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Compliant orthoses for repositioning of knee joint based on super-elasticity of shape memory alloys

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Abstract

People suffering from neuromuscular diseases may also face certain abnormalities in their walking pattern. Patients with quadriceps muscle weakness suffer from flexion contracture as well as flexion instability during the gait cycle. In this article, a knee-ankle-foot orthosis design is proposed with two different mechanisms for the stance and swing phases, addressing the needs of patients with quadriceps muscle weakness. The stance phase mechanism locks the knee joint movement from the initial contact until the end of mid-swing and after mid-stance phase, the knee joint can flex freely. OpenSim was utilized to simulate patients with muscle weakness as well as calculating the required moment to mimic the stiffness of a normal knee joint. The super-elasticity of shape memory alloys was then used to reproduce the calculated moment for different levels of muscle weakness. It is shown that by designing patient-specific orthosis, the stiffness profile of normal joint for each patient with distinct level of muscle weakness can be reproduced.

Keywords

Knee-ankle-foot orthosis, shape memory alloy, numerical simulation, quadriceps weakness, OpenSim

Introduction

Walking is the prominent form of human locomotion. However, normal walking patterns are not accessible for millions of people due to the gait disabilities caused by Neuromuscular disorders (Kirkup, 2007). Muscle weakness of the lower extremities is caused by various diseases, such as post-polio, spinal cord injury, multiple sclerosis, trauma, brain injury, muscular dystrophy, leg paralysis, and paresis (Cullell et al., 2009; Lelas et al., 2003). Statistics demonstrate that 0.5%–1% of European population suffer from muscle weakness (Bowker, 1993; Yates, 1968).

Knee extensor muscles play a crucial role throughout the gait cycle. Their basic role is to control the rate of knee flexion caused by the ground reaction force (GRF) and the inertia of leg movement in the swing phase. In patients with quadriceps weakness, knee flexion exhibits uncontrolled behavior at the end of the stance phase putting the patient at risk of falling. Moreover, problematic extension of the leg during swing phase results in improper movement patterns in normal gait cycle. Quadriceps muscle weakness is compensated by hyperextension of knee joint during the stance phase of gait cycle (Bernhardt et al., 2011). This action leads to unsafe and difficult gait cycle for the patients and as a result forcing them to move at a slower pace and shorter distance.

In 2002, the statistical study carried out by Nielson (2002) for Orthotic and Prosthetic Education demonstrated that more than 2 million people in North America are paralyzed completely or partially, 20.3% of which utilize orthoses to improve their gait pattern. Knee-ankle-foot orthoses (KAFOs) are prescribed as a part of the solution for improving joints performance and stability. KAFOs are designed to improve the abnormal movement of the lower limbs in knee and ankle joints as well as having great mental influence on them. These devices can be divided into three categories based on their performance including (1) passive KAFOs, (2) stance control KAFOs, and (3) dynamic KAFOs (Tian et al., 2015). Traditionally, passive KAFOs use a simple mechanism to lock the knee joint

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or leave the knee to flex freely during the gait cycle. They provide the stability required for the patients to walk by keeping the knee in a fixed position but cause abnormal gait pattern. As the patient walks with the fixed knee, it is not possible to flex it during the swing phase. Therefore, the patient inevitably swings the body to the side of the non-affected leg while the knee is locked which also causes excessive energy consumption while walking (Cullell et al., 2009). Stance control knee-ankle-foot orthoses (SCKAFOs) lock the knee while standing and allow it to move freely during the swing phase. These systems prevent the body from swinging while walking and provide the adequate stability for patients to withstand the body weight during stance phase (Rietman et al., 2004). Dynamic KAFOs try to mimic operation of a healthy knee by controlling the knee in both stance and swing phases.

Besides controlling position and kinematics of joints, these orthoses control the joints motion by generating the required moment via using active and passive actuators such as spring (Cullell et al., 2009), pneumatic (Sawicki and Ferris, 2009), hydraulic (Schmalz et al., 2016(and super-elastic alloys (Tian et al., 2013, 2015). The most significant limitation of dynamic KAFOs has been their dependence on external power source which has restricted their application to the laboratory.

Bhadane-Deshpande (2012) designed a knee-ankle brace using a shape memory alloy (SMA) element in order to mimic the stiffness profile of a healthy ankle (Bhadane-Deshpande, 2012). By embedding the SMA wires in conventional braces, they designed a brace for patients with normal plantarflexion of ankle joint but having trouble in dorsiflexion motion. In order to create a normal ankle stiffness profile, various combinations of SMA and super-elastic alloy were simulated and tested. Bhadane indicated that the use of two parallel SMA wires is very applicable to mimic the healthy ankle stiffness profile and behavior. However, a complicated control system is needed because of slow response time of the SMA alloy due to heating and cooling time restriction.

Deberg et al. presented an actuator made of Nitinol super-elastic alloy which provides a much faster response time and makes the brace more applicable and efficient for actual gait (Deberg, 2012; Deberg et al., 2014). Ankle plantarflexion tries to tension SMA wires preventing over-plantarflexion and stores energy to help dorsiflexion. Motion analyses were conducted and the results showed that this brace can improve abnormal gait cycle in patients with foot drop.

A brace, which uses a super-elastic SMA rod as the actuator, based on multi-axial loading of rod which is located parallel to the axis of the ankle, was suggested by Gorzin et al. (Andani and Elahinia, 2014). It was subjected to torsional loading due to the ankle rotation and also compressive loading because of linear motion of the solenoid actuator. Multi-axial loading has made it possible to adjust torsional stiffness of the rod during gait cycle and to create different levels of stiffness profile at various speeds.

Another model for braces with super-elastic SMA actuator under bending moments consisting of super-elastic hinges, an adjustable joint, a linear actuator and a slider was proposed by Gorzin et al. (Mataee et al., 2015). In this design, the linear actuator determines the position of the slider and adjusts the length of the hinge which results in creating different stiffness needed in the ankle. The plantarflexion causes the deformation of hinge which leads to the generation of bending moment in the hinge. Releasing this energy after the instance that the foot leaves the ground assists the dorsiflexion motion.

Pittaccio et al. (2015) developed a rehabilitation device called “Toe-up” for patients suffering from muscle weakness in the ankle joint area. Joint actuator includes two pseudo-elastic SMA springs and several Nitinol wires. Four series of SMA wires were embedded in the operation so that they could provide the tensile force required in the joint. Initially, both springs stretched the SMA wires and hold the position of ankle joint in plantarflexion state. With the involvement of SMA actuator, length of wires shortens to the initial state of dorsiflexion. Then, the springs recoil the ankle joint to its original position to prepare for the next cycle during which the actuator has no involvement in the system.

Another investigation conducted by Pittaccio et al. in 2012 showed that Nitinol alloy with super-elastic properties can be applied in actuator springs with special shapes so as to keep the ankle in the fixed position and to relieve spasticity and spasms around ankles. The mechanism used contains two springs composed of Nitinol super-elastic material and shaped in the form of a capital letter omega (Ω). This particular shape allows the material to be loaded uniformly along its entire length, to avoid stress concentration, and to have a nonlinear recovery of force along the length (Pittaccio and Viscuso, 2012).

Regarding to shape memory property of SMA, Sterling et al. designed a flexible orthosis for knee and ankle joints using SMA wires as mechanical actuator. In each actuator, four SMA wires were positioned parallel to each other to produce the moment required for joint movement. Due to the electrical current through the wires and an increase in their temperature, the wires' length is reduced and results in extension and flexion motions of knee joint. Five actuators were applied in the knee joint, four of them were embedded to create flexion on the dorsal surface of the knee and one in the frontal surface to create extension. Since the process of cooling and heating of SMA is slow, application of this orthosis is limited to rehabilitation devices (Stirling et al., 2011).

In 2013, a dynamic orthosis with SMA actuator for patients with quadriceps muscle weakness with two super-elastic rods and two linear rotational springs with different dimensions was used to mimic knee joint stiffness in stance and swing phases, which was proposed by Tian et al. (2013, 2015). In order to reproduce the stiffness of healthy joint for flexion of the knee, the super-elastic rod is subjected to torsional loading. In this study, it was assumed that the patient has no ability for extension of the knee joint and super-elastic rod generates the entire moment required to mimic the stiffness of healthy knee joint.

Patients with quadriceps muscle weakness do not have the adequate capability to create the stiffness required in the knee joint, which causes the abnormal gait cycle. The purpose of this study is to design a knee orthosis to create a normal motion of the knee in patients with weakness in the knee extensor muscles. Two different mechanisms are proposed to control knee motions in stance and swing phases. By embedding the SMA actuator on the conventional braces, the stiffness of normal knee joint is reproduced and smoother gait pattern is achieved. At the beginning in the stance phase, using the knee joint automatic system proposed by Rietman et al. (2004) for patients with quadriceps muscle weakness, knee joint movement from the initial strike to mid-stance phase is locked and then in the swing phase, the joint is allowed to perform the flexion motion freely. Because of the free movement of the joint in terminal-stance and pre-swing phases, quick and smooth phase shift is achieved during gait cycle. This mechanism is only designed for patients with quad muscle weakness so as to assist them in controlling flexion of the knee joint in stance phase. Finally, in the swing phase, the patient's knee joint movement is controlled by the super-elastic SMA actuator.

The mechanisms proposed for stance and swing phases have been used in parallel to each other in the orthosis. During initial-contact phase, the orientation of patient's foot is such that the control mechanism of stance phase locks the knee joint in order to prevent its uncontrolled flexion and super-elastic SMA beam is not under loading. At the end of mid-stance phase, the moving component with eccentric mass, which is responsible for locking and releasing knee joint, enables the extension of knee joint due to the orientation of patient's foot at the end of mid-swing and the gravitational force applied to the component. Free extension motion of the knee joint in the terminal-stance phase leads to a smooth phase shift from stance to swing. Continuing the gait cycle, knee joint flexion motion in the swing phase induces energy storage in the SMA beam which is released to the knee joint at the end of swing phase to compensate for quadriceps muscles weakness so the patient experiences a more natural and smoother gait cycle.

The above-mentioned orthoses try to improve patients' gait by reproducing total stiffness of healthy joint. But the patients' weak muscles are not completely powerless and produce some of the required moment for patients. Healthy muscles lose their activity and their power is weakened after a while, by producing all of the required moment during the gait cycle. Also, by producing all of the required moment for the joint during the gait cycle, the stiffness of a normal joint cannot be achieved. This type of design not only decreases the ability of healthy muscles able to apply force to some extent but also causes moment production more than required which leads to applying more pressure on flexion muscles in passive orthoses. Motion analysis data set makes us reproduce the required moment compatible with each patient's need so that the normal joint stiffness is obtained. Also, the use of gear in the orthosis causes the patients with ligament deficiency to be supported.

Using motion analysis and simulation of patient in OpenSim software, the moment required to modify the patient's specific kinematic can be achieved by placing an actuator in their knee joint. In this simulation, because of the use of a proportional–derivative (PD) control loop in OpenSim software while finding muscles activities (Mataee et al., 2015), the optimum value of moment required for each patient can be achieved using their motion analysis data. Thereby, this method enables the simulation and design of orthoses for patients with various amounts of quadriceps muscle weakness. Finally, the super-elastic alloy dimensions are evaluated to regenerate the stiffness required, using finite element method (FEM) in Abaqus software and the user material subroutine written for SMA based on Brinson constitutive equations (Poorasadion et al., 2014).

Gait analysis

Gait cycle generally consists of two phases: stance and swing. In one cycle, stance phase starts the moment when the foot first touches the ground and lasts until the foot leaves the ground. Right at this moment, swing phase gets started and contains the whole time that the foot swings in the air and finally ends when the foot contacts the ground. Both these phases comprise some sub-phases (Vaughan et al., 1992). Sub-phases are categorized based on gait cycle percentage so as to clearly determine the events and phases. Each sub-phase of gait cycle can be described as follows:

- Initial contact (0% of gait cycle)

This stage is the first moment that the foot hits the ground in which gait cycle begins with the shock absorption of the foot strike to the ground and the appropriate orientation of the foot on the ground.

- Loading response (0%–10% of gait cycle)

This is the second subdivision of gait cycle. It starts the moment when the heel strikes the ground and lasts as long as the foot is completely in contact with the ground.

- Mid-stance (10%–30% of the gait cycle)

In this phase, the foot holds the whole body's weight so that the other leg can swing in the air.

- Terminal-stance (30%–50% of the gait cycle)

This part begins with raising the heel from the ground and ends with the strike of other foot to the ground which it leads to accelerating the foot that is in the stance phase.

- Pre-swing (50%–60% of the gait cycle)

This part begins when the front heel strikes the ground and lasts until the foot in the stance phase leaves the ground.

- Early-swing (60%–75% of the gait cycle)

This part is the beginning stage of swing. It starts the moment when the foot leaves the ground and lasts till the knee joint experiences the maximum flexion. In this stage, the knee flexion will reach up to a maximum of 60°.

- Mid-swing (75%–90% of the gait cycle)

It represents the phase between the maximum torque in the swing file and the time when the tibia is located vertically. The foot in the swing phase maintains its forward movement like a pendulum due to the inertia forces.

- Terminal-swing (90%–100% of the gait cycle)

During the terminal swing, tibia retains its vertical position. The tibia movement is associated with the deceleration to provide the knee extension rotation for next foot contact (Vaughan et al., 1992).

Characteristics of a normal knee

By studying the kinematics and kinetics of normal knee during the gait cycle, the patient's main requirements to achieve a normal walking pattern are identified so that by means of orthosis their gait pattern is improved. The main movements of the knee joint during walking happen in the sagittal plane. Thus, kinematics of healthy and abnormal knees is investigated in the sagittal plane.

In the normal gait, when the heel strikes the ground, the knee flexion angle is at 0°. With this strike, extension moment is created so as to control the knee flexion in the loading response phase. At the end of loading response phase, the knee joint angle reaches 15° of flexion. Then, the flexion moment is created to damp the extension motion in the mid-stance phase. As a result, when the heel leaves the ground at the end of the mid-stance, the knee joint is at a 5° flexion. At the beginning of the swing phase, the joint flexion angle of 60°, which is the maximum value of flexion throughout the gait cycle, is controlled by applying extension moment. Finally, the knee flexion moment decelerates the forward motion of the foot and prepares the conditions for the next cycle. In conclusion, at the end of the terminal swing phase, the knee angle returns to 0° and the next cycle starts. Variations of knee flexion angle, extension and flexion moment during the gait cycle have been normalized based on user's weight and have been reported in the literature (see, for example, Tian, 2015).

The knee joint stiffness represents the knee joint resistance as a function of the rotational displacement of the joint. The joint stiffness indicates the amount of moment around the knee joint versus rotation angle. The joint stiffness consists of the intrinsic stiffness and reflex stiffness. The intrinsic stiffness is related to the anatomy (structure) of the joint and muscles, whereas the flex stiffness depends on the muscles' functionality in flex and reflex movements (Capaday, 2002; Ludvig and Kearney, 2010).

The stiffness of knee joint during walking at normal speed is obtained through the combination of the flexion angle and the generated moment data. The stiffness of healthy joint is depicted in Figure 1 by dashed line. The stiffness profile of a healthy knee consists of two stance and swing section. Point 1 is the heel strike, point 2 is the foot flat, and point 3 is the heel off which they include the loading response and mid-stance phases during the gait cycle. Also, points 3 and 4 demonstrate the beginning of terminal-stance phase and the end of initial-swing phase, respectively, and point 5 represents the heel strike instance to the ground at the end of terminal-swing phase. The aforementioned points represent terminal-stance, pre-swing and swing phases. During loading response and mid-stance phases, the stiffness profile of knee joint has higher slope and smaller hysteresis area, while the rest of the points on stiffness profile has lower slope and larger hysteresis area (Tian, 2015; Tian et al., 2014). Therefore, an ideal knee brace should propose two distinct patterns for the stiffness so that they can adapt to knee requirements during walking. The corresponding points for the patient's knee similar to the healthy one are also shown in Figure 1 which shows the similar phases.

Abnormal walking gaits caused by weak quadriceps

Study of gait cycle for patients with quadriceps muscle weakness helps to a better understanding of their

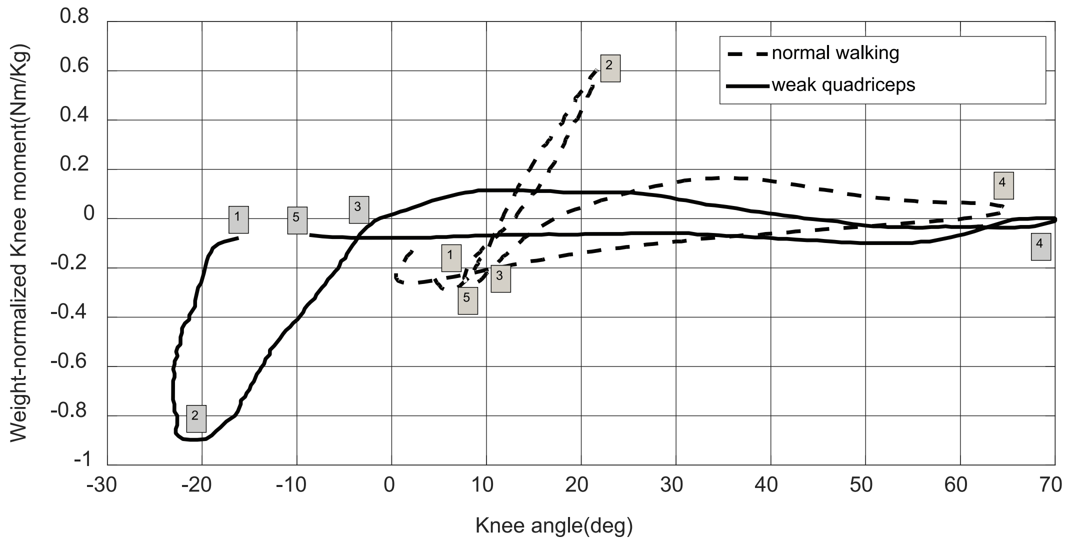

Figure 1. Stiffness of healthy joint versus stiffness of severe weakness of quadriceps muscle.

muscles activation pattern and kinematics. An approach to overcome the absence of knee extensor power and refrain from uncontrolled knee flexion during stance phase is to prohibit the GRF from crossing behind the knee joint. This can be accomplished by an increase in hip extensor activity and anterior trunk bending (that moves the center of gravity of the body forwards) and controlling the flexion movement by gluteal muscle. Some likely long-term outcomes of this situation are over-loading of hamstring muscles and hyperextension of the knee because of the continued throwing of the joint into full extension for dynamic safety (Bernhardt et al., 2011).

If hyperextension happens, the knee joint will inherently be more stable during stance phase because of the displacement of the joint behind the line of action of the GRF. However, the increased extension moment will cause further hyperextension deformity which possibly leads to a serious clinical concern. However, as it may occur in some syndromes, when the patients suffer from the weakness of gluteal and/or knee flexing muscles, they have to lock their knee by means of the KAFO (Cullell et al., 2009).

Figure 2 indicates that if patients have slight quadriceps weakness, their knee kinematic and kinetic profiles will be very similar to those of healthy subjects. These patients can still perform adequate knee extension during the gait cycle. In some individuals, the lack of knee extension moment is compensated with the help of orthotics. However, as the quadriceps weakness increases, patients tend to hold their legs in hyperextended positions during the stance phase. Such walking habits make it very difficult to measure the residual muscle strength as well as to calculate the moment required for compensating the weakness of muscles. Usually, locking orthoses which hold the knee in full

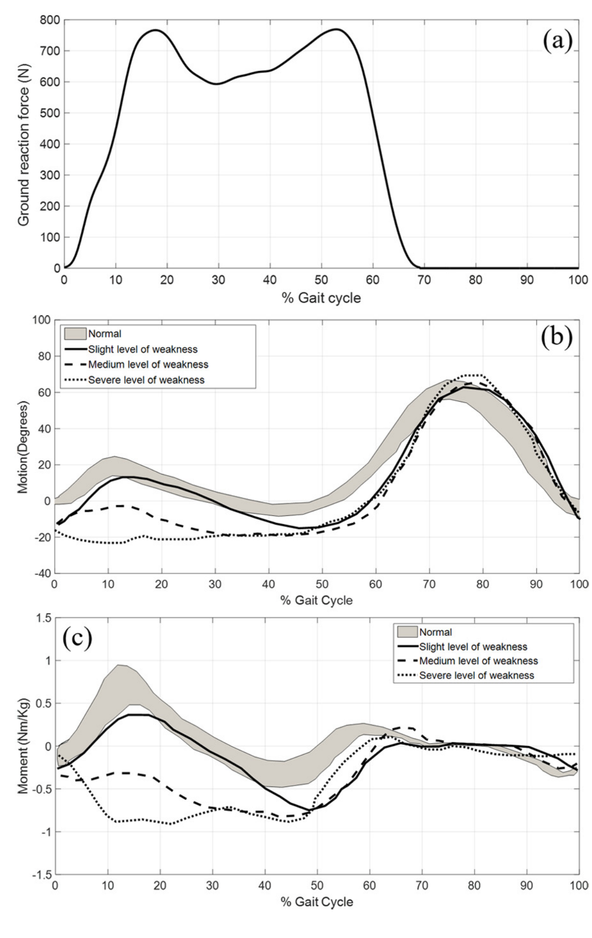

Figure 2. (a) Ground reaction force, (b) kinematics and (c) kinetics characteristics for three patients suffering from different levels of quad muscle weakness (Bernhardt et al., 2011).

extension and provide enough stability is prescribed for patients with severe muscle weakness. Moment profile of patients with severe quadriceps deficiency was

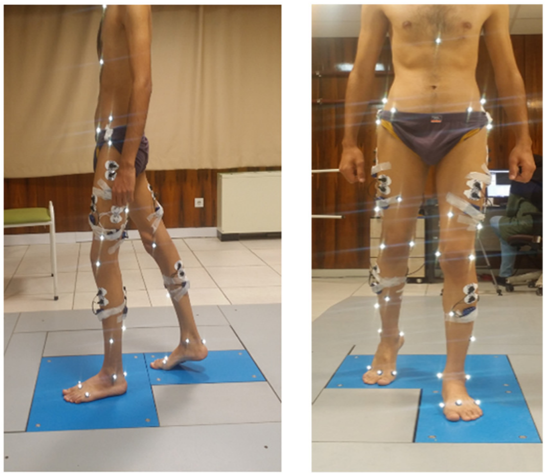

Figure 3. The photograph of walk way layout showing EMG sensors and markers.

extracted from Figure 2. Like the stiffness profile of a healthy knee, stiffness profile of a patient exhibits two main sections. The stance part on the left-hand side has similar pattern to healthy individuals but in the opposite direction, and the swing portion on the right is similar to healthy subjects. Figure 2 illustrates that patients with quadriceps weakness perform hyperextension during the stance and need further flexion moment to balance walking.

Motion analysis data collection

Experimental data of this research include gait analysis, electromyography (EMG), and (Andani, 2013; Deberg et al., 2014) patients' anthropometric data. Six dynamic tests and three static tests were conducted during data collection. Execution time of each dynamic test was about 5 s and comprises five steps, while execution time of each static test was about 10 s. In motion analysis test, 43 markers were used in each time step to determine joint angles (Figure 3).

One of the issues faced by the researchers in the field of gait modeling is the transformation of the data format. Input data for OpenSim software should be in .trc format for marker positions and .mot format for force plate data. The recording software system for motion analysis does not create files in these formats. Therefore, it is necessary that the data be prepared in the appropriate formats as input for the OpenSim software. In this study, the marker positions are recorded by VICON cameras and the GRF data are recorded using a force plate. The raw marker position data collected from the motion analysis are processed and eventually transformed to a .trc format file and the force plate data are transformed to a .mot format file by MotoNMS software; these form the input data for OpenSim. This process is shown in Figure 4.

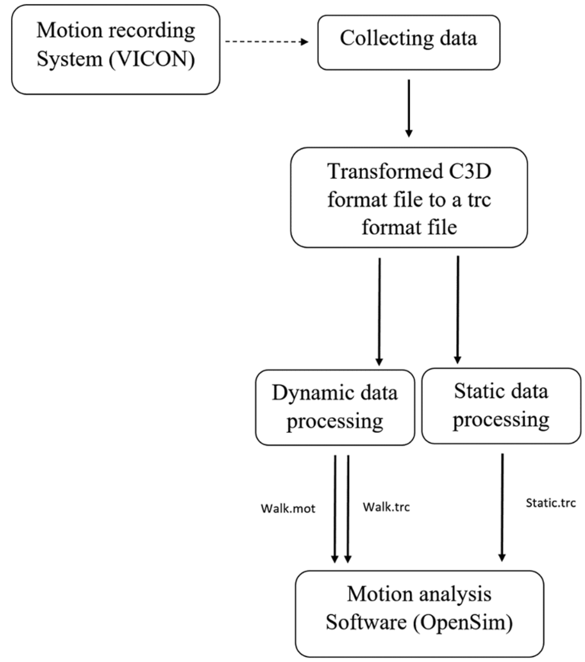

Figure 4. Processing of the raw recorded data into OpenSim-compatible formats.

Adjustable stiffness concept

A perfect orthosis leads to the modification of patient's gait pattern by reproducing the stiffness of a healthy knee joint. According to the proposed concept in this article, a super-elastic SMA beam is used to help the knee joint by storing energy during flexion and releasing it during extension. By positioning the SMA beam in parallel to the joint, the beam undergoes the same rotational displacement as the knee; thus, the knee rotation is considered as an input for basic loading condition. If it is used in line with the joint, a similar moment is applied to the beam and knee. The stiffness profile of the knee joint in the swing phase has a lower slope and greater hysteresis area which indicates different required moments for flexion and extension of the joint during the gait cycle. Hysteresis behavior of super-elastic SMA allows reproduction of the stiffness of a healthy knee.

SMA

Identification of SMA behavior and its loading response on the knee joint is essential in designing the orthotic device. In recent years, due to the good compatibility with the human body, weight reduction and low volume and desirable nonlinear mechanical properties, SMA has been utilized in a broad range of engineering applications such as medical and aerospace, including cardiovascular stents, cellular phone antennae, and orthodontic arches (Mataee et al., 2015). This category of material exhibits two distinct behaviors:

shape memory effect (SME) property at low temperature and super-elastic property at high temperature. These behaviors have been attributed to a solid-state phase change between austenitic and martensitic crystal structures. This phase change is a thermo-mechanical phenomenon caused by temperature and/or stress variations. Super-elasticity or pseudo-elasticity leads to recovery of a large amount of strain through mechanical loading and unloading without any change in the SMA temperature. This property occurs when the loading and unloading happen at a temperature higher than austenite finish temperature at zero stress (i.e. A_f). Thermo-mechanical loading route starts at temperatures above the A_f in which the austenite phase is stable. Then, as a result of applying force to the alloy, detwinned martensitic phase will form and dissolved after removing the load (Brinson and Huang, 1996). Nitinol has fulfilled many applications that require large deformation during loading and unloading because of this unique elastic property.

Orthosis mechanism in stance and swing phases

Stiffness profile of the knee joint can be divided into stance and swing phases; hence, different mechanisms in each phase are required (Tian, 2015). During stance, patient's leg bears the body weight, thereby maintaining the stability of the knee joint is very important in this phase. Furthermore, patients with muscle weakness due to their inability to generate extension moment are not capable of controlling flexion in the loading response phase. On the contrary, at the end of the swing phase due to muscle weakness, the patient is not able to extend its leg and must be assisted by super-elastic actuator (Tian, 2015).

Locking or releasing of the designed mechanism occurs by changing orientation in the sagittal plane. Stance mechanism was proposed by Rietman and consists of two main components that are attached to the patient's thigh and shank. The joint controlling mechanism in the stance phase includes two moving pieces that lock or release the knee joint based on the leg orientation in the sagittal plane (Rietman et al., 2004).

Biaxial hinge is an excellent support for the knee allowing natural joint movement of rotational and transitional displacement as opposed to the conventional rotation about an axis. The proposed orthosis for swing phase is depicted in Figure 5(a). Therefore, two gears are used in the proposed orthosis that are attached to the thigh and shank. Using the gears results in the flexion range splits into half resulting displacement of super-elastic beam splitting half as well. In addition, due to the fixed axes of the gears, the designed device can also support patients with ligament laxity. The schematic of the SMA actuator for swing phase is depicted in Figure 5(b). During flexion, the cantilever SMA beam is subjected to the bending load and extension motion of the knee joint is achieved by releasing the stored energy in the beam. Patients with different physical conditions and muscle weakness need different moments to correct the walking pattern. Therefore, patient-specific design of the dimensions of the SMA is of particular importance. Also, knee joint stiffness is different when walking at different speeds or on surfaces with positive and negative slopes so it is necessary that the amount of moment produced by the SMA beam is different in these situations. Hence, in this design, a longitudinal slider is placed at the end of the beam which makes possible the adjustment of the stiffness of the SMA element for different speeds of walking, or walking on sloping surfaces by varying the effective length of the SMA.

As is visible in Figure 5, during flexion, the calf moves such that the SMA element is bent and energy is

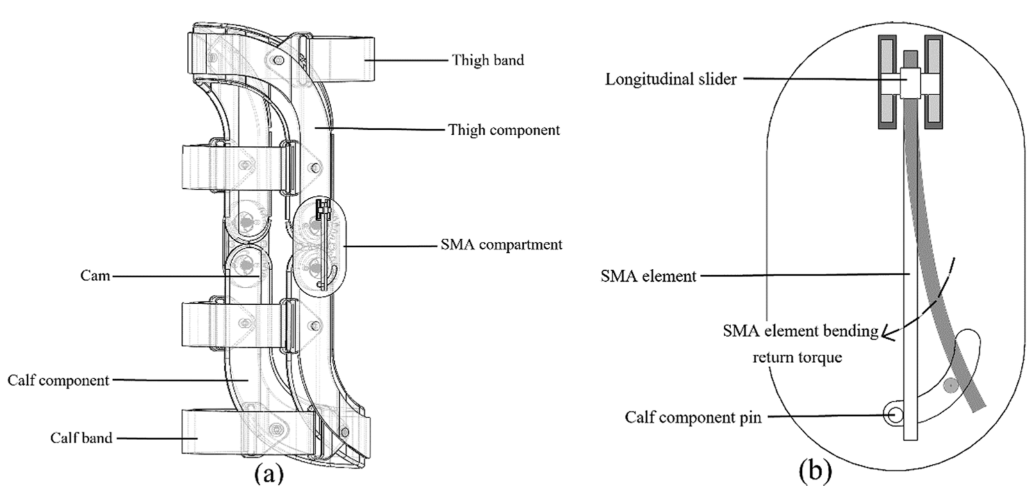

Figure 5. (a) Proposed design for the biaxial hinge knee orthosis and (b) schematic of SMA actuator.

Table 1. Constitutive equations of Abaqus user material subroutine experiment (Sayyaadi et al., 2012).

$$\xi = \xi_S + \xi_T \quad (1)$$

$$\sigma = E(\xi)(\varepsilon - \varepsilon_L\xi_S) + \Theta(T - T_0) \quad (2)$$

$$E(\xi) = E_A + \xi(E_M - E_A) \quad (3)$$

For $T > M_S$ and $\sigma_s^{cr} + C_M(T - M_S) < \sigma < \sigma_f^{cr} + C_M(T - M_S)$ (4)

$$\xi_S = \frac{1 - \xi_{S0}}{2}\cos\left\{\frac{\pi}{\sigma_S^{cr} - \sigma_f^{cr}}\left[\sigma - \sigma_f^{cr} - C_M(T - M_S)\right]\right\} + \frac{1 + \xi_{S0}}{2}$$

$$\xi_T = \xi_{T0} - \frac{\xi_{T0}}{1 - \xi_{S0}}(\xi_S - \xi_{S0})$$

For $T < M_S$ and $\sigma_s^{cr} < \sigma < \sigma_f^{cr}$ (5)

$$\xi_S = \frac{1 - \xi_{S0}}{2}\cos\left\{\frac{\pi}{\sigma_S^{cr} - \sigma_f^{cr}}\left(\sigma - \sigma_f^{cr}\right)\right\} + \frac{1 + \xi_{S0}}{2}$$

$$\xi_T = \xi_{T0} - \frac{\xi_{T0}}{1 - \xi_{S0}}(\xi_S - \xi_{S0}) + \Delta_{T\varepsilon}$$

If $M_f < T < M_S$ and $T < T_0$ (6)

$$\Delta_{T\varepsilon} = \frac{1 - \xi_{T0}}{2}\left\{\cos\left[a_M\left(T - M_f\right)\right] + 1\right\}$$

Else $\Delta_{T\varepsilon} = 0$

For $T > A_S$ and $C_A\left(T - A_f\right) < \sigma < C_A(T - A_S)$ (7)

$$\xi = \frac{\xi_0}{2}\left\{\cos\left[a_A\left(T - A_S - \frac{\sigma}{C_A}\right)\right] + 1\right\}$$

$$\xi_s = \xi_{s0} - \frac{\xi_{s0}}{\xi_0}(\xi_0 - \xi)$$

$$\xi_T = \xi_{T0} - \frac{\xi_{T0}}{\xi_0}(\xi_0 - \xi)$$

stored. From mid-swing toward the end of the gait cycle, the SMA element bending torque extends the knee. Abaqus simulations are carried out to find the appropriate element dimensions. The element is considered to be a cantilever beam; the boundary condition is that the element is encased at the longitudinal slider connection. The calf component pin force is applied on the element, storing energy.

Numerical model for SMA element of the proposed orthosis

Numerous methods have been developed to apply mathematical calculations into SMA analysis. FEM is one of the most widely used and powerful numerical methods that has been used in many studies. In this article, nonlinear behavior of SMA is simulated by means of FEM in Abaqus using a user material subroutine developed based on Brinson constitutive equations (Poorasadion et al., 2014).

One-dimensional (1D) SMA model, Tanaka, Liang-Rogers, and Brinson are the most common 1D models, is used based on bending loading conditions. Tanaka and Liang-Roger constitutive models only describe phase transition *from martensite to austenite* and vice versa. Since SME at a temperature lower than martensite start temperature (M_s) is often induced through transformation of detwinned martensite to twinned martensite, such models cannot describe martensite twinning process which cause SME. In Brinson and Huang's model, by separating the martensite volume fraction (ξ) into temperature-induced martensite (ξ_T) and stress-induced martensite (ξ_S), the transformation phase equation of Liang and Roger with critical stress is modified to propose the denotation of ξ_S and ξ_T to allow for SME at temperatures below M_s (Brinson and Huang, 1996). The constitutive equations of Abaqus user material subroutine are briefly indicated in Table 1, which are described in detail by Sayyaadi et al. (2012).

In equations of Table 1, martensite volume fraction (ξ), stress (σ), strain (ε), temperature (T), maximum recoverable strain (ε_L), module of elasticity (E), module of elasticity in martensite and *austenite phases* (E_M and E_A), detwinning start and finish stresses (σ_s^{cr} and σ_f^{cr}), and M_s, M_f, A_s, and A_f which, respectively, mean martensite start, martensite finish, austenite start, and austenite finish temperatures are material parameters. ($T_0, \xi_{S0}, \xi_{T0}, \xi_0$) represent the initial state of the material, also C_M, C_A, a_A, and a_M are material constants.

In as much as patients with muscle weakness demand various moment to modify their walking pattern, several SMA beams having various geometry and property were analyzed in Abaqus-Standard 6.14 in a quasi-static regime. A two-node cubic beam and a two-node two-dimensional (2D) linear rigid link were used to form the cantilever SMA beam and calf component pin, respectively. A mesh independency check was

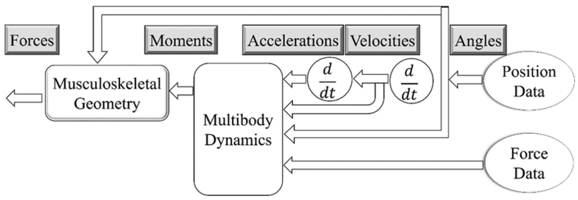

Figure 6. Data analysis process in OpenSim software (Delp et al., 2007).

performed to ensure the validity of the results. In this regard, a mesh seeding of ~2 mm was employed for the SMA beam. As two gears were used in the proposed orthosis, the bending range of SMA beam simulated was half of the flexion range of the knee. It is noted that loads correspondent to SMA beam arises from the knee flexion. The SMA element was fully fixed at one end and the surface to surface contact option was adopted to simulate the interaction between the SMA element and the calf component pin. The loading and boundary conditions resemble the conditions depicted in Figure 5(b).

OpenSim software

The extent of quadriceps muscle weakness differs for different patients and as a result it is not possible to improve all patients' walking pattern using a single orthosis design. Therefore, in this study, using a specific patient motion analysis data, appropriate orthoses is designed to reproduce the stiffness of normal joint for the mentioned patient. In order to analyze the data in OpenSim software, the marker position data are recorded by VICON cameras and the force data are recorded using the force plate, and given as an input to the software. In this phase, using the marker position data, the dimensions of the general model are made proportional to the individual under study. Then, by performing derivative and reverse kinematic operations, the dynamics of each joint are obtained. In the following, the inverse dynamic method is determined by the resulting moments and the use of force profile. In order to correct the model kinematics such that it is in agreement with the experimental forces, a Residual Reduction algorithm is used. Using the Computed Muscle Control (CMC) algorithm, the muscle forces are found such that the forward dynamics closely follows the subject's movement. Data analysis process in OpenSim software is depicted in Figure 6 (Delp et al., 2007).

Using motion analysis test and modeling the patient in OpenSim, muscles activities can be obtained during the gait cycle. Comparing this data with normal muscle activity, the extent of extensor muscles weakness can be determined. Placing an active actuator in the patient's knee joint, incorporating muscle weakness in the model and utilizing kinematic of normal walking pattern in OpenSim, the required moment to achieve the desired kinematics is calculated by CMC algorithm. The value of moment that must be developed by the active actuator in OpemSim is equal to the difference of generated torque between healthy and sick subjects with the same kinematic conditions. Given a certain patient's kinematic, CMC algorithm calculates the amount of muscle excitations during the gait cycle. This algorithm uses a static optimization criterion and a PD controller to calculate force distribution across muscles in each time step such that a forward dynamic simulation that closely tracks the patient's kinematics is generated. When the patient is suffering from muscle weakness, his or her muscles are not able to generate enough force to achieve a healthy person's kinematic. Embedding an active actuator in the knee joint, optimum amount of moment required to produce the desired kinematic in the forward process can be calculated in each time step with respect to anatomy and synergy of muscles. Simply stated, the active actuator produces the moment required in each time step to obtain the desired kinematic (Thelen and Anderson, 2006). On the contrary, rotational movement of the active actuator equals the flexion angle of the knee joint and therefore the active actuator should be parallel to the joint. The schematic of the CMC algorithm applied to gait and optimization process is briefly indicated in Figure 7, which is described in detail by Thelen and Anderson (2006).

Considering that the extent of extensor muscle weakness differs among patients, it is expected that the diagram of generated torque by active actuator to be also different for various patients during gait cycle. Therefore, the moment required for each patient individually must be calculated to modify their kinematic. Needed torque is generated for the joint in the mid-swing and terminal-swing phases using bending stiffness of the super-elastic SMA beam.

KAFO based on bending stiffness

The relationship between bending moment and rotational displacement in an Euler–Bernoulli cantilever beam is as follows

$$M = \theta\left(\frac{EI}{L}\right) \tag{8}$$

where M is the bending moment, and I, L, and θ are moment of inertia, effective length, and rotation angle of the beam, respectively. The term EI/L represents the bending stiffness of the beam. In order to adjust the bending stiffness of beam, any of the three parameters E, I, and L can be varied. In this study, the desired stiffness is achieved by changing the effect length and cross section of super-elastic SMA beam.

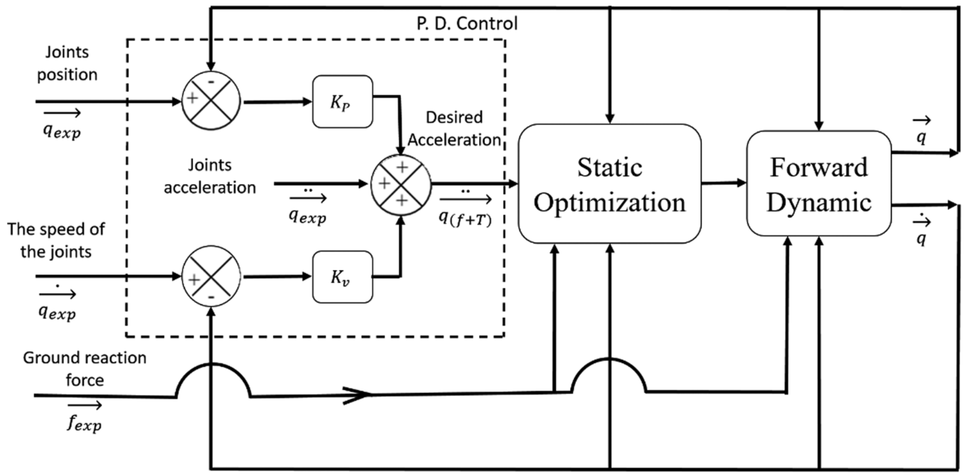

Figure 7. Schematic of the computed muscle control algorithm applied to gait (Thelen and Anderson, 2006).

Table 2. Material parameters adopted for Gillet et al. (1998) experiment.

Property	Unit	value
Moduli	GPa	$D_m^+ = 10$, $D_m^- = 10$, $D_a = 73.2$, $D_m^T = 10$
Transformation stresses	MPa	$\sigma_s^+ = 60$, $\sigma_f^+ = 720$, $\sigma_s^- = -60$, $\sigma_f^- = 440$
Stress–temperature slopes	MPa/°C	$C_M^+ = 2$, $C_A^+ = 2.9$, $C_M^- = 2$, $C_A^- = 2.3$
Transformation strain	–	$\varepsilon_L^+ = 0.035$, $\varepsilon_L^- = -0.03$
Thermo-elastic modulus	MPa/°C	$\theta = 0.55$
Transformation temperatures	°C	$M_f = -110$, $M_s = -105$, $A_s = -104$, $A_f = -90$

The behavior of SMA is characterized using a nonlinear function of stress, strain, and temperature which are independent of each other. Parameters of SMA beam were obtained based on Gillet et al. (1998) experiments in 1998. It is imperative that A_f temperature for this alloy is -90°C, which ensures that in daily usage of the orthosis at ambient temperature, the alloy shows super-elastic property.

The values of SMA parameters can be seen in Table 2. Where D_a and D_m^T are the elastic for fully austenite and fully twinned martensite SMA, respectively, while D_m^+ and D_m^- are the elastic moduli for fully detwinned martensit under tension and compression, respectively.

Results

In the majority of previous studies, researchers have assumed that patient had no ability to perform the extension. Therefore, they generate all of the extension moment required for healthy knee joint during mid-swing and terminal-swing phases to reproduce the normal knee stiffness in the swing phase. In many patients with moderate muscle weakness, the patient is able to exert some extension moment during the gait cycle and generation of the whole extension moment of the healthy knee joint is not necessary. Exerting unnecessary stress on the hamstring muscles and also muscle weakness in the remaining healthy quadriceps fiber can be caused by this assumption.

Knee joint stiffness of a healthy person decreases with walking speed. Hence, behavior and stiffness of the knee joint must be considered at various speeds to mimic them more precisely (Mataee et al., 2015). In order to reproduce different stiffness corresponding to different walking speeds, as shown in Figure 5, a longitudinal slider is used to change the effective length of the SMA beam to achieve this property.

In this article, a process that can be used for different levels of quadriceps weakness has been developed and applied to three patients with varying degrees of muscle weakness. In order to regenerate the healthy joint stiffness and obtain the desired kinematic, the SMA element has to produce the extension moment created by the active actuator (simulated) in mid-swing and terminal-swing phases. Extensor muscles of the knee joint consists of four muscles including vastus lateralis, vastus medialis, vastus interalis, and rectus femoris, and patients with different levels of quadriceps weakness have weakness and disability in one or more of the mentioned muscles (Tian, 2015). The three patients with muscles weakness have been described based on Table 3.

It is natural that the second patient needs to produce much less moment by the SMA beam than the first

Table 3. Characteristic of patients with different levels of quadriceps muscles weakness.

	Vastus lateralis	Vastus medialis	Vastus interalis	Rectus femoris
First patient	−	−	−	−
Second patient	−	+	−	−
Third patient	+	−	+	−

patient because of the vastus medialis muscle being healthy. Also, this assumption is true for the third and the second patient as well. In this study, the design procedure is executed for each of the above three patients with different levels of muscle weakness.

Figure 8 displays that different amount of torque generation, which is achieved by manipulating the cross-sectional of the SMA beams is needed for patients with different levels of muscle weakness to reproduce the stiffness of the knee joint. Dimensions of SMA beams are obtained as 3.2×5 mm, 2.8×5 mm, and 2.5×5 mm for the first, second, and third patients, respectively. In all the three cases, length of the superelastic beams is considered to be 6 cm. Width of the SMA beam should be deep enough so as to make it possible to reproduce the stiffness of the active actuator (simulated). Also, there are limitations for the maximum width of the beam so that the patients do not face any trouble while using the device under their clothing. Both demands are met by considering the width of 5 mm.

In the case of the first patient, patient's simulation in OpenSim, due to the absence of knee joint extensor muscle and the patient's disability in generation of the required extension moment, all moment required for the joint extension movement is generated by the active actuator embedded in the knee joint, as shown in Figure 8(a). However, in the second and third patients, due to the normal activity of some extensor muscles of the knee joint, extension moment of the active actuator has been calculated to be zero at some angles, and the muscles are capable of producing some portion of extension moment in the mid-swing and terminal swing phases. In addition to reducing the maximum moment generated by the active actuator, in the case of second and third patients, according to Figure 8(b) and (c), the moment generated by the active actuator becomes zero at angles below 30°. In other words, the patient requires significant amount of moment for the knee joint extension at the beginning of mid-swing, the majority of which has to be generated by the active actuator. However, as previously discussed, knee joint extension is controlled by the flexion moment and as it can be seen in Figure 8(a) to (c), the patient's need to the extension moment is reduced during mid-swing and terminal swing phases. For the second and third patients, the remaining healthy extensor muscles at the beginning of terminal-swing, which the joint angle is about 30°, are able to generate the extension moment required to continue the extension movement which makes the moment generated by the active actuator equal to zero. For the second and third patients, the magnitude of extension moment produced by SMA beam at angles below 30° is controlled with generation of flexion moment by hamstring muscles.

Vastus medialis muscle of the second patient and vastus lateralis and vastus interalis muscles of the third patient are healthy from the muscular activity point of view. Muscle activation during the gait cycle has been illustrated in Figure 9 where the curves include that of a healthy person and a patient suffering muscle weakness with and without the proposed orthosis. All three aforementioned muscles have normal muscular activity in the healthy subject. However, when other extensor muscles have muscular weakness, the activity of the remaining healthy muscles is increased beyond its normal range to compensate the weakness by generation of extension moment. Increasing the activity of these muscles slightly improves the patient's kinematic, but is not able to compensate the weakness effects of other extensor muscles. Excessive activity of the remaining healthy muscles leads to unsafe gait cycle and early fatigue or injury of the aforementioned muscles. In the case that the patient uses the orthosis, in all three of the above muscles, it is observed that the activity of these muscles is returned to the normal levels and possible damages are prevented in swing phase which begins at 1.17 s in Figure 9(a) to (c).

Extensor muscles of the knee are responsible for generating the extension moment to control the flexion movement in the loading response phase and to create extension movement in the mid-swing and terminal-swing phases. As it can be seen in Figure 9(a) to (c), healthy extensor muscles of the knee compensate for the weakness of other extensor muscles during loading response, mid-swing and terminal-swing. Based on the patient's knee joint kinematic, the swing phase begins at 1.17 s and the SMA beam as the actuator of the mechanism is placed under loading during mid-swing and terminal swing phases. Flexion taking place in the initial-swing phase does not require any assistance from the active actuator due to the healthy flexing muscles. Active actuator activity increases with progression of the gait cycle which is because of the need for extension moment during mid-swing and terminal-swing. Moreover, during the stance phase, the locking

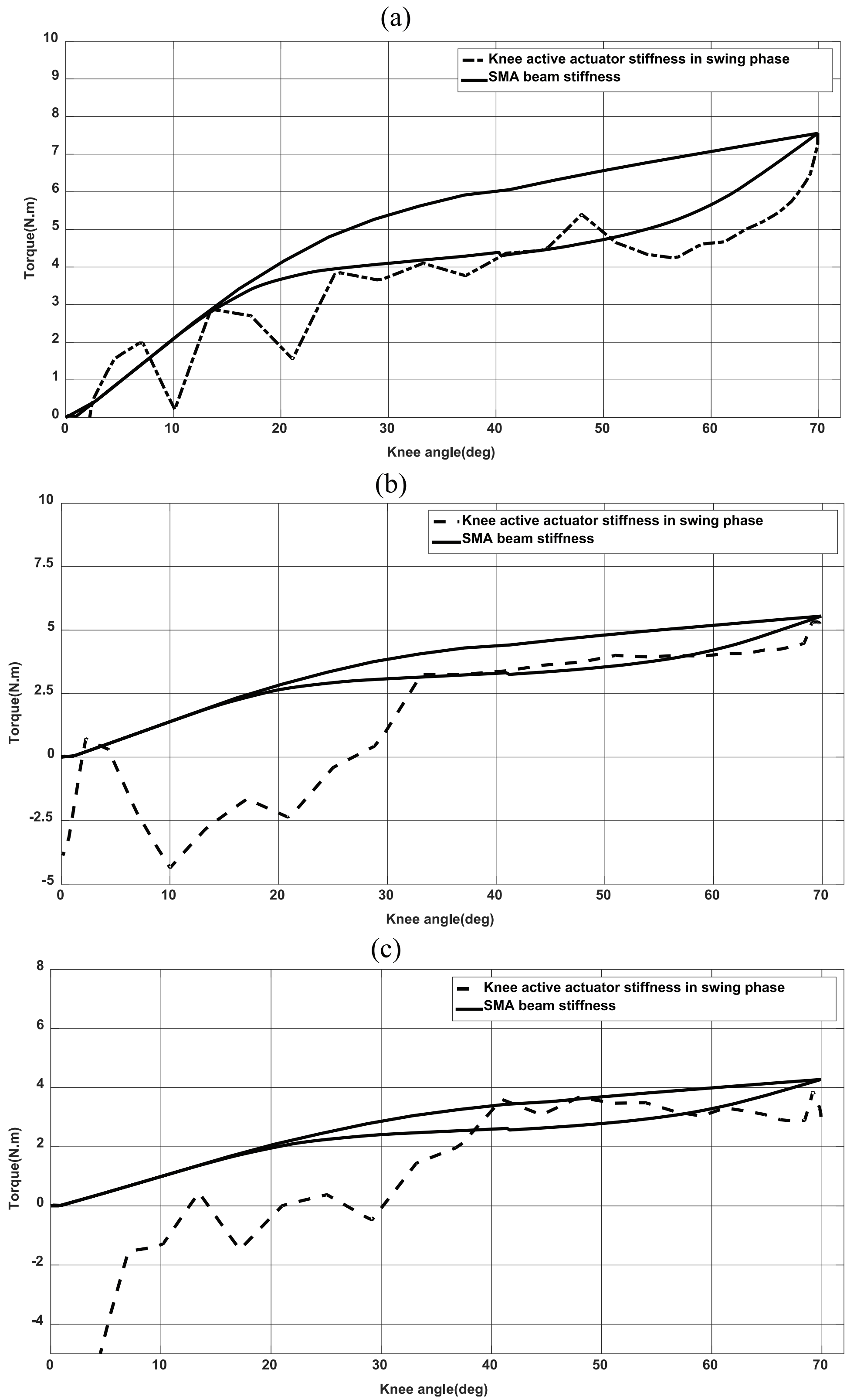

Figure 8. Appropriate SMA elements designed to reproduce the stiffness of active actuator (simulation) for different patients: (a) first patient, (b) second patient, and (c) third patient.

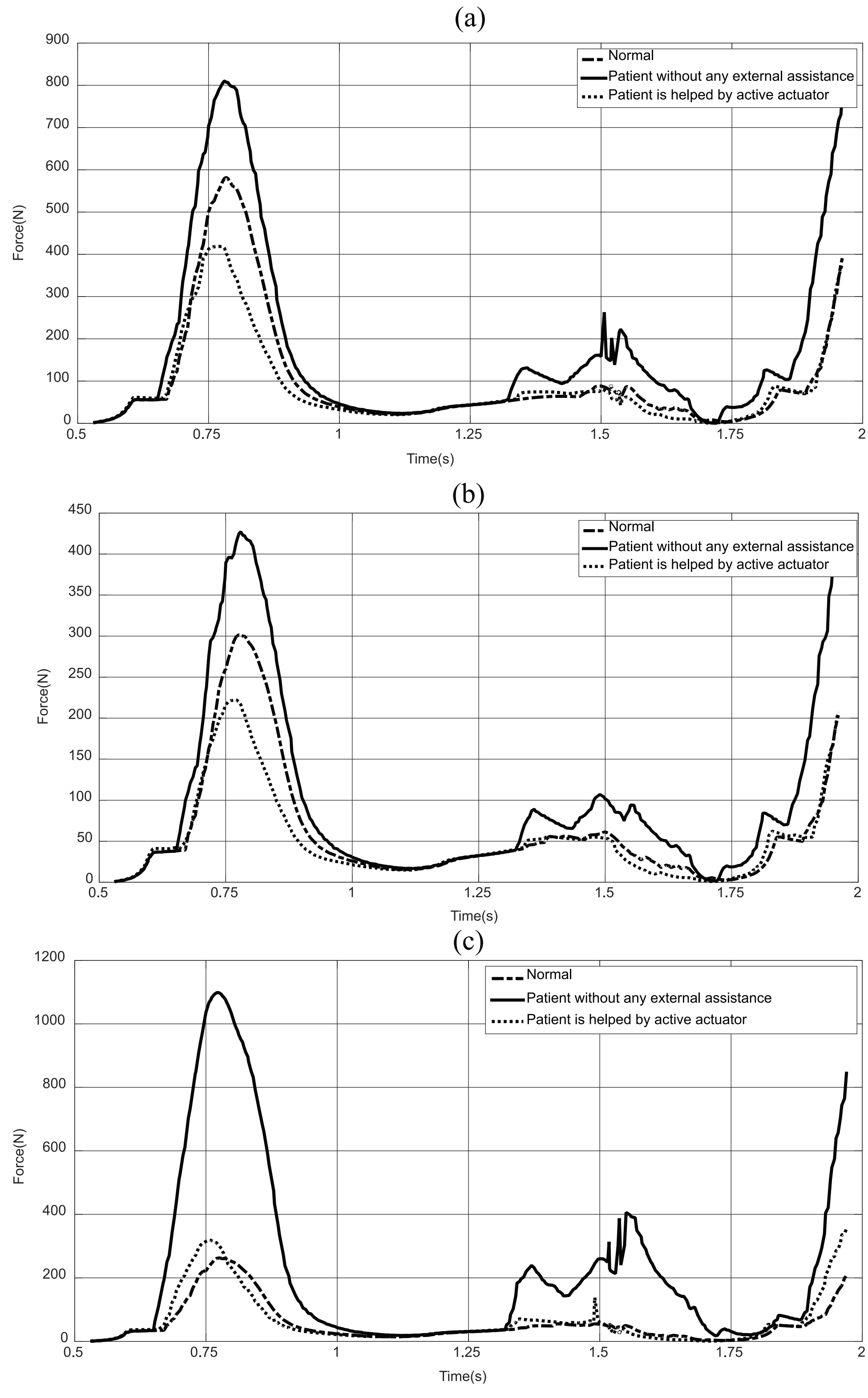

Figure 9. The gait cycle for three cases: a healthy subject, the second and third patients with muscle weakness and when both second and third patients use the proposed device to improve their motion pattern: (a) vastus lateralis, (b) vastus interalis, and (c) vastus medialis.

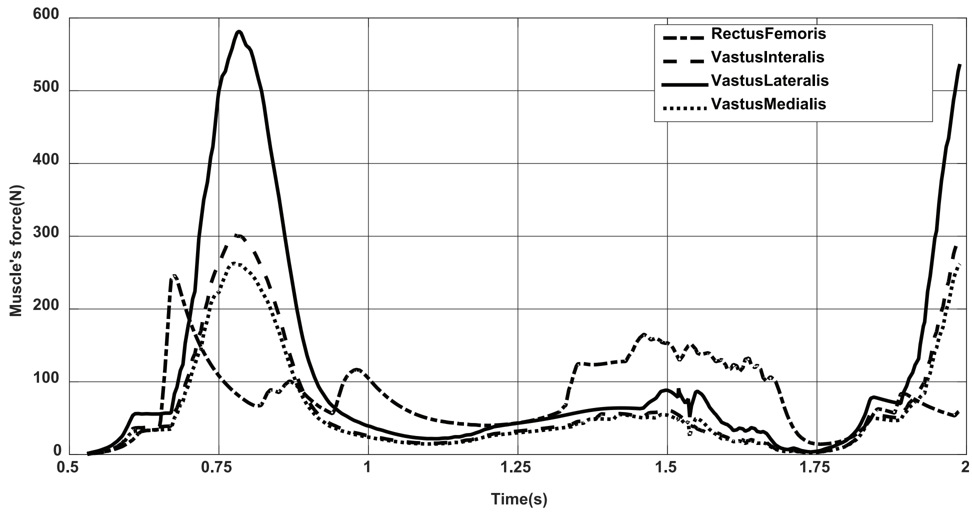

Figure 10. Extensor muscles activity for a normal gait cycle.

mechanism of the knee is responsible for controlling knee flexion and maintaining stability during weight-bearing.

By using model 2392 in OpenSim, extensor muscles activity for a normal gait cycle is obtained. As it can be seen in Figure 10, rectus femoris muscle has more activity in the mid-swing and terminal-swing phases compared to other muscles. Consequently, if the patient suffers from weakness in rectus femoris muscle, extension movement of the knee joint will be problematic. It can be shown that if this muscle is healthy, it will be able to compensate for weakness of the rest of extensor muscles in the swing phase by increasing its activity. In such a case, the moment generated by the active actuator to help the extension movement during mid-swing and terminal-swing is negligible.

Conclusion

Conventional passive orthoses comprise springs with constant stiffness; therefore, they are not patient specific and do not comply with the torque required by each patient and thus cannot appropriately assist the patients. Active orthoses, due to actuator and battery size, are voluminous and also heavy and are not convenient for daily use. The nonlinear properties of the SMA element allow a more accurate mimicking of the healthy knee's torque profile, a characteristic not evident in conventional passive orthoses. On the contrary, the healthy knee joint consists of hysteresis characteristics; thus, reproducing this behavior is not possible using strictly linear materials. An SMA element, due to its hysteresis characteristics, is a suitable option. In this article, a small size and light weight orthosis was designed which can mimic the stiffness pattern of healthy knee joint. An SMA super-elastic beam was used as actuator to produce the moment required for knee joint extension in the swing phase. The device was designed for three patients with different levels of quadriceps muscles weakness and it was shown that the same procedure can be prescribed for any patient suffering from quadriceps weakness. Motion analysis tests conducted on each patient were used to optimize the moment required to modify the patient's kinematic in accordance with their muscles excitation and activity during gait cycle. By simulation of SMA beam in Abaqus, appropriate dimensions of the beam were calculated to generate the required moment for the patient during mid-swing and terminal-swing phases. Furthermore, in order to mimic the joint stiffness in the stance phase, a locking mechanism, designed for patients with quadriceps muscle weakness, was utilized. This mechanism locks knee flexion from the initial contact to mid-stance but the joint is left free during the swing phase.

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