Gait & Posture 34 (2011) 149–153

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Review

Efficacy of clinical gait analysis: A systematic review

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ARTICLE INFO

Article history:
Received 25 October 2010
Received in revised form 3 February 2011
Accepted 10 March 2011

Keywords:
Gait analysis
Efficacy
Effectiveness
Evidence based medicine

ABSTRACT

The aim of this systematic review was to evaluate and summarize the current evidence base related to the clinical efficacy of gait analysis. A literature review was conducted to identify references related to human gait analysis published between January 2000 and September 2009 plus relevant older references. The references were assessed independently by four reviewers using a hierarchical model of efficacy adapted for gait analysis, and final scores were agreed upon by at least three of the four reviewers. 1528 references were identified relating to human instrumented gait analysis. Of these, 116 original articles addressed technical accuracy efficacy, 89 addressed diagnostic accuracy efficacy, 11 addressed diagnostic thinking and treatment efficacy, seven addressed patient outcomes efficacy, and one addressed societal efficacy, with some of the articles addressing multiple levels of efficacy. This body of literature provides strong evidence for the technical, diagnostic accuracy, diagnostic thinking and treatment efficacy of gait analysis. The existing evidence also indicates efficacy at the higher levels of patient outcomes and societal cost-effectiveness, but this evidence is more sparse and does not include any randomized controlled trials. Thus, the current evidence supports the clinical efficacy of gait analysis, particularly at the lower levels of efficacy, but additional research is needed to strengthen the evidence base at the higher levels of efficacy.

1. Introduction

The appropriate role of gait analysis in clinical care remains controversial. Proponents argue that gait analysis provides important information needed to optimize the care of patients with complex walking problems [1]. Opponents counter that, although gait analysis is a useful tool for research, as a clinical tool it adds unnecessary cost without providing any proven benefits to individual patients [2]. Consequently, the utilization of gait analysis is highly variable [3]. Whether or not gait analysis is used is largely determined by individual physician preference, availability of motion analysis services, and insurance coverage, which is also highly variable. The uneven utilization and reimbursement are at least partially due to differences in interpreting the evidence related to the efficacy of clinical gait analysis.

Evaluating the clinical impact of a diagnostic test is complex because diagnostic tests have an indirect effect on patient outcomes [4,5]. By influencing the treatment decision-making process, gait analysis may affect patient management and, consequently, patient outcomes. Fryback and Thornbury have proposed a widely used framework for evaluating the efficacy of a diagnostic test [4,5]. This framework organizes evidence of efficacy into a hierarchy of levels ranging from technical data acquisition to treatment decision-making to patient and societal outcomes. This framework was first used to evaluate magnetic resonance imaging, but can also apply to diagnostic tests in general [6,7]. It is widely used in medical technology assessments such as those conducted by the United States (U.S.) Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program, which provides information contributing to coverage decisions by the U.S. Centers for Medicare and Medicaid Services and insurance carriers [6,7]. In this review, we utilize this framework to evaluate clinical gait analysis.

The aim of this systematic review was to evaluate and summarize the current evidence base related to the clinical efficacy of gait analysis. As noted above, the review was performed using the established framework developed by Fryback and Thornbury [4,5]. Evidence of efficacy is needed by patients,

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0966-6362/$ – see front matter © 2011 Published by Elsevier B.V.
doi:10.1016/j.gaitpost.2011.03.027

families, healthcare providers, insurers and policy makers to better determine and agree on the appropriate clinical use of gait analysis. It is also important to establish the current evidence base to understand what evidence exists and what additional research is needed.

2. Methods

A literature review was conducted to identify references related to human gait analysis published between January 2000 and September 2009. We limited our search to Medline/PubMed databases as these contain most of the reports on instrumented gait analysis. We next identified search terms using MEDLINE thesaurus online and Medical Subject Headings (MeSH). Our search terms included gait, locomotion, walking, biomechanics, kinematics, and electromyography combined with the terms analysis, evaluation, and diagnostic techniques. We also used the combined terms of gait analysis, motion analysis, and biomechanic analysis. The articles identified by the search were screened to determine whether they were related to gait analysis in humans; references not related to human gait analysis ($N = 83$) were excluded. Additional older references known to the reviewers were also included. The search was limited to English language references.

The Fryback and Thornbury framework for technology assessment was adapted for application to gait analysis (Table 1). The levels of efficacy were (1) technical efficacy, (2) diagnostic accuracy efficacy, (3 and 4) diagnostic thinking and treatment efficacy, (5) patient outcomes efficacy, and (6) societal efficacy. A score of 7 was added for studies that used gait analysis as a descriptive or outcome measure, but did not provide information related to efficacy. Technical efficacy refers to the physical process of obtaining data, including the accuracy and reliability of the equipment used and the procedures employed in data collection (e.g., marker placement, anthropometric measurements, model used to analyze data, processing methods used to obtain kinematics, kinetics, and temporospatial parameters). Diagnostic accuracy efficacy refers to interpretation of the data collected, including performance in classifying patients and making diagnoses, interpreting data for individual patients (e.g., through pattern recognition or automatic or semi-automatic interpretation), and identifying measures predictive of good or bad outcomes for specific treatments. Diagnostic thinking and treatment efficacy refers to the impact of gait analysis on treatment decision-making and the treatment actually done (change in treatment or reinforcement of treatment plan). This category combines the Fryback and Thornbury levels 3 (diagnostic thinking) and 4 (therapeutic) because they are tightly coupled in gait analysis. Patient outcomes efficacy refers to the effect on outcomes for individual patients. Societal efficacy reflects cost effectiveness or cost-benefit analysis from a societal viewpoint (e.g., savings to health care system, more efficient use of resources, etc.).

Using this framework, all identified references were initially scored independently by two of four reviewers. Reviewers were allowed to assign multiple scores to references that addressed multiple levels of efficacy. References identified as addressing efficacy by at least one of the reviewers (scores 1–6) were then also scored by the remaining two reviewers. After the initial scoring, the review criteria were discussed and clarified using 12 references with discrepant scores to focus the discussion. All references with discrepant scores were then independently re-evaluated by the individual reviewers; discussion and re-scoring was performed iteratively until agreement was achieved among at least three of the four reviewers. The final scores were those agreed upon by at least three of the four reviewers.

3. Results

1528 references were identified relating to human instrumented gait analysis. Of these, 240 were identified by the first two reviewers as addressing efficacy levels (scores 1–6) and appropriate for additional review. The majority of the excluded references ($N = 1063$) used gait analysis as an outcome or descriptive measure only, e.g., using gait kinematics to evaluate the outcome of a surgery without evaluating the efficacy of the gait analysis itself. Other excluded references were not focused on classic instrumented clinical gait analysis ($N = 142$).

Based on the scores of all four reviewers, 105 original articles addressed technical efficacy, 78 addressed diagnostic accuracy efficacy, eight addressed diagnostic thinking and treatment efficacy, four addressed patient outcomes efficacy, and one addressed societal efficacy. An additional 22 original articles addressed multiple levels of efficacy (Fig. 1). Of 18 review articles, five addressed technical efficacy, four addressed diagnostic accuracy efficacy, two addressed diagnostic thinking and treatment efficacy, and seven addressed multiple levels of efficacy.

3.1. Technical accuracy (level 1)

Over half of the studies relating to efficacy addressed technical accuracy ($N = 116$ original articles). These included direct assessments of accuracy and reliability, as well as the development of methods to improve the quality of the data collected.

3.2. Diagnostic accuracy (level 2)

The next largest group of studies addressed diagnostic accuracy ($N = 89$ original articles). These studies evaluated the efficacy of gait analysis in classifying patients into diagnostic groups or identifying measures to select treatments or predict outcomes. Studies developing methods to improve the usefulness of the data interpretation were also included.

3.3. Diagnostic thinking and treatment efficacy (levels 3–4)

11 original articles evaluated the impact of gait analysis on clinical decision-making and treatment. The results consistently showed that treatment plans change after consideration of gait analysis data and that the treatment ultimately performed differs from the plan before gait analysis. Specifically, treatment plans with and without gait analysis differed in a high percentage of patients (52–89%) and procedures (40–51%) [8–13]. In addition, 37–39% of the procedures planned before gait analysis were not ultimately done, and 28–40% of the procedures actually done were not planned before gait analysis [11,13]. Gait analysis recommendations were followed in a high percentage of cases, with 92–93% of recommendations for specific surgical procedures being followed [13,14] and 77% of patients having an exact match between the surgeries recommended by gait analysis and the surgeries ultimately performed [14]. This suggests that the changes in treatment are at least partly due to the addition of gait analysis. The specific articles pertaining to efficacy levels 3–4 and above are listed in Table 2.

3.4. Patient outcome efficacy (level 5)

Seven original articles evaluated the effect of gait analysis on patient outcomes (Table 2). All of these studies used case-control or case series designs; none were randomized controlled trials. These studies compared outcomes among groups of patients

Table 1
Scoring scheme based on hierarchical model of efficacy [5] adapted for gait analysis.

Score	Efficacy type	Description
1	Technical	Physical process of obtaining data (system and personnel)
2	Diagnostic accuracy	Effectiveness of data plus interpretation of data
3–4	Diagnostic thinking and treatment	Effect on decision-making and treatment
5	Patient outcome	Effect on outcomes for individual patient
6	Societal	Cost-effectiveness or cost-benefit from societal viewpoint
7	–	Gait analysis as a descriptive or outcome measure

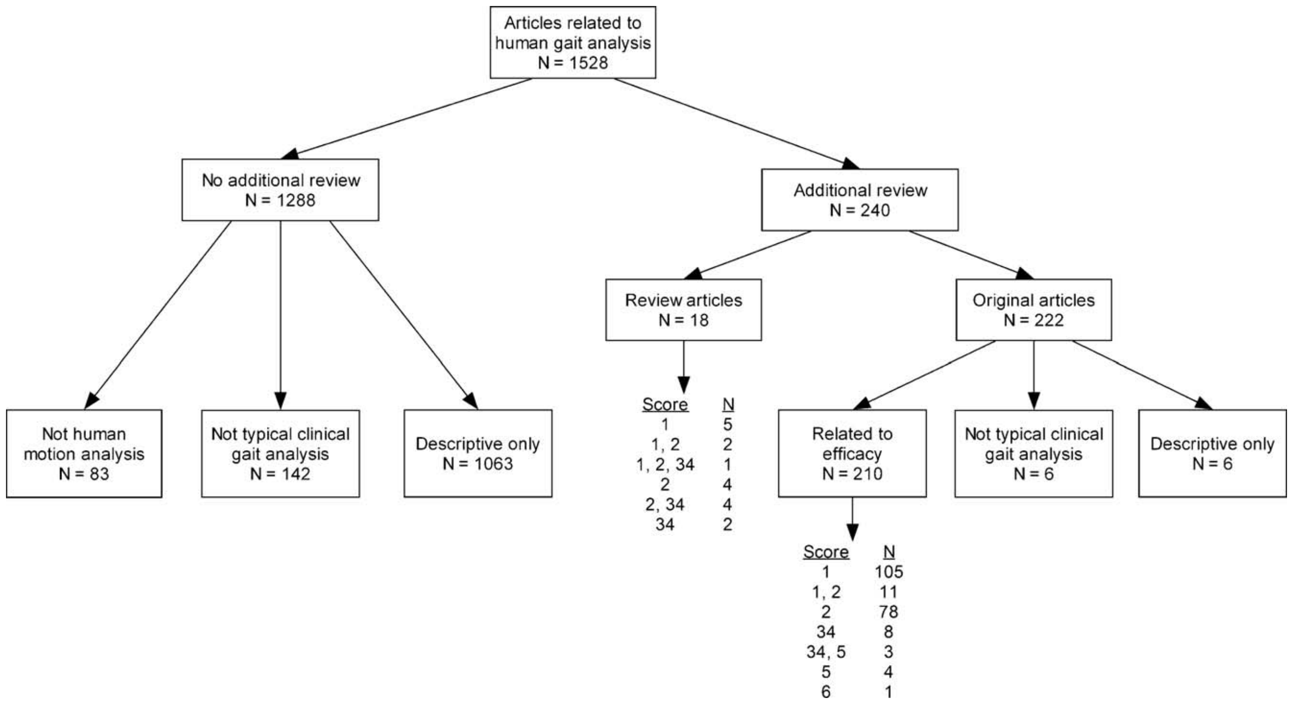

Fig. 1. Results of systematic review.

whose treatment followed gait analysis recommendations to different extents. Lee et al. reported that 15 children who had surgeries recommended by gait analysis all improved after surgery, compared with only two of seven children having other surgeries [15]. Gough and Shortland reported that contractures and gait improved in children who had multilevel surgery as recommended by gait analysis, remained stable in children who had no surgery as recommended by gait analysis, and worsened in children who did not undergo surgery despite its recommendation by gait analysis [16]. Filho et al. observed a relationship between the degree to which gait analysis recommendations were followed and improvements in gait [17]. Lofterod and Terjesen reported positive kinematic outcomes in children who received surgical or non-surgical treatment consistent with gait analysis recommendations [18]. Molenaers et al. found that patients managed with gait analysis had a lower prevalence of surgery at all ages and a lower rate of multiple surgeries than historical controls managed without gait analysis [19]. Finally, Chang et al. found that children who had surgery in accordance with gait analysis recommendations had a significantly higher rate of positive outcomes than matched cases who had the same surgeries recommended but no surgery done [20].

Table 2
Original articles addressing higher levels of efficacy (levels 3–6).

Level	References
3–4	Kay et al. [11] Lofterod et al. [13] Smith et al. [28] DeLuca et al. [9] Sankar et al. [29] Kay et al. [12] Wren et al. [14] Cook et al. [8]
3–5	Filho et al. [17] Fuller et al. [10] Lofterod et al. [18]
5	Chang et al. [20] Lee et al. [15] Gough et al. [16] Molenaers et al. [19]
6	Wren et al. [25]

3.5. Societal efficacy (level 6)

Only one study was found relating to societal efficacy (Table 2). This study retrospectively compared ambulatory patients with cerebral palsy who had lower extremity orthopaedic surgery with ($N = 313$) and without ($N = 149$) pre-operative gait analysis. Patients who underwent gait analysis had more procedures and higher cost during the index surgery, but less subsequent surgery, with no difference in the total cost or number of procedures. The authors concluded that clinical gait analysis results in less disruption to patients' lives without increasing costs.

4. Discussion

Gait analysis allows for a more accurate assessment of gait deviations than visual gait assessment [21,22], and gait analysis is widely accepted as a useful research tool [2,3]. The clinical use of gait analysis, however, remains variable. While this variability may have multiple causes, including lack of availability, reimbursement, and training, it is also due, at least in part, to the perception that there is a lack of evidence supporting the clinical efficacy of gait analysis.

The vast majority of research on gait analysis efficacy has focused on methodology for data collection and interpretation. While this body of literature includes both "positive" and "negative" articles [23], in general, it provides strong support for the technical and diagnostic accuracy efficacy of gait analysis. A smaller group of studies has provided strong evidence suggesting that gait analysis changes treatment decision-making. These results are supported by recent data from a randomized controlled trial [24] which demonstrated that gait analysis not only changes treatment decisions when it disagrees with the original treatment plan, it also reinforces decisions when it agrees with the original plan.

The effect of gait analysis on patient outcomes is less well established. No data are available from randomized controlled trials, and prior to 2002 there was only a single study in this area [15]. In recent years, however, a number of cohort comparisons and case-control studies have examined the relationship between gait analysis and patient outcomes. These studies have consistently found that gait and functional outcomes are superior when gait analysis is done and treatment follows gait analysis recommendations. More specifically, function improves when surgery is done and is consistent with gait analysis recommendations, function is maintained when no surgery is done as recommended by gait analysis, and function deteriorates when surgery is recommended by gait analysis but not done or other surgeries are done.

At the societal level, only one published study was found on the cost-benefits or cost-effectiveness of gait analysis [25]. This study reported that patients who had received pre-operative gait analysis had more surgeries done initially, but fewer subsequent surgeries. The reduced incidence of surgery was achieved without increasing costs and presumably resulted from the gait analysis enabling the surgeons to perform single-event multi-level surgery (SEMLS) [26]. Since this was a retrospective study performed at a single center, additional research is needed to corroborate this result and to further investigate the societal impact of gait analysis. An additional abstract has indicated that SEMLS facilitated by gait analysis is much less costly than performing the same procedures in a staged manner, even after the costs of the gait analysis test are taken into account [27].

The current examination of efficacy focuses on the ability of gait analysis to affect the care of an individual patient who receives the test. This review does not consider another possible benefit of gait analysis, which is its role as an educational tool to improve the decision-making skills of a treatment provider such as an orthopaedic surgeon. For example, reviewing quantitative gait analysis data on patients pre- and post-operatively may provide feedback to surgeons so they can learn from their mistakes and successes to be able to provide better care for future patients. In addition, seeing gait analysis data from one patient may improve a surgeon's ability to treat another patient with similar problems, even without gait analysis data from the second patient. This type of educational efficacy was not included in the current review.

This review attempted to be as comprehensive as possible, but it is likely that some relevant articles were missed. A starting date for the literature review had to be chosen, and the year 2000 was selected to capture most of the relevant literature. Because of the small number of studies in levels 3–4 and above, two earlier articles of historical significance (Lee et al. [15] and DeLuca et al. [9]) were included to make the review of higher level articles more complete. It is possible that other articles were missed because they preceded the start date of the search or because they were not captured by the keywords investigated.

It should be noted that limited evidence for the higher levels of efficacy, including lack of evidence from randomized controlled trials (RCTs), does not mean gait analysis is not effective. To the contrary, the existing evidence suggests that gait analysis is effective at all levels studied, including the patient outcome and societal levels. The main weakness of the current evidence base is the limited number of studies at the higher levels of efficacy and the lack of RCTs. The lack of data from RCTs is not unique to gait analysis. Randomized trials of clinically available procedures are often difficult to justify due to ethical concerns. Surgeons who use gait analysis clinically are often reluctant to withhold this service from patients whom they believe would benefit from the test. Also, RCTs of diagnostic tests are complex because many factors affect patient outcomes, such as heterogeneous patient characteristics and the variety of multi-level surgical procedures that often follow gait analysis. Such issues may necessitate the use of alternative study designs [4,5].

In summary, the existing evidence supports the efficacy of clinical gait analysis, particularly at the lower levels of efficacy (levels 1–4). Evidence is sparse at the higher levels of efficacy (levels 5–6), and no data are available from RCTs. However, the evidence that does exist is supportive of gait analysis. Additional research is needed to further investigate the higher levels of efficacy.

Conflict of interest

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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