CHARLES UNIVERSITY

Second Faculty of Medicine

Summary of the Dissertation

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 implantátu

Bassel El-Osta

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Author: Dr. Bassel El-Osta

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

              Department of Orthopaedics and Traumatology

              Second Faculty of Medicine, Charles University

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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 bio-medically 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.

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1. Introduction

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. [1] Foot drop is a problem that the patient is not able to dorsiflex due to problem in the extensor muscles. The muscles are supplied by the fiber derived from the L4-S1 nerve root and it called common peroneal nerve. The injury to this nerve can cause a permanent disability. [2]

The foot drop can be results of trauma, laceration, even after elective arthroplasty. 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. [3]

Considering 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.

This dissertation will focus on the creativity of the suitable endo-prosthesis, the forces and the contra-forces that will be generated, finally on the behavior and the mechanical issues of the device.

2. Aims and hypothesis of the work

The problem of foot drop is critical for patient normal life, and it does create significant disability. So, the principal aim of our study is to create a unique biomechanical prototype device that would improve the quality of life for patients suffering from foot drop and from injury to the common peroneal nerve.

For this purpose, we will be creating and using Bio-Mechanical endo-prosthesis which will fit surgically under the skin.

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.

3. Material and Methods

3.1. Idea development

The idea of the PD came after studying the mechanism of the muscles in dorsiflexion. The skeletal muscles are organized multi nucleated myofibers, whose function is to generate length and velocity dependent forces for movement or stability. Their function depends on their intrinsic properties and extrinsic arrangement. [4] The parallel elastic component is suggested to consist of the membranes surrounding the contractile components which includes the sarcolemma, sarcoplasmic retinaculum, [5] the perimysium and the epimysium, while the series elastic components reside in the tendons and aponeuroses. [6] 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. [7]

3.2. Approach

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 [8] or approximately 2 kilograms. 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 plantarflex their foot (active), after which the device operator brought the foot back up to the neutral position to the measurement of the passive force.

3.3. Calculation of Achilles tendon 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). 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 (Bx) and at the junction between the extensor mechanism and inferior extensor retinaculum, a 90° vertical line was drawn (By). 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. So, we used the following Physic formula to calculate Achilles tendon forces using the below parameters.

$T = 0.05$ 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)

W = Body Weight * 1.4% * L / 2

$F = 9.8 * W$

$By * T / (\cos(-10)) = (W * D) + (F * L)$

3.4. Calculation of the vector 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. Another line was then drawn from the center of rotation along the angle of the metatarsal bones using X-rays for accuracy. A line perpendicular to the 180° plane was

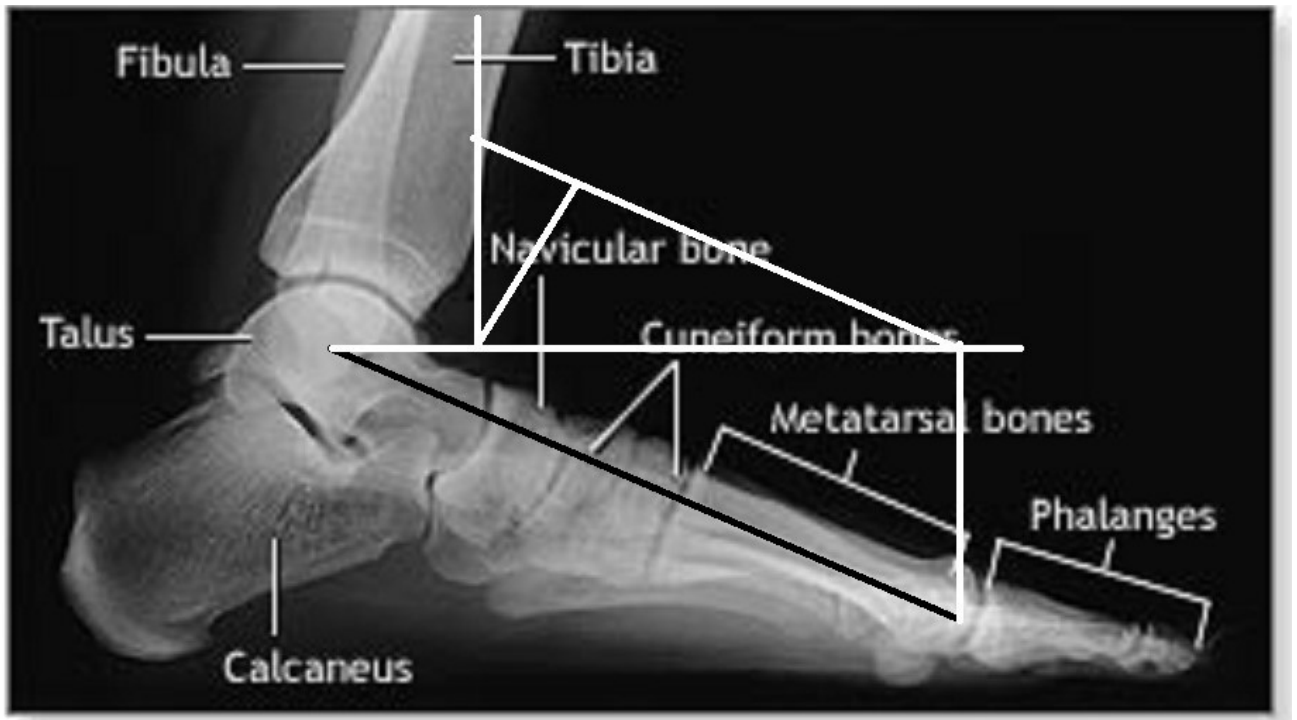then extended to the line along the metatarsal plane. This created a triangle, the 3 borders being By X and Y.

Figure 1. Foot X-ray showing the vectors of forces.

The vectors are presented in different directions which will lead to calculate the forces using the appropriate formulas in order to obtain the absolute and correct strength and weight.

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

$$X2= \overline{!Y^{\#} + By^{\#}} \overline{!Y^{\#} + By^{\#}}$$

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

The formula to calculate the movement was:

$$Xm = X - Xp = Y/\cos20 - Yp/\cos10 = 6.2 \text{ mm}$$

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. (Fig 1)

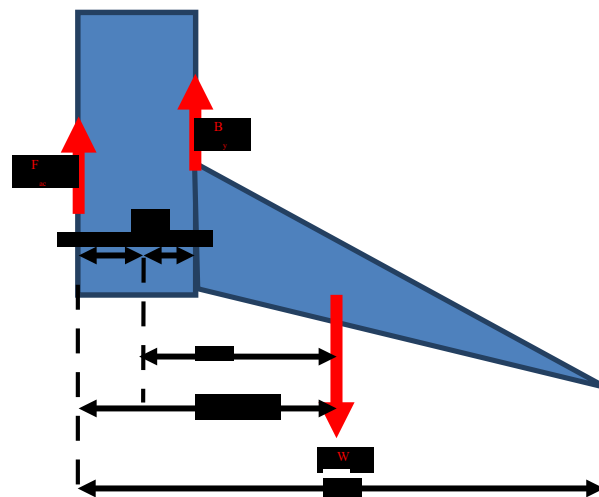## 3.5. Data Calculation Formula

Figure 2. Foot Forces Diagram.

The foot diagram showed the distance from the center of motion posteriorly and anteriorly. Not only, but the distance from the center of rotation to the mid-point for weight as well as from the flexion forces towards the mid weight point.

$$\overline{!Y^\# + By^\#} ! \overline{Y^\# + By^\#}$$

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

$$' \text{Moments} = 0$$

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

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

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. (Fig 2)

3.6. Physics behind the study

There are so many physical properties and parameters, and laws should be respected. there are restrictions in choosing the material. The material must be adaptable by human body therefore the best option was stainless steel 316A. We opted to use Wire springs which 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:

$$C = \frac{D}{d}$$

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

$$K_5 = \blacksquare$$

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.

$$K_9 = \text{::}\underline{\quad}\text{;;}<<=: + 0.614C \qquad K_A = \qquad \text{::}\underline{\quad}\text{;;}B<\#C$$

The first of these Kw 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 Kb is preferred. Kb is defined as Bergstrasser factor.

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

$$T = K_A D\underline{\quad}\text{GEFHI}$$

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

$$K \approx \frac{\text{HJK}}{\underline{\quad}\text{DFIL}}$$

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.

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.

Sut is defined as tensile strength.

$$S_{NO} = \frac{A}{d_Q}$$

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

$$0.\,\blacksquare \qquad S_{NO}$$

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

is 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:

$$\sigma_w = F[K_w \pi \overline{dc} + \frac{16D}{\pi d\#} \quad \frac{4}{}]$$
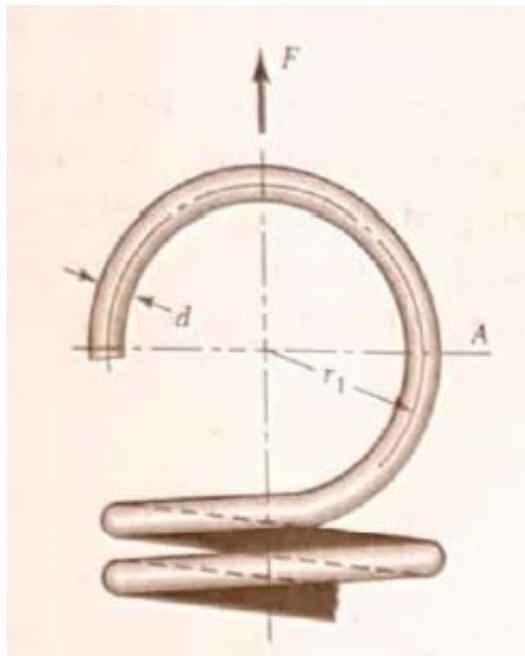

Figure 3. The Hook Diagram.

The hook is showing the different distances from the center of cross diameters, the radius as well as the forces plus distances. This diagram is used in order to calculate the forces exercised by the hook of the spring.

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

$$K_w = \quad \blacksquare$$

$$C = = \underline{\quad} d \quad \frac{2 \quad r\#}{}$$

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. (Fig 3)
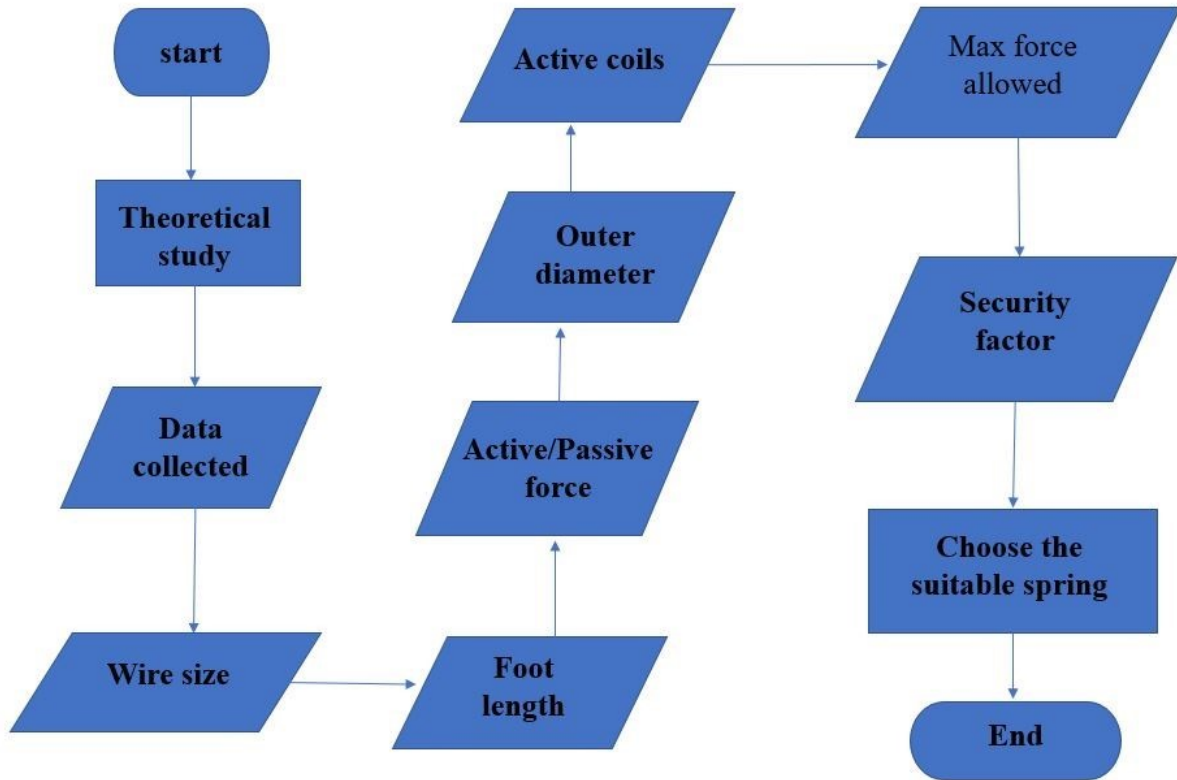
4. Results

Figure 4. The Flowchart.

This particular chart showed in the process of creation of the device from start to an end. The chart is to make sure and clear that every single step is well performed and adjusted accordingly and will be compatible with the following step.

Spring strength was calculated on different wire dimeter due to limitation in the market. We can only find 1.2 mm, 1.4 mm, 1.6 mm, 1.8 mm, 2 mm. 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 should be the following: Outer diameter less than 10mm. (Fig 4)
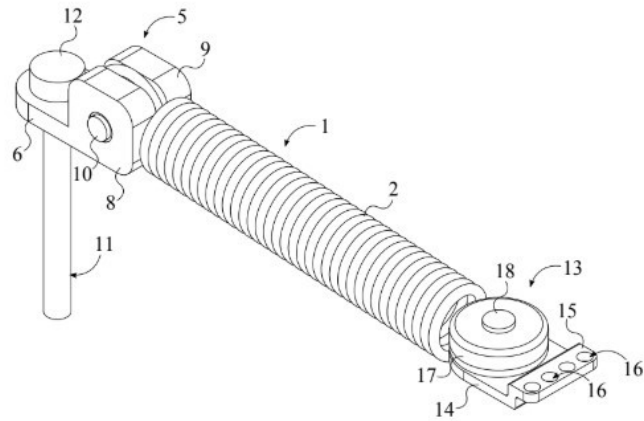
4.1. Design drawing

Figure 5. Design top view.

The view is showing the full device assembled where the top end will be attached to the bone with a screw and the distal part will be attached to the muscles using PDS.
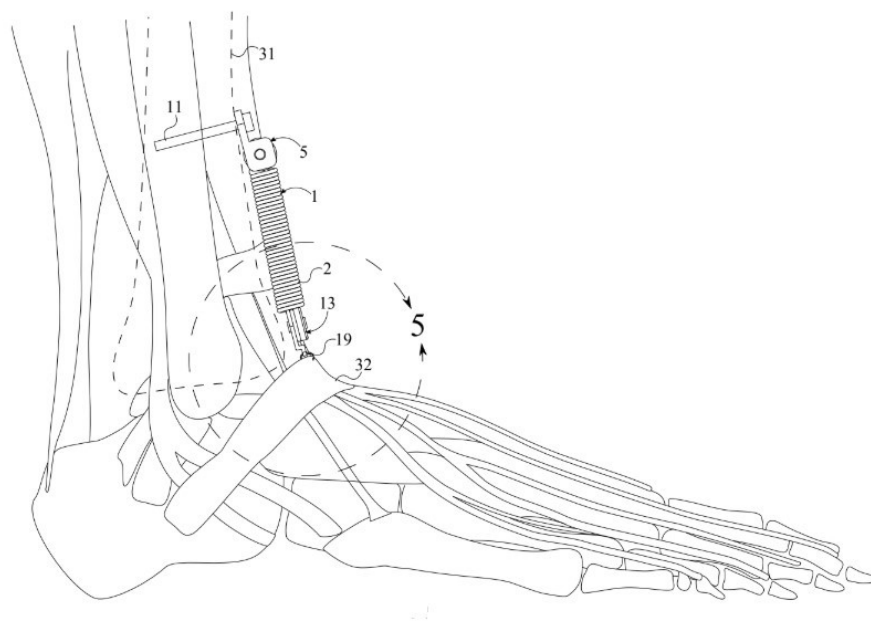

Figure 6. Side view.

This is the projected attachment of the device to the foot in the final design.
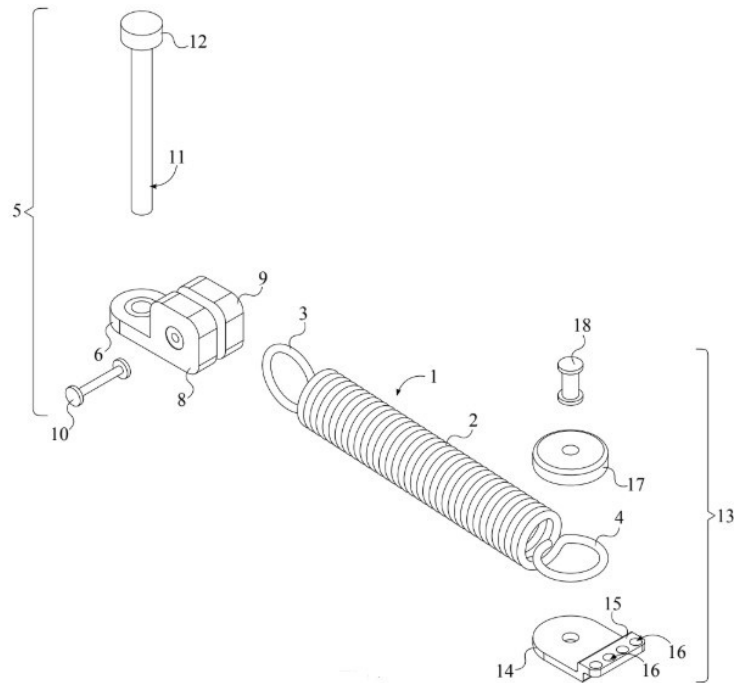
Figure 7. Compartment of the device.

This diagram is showing the different part of the device which is consistence of 7 items, and they will be assembled very easily during the operation.

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. Four holes in raw.

16. Each hole is 2.5 mm.

17. Might not be applicable.

18. Screw to hold the spring.

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 Polyethylene terephthalate. 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. 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.

We implemented it into two cadaveric limbs at the FN Motol anatomical laboratory for thorough evaluation. This procedure has happened under the supervision of prof. Trč 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.

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 2mm 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.

An official request for patent has been made and seek 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).**

The first patients have been found and we have gone 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. (Fig. 5, 6 and 7)

5. Discussion

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 as a result of peroneal nerve palsy is of particular concern to orthopedic surgeons. It is seen after total knee arthroplasty or proximal tibial osteotomy. [9] 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 terms of treating foot drop, there are many methods that can be used.

5.1. 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 paresthesia'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. [10] The most used AFO in foot drop is constructed of polypropylene and inserts into a shoe.

5.2. Surgical Therapy

Foot drop due to direct trauma to the dorsi-flexors generally requires surgical repair. If foot drop is secondary to lumbar disc herniation (a finding in 1.2-4% of patients with this condition), consider discectomy. 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. [11] It has been suggested that a tendon transfer may be considered if there is no significant neural recovery at 1 year. [12] 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, well-aligned foot and ankle.

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.

6. Conclusion

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.

7. 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. 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. [13]

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9. List of author's publications

Publications related to the dissertation thesis Publications

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El-Osta B, Wilson R. Concepts in Foot Drop Management - Review of the Current Literature. Acta Scientific Orthopaedics 2019. doi: 10.31080/asor2019.02.0106. IF 0.810 (2020)

El-Osta B, Kamali W, Hmouda B, Fawal M. Foot drop Inventory Management Sixth International Conference on Advances in Biomedical Engineering (icabme) ©2021 ieee | doi: 10.1109/icabme53305.2021.9604897   **IF 5.224** (2021)

Publications non-related to dissertation thesis:

Publications with impact factor (IF):

Moghul MR, El-Osta B, Osborne A, Hollingdale J. Multiple Sclerosis and Repeat Dislocations of Total Knee Replacements: A Case Report. Journal of Medical cases, doi: https://doi.org/10.4021/jmc391w **IF 0.757**

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