RESOURCES

Existing Facilities: The Stanley E. Fulton Biomechanics and Motor Behavior Laboratory

Instrumentation in the lab includes:

- VICON 3D Motion Analysis System with 8 cameras (MX13): The system has the advantage of using reflective markers, real time data collection capacity and VICON Bodybuilder and Polygon Software for immediate data analysis capabilities. The MX13 cameras have 1.3 megapixel resolution up to 480 Hz and will operate up to 1000 Hz at reduced resolution. The system also allows acquisition of other 3rd party capture devices including electromyography, force platforms, time code and any other digital devices.
- Peak Motus 3D Video Analysis System: This system captures and analyzes motion patterns via videotapes and optical capture method with automatic digitizing. It allows data collection in both laboratory setting and outdoor environment. The KineCalc software gives flexibility to calculate kinematics using any algorithms. The system allows synchronized data acquisition from other devices.
- Therapeutic Unlimited 8-channel Electromyography (EMG) Model 544: Surface EMGs from eight channels are available to monitor muscle changes during the gait cycle and compare to normative data. The electrodes have high impedance buffering gain stage in the head of the electrode to reduce the noise due to movement artifact. This EMG equipment is tethered to the subjects during data collection.
- Delsys Myomonitor III 16-channel EMG System: This system is supplied with an autonomus datalogger and therefore provides full mobility to the subjects. The system has long battery duration per charge for 8 hours and data capacity of 1 GB. The parallel-bar electrodes do not require gel or skin preparation. The EMGworks software allows real-time signal inspection, comprehensive signal analysis, and accepts other auxiliary signals.
- 4 AMTI Biomechanics Force Platforms: This system allows analysis of kinetic components of gait in the x, y and z axes during stance phases of the two lower extremities in the gait cycle. Force data can be synchronized with the Peak Motus and the VICON system and analyzed using the corresponding softwares. Two platforms are currently located in the biomechanics laboratory and two others in the physical therapy gait laboratory.
- Biodex System 3 PRO Isokinetic dynamometer: The dynamometer measures isometric and isokinetic muscle strength and has significant applications in neuromuscular testing and rehabilitation. It can measure up to 500°/s concentric velocity and 300°/s eccentric velocity. The Biodex Advantage software includes assessment and treatment protocols to assist patients with physical impairments return to function.
- 2 Redlake High Speed Cameras: Each camera can operate up to 500 Hz with full resolution. Image data can be analyzed using the Motion Scope High Speed Digital Imaging System or imported into the Peak Motus 3D Analysis System.
- KT-100 knee arthometer: This device provides objective measurement of the sagittal plane motions of the tibia relative to the femur. The ‘drawer motion’ occurs when an examiner applies force to the lower limb or when the

quadriceps muscles are contracted. The KT-100 is an accurate instrument for clinical assessment of ACL and PCL integrity.

There will be the requirement for additional equipment for the enhancement of the capabilities of this research. These include:

- 3 Electromechanical actuators @$20,000/each
- 6 Electrogoniometers @$6500/each
- 1 FDA approved Treadmill @ $10,000
- 1 Sparc Workstation @ @25,000
- 4 Pentium4 Computers @ $2,500/each
- 10 precision motors @ $3,000/each
- Precision ballscrews
- Mechanical components
- Electrical/electronic components

We will utilize the Stanley E. Fulton Biomechanics and Motor Behavior Laboratory to support both SGES engineering testing throughout the years of the project as well as clinical testing during rest of the years.

UTEP Research Laboratory

The UTEP Research Machine Shop, the measurement laboratory, and the Laboratory for Industrial Metrology and Automation, will be used for the engineering design, manufacture, testing, and validation of the Smart Gait Emulator System. UTEP has all the facilities required to perform work in the multi-disciplinary area involving mechanical and electrical engineering, and computer science.

We will utilize the UTEP Machine shop, the measurements laboratory, and the Stanley E. Fulton Biomechanics and Behavior Laboratory to support both SGD engineering testing during the entire project performance.

Automated Diagnosis and Therapy in human gait using the methods of computational intelligence

A: Specific Aims

The need for an effective gait assistive device is evident from the high incidence of upper motor neuron syndromes. Hemiplegic stroke, paraparesis from spinal cord injuries, and other upper motor neuron syndromes such as multiple sclerosis and cerebral palsy cause serious neurological impairments and mobility-related disability. Approximately 700,000 Americans suffer a stroke, 10,000 suffer traumatic spinal cord injury, and over 250,000 are disabled by multiple sclerosis. Approximately 1 in 500 children [1] suffers from cerebral palsy, one of the most common chronic childhood disorders that often impair mobility [2]. With the aging of the U.S. population, the prevalence of people disabled by stroke is likely to rise over the next 10-20 years. Therefore, research efforts are needed to improve the effectiveness of rehabilitative treatments for sensorimotor disabilities, and especially for ambulation, balance, and maintenance of physical fitness across these neurologic diagnoses. With the 25-50% reduction in inpatient rehabilitation length of stay following stroke and spinal cord injury in the past 10 years and the decline in outpatient care days covered by insurers, efficacious and cost-effective interventions that positively impact the recovery of balance and walking have become critical [3].

We propose the development of a new method to deliver therapy to patients with gait disabilities unlike previous attempts such as partial weight bearing treadmill training (PWBTT). Whereas the preponderance of data from clinical trials suggests that partial weight bearing treadmill training (PWBTT) increases the likelihood of independent overground walking and improvements in walking speed and walking distance in patients with acute and chronic stroke and spinal cord injury, the technique has clear limitations. The physical demands on therapists to manually assist the trunk and legs of subjects at treadmill speeds greater than 0.8 mph is substantial, and the ability of therapists to optimize sensory inputs associated with the step cycle, such as kinematics and temporal symmetries during certain aspects of the stance and swing cycles, is constrained by all the various tasks they must simultaneously perform and monitor as they sit by the subject's legs. In order to relieve the therapist from having to perform numerous tasks simultaneously during a treatment session, robotic assistive devices have become a focus of clinical research.

The Smart Gait Emulator System (SGES), a multi-axis robotic device, will offer capabilities unavailable using current gait therapy devices and methods. Current commercial robotic assistive devices automatically drive the limbs passively through preset gait cycles. The devices do not take into account the kinematics and torques that a subject can generate, or incorporate the subject's growing ability to ambulate. Actively guiding passive limbs during step training is not an effective strategy to enhance motor learning of a complex motor skill such as walking. Step-training that incorporates sensory feedback, provides feedback about kinematics and torques, and proceeds at walking speeds typical of overground ambulation is more likely to drive basic mechanisms of motor learning and representational plasticity for the lower extremities [4]. Potential health benefits resulting from these capabilities include more effective and individualized therapy programs; the opportunity to lessen one of the most common disabilities in patients who suffer neurological diseases; reduce the time and labor needed to deliver therapy; and enhance gait-related diagnostic and research tools. To

accomplish this, we will develop a mechanical device based on the concept of task-oriented Partial Weight Bearing Treadmill Training (PWBTT) along with an innovative knowledge-based control system that includes an intelligent sensing, a data acquisition, processing and effectuation scheme. The end result will be a therapy system that offers the patient, the doctor, and the therapist a new set of tools to test in clinical trials to improve gait therapy. The proposed device will also be well suited for use in gait diagnostic and clinical research efforts. For example, perturbations during the step cycle can be incorporated into the control scheme to test postural adjustments and evaluate mechanisms of motor control. Development of the feedback system may also lend itself to other devices for overground walking and for improving functional use of a paretic upper extremity.

The proposed development effort is designed to continue the development of a prototype Smart Gait Emulator System, assess its safety in a trial phase, and set the ground work to assess its utility in the clinical setting. The proposed development effort is structured to assess the following hypotheses:

- This new system will be able to offer both passive gait training and locomotor training with optimal feedback about kinematics and forces.
- The system will be safe for use in able-bodied adult subjects and in disabled adults who have a hemiparesis or paraparesis, across typical body sizes and leg lengths.
- The data acquisition and presentation capabilities of the new device will provide a more thorough understanding of gait data directly related to a patient's locomotor therapy during treadmill training.
- Data from able-bodied persons collected during SGES testing will be similar to data gained from overground gait analysis.
- Data related to improved gait parameters during SGES training of disabled subjects will be reflected in parallel improvements in overground walking as training progresses.
- The data gathering capabilities of the SGES will improve the quality of data about pathological gait deviations during treadmill walking at normal casual walking speeds and provide objective data of outcome measures of change in individuals.
- Data gathered from the SGES can dramatically improve the analysis and use of the information contained in the data, by the patient, therapist, and doctor.
- The data gathered using the SGES will provide greater insight in the dynamic system's properties of the developing individual gait characteristics as treatment progresses.

B: Background and Significance

Locomotor disabilities are most commonly caused by neurological diseases or insult to the nervous system. Stroke survivors, for example, show marked decreases in their ability to ambulate 6 months post-insult, with 20% of them unable to walk without physical assistance and half of them walking at less than 50% of normal casual speed. These changes in mobility translate into a significant reduction in the patients' quality of life, and increase the burden of therapists and the health care system in treating these

patients. Efforts to improve walking ability and efficiency have been undertaken, using rehabilitative strategies such as PWBTT to establish or re-initiate normal gait patterns in human subjects following injury [5-13]. The design of our SGES is based on data obtained through this type of training.

Recovery of locomotor activity following spinal cord injury has been extensively studied in animal models. Rats and cats that have undergone complete low-thoracic spinal cord transection can be trained to walk on a treadmill, and have been shown to accomplish full weight-bearing stepping at normal speeds [14, 15]. Other data suggest, however, that this type of training induces a motor task-specific kind of learning. For example, Hodgson et al. showed that spinalized cats trained to step were less able to stand and bear weight without the motion of walking, whereas animals trained to stand were deficient in their ability to walk on a moving treadmill [6, 17]. The re-establishment of ambulation following treadmill training may be due to the activation of central pattern generator (CPG) neurons in the spinal cord, in which locomotor-associated motor neuron pools are activated in response to sensory input coming from the limbs [18]. An important aspect of this behavior is that it occurs in the absence of supraspinal input. Crucial to the success of this training, therefore, is the coordination of sensory input to the spinal cord. The ability to step in both human and animal subjects is highly influenced by the pattern of loading placed on the legs and by the kinematics of the gait cycle [19].

Animal studies have led to the development of measures to assist human patients following spinal cord injury (SCI). Wernig et al. [9, 10] demonstrated a significant increase in the ability to ambulate independently or semi-independently following intensive PWBTT in people with incomplete spinal cord transections. Moreover, the positive effects of this intervention persisted for more than 6 years following training. In patients with complete SCI, Dietz et al. showed improved gait patterns as a result of treadmill training, possibly due to the normalization of muscle activation patterns [20]. In support of this idea, Harkema et al. recorded electromyographic (EMG) data in lower limb muscles during stepping in complete SCI patients, and showed that their ambulatory patterns were, in fact, regulated by sensory input to the lumbosacral spinal cord [21]. Results from both human and animal experiments, therefore, provide evidence that spinal cord CPGs can control locomotion, and that their activity is largely a function of proprioceptive and other sensory inputs from the limbs. Step-related cues can thus alter CPG activity somewhat independently of higher central nervous system activation. Currently in progress is a multi-center, randomized clinical trial sponsored by the NIH/NICHD, investigating the response of patients with incomplete SCI to treadmill training.

In addition to SCI, patients with brain injury or disease also have been shown to respond positively to PWBTT. One problematic variable in patients learning to walk after a neurological insult is that of maintaining balance during locomotion. The trunk stability provided by PWBTT allows for gait training, through the performance of repetitive and complicated motor activities, without the interference of vestibular reflexes. For example, adult hemiplegic stroke patients who failed to respond to traditional physical therapy interventions showed a 123% improvement in swing symmetry, with a 24% improvement in stance symmetry, after PWBTT [5]. These results were obtained in 25 training sessions carried out over 5 weeks, with the amount of body weight support provided decreasing from 31% to 0% (full weight-bearing) in 7 out of 9 patients. Further comparisons between subjects walking under different levels of body weight support versus normal overground ambulation showed that partial weight support provided the most efficacious circumstance for reducing spasticity, limiting co-contraction of antagonistic muscle groups, and producing appropriate gait patterns [6]. In another

controlled study of partial compared to no body weight support in 100 patients, increased performance, as evidenced by positive outcomes in balance, speed, endurance and recovery was seen in the partially supported group following a 6-week treadmill training intervention [8]. Other investigations have resulted in rehabilitative success following PWBTT in stroke (39] and Parkinson's [40] patients.

Young people with neurological disorders also benefit from this type of training. In very young (15-28 months) children suffering from cerebral palsy, PWBTT increased locomotor skills according to both clinical measures and video gait analysis [12]. Similarly, cerebral palsy-afflicted children with minimal walking ability undergoing 3 months of PWBTT at a treatment rate of 3 times per week improved significantly in tests of general mobility, gross locomotor function and transfers [13]. Lastly, a case study by McNevin [11] on a 17-year-old female subject with spastic cerebral palsy showed a decrease in exercise-associated pulse rate and blood pressure, with a concurrent increase in ambulatory speed, as a result of treadmill training with ~30% body weight support.

Taken together, these studies convincingly demonstrate the ability of PWBTT to improve locomotor function in patients with central nervous system damage. This has not been the case, however, in all training interventions of this type. For example, two trials [22, 23] failed to produce improvements in overground ambulatory speeds in subjects exposed to treadmill training, but this may have been due to confounds in the experimental design (e.g., slow treadmill speeds during training, poor description of body weight support manipulations, and lack of data regarding the kinetics, kinematics and temporal symmetries during training). No training method has been published, in fact, that has been shown to be reproducible. Toward this end, our system will therefore allow for the recording and manipulation of multiple parameters related to locomotion, and the disruption of variables within those parameters, to guide the development of patient-specific training paradigms. Successful outcomes of the proposed experiments will assist therapists in the goal of improving function in patients with various kinds of neurological disorders.

PWBTT Device Evolution

Key capabilities needed in a PWBTT device to provide effective gait therapy include:

1. A means for the machine to support the patient and adjust the weight-load placed on the lower extremities during therapy, ranging from no load (the machine bears the full weight of the patient) to full load (the patient supports his/her full weight).
2. A treadmill, or similar arrangement, that allows the patient to walk in place.
3. The ability to assist the patient's lower extremities to train an effective overground gait pattern that is energy-efficient.

The first two features are easily realized using commercially available harnesses and treadmills. Providing the appropriate gait motion for an individual patient during training sessions is the key capability of the SGES machine and presents the significant engineering challenge. In order to train "the right motion" the machine must mimic the individual patient's gait to a reasonable degree. As such, a review of assistive gait devices is the focus of the review that follows.

Frequently, fitness equipment has been adapted for use in therapy. Fitness machines like cross-country ski trainers, the Power Walker from Kettler, and the FM340 Skier from BioTrans are used for practicing and training "gait-like" movements. These machines only provide a flat sliding motion of the foot and offer a poor representation of the human gait. The Miha Crosswalker (Miha GmbH), the Body Trainer (Reebok), and the Cross

Trainer (Life Fitness) add a lifting of the foot (heel higher than the toe) during the swing phase of the gait, providing a “better” gait simulation, based on a 50/50 stance/swing gait cycle.

Going beyond the use of exercise equipment for gait therapy, the first PWBTT machines were simple in concept and design. They relied on the gait therapist to deliver the desired training gait to the patient, while they walked on the treadmill. This was accomplished through a “hands-on” method where the therapist held the patient’s leg(s) and moved the limb(s) through the desired motion. Again, the patient’s body weight was supported in a harness. Limitations of this approach are:

- it is highly labor intensive;
- the therapist must first learn and become proficient with the procedure and the motion to be given during treatment;
- repeatability and consistency in the gait motion delivered from session-to-session and patient-to-patient is difficult to maintain;
- multiple therapists are frequently needed for each patient in order to maintain proper positioning of the hips and upper / lower legs and joints;
- it is physically demanding on the therapist which limits the duration of each session, and demands a “recovery period” for the therapist(s).

To remedy the problems associated with using therapists to provide the desired gait patterns, some investigators developed gait trainers in which the individual’s legs were positioned on foot plates that moved backward and forwards. Tests with non-ambulatory adults post-stroke adults were conducted using this device [24, 25].

The restoration of healthy locomotion (gait) after stroke, traumatic brain injury, and spinal cord injury, is a major task in neurological rehabilitation. Motor-learning and control research clearly favors task-specific repetitive training [4]. The complexity of the interactions of the various components of human gait has been researched and documented extensively, and to date it is the experienced clinician who continues to perform functional gait assessment and training in the absence of virtually any technological assistance. The need for improved neurological rehabilitation strategies and smart training devices is, therefore, self-evident.

C. Preliminary Studies/Progress Report:

As a Research Scientist, Dr. Thompson Sarkodie-Gyan worked together with a group of doctors and surgeons at the Free University Berlin’s Department of Orthopaedics and Neurological Rehabilitation. The team consisted of neurosurgeons that treated neurologically impaired patients in the Neurological and Rehabilitation Clinic (Klinik Berlin). There was no training equipment for rehabilitation at the time. After conceiving the idea of building a training equipment to rehabilitate impaired patients, the project statement (ideas) was formulated in medical terms. Dr. Sarkodie-Gyan then matched these medical ideas into engineering philosophy, concepts and methodologies. After extensive research he fabricated a prototype of the gait training device in his laboratory (Laboratory for Intelligent Systems Technology, Univ. of Teesside, UK). The first Gait Trainer, Gait Trainer I, [34], was built and patented in Germany in 1997(Patent # 197 259 73) as a result. After extensive clinical trials, a revised version, the Gait Trainer II, evolved in 1998 [6, 25, 35, 42, 43]. This was also patented in Germany (Patent # 198 05 164) and is currently in use in the Klinik Berlin (Department of Neurological

Rehabilitation of the Free University, Berlin) and also commercially, the GTI, see the webpage indicated below. http://userpage.fu-berlin.de/~bhesse/Gangreha/gte.html

The first project commenced with the Fast Track fitness machine (American Harvest, Inc.) on which foot plates were added. A drive mechanism using an electric motor and a gear system to move the foot plates was designed and incorporated into the system. Gait cadence was controlled by the speed of the drive mechanism, and adjustable stride length was also provided. This initial model gave a symmetrical (50/50) swing/stance cycle. One therapist could assist the subject's movement by standing behind the patient and helping in shifting the body weight and promoting hip extension. This was the Gait Trainer I.

After initial testing, improvements were made to the design of the Gait Trainer I, and a second version, the Gait Trainer II, was constructed. This design addressed several new and important capabilities:

- further reduced physical demands on the therapist during therapy;
- emulating the 60/40 swing/stance characteristics of the human gait;
- controlling the vertical displacement of the patient's CoM;
- allowing the lifting of the foot, as occurs in the human gait cycle;
- adjustable "mechanical assistance" from the machine during the gait cycle.

The last capability allowed the device to fully power the gait cycle for the patient (no contribution from the patient's muscles and limbs), or to "blend power" from the motor and the patient, allowing the patient to assist, or resist, during the gait motion. A more advanced drive and planetary gear system was used to provide these higher quality gait characteristics. A double crank and rocker assembly provided the desired foot motion. Figure 1 shows a picture of the second version of the gait trainer, referred to as "Gait Trainer-II".

Figure 1. Gait Trainer-II Delivered Improved Gait Therapy.

Testing the Gait Trainer-II: A clinical study was conducted to compare therapy using the advanced trainer (Gait Trainer II) against the treadmill-based exercise device [25, 35]. Summary results for a hemiparetic subject showed:

- Two therapists were needed to provide gait motion on the treadmill, whereas only one therapist gently helped with knee stabilization on the Gait Trainer-II. The effort required on the treadmill was extremely taxing on both therapists.
- The machine-support helped with the movement of the feet both during stance and swing while the motor-driven treadmill only helped with the stance phase.
- The machine adapted to the impairment level of the paretic subject in such a way that he could assist the gait motion both during the stance and swing cycle, according to his abilities.
- The machine-assisted Center of Mass control supported the weight-shifting and trunk position of the subject. On the treadmill, another therapist was required for this task.

The gait-like pattern of the hemiparetic subject on the new device, Gait Trainer II, versus the treadmill showed:

- better gait symmetry
- impact-free motion delivery
- better use of weight-bearing muscles
- lower oxygen consumption at comparable velocities
- proper vertical movement of the Center of Mass
- delivery of consistent and repeatable motion profiles

Additional clinical observations included:

- The impact-free transition from swing to stance showed the absence of the so-called premature activity of the plantarflexors as observed on the treadmill. This stretch-sensitive activity is regarded as a major cause of pathological extensor spasticity.
- Another benefit of the symmetric movement on the gait trainer was the increased physiological activation pattern of the erector spinae. Instead of the tonic pattern seen on the treadmill, it exhibited two crests during the double support phases. In healthy subjects, these peaks of muscle activation help to control the trunk movements during the double support phases.
- The amount of activity of the paretic vastus lateralis, biceps femoris and adductor magnus muscles was even larger on the gait trainer, probably due to a larger hip extension, one of the major peripheral drives for the activation of these relevant weight-bearing muscles. Also, the patient could not shorten the single stance period of the paretic limb (as during treadmill walking), consequently, the actual loading time of the paretic limb was longer.

Shortcomings of the Gait Trainer-II

Results from the testing described above showed an improvement in gait emulation with the Gait Trainer-II, but did not meet expectations regarding:

- the 60/40 gait stance/swing ratio was fixed with the planetary gear assembly and so adjustment could not be made for differences between test subjects or stride and speed variations;
- the foot plates could not simulate the "ground resistance" normally encountered while walking, and which the treadmill devices offer.

Dr. Sarkodie-Gyan's next design was at the UTEP Human Performance Research Cooperative and it addressed these issues. It also forms the basic philosophy underlying the conceptualization of the Smart Gait Emulator System for automated diagnosis and therapy in human gait using the methods of computational intelligence.

D: Research Design and Methods:

Based on his previous work developing PWBTT-based gait trainers, Dr. Sarkodie-Gyan has continued work in this area through his position as Associate Professor of Electrical and Computer Engineering at the University of Texas at El Paso (UTEP). He has developed a detailed mechanical design of the Smart Gait Emulator System (SGES) which is detailed in the following section.

The Smart Gait Emulator System:

This research proposal addresses the diagnostics and therapy of human locomotion system. This involves the modeling and the simulation of a mechanical leg capable of emulating human locomotion, and an intelligent tool for diagnosis and therapy.

With the models and simulations as a scientific approach and basis to understand gait, a foundation will be established for the design of optimal strategies for restoring ambulation to individuals with neurologic impairments. The analysis enables the kinematic gait characteristics of the human robotic-assistive device to be adjusted in order to facilitate the emulations of a range of gaits during motion, thus allowing patient-initiated kinematic patterns to be completed or refined.

The model may be used to offer both passive gait training and locomotor training with optimal feedback about kinematics and forces; and the data acquisition capabilities of the assistive device may help to improve the quality of data about pathological gait deviations during treadmill walking at normal casual walking speeds, and also provide objective data of outcome measures of change in individuals.

The Mechanical Design:

In recent years, extensive efforts have been invested in the modeling, analysis, and simulation of human biomechanics that address the physiological walking patterns of the human. It is well known that the inherent structure of the human body is complex. Even in the presence of high complexities inherent in the modeling and analysis of human locomotion, some good results have been reached and assumed that may be as a close approximation of the models. Therefore, the modeling of linkages has been the basis of analysis of the mechanics of human locomotion for several years. The dynamics of human locomotion equations of motion have been derived and the direct and/or inverse

problems have been attempted [1-6]. These mathematically-based scientific approaches establish the human locomotion system under consideration of the gait determinants like the motion of the center of mass (horizontal and vertical), pelvic tilt and rotation, hip/thigh flexion/extension, thigh abduction/adduction, knee flexion/extension, and ankle motion.

Jensen in [44] took advantage of these available and already established methodologies to model the human locomotion system for providing required motions for correct gait parameters. In order to size the corresponding actuations, simulations involving the displacement versus time, velocity versus time, and acceleration versus time, were run. The output of these simulations enabled the actuation components including the ballscrews, motors, gearboxes, gears, timing pulleys and the timing belts to be optimally selected. The dynamic analysis enabled the sizing and choosing of the corresponding actuators. The dynamic analysis also enabled the computation of variables like the variations in length, velocities and forces of the actuators that controlled the three leg sections. The analysis was performed using gait data from the normal male and normal female, respectively according to [47].

SGES Mechanical Assemble:

There are two leg assemblies in the SGES, one for each of the patient's leg. Each leg consists of four sections: a calf assembly, a thigh assembly, a hip assembly, and a height adjustment assembly. This design allows the SGES to precisely mimic the motion of a human leg. The leg sections are stacked together in an alternating manner to maximize the degree of rotation of each joint (especially the hip and the ankle). Padded cuffs are used in each section to attach the patient to the mechanical leg: at the ankle, just above the knee, and around the lower torso. This positioning allows for maximum leverage on the patient's legs by the mechanical device, and also maximizes patient comfort. The uppermost leg section is used as an overall height adjustment to allow proper contact between the patient's feet and the treadmill. The SGES system may be broken down into four main categories: the patient lift system, the treadmill, the frame, and the mechanical legs.

The Patient Lift System:

The main purpose of the patient lift system is to hoist the patient up and provide the body weight-support (BWS). This system will be able to hoist the patient in the rear of the machine, away from the mechanical legs, and transport the patient to the front in order to attach him/her to the mechanical legs. The current frame design has been integrated with the patient lift system. This design makes it easier to attach the patient to the lift system while maintaining proper support of the patient during the lifting process [1].

The SGES is able to provide BWS by using a combination of a modified climbing harness, a cable system and an actuator. The system is not only designed to provide BWS, but also to help in providing the correct vertical COM motion. Figure 2 shows a three dimensional CAD model of the lift system.

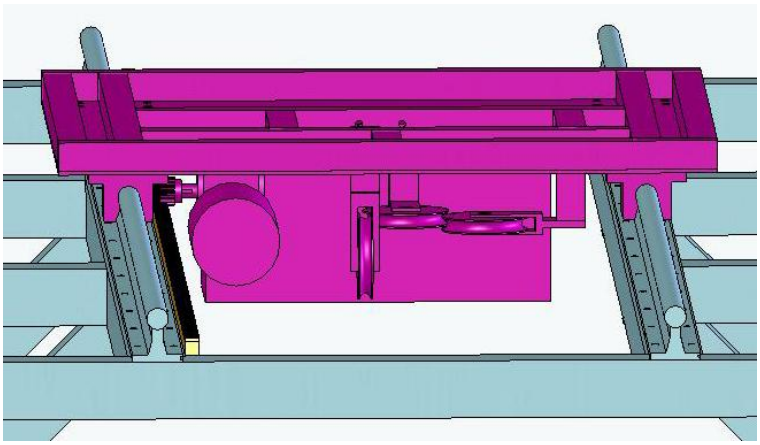

Figure 2. SGES Lift System minus the actuator and the harness setup.

The patient lift system is connected to the top rail system of the frame by two 0.75 inch linear shafts. A lift system mounted to linear shafts allows forward and aft movement. Moving the patient lift along the rail system eases the incorporation of the patient into the mechanical legs. The lift system contains a winch and a set of pulleys to lift the patient safely from a standing or sitting position, thus reducing potential physical harm to the patient if they are unable to readily be lifted in a standing position [2].

A DC right angle gear motor was selected to enable motion in the forward and aft directions. The DC motor utilizes a variable speed controller to allow for speed control and adjustments. A speed controller permits the physical therapist to adjust the speed according to the patient's needs. The gear motor also exploits a worm gear system, which acts as an electro-mechanical stop for adding to the degree of safety. In the technical considerations, a Leeson DC gear motor was selected. The maximum output speed for the motor was selected to be 125 rpm. With a maximum shaft speed of 125 rpm and pinion gear diameter of 1", the speed of the patient lift may vary from 0 to 6.54 inches per second [2].

A rack and pinion was selected to provide linear actuation, converting the rotary motion into linear motion. This system was chosen because of the overall size and design. The rack and pinion system fits under the patient lift system allowing for a low profile design [2].

The Treadmill:

The treadmill, shown in Figure 3, is the device the patient walks along. The treadmill simulates the ground reactive forces experienced while walking. The treadmill also provides a smaller working area by allowing the ground to move instead of vice versa.

Figure 3. GaitKeeper Treadmill from Litegait [3].

The fact that the whole system has to work in unison requires that the treadmill used be adjustable in speed for different sized-patients. The GaitKeeper 2000L Model from Litegait treadmill was selected for this project. Its parameters are as depicted in the Table 1.

Table 1. GaitKeeper Models and Specifications [3].

Specifications		
	1800S and 1800L	**2000L**
Drive Torque	140 in-lbs	140 in-lbs
Motor	2 HP Continuous Duty	2 HP Continuous Duty
Speed Range	0.1 – 4 mph	0.1 – 7 mph
Speed Adjustment	0.1 mph increments	0.1 mph increments
Elevation	Up to 15% grade	up to 15% grade
Walking Surface	18” x 51”	20” x 51”
Maximum Patient Weight	350 lbs	350 lbs
Base Dimensions	23” x 69”	25” x 69”

The Frame

The frame, as shown in Figure 19, is the main support structure and therefore has to be rigid enough to support the weight of the mechanical legs, the patient lift system, and the patient. All these mentioned components are attached to the frame in a particular manner. The y-slides attach the mechanical legs to the frame via the linear shafting and bearings. The patient lift system is attached to the frame by the linear bearings on top of the frame and the patient is attached to the frame through the patient lift system.

The inner width of the frame is 42 inches. This is necessary in order to accommodate any standard sized treadmill. The overall width of the frame is 98 inches. In order to provide proper lifting of various sized patients, the overall height of the system is 102 inches. The total length of the frame is 96 inches, in order to provide sufficient stability during use and an area in which to load the patient. Because of the large size of the

frame, it was constructed in several sections. Each section is small enough to fit through a standard sized door. These sections can then be transported to the desired location, and bolted together [2].

The Mechanical Legs

The objective of the mechanical legs is to assist the patient's legs through the correct gait motion or to follow the patient's legs through the motion during the data acquisition mode. The mechanical legs of the SGES are complex electromechanical devices that can be separated into 6 pieces; the y-slide, the x-slide, the z-slide, the hip/thigh flexion/extension, thigh abduction/adduction, and the knee flexion/extension. All of the six pieces are assembled together, as shown in Figure 4.

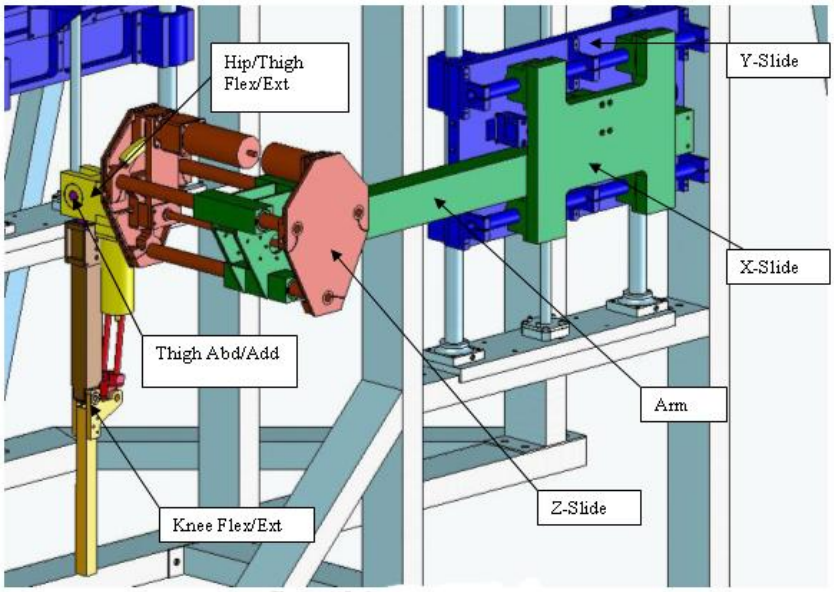

Figure 4. SGES Mechanical Legs.

The Y—Slide:

The y-slide controls the motion of the patient, and it also serves for adjustment. This slide controls the pelvic tilt and also the vertical center of mass motion. It may provide height adjustments for different patients' heights. The y-slide adjusts up and down in order to align the patient's hip joint with that of the SGES. Once aligned, the y-slide exhibits adequate range of motions in order to provide the necessary motion control. The y-slide may be viewed in Figures 5 and 6. The motion of the y-slide is accomplished using a linear ball screw and a DC motor for sliding the system up and down the linear shafts via the linear bearings. The Y-slide is located on the outside of the frame to maximize the internal space in order to keep the overall width of the frame to a minimum.

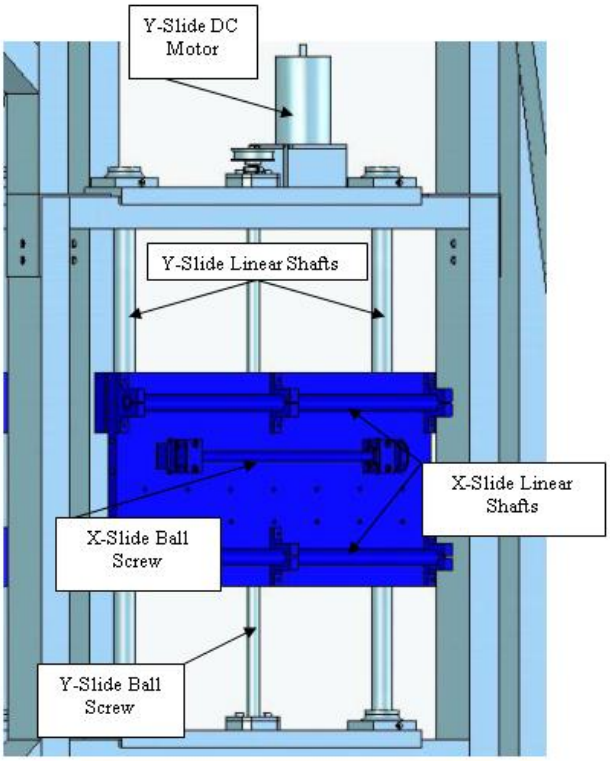

Figure 5. SGES Y-slide Outside View.

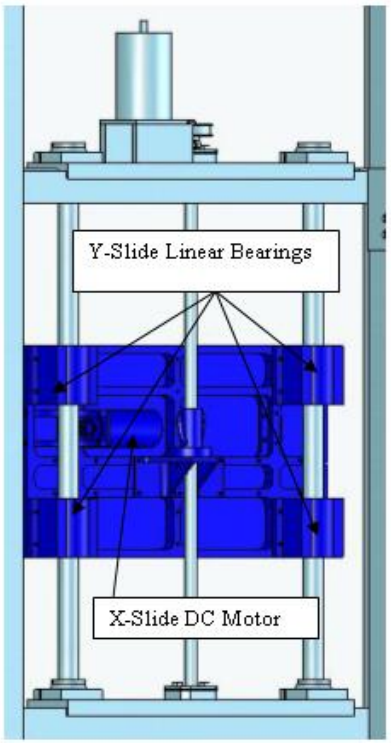

Figure 6. SGES Y-slide Inside View.

As mentioned, the role of the Y-slide is to provide the vertical center of mass motion and the pelvic tilt. Figure 7 illustrates a simulation of the pelvic tilt and the vertical center of mass motion required for a normal female to walk. Figure 8 shows the required right and left y-slide motion necessary to provide this motion.

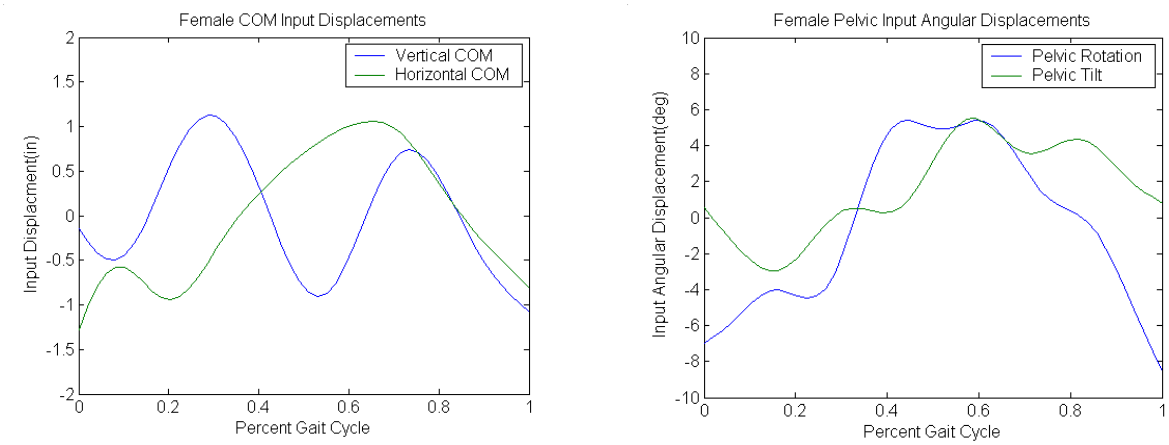

Figure 7. Female COM and Pelvic Motion.

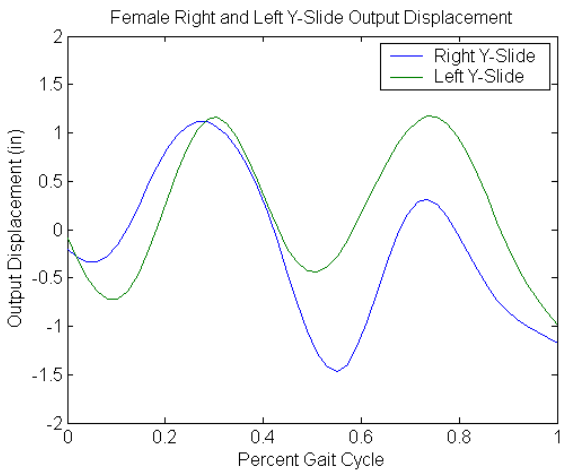

Figure 8. Required Y-slide motion to implement the correct Vertical COM and Pelvic Tilt Motion.

The X-Slide and Arm

The X-slide helps control the hip flexion/extension or the pelvic rotation. The function of the arm, is to put some distance between the patient's legs and the frame to allow better visibility of the patient's legs and ease the attachment of the patient's legs to the mechanical legs for the therapist. At the end of the arm is the attachment for the Z-slide. The linear motion in the x-slide is created by using a linear ballscrew that converts the rotary motion of the DC motor to linear motion along the linear shafting via the linear bearings. The X-slide and arm may be seen in Figure 9.

The mechanical arm is needed to connect the X-Y slide system to the z-slide and the mechanical legs. Figure 9 shows the design of the mechanical arm connected to the slide system. Patient's hip height, Y-slide height, and the treadmill height have much influence on the mechanical arm design. The mechanical arm must be rigidly designed to support the weight of the mechanical legs as well restricting a significant deflection when subjected to dynamic loading.

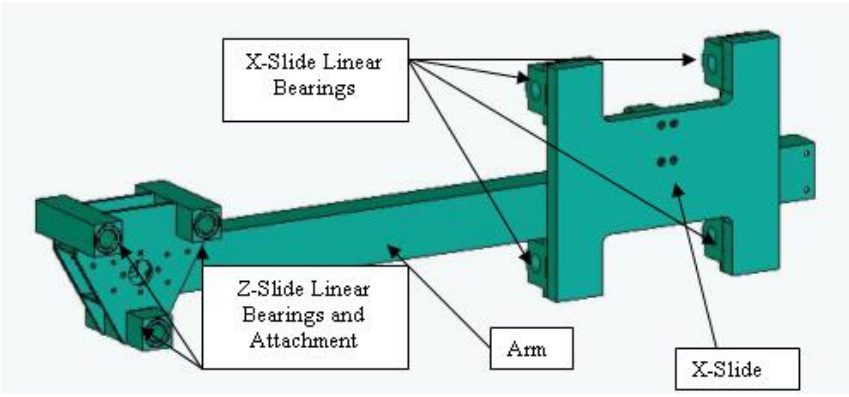

Figure 9. X-slide, arm assembly and Z-slide attachment.

The pelvic rotation seen in Figure 7, is controlled by the motion of the x-slide. The necessary left and right x-slide motion can be seen in Figure 10.

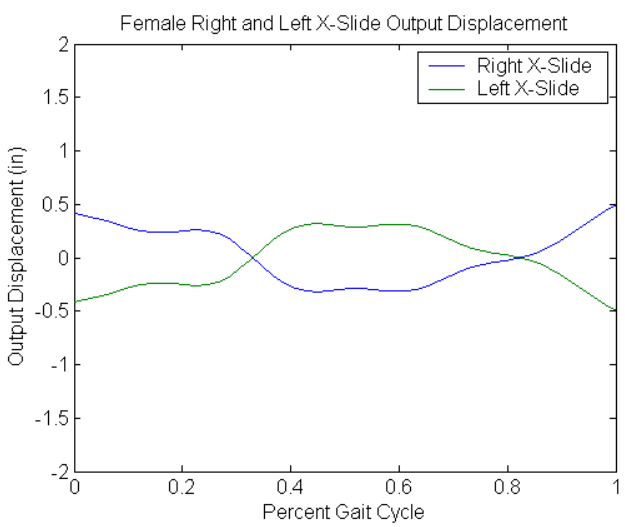

Figure 10. Required x-slide motion necessary to provide the correct pelvic rotation.

The Z-Slide

The Z-slide, shown in Figure 11, provides the adjustment and the horizontal COM motion control. The adjustment is required in order to have a universal machine for varying patient sizes. The horizontal COM motion allows the patient to walk normally and shift his/her weight from side to side while in a single limb support. The linear bearings, linear shafting, ballscrews and the DC motor provide the motion. The Z-slide also serves as a mounting point for the hip joint.

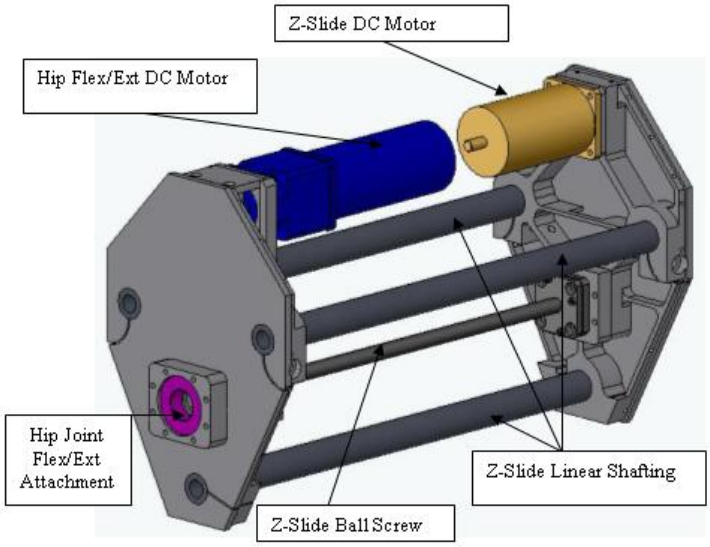

Figure 11. Z-slide.

The z-slide produces the horizontal center of mass motion necessary for the patient ambulation. The graph of Figure 12 shows the required z-slide motion necessary to provide the horizontal com motion seen in Figure 7.

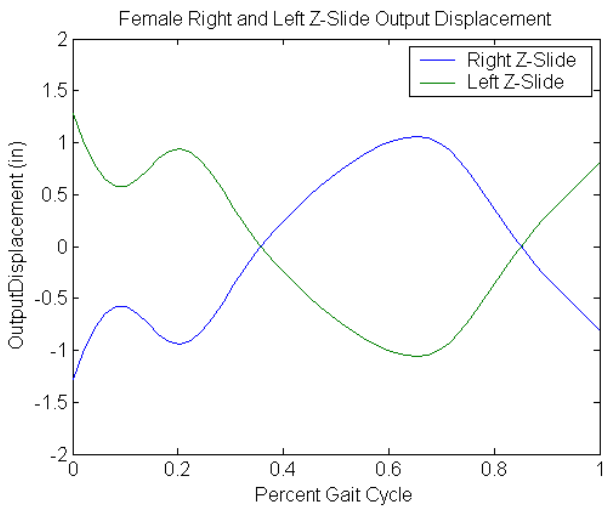

Figure 12. Required Z-slide motion for horizontal com motion.

The Hip Joint

The hip joint, shown in Figure 13, controls the flexion-extension motion of the hip joint and the thigh. The joint attaches to the bearings in the z-slide, which allows for flexion-extension motion. The joint motion is provided by a pinion gear and a DC motor that are also attached to the Z-slide. The thigh section of the mechanical leg attaches to the hip joint, thus providing the flexion-extension motions and the abduction-adduction motions of the thigh. The DC motor, worm and worm gear provide the thigh abduction- adduction motions.

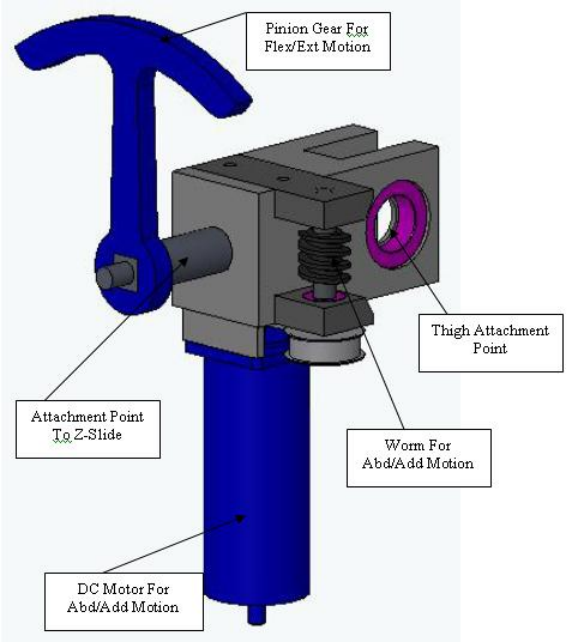

Figure 13. SGES Hip Joint.

A motor and a gearbox assembly will power the frontal thigh rotation or flexion-extension motions. The angular acceleration of the thigh is very high, resulting in a high torque needed to rotate the thigh. A commercially gearbox for the safe transmission of

the required torque, and also of lightweight, was nonexistent. Hence, a large gear was attached to the rotating shaft of the thigh as a solution. A small pinion gear attached to the end of the gearbox will rotate this large gear. This system results in over a 90% decrease in the output torque of the gearbox. It was then possible to use a commercially available planetary gearbox with an approximate 7:1 reduction to drive the pinion gear. The large gear for the rotation of the thigh is a custom made one. This system could turn out to be fairly expensive; however, it is much cheaper when compared with the alternative option of using a linear actuator to rotate the thigh [2].

The transverse thigh rotation is powered by a worm gear shown in Figure 9. Not shown is a timing belt that will transmit power from the motor to the worm gear. The worm gear only needs to rotate through approximately 20º to account for the necessary range of motions. To reduce cost, a commercially available gear will be purchased and dimensioned to the proper specifications.

The Thigh Section

The thigh section, shown in Figure 15, aligns and attaches to the thigh section of the patient's leg. The thigh section controls the flexion/ extension and the abduction/ adduction motions of the thigh. The thigh section of the mechanical leg is adjustable in length allowing patients of varying sizes to be able to use the machine. The adjustability of the thigh section ultimately aligns the knee joint of the machine to that of the patient. The flexion/extension motions are accomplished by rotating the hip joint. The abduction/ adduction motions are achieved by rotating the worm and worm gear.

The thigh length adjustment is shown in Figure 15. This design uses a square plastic bushing attached to the lower thigh that slides on the aluminum tubing of the upper thigh. A pin is inserted through one of four holes in the lower thigh and screwed into a concentric hole on the opposite side of the lower thigh. An adjacent side of the lower thigh has a slit in it. This slit allows the pin to lock the upper thigh in place, clamped between the two sides of the lower thigh. The entire pattern allows adjustment to the nearest 0.125 inch which should be sufficient to align the patient's knee joint with that of the mechanical leg.

The combination of the hip joint and the thigh section of the mechanical leg imparts the flexion/extension (Frontal Thigh Rotation) and abduction/adduction (Transverse Thigh Rotation) motions as illustrated in Figure 14 to the patient. The significant feature is that the motion of the mechanical leg is the same as the patient's leg, ignoring the patient attachment errors.

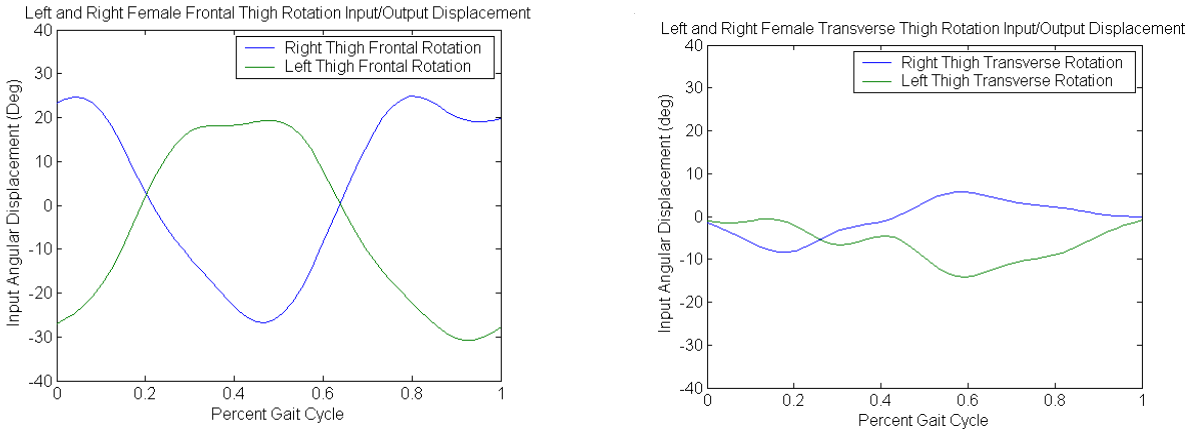

Figure 14. Patient and Mechanical Legs Motion for Frontal and Transverse Thigh Rotation.

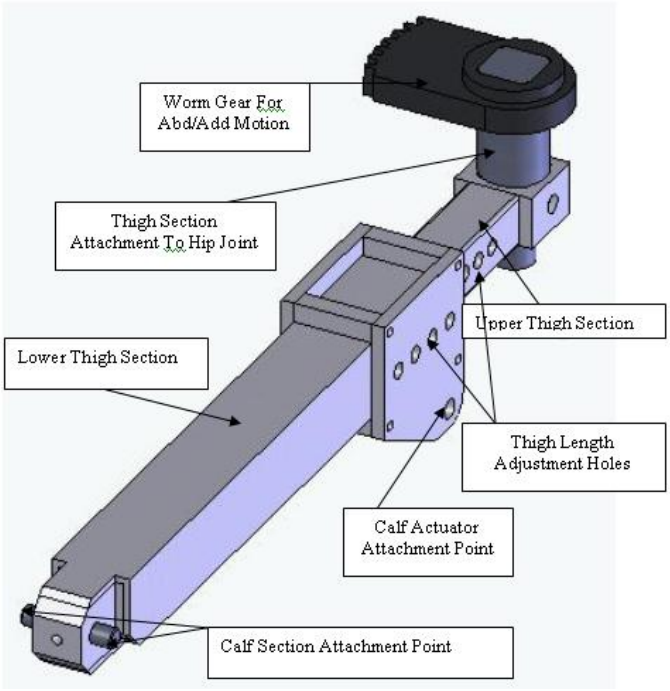

Figure 15. SGES Thigh Section.

The Calf Section

The calf section, shown in Figure 16, of the mechanical leg aligns and attaches to the calf of the patient and provides the flexion/extension of the knee joint and the calf. The motion is produced by a linear actuator that attaches to the lower thigh section and the calf section, which produces the motion across the knee joint. The calf section is made out of aluminum.

The calf section controls the knee flexion and extension motions. The motion of the calf is controlled by a linear actuator that attaches between the lower thigh section and the

calf. The knee flexion/extension motions are illustrated in Figure 17. The required knee actuator motion is shown in Figure 18.

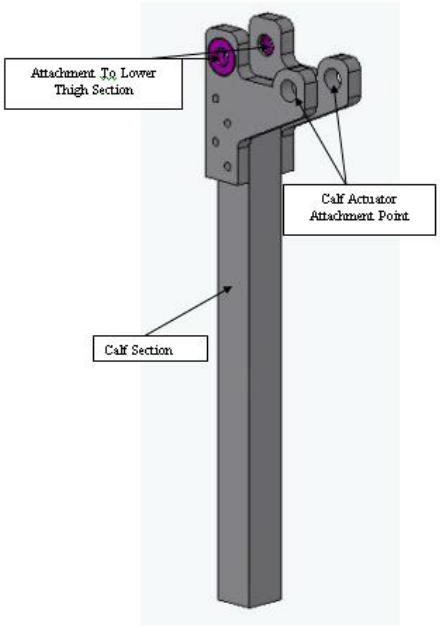

Figure 16. SGES Calf Section.

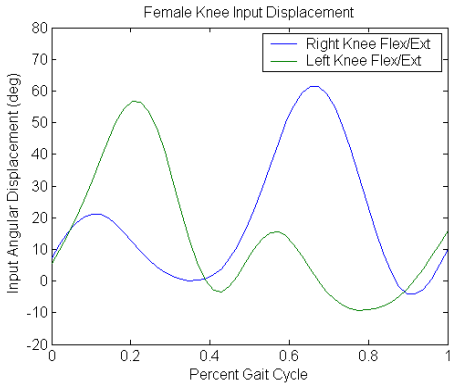

Fig. 17. Female Knee Flexion/Extension Motion

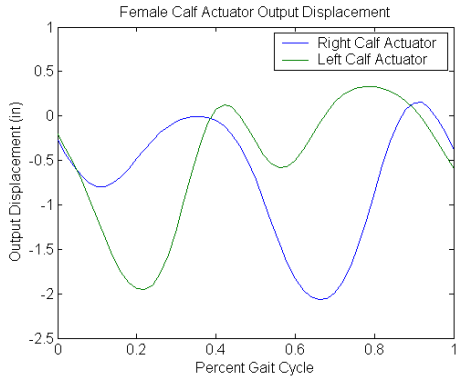

Figure 18. Required Calf Actuator Motion for correct knee motion.

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Patient Attachment

In order for the smart gait emulator system to impart the correct gait data to the patient, the mechanical components need to be properly attached to the patient's hips and legs. This attachment should be fairly rigid to minimize the amount of error introduced to the patient. Cuffs are implored for the attachment of the patient's legs to the mechanical legs at the mid-thigh and upper ankle. The size of the cuffs must be adjustable to fit a wide range of patient sizes. In addition, the position of the cuffs should be adjustable in order to properly align the patient's knee and hip joints with the joints of the mechanical legs. The proper hip motions are provided by a belt that secures the patient's waist to the machine. The design of the patient attachments may be modified when the frame and mechanical legs are re-constructed. This will allow us to experimentally determine the safest, most comfortable method of attaching the patient to the SGES.

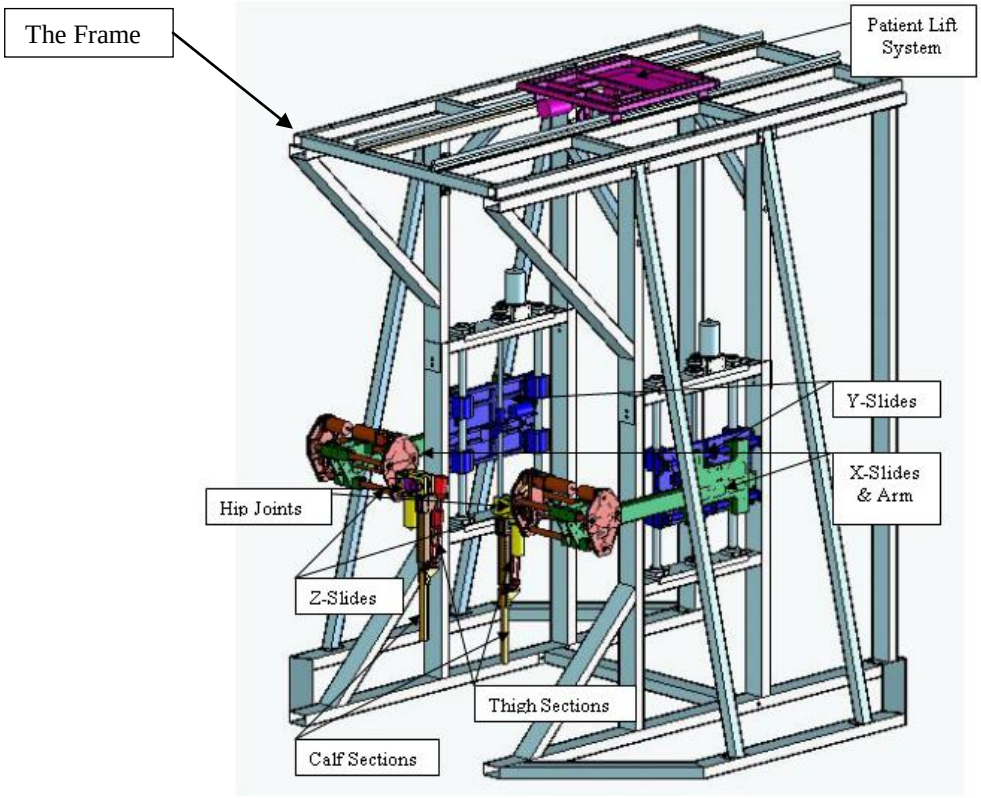

Figure 19. Smart Gait Emulator System

During years 1 and 2 of our proposed development, our team will aim to complete the final design of the model to be studied, fabricate parts, and build a working prototype based on the work accomplished to date.

The automation of diagnosis and therapy

The data acquisition in human locomotion involves the utilization of a sensor type out of the two most popular ones, the electrogoniometer, and the three-dimensional surface marker system, respectively. The human gait kinematic data will be measured by either of these sensing devices.

For the acquisition of data in this project, the gait facility within the Stanley E. Fulton Laboratory for Biomechanics and Human Motor Behavior is used. A 3D marker system is applied in recording gait data from the subject.

Pilot gait data will be collected on 10 able-bodied adults. The sample of 10 individuals will represent the adult range of height and weight outlined for Body Mass Index by the National Institutes of Health [32]. According to these guidelines, height measures range from 58-76 inches in height and body

weight measures range from 90-287 pounds in adult males and females. Using the calculations outlined by Winter [33], individual body segmental parameters can be determined for the anthropometric body proportions.

Pilot data collected on the 10 adult subjects will be anthropometric data (height, weight, thigh length/girth, shank length length/girth, foot length length/girth and width and head, arm and trunk length/girth (HAT segment) to form the overall anthropometric proportions of the subject. Next, each pilot subject will be given a full gait analysis study that yields the following comparative data collected from left initial contact (heel-strike) through the next left initial contact to obtain a full gait cycle (stance and swing phase): (a) joint angle changes (deg) at the hip, knee and ankle; (b) time in single stance (s); (c) step length length (cm); (d) stride length (cm); (e) cycle time (s); (f) joint moments (Nm/kg); and (g) power (W/kg) generation versus absorption.

From the gait data collected, a "normal" algorithm database that can be adjusted according to the individuals' height, weight, thigh and shank length will be developed.

The system involving the automated diagnosis and therapy in this project embeds intelligent components. They may be described as follows:
Figure 20 illustrates the data acquisition and processing system. The function of this system is as follows:

1. The dynamic system consists of the patient harnessed in the smart gait emulator system, and the treadmill that simulates the ground reaction forces.

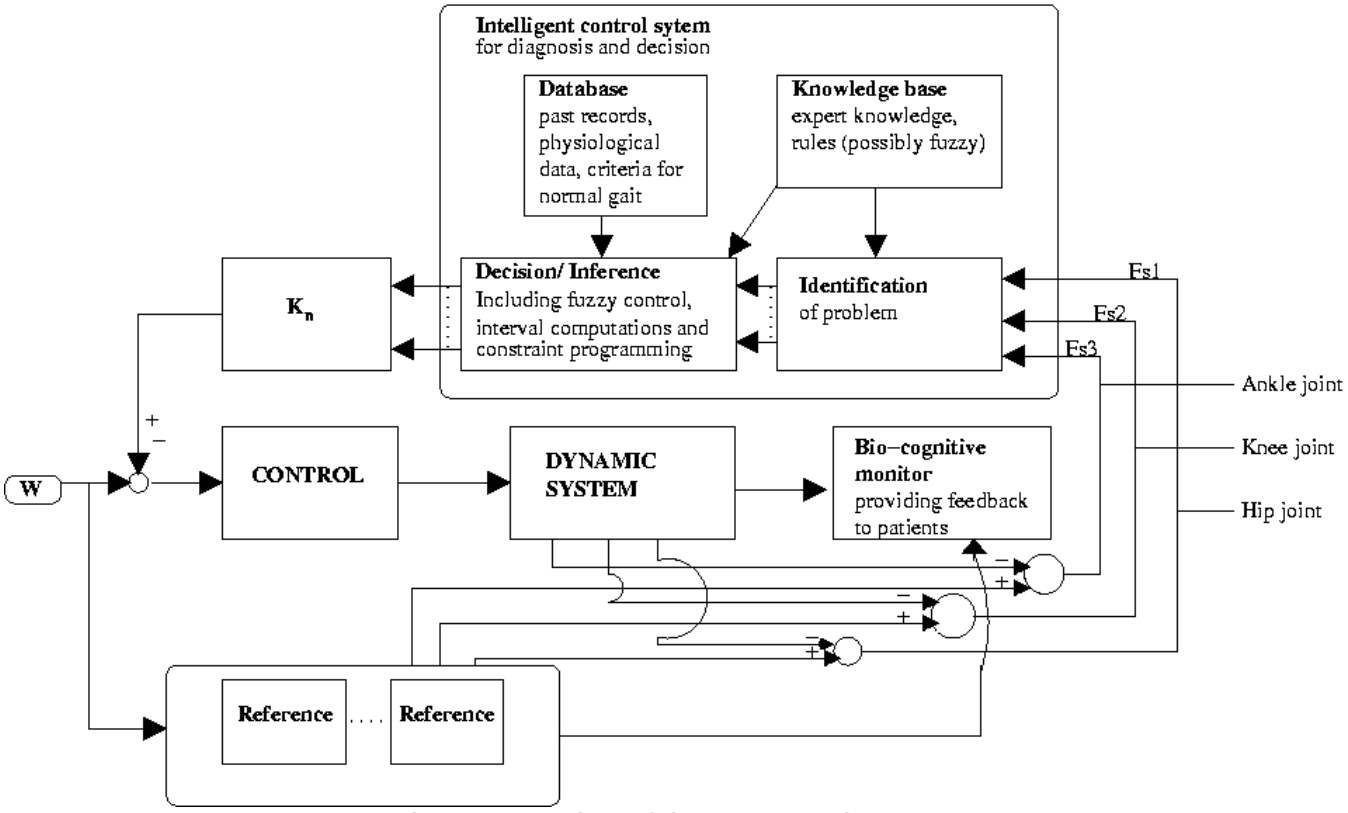

Fig. 20. Overview of the automated system.

2. From this dynamic system, the gait parameters of the human-subject are measured and recorded.

3. an intelligent system will analyze the measurements obtained from the dynamic system, compare these measured data with the reference ones;

4. a diagnosis will be obtained after this stage, and an adjustment of the therapy will be sent to the control vector, Kn, as feeding back for the control component at the entry of the dynamic system.

Besides these components, a monitor to display the bio-cognition of the subject completes the system by providing the user with a real-time feedback about how well he/she is performing, compared against the expected reference data.

A more detailed description of the significant components follow:

1. the intelligent system;
2. the reference component;
3. the bio-cognitive display

1. The Intelligent System

In Figure 21, the intelligent system is illustrated:

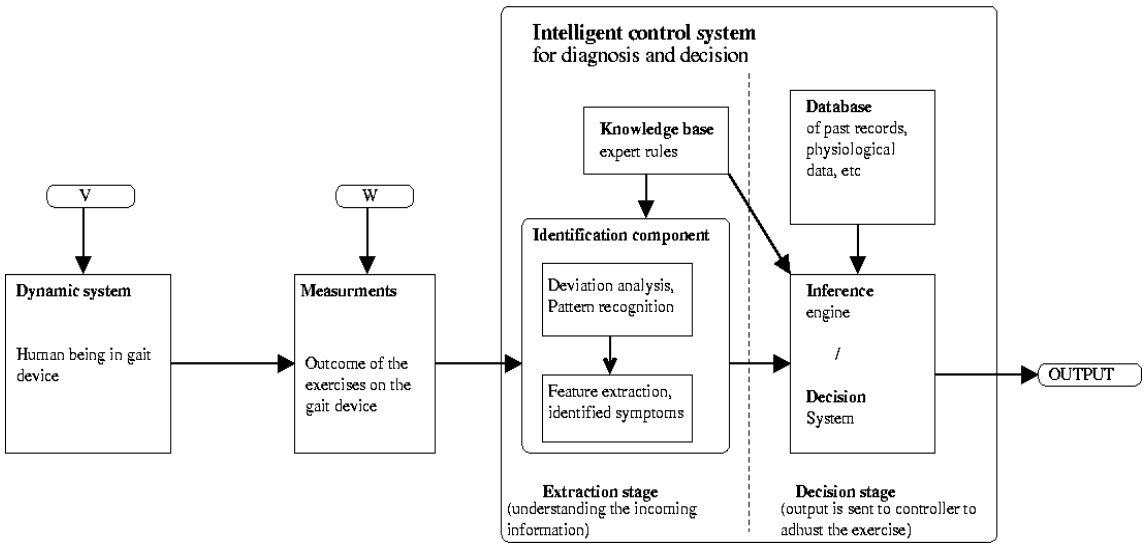

Fig. 21. Principle of the computational intelligence.

- As input to the system are the data recordings of the human locomotion system. These data are compared to the reference data (which constitute the ultimate goal in terms of performance); and
- returns a diagnosis in terms of a new instruction/exercise to send to the controller.

As pointed out in Figure 21 within the intelligent system:

- the measured information is the input to the extraction stage which establishes a first diagnosis of the pathology of the subject regarding any problems recorded during the exercise or also any positive outcome; and
- information flows into the decision part of the system, where the actual decision in terms of another set of exercises are fed into the controller.

The ***extraction stage*** is itself divided into two successive parts. The first part consists of the analysis of the deviations between the measurements from the dynamic system (depicted

through the comparisons of the graphs of the joints' movements), and the second part in recognizing patterns of symptoms that may show at this stage.
At this point in the process, expert knowledge is applied to enable the system to estimate the pathologies from observing the results obtained.

The parts that constitute the extraction stage involve:

i. *pattern matching techniques*: for the estimation of measured and reference parameters. It may also be able to apply rules that are available in the expert knowledge base (that is that knowledge that is capable of determining similarities/dissimilarities between pathologies).
ii. *interval based fuzzy (IBF) techniques*: this may be applied in obtaining the results of the pattern matching, and the sampling of the graphs of the results and the reference. IBF techniques facilitate very little parameter variations in the observed pathologies even in the presence of larger deviations.

The ***decision stage*** involves the integration of the diagnosis obtained from the extraction stage. It is made of an inference engine that uses expert knowledge, but that also makes use of a database of facts documenting previous results, and common therapeutic exercises.

This component is built as a fuzzy and probabilistic expert system. Indeed, fuzzy rules are already used at the extraction stage, hence the output of this first stage is expected to contain fuzzy information. Regarding probabilities, they are essential (as mentioned later): the absence of universal knowledge of the pathologies makes most of the diagnoses mostly experience-based, a feature that is taken into account by probabilistic rules. The probabilities can then be modified depending on the experience (cf. machine learning component of the system) gathered through the use of the system [62].

Some other specific components inherent in the fuzzy system include:

iii. *constraint solving techniques* [56], [57], [58]: This makes it possible to discriminate more rapidly within the database of facts (or of previous results), which ones are appropriate to compare to and decide which exercise should be the next one;
iv. *machine learning techniques*: this allows the updating of the database of the expert knowledge. The need for learning is justified by the incapacity to predict all possible pathologies. The intelligent system may have to face unexpected situations and still be able to make decisions. In such situations, the system should be able to learn from experience, gather new data and acquire more expertise about them. For this reason, we need both a rational decision making system (as described before), and a machine learning sub-component for the integration of the feedback from exercises (providing evolution and control). For instance, when an exercise is prescribed and the results are not good after several trials (* number of trials to be defined by the metric of the learning component), the knowledge base is completed with the reinforced rule that this exercise was not appropriate: this translates in the probabilities of a rule being updated.

Additional features of the intelligent system:
Besides the above-mentioned parts that form the integral components of the intelligent systems, ensuring a reasonable diagnosis, allowing to control the therapy, two more issues are relevant for making the system consistent and refined.

Enforcing the consistency of the therapy:
Besides providing expert diagnosis and control of the therapy, there is a possible flaw that demands attention/caution. Therapy may swing into a cycle of "improvement-deterioration" if the same series of exercises were always repeated. Thus, a cycle forms that should be aborted.

It may be argued that excessive repetition of exercises in a cycle would lead to improvement. In view of the possible absence of sufficient information, a meta-control component may be implemented to assure the overall positive evolution of the therapy. This safeguard will integrate optimization techniques, in addition to constraint solving techniques as pointed out earlier. This control will be implemented in the decision part of the intelligent system. It will make intensive use of past results of the patient to guarantee the progression towards the expected goal. Optimization techniques will help minimize the discrepancy between the expected progression and the actual one.

Comparing to reference data:
In the previous description, we mentioned that actual measurements are compared against reference data. It may be pointed out, however, that reference data reflect a totally healthy movement. On the contrary, patients need to repair their walking pattern. Comparing them over time is oriented towards a minimization of the discrepancy. Considering the exercises designed for the patients which are therapeutic ones, not, all exercises may allow patients to perform even anywhere closer to the healthy pattern. As a result, if we compare the performance of patients against the reference data only, we miss one half of the analysis. Therefore we choose to evaluate the patient's performance, by using the analysis as the basis as opposed to the expected outcomes of the previous exercise.
As a result, we anticipate a finer diagnosis and a better choice of appropriate exercises. The corresponding techniques to be implemented (at the extraction stage of the intelligent system) are not different from the interval based fuzzy techniques described earlier. We plan, at a more advanced stage of the project, to substitute fuzzy techniques for more general ones, from multi-criteria decision making (encompassing fuzzy methods among others) [59], [60].

2. The reference component

The reference component of the system provides the reference data for the comparison of the patient's results against healthy gait behavior. Such reference data is obtained by matching the patient's description to categories that were established by Winter [33].
In this project, we plan to improve this component of the system. Indeed, our aim for improvement is motivated by the fact that the measured categories are too crisp. This means that should a patient's description fall exactly within the borderlines of two or more categories, a choice would be required for either of these categories, which would therefore impact the expectations in terms of "normal" gait. In order to avoid such situations of blind choice, we propose the following sequential approaches:

a. **Interval computations [Intervals]:** when faced with two or more possible categories, we will gather all data and aggregate them into an interval. For instance, suppose that a patient's description matches two categories then, two graphs of movement will correspond to each of the joints. Instead of disregarding one graph per joint, we will expect the final gait (after therapy) to fall anywhere between the two graphs. In other words, each measurement of the patient's gait should fall within an expected interval of values: [value_gait_1, value_gait_2] [61].

b. **Extrapolation*:*** once the above method has been validated, we will aim at refining it by extrapolating the features of both categories in order to approach a smoother, less discrete description of the expected gait instead of merging all possible values of two or more categories.

c. **Modeling and constraint solving:** when we reach a good understanding of the way we can extrapolate intermediate gaits, we will work in determining a model of the above-mentioned

mapping “patient-gait” to be able to predict with more accuracy and reliability the “expected” gait.
Once the model is determined, constraint solving techniques will help to determine which specific gait characteristics correspond to which specific patient. This improvement in the quality of the reference data is expected to strongly impact the quality of the intelligent system’s decisions.
In the course of this part of refining the model, we will monitor our results by always comparing the consistency of them to former beliefs (in the former model: discrete, and then extrapolated).

In addition, to assess the improvement of the reference component, we will keep track of the results obtained at each step of the refinement. We will therefore be able to evaluate the improvement in terms of:

- time to complete the therapy or, in case the therapy is too long to retrieve significant data, to reach milestones;
- number of adjustments / changes of exercises.

The result of such a study will be ground-breaking in terms of prediction of gait and more generally biomechanical behaviors, and therefore of the quality of diagnosis.

3. The bio-cognitive monitor

In addition to the system we have described, we plan to add a specific device that is only aimed at the patient (not related to the intelligent system). This device is a monitor, which the patient will have access to while doing his/her exercises.
The monitor will display in real time both the performance of the patient, and the performance of his/her expected healthy gait. At this stage, we do not consider relevant to include also the expected performance of the exercise, as discussed earlier. Indeed, we anticipate that patients may be able to auto-adjust / regulate their performance according to what they can observe on the monitor.
To assess the improvement brought by this extra device, we will carry out experiments with the display on as well as with the display off. This will provide us with a reasonable guess about how patients can be efficient actors of their therapy. Further experiments should include the display of false expected performance, to evaluate whether patients follow the false expectations or really auto-regulate themselves.

Gait Measurement and Analysis - a means to validate the SGES design

The SGES represents a next-generation gait therapy device. A key element of our program plan calls for various testing to be conducted to validate this claim. Critical to the device testing will be having a means to measure and analyze gait data and compare these measurements with those made by the SGES.We have included Dr. Joanne Link and Dr. Richard Brower from the Texas Tech University Health Science Center on our team to support test development and clinical testing. Their expertise, and the resources they manage, are critical resources to support our test plans, and bring “the clinical perspective” to this effort and our team.

Dr. Darla Smith (director) and Dr. Pui Wah Kong (co-director) of the Stanley E. Fulton Laboratory for Biomechanics and Human Motor Behavior, department of Kinesiology, and Dr. Loretta Dillon (PT), will participate in the design and analysis of all experiments with able and disabled subjects.

The overall SGES design is based on three top-level subsystems: the mechanical design and assembly, the data acquisition system, and the real-time motion control subsystem (model reference adaptive control scheme). All three subsystems work in concert with each other to provide the capabilities and functions described below.

E. Human Subjects Research:

Subjects:

Up to 6 able-bodied subjects and 2-3 persons who survived a stroke with persistent physical disability from a hemiparesis and 2-3 with a myelopathy with paraparesis or with spastic diplegia from CP will be studied. The disabled subjects will be able to walk over ground, but at less than one-half normal casual walking speed, i.e., under 1.8 mph. Every effort will be made to enroll women and minorities in this small Phase 1 safety trial. The rehabilitation population consists of 65% men and 35% women. In a similar gender distribution, our subjects will include the following races: 20% white, 70% Latino/Hispanic, and 5% black, and 5% others including Native Americans. We will not be able to achieve large enough numbers of subjects under the age of 21 to include this age group in a study of stroke. The elderly will not be excluded if they meet other entry inclusion criteria.

Methods of Subject Identification and Recruitment:

Subjects will be identified primarily by from the affiliated institutions of the Texas Tech Medical Center at El Paso. Flyers that announce the clinical component and approved by the IRB will be posted at these sites and circulated among receptive community physicians and therapists identified as likely to be familiar with potential subjects. Once identified, the potential subjects would need to come to Texas Tech University Medical Center.

Data Collection, Storage and Confidentiality

a) Data entries will contain only the subject's initials. The data sheets will be delivered to the manager's office by the blinded observer.

b) The data will be stored and secured by the data coordinator in locked file cabinets.

c) During the study, only the research group will have access to patient information. No other release of this information will take place.

Potential Risks and Discomforts

Risks or discomforts may accompany the treadmill training, including shortness of breath, muscle soreness, and joint strain.

Risk Classification:

Minimal risk has been associated with manual treadmill training and robotic training by reports in the literature. We anticipate no additional risks with our device.

Minimizing Risks:

Subjects will be trained by a therapist who will closely monitor the tolerance and safety of the physical therapy. The robotic device also has built-in safety factors.

Potential Benefits:

a) Potential benefits to participants include gains in functional walking and quality of life related to improved mobility.

b) Potential societal benefits include beginning to determine the optimal intensity of training and need for feedback to optimize kinematics, kinetics, walking speed, endurance, and quality of life in patients. These pilot studies may lead to larger clinical trials aimed at optimizing the rehabilitation of motor skills learning after brain injury and spinal cord injury.

Therapeutic Alternatives:

In general, subjects in this study would no longer qualify for any rehabilitation therapy under MediCare guidelines. Subjects could obtain conventional locomotor retaining or treadmill training at another facility.

Risk/Benefit Ratio:

The minimal risk from the studies is small compared to the benefit in our laboratory in using a robotic approach to improve mobility.

Payment for Participation:

No cash payments are offered. If the study is funded, we will pay for parking for subjects who do not have handicapped parking access for their assessment visits.

Financial Obligations of the Subjects:

No obligations will be incurred.

Emergency Care and Compensation for Research-Related Injury:

Any injuries and costs incurred in association with the research will not be the responsibility of the investigators, The subject assumes responsibility for any complications (injury, distress, related expenses) related to participation in this investigational program.

Personnel Inviting Participants:

Dr. Link and Dr. Brower will invite participation in the research. They have been involved in the process of Informed Consent and have been certified by the University process in ethical conduct with human subjects.

Process of Consent:

Consent will be obtained in an outpatient setting. Potential subjects will be encouraged to view the apparatus prior to signing the consent. All subjects must be able to read and understand the Informed Consent. For patients, a family member will be encouraged to participate in hearing the explanation of the study and to help the potential subject evaluate participation in the study.

After reading the consent, subjects will be asked to restate their understanding of their commitments over the time line of the study and to restate their understanding that they can stop their participation at any time without concern about their present or future care.

No information will be withheld that may influence participation in the study, other than information about the assigned therapy during the course of the study.

SCHEDULE:

The focus of this work involves the study of methods and new technologies to harness the benefits of mechatronics for health care. The solutions are dependent on innovation in the underpinning technologies of sensing, actuation, and the intelligent interpretation of sensory signals. The protocol covers two separate sections: (1) The design/ assembly and testing of a new concept for rehabilitation, namely, "the Smart Gait Emulator System (SGES)", and (2) a pilot clinical test to determine the safety and gather initial evidence for the effectiveness of the proposed SGES.

Development Plan:

Important factors that enable such a rapid development and demonstration of the SGES are:

- the advanced state of the mechanical assembly design, based on the work already accomplished at UTEP;
- use of computer aided modeling and simulation tools that allow mechanical and control system elements to be designed and tested "in the computer", reducing the need for physical implementations during design development and refinement;
- the use of commercial-off-the-shelf (COTS) components, that minimizes the number of custom parts to be machined or manufactured;
- our use of automated software development tools that "generate" software source code from higher level subsystem models, dramatically reducing software development and test time;
- planned use of existing and suitable test facilities and equipment that eliminates the need for test system development and integration.

The various assemblies and subsystems that make up the entire SGES, and their interconnections, are described below. However, first we present our development plan and schedule.

The major tasks to be accomplished during the entire 5 year program our development effort are shown in the following schedule. Key subtasks in each area are:

Timelines and Deliverables

Timelines	Deliverables
09/01/06-08/31/07	Task 1 – Program Management and Programmatics: Project management, team coordination, status reporting, and reviews will be accomplished under this task. Progress and status reports will be delivered at the end of each 3 month period, and reviews with the NIH are planned during months 6 and 12.
09/01/06-02/28/07	Task 2 – Finalize System Requirements: System design requirements and specifications to support the stated claims above will be finalized and documented. These will be used as the guidelines for completion of the

SGES detailed design in Task 4, as well as development of appropriate engineering and clinical test plans under Task 3;

Design of the intelligent system: gather techniques, choose languages, and interfaces; assess the theoretical model of it.

03/01/07-08/31/07

Task 3 – Engineering, Bioengineering, and Clinical Test Plan Development: In parallel with the final design and fabrication efforts, detailed test plans will be developed to specify the engineering and clinical testing to be accomplished during Year-2 to validate our claims and demonstrate SGES functions and capabilities.

Implement a prototype of the intelligent system, without the two extra features, as described before at the same time, design the interaction of the extra components

09/01/07-02/29/08

Task 4 – SGES Design Completion: While the development of the mechanical assembly design is mostly complete, final development of the computer controls design is required. Adjustments to the mechanical design to support full integration of the subsystems also will be accomplished. Note that acquisition and fabrication of most parts can begin (Task 5) as these components have already been identified, or require minimal design work to complete specification.

Run experiments of the intelligent system: at this point the whole system may be far from final, but this step aims mainly at showing the feasibility and validity of our design

03/01/08-08/31/08

Task 5 – Fabrication & Assembly: COTS components will be purchased, the few custom mechanical parts needed will be made, and subsystems will be assembled and integrated. Software module development / testing will be accomplished during this phase. As subsystem designs are tested and proper operation validated, per test plans from Task 2, staging for overall system integration and testing will be completed.

Integrate interval values of the referent: extension of our model to take this new feature into account.

09/01/08-02/28/09

Task 6 – System Integration: Subsystems will be integrated and connected so that the entire SGES assembly is made operational and ready for preliminary engineering testing.

Run experiments and adjust the design of our intelligent system to take into account interval reference data and to improve its performance

03/01/09-08/31/09

Task 7 – Preliminary Engineering Testing: Initial tests will be performed to verify that the various system operating modes are functional and that safety components and software are working properly. End-to-end signal testing will be accomplished to verify proper signal processing and communication. Similar testing to confirm that the system is safe to operate, and ready for performance testing and interaction with humans will be completed.

Design meta components to get feedback about how well our system

	behaves and how to improve it introduce the bio-cognitive monitor as an extra-device for therapy enhancement definition of the extra software components necessary to ensure real-time display design a tailored extrapolation method to refine the rough interval version of the reference data (to be continued during months 37-42)
09/01/09-02/28/10	Pilot Efficacy study Run intensive experiments about the impact of the bio-cognitive monitor Implement other optimization methods for the control of the positive progression of the therapy, so that we can compare them and understand which would be best fitted.
03/01/10-08/31/10	Safety and Development study
	Adjustment / refinement of the intelligent system
09/01/10-11/30/10	Final Analysis & Report Preparation
	Write the user manual comparison between the performance of the system itself, and the assessment of the positive progression of the therapy: we will look for a correlation, we expect the system to be consistent
12/01/10-02/28/11	Pilot Efficacy trial
	Release / patent of the whole system design of future improvement of the system
03/01/11-05/31/11	Safety and Development trial
06/01/11-08/31/11	Final Analysis & Report Preparation

PERSONNEL

Research Personnel

Our research team consists of the required multi-disciplinary expertise and resources to bear on this research proposal. The combined expertise of these individuals will offer competent, productive efforts toward the development of a bio-robotic system for rehabilitation therapy.

The Principal Investigator, Dr. T. Sarkodie-Gyan, exhibits expertise in Mechatronics (a synergestic combination of mechanical and electrical engineering, and computer science. He also has expertise in the development and testing of gait devices Dr. Sarkodie-Gyan will be responsible for the system integration involving the mechanical design, electrical/electronics, and control engineering aspects of the project.

The co-PIs are Dr. Joanne Link, MD., Dr. Martine Ceberio, PhD., and Mr. Kirt J. Jensen, MS.

Dr. Martine Ceberio has enormous expertise in fuzzy systems, constraint programming and machine learning;

Dr. Joanne Link, a co-PI, has enormous expertise in Neurology, and Director of the

Mr. Kirt Jensen has expertise in mechanical design, modeling and simulation. His MS thesis established the diagnostics of human locomotion. He is currently a senior engineer at Team Specialty Products Corporation.

Dr. Richard D. Brower, a co-Inv., is a Clinical Professor at the Texas Tech University Health Sciences Center; He has expertise in clinical neurology;

Dr. Darla Smith is a Research Professor and Director of the Stanley E. Fulton Biomechanics and Behavior Laboratory at UTEP while Dr. Pui Wah Kong is a research biomechanist and co-director of the biomechanics laboratory..

The PI, co-PIs, and co-Investigators will work together in a multidisciplinary team throughout the project.

• Dr. Sarkodie-Gyan, T., Ph.D.	UTEP, Department of Electrical & Computer Eng:	PI
• Dr. Joanne Link, MD.	Texas Tech University Health Sciences Center.	co-PI
• Dr. Martine Ceberio, Ph.D.	UTEP, Department of Computer Science	co-PI
• Mr. Kirt J. Jensen, MS	Team Specialty Products Corporation,	co-PI
• Richard Brower,	Texas Tech University Health Sciences Center.	co-Inv.
• Pui Wah Kong	UTEP, Department of Kinesiology	co-Inv.
• Darla Smith,	UTEP, Department of Kinesiology	co-Inv.
• Dr. Kristin Gosselink, PhD	UTEP, Department of Biological Sciences	co-Inv.
• Dr. Loretta Dillon, PhD	UTEP, Department of Physiotherapy	co-Inv.

CLINICAL TEST(S):

To pilot test the effectiveness of the Smart Gait Emulator System, we are proposing a comparative study of conventional treadmill-training model to our “Smart” Gait system. Specific hypothesis to be tested are:

- Patients who undergo passive, robotic-assisted PWBTT will improve less than 15% in overground walking speed. At the same intensity and duration of robotic-assisted PWBTT with sensory feedback to enhance motor learning, subjects will increase their walking speed by 40% over the pre-passive training and by at least 25% over the passive training.
- Patients who undergo passive, robotic-assisted PWBTT will improve less than patients who receive the same intensity and duration of robotic-assisted PWBTT with sensory feedback to

enhance motor learning, in measures of kinematics, joint moments and power measures of hip, knee and ankle that more closely approximate pilot data collected on pilot able-bodied subjects.

There will be 4 separate study phases to the clinical human subject testing as follows:

A. Pilot Efficacy Study: This will occur at UTEP (Stanley E. Fulton Laboratory for Biomechanics and Human Motor Behavior) with 4 abled bodied subjects of different sizes.
B. Safety and Development Study: There will be a total of 6 subjects: 2 adult subjects with post stroke hemiplegia and 2 adult subjects with a spinal cord injury (SCI), and 2 children with spastic diplegia. This will also occur at UTEP.
C. Pilot Efficacy Trial: There will be 12 total of subjects. 4 with hemiplegia, 4 with SCI, and 4 subjects with spastic diplegia cerebral palsy. This will occur at UTEP'S Stanley E. Fulton Laboratory for Biomechanics and Human Motor Behavior..
D. Pilot Phase 2-3 Safety and Efficacy Trial: 16 adult subjects with hemiplegia due to stroke.

Subjects and Clinical tests:

A Pilot Efficacy Study

Time 0-18 months. Four able-bodied subjects of different sizes (80, 120, 160, 190) pounds and different heights of, that is, 4'6' 5', 5.5', 6' will be recruited as a convenience sample to test the flexibility and safety of the Smart Gait Emulator System.

Safety and Development Study.

Time 18-24 months. We will study a total of 8 subjects total with up to 4 patients in any of the categories: with spastic diplegia from cerebral palsy, with chronic hemiparetic stroke, and with paraparesis from a spinal cord injury. All will be able to walk with less than minimal assistance. These subjects will enable us to fine tune the device and algorithms for feedback-assisted training and for safety. These subjects will be studied at the UTEP site with a physical therapist in attendance.

Pilot Efficacy Trial

Time 24-30 months. This time period will be devoted to a pilot study of efficacy at UTEP. We anticipate the recruitment of additional locations for the investigational system as the clinical program progresses. Twelve subjects will be involved: 4 patients with hemiplegia stroke, 4 with SCI, and 4 with spastic diplegia. Intervention will be 3 times/week for six weeks each with pre and post test outcome measures. Passive and active-assisted training will be performed to help set up following the Safety and Efficacy trial.

Safety and Efficacy Trial.

Time 30-36 months. This is the major clinical test of this project and will involve 16 adult subjects with chronic hemiparetic stroke, diplegia from traumatic brain injury.. Subject enrollment and testing will be performed at UTEP and Texas Tech Medical Center. Dr. Link and Dr. Brower will recruit and screen these subjects for inclusion/exclusion criteria:

1. Subjects over age 21 years with a single stroke due to an infarction or primary intracerebral hemorrhage occurring from 3 months to 5 years prior to training. An MRI scan or CT scan of the brain must reveal the symptomatic lesion.
2. Subject had been able to walk without restriction in the community prior to the stroke and lived free of supervision for mobility and ADLs.
3. At entry, subject walks at least 25 feet with minimal assistance or less help by the criteria of the Functional Independence Measure or walks independently for 50 feet in 18 or more seconds, equal to walking at less than 1.9 mph.
4. Adequate cognition with a Mini-Mental Status Score over 24/30.

5. No cardiopulmonary contraindication (such as angina, congestive heart failure, arrhythmia per subject's cardiologist/internist) to treadmill exercise to a maximal heart rate of 70% of maximal predicted ([220 - age in years] x 0.7).

6. No physical contraindication to training such as painful joints with walking, claudication, skin breakdown of the leg. No medical problem that may alter concentration, exercise tolerance, or study drug levels, such as the need for dialysis, exercise-limiting chronic obstructive lung disease, or active malignancy.

7. No other ongoing neurologic disease that may interfere with training mobility, such as seizures more than once a year, incontinence that limits training, or a polyneuropathy that affects sensation or strength to impair balance or mobility.

Sixteen subjects with stroke who meet entry criteria will be identified. We will randomly assign 8 to start automatic robotic training and 8 to start with robotic-assisted training with feedback. The no-feedback condition will allow us to estimate the effects of training without a design aimed at optimizing motor learning and serve to mimic a commercial device such as the Lokomat. We will also gain insight into the stability of our measures performed serially. Baseline measures will be taken within 10 days before starting the intervention. Subjects will receive 18 sessions of their intervention (3/week for 6 weeks). Repeated measures will be taken overground within 1 week of completion. The subjects who received no feedback will cross over to 18 sessions with feedback and the group that did have feedback will cross over to the no-feedback training condition. Outcome measures will be taken within 1 week of completion. We will be able to train subjects in groups of 4 at a time, 3 days a week. Thus, each crossover will take 12 weeks to complete. The study will take 48 weeks for the 4 groups. We will recheck overground walking speed 2 months after the 36 sessions are completed to look for persistence of any effects of the training. If a subject is unable to complete the 18 sessions for personal reasons or within a maximum of 8 weeks, we will aim to obtain final outcome measures at the time of drop out.. In studies of patients with hemiplegic stroke who fit the above criteria, Dr. Dobkin's reported subjects have generally achieved an increase in overground walking speed of 30-50% within 18 sessions of manual training.

SUBJECTS	Automatic Stepping (total 8)	Feedback - Assisted Stepping (total 8)	Crossover (total 16)
Stroke	2	2	2 x 2

If time allows, we will also test 6 subjects with CP and spastic diplegia in a similar crossover design. These subjects will be recruited from the affiliated institutions of the Texas Tech Medical Center at El Paso.

Data Analysis

Overground gait analysis will take place in the Clinical Gait and Motion Analysis Lab at the UNM Health Sciences Center. Changes will be measured by comparing assessments (overground walking speed, gait analysis parameters of joint kinematics, joint moments and power measures of hips, knees and ankles) at pre-training, at the end of the the first 6-week intervention, and at the end of the second 6-week intervention. Overground walking speed (the primary outcome measure for the stroke efficacy pilot trial), temporal symmetries of the legs for stance and swing phases, and changes in hip and knee joint angles, among other variables, will be compared using a 2 way repeated analysis of variance (ANOVA) with two factors (time X measure).

Anticipated Results:

We anticipate that the subjects will demonstrate greater increases in measured parameters of gait post-intervention with the Smart Gait Emulator in the feedback mode as compared to no feedback. Subjects who receive feedback first, then no feedback will show little additional gain. The safety and flexibility of the system ought to be evident from these preliminary studies and allow us to modify the system, as well as begin to gather the data needed for efficacy trials. We expect to find the following changes primarily for the feedback mode:

a) greater overground walking speed with an increase of 40% over the pre-passive or no training

b) greater symmetry in stride and step lengths

c) greater symmetry in pelvic rotation and obliquity in right versus left sides of the body

d) more hip and knee extension during stance phase of gait

e) greater symmetry in ankle dorsiflexion for heel-strike and during the swing phase of gait

f) greater symmetry in joint moments during gait

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