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Outcomes of lower extremity orthopedic surgery in ambulatory children with cerebral palsy with and without gait analysis: Results of a randomized controlled trial

Tishya A.L. Wren [a,b,*], Norman Y. Otsuka [c], Richard E. Bowen [d,e], Anthony A. Scaduto [d,e], Linda S. Chan [f], Sandra W. Dennis [a], Susan A. Rethlefsen [a], Bitte S. Healy [a], Reiko Hara [a], Minya Sheng [f], Robert M. Kay [a,b]

[a] Children's Orthopaedic Center, Children's Hospital Los Angeles, Los Angeles, CA, United States
[b] Department of Orthopaedic Surgery, Keck School of Medicine, University of Southern California, Los Angeles, CA, United States
[c] NYU Hospital for Joint Diseases, NYU Langone Medical Center, New York, NY, United States
[d] Department of Orthopaedic Surgery, Geffen School of Medicine at UCLA, Los Angeles, CA, United States
[e] Orthopaedic Hospital, Los Angeles, CA, United States
[f] Department of Pediatrics, Children's Hospital Los Angeles, Los Angeles, CA, United States

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A B S T R A C T

This study examined the impact of gait analysis on surgical outcomes in ambulatory children with cerebral palsy (CP) through a randomized controlled trial. 156 children with CP (94 male; age 10.2 ± 3.7 years) underwent gait analysis and were randomized to two groups: Gait Report group ($N = 83$), where the referring surgeon received the patient's gait analysis report, and Control group ($N = 73$), where the surgeon did not receive the gait report. Outcomes were assessed pre- and 1.3 ± 0.5 years post-operatively. An intent-to-treat analysis compared outcomes between the two groups. Outcome measures included the Gillette Functional Activity Questionnaire (FAQ), Gait Deviation Index (GDI), oxygen cost, gross motor function measure, Child Health Questionnaire (CHQ), Pediatric Outcomes Data Collection Instrument (PODCI), and Pediatric Evaluation and Disability Inventory. The outcomes that differed significantly between groups were change in health from the CHQ, which was rated as much better for 56% (46/82) of children in the Gait Report group compared with 38% (28/73) in the Control group ($p = 0.04$), and upper extremity physical function from the PODCI. Gait outcomes (FAQ and GDI) improved more when over half of the recommendations for a patient were followed or the recommended extent of surgery (none, single, or multi-level) was done ($p \leq 0.04$). On average, however, only 42% of the recommendations were followed in the Gait Report group, compared with 35% in the Control group ($p = 0.23$). This is much less than the >85% reported in previous studies and may account for the lack of differences between groups for some of the outcome measures.

1. Introduction

Gait analysis has a well documented impact on clinical decision-making. Surgical and non-surgical treatments change significantly after gait analysis [1–5]. Gait analysis can also reinforce surgical decisions when it supports the original treatment plan [6]. A number of recent studies have suggested that patient outcomes improve when treatment follows gait analysis recommendations. Chang et al. found that children who had surgery following gait analysis recommendations had a significantly higher rate of positive outcomes than matched cases who had the same surgeries recommended but no surgery done [7]. Gough and Shortland observed improvement in joint contractures and gait in children who had multilevel surgery as recommended by gait analysis, while children who did not have the recommended surgery worsened [8]. Molenaers et al. found that patients managed with gait analysis needed less surgery than historical controls managed without gait analysis [9]. Filho et al. observed that post-surgical improvements in gait increased when a higher percentage of gait analysis recommendations were followed [10]. Thus, existing studies suggest that gait analysis alters treatment decision-making and improves patient outcomes.

The purpose of the current study was to examine the impact of gait analysis on surgical outcomes through a randomized controlled trial (RCT). Ambulatory children with cerebral palsy

* Corresponding author at: Children's Hospital Los Angeles, 4650 Sunset Blvd., #69, Los Angeles, CA 90027, United States. Tel.: +1 323 361 4120; fax: +1 323 361 1310.
E-mail address: twren@chla.usc.edu (Tishya A.L. Wren).

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(CP) were randomized into two groups where the referring surgeon either received or did not receive a gait analysis report. Pre- to post-operative changes were compared between the two groups, and the relationship between outcomes and the degree to which gait analysis recommendations were followed was examined.

2. Materials and methods

This was a prospective RCT registered at ClinicalTrials.gov (5R01HS014169). Written informed assent/consent were obtained from participants and parents following IRB-approved protocols.

2.1. Participants and randomization

Ambulatory children with CP, ages 3–18 years, who were candidates for lower extremity orthopedic surgery to improve their gait were recruited from the orthopedic clinics at a pediatric specialty hospital in a large metropolitan area. Children were referred by four board-certified pediatric orthopedic surgeons who routinely cared for children with CP, but did not routinely use gait analysis. Exclusion criteria were surgery within the preceding year and botulinum toxin injections within the preceding 6 months.

All participants underwent pre-operative gait analysis at a nearby gait laboratory in a tertiary pediatric medical center. The gait study included physical examination, slow motion videotaping, instrumented gait analysis, and dynamic electromyography. Standard clinical gait reports were produced. The participants were then randomized to two groups: (1) Gait Report group, where the referring surgeon received the patient's gait analysis report and (2) Control group, where the referring surgeon did not receive the gait report. The randomization was implemented by sealed envelopes using computer-generated random numbers balanced in groups of 8. Group assignments were generated by the study statistician and unsealed by an individual not involved in data collection or patient care. By design, the participants and data collection personnel were blinded to the group assignments. The referring surgeons were not blinded since they reviewed gait reports for half the patients.

2.2. Intervention

The intervention in this study was receipt of the gait analysis report for patients in the Gait Report group. The gait report included a summary of all test results, plus treatment recommendations from the gait laboratory physician. This additional information was available for inclusion in pre-operative treatment planning for patients in the Gait Report group. The gait laboratory physician conducted two training sessions before the start of the study to familiarize the treating surgeons with gait analysis data collection and interpretation. Since the gait report includes a summary of findings and treatment recommendations, it can be used by referring surgeons with limited background in gait analysis. Patients were re-evaluated by the treating physician the day before surgery with physical examination, observational gait analysis, and review of the patient's medical records with or without the gait analysis report.

2.3. Data collection

Outcomes data were collected pre-operatively and approximately 1-year post-operatively. The primary outcome measures were the walking scale of the Gillette Functional Assessment Questionnaire (FAQ) [11], the Gait Deviation Index (GDI) [12], and the oxygen cost of walking (O_2 cost) [13]. Secondary outcome measures included the gross motor function measure (GMFM-66) [14] and health-related quality of life questionnaires (Child Health Questionnaire (CHQ) [15], Pediatric Outcomes Data Collection Instrument (PODCI) [16], and Pediatric Evaluation and Disability Inventory (PEDI) [17]).

The FAQ is a validated 10-point scale describing the child's typical walking ability [11]. It was scored based on interview and parent report. The GDI is a summary index calculated from gait kinematics to describe the magnitude of deviation of the child's gait from normal [12]. It was calculated using kinematic data from the gait analysis tests.

O_2 cost is a measure of the energy expenditure required for walking [13]. Participants rested quietly in a chair for 5–10 min and then walked at a self-selected speed for 5–10 min with their typical orthotics and/or assistive devices. Inspired and expired gases were measured on a breath-by-breath basis using a COSMED (Rome, Italy) K4 b^2 system. Steady state values from 3 to 5 min of sitting and walking were analyzed to calculate O_2 cost (ml/kg/m) [13].

GMFM is a measure of gross motor function commonly used to evaluate the functional abilities of children with disabilities [14]. GMFM domains C–E were tested by a trained physical therapist, and GMFM-66 scores were calculated using the Gross Motor Ability Estimator software [18].

The CHQ, PODCI, and PEDI questionnaires are validated instruments commonly used to assess general and functional quality of life. The CHQ and PODCI were completed by the child's parents using written questionnaires. The PEDI was administered through interview of the parent by a trained interviewer. The instruments were scored following their standard instructions.

2.4. Statistical methods

Our primary interest was comparing pre- to post-operative change for each outcome measure between the experimental and control groups. We first compared the baseline characteristics of the two groups of participants in the event that significant differences existed between the two groups. If differences in baseline characteristics occurred, adjustments would be made in the comparison of change. If no significant differences in baseline characteristics occurred, the difference of change between the two groups was evaluated, and the mean difference and its 95% confidence interval (CI) were derived. The 2-sided Student's t-test was used to assess mean differences, and the Chi-square or 2-sided Fisher's exact test was used to evaluate differences in proportions with a significance level of $p < 0.05$.

Concordance between the surgery done and the gait analysis recommendations was expressed as a percentage for each participant by dividing the number of procedures where the surgery followed the gait analysis recommendation by the total number of procedures initially planned, recommended by gait analysis, or done. Procedures were counted separately for each side and included psoas lengthening, hip adductor lengthening, hamstring lengthening, rectus femoris transfer, triceps surae (gastrocnemius or tendo-achilles) lengthening, posterior tibialis lengthening or transfer, anterior tibialis transfer, femoral derotation osteotomy, and tibial derotation osteotomy. The relationship between concordance and outcome measures was examined, and differences in outcome between patients with $\leq$50% vs. >50% concordance were assessed using Mann–Whitney and 2-sided Fisher's exact tests.

The agreement in extent of surgery between the gait analysis recommendations and the surgery ultimately performed was also assessed. The extent of surgery was classified as no surgery, single level surgery, or multi-level surgery (2 or more levels). The levels considered were foot and ankle, tibia, knee, femur, and hip (unilateral or bilateral). Each patient was classified as having either the same or different extents of surgery recommended and done. The relationship between agreement in extent of surgery and outcomes was assessed using Mann–Whitney and 2-sided Fisher's exact tests.

3. Results

A total of 186 children enrolled in the study; 156 (82%) returned for the follow-up visit (Fig. 1). All participants had gait analysis within 5 months of their initial referral, and surgery was done an average of 2.4 months later, with all participants but one having surgery within 10.5 months of baseline. The mean $\pm$ standard deviation (SD) of the duration of follow-up was 1.3 $\pm$ 0.5 years after surgery or 1.5 $\pm$ 0.5 years from baseline. Baseline demographic and clinical characteristics did not differ between the two groups (Table 1).

3.1. Comparison between groups

FAQ score improved in 31% (26/83) of children in the Gait Report group and 25% (18/73) of children in the Control group (Table 2), indicating improved walking ability in both groups. GDI improved by an average of 5.1 and 5.3 points in the Gait Report and Control groups, respectively, indicating a more normal gait pattern in both groups (5 points represents half a SD closer to normal). O_2 cost did not change significantly in either group. GMFM scores changed in both groups by an amount that was statistically, but not clinically, significant [18]. While both groups improved significantly in terms of walking ability ($p \leq 0.0001$ for change in FAQ and GDI within each group), there were no significant differences in the magnitude of change between the two groups.

On the CHQ, change in health was significantly better for patients in the Gait Report group compared with the Control group; it was rated as much better for 56% (46/82) of children in the Gait Report group compared with 38% (28/73) of children in the Control group ($p = 0.04$). Global health improved significantly in the Gait Report group ($p = 0.04$) but not in the Control group ($p = 0.14$). Similarly, the impact of the child's disability on the parents' time and emotions improved significantly only in the Gait Report group ($p \leq 0.02$). Self esteem showed a trend toward improvement in the Gait Report group ($p = 0.06$), but did not change in the Control group. Although these measures improved only in the Gait Report group, the difference in pre- to post-operative change between groups was not statistically significant.