KineAssist: Design and Development of a Robotic Overground Gait and Balance Therapy Device

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Background and Purpose: Balance and mobility training consists of activities that carry a high risk for falling. The purpose of this article is to describe a novel robotic system for allowing challenging, yet safe, balance and mobility training in persons at high risk for falls. **Method:** With no initial preconceptions of what device we would build, a user-needs analysis led us to focus on increasing the level of challenge to a patient's ability to maintain balance during gait training and also on maintaining direct involvement of a physical therapist (rather than attempting robotic replacement). The KineAssist® is a robotic device for gait and balance training that has emerged from a unique design process of a start-up product of a small company and a team of therapists, engineers, mechanical design experts, and rehabilitation scientists. **Results:** The KineAssist® provides partial body weight support and postural control on the torso; allows many axes of motion of the trunk and pelvis; leaves the patient's legs accessible to a physical therapist's manipulation during walking; follows a patient's walking motions overground in forward, rotation, and sidestepping directions; and catches an individual who loses balance and begins to fall. **Discussion** and **Conclusion:** Design and development of the KineAssist® proceeded more rapidly in the context of a small company than would have been possible in most institutional research contexts. A prototype KineAssist® has been constructed and has received US Food and Drug Administration (FDA) classification and institutional review board clearance for initial human studies. The acceptance of KineAssist® will ultimately depend on improved patient outcomes, the use of this new tool by therapists, the ease of use of the system, and the recognition of the unique value it brings to therapeutic recovery. **Key words:** *device development, gait and balance training, robotics*

The job of a physical therapist is physically demanding and challenging. Working with patients who have balance and mobility impairments puts therapists at risk for falling during training sessions. Clinicians use their bodies to lift, move, and provide "safety nets" for patients who may be up to three times larger than they are. The intensity and duration of physical therapy sessions are often limited due to exhaustion of the clinician. Safety concerns sometimes limit the extent to which the clinician is able to challenge the patient as much as possible to enhance learning, because falls and other injuries are not desirable.

Robots are tireless, precise devices that can do repetitive motion. In these rather early days in the development of human–machine interactions, there are many unrealized functions that robotic technology can do for rehabilitation. The device

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can *facilitate*, rather than replace, the efforts of a therapist. This collaborative approach in rehabilitation robotic design was utilized by starting with the end user (clinician) and implementing the feedback received to create a device that assists with functional mobility in stroke rehabilitation.

The resulting KineAssist® device works with a therapist during a multitude of functional tasks that typically take place during a physical therapy session. The therapist is the person guiding the training session, based upon their wide repertory and knowledge of appropriate exercises. The robot remains dormant until either the patient or the therapist decides to act. The robot can also provide assistance using several programming modes, depending on need. Meanwhile, the therapist can administer training challenges and guidance rather than worrying about falls and preventing a person from losing his or her balance. In fact, a therapist may choose to challenge a patient so that loss of balance occurs, if therapeutically appropriate.

The purpose of this article is to describe the design process that led to this exciting prototype system and to discuss some of the problems, issues, and successes of this interdisciplinary project.

Assessment of Needs

To identify opportunities for robotics, our approach was first to assemble an inclusive team. Several engineers, therapists, and designers met and planned for an immersive understanding of therapists' and patients' needs and what new technology might offer. We partnered with several industrial design specialists at IDEO, a Palo Alto, California, consulting company with a branch office in Evanston, Illinois. An interesting philosophy emphasized by IDEO was that often the market does not know what the market really needs, and so observing, asking questions, and learning by example lead to great new insights. Sometimes a question is asked for which there really isn't a solid answer, pointing to an unmet need or a new manner of thinking about solutions.

Based upon funding from the Advanced Technology Program at the US National Institute of Standards and Technology (NIST) of the US Department of Commerce, and additional financial support from the Rehabilitation Institute of Chicago, the original proposal had no stipulation of any particular device at the outset. Instead, the entire team, through direct observation mixed with periods of discussion, attempted to discover a list of user needs through observations and interviews during physical therapy settings. The team conducted observations in a broad range of physical therapy settings in the Chicago area. These sites were chosen to encompass the range of patients, tasks, and environments where physical therapy is delivered. We observed inpatient, outpatient, and home settings. We visited both hospital-based and private clinics. We observed therapeutic tasks by patients with both orthopedic and neurological diagnoses. Diagnostic categories included joint replacement, lumbar diagnosis, traumatic brain injury, spinal cord injury, stroke, burns, pediatrics, and Parkinson's disease.

Interlaced between these sessions, the team was involved in discussions to determine key tasks for which needs are the greatest and attempted to assess the kinematics required to support these tasks with a robotic device. This often involved drawing cartoons and pictures, a rather unconventional and enjoyable approach to device design. Our mix of backgrounds—from physical therapy to cognitive psychology to engineering to industrial design—was useful in generating a rich range of perspectives around what we saw and allowed us to have a shared understanding of the physical therapy world. It was well into the third month of the project before there was any focus on any specific device.

We discovered that therapists tend to be very practical. They often want to use very simple machines or no machine at all, and they often prefer to use their own hands. Devices that allow them to actually do the work that they need to do are important. Clinicians are skilled at guiding the motion of the legs manually, and they prefer to manage the treatment that way.

We also learned that there was nothing out there to help clinicians train a variety of balance activities with substantial challenges that might initiate a fall. As a result, we identified that the area of greatest need that we could address with techniques from human–interactive robotics was the practice of overground walking in combination with balance, while maintaining close interaction between patient and clinician. Practicing gait in functional overground contexts, as opposed to treadmills, is widely desirable. Perhaps most important, clinicians wish to challenge patients at or beyond their level of comfort, without risk of falls that could injure the clinician or patients.

Focus on Balance Activities

The design approach led us to understand the role of therapy that focuses on dynamic standing as a pathway to recovery of function. In one of the most prevalent causes of motor disability, stroke, the majority of individuals must recover from significant gait and balance limitations. These include the inability to effectively control standing and walking.[1] Only 37% of stroke survivors are able to walk after the first week[2,3] and even among those who achieve independent ambulation, significant residual deficits persist in balance and gait speed 6 months after stroke.[4,5] Common deficits that prevent ambulation include the inability to bear loads, to generate propulsive forces, to move limbs swiftly through s trajectory, and to control lateral stability.[6–9] Most patients do not walk with a normal locomotor gait pattern. Rather, they use compensatory strategies that include the assistance of another person or devices such as walkers or orthotics. Internally based compensatory strategies include reduced gait velocity, increased stance and double support time, knee hyperextension in stance, and hip circumduction during swing phase. Although the majority of stroke survivors will achieve some level of ambulation, there continues to be a strong need for therapeutic interventions that can reduce their need for long-term physical assistance. Such biomechanically inefficient and unstable locomotor gait patterns can lead to secondary damage over time. One readily identifiable deficit that occurs as a result of hemiparesis is decreased speed of locomotion.[9–11] Walking speed is an effective indicator of the degree of abnormality in gait quality, overall functional status, and clinical progress in people with paraparesis.[12,13] Furthermore, gait speed has been found to correlate with ability to balance on either one or both lower extremities, degree of lower extremity force recovery, Barthel Index score, degree of ambulatory independence, cadence of gait, and rating of overall gait appearance.[14–16]

Recent findings have suggested that repetitive training for locomotion is indeed effective in foestering recovery. Spinal transected cats recovered the ability to step on a moving treadmill belt after they were trained on a treadmill with some body weight support and stimulation and assistance in paw placement.[17–19] Spinal locomotor pools may include a central pattern generator for alternating flexor and extensor leg muscle activity. Barbeau and collegues attempted such a technique on human patients, suspending them over a treadmill using an overhead lift for body weight support and clinician-provided assistance to the legs.[20] Since then, many studies have reported the effectiveness of treadmill training with individuals poststroke.[21–27]

Most important, clinicians' safety concerns often limit the amount of challenge they can introduce in a therapeutic setting, even though the patients must face the challenges of these balanced activities in therapy if they are to recover. For example, if a patient starts to lose balance and fails to recover, he or she has learned more than if he or she never had the chance to experience the balance loss. However, safety concerns over an injury from an actual fall, and the patient's distrust that can result when a therapist fails to prevent a loss of balance, tend to limit challenge opportunities like this. The clinician is prevented from practicing with the patient alone in functional environments. Sessions are confined to parallel bars or unrealistic harnessing systems that are mounted over treadmills. In current practice, functional practice is not a realistic option due to the need for multiple people to assist in case safety is compromised. Realistic challenge has not been well integrated into clinical practice because of the limitations imposed by safety. In an ideal setting, clinicians would try to get patients into more realistic, functional environments as quickly as possible. Patients who do not move out of the parallel bars at the appropriate stage in their rehabilitation may use the bars as a psychological crutch, preventing the development of skills and confidence for a real-world setting. It is clear that technology may help move the therapists closer to their goals.

Design Development Using State of the Art Tools

Rehabilitation technology based on treadmills and robotics has been introduced recently. Colombo and colleagues have designed a robotically driven gait orthosis that operates by computer interface with a standard treadmill[28] and is now commercially available under the name Lokomat®. The AutoAmbulator®, funded by HealthSouth, is a treadmill-based device that features an overhead harness system to support body weight, mechanically powered braces to move the patient's legs, and numerous sensors to track vital signs, movement, and contact speed. Leg exoskeletons have been constructed to generate spring-like assistive joint torques using Bowden cables and series elastic actuator technology in the LOPES® system.[29] Schmidt and colleagues have developed a system that uses moving programmable footplates.[30] The ankles can also be moved using linear actuators mounted on the handrails of a treadmill.[31] While these machines are merely a scattering of examples and the remainder of developed or developing robotic devices are too numerous to mention here, it is important to note that all have given minimal attention to balance. Furthermore, most therapeutic devices have been designed to simulate the role that a clinician could play, eliminating the skills of the clinician. Consequently, the design focused on novel methods of assisting the balance component of standing activities.

In addition to many design and development discussions, one critical design philosophy we used was to develop experience prototypes as early as possible with the quickest means as possible. This led to our experiencing mistakes as early as possible and learning from them. Our first attempts included inclined devices and treadmills, planar joints, bicycle pedals, and harnesses that would lower the amount of gravitational force on someone while they were walking and provide them with assistance. Many concepts did not move in the direction of our ultimate design, but spending a small amount of money on a cheap treadmill and some other materials from the hardware store led to a great deal of learning. For example, we explored the possibility of a gait training device that would allow people to walk while leaning back on an inclined surface. Our experience prototype revealed that the mechanics of gait were unrealistically altered and quite difficult even for a healthy individual. The therapists that tried it told us they would have little interest in such a therapy device.

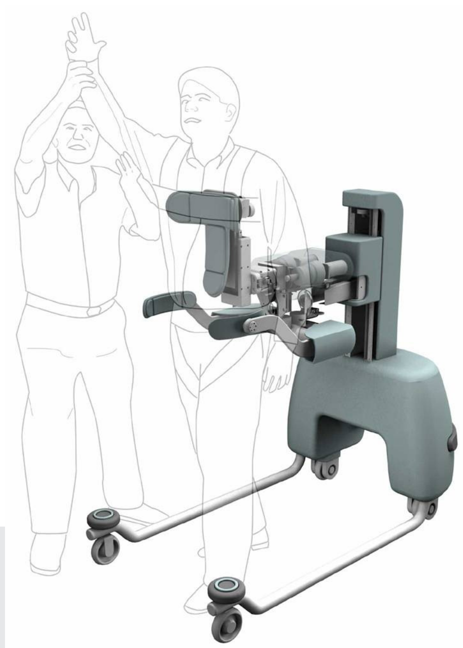
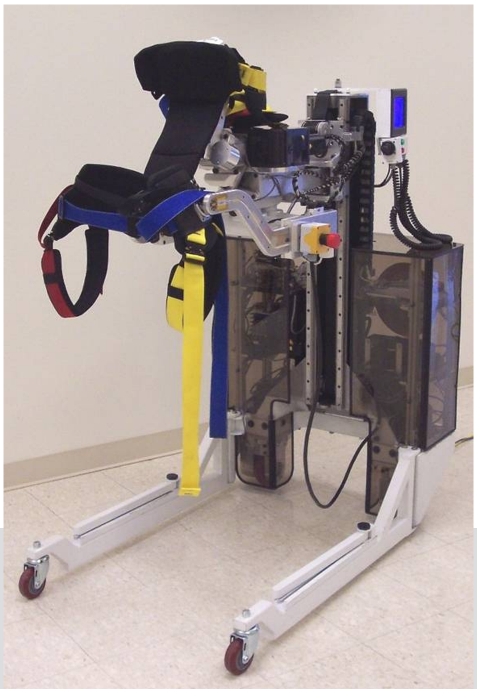


Figure 1. Artist's rendition of the design conception of the KineAssist®. A physical therapist works with a patient on balance exercises, and value of technology is realized only when both individuals work together with the robot.

Design Description

Our resulting design, the KineAssist®, shown in **Figure 1**, has two major components: a mobile base system and a brace system. The mobile base is omni-directional and uses Cobot technology originally developed by Peshkin and Colgate at Northwestern University for assistive devices in materials handling.[32] Cobotics is software that forms the basis of a new class of technology that senses human movement and allows devices to follow and take direction from this movement. This adds precision and safety to lifting, guiding, and positioning. This admittance control methodology renders a haptic display that compensates for the inertial effects of the robot, rendering the



A

B

Figure 2. The initial KineAssist® alpha prototype.

system virtually undetectable and allowing easy forward and turning motions while the machine moves in response to the motion of the patient. Force sensed at the pelvic harness is used to drive the motion of the system. The trunk and pelvis mechanism allows the patient's bending motions both left-right, forward-backward, rotations about a person's transverse axis, and hip rotations about the forward axis. A torso mechanism attaches at chest level and can prevent collapse of the trunk. A software-driven "safety zone" limits the patient's upper body range of motion where the trunk support implements an adjustable, compliant constraint that catches the patients when they lose balance. In addition to simply acting as a fall-arresting device, this device can partially support the patient's weight at the level of the pelvis, and the system is also capable of comfortably applying forces to the body. The therapist has the freedom to change parameters and assist or challenge the patient to the level that is necessary to gain the best clinical outcomes.

The legs of the mobile base are shown in **Figure 2** in their parallel configuration, which allows the KineAssist® to pass through a standard door opening. The legs may also be angled outward 30° to allow a patient more room for side stepping. The motion of the mobile base is powered and is highly responsive to the patient's desires for motion, so that the patient does not have to pull the base. The patient's intent for motion is detected by a combination of passive sliders and integrated force sensors incorporated into the pelvic part of the patient support structure. Control algorithms move the base in response to the patient's forces and motions, so that the patient's walking and turning motions are unconstrained.

Pelvic and torso harnesses serve as the interface between the machine and the patient and provide the means of comfortably applying desired forces to the body as well as acting as a fall arrest device. The harnesses were custom designed; they are modified circus harnesses. Harnesses may seem commonplace, but they can be a key factor in the success or failure of a rehabilitation device. Because body weight support protocols can apply large vertical forces, comfort is essential and hard to achieve. Many harness systems impinge on the groin area and cause such pain that patients cannot withstand the duration of training intended.

Harness design also plays a major role in the time it takes to get a patient set up for a period of therapy. Twenty minutes is a typical set-up time for other body weight support systems. In a 1-hour session, a 20-minute set-up time is a major deterrent to use. By a combination of good harness design and a system for harnessing while the patients are seated (rather than reclined), patients may be set up in the KineAssist® typically in 5 minutes. Our harnessing system is particularly critical because the intent of the KineAssist® is to allow the clinician to challenge the patient up to or beyond the patient's comfort zone. Falls are likely; the KineAssist® must be able to slow and stop the patient without pain.

The KineAssist® is able to produce unweighting of the patient (partial body weight support training) up to 150 lbs of vertical force. The vertical column is powered to provide this force continuously and at the same time to easily allow the vertical motions of the pelvis and torso, which are a part of normal gait. The unweighting feature is rated to 150 lbs, but the KineAssist® is designed for patients up to 350 lbs, and it can safely bring such a patient to a stop after only a few inches of fall. (The threshold distance for identifying and stopping a fall is selected by the clinician.)

The trunk and pelvic mechanism allows bending motions both left-right, forward-backward, rotations about a person's transverse axis, and hip rotations about the forward axis. The trunk and pelvis mechanism is designed to allow the patient's natural walking body dynamics to occur unimpeded while providing safety.

Postural control may be used by the clinician to set the trunk and pelvic components independently of each other to maintain a person in a desired posture. The prescribed posture is then actively (under computer and motor control) maintained by the application of bias forces to the patient's torso. In addition, the clinician may perturb the patient by, for example, pushing on the patient's shoulders or hips. However, even though the device does not actively perturb the patient, it will actively monitor and allow the patient to make motions necessary to recover from the perturbation while preventing him or her from falling outside of the safety zone if the patient is unable to recover from the perturbation. Finally a stabilization function defines how much support the device gives the patient at the trunk level. This can be adjusted by the depending on how much stability the clinician feels the patient requires—from a somewhat rigid embrace to completely free.

We have discovered several significant challenges in this design cycle. One challenge was to design an appropriate pelvis interface that accommodates a wide variety of body shapes while allowing the necessary degrees of freedom and control from the robot. Another challenge was to instantaneously move a heavy (approx 400 lbs) robotic mechanism, designed first for safety, in response to very small motions and forces exerted by the patient. Adaptive haptic algorithms improved this transparency aspect of the device. The controls also had to accommodate specific modes of operation, because an impending fall is defined differently for walking than for the sit-to-stand motion (**Figure 3**).

Future Goals

A currently funded technology transfer research grant from the National Institute of Child Health and Development/National Institutes of Health is now dedicated to showing that this device does what it was designed to accomplish. More specifically, does this device get in your way when you're trying to move freely? Ideally, the device should not to resist at all and should follow a person along, however such idealizations are impossible and the limits of the machine are currently being quantified. We are identifying how some tasks are more difficult for perfect control. For example, initiation of walking seems to produce a small amount of resistance in healthy people and in stroke patients.

A second goal addresses the important question of how walking therapy can influence free walking speed and time to fatigue. Finally, the KineAssist® allows us to address some more novel and radical ideas, such as the concept of repeated challenge as

Figure 3. The KineAssist® in action as an individual plays catch with the therapist. (Both the patient and the physical therapist are employees of Kinea Design LLC.)

a therapy, where the therapist deliberately makes walking more difficult in training using perturbations and forces that destabilize. When the patient leaves such rehabilitation settings, we hypothesize that they will have learned more and perhaps have minimized a motor deficit. Such novel but easily programmable strategies are now possible with such a robotic device, and a new and widely imaginative set of possibilities are now realizable with this new technology.

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