

June 12, 2023

GCMAS motion analysis position statement

Gait analysis, while an emerging technology in the 1980s utilized by pioneering clinical centers of excellence, became a valued, critical evaluation and treatment decision-making tool for cerebral palsy (CP) and stroke care by the 1990s. There are currently 22 clinical gait labs in the USA which have achieved the rigorous national accreditation process. The primary use of clinical gait analysis is to inform rehabilitation and orthopedic surgical decision-making in children, and adults, with physical disabilities and impaired ambulation. Correction of the complex multi-level structural musculoskeletal deformities often requires 6 to 10 separate synergistic operative procedures. The information from comprehensive gait analysis was critical to the development of safe, effective, and efficient single-event (e.g. during a single surgery) multi-level surgery (SEMLS) techniques over the last 25 years. SEMLS are not only preferred by families and children (over annual surgeries during childhood) but also more effective in improving function and reducing disability. The complex decision-making to plan SEMLS procedures is primarily based on gait analysis data that allows for a more comprehensive understanding of gait pathomechanics and therefore, more informed treatment decisions for each patient. We appeal the denial based on the following points:

1. Gait analysis provides the most accurate, quantitative, clinically accessible method of movement assessment, far superior to what is available with visual assessment or other static measures of ambulation (page 3-4).
2. Gait analysis provides the necessary information to guide treatment that is not available through traditional static measures such as x-rays or physical examination (page 5-7).
3. Evidence demonstrates improved outcomes for individuals when surgical recommendations, based on findings from three-dimensional gait analysis, were followed (page 8-9).
4. Cost analyses demonstrate that gait analysis will save patients and insurance companies money or at least be cost-neutral (page 10).
5. Orthopedic surgery based only on visual analysis can result in additional iatrogenic deficits due to the difficulty in adequately assessing complex gait disorders without clinical gait analyses (page 11-12).
6. Motion analysis has been found to be essential for assessment leading to improved outcomes in the care of adults with Parkinson's disease and Stroke (page 13-16).

In the attached document, we have highlighted peer-reviewed evidence that addresses each of the above points. Evidence-based medicine relies on evidence aggregated across levels of research rigor to provide the depth and breadth of knowledge to ensure patients receive optimal care and have optimal long-term outcomes. In childhood onset movement disorders, such as CP, long-term prospective cohort studies with objective outcome measures are considered of equal value as randomized controlled trials in understanding movement outcomes (Thomason, 2012). Examples of these efforts have also been provided in the attached information.

Both Blue Cross and Cigna now consider Gait Analysis to be medically necessary for pre-operative assessment for patients with cerebral palsy, based on the current evidence base. We hope that after review of the information provided, which includes updated literature published since Aetna's last review, your organization will also see the benefit of providing this essential service to your members with neuromuscular disorders who have complex gait issues that require treatment.

The fundamental question: is a clinic visit with a limited clinical exam and visual assessment of a gait pattern in a small space adequate to make fully informed comprehensive orthopedic surgical decisions on persons with complex gait deviations? What we have learned from decades of practice with a standard of care that included comprehensive gait analysis for pre-operative decision-making and post-operative objective evaluation of outcomes is that a clinic visit it is not adequate. An international group of 17 orthopedic surgeons with over 300 years of combined experience has reached consensus through a standardized iterative Delphi process on a range of dynamic data from 3D gait analysis that are critical to making the most informed surgical decisions to improve ambulatory function for their patients (McCarthy, 2020; Rutz et al., 2020). These physicians include specific 3D gait analysis parameters outlined in these papers as part of their best-practice indications for common surgical procedures in children with CP.

Thank you for your time and consideration,

The Gait and Clinical Movement Analysis Society Reimbursement Committee

Chris Church, MPT, Nemours duPont Hospital for Children

Sylvia Ounpuu, PhD, Connecticut Children's Hospital

Christine Doss, MD, Emory University

Carole A Tucker, PhD, PT Temple University

Susan Rethlefsen, PT, DPT, Los Angeles Children's Hospital

John Henley, PhD, Nemours duPont Hospital for Children

Gait analysis provides the most accurate, quantitative, clinically accessible method of movement assessment, far superior to what is available with visual assessment or other static measures of ambulation.

- Visual gait assessments (even that aided by video recording) are limited by the fact that they only provide subjective information about outward appearances of gait and are prone to poor reliability (Krebs 1985).
- Observational gait assessment tools have been found to be inaccurate when compared with computerized gait analysis. Wren, et al. compared the observational Physician's Rating Scale to computerized gait analysis data and found that when using it clinicians incorrectly identified two of the most common gait problems in cerebral palsy, excessive plantarflexion and excessive hip flexion in stance phase. Such inaccuracy could lead some clinicians to assume presence of fixed contractures that are not present, and to recommend surgery that could be either unnecessary or harmful. (Wren, 2005) Similarly, Ong, found only 52% agreement between the Edinburgh Visual Gait Score (EVGS) and computerized gait analysis, when the EVGS is used by clinicians inexperienced in gait analysis. (Ong, 2008) Orozco et al., found 52-73% agreement between EVGS and computerized gait analysis, with limited accuracy for visual assessment of rotational alignment of the lower extremities (Orozco, 2016).
- Evidence exists that the "informal visual analysis of gait abnormalities", which unfortunately is the standard of care in many locations, is not acceptable. It has been well documented that there is considerable variation in observer agreement for the most common clinical assessment measures. The most recent extensive review of this topic:
 - Rathinam (2014) systematically reviewed the available pediatric observational gait analysis tools and examined their reliability and validity compared to instrumented gait analysis (IGA). None of the tools accomplished the level of IGA's consistency. According to the authors, observational gait analysis tools are valuable to determine the effect of a clinical intervention on gait but they cannot be used for pre-surgical planning or diagnostic purposes due to their limited reliability and validity.
- Correlation of gait parameters with physical exam and static measures (x-ray/CT scan) is poor, indicating isolated structural static measures of body structures are inadequate to determine their additive effect on gait. Dynamic multifactorial assessment such as provided by clinical gait analysis is necessary for surgical planning to correct gait disability. (Desloovere, 2006, Domagalska, 2013, McMulkin, 2000, Orendurff, 1998, Aktas, 1998, Radler, 2010).
- Range of motion clinical examinations are inadequately reliable. Keenan (2004) conducted a repeatability study of the measurement of passive joint ROM in children with CP. The authors found considerable variation in observer agreement in measuring joint range of motion in children and young adults with spastic cerebral palsy. The authors recommend a more comprehensive assessment of range of motion. Instrumented gait analysis provides such comprehensive assessment.
- Gait analysis using standardized/optimized methods performed by trained personnel provides accurate documentation of movement pathology in terms of joint and segment motion (Schwartz, 2004).

- Clinical gait analysis data is repeatable across different providers. A high level of consistency of kinematic and kinetic data across different gait analysis labs supports motion analysis techniques as a reliable method of assessing human locomotion for clinical purposes (Pinzone, 2014).
- Evidence shows that trained clinicians change their treatment decisions on primary gait deviations when they are provided comprehensive gait analysis data compared to a visual assessment and clinical exam alone in patients with a variety of gait pathologies due to the increased understanding of complex gait issues that is possible with comprehensive gait analysis data.
 - The addition of gait-analysis data resulted in changes in surgical recommendations for patients with cerebral palsy 52% of the time (DeLuca, 1996) and 89% of the time (Kay, 2000) and 70% of the time (Lofterod, 2007). An increase in surgical recommendations was observed for the gastrocnemius (59%) and rectus femoris (65%), whereas decreases were observed for the hamstrings (61%), psoas (78%), hip adductors (83%), femur (86%), and tibia (64%) (DeLuca, 1996). In the Kay study, of the 273 surgical procedures recommended before the gait study in the 70 patients, 106 (39%) of these procedures were not done when the gait laboratory data were considered. In the Lofterod study, of the 253 specific surgical procedures proposed, 97 procedures were not recommended after gait analysis and 65 additional procedures were recommended after the analysis.
 - Similarly, Mueske (2019) made recommendations for ambulatory children with spina bifida before and after consulting gait analysis data. Pathology identification changed for common gait problems including crouch (28% of cases), tibial rotation (35%), pes valgus (18%), excessive hip flexion (70%), and abnormal femur rotation (75%). Recognition of excessive hip flexion and abnormal femur rotation increased after consideration of gait analysis data ($p < 0.05$). Surgical recommendations also frequently changed for the most common surgeries including tibial derotation osteotomy (30%), anterolateral release (22%), plantar fascia release (33%), knee capsulotomy (25%), 1st metatarsal osteotomy (60%), and femoral derotation osteotomy (89%). At the patient level, consideration of gait analysis data altered surgical recommendations for 44% of patients.
 - Ferrarin (2015) found that comprehensive gait analysis data significantly influenced the therapeutic planning and reinforced decision-making for chronic post stroke patients. Based on the analysis of gait analysis data, 71% of post stroke patients had their treatment planning changed in some components.

Gait analysis provides the necessary information to guide treatment that is not available through visual assessment or traditional static measures such as x-rays or physical examination.

CPT Code 96000 and 96001 – Kinematics

- Kinematics are those parameters used to describe the joint and segment angles in three dimensions during gait. Although there is some ability to visually assess joint kinematics, complex multiplanar pathology makes the visual assessment of joint motion inaccurate as discussed above. A common example of the benefit of motion analysis is in the assessment of the transverse plane motion (Wren 2013a).
 - Gait analysis improves gait outcomes for the correction of transverse plane deformity if the gait recommendations for the correction of rotational deformity are followed (Wren 2013a)
 - Dynamic evaluation of the complex rotational movements of the pelvis and hips (which are often asymmetric) in the transverse plane is necessary to optimize surgical treatment outcomes (Dreher 2007, Kay 2004)
 - Gait analysis also benefits the understanding sagittal plane function of the ankle by reducing excessive triceps surae lengthenings through differentiation between apparent equinus and real equinus with ankle kinematics (Wren, 2013b)
 - Gait analysis data can differentiate between three clinically relevant kinematic patterns in children with Charcot-Marie-Tooth disease (Ferrarin, 2012; Ounpuu, 2013; Wojciechowksi et al., 2017) and is therefore an important clinical decision-making tool for determining optimal treatments for improving gait function including orthoses (Ounpuu, 2021)

CPT Code 96000 and 96001 – Kinetics

- Kinetics are those parameters used to describe the mechanisms that cause movement such as ground reaction forces, joint moments, and joint powers. Kinetics cannot be visually assessed and can often determine why a particular gait deviation is occurring (Gage 2001), provide additional justification for surgical intervention (Adolfson, 2007) and assess the effectiveness of intervention (Ounpuu, 1996).
 - Reduced toe drag and tripping following rectus femoris transfer is associated with a normal hip flexion power generation at toe-off (Miller, 1997)
 - Increased knee extensor moments in terminal stance are correlated with reduced peak knee flexion in swing and therefore are an indicator for addressing excessive knee flexion with rectus transfer surgery (Golderg, 2006).
 - In children with hemiplegia, self-selected walking speed significantly correlates with maximum hip flexion moment on the affected side and maximum ankle and hip powers on both sides (Olney, 1994)
 - Changes in kinetic patterns can be affected by orthoses (Ounpuu, 1996)
 - Despite a similar visual appearance of reduced knee flexion among subjects with a spastic paretic stiff-legged gait pattern, each individual has unique kinetic mechanisms associated with this observed gait pattern (Kerrigan, 2001)

- Ankle kinetics, including timing and peak ankle moment and power generation can be improved following gastrocnemius lengthening (Rose, 1993; Adolfsen, 2007 and Cruz, 2011)
- Mean knee kinetics moments show improvements pre to post-surgical intervention following multi-level surgery (Adolfsen, 2007; Cruz et al., 2011) and provide an increased understanding of the pathomechanics and associated implication of crouch gait related to surgical decision-making and outcomes evaluation
- Long-term surgical outcomes show that ankle kinetic benefits noted at 1 year post-surgery can be maintained to 10 years post-surgery (Ounpuu, 2015)
- Kinetic ankle phenotypes in children with Charcot-Marie-Tooth disease lead to more informed treatment decision-making through an improved understanding of the pathomechanics of gait function (Ounpuu, 2013; Jani-Acsadi, 2015)

CPT Code 96001 or 97750 – Pedobarograph

- Pedobarograph or foot pressure data include a map of the pressures underneath the foot during the stance phase of gait. The relative areas of higher vs. lower pressures are quantified by pressure measurements and highlight parts of the stance phase that can be problematic as well as provide the path of the center of pressure. Foot pressure data provide reliable and valuable information about the impact of bony deformity and muscle weakness of the foot/ankle as well as the ability of the patient to weight bear over the distal aspect of the foot (Riad, 2007). Foot pressures also provide valuable information about ability to weight bear over the distal aspect of the foot and associated plantar flexor strength which may be very difficult to measure in a standard clinical exam for some patient demographics.
 - Foot pressure data are a valuable tool for orthosis design and evaluation, tracking disease progression over time, and evaluating surgical outcomes in a variety of pathologies including cerebral palsy, clubfoot, and Charcot- Marie-Tooth (Hughes, 1993, Chan, 2007; Jeans 2017; Bennet, 2007; Skopljak, 2014)
 - Foot pressure data are an accurate measure of the valgus and varus foot dysfunction during gait (Chang, 2002), which may not be otherwise apparent.
 - Foot pressures are relevant for determining treatment needs and effectiveness in the diabetic foot (Young, 1992).

CPT Codes 96002 (Surface EMG) and 96003 (Fine Wire EMG)

- Surface or fine wire electrodes are used to record electromyogram (EMG) activity during gait which cannot be assessed visually or otherwise and directly guides treatment including surgery
 - Correction of toe drag and tripping using rectus femoris transfer is associated with abnormal rectus firing in the swing phase of gait, but the normal activity of the vastus medialis muscle in the swing phase (Miller, 1997). Motion analysis incorporating dynamic EMG is the only way of knowing if the rectus femoris is active during the mid-swing phase to provide a basis for a rectus femoris surgical procedure.
 - Either the tibialis anterior or the tibialis posterior can cause a varus foot deformity in children with Cerebral Palsy. Good treatment outcome depends on determining which

muscle is firing out of phase and causing the deformity before completing a split anterior tibialis or split posterior tibialis tendon transfer (Scott, 2006, Michlitsch, 2006, Perry, 1977)

- Both kinetics and EMG greatly enhance the clinician's ability to distinguish primary from secondary or compensatory gait deviations (Davids 1999, Ounpuu 1996). Understanding the mechanisms of a gait pattern helps the clinician recognize pathology-specific concerns to guide treatment protocols. For example, crouch gait could be caused by plantar flexor moment insufficiency, bony deformities such as external tibial torsion, distal tibial valgus, pes valgus, femoral anteversion, knee flexion contractures, patella alta, soleus weakness, and/or knee extensor lag (Gage, 2001). Visual assessment and physical exams are unable to determine the mechanism of crouch gait and distinguish primary from secondary gait deviations.

Evidence demonstrates improved outcomes for individuals when surgical recommendations, based on findings from three-dimensional gait analysis, were followed:

- In a randomized controlled trial, gait outcomes were better for the majority of parameters in the group of patients where motion analysis recommendations were followed versus the control where they were not (Wren, 2013a)
- Wren (2013b) conducted a randomized controlled trial to determine if gait analysis improves correction of excessive hip internal rotation in ambulatory children with spastic cerebral palsy (CP). The authors concluded that gait analysis can improve outcomes when its recommendations are incorporated into the treatment plan.
- Niklasch (2015) evaluated outcomes of femoral derotation osteotomy (FDO). The authors concluded that it is less likely to have unsatisfactory outcomes if the amount of FDO is defined according to the findings of gait analysis compared with clinical examination.
- Schwartz (2014), using a large retrospective cohort of 1088 limbs defined treatment guidelines for the femoral derotation osteotomy. The findings of this study showed that excessive internal hip rotation during gait as documented by motion analysis is a critical indicator for FDO's and ultimately the best surgical outcome in terms of gait findings.
- Wren (2011b) conducted a systematic review to evaluate and summarize the current evidence base related to the clinical efficacy of gait analysis including the use of gait analysis in patients with cerebral palsy. This body of literature provides strong evidence for the technical, diagnostic accuracy, diagnostic thinking, and treatment efficacy of gait analysis. The systematic review was updated in 2020 (Wren, 2020). The results confirmed the efficacy of gait analysis in changing and reinforcing clinicians' treatment decisions, increasing clinician confidence in treatment plans, increasing agreement among clinicians regarding treatment decisions, and the potential for gait analysis to improve patient outcomes.
- Lamberts (2016) completed a systematic review of the outcomes of SEMLS on gait in children with CP. Of the 50 studies reviewed, the majority reported improvements after SEMLS based on 3D gait analysis.
- Morais Filho (2008) investigated if recommendations based on three-dimensional gait analysis are associated with better postoperative outcomes in patients with cerebral palsy. According to the investigators, the patients whose treatment matched the recommendations from three-dimensional gait analysis showed a more significant improvement in walking.
- Wren (2008) retrospectively evaluated 756 ambulatory patients with cerebral palsy who underwent lower extremity surgery to improve their walking ability. The need for future surgery was compared between the 578 who had three-dimensional gait analysis testing before their initial surgery and the 178 patients who did not have gait analysis testing before their initial surgery. After adjusting for GMFCS level, the mean number of additional surgeries per person-year was significantly lower in those who had gait analysis testing before their initial surgery.
- Ferrari (2014) assessed the rate of agreement on muscle-skeletal diagnosis and surgical recommendations in patients with diplegic CP, by two blinded, experienced clinicians based on clinical assessment alone and gait analysis (GA) in addition to clinical assessment. The authors found that the availability of a GA laboratory supported diagnostic reasoning for children with CP who are indicated for surgery.

- Fuller (2002) assessed the influence of gait analysis upon surgical planning in patients with upper motor neuron syndrome and gait dysfunction. They found that instrumented gait analysis alters surgical planning for patients with equinovarus deformity of the foot and ankle and can produce a higher agreement between surgeons in surgical planning.
- Thomason (2011 a) have documented in a randomized controlled trial using motion analysis techniques the short-term benefits of SEMLS in patients with CP in comparison to a control group that did not have surgical intervention. The same study cohort went on to maintain these benefits over the long-term (Thomason, 2013). In all cases, motion analysis data was used to determine surgical strategy and evaluate objectively treatment outcomes.
- Chang (2006) found that patients treated with SEMLS as determined by motion analysis showed improved outcomes than those that did not have surgical intervention. Kinematic outcomes assessed in both the surgical and control groups showed that the surgical group with SEMLS based on gait analysis were 3.68 times more likely to have a positive outcome.
- Vuillermin (2011) conducted a population-based retrospective study of patients from the Australian Cerebral Palsy Register who underwent gait analysis between 1995–2009. Gait analysis became standard of practice in Australia in 1995 and was used as an outcome assessment tool in this study. Those evaluated early in the study period had undergone treatment without pre-operative gait analysis, while those evaluated in later years received treatment informed by gait analysis. The primary finding was that the prevalence of severe crouch gait declined dramatically, from 25% to 4%, after the introduction of gait analysis. Severe crouch is one of the most common gait problems affecting the CP population and increases with age and growth [Rethlefsen et al., 2017, Wren et al., 2005], likely leading to the cessation of walking over time for many patients. Prevention of crouch gait would vastly improve the quality of life for patients with CP and their caretakers.

Cost analyses demonstrate that gait analysis leads to fewer repeat surgeries and a lower/equivalent cost of care.

- Clinical gait analysis is associated with a lower incidence of additional surgery, resulting in lesser disruption to patients' lives. Costs (including the cost of gait analysis) are equivalent for 2 groups of children with CP – 1 who had a pre-op gait analysis (GA), and 1 that did not have a gait analysis (NGA) (Wren, 2009)
 - Patients in the gait analysis (GA) group had more procedures (GA: 5.8, No Gait Analysis (NGA): 4.2; $P < 0.001$) and higher cost (GA: \$43,006, NGA: \$35,215; $P < 0.001$) during index surgery, but less subsequent surgery. A higher proportion of patients went on to additional surgery in the NGA group (NGA: 32%, GA: 11%; $P < 0.001$), with more additional surgeries per person-year (NGA: 0.3/person-year, GA: 0.1/person-year; $P < 0.001$) resulting in higher additional costs (NGA: \$3009/person-year, GA: \$916/person-year; $P < 0.001$). The total number of procedures (GA: 2.6/person-year, NGA: 2.3/person-year; $P = 0.22$) and cost (GA: \$20,448/person-year, NGA: \$19,535/person-year; $P = 0.58$) did not differ significantly between the 2 groups.
- SEMLs planned with gait analysis costs less than staged surgical intervention (Ounpuu, 2020)
 - The charges of staged surgical intervention ranged from 20% to 47% higher than SEMLs depending on the number and complexity of the orthopedic surgical recommendations. The mean difference was \$43,606 more for staged surgery. The findings of this study show that SEMLS in conjunction with CGA as part of the surgical decision-making process result in reduced costs when compared to performing the same surgeries sequentially without the benefit of CGA. Therefore, the gait analysis/multilevel surgery has a financial benefit in addition to the many other benefits including improved understanding of pathomechanics of gait abnormalities, reduced time away from work (parents) and school (patients).
- Compared to surgical intervention based on visual assessment of gait alone, surgery completed with the guidance of gait analysis resulted in an altered surgical plan and cost savings (DeLuca, 1997, Loftrod, 2007))
 - The addition of gait analysis data resulted in changes in surgical recommendations in 52% of the patients, with an associated reduction in the cost of surgery, not to mention the human impact of an inappropriate surgical decision, which is more likely without gait analysis (DeLuca, 1996)
 - The addition of the gait analysis data resulted in 13% reduction in the number of procedures recommended with likely reduced surgical costs (Loftrod, 2007). Loftrod also reported a good accordance between gait analysis recommendations and surgery performed (92%).

Iatrogenic problems can result from proceeding with orthopedic surgery based only on visual analysis due to the difficulty in assessing complex gait disorders without accurate measures.

As evidenced by the following case study:

- 15-year-old male with Triplegic Cerebral Palsy.
- Pre-op: complex torsional malalignment with backward rotation of the left side of the pelvis, internal rotation of the left femur, and left external rotation/torsion of the tibia.
- Based on visual assessment it appeared that the right femur was internally rotated, with the right knee pointing in, and the left femur was neutral (see Figure 1 below). However, the backward rotation of the pelvis on the left gives the visual mis-perception that the femur is normally aligned, fooling the naked eye. The external rotation of the tibia on the left also give the visual impression of normal alignment on that side. The detailed kinematic gait analysis data pre-op showed normal right hip rotation and increased left hip internal rotation (opposite of what was seen visually), with compensatory backward pelvic rotation on the left.
- Recommendations based on the gait analysis data: Left femoral derotation (external) to correct internal femoral torsion, left tibial derotation. No surgery was recommended on the right side.
- The referring surgeon chose not to follow the recommendations based on gait analysis and instead performed surgery based on physical exam and subjective visual assessment only. The patient underwent a right femoral derotation osteotomy, and a right tibia derotation osteotomy. These bony derotation procedures where in direct opposition to the recommendations based upon the objective data obtained via gait analysis.
- Post-op: The patient experienced worsening of left pelvis retraction and left hip internal rotation, an increase in the trunk and pelvic malrotation, all in effort to normalize his foot progression to accommodate his now badly mal-aligned right leg. The right hip, which via kinematics showed normal rotational alignment (pre-op) testing, now showed external rotation. PODCI scores his/caregiver's overall global functioning and happiness were significantly lower as compared to pre-op results (Table 1). The patient experienced a decline in function, requiring more extensive walking aids after surgery (trough walker, versus a single cane pre-operatively).
- Recommendation: 2nd surgical intervention including a left femoral derotation osteotomy to correct his left hip malrotation.
- The negative result of this patient's initial surgery highlights the limitations of using visual assessment to determine surgical plans. For this patient, his surgical outcome based on the physician examination and visual assessment resulted in decreased function, significant worsening of his rotational malalignment, the need for two surgeries rather than one, and two rehabilitation periods rather than one. This led to overall increased money spent for two surgeries and rehabilitation periods, prolonged recovery periods, and overall decreased patient satisfaction.

Scale	2015-08-07 POSTOP	2013-11-22 PREOP
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Upper Extremity and Physical Functioning	79	83
Transfer and Basic Mobility	62	79
Sports and Physical Functioning	12	43
Pain / Comfort	85	89
Happiness	35	80
Global Functioning	59	74

Figure 1: Pre-Op Photo showing left pelvis retraction and visual appearance of possible right hip internal rotation. Post-Op showing worsened left pelvis retraction and need for greater supportive assistive device.

PRE-OP



POST-OP



Motion analysis has been found to be essential for assessment leading to improved outcomes in the care of adults with Parkinson's disease and Stroke

Parkinson's disease (PD) is one of the fastest growing neurological disorders (Yang, 2020), and it is estimated that it affected up to 1 million Americans in 2020 (Marras, 2018). The cardinal features of PD are tremor, bradykinesia, and rigidity. As the disease progresses, more symptoms develop which may include postural instability, gait/balance impairment, motor fluctuations, dyskinesias, mood disorders, and cognitive impairment.

Tremor is a rhythmic involuntary oscillatory movement that can affect various body parts (Harish, 2009), predominantly the extremities in PD. Tremor can be a disabling symptom for PD patients, and is the presenting symptom in approximately 70-80% of patients with PD (Hoehn, 1967). The Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) is the clinical standard for parkinsonian tremor measurement, however, it is a subjective assessment performed by the qualitative judgment of a neurologist. Objective and accurate quantification of tremor is increasingly essential to assess the clinical state as well as to determine the efficacy of therapeutic intervention.

3D motion analysis has been described to provide a quantitative evaluation of tremor. In a study of PD patients with hand tremor, Rajaraman concluded that utilizing 3D motion analysis to analyze tremor provides a robust, single quantitative measure of tremor amplitude that is likely to reflect the functional impact of tremor (Rajaraman, 2000). In another study, 3D motion capture provided objective detection of tremor that provided detailed characteristics including peak amplitude, frequency, and distribution pattern (Fransson, 2020), all of which are more objective and sensitive than what a clinician can glean from a physical examination. Accurate quantification of tremor via 3D motion analysis can guide the optimization of medical treatment, as well as objectively quantify tremor response before and after treatment, whether it's pharmaceutical or surgical. Figure 2 provides an example of tremor analysis in a PD patient.

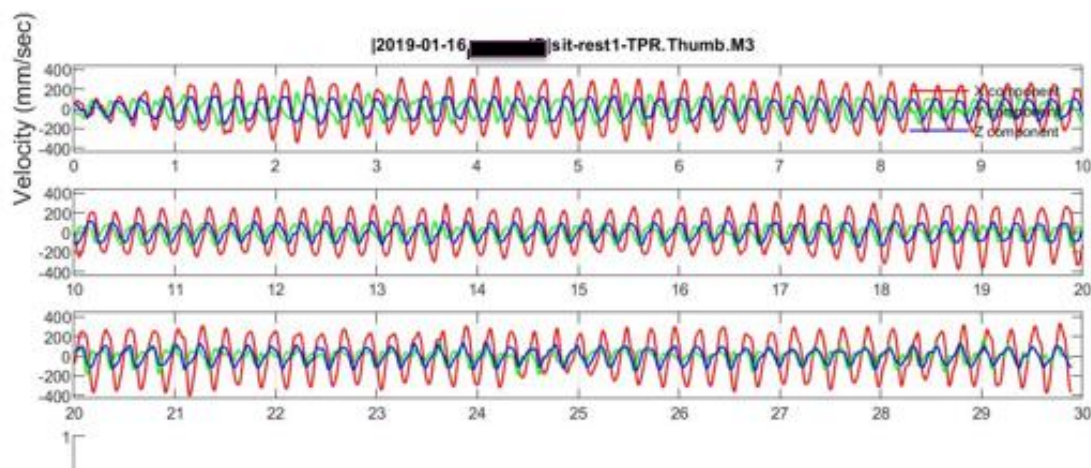


Figure 2. Timed Series of Right Thumb Rest Tremor in a PD Patient

Analysis of tremor via 3D motion capture is not limited to PD (van Brummelen, 2020), although this is the most common use described in the literature. Other tremor types that are commonly analyzed in

our lab include essential tremor (ET), the most common cause of action tremor in adults, as well as non-physiological tremor, which may be complex and difficult to identify by clinical exam alone. 3D motion capture may also yield more information to a clinician when a patient carries a diagnosis with a specific tremor type, and also displays features of a separate superimposed tremor diagnosis (e.g. PD and ET, ET and non-physiological).

In more advanced disease, gait impairment becomes a more disabling feature for PD patients. The MDS-UPDRS includes one measurement to assess gait, and its use is limited by subjective evaluation as well as the paucity of quantitative objective measures of gait kinematics. In contrast, 3D motion capture of gait analysis yields additional data including spatiotemporal parameters (i.e. speed, stride/step length, velocity, swing, step width) as well as 3D limb kinematics (often expressed in terms of joint range of motion in the sagittal and frontal plane) (Cossu, 2017). This approach is advantageous as it is capable of detecting even subtle changes in gait indices subsequent to pharmacological, rehabilitative, or surgical treatments.

In a study of PD patients using 3D motion analysis (Alcock, 2018), it was postulated that step length is the primary determinant of minimum toe clearance and interventions that focus on increasing step length may potentially reduce the risk of trips and falls. Such analysis and potential intervention(s) are critical to the prognosis of PD patients, as among the primary motor features of PD, postural instability and gait impairment is the least responsive to dopaminergic therapy (Koller, 1989) and is a major contributor to disability in patients with PD (Muslimovic, 2008).

In patients that fail medical therapy for motor fluctuations and/or dyskinesias or are intolerant to standard PD meds, surgical therapy with deep brain stimulation (DBS) may be considered. 3D motion capture in DBS PD patients was described as early as 2007 (Carpinella, 2007), and demonstrated that both subthalamic nucleus (STN) DBS as well as levodopa therapy increased the walking speed as well as amplitude of arm and leg swing movement during ambulation. The combination of these two treatments augmented each other, yielding additive effects on gait speed as well as upper and lower limb range of motion (Carpinella, 2007). The possible existence of synergistic effects of STN-DBS and levodopa on gait patterns was also demonstrated in other studies (Krystkowiak, 2003, Ferrarin, 2004, Ferrarin 2005). 3D motion capture will be increasingly important in identifying early risk for falls and could enable intervention before falls that result in injury, increased morbidity, and even subsequent mortality.

Figure 3 provides an example of reduced range of motion in the arms (i.e. arm-swing), which is a common feature of PD patients. Lower limb and trunk kinematics after STN-DBS in PD patients has also been investigated (Defebvre, 1999, Grasso, Peppe, 1999, Ferrarin, 2002, Ferrarin, 2004, Ferrarin, 2005, Peppe, 2010), and some studies suggested that DBS was effective in increasing the range of motion (ROM) at the hip, knee, and ankle level (Faist, 2001, Ferrarin, Lopiano, 2002, Ferrarin, 2004, Ferrarin, 2005, Peppe, Pierantozzi, 2010). Di Giulio recently used 3D motion capture to investigate the relationship between gait performance and STN-DBS frequency in PD patients, concluding that frequency change produced a larger effect on gait performance than voltage change, with an optimal frequency range of 60-140 Hz (Di Giulio, 2019). Further similar studies utilizing 3D motion capture can provide critical information on the management and stimulation settings in this patient population.

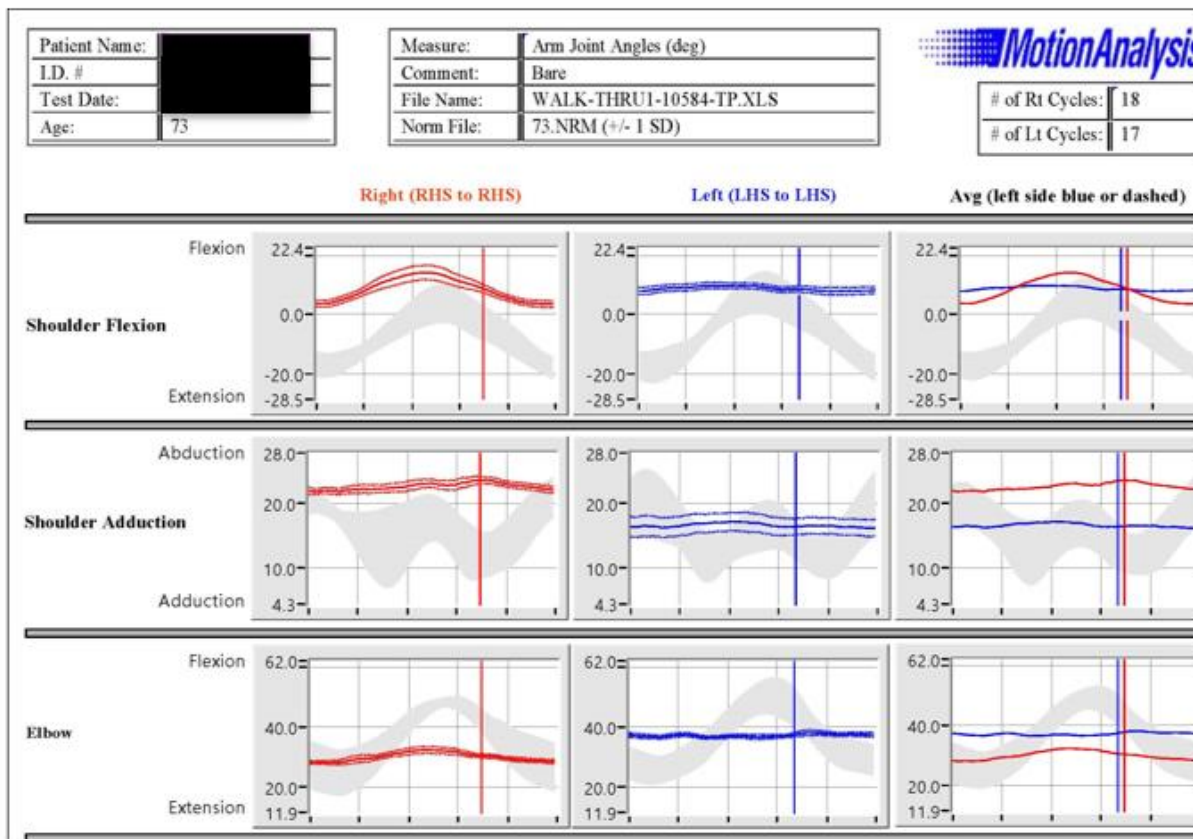


Figure 3. 3D Kinematics of Arm Joint Angles in a PD Patient. Note that the normal range is in gray, and both arms show reduce arm-swing, left more so than right.

The use of 3D motion capture and gait analysis has gained more recognition in the literature to assess PD patients before and after DBS therapy (Lizarraga, 2016, Roper, 2016, Cossu, 2017, Di Giulio, 2019, Kuhner, 2019). A recent small pilot study on PD patients treated with STN-DBS vs. healthy controls concluded that the jerk of the foot as captured by 3D motion capture was an optimal signal to separate healthy subjects from PD patients (Kuhner, 2019). Furthermore, Kuhner stated that “this biomarker is invisible to clinicians’ naked eye and is therefore not included in current motor assessments such as the UPDRS. We therefore recommend that more extensive investigations be conducted to identify the most powerful biomarkers to characterize motor abnormalities in PD.” This further supports the use of 3D motion capture in PD patients to provide a more comprehensive, objective assessment of gait analysis.

Stroke is the second leading cause of death and a major cause of disability worldwide (Katan, 2018). Its incidence is increasing as the aging population grows (Mortality and Causes of Death 2016).

Hemiparesis is the most common impairment after stroke, resulting in varying degrees of gait impairment (Belda-Lois, 2011). 3D gait analysis is considered the gold standard for gait-assessment in patients with stroke and has been well documented (Pittock, 2003, Bleyenheuft, 2009, Roche, 2015). 3D gait analysis provides precise measurements of spatiotemporal, kinematic, and kinetic gait parameters (McGinley, 2009). Studies have demonstrated the reliability of these systems in stroke patients, specifically analyzing kinematic patterns in the sagittal plane (Kadaba, 1989, McGinley, 2009) as well as for spatiotemporal parameters (Oken, 2008, Yavuzer, 2008).

Geiger recently studied the Minimum Detectable Change (MDC) for paretic-limb kinematic and spatiotemporal parameters in the swing and stance phase as measured by 3D gait analysis, in attempt to improve collection of data and subsequent tailored treatment in hemiparesis following stroke (Geiger, 2019). Their findings demonstrated that the reliability of kinematic and spatiotemporal data over 3 gait analyses at 7-day intervals were very good, but lowest between the second and third sessions, suggesting that patients should attend a baseline familiarization session prior to formal evaluations to further enhance treatment benefit (Geiger, 2019). Another study analyzed 17 patients with hemiparesis after stroke, and 3D gait analysis found significant asymmetry in trunk motion between the affected and unaffected sides that varied across the gait cycle (Titus, 2018). This suggests that the trunk may be an area to target in post-stroke gait rehabilitation.

Insufficient foot-clearance is an important alteration in gait pattern seen after stroke (Nikamp, 2018) and can be caused by decreased hip (Woolley, 2001) and knee flexion (Woolley 2001, Chen, 2005) as well as decreased ankle dorsiflexion (Woolley 2001, Roche, 2015). A pilot study in stroke patients undergoing 3D gait analysis with and without ankle-foot orthoses (AFOs) indicated that early or delayed AFO-use post-stroke does not influence pelvis, hip, and knee movements after about 6 months, despite the fact that AFO-use properly correct drop foot (Nikamp, 2018). These results suggest that although AFOs should be provided to improve drop-foot post-stroke, it is not intended to influence the development of subsequent compensatory patterns around the hip and pelvis. 3D gait analysis will be increasingly important for rehabilitation of stroke patients, which will improve recovery, reduce morbidity, and potentially promote return to independence.

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