Outcome domains and measures after lower limb orthopaedic surgery for ambulant children with cerebral palsy: an updated scoping review

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**ABBREVIATIONS**
ICF-CY International Classification of Functioning, Disability and Health – Children and Youth
PODCI Pediatric Orthopaedic Data Collection Instrument
PROM Patient-reported outcomes measure

**AIM** To determine the reported outcome domains and measures used to assess lower limb orthopaedic surgery of ambulant children and young people with cerebral palsy (CP) and map these outcomes to the International Classification of Functioning, Disability and Health – Children and Youth (ICF-CY) framework.

**METHOD** This updated scoping review included studies published between January 2016 and July 2019 in five databases: MEDLINE, PubMed, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials. Studies were included if participants were ambulant individuals with CP aged between 0 and 20 years who had undergone lower limb orthopaedic surgery. Health outcome domains and measures were identified and classified using the ICF-CY framework.

**RESULTS** Forty-four eligible studies were identified with a total of 40 different outcome domains recorded. Among eligible studies, 44 (100%) measured body function and structural impairment and seven (16%) measured activity limitation and participation restriction. The most frequently reported outcome was gait pattern (n=37, 84%). Few studies reported adverse effects of surgery (n=13, 30%). Twenty-nine different outcome measures were identified. Patient-reported outcomes measures were used in 10 studies (23%).

**INTERPRETATION** The review highlights a heterogeneity in the reported outcome domains and measures used in CP studies. The majority of the reported outcomes focus on the ICF-CY domain of body function and structure. The review also highlights a notable shift towards patient-reported outcomes in recent years. Development of a core outcome set for lower limb orthopaedic surgery would guide researchers to use more consistent and complete measurement sets.

Cerebral palsy (CP) is the most common cause of childhood physical disability, affecting 2 to 3 per 1000 live births.1 Approximately two-thirds of these children are ambulant, in Gross Motor Function Classification System (GMFCS) levels I, II, and III.2 Musculoskeletal deformities and resulting gait abnormalities are common and progressive during childhood, leading to pathological and compensatory gait patterns.3 Many children with CP undergo lower limb orthopaedic surgery to address secondary musculoskeletal deformities and gait abnormalities, and to improve or maintain mobility.4

The World Health Organization has produced the International Classification of Functioning, Disability and Health – Children and Youth (ICF-CY) to consider health outcomes. It categorizes health outcomes into the following components: (1) body structure and function impairment, (2) activity limitation, and (3) participation restriction.5 Each of these levels is subdivided into chapters that cover a range of health domains. It has been suggested that outcome evaluation would be improved by using measurement tools across each ICF-CY domain alongside specific quality of life measurement tools, as this would...
provide direct benefits to the patient and also contribute to improvements in clinical practice.6

More than 78 different outcome measures have been used in the assessment of interventions in CP.7 Between 1990 and 2011, 32 outcome measures were used to assess lower limb orthopaedic surgery for ambulatory children and young people with CP.4 The review by Zanudin et al.8 indicates that not all outcome measures perform consistently well with their psychometric properties (i.e. validity, relevance, reliability, and responsiveness to change).

In response to the variability in outcome measures used, many professional and scientific organizations, including the Core Outcome Measures in Effectiveness Trials initiative, have recommended standardized outcome measures for use in health research and practice.9 Although there is strong support for standardized measures for CP interventions,10–12 there is no consensus on the most important outcomes and outcome measures for assessment. This makes it challenging to compare and synthesize results across research performed in the field of lower limb orthopaedic surgery for ambulant children and young people with CP.13–15

Adoption of an accepted, standardized, and minimum collection of outcomes measures, known as a core outcome set, requires both input from relevant stakeholders and evaluation of the outcome measures’ psychometric properties.16 A key initial step in this process is to identify and summarize existing outcome domains and outcome measures used in published clinical trials through a scoping review.

A previous review4,17 identified 310 studies published between 1990 and 2015 which used outcome measures after lower limb orthopaedic surgery in children and adolescents with CP aged 0 to 20 years. From these 310 studies, 21 outcome measures assessed the ICF-CY domain of body structure and function, 10 measured activity and participation level, and three studies used a quality of life measure.4

The review by Wilson et al. identified outcome measures in published research between 1990 and 2015.5,17 However, in recent years, researchers and health care professionals have become more aware of patient priorities and have acknowledged the value of patient-reported outcomes. There has been a significant rise in studies published in recent years, with a 46% increase between pre- and post-2001.9 Therefore, before attempting to develop a core outcome set for future CP trials, it is important to update findings from the previous review to include studies published since 2016. Hence, the aim of this project was to: (1) undertake a scoping review of studies published between 2016 and 2019 in order to identify additional reported health outcome domains in lower limb orthopaedic surgery clinical trials for ambulant children and young people with CP, (2) identify which outcome measures were used to assess each ICF domain, and (3) compare the outcome measures used in the published literature before and after 2016.

What this paper adds

- There is heterogeneity in outcome domains and measures used across cerebral palsy studies.
- There is a trend towards increased use of patient-reported outcome measures in recent studies.
- Outcome domains in addition to specific outcome measures are identified and reported.
- Surgical adverse events are insufficiently reported.
- Nine additional outcome measures are identified.

METHOD

According to the Cochrane Review recommendation, a review update should be reconducted using the same methods as the original review,18 therefore, this review was in line with the methodology of the original scoping review.4 The protocol was drafted using the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols.19 The review was conducted and reported using recent recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-analysis – Scoping Review.20

Source and search

The search database and search terms were replicated from the original review and performed for the period between January 2016 and July 2019 using five electronic databases: MEDLINE (Ovid and in progress), PubMed, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials. The key search terms included ‘cerebral palsy’ AND ‘surgical procedures’ OR ‘surgery’ OR ‘operative’. The reference lists of all included studies were searched to identify any potentially relevant studies. Appendix S1 (online supporting information) shows specific key terms and how they were combined for each database.

Eligibility criteria

The title and abstract of potential studies identified were screened using the following inclusion criteria: (1) all study designs, provided that they reported at least one outcome measure; (2) studies that included both children and young people with CP; (3) children and young people diagnosed with ambulatory CP in levels I to III of the GMFCS; (4) participants aged between 0 and 20 years old; (5) any lower limb orthopaedic surgery; and (6) the full article was published in English.

Studies were not eligible if they met the following exclusion criteria: (1) observational investigations and qualitative studies that did not include an outcome measure; (2) grey literature; (3) studies involving participants older than 20 years; (4) reported treatment other than orthopaedic surgery to the lower limbs (e.g. upper limb surgery, physiotherapy); (5) reported surgery performed only for hip dysplasia.

Study selection process

The potential studies were exported into the reference manager, EndNote X8.2, in which duplicated studies were...
removal. A two-stage screening process was then undertaken. First, the titles and abstracts of potential studies were assessed against the inclusion criteria. Second, a full-text screening of studies included after the first stage was undertaken.

Two independent reviewers (HA, NW) conducted the screening process. Discrepancies were resolved by discussion and approved before data extraction.

**Data extraction**
A predesigned standardized data-extraction form was developed using Microsoft Excel to document essential data in a systematic manner. Data were extracted by two independent reviewers (HA and NW). Participant data items included: (1) number of participants, (2) age range, (3) sex ratio, and (4) GMFCS level. Intervention data were related to (5) surgery type. Study data items included: (6) date of publication, (7) study aim, (8) the country of origin, and (9) study design. Outcome data items included: (10) outcome domains and (11) outcome measures used. Outcome measures were only selected if at least one published study reported their psychometric properties. This was verified by checking the reference lists of eligible studies and also searching the bibliographic PubMed database for each outcome measure. If the outcome measures’ psychometric properties had not previously been evaluated, these were excluded from further review.

**Data analysis**
The content of each of the identified outcome domains and outcome measures was classified according to the ICF-CY domains. Adverse effect and harm outcomes were added as a fourth domain, consistent with previous recommendations. Data were then summarized using descriptive analysis, including the frequency and proportion of each reported outcome domain and outcome measures used to assess identified outcome domains.

**RESULTS**

**Selection of sources of evidence**
The literature search identified 5754 studies and the references lists screening yielded an additional 29 studies. All potential studies (n=5783) were imported into Endnote X8, 2241 duplicates removed, 3542 titles/abstracts screened, 3378 studies excluded, and 164 full texts screened. Of these, 120 studies were excluded: the majority of the excluded studies (n=68) were conference abstracts; 19 included non-ambulatory CP; 11 included adults with CP; 11 were related to hip dysplasia surgery for severe non-ambulant CP; one study included other disabilities; data were unavailable in one study; one study did not report outcome measures; and one was a validation study. Thus, the review included 44 studies on the effectiveness of lower limb orthopaedic surgery. The selection process details are outlined in Figure S1 (online supporting information). Full references for the included studies are provided in Table S1 (online supporting information).

**Characteristics of sources of evidence**
Only two (5%) of the 44 eligible articles were randomized controlled trials, and the remaining 42 articles (95%) were retrospective studies. The 44 studies addressed several orthopaedic surgical procedures in the lower limb, including bony surgery, soft tissue surgery, and combinations of bony and soft tissue surgery in the form of single event multi-level surgery. Sample size ranged from 6 to 314 (median 34). The majority of studies reported the GMFCS level (37 out of 44 papers, 84%).

**Outcome domains**
There were 184 reported outcomes describing 40 different outcome domains (Table 1). Outcomes were grouped into ICF-CY domains: (1) body structure and function and (2) activity and participation. Outcome groups were expanded to include the domains relating to (3) adverse effect and harm.

All studies identified reported outcomes relating to the impairment of body function and structures. Twelve outcomes that reflected body function and structure impairment domain made up 48% of the total reported outcomes (n=184). The most common outcome was ‘gait pathology and pattern’ (n=37, 84%), followed by ‘joint mobility’ (n=20, 45%), ‘muscle tightness’ (n=7, 16%), ‘muscle strength’ (n=6, 14%), and ‘pain level’ (n=4, 9%).

Only seven (16%) studies reported outcome domains related to the activity and participation level of the ICF-CY. Nineteen different outcomes related to activity and participation were identified, making up 37% of the total outcomes reported (n=184). Walking related outcomes were the most frequent and were represented within five studies (11%). Other less frequently reported outcomes included: ‘engaging in sports activity’, ‘self-care’, ‘standing and sitting ability’, and ‘activity engagement level’ (Table 1).

Only 30% of the studies (n=13) reported adverse events after lower limb surgery. The most commonly reported adverse event, reported in seven studies (16%), was infection, followed by recurrent surgery reported in five studies (11%). Other less frequently reported adverse events included: surgery failures such as implant failure and non-union, fracture, overcorrected surgery, complex regional pain syndrome, and depression.

**Outcome measure instruments**
Overall, there were 30 different outcome measures identified in the 44 studies. Dogan’s Scale was excluded as its psychometric properties have not been investigated. Thus, 29 outcome measures were included (Table 2). Outcome measures were categorized according to: (1) body function and structure, (2) activity and participation, and (3) adverse event and harm.

There were 23 clinician-administered measures (79% of the instruments), and six self-proxy administered measures: (1) Pediatric Orthopaedic Data Collection Instrument (PODCI), (2) Patient-Reported Outcome Measures
Information System,23 (3) Gillette Functional Assessment Questionnaire,24 (4) Pediatric Evaluation of Disability Inventory,25 (5) computerized adaptive tests,26 and (6) Mobility Questionnaire.27

Twenty (69%) of the outcome measures used were applied in the measurement of impairment of body structure and function. Outcome measures assessing gait pathology were the most common (37 out of 44 studies, 84%) and included gait analysis and its parameters: kinematics, kinet-ics, Gait Profile Score, Gait Deviation Index, and Gillette Gait Index. Clinical examination was the second most common outcome measure used and included: (1) joint range of motion data using a goniometer (n=17, 39%), (2) muscle strength using manual muscle testing (n=6, 14%), and (3) muscle spasticity using the Modified Ashworth Scale (n=5, 11%), Tardieu Scale (n=2, 5%), and Duncan Ely’s sign (n=1, 2%). Pain was only measured in four studies, as part of multi-dimension outcome measures such as PODCI, Patient-Reported Outcome Measures Information System, and computerized adaptive tests.

The patient and proxy (parent/carer) measures most commonly administered by questionnaires or interviews with health professionals were those used to assess the impact of surgery on activity and participation level such as walking, mobility, social function, and level of independence. However, there was inconsistency in the choice of measures: Gillette Functional Assessment Questionnaire (n=3, 7%), PODCI (n=3, 7%), while the Patient-Reported Outcome Measures Information System, Mobility Questionnaire 47, computerized adaptive tests, and Pediatric Evaluation of Disability Inventory had equal representation within the studies (n=1, 2%). Functional Mobility Scale (n=1, 2%) and Gross Motor Function measures (n=2, 5%) were the only clinician-administered tools for assessing motor function outcome. Surgical adverse events (complications) and harm were measured using the Clavien-Dindo system (n=3, 7%).
Timing of assessment

The timing of the outcome assessment ranged from less than 1 year to over 10 years postsurgery (Table S1). Short-term assessment (within 1y) was reported in 16 studies (36%), mid-term assessment (3–5y) in nine studies (20%), and long-term assessment (>10y) was only reported in three studies (7%). There was also variability in the follow-up point used within some studies (n=16, 36.5%), for example, Bittman et al.18 assessed outcomes at a range of time points between 6 to 36 months postsurgery.

All assessments of body structure and function were reported within different follow-up points, for example, 3D gait analysis to assess gait pattern at a range of time points from less than 1 year up to 10 years postsurgery. Of the studies reporting activity and participation outcome measures used decreased slightly from 34 in pre-2016 to 29 after 2016. As with the original review, the study designs were mostly retrospective and body structure and function were the most frequently measured outcomes.

Comparison of the literature before and after 2016

A comparison of pre- versus post-2016 literature was based on the outcome measures, as outcome domains were not identified in the original review. The number of outcome measures used decreased slightly from 34 in pre-2016 to 29 after 2016. As with the original review, the study designs were mostly retrospective and body structure and function were the most frequently measured outcomes.

Nineteen of the measurement tools included in the previous reviews4,17 were not identified in the updated review and nine additional measurement tools were identified that were not included in the previous review (Table 3).

Although the number of outcome measures used to assess the impact of lower limb surgery remains stable between reviews, there were differences in the type and frequency of outcome measures used. For example, the Gillette Gait Index was identified in studies both before and after 2016: however, the frequency was varied (n=20, 6% and n=1, 2% respectively; Table 4). In the updated review, quality of life was measured using multi-dimensional patient-reported outcomes measures (PROMs) such as Patient-Reported Outcome Measures Information System, rather than disease-specific outcome measures such as CP-Quality of Life29 or Paediatric Quality of Life Inventory.30

The GMFCS has been used in recent studies to describe study samples in terms of motor function level. Compared to pre-2016 findings, the GMFCS increased from 39% of the identified studies since its origin from 2003 to 2016, and 84% over the 2016 to 2019 period.

DISCUSSION

This updated review included additional studies with relevant clinical information on the outcome domains and outcome measures used in lower limb orthopaedic surgery in CP. The review identified 44 studies after 2016, suggesting that research in this field continues to expand. The updated review not only identified the outcome measures used in assessing lower limb orthopaedic surgery in CP but also provides novel information on what was measured based on the ICF-CY framework. Despite the relatively short period of time (2016–July 2019), the studies measured 40 different outcomes with no single outcome reported in all identified studies. The revised search yielded 29 outcome measures, of which nine were unique to this review which can be attributed to the continued development and expansion of CP outcome measures.

The majority of outcome domains and outcome measures identified mainly addressed the ICF-CY domains of impairment and functional levels, which was similar to the previous scoping reviews.4,17 Our observation may reflect that the natural history of children with CP is characterized by deterioration in posture and gait due to musculoskeletal pathologies, such as bone deformities and joint contractures. Therefore, health professionals might focus on improving children’s gait outcomes by addressing their musculoskeletal pathology.7

As observed in the previous review, there was an imbalance in the choice of the ICF-CY domains that were measured in the identified studies, favouring body structure and function. Although this may reflect the focus of
Table 4: Common outcome measures according to two-time period

| Outcome measures                                                                 | Pre-2016 | Post-2016 |
|----------------------------------------------------------------------------------|----------|-----------|
| Body function and structure                                                      | n (%)    | n (%)     |
| Clinical examination                                                             | 208 (67) | 31 (70)   |
| Gait analysis (kinematics with or without kinetics)                              | 192 (62) | 37 (84)   |
| Gait velocity                                                                    | 95 (31)  | 8 (18)    |
| Gait Profile Score                                                               | 11 (4)   | 8 (18)    |
| Gait Deviation Index                                                             | 20 (6)   | 12 (27)   |
| Gillette Gait Index                                                             | 20 (6)   | 1 (2)     |
| Radiology                                                                        | 77 (25)  | 7 (16)    |
| Foot pressure data                                                               | 8 (3)    | 3 (7)     |
| Oxygen consumption                                                               | 6 (3)    | 2 (5)     |
| Timed Up and Go                                                                  | 1 (1)    | 1 (2)     |
| Activity and participation                                                       |          |           |
| Gross Motor Function measure                                                     | 23 (7)   | 2 (5)     |
| Pediatric Evaluation of Disability Inventory                                     | 1 (1)    | 1 (2)     |
| Gillette Functional Assessment Questionnaire                                     | 13 (4)   | 3 (7)     |
| Functional Mobility Scale                                                       | 16 (5)   | 1 (2)     |
| Pediatric Orthopaedic Data Collection Instrument                                 | 10 (3)   | 3 (7)     |

The findings identify some trends in the use of PROMs for lower limb surgery. Various PROMs are available in this field, covering the majority of the outcome domains including pain, mobility, walking ability, independence, and social function. The PODCI and Gillette Functional Assessment Questionnaire were the most commonly used PROMs. This is likely because of the ability of PODCI to assess the impact of surgery across multiple domains of functioning (physical, mobility, and sport), pain, and happiness: the Gillette Functional Assessment Questionnaire assesses walking ability and mobility domains, which are recognized as important domains for children and their parents.3,11,12

Identified PROMs do not assess certain key outcomes such as joint range of motion, spasticity, and gait pathology, which are more likely to be assessed by the clinicians. Therefore, PROMs could be viewed as complementary measures to be used together with clinician-reported measures. Although several PROMs provide a self-assessment from the perspective of children or proxy, they differ in their level of objectivity, outcome assessed, feasibility, and cost. Little standardization was found across the five studies using PROMs, leading to limited ability to synthesize studies to explore the effectiveness of surgical interventions.9

Our findings highlight the limited use of quality of life outcome measures. Compared to the original review, where four studies reported quality of life as an outcome, no studies in this review specifically measured quality of life. McGinley et al.14 reported that ‘The relationships between orthopaedic deformities, function, and gait and both health-related quality of life and quality of life are poorly understood and are certainly not linear’. The majority of the studies assessed the short-term outcome postsurgery, and it may be that a 12- to 24-month time frame is insufficient to measure significant changes in an individual’s quality of life. Our findings are consistent with the study by Cuomo et al.33 who found that multilevel surgery had no impact on the children’s psychosocial well-being and state of happiness outcomes over a 12-month period postsurgery. Further research is needed to investigate the impact of the surgery on children’s quality of life over a longer period of time.

The review identified limited reports of adverse events which may indicate potential selection bias in reported outcomes within studies.13,14 Repeated surgeries and side effects (e.g. infection, neurovascular complications) were reported as adverse events of surgery; however, this accounts for less than 25% of the total outcomes identified, and was reported in only 15 out of 44 studies (34%). This imbalanced reporting between the benefits and harms can lead to a poor understanding of the impact of the surgery on an individual’s health.14 Furthermore, clear knowledge of postoperative complication risk is important since it can inform surgery choice by clinicians and is considered a key element for the patient to understand before giving consent for surgery.35

The heterogeneity in outcome measures across studies (n=29) was likely compounded by the variation of follow-up periods across studies. Investigating the maintenance of the surgical outcomes at different time points should be evaluated, but consistency in follow-up time points across studies is recommended to support comparisons in future systematic reviews and meta-analyses.36 Future studies are needed to identify the most clinically meaningful follow-up time points since surgery usually takes time to have an effect on a child’s level of activity and function.

The findings highlight the heterogeneity in outcome domains and measurement tools used in the literature. This heterogeneity has led to widely known problems of outcome reporting bias that makes it difficult to conduct meta-analyses of trial findings. This resonates with previous reviews regarding post-lower limb orthopaedic surgery outcome assessment in children with CP.4,13–15,17 One approach to improve this is to develop a core outcome set37 for lower limb orthopaedic surgery, which should be measured and reported as a minimum for all trials. It is also important to consider the rigorous evaluation of the
psychometric properties of the available outcome measures. An evaluation of the psychometric properties of common gait-related measures in CP has recently been published. These measures were appraised using the modified Consensus-based Standard for the selection of health measurement Instruments checklist. Further research should carefully consider this evaluation when determining core outcome measures set in this field.

To our knowledge, this is the first systematic scoping review that aims to underpin the development of a core outcome set for children with CP undergoing lower limb orthopaedic surgery. This revised review provides novel evidence including: (1) a comprehensive overview of the outcome domains assessed in this field of research alongside the outcome measures used, (2) a notable shift in use of patient-reported outcomes which is becoming common clinical practice, and (3) under-reporting of adverse events of patient-reported outcomes which is becoming common side the outcome measures used.

This review has some limitations. First, as in the original review, this review only included peer-reviewed articles published in English. Therefore, it may not include all relevant outcome domains and outcome measures. Another limitation of this review is including all peer-reviewed studies regardless of the study’s methodological quality.

CONCLUSION
A broad range of effectiveness outcome domains was identified from the literature with the focus predominantly on children’s body structure and function. The review highlights the dominance of clinical-based assessment with an increasing shift and awareness toward the use of patient-reported outcomes among researchers over recent years. It is evident that such domains are measured in different ways, with few consistently applied outcome measures. This heterogeneity reflects the challenges in conducting a review of effectiveness. It was also notable that few studies reported adverse event outcomes, which is of concern given the importance of understanding the adverse events in the surgical consenting process. Work needs to be done to standardize the outcome domains and outcome measures. An international core outcome set in this field should be developed to help improve future clinical trials.

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SUPPORTING INFORMATION
The following additional material may be found online:

Appendix S1: Search terms in each database.
Figure S1: PRISMA flowchart.
Table S1: Included studies.

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