Patient-specific ankle orthosis utilizing a variable stiffness mechanism

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Abstract

Background: People with neuromuscular diseases may be confronted with specific abnormalities in their walking pattern. Foot drop is a neuromuscular dysfunction in which the patient is unable to produce the variable nonlinear torque needed in the ankle. It is one of the most common causes of gait disorder. Foot slapping during heel strike and toe dragging during swing phase are caused by the weight of the foot for Foot drop patients.
Methods: Since the type and the levels of muscular weakness change from patient to patient, a single orthosis cannot enhance each patient's gait pattern, and a patient-specific study via motion analysis should take place. For each patient, motion analysis experiments were utilised to optimise the torque required to correct the kinematics based on muscle activation and activity during the gait cycle. To model individuals with muscular weakness and determine the force necessary to mimic healthy ankle joint stiffness, OpenSim was used. By developing a patient-specific orthosis, the healthy joint stiffness profile for each patient may be restored. Simulations in MATLAB provided the cam-follower mechanism parameters, generating a variable stiffness spring based on the extra necessary torque. The variable stiffness mechanism was employed as an actuator to address patients' needs during the gait cycle.
Results: Proposed passive Ankle-Foot Orthoses (AFO) in this study, which combines a standard AFO with a nonlinear variable stiffness system is addressing the needs of foot drop patients. The torque is reproduced using a cam-follower mechanism, which is carried out for various patients with various types of muscle weakness. It is shown that the stiffness profile of a healthy ankle joint for each patient with a particular muscle weakness may be replicated via developing this patient-specific orthosis.
Conclusion: Traditional AFOs, despite their benefits, are unable to have the ankle torque in each instant. Furthermore, the need for external power supply, being bulky, large, and costly would not enable active AFOs to respond to daily demands of the patient, although they might follow the pattern of ankle stiffness very well. In this study, a novel small size and light weight orthosis was designed to improve patients walking pattern via mimicking the stiffness pattern of healthy ankle joint. This nonlinear and portable designing of AFOs open a new era in rehabilitation.
***Keywords*:** Dynamic simulation, Ankle-foot orthosis, Musculoskeletal model, OpenSim, Foot drop, Gait cycle

Background

Millions of people cannot follow normal walking patterns due to neuromuscular disorder impairments [1]. Foot drop is a motor disorder resulting from general or partial paralysis of the muscles innervated by the common peroneal nerve or paralysis of the anterior tibial muscle and the peroneal group, which causes foot slap after heel strike and toe drag during the swing phase. Controlled plantarflexion is required after heel strike, but the foot of patients suffering from foot drop moves uncontrollably towards the ground and results in an undesirable slapping [2]. Toe drag alters locomotion and increases the risk of tripping. Foot drop patients either drag their toes on the ground or bend the knee of the suffering leg, raising their foot higher to prevent dragging, leading to a "steppage" gait [3]. These patients walk with difficulty and suffer from premature fatigue affecting the speed and distance of walking. Neurodegenerative disorders of the brain, including stroke, cerebral palsy, motor neuronal disorders such as polio, some forms of muscular spasm atrophy, amyotrophic lateral sclerosis, damage to the nerve root such as spinal cord stenosis, and peripheral neurological disorders may also cause foot drop [2].

Immobilization and muscle disuse may cause further problems like muscle shortening and worsening of contractions and spastic reflexes [4, 5]. AFOs are one of the most common treatments for foot drop [6]. A statistical study in 2002 by Nielson showed that over 2 million people in North America suffer from various types of paralysis, out of which 20.3 % use orthoses to improve their gait [7]. AFO designs enable ankle and foot protection and the alignment necessary for relieving contraction force on muscles, strengthening weak or paralyzed muscles of the ankle and foot, and correction and prevention of further deformities [8].

Active devices, which use external energy sources to accurately generate the required torque, have been used to treat foot drop disorders [9, 10]. Series elastic actuators are common in these devices, allowing safer human-robot interactions [11]. Using series or parallel springs allows for lower power requirements [12, 13].Since the ankle stiffness follows a nonlinear pattern during the gait cycle, the use of mechanisms and materials with nonlinear properties is common. Realmuto et al. used a cam-follower mechanism in their ankle prosthesis in order to minimise the active torque required from their actuator [14]. Although Passive devices provide approximate torques, they are lighter and more compact than active devices [15]. Due to their nonlinear properties, nonlinear elements can be used to alter the patient ankle stiffness [16, 17]. Cullell et al. divided the nonlinear ankle stiffness into two phases. A mechanism comprised of two springs with different stiffnesses was used; by engaging and disengaging one of the springs, the best stiffness for each phase was achieved [18]. Using two springs in order to create a nonlinear stiffness for the ankle of biped robots was studied by Ghorbani and Wu [19]. Their results show that adjusting the stiffness of the springs highly affects bipedal walking energetics. Furthermore, it has been showed that the mechanical behaviour of the orthosis should match the necessities of users, in order to optimise the advantages of the orthosis [20, 21]. Another study showed that the optimum stiffness of AFO greatly differed among patients with various level of muscle weakness, due to the different effects of AFO stiffness on ankle angle and ankle power [22]; Hence, The stiffness of AFO should be set individually to best improve the gait pattern [22]. Two distinct patient-specific orthoses were developed for the knee and ankle joints using the super-elasticity of shape memory alloys, that in addition to small size and light weight, can improve the walking pattern of patients suffering from muscles weakness. These orthoses were designed for three different patients with different levels of muscle weakness, and it has been shown that the same procedure can be applied to all patients suffering from muscle weakness [20, 21].

The muscles of the patients' affected foot can produce part of the required torque. The orthosis must only recompense the deficit in torque, and allow for competent muscles to take part in locomotion, or the disuse will weaken the muscles. This study aims to design an ankle orthosis to provide patients with dorsiflexor muscle weakness with normal ankle movement. The torque required to correct a patient's kinematics is calculated using motion analysis, utilizing OpenSim software and simulation of the patient while having placed a virtual actuator in the patient's ankle joint. This approach makes possible the simulation and design of orthoses for patients with different degrees of muscle weakness. By combining a variable stiffness torsional spring (comprised of a cam-follower mechanism) with a regular brace, the stiffness of a healthy ankle joint is reproduced and a more natural gait pattern can be achieved. Differential equations for the cam profile are found based on ankle angle, the desired output torque and cam-follower specifications such as follower diameter [23]. The equations are solved using a MATLAB program, resulting in the cam profile required for the design of a variable stiffness spring utilised in the patient-specific foot drop orthosis.

Healthy and patient ankle behaviour

In the locomotion of a healthy subject, after initial contact, the foot moves towards the ground due to its momentum. The movement of the body over the foot causes a dorsiflexion torque, causing the plantarflexor muscles to go under loading towards the end of mid-stance. During terminal stance, the ankle plantarflexes due to the contraction of the plantarflexor muscles, leading to push off, which moves the body forward. During initial swing, the pretibial muscles cause the foot dorsiflexion. At the end of the swing phase, the ankle position is controlled in order to prepare for the next heel strike [24, 25].

Since the main movements of the ankle joint occur in the sagittal plane, its motion is evaluated in this plane. The gait cycle can be divided into four main phases based on ankle motion, seen in table 1 [2, 26, 27].

Table 1. Four phases of ankle movement during gait

Step	Phase	movement
1	Loading response	Controlled plantarflexion
2	Mid and terminal stance	Controlled dorsiflexion
3	Pre-swing	Powered plantarflexion
4	Swing	Position control

The ankle resistance to rotation is considered as the ankle joint stiffness [28]. This stiffness is comprised of the intrinsic and reflex stiffness. The intrinsic stiffness is associated with the muscular structure of the joints, and the reflex stiffness is associated with muscle function in flex and reflex actions [29]. The ankle joint stiffness is found by combining the ankle angle and the corresponding torque data throughout the gait cycle for walking in normal conditions [30]. A study on ankle stiffness was conducted by Bhadane-Deshpande, investigating healthy and foot drop subjects walking at various speeds [2]. The angular changes of the weight-normalised ankle torque for both a healthy subject (solid line) and a foot drop patient (dashed line) can be seen in figure 1. It is evident in figure 1 that the affected foot of the patient remains in plantarflexion during swing, and does not return to dorsiflexion in order to prepare for the next heel strike (toe drag). There is also a major flaw in controlled plantarflexion (foot slap).

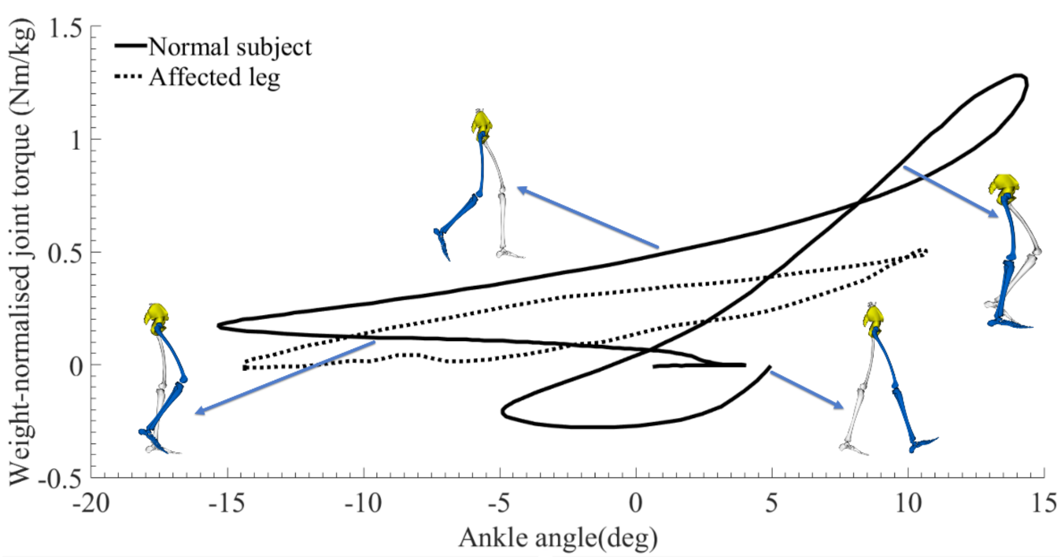

Figure 1. The ankle torque-angle behaviour for a healthy subject and a patient with pretibial muscle weakness [2]

The phases requiring stiffness modulation assistance, are early stance and swing. Although a simple linear rotational spring is cable of offering stiffness, the adjustment of stiffness in order to correspond to the precise stiffness needed at each instant is of importance [31] and thus using a variable stiffness spring is proposed. The early stance and mid-swing phases of a pretibial weakness patient require increased stiffness. Since swing constitutes 40 percent of the gait, the proper motion of the body during this phase is essential for proper locomotion. In this study, stiffness modulation is focused on the swing phase, but it will be shown that this is also beneficial for loading response.

Methods

Design process of proposed orthosis

An illustration of the process undergone during this study is shown in figure 2. In designing an orthosis for foot drop patients, the gait of a healthy person must first be attained and studied [32]. Motion analysis was carried out on one of the authors, and marker positions representing various body points and the data from the force plate representing the ground reaction force were obtained. Carrying out OpenSim simulations using these data, the kinetics of the subject were gathered and the excess required torque for various weaknesses was obtained; torque which must be provided by the orthosis in order to return the patient ankle stiffness to a healthy one. Since the level of pretibial muscle weakness differs from patient to patient, a single orthosis cannot improve every patient's gait pattern; hence, motion analysis data for each type of patient was studied in order to design an appropriate orthosis for each patient. Based on the excess required torque, simulations in MATLAB resulted in the cam-follower mechanism specifications, yielding a variable stiffness spring. Using the variable stiffness spring, an orthosis is designed for each patient.

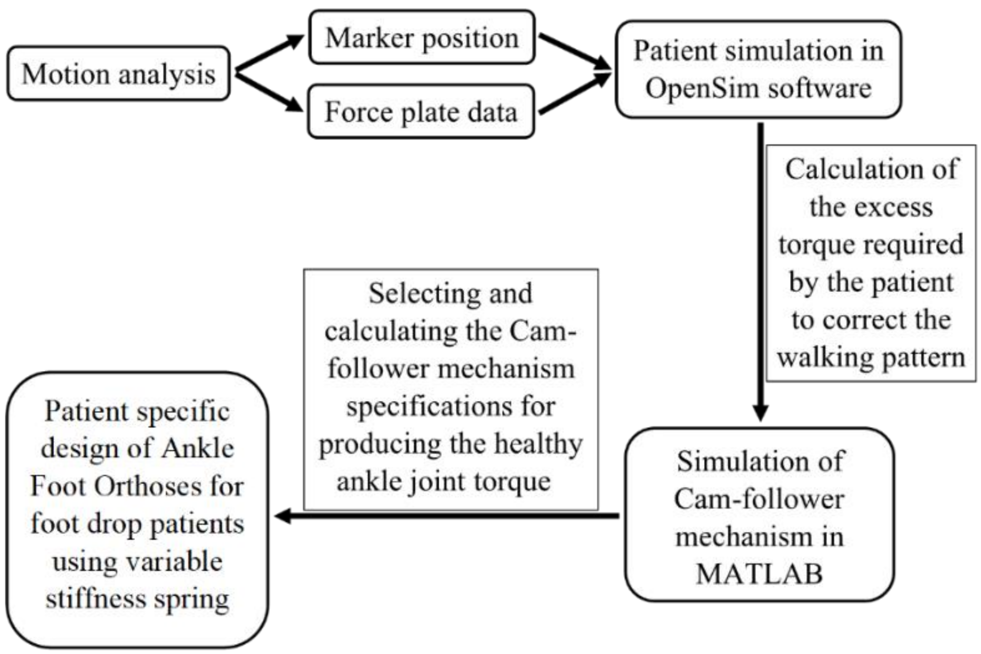

Figure 2. Design process of the proposed patient-specific orthosis for foot drop patients

Gait analysis and OpenSim software

The experimental data is comprised of the gait analysis and anthropometric data of a 25-year-old 75 Kg healthy male subject. The data collection included three static and six dynamic tests, with approximately 5 and 10 seconds run time each, respectively. Dynamic tests had 5 steps. Joint angles were measured using 43 markers placed on the subject's body, and their positions were recorded by VICON cameras [33]. The ground reaction force data were recorded using a force plate. The marker position and force plate data were transformed to trc and mot format files respectively. Using the static data, in which the subject stands still, the general model of the subject is scaled. The moments and forces causing the motion are found through inverse dynamics. A Residual reduction algorithm is used to correct model kinematics towards accordance with experimental forces recorded. The forces of the muscles, modelled as Hill muscles, are found using the Computed muscle control (CMC) algorithm. The pictures of the healthy subject and marker placement during data collection can be seen in figure 3.

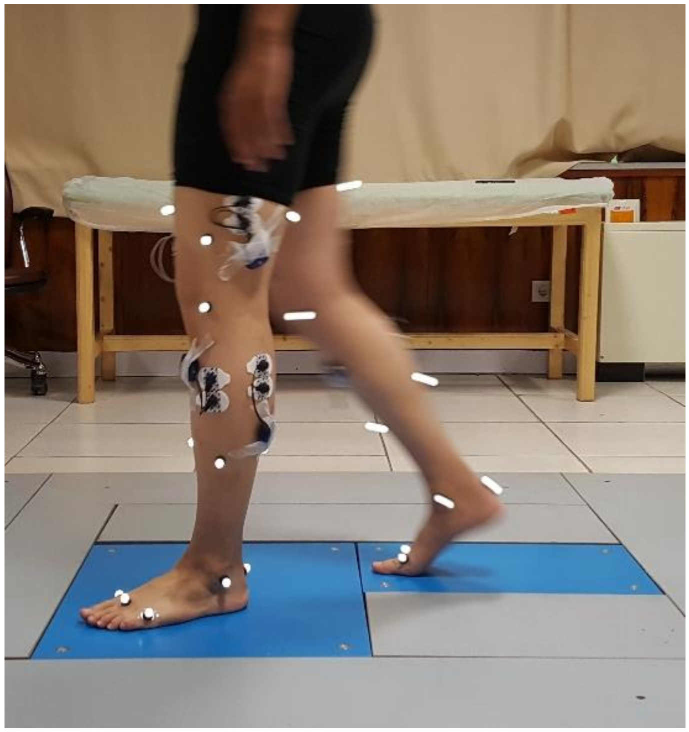

Figure 3. Healthy subject under gait analysis

A virtual actuator is placed in the ankle joint of the patient's model in OpenSim, and the relevant disorder of each patient is applied. Using healthy gait kinematics, the excess torque the virtual actuator must provide in order to achieve the required kinematics is calculated using the CMC algorithm. This torque should equal the torque difference between a healthy subject and that which the patient can provide under similar kinematic conditions. The CMC algorithm calculates the distribution of force between muscles in each instant using a static optimization criterion and a PD controller; a forward dynamics simulation following the patient kinetics is created. The optimum actuator torque required to produce the kinematics in the forward dynamics process is calculated at each instant according to the anatomy and muscle cooperation [34]. OpenSim model 2392 is used for simulations, comprised of 23 degrees of freedom and 92 muscles.

Since the level of muscle weakness varies among patients, the actuator torque requirements will also vary. The torque required to correct the kinematics of each patient should be individually calculated. This torque is to be provided by the proposed variable stiffness spring mechanism of the orthosis. The process, which can be applied for any patient, is shown for three groups of patients with different degrees of muscle weakness. Tibialis anterior, hallucis longus, digitorum longus and fibularis tertius muscles comprise dorsiflexor muscles of the ankle. Patients with pretibial weakness have a disability in one or more of the mentioned muscles.

Three patients, each with a different combination of weaknesses in three of the muscles described in table 2 are chosen for analysis.

Table 2. Characteristic of patients with various levels of pretibial muscle weakness; the plus sign is used to show intact muscles and the minus sign to show dysfunctional muscles

	tibialis anterior	hallucis longus	digitorum longus	fibularis tertius
first patient	-	-	-	-
second patient	-	+	+	-

third patient	-	+	+	+

The first patient is modelled to have lost all the ankle dorsiflexor muscles; the actuator must provide all of the dorsiflexion torque. The second patient has weaknesses in the tibialis anterior and fibularis tertius; while his digitorum longus and hallucis longus are healthy. This means that a torque less than that of the first patient is required to correct the gait pattern. The third patient has only a weakness in the tibialis anterior; because of the competence of other muscles contributing to dorsiflexion, a lower actuator torque than the first and second patients is expected. The ankle actuator torque in OpenSim in order to restore the ankle stiffness can be seen in figure 4, for each patient.

The muscle activity of the 4 anterior compartment muscles, for a 25-year-old healthy male subject, is shown in figure 4. In the motion analysis, data acquisition began during terminal-stance. Since the start of a gait cycle is generally considered to be heel strike, the gait percentage of figures 4, 8 and 9 are numbered based on this premise.

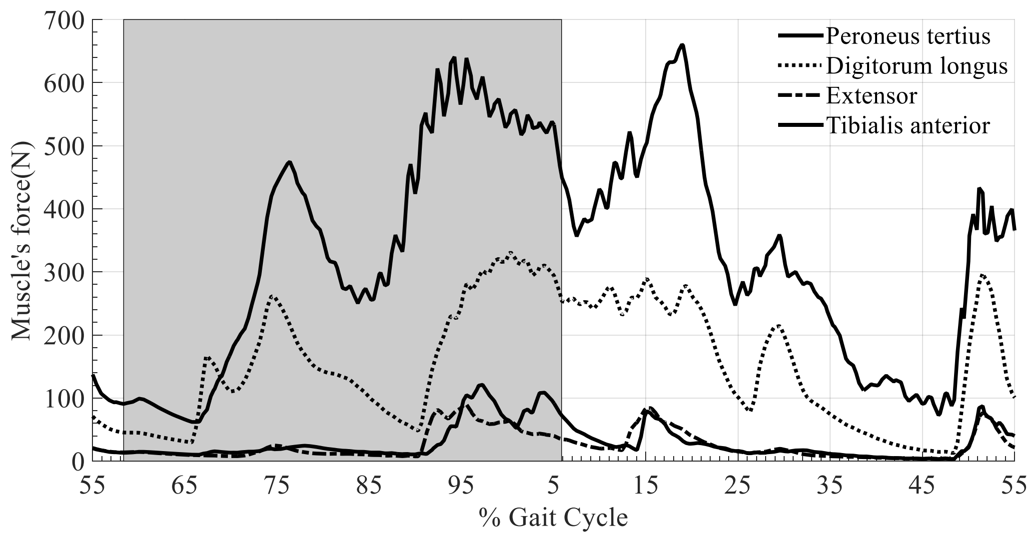

Figure 4. 70 Kg 25-year-old healthy male subject anterior compartment muscles' activity

It is clear that the tibialis anterior and digitorum longus muscles are more active than others during the initial contact and swing phases (shown in grey); for a patient suffering from anterior compartment weakness (e.g., foot drop), the shortcoming of these two muscles is more effective in the motor disability.

The proposed orthosis mechanism

In the proposed orthosis a variable stiffness rotational spring operates in parallel with the ankle joint. During plantarflexion, energy is stored in the spring, and is later released when torque towards dorsiflexion is required and the patient is incapable of providing the requirement (i.e., swing).

As is shown in figure 5-(a), the proposed orthosis is comprised of a variable stiffness spring attached to a hinged AFO. The main parts of the variable stiffness spring package are a rolling follower and its shaft, a cam, a linear spring and the case. The follower shaft is attached to the shank segment of the orthosis and the cam is attached to the foot segment. One such mechanism is placed on each side of the orthosis, in order to balance the loading and allow for smaller springs. The orthosis is designed such that it can be worn within a shoe; the lower part goes into the shoe and the shank segment is strapped around the leg.

Since a linear torsional spring is incapable of following the torque-angle profile required in order to restore ankle stiffness (obtained from the torques shown in figure 1), more complex combinations must be used. The use of a cam-follower mechanism allows for the exact torque-angle profile which is needed; it is thus chosen for the proposed orthosis, creating a variable stiffness torsion spring. A schematic of the mechanism can be seen in figure 5-(b).

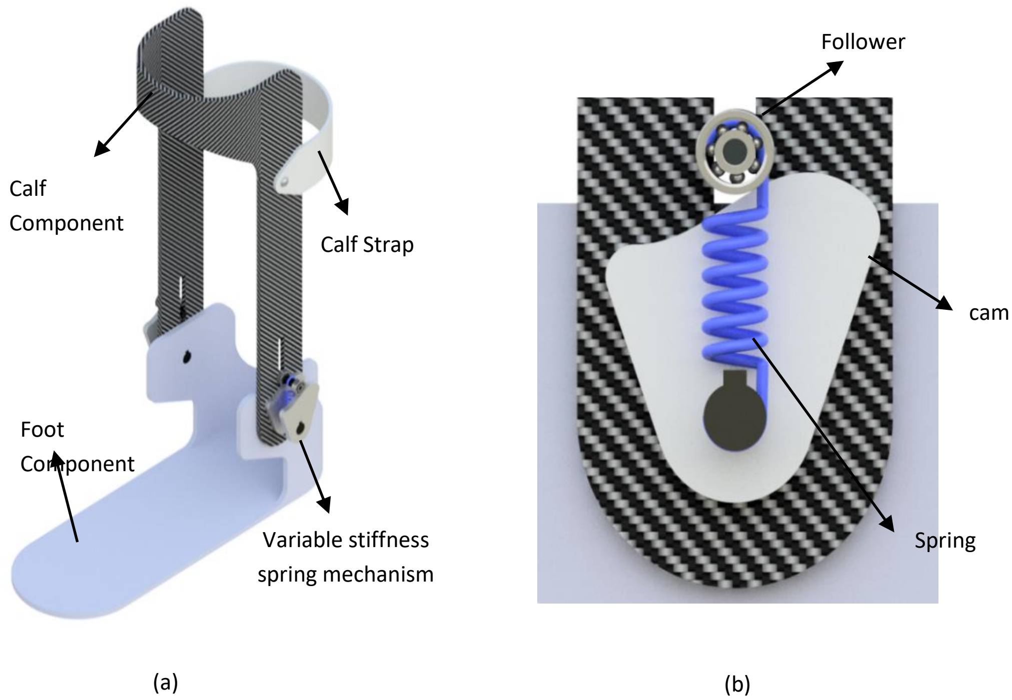

Figure 5. (a) The Proposed design for the ankle foot orthosis, (b) Variable stiffness spring cam-follower mechanism

When the ankle enters plantarflexion during swing and also initial contact, the follower moves along the cam profile which increases in radius, creating a resistive torque. The patient must overcome this torque in order for energy to be stored within the mechanism. Since the weakness of the patients under study is within the anterior compartment, the plantarflexors are left intact and are expected to be able to overcome the excess resistive torque (approximately 16 Nm, in comparison with approximately 100 Nm that a 70 Kg subject requires in plantarflexion, and is fully capable of providing). After Toe off, after reaching maximum plantarflexion, movement towards dorsiflexion is assisted by the orthosis. During swing, the loading of the dorsiflexors initially helps dorsiflexion to some extent but is not enough to prevent toe drag; at this time the variable stiffness spring assists the ankle dorsiflexors. At each instant, the proposed orthosis mechanism provides the required torque, with respect to the ankle angle, providing the additional stiffness necessary to restore healthy ankle stiffness. Although the variable stiffness spring is designed for assistance during swing, the orthosis will also assist the patient during initial contact. After heel strike, the plantarflexion of the ankle incites resistance in the orthosis. Under these circumstances, the orthosis will provide torque towards dorsiflexion. This torque will increase the ankle stiffness; it will not however be enough to fully restore the healthy stiffness preferred. Since the mechanism was designed for the swing phase- due to its importance in locomotion and the percentage of gait it covers (40% compared to 10% during controlled plantarflexion) - it will inevitably not be able to provide the exact torque desired during initial contact. Nonetheless, the stiffness during initial contact will be improved to some extent, and foot slap will be moderated.

The proposed variable stiffness spring mechanism

The schematic of the proposed cam-follower mechanism is shown in figure 6. This mechanism consists of a follower, rolling on the cam profile. A tension spring connects the centre of the cam to the centre of the follower, ensuring its contact with the cam. The mechanism applies torque in the direction which causes spring length to decrease. A torque applied on the mechanism opposite to this direction stores energy within the spring. The tension of the spring and the profile of the cam will cause a torque which is in accordance with angle. Using the required torque based on ankle angle and choosing the mechanism specifications (follower diameter, spring stiffness, initial and secondary length) the differential equations governing the cam profile are obtained.

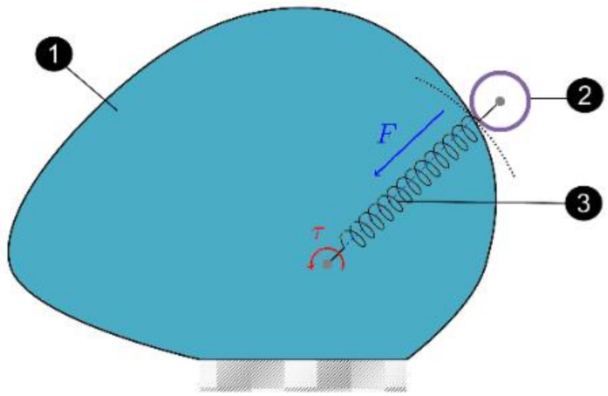

Figure 6. Schematic of the proposed cam-follower mechanism; (1) the cam, (2) the follower and (3) the linear spring [16]

The cam profile need not include the whole 360 degrees; it must only include the angles of dorsiflexion and plantarflexion which the foot will experience. The cam is designed so that in case of an ankle movement exceeding that of the normal gait, it will maintain the maximum torque for plantarflexion and minimum torque (zero) for dorsiflexion.

In the torque-angle requirement, shown in figure 7, after reaching maximum dorsiflexion, a plantarflexion movement with different torque is seen. This means that the orthosis must provide two torques at a single angle; the cam-follower creates a one-to-one function, so this is unachievable. During the return from dorsiflexion to plantarflexion, the mechanism will follow the same profile as when moving towards dorsiflexion. This will lead to an applied torque slightly more than what is needed.

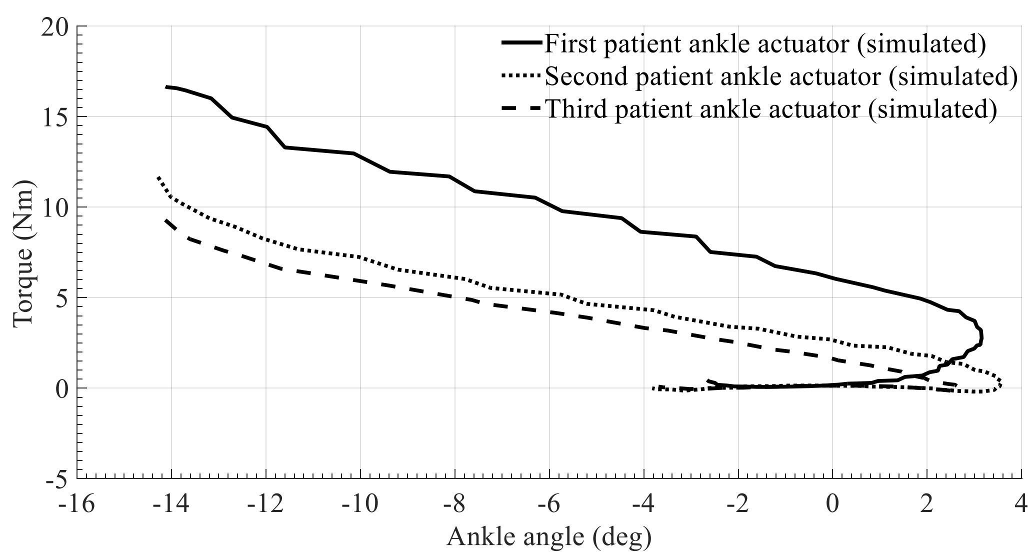

Figure 7. Torque applied by actuator (OpenSim simulation) in order to compensate weakness and possible torsion spring

Results

Many patients with moderate or partial muscle weakness are capable of providing part of the dorsiflexion torque they require and the provision of the entire dorsiflexion torque is unnecessary and may cause excess pressure on plantarflexor muscles and pretibial muscle atrophy.

Simulations show that the required excess torque for some patients is similar. Tables 3 and 4 show the different weakness scenarios that require similar torque to the first and third patients respectively. The orthoses designed for the gait correction of each of these two patients will be similar to the other three scenarios.

Table 3. Characteristics of scenarios with similar levels of dorsiflexor weakness to the first patient; the plus sign showing intact muscles and the minus showing dysfunctional

scenario	tibialis anterior	hallucis longus	digitorum longus	fibularis tertius
1st scenario	-	-	-	+
2nd scenario	-	+	-	-
3rd scenario	-	+	-	+

Table 4. Characteristics of scenarios with similar levels of plantarflexor weakness to the third patient; the plus sign showing intact muscles and the minus showing dysfunctional

scenario	tibialis anterior	hallucis longus	digitorum longus	fibularis tertius
4th scenario	+	-	-	-
5th scenario	-	-	+	+
6th scenario	+	+	-	-

Although a linear torsional spring may improve the patients gait pattern, since it is does not follow the exact stiffness required in each instant, the possible improvement in the patient's gait is limited. The compatibility of the variable stiffness spring mechanism with the required stiffness profile allows for better gait improvement.

In figure 8 and figure 9, the muscle activation for the muscles which are still intact in the second and third patient, are shown respectively. The fibularis tertius in the second patient and the hallucis longus and fibularis tertius in the third patient are healthy. The curves include the torque of a healthy person and a patient suffering from muscle weakness, with and without the actuator. For a healthy person, all of the aforementioned muscles will have normal activity. In a disabled person, the weakness of some dorsiflexor muscles calls for other healthy muscles to function more, in order to compensate the shortcoming. The increase in the activity of these muscles leads to a slight improvement in the patient's kinematics, but is inadequate for compensating the weakness. The overuse of the healthy muscles also leads to an insecure gait, may lead to early fatigue, and also damage the healthy muscles. It can be seen that with assistance, the activity in all three muscles returns to normal level, especially during the swing and loading response phases shown as the grey area.

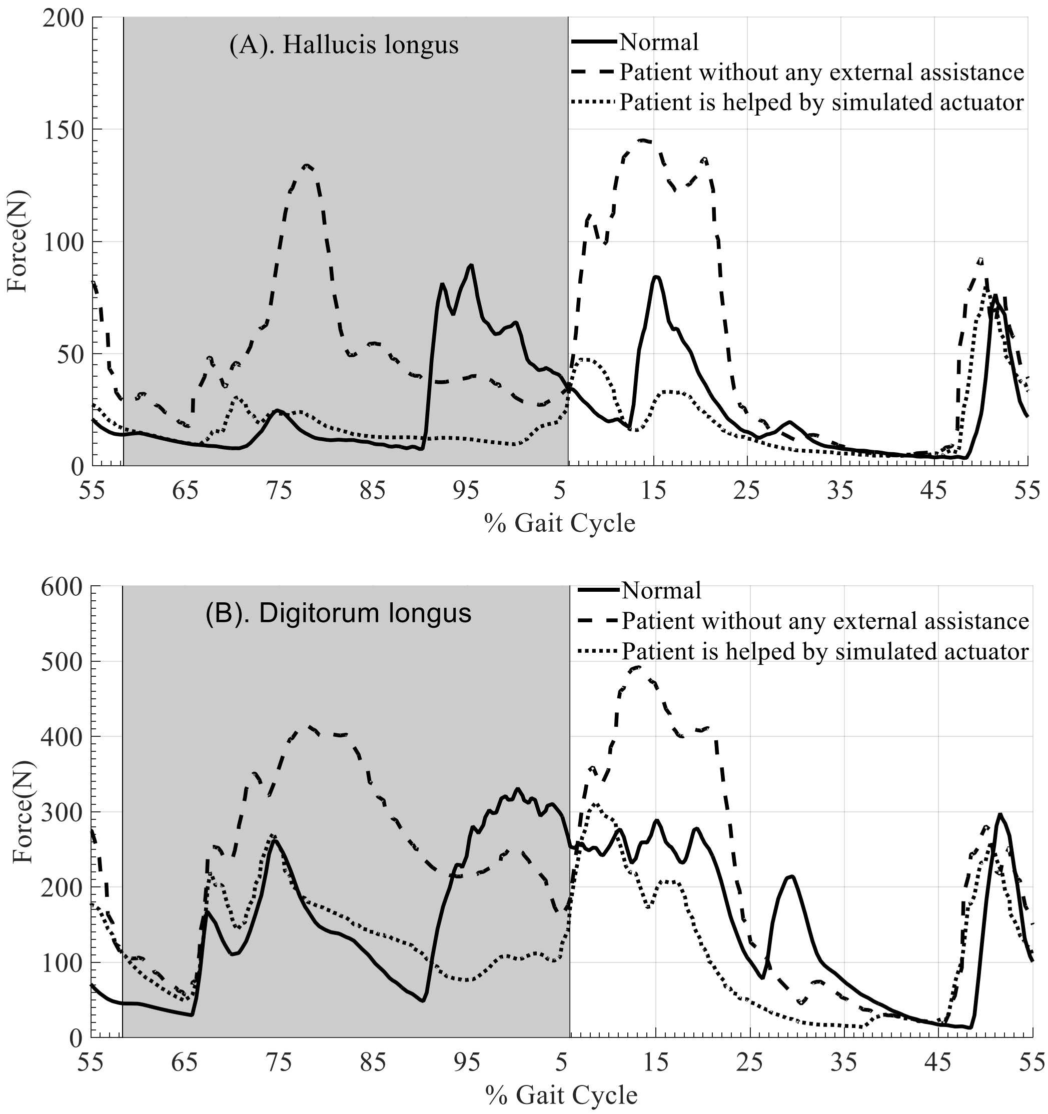

Figure 3. Actuation of intact muscles for the second patient; (A) the Hallucis longus and (B) the Digitorum longus muscle

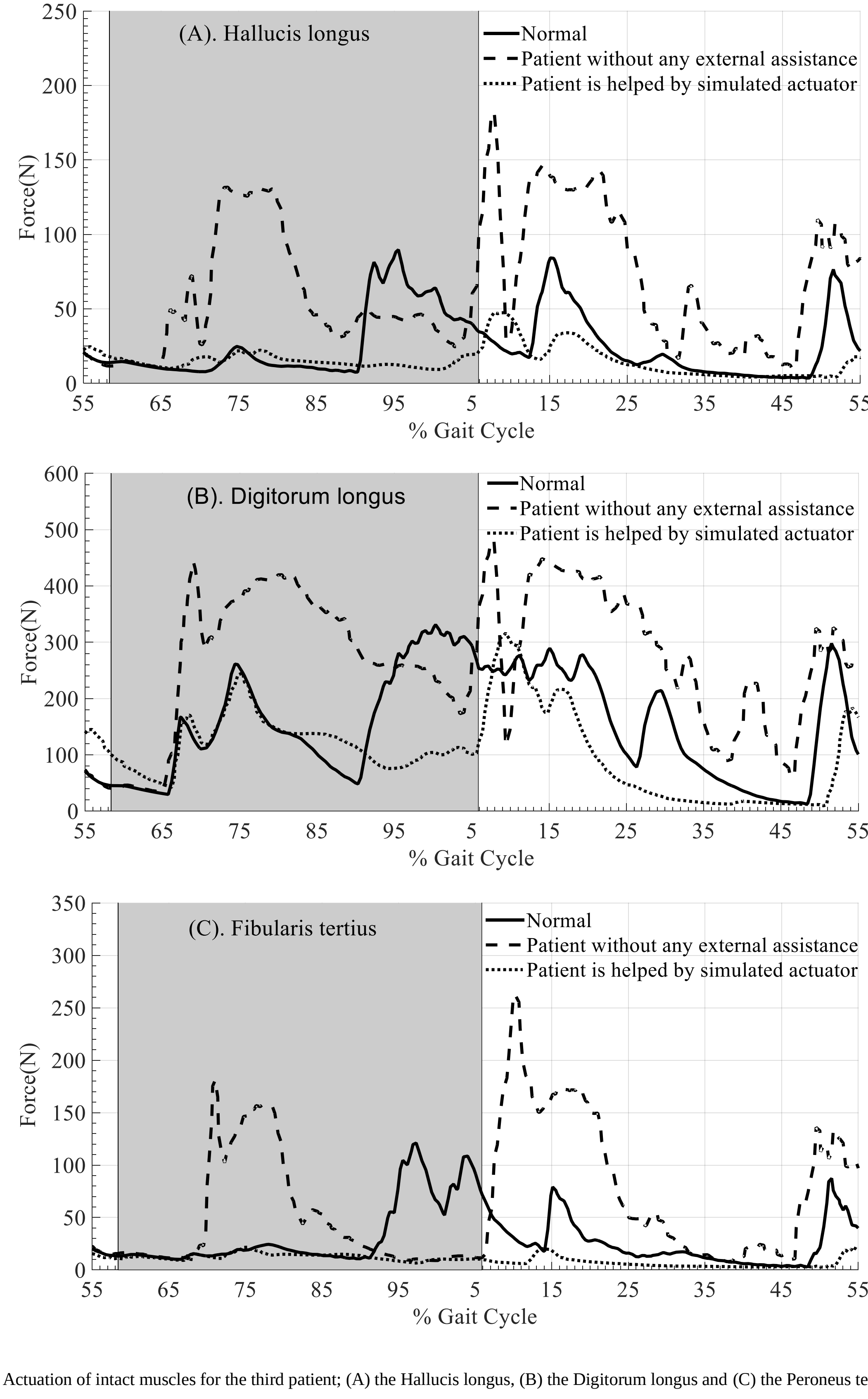

Figure 4. Actuation of intact muscles for the third patient; (A) the Hallucis longus, (B) the Digitorum longus and (C) the Peroneus tertius muscle

The cam profile and the torque-angle curve of the designed cam for the first, second and third patients can be seen in figure 10, figure 11 and figure 12, respectively. These curves exactly follow the required torque shown in figure 7, from plantarflexion to maximum dorsiflexion. As it was discussed, the slight movement from maximum dorsiflexion towards plantarflexion, cannot be followed due to the one-to-one nature of the mechanism. Maximum plantarflexion corresponds to maximum torque. The cam profiles are such that the maximum torque is maintained if the patient's ankle goes further into plantarflexion. After reaching maximum dorsiflexion, which corresponds to minimum torque, the torque applied by the mechanism goes to zero, if the ankle dorsiflexes beyond that point. The cam-follower mechanism comprising the variable stiffness spring for the patients have a linear spring with a stiffness of 8000 Kgm2s-2, initial length of 2.5 cm and secondary length of 7 cm. The radius of the follower is 0.5cm.

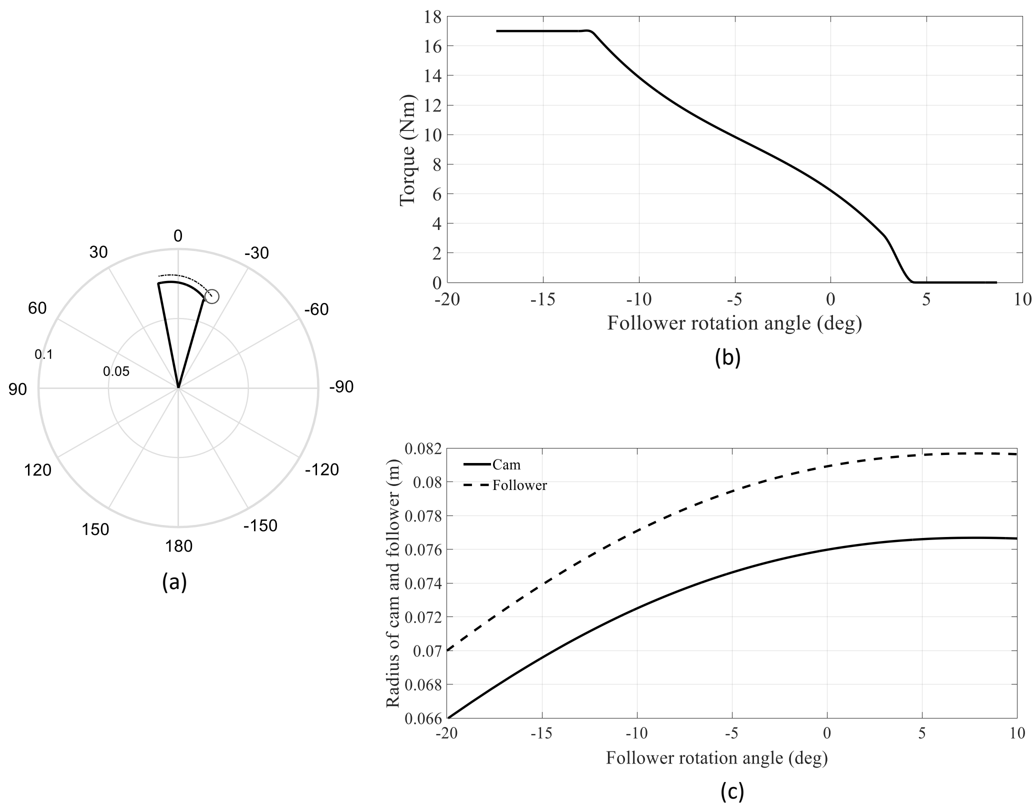

Figure 5. Cam profile design for the first patient; (a) the polar plot of the cam, (b) the torque-angle profile of the mechanism, (c) the radius-angle profile of the cam and follower

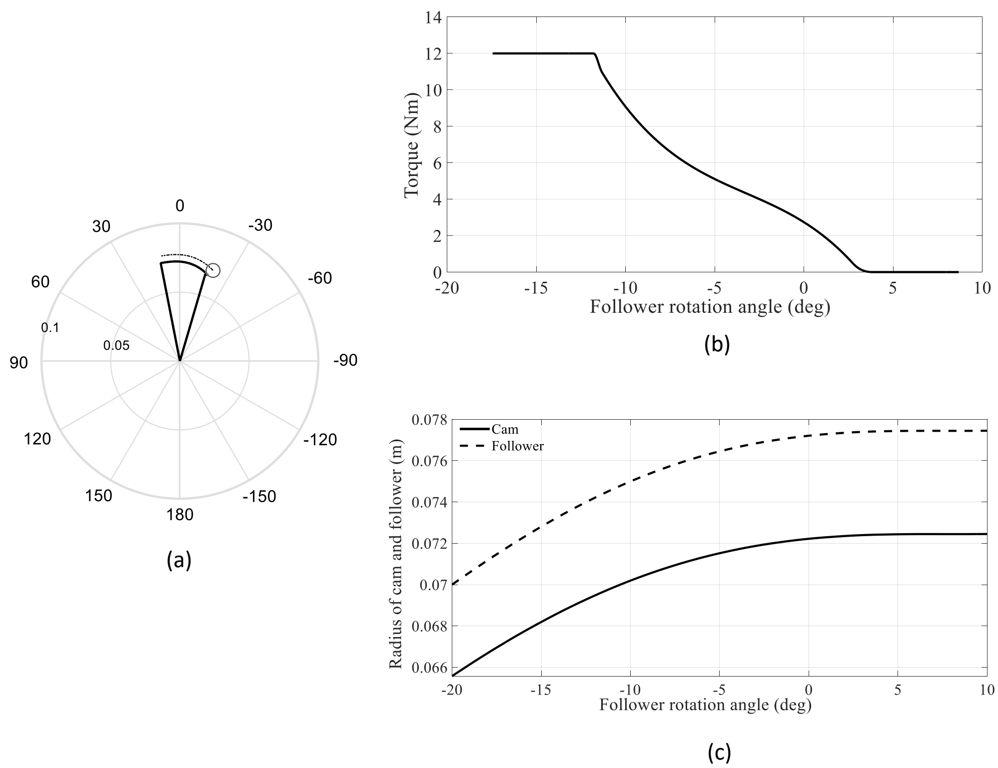

Figure 6. Cam profile design for the first patient; (a) the polar plot of the cam, (b) the torque-angle profile of the mechanism, (c) the radius-angle profile of the cam and follower

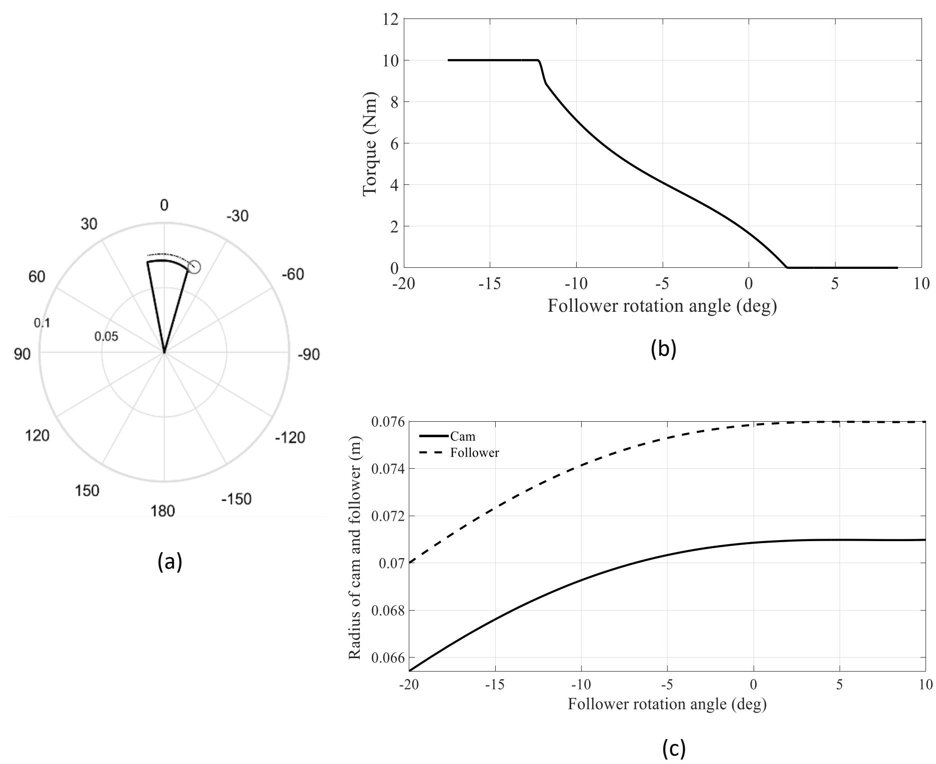

Figure 7. Cam profile design for the first patient; (a) the polar plot of the cam, (b) the torque-angle profile of the mechanism, (c) the radius-angle profile of the cam and follower

Conclusion

Conventional passive orthoses make use of a spring with constant stiffness; therefore, they do not provide a patient-specific stiffness profile for each type of weakness. Active ankle orthoses are also used to help patients requiring assistance during phases which a dorsiflexion torque is required; these devices however, cannot be used on a daily basis due to either their excessive weight, size and the need for an external power source, or the fact that they require a complex control system which increases the cost. In this study, a passive orthosis was designed to imitate the stiffness of a healthy ankle. By using a variable stiffness spring - comprised of a cam-follower mechanism creating a nonlinear torsional spring- attached to the hinged AFO to assist the patient during the swing phase, reducing toe drag is possible. This variable stiffness spring also applies torque towards dorsiflexion and assists controlled plantarflexion after heel strike to prevent foot slap. The device was designed for three patients with various pretibial muscle weaknesses. It was demonstrated that this process can be used individually for any patient suffering from pretibial muscle weakness. The torque needed to restore the patient's kinematics, according to muscle stimulation and activity during the gait cycle, was optimised using motion analysis tests for each patient. The profile and specifications of the cam and follower mechanism used to create the variable stiffness spring, were calculated in order to generate the torque each patient required.

Declarations

Ethics approval and consent to participate

Gait analysis (including motion capture) was carried out on the first author of this paper, with his consent.

Ethics approval and consent to participate

The first author has given consent for publication of all data obtained during the tests, including photographs.

Availability of data and materials

All data regarding various sections of this study (including gait analysis, simulations and mechanism design) are available from the corresponding author upon request.

Competing interests

The authors declare that they have no competing interests.

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Author Contributions

Concept and design: FS, AB. Tests: FS. Analysis of data and computations: FS, AB. Revision of manuscript and scientific assessment: MRZ. Administration and supervision of study: MRZ.

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