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Medical Policy Manual

Topic: Gait Analysis

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Section: Medicine

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Gait analysis (GA) is the quantitative assessment of coordinated muscle function; evaluation is conducted in a laboratory and typically involves a dedicated facility and staff. A visual assessment of walking is supplemented by video recording. Videos can be observed from several visual planes at slow speed, allowing detection of movements not observable at normal speed. Joint angles and various time-distance variables, including step length, stride length, cadence, and cycle time, can be measured. Electromyography (EMG), assessed during walking, measures timing and intensity of muscle contractions. This calculation allows determination of whether a certain muscle's activity is normal, out of phase, continuous, or clonic.

Gait analysis has been proposed as an aid in surgical planning, primarily for cerebral palsy (CP), but also for other conditions such as clubfoot. In addition, gait analysis is being investigated as a means to plan rehabilitative strategies (i.e., orthotic-prosthetic devices) for ambulatory problems related to cerebral palsy, aging, stroke, spinal cord injury, and other conditions.

Kinematics is the term used to describe movements of joints and limbs such as angular displacement of joints and angular velocities and accelerations of limb segments. The central element of kinematic assessment is some type of marker system that is used to represent anatomic landmarks, which are then visualized and quantitatively assessed by videotaped observations or optoelectronic data. Movement data are compiled by computer from cameras oriented in several planes, and the movement data are

processed so that the motion of joints and limbs can be assessed in three dimensions. The range and direction of motion of a particular joint can be isolated from all the other simultaneous motions that are occurring during walking. Graphic plots of individual joint and limb motion as a function of gait phase can be generated.

Inertial and magnetic measurement systems (IMMSs) are under investigation for the assessment of joints and limbs in 3-dimensions.[1,2] Rather than videotaped or optoelectronic calibration of markers placed on anatomic landmarks, IMMS systems involve sensor units that are comprised of miniaturized 3-dimensional accelerometers, gyroscopes, and magnetometers that are attached to body segments. The 3-dimenstional orientation of each sensor is measured in relationship to an earth-based coordinate system through the use of computerized algorithms. One protocol, the "Outwalk" protocol, has been developed to allow the use of an IMMS system for gait analysis.

A non-profit organization established in 1997, the Commission for Motion Laboratory Accreditation evaluates and accredits motion laboratories within clinical facilities. A multidisciplinary team uses a set of criteria to evaluate laboratories in the areas of administration (e.g., staffing, policies, and procedures), equipment (e.g., accuracy and precision), and data management and reporting (e.g., control and clinical data sets).

Regulatory Status

In May 2003, the Peak Motus Motion Measurement System (Peak Performance Technologies) was cleared for marketing by the FDA through the 510(k) process. This system uses off-the-shelf video cameras and sensors and proprietary software to document human movement in two- or three-dimensional space. The FDA determined that this device was substantially equivalent to existing devices and is indicated for assessment and training of limb or body motion in gait analysis, pre- or post-rehabilitation evaluation, physical therapy, and similar applications.

In January 2004, the Coda cx1 Motion Analysis System (Charnwood Dynamics Ltd) was cleared for marketing by FDA through the 510(k) process. The system uses infrared light sight sensors and software data analysis to measure the 3-dimensional movement of patients. FDA determined that the device was substantially equivalent to existing devices and is indicated for analysis of the 3-dimensional motion of the limbs and body of patients who have some impairment of movement functions due to a neurologic or orthopedic cause.

MEDICAL POLICY CRITERIA

I. Gait analysis may be considered **medically necessary** in children and adolescents with cerebral palsy to select surgical or other therapeutic interventions for gait improvement.

II. All other indications for gait analysis are considered **investigational.**

SCIENTIFC EVIDENCE[3]

Assessment of a diagnostic technology typically focuses on 3 parameters: 1) technical feasibility; 2) diagnostic performance (sensitivity, specificity, and positive [PPV] and negative predictive value [NPV]) in

appropriate populations of patients; and 3) demonstration that the diagnostic information can be used to improve patient outcomes (clinical utility).

- Technical feasibility of a device is typically assessed with 2 types of studies, those that compare test measurements with a gold standard and those that compare results taken with the same device on different occasions (test-retest). Demonstration of technical feasibility should include an assessment of its reproducibility and precision.

- Diagnostic performance is evaluated by the ability of a test to accurately diagnose a clinical condition in comparison with the gold standard. The sensitivity of a test is the ability to detect a disease when the condition is present (true-positive), while specificity indicates the ability to detect patients who are suspected of disease but who do not have the condition (true-negative). Evaluation of diagnostic performance, therefore, requires independent assessment by the 2 methods in a population of patients who are suspected of disease but who do not all have the disease.

- Evidence related to improvement of clinical outcomes with use of this testing assesses the data linking use of a test to changes in health outcomes (clinical utility). While in some cases, tests can be evaluated adequately using technical and diagnostic performance, when a test identifies a new or different group of patients with a disease; randomized trials are needed to demonstrate impact of the test on the net health outcome.

Literature Appraisal

Accuracy/Reliability

Systematic Reviews

- A systematic review of 18 studies on gait classification systems was published in 2007.[4] The review included studies that involved classification of gait impairment based on kinematic, temporal-spatial kinetic, or electromyographic (EMG) data. Fifteen studies used three-dimensional gait analysis, 1 study used video observation analysis and 6 studies used EMG data. The authors assessed the overall methodological quality of the studies as low. Many studies appeared to classify patients arbitrarily rather than using clear clinical decision-making principles. Only two studies evaluated the reliability of classification, and the methods for determining the validity of classification systems were inadequate.

- In 2009, McGinley et al. published a systematic review of studies of intersession and interassessor reliability of 3-dimensional kinematic gait analysis that included 15 full manuscripts and 8 abstracts.[5] Similar to the 2007 systematic review summarized above, the authors noted variability in methodologic quality across the studies, but concluded that most studies demonstrated interassessor error of between 2 and 5 degrees of measurement, which the authors considered was “reasonable but may require consideration in data interpretation.”

Clinical Trials

Since the systematic reviews were published, Benedetti et al conducted an analysis of between-site consistency in gait analysis measurements of 1 healthy subject at 7 different laboratories.[6] The authors concluded that there was generally high concordance of segment and joint kinematics, except in the knee and the hip.

Impact on Health Outcomes

The ideal study design to demonstrate the clinical utility of gait analysis would be a randomized controlled trial (RCT) comparing treatment decisions and health outcomes in patients managed with and without gait analysis.

In 2011, Wren and colleagues published a systematic review of literature on the efficacy of GA.[7] The authors identified seven studies evaluating the effect of GA on patients' health outcomes; none were RCTs. The studies addressed a variety of clinical conditions, so the authors were not able to pool findings. The systematic review also identified studies evaluating other aspects of GA including technical accuracy, diagnostic accuracy, and societal efficacy (i.e., impact on number and cost of procedures). The authors concluded that, although there is lower-level evidence (e.g., case series, case-control studies) supporting GA, there is a lack of evidence from RCTs on the effect of GA on health outcomes.

Specific Applications of Gait Analysis

In addition to the literature addressing gait analysis in general, several studies investigated specific indications for GA.

Pre- and/or Post-Surgical Evaluation for Children with Cerebral Palsy

One randomized controlled trial was published after the 2011 systematic review summarized above.

- Wren and colleagues compared post-surgery health outcomes in children with cerebral palsy who were managed with and without gait analysis.[8] This was a single-center, single-blind study. The trial included 186 ambulatory children with cerebral palsy who were candidates for lower extremity surgery to improve their gait. All participants underwent gait analysis at a gait laboratory. Patients were randomized to a treatment group in which the surgeon received the gait analysis report or a control group in which the surgeon did not receive the report. The reports included a summary of test results and treatment recommendations from the gait laboratory physician. The same surgeons treated the intervention and control patients i.e., they received gait reports for half of the patients. Patients were re-examined the day before surgery (i.e., following gait analysis) for pre-operative treatment planning. Outcomes were assessed pre-operatively and approximately 1 year post-surgery. There were three primary outcomes:
  1) pre- to post-surgical change between groups in the walking scale of the Gillete Functional Assessment Questionnaire (FAQ),
  2) the Gait Deviation Index (GDI), and
  3) the oxygen cost of walking, a measure of the energy expended while walking.

  A total of 156 of 186 (84%) participants returned for the follow-up examination; analysis was not intention to treat. There was no statistically significant difference between groups in any of the three primary outcomes. For example, the proportion of patients improved according to the FAQ was 31% in the intervention group and 25% in the control group (p=0.38). There were significant differences between groups at the p=0.05 level for 2 of 19 secondary outcome variables; p values were not adjusted for multiple comparisons. The authors noted that physicians followed only 42% of recommendations in the gait analysis report for patients in the treatment group, which may partially explain the lack of significant differences between groups in the primary outcomes and most of the secondary outcomes. They further noted that there was a positive relationship between gait outcomes

and following gait analysis recommendations.

- In 2013, Wren et al published a secondary analysis of data from the RCT previously described to evaluate the impact of gait analysis on the correction of excessive internal hip rotation among ambulatory children with cerebral palsy.[9] In the secondary analysis, the authors included the subset of children for whom the gait laboratory recommended external femoral derotation osteotomy (FDRO) to correct excessive passive and active internal hip rotation and who had both pre- and postoperative data available. As in the primary study, the intervention was receipt of the gait analysis report by the treating orthopedic surgeon for participants in the intervention group; in this subset of patients, all patients had had FDRO recommended by the gait analysis report, but the decision to actually perform surgery was up to the treating surgeon. Physical measurements for this subanalysis included femoral anteversion, maximum hip internal and external rotation range of motion, and rotational alignment during gait. The primary outcome variables included femoral anteversion and mean hip rotation and foot progression in the stance phase of gait. Outcomes postsurgery and change in variables pre- to postsurgery were compared between intervention and control groups, with additional analyses based on whether patients in the gait report (intervention) group had had the gait report recommendations followed.

  This subanalysis included 44 children (65 limbs) in whom FDRO was recommended. FDRO was performed in 7/39 limbs in which it was recommended in the gait report (intervention group); it is not clear how many children in the control group for whom FDRO was recommended received surgery. There were no significant differences in outcomes between the gait report and control groups on intent-to-treat analysis. However, among children in the intervention group who had FDRO done (n=7 limbs), the limbs demonstrated greater improvements in femoral anteversion (-32.9° vs -12.2°; p=0.01), dynamic hip rotation (-25.5° vs -7.6°; p=0.001), and foot progression (-36.2° vs -12.4°; p=0.02) than limbs in the control group. The discrepancy between the intent-to-treat and per-protocol results may be related to generally poor compliance with the gait report recommendations, as only 7 of 39 recommended FDROs performed in the gait analysis group. Interpretation of this study's significance is limited by its subgroup analysis design and the small number of patients who received gait analysis and FDRO.

- Schwartz et al published an evaluation of the role of a random forest algorithm (a statistical method used to predict an outcome for a particular observation based on a series of predictor values) that included gait analysis to predict outcomes after single-event, multilevel surgery for patients with ambulatory cerebral palsy that either did or did not include psoas lengthening.[10] The study authors report that their random forest algorithm was able to generate criteria that are predictive of good outcomes for patients undergoing a single-event, multilevel orthopedic surgery. However, the study based on a retrospective analysis of a motion analysis center database and is thus subject to bias. In addition, the complexity of the random forest decision algorithm makes it is difficult to determine the degree to which gait analysis independently predicts outcomes.

Pre- and/or Post-Surgical Evaluation for Conditions Other Than Cerebral Palsy

- In a study by Suda et al, gait analysis recommendations in 60 patients with neurogenic intermittent claudication were evaluated and compared with 50 healthy controls.[11] The authors concluded that gait analysis provided useful quantitative and objective information to evaluate postsurgical treatment. However, the study does not address how the gait analysis influenced treatment decisions or affected health outcomes.

- Sankar et al reviewed the records of 35 children (56 feet) who had recurrent deformity after treatment of idiopathic clubfoot.[12] Gait lab recommendations were compared to surgical plans prior to gait analysis, and then to the actual surgery received. Thirty of 35 (86%) of children underwent surgery. GA resulted in changed procedures in 19 of 30 (63%) patients. GA was found to influence clinical decisions, but, like the study by Suda et al, this study did not evaluate whether these changes resulted in improved health outcomes.
- Gait analysis has been used in the assessment of multiple other conditions (eg, knee pain in older patients with osteoarthritis[13], gait after acute stroke[14], and of frailty in older patients[15]); however, the evidence linking the use of gait analysis to outcomes in these conditions is limited.

Clinical Practice Guidelines

No clinical practice guidelines from U.S. professional societies were found that address gait analysis.

Summary

Current evidence comparing health outcomes in patients with cerebral palsy managed with and without gait analysis is limited to data from a single randomized controlled trial. The reported outcomes are difficult to interpret because surgeons followed only a minority of recommendations in the gait analysis reports. Despite the lack of reliable evidence, comprehensive gait analysis has evolved to a standard of care to select surgical or other therapeutic interventions for gait improvement in children and adolescents with gait disorders associated with cerebral palsy. Gait analysis may be considered medically necessary in this population.

Several studies conducted among patients with conditions other than cerebral palsy have suggested that gait analysis recommendations impact treatment decisions; however, the impact of these decisions on health outcomes is unknown. Therefore, gait analysis is considered investigational for indications other than cerebral palsy.

REFERENCES

1. Cutti, AG, Ferrari, A, Garofalo, P, Raggi, M, Cappello, A. 'Outwalk': a protocol for clinical gait analysis based on inertial and magnetic sensors. *Med Biol Eng Comput*. 2010 Jan;48(1):17-25. PMID: 19911214
2. van den Noort, JC, Ferrari, A, Cutti, AG, Becher, JG, Harlaar, J. Gait analysis in children with cerebral palsy via inertial and magnetic sensors. *Med Biol Eng Comput*. 2013 Apr;51(4):377-86. PMID: 23224902
3. BlueCross BlueShield Association Medical Policy Reference Manual "Gait Analysis." Policy No. 2.01.03
4. Dobson, F, Morris, ME, Baker, R, Graham, HK. Gait classification in children with cerebral palsy: a systematic review. *Gait Posture*. 2007 Jan;25(1):140-52. PMID: 16490354
5. McGinley, JL, Baker, R, Wolfe, R, Morris, ME. The reliability of three-dimensional kinematic gait measurements: a systematic review. *Gait Posture*. 2009;29:360-9. PMID: 19013070
6. Benedetti, MG, Merlo, A, Leardini, A. Inter-laboratory consistency of gait analysis measurements. *Gait Posture*. 2013 Sep;38(4):934-9. PMID: 23711987
7. Wren, TA, Gorton, GE, 3rd, Ounpuu, S, Tucker, CA. Efficacy of clinical gait analysis: A systematic review. *Gait Posture*. 2011 Jun;34(2):149-53. PMID: 21646022

8. Wren, TA, Otsuka, NY, Bowen, RE, et al. Outcomes of lower extremity orthopedic surgery in ambulatory children with cerebral palsy with and without gait analysis: Results of a randomized controlled trial. *Gait Posture*. 2012 Dec 6. PMID: 23219787
9. Wren, TA, Lening, C, Rethlefsen, SA, Kay, RM. Impact of gait analysis on correction of excessive hip internal rotation in ambulatory children with cerebral palsy: a randomized controlled trial. *Dev Med Child Neurol*. 2013 Oct;55(10):919-25. PMID: 23738949
10. Schwartz, MH, Rozumalski, A, Truong, W, Novacheck, TF. Predicting the outcome of intramuscular psoas lengthening in children with cerebral palsy using preoperative gait data and the random forest algorithm. *Gait Posture*. 2013 Apr;37(4):473-9. PMID: 23079586
11. Suda, Y, Saitou, M, Shibasaki, K, Yamazaki, N, Chiba, K, Toyama, Y. Gait analysis of patients with neurogenic intermittent claudication. *Spine (Phila Pa 1976)*. 2002 Nov 15;27(22):2509-13. PMID: 12435983
12. Sankar, WN, Rethlefsen, SA, Weiss, J, Kay, RM. The recurrent clubfoot: can gait analysis help us make better preoperative decisions? *Clin Orthop Relat Res*. 2009 May;467(5):1214-22. PMID: 19093158
13. Asay, JL, Boyer, KA, Andriacchi, TP. Repeatability of gait analysis for measuring knee osteoarthritis pain in patients with severe chronic pain. *J Orthop Res*. 2013 Jul;31(7):1007-12. PMID: 23508626
14. Ferrarello, F, Bianchi, VA, Baccini, M, et al. Tools for observational gait analysis in patients with stroke: a systematic review. *Phys Ther*. 2013;93:1673-85. PMID: 23813091
15. Schwenk, M, Howe, C, Saleh, A, et al. Frailty and technology: a systematic review of gait analysis in those with frailty. *Gerontology*. 2014;60:79-89. PMID: 23949441

CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	96000	Comprehensive computer-based motion analysis by video-taping and 3-D kinematics
	96001	Comprehensive computer-based motion analysis by video-taping and 3-D kinematics; with dynamic plantar pressure measurements during walking
	96002	Dynamic surface electromyography, during walking or other functional activities, 1 to 12 muscles
	96003	Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle
	96004	Review and interpretation by physician or other qualified health care professional of comprehensive computer-based motion analysis, dynamic plantar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report

CODES	NUMBER	DESCRIPTION
HCPCS	None	