BACHELOR THESIS

REDESIGN OF AN OFF-LOADING ANKLE BRACE

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Abstract

Cartilage damage in the ankle is a common injury for younger active persons who e.g. perform sports and sprain their ankle. An osteochondral defect is a lesion involving ankle cartilage damage. Osteochondral defects often require microfracture surgery. The rehabilitation after the surgery can take up to 1 year before the patients can fully return to their sport. There is a potential benefit of off-loading the joint with for example a special ankle brace that can support the process of a weight-bearing recovery. Such a device is not yet on the market. The first design for an off-loading ankle brace has been made and tested in a previous project. The purpose of this study is to improve this design so that the device can be used for performance testing with healthy subjects. New requirements were set partly based on the problem analysis performed with the old device. The device should be for example comfortable for the user, sufficiently off-load the ankle, and have a maximum weight of 1200 grams. Several concepts were considered to improve the comfort and robustness of the device. The final design consists of two 3D-printed organic-formed PLA shells, one at the front and one at the back of the leg for support. The mechanical stop is improved to enhance performance and an extra strap is placed at the end of the levers to improve robustness. The levers are made adjustable for different heights. The device itself is 884 grams which makes it 300 grams lighter than the old device, which improved comfort. The new device has been tested through a pre-test questionnaire by 10 test subjects, and with a NASA Task Load Index by one test subject. There are still areas for improvement, but the brace has improved on the previous design in terms of comfort and robustness.

Contents

Introduction

Cartilage damage in the ankle is a common injury for younger active persons who e.g. perform sports and sprain their ankle. Cartilage damage [1] in the ankle can occur easily in sports involving running and jumping. An osteochondral defect is a lesion involving ankle cartilage damage, see Figure 1. This is a common problem for these active individuals due to the long rehabilitation time, and the fact that cartilage can never fully recover to its original structure[2]. Osteochondral defects often require surgery.

Figure 1 Representation of an osteochondral defect in de ankle [3].

Osteoarticular Transfer System procedure and a Microfracturing procedure are the two most used operations to repair cartilage damage [4]. Microfracture surgery is an effective treatment technique for osteochondral defects less than 15 mm. For this study, it is assumed that the lesion is less than 15 mm and the patients have undergone microfracture. Microfracture is performed to remove the damaged cartilage. The procedure of this operation is drilling small holes in the cartilage and the bone surface to stimulate the growth of new cartilage cells, see Figure 2.

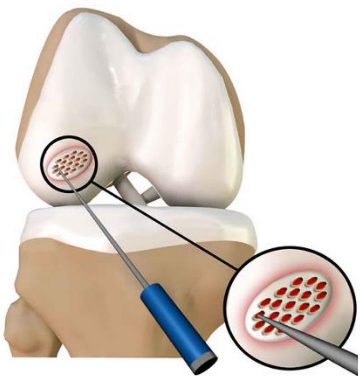

Figure 2 Microfracturing procedure[5]

Although microfracture surgery is a minimally invasive treatment, the rehabilitation can take up to 1 year[6] before the patients can fully return to their sport, without a new rehabilitation technic. Cartilage heals the best with mechanical forces such as the normal gait of the patient [7]. When the cartilage is damaged, the weight on the healing ankle in normal gait is too heavy. It is necessary for the recovery that the ankle muscles stay active.

In early studies, it was thought that in the first weeks after surgery no weight should be placed on the ankle. However, new studies[8] show that a faster recovery time is achieved if weight-bearing takes place immediately after the first post-surgery appointment.

The precise weight-bearing process can only be found in the literature for knee cartilage injuries[9]. In most of these studies, weight bearing is described as a few hours a day of weight bearing as tolerated, without specifying an exact percentage of body weight. Knee cartilage is much thicker than ankle cartilage and the rehabilitation after surgery is slightly longer than that of an ankle. Therefore, the values for weight bearing cannot be compared with knee and ankle rehabilitation.

There are rehabilitation programs [10] found in the literature that suggest a weight-bearing process for the ankle but with a walking boot and crutches. The programs do not suggest the precise weight, but it is known that for 6 weeks the allowed weight on the ankle should be slightly more each week.

In the first week, it is advised to not put any weight on the damaged ankle. For the next 6 weeks, partial weight bearing is encouraged to a point where it is still tolerated. If the rehabilitation is going well, patients are allowed to run 12 weeks post-surgery. They can return to their sports after 4 to 6 months.

An ankle brace to aid this recovery is not yet on the market. A weight-bearing recovery is now done with crutches. Since the target group for this recovery is often young and active, walking with crutches for at least 4 months can interfere with their daily activities. With crutches, it is also not possible to measure exactly how much weight is placed on the ankle and how much the crutches support. The weight-bearing process is therefore not reliable with crutches. Therefore, there is a benefit to an off-loading ankle brace device that can support the process of a weight-bearing recovery.

A design for an off-loading ankle brace has already resulted from a previous study [11], see Figure 3. The design of this brace consists of an attachment to the lower leg (Figure 3 C and D) with two levers (Figure 3 A) attached that is stretched by a spring. The attachment to the lower leg consists of a deformable custom plastic shell (Figure 3 D) and the levers are attached to this by a metal frame (Figure 3 C). While walking, the levers touch the ground before the foot and the spring is stretched, shifting part of the weight to the lower leg instead of the ankle. A mechanical stop (Figure 3 E) stops the stretched lever. The previous design was tested with a force plate, which showed that the device does off-load the ankle, meaning the device works. However, the device cannot yet be used, and needs improvement. The purpose of this study is to improve this design so that the device can be used.

Figure 3 The previous design with A) The lever, B) the bent end of the lever with in black the anti-slip material, C and D) the attachment to the lower leg with padding in D and E) the mechanical stop

Problem analysis

The prototype from the previous study does not yet meet all the needed requirements. The design must therefore be improved in various aspects. The parts of the design that need improvement are discussed in this section.

Several test subjects have been wearing the prototype of the previous study and walking a few meters with it. From these tests, several requirements came out that are not yet satisfactory.

These tests have shown that the mechanical stop of the old design does not work properly, see Figure 3 E. When stretching the spring, the lever detaches from the connection part and the mechanical stop. Due to an unexpected movement or hard release of the spring, it often happens that the lever shoots over the mechanical stop. When this happens, the mechanical stop no longer works, and the user must stop walking to manually return the lever to the mechanical stop. When the mechanical stop does not work properly, the levers are also not hitting the ground at the same time. The device will not be able to sufficiently off-load the ankle when the mechanical stop does not work. Another requirement that is not yet met is that the device must be robust and still work in case of unexpected movements.

Tests have also shown that when walking, the levers shear apart on the ground when the subject puts its weight on the levers, see Figure 4. This will cause the weight bearing to be different in practice than theoretically calculated with the correct spring. This will affect the ability to sufficiently off-load the ankle. The material around the end of the lever that is supposed to be anti-slip material does not work properly and is way too slippery and wears off quickly. This will make the levers slide apart even more on the ground. To prevent this an extra band at the levers is needed. Several places to place this extra strap were considered. In the middle of both levers would work best against the levers shearing apart, but this place is not possible because the strap would get in the way of the foot. The upper end of the levers was also considered as a place for the strap, but here the strap gets in the way of the heel of the foot. In the end, the best place proved to be the end of the levers, where the strap runs exactly over the user's toes and is the least in the way. Tests with the previous design showed that this works, and the levers no longer slide apart.

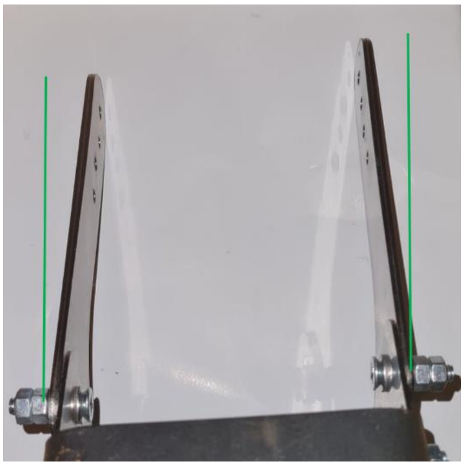

Figure 4 Representation of the levers shearing apart on the ground. The green lines represent the position of the levers when the subject puts weight on them.

All the test subjects mentioned that the device was also not comfortable and was able to move a lot around the leg. In the previous design, the connection to the lower leg consisted of a deformable custom plastic shell, see Figure 3 D. This would be a fitted connection to the leg if the device was person specific. To meet the requirements, the new design needs to fit around any leg without too many changes to the brace. This is not the case in the old design because the shell around the leg is custom-made for one specific user. The device does not stay in the same place around the leg while walking, which causes the brace to not work optimally. The report from the previous study also states that there should be a new method to fixate the device to the lower leg.

To ensure that the foot does not move too much in the brace while walking consideration has been given to an extra strap under the foot. This strap runs under the foot and is attached to the brace. This should prevent the brace from sliding up the leg. On the previous prototype, this extra band was tested out by adding this band and walking with it. The band seemed to do its job and the brace stayed better in place. However, a major problem with this extra band is that now there is again extra weight on the ankle while walking. In this way, the brace is not off-loading as much weight as wanted. Therefore, it is decided to omit this band and a new method for this problem should be thought of.

Not every patient has the same height but one of the new requirements of the device is that every patient should be able to use the brace. The previous design was based on a specific length. When the brace is used by smaller patients the back of the lever could hit the ground. This will lead to the device interfering with daily activities. In the new design, this part should not be able to hit the ground.

Requirements

To improve the design the device should met several requirements, these requirements are presented is this section. The requirements are deducted from the previous study and the problem analysis.

The set of requirements for the device from the previous study consist of the following requirements:

- Non-invasive device
- Adaptable level of unloading
- Enable daily activities
- Provide user comfort

This set of requirements will be added with new requirements which leads to the following requirements:

1. The device must be user-friendly and comfortable
    - Device should not interfere with the daily activities, walking and climbing stairs
    - Device should fit everyone and should be easy to put on and take off
    - Device must be as slim as possible, and the padding should be thick enough that the shin does not hurt

The first requirement states that the device should be as slim as possible and not hurt the shin. To not hurt the shin, the padding should at least be 1.5 cm thick, what testing with the old design has proven. To make the device as slim as possible and not interfere with daily activities, the levers should not be thicker than the old design, so thinner than 3 mm.

2. The device must be able to sufficiently off-load the ankle
    - The device must be able to off-load 100% of the body weight

- After that, the device should be able to off-load a certain % less body weight each week

In the second requirement, the worst-case scenario for 100 percent body weight is set at 90 kilograms. The device should be able to off-load this weight in the first days if the patient weighs 90 kg, but the device should also be able to off-load less weight such as 10 percent of the body weight in the last days of rehabilitation.

3. The device must be robust
   - Device should not have any parts that can break off or break down due to fatigue
   - Device must still work in case of unexpected movements

4. The device must meet all the material requirements
   - Device must be lightweight and not too heavy on the leg
   - Device material must be strong enough to lift 100% of the body weight
   - quickly and not slip, so it must have a high coefficient of friction

In the fourth requirement, it is stated that the device should also meet the material requirement. The device should not be heavier than a foot prosthesis so that the patient can wear the brace around the leg without problems. A normal foot prosthesis such as the New Elan from Endolite has an average weight of 1200 gram[12]. Therefore, the maximum weight of the device is set to 1200 grams. The attachment to the lower leg should not be heavier than a normal ankle brace, the maximum weight of the attachment is set to 400 grams. The material of the levers must be strong enough to lift 90 kg, this weight should be taken in consideration when choosing the materials of the device.

The friction force between the device and the ground should be as large as possible to prevent slipping. The friction force can be calculated using the following formula:

$F_{w,max} = \mu * F_n$

With μ being the coefficient of friction that depends on the two materials. The formula shows that to make friction force as large as possible, the coefficient of friction must also be as large as possible. In this study, it is assumed that the surface, on which the patients walk with the device, is concrete. The coefficient of friction between concrete and metal is 0.5, which is relatively low [13]. The anti-slip material must have a higher coefficient of friction than 0.5.

Concepts

From the problem analysis, several concepts were devised to solve the problems of the previous design and meet the set requirements. These concepts are discussed in this section.

Attachment to the lower leg

Multiple concepts for the attachment to the leg were considered. In the first concept, the deformable plastic shell was removed and replaced with 3 steel bands. In between these bands and the already existing attachment to the leg, a thick layer of foam should be added. The soft padding is supposed to fit the device around the leg without hurting the shin. By using less or more padding, the brace should be able to fit any leg. A disadvantage of this concept is that the metal frame is not an organic form, which means that the device still does not fit properly around the leg. The metal frame is also heavy on the leg.

A second concept was considered that is made from a plastic cone. In this way, the shell would be lighter than the metal concept. This cone still needed a thick layer of padding to ensure it would fit around any leg. The biggest problem with the previous design was the brace moving back and forth and not being able to secure the brace properly. In this concept, this is solved with an extra cone on the back of the leg, so on the calf, see Figure 5. This cone is smaller and narrower than the cone around the shin. Connecting the two cones together with Velcro ensures that the brace cannot move around too much, because it is also secured at the back of the lower leg.

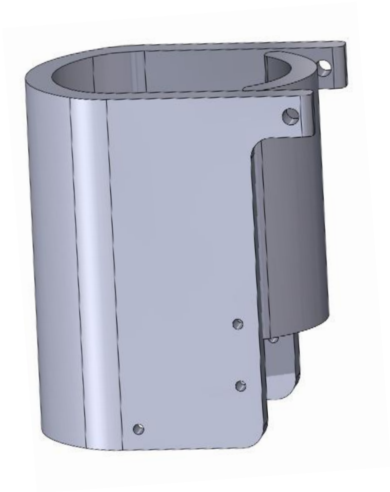

Figure 5 Drawing of the second concept, the front shell, and a back shell

The idea of the second concept is on the right track to improve the requirements 1 and 4 (comfort and lightweight). However, it still does not have an organic shape, so the chances of the brace staying properly in place are slim. Since almost every lower leg has a relatively similar shape, thinner at the bottom and wider towards the top, this shape was looked at to improve the concept. The third concept consists of the idea of the second concept, only in the shape they differ. The cone at the front is straight with an increasingly wide diameter towards the top, as a shin also has this shape. A general calf is not straight but has a curve. Therefore, the cone at the back is also curved and the diameter at the top is larger than that at the bottom, see Figure 6. This would require less thick padding to make this concept fit around any leg.

Figure 6 The front and back shell with an organic shape

Adjustable levers

Not every patient has the same height but in requirements 1 it is stated that every patient should be able to fit and use the brace. To make the lever adjustable, several concepts were considered.

The lever consists of two parts, the lever itself and the end of the lever which is curved. The first concept was based on the adjustable mechanism of a crutch as can been seen in Figure 7. In this concept, there are holes in the lever and buttons at the end of the lever. Because the buttons can fall into different holes, the lever is adjustable. If the lever is not round like a stool, this mechanism is very difficult to make. This is because with a flat lever, this mechanism is not strong enough and the button will easily fall out of the holes.

Figure 7 The adjustable concept of a crutch [14]

The second concept consists of an easier screw mechanism. There are four holes in de lever and two screws in the end of the lever part. The lever can be made longer and shorter by loosening the nuts on the end of the lever and placing both screws in the holes higher or lower and retightening the nuts. The advantage of this concept is that it is easy to implement. A major disadvantage is the user-friendliness of this concept. This is because the user cannot change the length of the lever by hand but needs tools to do so. For this reason, this concept is not ideal and a concept where no tools are needed to adjust the length of the levers should be looked at.

The last concept has the same screws as the second concept, but the holes are now replaced by a track. In this track, the screws can move from one hole to another hole without loosening the screws. These screws can move through the track and be clicked into two different height positions. The same method is used for the adjustable spring, the spring itself can move through the track in one of the two cut-outs. The track at the bottom of the lever is made so that while walking with the brace the screws will stay in place as can been seen in Figure 8. The force on the end of the lever is upwards and a little to the right, to make sure the screws are held in place, the track is also made to the right and upwards. While walking, the spring is stretched and has a force upwards and to the right, so the track is also made in this way to secure that the spring will stay in place. In this concept, the user can make the levers longer or shorter without using any tools. This is the main reason why this concept has been chosen to make the levers adjustable.

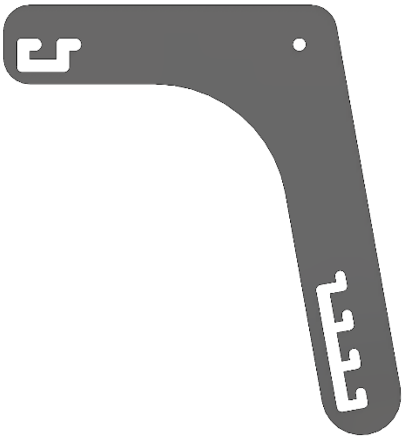

Figure 8 The tracks for the spring and the end of the lever on the levers.

Materials

Since a shell made of metal or steel is going to be too heavy around the leg, and therefore no longer meets the material requirements, other materials have to be looked at. Both shells have an organic shape, plastic is easily deformable, so different types of plastic were looked at. One plastic already used in other existing braces is ABS plastic [15]. ABS is a thermoplastic polymer consisting of acrylonitrile, butadiene, and styrene monomers. Acrylonitrile provides the resistance, hardness, and rigidity of this plastic. Another deformable plastic being looked at is PLA [16]. PLA is also and thermoplastic polymer and is the most widely used filament for 3D printing. PLA has a higher tensile strength[17] than ABS, namely 37 MPa and ABS 27 MPa. For this reason, PLA is more suitable as prototyping material for both shells than ABS is.
Furthermore, Nylon[18] was also considered, which also has high strength and stiffness. Nylon has a tensile strength of 50 MPa, which is a lot higher than PLA and ABS. With higher tensile strength, the shell does not need to be as thick, making it lighter. Nylon would therefore be the best material to use for making the shells in the final product.

The levers should be relatively the strongest, as they lift a large part of the weight. Consideration has been given to making the levers also from plastic so that the brace becomes a whole of similar material. Since plastic is a lot weaker than steel, the levers would have to be thicker if made of plastic. One of the requirements is that the device should be made as slim as possible, if the levers become too thick, the device is no longer slim and will be in the way while walking. Using column buckling, the necessary thickness for the levers was calculated from steel and from PLA. The Euler formula was used for this purpose:

$$F = \frac{\pi^2 * E * I}{L^2}$$

Where E is the modulus of elasticity of the material in MPa, L is the length of the lever in mm, and I is the moment of inertia in mm^4. And I is given with the formula:

$$I = \frac{b * h^3}{12}$$

From this, steel requires a thickness of 1.7 mm and PLA a thickness of 7.9 mm, see Appendix A. Since there is still a safety factor on top of these dimensions, the PLA levers need to be almost 1 cm thick. This is the reason for choosing to make the levers from steel.

Several ways and materials were devised to overcome the anti-slip material from breaking down quickly. Since anti-slip is not needed on the entire underside of the lever, one idea was to apply only a strip of thicker anti-slip material. However, this strip is difficult to attach properly without coming loose. An anti-slip coating is a better solution to this problem, this involves melting a rubber around the end of the levers. This sticks well because it has the shape of the levers, and since rubber has a high coefficient of friction, this is the best material to use.

Extra parts

The PLA shell may not strong enough to hold a maximum of 90 kg weight. To prevent the cone from breaking or bending, there should be a metal frame that will support the shell. This frame will consist of three additional straps of thin steel that are going to be bent on top of the shell at the front. At the sides of the shell are also going to be two straps added to secure these extra straps.

Spring constants

In the previous study, the spring strength required to off-load a certain percentage of body weight was calculated, among other things, from the length and angle of the levers. In the new design, the length of the levers is adjustable, this changes the length of L1 and the length of L2, see Figure 14. The original length of L1, when it is at its largest length, is 100 mm, seen from the rotation point of the lever. The holes in the track for adjusting the spring are 15 mm apart. The new length of L1 when set to its shorter position is 85 mm. The original length of L2 is 150 mm. The holes of the track for adjustability of the end of the lever are 15 mm apart from each other. The lever can therefore be extended to 165 mm. The angle of the levers, the angle between L1 and L2, is not changed. If either of these lengths is adjusted, and the spring remains the same, the level of off-loading changes. To achieve the same level of off-loading, the spring constant and hence the spring must be changed. The Matlab script, see Appendix D, to determine various parameters of the previous design was used to determine at which length and spring constant which off-loading level is achieved. The following figures plot the off-loading level against the necessary spring constant for the different lengths of the levers. Since the device uses two springs for off-loading, the spring constant of the springs is taken separately times two.

The original design had a spring rate of 0.6 N/mm, with this comes an off-loading level of around 30%, as the springs together give a spring rate of 1.2 N/mm. This off-loading level was calculated with a weight of 85 kg. Since the new test subjects weigh around 70 kg, this value was also changed. As a result, with two springs with a spring constant of 0.6 N/mm, the device would have an off-loading level of about 37% at L1 is 100 mm and L2 is 150 mm, see Figure 9. The device has an off-loading level of 35% at L1 is 85 mm and L2 is 150 mm, see Figure 10. At L1 is 100 mm and L2 is 165 mm, the device also has an off-loading level of 35%, see Figure 11. To achieve the same off-loading level, so 37%, the device needs springs with a combined spring constant of around 1.26 N/mm.

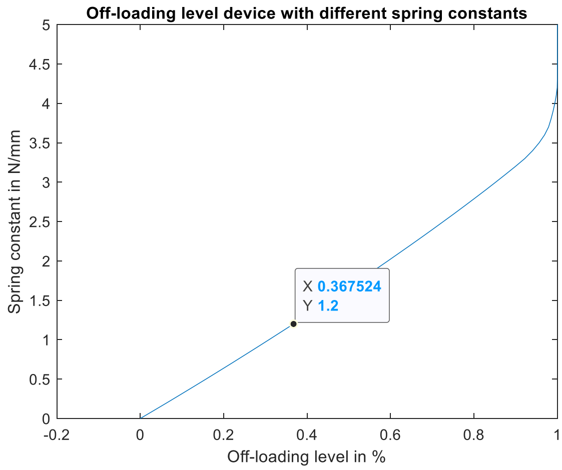

Figure 9 Graph of the off-loading level against the spring constants

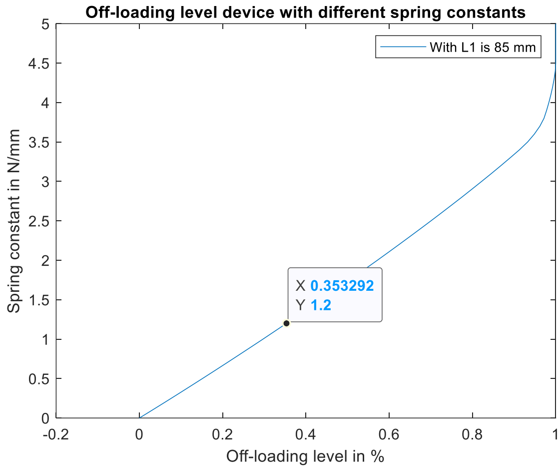

Figure 10 Graph of the off-loading level against the spring constants, with L1 is 85 mm

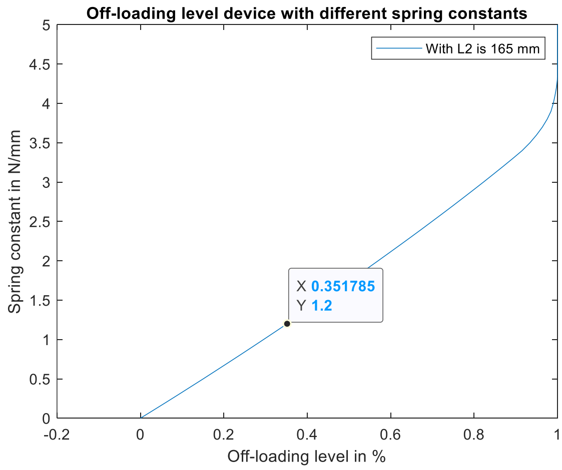

Figure 11 Graph of the off-loading level against the spring constants, with L2 is 165 mm

This same Matlab script shows that there is 1.2 times the body weight on the device as force, this comes from the GRF (Ground Reaction Forces). This was used in calculating the thickness of the levers.

Prototype

In this section the full prototype and how it was fabricated is described. The Solidworks drawings of the whole prototype, and the construction of the prototype can be seen in Figures 12 and 13. De Solidworks drawings of different parts with their dimensions can been seen in Appendix C.

Figure 12 Left: front view of the Solidworks drawing of the prototype. Right: construction of the prototype without the back shell, with A) The lever, B) the bent end of the lever with the anti-slip material, C) the attachment to the lower leg, D) The extra band at the end of the levers, E) the mechanical stop and F) the Velcro to connect the two shells together.

Figure 13 Left: back view of the Solidworks drawing of the prototype. Right: construction of the prototype with the back shell attached.

Material

The new design consists of two kinds of material, steel for the lever parts and PLA for the shells. Both shells are made from 3D-printed PLA. In the concept, it was explained that nylon was the chosen material. But nylon needs to be printed with the Selective Laser Sintering (SLS) technique. One advantage of this is that the shell is strong enough because this is a strong printing technique. However, a disadvantage is that this is a lot more expensive printing technique than the Fused Deposition Modeling (FDM) printing technique, which is used when printing with ABS and PLA materials. When making the prototype, it was chosen to print it from PLA using FDM as the printing technique. The shells were printed with an Ultimaker^3 3D printer.

The levers, mechanical stop, and the extra bands are laser cut from steel. The steel used for laser cutting is steel37 [19], this is not the strongest type of steel. However, it is convenient to work with, so this can be used to make certain parts of the brace, such as bending the extra straps.

The weight of the prototype was determined via Solidworks, by adding the material properties to various parts. This showed that the weight of the attachment to the leg, so the shells, is around 388 grams. This is less than the 400 grams mentioned in the requirements. The total weight of the brace is around 812 grams, which is also less than the 1200 grams specified in the requirements.

Attachment to the lower leg

For the attachment to the lower leg, two shells are used, one at the front and one at the back. Both shells have a wider increasing diameter towards the top, as the lower leg also has this shape. The dimensions of these shells should be made for an average leg, so that people with thinner legs can use more padding to make the brace still fit properly. To make the prototype, the dimensions of the researcher's leg were used. This involved measuring the circumference in two places on the lower leg. The diameter of the shell had to be smaller than half this circumference, otherwise, the two shells would touch each other. However, a margin was taken to allow for padding in the shells so that the brace still fits. The shell at the front is 170 mm long with a top diameter of 136 mm and at the bottom a diameter of 112 mm. The back shell had to fall in between the springs so has a height of 100 mm with a diameter of 130 mm at the top and 106 mm at the bottom. Both shells have a thickness of 7 mm.

Adjustable levers

The levers have similar dimensions to those of the previous design, as these dimensions worked well. Since the levers are now adjustable, the length is different. The levers consist of two lengths that are both adjustable, L1 and L2, see Figure 14. L1 is adjustable to 100 and 85 mm. So, if the user is smaller and the back of the lever hits the ground while walking, L1 can be reduced to 85 mm. L2 is adjustable from 150 mm to 165 mm. If the user is too tall and the levers do not touch the ground before the toes, L2 can be lengthened to 165 mm.

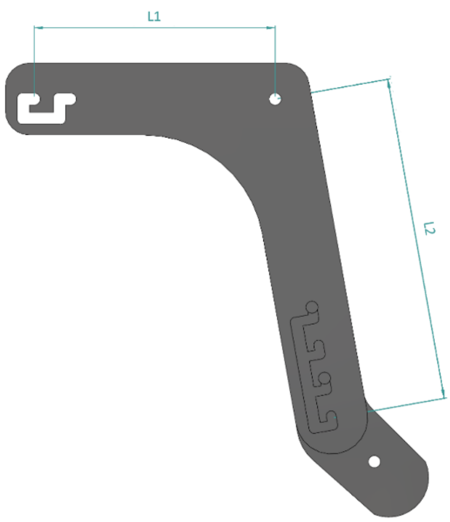

Figure 14 Lengths of the lever L1 and L2

The required thickness of the material was calculated using the Euler formula, as can been seen in the section concepts. This showed that steel needs a thickness of 1.7 mm for the levers. As steel37 is slightly weaker than the steel used in the calculations, a safety factor was added, and the choice was made to make the levers 2 mm thick. This is still thinner than the previous design (3 mm), which makes the device lighter. The width of the levers is 30 mm.

The track for the spring has a width of 5 mm, and the track for the end of the lever has a width of 4 mm. The end of the screws has a diameter of 6 mm so they cannot fit through the track.

Mechanical stop

The concept of the mechanical stop is needed for the design, but it did not work as required in de previous design. The first consideration taken to remedy this is to make the attachment part longer, in this case, the front shell. In the previous design, a corner was taken out of the attachment part, this is probably done so that the design would be lighter, this corner has not been taken away in the new design. By making the attachment part longer, the lever stays longer in contact with it during the stretching of the spring, giving the lever less play to move back and forth vertically. This will reduce the chance of the lever falling out of the mechanical stop. The mechanical stop itself has become more robust. The mechanical stop consists of two parts, a lower part, and an upper part, see Figure 15. The lower part is attached to the connection part to create height for the upper part, this part will lay over the lever which will also hold the lever vertically in place. The upper part of the mechanical stop is long enough that if the spring is stretched it will still lay partly over the lever. Both parts of the mechanical stop are 4 mm thick and 20 mm in width. The lower part is 55 mm long and the upper part is 90 mm long.

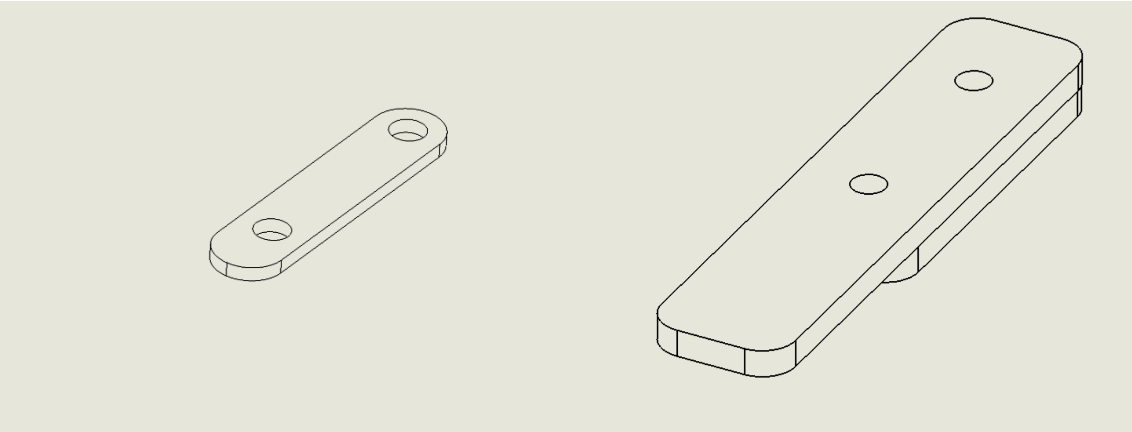

Figure 15 Left: the old mechanical stop. Right: the new mechanical stop.

Extra parts

Besides the shells and the levers, other additional parts are needed for the prototype.

Additional bands

The problem analysis has shown that when walking, the levers shear apart on the ground. To prevent this an extra band is placed at the end of both levers. Tests with the prototype showed that this works better, and the levers no longer slide apart. But further testing shows that the extra band still gets in the way of the toes while walking. This allows the band to push on the toe, reducing off-loading and reducing comfort. Therefore, for the prototype, it was decided not to run the extra band straight across the levers, but in an arc upwards, see Figure 6 D. The extra strap is 20 mm wide and has and thickness of 1.5 mm, so it was bendable.

The metal frame described in the concepts turned out to be superfluous while making the prototype after all. This metal frame would give extra strength to the 3-D printed PLA shell so that it would not break. But the PLA printed well so it was strong enough even without the metal frame.

Anti-slip material

The anti-slip material was supposed to be from a rubber that should be melted around the end of the levers. The material that was supposed to be used for this was too thick to bend and melt around the levers. Therefore, to make the prototype, it was decided to use an inner tube from a bicycle tyre. This was also made of rubber and was fixed around the end of the levers with glue.

Evaluation

The new prototype has been tested by 10 test subjects. They were first shown the device without explanation and were asked some questions, to test if what the brace is and how it works is logical. Then one of these 10 subjects was asked to put the device on and walk 10 meters. After these tests, he/she was asked to fill out the rest of the questionnaire about the comfort of the device. Through the NASA Task Load Index the workload, of putting the device on and walking with the device, has been granted. A few characteristics were also asked in the questionnaire, such as the weight and circumference of the calf. These characteristics were asked to see if the device would fit the test subject.

70% of the questioned knew the device was for the ankle by only looking at the device. The rest thought it was for another body part such as the knee. 80% of them thought the brace could be used for both legs, and 70% would want to wear the device for a full or half day if it was a replacement for crutches.

The complete filled-out questionnaire can be found in Appendix B. The pre-test questions were asked verbally, so the questions cannot be answered using the following questions. An informed consent form, for the test subject who tested the device in person, has been filled out.

Discussion

In this study, a redesign of an off-loading ankle brace was proposed. From testing with the new device, some findings and recommendations for further research emerged. These will be discussed in this section.

From testing with the prototype, before it was finished, it has already emerged that the extra strap at the end of the levers, can get in the way of the toes. This causes the toes and the levers to hit the ground almost simultaneously, which prevents the device from off-loading the ankle optimally. To solve this, instead of the strap running straight across the end of the levers, it has been bent over in an upward arc, see Figure 12 D. This gives the toes more room and would allow the levers to hit the ground earlier than the toes. This partly solved the problem, but for a subsequent design, the extra strap could be attached to a different place. This could perhaps be at the top of the levers so that it runs over the foot. Further testing should show whether this is actually a better place.

When making both shells, so the front and back shell, the dimensions of the lower leg of the researcher were used. As the shells needed padding for comfort after 3D printing, the dimensions were increased. This made the shell larger at the back than it needed to be. Both shells now almost connect to each other, which is not necessary for attaching the brace to the lower leg. To solve this, the padding of the back shell could be made thicker. This will also increase comfort. To ensure that in a subsequent design the brace will also fit users with thinner legs, the shell at the back should be made less wide. Now, when the brace is put on by a user with a thinner leg than the researcher, the front and back shells touch each other, causing the back shell to get in the way when off-loading the ankle.

The shell at the front presents the same problem. Now, it is mainly looked at from the perspective that if the user has a thinner leg than the dimensions of the brace, more padding can be added to the brace. However, if the user has a thicker leg, not much padding can be taken away, as this also reduces comfort. Just as the levers are adjustable, the next design should also make the shell adjustable. To achieve this, a shell that can be extended could be considered, so that the shell can have a larger circumference when a user with a larger leg wants to use the device.

The mechanical stop had to be improved as it did not work as desired. Among other things, the mechanical stop was given a part that runs over the lever so that the lever cannot fall out of the mechanical stop anymore, see Figure 15. During testing with the device, it turned out that this part of the mechanical stop is not yet long enough. The levers can still fall out of the mechanical stop when off-loading the ankle. In this case, the levers get stuck on top of the extended part of the mechanical stop, and the user has to put the levers back into the stop. This does not occur every time while walking with the device, but too often that it is a problem. To avoid this in the next design, this part of the mechanical stop should be made 1 cm longer.

The requirements and problem analysis showed the need for an anti-slip material under the levers. The concept selected is to use a rubber coating as the anti-slip material. In the prototype, an inner tube of a bicycle tyre was used. This is also made of rubber (Isobutylene-isoprene rubber) but is attached to the levers with glue instead of melting it around the end of the levers. For the next design, it is recommended that the rubber is attached by melting it around the levers. This allows the anti-slip material to stay in place better and the part of the lever that actually comes into contact with the ground to have a thicker layer of anti-slip material, so it wears less quickly.

Because there is not only a shell on the front of the leg but also a shell on the back of the leg, there is more surface area to transfer the force from the ankle to the leg. This shear stress, which occurs when the user starts walking with the device, can be too high with a small surface area and pinch off blood vessels. The surface area in contact with the leg in the new design is similar to that of the old design due to the shell at the back. As a result, the shear stress is low enough that the device will not harm the user's leg. However, it could still pinch the leg if the user pulls the Velcro of the back shell too tight.

The requirement was set at 1200 grams for the maximum weight. The weight of the old device was measured and is 1110 grams. According to the Solidworks model, the weight of the new design should be around 812 grams. In reality, the device weighs 884 grams. This is because extra elements such as screws, nuts, springs, and padding were not included in determining the weight in Solidworks. The device is still a lot lighter than it was listed as a requirement, namely over 300 grams lighter. As a result, the device has met all material requirements. The new design is a lot lighter than the old design, so this is an improvement in terms of weight

The material from which the brace is made is still not optimal. The use of a plastic shell is an improvement over the old design. In the concepts, it was discussed that Nylon was the strongest and therefore the best material to use for the shells. However, for the prototype, it was decided to make them out of PLA. This is because Nylon printed via the SLS technique was very expensive for a prototype. Since Nylon is indeed much stronger, for the actual production of the device it is recommended to use Nylon instead of PLA.

Steel was still used to make the levers and the mechanical stop. Steel [20] is a strong material, it has a tensile strength of around 400 MPa. Steel's high density of 7.85 g/cm3 also makes it a relatively heavy material to use in a brace. The next design could look at a metal that has a similar tensile strength to steel but a lower density. This will make the levers a lot lighter, making the brace feel lighter on the leg overall. This will improve comfort even more. Titanium is a fitting replacement for the steel parts of the device. In fact, titanium[21] has a tensile strength of 240 MPa and a density of 4.51 g/cm3 this makes titanium almost half as light as steel. The tensile strength should also be sufficient for the levers, the levers need to be one mm thicker at most.

To test the new prototype, a questionnaire completed by 10 test subjects was used. The original plan was to have all these test subjects also test the device itself, so not just complete the pre-test. Now the device itself was only tested by one test subject, besides the researcher. However, 10 test subjects completed the first part of the questionnaire, so conclusions can be drawn from this part. But the device should be tested by more than one test subject, to be able to draw useful conclusions from the last part of the questionnaire. Also, the test subject who tested the device did not wear the old design. This makes it difficult to evaluate how far comfort has improved. The test subject did indicate that he/she did not suffer from pain while putting on and walking with the device.

The completed pre-test questionnaires revealed a number of improvement points for the device. The majority understood that the device was intended for the leg or ankle. Most also understood that the brace, such as many braces, can be used for both feet. When asked how to put the device on, many people thought that the Velcro should run over the spring instead of under it. In the follow-up, it would therefore be helpful if a short manual is provided with the device, showing how to put the device on. A number of respondents said that, based on its appearance, they would be willing to walk around with the device all day if it were a replacement for crutches. This shows that the device is a benefit compared to crutches. Some test subjects did wonder if the device could also be worn with a shoe. During tests with shoes on, it was found that the shoe then often hits the ground before the levers, making off-loading less effective

The NASA TLX test showed that putting on and walking with the brace was not very demanding both physically and mentally. The overall score of the NASA TLX test about the device was positive. However, it was pointed out that the device is slightly downward tilted so that when the brace is not on the ground it came off the leg a bit. This is probably because the brace was not tight enough around the leg. Comfort was therefore not yet optimal for this test subject. However, the test subject did indicate that if the mechanical stop would always work, he/she would trust the device and would prefer to use it instead of crutches. The appearance of the device was seen as medically professional. It was also indicated that it feels odd at first having to put your toes down first instead of your heel. This requires the test subject to get used to walking with the brace, but it was also indicated that this gets used quickly.

Conclusion

A new design has been created for an off-loading ankle brace. In the new design, the focus has been on improving certain parts that did not yet work well in the previous design. The comfort of the device has been improved by using an organic shape shell with thick padding. Comfort has also been improved by making the device less heavy on the leg. The mechanical stop has been improved by, among other things, making it longer, but tests showed that it still needs to be longer. The device's levers have been made adjustable so that users of different lengths can use the brace. While walking with the brace, the screws stay well in place, which leads to the conclusion that the adjustability mechanism works. Tests showed that using a 3D printed PLA shell is strong enough without the use of a metal frame. The levers no longer slide apart on the ground by using an extra bent band across the ends of the levers. Follow-up research still needs to look at a way in which the shell is also adjustable, and a material for the anti-slip layer. A nylon shell and titanium levers could also be considered, as this would make the device even stronger and lighter. There are still areas for improvement, but the brace has improved on the previous design in terms of comfort and robustness.

References

[1] Bergen C van (Christiaan JA, GVO). Treatment of osteochondral defects of the talus 2014.

[2] Dahmen J, Karlsson J, Stufkens SAS, Kerkhoffs GMMJ. The ankle cartilage cascade: incremental cartilage damage in the ankle joint. Knee Surgery, Sport Traumatol Arthrosc 2021;29:3503–7. doi:10.1007/S00167-021-06755-W/FIGURES/2.

[3] Osteochondral Lesions of the Ankle El Paso | Ankle Pain | Arthroscopy El Paso n.d. https://www.epfootandankle.com/osteochondral-lesions-of-the-ankle-foot-ankle-surgeon-el-paso-texas.html (accessed December 12, 2022).

[4] Medda S, Al'Khafaji IM, Scott AT. Ankle Arthroscopy With Microfracture for Osteochondral Defects of the Talus. Arthrosc Tech 2017;6:e167. doi:10.1016/J.EATS.2016.09.013.

[5] Arthroscopic Debridement - Academy Orthopedics n.d. https://www.academyorthopedics.com/orthopedic-specialties/knee-surgery/knee-osteoarthritis/arthroscopic-debridement/ (accessed December 12, 2022).

[6] Chuckpaiwong B, Berkson EM, Theodore GH. Microfracture for Osteochondral Lesions of the Ankle: Outcome Analysis and Outcome Predictors of 105 Cases. Arthrosc J Arthrosc Relat Surg 2008;24:106–12. doi:10.1016/J.ARTHRO.2007.07.022.

[7] Schmitt LC, Quatman CE, Paterno M V., Best TM, Flanigan DC. Functional outcomes after surgical management of articular cartilage lesions in the knee: a systematic literature review to guide postoperative rehabilitation. J Orthop Sports Phys Ther 2014;44:565–78. doi:10.2519/JOSPT.2014.4844.

[8] Deal JB, Patzkowski JC, Groth AT, Ryan PM, Dowd TC, Osborn PM, Anderson CD, Ficke JR, Kirk KL. Early vs Delayed Weightbearing After Microfracture of Osteochondral Lesions of the Talus: A Prospective Randomized Trial. Foot Ankle Orthop 2019;4:1–6. doi:10.1177/2473011419838832.

[9] Stark M, Rao S, Gleason B, Jack RA, Tucker B, Hammoud S, Freedman KB. Rehabilitation and Return-to-Play Criteria After Fresh Osteochondral Allograft Transplantation: A Systematic Review. Orthop J Sport Med 2021;9. doi:10.1177/23259671211017135/ASSET/IMAGES/LARGE/10.1177_23259671211017135-FIG2.JPEG.

[10] Van Eekeren ICM, Reilingh ML, Van Dijk CN. Rehabilitation and return-to-sports activity after debridement and bone marrow stimulation of osteochondral talar defects. Sport Med 2012;42:857–70. doi:10.2165/11635420-000000000-00000.

[11] Natenstedt J, Dankelman J, Gabrielle Tuijthof ir J. Joint unloading ankle brace to aid cartilage regeneration. Biomed Eng (NY) 2015;3.

[12] New Elan - Endolite Catalogue - Endolite India - Prosthetic, Orthotic Clinical Services, Artificial Limbs n.d. https://www.endoliteindia.com/products/elan (accessed December 8, 2022).

[13] Rabbat BG, Russell HG. Friction Coefficient of Steel on Concrete or Grout. J Struct Eng 1985;111:505–15. doi:10.1061/(ASCE)0733-9445(1985)111:3(505).

[14] Dunimed comfort set elleboogkrukken / loopkrukken (Per paar) | Podobrace.nl n.d. https://www.podobrace.nl/shop/product/dunimed-comfort-set-elleboogkrukken-loopkrukken-per-paar/?gclid=EAIaIQobChMIxvWXvtG_-wIVvgUGAB27wQRpEAkYByABEgKLjvD_BwE (accessed December 8, 2022).

[15] Stiffeners Ankle support | Reh4Mat – lower limb orthosis and braces - Manufacturer of

modern orthopaedic devices n.d. https://www.reh4mat.com/en/usztywnienia/plastic-stiffening/plastic-flat/ankle-support/ (accessed December 8, 2022).

[16] Wang R. PLASTICS: INFORMATION AND PROPERTIES OF POLYMERIC MATERIALS n.d.

[17] 3D printing with PLA vs. ABS: What’s the difference? | Hubs n.d. https://www.hubs.com/knowledge-base/pla-vs-abs-whats-difference/ (accessed December 8, 2022).

[18] Guide to Selective Laser Sintering (SLS) 3D Printing n.d. https://formlabs.com/eu/blog/what-is-selective-laser-sintering/ (accessed December 8, 2022).

[19] EN 1.0037 High Manganese Carbon Steel, t < 16 mm n.d. https://www.matweb.com/search/DataSheet.aspx?MatGUID=e0e5f672742f48bca6a5109eb1004234&ckck=1 (accessed December 8, 2022).

[20] EN 10210-1 Grade St 37-3 - Low Carbon Steel - Matmatch n.d. https://matmatch.com/materials/minfm31317-en-10210-1-grade-st-37-3 (accessed December 8, 2022).

[21] Titanium Properties - Kyocera SGS Europe n.d. https://kyocera-sgstool.co.uk/titanium-resources/titanium-information-everything-you-need-to-know/titanium-properties/ (accessed December 8, 2022).