and PAI (0.72 and 0.75, respectively).

Max 1 had a strong level of association with the 6MWT (Spearman's ρ=0.62; 95% confidence interval 0.42–0.77) as did PAI (Spearman's ρ=0.61; 95% confidence interval 0.40–0.76).

The average minutes/day and steps/day accumulated within each cadence band for the overall sample and by GMFCS are presented in Table 6-2 and Figure 6-2. During monitor wear time, children with CP spent on average 292 minutes/day at 1–59 steps/minute; 22.6 minutes/day at 60–79 steps/minute; 14.8 minutes/day at 80–99 steps/minute; 9.8 minutes/day at 100–119 steps/minute; and 3.3 minutes/day at ≥120 steps/minute. Accumulated minutes at >60 steps/day varied between the GMFCS levels; 68.7 minutes were accumulated at GMFCS level I, 48.2 minutes at level II, and only 18.7 minutes at level III (*P*<0.0001). Significant differences were noted between the three GMFCS levels at the following cadence bands: 20–39 steps (*P*=0.0001) and 40–59 steps (*P*=0.0005). For the cadence bands of 60–70 steps (*P*=0.0007) and 80–99 (*P*=0.0009) steps, a difference was found only between GMFCS levels II and III.

On average, 5,408 steps/day were accumulated at 1–59 steps/minute and fewer than 430 steps/day were accumulated at ≥120 steps/minute. There were significant differences between the GMFCS levels, with differences noted for number of steps/day accumulated at cadences of 20–39 steps (*P*<0.0001), 40–59 steps (*P*=0.0003), and 60–70 steps (*P*=0.0006).

(A)
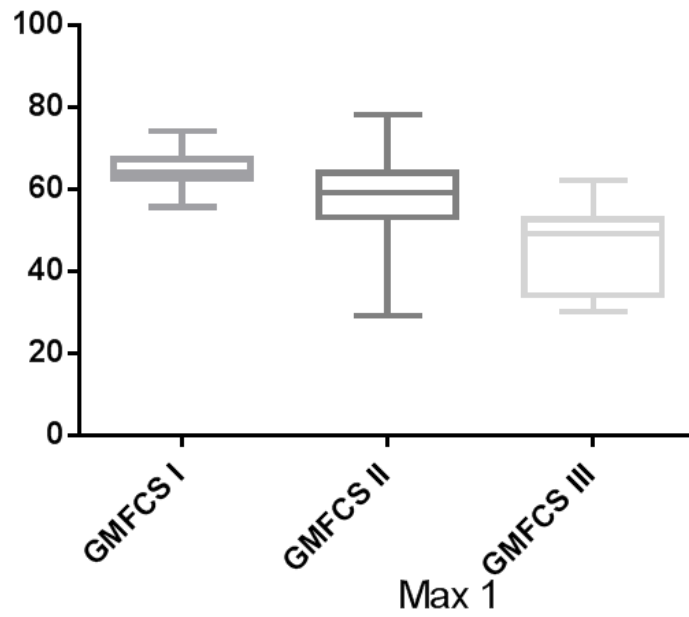
(B)
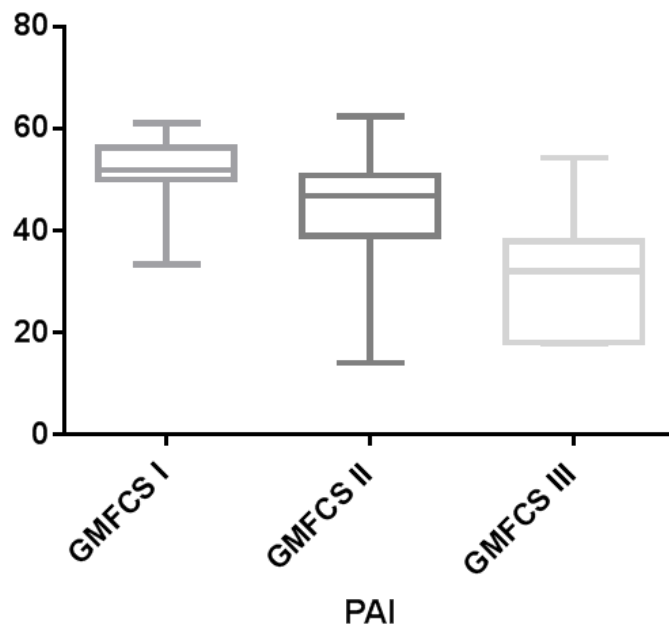
Figure 6-1 Box and whisker plots showing the distribution of Max 1 and PAI values by GMFCS level averaged across two days of monitoring. (**A**) Max 1 and (**B**) PAI. The median value is represented by the solid horizontal line, the 25th to 75th percentile by the box, and the 5th to 95th percentile by the whiskers.
Abbreviations: GMFCS, Gross Motor Function Classification System; PAI, Peak Activity Index

Table 6-2 Time and steps per day accumulated in cadence bands during wear time

	1–19		20–39		40–59		60–79		80–99		100–119		≥120	
Time (minutes/day)														
All	183.4	(41.5)	67.7	(25.2)	38.1	(19.0)	22.6	(12.0)	14.8	(8.7)	9.8	(8.6)	3.3	(5.1)
GMFCS I	180.4	(34.0)	84.5	(17.3)	50.0	(13.9)	29.6	(12.3)	18.8	(7.0)	15.3	(9.6)	5.0	(5.4)
GMFCS II	181.5	(44.2)	65.1	(24.2)	36.5	(18.2)	21.8	(9.9)	14.9	(8.4)	8.4	(6.9)	3.1	(5.2)
GMFCS III	202.6	(44.9)	40.32	(16.8)	18.5	(14.5)	10.1	(9.5)	4.7	(5.5)	3.5	(7.4)	0.4	(1.1)
Steps per day														
All	1,457	(353.4)	2,034	(779.1)	1,917	(951.5)	1,593	(841.3)	1,345	(786.9)	1,090	(969.8)	430.7	(656.1)
GMFCS I	1,567	(272.1)	2,581	(537.0)	2,522	(6892.)	2,091	(844.5)	1,734	(615.2)	1,687	(1078)	647	(681)
GMFCS II	1,423	(390.8)	1,945	(735.5)	1,832	(910.1)	1,537	(702.5)	1,350	(763.8)	947	(790.8)	407.5	(681.5)
GMFCS III	1,360	(316.4)	1,187	(517.8)	934	(730.9)	707	(665.7)	437	(497.4)	380	(824.2)	44	(115.3)

Note: The values shown are the mean and standard deviation for participants with two valid days of StepWatch monitoring. **Abbreviation:** GMFCS, Gross Motor Function Classification System
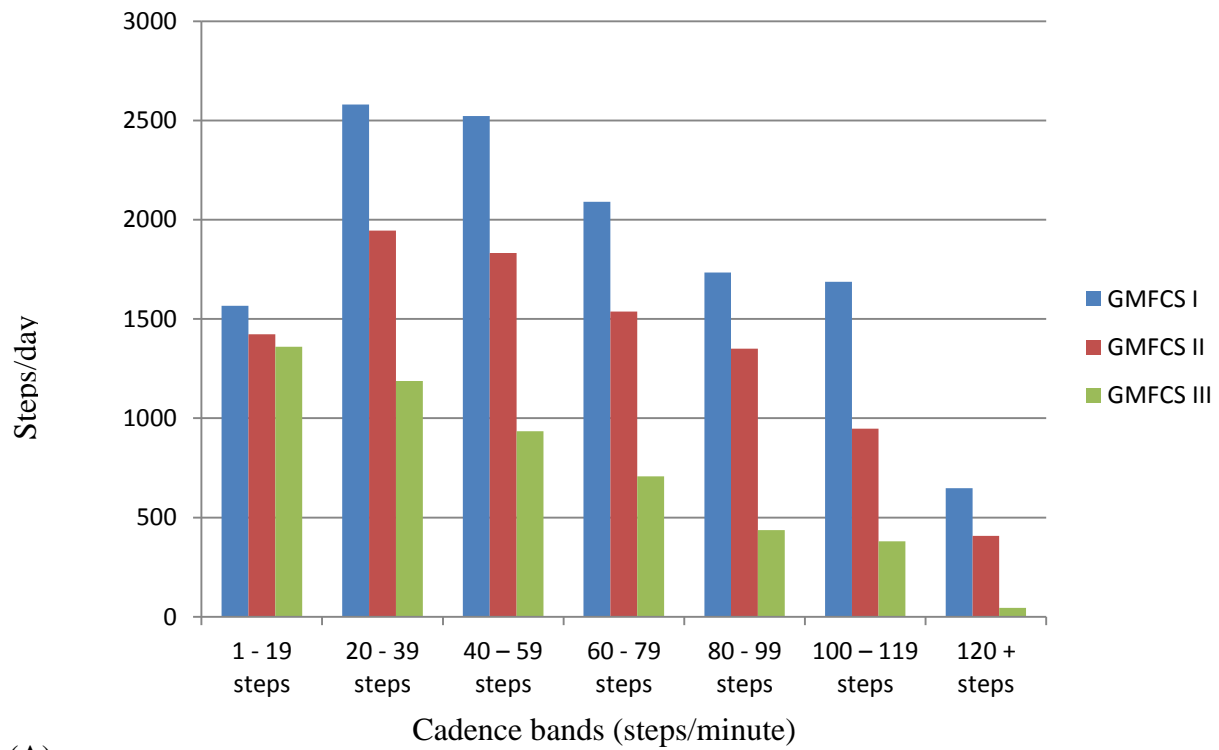
(A)
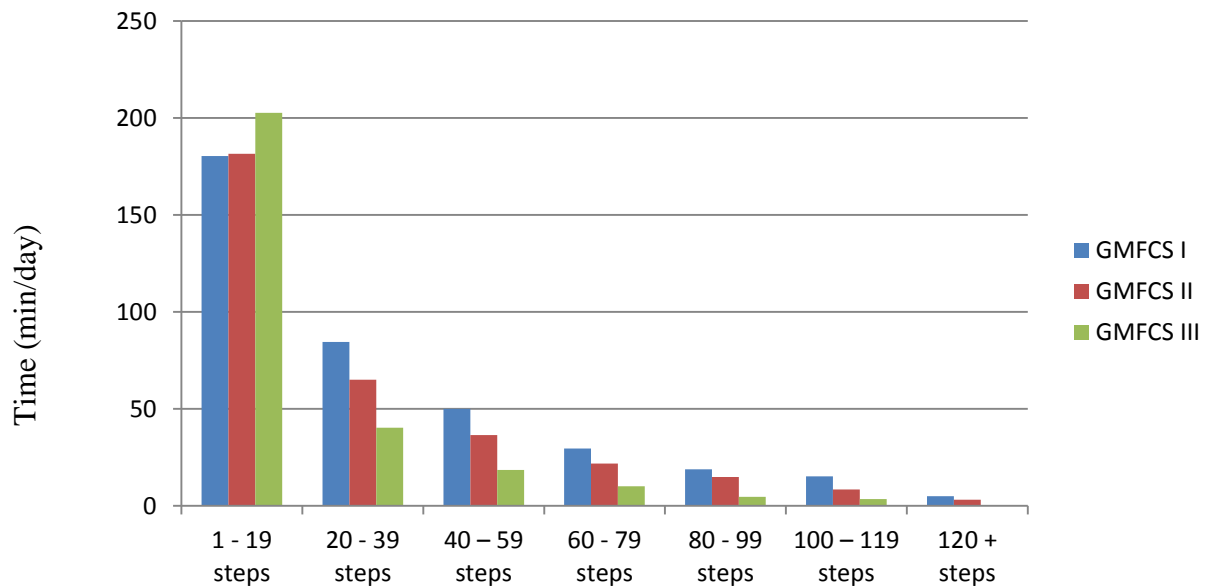
(B)

Figure 6-2 (**A**) Steps per day and (**B**) time (minutes/day) accumulated within each cadence band for each GMFCS level. **Abbreviation:** GMFCS, Gross Motor Function Classification System

6.2.5   Discussion

The purpose of this study was to investigate the intensity of physical activity in children with CP using a validated measurement device, i.e., the StepWatch activity monitor. We found that two measures of high intensity activity, i.e., Max 1 and PAI, are both repeatable and valid, with ICCs >0.7 for two days of monitoring and strong levels of association with the 6MWT, a validated measure of walking capacity. These measures clearly discriminated between GMFCS levels, and showed that children who function at GMFCS level I or II can achieve short bursts of intense activity similar to that reported in typically developing children. However, the initial data on cadence bands for children with CP showed that most daily activity was of low intensity, with only a limited time during the day spent at a cadence at or above slow walking (>59 steps/minute).

Both Max 1 and PAI are measures of peak cadence and thought to reflect best ambulatory performance under natural, free-living conditions.[321]   These measures have been shown to discriminate between children who are normal weight, overweight, and obese, and to decrease with age in typically developing children and adolescents.[203] We found that both measures had acceptable repeatability in children with CP over two days of monitoring, with ICCs >0.7. Both measures had a strong association with the 6MWT, a clinic-based measure of submaximal endurance. This finding is similar to that of previous work in neurologically impaired adults which also concluded that Max 1 and PAI are indicative of maximal physical performance and thus reflect walking capacity in a community setting.[330,331]

 Normative data for both peak one-minute cadence and PAI were reported for 2,610 US children in the 2005–2006 National Health and Nutrition Examination Survey.[306]   The reported peak one-minute cadence values in that study were 124±1 steps/minute for children aged 6–11 years and 116±0.9 steps/minute for children aged 12–15 years, and are very similar to the cadence of 118±11 steps/minute adopted by typically developing children when walking at self-selected speed in a gait laboratory.[332] Over 80% of children with CP GMFCS level I and almost half of children with CP GMFCS level II achieved a peak one-minute cadence value of >120 steps/minute at some point in their day, equivalent to that of their typically developing peers. Similarly, many children who functioned at GMFCS levels I and II were able to achieve a PAI (or peak cadence over 30 minutes) of 45 for one leg, i.e., equivalent to the reported PAI values for both legs of 87±0.8 in typically developing children aged 6–11 years and 86±0.7 in their counterparts aged 12–15 years.[203] Children with CP GMFCS level I or II have been

shown to have an effort of walking similar to that of typically developing children. It is perhaps not surprising then that they can generate peak cadences similar to those of their peers over short time periods.[208]

Overall, children who functioned at GMFCS level II had the most variable Max 1 and PAI. This heterogeneity in children with CP classified as GMFCS level II has been noted before, with overlaps in physical ability for children classified as GMFCS I or II[49,267] and difficulties reported in classifying children between these levels[35,37]. We did not find any impact of gender or age on these results, which is consistent with existing literature on GMFCS showing that functional ability in children with CP is related to GMFCS level but not to age or gender.

Children with CP functioning at GMFCS level III had significantly lower PAI and Max 1. Other researchers have also found that children functioning at GMFCS level III may not be able to generate a walking speed that reaches 120 steps/minute, even for only one minute in a day.[208] This is likely because the effort of walking in children with CP GMFCS level III is greater, with a higher heart rate reserve at each level of stepping, compared with children functioning at levels I and II. This group of children also have greater energy expenditure on sitting and standing, possibly due to greater difficulty in stabilising the trunk and the recruitment of additional muscles. Overall, this suggests that interventions to improve walking patterns in this group of children need to reduce energy expenditure if they are to be successful in increasing walking activity in the community.

Whilst maximal physical performance is important, the amount and intensity of physical activity within a day have been shown to be related to many health outcomes. Moderate and high activity is thought to be important for maintaining or improving cardiovascular fitness,[322] and sedentary behaviour in children has been associated with an unfavourable body composition, decreased fitness levels, and lowered scores for self-esteem and prosocial behaviour[333]. Thus, lower Max 1 and PAI for some children with CP, when compared with typically developing children, may not be important as how much time a child spends in higher intensity activities.

In the USA, typically developing children have been reported to spend 46.2 minutes/day at a rate above purposeful steps, i.e., >59 steps/minute.[203] This study, by Barreira et al, has shown that children who are GMFCS level I or II spend more time/day at a rate above purposeful steps (68.7 minutes/day and 478.2 minutes/day, respectively) than typically developing children in the USA. However, if norms

reported for children in The Netherlands[209] are considered, with 100 minutes/day spent at rates above purposeful steps, then all three groups of children are less active.

Overall, these data suggest that independently ambulatory children with CP do achieve the peaks of high intensity activity seen in typically developing children, but that these bursts of activity may not be sustained for the same length of time as in their peers, depending on the comparison group.[334,335] Of concern, the levels of activity documented in our study are probably not sufficient for a healthy lifestyle. Children and adolescents have been recommended to spend at least 60 minutes/day performing moderate to vigorous intensity physical activity.[336] The cadence value associated with moderate to vigorous intensity physical activity for adults is >100 steps/minute, and may be >120 steps/minute in children.[337] Even if the adult definition is used, children who are GMFCS level I are spending only 13.1 minutes per day at >100 steps/day, and even lower values are seen for children who function at level II.

There are several limitations to this study. Our study population was a convenience sample of children referred for gait analysis, and may not be representative of the general population of children with CP.[323] However, our cohort does reflect the children who would be considered for major orthopaedic surgery to improve their walking ability. Some activity may have been underreported, e.g., swimming or physical activity in a wheelchair. The average amount of time the children spent wearing the monitor in our study was also lower than in other reports, and may be a source of bias. For example, in the study by Barreira et al, the range was 804–843 minutes/day.[203] We also accept that the cadence bands represent an average of activity over a minute. It is unlikely that children spent the minute walking at 20 steps/minute; rather, they are likely to have taken several steps at a higher rate before sitting down for the remainder of the minute. Nevertheless, this work does provide data for this group of children, and can be compared with those of other groups of children.

In conclusion, the results of this study indicate that alternative StepWatch outcome measures, i.e., Max 1 and PAI, are repeatable in this group of children with CP and correlate well with measures of walking capacity, suggesting that they do represent a measure of peak performance in the natural environment. Further, the standard outputs from the StepWatch activity monitor afford the ability to look at the amount of time spent in difference cadence bands and are useful for measuring both time spent in high intensity activity and in more sedentary behaviour. Changes in time spent at high intensity activity or in sedentary behaviour may be useful to assess in future interventional studies.

6.3 Commentary

This manuscript looked at alternative output measures from the StepWatch activity monitor, i.e., Max 1, PAI, and eight cadence bands. This is novel work in children with CP. Both Max 1 and PAI had acceptable ICCs of >0.7 for two days of monitoring and >0.75 with extended days of monitoring. Repeatability analysis using a Bland-Altman plot showed that the percentage repeatability for Max 1 and PAI were both better than for total step count. It was interesting that 56% of children with CP GMFCS level I or II had a Max 1 >120 (81% for GMFCS level I and 44% for GMFCS level II), which is the same Max 1 achieved by typically developing children. The findings of this work indicate that these alternative output measures could be used in conjunction with total daily step count in clinical studies using the StepWatch™.

Our finding that there was considerable overlap of Max 1 and PAI between children classified as GMFCS level 1 or level II has also been reported by a recent study investigating kinematic and spatiotemporal parameters in children with bilateral spastic CP.[338] The authors of that study reported that whilst there was a wide variation in findings within GMFCS levels, there was greater kinematic similarity between GMFCS levels I and II.

The amount of time spent at different cadences/intensities may be another dimension to consider in intervention studies. From the previous work presented in this thesis, a change in total step count would be difficult to achieve in an intervention study.[327] It would of interest to know if a surgical intervention in a child with CP could decrease sedentary behaviour or increase moderate to intense activity, because this would have potential long-term health benefits for the child. Previous work by Van Wely et al[205] showed that a physical activity stimulation program for children with CP did not improve physical activity as measured by the StepWatch activity monitor at 6 or 12 months post intervention. Van Wely et al looked at both total step count and time spent at low (<15 strides/minute), moderate (15–30 strides/minute), and high (<30 strides/minute) intensity levels. In their paper, they suggest several reasons for physical activity levels not changing, including their intervention of 6 months being perhaps too short and that the two groups did not contrast sufficiently to show a difference. They felt that there could be selection bias involving children, families, and therapists who were more interested in physical activity and so were more likely to participate in the study and increase their physical activity.

Chapter 7 Gait Deviation Index correlates with daily step activity in children with cerebral palsy

7.1   Preface

Chapters 4 and 5 looked at outcome variables from the StepWatch™ activity monitor and established the repeatability for total step count, Max 1, and Peak Activity Index. The following manuscript correlates the Gait Deviation Index, a single representative measure derived from three-dimensional gait analysis, with these outcome variables from the StepWatch.

The Gait Deviation Index is a a dimensionless parameter based on 15 separate gait features, which quantitates the extent to which the kinematic profile of a child with CP deviates from an averaged control dataset.[86] Schwartz et al found that typically developing children had a mean GDI of 100 and that there was a normal distribution. For the GDI, a change of 10 represents one standard deviation away from a normal gait and that a lower score represents greater gait pathology.[86]

Chapter 5 also established that using two days of StepWatch activity monitoring reduced selection bias by increasing the number of participants in Gross Motor Function Classification System functional levels I and II. This work influenced the definition of a day and minimum number of days used for this research study.

The work in this chapter is novel in that it further validates the Gait Deviation Index, as it has not previously been correlated with daily step activity in children with cerebral palsy. The following section contains a reformatted reproduction of the article "Gait Deviation Index correlates with daily step activity in children with cerebral palsy" published in *Archives of Physical Medicine and Rehabilitation,* Volume 96, Issue 10, pages 1924-7, October 2015. *Archives of Physical Medicine and Rehabilitation* is the official journal of the American Congress of Rehabilitation Medicine, and covers research in the fields of physical medicine and rehabilitation. Permission has been obtained from the journal to include this work in this thesis.

7.2 Gait Deviation Index correlates with daily step activity in children with cerebral palsy

BRIEF REPORT

Gait Deviation Index Correlates With Daily Step Activity in Children With Cerebral Palsy

Nichola C Wilson,[1,2] Nada Signal,[3] Yanto Naude,[3] Denise Taylor,[3] N Susan Stott[1,2]

[1]Department of Surgery, The University of Auckland; [2]Paediatric Orthopaedic Department, Auckland City Hospital; [3]Health and Rehabilitation Research Institute, Auckland University of Technology

Funding

7.2.1 Abstract

Objectives: The aim of this study was to examine the relationship between Gait Deviation Index (GDI), a multivariate measure of overall gait impairment, and measures of both community walking performance and walking capacity within the clinic setting in ambulatory children with cerebral palsy (CP).

Design: Cross-sectional study.

Setting: Gait analysis, six-minute walk test (6MWT), and self-selected walk speed (WS) were performed in the laboratory and clinic settings. Activity monitoring was conducted in each participant's community environment.

Participants: Children with CP (n=55, aged 6–18 years) with Gross Motor Function Classification System levels I, II, or III.

Interventions: Not applicable

Main outcome measures: GDI, derived from gait analysis data; community walking performance, captured by an activity monitor; and walking capacity, measured in the clinic by 6MWT and WS.

Results: The 55 children had a median GDI of 78.86 (53.07–105.34). A moderate strength of association was found between GDI and daily step count (Spearman's ρ=0.58, 95% confidence interval [CI] 0.37–0.74, P<0.0001). Weaker associations were found between GDI and 6MWT (Spearman's ρ=0.4718, 95% CI 0.2283–0.6597, P<0.0003) and between GDI and WS (Spearman's ρ=0.3949, 95% CI 0.1368–0.6028, P<0.0028).

Conclusion: The GDI has a moderate relationship with daily step count, suggesting that interventions with a positive effect on gait kinematics may also impact on walking performance in the community setting. Whilst the deviation of the GDI from normal provides valuable information, other measures are required to provide a full picture of a child's walking capacity and performance.

7.2.2   Introduction

Three-dimensional gait analysis (3DGA) is an assessment tool that is commonly used in children with cerebral palsy (CP) to aid decision-making prior to lower limb orthopaedic surgery and to assess surgical outcomes.[277] However, the information obtained from 3DGA is complex and requires skill to interpret. Therefore, a number of tools have been developed that derive a single representative score of gait impairment from 3DGA data. One such example is the Gait Deviation Index (GDI).[86] The GDI is a dimensionless parameter based on 15 separate gait features and quantitates the extent to which the kinematic profile of a child with CP deviates from an averaged control dataset.[86] It has concurrent validity with measures of motor performance in children with CP, including the Gillette Functional Assessment Questionnaire[86] and the Gross Motor Function Measure[143]. However, the relationship of the GDI to other measures of walking capacity and performance has not been investigated.

Walking capacity, or what a child can do in a controlled safe environment, is often assessed in the clinic by walking tests, such as the six-minute walk test (6MWT) and self-selected walking speed over

one minute. Both walking speed and the 6MWT are reliable and valid measures of walking capacity in a child with CP.[179,339] Walking performance, or what the child does on a daily basis in the community, can be assessed by monitoring with an accelerometer. One such monitor is the StepWatch activity monitor, a waterproof, microprocessor-linked accelerometer worn at the ankle, which has established criterion validity in this population.[201] Measures captured by the StepWatch activity monitor include total step count per day, percentage of time spent inactive, and percentage of time spent at low, medium, and high levels of activity (<15 steps/minute, 15–42 steps/minute, and >42 steps/minute, respectively).[201]

This study examined the relationship between GDI and measures of both community walking performance (daily step count and level of activity) and walking capacity within the clinic setting (self-selected walking speed and 6MWT) in ambulatory children with CP.

7.2.3 Methods

Participants

The study was approved by the Northern X Regional Ethics Committee and the Auckland District Health Board Research Office. Inclusion criteria were: a diagnosis of CP, age 6–18 years, Gross Motor Function Classification System (GMFCS) functional level I, II, or III,[35] and scheduled for a clinically indicated 3DGA. Children were excluded if they had significant illness, injury, or surgery within the previous 6 months that could have impacted on usual activity levels in the community; were unable to complete 3DGA; or had treatment planned following 3DGA that would not allow wearing of the monitor for a week. Written consent was secured from each child's parent or guardian and assent was obtained from the child.

Procedure

On the day prior to 3DGA, a 6MWT was carried out using a 25 m circuit, asking the child to walk at a self-selected speed and allowing for rest periods over the six minutes, according to standardised guidelines.[174] The 3DGA data were captured using a Qualisys Oqus system (C-Motion, Inc., Germantown, MD, USA) and processed using Qualisys Track Manager and Visual 3D software. Data were captured during the middle 4 m of a level 8 m walkway; a minimum of five representative trials were averaged to derive self-selected walking speed (WS) and three-dimensional kinematics.

The StepWatch activity monitor (Orthocare Innovations, Mountlake Terrace, WA, USA) was fitted on the day of the 3DGA and preprogrammed for each subject by specifying their height and gait characteristics. The accuracy of step detection was tested by manually correlating the triggered flashes from the internal LED light with the steps taken when the subject was asked to walk for a short period at different speeds. Greater than 95% step detection accuracy was achieved for all participants. The subjects were instructed to wear the monitor for all waking hours for the next seven days, except when bathing or swimming, and then to return the monitor by post to the principal investigator (NCW). All data capture was completed during the school term, and school days were used for the analysis.

Data analysis

Each participant's GDI was calculated from a representative gait cycle for both the left and right sides of the body. The mean of the two sides was used for analysis, as advocated by Sangeux et al.[340] The first two complete week days of accelerometer data (i.e., those closest to the date of 3DGA) were used to define the average daily step count and levels of activity, as recommended by Rich et al.[313] A day was defined as at least 10 hours per day of recorded activity with no longer than two hours of zero data capture. The StepWatch activity monitor captures step activity of a single leg, so the step counts were doubled to obtain the overall total step count.

Statistical analysis

The level of association between GDI, average daily step count, 6MWT, WS, and levels of activity were tested using Spearman's rank correlation coefficient (ρ) performed with GraphPad InStat 3.10.6 (GraphPad Software Inc, San Diego, CA, USA). A multiple linear regression model was performed with R 3.0.2 (R Foundation for Statistical Computing, Vienna, Austria), and SAS 9.4 (SAS Institute Inc, Cary, NC, USA) was used to examine the relationship between total step count and GDI. Study participants with GMFCS level III were excluded from the model on the advice of the statistician due to the small group size. The model was adjusted for confounding variables, i.e., age, gender, GMFCS level, and bilaterality of CP.

7.2.4 Results

Sixty-nine participants were recruited into the study. However, seven children did not record any activity data on their monitor and a further seven did not have data sufficient to meet the a priori definition of a day. Fifty-five of the 69 participants were thus included in the final analysis. Children

included in the final analysis were similar to those who were excluded in terms of gender, age, and GMFCS level (Table 7-1). For the 55 participants with two full days of accelerometer data, the median daily step count was 10,468 (range 1,686–17,263). Just over half of the participants (55%) had a step count of more than 10,000 steps/day (Figure 7-1), with 14 of 16 participants functioning at GMFCS level I meeting this target but only 16 of 32 participants functioning at GMFCS level II.

Table 7-1 Participant demographics

	Participants recruited into study **(n=69)**	**Participants with completed data capture** **(n=55)**
Median age in years (range)	11 (6–18)	11 (6–16)
Gender (F:M)	33: 36	26: 29
GMFCS (I, II, III)	22, 37, 10	16, 32, 7
Bilateral CP (n)	38	32
Median GDI (range)	78.86 (51.88–105.34)	78.86 (53.07–105.34)
Median 6MWT (range)	459 m (200–698)	481 m (200–698)
Median WS (m/sec) (range)	1.00 (0.34–1.36)	1.00 (0.34–1.32)

Abbreviations: 6MWT, six-minute walk test; CP, cerebral palsy; GMFCS, Gross Motor Function Classification System; GDI, Gait Deviation Index; WS, walking speed

The mean percentage time spent inactive over 24 hours was 76%±5.9% across the group. For all children, the most common (or modal) level of activity in the 24 hours was low (<15 steps/minute for one leg), with a mean occurrence of 15.51%±3.5%. Percentage time spent in medium activity (defined as 15–42 steps/minute for one leg) averaged 6.5%±2.9% and in high activity (defined as >42 steps/minute for one leg) averaged 1.7%±1.2% for the 24-hour period. There was no correlation between GDI and percentage time spent in low activity (ρ=0.001); a moderate correlation between GDI and percentage time spent in moderate activity (ρ=0.467; 95% confidence interval [CI] 0.223–0.656, P<0.001); and a higher but still moderate correlation between GDI and percentage time spent in high activity (ρ=0.531; 95% CI 0.30–0.70, P<0.0001).

A moderate strength of association was found between GDI and average daily step count (Spearman's ρ=0.5, 95% CI 0.37–0.74), *P*<0.0001). Weaker associations were found between GDI and 6MWT (Spearman's ρ=0.4718, 95% CI 0.2283–0.6597, *P*<0.0003) and between GDI and WS (Spearman's ρ=0.3949, 95% CI 0.1368–0.6028, *P*<0.0028).

The relationship between average daily step count and GDI was examined by a multiple linear regression model, adjusted for potentially confounding variables of age, gender, GMFCS, and bilaterality of CP (Table 7-2). Data from children with CP GMFCS level III were not included in the model because the number of subjects in this group (n=7) was too small. The model shows strong evidence that the average step count increases as the GDI increases. The confounding variables were not statistically significant, although there was a trend for participants with bilateral CP to have a lower GDI (*P*=0.07).
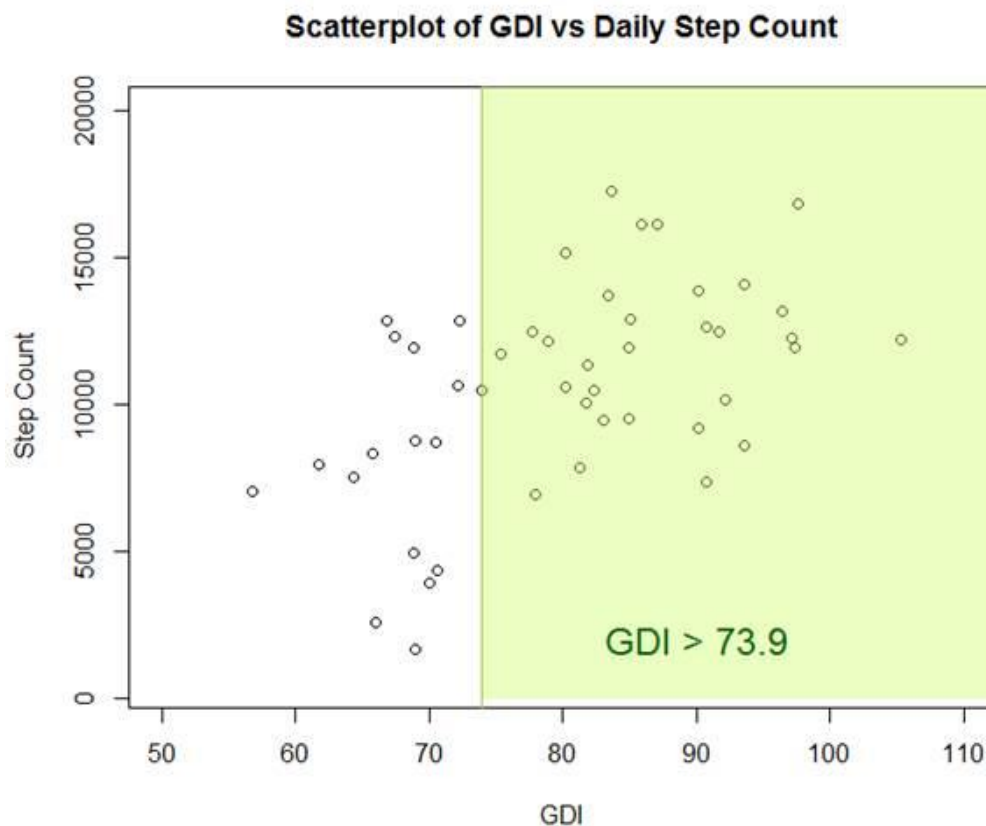
Figure 7-1 Scatter plot of GDI versus average daily step count for all 55 participants. Thirty-three participants had a GDI above the lower limit of normal for GDI (i.e., >73.9). Twenty-five of these 33 participants took >10,000 steps per day. **Abbreviation:** GDI, Gait Deviation Index.

Table 7-2 Multiple linear regression model examining the relationship between average daily step count and Gait Deviation Index

Parameter		Estimate	P-value
GDI		114.617	0.009
GMFCS	I	1,176.760	0.285
GMFCS	II	0.000	.
Gender	F	−682.802	0.419
Gender	M	0.000	.
Age		−180.681	0.269
Bilateral involvement		−1764.381	0.074
Unilateral involvement		0.000	.

Abbreviations: GDI, Gait Deviation Index; GMFCS, Gross Motor Function Classification System

7.2.5 Discussion

This study of ambulatory children with CP explored the relationship between the GDI and measures of both walking performance in the community and clinic-based measures of walking ability. A moderate correlation was found between the GDI, a multivariate measure of gait impairment, and average daily step count, with up to a third of the variation in daily step count related to changes in the GDI (R^2=0.33). GDI did not correlate with time spent in low activity, but did have a moderate strength of association with percentage time spent in high activity. In contrast, weaker associations were found between GDI and clinic-based assessments of walking ability (6MWT, WS), suggesting that, over short distances, altered joint kinematics have a lesser impact on "best" walking capacity.

The moderate relationship between GDI and daily step count has important clinical implications. Lower limb surgery for children with CP often targets improvements in joint kinematics, with the assumption that such improvements will lead to improved walking activity in the community. For example, a recent study of 97 children with CP who underwent surgery to improve gait pattern showed an increase in GDI from 54.5 to 67.8 over an average of 10 years' follow-up.[140] The findings of the current study provide cautious support for the possibility that these postoperative improvements in joint kinematics may be reflected in increased walking activity in school and home environments, and possibly increased time in high step rate activities. However, it will be important to confirm this with

prospectively collected data and determine whether the relationship holds true across the different GMFCS levels.

In typically developing children, GDI has been reported to range from 73.9 to 129.9, with a mean value of 100;[86] however, it is not clear whether GDI is influenced by age or gender. A number of our children with CP had GDI scores that fell within the lower half of the normal range, with the highest score being 105.3. The step counts recorded for these children had a wide range, but many met the value of 10,000 steps per day, which has been identified as a minimum cut point for physical activity when referenced to body mass index.[341] This target was met by the majority of children who functioned at GMFCS level I, but by only half of those functioning at GMFCS level II. This variation may reflect differences in both personal and environmental factors, and these are potential targets for rehabilitation.

The association between GDI and percentage time spent in high activity could indicate that children who are more physically able have the ability to vary their intensity of activity more and also spend more time in a higher band of intensity of activity. Work in typically developing children using the same definition of "low", "medium", and "high" intensity found that these children were active nearly 50% of the time and spent nearly 10% of the time in high physical activity levels.[201] This is much higher than in our group of children with CP, who were active approximately 25% of the time and spent less than 2% of the time in high physical activity levels. This large discrepancy may reflect a difference in the definition of a day used; the work by Bjornson et al defined an incomplete day as greater than three hours of inadequate monitoring during daytime hours (0600–2200)[201], whereas in this study we used the definition of wear time greater than 10 hours with less than two hours of zero data capture.

The weaker association between GDI and WS in the laboratory when compared with GDI and daily step count suggests that altered joint kinematics, as represented by the GDI, have a lesser impact in the ideal and safe walking environment of the laboratory. Ways to adapt the laboratory to better mimic conditions in the community might include altering the floor surface or asking the child to walk up a step or a graduated slope, akin to a ramp in the community.

Study limitations

The sample size for GMFCS level III was small, limiting subgroup analyses that would have been helpful to look further at the influence of GMFCS on the relationship between GDI and measures of

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usual daily walking activity. Another potential limitation was use of the average GDI rather than the individual leg GDI, particularly given that participants with both unilateral and bilateral CP were included. It is known that, in unilateral CP, the other side may show compensatory changes and that in bilateral CP involvement can be asymmetrical.[340] The GDI includes parameters from multiple anatomical levels and from both limbs, and the total step count is influenced by both limbs, so the authors elected to use the average GDI to look at overall gait impairment.

7.2.6 Conclusion

A moderate level of association was found between GDI and concurrent mean daily step count in the school and home environment. This suggests that interventions targeting joint kinematics may influence activity in the community in a positive way. Further work is needed to explore this possibility.

7.3 Commentary

This article presents the relationship between a single representative score derived from 3DGA data, the GDI, and community walking in children with CP. A moderate strength of association was found between GDI and average daily step count. This was higher than the association with a clinic-based measure of capacity, the 6MWT. This suggests that a change in joint kinematics has more impact on activity in the free-living environment outside the clinic or gait laboratory.

Use of these single representative scores seems to be increasing in surgical papers, and may be because clinicians who do not work in a gait laboratory find it easier to interpret one number. Thus, it is important to compare the GDI with other known and frequently used clinical measures.

As discussed in Chapter 6, the definition of cadence bands can vary for the StepWatch activity monitor. This paper uses the definition of intensity bands devised by Bjornson et al,[201] where low activity is <15 steps/minute for one leg, medium activity is 15–42 steps/minute for one leg, and high activity is >42 steps/minute for one leg. A moderate correlation was found between GDI and medium and high activity. When the eight cadence bands, as defined by Tudor-Locke et al and used in Chapter 6, are correlated with GDI, the correlation of slow walking or faster walking (>59 steps) is r=0.5710 (CI 0.3603–0.7263), while GDI versus fast ambulatory activity (>120 steps) was poorly correlated

(r=0.2731, CI 0.0084–0.5021). This low correlation for GDI versus fast ambulatory activity may be because only 3.3 minutes per day on average was spent at this intensity of activity.

Other single representative scores derived from 3DGA data are available, including the Gait Profile Score, which is similar to the GDI, and some authors have suggested it is not necessary to report both.[342] The Gait Profile Score has some advantages over the GDI because the movement analysis profile for different joints can be calculated, giving the clinician more indication of where the joint kinematics have changed.

Chapter 8 Pilot study of the short-term impact of lower limb orthopaedic surgery on children with cerebral palsy across the International Classification of Functioning, Disability and Health

8.1 Preface

This chapter describes the methods and results of a clinical study looking at the short-term outcomes following lower limb orthopaedic surgery in children with cerebral palsy using measures across the International Classification of Functioning, Disability and Health spectrum and assesses the feasibility of using measures of activity and participation. This study is the clinical application of the programme of research presented in this thesis.

The Gait Deviation Index was used as the primary outcome measure of body function and structure. As outlined in Chapters 1 and 7, this is a single representative score of gait pathology from three-dimensional gait analysis.[86] A score of 100 would represent a typical gait pattern, with a change of 10 being one standard deviation away from the normative value.

Multiple measures of activity and participation were used, including measures of direct observation, self-report, parent report, and objective activity monitoring. Direct observation was undertaken with the GMFM-66 D (i.e., standing) and GMFM-66 E (dynamic function, i.e., walking, running, and jumping) and the six-minute walk test. Self-report was with the Activity Scale for Kids and Children's Assessment of Participation and Enjoyment questionnaires. Use of these two questionnaires to assess the short-term outcomes of surgery is novel, as they have not previously been used to look at changes following surgery.[277] Both of these outcome measures have been shown to be valid and reliable.[158] Parent report was with the Functional Mobility Scale, which was investigated in Chapter 4. The StepWatch™ activity monitor was used an objective measure of activity levels over time. Use of the StepWatch in this programme of research has been outlined in Chapters 5, 6, and 7.

The following manuscript prepared for publication presents novel information on the short-term impact of lower limb orthopaedic surgery in children with cerebral palsy and on the feasibility of using outcome measures assessing activity and participation.

8.2 Manuscript: Pilot study of the short-term impact of lower limb orthopaedic surgery on children with cerebral palsy across the International Classification of Functioning, Disability and Health

Nichola C Wilson,[1,2] Anna Mackey,[1,2] Yanto Naude,[3] Jason Donovan,[4] N Susan Stott[1,2]

[1]Department of Surgery, Faculty of Medical and Health Sciences, The University of Auckland; [2]Paediatric Orthopaedic Department, Starship Children's Hospital, Auckland City Hospital; [3]Health and Rehabilitation Research Institute, Auckland University of Technology; [4]Orthopaedic Department, Waikato Hospital

8.2.1 Abstract

This study assessed the early impact of lower limb surgery in cerebral palsy. Thirteen children were recruited. The Gait Deviation Index (GDI) assessed body function and structure. Activity and participation were measured using activity monitoring and questionnaires. Data ascertainment was most complete for the GDI (90%). At six months post-surgery, the GDI had increased. Total daily step count decreased by 42% at three months, and was still lower than baseline at six months. The questionnaires showed a reduction in diversity and intensity of activities, but no change in enjoyment. Data ascertainment was lowest for activity and participation measurements, with surgery leading to an improvement in GDI but restriction in diversity and intensity of activity.

8.2.2 Introduction

Orthopaedic surgery is commonly required for children with cerebral palsy (CP) to address muscle contracture and bony deformity. This surgery is often complex, and requires a prolonged period of rehabilitation to gain maximum benefit from the procedure.

The surgery is frequently guided by three-dimensional gait analysis (3DGA), which has been demonstrated to affect surgical decision-making.[343-348] 3DGA is also one of the most frequently used outcome measures in published papers looking at the outcomes of lower limb orthopaedic surgery[277], and is reliable and repeatable[83]. However, 3DGA is performed in the controlled environment of a laboratory, and it is not certain if the improvements seen in 3DGA outputs following surgery[69,81,137,227,349,350] are reflected in free-living situations.

The introduction of the International Classification of Functioning, Disability and Health (ICF) in 2001 helped shift the thinking about disability and inability to what a person is able to do in the real world.[102] It introduced the concepts of body function and structure, and activity and participation being influenced by environmental and personal factors. Many researchers have embraced this, and recommended a shift to looking more at activity and participation.

The desire to look at outcomes more reflective of community activity and participation has been controversial, with many feeling that these outcomes would more accurately reflect the outcomes of interest to children and their families[90,93,95,226], whilst others support the view that outcomes should focus on what can be changed by surgery alone, i.e., body structure and function.[128]

Much is known about the medium-term outcome of lower limb orthopaedic surgery, particularly in the body structure and function domain[90,128,137], but relatively little is known about the short-term impact of this surgery in children with CP. The short-term impact is important to know to help with planning and guiding families and to focus the rehabilitation input. This pilot study assessed the short-term impact of lower limb orthopaedic surgery across the ICF spectrum and the feasibility of activity and participation measures.

8.2.3 Methods

This study was approved by the Northern B Health and Disability Ethics Committee and the Auckland District Health Board Research Office. Children were recruited when they attended for their 3DGA. Inclusion criteria were a diagnosis of CP, age 6–18 years, and Gross Motor Function Classification System level I, II, or III. Children were excluded if they had significant illness, injury, or surgery within the previous six months that may have impacted on their usual activity levels in the community, or if it was not possible to complete a 3DGA. Written consent was secured from each child's parent or guardian and assent was obtained from the child.

The decision to proceed to surgery from gait analysis was made by the surgeon referring the patient for 3DGA. Surgery was performed by five paediatric orthopaedic surgeons, with no alteration in standard postoperative management or physiotherapy for this study. The definition of single-event multilevel surgery used was that of McGinley et al, i.e., two or more soft tissue or bony surgical procedures at two or more anatomical levels.[70] For this study, children had assessments at baseline and at three and six

months postoperatively. Outcome measures with established psychometric properties were selected to span the ICF.

Outcome measures

Based on the ICF, the outcomes measured were: body function and structure (Gait Deviation Index [GDI]; activity and participation (Gross Motor Function Measure [GMFM], Functional Mobility Scale [FMS], and six-minute walk test [6MWT]; and activity monitoring (Activity Scale for Kids [ASK] and Children's Assessment of Participation and Enjoyment [CAPE]).

Body function and structure measures

All children were assessed by an experienced physiotherapist in clinic prior to surgery. Standardised range of motion measures and assessment of tone were carried out in all children, but are not reported in this study. All patients underwent 3DGA using the Qualisys Oqus system (C-Motion, Inc., Germantown, MD, USA) with processing of data using Qualisys Track Manager and Visual 3D software. The GDI was used as the primary outcome measure for 3DGA, and was calculated from a representative gait cycle for both the left and right sides using kinematics from the pelvic and hip angles in all three planes, knee flexion/extension, ankle dorsiflexion/plantar flexion, and foot progression. The mean of the left and right sides was used for analysis, as advocated by Sangeux et al.[340]

Activity and participation measures

The FMS and GMFM-66 D (standing) and E (dynamic function, i.e., walking, running, and jumping) were administered by the investigators.[81,159-161,165]. A 6MWT was carried out at baseline and six months postoperatively using a 25 m circuit, asking the child to walk at a self-selected speed and allowing for rest periods over the six minutes, according to standardised guidelines.[174] The results for these tests are not presented in this study.

To obtain an objective measure of physical activity, the StepWatch activity monitor (Orthocare Innovations, Mountlake Terrace, WA, USA) was fitted to the less impaired lower limb. The StepWatch was then calibrated in clinic to each subject's walking pattern to achieve accuracy to manual counting of greater than 95%. The accuracy check was performed by asking the child to walk at varying speeds in the clinic and manually correlating the triggered flashes from the internal LED light with the steps

taken. All participants were given verbal and written instructions to wear the monitor for a continuous seven-day period, removing it only for sleeping, swimming, bathing, and showering. Data were collected throughout the year, except for school holidays.

Two self-report tools of activity and participation were used, i.e., ASK[157] and CAPE.[351] The two versions of the ASK were given to the participants to complete. The performance version measures what the child "did do" during the previous week, whereas the capability version measures what the child "could do" during the previous week.

Data analysis

Analysis of the StepWatch data used the first two complete week days of data (i.e., those closest to the date of the 3DGA), as recommended by Rich et al[313]. A complete day was defined as at least 10 hours per day of recorded activity with no longer than two hours of zero data capture. The StepWatch activity monitor outputs total step count, Max 1 (highest number of recorded steps in a one-minute period), and Peak Activity Index (PAI; a non-continuous measure calculated from the average step rate of the highest 30 minutes of the included time in a day]) were used for the analysis. The monitor captures step activity of a single leg, so the step counts were doubled to obtain the overall total step count.

Statistical analysis

The statistical analysis was performed using GraphPad InStat 3.10 6 (GraphPad Software Inc, San Diego, CA, USA). Fisher's Exact test was used for analysis of contingency tables. The paired *t*-test was used for comparisons between time intervals.

8.2.4   Results

Twenty-eight children were recruited for the study, 13 of whom proceeded to surgery. The baseline characteristics of these groups are shown in Table 8-1.

Table 8-1 Baseline characteristics

	Recruited for study (n=28)	Proceeded to surgery (n=13)	Did not have surgery (n=15)	*P*-value
Age (years), (range)	12 (6 –18)	12 (9–14)	10 (6–18)	0.2454
Gender, n male (%)	11 (39)	5 (38)	6 (46)	1.00
GMFCS level, n (%)				
I	5	1	4	
II	19	10	9	
III	4	2	2	
Type of CP, n (%)				1.00
Unilateral involvement	9 (32)	4 (30)	5 (33)	
Bilateral involvement	19 (68)	9 (70)	10 (67)	

Abbreviations: CP, cerebral palsy; GMFCS, Gross Motor Function Classification System

The average times from baseline assessment to day of surgery, from surgery to the three-month assessment, and from surgery to the six-month assessment were 213, 100, and 177 days, respectively. Table 8.2 gives the details for each of the children who underwent surgery, including seven who underwent single-event multilevel surgery. One child withdrew from the study because the family relocated to another city after the surgery. At the three-month assessment, one child did not attend due to illness of a family member, one child was not able to be contacted, and two children declined to complete the questionnaires and activity monitoring. At six months, two children declined to complete the questionnaires and activity monitoring, three initially agreed to complete the questionnaires but then decided not to do so, and six declined StepWatch activity monitoring. At each time point, one child who wore the StepWatch activity monitor did not achieve the a priori definition of two days' monitoring.

Data ascertainment was most complete for 3DGA (90%), with lower compliance for the ASK-c (69%), ASK-p (64%), CAPE (62%), and activity monitoring (51%).

The GDI improved in ten of 12 children from baseline to six months postoperatively. At three months after surgery, the GDI had increased from baseline by 3.4, with a further increase by six months to 75.6 (70.0 versus 75.6, P=0.017; see Table 8-3).

Ten children wore the StepWatch monitor for an average of 721 minutes at baseline, six children wore it for an average of 692 minutes at three months, and four children wore it for an average of 755 minutes at six months. The total step count, Max 1, and PAI for each time point are shown in Table 8-4. For children with two or more time points of activity monitoring, there was a trend of reduction in total daily step count at three months that had not returned to baseline at six months.

The results for the ASK-c and ASK-p questionnaires measuring activity and participation indicated no change between baseline and three and six months postoperatively (ASK-c baseline 69, three months 70, six months 70; ASK-p baseline 65, three months 60, six months 60). The CAPE questionnaire showed a 24% reduction in diversity of activity at three months (baseline 29 versus 22, P=0.048) and still lower than baseline at six months (baseline 29 versus 22, P=0.048). There was a 53% reduction in intensity of activity at three months that remained unchanged at six months (4.9, 2.3, 2.4). There was no change in enjoyment as measured by the CAPE (3.9, 3.9, 3.9).

Table 8-2 Demographics and surgery for each participant

Patient		GMFCS	Gender	Age at baseline (years)	Bilateral/ Unilateral	Surgery - SEMLS
1		I	F	12	Bilateral	Right derotational osteotomy proximal femur + lateral column lengthening plus Cotton osteotomy + talonavicular plication and tibialis posterior advancement + Beaumont's gastrocnemius slide and soleal strike; Botulinum toxin type A to right gastrocnemius and bilateral medal hamstrings; iliac crest bone graft
2		II	F	13	Bilateral	Left proximal femoral varisation and derotational osteotomy left adductor lengthening, left over the brim psoas release, bilateral gastrocnemius slide and soleal strike, right lateral column lengthening plus Cotton osteotomy, right tibialis posterior advancement and spring ligament plication
3		II	F	10	Unilateral	Bilateral femoral derotation osteotomies and left calf lengthening
4		II	M	11	Bilateral	Bilateral femoral derotation osteotomies, bilateral psoas lengthening at the pelvic brim and bilateral Strayer gastrocnemius fascia lengthening with below knee casts
5		II	F	12	Bilateral	Bilateral psoas over the brim release, right external rotation tibial osteotomy, Botulinum toxin type A bilateral psoas, iliacus, hamstring and gastrocnemius
6		III	M	9	Bilateral	Derotational osteotomy left distal tibia and right proximal calf lengthening (gastrocnemius aponeurosis)
7		III	F	11	Bilateral	Open tenotomy left adductor longus; bilateral femoral derotational osteotomies; bilateral lateral column lengthening and Botulinum toxin type A to bilateral medial hamstrings
						Surgery – Non-SEMLS
8		II	M	13	Bilateral	Left Baker's calf lengthening
9		II	M	12	Bilateral	Left Strayer's gastrocnemius lengthening with soleal strike. Botulinum toxin type A injections to bilateral gastrocnemii, tibialis posterior and left rectus femoris
10		II	F	10	Bilateral	Bilateral psoas over the brim release and Botulinum Toxin A to bilateral hip flexors, hamstrings and gastrocnemii
11		II	F	14	Unilateral	Right proximal calf lengthening (gastrocnemius fascia); Botulinum toxin type A right medial hamstrings and calf
12		II	M	13	Unilateral	Right split tibialis anterior tendon transfer, intramuscular lengthening of tibialis posterior and Strayer lengthening of right calf (gastrocnemius fascia)
13		II	M	12	Unilateral	Left Tendo Achilles lengthening; Botulinum toxin type A to left medial hamstrings

Abbreviations: GMFCS, Gross Motor Function Classification System; SEMLS, single-event multilevel surgery

Table 8-3 Change in Gait Deviation Index for each participant

Subject	GDI Baseline	3	6	
1	77.69	85.05	88.30	
2	51.88	64.34	56.08	
3	61.75	71.85	70.69	
4	68.83	72.86	84.09	
5	64.4	62.2	72.2	
6	53.07		72.60	
7	71.62	66.71	65.28	
8	84.95	88.53	89.36	
9	81.92	81.92	75.06	
10	68.96	72.32	72.53	
11	84.22		92.68	
12	65.82	68.61	70.51	
13	75.32			
Mean	70.0	73.4	75.8	P=0.3837
SD	10.8	8.9	10.8	
Minimum	51.8	62.2	56.1	
Maximum	85.0	88.5	92.7	

Abbreviations: GDI, Gait Deviation Index; SD, standard deviation

Table 8-4 Total step count, Max 1, and Peak Activity Index at baseline and at three and six months postoperatively.

	Step count			Max 1			PAI		
Subject	**Baseline**	**3**	**6**	**Baseline**	**3**	**6**	**Baseline**	**3**	**6**
1	12,477			56			48		
3	7,966	2,184	3,434	58	45	55	40	21	36
5	7,542	2,643		59	44		49	22	
6	2,603			30			18		
7	6,673	3,070	1,279	58	36	44	43	25	24
8	9,534	6,277		48	55		42	49	
9	11,336	6,382		63	55		49	37	
10	8,778	9,338	5,842	52	63	61	40	49	51
11			8,350			57			37
12	8,326			56			41		
13	11,336			63			49		
Mean	8,657	4,982*	3,978	54	50	54	42	34	37
SD	2,831	2,813	2,507	10	10	7	9	13	12
Minimum	2,603	2,184	1,279	30	36	44	18	21	24
Maximum	11,336	9,338	8,350	63	63	61	49	49	51

Abbreviations: PAI, Peak Activity index; SD, standard deviation

8.2.5 Discussion

This study addressed the short-term impact of a range of lower limb surgeries in children with CP across the ICF. It also looked at the feasibility of activity and participation measures. We found that there was a discrepancy in the ascertainment of data collected across the ICF, which was much better for body function and structure outcomes than for activity and participation outcomes. An

improvement in the GDI, a measure of body function and structure, was seen at six months. There was an impact on activity and participation, with a trend towards a decrease in diversity and intensity at three and six months postoperatively as measured by the CAPE.

The primary outcome measure assessing the body function and structure domain, the GDI, had the best data ascertainment. Overall, an increase was seen from baseline to six months postoperatively. Ten of 12 children who had baseline and six-month 3DGA data showed improvement in their GDI, with a trend of those having the lowest preoperative scores showing the greatest increase. The finding of those subjects with the most deranged gait having the largest improvement is supported by several other studies. Cimolin et al[352] used the GDI to assess gastrocnemius fascia lengthening and found a strong correlation between the preoperative GDI and percentage improvement. The work by Rutz et al[353] used an alternative multivariate measure, i.e., the Gait Profile Score (GPS), and found that children with the most abnormal gait patterns preoperatively who underwent single-event multilevel surgery had the most chance of improvement in GPS. In their study, one quarter of 110 children with spastic diplegia showed changes in GPS that were less than the minimally clinically important difference, and the majority of these children had the least impaired gait patterns.

There is no reported value for the minimally clinically important difference for the GDI, but this index has been used by a number of groups to evaluate the results of lower limb orthopaedic surgery[79,227,350,352,354]. A range of group mean changes for preoperative and postoperative GDIs has been reported; for example, a change in GDI of 6 for children having a range of soft tissue and bony surgeries[227] and a change in GDI of 12.5 for gastrocnemius fascia lengthening in children with CP[352].

The StepWatch data showed a change in most children, but did not reach the threshold for those changes to be clinically significant, and this may be due to natural variability. Only child 3 in our study had a change in the number of steps in a three-month interval that was greater than the repeatability of 5,573 steps reported by Wilson et al[327]. The repeatability figure of 5,573 represents the value 95% of repeated observations with the StepWatch activity monitor would be expected to be within the first observation. Wilson et al[327] consider it unlikely that total step count would be useful in a clinical study due to its variability, and our findings would support this.

Child 3, who had a meaningful change in daily step count, had undergone proximal femoral osteotomies, and it is perhaps not unexpected that her walking would be significantly reduced at three months postoperatively. By six months, this child's daily step count had not returned to

baseline. Another child who had bilateral femoral osteotomies completed three time points of accelerometer data but did not reach the 5,573 threshold; however, this child did decrease the number of steps taken by half between baseline and three months postoperatively. This child did reach the repeatability threshold for both Max 1 and PAI as established by Wilson et al.[355] However, the mean Max 1 and PAI for the group remained relatively unchanged during the period of the study. This indicates that for some children there is a difference in activity monitoring that reflects a real change in both total activity and best ambulatory performance in the community.

The ASK-c and ASK-p did not show a change over the six-month period of this study. This may be due to the small patient numbers, the heterogeneity of both the patients and the surgical procedures performed, or because these measures are not responsive to change following surgery. The CAPE demonstrated a reduction in diversity and intensity at three and six months postoperatively. This is useful information to be able to share with families with regard to the impact of lower limb surgery on their child's activity and participation.

In this study, we noted poor compliance with the study questionnaires and activity monitoring, which are not components of standard care at our institution. Many parents declined the additional questionnaires because they did not want to have to supervise their completion in time already allocated to completing homework, physiotherapy exercises, and other afterschool activities. We considered requiring completion of the questionnaires at the time of the clinic appointment, but the additional time required was considered too onerous when the children were already undertaking a two-hour assessment. This would be something to consider changing in future studies. Several barriers to activity monitoring were identified, including some children not liking others seeing the monitor over the summer months when wearing shorts, parents of children with behavioural problems having difficulty getting their children to comply, and return of the monitors requiring repeated reminders by the investigators. For ethical reasons, payment or gifts could not be given as an inducement to complete the study. The move to being able to monitor activity with smartphones may improve compliance with activity monitoring, given that increasing numbers of children and adolescents own these devices.[356]

One way to improve the collection of outcome measures across the ICF is for such collection to become part of standard care. This would fit with the shift in some health care systems where they are looking at requiring outcomes to be collected as part of standard care,[357] with these data being made available to the public. As clinicians, we have a role in ensuring that these outcomes are diverse and measure outcomes of interest. However, introduction of more outcomes tools can meet

with resistance for a variety of reasons,[94] including limited resources with regard to time, personnel, costs associated with purchasing and licensing, and inefficient methods for data management, leading to poor accessibility with little or no use of the data collected.[94]

The results of this study are limited by its small sample size and poor data ascertainment for activity and participation measures. There was also a delay between the baseline gait analysis and surgery, which reflects the clinical reality of limited operating room time and long waiting lists. However, this study does give an outline of the difficulties of interpreting outcome results in a diverse group of children. It is challenging in the CP population to make results of studies generalisable due to the heterogeneous nature of the condition. Few centres have sufficient numbers of children to recruit into surgical studies, and collaboration between centres would assist with increasing patient numbers.

8.2.6 Conclusion

This study found that the majority of children having lower limb orthopaedic surgery showed an improvement in their GDI by six months. Ascertainment of data for the activity and participation domains was lower than that for body function and structure. The surgery had an impact on activity and participation, with a trend of reduction of diversity and intensity of activity following surgery.

8.3 Commentary

This paper looks at the impact of lower limb orthopaedic surgery in children with CP. Although we found an improvement in the GDI, a measure of body function and structure, a trend of reduction in total number of steps and diversity and intensity of activity was found. This is important information to be able to share with children, their families, and therapists, as although it is likely that improvements in walking would be seen over this short time period, it is unlikely that an increase would be seen in the amount of activity that the child does in the community.

Six months is a short time period following lower limb orthopaedic surgery, particularly in children who have had single-event multilevel surgery, with studies showing that improvements are seen out to two years following surgery. It may be that the reduction in total number of steps and diversity and intensity of activity would be reversed and perhaps increased if studied further out from the time of surgery.

The participants in this study included all ambulatory children with CP and did not exclude on the basis of motor type. Interestingly, the child whose GDI decreased significantly between three months and six months postoperatively and whose ASK scores were decreased at six months from preoperatively had spastic/dystonic CP with marked dystonia. There is increasing discussion among surgeons about the influence of dystonia on surgical outcomes and the more unpredictable nature of outcomes due to this movement pattern. Currently, the Hypertonia Assessment Tool is the method most commonly used to assess for dystonia, but only confirms its presence or absence, and cannot grade severity.

Heterogeneity of function is a common feature in studies of children with CP. Three of our 13 children who underwent surgery had had magnetic resonance imaging of the brain at some point in their care. This highlights the fact that despite magnetic resonance imaging being recommended for children with CP[19], this is not standard practice in New Zealand. It may be that grouping children

by type of brain injury may give a better understanding of surgical outcome and help target intervention.

This research was also a pilot study investigating the feasibility of using measures of activity and participation. Table 8-5 shows the data ascertainment for each measure, with those asterisked being standard of care at our centre. The outcome measures that were standard care had much higher data ascertainment than those that were additional for this study, with activity monitoring being the lowest.

Table 8-5 Data ascertainment for each outcome measure

	GDI	FMS	6MWT	GMFM	ASK-c	ASK-p	CAPE	SW
Baseline (n=28)	28* (100%)	28* (100%)	27* (96%)	28 (100%)	24 (86%)	24 (86%)	22 (78%)	12 (43%)
Baseline surgery group (n=13)	13* (100%)	13* (100%)	12* (92%)	13 (100%)	11 (85%)	11 (85%)	10 (77%)	10 (77%)
3 months post surgery (n=13)	10 (76%)	6 (46%)	N/A	9 (69%)	8 (62%)	7 (54%)	6 (46%)	7 (54%)
6 months post surgery (n=13)	12* (92%)	12* (92%)	11* (92%)	12 (92%)	8 (62%)	8 (62%)	8 (62%)	5 (38%)

Note: *indicates standard care. **Abbreviations:** 6MWT, six-minute walk test; ASK-c, Activities Scale for Kids (capability); ASK-p, Activities Scale for Kids (performance); CAPE, Children's Assessment of Participation and Enjoyment; FMS, Functional Mobility Index; GDI, Gait Deviation Index; GMFM, Gross Motor Function Measure; SW, StepWatch activity monitor

As seen in this study, the total daily step count as measured by the StepWatch activity monitor was shown not to change in two physical therapy intervention studies (Learn 2 Move[205] and the intense physical therapy intervention reported by Christy et al[206]). The study by Christy et al found that community walking performance as measured by the StepWatch activity monitor did not improve following an intense physical therapy program at three weeks or three months following the intervention;[206] however, in the results of the qualitative analysis of this study, parents perceived that the therapy enabled greater participation in the community, including in sports.[358]

A decrease in the number of children completing their activity monitoring was seen in the study by Van Wely et al,[205] but to a much lesser extent than seen in our study. At six months, 17% of children had not completed activity monitoring in their study, compared with 58% of the children in our study. In New Zealand, there are strict ethical guidelines that do not allow incentive payments for participation in research, and this may be one reason for our lower data ascertainment rate for non-standard outcome measures compared with other studies.

In this study we chose two activity and participation measures, the ASK and CAPE, which had not previously been used in surgery studies, to see if these measures demonstrated responsiveness. Due to the small number of respondents, conclusions must be drawn with caution. However, the ASK-c and ASK-p did not demonstrate a change over the six-month period, whilst the CAPE diversity and intensity domains did.

Several other papers have looked at the relationship between outcomes for body function and structure and those for activity and participation. Firstly, Abel et al[115] examined passive joint range of motion, Ashworth scores, gait temporospatial and kinematic parameters, the GMFM, and the Pediatric Outcome Data Collection Instrument (PODCI) in 129 ambulatory children and adolescents with CP. They postulated that the more substantial the impairment, the greater the functional impairment as measured by the GMFM and PODCI. However, their research did not support their hypothesis, with weakness seen in all bivariate relationships. In the multiple regression analysis, no combination of the impairment measures explained more than 20% of the variance in the GMFM or PODCI. Secondly, the paper by Gorton et al[359] looked at 75 children with spastic CP who underwent surgery to improve gait and a matched cohort of children who did not have surgery. They assessed the children before surgery and one year following surgery using the GMFM, PODCI, Pediatric Quality of Life Inventory, Functional Independence Measure for Children (WeeFIM), and Gillette Gait Index. A statistically and clinically significant difference was found for the Gillette Gait Index, but not for any of the measures of activity and participation. They

concluded that changes occurred at the ICF body structure and function level, but did not translate into clinically significant changes in activity and participation.[360]

Other work has used qualitative data obtained by open-ended interview to cover all aspects of functioning for children with CP five years following single-event multilevel surgery[361] and used the GPS to assess objective change. They found for the majority of the ten children studied, the GPS had improved from baseline to five years following surgery. While the qualitative data supported improvement in body structure and function, not all participants reported increased self-efficacy or being more independently functioning in daily life.

There has been debate in the literature as to whether changes in the ICF activity and participation domain have not been demonstrated due to the lack of appropriate outcome tools, whilst others contend that it would not be expected that surgery would change activity and participation. It may in fact be that orthopaedic surgery does not change activity and participation, and that it is other factors that influence this. This would not make lower limb orthopaedic surgery redundant, but rather clarify expectations for the family. Furthermore, surgery may have an impact on long-term musculoskeletal health which, given the long-term follow-up required, is unlikely to be shown in a research study.

Chapter 9 Discussion

This thesis presents a programme of advanced research intended to make a novel contribution to the body of literature on assessment of outcomes of lower limb orthopaedic surgery in children with cerebral palsy (CP). CP remains an important condition in paediatric orthopaedics, with evidence that only one in two affected children walk independently.[312] For many children with CP, orthopaedic surgery will be part of their care. This is a commitment for the child, their family, and the health care system, so it is important that the surgery performed is of maximum benefit. Measurement of outcomes is an important part of this.

Measuring outcomes has come a long way since evidence-based medicine first became popularised by Sackett in the 1980s. Clinicians have started to look at patient-focussed outcomes and taken a broader view of what is a "successful" outcome. The introduction of the International Classification of Functioning Disability and Health (ICF) has been part of this shift, with the emphasis on activity and participation.

The opening chapter of this thesis introduced this field of research, firstly with the controversy concerning the definition, aetiology, and classification of CP and how this contributes to the difficulty in measuring outcomes for CP. With the advancing fields of magnetic resonance imaging and genetic testing, it is likely that the aetiology of CP will become better defined, enabling interventions to be targeted to the groups most likely to benefit. Finally, many of the outcome measures currently available were discussed in relation to the ICF.

The mapping review was unique in documenting the increasing body of literature looking at the outcomes of lower limb orthopaedic surgery, with an increase from eight papers in 1990 to 18 in 2011. During this time, 34 different outcome measures were identified. This is similar to the findings when other interventions have been studied, with the majority of these measures looking at the body function and structure domains of the ICF. However, there was an increase in activity and participation measures during the study period. This increase may also reflect the influence of evidence-based medicine and a change to prospective study design. Currently, activity and participation outcomes are generally not routinely collected in clinical practice, and therefore could not be studied retrospectively.

Another key finding of the mapping review was the poor uptake of the Gross Motor Function Classification System (GMFCS) in surgical papers. The GMFCS is a widely used classification

system for CP, and has been shown to be predictive for hip subluxation[43-45], scoliosis[46], and outcome from foot surgery[47] and adductor surgery to prevent hip subluxation[48]. Routine use of the GMFCS will increase the generalisability of results of studies looking at outcomes of lower limb orthopaedic surgery in children with CP.

The Functional Mobility Scale (FMS) was found in the mapping review to be the third most frequently used activity and participation measure. The FMS is part of standard care at our centre because it is reliable, simple to remember, and rapid to administer, so does not require additional time for the patient to complete, as compared with the Gross Motor Function Measure, which can take 45 minutes to complete, and the Gillette Functional Assessment Questionnaire, which has ten levels to recall. Novel work on further validation of this outcome measure was done looking at its relationship with capacity-based measures.

Walking capacity as measured by the six-minute walk test (6MWT), one-minute walk test (1MWT), and walk speed (WS) clearly discriminated Functional Mobility Scale (FMS) scores 5 versus 6 for independently ambulatory children across all the FMS distances. Children who were rated 1, 2, 3, or 4 at different FMS distances had lower walking capacity, but there was not a linear relationship, indicating that for those children the FMS score may be more around personal choice of walking aid rather than capacity. There is interesting work looking at the way adolescents move in their environment and evidence that personal choice influences their selected method of mobility.[280]

As previously mentioned, the GMFCS is a widely used classification system for motor impairment, but there is overlap between GMFCS level I and II,[49,267] with these two groups making up 60% of all children with CP[362]. The research presented shows that the FMS may be able to help differentiate these two groups of children. The children classified as GMFCS level II who have an FMS 5 score of 6 have significantly better walking capacity (as measured by the 1MWT, 6MWT, and WS) than those children, also GMFCS level II, who have an FMS 5 score of 5. A similar finding can be made for GMFCS level I children who have a FMS 500 score of 5 or 6. Thus, for surgical outcome papers, it could be helpful to subgroup children by both their GMFCS and FMS to look at outcomes.

Whilst the FMS is a very useful tool in clinical practice, it does not give an objective measure of ambulatory activity in the community. Steps make up the majority of physical activity performed in a day and provide an understandable measure of community participation. The StepWatch™ activity monitor was chosen for this research programme because it had been used in a number of studies for children with CP and was known to be

accurate.[200] Several areas of future research had been identified in the initial review, including the repeatability of the StepWatch activity monitor, influence of definition of a day on both repeatability and retention of participants, use of the other StepWatch outputs, and intensity of activity using cadence bands. These gaps in the literature were addressed in several parts of this research programme.

We found that the repeatability of the StepWatch activity monitoring improved when the definition of at least 10 hours of activity with less than two hours of no recorded activity was used, but that repeatability did not improve when the duration of monitoring was increased from two days to five days. This supports the work by Rich et al showing that two days of activity monitoring was acceptable.[313] The finding of no improvement in repeatability with longer monitoring is important, as a requirement that the monitor be worn for five consecutive days meant that there was a 50% drop in the number of participants with valid datasets. Our work for total step count demonstrated a repeatability of 5,573, indicating that 95% of repeated observations for the study participants would be expected to be within 5,573 steps of the first measure. In the pilot study presented in Chapter 8, only one child reached this threshold of change between baseline and three months.

Chapter 6 looked at two outcome measures from the StepWatch activity monitor that have only limited published data in CP and cadence bands as defined by Tudor-Locke et al to look at the intensity of activity in children with this condition. The Max 1 and Peak Activity Index (PAI) were demonstrated to be repeatable and valid measures in children with CP, clearly differentiating GMFCS levels. Both of these measures have previously been studied in adults, and are thought to reflect best ambulatory performance under natural free-living conditions.[321] Children who functioned at GMFCS level I had Max 1 and PAI values that were comparable with values published in the literature for typically developing children. Thus, these children can achieve periods of high intensity activity. As would be expected, children with CP functioning at GMFCS level III did not achieve these intensity levels.

We found that children with CP did not achieve 60 minutes of high intensity activity (>120 steps/minute). However, this was also found in a US study of typically developing children, in whom three minutes/day on average were spent at a cadence of >120 steps/minute.[203] As well as a focus on increasing moderate/high intensity activity to improve health, there is also an increasing body of evidence suggesting that any increase in physical activity is beneficial to health.[296] This study found that children with CP spent an amount of time in incidental movement (1–19 steps) similar to that found in typically developing children.

The initial mapping review also identified that, after clinical examination, three-dimensional gait analysis was the second most commonly used outcome measure for assessing the results of lower limb orthopaedic surgery. However, the relationship between the GDI, the single representative score of three-dimensional gait analysis, and community walking was not known. Novel work looking at the GDI and its association with community walking was done using the StepWatch activity monitor. The finding of a moderate association between the GDI and total step count indicated that improvements in GDI seen after surgery may also be associated with an increase in total step count in the community. However, multivariate analysis showed that up to one third of the variation in total daily step count was related to changes in the GDI, meaning that many other factors influence the total number of steps taken. This supports the earlier work with the FMS, which showed that personal choice influenced choice of mobility.

The final part of the advanced research programme was a pilot study looking at the short-term impact of lower limb orthopaedic surgery in children with CP across the ICF and to look at the feasibility of measures of activity and participation. This clinical study was undertaken over 20 months and recruited 28 patients, 13 of whom proceeded to surgery. Whilst this was a small pilot study, it should be remembered that the largest randomised controlled trial for single-event multilevel surgery in CP had only 19 children[81].

A key finding was the difference in data ascertainment between standard care measures and those that were additional for the research study. The principal investigator spent considerable time chasing surveys and monitors, but it was a balance between persistence for research and harassing a family. The difficulty in gaining a response seemed to lie in the fact that these families were overburdened, and that whilst they experienced a desire to be included in the research, finding the time to participate was often not possible. Thus, the feasibility of including multiple measures of activity and participation in a larger study seems poor.

The majority of children who had surgery had improvement in their GDI, the primary measure of body structure and function. The Gross Motor Function Measure, 6MWT, and ASK showed no change across the six-month study period. Total daily step count showed a trend towards a decrease at three months that had not returned to baseline at six months, although for the majority of the children this change did not reach the level defined in

Chapters 5 and 6 for a meaningful change. The CAPE showed a decrease in diversity and intensity at three and six months, with no change in enjoyment of activities.

Limitations

In the two clinical studies, in particular the pilot surgical study, there were small numbers of participants. Children functioning at GMFCS level III were the smallest group. This would be consistent with registry data in Australia showing that, at 5 years of age, 61.5% of children function at GMFCS levels I and II, with approximately 10% functioning at GMFCS level III[362].

In New Zealand, we do not currently have robust case registry data, so we are unable to define a sampling frame for ambulatory children with CP. This restricts our ability to assess potential selection bias in our study samples. Whilst we have some information regarding children currently under a paediatric orthopaedic service in one region, work by Parkes et al has shown that case and service registers have children that differ both clinically and demographically.[363]

It should be remembered that this research aimed to look at outcome measures for lower limb orthopaedic surgery, so the group of children recruited through orthopaedic clinics is likely to reflect those who would be potentially having surgery.

Another limitation of this study is the lack of information about other difficulties the participants had, in particular intellectual disability and behavioural problems. These difficulties may limit inclusion in studies and be a potential source of bias in results. A cross-sectional European study of children with CP aged 8–12 years found that around a quarter of the children had significant emotional and behavioural problems, as demonstrated by an abnormal total difficulty score on the Strengths and Difficulties Questionnaire.[364] This information was not collected as part of our research.

Not all forms of activity would have been detected using the StepWatch activity monitor to objectively measure physical activity. The monitor cannot be worn in a swimming pool, so may underreport physical activity, given that swimming is a frequent leisure activity for adolescents with CP[294]. School-aged children in our country frequently remove footwear in the classroom, so it is possible for the monitor to be removed for periods during the school day, leading to undercounting of steps taken. Further, the StepWatch activity monitor does not record physical activity in a wheelchair, which is how many children functioning at GMFCS level III would travel over longer distances.

This programme of research did not address environmental and personal factors. These factors are poorly studied in the paediatric orthopaedic literature,[93] but are likely to play a significant role in the outcome measures specifically relating to an increase in participation. Previous work has shown that parental factors influence the involvement of a child with CP in life situations. Surgery alone will not address this, but if the surgery is studied as part of a wider multidisciplinary approach that may influence personal factors, it may be that participation is more likely to change.

Future directions

During the course of this research programme, the core sets of the ICF to be measured were analysed by Schiariti et al.[145,365-367] This has been international collaborative work with professional experts in CP, and four orthopaedic surgeons were involved in the initial questionnaire to identify the most relevant categories and personal factors for CP. However, whilst there was consensus on what to measure, no consensus on how to measure the core sets of the ICF has been reached.[366] This work will continue, with new outcomes tools constantly being developed, for example, the Gait Outcomes Assessment List (GOAL) project currently being led by Dr Unni Narayanan, an orthopaedic surgeon at the Hospital for Sick Children in Toronto, Canada. This project is developing and validating a new goal-based outcome measure for gait-related interventions in children that will assess items across the ICF domains.

It is likely that collection of outcome measures across the ICF which are patient-focussed will become standard of care. The FMS is part of standard care in our institution, and this body of work confirms it as a useful outcome measure that we should continue to use. At our centre, we are looking at including the StepWatch activity monitor in our gait laboratory assessment. The StepWatch activity monitor is a valid and reliable of way at looking at walking activity and differentiates those children who walk regularly in the community from those children who only take a few steps. Information on step activity is useful when discussing surgery, especially if significant rehabilitation is required for the patient and family, given that some surgeries would not be appropriate for children who are taking very few steps per day. Smartphone Apps have potential for improving compliance with activity monitoring in the future, and the use of GPS tracking on smartphones is another potential way to assess activity.

The questionnaires used in the final study were frequently not completed, making it difficult to know if they would give valuable information. This study highlighted that having patients complete questionnaires at home and return them is unlikely to give useful information, and a different way of approaching completion of questionnaires would be necessary. Using iPads in the clinic waiting

area with an electronic questionnaire might increase the rate of completion of questionnaires, and is an area to pursue in the future.

As well as continuing to look at the optimal outcome measures to use, the work to define children with CP will advance, allowing more individualised treatment. As magnetic resonance imaging becomes standard of care, as recommended by the American Academy of Neurology,[19] it may be that the type of brain injury starts to become linked to surgical outcome. Also, better quantification of motor type and movement disorder is likely to be increasingly investigated as a baseline characteristic in surgical studies. Dystonia is a contraindication to selective dorsal rhizotomy,[368,369] and whilst it is not likely to become an exclusion criterion for orthopaedic surgical procedures, it is may be an important factor when assessing outcomes of lower limb orthopaedic surgery.

In conclusion, the management of children with CP remains important for paediatric orthopaedic surgeons. Improvement in our knowledge of the outcomes of surgery will assist with selecting the most appropriate operation, help guide discussion of risks, benefits and rehabilitation, and provide justification of the clinical and economic benefit of these expensive interventions.

Appendices

Table S1 Supplementary table showing included articles

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
1990	Crawford et al[370]	Retrospective	20	No	Clinical examination Radiology	
	Guttman et al[371]	Retrospective	15	No	Clinical examination Pain Radiology	
	Hsu et al[372]	Retrospective	49	No	Clinical examination Gait velocity Type of walking device	
	Pirani et al[373]	Retrospective	30	No	Clinical examination Gait velocity	
	Reimers et al[374]	Retrospective	38	No	Clinical examination	
	Shapiro et al[233]	Prospective	10	No	Clinical examination Gait velocity	
	Strecker et al[375]	Retrospective	100	No	Clinical examination Type of walking device	
	Sutherland et al[376]	Retrospective	22	No	Gait analysis Gait velocity	
1991	Barnes et al[377]	Retrospective	20	No	Clinical examination Type of walking device	
	Damron et al[378]	Retrospective	117	No)	Clinical examination Type of walking device	
	McCall et al[379]	Retrospective	101	No	Clinical examination	
1992	Dhawlikar et al[380]	Retrospective	126	No	Clinical examination Type of walking device	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Hadley et al[381]	Retrospective	24	No	Clinical examination Gait analysis sEMG	
	Lee et al[382]	Retrospective	23	No	Clinical examination Gait analysis Radiology Type of walking device	
	Norlin et al[383]	Retrospective	17	No	Clinical examination Gait analysis Gait velocity	
1993	Alman et al[384]	Retrospective	29	No	Clinical examination Radiology	
	Atar et al[385]	Retrospective	30	No	Clinical examination Type of walking device	
	Cheng et al[386]	Retrospective	45	No	Clinical examination Type of walking device	
	Damron et al[387]	Retrospective	52	No	Clinical examination Type of walking device	
	Etnyre et al[388]	Retrospective	24	No	Clinical examination Gait analysis Gait velocity sEMG	
	Koman et al[389]	Retrospective	10	No	Clinical examination Pain Radiology	
	Nene et al[390]	Retrospective	18	No	Gait analysis Physiological Cost Index sEMG	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Ounpuu et al[391]	Retrospective	78	No	Clinical examination Gait analysis sEMG	
	Ounpuu et al[392]	Retrospective	78	No	Clinical examination Gait analysis sEMG	
	Rose et al[393]	Retrospective	20	No	Clinical examination Gait analysis Gait velocity	
	Saji et al[394]	Retrospective	18	No	Clinical examination Radiology	
	Tenuta et al[395]	Retrospective	24	No	Clinical examination Pain Radiology	
1994	Damron et al[396]	Retrospective	200	No	Clinical examination	
	Hamel et al[397]	Retrospective	28	No	Clinical examination Radiology Type of walking device	
1995	Moens et al[398]	Retrospective	16	No	Clinical examination Radiology	
	Mulier et al[399]	Retrospective	17	No	Clinical examination Radiology	
1996	Camacho et al[228]	RCT	12	No	Clinical examination	
	Scott et al[235]	Retrospective	33	No	Clinical examination Gait analysis Radiology Type of walking device	
	Yngve et al[400]	Retrospective	33	No	Gait analysis	

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	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
1997	Miller et al[401]	Retrospective	25	No	Gait analysis Gait velocity sEMG	
	O'Bryne et al[402]	Retrospective	16	No	Gait analysis	
	Sala et al[403]	Retrospective	27	No	Clinical examination	
	Sutherland et al[404]	Retrospective	17	No	Clinical examination Gait analysis Gait velocity Type of walking device	
1998	Bhan et al[405]	Retrospective	26	No	Clinical examination Radiology	
	Chambers et al[406]	Retrospective	70	No	Clinical examination Gait analysis sEMG	
	DeLuca et al[407]	Retrospective	73	No	Clinical examination Gait analysis	
	Dodgin et al[408]	Retrospective	49	No	Radiology	
	Jenter et al[409]	Retrospective	17	No	Clinical examination Radiology	
	Jeray et al[260]	Retrospective	28	No	Clinical examination Radiology	
	Joseph et al[410]	Retrospective	12	No	Clinical examination	
	McAuliffe et al[253]	Retrospective	20	No		WeeFIM
	Stefko et al[411]	Retrospective	10	No	Clinical examination Gait analysis Gait velocity	

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	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Vedantam et al[412]	Retrospective	78	No	Clinical examination Pain Radiology	
	Vogt et al[413]	Retrospective	48	No	Type of walking device	
1999	Abel et al[232]	Prospective	30	No	Clinical examination Gait analysis Gait velocity	GMFM
	Damiano et al[414]	Prospective	20	No	Biomechanical model Gait analysis Gait velocity	
	Fabry et al[415]	Retrospective	15	No	Clinical examination Gait analysis	
	Rethlefsen et al[416]	Retrospective	16	No	Clinical examination Gait analysis Gait velocity Type of walking device	
	Saltzman et al[417]	Retrospective	57	No	Clinical examination Radiology Type of walking device	
2000	Andreacchio et al[418]	Retrospective	15	No	Clinical examination Radiology	
	Granata et al[419]	Prospective	40	No	Gait analysis Gait velocity sEMG	
	Katz et al[420]	Retrospective	36	No	Clinical examination	
	Oeffinger et al[421]	Prospective	8	No	Foot pressure data Radiology	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Repko et al[422]	Retrospective	35	No	Clinical examination Radiology	
	Saraph et al[231]	Retrospective	22	No	Clinical examination Gait analysis Gait velocity	
	Sayli et al[423]	Retrospective	16	No	Clinical examination	
	Steinwender et al[424]	Retrospective	16	No	Gait analysis Gait velocity	
2001	Abu-Faraj et al[249]	Prospective	12	No	Clinical examination Gait analysis Gait velocity Radiology Vertical plantar pressure	
	Beals et al[425]	Retrospective	20	No	Clinical examination Radiology	
	Borton et al[246]	Retrospective	132	No	Clinical examination Gait analysis Physician rating score Radiology	
	Davids et al[259]	Retrospective	16	No	Pain Radiology	
	Kay et al[426]	Retrospective	47	No	Gait analysis Gait velocity	
	Liggio et al[427]	Retrospective	11	No	Clinical examination Foot pressure data Gait analysis Radiology	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Molenaers et al[428]	Retrospective	52	No	Clinical examination Gait analysis Gait velocity	
	Saraph et al[429]	Retrospective	12	No	Clinical examination Gait analysis Gait velocity	
	Steinwender et al[430]	Retrospective	29	No	Clinical examination Gait analysis Gait velocity	
	Weigl et al[431]	Prospective	14	No	Radiology	
	Zwick et al[432]	Prospective	17	No	Clinical examination Gait analysis Gait velocity	
2002	Asakawa et al[433]	Prospective	6	No	Radiology	
	Baddar et al[434]	Retrospective	34	No	Clinical examination Gait analysis Gait velocity sEMG	
	Chang et al[242]	Retrospective	108	No	Clinical examination Foot pressure data Radiology	
	Kay et al[435]	Retrospective	37	No	Gait analysis Clinical examination	
	Novacheck et al[247]	Retrospective	56	No	Clinical examination Gait analysis Gait velocity Hip flexor index	Gillette FAQ

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Orendurff et al[436]	Retrospective	9	No	Biomechanical model Clinical examination Gait analysis	
	Ounpuu et al[437]	Prospective	20	No	Clinical examination Gait analysis Gait velocity	
	Saraph et al[438]	Retrospective	22	No	Clinical examination Gait analysis Gait velocity	
	Saraph et al[439]	Retrospective	25	No	Clinical examination Gait analysis Gait velocity	
	Yngve et al[440]	Retrospective	99	No	Assistive devices Gait analysis Gait velocity	
	Zwick et al[441]	Prospective	17	No	Clinical examination Gait analysis Gait velocity	
2003	Aminian et al[442]	Retrospective	9	No	Clinical examination Gait analysis	
	Carney et al[230]	Retrospective	23	Yes	Gait analysis	
	Kay et al[443]	Retrospective	48	No	Clinical examination Gait analysis Radiology	
	Murray-Weir et al[444]	Prospective	37	No	Clinical examination Gait analysis Gait velocity Type of walking device	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Pirpiris et al[445]	Prospective	28	No	Clinical examination Gait analysis Gait velocity	
	Saw et al[446]	Retrospective	24	No	Clinical examination Gait analysis Gait velocity Type of walking device	
	Van der Linden et al[447]	Retrospective	18	No	Gait analysis Gait velocity	
2004	Bourelle et al[448]	Retrospective	17	No	Clinical examination Radiology	
	Buckon et al[254]	Prospective	25	Yes	GMFM	PEDI GMPM Attribute
	Buurke et al[449]	Prospective	15	No	Clinical examination Observational gait analysis sEMG	
	Chang et al[450]	Retrospective	61	No	Clinical examination Gait analysis Gait velocity Type of walking device	GMFM
	Gough et al[451]	Retrospective	24	No	Gait analysis Gait velocity Type of walking device	
	Johnston et al[452]	Prospective	17	Yes	Gait analysis Gait velocity Energy cost of walking Clinical examination	GMFM

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Kay et al[453]	Retrospective	54	No	Clinical examination Gait analysis Physician rating score	
	Kay et al[454]	Retrospective	59	No	Gait analysis	
	Kay et al[455]	Retrospective	56	No	Clinical examination Gait analysis sEMG	
	Kondo et al[456]	Prospective	25	Yes		GMFM
	Metaxiotis et al[457]	Prospective	20	No	Clinical examination Gait analysis Gait velocity	
	Schwartz et al[245]	Retrospective	135	No	Gait analysis Normalcy index Normalised oxygen consumption	Gillette FAQ
	Thomas et al[458]	Prospective	25	No	Clinical examination Energy cost of walking Gait analysis	
	Vlachou et al[459]	Retrospective	8	No	Clinical examination Radiology	
	Wren et al[460]	Retrospective	12	No	Biomechanical model Clinical examination Gait analysis	
2005	Damiano et al[461]	Retrospective	64	No		GMFM PODCI

Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
Engsberg et al[462]	Prospective	32	No	Clinical examination Gait analysis Gait velocity	GMFM
Galli et al[463]	Retrospective	30	No	Clinical examination Gait analysis	
Graham et al[464]	Prospective	17	No	Clinical examination Gait analysis Gait velocity Radiology	
Inan et al[465]	Retrospective	160	No	Clinical examination Radiology	
Kim et al[466]	Retrospective	30	No	Gait analysis	
Lyon et al[467]	Retrospective	14	No	Clinical examination Gait analysis Gait velocity	
McMulkin et al[468]	Retrospective	28	No	Clinical examination Gait analysis Gait velocity Normalcy index	
Moreau et al[469]	Retrospective	12	Yes	Clinical examination Gait analysis Pain Type of walking device	
Noritake et al[470]	Retrospective	16	No	Clinical examination Radiology	
Ryan et al[471]	Retrospective	46	No	Clinical examination Gait analysis	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Saraph et al[472]	Retrospective	32	No	Gait analysis Gait velocity	
	Yoo et al[473]	Retrospective	56	No	Clinical examination Gait analysis Radiology	
	Yoshimoto et al[474]	Retrospective	17	No	Clinical examination Radiology Type of walking device	
2006	Arnold et al[475]	Retrospective	152	No	Biomechanical model Gait analysis Gait velocity	
	Arnold et al[476]	Retrospective	69	No	Biomechanical model Clinical examination Gait analysis Gait velocity	
	Carney et al[477]	Retrospective	16	Yes	Gait analysis	
	Carney et al[478]	Retrospective	17	Yes	Gait analysis	
	Chang et al[479]	Retrospective	20	No	Gait analysis	
	Cobeljic et al[480]	Retrospective	17	No	Radiologic Type of walking device	
	Dietz et al[276]	Retrospective	79	No	Clinical examination	
	Goldberg et al[481]	Retrospective	40	No	Gait analysis	
	Kokavec et al[482]	Retrospective	444	No	Clinical examination	
	Ma et al[483]	Retrospective	19	Yes	Gait analysis Clinical examination	FMS
	Massaad et al[484]	Retrospective	21	No	Gait analysis Gait velocity	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Morais Filho et al[485]	Retrospective	26	No	Clinical examination Gait analysis Type of walking device	
	Park et al[486] (Soft tissue surg)	Retrospective	16	No	Clinical examination Gait analysis Gait velocity	
	Rodda et al[234]	Retrospective	10	Yes	Clinical examination Gait analysis Gait velocity Pain Radiology	Gillette FAQ FMS
	Sanders et al[487]	Prospective	108	No		WeeFIM
	Saraph et al[488]	Retrospective	11	No	Clinical examination Gait analysis Gait velocity	
	Scott et al[236]	Retrospective	25	No	Clinical examination Gait analysis sEMG	
	Zeifang et al[489]	Prospective	32	No	Radiology Type of walking device	
2007	Adolfsen et al[490]	Retrospective	31	No	Clinical examination Gait analysis Gait velocity sEMG	
	Biedermann et al[491]	Retrospective	10	No	Clinical examination Radiology	
	Cuomo et al[252]	Prospective	57	No	Clinical examination	PODCI FAQ walking score Paeds QL

Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
Dreher et al[492]	Prospective	30	Yes	Clinical examination Gait analysis	
Fry et al[493]	Prospective	17	No	Clinical examination Radiology	
Gannotti et al[494]	Retrospective	20	Yes	Clinical examination Gait analysis Gait velocity Type of walking device	
Harvey et al[251]	Retrospective	66	Yes		FMS
Hemo et al[495]	Retrospective	13	Yes	Gait analysis Gait velocity	
Khan et al[75]	Retrospective	85	No	Clinical examination Type of walking device	
Lauer et al[496]	Retrospective	23	Yes	Gait analysis Gait velocity sEMG	
Lovejoy et al[497]	Retrospective	38	No	Clinical examination Gait analysis	
McMulkin et al[498]	Retrospective	80	Yes	Gait analysis Normalcy index	PODCI
Niiler et al[499]	Retrospective	68	No	Gait analysis	
Patikas et al[500]	Retrospective	34	No	Gait analysis Gait velocity sEMG	
Sakic et al[501]	Retrospective	856	No	Clinical examination Gait velocity Pain Radiology	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Seniorou et al[502]	Prospective	20	Yes	Clinical examination Gait analysis Gait velocity	GMFM
	Wren et al[248]	Retrospective	25	No	Gait analysis GDI Observational gait analysis	
2008	De Morais Filho et al [503]	Retrospective	12	Yes	Gait analysis Pain	
	Filho et al[504]	Retrospective	60	Yes	Gait analysis Gait velocity	
	Gordon et al[505]	Retrospective	48	Yes	Gait analysis GGI Gait velocity	
	Gough et al[506]	Retrospective	24	Yes	Clinical examination Gait analysis GGI	
	Gough et al[507]	Retrospective	45	Yes	Gait analysis GGI	
	Gupta et al[508]	Retrospective	34	No	Clinical examination	
	Khot et al[509]	Prospective	16	Yes	Clinical examination Radiology	FMS
	Klatt et al[510]	Retrospective	18	No	Clinical examination Radiology	
	Kun et al[511]	Retrospective	47	Yes	Foot pressure data Radiology	
	Lofterod et al[512]	Retrospective	15	Yes	Clinical examination Gait analysis Gait velocity	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Lofterod et al[513]	Retrospective	55	Yes	Gait analysis Gait velocity	FMS
	Muthusamy et al[514]	Retrospective	38	No	Clinical examination Gait analysis sEMG	
	Park et al[515]	Retrospective	47	Yes	Clinical examination Foot pressure data Gait analysis Pain	
	Poul et al[516]	Retrospective	30	No	Clinical examination	
	Stout et al[241]	Retrospective	73	Yes	Clinical examination Gait analysis GGI Gait velocity Radiology Normal net oxygen consumption Pain	PODCI Gillette FAQ
	Svehlik et al[517]	Prospective	11	Yes	Clinical examination Gait analysis Gait velocity	FMS
	Weiner et al[518]	Retrospective	89	No	Clinical examination	
2009	Adams et al[519]	Retrospective	42	No	Radiology	
	Amichai et al[239]	Prospective	18	Yes	Clinical examination HBCI during stair climb	Gillette FAQ
	Bialik et al[520]	Retrospective	20	Yes	Gait analysis	
	Bishay et al[521]	Retrospective	20	No	Radiology	
	El-Adwar et al[522]	Prospective	15	No	Clinical examination Radiology	

Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
Ettl et al[523]	Retrospective	19	No	Clinical examination Radiology	
Galli et al[524]	Prospective	32	No	Clinical examination Gait analysis Gait velocity	
Gorton et al[359]	Prospective	150	Yes	Gait analysis Gait velocity GDI GGI	PODCI WeeFIM GMFM
Jahn et al[244]	Retrospective	38	No	Biomechanical model Clinical examination Gait analysis	
Koca et al[525]	Retrospective	19	No	Clinical examination Gait analysis Gait velocity	
Lee et al[77]	Retrospective	279	Yes		PODCI Gillette FAQ
Lofterod et al[526]	Retrospective	34	Yes	Clinical examination Gait analysis	
Molayem et al[237]	Retrospective	15	No	Clinical examination Pain Radiology	
Park et al[527]	Retrospective	28	No	Clinical examination Gait analysis	
Reinbolt et al[528]	Retrospective	81	No	Gait analysis sEMG	

	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	Rethlefsen et al[529]	Retrospective	81	Yes	Clinical examination Gait analysis Gait velocity	
	Turriago et al[530]	Retrospective	32	No	Clinical examination Gait analysis Gait velocity Radiology	
	Tylkowski et al[243]	Retrospective	27	Yes	Clinical examination Gait analysis Gait velocity Oxygen consumption	
	Vlachou et al[531]	Retrospective	135	No	Clinical examination	
	Vlachou et al[532]	Retrospective	38	No	Clinical examination Radiology	
	Vlachou et al[533]	Retrospective	12	No	Clinical examination Radiology	
	Westwell et al[534]	Retrospective	25	No	Gait analysis Gait velocity Type of walking device	
	Wu et al[535]	Retrospective	13	No	Clinical examination	
2010	Akerstedt et al[238]	Prospective	11	Yes	Clinical examination Maximum outdoor gait distance Physiological Cost Index	GMFM CHQ
	Bernthal et al[536]	Prospective	23	No	Clinical examination Gait analysis Gait velocity	
	Datta et al[537]	Prospective	20	No	Clinical examination	

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	Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
	De Morais Filho et al[538]	Retrospective	1,039	Yes	Gait analysis	
	Jaddue et al[229]	Prospective	18	No	Clinical examination Type of walking device	
	Joseph et al[539]	Retrospective	17	No	Clinical examination Physiological Cost Index	
	Lee at al [76]	Prospective	61	Yes		PODCI Gilette FAQ
	Lofterod et al[540]	Retrospective	28	Yes	Gait analysis	
	Mitsiokapa et al[541]	Retrospective	58	Yes		GMFM
	Stebbins et al[542]	Prospective	12	No	Clinical examination Gait analysis sEMG	
	Svehlik et al[543]	Prospective	10	No	Gait analysis Oxygen utilisation	
	Thompson et al[544]	Prospective	20	Yes	Clinical examination Gait analysis Gait velocity GGI	GMFM
	Vlachou et al[545]	Retrospective	33	No	Clinical examination Radiology	
	Yoon et al[546]	Retrospective	30	No	Clinical examination Gait analysis Foot pressure data	
2011	Cimolin at el [352]	Retrospective	19	No	Gait analysis GDI	
	Cimolin et al[547]	Prospective	12	No	Gait analysis Gait velocity Clinical examination	GMFM

Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
Cruz et al[548]	Retrospective	42	Yes	Gait analysis Gait velocity	
De Coulan et al[549]	Retrospective	18	No	Clinical examination Radiology	FMS
Desailly et al[550]	Retrospective	16	No	Biomechanical model GDI	
Frost et al[551]	Retrospective	23	No	Clinical examination Radiology	
Ganjwala et al[552]	Retrospective	18	No	Clinical examination Gait velocity Physiological Cost Index	Gillette FAQ FMS
Goldberg et al[250]	Retrospective	2	Yes	Gait analysis Gait velocity SCALE	
Gordon et al[227]	Retrospective	51	Yes	Gait analysis GDI	Gillette FAQ PODCI mGAS
Healy et al[553]	Retrospective	32	No	Gait analysis	
Leidinger et al[554]	Retrospective	35	Yes	Clinical examination Radiology Type of walking device Use of orthosis	
MacWilliams et al[240]	Prospective	4	Yes	Clinical examination Gait analysis Gait velocity GDI	GMFM Gilette FAQ

Reference	Methodology	Participants (n)	Classification (GMFCS)	Body Structure/Function	Activity/Participation
Rutz et al[354]	Retrospective	29	Yes	Clinical examination Gait analysis Gait velocity GDI GGI GPS	
Senaran et al[555]	Retrospective	145	Yes	Clinical examination Radiology	
Svehlik et al[79]	Retrospective	32	Yes	Gait analysis GDI	
Szczepanik et al[556]	Retrospective	22	No	Radiology	GMFM
Thomason et al[81]	RCT	19	Yes	Clinical examination Gait analysis GGI GPS	GMFM CHQ FMS Positional activity logger
Truong et al[350]	Retrospective	87	Yes	Clinical examination Gait analysis Gait velocity GDI Hip flexor index	Gillette FAQ
Wang et al[557]	Prospective	15	No	Clinical examination sEMG	
Zwick et al[558]	Retrospective	33	Yes	Gait analysis GGI	

Abbreviations: GMFCS, Gross Motor Function Classification Scale; WeeFim, The Functional Independence Measure for Children; GMFM, Gross Motor Function Measures; Gillette FAQ, Gillette Functional Assessment Questionnaire; PEDI, Pediatric Evaluation of Disability Inventory; PODCI, Pediatric Outcomes Data Collection Instrument; FMS, Functional Mobility Scale; Peds QL, Pediatric Quality of Life Inventory; GDI, Gait Deviation Index; GGI, Gillette Gait Index; HBCI during stair climb, Heart Beat Cost Index During Stair Climb; CHQ, Child Health Questionnaire; SCALE, Selective Control Assessment of Lower Extremity; mGAS, Modified Goal Attainment Scale; GPS, Gait Profile Score.

Table S2 Supplementary table showing excluded articles by reason

	Reason for exclusion	Study
1	Not published in English	559-609
2	Not a primary study reporting the outcomes of lower limb surgery in CP	16,71,73,74,78,92,115,162,267,275,284,344,348,360,553,610-763
3	Did not include ambulatory patients with CP aged 0–20 years	764-767
4	Surgery carried out for hip dysplasia	349,768-847
5	Data for participants with CP could not be extracted separately, i.e., age/ambulatory status	848-852
6	Repeated paper	853

Table S3 Articles included in the updated review of reported outcomes of lower limb orthopaedic surgery in children with cerebral palsy

	Reference	Article Title
2012	Aiona at al[854]	Coronal plane knee moments improve after correcting external tibial torsion in patients with cerebral palsy.
	de Moraes Barros Fucs et al[855]	Surgical technique: Medial column arthrodesis in rigid spastic planovalgus feet.
	de Morais Filho et al[856]	Outcomes of correction of internal hip rotation in patients with spastic cerebral palsy using proximal femoral osteotomy.
	Dreher et al[857]	Development of knee function after hamstring lengthening as part of multilevel surgery in children with spastic diplegia: a long-term outcome study.
	Dreher et al[858]	Long-term results after gastronemius-soleus intramuscular aponeurotic recession as a part of multilevel surgery in spastic diplegic cerebral palsy.
	Dreheret al[859]	Long-term results after distal rectus femoris transfer as part of multilevel surgery for the correction of stiff-knee gait in spastic diplegic cerebal palsy.
	Dreher et al[860]	Long-term outcome of femoral derotation osteotomy in children with spastic diplegia.
	Dreher[269]	Distal rectus femoris transfer as part of multilevel surgery in children with spastic diplegia - a randomised clinical trial.
	Feng[861]	Comparison of hamstring lengthening with hamstring lengthening plus transfer for the treatment of flexed knee gait in ambulatory patients with cerebral palsy.
	Harvey et al[72]	Longitudinal changes in mobility following singe-event multilevel surgery in ambulatory children with cerebral palsy.
	Lin et al[862]	Mesh Achilles tendon lengthening - a new method to treat equinus deformity in patients with spastic cerebal palsy: surgical technique and early results.
	Mazis et al[863]	Results of extra-articular subtalar arthrodesis in children with cerebral palsy.
	Presedo et al[864]	Rectus femoris distal tendon resection improves knee motion in patients with spastic diplegia.

	Reference	Article Title
	Rutz et al[865]	Hip flexion deformity improves without psoas-lengthening after surgical correction of fixed knee flexion deformity in spastic diplegia
	Rutz et al[69]	Stability of the Gross Motor Classification System after single-event mulitlevel surgery in children with cerebral palsy.
	Rutz et al[866]	Distal femoral osteotomy using the LCP Pediatric condylar 90-degree plate in patients with neuromuscular disorders.
	Sebsadji et al[136]	Description and classification of the effect of hamstrings lengthening in cerebral palsy children multi-site surgery.
	Thawrani et al[867]	Rectus femoris transfer improves stiff knee gait in children with spastic cerebral palsy.
	Zwick et al[558]	Does gender influence the long-term outcome of single-event multilevel surgery in spastic cerebral palsy.
2013	Bishay et al[868]	Single-event Multilevel acute total correction of complex equinocavovarus deformity in skeletally mature patients with spastic cerebral palsy hemiparesis.
	Braatz et al[869]	Do changes in torsional MRI reflect improvements in gait after femoral derotation osteotomy in patients with cerebral palsy?
	de Morais Filho et al[870]	Does the level of proximal femur rotation osteotomy influence the correction results in patients with cerebral palsy?
	Dreher et al[871]	The effects of muscle-tendon surgery on dynamic electromyographc patterns and muscle tone in children with cerebral palsy.
	Dreher et al[872]	Long-term effects after conversion of biarticular to monoarticular muscles compared with musculotendinous lengthening in children with spastic diplegia
	Firth et al[873]	Multilevel surgery for equinus gait in children with spastic diplegic cerebral palsy: medium-term follow-up with gait analysis.
	Haumont et al[140]	Flexed-knee gait in children with cerebral palsy: a 10 year follow up study.
	Himpens et al[874]	Quality of life in youngsters with cerebral palsy after single-event multilevel surgery.
	Huang at al[47]	Medial column stabilisation improves early result of calcaneal lengthening in children with cerebral palsy.

Reference	Article Title
Kadhim et al[875]	Long-term outcome of planovalgus foot surgical correction in children with cerebral palsy.
Khouri et al[133]	Rectus femoris transfer in multilevel surgery: technical details and gait outcome assessment in cerebral palsy patients.
Kim et al[876]	Comparison of lateral opening wedge calcaneal osteotomy and medial calcaneal sliding-opening wedge cuboid-closing wedge cuneiform osteotomy for correction of planovalgus foot deformity in children.
Klotz et al[877]	Reduction in primary genu recurvatum gait after aponeurotic calf muscle lengthening during multilevel surgery.
Kwon et al[878]	Short-term effects of proximal femoral derotation osteotomy on kinematics in ambulatory patients with spastic diplegia.
Lee et al[879]	Rotational osteotomy with submuscular plating in skeletally immature patients with cerebral palsy.
Rethlefsen[880]	Repeat hamstring lengthening for crouch gait in children with cerebral palsy.
Rutz et al[353]	Explaining the variability improvements in gait quality as a result of single event multi-level surgery in cerebral palsy.
Rutz et al[881]	Are results after single-event multilevel surgery in cerebral palsy durable?
Schwartz et al[132]	Predicting the outcome of intramuscular psoas lengthening in children with cerebral palsy using preoperative gait data and the random forest algorithm.
Scully et al[882]	Outcomes of rectus femoris transfers in children with cerebral palsy: effect of transfer site.
Shore et al[883]	Subtalar fusion for pes valgus in cerebral palsy: results of a modified technique in the setting of single event multilevel surgery.
Sung et al[138]	Long term outcome of single event multilevel surgery in spastic diplegia with flexed knee gait.
Sung et al[126]	Calcaneal lengthening for planovalgus foot deformity in patients with cerebral palsy.
Svehlik et al[884]	The Baumann procedure to correct equinus gait in children with diplegic cerebral palsy: long-term results.

Reference	Article Title

	Reference	Article Title
	Thomason et al[137]	Single event multilevel surgery in children with bilateral spastic cerebral palsy: a 5 year prospective cohort study.
	Vegvari et al[885]	Does proximal rectus femoris release influence kinematics in patients with cerebral palsy and stiff knee gait?
	Wren et al[135]	Outcomes of lower extremity orthopedic surgery in ambulatory children with cerebral palsy with and without gait analysis: results of a randomised controlled trial.
	Wren et al[268]	Impact of gait analysis on correction of excessive hip internal rotation in ambulatory children with CP: a randomised controlled trial.
2014	Bozinovski et al[886]	Operative treatment of the knee contractures in cerebral palsy patients.
	De Mattos et al[887]	Comparison of hamstring transfer with hamstring lengthening in ambulatory children with cerebral palsy: a further follow up.
	Ferreira et al[888]	Effects of gastrocnemius fascia lengthening on gait pattern in children with cerebral palsy using the gait profile score.
	Galli et al[889]	Quantification of patellar tendon shortening in a patient with cerebral palsy.
	Hoiness et al[290]	Pain and rehabilitation problems after single-event multilevel surgery including bony foot surgery in cerebral palsy.
	Kadhim et al[134]	Crouch gait changes after planovalgus foot deformity correction in ambulatory children with cerebral palsy.
	Laracca et al[890]	The effects of surgical lengthening of hamstring muscles in children with cerebral palsy - the consequences of pre-operative muscle length measurement.
	Lee et al[139]	Rectus femoris transfer in cerebral palsy patients with stiff knee gait.
	Marconi et al[891]	Mechanical work and energy consumption in children with cerebral palsy after single-event multilevel surgery.
	Schwartz et al[892]	Femoral derotational osteotomy: surgical indications and outcomes in children with cerebral palsy.

	Reference	Article Title
	Tinney et al[893]	The transverse Vulpius gastrocsoleus recession for equinus gait in children with cerebral palsy.
2015	Abousamra et al[894]	Long-term outcome of internal tibial derotation osteotomies in children with cerebral palsy.
	Aiona et al[895]	Comparison of rectus femoris transfer surgery done concomitant with hamstring lengthening or delayed in patients with cerebral palsy.
	Blumetti et al[141]	Does the GMFCS level influence the improvement in knee range of motion after rectus femoris trasfer in cerebral palsy?
	Chung et al[896]	Recurrence of equinus foot deformity after tendo-achilles lengthening in patients with cerebral palsy.
	Church et al[897]	Persistence and recurrence following femoral derotational osteotomy in ambulatory children with cerebral palsy.
	El-Sherbini et al[898]	Midterm follow up of talectomy for severe rigid equinovarus feet.
	Er et al[899]	Long-term outcome of external tibial derotation osteotomies in children with cerebral palsy.
	Feger et al[900]	Comparative effects of multilevel muscle tendon surgery, osteotomies, and dorsal rhizotomy on functional and gait outcome measures for children with cerebral palsy.
	Inan et al[901]	Neurological complications after supracondylar osteotomy in cerebral palsy.
	Krupinski et al[902]	Long term follow-up of subcutaneous achilles tendon lengthening in the treatment of spastic equinus foot in patients with cerebral palsy.
	Lehtonene et al[361]	Does single-event multilevel surgery enhance physical functioning in the real-life environment in children and adolescents with cerebral palsy (CP)?: patient perceptions five years after surgery.
	Limpaphayom et al[903]	The split anterior tibialis tendon transfer procedure for spastic equinovarus foot in children with cerebral palsy: results and factors associated with a failed outcome.
	Mahmudov et al[904]	Comparison of single event vs multiple even soft tissue surgeries in the lower extremities with cerebral palsy.

Reference	Article Title
Mulcahey et al[905]	Computerised adaptive tests detect change following orthopaedic surgery in youth with cerebral palsy.
Niklasch et al[906]	Superior functional outcome after femoral derotation osteotomy according to gait analysis in cerebral palsy.
Niklasch et al[907]	Asymmetric pelvic and hip rotation in children with bilateral cerebral palsy: uni- or bilateral femoral derotation osteotomy?
Ounpuu et al[908]	Long-term outcomes after multilevel surgery including rectus femoris, hamstring and gastrocnemius procedures in children with cerebral palsy.
Sarikaya et al[909]	Improvement of popliteal angle with semitendinosus or gastrocnemius tenotomies in children with cerebral palsy.
Skiak et al[910]	Distal femoral derotational osteotomy with external fixation for correction of excessive femoral anteversion in patients with cerebral palsy.
Sossai et al[911]	Patellar tendon shortening for flexed knee gait in spastic diplegia
Terjesen et al[291]	Gait improvement surgery in ambulatory children with diplegic cerebral palsy.
Trehan et al[912]	Long-term outcomes of triple arthrodesis in cerebral palsy patients.
Yu et al[292]	Long-term ambulatory change after lower extremity orthopaedic surgery in children with cerebral palsy: a retrospective review.

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