

Health-Related Quality of Life Outcomes Improve After Multilevel Surgery in Ambulatory Children With Cerebral Palsy

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Background: Studies evaluating multilevel surgery to treat spastic deformity and functional deficits in cerebral palsy (CP) usually focus on data from instrumented gait analysis and clinical examination without examining functional and health-related quality of life (HRQOL) outcomes. Recently, outcome measures for well-being in children with a variety of musculoskeletal disorders have also been validated specifically for CP. Therefore, this study aimed to investigate the impact of multilevel surgery on the function and HRQOL in a group of ambulatory children with CP.

Methods: In a multicenter prospective trial, 57 ambulatory children with CP, mean age 9.5 years, underwent multilevel soft tissue surgery to correct sagittal imbalance. Validated clinical outcome measures for HRQOL were administered preoperatively and postoperatively with an average follow-up time of 15.2 months. The functional and psychosocial components of the Pediatric Outcomes Data Collection Instrument (PODCI), Pediatric Quality of Life Questionnaire (PedsQL), and the Functional Assessment Questionnaire Walking Score were used.

Results: Significant improvements in outcome scores occurred postoperatively in the following: PedsQL parent-total (17.6%; $P < 0.001$) and parent-physical sections (25.0%; $P < 0.001$), the Functional Assessment Questionnaire Walking Score (15.3%; $P < 0.001$), and the PODCI sections for transfers and basic mobility (15.8%; $P < 0.001$), sports and physical function (23.9%; $P = 0.012$), and global (12.9%; $P < 0.001$). Improvements also occurred in the PedsQL child-total (8.4%; $P = 0.104$) and child-physical sections (8.6%; $P = 0.189$), but these were not statistically significant. There were no significant changes in the PODCI parent-derived pain (-3.2% ; $P = 0.504$) and happiness sections (1.9%; $P = 0.645$).

Conclusions: Multilevel surgery in ambulatory patients with CP improves function and HRQOL. However, improved functional well-being does not imply improved psychosocial well-being, and patients and their families should be counseled accordingly.

Level of Evidence: Therapeutic Level II. See Instructions to Authors for a complete description of levels of evidence.

Key Words: health-related quality of life, cerebral palsy, FAQ Walking Score, PODCI, PedsQL

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Cerebral palsy (CP) is a static encephalopathy resulting in physical deformity, spasticity, weakness, poor balance, and impaired selective motor control. Not surprisingly, children with CP have impaired functional and psychosocial well-being compared with their normative peers.^{1–4} Orthopaedic surgeons have long performed surgery aimed at correcting deformity for children with CP assuming that improved deformity yields improved function and well-being. A number of studies have supported this concept in part, demonstrating that multilevel surgery improves physical deformity and function by correlating more normal scores in objective outcome measures such as clinical examinations and gait analysis.^{5–9} However, Abel et al¹⁰ has questioned the causal links between deformity and function, suggesting a nonlinear or threshold-mediated association. Regardless, the impact of surgery on parent and child perception of well-being is potentially independent of both deformity and function and therefore deserves further study.¹¹

A state of well-being encompasses both functional and psychosocial perceptions that are multifactorial in nature. Health-related quality of life (HRQOL) questionnaires addressing both parent and patient perceptions of function, comfort, and happiness have been developed and validated for children suffering from a variety of neuromuscular disorders.^{12–16} However, these outcome tools have only recently been validated specifically for children with CP.^{17,18} Two subsequent studies have demonstrated that objective functional measures can predict functional well-being, but are not well correlated to psychosocial well-being.^{10,11} However, they were not designed to assess changes in well-being subsequent to surgical intervention, and any positive correlation to surgery would have to be inferred. To specifically address this association, a recent study by Damiano et al¹⁸ was able to show that an improvement in function is linked to an improvement in functional well-being without significant impact on psychosocial well-being. However, substantial variations in responsiveness occurred between similar domains of the Gross Motor Function Measure (GMFM) and the Pediatric Outcomes Data Collection Instrument (PODCI) and the authors concluded that each validated

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TABLE 1. PedsQL and FAQ Walking Score Functional Outcomes

	No. Subjects	Preoperative Mean	Postoperative Mean	Percent Change*	Standard Error	P
PedsQL parent total	57	56.83	66.86	17.6	1.87	<0.001
PedsQL child total	30	61.12	66.23	8.4	2.34	0.104
PedsQL parent physical	57	48.19	60.24	25.0	2.82	<0.001
PedsQL child physical	30	57.65	62.64	8.6	2.85	0.189
FAQ Walking Score	57	6.94	8.00	15.3	0.29	<0.001

*[(postoperative mean) – (preoperative mean)] × 100 / (preoperative mean).

outcome measure uniquely weighs its results. Together, these studies have begun to accurately assess HRQOL outcomes and suggest a need for further investigations to better correlate surgical intervention to improved HRQOL in children with CP. They also highlight the potential challenges of interpreting subjective outcome measures.

Our hypothesis was aligned with the common belief that multilevel muscle-tendon lengthening (MTL) surgery to improve function will also improve functional and psychosocial well-being. This study was designed to prospectively assess HRQOL in ambulatory children with CP undergoing multilevel MTL surgery using a raft of validated outcome measures. A baseline assessment and a 12-month postsurgical assessment of HRQOL were performed using version 2 of the PODCI,¹² version 4 of the Pediatric Quality of Life instrument (PedsQL),^{15,19} and the Gillette Functional Assessment Questionnaire (FAQ) Walking Score.²⁰

METHODS

Five Shriners Hospitals participated in this study. The study was approved by the institutional review board of Shriners Hospitals. All patients with the following inclusion criteria were considered: a child with a diagnosis of CP aged 4 to 18 years, a history of household or community ambulation, and 1 or more surgical indications for MTL surgery (greater than 30 degrees hip flexion contracture, less than 30 degrees passive hip abduction, a greater than 45 degrees popliteal angle, and less than 0 degrees of passive ankle dorsiflexion). All patients underwent MTL surgery as

indicated by their physical findings. Iliopsoas recessions were performed for hip flexion contractures, adductor tenotomies were performed for adduction contractures, hamstring lengthenings were performed for knee flexion contractures, and tendoachilles lengthenings or gastrocnemius recessions were performed for equinus contractures. Each patient received standard postsurgical care and underwent casting or bracing to maintain correction of their deformities in the acute postsurgical setting.

The participants were assessed by clinical examination and by validated outcome measures at presurgical baseline and approximately 12 months of postsurgery (mean, 15.2 months). The validated outcome measures administered before surgery and at 1-year follow-up included the FAQ Walking Score, the PODCI (transfers and basic mobility, sports and physical function, pain, happiness with physical condition, and global), and the parent- and child-derived physical summary scores of the PedsQL (physical and total). The same caregiver completed the baseline and follow-up forms.

STATISTICAL METHODS

The data were assumed to be nonparametric in its distribution and, therefore, Wilcoxon signed rank tests were used to detect significant differences between paired observations of preoperative and postoperative outcome measures.

RESULTS

A total of 57 participants from the 5 institutions were identified, enrolled, and completed preoperative and

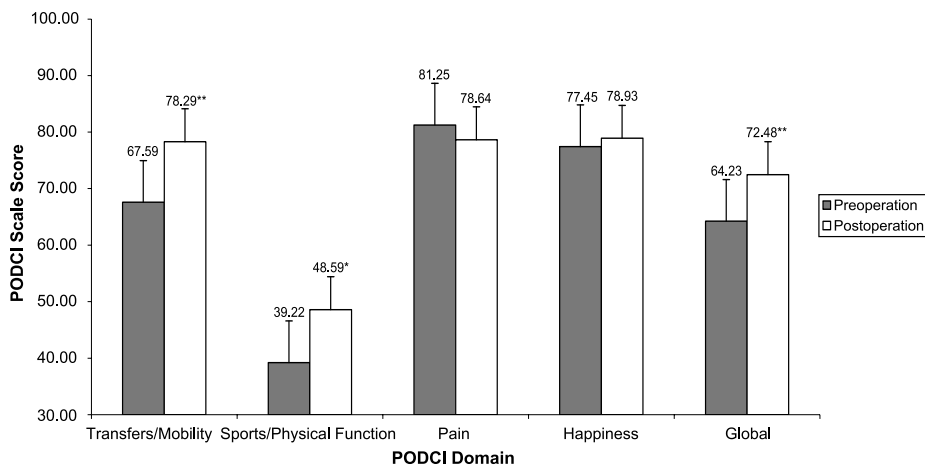


FIGURE 1. PODCI domain outcomes scores for both preoperative (preop) and postoperative (postop) questionnaires. (* $P < 0.012$, ** $P < 0.001$).

postoperative HRQOL evaluations. Patient demographics and presurgical and postsurgical HRQOL scores were collected from each institution. Patient ages ranged from 5 to 15 years (mean, 9.5 years), with follow-up ranging from 10 to 30 months (mean, 15.2 months). Of 57 patients, 27 were too young to effectively comprehend and complete the child-based questionnaires. This is reflected by a decrease in subjects that were able to participate in the child-based portions of the HRQOL evaluation.

The PedsQL and FAQ Walking Score outcomes are listed in Table 1. The PODCI results are depicted in Figure 1. Significant improvements in outcome scores occurred postoperatively in the following: PedsQL parent-total (17.6%; $P < 0.001$) and parent-physical sections (25.0%; $P < 0.001$), the FAQ Walking Score (15.3%; $P < 0.001$), and the PODCI sections for transfers and basic mobility (15.8%; $P < 0.001$), sports and physical function (23.9%; $P = 0.012$), and global (12.9%; $P < 0.001$). Improvements also occurred in the PedsQL child-total (8.4%; $P = 0.104$) and child-physical sections (8.6%; $P = 0.189$), but these were not statistically significant. There were no significant changes in the PODCI parent-derived pain (-3.2% ; $P = 0.504$) and happiness sections (1.9%; $P = 0.645$).

DISCUSSION

A basic tenet of orthopaedic surgery is that structure affects function and quality of life. In the context of CP, the role of an orthopaedic surgeon has been to correct flexion contractures and rotational deformities with a goal of improved range-of-motion and ambulation. As a result, treatment of deformity with multilevel surgery has become a major focus. Current surgical concepts began with the realization that the deformities in children with CP were multilevel in nature,^{21,22} and the full benefit of any surgery can only be obtained when all contractures of the hip, knee, and ankle have been corrected.²³ Gait analysis has shed light on the complex 3-dimensional multilevel interactions of muscles and joints²⁴⁻²⁶ and has provided a platform to advocate that multilevel surgery effectively corrects deformity and improves function.^{25,27} Despite the evidence of functional gain, laboratory-based gait analysis may not provide a comprehensive measure of community function.⁶ Furthermore, the relationship between structure and function is not direct and may not be linear, suggesting the importance of other factors such as motor control and voluntary strength deficits.¹⁰ When combined with the increasing appreciation of the broad functional and psychosocial impacts of CP,²⁸⁻³⁰ outcome research must now take the quest for information "...outside the gait laboratory and into the home and the community..."⁵

This prospective clinical study was aimed to assess changes in HRQOL in children with CP after multilevel surgery. To measure change in function, all patients received a FAQ Walking Score, which is a parent-derived assessment encompassing a range of walking abilities from nonambulatory to ambulatory in all community settings and terrains. This walking scale has proven an excellent and reliable measure of walking ability that correlates to standardized

functional outcome measures, energy expenditure, and gait-analysis information.²⁰ To assess the change in perception of function, the parents completed the functional domains of the PODCI (transfers and basic mobility, sports and physical function, global) and both parents and children completed the functional sections of the PedsQL (physical and total). Despite the strong correlation between the GMFM and the functional domains of the PODCI in prior studies, we chose not to use the GMFM due to its noted ceiling effect in more functional children with CP.^{10,11,18} To assess the change in perception of psychosocial well-being, parents completed the psychosocial domains of the PODCI (pain and happiness with physical function). All assessments were completed preoperatively for a baseline measurement and during a 1-year postoperative follow-up clinical examination. Significant improvements in outcome scores occurred postoperatively in the following: the FAQ Walking Score, the PedsQL parent-total and parent-physical sections, and the PODCI sections for transfers and basic mobility, sports and physical function, and global. There was no significant impact on the child's perception of functional well-being, nor was there a measurable impact on the parent or child's perception of pain and happiness. In essence, the outcome data suggest a direct and/or indirect association between functional improvement and the parental perception of improved functional well-being, but no measurable impact on psychosocial well-being.

There are several limitations in this study that deserve mention. The analyses rely on surrogate parental assessment of subjective outcomes because only the parent forms for the PODCI were completed, and many children were too young to effectively complete the PedsQL child forms. The lack of statistical significance in the child subsets of the PedsQL may be a result of inadequate power or sensitivity to change. However, parent perception of well-being and HRQOL has been shown to be an adequate surrogate,¹² and this study was able to show a significant improvement in all parent-derived functional domains of the PedsQL and the PODCI. It is also possible that a 12-month follow-up may not provide enough time to measure change in a developmentally delayed population. Although the PODCI has been shown to be sensitive to change over a 9-month period,¹² this may be specific to both age and degree of impairment. Although a longer follow-up time may reveal greater differences in patient or parent perceptions of the treatment effect, the continually progressive nature of the disorder may confound the issue. A recent study by Saraph et al³¹ demonstrated a general decline in gait function 1 year after a single-event multilevel surgery, suggesting a peak effect 1 year post-surgically and highlighting the importance of both short- and long-term follow-up. This study is also vulnerable to variable surgical outcomes that may affect HRQOL outcomes. Technical surgical data were available from a single institution (data not shown), which demonstrated improved gait analysis parameters as well as hip extension, hip abduction, knee extension, and ankle dorsiflexion after multilevel MTL surgery. These outcomes correlate well with other reports of technical surgical outcomes,³²⁻³⁶ suggesting that surgical outcome variability is relatively

minor. Lastly, a nonsurgical cohort would have strengthened the findings; however, these cohorts are also subject to bias unless randomized, which has complicated ethical considerations when surgical intervention is considered the current standard of care. Although a nonsurgical cohort may theoretically show similar functional improvements, we feel that this is unlikely. The natural history of gait and function in this population is deterioration with the passage of time.³⁷ Further investigation in the form of a randomized controlled trial may be appropriate to address this issue.

Both the functional and psychosocial outcomes from this study largely agree with current reports of HRQOL outcomes in this population. A cross-sectional study of 90 ambulatory children with CP by Pirpiris et al¹¹ also revealed a strong correlation between physical function and the functional well-being domains of the PODCI and PedsQL without a significant correlation between physical function and psychosocial well-being. Interestingly, the FAQ Walking Score was the strongest functional predictor of pain in their study; however, our study did not show a statistically significant association ($P = 0.504$). This supports the intuitive notion that patients with less pain are able to ambulate better. Although multilevel MTL may not affect pain and its impact on ambulation, it can improve the physical restrictions on ambulation, thereby improving ambulation without improving pain. This finding parallels the results in the prospective study by Damiano et al,¹⁸ which examined presurgical and postsurgical changes in functional and psychosocial outcomes after children with spastic CP. The patients underwent one of the following: MTL, intrathecal baclofen pump implantation, or selective dorsal rhizotomy. Only the intrathecal baclofen pump group demonstrated improved pain scores, with the selective dorsal rhizotomy group showing a negative correlation and the MTL group without any significant correlation. Similar to the findings of this study, the MTL group demonstrated a significant improvement in the PODCI sports and physical function and global function scores. In contrast to our study, the MTL group did not demonstrate a significant improvement in the PODCI transfers and basic mobility scores but were able to demonstrate a significant improvement in the PODCI happiness scores. These differences may be a result of the different populations included in each study. Although our study focused on ambulatory children with CP, the study by Damiano et al included both ambulatory and nonambulatory patients. Although these subgroups were not analyzed separately and any differences are speculative, it is possible that nonambulatory children with CP experience less benefit from MT contracture release, and this affected the total scores. As noted in the study by Abel et al, there does not seem to be a linear relationship between function and well-being,¹⁰ and the overall impairment of nonambulatory children may set a higher functional threshold to yield a measurable improvement.

Perhaps the most intriguing finding of this and the aforementioned studies is the lack of association between functional and psychosocial well-being, reflected by no appreciable impact on the PODCI domains of pain and happiness. Until recently, the measures for pain and comfort

and happiness were not validated in ambulatory CP patients as a result of a lack of accurate classification of functional impairment¹² and incomplete data sets.²⁰ However, the completion rates were extremely high in the study by Pirpiris et al,¹¹ and the weak correlation between functional and psychosocial well-being seems to be a valid and recurrent finding. It is also possible that changes in the perception of comfort, freedom from pain, and a general state of happiness are not easily appreciated over a 12-month period. However, this seems to be a reasonable duration because patients in the acute postsurgical setting would likely experience an acute increase in pain and discomfort, and patients several years postsurgically will eventually experience recurrent deformity. Others have speculated that the weak correlation may be a result of the complex relationship between morbidity measures and psychological adjustments in children with chronic conditions.³⁸ Any impairment, irrespective of the severity, may have detrimental effects on both parental stress³⁹ and parent and child psychosocial well-being.^{4,38} Because the relative importance of factors other than functional well-being seems to be the most compelling argument for these findings, one is obliged to question whether surgical intervention to improve functional well-being has any benefit if it does not similarly impact psychosocial well-being. The answer to this most likely depends on an individual's importance placed on functional well-being and that individual's expectations of surgical outcomes. It is possible that a subset of children with CP will derive great pleasure from improved functional well-being, and this is entirely dependent on their personality and social setting. The key would be to identify these patients as the best candidates for surgical intervention and to counsel all patients and their families appropriately on the expected surgical outcomes pertaining to functional and psychosocial well-being.

In conclusion, this study suggests that improved function is associated with improved functional well-being in ambulatory children with CP after undergoing multilevel MTL surgery at 1-year follow-up. Long-term follow-up is needed to assess these effects over time. This study also lends support to the growing suspicion that psychosocial well-being is independent of functional well-being. This may be due to the complexity of the psychosocial makeup of children and families dealing with chronic impairment and the relative importance of other, yet unidentified, factors. Although we cannot extrapolate that improved functional well-being will improve psychosocial well-being, we also cannot assume that an individual will not experience happiness with improved function. At best, we should treat the individual CP child and family with a realistic counsel of the potential functional benefits of multilevel MTL surgery and temper the expectations of psychosocial improvement.

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