Evaluating and Addressing Disease Progression in Hip Osteoarthritis

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Background

The Kinoped® Lower Extremity Rehabilitation, Injury Prevention, and Performance Improvement System produces variable resistance on three axes through a "ground effect" footplate that moves in 3D, creating simulated ambulatory environments throughout a user's functional range of motion (ROM) and across various modes of ambulation. The user manages external forces (resistance) with plantar force against the footplate as they move their foot through ambulatory motion patterns, thus experiencing simulated ground reaction force vectors (GRFVs) with variable simulated gravitational and inertial values. The user reacts to the resistance of the footplate by applying plantar force in order to load the joints and to create moments of force that initiate specific muscular activations in specific sequences.

The Kinoped® is a horizontal exercise device that places the user in a biomechanically correct "standing" posture, supporting a user's trunk and head with no contact from the user's hips to the bottom of their feet. By stabilizing the pelvis and providing a functional stance phase ROM, the Kinoped® creates a plantar rocking experience without the constraint of shoes, allowing for "natural" ambulation over infinite virtual environments.

The Kinoped® captures gait biomechanics during ambulation (ROM, force, muscular activation) over nine axes (three each at the hip, knee, and foot/ankle complex). This kinematic, kinetic, and force data can be input into the Kinoped® as is or modified to improve kinematics and reduce voluntary activation deficits. This data is then uploaded to the Kinoped®, and the resultant motion patterns are displayed using virtual reality (VR) to create a virtual 3D ambulatory environment. The user follows the visual guides and moves their foot with active plantar force, allowing for the performance of thousands of repetitions of biomechanically correct motion patterns in order to correct gait kinematics, develop comprehensive hip and foot/ankle complex strength, and improve proprioception.

The Kinoped® as a Diagnostic Device

The Kinoped® contains numerous positional, 3D inertial, force, and biometric sensors to capture dynamic performance data over nine axes of movement during device use. In addition to allowing for "real-time" command and control, the data captured by the Kinoped make it an ideal platform for diagnosis of complex lower extremity conditions and diseases, including osteoarthritis (OA).

Compared to current diagnosis devices such as motion capture cameras, force plates, and MRIs, the Kinoped® offers numerous diagnostic advantages, including:

- Significant reduction of voluntary activation deficit – When using full weight-bearing diagnostic tools such as motion capture cameras and force plates, individuals with conditions such as OA may experience voluntary activation deficit, making it difficult to distinguish whether captured kinematics reflect compensation due to pain or are due to abmormal physiology. By reducing gravitational (fz) forces by as much as 90 percent, the Kinoped® provides a platform to evaluate gait mechanics while significantly reducing the pain associated with weight bearing. The Kinoped® will incorporate sensors to monitor pain levels of patients under full and modified gravitational values in order to identify and address the impact of voluntary activation deficit.

- Elimination of upper extremity contribution to lower extremity kinematics – The Kinoped® features a fixed-pelvis moving-foot design, as opposed to the fixed-foot moving-pelvis experience of ambulation, eliminating upper extremity “noise” from lower extremity gait diagnosis.
- Expanded ROM - Because the pelvis is fixed, leg motion patterns on the Kinoped are exaggerated to include hip and pelvic movements. These expanded movements significantly aid in the visual and analytical diagnosis of gait biomechanics.
- Dynamic 3D as opposed to static 1D evaluation – While an MRI provides a comprehensive view of structural and soft tissue damage due to diseases and conditions such as OA, it does so from a static perspective largely limited to the sagittal plane. With the Kinoped®, assessment of three planes of movement, including the frontal plane, can be recorded using the most accurate motion capture system available at a resolution of up to 500 times a second. The resulting data can illustrate gait kinematics from a reduced weight-bearing perspective in 3D, differentiating between abnormal stress/normal physiology and normal stress/abnormal physiology in users presenting with conditions such as OA.
- Extended evaluation period – While MRI represents a static perspective and both force plates and motion capture cameras offer at best a few steps of evaluation over 2D surfaces, the Kinoped® can capture ambulatory motion patterns over thousands of steps and over a wide variety of simulated surfaces, providing a much more comprehensive perspective of ambulatory performance over a variety of surfaces (i.e., simulated hard or soft surfaces such as steps or sand).
- Evaluation of motion control – By providing for 3D visual guidance with variable resistance, the Kinoped® allows for evaluation of speed, strength, ROM, and proprioception (e.g., control). Tests can be developed to identify specific or global ambulatory performance and can be replicated under identical conditions and across identical motion patterns on a recurring basis, allowing for a non-invasive visual and statistical perspective of ambulatory health and fitness over time.

According to Guilak (Guilak, Farshid Ph.D. *Biomechanical factors in osteoarthritis*. *Best Pract Res Clin Rheumatol*. 2011 Dec; 25(6): 815-823.), “Biomechanical loading is clearly necessary for the maintenance of cartilage homeostasis…However, abnormal, altered, or injurious loading is associated with inflammatory and metabolic imbalances that may eventually lead to OA… recent studies indicate that exercise may play many important beneficial roles in an overall therapeutic regimen for osteoarthritis. These include decreased pain, increased mobility, and increased muscle strength.

“Clearly there is an urgent need,” he concludes” to develop more effective clinical modalities for the treatment or prevention of OA, particularly for the significant obese population.”

The Kinoped® as a Rehabilitation Device

The Kinoped® is the first lower extremity rehabilitation device that is designed to address the full spectrum of lower extremity ambulatory performance objectives.

Current devices and protocols attempt to accomplish functional lower extremity objectives such as biomechanical performance improvement (i.e., strength, speed, endurance, proprioception, ROM, and motor control), prevention of injuries (i.e., ligament, tendon, and muscle tears and strains), and correction of ambulatory kinematics (patterns of movement during gait and running) and kinetics (muscular activation patterns). However, these approaches fail to adequately address global ambulatory objectives. This inability of existing devices and programs to effectively manage interconnected neuromuscular challenges has significantly impacted individual and societal ambulatory health and fitness, a situation that has been exacerbated by radical changes to our ambulatory environment and physical activity levels.

Although human ambulation may appear to be a linear experience, in fact it is a complex 3D body mass displacement process that relies on constant weight transfers across alternate supporting legs. Recent gait analysis studies have defined the significant biomechanical challenges faced by the legs in order to adapt to the ground forces that must be managed during ambulation. Ground reaction vectors are primarily implemented by changing gravitational forces, acceleration, and inertia acting on the moving center of mass. At ground level, these forces are also conditioned by two integrated factors acting on both sagittal and frontal planes: Fluctuating angular leg positioning and plantar rocking relative to (normally) stable ground. Accordingly, effective lower extremity health and fitness protocols must address the functional challenges of ambulation by providing for plantar contact and replicating the ground forces experienced during human ambulation.

Ambulation strategies rely on deeply integrated neurological and biomechanical systems that control complex eccentric/concentric muscular activations along kinetic chains. Such specific 3D joint movements allow the body to respond to ground forces while maintaining proper biomechanical alignment and following precise kinetic and kinematic patterns during ambulation. These ambulatory strategies evolved in a 3D world where every step required acute kinesthetic awareness and the continuous involvement of hip and foot/ankle-complex stabilizers. As humans have abandoned rural lifestyles for urban ones, the physical environments over which we ambulate have been radically flattened, largely due to the advent of compacted asphalt (patented 1903) and concrete (patented 1911) roads and walkways, which have replaced the dirt, stone, and gravel roads and trails on which we previously trod. In effect, we have transformed our natural 3D ambulatory environment into a largely two-dimensional (2D) environment that significantly reduces muscular activation and diminishes the need for precise neuromuscular control. The mostly automatic process of ambulating over "safe" surfaces without a means to replace the biomechanical challenges of ambulating across a variable 3D environment has contributed to an epidemic of poor ambulatory health and led to decreased proprioception and a resultant increase in lower extremity injuries.

Over the past 50 years, significant technological advances have revolutionized lower extremity surgical devices, procedures, and techniques. At the same time, sophisticated technological approaches and intensive research have improved injury diagnosis and have significantly advanced our understanding of kinematics, kinetics, and biomechanics. However, the devices and protocols used to accomplish lower extremity performance improvement, injury prevention, and rehabilitation objectives have not kept pace with these advances.

The Kinoped® was designed with a global perspective of the complex lower extremity neuro-biomechanical requirements necessary in order to maximize athletic performance, reduce injuries and minimize their impact, and optimize rehabilitation outcomes.

The difficulty of addressing specific lower extremity muscle groups in a functional manner has led to a plethora of products and protocol, including devices that either partially or fully stabilize the body and pelvis (i.e., leg press, bicycle, leg lifts). For the most part, the isolation of leg movements is either an unintended consequence in the design of these products (i.e. bicycle, leg press), or an attempt to isolate specific muscle groups (i.e., ground-based leg lifts, adduction/abduction devices). During gait, leg movements are combined with 3D pelvic movements to allow ambulation using an alternating-leg approach. Existing stable-pelvis approaches attempt to fulfill multiple goals such as addressing specific biomechanical deficits, promoting progressive training parameters, facilitating real-time performance monitoring, and improving cardiovascular health. But these current devices that stabilize the pelvis cannot account for these combined pelvic/leg motions. Furthermore, because they are absent a moving body mass, they cannot replicate the kinematic and kinetic requirements of ambulation, including the two-plane plantar rocking phase that is central to managing ground reaction forces.

Current devices used to improve lower extremity performance (including, but not limited to, bicycles, stationary cycles, elliptical machines, treadmills, leg presses, balance trainers, and adduction/abduction machines) may accomplish isolated objectives, but they cannot comprehensively address the full spectrum of requirements necessary for optimal ambulatory performance.

For example, stationary cycles improve cardiovascular fitness, but alter ambulation kinematics and kinetics because they:

- Place the hips in a non-ambulatory flexed position that operates outside of the functional sagittal ROM of walking and running gaits
- Operate predominantly on a single plane (sagittal) in a seated position, which significantly limits the activation of hip stabilizers
- Rely primarily on a single major muscle group (quadriceps), thus contributing to muscular imbalance (i.e., hamstrings)
- Automate lower extremity performance, which contributes to decreased kinesthetic proprioception
- Operate primarily in a concentric mode, limiting critical eccentric involvement, and
- Bypass plantar rocking in favor of a mid-sole application of force that fails to replicate the functional ground reaction force vectors (GRFVs) experienced during ambulation. Ground forces load the joints and allow for the creation of the moments of force that initiate sequential activations of lower extremity muscular groups.

In another example, powered treadmills may improve cardiovascular fitness and support functional kinematics, but alter kinetics because they:

- Provide powered propulsion, reducing the concentric activation of hip extensors and plantar flexors during terminal stance and exaggerating eccentric hip flexor responses during loading response
- Fail to provide a variable 3D ambulatory environment, limiting the activation of hip and ankle stabilizers, and
- Provide a predictable environment that results in repetitive and stereotyped motion patterns, that fail to challenge proprioception and motor control abilities.

Current physical therapy programs are comprised of infrequent episodic interventions reliant on therapist-led ground-based exercises, segmented muscle strengthening, analgesic modalities, and subjective or non-specific performance monitoring. Such programs require patients to perform the majority of their rehabilitation in non-clinical settings through the unmonitored execution of prescribed routines using simplistic modalities. This results in poor outcomes due to systemic non-compliance and a failure of patients to properly execute (if they even undertake) the prescribed protocol. These programs also fail to satisfy global evidence-based ambulatory health and fitness requirements, are largely static, fail to address 3D human kinetics and kinematics, and lack the critical dynamic components necessary in order to maximize ambulatory proprioception.

For example, a typical therapy program following hip-replacement surgery relies on ground exercise routines that isolate hip muscle groups (i.e., leg lifts for adductor/abductors and hip flexors), coupled with the use of a stationary cycle to improve endurance. These programs may also incorporate various devices such as parallel bars and walkers to address weight-bearing issues. Such programs:

- Engage isolated muscle groups, limiting global neuromuscular performance
- Utilize non-functional assisted weight-bearing approaches, precluding the development of hip-level control
- Fail to train the neuromuscular system to respond to ground forces, thus failing to address weight-bearing deficiencies in a functional manner
- Rely on exercises that do not involve ambulatory plantar rocking, thus failing to activate functional kinetic chains
- Provide little to no real-time feedback, hindering proprioceptive improvement and motor control, and
- Reinforce poor gait kinematics with predictable compensations.

For example, standard anterior cruciate ligament (ACL) rehabilitation and injury prevention programs typically include 0-40 degrees closed-chain knee extension strengthening exercises (i.e., leg press or squats), 40-90 degrees open-chain knee extension exercises (i.e., leg extension machines or ankle weights), isolated hip abduction (i.e., abduction machines, ankle weights, or elastic bands) and global lower limb fitness, (i.e., stationary cycles). Such protocols:

- Do not incorporate the two-plane ambulatory plantar rocking process that is required in order to activate integrated hip, knee, and foot/ankle complex functional muscular responses
- Utilize stationary cycles, thus creating a non-functional flexed-knee, flexed-hip motion pattern that primarily activates concentric quadriceps responses and which contributes to quadriceps/hamstring muscular imbalance (one of main cause of ACL injuries)
- Primarily operate in a single (sagittal) plane, promoting hip stabilizer weakness, and
- Fail to engage foot/ankle stabilizers through plantar rocking on the frontal plane, contributing to overall supinator weakness and a lack of control.

Hip and foot/ankle stabilizer weakness is a key contributor to OA, ACL, Achille's tendon, and other lower extremity injuries.

Since existing devices and protocols were not designed with the explicit objective of globally satisfying the evidence-based components of human ambulation necessary to obtain and sustain optimal lower extremity health and fitness, they are, unsurprisingly, ineffective at satisfying said requirements. No current device or protocol comes close to addressing even a bare majority of required functional ambulatory elements; further, no combination of current devices or protocols can safely satisfy all of the ambulatory requirements necessary in order to achieve and maintain optimal human ambulatory performance.

Unlike other rehabilitation devices and protocol, the Kinoped® simulates 2D and 3D ambulatory environments through the real-time angular adjustment of a ground effect footplate that provides consistent resistance in three axes. The user applies plantar force opposing footplate resistance as they follow on-screen guidance, gameplay, or therapist/trainer instructions in moving the footplates in 3D to navigate various functional and non-functional virtual ambulatory environments in order to achieve specific or global ambulatory performance objectives. The Kinoped®:

- Utilizes a stable pelvis approach that allows for the performance of functional 3D kinematic and kinetic parameters during simulated ambulation. This approach allows for the execution of focused lower extremity objectives and accurate performance monitoring while following precise kinematic and kinetic parameters associated with ambulation.
- Elicits natural plantar rocking on sagittal and frontal planes and simulates GRFV values across various ambulatory environments in order to create moments of force about all seven biomechanical axes (per leg) during various gaits in order to activate functional ambulatory muscular responses.
- Allows for performance of complete ambulatory gait cycles in order to correct or improve gait biomechanics and perform functional training in order to address global ambulatory objectives.
- Provides for performance of distinct segments of ambulatory gait cycles in order to address specific ambulatory objectives.
- Displays a "real-time" visualization of actual and optimal kinematic and kinetic performance in order to address proprioception and motion-control issues.
- Can vary GRFV values associated with specific 3D ambulatory segments in order to simulate different gravitational and inertial performance environments so as to allow for incremental training and for use by individuals with limited weight-bearing capabilities or for those in low-gravity environments.
- Adapts to user performance by modifying device resistance and ROM values according to therapist or trainer-defined algorithms in order to optimize ambulatory performance.
- Allows for unilateral or bilateral performance based on the performance characteristics of each limb, in order to promote optimal biomechanics and allow for maintenance of one limb while the other limb is undergoing progressive rehabilitation.
- Provides a functional, foot-activated game controller that maximizes a user's lower extremity speed, strength, ROM, and control, by having them play foot-operated video games built on segments of functional and non-functional ambulatory patterns and their associated variable simulated GRFV values.

Abstract

The overall goal of this proposal is to evaluate the Kinoped's® efficacy as a lower extremity diagnostic tool and as a rehabilitation platform for patients with hip OA. This study would consist of two components:

- Analysis of the Kinoped® as a lower extremity diagnostic tool – The initial phase of the study will entail development of an evaluation protocol for the Kinoped® and then applying said protocol to assess the device's efficacy in diagnosing biomechanical factors that contribute to the onset and progression of OA. The information gathered will be reconciled with data from the previous

study in order to identify similarities and differences in findings and to validate the Kinoped® as a lower extremity diagnostic tool for individuals presenting with OA.

- Analysis of the Kinoped® as a lower extremity rehabilitation and injury prevention system – The second phase of the study will entail development of a rehabilitation protocol for the Kinoped® and then applying the protocol in order to assess its efficacy in slowing or reversing the progression of OA. This study will be validated through techniques validated in the previous study in addition to evaluation by the Kinoped® diagnostic protocol.

The central hypothesis is that by using the Kinoped to identify and address issues with gait kinematics and kinetics, individuals presenting with OA due to abnormal stress/normal physiology as well as normal stress/abnormal physiological factors can improve their kinematics, reduce pain and edema, increase speed, strength, and ROM, and improve their proprioception, thus slowing the progression and lessening the adverse impacts of OA. To accomplish this, we need to use the Kinoped to identify kinematic and kinetic functional deficiencies in patients presenting with OA and compare the results with the baseline established by MRI analysis, develop protocol to directly address those deficiencies, have patients perform the protocol on the Kinoped® on a regular basis over an extended period of time, and assess the program’s effectiveness in slowing or reversing the progression of OA as compared to current best practices over three years with the following specific aims:

Aim I – To identify hip kinematic and kinetic deficiencies in patients presenting with OA, and associate them with hip and knee cartilage composition and condition through an objective, repeatable, non-invasive diagnostic approach and validated by existing diagnostic tools

Aim II – To design and implement a protocol specific to each patient designed to improve hip kinematics and kinetics while reducing pain and edema, and

Aim III – To assess the efficacy of the Kinoped® in slowing or reversing the effects of OA as determined by objective clinical results and subjective patient feedback.

Public Health Relevance

Hip osteoarthritis affects an estimated 27 million individuals in the United States, with an annual cost of over 185 billion dollars. This proposal will evaluate the use of the Kinoped® Lower Extremity Rehabilitation, Injury Prevention, and Performance Improvement System as a platform to identify and address biomechanical deficiencies and to positively impact the onset, progression, and effects of OA. This approach reflects a comprehensive conservative intervention aimed at slowing or reversing the disease process.