Charles University
Second Faculty of Medicine

Doctoral study programme: Experimental Surgery

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Can the adverse complications of foot drop be prevented by an endoprosthesis: design and development of a prototype device

Lze nepříznivým komplikacím peroneální parézy předejít implantací endoprotézy: návrh a vývoj prototypu zařízení

Dissertation Thesis

Supervisor: prof. MUDr. Tomáš Trč, CSc., MBA

Prague 2023

DECLARATION

I declare hereby that I made this dissertation thesis by myself and that I mentioned and cited properly all the sources and literature. At the same time, I declare that this thesis was not used to obtain another or the same title.

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Prague, 13.03.2023 *Dr. Bassel El-Osta*

ACKNOWLEDGMENT AND STATEMENT

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I believe that this work has no conflict of interest, and it was not sponsored by any commercial or non-commercial companies.

I like to dedicate this thesis to my first teacher in life, my mom, and my beloved wife, and the three kids that they supported me all way through these past 5 years.

Finally, I want to dedicate my whole work and everything to my father soul that because of him, I manage to achieve what I am achieving.

ABSTRACT

Foot drop is a very old problem since Jacob from the bible was limping when he was wrestling with the angels. Foot drop occurs very often, and it is a very common condition in trauma, after surgery, and neurological diseases.

The aim of this project is to identify an endo-prosthesis and test it bio-mechanically and biomedically in order to resolve the problem.

This endo-prosthesis must improve the quality of life for patients suffering from foot drop due to the injury to the common peroneal nerve. The device that must be created should be small and surgically will be attached to the muscle internally and work as if the muscles and nerve were intact. The device would be tested outside the human body. It is important to

throw light on that the device should be made of a material that is accepted by the human body and should have a stiffness that is close to the weight of the foot to ensure a normal motion. The intent of this bio-mechanical device is to help patients suffering from foot drop to restore normal motion.

An endo-prosthesis that is implanted in the foot might be the solution to foot drop disease. The endo-prosthesis has a major role to do the opposite movement and bring the foot into the dorsiflexion position and insure the plantar and lateral movement of the foot. Therefore, the device must be small to be implanted under the skin and adaptable to human tissue to avoid degradation and rejection.

Keywords: *A*chilles' tendon, active force, AFO, anterior tibialis tendon, common peroneal nerve, dorsal flexion, Endo-prosthesis, foot ligaments, passive force, plantar flexion, posterior tibialis tendon.

Abbreviations

SW	Swing Phase
IC	Initial Contact
TC	Terminal Contact
PD	Prototype Device
SEC	Series Elastic Component
PEC	Parallel Elastic Component
CoCr	Cobalt Chrome
EDL	Extensor Digitorum Longus
EHL	Extensor Hallucis Longus

AFO Ankle Foot Orthosis

TABLE OF CONTENTS

1. INTRODUCTION

1.1. History

Foot drop has been a problem for humans throughout the ages. Arguments can be made that the biblical story of Jacob limping after wrestling with an angel may represent the first recorded occurrence of foot drop.

The case history is based on the original Hebrew text found in the Bible book of Genesis (Chapter 32:25-33) as interpreted by traditional Jewish commentaries on the Bible.

Jacob sustained a hip injury in hand-to-hand combat with an adversary or through an intense physiological reaction to a prophetic vision of such a battle. He appears to have sustained neurological injury to his sciatic nerve as well as musculoskeletal damage to his hip.

These injuries caused a temporary limping gait. Jacob probably sustained a neurapraxia of the sciatic nerve. The differential diagnosis of his musculoskeletal hip injury includes hip dislocation, fracture, soft tissue trauma, and articular pathology as well as foot drop as a result of the sciatic nerve injury. [1]

1.2. What is foot drop

Foot drop is a deceptively easy name for a very complex problem. Foot drop is a problem that the patient is not able to dorsiflex due to problem in the extensor muscles. These muscles help the body clear the foot during swing phase and control plantarflexion of the foot on heel strike.

Weakness in this group of muscles results in an equinovarus deformity. During gait, the force of heel strike exceeds body weight, and the direction of the ground reaction vector passes behind the ankle and knee center. (Fig 1)

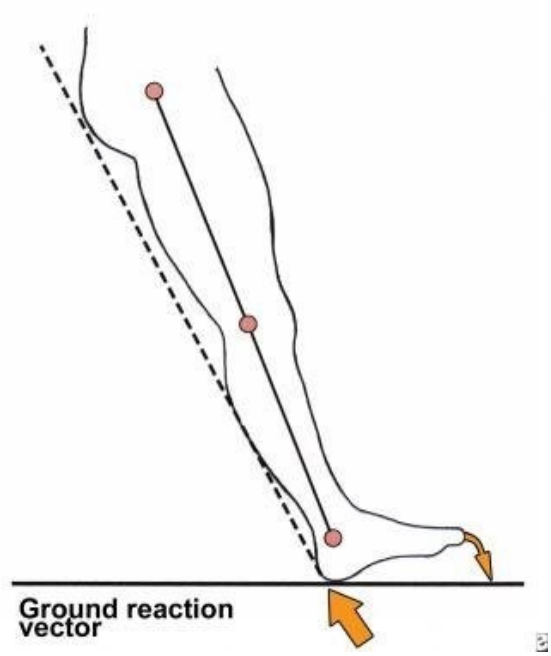


Figure 1. Ground Reaction Forces.

This gate is usually referred to as step-page gait, because the patient is tending to walk with an exaggerated flexion of the hip and knee in order to prevent the toes from catching on the ground during swing phase which will lead to a fall or further.

1.3. Anatomy

Fibers from the dorsal branches of the ventral rami of L4-S1 are found in the peroneal nerve, which is paired with the tibial nerve to constitute the sciatic nerve.

The sciatic nerve leaves the pelvic cavity at the greater sciatic foramen, just inferior to the piriformis. It bifurcates to form the peroneal and tibial nerves either in the distal third of the thigh or at the mid-thigh level.

The peroneal nerve crosses laterally to curve over the posterior rim of the fibular neck to the anterior compartment of the lower leg, dividing into superficial and deep branches. The superficial branch travels between the two heads of the peronei and continues down the lower leg to lie between the peroneal tendon and the lateral edge of the gastrocnemius. It then branches to the ankle anterolateral to supply sensation to the dorsum of the foot. [2], (Fig 2)

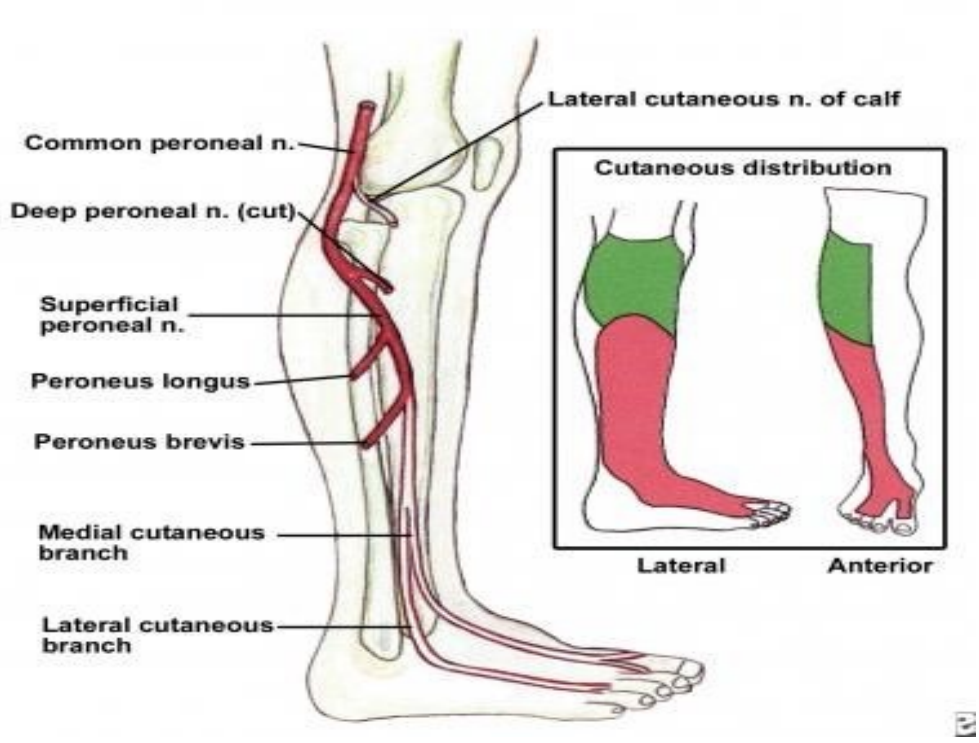


Figure 2. Common and superficial peroneal nerves, branches, and cutaneous innervation.

The deep branch divides just after rounding the fibular neck. Its initial branch supplies the tibialis anterior, and the remaining branches supply the EDL, the EHL, and a small sensory patch at the first dorsal web space. (Fig 3)

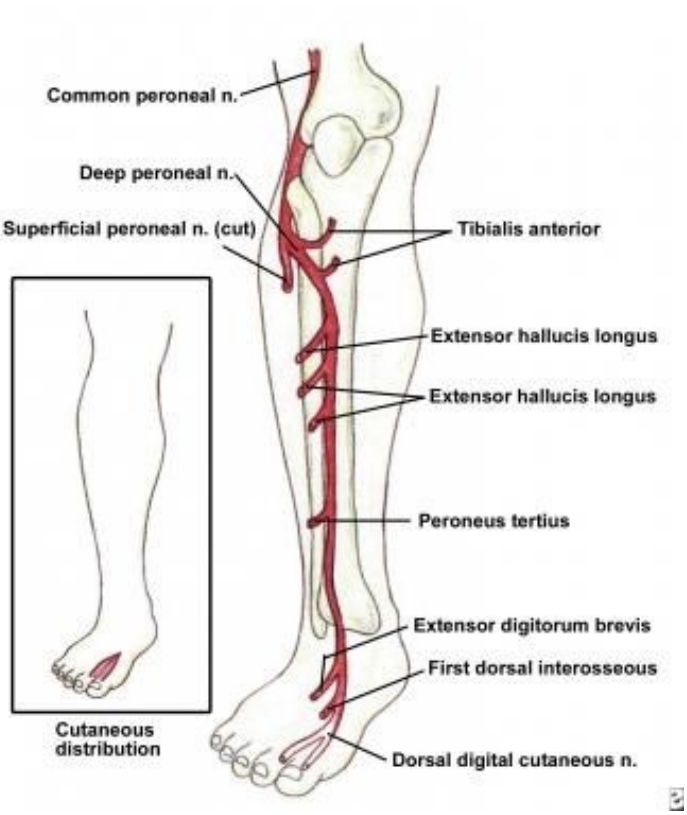


Figure 3. Deep peroneal nerve, branches, and cutaneous innervation.

The peroneal nerve is susceptible to injury all along its course. In that it is part of the sciatic nerve, its funiculi are relatively isolated from those of the tibial nerve. Therefore, trauma to the sciatic nerve may affect only one of its divisions.

The funiculi of the peroneal nerve also are larger and have less protective connective tissue than those of the tibial nerve, making the peroneal nerve more susceptible to trauma. In addition, the peroneal nerve has fewer autonomic fibers; thus, in any injury, motor and sensory fibers bear the brunt of the trauma.

The peroneal nerve runs a more superficial course than the tibial nerve does, especially at the fibular neck, and this relatively exposed position makes it vulnerable to direct insult. Its close adherence to the periosteum of the proximal fibula renders it susceptible to injury during surgical procedures in this area.

1.4. Pathophysiology

The pathophysiology of nerve damage that commonly causes foot drop is as follows. The functional integrity of an axon and its target depends on the continued supply of trophic

substances synthesized in the neuronal Perikaryon and transported down the axon (exoplasmic flow).

A laceration interrupts exoplasmic flow; a crush injury may compromise it as well. A double-crush phenomenon occurs when a proximal insult in a nerve root diminishes exoplasmic flow, making it more susceptible to injury.

A distal lesion further compromises exoplasmic flow, and clinical palsy results. This is the phenomenon thought to be responsible for the increased risk of foot drop after hip replacement in a patient with pre-existing spinal stenosis.

The spinal stenosis causes the proximal compromise, and intra-operative stretch of the sciatic nerve provides the distal insult.

1.5. Etiology

Foot drop can be as a result of trauma, arthroplasty surgery, a neurophysiological deficit or even a tumor. It is currently a problem that both doctors and patients are finding difficult to resolve.

Trauma resulting in injury to the common peroneal nerve may cause foot drop; specifically, a fracture to the head of the fibula and extensive injury to the proximal part to the tibia and fibula. Compartment syndrome of the lower limb may also cause a temporary injury to the common peroneal nerve, resulting in foot drop. [3]

Some are surgical emergencies such as Compartment syndrome and are not associated only with fracture or acute trauma. March gangrene, a form of anterior compartment syndrome, is thought to be due to oedema and small hemorrhages in the muscles of the anterior compartment occurring after strenuous activity in individuals not accustomed to it. Deep posterior compartment syndrome also may result in foot drop as a late sequela due to contracture formation.

Neurologic causes of foot drop include mono-neuropathies of the deep peroneal nerve, the common peroneal nerve, or the sciatic nerve. Lumbosacral plexopathy, lumbar radiculopathy, motor neuron disease, or parasagittal cortical or subcortical cerebral lesions also can manifest as foot drop. These lesions can be differentiated by means of clinical and electro diagnostic examinations.

A common behavioral cause of foot drop is habitual crossing of the legs. [4] These cases typically resolve with discontinuance of the habit.

Arthroplasty knee surgery carries the risk of developing foot drop. This is a consequence of nature of the procedure, whereby the surgeon retracts the soft tissue away from the surgical field. This may affect the patient's rehabilitation and contribute to further distress after surgery.

Neurophysiological features are mainly related to chronic or congenital disease such as muscle dystrophy, children hemiplegia. They can cause demyelination of the nerve which will lead to stop the impulse arriving to their destination. This can result in foot drop.

Tumors in close proximity to the common peroneal nerve may exert pressure which can impair nerve function either temporarily or permanently.

Presently, there are a number of apparatuses that may be used to treat foot drop. Ankle-foot orthoses are devices made from either hard material with minimal flexibility; their main purpose being to keep the foot in a single position.

Alternative orthoses made from a softer material serve the same purpose but may offer slightly more flexibility and are less damaging to the overlying tissue of the foot. However, both types of orthoses are very much visible to the eye and do not offer the patient much freedom to wear footwear of their choosing. Other treatments involve the use of nerve stimuli devices. This is an option whereby the patient must undergo surgery and thereafter carry the device at all times, deeming it an impractical and inconvenient choice of treatment.

The psychological issues and stigma associated with foot drop along with other consequences such as gait disturbances should also be taken into account. They can result in a lack of treatment compliance and in the long term, may result in the patient developing depressive symptoms.

Taking into account the aforementioned issues, it would be ideal to create a device that is effective in treating foot drop and one that is simultaneously acceptable to patients. In order to achieve maximum patient satisfaction, the device would have to provide comfort, flexibility to wear footwear of any choice and a high level of functionality without any additional support.

Problems that may arise could be during the measurement of muscle forces, the mechanical axes, the strength of attachment during the cadaver-testing phase; due to the lack of flexibility they possess, we may encounter false or misleading results.

1.6. How foot works

In order to understand the aim of this study is crucial to be aware of the foot anatomy, mechanics and physiology.

The foot can be subdivided into the hindfoot, the mid-foot, and the forefoot: The hindfoot is composed of the talus or ankle bone and the calcaneus or heel bone. The two long bones of the lower leg, the tibia and fibula, are connected to the top of the talus to form the ankle. Connected to the talus at the subtalar joint, the calcaneus, the largest bone of the foot, is cushioned inferiorly by a layer of fat.

The five irregular bones of the mid-foot, the cuboid, navicular, and three cuneiform bones, form the arches of the foot which serves as a shock absorber. The mid-foot is connected to the hind- and fore-foot by muscles and the plantar fascia.

The forefoot is composed of five toes and the corresponding five proximal long bones forming the metatarsus. Similar to the fingers of the hand, the bones of the toes are called phalanges and the big toe has two phalanges while the other four toes have three phalanges. The joints between the phalanges are called interphalangeal and those between the metatarsus and phalanges are called metatarsophalangeal (MTP). [5]

It has four range of movement, namely: Dorsiflexion, Plantarflexion, inversion and eversion. For the purpose of this study, the most important 2 movements are Dorsiflexion (Extension) which is the movement which decreases the angle between the dorsum (superior surface) of the foot and the leg, so that the toes are brought closer to the shin. This is achieved by using the anterior compartment of the leg and the namely four muscle: tibialis anterior, extensor halluces longus, extensor digitorum longus and fibularis tertius (peroneus tertius). These muscles are attached mainly to the first metatarsal head, base of proximal phalanx of the hallux, metatarsal phalangeal joint and extensor retinaculum. The innervation of this compartment is from the common peroneal nerve that it lies just behind the fibula head. [6]

And Plantar flexion is the movement which increases the approximate 90-degree angle between the front part of the foot and the shin, as when depressing an automobile pedal.

This is achieved by using the following muscles and compartments: Primary muscles for plantar flexion are: Posterior compartment of leg (gastrocnemius, soleus, plantaris, flexor halluces longus, flexor digitorum longus, tibialis posterior) and Lateral compartment of leg (only weak participation: peroneus longus, peroneus brevis). However, the main muscle or tendon that will be interesting us is the Achilles tendon which is attached to the calcaneum in the posterior part. Those muscles are mainly innervated by the tibial nerve. [7]

1.7. Stance and Walking

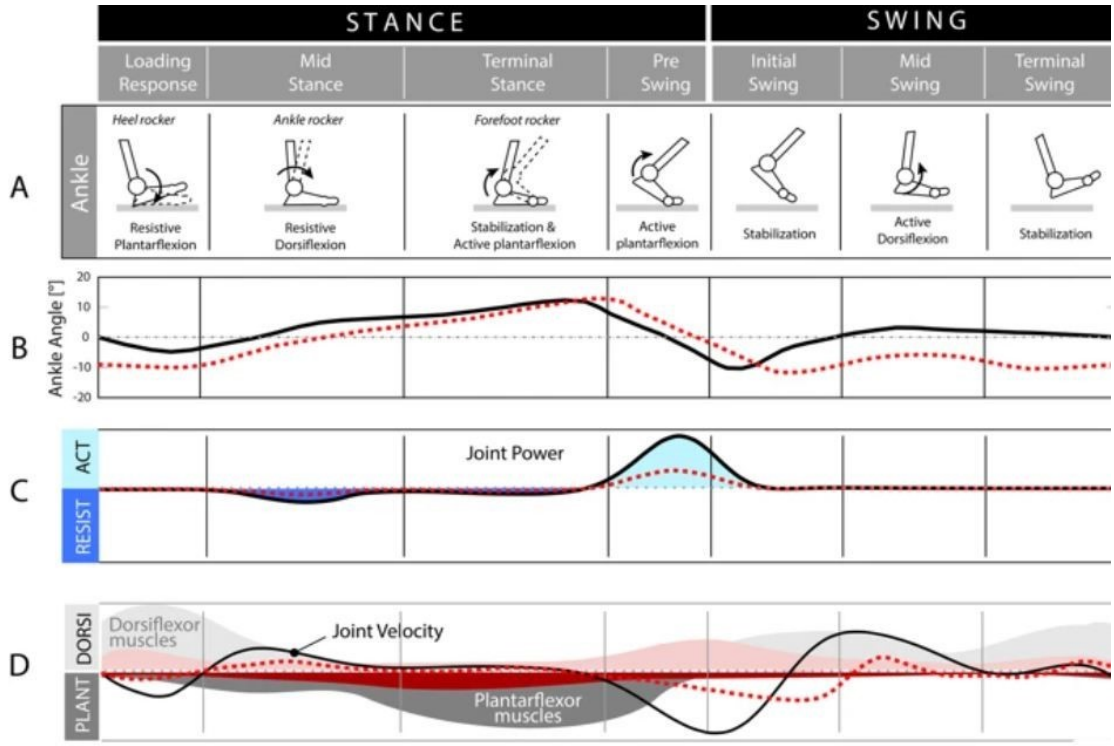


Figure 4. Biomechanics of walking.

The figure mentioned above describes the biomechanics of the ankle in the gait cycle (Fig 4). The black continuous line graph represents the biomechanics of a health ankle while the red segment in the graph represents the biomechanics of a foot drop patient. Meanwhile, panel D in red represents the muscle activity of foot drop patient. However, taking into consideration figure 2 C and D muscle activity in the plantarflexion is good while it is almost zero in dorsiflexion which leads to foot slap. This weakness in some cases lead the patient to be unable to support their own weight.

Therefore, it is vital to come up with an appropriate strategy of intervention to overcome foot drop. Conventional treatment involves the use of an ankle-foot orthosis (AFO), which keeps the ankle joint in a neutral position. Moreover, techniques based on robotic and/or electrical stimulation assistance are being developed and represent promising alternatives. As well as the Endo-Prosthesis in this study is a major competitor to these treatments and has tremendous future to be the best among them all. [8]

1.8. Normal gait versus step-page gait cycle

Foot drop term refers to an abnormal neuromuscular disorder that affects the patient's ability to achieve dorsiflexion movement. Also, known as the inability to point toes toward the body or move the foot ankle inward and outward. Therefor the normal gait cycle is affected.

1.8.1. A normal gait cycle

Swing phase (SW): the phase where the foot is not in contact with the ground where in this phase all the portions of the foot are in forward motion.

Initial contact (IC): the period where the foot initially in contacts with the ground. Heel strike where the contact start with the heel then to a full foot contact with the ground.

Terminal contact (TC): when the foot leaves the ground to start the swing phase where the toe is the last part that should leave the ground. However, after this phase SW is the next phase.

1.8.2. Step-page gait cycle

SW: since a foot drop patient has lost the ability to point his toes, there will be a great flexion at the knee to recap the unachievable dorsiflexion motion. A stair-climbing motion will provide the foot not to be in contact with the ground and in forward position.

IC: foot slap on the ground while heel-toe foot strike is never achieved.

TC: foot drop patient may not have the ability to support their body weight with the damaged foot. Therefore, a cane or walker might help them sustain balance. (Fig 5)

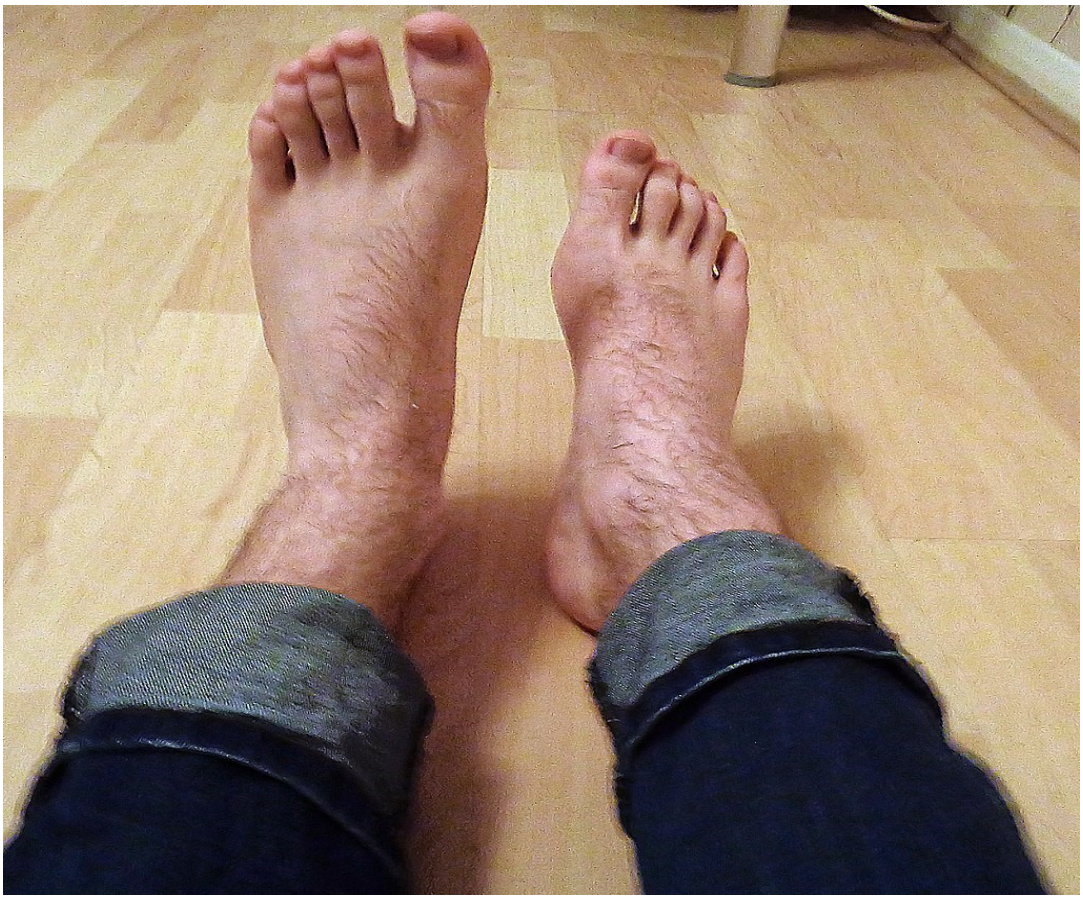


Figure 5. Foot Drop Patient.

1.9. Hypothesis

Foot drop has so far no solution and therefore the engineering of prototype device is very important. In our case, the hypothesis is to evaluate an internal mechanical device that will be attached to the hard and soft tissue and will be able to act as normal tendon.

1.10. Literature review

We presented a review of current literature with the aim being to identify the highest quality papers available describing current management practices for foot drop using Hawker data extraction methodology. No comparison has been made between heterogeneous treatment methods, the emphasis here has been to assimilate and categorize the many treatment methods being applied in clinical practice.

A search of the available literature from 1970 to the present was undertaken using specific key words. Out of close to 3600 articles, 12 of the most relevant articles were selected for review. These were the highest quality articles describing current treatment methods for foot drop. This review has highlighted the international interest in the problem

of foot drop and the varied approaches to management, however it is clear that a best option has yet to be defined, and clinician preference remains the deciding factor in choice of management option.

Reviewed publications were found not to compare treatment methods under consistent criteria, and superiority of one treatment method over another method was not indicated by any publication. This review indicates that although many treatment modes exist, no meaning- full comparison can be made between these heterogeneous methods, and thus- a best practice method remains undetermined. The development of valid efficacy measures is the next step to comparing treatment methods and thereby discerning the most successful methods for management of foot drop. [9]

2. AIM

The principal aim of our study is to create a unique bio-mechanical prototype device that would improve the quality of life for patients suffering from foot drop and from injury to the common peroneal nerve.

The prototype device to be created would be small and can be surgically fitted. The device logically has to be attached to the soft tissue responsible for the foot drop internally from one side and hard tissue such bone on the other side. Not only, but it should work as if the muscles and nerve were intact.

Having such a PD fitted would help to improve the patient's range of movement in their foot and ankle to a level that is as close to normal as possible and to achieve maximum patient satisfaction. Subsequently this may lower the incidence of associated psychological problems.

Secondly, patients would be free of external apparatus and able to choose their clothing without restriction. Therefore, the PD has to be small in order for it to be implanted under the skin and adaptable to human tissue to avoid degradation and rejection.

The device would have to be inserted by a foot and ankle or orthopaedic surgeon to minimize complications. Ideally, this would be carried out by minimally invasive surgery to reduce the risk of surgically associated complications such as infection, scarring and excessive bleeding.

The PD if successful will cancel every other device or any other treatment and it will present a new revolution in the world of orthopaedics.

Finally, it must be taken into consideration that the implant may need a revision like any other prosthesis such as a hip or knee implant. It is important to note that in the first instance it will be difficult to know precisely how long it will last. And in order to develop our device, we will need to create it, receive patent, test it in the lab, implemented in cadaver than take it to it is final destination and implemented in real patients.

3. MATERIALS AND METHODS

The PD we aimed to create must be a bio-mechanical that it will be able to be attached proximally to the tibial bone to provide stability and to the adjusting muscles distally which responsible for the dorsiflexion.

The idea of the PD came after studying the mechanism of the muscles in dorsiflexion. The skeletal muscles are organized multinucleated myofibers, whose function is to generate length and velocity dependent forces for movement or stability (Fig 6). Their function depends on their intrinsic properties and extrinsic arrangement. [10]

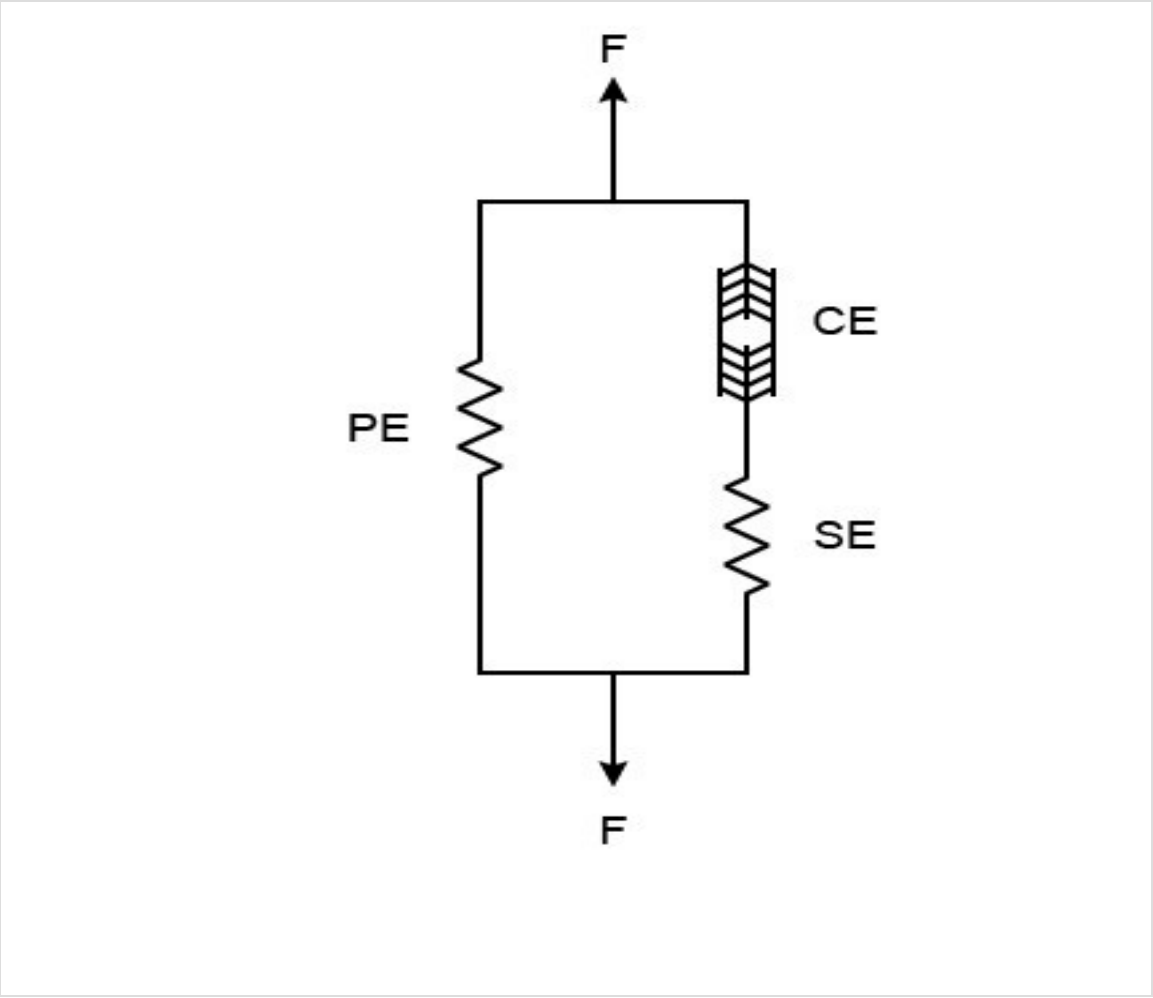


Figure 6. Elasticity of forces.

The skeletal muscles could be organized in three different components based on their function and architecture [11], namely:

- The Series Elastic Component (SEC)

- The Parallel Elastic Component (PEC)
- The Contractile Component

The series and parallel elastic component are defined in relation to their arrangement with the contractile components, the later arranged in line with the contractile components. The parallel elastic component is suggested to consist of the membranes surrounding the contractile components which includes the sarcolemma, sarcoplasmic retinaculum, the perimysium and the epimysium, while the series elastic components reside in the tendons and aponeuroses. [10]

Elasticity is one of the properties of a muscle, necessary for optimal function. These non-contractile components contribute to the passive force generated by the muscles. It is thought that the PEC distributes forces during passive and maintains the alignment of muscle fibers while the SEC serves to store up elastic energy to be released during muscle contraction [12] and play a role in stability during isometric contraction. [13]

As mentioned above, the PD has to be flexible construct matching the muscles function in the way of elasticity. The only known construct that can easily do this function is the spring.

Not only, but the PD must be able to take the weight of the foot while being able to handle the opposing forces of the extensor mechanism. The weight of the foot is well known and it is around 1.4% of the total body weight according to Plagenhoef. [14]

The next important parts that came to mind was the attachment of the device to either end specially that it has to be similar to the muscle attachment which means bone one side and tendon to the other side.

Relatively, the device has to be studied how it will be attached together or has to be one single piece.

The small size of the implanted device will be vital as to not disturb the surround tissue and ease biological adaptation to the soft tissue.

The implant started to be engineered by myself and designed on paper as well as drawn in order to have the first initial thoughts. Then, we started to develop it in the Bioengineering department at the Royal National Orthopaedic Hospital in UK subsequently followed by the City University in The Lebanon due to my relocation.

The initial design was made of 5 pieces. The proximal attachment which is the round device with a 4.0 hole in order to attach the device to the bone using 4.0 cannulated screw.

Then it comes the design of the screw that it will attach the proximal device to the spring. Similarly, another screw to attach the distal part to the spring as well.

The spring was initially unknown of which material has to be, but after looking at all available material this is including CoCr, Stainless steel, Titanium, Polymer, Aluminum and Nitinol it has been identified and determined that it will be from medical 316 A Stainless steel. The design has been studied according to Wolff's law who states that bone in a healthy person or animal will adapt to the loads under which it is placed. [3] If loading on a particular bone increases, the bone will remodel itself over time to become stronger to resist that sort of loading. [11, 15] The internal architecture of the trabeculae undergoes adaptive changes, followed by secondary changes to the external cortical portion of the bone, [14] perhaps becoming thicker as a result. The inverse is true as well: if the loading on a bone decreases, the bone will become less dense and weaker due to the lack of the stimulus required for continued remodeling. [16] This reduction in bone density (osteopenia) is known as stress shielding and can occur as a result of a hip replacement (or other prosthetics). The normal stress on a bone is shielded from that bone by being placed on a prosthetic implant.

The study will initially be carried out in the biomechanical laboratory, Than on cadavers and later, implemented into volunteer patients after ethical approval and consent.

3.1. Approach

In order to achieve a good result, we decided to take a systematic approach to the study. Firstly, we needed to study the forces that are usually generated from the foot itself, the opposing forces of the ground against the foot and the surrounding soft tissue. It is well known from previous literature that the weight of the foot is approximately 1.4% of the body weight [17] or approximately 2 kilograms. The soft tissues that needed to be measured specifically were:

1. Achilles Tendon - Flexor forces
2. Extensor Digitorum Longus
3. Anterior Tibialis — Extensor
4. Extensor pollicis

5. Inferior extensor retinaculum

After calculating the above-mentioned forces, we needed to calculate the forces that the implant will apply against the flexor mechanism.

The next task was to identify a suitable metal to create the implant. It needed to be safe, durable and flexible. The only metal that was identified to meet these criteria in the study's time constraints was stainless steel.

In terms of design, the spring needed to be created in such a way that soft tissue would not become trapped between the coils and cause pain. Therefore, we managed to look at all previous attachment and designs and unfortunately, we didn't find anything similar in the literature.

So, we opted to have the device as small as possible but to prove the theory first we decided to just make the first prototype as availability allowed.

Finally, the optimal area of insertion needed to be recognized to preserve the anatomy of the lower limb as much as possible, this will be discussed at later stage.

In order to achieve the desired results, it was crucial to investigate the mean weight of the foot and the forces exerted by the flexor and extensor muscles. These measurements were recorded in Newton's. In order to achieve this, we carried out a pilot study. A handheld scale was used to measure the weight of the foot and the forces exerted in active and passive motion. For that we recruited 23 adults indiscriminately (12 males and 11 females). The forces were analyzed by one person using a handheld rope and pulley device. The individual was asked to plantar-flex their foot (active), after which the device operator brought the foot back up to the neutral position to the measurement of the passive force. (Fig 7)

Figure 7. Calculation of passive forces.

Once all these aims were met, the final phase was to implant the device into cadaveric limbs and record the results.

3.2. Calculation of Forces

In order to measure the individual forces, the angulation of the extensor and flexor mechanisms in relation to a 180° plane (i.e., parallel to the ground). In order for this to be done approximately, the true assumption that the foot rotates at the talus bone had to be made. The distances between this center of rotation and the forward extensor and backward flexor mechanisms were then measured and this was found to be 5 and 6 centimeters respectively.

From the extensor mechanism, this plane was extended ($B_{x)}$ and at the junction between the extensor mechanism and inferior extensor retinaculum, a 90° vertical line was drawn (B_y). Subsequently another line was drawn parallel to the extensor mechanism (B). As a result, the angle between the extensor mechanism and 90° plane was measured to be 10°. This method was then repeated for the flexor mechanism. (Fig 2)

We can assume that the foot is 1.4% of the total body weight. And therefore, we were able to calculate the weight of the foot as W = Body Weight * 1.4% * L / 2.

Subsequently, we calculated the force in passive and active motion as F = 9.8 * W.

We then determined the forces of the anterior compartment where the device should be attached using a well-known formula:

$_y$* T /(COS (-10))= (W*D) + (F*L)

= B_y/ cos (-10)

$_x$ = B sin (-10)

= 0.05 meters (distance between center and tendon)

W = Weight of foot (Kilograms)

D = Distance between center of rotation to the sole of the foot (Centimeters)

F = Force (Newton's)

L = Shoe size (European Centimeters)

Using the same formula we can calculate the forces of the Achilles tendon but in this case is not necessary and it will have no influence on the device itself and logically has to be equal to the anterior forces.

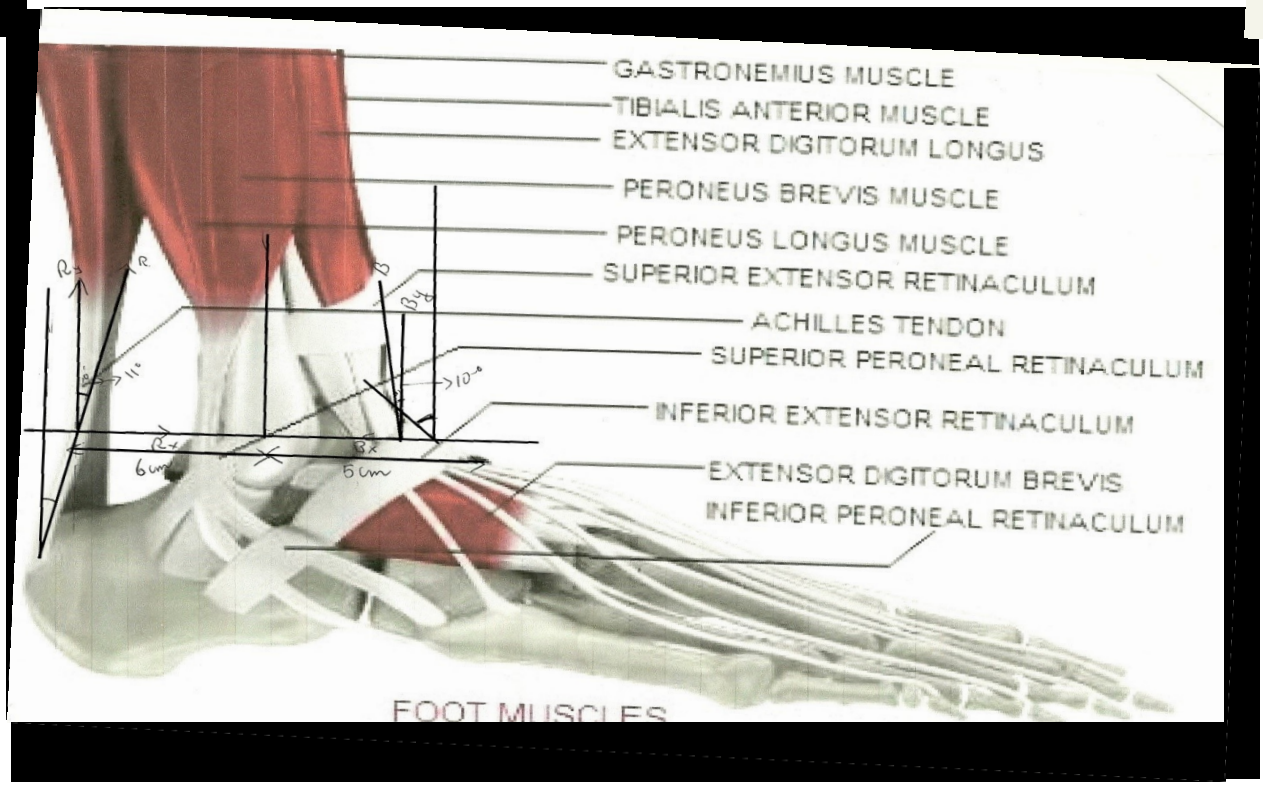


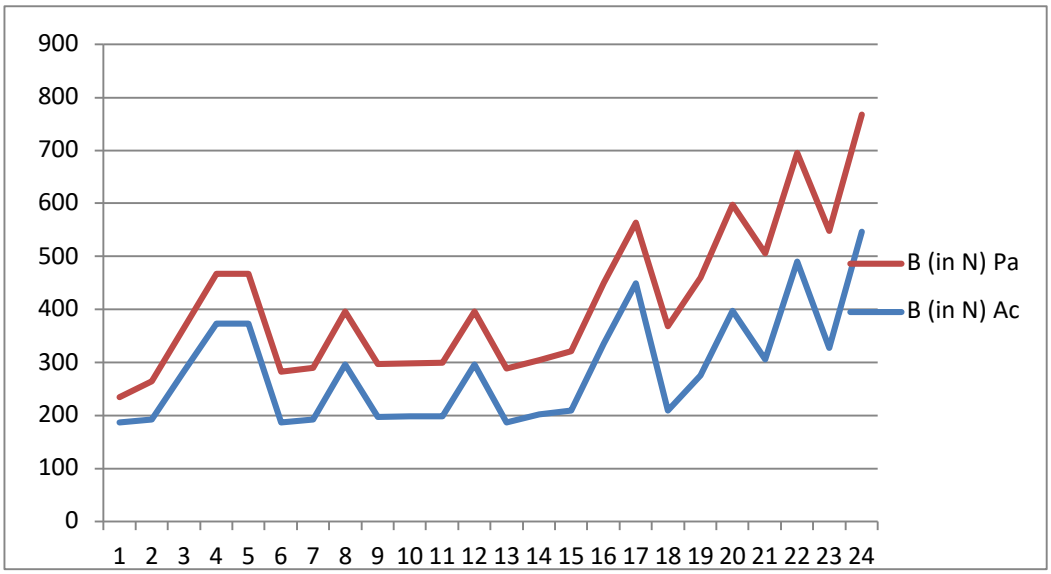
Figure 8. The anatomy of the foot.

B_y * T / (COS(-10)) = (W * D) + (F * L) B= By/ cos (-10) Bx= B sin (-10)													
Ref N	Foot W (N)	Foot D	Active F		Passive F		Foot L (Size)		By		Bx	B (in N)	
			Kg	N	Kg	N	EU	Cm	Ac	Pa		Ac	Pa
2	7.7	11.9	4	39.2	1	9.8	37	23.8	184	47		187	48
23	7.3	12.25	4	39.2	1.5	14.7	38	24.5	189	72		192	73
20	8.5	11.65	4	39.2	1.8	17.6	36	23.3	278	81		283	82
13	8.5	11.9	3	29.4	2	19.8	37	23.8	367	93		373	95
10	8	11.9	8	78.4	2	19.8	37	23.8	367	93		373	95
8	9.3	11.9	4	39.2	2	19.8	37	23.8	184	94		187	96
18	7.4	12.25	4	39.2	2	19.8	38	24.5	189	96		192	98
14	9.6	12.55	6	58.8	2	19.8	39	25.1	291	99		296	101
15	9.3	12.55	4	39.2	2	19.8	39	25.1	194	99		197	101
16	13.5	12.55	4	39.2	2	19.8	39	25.1	195	99		198	101
17	9	12.7	4	39.2	2	19.8	40	25.4	196	99		199	101
4	13.7	12.55	6	58.8	2	19.8	39	25.1	291	99		296	101
3	8.9	12.7	5	49	2	19.8	40	25.4	184	100		187	102
19	8.6	12.85	4	39.2	2	19.8	41	25.7	199	101		202	103
24	10.5	13.35	4	39.2	2	19.8	43	26.7	207	110		210	112
21	10.7	14.3	6	58.8	2	19.8	46	28.6	331	113		336	115
12	13	14.3	8	78.4	2	19.8	46	28.6	442	113		449	115
22	13.5	13.35	4	39.2	3	29.4	43	26.7	207	156		210	159
11	6.9	11.75	6	58.8	4	39.2	36	23.5	272	181		276	184
9	11.4	12.7	8	78.4	4	39.2	40	25.4	392	197		398	200
7	9.9	13	6	58.8	4	39.2	42	26	301	197		306	200
6	12	13.95	9	88.2	4	39.2	45	27.9	483	202		491	205
5	11.3	13.95	6	58.8	4	39.2	45	27.9	323	216		328	220
1	15.64	13.95	10	98	4	39.2	45	27.9	538	217		547	221

Table 1. Summarizes the calculations of the passive forces for all 23 individuals in Newton's.

Ref Number	Foot W (N)	Foot D	Active F		Passive F		Foot (Size)	L	By		Bx	B (in N)	
	Kg	N	Kg	N	Kg	N	EU	Cm	Ac	Pa		Ac	Pa
2	7.7	11.9	4	39.2	1	9.8	37	23.8	184	47		187	48
8	9.3	11.9	4	39.2	2	19.8	37	23.8	184	94		187	96
3	8.9	12.7	5	49	2	19.8	40	25.4	184	100		187	102
23	7.3	12.25	4	39.2	1.5	14.7	38	24.5	189	72		192	73
18	7.4	12.25	4	39.2	2	19.8	38	24.5	189	96		192	98
15	9.3	12.55	4	39.2	2	19.8	39	25.1	194	99		197	101
16	13.5	12.55	4	39.2	2	19.8	39	25.1	195	99		198	101
17	9	12.7	4	39.2	2	19.8	40	25.4	196	99		199	101
19	8.6	12.85	4	39.2	2	19.8	41	25.7	199	101		202	103
24	10.5	13.35	4	39.2	2	19.8	43	26.7	207	110		210	112
22	13.5	13.35	4	39.2	3	29.4	43	26.7	207	156		210	159
11	6.9	11.75	6	58.8	4	39.2	36	23.5	272	181		276	184
20	8.5	11.65	4	39.2	1.8	17.6	36	23.3	278	81		283	82
4	13.7	12.55	6	58.8	2	19.8	39	25.1	291	99		296	101
14	9.6	12.55	6	58.8	2	19.8	39	25.1	291	99		296	101
7	9.9	13	6	58.8	4	39.2	42	26	301	197		306	200
5	11.3	13.95	6	58.8	4	39.2	45	27.9	323	216		328	220
21	10.7	14.3	6	58.8	2	19.8	46	28.6	331	113		336	115
13	8.5	11.9	3	29.4	2	19.8	37	23.8	367	93		373	95
10	8	11.9	8	78.4	2	19.8	37	23.8	367	93		373	95
9	11.4	12.7	8	78.4	4	39.2	40	25.4	392	197		398	200
12	13	14.3	8	78.4	2	19.8	46	28.6	442	113		449	115
6	12	13.95	9	88.2	4	39.2	45	27.9	483	202		491	205
1	15.64	13.95	10	98	4	39.2	45	27.9	538	217		547	221

Table 2. Summarizes the calculations of the active forces for all 23 individuals in Newton's.



Graph 1. Chart showing the plot of active and passive forces.

In order to calculate the vectors of the inferior extensor retinaculum, the ground, Achilles tendon and weight of the foot, a 180° plane (i.e., parallel to the ground) was drawn. In order for this to be done approximately, the true assumption made previously that the foot rotates at the talus bone had to be taken into consideration. Another line was then drawn from the center of rotation along the angle of the metatarsal bones using X-rays for accuracy (Fig 9). A line perpendicular to the 180° plane was then extended to the line along the metatarsal plane.

This created a triangle, the 3 borders being $B_{y,}$ X and Y. (Graph 2)

Y can now be calculated as we know the angle between the X & Y. The formula used is Tang 20= B_y / Y.

X can then be calculated using the formula of Cos20=X/Y. Therefore, X= Y * Cos20. There is another way to calculate Force X by simply applying the following formula: X^2= $!\overline{Y^{\#} + By^{\#}}!\overline{Y^{\#} + By^{\#}}$.

Finally, and in order to calculate the forces of the IER we can draw an opposite line inside the triangle that we created initially and it will have the same angle like the xy angle which means 20 degree. From that we can calculate the forces by the following formula Q= Cos20.By.

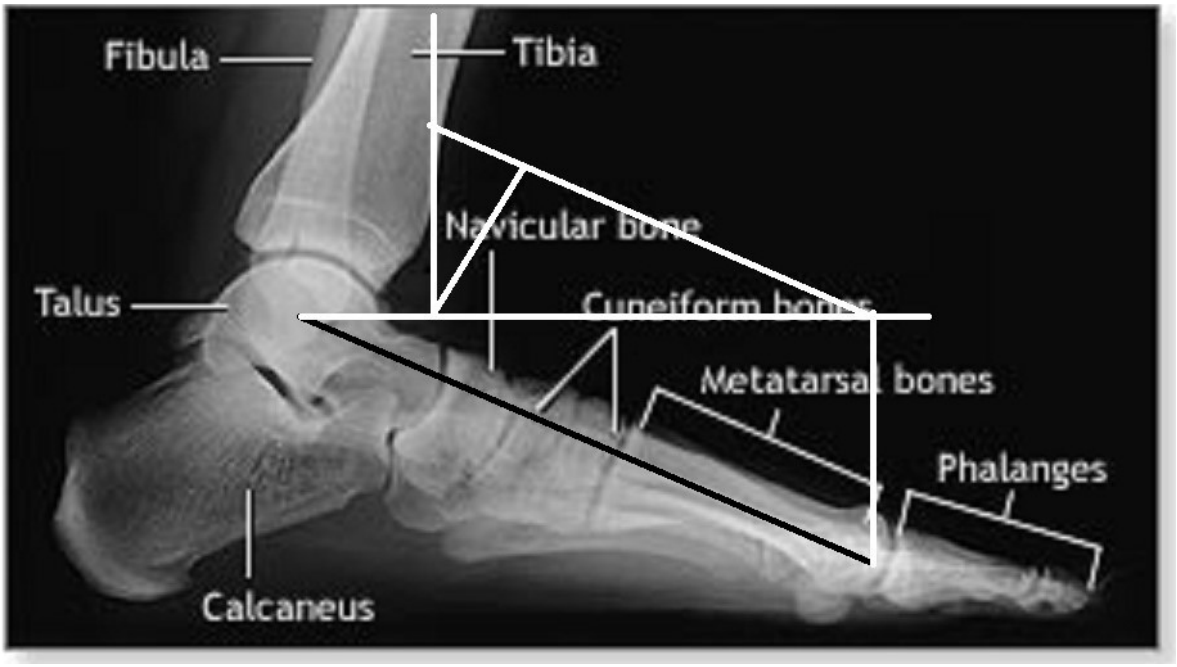
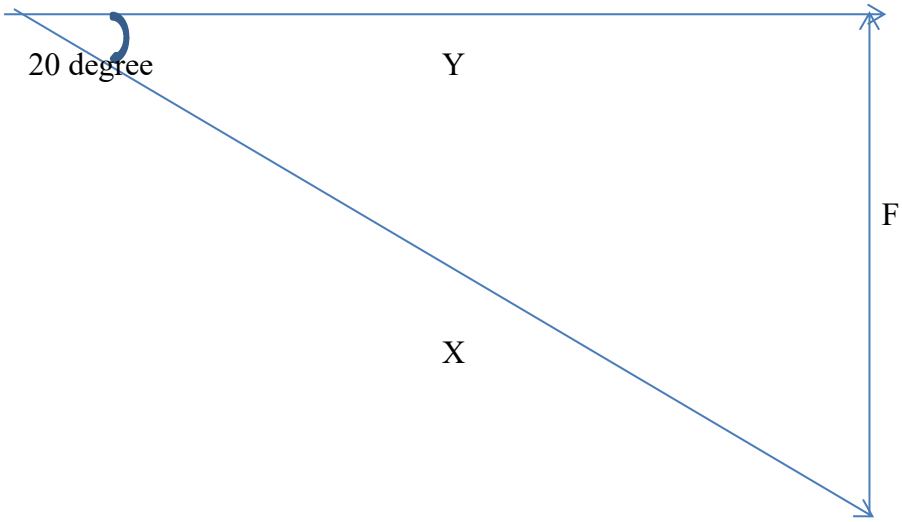
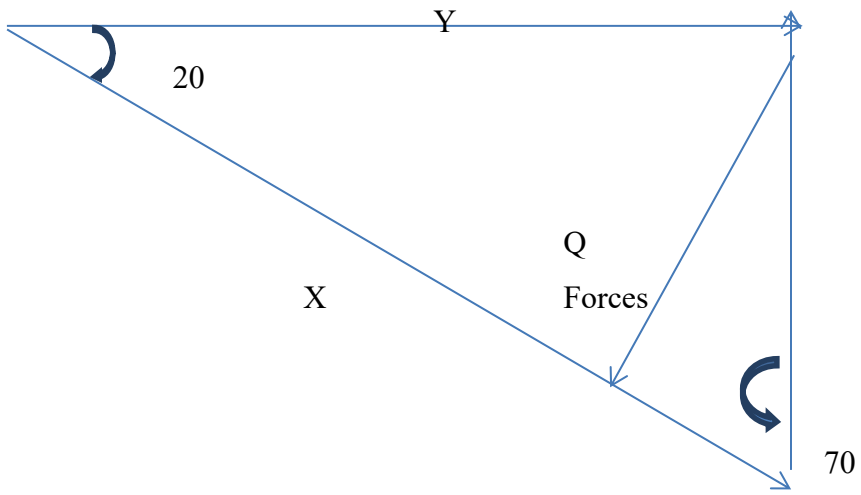


Figure 9. Foot X-ray showing the vector.



Graph 2. This resembles to the vector of forces acting on the foot. X is the Tendons forces, Y is the ground force, F is the perpendicular force and the angle acting between the forces is 20 degree.



Graph 3. The same as graph 2 with addition of Q force which resemble to inferior extensor retinaculum forces.

Finally, the formula to calculate the movement was: Xm= X- Xp= Y/cos20 - Yp/Cos10 = 6.2 mm which means if we want more from 20 to 0 degree it will move 12 mm. As a result we calculated the formula above and we draw a chart that led us to calculate a zone of forces which can be exercised by different individual and this led us to know the thickness as well as the best possible material for the device.

Ref Number	Foot W (N)	Foot D	Active F		Passive F		Y Force		X Force	
			Kg	N	Kg	N	Ac			
2	7.7	11.9	4	39.2	1	9.8	107	2	7.7	11.9
23	7.3	12.25	4	39.2	1.5	14.7	107	23	7.3	12.25
20	8.5	11.65	4	39.2	1.8	17.6	107	20	8.5	11.65
13	8.5	11.9	3	29.4	2	19.8	81	13	8.5	11.9
10	8	11.9	8	78.4	2	19.8	215	10	8	11.9
8	9.3	11.9	4	39.2	2	19.8	107	8	9.3	11.9
18	7.4	12.25	4	39.2	2	19.8	107	18	7.4	12.25
14	9.6	12.55	6	58.8	2	19.8	162	14	9.6	12.55
15	9.3	12.55	4	39.2	2	19.8	107	54.5	114	58
16	13.5	12.55	4	39.2	2	19.8	107	54.5	114	58
17	9	12.7	4	39.2	2	19.8	107	54.5	114	58
4	13.7	12.55	6	58.8	2	19.8	162	54.5	173	58
3	8.9	12.7	5	49	2	19.8	134	54.5	143	58
19	8.6	12.85	4	39.2	2	19.8	107	54.5	114	58
24	10.5	13.35	4	39.2	2	19.8	107	54.5	114	58
21	10.7	14.3	6	58.8	2	19.8	162	54.5	173	58
12	13	14.3	8	78.4	2	19.8	215	54.5	229	58
22	13.5	13.35	4	39.2	3	29.4	107	81	114	86.2
11	6.9	11.75	6	58.8	4	39.2	162	107	172.4	114
9	11.4	12.7	8	78.4	4	39.2	215	107	229	114
7	9.9	13	6	58.8	4	39.2	162	107	172.4	114
6	12	13.95	9	88.2	4	39.2	245	107	261	114
5	11.3	13.95	6	58.8	4	39.2	162	107	172.4	114
1	15.64	13.95	10	98	4	39.2	270	107	287	114

Table 3. Motion forces of all the 24 individuals.

The Q Force which represent the ligament attachement will be calculated Q=Cos20*								
Ref Number	Foot W	Foot D	Active F		Passive F		Q Force	
	(N)	Cm	Kg	N	Kg	N	Ac	Pa
2	7.7	11.9	4	39.2	1	9.8	37	9.2
23	7.3	12.25	4	39.2	1.5	14.7	37	14
20	8.5	11.65	4	39.2	1.8	17.6	37	16.5
13	8.5	11.9	3	29.4	2	19.8	28	18.6
10	8	11.9	8	78.4	2	19.8	74	18.6
8	9.3	11.9	4	39.2	2	19.8	37	18.6
18	7.4	12.25	4	39.2	2	19.8	37	18.6
14	9.6	12.55	6	58.8	2	19.8	55	18.6
15	9.3	12.55	4	39.2	2	19.8	37	18.6
16	13.5	12.55	4	39.2	2	19.8	37	18.6
17	9	12.7	4	39.2	2	19.8	37	18.6
4	13.7	12.55	6	58.8	2	19.8	55	18.6
3	8.9	12.7	5	49	2	19.8	46	18.6
19	8.6	12.85	4	39.2	2	19.8	37	18.6
24	10.5	13.35	4	39.2	2	19.8	37	18.6
21	10.7	14.3	6	58.8	2	19.8	55	18.6
12	13	14.3	8	78.4	2	19.8	74	18.6
22	13.5	13.35	4	39.2	3	29.4	37	28
11	6.9	11.75	6	58.8	4	39.2	55	37
9	11.4	12.7	8	78.4	4	39.2	74	37
7	9.9	13	6	58.8	4	39.2	55	37
6	12	13.95	9	88.2	4	39.2	83	37
5	11.3	13.95	6	58.8	4	39.2	55	37
1	15.64	13.95	10	98	4	39.2	92	37

Table 4. Calculation of Q forces.

3.3. Data Analysis

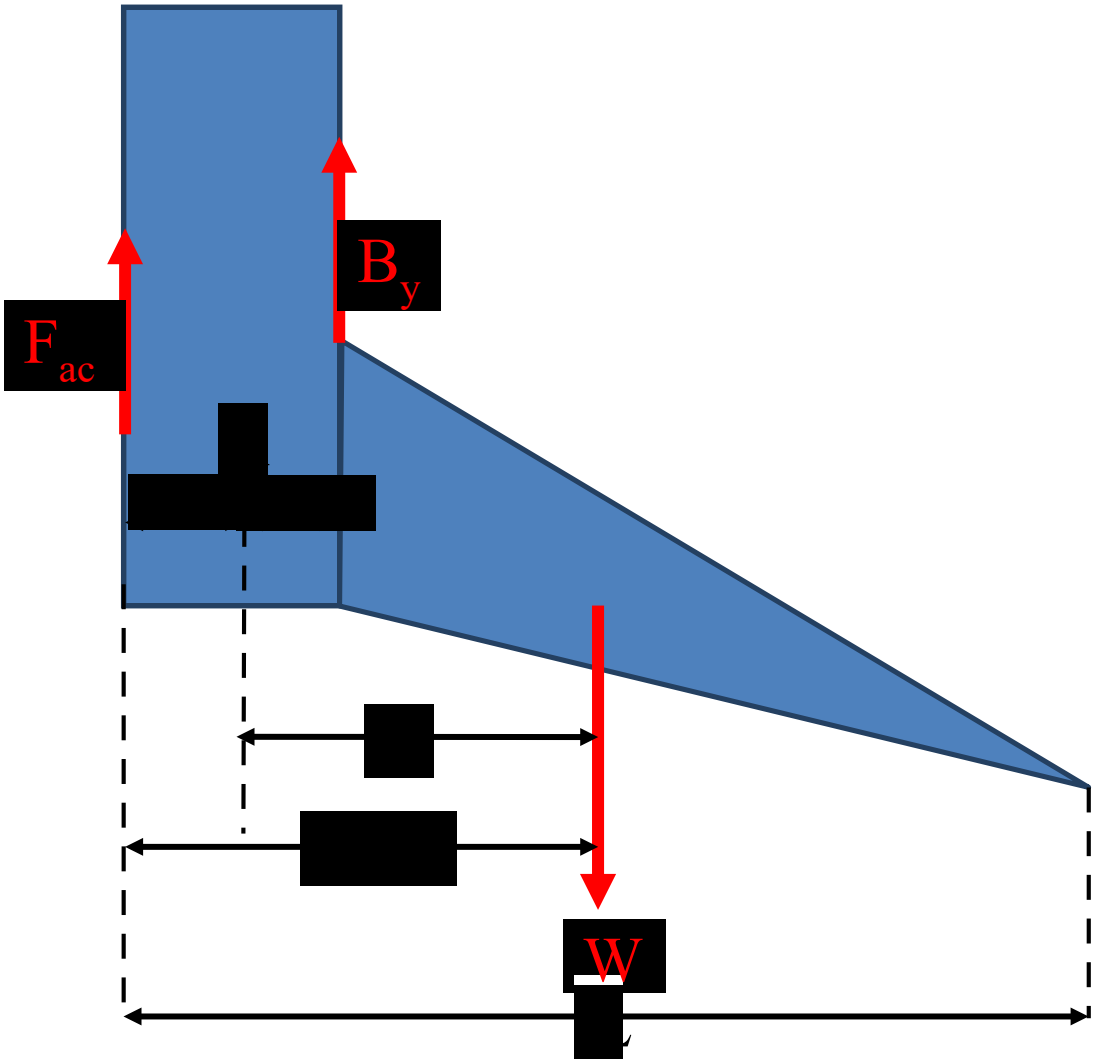


Figure 10. Foot Forces Diagram. [5]

!Y# + By#!Y# + By#

"B_y" the inferior extensor, force is calculated from the following formula:

' Moments = 0

$W \times D - B_y \times 0.05 + F \times 0.06 = 0$

$B_y = (1/0.05)\,[W \times (L/2 - 0.06) + F \times 0.06]$

Knowing that 0.05 is the center of rotation of the ankle complex.
W is the body weight multiplied by 1.4% to get the foot weight.

L is the length of the foot.

F if the force collected while achieving dorsiflexion and plantar flexion.

Figure 11. Active versus Passive force of 20 female normal.

The next step was to find a suitable stiffness k which leads to find the spring dimensions.

3.4. Physics behind the study

While designing a spring `there are so many physical properties and parameters, and laws should be respected. I will discuss in detail the calculation process till reaching the optimum values needed. First, there are restrictions in choosing the material. The material must be adaptable by human body therefore the best option was stainless steel 316. However stainless steel 316 is available in the market and has an average price. In general, springs may be classified as wire spring, flat springs, or special shaped springs in our study we are seeing wire spring. There are variations within these divisions. Wire springs include helical springs of round or square wire, made to resist and deflect under tensile, compressive, or torsional loads. We designate D as the mean coil diameter and d as wire diameter. Now we define the spring index. [18]

$C =$ ■ (2-1)

It is preferable that this index ranges between 4 – 12. Ks is defined as shear stress:

$K_S = \frac{\#}{7\#789}$ (2-2)

The use of round-wire spring should always be considered since they have an economical advantage over the special- section of the spring as well as a strength advantage. Furthermore, we can move to the curvature effect. The curvature of the wire causes a localized increase in stress on the inner surface of the coil, which can be accounted for with a curvature factor this factor can be applied in the same way as a stress concentration factor. This factor has a direct effect on the shear stress.

$K_W = \frac{;;}{77<<9;} + 0.614C$ (2 – 3) $K_A = \frac{;;}{778<\#B}$ (2-4)

The first of these K_w is called the Wahl factor, and the second the Bergstrasser factor since the result of these two equations differ by the order of 1 percent K_b is preferred. K_b is defined as Bergstrasser factor.

To predict, T that is defined as the heat stress using the stress-correction factors we will use:

$T = K_A \frac{C}{E^{D2}3F}$ (2 - 5)

Deflection of helical spring: the deflection force relations are quite easy to be obtained by using Castiglioni's theorem:

$K \approx C^3 2^G{}_F H_I$ (2 - 6)

Spring material: Springs are manufactured either by hot or b cold working processes, depending upon the size of the material, the spring index, and the properties desired. Winding of the spring induces residual stresses through bending. But these re normal to the direction of the spring torsional working stresses in a coil spring. Spring material may be compared by an examination of their tensile strengths; these vary so much with wire size that cannot be specified until the wire size is known. The material and it's processing also,

of course influence tensile strength. It turns out that the graph of tensile strength versus wire diameter is a straight line for some materials when plotted on log-log paper.

S_{ut} is defined as tensile strength.

$S_{KL} = 3\_\_\__{MN}$ (2 - 7)

A very rough estimate of the torsional yield S_{sy} strength can be obtained by assuming that the tensile yield strength is between 60 and 90% of the tensile strength:

0.[redacted] S_{KL} (2 - 8)

The recommended range of active coils is [redacted] to maintain linearity when a spring is about to close, it is necessary to avoid gradual touching coils (due to non-perfect pitch). A helical coil spring force deflection is ideally linear. While designing a spring a strategy must be followed: choose a wire size "d", with all decisions made, generate a column of parameters d, D, C, OD or ID, Na, Ls, L0, and from B_y incrementing wire size available, and cavity limitation which the spring will be inserted in the elimination of happens. The recommended spring to be less outer diameter then 1 cm and length less then 4 cm. Moreover, the spring with the highest security factor is preferable.

Extension springs: extension spring differ from compression springs in that they carry tensile loading they require some means of transferring the load from the support to the body of the spring, and the body is wound with the initial tension. Stress in the body of the extension spring are handled the same as compression springs. In designing a spring with a cross hook end, bending and torsion in the hook must be included in the analysis.

Using the following equation:

$\sigma_M = F[K_M\ 9EY32F + E;3Z]$ (2 -9)

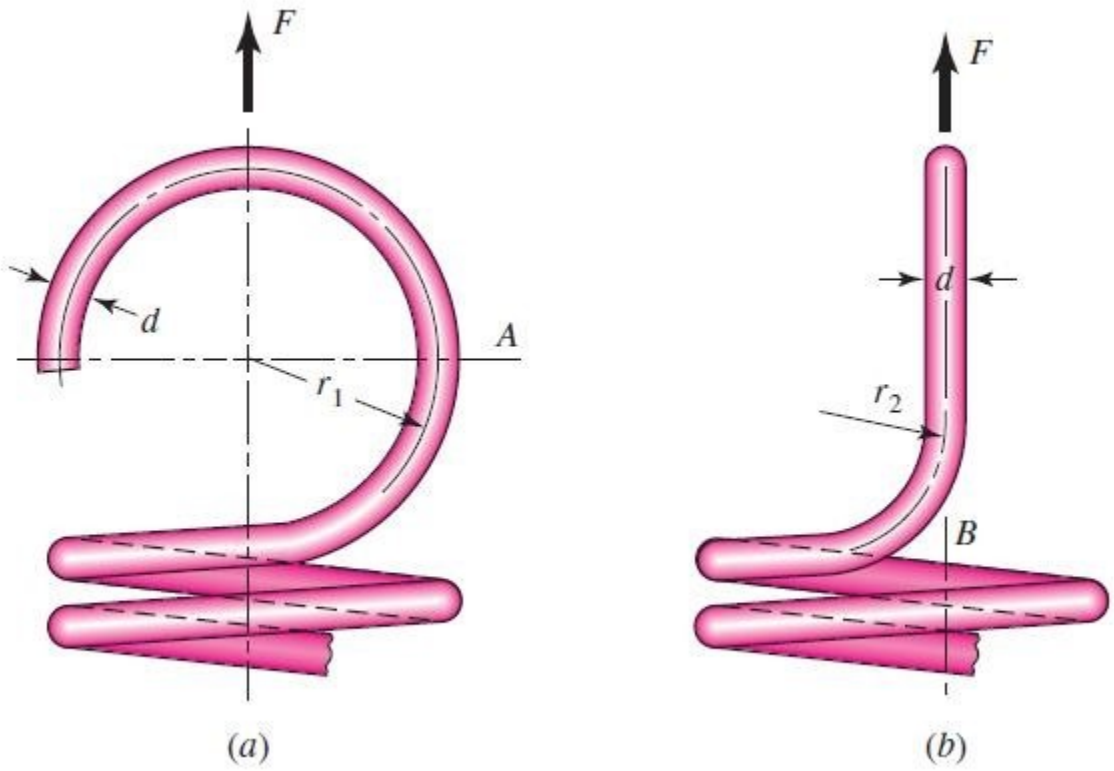


Figure 12. Hook end.

Also (KA) is a bending stress- correction factor for curvature given by:

$$K_M \quad \frac{7^Z < 7_\ < 9}{} = ;; \quad 7\backslash(7\backslash<9)$$

$$C_9 = \frac{\#}{\_\_3} \quad {}^{-Z} \qquad (2 - 10)$$

When extension springs are made with coils in contact with one another, they are said to be close wound. Spring manufacture prefer some initial tension in close wound in order to hold the free length more accurately. The corresponding load-deflection curve

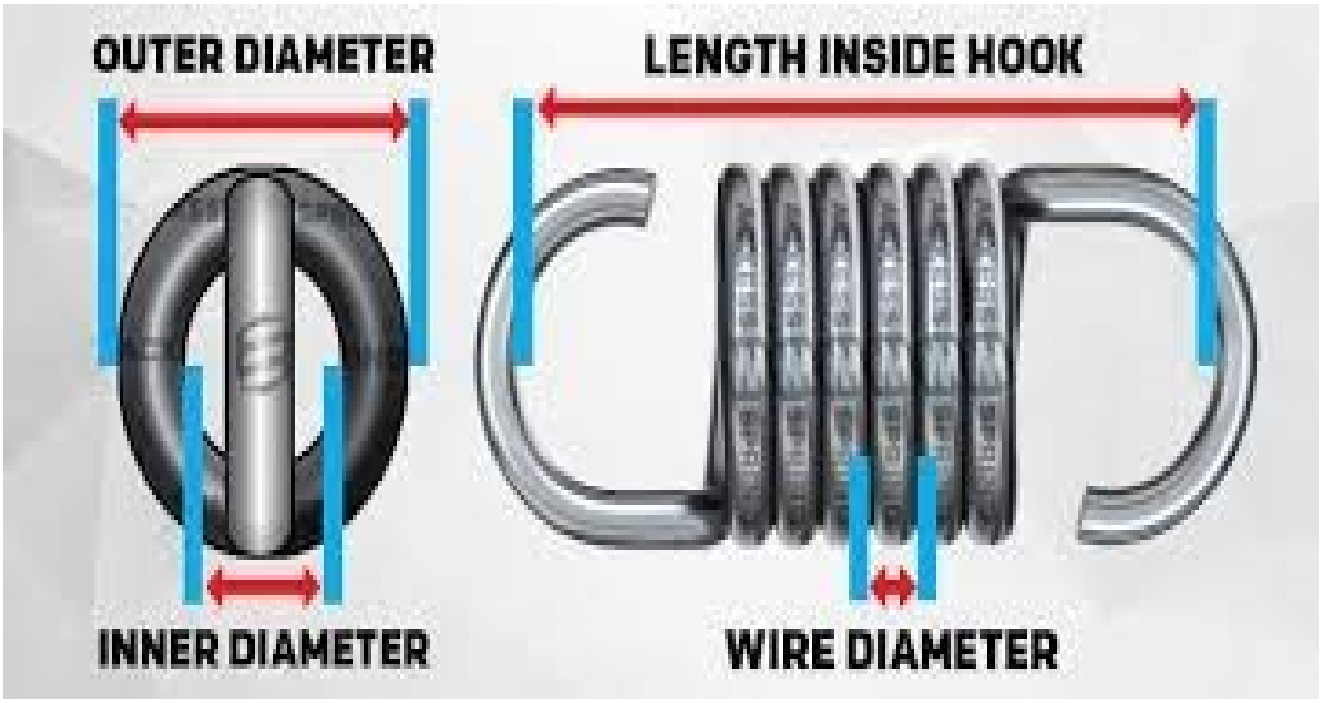


Figure 13. Parameters measurement.

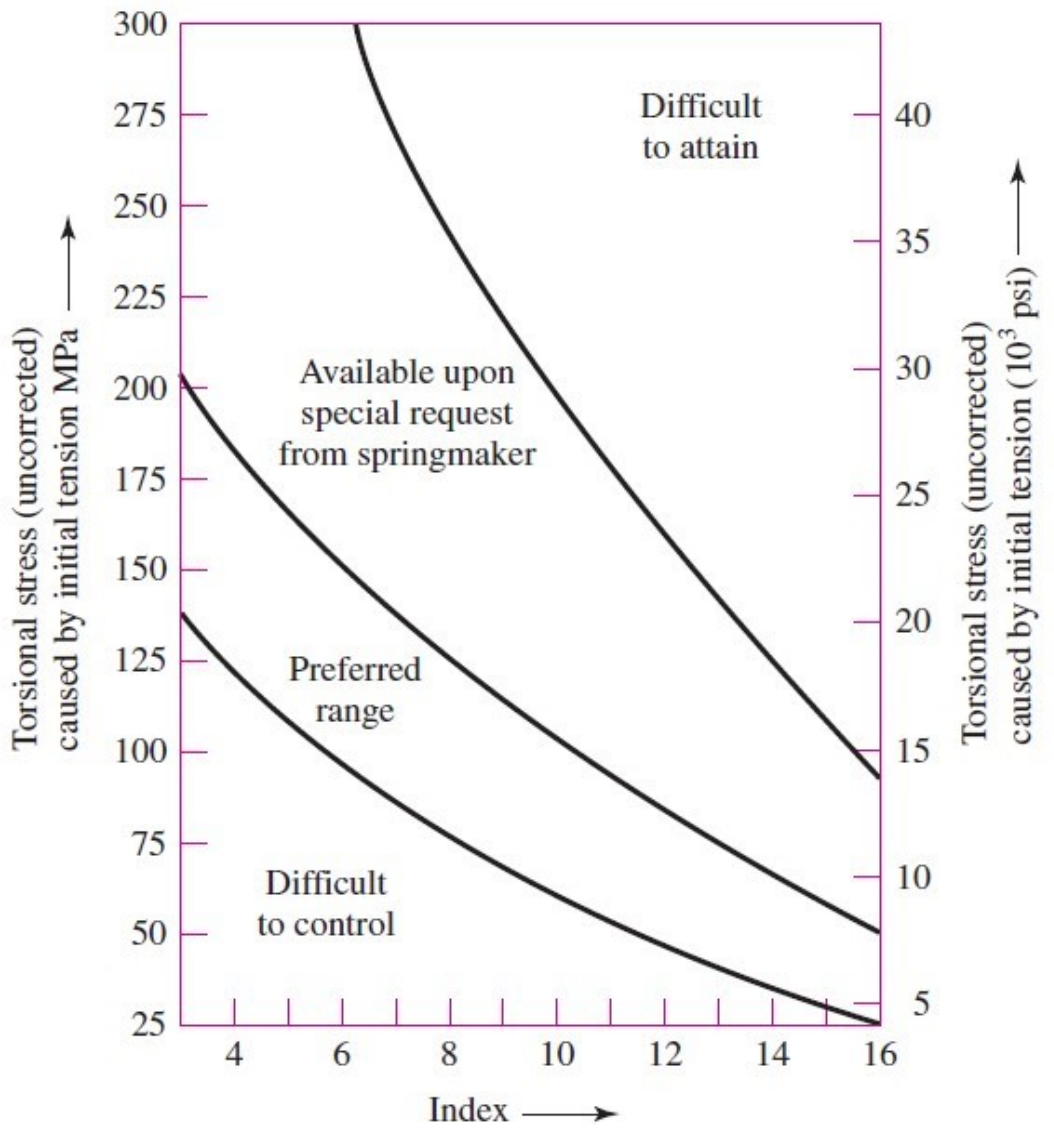


Figure 14. The initial tension.

Free length is L0 and Fi the initial tension in the spring that must be exceeded before the spring deflects. So, the deflection relation:

$$F = Fi + Ky \qquad (2-11)$$

Where K is the spring rate. The free length L0 of a spring measured inside the end loops or hooks as shown in the figure 12. L0 can be expressed:

$$L_c = 2(D-d) + (N_A + 1)d = (2C - 1 + \quad N_A)d \qquad (2\text{-}12)$$

D is the mean coil diameter.

Nb is the number of body coils.

C is the spring index.

Na is the number of active coils.

$N_h = N_A +$ ^{H_i} (10-40)

G is the shear modulus.

E is the tensile modulus of elasticity.

3.5. Results

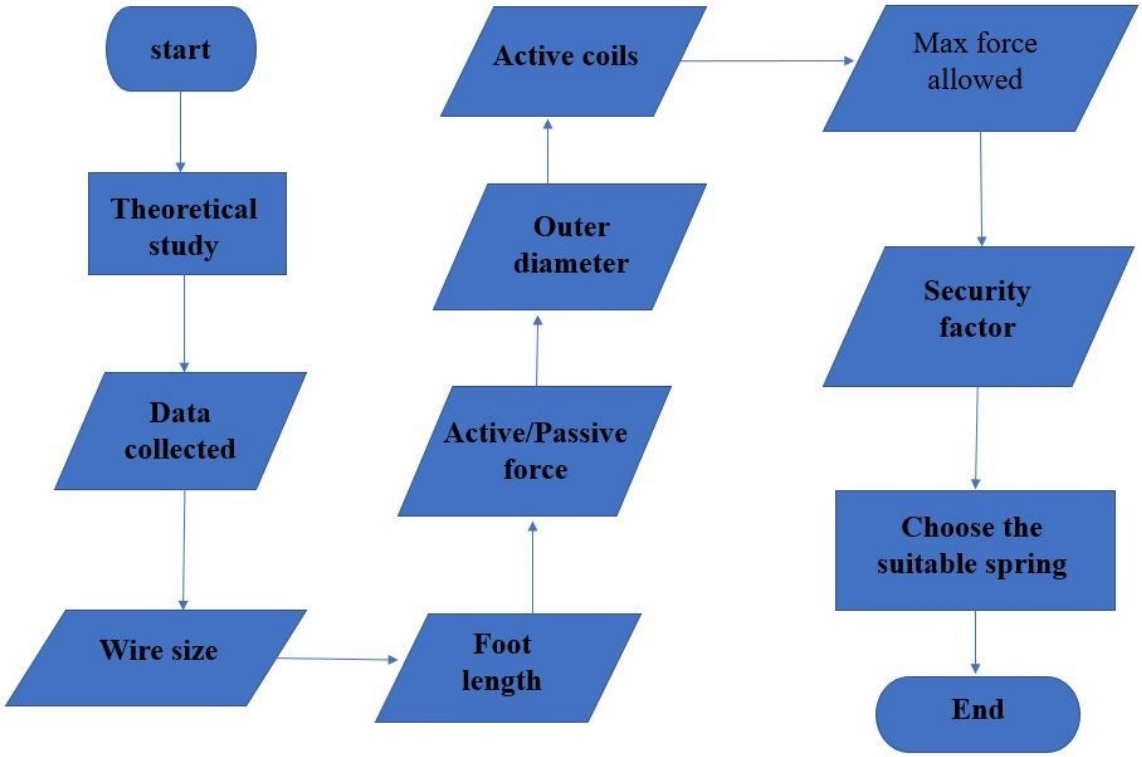


Figure 15. Flowchart.

Indexes from 4 to 8 was calculated on different wire dimeter due to limitation in the market. We can only find 1.2mm, 1.4mm, 1.6mm, 1.8mm, 2mm. this factor helped in limiting the options. Also, filter was made to eliminates the unwanted springs because their limitation does not fit the cavity in the human body.

Conditions:

Outer diameter less than 10mm,

[redacted],

$0 < \Delta l \leq 1mm$, Maximum

Load $>$ By Max,

Maximum load at A $>$ By Max.

4. DESIGN IMPLEMENTATION AND PROBLEMS FACED

In this chapter the design drawing and parts label and problems faced are discussed in detail.

4.1. Design drawing

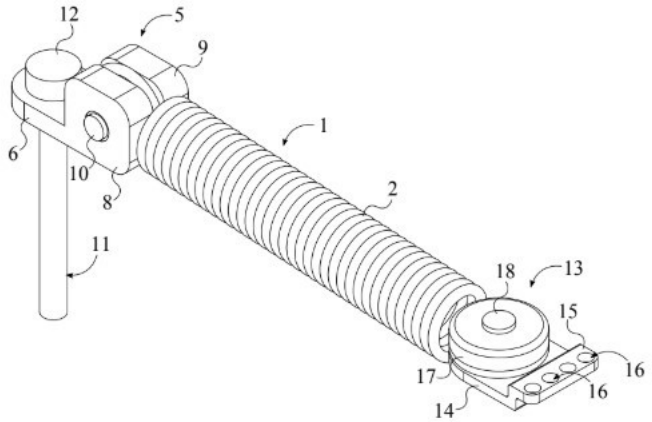


Figure 16. Design top view.

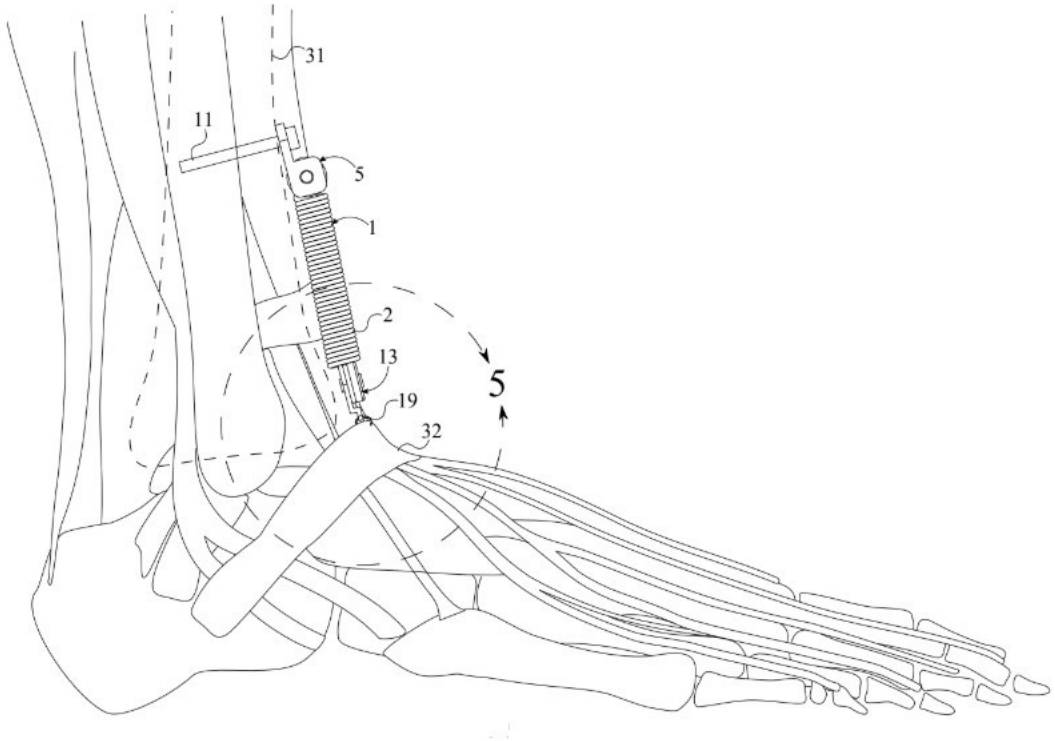


Figure 17. Side view.

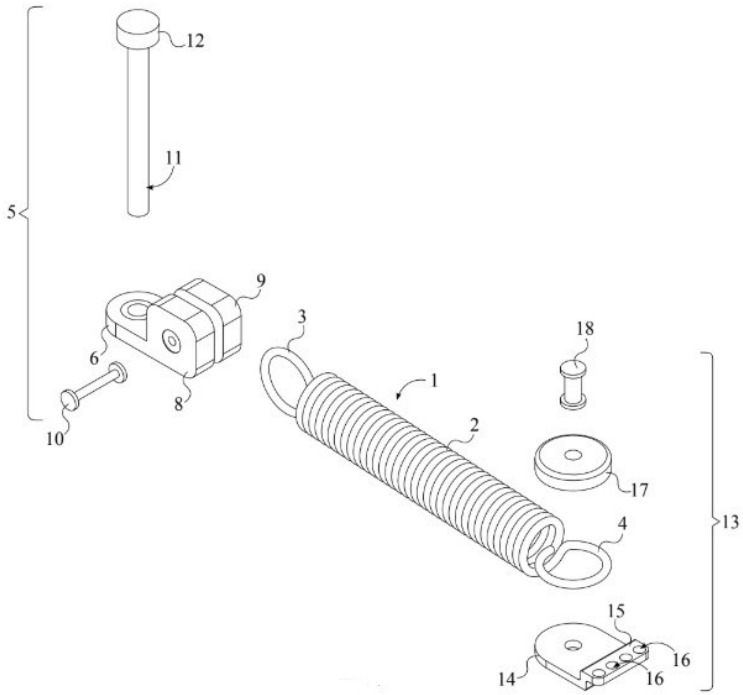


Figure 18. Compartment of the device.

4.2. Design Mechanics

1. Spring outer diameter should be less than 1 cm due to the shortage in space inside the food of the patient.
2. Wire diameter should be less then 2mm to have an acceptable stiffness.
3. Diameter of the first turn of the spring should be maximum 1 cm.
4. Diameter of the last turn should be perpendicular to the first and same size.
5. Upper attachment should not be long.
6. Length of the surface is not more than 4 cm.
7. Height of the upper attachment not more than 2 cm.
8. Edge from the bottom should not be sharp.
9. Edge from the top should not be sharp.
10. Screw should be internal and should hold the spring.
11. Screw length more than 4 cm to hit the boon.
12. Diameter of the screw is 4 mm.
13. Lower attachment.
14. Edge is never sharp.
15. 4 holes in raw.

16. Each hole is 2.5 mm.
17. Might not be applicable.
18. Screw to hold the spring.

After all the calculations were made, we looked at the springs that were available to us. They were made from stainless steel and used to oppose the force of the extensor compartment. We added two attachments to both ends of the springs enabling them to be attached to the tendon using Ethilbon sutures which are a surgical, no absorbable, braided, and sterile type of suture composed of Polyethyleneterephthalate. The sutures themselves are comprised of high molecular weight, long-chain, linear polyesters that have recurrent aromatic rings as an integral component. Each are uniformly coated with polybutilate or poly {oxy-1, 4 butanediyloxy-1, 6-dioxo-1, 6 hexanediyl}. The highly adherent coating is a relatively non-reactive and no absorbable compound which acts as a lubricant to modify the suture's physical properties and consequently improve its handling qualities. The suture is braided to optimize handling and is dyed green to enhance its visibility in the surgical field. [19]

In future development, we will be looking into covering the spring device with a different material such as that of The Leeds-Keio ligament which consists of an outer capsule made up of bundles of collagen fibers running perpendicular to the long axis of the ligament. Septa were seen emerging from the capsule and composed of bundles of collagen fibers surrounding the bundles of Dacron fibers. Each thread of Dacron was surrounded by a layer of connective tissue containing periodic acid-Schiff (PAS)-positive cells. The bundles of collagen fibers making up the outer capsule, the septa and the layer of connective tissue surrounding the Dacron threads were positive for anti-type I collagen antibody. The rehabilitated Leeds-Keio ligament presented a specific organization at the septa zone, showing a layer of collagen fibrils alternating with a layer of cells. [10]

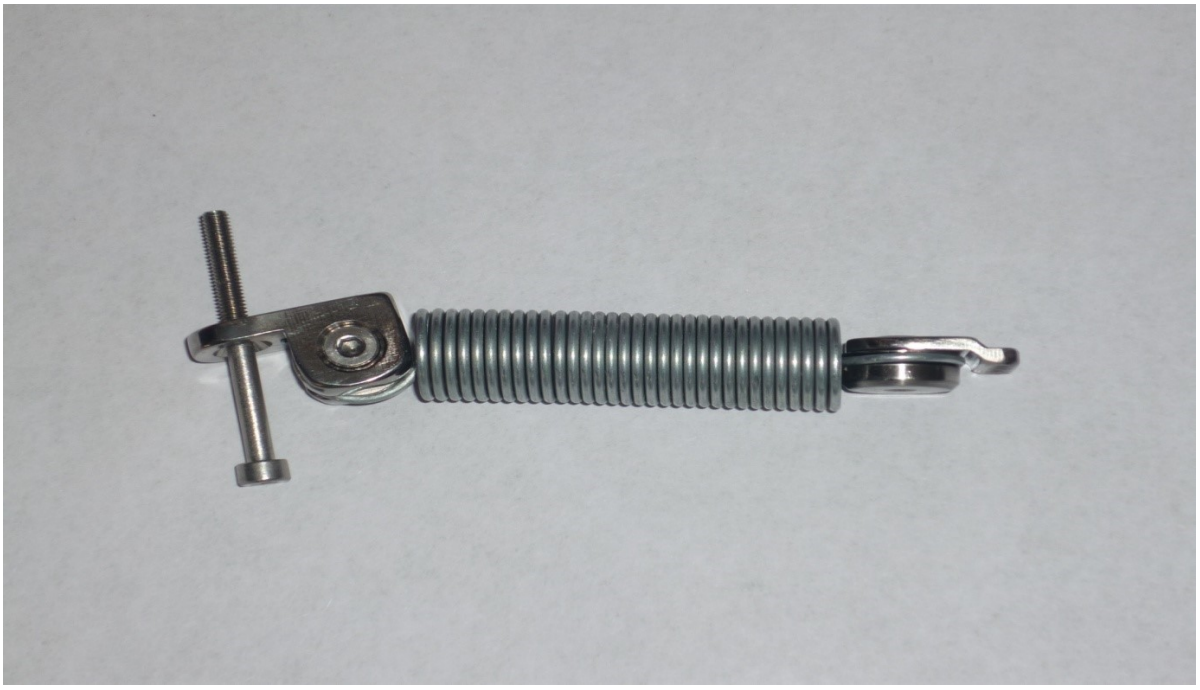


Figure 19. Design of the spring lateral view.

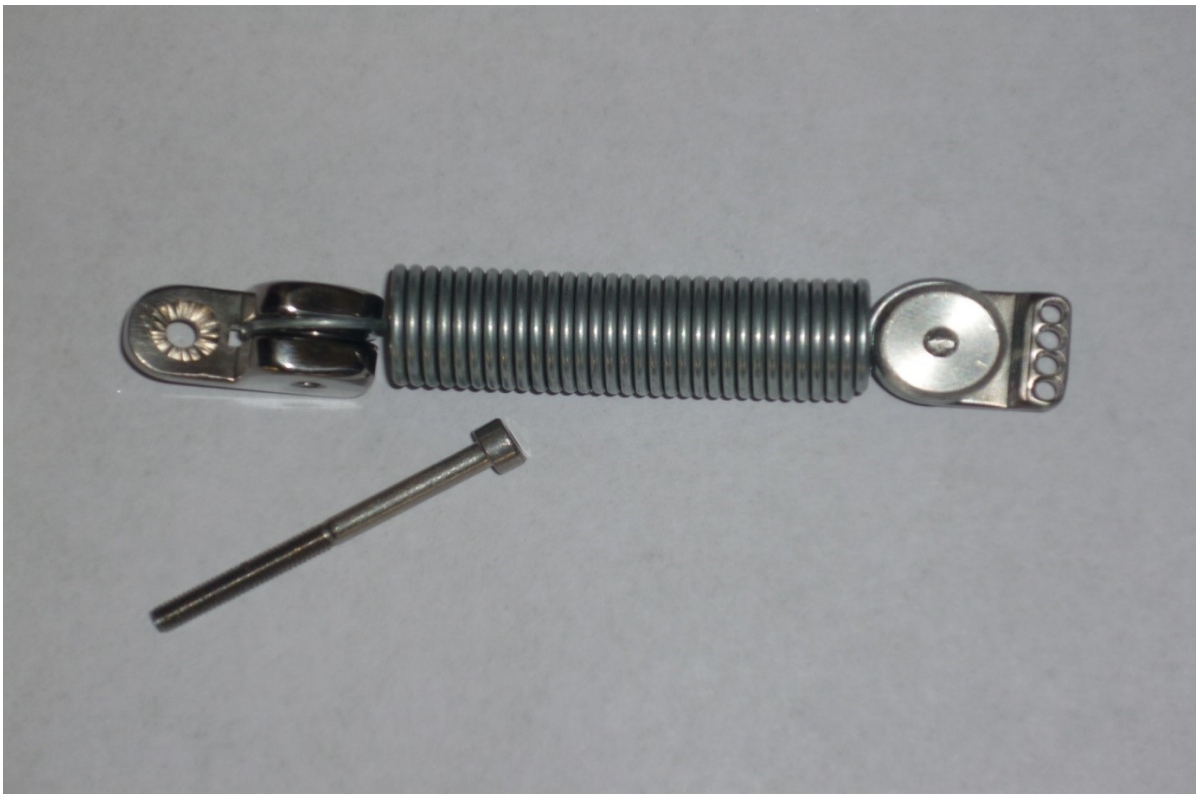


Figure 20. Design of the spring AP view.

Once the device was created (Fig19&20), we implemented it into two cadaveric limbs at anatomical laboratory for thorough evaluation. This procedure has happened under the supervision of prof. MUDr. Tomáš Trč, CSc., MBA, who implemented one

device himself. He successfully did that, and it has been tested by himself. The procedure as quite of a success. Then the following day, we implemented in another fresh cadaver, and the results were identical. But before we did the trial, we created and followed a protocol which can be seen below.

5. PROTOCOL

The next phase of this project was to test the device. We used cadaver to test the spring, looking at the range of movement it offered, the forces exerted and generally, its function. The disadvantage of using cadaveric tissue was that it differed from living human tissue in terms of joint stiffness and could not offer the same range of movement as a living person which, therefore, could produce inaccurate results in terms of forces and false expectations of how the device would work in reality.

For that, we introduced the following protocol:

Aim:

1) To determine the forces required for intact dorsiflexion and plantar flexion of the foot. This will be achieved simply by using a spring balance to measure the force required.

2) To dissect down to the anterior tibialis, isolate the tendon and estimate the forces needed for dorsiflexion of the foot using a spring balance.

3) Attach the proximal part of the device to the lateral surface of the tibia using bone screws, measure the anatomical position of the attachment and then attach the distal part of the device to the site where the muscle tendons insert into so that the foot dorsiflexes when the spring is activated (dorsiflexion will be measured using a goniometer). After these procedures are carried out, the spring's length will then be measured. NB the position of the device will have to be adjusted to dorsiflex the foot.

4) Measure the forces needed to plantar flex the foot whilst also measuring the spring length and measure the degree of plantar flexion. Following this, the implant will be moved proximally onto the tibia, the anatomical position measured, and the procedure repeated. This will be carried out in at least 3 different positions.

Steps:

1- We requested cadavers and were allocated by laboratory attached to the Second Faculty of Medicine, Charles University.
2- The cadaver's leg was then prepared by measuring the shoe size (which is in our case 42 or 10), the cadaver was then placed in the neutral position.
3- The range of movement was being tested before the dissection (15 degrees in extension and flexion).

4- The heel strike was being tested before the dissection and was found to be normal.
5- The forces exerted by the Achilles tendon was measured before the dissection (which was found to be approximately 3 kg or 29.4 Newton).
6- The skin was then dissected.
7- The length of movement of the tendon was then measured and was found to be approximately 2 cm in both flexion and extension.
8- Tenotomy of the anterior compartment of the leg well above the superior extensor retinaculum. In our study, we dissected the Anterior tibialis and the extensor digitorum only. The reason for this was that if the tibialis anterior was dissected solely, the foot would extend in inversion. However, if also we attached the device to the extensor digitorum than the foot will have a normal range of movement.
9- Measuring the angle of foot drop as it is only the Achilles exerting forces. This was found to be equal to approximately 15 degrees.
10- The spring then had to be measured with a 3kg weight attached to it. The length was measured and found to be 10 cm. In order to achieve the desired results, we had to stretch the spring to 10 cm and then attach it both distally and proximally.
11- Insert the spring into the leg under the anterior compartment with the foot held in the neutral position.
12- Attach the proximal part of the tendon with Ethilbon 1, with the distal end of the spring being attached through a hole that was created.
13- Next step was to test the spring and analyze the range of movement of the foot.
14- Steps 2,3,4 & 5 were then repeated after everything was in place.
15- Finally, the results were recorded thorough videos and pictures which are attached.

6. RESULTS

Once the cadaver was dissected, it was found that the extensor tibialis and extensor digitorum were working together in order to extend or dorsiflex the foot.

We monitored the movement of the tendon and found that it moved a maximum of approximately 2 cm in each direction from the neutral position. Taking this into consideration with the anatomy of the superior and inferior extensor retinaculum, they both remained intact to keep the tendon in place and facilitate a full range of motion of the foot.

On the contrary, we decided to move away from the superior extensor retinaculum and divided the tendon approximately 2-3 cm above the superior border. This was done to provide an easier range of movement for the tendon to cover the spring with muscle, preventing it from being in contact with the skin and thereby preventing irritation and device failure.

Therefore, we dissected both tendons and attached them to the distal part of the spring. The spring itself was already under a tension of 3 kg and had been attached to the proximal part of the bone. It was attached with a screw that had been inserted into the bone. The screw was durable and inserted using a 2 mm drill. The tendons were then attached with Ethilbon sutures (type 1) which are made from a very strong material and a modified Kessler knot was tied on the tendon where a 4-hole attachment was designed specifically for the spring.

As a result, the foot was held in Neutral position with extension of the toes but there was no foot drop. (Fig. 21, 22)

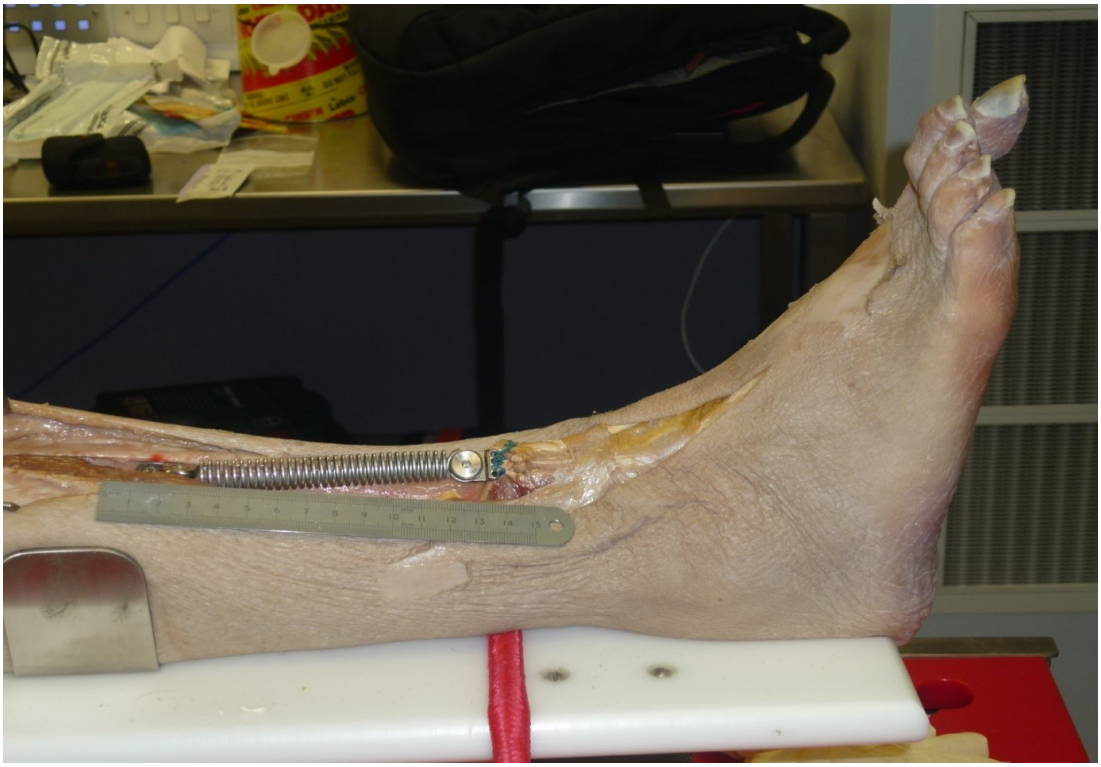


Figure 21. Device in situ holding the foot in extension (Dorsiflexion).

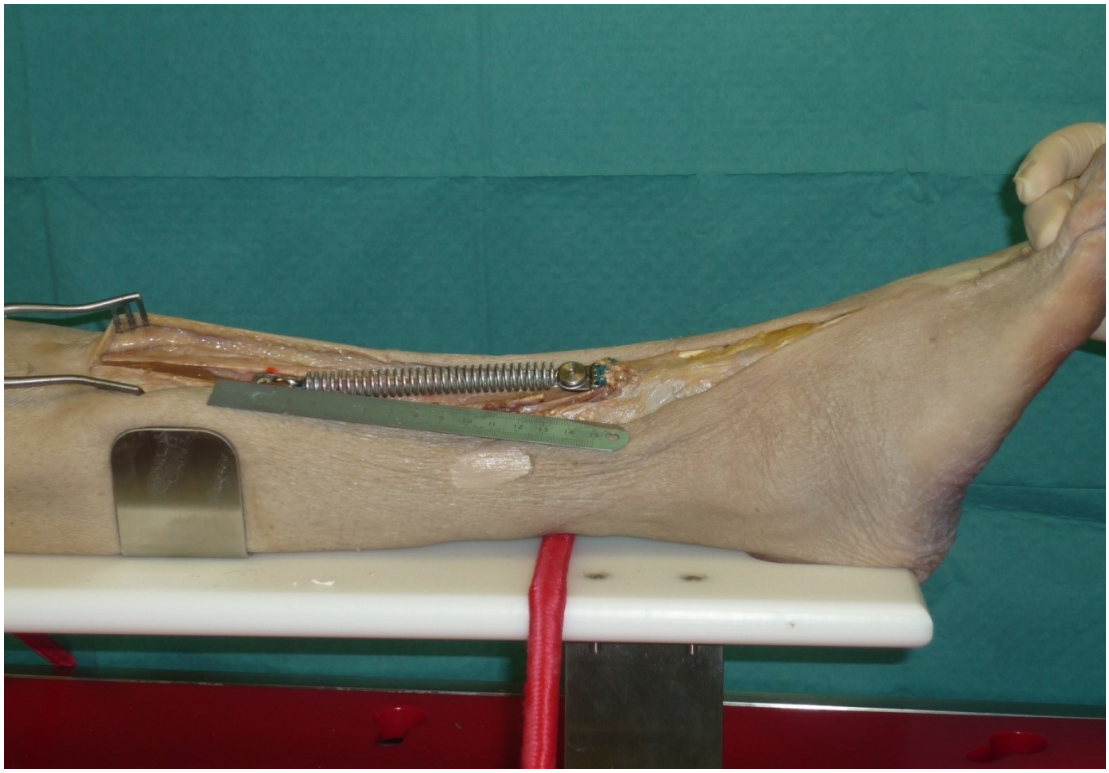


Figure 22. Device in Situ in full flexion (plantar flexion).

7. REAL IMPLEMENTATION

After finishing all the study necessary and following successful trial on cadaver the challenge was to identify the first patient in the world who will volunteer for such project.

Before doing that, an official request for patent has been made and seeks from the US patent department. The patent took almost 2 years to be approved but this has been achieved and the Grant Number is **(US9788936B2).**

Not only, after we received the patent, we moved forward with an application for Ethical approval from the Lebanon Ministry of health and Medical council. This was approved by the local ethical committee.

The following step was to find the first ever volunteer patient who will be accepting the surgery and accepting the cons and pros of the surgery.

Once the first patients have been found, we went through all the ethical explanation of the nature of the surgery. Not only, but we explain the nature of the complication and he might need further surgeries and more than once until the device will reach it final stage. After his full consent, the surgery has been carried out in July 2019.

The surgery has been carried out exactly similarly to the cadaver protocol with only one difference that the tendon was kept intact, and the foot was held in completely neutral position.

The patient has walked in the second day, and he walked almost perfectly fine with no foot drop, and he was able to do almost full heel strike.

This was the case for 3 months until the spring has failed and then we enter the final phase of the implant improvement and study.

7.1. Final improvement

After failing, the team started to look at the problem more closely that led to such a failure. It has been found that the Wolfs law was not met, and the spring has failed due to the forces that has been exercised over time over the spring. The latter has failed the spring.

The other point, the team found out and suggested that different foot weight must have different spring diameter in order to strengthening it. It was suggested that for instance, a body mass of 100 kg needs 1.6 or 1.8 mm spring diameter. While female foot needs to have 1.4 and 1.6 mm. The other suggestion was that the Achilles' tendon forces vary between male and female, between an athlete and normal person and finally between the bodies weight.

Taking into consideration all the above, it has been decided to create 4 different sizes for spring diameter.

The diameter has to be 1.2 mm, 1.4 mm, 1.6 mm, 1.8 mm. The rationale behind this idea, that all the diameter has to be available in order to achieve best results. For instance, a kid will need 1.2 mm, where a man of 120 kg will need 1.8 mm. But the dilemma was how to choose?

It has gone through the mind that before surgery, every single patient will go a full preparation in the clinic. He/she will have their body weight taken, foot weight taken and calculated, the full strength of the Achilles' tendon taken.

Taking into consideration the above calculation methods that has been discussed, and using the formula that has been achieved, we started to match the patient to the adjuvant spring.

The initial patient has been re-operated very successfully in January 2020 and he is still happy with the results until today.

Furthermore, 3 more patients had the device inserted and they are still doing well.

One of them however, had an open wound without infection and after full investigation, we found out that his skin doesn't close by any means after surgery and it takes such long time. Therefore, the device was taken out.

The device will be implemented in more and more patients once the final prototype became perfect or an industry will adopt it.

8. DISCUSSION

Foot drop is a deceptively simple name for a potentially complex problem. Foot drop can be associated with a variety of conditions such as dorsiflexion injuries, peripheral nerve injuries, stroke, neuropathies, drug toxicities, or diabetes.

There are many conditions associated with foot drop: Peroneal neuropathy caused by compression at the fibular head is the most common compressive neuropathy in the lower extremity. Foot drop is the most notable symptom. All age groups are affected equally but it is found to be more common in males (male-to-female ratio, 2.8:1). Ninety percent of peroneal lesions are unilateral and can affect the right or left side equally.

Foot drop as a result of peroneal nerve palsy is of particular concern to orthopaedic surgeons. It is seen after total knee arthroplasty or proximal tibial osteotomy. The estimated rates of this complication occurring are 0.3-4% after total knee arthroplasty and 3-13% after proximal tibial osteotomy. [20] Ischemia, mechanical irritation, traction, crush injury, and laceration may also cause intraoperative injury to the peroneal nerve. Correction of a severe valgus or flexion deformity has also been suggested to stretch the peroneal nerve and lead to palsy. Postoperative causes of peroneal nerve palsy include hematoma or constrictive dressings.

In a study by Cohen et al, the relative risk of palsy was 2.8 times greater for patients who had received epidural anesthesia for total knee arthroplasty than for those who received general or spinal anesthesia. [5] One postulation is that epidural anesthesia is likely to decrease proprioception and sensation, and this continues to some extent postoperatively, allowing the limb to rest in an unprotected state, susceptible to local compression. However, it is important to note that intraoperative neurological damage may not have been readily apparent in the immediate postoperative period due to ongoing effects of epidural anesthesia. In this same study, the relative risk of palsy was 6.5 times greater in patients who had a prior lumbar laminectomy.

A series of patients who developed foot drop following primary hip arthroplasty were carefully examined and found to have spinal stenosis. [21] Up to 70% of patients undergoing hip arthroplasty have electromyography evidence of nerve injury, but they rarely have clinical symptoms. [2] Patients with pre-existing spinal stenosis are believed to be at increased risk for foot drop following hip arthroplasty because of this proximal compromise. This is the double-crush phenomenon described in more detail in the pathophysiology section.

In terms of treating foot drop, there are many methods that can be used.

8.1. Medical Therapy

Foot drop is a very distressing injury, and the correct level of attention must be given to the patient's psychological needs. If painful paranesthesia's develop, they can sometimes be effectively managed with sympathetic blocks or laparoscopic synovectomy. Alternative treatments include the use of amitriptyline, nortriptyline, Pregabalin, and gabapentin. Local treatment with transdermal capsaicin or diclofenac may also alleviate symptoms. Even if there is significant pain, narcotic medications should be kept to a minimum. Optimizing glucose control in diabetic patients and managing vitamin deficiencies with supplements of B-1, B-6, or B-12 may also serve a useful purpose.

Erythropoietin is a naturally occurring hormone that is approved by the Food and Drug Administration (FDA) for the treatment of anemia but also has neuroprotective and possibly neurotrophic properties. The proposed mechanism of action is anti-apoptotic and anti-inflammatory, thereby promoting cell survival. Erythropoietin is given in 3 doses of 5000 U/kg over a week following nerve injury. It has a minimal side-effect profile and animal studies have shown that erythropoietin treatment has accelerated functional recovery after peripheral nerve injury. [22]

Treatment of foot drop is directed by its etiology. If foot drop is not amenable to surgery, an ankle-foot orthosis (AFO) is often used. An AFO is also used during surgical or neurologic recovery. The specific purpose of an AFO is to provide toe dorsiflexion during the swing phase, medial and/or lateral stability at the ankle during stance, and, if necessary, push-off stimulation during the late stance phase. An AFO is helpful only if the foot can achieve plant grade position when standing. Any equines contracture prohibits its successful use.

The most commonly used AFO in foot drop is constructed of polypropylene and inserts into a shoe. If it is trimmed to fit anteriorly to the malleoli and provides rigid immobilization. This is used when ankle instability or spasticity is problematic, such as in patients with upper motor neuron diseases or stroke. If the AFO fits posterior to the malleoli (posterior leaf spring type), plantar flexion at heel strike is allowed, and push-off returns the foot to neutral for the swing phase. This provides dorsiflexion assistance in instances of flaccid or mild spastic equinovarus deformity. A shoe-clasp orthosis that attaches directly to the heel counter of the shoe also may be used.

In patients in where foot drop is due to hemiplegia, peroneal nerve stimulation can be considered. This type of stimulation was first applied in 1961. Nerve stimulation has advantages to the AFO, as it provides active gait correction and can be tailored to individual

patients. In this system, a short burst of electrical stimulation is applied to the common peroneal nerve between the popliteal fossa and fibular head. A switch in the heel of the affected limb controls this burst. The stimulator is activated when the foot is lifted, and it is then stopped when the foot contacts the ground. This achieves dorsiflexion and eversion during the swing phase of gait.

In a study by Ring et al, the effects of a radiofrequency-controlled neuro-prosthesis were compared with those of a standard ankle-foot orthosis (AFO) in 15 patients with foot drop caused by stroke or traumatic brain injury. The authors found that compared with AFO, the studied neuro-prosthesis enhanced balance control during walking and, thus, more effectively managed foot drop. [15]

The nerve stimulator can be either external or implanted and radiofrequency activated. The use of electrical stimulation in stroke patients with spastic hemiplegia, was reported to be useful in approximately 2% of the cases. This method may enhance the gait speed and quality, and it can contribute to motor relearning. [23]

8.2. Surgical Therapy

Foot drop due to direct trauma to the dorsi-flexors generally requires surgical repair. When nerve insult is the cause of foot drop, treatment is directed at restoring nerve continuity, either by direct repair or by removal of the insult.

If foot drop is secondary to lumbar disc herniation (a finding in 1.2-4% of patients with this condition), consider discectomy. In the early phase of this condition, decreased blood flow due to compression is thought to lead to nerve root ischemia. The nerve root is more susceptible to compression injury than is the peripheral nerve because the vascular network of the nerve root is less developed, with no regional arteriolar blood supply. Foot drop due to nerve root injury may depend on the magnitude and duration of nerve root compression. Early decompression is recommended in cases accompanied by severe motor disturbance, especially in older patients. [24] A Japanese study of 46 patients with degenerative lumbar disease who presented with drop foot, noted that palsy duration and preoperative strength were the factors that most affected recovery after surgical intervention. [3]

Foot drop following hip replacement can also be treated with sciatic nerve decompression, particularly if there is any concern about bleeding at the operative site. Shortening of the hip prosthesis may be helpful if the limb was lengthened during surgery. [25]

A review of surgical management of peroneal nerve lesions demonstrated that neural repair is the first priority in selected patients with peroneal nerve palsy. [26] This may be accomplished with nerve decompression (either central or peripheral) or nerve grafting or repair. For foot drop from deep peroneal nerve injuries of less than 1-year duration, one study has reported success with transfer of functional fascicles to deep peroneal-innervated muscle groups, using either the superficial peroneal or tibial nerve as a donor. [27] Failing sufficient recovery with those measures, tendon transfer procedures may be considered. It has been suggested that a tendon transfer may be considered if there is no significant neural recovery at 1 year. If a foot drop is chronic and accompanied by contracture, Achilles tendon lengthening may be necessary to achieve adequate dorsiflexion.

In patients in whom foot drop is due to neurologic and anatomic factors (e.g., polio, Charcot joint), arthrodesis may be the preferred option. The goal is to achieve a stable, wellaligned foot and ankle. This may be accomplished via ankle arthrodesis, Lis franc arthrodesis, and triple or pantalar arthrodesis with or without Achilles tendon lengthening.

We can see clearly from the above method of treatment that they are very complicated, and the success rate is very low. Therefore, our new device has a huge advantage over currently available options as it is a device that it will be implanted under skin, it is cosmetically non-visible and compensate for the muscles that have been affected by a common peroneal nerve injury.

Moreover, the device itself does not need to have Tenotomy of the muscles as it can be stitched to the distal end of the muscle without the need for dissection.

This device is the 1st generation as it has some drawbacks; for example, it is a long device measuring approximately 10 cm, making it difficult to be accepted commercially.

Another problem is that its design is at a very preliminary stage, therefore we do not know how the device will fare for the patient in the long term in terms of longevity and adaptation to living tissue.

A potential setback may be due to the fact that stainless steel was used to create the spring which may prove to be sub-optimal in terms of durability causing it to erode the muscle and surrounding soft tissue. Consequently, this could lead to early failure of the device. Therefore, in future development stages we would like to use different materials such as titanium or one that possesses properties similar to that of an elastic band to achieve better stability, a higher level of durability and a smaller size.

One more problem has been creating a contour for the device. It is very important to have a sleeve for the spring because without it, it can result in the soft tissue sitting in

between the coils of the spring, causing the device to work sub-optimally or fail all together. On the other hand, using a spring sleeve would increase the diameter of the device, altering its cosmetic features and potentially making it harder to market the product commercially.

Perhaps the largest constraint to this project would be gaining ethical approval. Even before that stage, we would need to obtain more cadavers for further modification and testing of the device.

Due to the time constraints of the study, we were only able to create the implant from stainless steel. Ideally, with more time we would like to test different metals.

9. CONCLUSIONS AND FUTURE WORK

This idea of the device is simple in itself and has tremendous potential to be a very useful product in the future in the treatment of foot drop and its associated complications.

The device has many advantages compared to current treatment options, the main being those of a cosmetic nature as the device is internal and therefore not visible. It also provides an improved level of mobility and if suitable as a long-term treatment, the patient will be able to resume as normal level of activity as possible.

The device has very successful results as it achieved the goals to bring the foot in extension against the Achilles tendon forces.

The device has achieved almost complete normal gait with foot in 90-degree extension.

The device was managed to become so small so it will be very cosmetic to certain extend and we can bury it under the skin.

Given the potential, this device could be a success, however, it will need further development, and this will begin after an application for patency of the idea, research and ethical approval has been obtained. We also hope to start testing it in animals as soon as possible.

10. SUMMARY

The first aim of the study was to determine the problem with foot drop and the real anatomy and the concerns about it. Not only, but to confirm the hypothesis whether any endoprosthesis device will be a successful to aid the patient who suffer from foot drop to

walk normally. The results showed that the endoprosthesis will work very well in cadaver but unfortunately, we are not able to apply to a human being as yet. At the same time, we achieved that the endoprosthesis can contra force the Achilles tendon and it will balance in a way the patient walking almost normally. The second goal was to assess whether the device itself will have enough potential before it fails and the most important is to make sure that the endoprosthesis will be available for every individual. Hence, the patients differ from size to size and from weight to weight. Not only, but they differ from force to force. The hypothesis was partially confirmed. Although, there is huge difference between cadaver and real human body. The forces will be different, the motion will be different, and the needs are different. Therefore, the actual work must continue in order to achieve the best results with the best endoprosthesis.

The main contribution of this thesis to the current knowledge is a new invention that has tremendous future. This new invention is a pure mechanical endo-prosthesis. However, the endo-prosthesis allows patients restore normal motion. Moreover, comparing this new treatment to other treatments resulting freedom of choosing footwear, full recovery, lower cost, lifetime treatment. The patient will have great stepping gait and he will feel himself like any normal person. The patient probably will be able to go back to normal life and this is including sports if the device is well developed. In our study and our case, our hypothesis regarding the steppage gait and the functionality of the device worked very well and we achieved it in positive manner despite that the device will need further development. The endoprosthesis which was put in the cadaver has achieved its potential. This has been showed by the publication as well as presentation that took place in the IEEE and has been proven as new invention for new era. [18]

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FIGURES

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