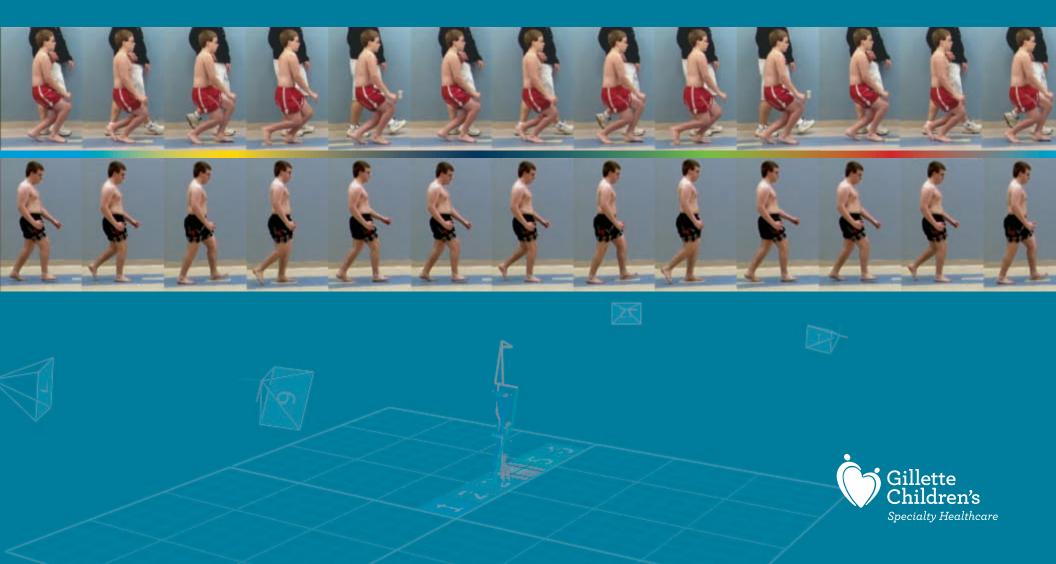
Gait and Motion Analysis for Treatment Planning and Outcomes Assessment



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A Message From the James R. Gage Center for Gait and Motion Analysis Medical Director

Specialists today make treatment recommendations and evaluate the effectiveness of that treatment using data gathered by sophisticated tools. High quality, safe patient care demands measurement and quantification. Our focus in the James R. Gage Center for Gait and Motion Analysis is gathering and providing that critical information before and after treatment.

These excerpts from the Gillette Children's Specialty Healthcare mission statement define our work model:

- "Help patients realize greater well-being, independence and enjoyment in life."
- "Value innovation and encourage medical staff and employees to develop creative approaches to quality care and services."
- "Pursue research and education to continually enhance the quality of our services."

That is who we are. That is the work we do.

This report will give you a glimpse into how motion analysis guides clinical decision-making and is incorporated into patient care. I hope you will find this report valuable.



The James R. Gage Center for Gait and Motion Analysis Team



Tom F. Novacheck, M.D., Medical Director of the Center for Gait and Motion Analysis

Tom 7 Moralled

Tom F. Novacheck, M.D. Medical Director, James R. Gage Center for Gait and Motion Analysis Pediatric Orthopedic Surgeon

Scope and Organization of the Outcomes Report

This is the first outcomes report from the James R. Gage Center for Gait and Motion Analysis (CGMA). It is intended for a broad audience that includes referring physicians, patients and families, payers, and policymakers who are interested in understanding the importance of outcomes, quality and experience for a population of patients who have highly complex conditions.

Through this report we intend to answer the following questions:

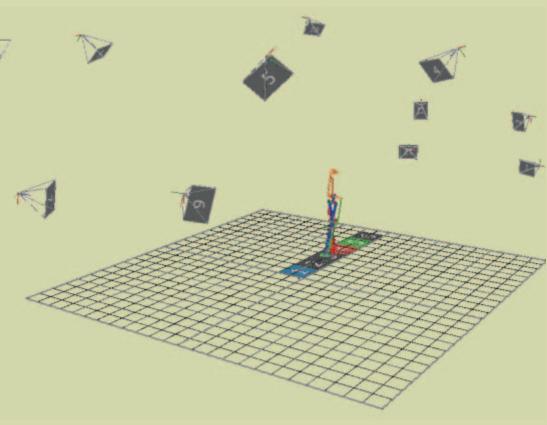
- Which patients utilize the CGMA?
- What are their clinical histories?
- What are their diagnoses?
- What procedures do they typically undergo?
- What are the outcomes of those procedures?
- What complications do they have?
- What is their experience of care?

Methodology

The methodological approach to this report is to describe the experience of a cohort of patients who visited the CGMA during a single calendar year, 2007. A total of 503 patients were seen that year. There were three referral patterns for these patients: those who were referred by Gillette Children's Specialty Healthcare (Gillette) physicians and who received care within the Gillette system (67 percent); those who were referred by outside physicians and who did not receive ongoing care within the Gillette system (23 percent); and those who were referred by outside physicians and who went on to receive care within the Gillette system (10 percent).

This report will describe a subset of patients (n = 391) who received care at Gillette. The patients were followed for 39 months after their initial visit to the CGMA. The 39-month timeline was chosen so that functional outcomes and other reported measures could be associated with the treatment plans that were derived from gait and motion analysis studies.

An outcomes report such as this differs from a traditional research study in that it is a snapshot in time designed to describe the experiences of a population of patients. No hypotheses are generated or tested and there are no comparison groups for analysis. The value in this approach is that it allows clinicians to better evaluate and understand multiple facets of the patients' overall care (clinical outcomes, experience, cost) in order to modify or improve that care through a careful consideration of the data presented. Patients and families, referring physicians, payers, and policymakers may also find this information helpful as they strive to make informed choices about the care that may be necessary for children, adolescents and young adults who have disabilities and complex medical conditions.



About the James R. Gage Center for Gait and Motion Analysis



The James R. Gage Center for Gait and Motion Analysis (CGMA) strives to enhance clinical care for people who have compromised movement. We use state-of-the-art technology to quantify the effects of musculoskeletal and neurologic abnormalities on function. Physicians request evaluations to guide treatment decisions and subsequently to evaluate the outcomes of the interventions. We perform approximately 500 tests each year.

Conditions involving the musculoskeletal and neurological systems may cause difficulty with walking and movement. Because movement issues are complex—and because every patient's needs are unique—the CGMA staff uses a collaborative approach that involves families in decision-making. Our team of experts in the study of human movement includes orthopedic surgeons, physical therapists, engineers and technicians.

Using advanced computer technology, we measure how muscles, joints and nerves interact to make movement possible. A team of orthopedic

surgeons and physical therapists analyzes the data and makes recommendations for treatment that are unique to the patient's walking and movement problems. The data derived from motion analysis and its interpretation are relayed to the referrer, patient and family so that clinical management decisions can be made that will lead to greater function and independence.

Quality assurance and education are critical for optimizing patient safety and future clinical outcomes. We also conduct research in three main areas: diagnosis and treatment planning, biomechanics of gait, and outcomes assessment.

A Typical Gait and Motion Analysis Visit

The main components of gait and motion analysis include an observational video, a musculoskeletal examination, a thorough survey of functional status and, finally, instrumented three-dimensional motion analysis.

Three-dimensional motion analysis is a complex process involving the use of a number of technologies: high-resolution motion tracking cameras, retroreflective markers, electromyography, ground reaction force plates and pedobarography. Along with a cardiorespiratory metabolic measurement system, the equipment enables us to measure:

- Motions of joints and body segments
- Force, movement and power at each joint
- Activity of muscles while walking
- Pressure distribution on the feet
- Walking energy expenditure

The data are combined with clinical experience, biomechanical principles, evidence guidance from the scientific literature, and information gained from self- or parent-reported questionnaires about a patient's function in the community to develop an individualized treatment plan. Other physicians, such as pediatric neurosurgeons and pediatric rehabilitation medicine specialists, may also be involved in the discussion.

We also use the data to assess a patient's current status. This may relate to the outcomes of a surgical treatment or may simply give a picture of a patient's current condition. In either case, the use of accurate, objective, quantitative data allows us to view the patient's gait in an unbiased light. Such data make up a significant component of this outcomes report.



During a gait and motion analysis, sensors and reflectors capture data for patients like Jack.

The James R. Gage Center for Gait and Motion Analysis



James R. Gage, M.D.

The Center for Gait and Motion Analysis opened in 1987 under the direction of Steven Koop, M.D., a pediatric orthopedic surgeon who was trained by James R. Gage, M.D.

Subsequently, Gage joined Gillette in 1990 as medical director. A pre-eminent expert in the impairments of gait associated with cerebral palsy, he developed state-of-the-art

treatments and instructed physicians at Gillette and throughout the world. He has edited a definitive clinical textbook about gait analysis and treatment for children who have gait disorders associated with cerebral palsy.

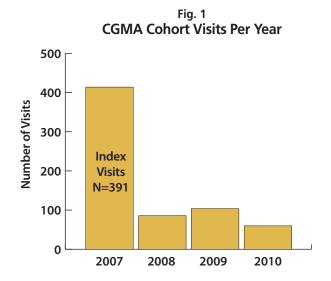
Since 1992, Tom F. Novacheck, M.D., has served as the CGMA medical director. Today, it is one of the busiest clinical motion analysis centers in the world.

Characterizing the Cohort

A total of 503 patients visited the James R. Gage Center for Gait and Motion Analysis (CGMA) in 2007. This report describes the experience of a cohort of 391 patients who received treatment at Gillette. They were followed for three years and three months (39 months total). Any treatments associated with inpatient admissions, procedures in the operating room under general anesthesia, or repeat visits to the CGMA were tabulated.

Patients Became Part of the Cohort at Various Stages of Their Care Path

For this report, the first visit for patients occurred in 2007. However, this visit may not have been the patient's first visit to the center. The purpose of this visit may have been for preoperative planning, or it could have been for postoperative assessment. Consequently, the 2007 cohort is a heterogeneous group; it includes patients seen for preoperative planning, for postoperative follow-up, for diagnostic purposes, or to assess their current status and function.



Cohort Patients Averaged 1.7 Visits in 39 Months

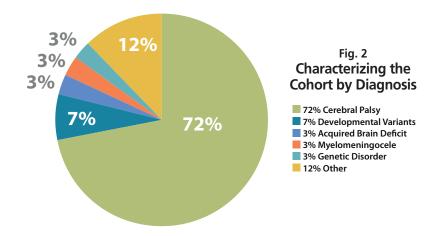
During the 39 months, there were a total of 656 visits to the CGMA among the 391 patients in the cohort (an average of 1.7 visits per patient). The patients had 418 visits the first year, then 80 to 100 return visits in 2008-2010. See Fig. 1. At initial visit, the average age of persons in the cohort was 12 years.

Diagnosis

In the CGMA, patients are seen for a wide variety of diagnoses. In fact, diagnosis alone is not a reason to send a patient to the center. The purpose of the center is to identify impediments to movement and recommend a treatment plan that will improve mobility, function and independence.

The patient cohort had the following diagnoses:

- 72 percent of patients in the cohort are children who have a primary diagnosis of cerebral palsy. Of these patients, 56 percent have diplegia, 20 percent have quadriplegia, 13 percent have hemiplegia and 11 percent have triplegia.
- The remaining 28 percent of patients have a variety of orthopedic, neurological and genetic disorders, including acquired brain deficits, myelomeningocele, or developmental variants such as leg length discrepancies, bony malalignments or flat feet. See Fig. 2.



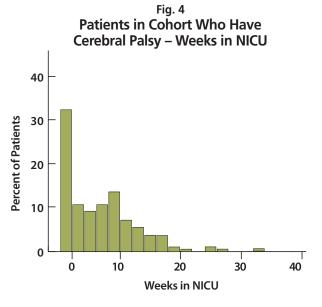
Because children who have cerebral palsy make up such a large portion of the patient population, and because the care of these children tends to be so complex, this report will focus extra attention on this group. In some cases, data will only be shown for the cerebral palsy group. In other situations, data will be divided into "cerebral palsy" and "other" diagnoses. We will clearly note where analysis of subgroups occurs.

Birth History Points to Complexity of Medical Conditions for Patients Who Have Cerebral Palsy

Within the cohort, premature birth was common among the patients who have cerebral palsy, and the majority of those children spent time in the neonatal intensive care unit (NICU). See Fig. 3 and Fig 4.

Patients in Cohort Who Have Cerebral Palsy – Prematurity

25
20
15
10
22
26
30
34
38
42
Gestational Age



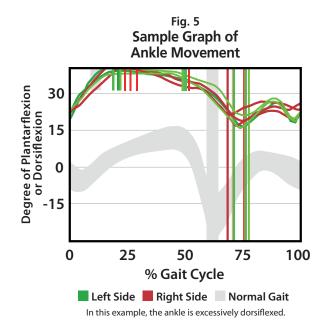
Measuring and Analyzing the Impact of Gait on Function and Independence

The ability to walk is central to mobility, independence and participation in the community. At the James R. Gage Center for Gait and Motion Analysis (CGMA), we view the goal of improved gait as a means for achieving greater function and independence. We assess the impact of gait impairments by measuring deviations, function and energy expenditure.

Measuring Gait

One of the key benefits of gait and motion analysis is the ability to accurately and quantitatively measure patients' gait patterns. See Fig. 5. These data allow us to objectively identify orthopedic and neuromuscular problems and then use clinical expertise and guidance from existing evidence to recommend treatments.

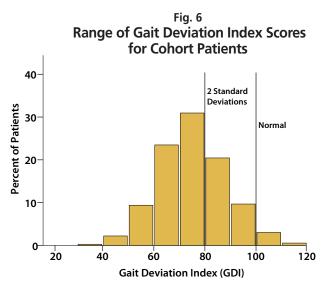
Gait data are also useful as tools for assessing outcomes. By measuring changes in the gait pattern after treatment, we also can gauge the efficacy of treatments in an unbiased and precise manner.



The Gait Deviation Index (GDI) is a validated measure used at our center to quantify how severely the gait of a patient is altered. The GDI summarizes the overall improvement (positive) or worsening (negative) of the patient's gait during the time interval studied. A five-point change in GDI is considered clinically significant.

The GDI encompasses the entire gait pattern and rates all deviations compared to a typical walking pattern. A GDI score greater than 100 means that the patient's gait is indistinguishable from that of typically developing children. Every 10-point decrease in the GDI score is equal to one standard deviation from the typical gait pattern.

As can be seen in Fig. 6, many patients seen in the CGMA have significant gait deviations. It is common for the patients' GDI scores to be more than two standard deviations away from normal, although we frequently see mild gait problems, too. Note that this value includes children being assessed both before and after treatment.



¹Schwartz MH, Rozumalski A. The gait deviation index: A new comprehensive index of gait pathology. Gait and Posture. 2008;28(3):351-357.

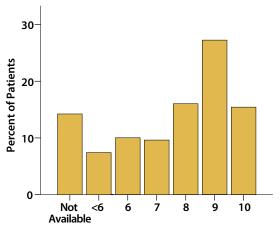
Measuring Function

The Gillette Functional Assessment Questionnaire (FAQ), seen on the right, is a self-reported measure of patients' overall ability to function in their communities.²

All of the patients evaluated in the CGMA (or their guardians) are asked to complete the FAQ. Patients who rate themselves at a Level 10 are able to readily keep up with their peers.

Patients who rate themselves at a Level 6 can walk for limited distances outside the home and typically use a wheelchair for longer distances. Patients who rate themselves below 6 typically walk only indoors or on a limited basis for exercise in therapy. The distribution of FAQ ratings shows that the majority of patients in the cohort function below the level of their typically developing peers (FAQ Level 10). See Fig. 7.

Fig. 7
FAQ Ratings for All Patients in Cohort



²Novacheck TF, Stout JL, Tervo R. Reliability and validity of the Gillette Functional Assessment Questionnaire as an outcome measure in children with disabilities. J Ped Orthop 2000;20:75-81.

Gillette Functional Assessment Questionnaire (FAQ)

Please choose one statement that best describes the patient's usual or typical walking abilities (with assistive devices typically used).

This patient:

- ☐ 1. Cannot take any steps at all.
- ☐ 2. Can do some stepping on his/her own with the help of another person.

 Does not take full weight on feet; does not walk on routine basis.
- ☐ 3. Walks for exercise in therapy and/or less than typical household distances.
- ☐ 4. Walks for household distances, but makes slow progress. Does not use walking at home as preferred mobility (primarily walks in therapy or as exercise).
- ☐ 5. Walks for household distances routinely at home and/or school. Indoor walking only.
- ☐ 6. Walks more than 15-50 feet outside the home but usually uses a wheelchair or stroller for community distances or in congested areas.
- □ 7. Walks outside for community distances, but only on level surfaces (cannot perform curbs, uneven terrain, or stairs without assistance of another person).
- □ 8. Walks outside the home for community distances, is able to get around on curbs and uneven terrain in addition to level surfaces, but usually requires minimal assistance or supervision for safety.
- 9. Walks outside the home for community distances, easily gets around on level ground, curbs, and uneven terrain but has difficulty or requires minimal assistance or supervision with running, climbing, and/or stairs. Has some difficulty keeping up with peers.
- ☐ 10. Walks, runs, and climbs on level and uneven terrain and does stairs without difficulty or assistance. Is typically able to keep up with peers.

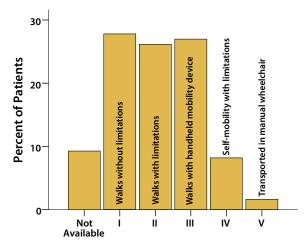
Measuring and Analyzing Gait's Impact on Function and Independence continued

An Additional Classification of Function Used for Patients Who Have Cerebral Palsy

The Gross Motor Function Classification System (GMFCS)³ is a widely accepted scale for classifying mobility among children who have cerebral palsy.

A significant number of children seen in the CGMA are ranked at Levels II, III and IV using the GMFCS – Expanded & Revised, which means their gait is moderately to severely affected. See Fig. 8.

Fig. 8
GMFCS Levels for Cohort Patients

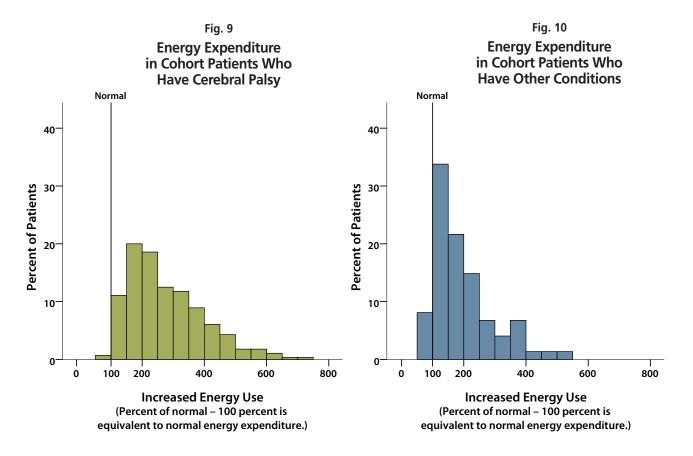


³GMFCS – E & R, Palisano, Rosenbaum, Bartlett & Livingston, 2007 CanChild Centre for Childhood Disability Research – McMaster University.

Measuring Energy Expenditure

Inefficient energy use is one of the most obvious indicators of the impact that high muscle tone, orthopedic deformities, weakness, balance problems and poor motor control have on the gait of the patients. Patients with these conditions commonly expend more than

twice the typical amount of energy. This is particularly evident for those patients who have cerebral palsy. See Fig. 9 and Fig. 10. Gait pathology can affect choices for mobility, since walking—at school, at home and during leisure activities—can be exhausting.



Treatments for Impaired Gait

The natural history of patients who have cerebral palsy is one of decline in ambulatory function. As a result, without treatment, the gait of patients who have the necessary motor skills to walk will deteriorate over time. For them, walking may become more exhausting and/or painful, and they will require more assistance to remain mobile.

Overview of Treatments

For children who have cerebral palsy, treatments to improve or maintain walking function typically include measures to reduce high muscle tone and orthopedic surgery to correct bony deformities, balance muscles and improve joint function. Gait analysis helps guide the specific types of intervention.

Treatments for the Management of High Tone

A range of tone management treatments was provided for patients in the cohort who have cerebral palsy.



Injectable medication is administered to reduce high muscle tone.

Injectable medications such as botulinum toxin A or phenol are injected directly into the muscle. Botulinum toxin A temporarily weakens the muscle and reduces high muscle tone. Phenol reduces high muscle tone by acting on the nerve, not the muscle.

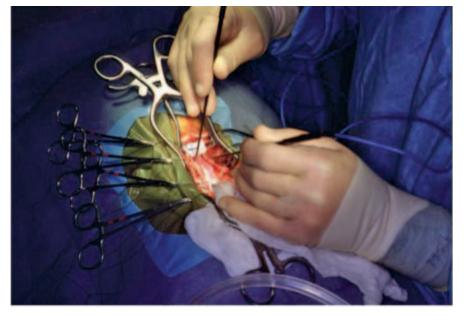
Botulinum toxin A injections given at multiple levels (e.g., hips, knees and ankles at the same time) may require general anesthesia in the operating room (OR), but do not require overnight stays. During the 39-month follow-up period, injectable medications accounted for 42 percent of procedures done in the OR under general anesthesia that did not require overnight stays.

An intrathecal baclofen pump (ITBP) delivers a medication (baclofen) to the intrathecal space around the spinal cord via a thin catheter that extends from an implanted pump to the spine. A neurosurgeon implants the pump under the skin of the abdomen during an inpatient stay.

During the 39-month period, 23 ITBP placements occurred.



ITBPs are implanted to lessen high muscle tone.



A selective dorsal rhizotomy reduces spasticity.

Selective dorsal rhizotomy (SDR) is a procedure intended to reduce spasticity, one type of high muscle tone. During an SDR, sensory nerve rootlets at the lumbar and sacral levels of the spinal cord are electrically stimulated to determine if they trigger a normal or an abnormal response. Those producing an abnormal response are cut, thus reducing spasticity. An inpatient stay is required for this procedure. **During the 39-month period, 37 patients in the cohort had an SDR.**

Treatments for Impaired Gait continued

Corrective Orthopedic Surgery of the Lower Extremities

For children who have cerebral palsy and those who have other complex musculoskeletal conditions, orthopedic surgery is often recommended to relieve contractures and correct bone and joint malalignments. For children who have cerebral palsy, tone management usually occurs first.



SEMLS corrects bony deformities, balances muscles and improves joint function during one episode of anesthesia.

Single-event multilevel surgery (SEMLS) refers to multiple bone and soft-tissue orthopedic procedures performed at more than one level (hip, knee, ankle or foot) during one episode of anesthesia. The approach is based on the premise that for children who have cerebral palsy and other complex gait disorders, it is best to correct all deformities simultaneously to optimize and balance muscle and joint function. SEMLS reduces the need for multiple isolated admissions and repeated episodes of anesthesia. Nearly 700 bony and 600 soft-tissue procedures took place during the 238 admissions for SEMLS among the patients in the cohort.

Additionally, SEMLS procedures may include at least one injectable medication. During the 39-month period, 86 of the 238 admissions for SEMLS (36 percent) included at least one botulinum toxin A or phenol injection.

Motolani works on improving function and coordination following a SEMLS.



Case Study 1

15-Year-Old Boy Who Has Cerebral Palsy

This 15-year-old boy who has cerebral palsy was referred to the Center for Gait and Motion Analysis to evaluate his worsening crouch gait. A product of a twin pregnancy, he was born at 26 weeks' gestation (14 weeks premature) with a birth weight of 2 pounds, 4 ounces. He did not start walking until he was 2 years old. He did not require assistive devices, but he did use ankle foot orthoses (AFOs) when he was younger. His family reported that he had knee pain after walking short distances, and he had difficulty walking unassisted.





Prior Treatment

He received botulinum toxin A injections in the calf muscles twice before age 5. At age 7, he underwent bilateral gastrocnemius and soleus recessions (lengthenings). He had botulinum toxin A injections in the hamstrings with serial casting at ages 11 and 13 for treatment of his developing crouch. All prior treatment was provided at another facility.

Gait Analysis

Gait analysis identified the following list of issues that contributed to his crouch gait and declining function:

- Bilateral knee flexion contracture
- Bilateral patella alta with stress fractures
- Bilateral rectus femoris contracture
- Bilateral psoas contracture
- Left internal tibial torsion
- Bilateral forefoot varus deformity

Procedures Performed During Single Event Multilevel Surgery (SEMLS):

- Bilateral distal femoral extension osteotomy
- Bilateral tibial tubercle advancement.
- Bilateral rectus femoris transfer to the gracilis
- Bilateral first cuneiform plantar flexion osteotomy
- Left distal tibial external derotation osteotomy

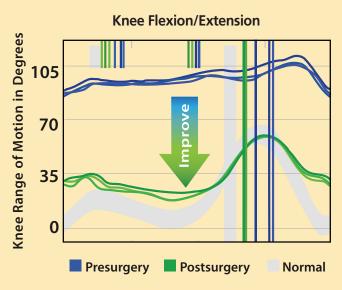
Outcomes of SEMLS

The family reported that, after surgery, the patient has less pain, and now pain "never" affects his walking ability. The patient and family also report "extreme satisfaction" with the results of his orthopedic surgery. They state that his strength, endurance and ability to keep up with friends have increased and that his self-esteem, mobility, social/peer interactions, independence and body image improved. His energy expenditure improved from 475 percent to 210 percent of normal. His gait deviation index improved from 38 to 83 (from 6.2 to 1.7 standard deviations below the mean for typical gait).





Improvement in Knee Flexion/Extension



Case Study 2

6-Year-Old Girl Who Has Cerebral Palsy

This patient was 6 years old when she was referred by an outside physician to Gillette's Spasticity Evaluation Clinic for consideration of selective dorsal rhizotomy surgery.

History

She was born 11 weeks prematurely with a birth weight of 2 pounds, 9 ounces, and she remained in a NICU for six weeks. She began walking at age 3 with the use of a walker; by age 4, she was walking without assistive devices. Previously, she had botulinum toxin A injections, but no orthopedic interventions.

FIRST GAIT ANALYSIS Spasticity Evaluation

A gait analysis study is an integral part of the assessments children undergo prior to the Spasticity Evaluation Clinic. Results indicated that her Gait Deviation Index (GDI) was 61 (four standard deviations below the mean for typical gait). Her energy expenditure was 285 percent of normal. In addition to having multilevel spasticity, she was noted to have bilateral internal femoral torsion and bilateral planovalgus foot deformity. The multidisciplinary team of physicians



recommended a selective dorsal rhizotomy (SDR) to reduce her spasticity, followed by orthopedic surgery to correct her remaining bony deformities.

SECOND GAIT ANALYSIS

She underwent an SDR approximately five months after her initial evaluation and had a second gait analysis one year after the SDR. At her second gait analysis, we noted that her GDI had improved from 61



to 75 (from 4 to 2.5 standard deviations below the mean). Her energy expenditure improved by 20 percent.

Orthopedic Assessment and Interventions

Although she no longer walked on her toes, the gait data showed that she continued to walk with excessive internal hip rotation and flat feet. Her parents reported that she continued to have difficulty with tripping and falling and that "her knees touch when she walks."

To address those issues, the second stage of the treatment plan—orthopedic surgery—was implemented. Gait analysis data confirmed that bilateral internal femoral torsion and bilateral planovalgus foot deformity persisted, but no contractures required treatment. She underwent a single event multilevel surgery (SEMLS) one year after her SDR. The procedures performed during the SEMLS were:

- Bilateral femoral derotation osteotomy
- Bilateral calcaneal lengthening osteotomy

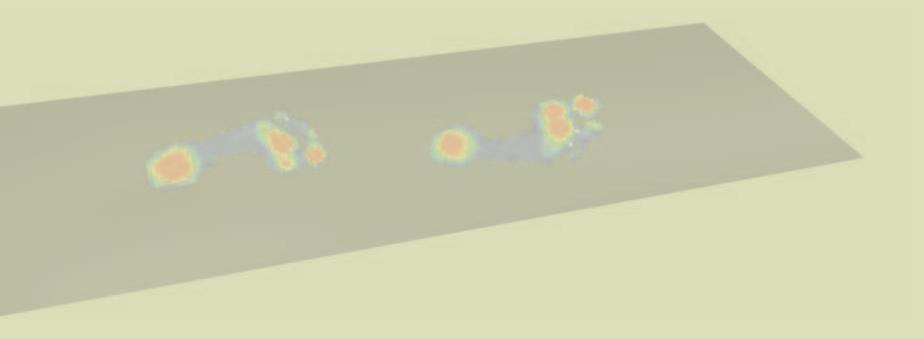
THIRD GAIT ANALYSIS

Outcomes

She had a third gait analysis approximately 10 months after the SEMLS. At this visit, her knees were no longer turned in, and her flat feet were corrected. Her GDI improved from 75 to 81 (from 2.5 to 1.9 standard deviations below the mean for typical gait). Because this is greater than a five-point change in GDI, it is considered clinically significant.

Her follow-up gait data showed improvements in the inturning of her hips as well as the ability to straighten her knees. Her energy expenditure improved an additional 40 percent—a total energy expenditure improvement of 60 percent—since before her rhizotomy. She and her parents noted that "everything is easier," the surgery has "changed her physical abilities," and she is better able to keep up with her peers. They said the results of the surgery were definitely worth the difficulties.





Hospital Utilization

Overview

Note: In this report, we describe two categories of hospital utilization. "Admissions" are overnight inpatient stays; "procedures" do not require an overnight stay, but utilize the operating room and general anesthesia. In addition, patients frequently have outpatient clinic visits and undergo outpatient clinic procedures. Those encounters are not described in this report.

The treatment summaries in this report are based on hospital utilization. The 391 children in the cohort had a combined total of 580 admissions or procedures.

- 75 percent of children who have a diagnosis of cerebral palsy had at least one inpatient admission or same-day procedure. See Fig. 11.
- 56 percent of children who have other diagnoses had at least one inpatient admission or same-day procedure. See Fig. 12.
- 30 percent of patients in the cohort were not admitted and did not have a same-day procedure.

The remainder of patients were treated on an outpatient basis or may have sought treatment at another facility.

Fig. 11 Hospital Utilization for Patients in Cohort Who Have Cerebral Palsy

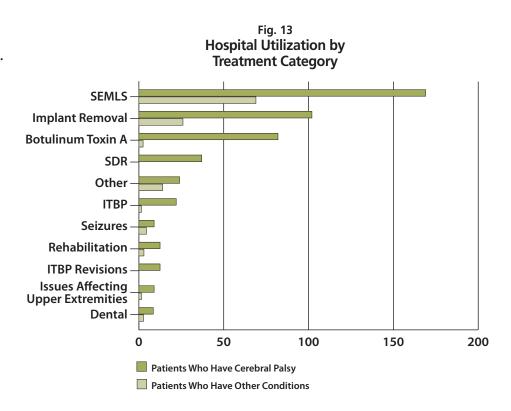
| Number of Admissions/ Procedures | Percent of Patients |
|--|---------------------------|
| 0 | 25% |
| 1 | 31% |
| 2 | 21% |
| 3 | 14% |
| 4 | 6% |
| ≥ 5 | 3% |

Fig. 12 Hospital Utilization for Patients in Cohort Who Have Other Conditions

| Number of Admissions/ Procedures | Percent of Patients |
|-------------------------------------|---------------------------|
| 0 | 44% |
| 1 | 24% |
| 2 | 16% |
| 3 | 11% |
| 4 | 4% |
| ≥ 5 | 1% |

Reasons for Utilization

Lower extremity SEMLS was the most common reason for inpatient admission, regardless of diagnosis. See Fig. 13. Because most single event multilevel surgeries include bony procedures that necessitate implants for stabilization, implant removal was the second most common reason for hospital utilization.



Hospital utilization related to tone management (botulinum toxin A, SDR, ITBP, ITBP revisions) occurred almost exclusively in children who have cerebral palsy. The category "Other" included admissions for complications, illness, infection, neurosurgery, pain, plastic surgery, and spinal fusion surgery.

A total of 33 percent of all utilization was for same-day procedures. The most common treatments performed included multilevel botulinum toxin A injections (42 percent) and implant removal (38 percent).

Complications

Although every effort is made to ensure the best possible outcomes for patients, complications do sometimes occur. The complications described in this report refer only to the complications the cohort of patients experienced. Only inpatient admissions were reviewed for medical and surgical complication occurrences.

The percentage of unplanned readmissions was 9.7, and unplanned returns to the operating room were 4.3 percent. The proportion of complications for the cohort during the 39-month period was 12.2 percent. The breakdown of complications can be seen in Fig. 14.

Fig. 14
Complications for Patients in Cohort

| Medical | 3.6% | | |
|--------------------------|------|--|--|
| Orthopedic | 2.3% | | |
| ITBP | 2.0% | | |
| Neurosurgical | 1.8% | | |
| Surgical site infections | 1.8% | | |
| Pain | .8% | | |

Finances

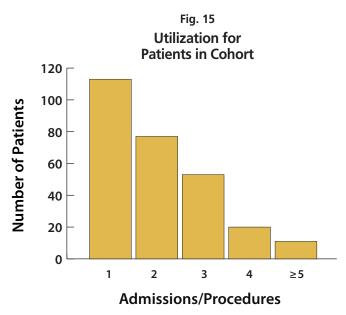
Hospital Utilization

As previously noted, "admissions" refer to overnight inpatient stays and "procedures" are done in the operating room under general anesthesia but do not require an overnight stay.

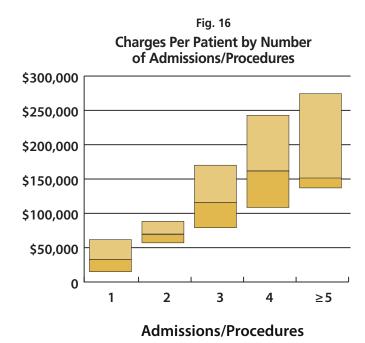
Inpatient admissions and same-day procedures are important drivers of patient care charges. However, 30 percent of patients in the cohort (n=119) were not admitted during the 39-month follow-up period. Patients who had inpatient stays averaged 2.1 admissions (n=272 patients with 580 total admissions), and 33 percent (n=194) of the cohort had same-day procedures. The cumulative admission/procedure total for individual patients ranged from 1 to 17. See Fig. 15.

Charges

The 25th to 75th percentile charges are shown in Fig. 16. The overall charges for the cohort during the 39-month period were \$24.9 million. The median charge per admission was \$66,095. The average charge per patient was \$92,040.



Note: 30.4 percent of patients in the cohort were not admitted.



Assessing Outcomes—Findings in Detail

How Outcomes Were Measured

Assessing outcomes requires repeat visits by the same individuals. Not all 391 of the cohort patients returned to the Center for Gait and Motion Analysis (CGMA) for repeat evaluation. Because the majority of children who returned are children with cerebral palsy, the numbers in those outcomes groups are larger. Outcomes data are also influenced by the fact that 30 percent of the cohort did not require inpatient admission and may not have repeated a gait analysis assessment during the 39-month follow-up period.

To evaluate outcomes, the following measures were used:

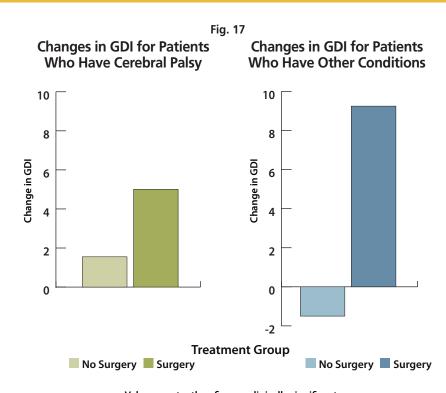
- Gait Deviation Index (GDI) see Page 8.
- The Gillette Functional Assessment Questionnaire (FAQ) see Page 9.
- Energy expenditure

GDI Shows Patients Improved or Maintained Function

The GDI summarizes the overall improvement (positive) or worsening (negative) of the patient's gait during the time interval studied. A five-point change in GDI is clinically significant.

Post-treatment gait analyses show that surgical treatment guided by gait analysis results in significant improvements in GDI scores.

The results also indicate that patients who did not require surgical intervention maintained their function. This outcome is important because the natural history for children with cerebral palsy is a decline in ambulatory function. Children with a diagnosis other than cerebral palsy experience even greater gains in gait quality following surgery. See Fig. 17.



Values greater than five are clinically significant.

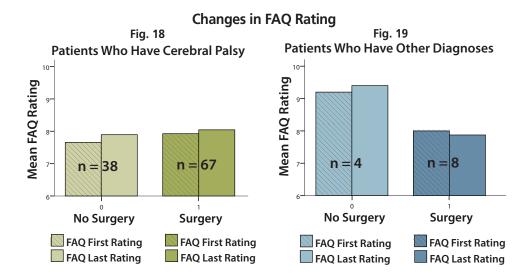
Assessing Outcomes—Findings in Detail continued

Patients Maintained Their Functional Walking Ability or Improved It Slightly

Typically, the walking level rating that patients report on the Gillette Functional Assessment Questionnaire (FAQ) remains relatively constant over time, and that was true for the cohort.

Patients who have cerebral palsy (n=105) showed improvements in function. See Fig 18. Their gains, while not statistically significant, are clinically important. For example, the difference between FAQ Level 7 and Level 8 is the difference between the ability to walk only on level surfaces (Level 7) versus the ability to negotiate steps, curbs and uneven terrain in the community (Level 8).

Among patients who have conditions other than cerebral palsy (n=12), the change was not statistically significant. See Fig. 19.



GMFCS Levels Largely Unchanged

Fig. 20 depicts GMFCS levels across the follow-up period. The majority (73 percent who had no surgery and 75 percent who had surgery) showed no change in GMFCS level. Approximately equal numbers of children improved or regressed one level.

Each GMFCS level (used to classify gait performance among people who have cerebral palsy) represents a range of mobility.* Consequently, a patient might experience some improvement in function but not change his or her GMFCS level. To reiterate, for patients who have cerebral palsy, maintaining function should be viewed as a positive outcome.

| Fig. 20 | | | | | | | |
|-----------------|-------------|-------|---------------|------|----------|------|--------|
| Treatme | ent Group | | GMFCS Initial | | | | |
| | | | I | П | Ш | IV | Total |
| -38 | ıal | I | 16% | 11% | | | 27% |
| No Surgery n=38 | GMFCS Final | II | 6% | 24% | 5% | | 35% |
| ger) | CS | III | | | 27% | 5% | 32% |
| Sur | ₩ | IV | | | | 6% | 6% |
| Š | פ | Total | 22% | 35% | 32% | 11% | 100% |
| | = | ı | 18% | 3% | | | 21% |
| -67 | iù E | Ш | 6% | 25% | 3% | 1% | 35% |
| <u>ٿ</u> م | S. | III | | 7% | 31% | 3% | 41% |
| Surgery n=67 | GMFCS Final | IV | | | 1% | 2% | 3% |
| Sur | 8 | Total | 24% | 35% | 35% | 6% | 100% |
| | | Im | proved | ☐ Ma | intained | ☐ Wo | rsened |

*GMFCS

Level I - Walks without limitations

Level II - Walks with limitations

Level III - Walks with handheld mobility device

Level IV - Self-mobility with limitations

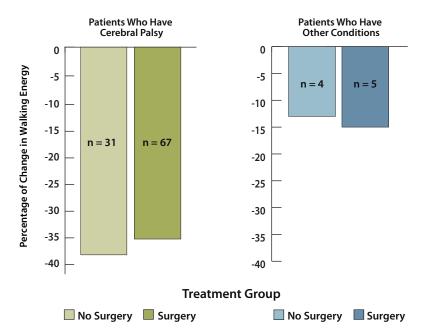
GMFCS – E & R, Palisano, Rosenbaum, Bartlett & Livingston, 2007 CanChild Centre for Childhood Disability Research – McMaster University.

Energy Expenditure Improved for All Patient Groups

Energy expenditure (as measured by oxygen consumption) improved for all patient groups—those who had surgery and those who were appropriately managed by nonsurgical means. See Fig. 21.

For this measure, a decrease in the percentage of energy expenditure (negative value) represents an improvement. Although the improvements were impressive, it is important to recognize that energy expenditure for all patients in the cohort remained well above normal.

Fig. 21
Improvement in Energy Expenditure



Patients Who Have Cerebral Palsy Improved Energy Expenditure by 37 Percent

Patients who have cerebral palsy reduced their energy expenditure by 37 percent (an improvement in energy expenditure). These reductions may be attributed to a number of factors:

- Decreased spasticity, achieved through selective dorsal rhizotomy, injectable medications, or intrathecal baclofen pump implantation
- Improved mechanical efficiency, achieved through better skeletal alignment or a more fluid gait pattern that allows proper transmission of muscle power into motion

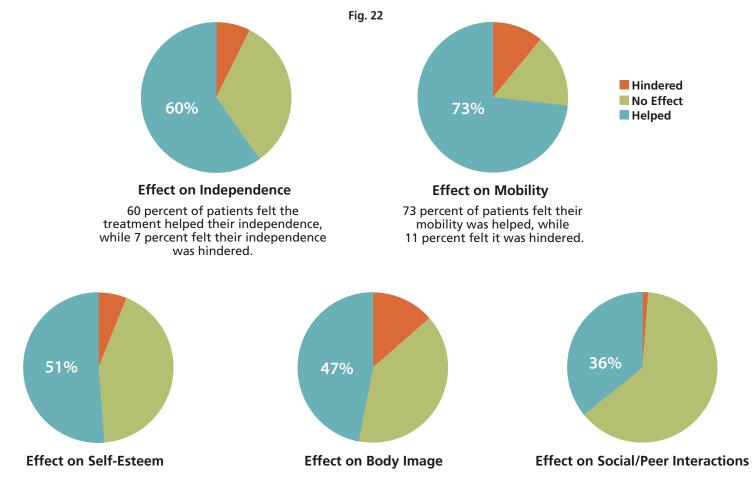
Energy Expenditure Improved 15 Percent for Patients Who Have Other Conditions

Among these patients, the improvements are largely attributable to improved gait pattern and skeletal alignment.

Assessing Outcomes—Findings in Detail continued

Patients and Their Families Report Benefits from Treatments Guided by Gait Analysis

Patients and their families were asked whether the treatments guided by gait analysis "Helped," "Hindered," or "Had No Effect" on the following areas: Independence, Mobility, Social/Peer Interactions, Self-Esteem and Body Image. These patient-reported outcome measures are from the Gillette FAQ. Because the primary target of gait-analysis-guided interventions are issues known to limit mobility and independence (such as muscle and joint contractures, spasticity, bony deformities, and foot instability), it is not surprising that patients and their families reported a high degree of benefit in these areas. See Fig. 22.



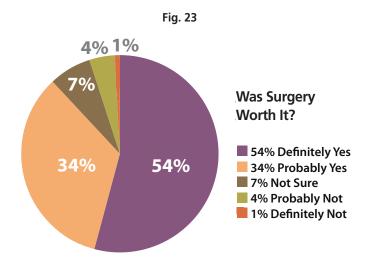
In addition, patients and their families reported benefits in Self-Esteem (51%), Body Image (47%) and Social/Peer Interactions (36%), while relatively few reported hindrance (6%, 14%, and 1%, respectively) in these areas.

What Do Families Say?

The complexity of treatments guided by gait analysis requires significant commitment on the part of patients and their families. For the patients who have surgical procedures, recovery presents unique challenges and burdens—often for an extended period of time. For example, during initial recovery from SEMLS or SDR, patients are often immobile, which may cause considerable family disruption.

As part of a one-year follow-up survey, families were asked, "Was treatment worth the difficulties encountered?" and "Were your expectations for surgery met?"

- 88 percent of respondents felt that surgery was worth the difficulties encountered ("Definitely Yes" or "Probably Yes"). This response represents a 17-fold difference when compared with the 5 percent of respondents who stated, "Probably Not" and "Definitely Not." See Fig. 23.
- 83 percent of respondents felt their expectations were met ("Definitely Yes" or "Probably Yes")—a 10-fold difference when compared with the 7 percent of respondents who stated, "Probably Not" and "Definitely Not." Chart not included.



Summary

We reviewed outcomes for patients who were evaluated in the James R. Gage Center for Gait and Motion Analysis (CGMA) during a 39-month period, and our review produced the following insights:

1. Gait analysis is a valuable tool for diagnosis and treatment planning.

- When gait analysis showed that surgery was indicated, patients experienced significant improvements in gait.
- For 30 percent of patients, gait analysis indicated that nonsurgical management was more appropriate. The patients who did not have surgery maintained their function, which is noteworthy, because typically, the gait of children who have cerebral palsy deteriorates over time.

2. By receiving appropriate data-guided diagnoses and treatment planning, patients had good outcomes.

Improved or stabilized gait

• Patients in this cohort, who had gait analysis to guide their surgical treatment, experienced significant improvements in gait.

Improved energy expenditure

- Patients who have cerebral palsy improved energy expenditure by 37 percent once they had interventions to reduce spasticity and restore musculoskeletal alignment.
- Patients who have other conditions saw a 15 percent improvement in energy expenditure.

Enhanced independence and mobility

Gait analysis guides the treatments for conditions that limit mobility, such as muscle and joint contractures, spasticity, bony deformities and foot instability. Interventions that address these conditions improve patients' independence and mobility, allowing them to participate more fully in family, school and community activities.

- After treatment, 73 percent of patients felt their mobility had improved, while only 11 percent felt it was hindered.
- In addition, 60 percent of patients felt they were more independent, while only 7 percent felt they were less independent.

3. Patients and their families reported treatment was worth the difficulties encountered and their expectations were met.

- Among parents, 91 percent of respondents were either "Extremely Satisfied" or "Satisfied"; 2 percent were "Extremely Dissatisfied" or "Dissatisfied."
- Among patient respondents (over 10 years of age), the numbers were similar, with 82 percent "Extremely Satisfied" or "Satisfied," and 2 percent "Extremely Dissatisfied" or "Dissatisfied."



Lucy works on improving her balance and strength following a selective dorsal rhizotomy.

After having a selective dorsal rhizotomy to reduce spasticity, Christopher rehabilitates with a therapeutic recreation specialist in Gillette's Peggy King Healing Garden.

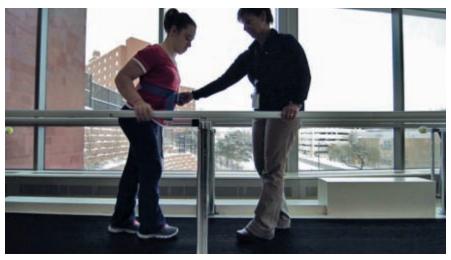


About Gillette

Established in 1897, Gillette Children's Specialty Healthcare is an international referral center for pediatric, adolescent and young adult patients who have complex neurological, muscular and skeletal conditions or disabilities. Among those conditions are brain and spinal cord injuries, cerebral palsy, complex epilepsy, complex orthopedic and neurosurgical problems, craniofacial issues, hydrocephalus, juvenile arthritis, movement disorders, muscular dystrophy, and spina bifida.

Treating individuals who have disabilities and complex medical conditions calls for an interdisciplinary team of experts and, in many cases, requires a lifetime of care. Depending on a patient's needs, the team may include physicians; nurse practitioners; nurses; physical, occupational, and speech therapists; orthotists; and other specialists. Our care teams take a patient- and family-centered approach, and we work closely with primary care clinicians to ensure that their patients' needs are met.

Abbi, who has had a selective dorsal rhizotomy followed by a single event multilevel orthopedic surgery, works on improving gait.



Centers of Excellence Offer State-of-the-Art Clinical Care

Gillette's seven centers of excellence provide care for specific patient groups:

- Center for Cerebral Palsy
- Center for Craniofacial Services
- Center for Pediatric Neurosciences
- Center for Pediatric Orthopedics
- Center for Pediatric Rehabilitation
- Center for Pediatric Subspecialty Care
- James R. Gage Center for Gait and Motion Analysis



Twins Dathan and Braden visit with Tom F. Novacheck, M.D., following surgeries and rehabilitation to correct musculoskeletal alignment.



Gillette at a Glance

- Each year, more than 25,000 patients come to Gillette from nearly every U.S. state and dozens of countries.
- Gillette partnered with Regions
 Hospital to be Minnesota's first Level I
 Pediatric Trauma Center.





LEVEL I PEDIATRIC TRAUMA CENTER

- Gillette is a 60-bed facility.
- In 2013, Gillette had 2,328 inpatient admissions and 146,261 outpatient visits.
- Gillette surgeons performed 1,736 inpatient and 1,823 outpatient surgeries in 2013.
- Gillette is accredited by the Joint Commission, the Commission on Accreditation of Rehabilitation Facilities (CARF) and the Commission for Motion Laboratory Accreditation (CMLA).

Looking Forward

Dear Colleagues,

We are happy to share the first outcomes report from the James R. Gage Center for Gait and Motion Analysis. This report is an important component of our commitment to continuously monitor the outcomes of the care we deliver and to optimize that care to best meet the specialized needs of the complex patients we serve.

At Gillette, the objective data gained from gait and motion analysis guides treatment planning and ensures that treatment is timely, effective and best designed to meet the needs of both patients and families. Although the timeframe for this outcome report was 39 months, the patients described in this cohort are likely to require future intervention and certainly will require future follow-up. Outcomes assessment in the longer term will be important to them.

As we look to the future, our surgeons, physicians, patients and their families will continue to rely on the innovative approaches to understanding complex clinical conditions afforded by the James R. Gage Center for Gait and Motion Analysis. This greater understanding will allow Gillette to continue to advance the care and treatment of pediatric, adolescent and young adult patients who have complex medical conditions or disabilities originating in childhood.

Sincerely,

Steven Koop, M.D. Medical Director many c madeock, ms

Mary Braddock, M.D. Associate Medical Director

This report is the result of a collaboration by Tom F. Novacheck, M.D.; Michael Schwartz, Ph.D.; Jean Stout, P.T., M.S.; and Mary Braddock, M.D.



Mary Braddock, M.D., and Steven Koop, M.D.

Peer-Reviewed Publications 2011 – 2013 From the Staff of the James R. Gage Center for Gait and Motion Analysis

2013

- 1. Esbjörnsson AC, **Rozumalski A**, Iversen M, **Schwartz MH**, Wretenberg P, Broström E. Quantifying gait deviations in individuals with rheumatoid arthritis using the gait deviation index. Scandinavian Journal of Rheumatology. E pub ahead of print. October. 2013.
- 2. Ketema Y, Gebre-Egziabher D, **Schwartz MH**, Matthews C, Kirker R. 2013. Use of gait-kinematics in sensor-based gait monitoring: A feasibility study. Journal of Applied Mechanics 81:041002, doi 10.1115/1.4024771
- 3. MacWilliams BA, Rozumalski A, Wervey R, Dykes DC, Novacheck TF, Schwartz MH. Three dimensional lumbar spine vertebral motions from bone pins during gait. Journal of Bone and Joint Surgery-Am. In press.
- 4. Schwartz MH, Rozumalski A, Novacheck TF. Femoral derotational osteotomy: Surgical indications and outcomes in children with cerebral palsy. Gait and Posture. 2013. doi: 10.106/j.gaitpost.2013.10.016.
- 5. Schwartz MH, Rozumalski A, Truong WH, Novacheck TF. Predicting the outcome of intramuscular psoas lengthening in children with cerebral palsy using preoperative gait data and the random forest algorithm. Gait and Posture. 2013;37(4):473-479.
- 6. Steele KM, Seth A, Hicks JL, Schwartz MH, Delp SL. Muscle contributions to vertical and fore-aft accelerations are altered in subjects with crouch gait. Gait and Posture. 2013;38(1):86-91.

2012

- 1. Baker R, McGinley JL, **Schwartz MH**, Thomason P, Rodda J, Graham HK. The minimal clinically important difference for the Gait Profile Score. Gait and Posture. 2012;35(4):612-615.
- 2. Barton GJ, Hawken MB, Scott MA, Schwartz MH. Movement Deviation Profile: A measure of distance from normality using a self-organizing neural network. Human Movement Science. 2012;31(2):284-294.
- 3. Benish BM, Smith KJ, **Schwartz MH**. Validation of a miniature thermochron for monitoring thoracolumbosacral orthosis wear time. Spine. 2012;37(4):309-315.
- 4. Galli M, Cimolin V, De Pandis MF, **Schwartz MH**, Albertini G. Use of the gait deviation index for the evaluation of patients with Parkinson's disease. Journal of Motor Behavior. 2012;44(3):161-167.
- 5. Joglekar S, Gioe TJ, Yoon P, Schwartz MH. Gait analysis comparison of cruciate retaining and substituting TKA following PCL sacrifice. Knee. 2012;19(4):279-285.
- 6. John CT, Seth AJ, **Schwartz MH**, Del SL. Contributions of muscles to mediolateral ground reaction force over a range of walking speeds. Journal of Biomechanics. 2012;45(14):2438-2443.
- 7. Langerak NG, Tam N, Vaughan CL, Fieggen AG, **Schwartz MH**. Gait status 17-26 years after selective dorsal rhizotomy. Gait and Posture. 2012;35(2):244-249.

- 8. Lonstein JE, Koop SE, Novacheck TF, Perra JH. Results and complications after spinal fusion for neuromuscular scoliosis in cerebral palsy and static encephalopathy using Luque Galveston instrumentation – Experience in 93 patients. Spine. 2012;37(7):583-91.
- 9. Steele KM, DeMers MS, **Schwartz MH**, Delp SL. Compressive tibiofemoral force during crouch gait. Gait and Posture. 2012;35(4):556-560.
- 10. Steele KM, van der Krogt MM, Schwartz MH, Delp SL. How much muscle strength is required to walk in a crouch gait? Journal of Biomechanics. 2012;45(15):2564-2569.
- 11. **Stout JL**. Gait: Development and Analysis. In PHYSICAL THERAPY FOR CHILDREN. Campbell SK, Palisano R, Orlin M (Eds.). St. Louis, Elsevier, 2012, 2006, 2000, 1994.
- 12. **Stout JL**. Physical Fitness During Childhood and Adolescence. In PHYSICAL THERAPY FOR CHILDREN. Campbell SK, Palisano R, Orlin M (Eds.). St. Louis, Elsevier, 2012, 2006, 2000, 1994.
- 13. **Stout JL**, Gorton GE, **Novacheck TF**, Bagley AM, Tervo RC, Bevans K, Tucker CA. Rasch analysis of items from two self-report measures of motor function: Determination of item difficulty and relationships with children's ability levels. Developmental Medicine and Child Neurology. 2012;54:443-450.
- 14. van de Walle P, Hallemans A, Schwartz MH, Truijen S, Gosselink R, Desloovere K. Mechanical energy estimation during walking: Validity

- and sensitivity in typical gait and in children with cerebral palsy. Gait and Posture. 2012;35(2):231-237.
- 15. van der Krogt MM, Delp SL, Schwartz MH. How robust is human gait to muscle weakness? Gait and Posture. 2012;36(1):113-119.

2011

- 1. Bagley AM, Gorton GE, Bjornson K, Bevans K, **Stout JL**, Narayanan U, Tucker CA. Factor and Item Level Analysis of the 38-Item Activities Scale for Kids-Performance. Developmental Medicine and Child Neurology. 2011;53:161-166.
- 2. Ganley KT, Paterno MV, Miles C, **Stout JL**, Brawner L, Girolami G, Warren M. Health-Related Fitness in Children and Adolescents. Pediatric Physical Therapy. 2011;23:208-220.
- 3. Healy MT, Schwartz MH, Stout JL, Gage JR, Novacheck TF. Is simultaneous hamstring lengthening necessary when performing distal femoral extension osteotomy and patellar tendon advancement? Gait and Posture. 2011;33(1):1-5.
- 4. Gorton GE, **Stout JL**, Bagley AM, Bevans K, **Novacheck TF**, Tucker CA. Gillette Functional Assessment Questionnaire 22 Item Skill Set: Factor and Rasch Analyses. Developmental Medicine and Child Neurology 2011; 53:250-255.
- 5. Hicks JL, Delp SL, **Schwartz MH**. Can biomechanical variables predict improvement in crouch gait? Gait and Posture.2011;34(2):197-201.

- 6. **Rozumalski A, Schwartz MH**. The GDI-Kinetic: A new index for quantifying kinetic deviations from normal gait. Gait and Posture. 2011;33(4):730-732.
- 7. Truong WH, Rozumalski A, Novacheck TF, Beattie C, Schwartz MH. Evaluation of conventional selection criteria for psoas lengthening for individuals with cerebral palsy: A retrospective, casecontrolled study. Journal of Pediatric Orthopaedics. 2011;31(5):534-540.
- 8. Van Gestel L, De Laet T, Di Lello E, Bruyninckx H, Molenaers G, Van Campenhout A, Aertbeliën E, Schwartz MH, Wambacq H, De Cock P, Desloovere K. Probabilistic gait classification in children with cerebral palsy: A Bayesian approach. Research in Developmental Disabilities. 2011;32(6):2542-2552.





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