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Influence of gait analysis on decision-making for lower extremity orthopaedic surgery: Baseline data from a randomized controlled trial[☆]

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ABSTRACT

Previous studies examining the influence of gait analysis on surgical decision-making have been limited by the lack of a control group. The aim of this study was to use data from a randomized controlled trial to determine the effects of gait analysis on surgical decision-making in children with cerebral palsy (CP). 178 ambulatory children with CP (110 male; age 10.3 ± 3.8 years) being considered for lower extremity orthopaedic surgery underwent gait analysis and were randomized into one of two groups: gait report group ($N = 90$), where the orthopaedic surgeon received the gait analysis report, and control group ($N = 88$), where the surgeon did not receive the gait report. Data regarding specific surgeries were recorded by the treating surgeon before gait analysis, by the gait laboratory surgeon after gait analysis, and after surgery. Agreement between the treatment done and the gait analysis recommendations was compared between groups using the 2-sided Fisher's Exact test. When a procedure was planned initially and also recommended by gait analysis, it was performed more often in the gait report group (91% vs. 70%, $p < 0.001$). When the gait laboratory recommended against a planned procedure, the plan was changed more frequently in the gait report group (48% vs. 27%, $p = 0.009$). When the gait laboratory recommended adding a procedure, it was added more frequently in the gait report group (12% vs. 7%, $p = 0.037$). These results provide a stronger level of evidence demonstrating that gait analysis changes treatment decision-making and also reinforces decision-making when it agrees with the surgeon's original plan.

1. Introduction

Gait analysis is a specialized medical technology used to evaluate patients with complex walking problems such as children with cerebral palsy (CP). Gait analysis is often performed prior to surgery to help decide which surgical procedures should be included in a multi-level surgical plan. Although gait analysis allows for a more accurate assessment of gait deviations than visual gait assessment [1,2], the use of gait analysis in clinical care remains controversial. Evidence is therefore needed to demonstrate the impact of gait analysis on treatment decision-making and, ultimately, on patient outcomes.

A number of studies have indicated that treatment decision-making changes after gait analysis [3–8]. Treatment plans developed without gait analysis are altered for 52–89% of patients after gait analysis data are considered [3–8]. In addition, in patients who underwent gait analysis, 37–39% of the procedures planned before gait analysis were not ultimately done, while 28–40% of the procedures actually done were added after gait analysis [6,8]. Post-operative care is also affected, with changes in bracing, physical therapy, or additional surgery being recommended in 84% of patients after gait analysis [7]. Thus, treatment decision-making clearly changes when gait analysis data are added to the decision-making process.

While previous research has provided valuable evidence that gait analysis alters decision-making, one limitation of these previous studies is that they all used observational cohorts, making it difficult to determine how much of the change results from the gait analysis. Many factors may influence decision-making, including additional clinical or radiographic evaluation, changes in function before surgery, intra-operative assessment,

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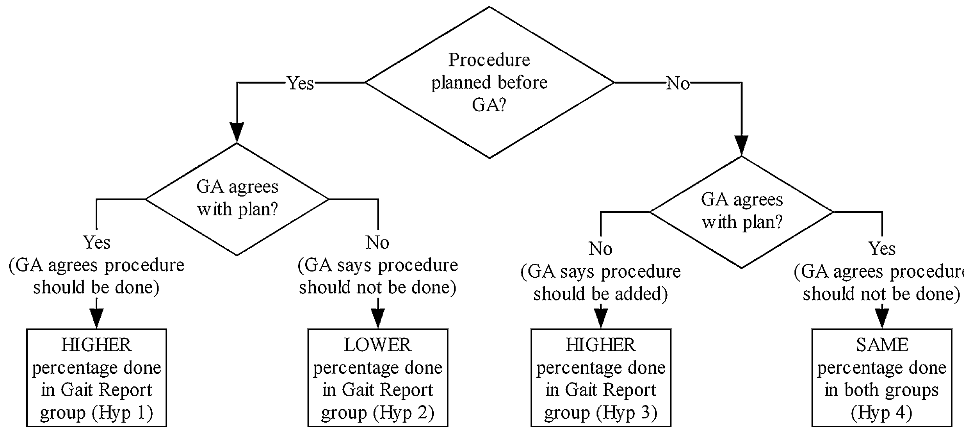

Fig. 1. Hypotheses based on surgical plan before gait analysis and gait analysis recommendations. GA = gait analysis.

and patient preferences [9]. The current study uses data from a randomized, controlled trial (RCT) to better isolate the effects of gait analysis on surgical decision-making. The RCT provides a control group showing how often surgical decisions change in an equivalent group without gait analysis.

Our main hypothesis was that decision making for lower extremity orthopaedic surgery is influenced by the recommendations received in a gait analysis report. Specifically, we hypothesized that (Fig. 1):

1. Surgeons are more likely to proceed with a planned surgical procedure if they receive a gait report supporting this plan.
2. Surgeons are more likely not to proceed with a planned procedure if they receive a gait report recommending against this plan.
3. If a procedure is not planned initially, it will be performed more often when the surgeon receives a gait report recommending the procedure.
4. If a procedure is not planned and the gait report agrees that it should not be done, receiving a gait report will have no effect because the procedure will rarely be done.

2. Materials and methods

This was a prospective randomized controlled trial registered at ClinicalTrials.gov (5R01HS014169). The protocol was approved by the Institutional Review Board at our institution, and written informed assent and consent were obtained from the participants and their parents.

2.1. Participants and randomization

The study included ambulatory children with cerebral palsy, age 3–18 years, who were candidates for lower extremity orthopaedic surgery to improve gait. Participants were recruited from the orthopaedic clinics at a pediatric specialty hospital in a large metropolitan area. The participants were referred by four board certified pediatric orthopaedic surgeons who routinely treat children with cerebral palsy as part of their clinical practice. Exclusion criteria were previous 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 including physical examination, slow motion videotaping, computerized gait analysis, and dynamic electromyography, and standard clinical gait reports were produced. The participants were then randomized to one of 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 personnel involved in data collection were blinded to the participants' group assignments. The referring surgeons were not blinded since they had to review the gait reports provided for half the patients.

2.2. Intervention

The intervention in this study was receipt of the gait analysis report for patients randomized into the gait report group. As noted above, a full clinical gait analysis was performed, and a standard clinical gait report was produced. This report included a summary of results from the physical examination, video analysis, computerized gait analysis, and dynamic electromyography, along with treatment recommendations from the gait laboratory physician. This additional information was available to the referring surgeon to incorporate into his decision-making prior to surgery. Patients were re-evaluated by the referring physician the day before surgery with physical examination, observational gait analysis, and review of the patient's medical records including the gait analysis report if available.

2.3. Data collection

Data regarding specific surgical procedures were collected at four time points: (1) referral by treating surgeon *before gait analysis*, (2) recommendations by gait laboratory surgeon *after gait analysis*, (3) surgery planned by treating surgeon *after gait analysis and before surgery* (with or without gait report, depending on patient's group assignment), and (4) actual surgery performed (recorded *after surgery*). At each time point, a form was completed documenting whether or not each specific surgical procedure was indicated. The procedures studied included psoas lengthening, hip adductor lengthening (ADD), hamstring lengthening (HSL), rectus femoris transfer, tendo-achilles lengthening or gastrocnemius recession (TAL/GR), anterior tibialis tendon transfer, posterior tibialis tendon transfer, posterior tibialis tendon lengthening, femoral derotational osteotomy (FDRO), tibial derotational osteotomy (TDRO), and foot osteotomy.

2.4. Outcomes and statistical methods

The main outcome measure for each hypothesis was the relative agreement (RA) between the gait report and control groups. The outcomes were studied for each of the surgeries listed above, as well as for soft tissue surgery, bone surgery, and all surgeries combined. The main unit of analysis was patient-side. For unilaterally involved subjects, only the affected side was included. For each group, agreement was defined as the percent agreement between the actual treatment and the gait analysis recommendations. To calculate this percent agreement, all procedures that were either planned initially, recommended by gait analysis, or done for a specific subject were counted in the denominator; the numerator then counted the procedures among these where what was done matched the gait analysis recommendation. For example, if a procedure was not planned before gait analysis, but was recommended by gait analysis, it was counted in the numerator only if it was done (matching the gait analysis recommendation). RA was defined as the ratio of the percent agreement of the gait report and control groups. RA was estimated with a 95% confidence interval. The 2-sided Fisher's Exact test was used to determine statistical significance.

2.5. Sample size

A target sample size of 240 was determined based on outcome measures for the ongoing clinical trial. Enrollment was stopped prior to reaching this target due to time constraints and the lower than expected volume of eligible patients. The original sample size calculations do not directly pertain to the analysis of baseline data presented in this paper, and we did not perform any additional power analyses specific to these baseline data.

3. Results

The study included 178 children with cerebral palsy; 90 were randomized to the gait report group, and 88 were randomized to the control group (Fig. 2). Table 1 presents a comparison of the

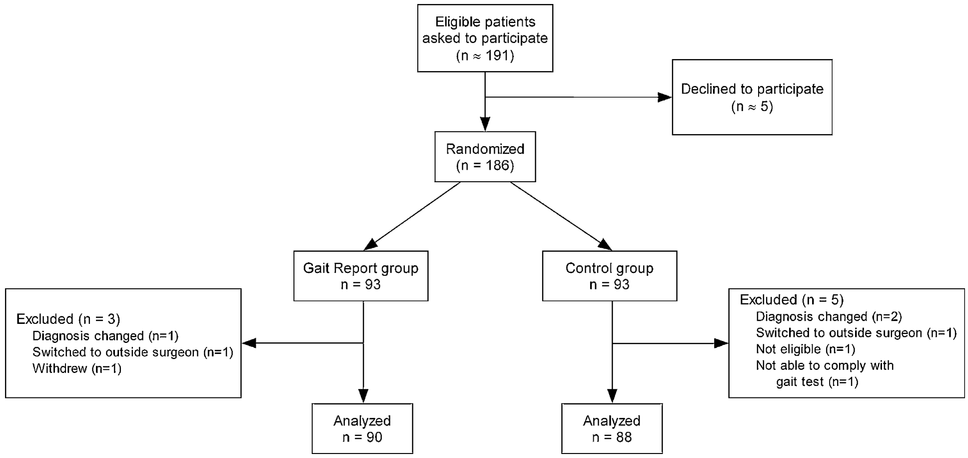

Fig. 2. Flowchart of patient inclusion. Screening for eligible patients was done in the clinic, and the number of patients who were asked to participate but declined was not recorded. This number has been estimated based on the recollection of the study coordinator, who stated that less than 5 patients declined to join the study.

demographic and clinical characteristics of the two groups. All subjects had gait analysis within 5 months of their referral, and surgery was done an average ± standard deviation of 2.5 ± 2.9 months later, with all subjects having surgery within 10.5 months except for two who had surgery at 1.5 and 2.2 years.

The decision-making results for all surgeries combined are depicted graphically in Fig. 3. The results for the procedures most commonly recommended or done in the study sample are summarized for each hypothesis in Tables 2A–2D. Results are not presented for the third time point (after gait analysis and before surgery) because results for the third and fourth time points (after surgery) were nearly identical.

When a procedure was planned initially and also recommended by gait analysis, it was performed more often in the gait report group, except for TAL/GR which was almost always performed regardless of group (Table 2A). Overall, in the control group, only 70% (93/133) of the originally proposed procedures were ultimately done. This percentage increased to 91% (110/121) in the gait report group (RA = 1.30, 95% CI = 1.15–1.47, $p < 0.001$). The results were particularly striking for bone procedures, which showed a difference of 81% (17/21) in the gait report group compared with 48% (15/31) in the control group (RA = 1.67, 95% CI = 1.10–2.54, $p = 0.002$).

When the gait laboratory recommended against a planned procedure, the plan was changed more frequently in the gait report group (Table 2B). Overall, the procedure was dropped in 48% (32/66) of cases in the gait report group compared with 27% (18/66) of cases in the control group (RA = 1.78, 95% CI = 1.12–2.83, $p = 0.009$). Triceps surae lengthening was the procedure most often planned but recommended against by the gait analysis. 40% (18/45) of GR/TAL were dropped in the gait report group compared with 12% (4/34) in the control group (RA = 3.40, 95% CI = 1.27–9.13, $p = 0.006$). The other procedures had only a small number of cases in which the gait analysis recommended against a planned procedure.

The gait report recommended adding procedures in a larger number of cases (Table 2C). These procedures were added more frequently in the gait report group where 12% (36/290) of the recommended procedures were done compared with 7% (15/227) in the control group (RA = 1.88, 95% CI = 1.06–3.34, $p = 0.037$). Triceps surae lengthening was the most commonly added procedure, followed by tibial derotational osteotomy, adductor lengthening, and hamstring lengthening.

When a procedure was neither planned before gait analysis nor recommended by the gait laboratory physician, it was rarely done. In this scenario, procedures were added in only 1% of cases in both groups (Table 2D).

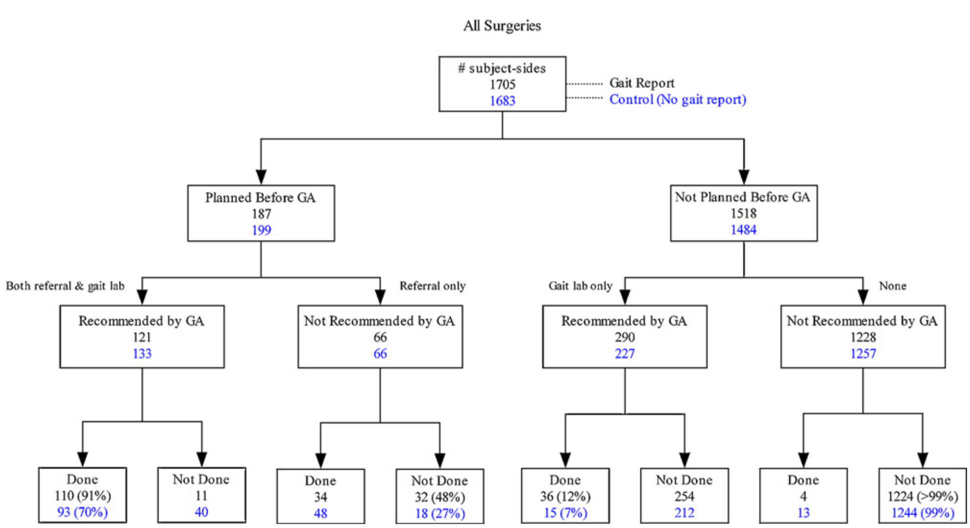

Fig. 3. Results for all surgeries. Top number represents gait report group; bottom number represents control group. GA = gait analysis.

Table 1
Characteristics of the study participants.

		Gait report (*N* = 90)	Control (*N* = 88)	*p*-Value
Age	Mean (SD)	10 yr, 3 mo (3 yr, 7 mo)	10 yr, 3 mo (4 yr, 0 mo)	0.985
Sex	Male	52 (58%)	58 (66%)	0.283
	Female	38 (42%)	30 (34%)	
Subtype	Hemiplegia	25 (28%)	23 (26%)	0.914
	Diplegia	50 (56%)	52 (59%)	
	Quadriplegia	15 (17%)	13 (15%)	
GMFCS	1	27 (30%)	30 (34%)	0.286
	2	21 (23%)	29 (33%)	
	3	31 (34%)	22 (25%)	
	4	11 (12%)	7 (8%)	

4. Discussion

Previous studies have clearly demonstrated that treatment plans differ before and after gait analysis [3–8]. This occurs when both the plans with and without gait analysis are formulated by different individuals (i.e., a referring surgeon and a gait laboratory surgeon) and when the plans are proposed by the same individual or team. The changes in treatment decision-making are associated with changes in the treatment ultimately performed [6,8]. While these studies provide compelling evidence that treatment changes after gait analysis, the extent to which these changes can be attributed to the gait analysis has been unclear due to the absence of an appropriate control group.

This study used a randomized controlled design to isolate the effects of the gait analysis. This allowed a baseline level of changes in treatment decision-making to be established in a control group for comparison with the group receiving the gait analysis data. Even without additional information such as a gait analysis report, treatment plans may change due to reconsideration of the treatment options, re-evaluation of the patient between the initial evaluation and surgery, changes in patient status, patient requests, or many other factors [9]. It is important to quantify this baseline level of uncertainty, controlling for important factors such as patient population and surgeon, so that the true effect of the gait analysis can be determined.

Table 2A
Results when a procedure was planned before gait analysis and recommended by gait analysis report (*both referral and gait lab*). Relative acceptance >1 indicates reinforcement of the original plan by gait analysis.

	Procedures done		Relative acceptance (95% CI)	*p*-Value
	Gait report	Control		
ADD	100% (36/36)	84% (21/25)	1.19 (1.00, 1.41)	0.024
HSL	89% (34/38)	75% (33/44)	1.19 (0.97, 1.46)	0.151
TAL/GR	94% (15/16)	100% (16/16)	0.94 (0.83, 1.06)	1.000
All soft tissue	93% (93/100)	76% (78/102)	1.22 (1.08, 1.37)	0.002
FDRO	78% (7/9)	40% (6/15)	1.94 (0.95, 3.96)	0.105
TDRO	83% (5/6)	67% (8/12)	1.25 (0.73, 2.14)	0.615
Foot osteotomy	83% (5/6)	25% (1/4)	3.33 (0.59, 18.9)	0.191
All bone	81% (17/21)	48% (15/31)	1.67 (1.10, 2.54)	0.022
All procedures	91% (110/121)	70% (93/133)	1.30 (1.15, 1.47)	<0.001

Table 2B
Results when a procedure was planned before gait analysis but not recommended by gait analysis report (*referral only*). Relative acceptance >1 indicates cancellation of procedures due to gait analysis.

	Procedures not done		Relative acceptance (95% CI)	*p*-Value
	Gait report	Control		
ADD	33% (1/3)	0% (0/5)	–	0.375
HSL	100% (2/2)	0% (0/4)	–	0.067
TAL/GR	40% (18/45)	12% (4/34)	3.40 (1.27, 9.13)	0.006
All soft tissue	47% (29/62)	18% (10/55)	2.57 (1.38, 4.78)	0.002
FDRO	100% (2/2)	60% (3/5)	1.67 (0.81, 3.41)	1.000
TDRO	50% (1/2)	75% (3/4)	0.67 (0.15, 2.98)	1.000
Foot osteotomy	– (0/0)	100% (2/2)	–	1.000
All bone	75% (3/4)	73% (8/11)	1.03 (0.53, 2.02)	1.000
All procedures	48% (32/66)	27% (18/66)	1.78 (1.12, 2.83)	0.009

Table 2C
Results when a procedure was not planned before gait analysis but was recommended by gait analysis report (*gait lab only*). Relative acceptance >1 indicates addition of procedures due to gait analysis.

	Procedures done		Relative acceptance (95% CI)	*p*-Value
	Gait report	Control		
ADD	13% (5/39)	9% (4/43)	1.38 (0.40, 4.77)	0.730
HSL	12% (8/68)	0% (0/42)	–	0.023
TAL/GR	38% (3/8)	0% (0/7)	–	0.200
All soft tissue	12% (22/177)	5% (8/152)	2.36 (1.08, 5.15)	0.033
FDRO	0% (0/32)	6% (1/17)	–	0.347
TDRO	27% (11/41)	15% (4/26)	1.74 (0.62, 4.90)	0.372
Foot osteotomy	8% (3/40)	6% (2/32)	1.20 (0.21, 6.75)	1.000
All bone	12% (14/113)	9% (7/75)	1.33 (0.56, 3.13)	0.639
All procedures	12% (36/290)	7% (15/227)	1.88 (1.06, 3.34)	0.037

Table 2D
Results when a procedure was not planned before gait analysis and was not recommended by gait analysis report (*none*). In this case, procedures were rarely done.

	Procedures not done		Relative acceptance (95% CI)	*p*-Value
	Gait report	Control		
ADD	100% (77/77)	100% (80/80)	–	–
HSL	100% (47/47)	100% (63/63)	–	–
TAL/GR	98% (84/86)	97% (93/96)	1.01 (0.96, 1.06)	1.000
All soft tissue	>99% (897/901)	99% (904/915)	1.01 (1.00, 1.02)	0.117
FDRO	100% (112/112)	100% (116/116)	–	1.000
TDRO	100% (106/106)	99% (110/111)	1.01 (0.99, 1.03)	1.000
Foot osteotomy	100% (109/109)	99% (114/115)	1.01 (0.99, 1.03)	1.000
All bone	100% (327/327)	99% (340/342)	1.01 (1.00, 1.01)	0.500
All procedures	>99% (1224/1228)	99% (1244/1257)	1.01 (1.00, 1.01)	0.049

Through comparison with the control group, we demonstrated two primary effects of gait analysis: (1) *changing* the original treatment plan and (2) *reinforcing* the original plan. These effects provide evidence supporting the efficacy of gait analysis in influencing treatment decision-making [10]. Previous studies have focused exclusively on the first effect since the second effect can only be observed in a controlled study. In cases where the gait analysis recommendations differed from the original treatment plan for a procedure, we found that 19% (68/356) of the gait analysis recommendations were followed in the gait report group, compared with a baseline rate of 11% (33/293) in the control group. On the patient level, an average of 38% of the gait analysis recommendations for each patient were followed in the gait report group compared with 27% in the control group. The higher percentages at the patient level reflect the contribution of cases in which decision-making was reinforced as well as cases in which it was changed. It should be noted that the rates found in this study are much lower than the rates reported in previous studies (86–93% for procedures [8,9]).

In the cohort studied, the treating physicians were more inclined to eliminate surgical procedures than to add procedures. The surgeons cancelled 48% of the planned procedures not recommended by gait analysis, but added only 12% of the additional procedures recommended by gait analysis. While the overall effect of the gait analysis was consistent among surgeries, the magnitude of the effect varied. For example, when the gait report was available, triceps surae lengthening was added in 38% of recommended cases, compared with 12% for hamstring lengthening and 0% for femoral derotational osteotomy. This may reflect a high threshold for particular procedures like femoral osteotomy.

The results of this study likely reflect, at least to some extent, the treatment practices of the surgeons and institutions involved in the study. Previous studies have reported a much higher acceptance rate of gait analysis recommendations (86–93%) than in the current study [8,9]. Those studies involved referring surgeons from the same institution as the gait laboratory, whereas the current study involved two different institutions. We have recently observed that outside physicians referring clinical patients to our gait laboratory follow an average of 75% of the gait laboratory recommendations, compared with 92–95% for surgeons within the institution. Therefore, it is not surprising that the outside physicians in this study deviated from the gait laboratory recommendations to a greater extent than the within-institution surgeons involved in previous studies. In addition, in the current study, the gait laboratory physician recommended adding many more procedures than he recommended eliminating, which may reflect a belief in the importance of single event multilevel surgery (SEMLS) to optimize biomechanics and function in children with CP, in contrast to the more common approach of sequential surgeries. The gait laboratory physician had been performing multi-level surgery, in conjunction with using gait analysis, for seven years prior to the start of the study. The referring physicians may have tended towards less extensive surgery due, in part, to their lack of access to a gait laboratory previously. Most previous studies have reported an overall decrease [8] or no change [5,6] in the total amount of surgery recommended after gait analysis, although the results differ for specific procedures [3,4]. Regardless, the general effects of gait analysis should be similar across institutions and practitioners, within the constraints of their individual practice patterns.

Changing decision-making and treatment is a necessary first step towards improving patient outcomes. While a number of studies have reported results that strongly suggest a positive effect of gait analysis on outcomes [11–14], no randomized trial has conclusively established whether gait analysis improves or does not improve outcomes. To our knowledge, this is the first randomized controlled trial on gait analysis. Data collection has recently been completed, and future research will analyze the follow-up data. The current paper examines only the baseline data and the decision-making effects of gait analysis. Future research will address the effects of gait analysis on patient outcomes.

The primary limitations of this study are the small number of surgeons involved and the absence of outcome data. This study involved a single gait laboratory and gait laboratory surgeon and four referring surgeons from another institution. Larger multi-center studies are needed to obtain more generalizable results. In addition, as mentioned previously, this study presents only the baseline data from our RCT. Future research will examine the post-operative and outcome data. It should be noted that this study does not attempt to isolate the effects of the gait analysis data alone. Instead, it evaluates the overall effect of receiving the gait analysis report, which includes both gait analysis data and treatment recommendations from the gait laboratory physician. This is the same information that would be received by a referring surgeon who ordered a clinical gait analysis test. It therefore reflects the role of gait analysis in actual clinical practice.

In summary, this randomized controlled study confirms the previous finding that gait analysis alters treatment decision-making and demonstrates that the changes in decision-making with gait analysis exceed the baseline level of change that occurs without gait analysis. In addition, when gait analysis agrees with the referring surgeon's original plan, it reinforces decision-making and increases the likelihood that the surgeon will proceed with the planned procedure. Since the surgeons in this study followed the gait analysis recommendations to a lesser extent that has been reported in previous studies, these results may underestimate the true impact of gait analysis on surgical decision-making in more generalized settings.

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Conflict of interest statement

None of the authors have any financial or personal relationships with other people or organizations that could inappropriately influence this work.

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