A Prospective Cohort Study of the Effects of Lower Extremity Orthopaedic Surgery on Outcome Measures in Ambulatory Children With Cerebral Palsy

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Background: Lower-extremity musculotendinous surgery is standard treatment for ambulatory children with deformities such as joint contractures and bony torsions resulting from cerebral palsy (CP). However, evidence of efficacy is limited to retrospective, uncontrolled studies with small sample sizes focusing on gait variables and clinical examination measures. The aim of this study was to prospectively examine whether lower-extremity musculotendinous surgery in ambulatory children with CP improves impairments and function measured by gait and clinical outcome tools beyond changes found in a concurrent matched control group.

Methods: Seventy-five children with spastic CP (Gross Motor Function Classification System levels I to III, age 4 to 18 y) that underwent surgery to improve gait were individually matched on the basis of sex, Gross Motor Function Classification System level, and CP subtype to a nonsurgical cohort, minimizing differences in age and Gross Motor Function Measure Dimension E. At baseline and at least 12 months after baseline or surgery, participants completed gait analysis and Gross Motor Function Measure, and parents completed outcome questionnaires. Mean changes at follow-up were compared using analysis of covariance adjusted for baseline differences.

Results: Surgery ranged from single-level soft tissue release to multilevel bony and/or soft tissue procedures. At follow-up, after correcting for baseline differences, Gillette Gait Index, Pediatric Outcomes Data Collection Instrument Expectations, and Pediatric Quality of Life Inventory (PedsQL) Physical Functioning improved significantly for the surgical group compared with the nonsurgical group, which showed minimal change.

Conclusions: On the basis of a matched concurrent data set, there was significant improvement in function after 1 year for a surgical group compared with a nonsurgical group as measured by the Gillette Gait Index, with few significant changes noted in outcome measures. Changes over 1 year are minimal in the nonsurgical group, supporting the possibility of ethically performing a randomized controlled trial using nonsurgical controls.

Level of Evidence: Therapeutic level 2. Prospective comparative study.

Key Words: cerebral palsy, outcomes, children, orthopaedic surgery

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Lower extremity musculotendinous surgery is standard treatment for ambulatory children with deformities such as joint contractures and bony torsions resulting from cerebral palsy (CP). Ideally, these procedures are completed during 1 surgical setting to balance joint forces about the hip, knee, and ankle[1–3] by lengthening shortened muscle-tendon units and realigning bony levers.[4,5] The objectives of surgical management in CP are to improve function, decrease discomfort, and prevent disabling structural changes.[6,7] The assumption is that by improving gait, function in general will improve.[5]

Recommendations for specific surgical procedures vary because of the heterogeneity and complexity of CP[2] and lack of evidence-based protocols. Soft tissue surgery changes musculotendinous unit length, but does not reliably improve gait or overall function.[8] Many children with CP have gradually worsening gait and overall function as they age, which complicates outcome assessment.[9,10] Some have suggested that the minimum goal of lower extremity musculotendinous surgery should be to maintain rather than improve gait and function.[11]

Considerable evidence exists for the short-term impact of individual procedures on gait, such as rectus femoris transfer,[12–21] hamstring lengthening,[12–14,16,21–30] and heelcord lengthening.[14,29,31–36] These are based on retrospective, uncontrolled studies with small sample sizes focusing on gait variables and clinical examination

measures. At present, there are no published randomized controlled trials on the effectiveness of lower extremity musculotendinous surgery in improving the function of ambulatory children with CP.

The purpose of this study was to assess change after lower extremity orthopaedic surgery using a prospective multicenter cohort design. Surgical effectiveness was assessed using measures of function and quality of life. Outcome measures included International Classification of Functioning, Disability and Health (ICF)[37,38] measures of Body Function and Structure, Activity and Participation, and Health Related Quality of Life. The hypothesis was that surgery improves impairments and function beyond changes found in a nonsurgical group over 1 year.

METHODS

This study is part of a 6-year prospective multicenter study at 7 pediatric orthopaedic facilities. It included both cross-sectional and longitudinal assessments of ambulatory children with CP. The background and methods have been reported earlier.[39]

Participants

Institutional Review Board approval was obtained at each site and consent, assent as appropriate, and Health Insurance Portability and Accountability Act forms were completed for participants. Inclusion criteria were diagnosis of CP, Gross Motor Function Classification System (GMFCS) levels I to III, age 4 to 18 years, and the ability to complete gait analysis. Exclusion criteria were earlier selective dorsal rhizotomy, orthopaedic surgery within the last year, botulinum toxin A injections in the last 6 months, or a currently operating baclofen pump.

Five hundred –and sixty-two participants completed the baseline study. Ninety-one subsequently received lower extremity surgery during the study period as part of their ongoing care. All participants were invited to complete a follow-up assessment; 387 participants (68.7%) returned. Of these, 18 were excluded because of missing data. From the remaining 369 (75 surgical, 294 nonsurgical), an individually matched cohort of 150 participants (75 surgical, 75 nonsurgical) was identified.

Procedures in the surgical group included both soft tissue and bony surgery (Table 1). Fourteen participants received botulinum toxin injections within the study window in addition to their surgery. Forty-one participants had no earlier surgery, 33 had earlier surgery, and previous surgical history was unknown for 1 participant.

The matched data set included 28 pairs in GMFCS level I (7 female, 21 male), 30 in GMFCS level II (10 female, 20 male), and 17 in GMFCS level III (12 female, 5 male). There were 56 pairs with diplegia or quadriplegia and 19 with hemiplegia. The involved side was selected for analysis for those with unilateral involvement and 1 side was randomly selected for those with bilateral involvement, resulting in 75 limbs in each of the surgical and nonsurgical groups.

TABLE 1. Details of the Number of Bony and Soft Tissue Procedures Performed on 75 Participants in the Surgical Group

	No. Participants
Number in surgical group	75
Surgical Procedures	
Soft tissue procedures only	50
Bony procedures only	5
Bony and soft tissue procedures	20
Soft Tissue Procedures	
Rectus femoris transfer	33
Hamstring lengthening	47
Heelcord lengthening	50
Other foot/ankle transfers	16
Adductor lengthening	13
Psoas lengthening	11
Bony Procedures	
Femoral derotation osteotomy	13
Tibia/fibula derotation osteotomy	7
Lateral column lengthening	3

Data Collection

Participants completed gait analysis, Gross Motor Function Measure (GMFM-88[40]; GMFM-66[41]), Gillette Functional Assessment Questionnaire,[42] Pediatric Quality of Life Inventory [PedsQL (Mapi Research Institute, Lyon, FR)],[43] Pediatric Outcomes Data Collection Instrument (PODCI),[44] and Pediatric Functional Independence Measure [WeeFIM (Uniform Data System for Medical Rehabilitation, Amherst, NY)],[45] at baseline and follow-up. Parent and child reported separately when appropriate. This study focuses on parent-reported measures. After the baseline study, participants received ongoing clinical care based on physician recommendations. Each participant was reassessed a minimum of 1 year after baseline or surgery. Average time between studies was 1.5 [standard deviation (SD) 0.4] years for the surgical group and 1.3 (SD 0.4) years for the nonsurgical group.

Analysis

The 75 participants who received surgery during the study period were individually matched with 1 of the 294 participants who did not have surgery after the completion of the study procedures. For each surgical participant, all nonsurgical participants who exactly matched by sex, GMFCS level, and type of involvement (hemiplegic or diplegic) were identified. Then, the nonsurgical participant with the smallest Euclidean distance between the normalized z scores for both age and GMFM Dimension E (Walking, Running, and Jumping) at baseline was selected. The z-score transformation normalizes distributions (mean of 0 and SD of 1). The resulting distances allow comparisons among scores in units of SDs.

The Gillette Gait Index (GGI) is calculated using 16 gait parameters from 1 representative stride.[46] Greater gait deviations from normal are reflected by a larger GGI. Under a separate protocol, 49 typically developing children and adolescents underwent gait analysis to establish 16 ± 5 as a mean normal score for the GGI.

Statistical Methods

Change in outcome scores and GGI between baseline and follow-up were calculated for the involved limbs. To compare mean response between surgical and nonsurgical participants at follow-up an analysis of covariance was constructed for each endpoint with covariates being the corresponding baseline measure and baseline Parent PODCI Transfers and Basic Mobility, GGI, gait velocity, earlier botox injection, earlier surgical procedure, and site, a surrogate for surgeon. These covariates were selected to account for differences at baseline, and possible differences in severity, earlier treatment, and treatment site. Statistical significance was determined at the 0.05 level throughout. Changes in surgical and nonsurgical group scores at follow-up were compared with a minimum clinically important difference (MCID) for a medium effect size.[47] As defined by Oeffinger et al,[47] MCIDs are changes greater than those expected to occur with standard of care (not including surgical intervention) in 1 year. Differences because of the type of surgical intervention and type of involvement were examined using analysis of variance ($P < 0.05$).

RESULTS

The Euclidean distance of the combined normalized age and GMFM Dimension E between the matched surgical and nonsurgical participants was used as an indicator of the quality of the matching process. Table 2 displays demographic and matching variables. The mean distance was 0.37 SDs (SD 0.32) for the group, indicating a close fit with low variability.

Outcome scores at baseline and follow-up for the surgical and nonsurgical groups are shown in Table 3. At follow-up, accounting for differences in corresponding baseline measure and baseline Parent PODCI Transfers and Basic Mobility, GGI Velocity, earlier botox injection, earlier surgical procedure, and site, a surrogate for surgeon, the adjusted mean GGI score is significantly higher in the nonsurgical group (266 ± 15) compared with the surgical group (201 ± 15, $P = 0.001$). The magnitude of difference between the groups increased with increasing GMFCS level ($P = 0.022$). The adjusted mean for the nonsurgical group is almost that observed at baseline whereas the adjusted mean for the surgical group is much lower than baseline. Figure 1 illustrates changes in GGI by GMFCS level.

TABLE 2. Mean (SD) of Demographic Variables Used for Matching Surgical and Nonsurgical Groups at Baseline Evaluation (N = 75 Matched Pairs)

Matching Components	Surgical	Nonsurgical
Age (y)	11.3 (3.1)	11.3 (2.9)
Height (cm)	139.7 (19.0)	139.8 (18.3)
Weight (kg)	38.7 (16.5)	40.5 (18.4)
GMFM Dimension E (%)	74.5 (26.4)	73.9 (26.1)
Matching (SD)	0.37 (0.32)	
N	75	75

GMFM indicates Gross Motor Function Measure.

After adjusting for baseline differences, the mean Parent PODCI Expectation subscore is significantly higher (better) at follow-up in the surgical group (78.4 ± 2.9) compared with the nonsurgical group (68.8 ± 2.9, $P = 0.013$). The mean PedsQL Physical Functioning subscore is significantly higher at follow-up in the surgical group (60.5 ± 2.2) compared with the nonsurgical group (54.7 ± 2.1, $P = 0.039$). The adjusted mean for the nonsurgical group is lower than at baseline whereas the adjusted mean for the surgery group is higher for both of these findings. No other subscores showed a statistically significant difference at follow-up after adjusting for baseline differences.

To evaluate the effect of earlier surgery in the surgical group, the 42 participants with no earlier surgery were compared with the 33 participants with earlier surgery. At baseline, those with earlier surgery were older (12.5 vs. 10.4 y, $P = 0.005$) and walked faster (82.8 vs. 71.5% normal, $P = 0.038$). Despite these differences, there were no significant differences between the groups from baseline to follow-up. There were no significant differences between groups because of the type of surgical intervention (bony vs. soft tissue vs. bony plus soft tissue) or involvement (hemiplegic vs. diplegic).

DISCUSSION

This study prospectively evaluated the changes in gait and function over 1 year in ambulatory children with CP. Within the study window, 75 participants had lower extremity orthopaedic surgery and completed follow-up assessment at least 12 months after surgery. These were individually matched to 75 participants who did not have surgery, either because it was not recommended based on full clinical assessment including 3-dimentional gait analysis, or because the family did not elect to move forward with surgery during the study period, creating a concurrent control group who received all standard care except surgery. Effectiveness of the matching process was shown by an average distance of 0.37 SDs between matching parameters for pairs of participants.

It was hypothesized that the surgical group would improve in function beyond changes found in the nonsurgical group. We expected the nonsurgical group to deteriorate slightly in function or remain stable and the surgical group to have a net improvement at 1-year follow-up in subscores related to function. The nonsurgical group received standard of care (observation, stretching and strengthening exercises, bracing and medication management, as necessary) within the study window. They did not have any surgery, botulinum toxin injection, or baclofen pump insertion. There is evidence of a gradual decrease in function in children with CP as they age,[9–11] perhaps resulting from a worsening strength-to-mass ratio. The findings of this study revealed no improvement or worsening between baseline and follow-up for the nonsurgical group that was statistically

TABLE 3. Mean (SD) of Outcome Scores at Baseline, Adjusted Mean (SE) of Outcome Scores at Follow-up With *P* Values for Comparing Means, and Minimum Clinically Important Difference for a Medium Effect Size

	Baseline		Follow-up			
	Surgical	**Nonsurgical**	**Surgical**	**Nonsurgical**	**ANCOVA *P****	**MCID (0.5)**
GGI	310 (274)	262 (167)	**201 (15)**	**266 (15)**	**0.001**	100
GMFM Dimension D	83.0 (17.9)	82.2 (18.7)	83.0 (1.2)	84.6 (1.2)	0.331	1.8
GMFM Dimension E	74.5 (26.4)	73.9 (26.1)	73.8 (1.3)	76.0 (1.3)	0.192	2.6
GMFM-66	75.0 (12.7)	74.4 (12.9)	75.0 (0.6)	76.2 (0.6)	0.172	1.3
PODCI Global Function	72.3 (14.6)	74.7 (13.6)	77.5 (1.4)	76.8 (1.4)	0.489	6.0
PODCI Upper Extremity	79.6 (18.6)	79.9 (15.1)	82.8 (1.4)	84.0 (1.4)	0.543	5.4
PODCI Transfers	79.8 (15.3)	83.4 (14.7)	86.0 (1.3)	86.4 (1.3)	0.795	6.4
PODCI Sports	54.2 (20.7)	55.8 (19.5)	57.5 (1.9)	57.0 (1.8)	0.850	6.8
PODCI Comfort/Pain	75.4 (23.1)	79.5 (22.7)	83.4 (2.8)	80.4 (2.7)	0.398	18.0
PODCI Happiness	75.6 (20.2)	75.2 (19.4)	78.9 (2.3)	78.4 (2.3)	0.850	15.6
PODCI Satisfaction	45.3 (34.3)	54.7 (32.3)	62.0 (4.2)	55.7 (4.1)	0.247	23.0
PODCI Expectations	73.7 (17.1)	72.8 (18.5)	**78.4 (2.9)**	**68.8 (2.9)**	**0.013**	21.2
PedsQL Physical Functioning	55.8 (19.8)	59.0 (19.7)	**60.5 (2.2)**	**54.7 (2.1)**	**0.039**	12.7
PedsQL Emotional Functioning	67.6 (17.5)	66.9 (16.0)	68.8 (2.0)	64.7 (1.9)	0.109	10.5
PedsQL Social Functioning	55.1 (20.5)	56.5 (19.2)	59.4 (2.5)	55.4 (2.5)	0.221	12.8
PedsQL School Functioning	64.9 (17.3)	61.8 (16.3)	67.1 (2.0)	64.6 (1.9)	0.320	12.3
WeeFIM SelfCare	86.7 (14.6)	92.6 (10.3)	90.8 (1.5)	92.4 (1.4)	0.385	5.0
WeeFIM Mobility	90.6 (10.6)	93.1 (7.9)	94.2 (1.0)	93.1 (0.9)	0.397	3.9
WeeFIM Cognition	94.4 (10.1)	95.4 (7.4)	94.8 (1.1)	93.9 (1.0)	0.482	5.5
Cadence (%normal)	97.6 (18.3)	98.9 (17.6)	101.1 (1.9)	102.1 (1.8)	0.700	8.1
Stride length (%normal)	78.7 (18.2)	79.6 (16.9)	77.2 (1.5)	75.7 (1.4)	0.409	5.8
Velocity (%normal)	77.8 (23.7)	78.9 (22.3)	79.1 (2.0)	78.6 (1.9)	0.844	9.1

Statistically significant findings are shown in bold, $P < 0.05$.

*From ANCOVA with means adjusted for the corresponding baseline measure and baseline Parent PODCI Transfers and Basic Mobility, GGI, Velocity, earlier Botox injection, earlier surgical procedure, and site, a surrogate for surgeon.

ANCOVA indicates analysis of covariance; GGI, Gillette Gait Index; GMFM, Gross Motor Function Measure; MCID, minimum clinically important difference; PedsQL, Pediatric Quality of Life Inventory; PODCI, Pediatric Outcomes Data Collection Instrument.

significant and none that exceeded a MCID. Earlier studies have looked at decreases over a longer time frame. A 12-month to 15-month time frame may be insufficient to measure significant changes in function without surgical intervention. Similarly, the effectiveness of surgery may need to be evaluated over a longer time period. Prevention or alleviation of musculoskeletal deformity because of orthopaedic surgery in childhood may result in lesser pain and disability in adults with CP, who are at risk for declining mobility at an earlier age than individuals without CP.[48]

The GGI showed improvement in the surgical group whereas no change was noted in the nonsurgical group over the 1-year time frame. This finding may reflect that surgeons use gait analysis to identify kinematic deviations and perform surgery to establish a more "normal" biomechanical alignment. GGI was designed specifically to quantify lower extremity kinematic deviations based on a composite score. GGI has been shown to correlate with other functional measures in individuals with CP.[42,49]

In this study, after accounting for baseline differences, statistically significant changes in functional

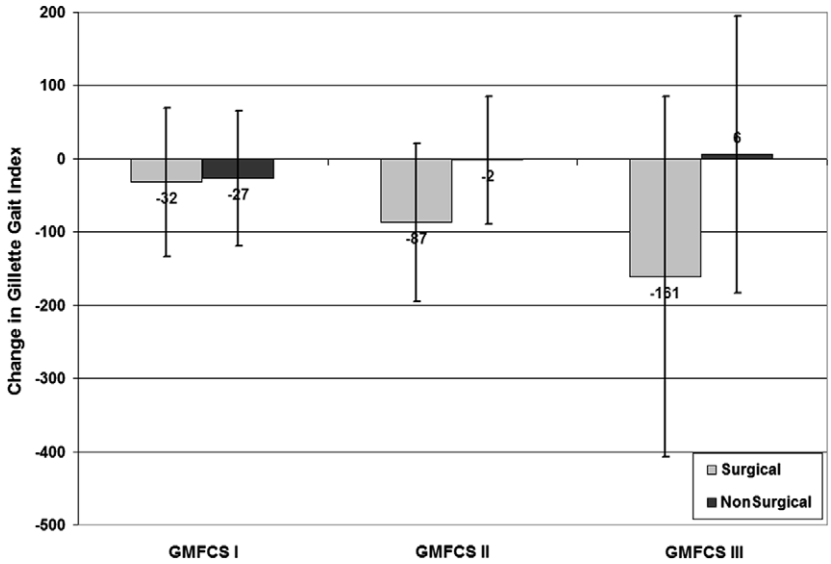

FIGURE 1. Change in Gillette Gait Index (GGI) by Gross Motor Function Classification System (GMFCS) level for the surgical and nonsurgical groups from baseline to follow-up. A negative change shows a GGI moving closer to normal. The standard deviation is shown as an error bar. This figure shows an effect of GMFCS level on magnitude of change after surgery for the surgery group, with no change in the nonsurgical group.

measures were noted for the PedsQL Physical Functioning subscore. In addition, the Parent PODCI Expectations score improved slightly in the surgical group and worsened slightly in the nonsurgical group. Neither of these changes exceeded a MCID. Changes in GGI, at the ICF level of Body Structure, do not consistently translate to changes in ICF measures of Body Function or Activity and Participation as measured by the study outcome instruments. This is consistent with the study of Abel et al,[8] who found at best a weak correlation between measures of impairment and measures of function.

This study compared results of a matched data set of participants from 7 pediatric orthopaedic centers. This was not a randomized controlled trial and the criteria for patient assignments by group were not standardized. The matching procedure created concurrent surgical and nonsurgical groups within the study window. Surgical treatment selections and procedures were not standardized. Surgical procedures were a heterogeneous mix ranging from soft tissue releases alone to multilevel bony and soft tissue procedures, making it difficult to draw conclusions about any specific surgical approach. Some of the participants had earlier surgery; others had not. The sampling reflected current treatment approaches by experienced pediatric orthopaedic surgeons to improve physical functioning in ambulatory children with CP. The study did not include nonambulatory children and the results should not be generalized to nonambulatory children with CP. Further randomized controlled trials with strict selection criteria and treatment protocols or large-scale practical clinical trials may be needed to understand the functional benefits from specific surgical procedures.

There were limitations in the matching process used in this study. There was no attempt to match based on preoperative gait kinematics, joint spasticity, or other clinical indications typically used in determining appropriateness for musculoskeletal surgery. Individual gait patterns were not available, only a combined assessment of the magnitude of gait deviation through the GGI; therefore, we are unable to determine whether the type of gait deviation altered the magnitude of change over 1 year. There may be other variables not included in the data collection and matching process that would improve matching. No a priori expectation existed for any of the enrolled participants to have surgery. Recommendations for surgery in the nonsurgical group are unknown. If surgery was recommended for these participants, but not performed, there might have been a greater expectation for decreased function over time. The surgical group had a trend for a higher baseline GGI, showing more differences from normal at baseline; however, the differences between the groups at baseline were minimal. Only WeeFIM SelfCare exceeded the threshold for MCID with a lower score in the surgical group. Thus, the 2 groups were as similar as possible at study initiation. The analytic methods used to evaluate outcome at follow-up accounted for differences between the groups at baseline.

Five participants had bony procedures alone in this study; an additional 20 had soft tissue procedures concurrent with bony procedures. The small sample sizes do not permit a well-powered analysis comparing outcomes based on types of procedures. Many of the participants (44%) had earlier surgery and bony correction may have occurred in this group before soft tissue procedures; however, this was not explicitly analyzed.

There was no attempt to correct for multiple comparisons in this study. The results showed consistent trends for improvement in the surgical group and worsening or no change in the nonsurgical group. Those parameters found to be statistically significant are consistent with expectations. It is unlikely that the results would change using a different threshold for statistical significance.

This study reflects clinical practice at 7 institutions over 1 year. The results provide a background for future randomized controlled trials or practical clinical trials to estimate sample and effect sizes, select outcomes of interest, and refine methodologic issues. Changes over 1 year are minimal in the nonsurgical group. This may support the ability to ethically perform a randomized controlled trial using a nonsurgical control group.

In conclusion, based on a matched concurrent data set, there were significant improvements in gait kinematics from baseline to follow-up for the surgical group compared with the nonsurgical group as measured by the GGI. PODCI Expectations and PedsQL Physical Functioning showed statistically significant improvements between the surgical and nonsurgical groups 12 months following baseline; however, these did not exceed an MCID. The greatest changes occurred at the ICF Body Structure and Function level, closest to the level of surgical intervention and did not translate into clinically significant changes in Activity and Participation. Measuring self-esteem, self-perception, and other Health-Related Quality of Life indicators and expanding measurement of impairments (such as body composition or strength) and participation may result in stronger links between function and orthopaedic surgical outcomes for future studies.

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