Ankle distractor

DESIGN OF A PERSONALIZED HINGED ANKLE DISTRACTOR FOR PEOPLE WITH END-STAGE ANKLE OSTEOARTHRITIS

Integrated Product Design
Master thesis
by Julia de Jong

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With the end of my graduation, my time as a student is coming to an end as well. During 7 years of studying, I learned many things about design and who I am and want to be as a designer.

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Enjoy reading!

JULIA

Ankle osteoarthritis (AOA) or degenerative joint disease (DJD) of the ankle, is a progressive condition characteristic by the thinning of cartilage between the tibia and talus bone. Eventually, this leads to complete ankle joint loss. When looking at surgical treatments, joint sacrificing treatments are the golden standard. Young active people with end-stage AOA find these treatments scary and often want to preserve their joint and ankle motion as long as possible. Therefore, they are postponing these surgical treatments and retain the painful symptoms that accompany AOA.

It is believed that ankle distraction arthroplasty is an alternative, joint sparing treatment. This technique uses an external frame to mechanically unload the ankle joint to support the regenerative capacity of the body to restore cartilage. This frame is fixed to pins in the tibia and talus. The current devices limit joint movements and restrict the surgeon in their pin placement, which results in a painful stiff joint during the treatment period. Furthermore, these devices do not always fit the patient properly. Therefore, the goal is to develop a personalized hinged ankle distractor that allows for ankle movement. This will be a new alternative treatment for young active people with end-stage AOA.

The developed ankle distractor is an external fixator that will be adjusted to the placement of the pins, allowing the orthopaedic surgeon for better pin placement. The pins are placed using a drilling and alignment guide. After this surgery, a CT-scan is made to determine the pin placement and the rotation axis of the patient which are both incorporated within the device. The location of the pins is used to personalise the clamps around the pins in the talus for ultimate fit. The rotation axis is used for the placement of the hinge that allows the foot to move. Within the device, the distraction and damping are combined into one mechanism, which allows for maintaining intra-articular fluid pressure. A combination of the distraction device and tibia and talus clamps will be placed at each side of the lower leg to allow for symmetrical distraction. This design results in semi-personalized distraction device that allows for walking with optimized patient comfort while maintaining a partially reusable system.

ABSTRACT

Amsterdam UMC	Amsterdam University Medical Centre
AOA	Ankle osteoarthritis
AIOS	arts in opleiding tot specialist (Dutch abbreviation), translation: specialist registrar
CFRP	Carbon fibre reinforced composites
CT-scan	Computerized tomography scan
DOF	Degrees of freedom
DJD	Degenerative joint disease
FEA	Finite element analysis
GRF	Ground reaction force
HA	Hydroxyapatite
MDR	Medical Devices Regulations
MIO	Medical Technical Innovation and development department
MUA	Manipulated under anaesthesia
OA	Osteoarthritis
OR	Operating Room
PC	Polycarbonate
PEEK	Polyetheretherketone
ROM	Range of motion
SOP	Standard operation procedure
TAA	Total Ankle Arthroplasty

LIST OF ABBREVIATIONS

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INTRODUCTION

CHAPTER ONE

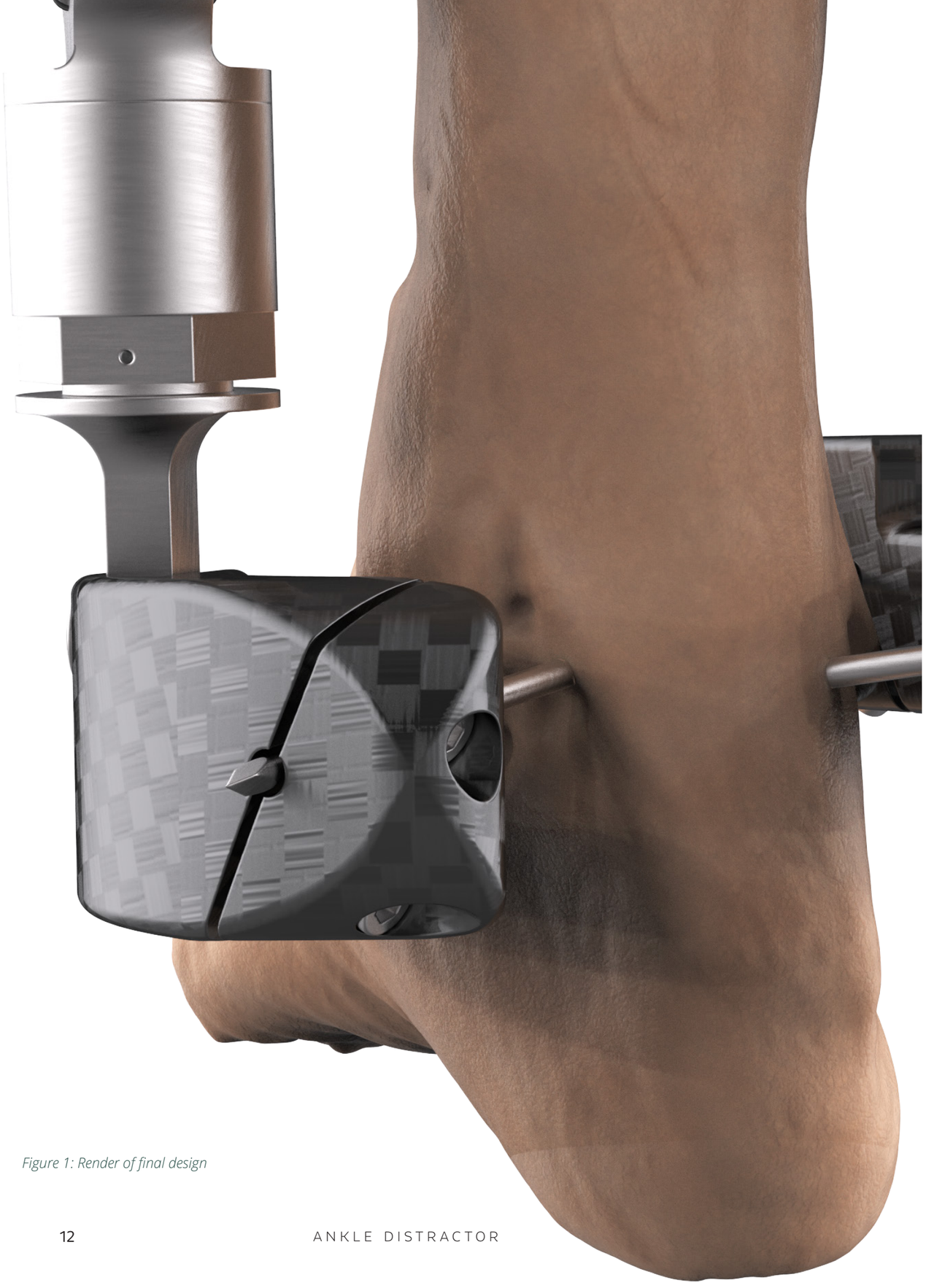


Figure 1: Render of final design

1.1. Background

This master thesis was done in collaboration with the Amsterdam University Medical Centre (Amsterdam UMC) location AMC and the TU Delft, faculty of industrial design engineering. The Medical Technical Innovation and development department (MIO) did the project together with orthopaedic surgeon Dr. S. A. Stufkens of the Amsterdam UMC.

Annually, the orthopaedics department of the Amsterdam UMC treats around 400 people who have disorders related to the foot, ankle, knee or hip. In this medical field, location AMC specializes in ankle-related issues and employs a team of specialists to treat cartilage injuries, deformities and osteoarthritis using the latest techniques. (Amsterdam UMC Locatie AMC - Speerpunten, n.d.) Dr. Stufkens is a foot and ankle specialist and approached MIO to help develop an alternative treatment for ankle osteoarthritis (AOA) using a new joint sparing technique called ankle distraction arthroplasty, which is also referred to as arthrodiastasis. This term is used in 1979 to describe joint distraction. Arthrodiastasis can be derived from arthro [joint], dia [through] and tasis [to stretch out] (Aldegheri et al., 1994).

AOA, or degenerative joint disease (DJD) of the ankle, is a progressive condition within the joint that results in thinning of cartilage which eventually leads to complete joint loss (Bernstein et al., 2017). The now-common joint sacrificing treatments focus on pain relief of this condition. They provide good results on the short-term, but might result in long-term problems. (Barg et al., 2013) Therefore, we are searching for a new method to relieve the pain and improve mobility.

1.2. Problem

Currently, there is no suitable treatment option for young active people with end-stage AOA, as the pain relief is only short-term and the problems reoccur. Often, they need to sacrifice their joint at a young age. Understandably, these patients want to preserve their joint and ankle motion as long as possible (Paley et al., 2008).

Therefore, we wanted to investigate the possibilities of treatment improvement of arthrodiastasis (ankle distraction arthroplasty). This method is proven/believed to be a viable alternative treatment for patients with end-stage AOA (Tellisi et al., 2009) and allows the body to regenerate the cartilage by mechanically unloading the joint with an

external fixator. However, most current devices and methods using this technique are not working properly because the joint is unable to move during the treatment period, resulting in a very stiff and painful joint. Moreover, the methods that do allow motion, involve complex procedures and require many pins/ wires to attach the fixator to the bone (Fragomen, 2022; Marijnissen et al., 2002; Paley et al., 2008; Paley & Lamm, 2005; van Roermund et al., 2002).

Therefore, a new type of procedure including a distraction device should be developed in which the patient should still be able to move their ankle to prevent the joint from getting stiff. This way, we want to make joint-sparing treatments suitable.

"Develop a personalized hinged ankle distractor which will be a new alternative joint sparing treatment for young active people with end-stage AOA. The device should have a limited impact on their daily life."

1.3. Methodology

A new alternative treatment and procedure is designed using literature, expert knowledge, observations, a co-creation session, prototyping and evaluations. The overall approach used during this graduation project is the double diamond method (van Boeijen et al., 2020). In figure 2 the four phases of this method can be seen: discover, define, develop and deliver.

In the discover phase, interviews, observations and, literature and desktop research are completed to get a better understanding of the problem and its context. For this project, the condition, anatomy, current treatments, patient experience, and the market were analysed. In the second phase, define, the main findings gathered during the analysis are interpreted. With these findings the program of requirements and target use scenario are created. These provide a clear starting point for the next phase: develop. Within this phase different concepts are created. In this project, these were developed by different brainstorm sessions, a co-creation session and feedback meetings. In the last phase, deliver, the final design is made into a prototype. This prototype is tested and evaluated with experts. Based on the test results and evaluations, the design will be improved. After the final test, recommendations on how to continue the development are formulated.

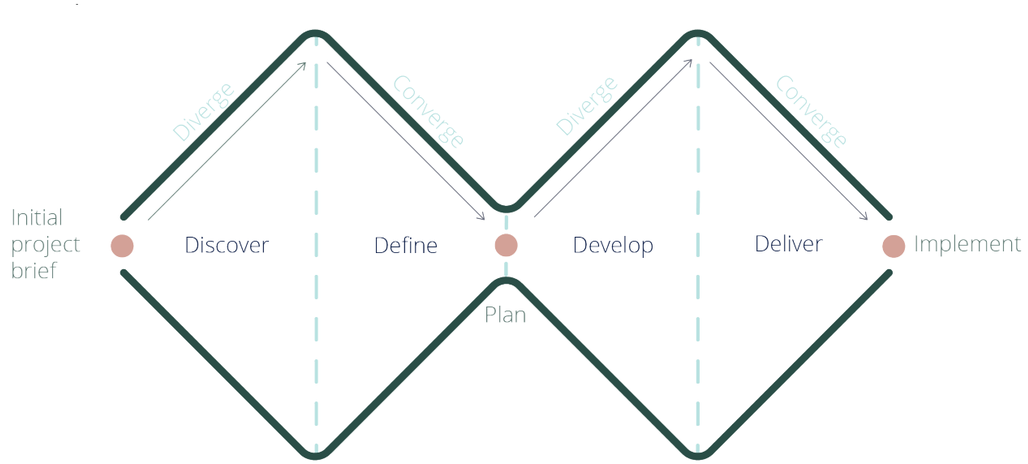


Figure 2: Double diamond method

2

READING GUIDE

CHAPTER TWO

[1]**Extra information**
Definitions or visuals are shown to give an additional explanation

This project is an interdisciplinary project, which is combining different expertise areas to get a better understanding of the problem and creating a solution that fits within the context.

Extra information[1] is added on the side to make the report more comprehensible for everyone.

In figure 3 an overview of the report can be seen. To get a better understanding of arthritis, the current treatments, the patients and other people involved during the treatment observations and interviews are performed. Furthermore, the working principles of distraction and the ankle joint are analysed. From all of these findings a problem statement and a program of requirements is made. Next to that the envisioned process is explained. Based on this, different ideas were generated which are combined into different concepts. One of these concepts is developed further into the final design and this is tested and evaluated.

Graphical content warning: The chapters with an exclamation mark next to it contain graphical imaging.

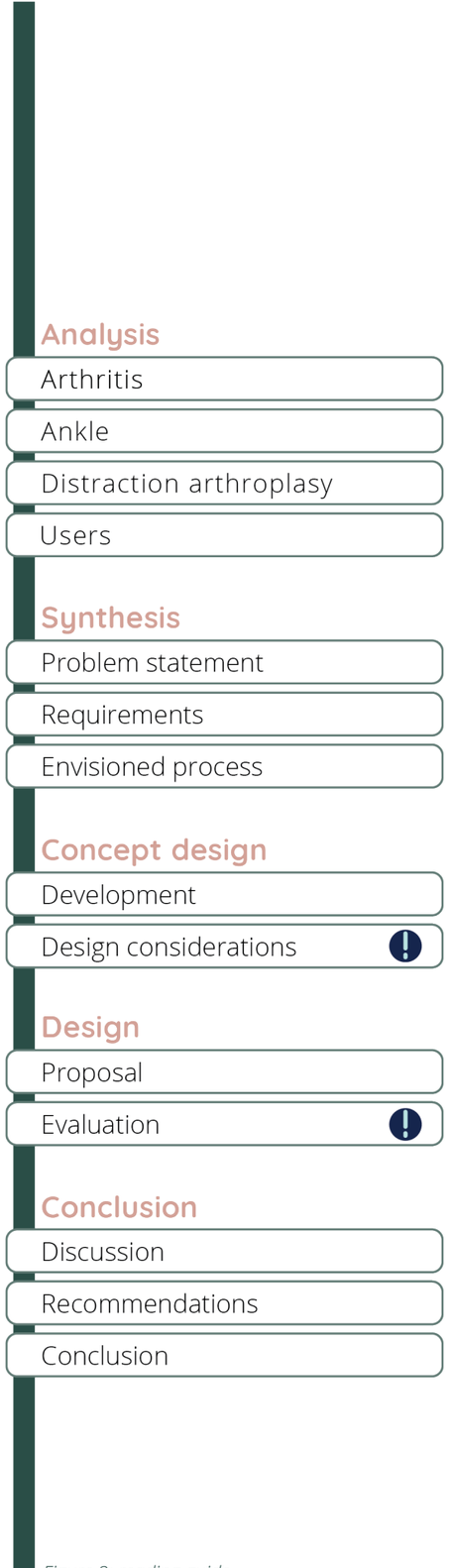


Figure 3: reading guide

ARTHRITIS

CHAPTER THREE

Arthritis is the overarching term for multiple conditions that cause pain or inflammation within a joint. Other symptoms include swelling of the joint, stiffness and reduced range of motion. Since it is a progressive condition, symptoms will get worse over time. There is no cure, so the main treatment goal is to reduce the symptoms and help improve the quality of life of the patient.

There are a lot of different types of arthritis, such as osteoarthritis, rheumatoid arthritis, gout, and lupus. One of the most common is osteoarthritis (OA), which mainly occurs in the hip, hands, spine or knees but also in the ankle. In the Netherlands, more than 1.5 million people suffer from osteoarthritis. Of these, about two-thirds are women. This number is growing, with an increase of 36% expected by 2040. (Artrose | Alles Wat Je Moet Weten • ReumaNederland, n.d.; Artrose | Volksgezondheid En Zorg, 2022)

The causes for OA vary per joint and sometimes no clear cause can be found (Valderrabano et al., 2009). These various causes make it more complicated to develop a unified treatment. When a patient has OA, the cartilage within the joint thins, which results in a rougher surface. This increases the friction between the bones, making it harder to move and causing pain and stiffness within the joint. Eventually the reduction in cartilage leads to complete joint loss. Sometimes new bone is formed within the damaged joint, creating additional pain and stiffness.

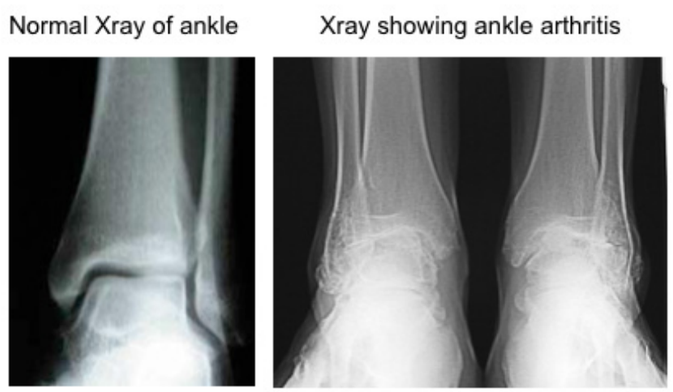


Figure 4: frontal X-ray image of the ankle joint (Ankle Arthritis | Dr. Mike Smith | Orthopaedic Ankle Surgeon | Adelaide, n.d.)

3.1. Ankle osteoarthritis

In AOA the cartilage of the tibia and talus are affected. In figure 4 an example of AOA can be seen. On the left, there is a healthy joint where there is a clear distinction between the tibia and the talus. On the right side, the AOA joint, this distinction is missing and became a blur.

There are multiple causes and risk factors for AOA, including sports with intense loading to the joint and obesity. (Lafeber et al., 2006) Nevertheless, AOA is mostly posttraumatic[2] (Bernstein et al., 2017; Saltzman et al., 2012), therefore it effects mostly relatively young people. It influences their quality of life in a negative way (Bernstein et al., 2017; Nguyen et al., 2015), but due to their age they are not willing sacrifice their joint yet. Therefore, finding a suitable treatment option is more challenging.

3.2. Current treatments

For AOA there are multiple treatments available to help reduce symptoms, with the main focus of pain relief and improving mobility. Different treatments are needed for the different stages of the progressive AOA condition. So based on the severity and the wishes of patient's, the most suitable treatments are selected. Preferably, keeping the joint intact as long as possible (Castagnini et al., 2016).

In figure 5, some treatment types can be seen. They are mapped based on the severity of the AOA and on the impact the treatment has on the daily life of the patient. In the upper right corner high impact surgeries can be found, for when the AOA is in the end – stage. In the lower left corner, treatment for the earlier stages of OA such as wearing a brace or physical therapy can be found.

For the high impact surgeries, there are two main types available: joint sparing and joint sacrificing (Barg et al., 2013). Within the Amsterdam UMC, location AMC joint sacrificing treatments are used to treat end-stage AOA. However, the goal is to change this into joint sparing treatments. Currently, these treatments are not used because these are only shifting the problem.

[2] **Posttraumatic OA**
Osteoarthritis as a result of a previous trauma

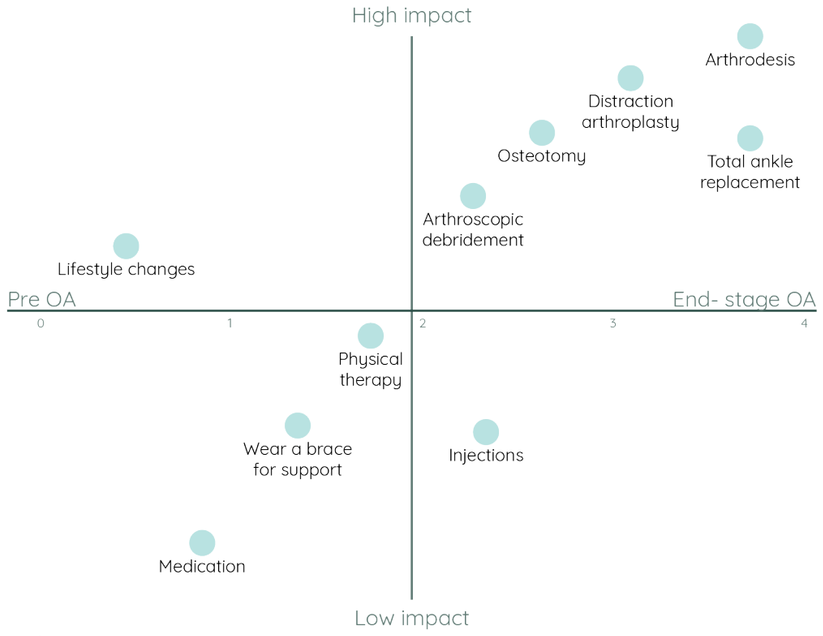


Figure 5: overview of treatments

[3]Osteotomy
It refers to cut and replace or reshape the bone to align the limb, thereby redistributing the (peak) pressure and slow down or stop the degenerative process.

[4]Arthrodiastasis
Distraction of the joint using an external fixator to mechanically unload the joint.

[5] Arthrodesis
The remaining cartilage is removed and screws are used to help fuse the bones together, resulting in a stiff but pain free joint.

[6] Total ankle arthroplasty
The bone and cartilage will be replaced with metal and polyethylene parts with the goal of preserving range of motion.

1) The goal of joint sparing treatments is to keep the bones intact and keep the function of the joint. These treatments consist of deformity correction by osteotomy[3] and/or arthrodiastasis[4] (Morse et al., 2007).

2) The second type is joint sacrificing treatment. With these treatments the bones are cut and the joint is replaced and the function of the joint will alter. These treatments are arthrodesis[5] and total ankle arthroplasty (TAA)[6] (Morse et al., 2007).

Since the context and protocol for these procedures is so specific, observations were done. A more detailed description of the observations and findings can be found in Appendix B. The goal of these observations was to obtain a better understanding of the surgical setting, the current surgical treatments and procedures, and to see how a damaged ankle joint works and looks like in real life. Currently, only the two joint sacrificing procedures (TAA and arthrodesis) are used to treat end-stage AOA. Both of these procedures were observed.

With both procedures a lot of people were present with each their own tasks and responsibilities. The surgeries are complex and require a high focus for a longer period of time, which can be mentally exhausting for the surgeon.

TAA

With TAA the joint of the patient is replaced with polyethylene and metal parts, therefore this is a joint sacrificing treatment. The goal is to preserve range of motion and relief pain. It is a complex procedure with a lot of different steps. Therefore, many instruments (figure 6 and hands are needed to be able to perform the procedure. To create a good entrance to the joint, bone levers are used which requires the presence two AIOS[7] instead of one (figure 7).

In the beginning of the surgery there is one moment in which the tibia and the talus are aligned. Based on this placement the entire prosthesis is positioned. This alignment and prosthesis placement need to be very precise. If the alignment is off or if the prosthesis is not the correct size the patient will have trouble using the joint later on. Therefore, the alignment is checked regularly throughout the surgery with a c-arm[8] that uses x-ray, requiring everyone present to wear a lead apron. The heavy lead apron needs to be worn throughout the entire surgery, which is physically exhausting. Next to that, it takes time and high concentration to find the right size of the prosthesis, which can be mentally exhausting.

Arthrodesis

Arthrodesis is the treatment where the bones are attached to each other using screws. This will alter the function of the joint and therefore it is a joint sacrificing treatment.

For this procedure the patient is laying on the stomach. Therefore, the patient is brought to sleep before being transferred to the surgery table. Everyone in the room helps lifting and turning to patient onto the surgery table. This can be a hassle, since it may be difficult to reach the patient and the wires and IV needles need to stay in place while moving.

When the patient is on the stomach two small incisions are made next to the Achilles tendon for the arthroscope[9] and the other needed instruments. A distraction device (see figure 8) is used to create more space within the joint. This is a sort of rope going around the foot and the body of the surgeon. The surgeon uses his whole body to perform the distraction, which requires a lot of power. This added room is needed for better access and the visibility within the joint

Figure 6: Instruments used during surgery

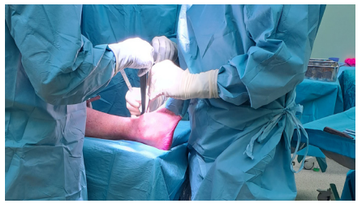


Figure 7: Bone levers used to open the joint in surgery

[7]AIOS
Dutch abbreviation for Arts in opleiding tot specialist, translation: specialist registrar

[8]C-arm
Device used to take X-ray images during surgeries

[9]Arthroscope
A tube that is inserted in the body, holding a camera and light for viewing. The camera is connected to a monitor so the surgeon can see what he is doing.

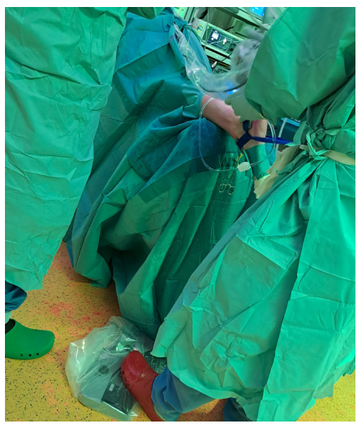


Figure 8: Surgical ankle distractor

3.3. Conclusion

AOA is a progressive condition in which the cartilage of the ankle joint is decreasing. This results in a rougher surface, which increases the friction between the tibia and the talus making movement difficult and causing pain and stiffness within the joint. It often has a negative influence on the quality of life of young active people.

When treating AOA, the main focus is to reduce the symptoms. Overtime these symptoms get worse, each stage requiring a different treatment. Unfortunately, it differs per patient if a treatment is successful, therefore choosing the right treatment is not a one-size-fits- all strategy. So sometimes it can take a while to figure out the best working treatment. For end-stage AOA there are two surgical treatments available: joint sparing or sacrificing. Joint sparing is the preferred way of treating, but is not the standard. If there are no other treatment options left, the patients can undergo a joint sacrificing treatment.

During these surgeries a lot of people need to be present to make sure everything can go smoothly. They take a long time and a high focus level is required throughout the entire surgery. In the TAA surgery, X-ray is used to make sure the bones are aligned, everyone present has to wear a lead apron, which is quite heavy. Moreover, there is one moment to align the bones, if this is off it cannot be changed later and the patient will suffer from this.

In both surgeries, a lot of different instruments are used during the procedure to hold certain parts in place. Furthermore, a form of distraction is used during the surgeries to create more space within the ankle joint. These distractors require a lot of force to be successful in performing the distraction.

3.3.1. Requirements

Based on the analysis of OA and the current treatment and their procedures some important factors for the design were discovered.

- ◊ Throughout treatment, movement of the joint needs to be possible to prevent stiffness within the joint
- ◊ The device should be sterile before placing it in/on the patient to prevent infections.
- ◊ For the current procedure the consequences of a small human error are big for the patient. Therefore, the device and new procedure should leave little to no room for human errors. The consequences can be limited by making it possible to correct them and provide clear feedback to the surgeon.
- ◊ Making the surgery less complex, makes it less exhausting for the surgeon. Furthermore, less and simpler instruments should be needed to place the device.

4

THE ANKLE

CHAPTER FOUR

The ankle joint is one of the most important weight-bearing joints in the human body. It connects the lower leg bones - tibia and fibula - to the foot bones - talus and calcaneus -. The ankle joint is responsible for controlling the movement of the foot, allowing for various actions such as plantarflexion, dorsiflexion, inversion, and eversion. For better understanding of the application of the new device, this chapter discusses various components of the ankle and their functions as well as the forces within the joint.

4.1. Anatomy of the ankle

Within the foot and ankle there are 26 individual bones, together with the tibia and fibula they form 3 joints (Gray, 2009). In this chapter, a summary of the bones, joints and ligaments is given. A more detailed description can be found in appendix C.

4.1.1. Bones

The ankle joint complex exists of the lower leg and the hindfoot[10]. The joint forms the link which allows the lower limb to interact with the ground. This is an important aspect for the daily life (Brockett & Chapman, 2016). In the lower leg and hindfoot there are four bones: tibia, fibula, talus and calcaneus. In figure 9, these bones are shown.
The tibia and fibula are both located in the lower leg. The distal[11] tibia and distal fibula are referred to as the medial[12] and lateral[13] malleolus, respectively. Both malleoli form the socket of the joint (Webster, 2021). The hindfoot exists of the talus and calcaneus (Oatis, 2009). The calcaneus is the most posterior[14] bone of the foot and it is the largest and strongest. The talus exists of the head, body and neck and rests on the anterior[15] part of the calcaneus (Brockett & Chapman, 2016).

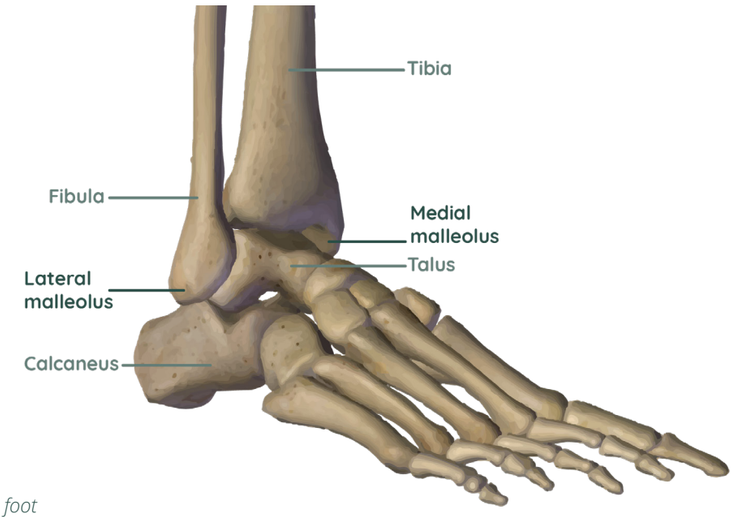


Figure 9 : Bones of the lower leg and foot

4.1.2. Joints

The ankle joint exists of multiple joints (figure 10): the subtalar joint, the tibiofibular joint, and the tibiotalar joint (Brockett & Chapman, 2016).
The subtalar joint, also known as talocalcaneal joint, is the joint between the talus and calcaneus. Studies have shown that the main contribution of this joint is during inversion, eversion and adduction, abduction. During plantar and dorsiflexion, the contribution is limited (Oatis, 2009).

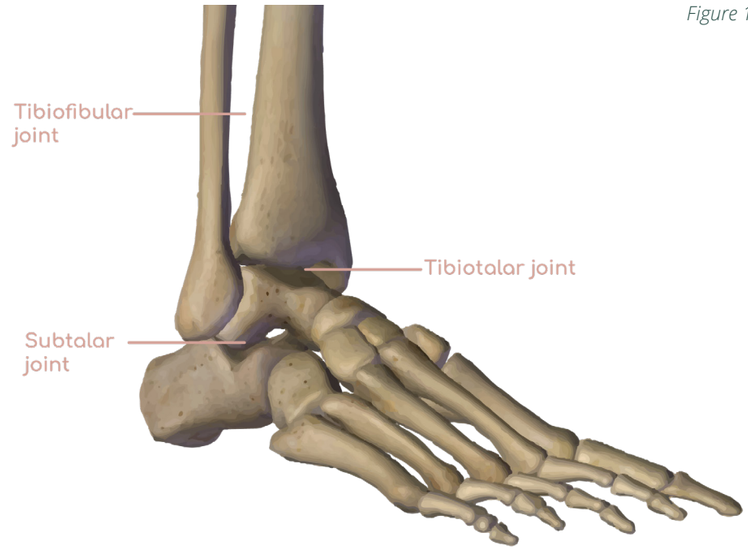


Figure 10: Joints in the ankle

The tibiofibular joint can be described as a separate joint and as a part of the tibiotalar joint. (Espregueira-Mendes & Vieira da Silva, 2006). The main function of this joint is adding stability to the foot and ankle rather than providing motion. (Brockett & Chapman, 2016)

The tibiotalar joint, also known as the talocrural joint, is a synovial joint[16] and forms the connection between the lower leg and the talus. This joint can be described as a mortise and tenon joint. Whereby the malleoli of the fibula and tibia form the mortise of the joint, as previously mentioned, and the talus is the tenon (Webster, 2021).

[10]Hindfoot
Posterior part of the foot and exists of the talus and calcaneus (van der Heiden & Kaplan, 2022).

[11]Distal
Located away from the centre of the body.

[12]Medial
Located towards the middle of the body.

[13]Lateral
Located towards the side of the body.

[14]Posterior
Located towards the back of the body.

[15]Anterior
Located towards the front of the body.

[16]**Synovial joint**
Synovial joint which is surrounded with a capsule with fluid inside and is reinforced by ligaments.

[17]**Ligament**
A band that connects bones or pieces of cartilage with each other.

This hinge joint mainly enables plantar- and dorsiflexion (Brockett & Chapman, 2016). In someone with AOA, the tibiotalar joint is often affected and the subtalar joint is still intact. Therefore, distraction will take place between the talus and the tibia and thus this study focuses on this joint.

4.1.3. Ligaments

Within the ankle and foot there are a lot of ligaments[17] to provide support and limit movement of the ankle. The ligaments of the ankle joint can be divided into two groups based on their location: lateral and medial ligaments.

The lateral ligaments (figure 11)are attached to the lateral malleolus and are there to resist inversion. It consists of three major bands and some smaller ones. The most important ones are the talofibular ligaments, anterior and posterior, forming the connection between the talus and fibula. The third major band is the ligament for the fibula to the calcaneus: calcaneofibular ligament. (Brockett & Chapman, 2016; Oatis, 2009; Webster, 2021)

The medial collateral ligaments (figure 12) are located on the medial side of the ankle and are resisting eversion. It contains superficial and deep ligaments and exists of three major ligaments and some smaller ones. The major superficial ligaments are tibiospring going from the

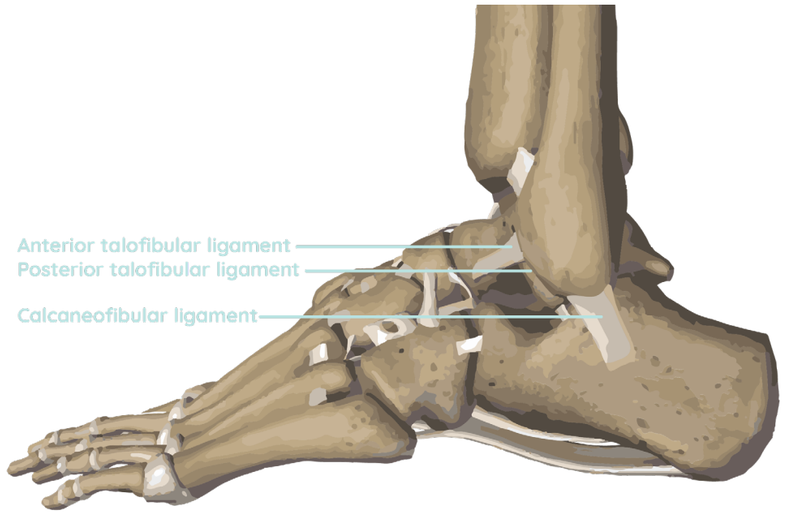


Figure 11: Lateral ligaments

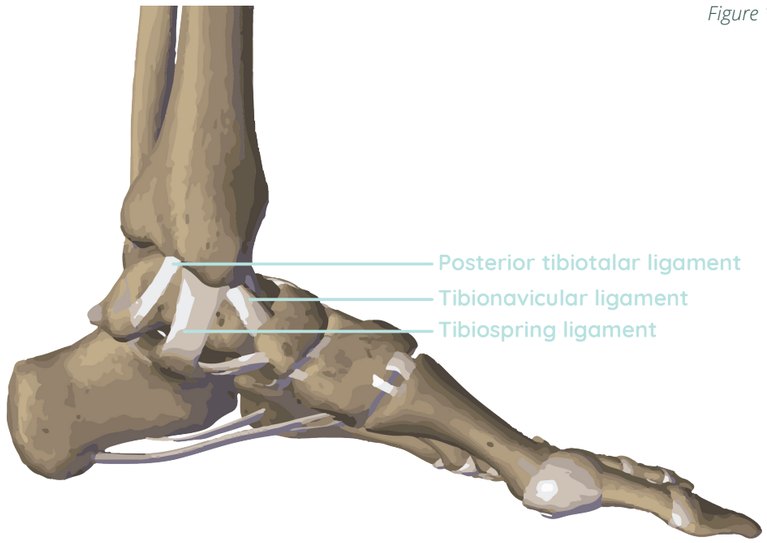


Figure 12: Medial ligaments

medial malleolus to the anterior part of the tibia and the tibionavicular ligament which is attached to the tibia and the navicular[18]. The last major band is located deeper in the ankle and is called the posterior tibiotalar ligament, going from the tibia to the talus (Brockett & Chapman, 2016; Gray, 2009; Oatis, 2009). Together they form a triangular shape and therefore they are also referred to as deltoid ligaments. Furthermore, they are stronger than the lateral collateral ligaments (Webster, 2021).

4.2.Kinematics of the ankle

4.2.1. Movements

Within the ankle joint, multiple movements are possible (figure 13). The most important movement is dorsi- and plantarflexion (Brockett & Chapman, 2016). This movement happens in the sagittal plane[19] around the medial-lateral axis. Hereby moving your toes towards you is dorsiflexion and pointing your toes is plantarflexion. The other movements are eversion and inversion, occurring in the frontal plane[20] around the long-axis of the foot whereby moving the sole of your foot inwards is inversion and moving outwards is eversion. The final movements are abduction and adduction, occurring in the transverse

[18]**Navicular**
A crescent-shaped bone that is the connection between the talus and the cuneiform bones in the foot (Oatis, 2009).

[19]**Sagittal plane**
The plane that cuts the body from front to back dividing it into a left and right part (Calais-Germain, 2005).

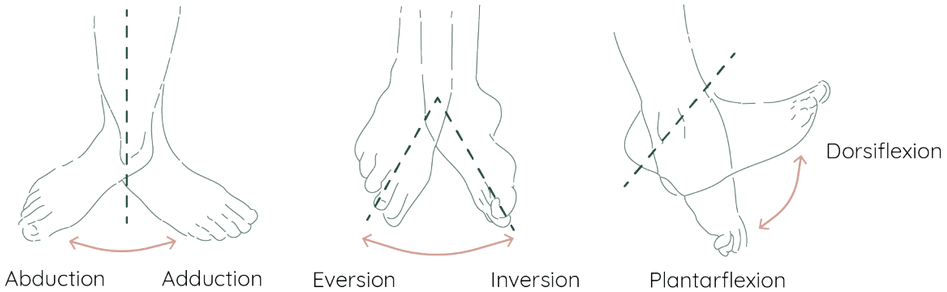


Figure 13: Movements of the foot.

[20]Frontal plane
The plane that cuts the body from side to side dividing it into a ventral (front) and dorsal (back) part (Calais-Germain, 2005).

[21]Transverse plane
The plane that cuts the body horizontally dividing it into a cranial (top) and caudal (bottom) part (Calais-Germain, 2005).

	Pronation	Supination
Sagittal plane	Dorsiflexion	Plantarflexion
Frontal plane	Eversion	Inversion
Transverse plane	Abduction	Adduction

Table 1: combined movments of the foot

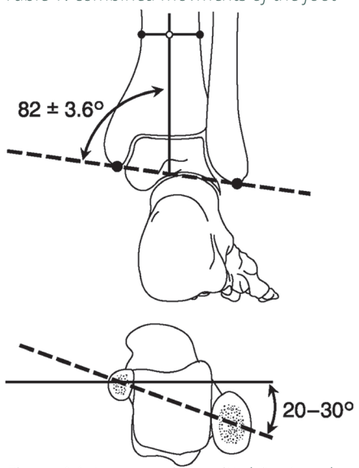


Figure 14: Inman axis, sagittal (top) and axial (bottom) (Paley et al., 2008; Paley & Lamm, 2005)

plane[21] of the foot around longitudinal axis through the leg (parallel to the long axis of the tibia). Hereby moving your foot inside is adduction and moving your foot outside is abduction. The combination of these motions creates a three-dimensional or triplanar motion, which are called supination and pronation. These three-dimensional motions determine the position of the sole of the foot, medial or lateral (table 1) (Brockett & Chapman, 2016; Oatis, 2009).

4.2.2. Rotation axis

The movements that are described above happen around a rotation axis. As this project focuses on the distraction of the tibiotalar joint, we will only specify this rotation axis. Within the literature this axis of rotation is described in two different ways. Some consider it to be a simple hinge joint, whilst others suggest that it is a multi-axial joint due to the internal and external rotation that occur during dorsiflexion and plantarflexion, respectively. (Brockett & Chapman, 2016)

In the 1950s a number of authors has proposed the multi-axial joint, with a plantarflexion and dorsiflexion axis. Motion around these axes does not happen simultaneously. The transition between these axes occurs close to the neutral position of the joint (Barnett & Napier, 1952; Hicks, 1953). For the simple hinge joint it was suggested that the ankle rotates about the Inman axis, that lies between both malleoli (Bernstein et al., 2017). In the current distraction techniques this is the rotation axis that is used (figure 14)

4.2.3. Range of motion

For every patient the ankle range of motion (ROM) is different (Grimston et al., 1993), however in the literature normal values of ROM can be found. From these values it can be concluded that women have a greater ROM than men and that the ROM decreases with an increasing age independent of the gender (Grimston et al., 1993; Oatis, 2009). AOA often causes the patients' ROM to be restricted (Brockett & Chapman, 2016).

The main movement is caused by the tibiotalar joint and happens in the sagittal plane. The overall ROM in this joint is between 65° - 75°, which exists of 10° - 20° in dorsiflexion and 40°- 55° in plantarflexion. In the frontal plane the total ROM is 35°, which exists of 23 ° of inversion and 12 ° of eversion (Brockett & Chapman, 2016; Stauffer et al., 1977). This full ROM is not used within daily activities. For walking a maximum 30° of plantar- and dorsiflexion is needed. When ascending stairs 37 ° is needed and 56 ° is needed for descending (Nordin & Frankel, 2001).

4.3. Forces transmission

The ankle is a weight-bearing structure that has to withstand large impacts. The force distribution is determined by the position of the ankle. During weight-bearing about 90% of the load is transmitted from the talar dome to the tibial plafond[22]. The rest of the load is distributed through the medial and lateral facets. (Nordin & Frankel, 2001; Oatis, 2009)

Within the ankle joint there is a larger load-bearing surface compared to the hip or knee, which results in lower stresses within the joint. (Nordin & Frankel, 2001) If the ankle joint is in neutral position the contact area of the talus is reduced, but an increase of 5% with loads of 490N and 980N. If the load is higher, the articular cartilage will start to deform. (Oatis, 2009)

Activities, such as standing on one foot, result in a higher ground reaction force (GRF). If a person was standing on one foot the GRF would be equal to the body weight of this person. The moment on the ankle joint during normal walking varies between 83 Nm to 117 Nm (Oatis, 2009).

When walking the force is constantly changing based on gait phase and different walking cadences (figure 15). If there is a higher pace, there are two peak forces of 3 and 5 times the body weight. With a slower pace there is one peak force of 5 times the body weight. When running this peak force can be up to 13 times the body weight. (Nordin & Frankel, 2001)

[22]Tibial plafond
Distal end of the tibia.

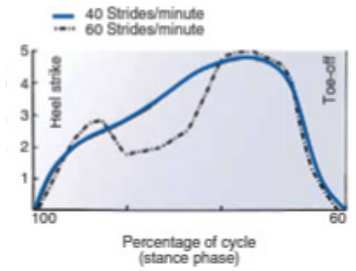


Figure 15: ankle joint reaction force

4.4. Conclusion

Within the ankle there are 4 important bones, which can be divided into two parts: the hindfoot (talus and calcaneus) and the lower leg (fibula and tibia). Their shape allows for certain movements while limiting other movements. These movements happen in the three joints of the ankle: Subtalar, tibiotalar and tibiofibular. Each joint has its own movement, which contributes to the bigger picture. The subtalar joint contributes to inversion (23º) and eversion (12º) with a total ROM of 35 °. The tibiotalar joint, has a ROM of 65º- 75 °, 10º-20º in dorsiflexion and 40º-55 ° in plantarflexion. The tibiofibular joint is adding stability to the ankle. For daily activities, such as walking, only a part of the full ROM is used.

Ligaments provide stability within the ankle joint. There are 2 main groups: medial collateral ligaments (deltoid) and lateral collateral ligaments. The medial ligaments limit eversion and the lateral ligaments limit inversion. The whole ankle joint is surrounded by these ligaments which makes access to the bones difficult.

The rotation axis of the movement facilitated by the tibiotalar joint can be described as a simple hinge joint but also as a multi-axial joint within the literature. For the distraction, the simplified Inman axis between both malleoli is used as the rotation axis.

During daily activities, the ankle has to resist a lot of impact. From this impact around 90% goes through the tibial plafond. During walking, peak pressures of 3 to 5 times the body weight occurs dependent on the gait cycle and the walking pace. During more extreme activities such as running the peak force can lead up to 13 times the body weight.

4.4.1. Requirements

Based on the analysis of the ankle anatomy and kinematics some important aspects for the design were discovered.

- ◊ When the device is attached to the pins, a ROM of around 60 º still needs to be present so the impact on daily life is small.
- ◊ Within the ankle joint there are high forces, which have to be absorbed by the device. When under these high peak forces, the device should not break.
- ◊ The pins, necessary for joint distraction, should have enough support within the bones to prevent them from moving up and down within the bone. A bigger distance between the separate pins creates a better force distribution and adds more stability to the design.

5

DISTRACTION ARTHRO-PLASTY

(STATE-OF-THE-ART)

CHAPTER FIVE

[23]**Intra-articular fluid**
Fluid that is located within the joint capsule

[24]**Ligamentotaxis**
Principle of aligning fracture fragments by applying tension across the fracture.

[25]**Ilizarov fixator**
A type of external fixator used to reconstruct, reshape or lengthen bones. It exists of rings, rods, Kirschner wires (pins made of stainless steel) and adjustable nuts.

Ankle distraction arthroplasty is believed to be a new alternative joint sparing treatment for patients with end-stage AOA (Tellisi et al., 2009). But what is distraction arthroplasty? What do the current procedures look like? Which devices and methods are being used for his treatment?

5.1. The technique

Ankle joint distraction arthroplasty is a technique whereby an external frame is placed across the joint(van Roermund et al., 2002). It has evolved into a suitable alternative joint preserving treatment (Paley & Lamm, 2005). The first reported joint distractions are of the knee and ankle and were performed in 1978(Volkov & Oganesian, 1975) followed by the first ankle distraction in 1978 (Judet & Judet, 1978) and the hip in 1994 (Aldegheri et al., 1994). The big advantage of distraction arthroplasty is the conservation of the original articulating joint (van Roermund et al., 2002).

The technique is based on the hypothesis that OA cartilage has regenerative capacity if there is no mechanical stress on the cartilage and if intra-articular fluid[23] pressures is maintained (Bernstein et al., 2017; van Roermund et al., 2002). There are three possible mechanisms that have been involved in the clinical benefit of distraction: (van Roermund et al., 2002) 1) Temporary relief of mechanical stress, this prevents further damaging the cartilage through wear and tear. 2) Maintaining intermittent fluid pressure, this is caused by the (un)loading and joint movement during the distraction period. The intermittent fluid pressure provides nutrition for the cartilage. 3) Diminished impact on cartilage, which makes reparation easier.

To provide this environment, Vidal's principle of ligamentotaxis[24] is used (Paley & Lamm, 2005). By placing a hinged external frame, the joint is distracted creating a distance between the damaged articular surfaces and maintain the intermittent fluid pressure (van Roermund et al., 2002). Within the literature different procedures for distraction arthroplasty are described. There are two procedures that are more common: the Baltimore method(Paley et al., 2008) and the method of van Roermund and colleagues (Marijnissen et al., 2002; van Roermund et al., 2002), both of these procedures include an Ilizarov fixator[25]

5.2. Market analysis

As previously mentioned, there are two commonly used procedures for distraction using an Ilizarov fixator. However other distraction devices are available on the market with their own procedures. In this chapter, an overview of the current distraction devices, techniques and similar devices is provided. In table 2 an overview of distractors and similar devices is shown, while a more detailed description per device can be found in appendix D.

Firstly, there are different external fixators on the market, such as the Hoffmann 3 (Hoffmann 3 | Stryker, 2022), which is currently being used in the AMC to treat fractures , and the Ilizarov which is used as ankle distractor (Paley et al., 2008; Paley & Lamm, 2005). Both devices can be adjusted around the pin placement, so that it fits the patient perfectly. However, assembling the device takes time, since it needs to be built around the leg of the patient .

The Xcaliber by Orthofix is a device that is ready to use, which allows for a short surgery time. However, it is a single use item. The device is lightweight, making it easy to apply and more comfortable for the patient. When installing the device, the device is used as a drilling guide to place the pins, allowing for less variation in pin placement. After distraction is performed and all the clamps are locked, the distraction unit can be removed (Orthofix, n.d.-b; XCaliber Articulated Ankle Fixator - Orthofix - US, 2021). The ProCallus by Orthofix is similar to the Xcaliber, however it is modular so the clamps can be changed (Orthofix, n.d.-a). With both of these devices there is no hinge incorporated in the design, resulting in a stiff and painful joint

During ankle surgeries, fabric distractors are already used. This is done to create more space within the joint for easier access. However, these are only used for a short period of time during a surgery.For the Knee a device with limited disadvantages has been made: The KneeReviver made by Arthrosave . This is a distraction device for the knee joint. Similar to the Xcaliber, the device is used as a drilling guide to place the pins, allowing for less variation in pin placement. The device is attached on both sides using 8 extra-articular placed pins. It is important that the frame and wounds are cleaned to prevent pin-tract infections . The device is lightweight and can be adjusted to their morphology, which increases the patients' comfort. (van Heerwaarden & Verra, 2020) With this device the distraction time is only 6 weeks and moving the knee

[26]**Arthrosave**
Company started after years of academic research in UMC Utrecht

[27]**Extra-articular**
Anatomical term for a location outside of the joint.

[28]**Pin-tract infections**
Infections of the skin around the pins that are entering the body

joint is not possible, therefore after 6 weeks the knee is manipulated under anaesthesia (MUA) to make the joint flexible again.

5.3. Conclusion

Ankle joint distraction arthroplasty is a technique whereby an external frame is placed across the joint to lower the mechanical stress on the cartilage. Which allows the body's regenerative capacity to repair cartilage. Different distractors and similar devices are available on the market. Based on the market analysis some important factors to consider for the design were discovered.

5.3.1. Requirements

Position & shape:

- ◊ The positioning of the device should enable easy access for cleaning to prevent infection.
- ◊ The morphology of the lower leg and foot can be taken into account to prevent interference with the other leg during daily activities.

Distraction technique:

- ◊ To prevent joint stiffness, a hinge should be incorporated into the design. Furthermore, intermittent fluid pressure can be maintained by using springs.

Use:

- ◊ A lightweight device allows for easier placement and increases the comfort of the patient.
- ◊ A modular device makes it easier to adapt for more patients since the pin placement is not limited by the device.
- ◊ Using the device as a drilling guide results in less variation for pin placement, limiting the surgeon to attach the device to the bones.

[29] **Synovial fluid**
Joint fluid located within the joint. The fluid lubricates the cartilage and provides nourishment.

[30] **Tibial pilon fracture**
Fracture at the bottom of the tibia, but a pilon fracture often affects the fibula as well.

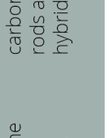
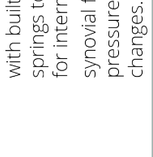
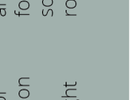
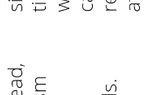
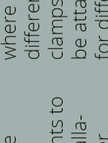
	Use case	Time period	Weight bearing	Material & weight	Hinge	Distraction mechanism	Parts	Pin placement	Ease of use
External fixator 	Provide stabilisation of open and unstable fractures	Shorter period of time	Not allowed	Metal, carbon fibre	Yes	Metal rods between two rings placed around the foot and lower leg.	Couplings with thumb-wheels, carbon fibre rods and hybrid pins	Different parts can be combined and adjusted around the pin placement, that is done first.	It exists of different building blocks and per patient the devices are built around the pins.
KneeReviver 	A distraction device for the knee joint.	6 weeks	Allowed	Lightweight	No	N.A.	Two distractors with built-in springs to allow for intermittent synovial fluid[29] pressure changes.	The device is used as a guide to determine the location of the pins.	
Surgical distractor 	To create more space within the joint during surgery.	During surgery	N.A.	Fabric strap	No	A device can be used or the surgeon uses his bodyweight to pull	A fabric strap around the foot and sometimes a rod attached	N.A.	Easy to set up
Xcaliber 	Designed for tibial pilon fractures[30]	N.A.	N.A.	Radiolucent material, lightweight	No	Distraction using thread, mechanism can be removed afterwards.	Compression-distraction unit, with thread, can be removed afterwards.	The holes in the fixator can be used as a template for the placement of the pins in the tibia.	Ready to use which allows for a short surgery time
ProCallus 	Modular system used for fractures, angular corrections, joint fusion and joint distraction.	N.A.	N.A.	Radiolucent material.	No	One device, with some surgical instruments to help installation easier.	One device where different clamps can be attached for different use cases.	Determined using the pin guide.	It is a simple design and therefore it can be applied quickly, also in emergency situations

Table 2: market overview (Hoffmann 3 | Stryker, 2022; van Heerwaarden & Verra, 2020; Professionals - Arthrosave, 2022)

STAKEHOLDERS

CHAPTER SIX

Multiple people are involved throughout the process of ankle distraction arthroplasty. In figure 16 an overview can be seen with all the people involved. They are placed within the diagram (Ashby, 2015) based on their influence/power and interest towards the procedure.
The key players in this process are the orthopaedic surgeon and the

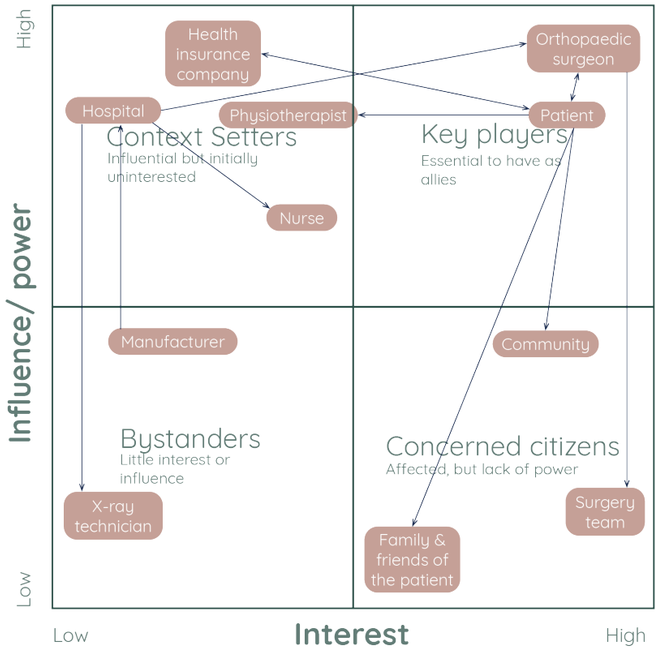


Figure 16: Stakeholder diagram

patient, because they have a high interest and a lot of influence and power within this procedure, since they are the end-users of the devices.

Other people that are involved have a supporting role throughout the process. The patient is directly supported by their family and friends, but also by the community. Also, there is an entire team of medical staff from the hospital that helps with various aspects during treatment. During the surgery, a team is present to assist the surgeon. Before, during and after the treatment, the x-ray technician will take scans and photos of the patient if needed. During hospitalization, a nurse will help and care for the patient as needed. During the distraction period, the physiotherapist will guide the patient through their revalidation process.

Finally, there are authorities involved in the production and distribution process, such as the hospital, manufacturers and health insurance companies.

6.1. Orthopaedic surgeons

As mentioned above, the orthopaedic surgeon is one of the end-users of the device. Therefore, multiple meetings, discussions and observations were done to get a better understanding of their point of view.

These observations were done at the outpatient clinic, even though the patients that visited during the observation were not suffering from OA, their overall treatment by medical staff is similar. The people that where observed are one orthopaedic surgeon, one AIOS and one PhD candidate. One of the main things that immediately stood out was the way of communication, everything has to go as fast as possible since there is limited time and a lot of jargon is used. Another interesting thing that was found is that their goal is to only operate if the patient is experiencing complaints, even if the images show a bone cyst[31].

During the meetings and discussion a few topics kept returning, since they are of high importance according to the orthopaedic surgeon. The first one is about the rotation axis of the ankle joint. When the current distractors have a hinge, it is often a fixed point and cannot be changed. This point is not following the natural movement . The second one is about the procedure, with the current procedures there is a lot of room for a human error. These small errors can have big consequences for the patient, and should therefore be limited. Finally, the main goal for the orthopaedic surgeon is to have a device that is as simple as possible, while also resembling the situation in the actual ankle joint as similar as possible.

6.2. Patients

The other end-users of the device are patients with end-stage AOA. To get a better understanding about living with (A)OA, the daily problems that occur and treatments and their impact, user research was done.

[31] **Bone cyst**
Hole filled with fluid inside the bone.

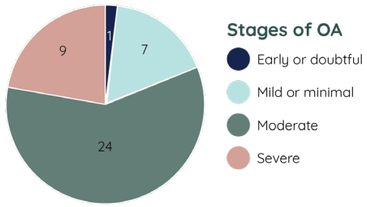


Figure 17: Stages of OA, participants (n=41)

This user research existed of multiple parts: 1) questionnaire, 2) sensitizing booklet and 3) interviews. The questionnaire was answered by 41 participants, with different stages (figure 17) and locations of OA. The sensitizing booklet and interviews were combined into one test with 5 respondents, all suffering from different stages of AOA. In appendix E, these different parts and methods are described. The results from the research can be categorized in the following topics:

Daily schedule

Participants said that they are adjusting their daily and weekly schedule around their activities. After intense activities they need to have a moment of rest to recover. Often, they plan activities in the morning and in the afternoon, they take time to rest. When activities take a longer period of time or have a higher intensity, they will result in a longer period of rest.

> ***"If I do something intense in the morning for example walk through a museum for an hour and a half or so, I can't do another museum in the afternoon which I could do before. I do take that into account with planning then. In the afternoon then just rest or do something really quiet where I also know I can just sit down at any time if I want to." – Participant 4 (translated from Dutch)***

> ***"Activity is also, for example, volunteering and I do that once a month, a whole Saturday from 09:15 in the morning until 16:00. So, then I go out the door at 08:30 and come home around 17:00 and then I do need more days to take it easy." – Participant 2 (translated from Dutch)***

Another topic often mentioned has to do with the unpredictability of getting tired. This can result in having to cancel something or do something and suffer the consequences later on. It can be really annoying and frustrating to really look forward to an activity and then be too tired to actually enjoy it.

Treatments

People undergo a lot of different treatments to figure out which treatment works best for them.

> ***"You also notice that it is such an interplay of bones and muscles and the rest of your body and that there is no one truth, so you are searching every time. To find what works and what doesn't work, that's very individual and it's not only physically but also mentally intensive." – Participant5 (translated from Dutch)***

Most participants are undergoing physiotherapy in combination with custom footwear. They go to the physiotherapist once a week for about one hour and do exercises at home as well. The custom footwear are orthopaedic shoes[32] which are often recommended by the orthopaedic surgeon. Most participants also used some type of pain relief medication, such as paracetamol.

One participant had an ankle arthrodesis performed, while others said they put off such drastic treatments as long as possible because they are unwilling to sacrifice their joint function.

> ***"Fixating the joint was a possibility, but I said no to that right away if that is necessary, I really shouldn't be able to walk anymore I will wait as long as possible. So, I declined that one. I try to rule out drastic things like that as long as possible because I have no idea what will happen to my foot.***
>
> ***It's not yet so bad that I think it's necessary to fuse the ankle, that's a fact, and the only disadvantage is that I'm getting older, and I don't know to what extent my body will be able to cope with an operation like that in 10 years." – Participant 3 (translated from Dutch)***

Walking

Almost everybody reported to try and walk every day to move the joint. This often exists of walking for 30 minutes then taking a break and walking again. People can often keep this up to a total walk of about 4 hours. If the ground is uneven, such as cobblestones or in the woods, walking becomes more difficult and people need to pay extra attention. Sometimes Nordic walking poles can provide additional stability in this regard. What also stands out is that a number (n=3) of people say they have dogs so they have a good incentive to walk every day.

[32]Orthopaedic shoes
Footwear that is designed to support the feet, ankle and leg and provide pain relief. There are many different types.

"I do like to take walks and then take a few more breaks, rest periods, that does help. I used to just walk more. The occasional rest moment to refuel, but not too long because then it gets too stiff again. 30 to 45 minutes of walking to break in total up to 3 to 4 hours of walking. " – Participant 6 (translated from Dutch)

Mobility

When discussing distraction as alternative treatment, another important topic arises: freedom of movement. People stated that their movements are already limited due to the AOA and with such a device it shouldn't become more since moving is important to prevent joint stiffness. Now most people use the car to go to more intense activities, such as grocery shopping, the (electric) bike or walking for things that are close by.

Distraction

Participants are divided on the topic of distraction, but most of them would consider it if it is proven to help and if they experience too much pain in their ankle joint. The idea behind it is often seen as cruel and frightening, but since it is temporary people think it will be okay.

6.3. Conclusion

Ankle distraction is a procedure that involves multiple people with varying levels of influence and interest throughout the process. The orthopaedic surgeon and patient are the key-players, as they have the highest interest and influence with this procedure since they are the end-users. Other involved people have a supporting role.

Understanding the perspectives of the end-users is essential in developing and implementing a new treatment. User research has shown that living with (A)OA has a significant impact on the daily schedule of the patient. They undergo various treatment to figure out which works best. Most of the participants walk every day to move the joint. Important aspects to take into account for such a treatment are freedom of mobility and fear towards the device.

6.3.1. Requirements

Based on the stakeholder analysis some important factors to consider for the final design were discovered.

Technical aspects:

- ◊ The device should be as simple as possible. Whereby there is a high preference for a mechanical solution instead of an electrical or automized one.
- ◊ The actual joint situation should be mimicked by the device as close as possible.

Daily living:

- ◊ Daily activities should continue as normal as possible. Patient should still be able to wear normal pants and shoes, be able to ascend and descend stairs, shower, etcetera.
- ◊ The device should be discrete, subtle and friendly. In this way, the treatment looks less scary for the patient and is not too obvious for other people.
- ◊ Patients will be walking around with the device and should not get caught behind something with the device.

7

SYNTHESIS

CHAPTER SEVEN

7.1. Problem statement

Currently, there is no suitable treatment option for young active people with end-stage AOA. Arthrodesis is the gold standard when it comes to treating end-stage AOA (Nguyen et al., 2015) and other treatments that are commonly used are also joint sacrificing. These treatments provide good results in the short-term but might result in long-term problems (Barg et al., 2013). Patients are postponing these current surgical treatments as long as possible because they are either afraid or they want to preserve their joint and ankle motion (Paley et al., 2008).

Arthrodiastasis (ankle distraction arthroplasty) is believed to be an alternative treatment for end-stage AOA (Tellisi et al., 2009). However, with the current distraction devices, the joint is unable to move, due to the absence of a hinge in the device. Moreover, with these devices the placing of the pins is standard for everyone. This limits the procedure, since the presence of scar tissue in the location where the pins should be placed restricts the surgeon in properly placing the device. The scar tissue in combination with the absence of a hinge leads to a very stiff and painful joint during the current distraction treatment. Furthermore, for the distraction to work the joint needs to be mechanically unloaded, however, some pressure is needed to help regenerate the cartilage.

Besides the technical aspects, physiological aspects should also be taken into account. For instance, the distraction treatment is for a long period, around 1 year, and therefore is considered as a commitment. Therefore, it is recommended that this treatment is for patients who are willing to follow instructions (Nguyen et al., 2015). Furthermore, people are feeling anxious and scared towards the current devices and feel that they will limit them too much in their daily life.

To make joint-sparing treatments suitable, a new type of distraction device should be developed. With this device, the patient should still be able to move their ankle to prevent them from getting a stiff joint. Furthermore, the device needs to be customizable to make sure that the pins can be placed in the correct location where they have enough support. Lastly, the patient should be willing to undergo this treatment and be able to continue with their daily life without too much struggle. When combining all of this, the following problem statement can be formulated:

"DEVELOP A ***PERSONALIZED HINGED ANKLE DISTRACTOR*** WHICH WILL BE A ***NEW ALTERNATIVE*** JOINT SPARING TREATMENT FOR YOUNG ACTIVE PEOPLE WITH ***END-STAGE AOA***. THE DEVICE SHOULD HAVE A ***LIMITED IMPACT*** ON THEIR DAILY LIFE."

7.2. Requirements

The findings from the research, shown in previous chapters, can be summarized into a list of requirements. The list of requirements is sorted into themes using the checklist of Pugh and can be found in appendix F. The requirements that are the reason for this project are the most important and are formed into design drivers which are used in the development phase. The development phase is an iterative process and therefore, the requirements might be added, removed are adjusted.

Comfort

The current surgical procedures are complex and exhausting for the surgeon, both mentally and physically. For the distraction treatment, the **procedure should be less complex**, resulting in l**ess instruments needed**, making it more comfortable for the surgeon. Furthermore, the device should **be placed on the pins with simple tools** such as tweezers or allen keys to make it easier. A **lightweight** device will allow for easier placement and increases the comfort of the patient.

To increase the comfort of the patient, the device should have a **limited impact on the daily life**. The patient should still be able to wear normal pants and shoes, ascend and descend stairs, shower, etcetera. Furthermore, they should still be able to walk around, so there should be **enough ROM** within the device and should **not get caught behind something** with the device. If the morphology of the

lower leg and foot are taken into account, **interference with the other leg can be prevented** during these daily activities. Finally, the device **should be discrete, subtle and friendly looking**. In this way, the treatment looks less scary for the patient and is not too obvious for other people.

Distraction technique

The device should have a distraction mechanism that **allows for 2 mm distraction**. This mechanism is as simple as possible, whereby there is a **preference for a mechanical solution** instead of an electrical or automized one. Throughout the procedure the distraction mechanism is only needed to perform the distraction, so it could be possible to remove afterwards.

In order for the distraction technique to work, distraction should be **provided for about 3 months**. To **prevent joint stiffness** during this treatment and **maintain intra-articular fluid pressure** certain movement should be allowed. Joint stiffness can be prevented when the patient is able to use their ankle joint, therefore **a hinge should be incorporated** into the device. Intra-articular fluid pressure can be maintained by **adding a damping mechanism** into the device. Furthermore, this increases the comfort for the patient. Finally, the device should allow for movements, **similar to the movements within the actual ankle joint.**

Modular & customizable

The current devices use a drilling guide, allowing for less variation in pin placement. This is limiting the surgeon to place the pins in a good position to provide enough support. If the device is adjustable per patient, the **pin placement allows for more variation**, making it easier for the surgeon. The device should be modular, so it can exist of **standard and personalised parts**. In this way, the treatment will be suitable for more patients.

In the current devices with a hinge, the rotation axis is estimated by the surgeon, which always results in an error margin. Since it is an estimated guess of the surgeon. When **the pins are placed separately from the device**, a CT-scan can be used to determine the **exact location of the rotation axis**. Therefore, the **pin fixation and rotation axis should be customizable**.

Safety

For the current procedure the consequences of a small human error are big for the patient. Therefore, the device and new procedure **should leave little to no room for human errors**. The device should enable the surgeon to **correct a small mistake**. Furthermore, if the device is made based on the CT-scan mistakes are limited. Another option is to **provide clear feedback to the user**.

Within the ankle joint there are **high forces, which have to be absorbed into by the device, without breaking it**. Furthermore, the **pins should have enough support within the bones**, to prevent them from moving up and down within the bone during high peak forces. Distributing the force across a bigger area allows for more stability within the design, therefore the **distance between the pins should be at least 5 cm**.

During the distraction period there is always a direct connect to the bones via the pins, creating a high infection risk. To prevent infection the **device and pins should be sterile** before placing it. Furthermore, **at least 1 cm distance between the device and the skin** is needed so the patient can reach and clean the pin sties.

7.3. Envisioned process

The ankle distractor will be part of a treatment for end-stage AOA. Therefore, an overview (figure 18) of the envisioned treatment process is created to make sure that the final design can fit within this context.

During the indication the patient with AOA visits the outpatient clinic and discusses the treatment with the orthopaedic surgeon. This discussion is about the conditions of the treatment, the inclusion and exclusion criteria and complications that can occur.

After this, the patient decides whether to continue with the treatment or not. If the patient is still willing to undergo the treatment, a day of hospitalization is scheduled. At this day, the pins will be placed during a minimally invasive surgery. After the surgery the patient receives instructions about wound care to prevent pin-site infections. 1 or 2 weeks later, the patient has to return to the hospital to take a CT-scan and visit to outpatient clinic for a check-up. The CT-scan is used by the x-ray technician to determine the rotation axis of the ankle.

If the wounds are healing properly, a new appointment is scheduled a week later to place the distraction device. This can be done at the outpatient clinic. After the device is placed the patient receives clear instructions about what to do if something happens. During the distraction, the patient has to perform daily exercises and clean the pin sites every day. Every week the patient has to go to the physiotherapist to do more complex exercises under guidance. Furthermore, the patient needs to go to the outpatient clinic every 2 weeks for a regular check-up. During this check-up the mental and physical wellbeing of the patient is discussed and the pin-sites are checked for infections.

After about 3 months the distraction device and pins are removed during a day surgery. 2 weeks later the patient comes back to the hospital for a post operation check-up and 1 year later the patient comes back to see the final results of the treatment.

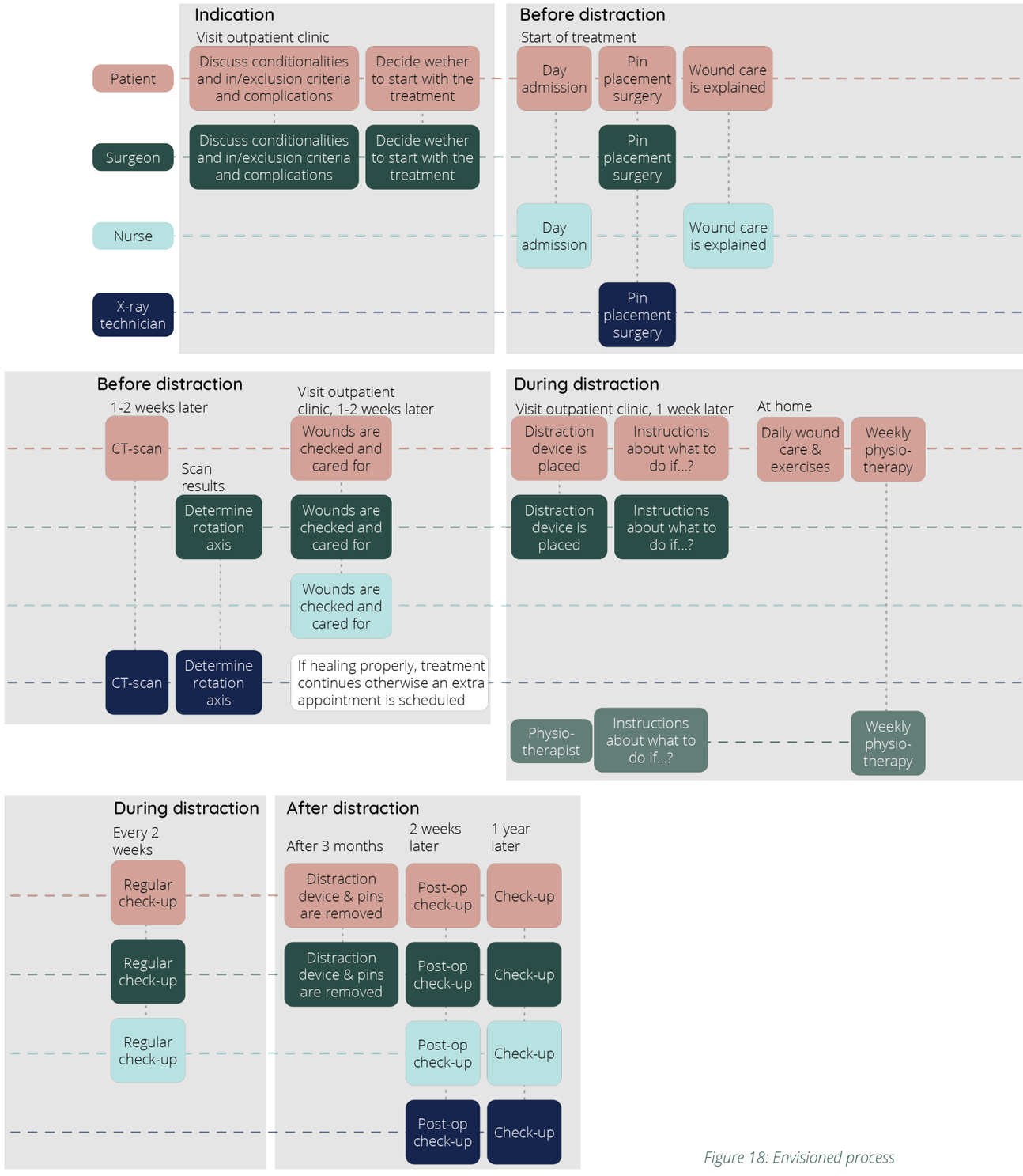
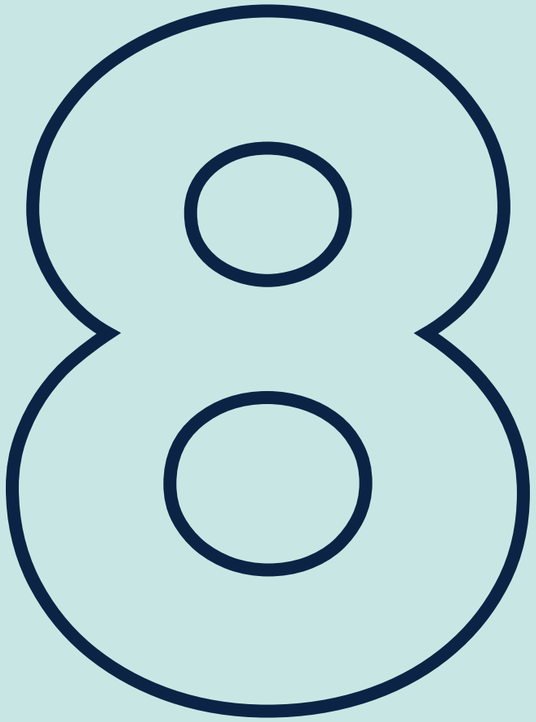


Figure 18: Envisioned process



DEVELOPMENT

CHAPTER EIGHT

Based on the defined requirements, context and envisioned process, ideas were generated. These ideas led to different concept direction, which resulted in the final concept. In this chapter, this process and steps that were taken along the way are described.

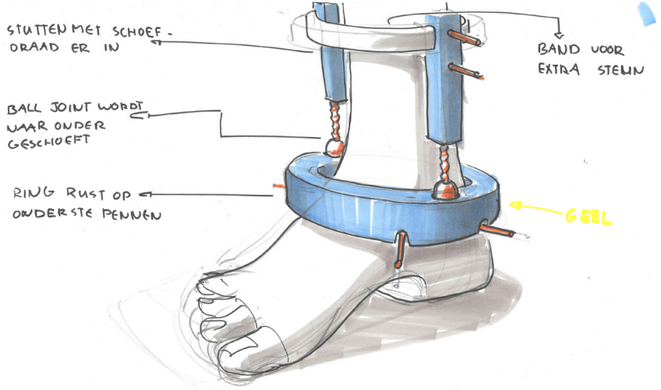
8.1. Ideation

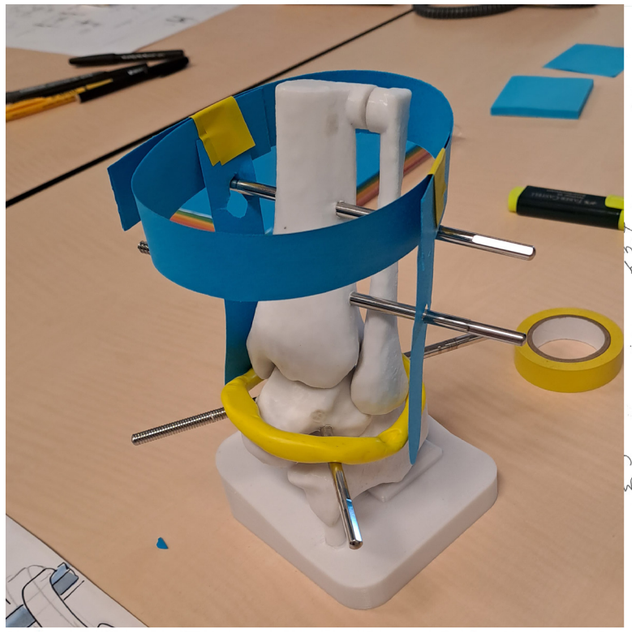
Since this a quite complex project, a good solution requires knowledge of different fields: medical, engineering and design. To combine these knowledge areas and bring them together in a concrete solution, I organized a co-creation session. At this session there were 3 people from the department of orthopaedics, 5 people from MIO and 3 industrial design engineering students. These were divided into teams so that the knowledge was distributed. After a brief introduction of the problem, they started coming up with different ideas from which eventually each team came up with a concept with a corresponding prototype or poster to explain it. In appendix G the presentation can be seen.

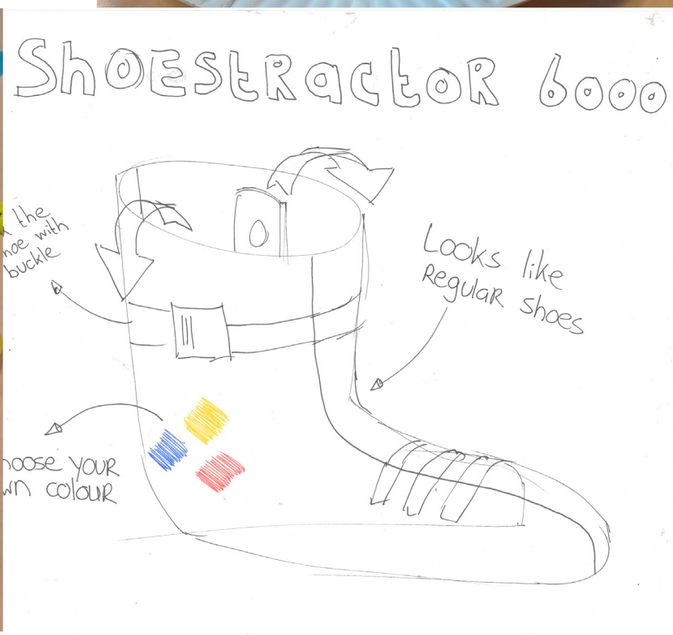
During this co-creation session different topics were discussed. These topics together with the design drivers and requirements resulted into 5 focus areas: Distraction, hinges, damping, personalization and pin fixation. Based on these focus areas more ideas were generated and combined into more elaborated promising ideas.

At the end of the session, every team presented their most promising idea with a poster and a prototype. An overview of these can be seen in figure 20.

Figure 19: Co-creation session







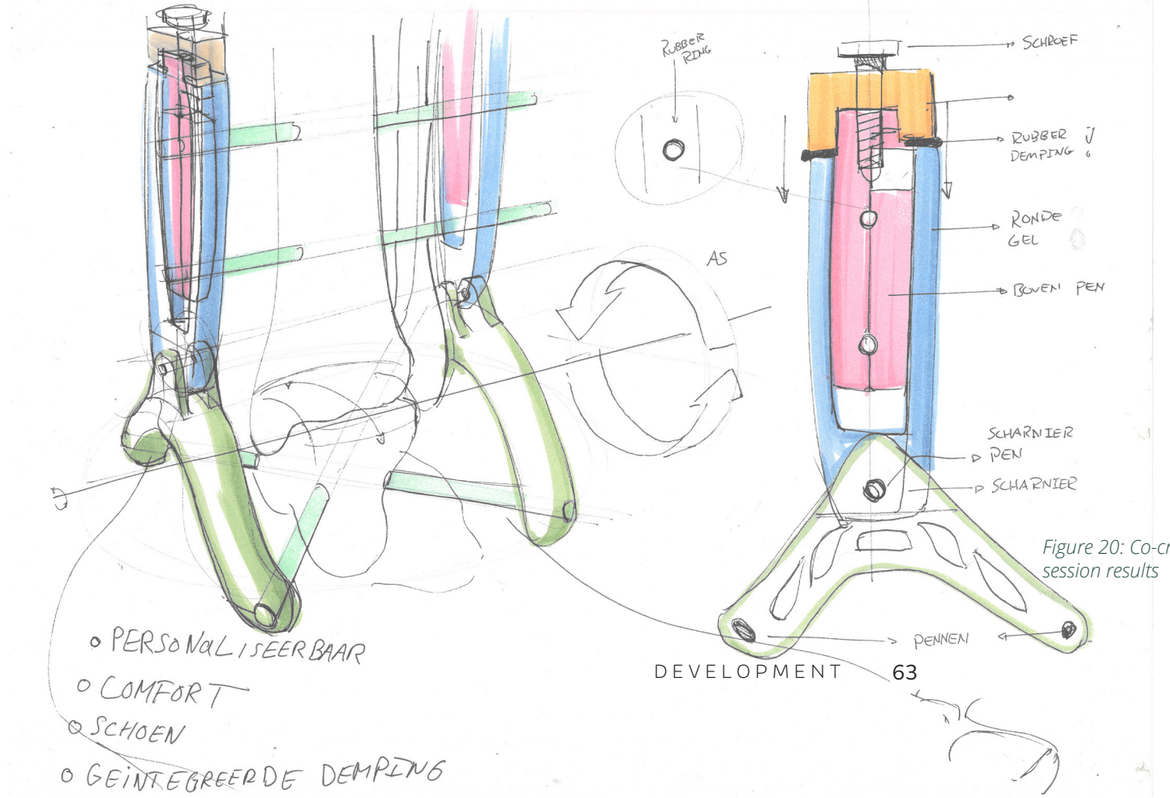


Figure 20: Co-creation session results

8.2. Conceptualization

The most promising ideas were combined into four concepts, which all have a different distraction mechanism whilst the pin fixation is similar in all of them. Furthermore, the assembly for each concept is different, some parts are tailor made and some are standardized. But all of the concepts are a solution to the problem statement.

8.2.1. Concept 1: Two sided- screw distraction

The first concept, two sided- screw distraction, exists of two similar devices, one on each side of the leg. The device has a distraction mechanism that exists of a thread, with two stabilisation rods. To perform the distraction, the thread can be twisted until the needed distraction distance is reached. This distraction mechanism is incorporated into the top part of the device.

To fixate the device on the pins, holes are made in the standardized part at the correct location. After this, both parts (top and bottom) are clamped around the pins using small screws. The bottom part has a sliding mechanism for the hinge, which allows the surgeon to fixate it on the location of the rotation axis of the patient.

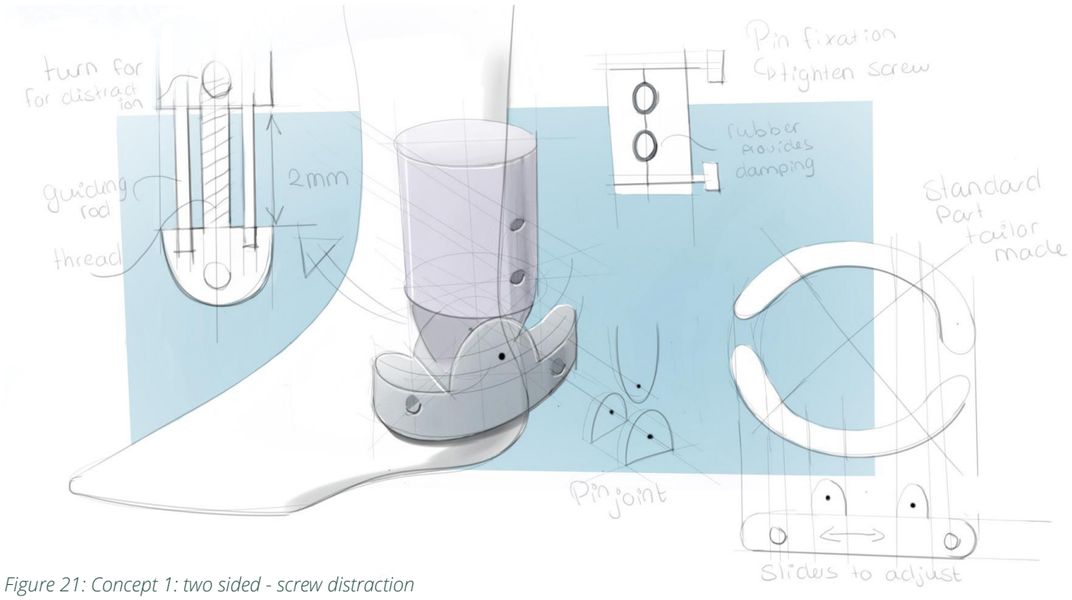


Figure 21: Concept 1: two sided - screw distraction

8.2.2. Concept 2: Building blocks

The second concept, building blocks, makes use of an external frame build around the ankle joint. The distraction will be performed at the back of the leg, by turning a gear, which is connected to two gear racks on each side of the leg. This enables distraction at both sides of the leg with one turn.

The parts around the pins are personalized pieces to allow for a tight fit, fixating the device. Standardized parts are combined with these personalized parts to create the whole frame that positions the pin joint at the rotation axis of the patient.

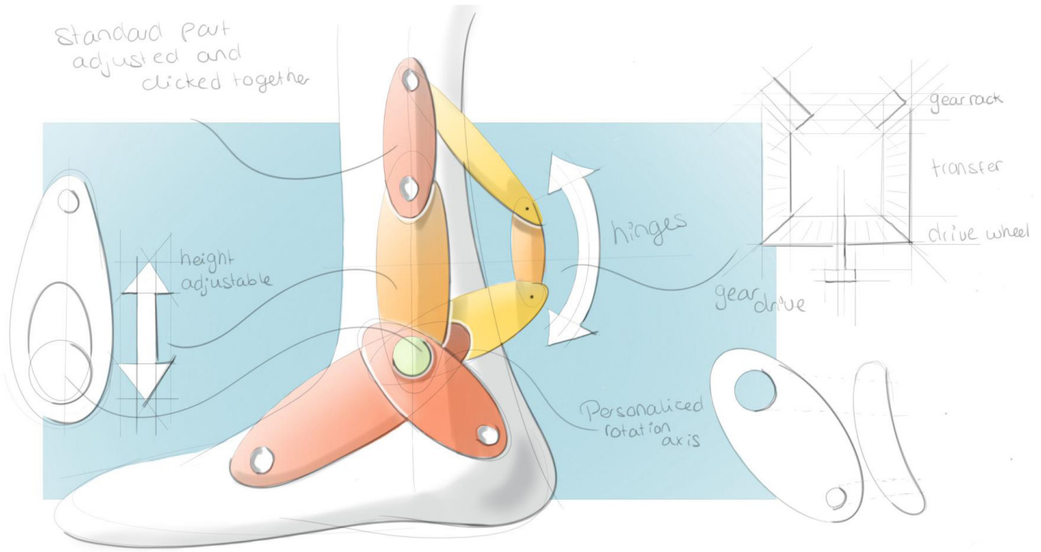


Figure 22: Concept 2: building blocks

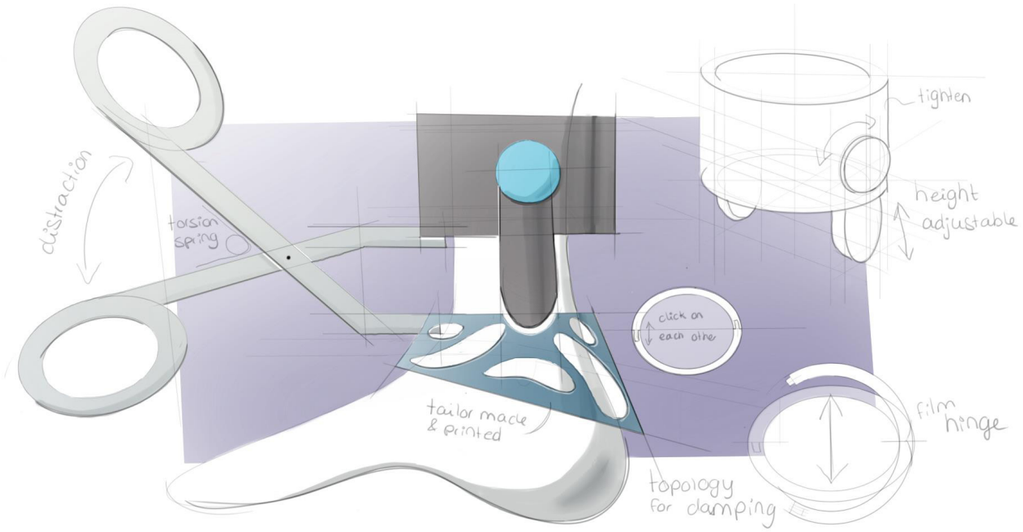


Figure 23: Concept 3: Seperate distraction

8.2.3. Concept 3: Separate distraction

The third concept, separate distraction, uses pliers with a torsion spring to perform the distraction. After completing the distraction, the frames will be placed around the pins and the pliers will be removed.

The top frame is a standardized part that will be available in different sizes. At each side of this part there are two pins with adjustable heights. This way the distraction distance can be set properly. The bottom part will be custom made, taking into account the location of the pins, the rotation-axis, and the needed level of damping. This allows the hinge to be similar to the articulation surface of the ankle joint.

8.2.4. Concept 4: Distraction - damping combined

The fourth and last concept, distraction – damping combined, exists of three components: two distraction devices and one U-ring. During the pin placement surgery, a drilling template will be used to make sure that the pins are placed horizontally and parallel to each other at a fixed distance.
The distraction is performed by removing a pen from the device. This action releases a spring which enables the distraction whilst allowing damping. In the U-ring, located around the foot, slots will be made at

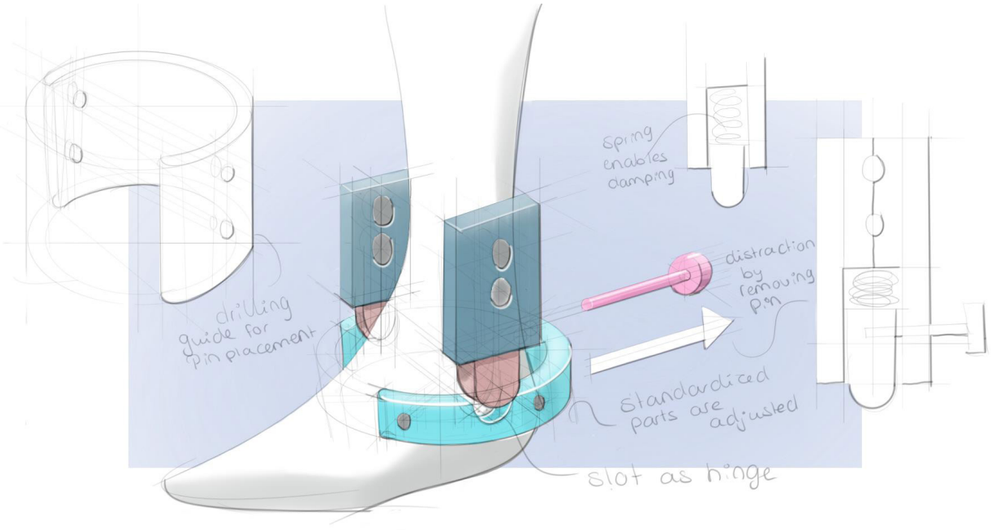


Figure 24: Concept 4: distraction - damping combined

the location of the rotation axis using a milling machine. This allows for a hinge similar to the articulation surface of the ankle joint.
Within the U-ring, holes will be made at the location of the pins to allow for a tight fit. Next to that, the top part is a standardized part, with pre-drilled holes, so to fixate the device small screws need to be turned.

8.3. Concept selection

All concepts are in line with the requirements. Therefore, a list of selection criteria was used to select the most promising concept.
The first criteria focus on the feasibility of the design. To make implementation, production and testing easier, it would help to have a design producible with the available techniques. Furthermore, the device must be as simple as possible while the costs should not be excessive.

Other criteria have to do with the comfort of the patient and the surgeon. For the patients the device should have a minimal impact on their daily life and have a discrete, nice, and friendly look. For the surgeon, the ease of use during the procedure is more important.

The final criteria have to do with the customisation of the device. It should be easy to personalize and for the surgeon it should be easily

attachable to the pins. Another aspect to consider is the cleanability of the device, as it is important to minimize the risks of infections. Moreover, it would be sustainable if parts of the device can be sterilized and reused.

The weighted criteria method (figure 25) was used to decide which concept is the most promising according to the previously mentioned criteria. Each criterium was given a weight, wherein the most important ones weigh the most. Then the concept is rated from 1-10 on every criterium. Every score is multiplied by the weight, these totals are combined into the final score per concept. The concept with the highest number will be the most promising concept.

As can be seen in figure 25 concept 4: distraction – damping combined has the highest rating with a score of 685 and therefore would be the most promising. However, the score of concept 1: two sided- screw distraction is a close second with a total score of 680. Since the grading is subjective, this result is not conclusive. However, the differences with the other concepts are big enough to conclude that concept 1 and concept 4 are better based on these selection criteria. After proposing the different concepts and discussing the results from the weighted criteria method with the orthopaedic surgeon, it was concluded that concept 3: separate distraction is too futuristic concept and that concept 2: building blocks is too similar to an external fixator which takes time to install. Therefore, it was decided to combine concept 1 and 4.

		Concept 1		Concept 2		Concept 3		Concept 4	
	Weights	**Score**	**Total**	**Score**	**Total**	**Score**	**Total**	**Score**	**Total**
Feasibility									
Implementation (producability)	20	7	140	8	160	5	100	7	140
Simple design	15	7	105	5.5	82.5	7	105	7	105
Costs	5	5	25	6	30	4	20	6	30
Comfort									
Low impact daily life	5	6	30	4	20	7	35	6	30
Looks (discrete, nice/friendly)	10	7	70	6	60	9	90	7	70
Ease of use	20	7	140	5	100	6	120	8	160
Customizable									
Personalisation	15	8	120	7	105	6	90	6	90
Cleanability / reusable	10	5	50	6	60	7	70	6	60
Total score	100		680		617.5		630		685

Figure 25: weighted criteria

8.4. Final concept

The final concept is a combination of concept 4: distraction-damping combined and concept 1: two-sided screw distraction, which is shown in figure 26 .

The distraction mechanism will be a combination of both distraction mechanisms. It exists of a thread, with two stabilisation rods and a damping mechanism. To perform the distraction, the thread can be turned until the needed distraction distance is reached. When the distraction is performed, vertical movement is still allowed through the damping mechanism to maintain intermittent fluid pressure. Moreover, rubber will be integrated within the pin fixation to incorporate some extra damping within the device for patient comfort. This distraction-damping mechanism can be attached to the top part of the device, the tibia clamp.

The combination of the lower parts - the distraction device and talus clamp - and the top parts- the tibia clamp-, will be placed at each side of the lower leg to allow for symmetrical distraction.

To guarantee parallel pin placement at a fixed distance, a separate drilling template will be used during the pin placement surgery. This allows for easier pin fixation and the use of reusable clamps. The device will be fixated on the pins by tightening small screws located within the clamps.

The hinge is positioned in the lower part of the device in such a way that it allows for a pin-joint at the rotation axis of the patient. The top part of the hinge is formed by the bottom of the distraction mechanism, while the lower part of the hinge is formed by the clamps around the pins placed in the talus.

This leaves us with a semi personalized device, that allows for symmetrical distraction and damping. Furthermore, the device is easy in use and allows for movement of the foot.

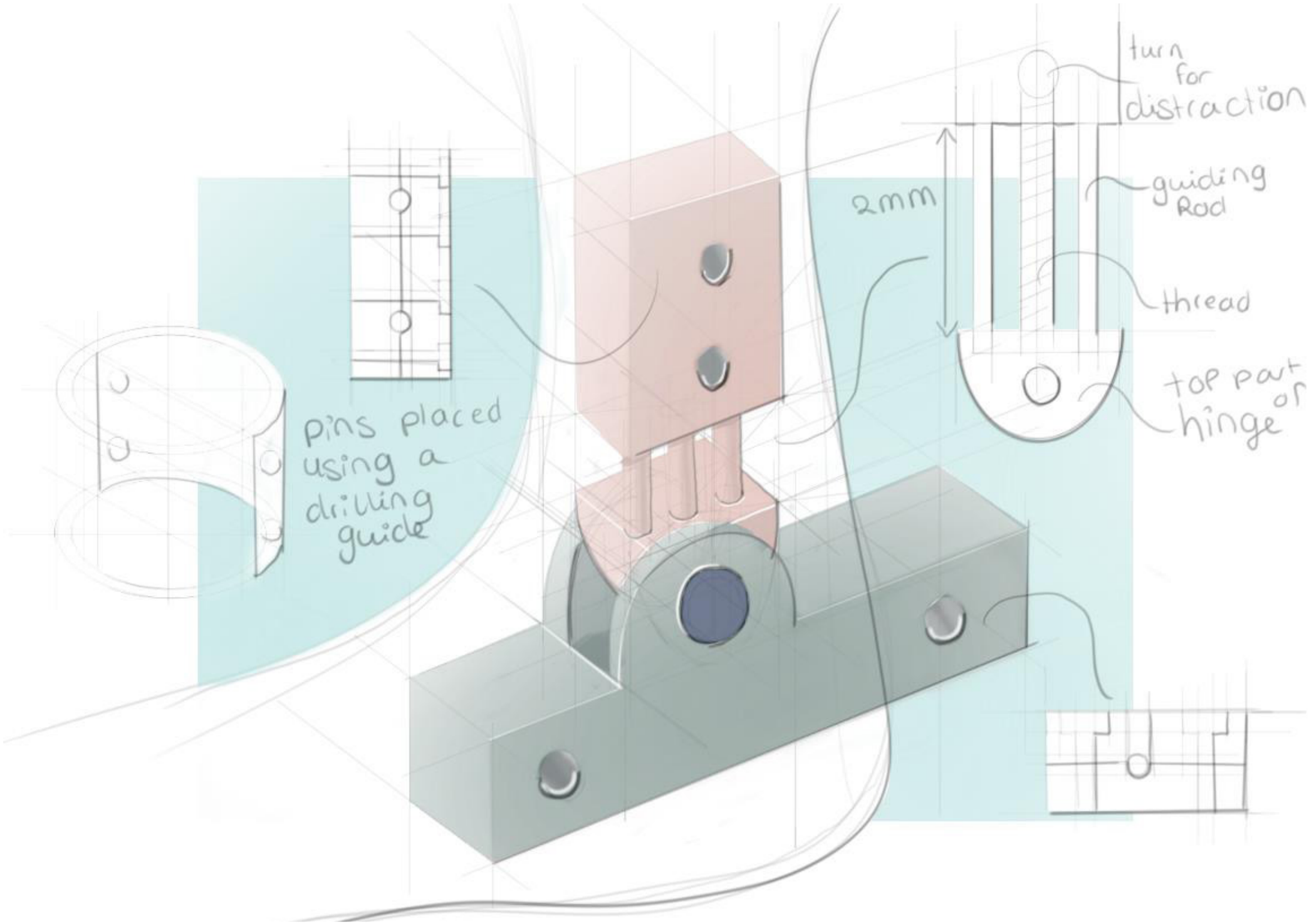


Figure 26: Final concept

DESIGN CONSIDERATIONS

CHAPTER NINE

Several considerations were taken into account when developing the ankle distractor, based on the different features of the design, including: the pins, damping, distraction mechanism, hinge types and materials. In this chapter, the most important design choices, considerations and outcomes are discussed.

9.1.Pins

The distractor will be attached to the bones using Steinmann pins, from now on referred to as pins. The tibiotalar joint need to be distracted, therefore the pins are pierced through to the tibia and talus. The tibia is a long, strong bone which allows for rather easy pin placement. However, the difficulties lie in piercing the smaller talus, surrounded by other bones and tissue.

9.1.1. Pin types

There are different types of pins that can be used to attach the distractor to the bones. To be able to make a choice, the first thing to select is length and diameter. The pins should be thick enough to be able to withstand the forces, but they still need to fit within the bone. Furthermore, they also need to be long enough to have enough room to attach the device.

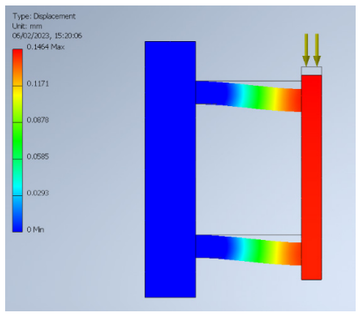


Figure 27: simulation of the deflection

A use scenario was created to estimate the deflection of the pins. In this scenario, it was assumed that the device will be attached at a distance of 1 cm from the skin, with a thickness of 5 mm. An extra 5 mm is added to the distance as a safety margin. The material of the pins is stainless steel. The diameter of the pins should be as small as possible to limit the chances of hitting each other within the talus, while still being able to withstand a high distraction force. Together with the orthopaedic surgeon it was decided that a deflection of 10% is acceptable. When simulating, the pins with a diameter of 4.5 mm showed a deflection of 0.15 mm when a distraction force of 1000 N is applied (figure 27). Therefore, the pins with a diameter of 4.5 mm were chosen. The length of the pins is dependent on the thickness of the lower leg.

Different variations of Steinmann pins are available (figure 28). They can have a smooth surface, but can also be threaded. This thread can be located at the centre of the pin or on the ending. Furthermore, the endings can be sharp (trocar) or can be a drill bit. The pins should

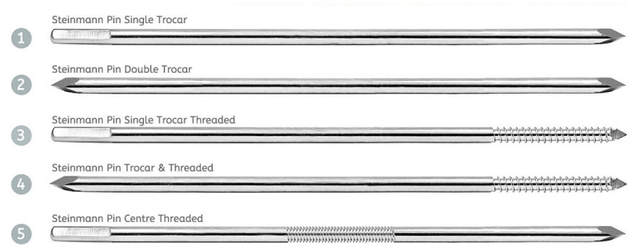


Figure 28: type of steinmann pins

have enough support from the bone and be able stay in place when weightbearing on the leg and foot. Together with the orthopaedic surgeon it was decided that it is best to use the pins with a thread in the centre and a sharp end, since they are harder to move. Furthermore, there is a possibility to use hydroxyapatite (HA)-coated[33] pins to improve bone attachment (Bal et al., 2020).

[33]Hydroxyapatite (HA)
It is present in bones and helps to form new bone. It can be used to boost bone regeneration.

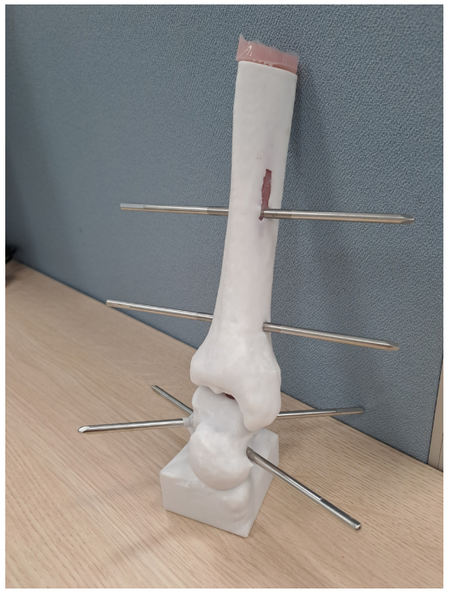
9.1.2. Location & placement

In the current devices , the device itself is often used as a guide to help determine the location of the pins. This limits the freedom the surgeon has to place the pins. Therefore, it was decided to place the pins first, so the surgeon can look for the best location and then device the device can be adjusted to the pins.

The location of the pins is estimated based on a pre-made CT-scan. During the surgery a small incision is made at this location. For the placement of the pins in the tibia a drilling guide and an alignment template are used to allow for an accurate placement. For the pins in the talus, only an alignment template is used to ensure that the pins will not hit each other, but still allow for enough freedom in placement. Furthermore, throughout the entire procedure x-ray is used to determine and verify the placement. If the location is determined, the pin is placed in the drill and drilled into the bone. After one pin is placed, the foot is moved to check if the pin is not limiting the movements. At the end of the procedure if all the pins are placed, the sharp endings are cut off.

The location of the pins towards each other and the bones is important. To get a better understanding of how the bones are related to each other and where the pins could be placed two models were made.

First the bones were printed and then the pins were placed by the orthopaedic surgeon at the determined locations. For the first model (figure 30), the location of the pins was estimated by hand and the pins were placed using a drill. Afterwards the sharp ends were cut off using a bolt cutter. For the second model (figure 29) a CT-scan of the cadaver leg (chapter 9.4) was used, and silicone was added to simulate the force needed for distraction. From these models, it can be concluded that the final pins in the tibia will be located before the fibula with a spacing of 6.5 cm. The pins in the talus will be crossing each other, therefore they need to be placed carefully, to prevent them from hitting each other.



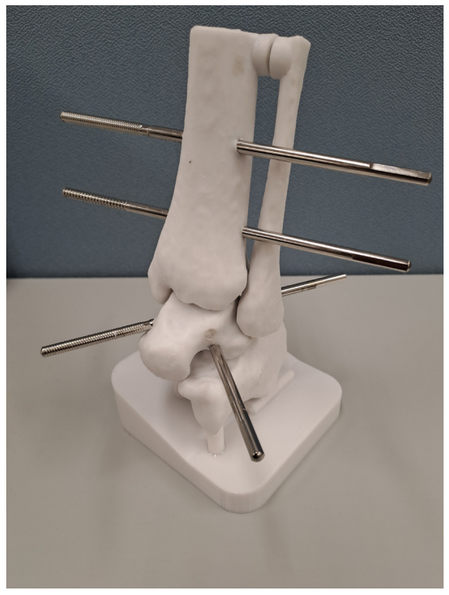


Figure 29: Model 2 of tibia and talus with pins

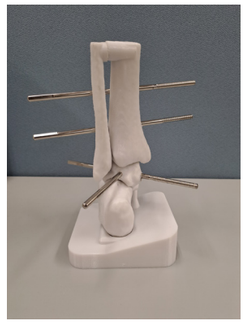


Figure 30: Model 1 of tibia and talus with pins

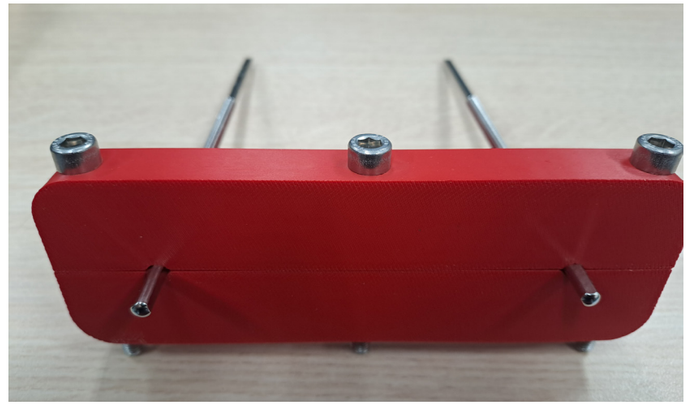


Figure 31: Standardized clamps for the tibia pins

Figure 32: Standardized clamps for the tibia pins

9.1.3. Pin fixation

The device needs to be attached to the pins, which is done by using clamps. For the pins in the tibia different clamps are needed than in the talus.

The tibia pins are placed using a drilling guide. So, these will have a fixed distance between them, allowing for the use of one clamp for both pins (figure 31,32). To ensure a tight fit, screws will be used to tighten the clamp around both pins. The clamp will be pre-assembled so it can slide on the pins before tightening the screws, making the installation of the device easier. The pin placement in the talus bone allows for more variation, therefore one clamp per pin is needed. The design of the clamp is similar (figure 33) as the one above, but it is smaller and two screws are used instead of three.

Different clamping designs were tested to examine the possibilities of incorporating damping. It turned out that this made the placement of the clamps more complicated and there was only a little damping. Also, the resistivity of the material decreased, leaving a dent (figure 34) and loss of damping. Therefore, it was decided not to implement damping in the pin clamps, but to apply a separate damping system.

The clamp for the tibia pins is not patient-specific and can therefore be reused. However, a connection piece between the distraction mechanism and clamp will be required. For the talus clamps, it is decided to have a pre-made part which is available in different sizes and needs to be adjusted per patient. This is done by milling a hole and slot at the correct angle and location for both pins. Furthermore, for every pin a screw hole needs to be tapped, so that the clamp can be tighten around the pin.

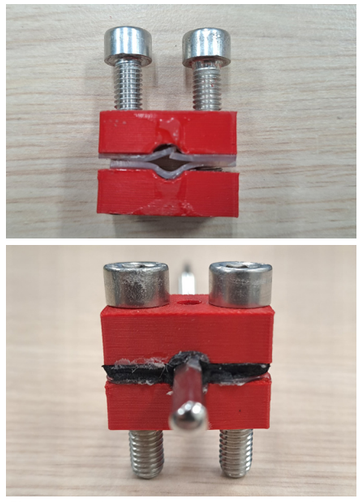


Figure 32: Clamp for the talus pins with silicon (top) and with neoprene (bottom)

Figure 34: Dent on the inside of the clamp

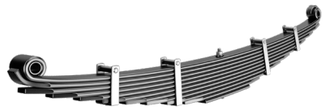


Figure 35: Leaf spring

Figure 36: Cup springs

Figure 37: Heavy duty compression springs

9.2. Damping

In chapter 5.1, it is described that intra-articular fluid pressure needs to be maintained. This can be done by incorporating a damping system within the design. It was decided, that it should be a separate damping system and could not be incorporated within the pin fixation.

There are a lot of different damping mechanisms available on the market, however in this context there is limited space. The distraction mechanism, damping system and hinge should be incorporated in the design between the lower tibia pin the rotation axis. Furthermore, the device should be lightweight and be as simple as possible. Therefore, it was decided to not use complex damping systems such as gas springs or hydraulic dampers, but incorporate a spring within the design.

The spring need to withstand high peak forces and cannot deform. Therefore, leaf springs, cup springs and heavy duty compression springs were considered. However, a leaf spring (figure 35) appeared to be challenging to incorporate in the design and is seemed a bit too much. Cup springs (figure 36) seemed more promising, since these are easier to incorporate in the design. They exist of different discs which are stacked on top of each other, so they can be adjusted based on the weight of the patient. Furthermore, heavy duty compression springs (figure 37) were analysed, these are also easy to incorporate in the device. Furthermore, they are even easier to adjust for the patient, because they are one part instead of multiple discs combined. Since these springs have different stiffnesses, they can be changed to suit the weight of the patient. Finally, it was decided to use heavy duty compression springs within the design, because they exist of one part and are adjustable per patient based on their weight.

9.3.Distraction mechanism

The distraction mechanism is one of the most important aspects of the device. Within the selected concepts there are two different possible distraction mechanisms, one using thread and the other one using a spring. The distraction mechanism with the spring looked the most promising at first, since this had the potential to combine distraction and damping into one mechanism (figure 38). The spring is placed under tension and blocked by a pen. The device will be attached to the pins and then the pen is removed, resulting in distraction. However,

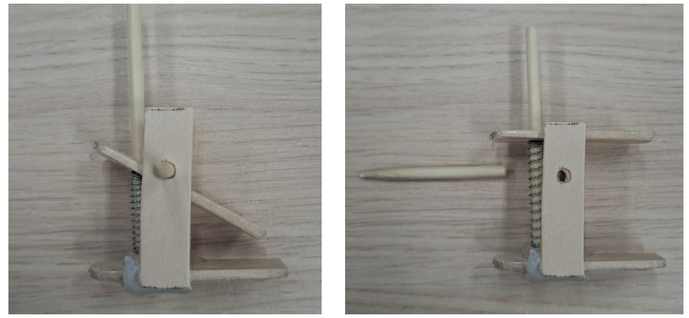


Figure 38: Distraction mechanism 1 without distraction (left) with distraction (right)

the distraction distance cannot be guaranteed and the force from the spring needed to perform the distraction is linear . To perform the distraction, it is better to have a constant force. Therefore, it was decided to develop a screw distraction mechanism.

Two screw distraction mechanisms were made to see which design suits our purpose best. Both mechanisms use an M6 thread with a pitch of 1, this means that the vertical distance after 1 rotation is 1 mm. In the first mechanism, a hexagon and a wrench are used to perform the distraction. When the hexagon is turned, the thread will push the bottom part away creating distraction. This bottom part is see-through allowing the surgeon to see the distance. In the second mechanism the brass part can be rotated, the pins in the design are providing feedback to the user. One pin further means an increase in distraction distance of 0.25 mm.

From both mechanisms a prototype (figure 39,40) was made and these were discussed with the orthopaedic surgeon. It could be concluded that the first mechanism still allows for human errors and reading the distraction distance is challenging. The second mechanism has less user error and provides better feedback. However, performing the distraction would call for more forces and thus be more challenging. Furthermore, both distraction methods are static and the distraction distance should be adjustable to allow for intra-articular fluid pressure.

These findings were combined into a new distraction mechanism (figure 41). This mechanism is a combination of distraction and damping, which are combined by a screw and housing. The bottom part enables the distraction, by untightening the screw the disc moves up until it reaches the top position. In this position a distraction of

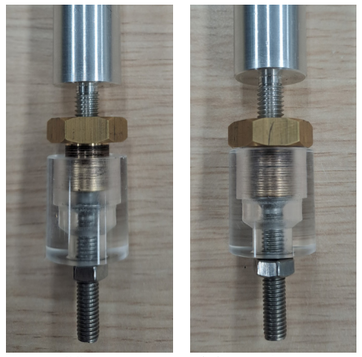


Figure 39: prototypes of distraction mechanism without distraction (left) and with distraction (right)

Figure 40: prototypes of distraction mechanism without distraction (left) and with distraction (right)

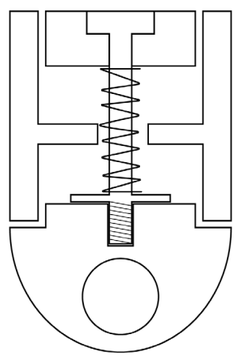


Figure 41: Distraction - damping combined

2 mm is reached. The top part, has a spring and a block around the screw. In this part there is no thread on the screw so these components can move up and down without resistance to provide damping. The spring is located on top of the disc, in this way there is always a fixed distraction distance, even if high force is applied. The spring is chosen based on the weight of the patient to allow for proper damping. Both mechanisms are encapsuled so the inside cannot be reached during use.

From this new distraction mechanism, a prototype was made and tested. In this test it became clear that in the case of damping, there will be no distraction. Since the top part, can always move back to its original position. Furthermore, performing the distraction whilst attached to the pins was very inconvenient and frustrating.

Based on the findings another mechanism was designed. Within this

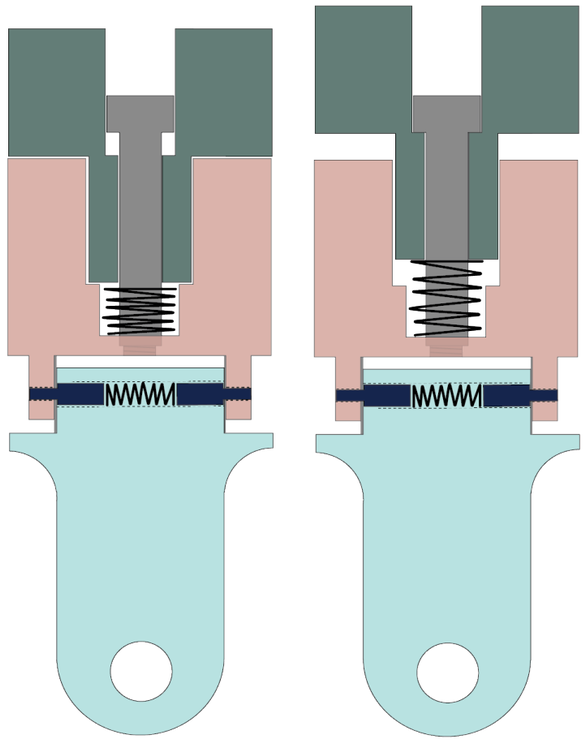


Figure 42: Final distraction mechanism without distraction (left) and with distraction (right(

mechanism (figure 42) the distraction is performed, using a wrench on the hexagonal part (pink). Inside the thread there are two small pins (dark blue), that are being pushed out by a spring when the correct distraction distance of 2 mm is reached. This makes it easier for the user to just turn the hexagonal part until it is not possible anymore, always resulting in a distraction of 2 mm. The top part (green) is attached to the hexagonal part with a M6 screw, surrounded by a spring. The screw is partially threaded so the part can move up and down without resistance. To make sure that the distraction distance does not become zero an extra ring is added, which makes it impossible for the spring to be fully pressed.

9.4. Hinge

As previously stated, a hinge should be incorporated within the design to allow for mobility of the patients. Different hinge mechanisms were generated during the ideation phase. Finally, three hinges looked the most promising (figure 43), each hinge has a different amount of degrees of freedom (DOF). Since the distractor should allow movement within the tibiotalar joint while ensuring distraction, it was decided to use a pin joint as hinge, only allowing for plantar- and dorsiflexion and not for inversion and eversion. Therefore, it was decided to use a pin joint for the hinge design.

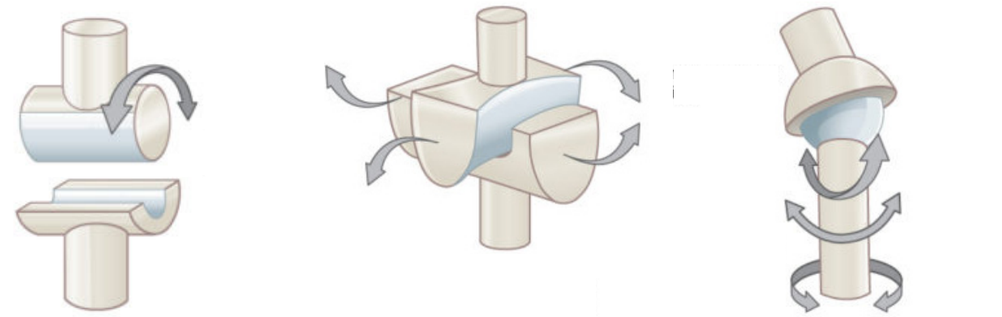
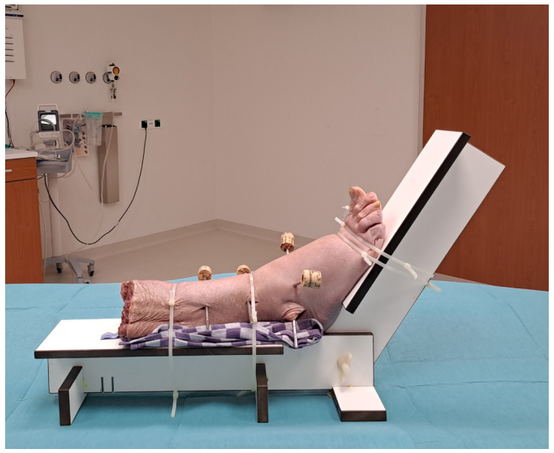


Figure 43: Types of hinges: pin joint (left), sadlle joint (middle) and ball joint (right) (Types of Synovial Joints | Biology for Majors II, n.d.)

The hinge should rotate around the rotation axis of the ankle. The currently used Inman axis is prone to human error and does not resemble the actual rotation axis of the patient enough. Therefore, it was decided to use a CT-scan[34] to determine the rotation axis per patient. To verify if this method would work and which data is needed to determine the rotation-axis, a test was done. For this test, a cadaver

[34]Computed tomography (CT-scan)
An imaging procedure that uses x-ray and a computer to create a 3D image of the inside of the body



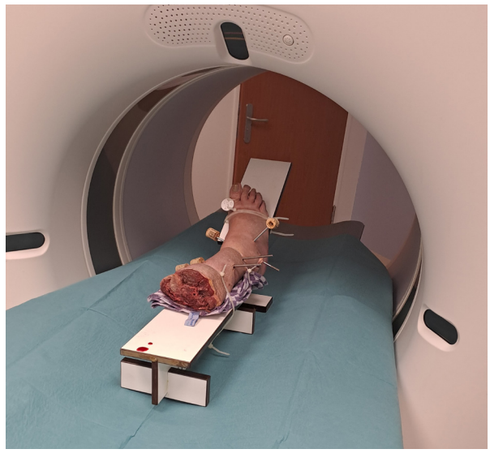


Figure 44: Cadaver leg in holder for CT-scan

leg was placed on a holder in the CT-scan (figure 44). This holder allowed the leg to be scanned in different positions, ranging from fully plantarflexed to fully dorsiflexed.

The data from this scan was segmented and analysed. Based on the segmentation of the scan three different rotation axes can be derived (figure 47). Each with a different procedure to deterime the axis. The first one (pink) is the kinematical axis of the ankle joint. This axis is derived from the scans with the foot fully plantarflexed and fully dorsiflexed using the Articulus software. If the difference between fully plantarflexed and fully dorsiflexed is bigger, the axis becomes more accurate. The second one (lilac) is derived from the talar dome[35](figure 45). This is done by creating a cylinder (figure 46) based that overlaps with this surface. The center of this cylinder can be seen as the axis. in the same way as the first axis. The last one (blue) is the axis derived from the distal articular surface of the tibia, in the same way as the second axis.

[35]Talar dome
The top of the talus, covered with cartilage, that is dome shaped.

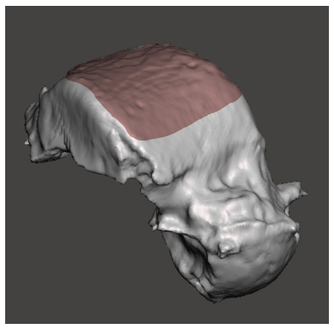


Figure 45: Articular surface of the talus used to determine the cylinder

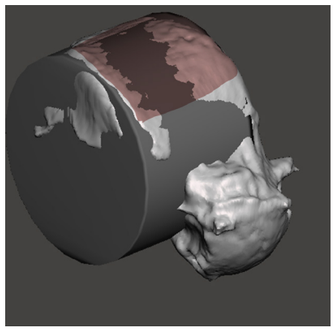


Figure 46: Cylinder created based on the articular surface of the talus

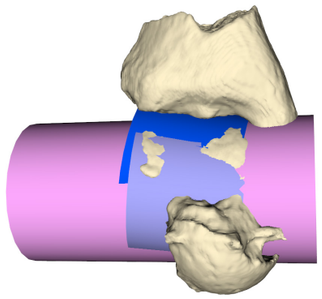


Figure 47: Different rotation axis of the ankle joint (source: Iwan Dobbe)

To determine which axis would be best to use within the design, different aspects have to be considered. The articular surfaces used to determine the axis can be damaged at people with end-stage AOA and they have a limited ROM.

The kinematical axis (pink) would be the best to use, because this allows the movements to be as close to the actual situation as possible. However, this axis changes with the movement of the foot. Furhtermore, the limited ROM of patients with AOA can cause an inaccurate determination of the kinematical axis. Next in line, the axis based on the talus would provide the best estimation of the rotation axis. However, it was noted when analyzing the scans that the talus moved in multiple directions. This could have been caused by the shape of the talus bone, which allows for more wiggle in plantarflexion or by the fact that the tissue of the cadaver leg is less suportive. It is not known whether this movement is also present in patient with AOA and should thus be investigated in the future. Because of this finding, it cannot be guaranteed that there is no bone to bone contact when articulating. This means that if the talus bone is tilted during scanning, the rotation axis will be a bit off. If this is the case, bone to bone contact will take place when fully plantar- and dorsiflexed. Therefore, it was decided, together with a biomedical engineer who is a specialist in medical imaging and analysis, to use the rotation axis that is derived from the distal articular surface of the tibia (blue). This axis can guarantee no bone to bone contact, because the tibia is not moving during the scans. Furthermore, the articular surface of the tibia is often less damaged compared to the articular surface of the talus bone.

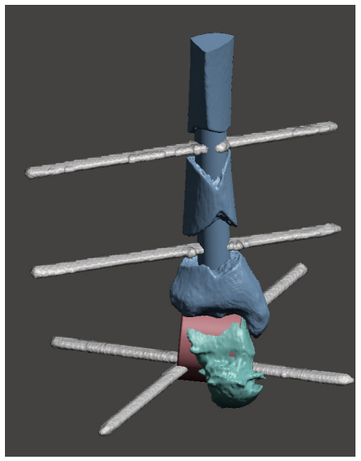


Figure 48: Results of the CT-scan

To determine if the previous made assumptions are correct and if there is still enough movement possible, a prototype with corresponding rotation axis is made based on the CT results (figure 48). This prototype is made without a distraction mechanism and printed out of PC (polycarbonate) (figure 49)

This prototype is tested on the same cadaver leg. The test existed of two parts: 1) installing the device and 2) validating the determined rotation axis. The instalation of the prototype was a bit of a hassle. On the one hand, a cadaver leg need to be hold in place while the screws and nuts needed to be attached. This will be easier in the future clinical practice, when a patient can hold their foot still in mutliple positions. On the other hand, it was hard to figure out which was the device for

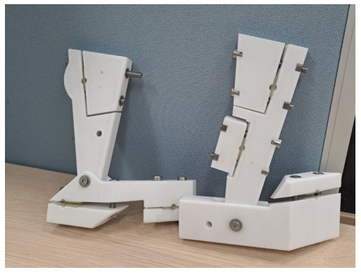


Figure 49: prototype printed out of PC

Figure 50: medial side of cadaver leg during testing

Figure 51: Prototype hold in place with hands

[36]**Scattering**
The process in which radiation is deflected by a material.

Figure 52: Top part of the prototype touching the bottom part

the lateral side and which was for the medial side.

The part on the lateral side could be placed on the pins, however the pins were a bit to short to attach the lower part of the prototype. Therefore this was hold in place with hands (figure 51) to still be able to test the hinge.

The device for the medial side didn't seem to fit on the tibia pins (figure 50), but the pin fixation for the talus pins was good. After, the test it was realised that the design was assembled wrong and that the top part should have been rotated 180°. In that case it would probably fit better.

To validate the movement of the leg, one person hold the device in place on the lateral side and the another person moved the leg forwards and backwards. The movements were smooth and it felt like there was not much restistance. The limiting factor was the prototype, the leg couldn't go to maximal dorsiflexion, because the top part was against the lower part (figure 52).

From this test, it could be concluded that the limiting factor during movement was the prototype and had nothing to do with the cadaver leg. Furthermore, the renewed device should allow for more variation in the pin placement, since it is hard to determine the exact postion due to scattering[36].

9.5. Materials

For the final design different materials were taken into consideration. In table 3 an overview of these materials and their properties is given. The device needs to be cleaned by the user throughout the distraction period of 3 months. Therefore, it needs to be able to withstand ethanol and water with soap. Ethanol is used to clean the device and pins daily and the device can come in contact with water and soap when the patient is showering for instance. Furthermore, parts of the device need to be sterilised for the next patient. At the Amsterdam UMC, location AMC, an autoclave is used to sterilise instruments, this method will also be used for the distractor. Therefore, the materials need to resist temperatures up to 150° under a pressure of 5 bar (500 kPa).

Material	Machinability	Costs (€/kg)	Density (kg/m3)	Yield strength (MPa)	Tolerance up to high temperature (150°)	Water & soap resistant	Ethanol
Stainless steel	2.5	2.97	7515	698.5	Excellent	Excellent	Excellent
Titanium	2	20.97	4610	89.5	Excellent	Excellent	Acceptable
Aluminium	4.5	2.2	2710	190.5	Acceptable	Acceptable	Acceptable
CFRP	2	32.49	1550	800	Excellent	Excellent	Limited use
PEEK	3.5	58.76	1310	91	Excellent	Excellent	Excellent
PC	3.5	2.44	1200	62.15	Acceptable	Excellent	Excellent

Table 3: material properties (Granta Eduapack, 2020)...

Other material properties to consider have to do with the feasibility of the design. The material should be machinable, to make it easier to make custom parts. However, the final design should be lightweight and not break. To determine if the material is able to withstand all the forces, the yield strength is taken into account. This value should not be passed, otherwise plastic deformation will occur. If this is the case, it cannot guarantee a sufficient distraction. To limit the expenses, material costs were also considered.

If we look at the cleanability of the device, carbon fibre reinforced composites (CFRP) does not fulfil the requirement of cleaning the device with ethanol and thus cannot be used for the final design. Even though it is lightweight and has a high yield strength. This yield strength is only high when the material is subjected to pull forces.

Regarding machinability aluminium ranks the highest, however it still needs to be anodized or have another post-processing treatment to make sure it doesn't corrode. After aluminium, polyetheretherketone (PEEK) and PC rank the highest on machinability, but have a lower rating on price and yield strength, respectively. Therefore, these materials are also not suitable for the final design.

This leaves stainless steel and titanium is the last options. Both materials can be cleaned according to the description and are a bit harder to machine. Stainless steel is cheaper and stronger than

titanium. Since stainless steel is stronger, less material is needed to withstand the forces which results in a lighter device. Therefore, it was decided to make the final design out of stainless steel.

9.6. Combining the parts

All of the features and separate parts are combined within one design. This design exists of standard parts and tailor-made parts. In this chapter, all separate parts and the connections between them are discussed.

As previously explained, the tibia pins will be placed using a separate drilling guide therefore the clamps around these pins can be a standard part. The placement of the pins located in the talus allows for more variation, therefore the clamps around these pins cannot be standard. Furthermore, the position of the rotation-axis varies per patient. It was decided to incorporate the rotation axis and the clamps for the talus pins into one part, to make the design more cohesive. Furthermore, it makes it harder to get caught behind something with the device.

The standard part around the talus clamps and the rotation-axis is curved (figure 53) following the shape of the foot and therefore allowing a smaller design. The hole for the rotation-axis is already made in the curved part. Together with a negative mould of the same curve, this makes it easier to fixate the part in the machines. To personalise this part, data from the CT-scan is collected to determine where the holes for the pins should be and at what angle. Based on this information, the holes and slots are milled under the determined angle at the right

Figure 53: Curved lower part of the design

location. When this is done, holes are tapped in the side to place the small screws for a tighter fixation.

The distraction mechanism is the connection between both clamps (figure 54) where the bottom part is connected to the talus clamp and the top part is connected to the tibia clamps. This mechanism (figure 56) is a standard part except for the included spring. The spring (yellow) differs per patient, because the weight and damping forces differs as well. A spring can be selected based on the weight of the patient in placed within the standard part.

The lower part (left) of the distraction mechanism can be slide into the standard curved part and connected via the hole of the rotation axis. This is done by placing the rotation axis within the holes and then secure it with a washer and screw on both sides. The top part of the distraction mechanism can be placed around the lower part of the tibia clamps and then tighten with a screw (figure 55) .

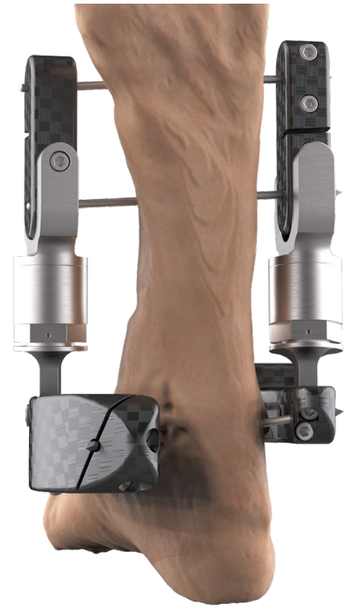


Figure 54: Distraction mechanism as connection between the pins

Figure 55: Connection between tibia clamps and distraction mechansim

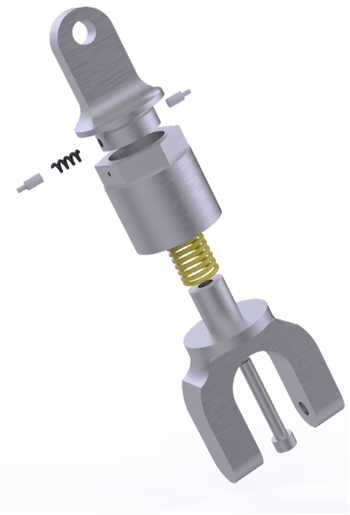


Figure 56: Distraction mechanism

10

FINAL DESIGN

CHAPTER TEN

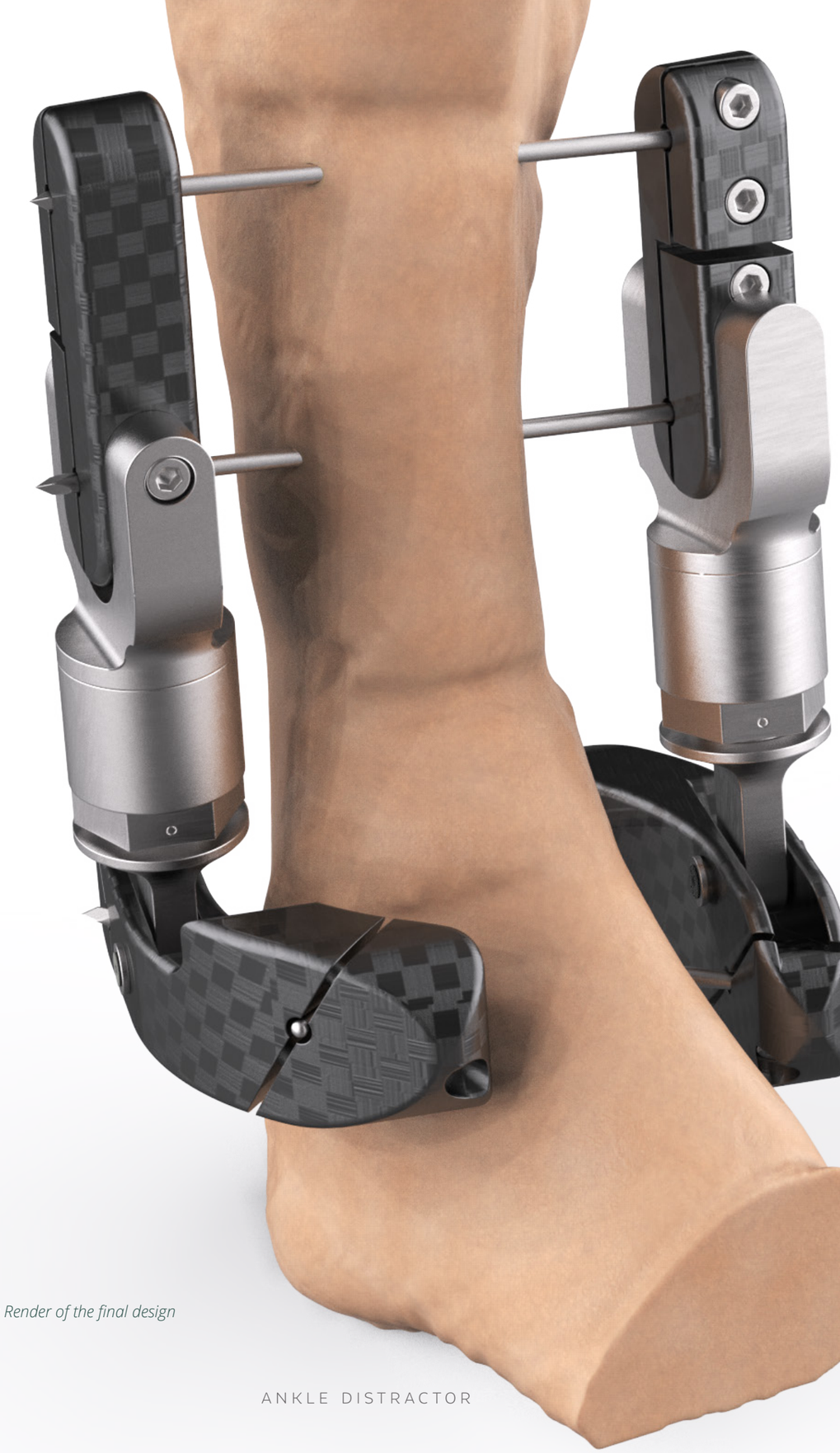


Figure 57: Render of the final design

The final design is an ankle distractor that exists of multiple components, a distraction mechanism and clamps. A combination of these components will be placed on each side of the leg to allow for a symmetrical distraction (figure 57). If the patient together with the orthopaedic surgeon decides to undergo the treatment, a day surgery will be scheduled. At this surgery the pins will be placed in the tibia and talus bone. A small incision is placed at the pre-determined location of the pins, then using an alignment guide and X-ray for accurate placement, the pin is drilled into the bone. For the pin placement within the tibia, a drilling guide is used.

This drilling guide, makes it possible to have standardized clamps to attach the device on the tibia pins. To determine the angle and position for the clamps of the talus (figure 58) and the location of the rotation axis a CT-scan is made. Based on this scan, the curved bottom part of this device is adjusted to fit the patient. At the location of the rotation axis a hole is made to allow for the placement of a pin-joint hinge (figure 59). The angle and positions of the pins in the talus are used to create clamps at the right location.

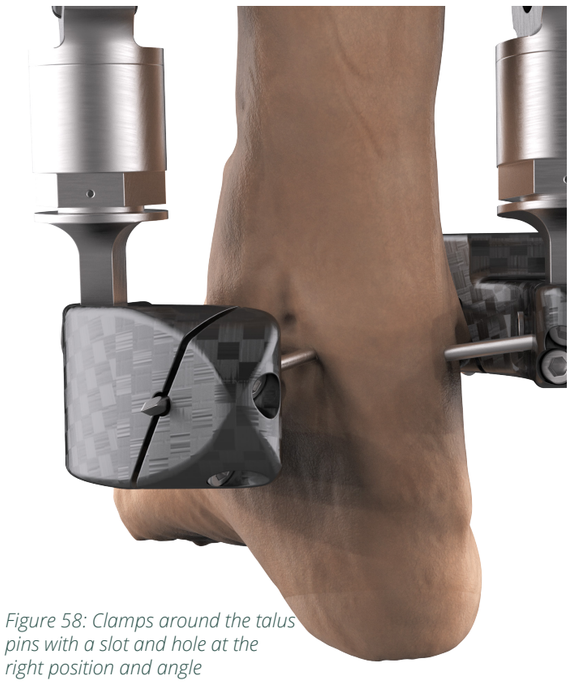


Figure 58: Clamps around the talus pins with a slot and hole at the right position and angle

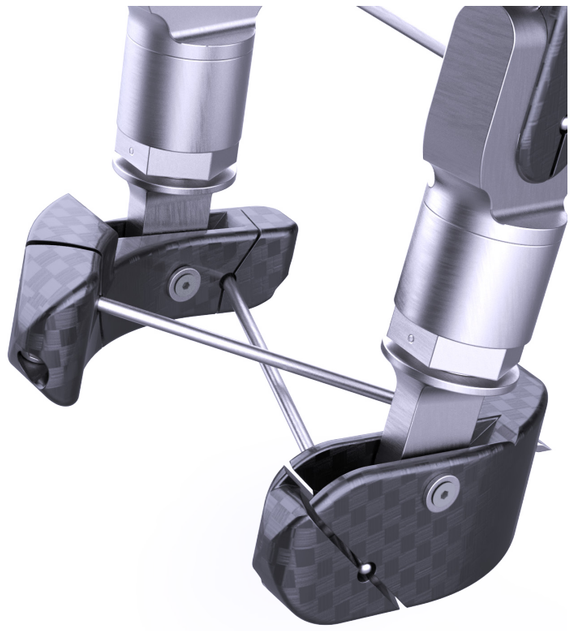


Figure 59: rotation axis incorporated within the design

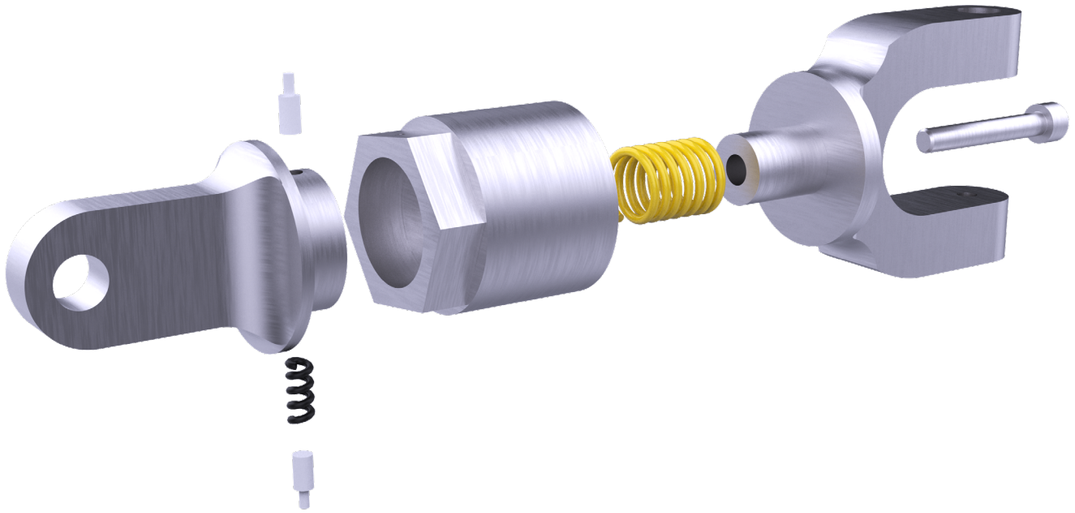


Figure 60: Exploded view of the distraction mechanism

Both clamps are connected through the distraction mechanism (figure 60). The bottom part of the distraction mechanism is connected to the clamps around the talus via the rotation axis and the top part of the mechanism is connected to the lower part of the tibia clamps and attached by a screw.

Within the distraction mechanism, distraction and damping are combined, which allows for a dynamic distraction. Within the thread, holes are made to place two small pins and a spring. If these holes line up the pins will be pushed out by the spring, which provides the user with feedback about the distraction distance. In the top part of the mechanism, a heavy duty compression spring is incorporated to allow for damping during daily activities and maintain intra-articular fluid pressure. Because of the shape of the inside of the top part, the spring cannot be fully pressed, which makes bone to bone contact impossible. The weight of patients varies, and thus a different spring stiffness is needed. Therefore, the spring can be changed per patient.

If the parts are adjusted for the patient and assembled, the patient will return to the outpatient clinic. If the wounds around the pins are healing well, the ankle distractor is placed at each side of the leg. This is done by sliding it on the pins and tightening the M6 screws using an allen key (figure 61), when it is in the right place. To prevent the surgeon from accidentally tightening the wrong screws, m4 screws are used for the joints during assembly. Tightening these screws is not necessary during the montage of the device. Once the device is in the proper position and all screws are properly tightened, the distraction

Figure 61: M6 screws tightened with an allen key

Figure 62: Hexagonal part turned to perform the distraction

can be performed with a wrench. This is done by placing the wrench around the hexagonal part (figure 62) and turning it. At the moment when a click can be heard and felt, and no more rotation is possible, the distraction of 2 mm has been reached.

Once the distraction is performed, the patient will walk around with the device on for 3 months. During these 3 months, daily activities such as ascending and descending stairs, showering and walking are possible. Furthermore, the patient will have to do daily exercises and clean the wounds around the pins. Moreover, once a week the patient will go to physiotherapy for additional exercises and every other week to the hospital for a check-up.

11

EVALUATION

CHAPTER ELEVEN

In this chapter, the final design is evaluated using two different tests. First, a digital simulation is made to get a better understanding of the force distribution within the design. Second, a pilot test on the cadaver leg was performed to examine the interaction between the device and both pins and ankle and to check the working of the distraction mechanism.

11.1.Finite element analysis

A finite element analysis (FEA) is performed on a simplified model of the final design to study whether the device can withstand high forces. This analysis is also used to estimate the consequences of people misusing the device, for instance running or other activities which result in a high GRF .

To perform the FEA, the following simplifications were made within the model:

- ◊ The clamps around the pins are considered to be one part, instead of two which are combined with screws.
- ◊ The connection pieces are already attached to the clamps, instead of it being a separate part.
- ◊ The damping and screw connections are not taken into account during these analyses.

Two scenarios were created to simulate the deflection and the Von Mises stress within the device with the following assumptions:

- ◊ The device is worn by a person of 100 kg
- ◊ The patient has little scar tissue within his joint which results in a distraction force of 500N (personal communication, 2023).
- ◊ The distance between the device and the bones is estimated at a total of 20 mm
- ◊ The skin and other tissue are not accounted for
- ◊ The material of the device and of the pins are both stainless steel.

Within the first scenario the patient is just walking around. This results in a GRF of 5 times the body weight. As described in chapter 4.3, 90% of this force is going into the tibia where the force is distributed across the two pins. This results in a force on the device of 2250 N per pin. Within the second scenario, the patient is not walking, but running, resulting in a GRF of 13 times the body weight. This results in a force on the device of 5850 N per pin. As described in chapter 9.1.1, a deflection of 10% of the distraction distance is still acceptable.

If the Von Mises stress is higher than the yield strength of the material, which in this case is 698.5 MPa, the material will start to plastically deform. Therefore, this value cannot be exceeded.

For both these scenarios an FEA simulation was run in Autodesk Inventor (version 2023, Autodesk, San Rafael, CA, USA). In the first scenario, walking, the maximum deflection is 0.007 mm (figure 63) and the maximum Von Mises stress is 3.242 MPa (figure 63). The deflection increases from the middle of the distraction mechanism to the top. It is the highest at the top left corner of the tibia clamp. The location of the highest Von Mises stress is hidden within the model at the rotation axis. Furthermore, the stress is slightly higher in the centre of the pins compared to the rest of the model.

For the second scenario, running, the maximum deflection is 0.018 mm (figure 64) and the maximum Von Mises stress is 5.907 MPa. Similar

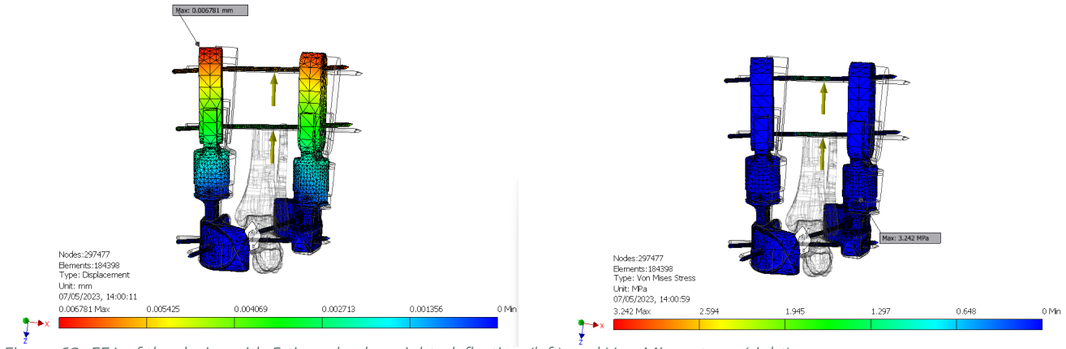


Figure 63: FEA of the device with 5 times body weight, deflection (left) and Von Mises stress (right)

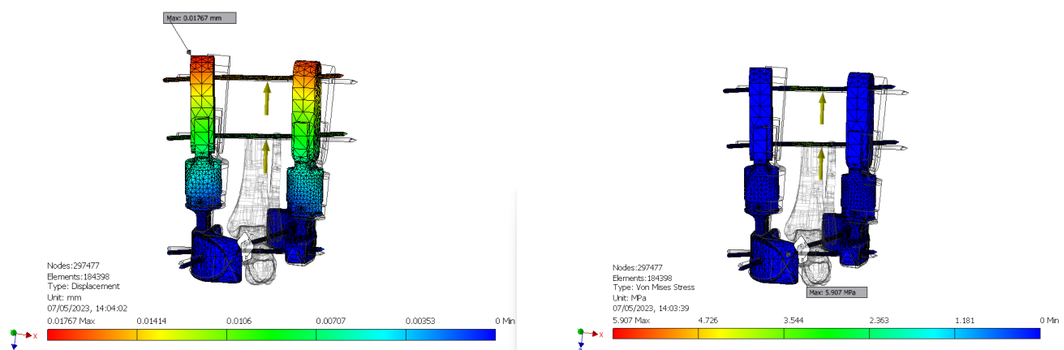


Figure 64: FEA of the device with 13 time s bpdy weight, deflection (left) and Von Mises stress (right)

to the first scenario, the deflection increases from the middle of the distraction mechanism to the top, where it is the highest at the top left corner of the tibia clamp. The location of the highest Von Mises stress is again hidden at the rotation axis and the stress is slightly higher in the centre of the pins compared to the rest. All of these values are within the safe range as described above.

Something interesting to mention is that the whole device is moving slightly to the left, this is because of the angle within the talus pins. The right part is higher the then the left part, resulting in a tilt of the device to the left.

Based on these scenarios, it can be concluded that the device can withstand the forces for which it is designed as well as excessive forces and stress. Therefore, patients can use it as advised, but do not have to worry when they want to walk a little faster.

11.2. Final test: cadaver leg

To examine the working principles of the final design, a final test was performed on a cadaver leg.

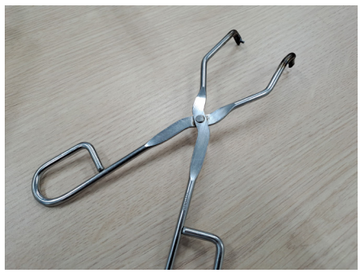


Figure 65: Special made pliers

For this test a prototype (figure 66) was made out of aluminium and PC , because these materials are easier to machine (aluminium) and 3d-print (PC). This minimizes the time that was needed to create the prototype. During the assembly of the prototype, it became clear that there were two distraction distances possible within the device due to play in the system. At a distraction distance of about 1.5 mm the pins inside the mechanisms were already able to move out a little. This resulted in an interruption within the thread, making it impossible to turn the hexagonal part. For this test this was fixed by using a special made pliers (figure 65) to force the small pins to go inside and turning the hexagonal part resulting in a distraction of 2 mm.

Because the room between the lowest tibia pin and the rotation axis is limited, it was decided to place the distraction mechanism next to the clamps instead of underneath. However, the damping mechanism could therefore not be tested because the top port of the distraction mechanism will start to tilt.

The main focus of this test was the interaction of the device, especially positioning the device on the pins and performing the distraction.

Figure 66: Prototype for the final test

Another goal was to validate the visibility of the bones on an x-ray and a CT-scan despite the scattering caused by the metal in the device. The last purpose was to verify if there the gap within the join is increasing when distraction is performed.

To examine the interaction, the montage was done in the dissection room. The prototype was already pre-assembled making it easier to

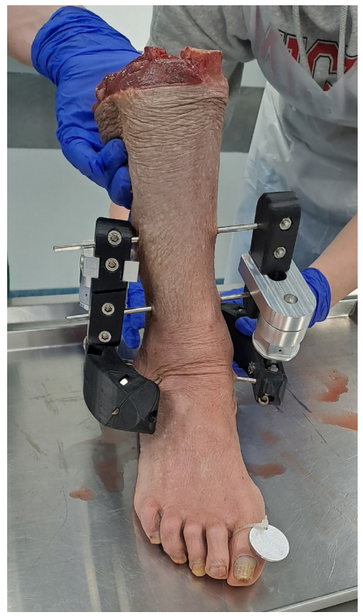


Figure 67: Leg hold in place to make screw tightening easier

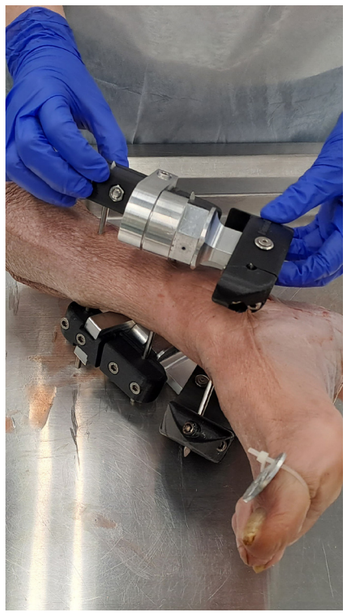


Figure 68: Prototype slide onto the pins

Figure 69: Allen key used to tighten the screws

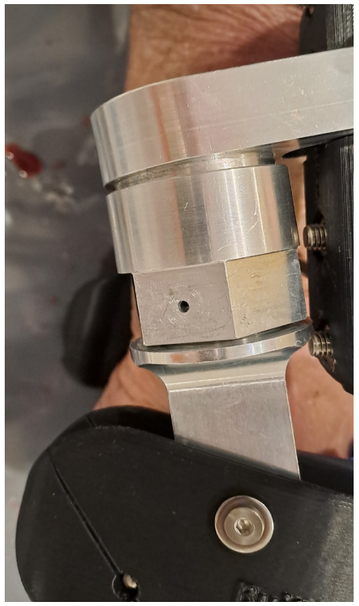


Figure 70: Schranking effect within the device

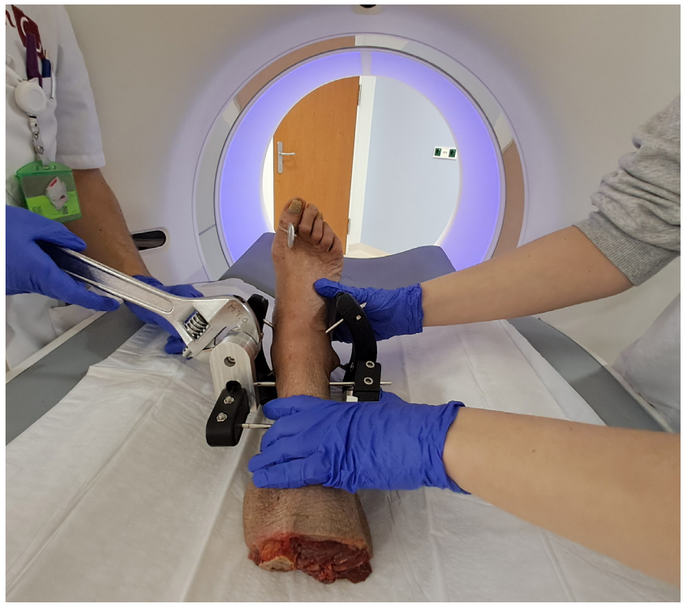


Figure 71: Distraction performed using a wrench

place onto the pins (figure 68).The nuts were staying in place because of the extrusion made into the design. This way, only one allen key was needed to tighten the clamps (figure 69), which made the montage of the device rather easy.

It took a total of 15 minutes. In this situation, an extra pair of hands was needed to hold the leg into a standing position to be able to reach some screws (figure 67). However, in clinical this will not be necessary since a patient can hold their feet still, requiring only 1 person for the montage.

The distraction is performed using a 34 mm wrench (figure 71) and went rather smooth. Then we found that this also could be done by hand . Furthermore, it was noticed that after distraction schranking took place (figure 70). It was not taken into account that the distraction device is placed next to the clamps, which results in an extra moment creating the schranking effect.

To examine the possibilities of medical imaging, x-ray images and CT-scans were made both with and without distraction. First the X-ray images (figure 72) were taken, the leg was placed in the position that would be done for patient as well, using a wedge to create a clear image.

For the CT-scan, a higher radiation doses is applied to minimize the scattering due to the metal in the device. The leg was scanned in different positions to confirm that movement is still possible and that there is no bone-to-bone contact. The first position was in extreme (18°) plantarflexion (figure 73) and the second neutral (figure 74). No scan of extreme dorsiflexion was made, because it was not possible to fixate the foot in this position.

Figure 72: Taking X-ray images of the leg

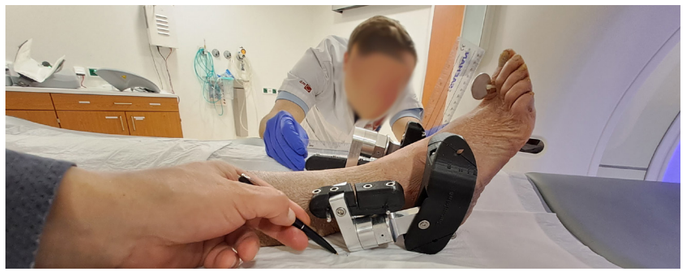


Figure 73: Positioning the leg in 18° plantar flexion

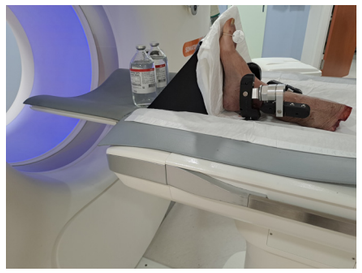


Figure 74: Leg in neutral position

The tibiotalar joint was still clearly visible in both x-ray and the CT. Therefore, images could be used to compare the difference in distance in the joint for the absence or presence of distraction. On the X-ray images without distraction a distance of 3.4 mm and 3.6 mm could be measured between the tibia and the talus. On the images with distraction a distance of 3.8 mm and 4.1 mm, respectively, could be measured. So, it can be said that after performing the distraction there is an increase in distance of 0.5 mm.

In the CT-scan of the lower leg in neutral position the distances measured without distraction are, 1.77 mm (sagittal plane) and 4.14 mm (frontal plane). With distraction distances of 2.35 mm (sagittal plane) and 4.66 mm (frontal plane) were found. From this scan it could be concluded that there is an increase of 0.58 mm in the sagittal plane and of 0.52 mm in the frontal plane. In the CT-scan of the lower leg in 18° plantarflexion (figure75) without distraction a distance of 3.04 mm (sagittal plane) and 3 mm (frontal plane) could be measured. With distraction these distances are 3.48 mm (sagittal plane) and 3.62 mm (frontal plane) resulting in an increase of 0.44 mm in the sagittal plane and 0.62 mm in the frontal plane. These values correspond with the findings in the x-ray images.

Based on the X-ray images and both CT-scans, it can be concluded that there is an increase in distance of around 0.5 mm within the ankle joint. This value is lower than expected. However, it should be mentioned that these images are taken at slightly different angles, which can result in a different measurement. Furthermore, the cadaver leg has been defrosted multiple times resulting in extra weak tissue, which also has an effect on the distraction distance. Next to that this tissue is not representative for actual tissue, especially when looking at forces, the tissue of the cadaver leg is a lot weaker, which allowed us to perform distraction by hand instead of actually using a wrench. It is expected that in the actual situation the force needed to perform the distraction is way higher, around 500N for a normal joint.

So, it can be said that there is an increase in the distance, but it is uncertain if this is fully caused by the device or if other factors such as the angle of the image also take part to these results. To actually be able to verify the distraction distance, further testing is needed with a test set-up that allows the leg to always be in the same position. This makes sure that the photo or scan is always taken from the same angle, furthermore it would be better to use a leg that is defrosted less.

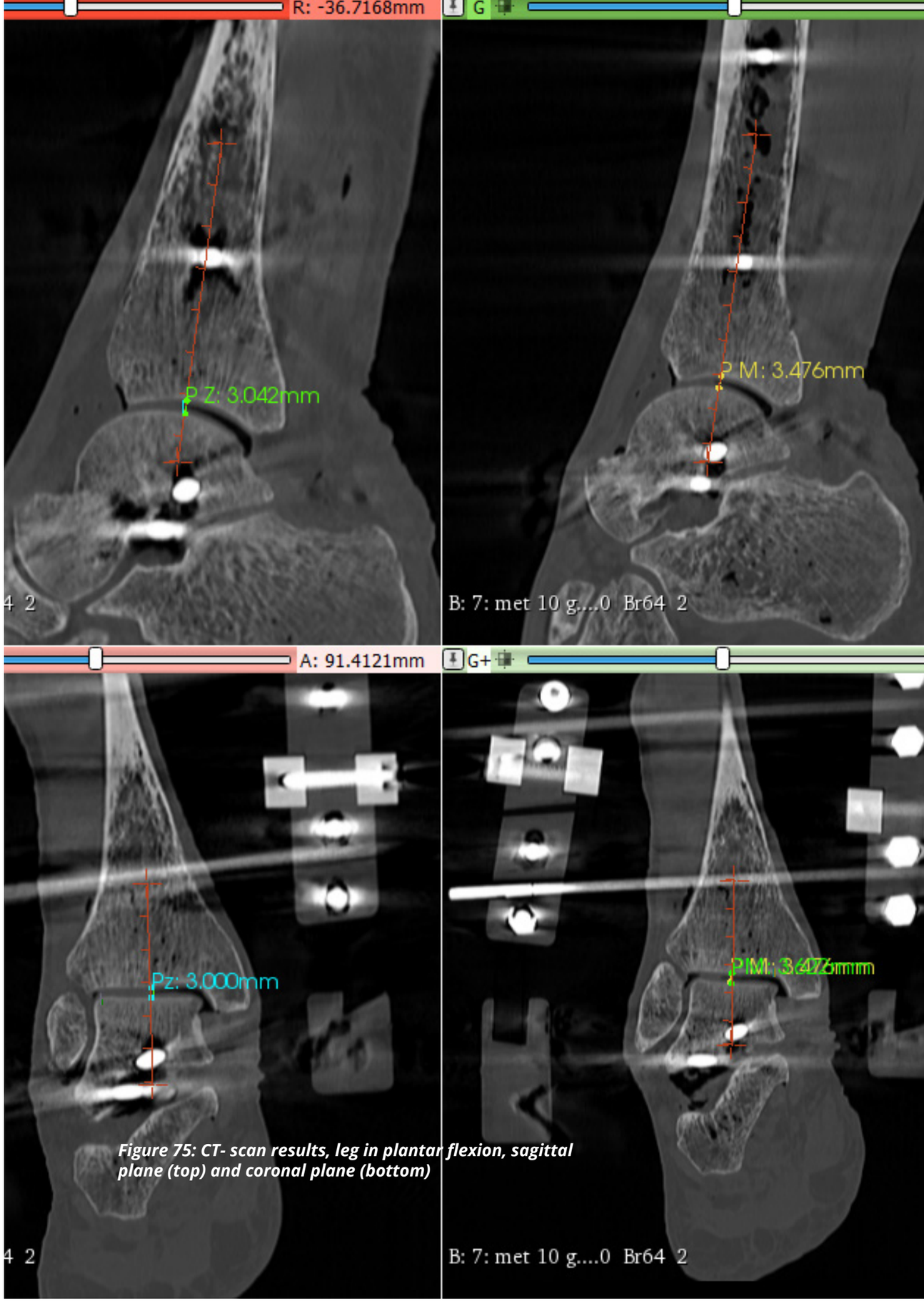


Figure 75: CT- scan results, leg in plantar flexion, sagittal plane (top) and coronal plane (bottom)

12

DISCUSSION

CHAPTER TWELVE

The current design will be part of a new joint sparing treatment for people with end-stage AOA. It is based on the technique of distraction arthroplasty and will be the first device on the market specifically designed for use on the ankle joint.

Compared to similar devices on the market, this device is partially personalized. It is a combination of standardized parts, that are easy to adjust per patient and combined with personalized part. The pins will be placed first, and the clamps of the design are adjusted for the location of the pins. This gives the orthopaedic surgeon more freedom when placing the pins compared to the Xcaliber, ProCallus or KneeReviver (chapter 5.2).

Moreover, the current devices often limit the movements of the foot due to the absence of a hinge. In the current devices that do incorporate a hinge, the rotation axis is estimated by the surgeon which often results in a slight misfit and thus discomfort. Within the new device, the rotation axis will be determined using a CT- scan and incorporated within the personalized parts. This allows for movement of the foot around the rotation axis of the patient and thus more patient comfort. Lastly, the developed device includes a damping mechanism. This allows for intermittent fluid pressure, which provides the needed nutrition to restore the cartilage. Therefore, the treatment is more prone to succeed.

Besides the difficulties that this design overcomes, there are still some adaptations that need to be done. Currently, a limitation of the prototype is its size and weight. It is still unknown whether the current design can still allow movements other than dorsi- and plantarflexion. If so, it is possible that the device can touch the skin over and over again, due to the length and curvature of the clamps around the talus pins. After a while this could cause irritation of the skin. However, the final device will be made out of stainless steel, which a stronger material. Therefore, the design can be optimized with less use of materials resulting in a lighter device even though stainless steel is heavier than aluminium.

Moreover, the working principles of the device, such as the distraction mechanism, need further testing to compare this to other devices. Furthermore, within the performed tests damping is not taken into account. For further testing a new prototype should be made, with damping included and this should be tested on a new cadaver leg.

For a new test, the pin placement should be done using a drilling and alignment template to be able to use a standardized design. Also, the distance between the talus pins and lowest tibia pin should be bigger than the current tests, so the distraction mechanism can be placed between the upper and lower part of the device. If this is the done, the damping mechanism can be tested properly. Furthermore, for this test a standard operation procedure (SOP) should be developed. This allows the leg to be in the exact same position when scanning and also makes it possible to scan the foot in plantar- and dorsiflexion. The test should be planned well ahead so that the all the involved parties (orthopaedic surgeon, CT technician, biomedical engineer and designer) can be present during the test.

The last test that needs to be performed is a proof of principle test. This test will take place for a longer period of time to allow for a walking simulation during the distraction. The cadaver leg will be placed in a support holder in such a way that the foot can be moved using a motor. To simulate the weight of the patient, weight will be placed on top the cadaver leg. To goal of this test will be to measure the pressure differences over time within the joint when moving the leg. Therefore, pressure sensors will be placed on top of the articulating surfaces and the foot is moved for x amount of cycles. Based on these findings the design can be optimized, and eventually clinically tested.

13

RECOMMENDATIONS

CHAPTER THIRTEEN

The final design is a promising start for a new AOA treatment. Therefore, more iterations should take place before the product can be clinically tested. In this chapter, some improvements of the current design, extra features and other recommendations are described.

Improvements

During the final test it became clear that some improvements on the current concept can be made. First of all, the current prototype, made out of aluminium and PC, weighs around 1000 gram (500 gram per side) and is quite bulky. If the device would be made out of stainless steel, with the current measurements it would become heavier and more uncomfortable for the patient. Moreover, with this prototype it could happen that in some movements, for instance inversion and eversion, the device will touch the skin which can cause irritation. Therefore, it would be better to make the device smaller. This would make it lighter, but also more subtle.

Second, even though the distraction mechanism provides clear feedback to the user when the distraction distance is reached, there is some slack within the design resulting in a distraction feedback at 1.5 mm or 2 mm. By removing this slack, a certain distraction of 2 mm can be reached. Furthermore, it could be considered to only have 1 pin within the distraction mechanism. If this is done the diameter of the device can be made smaller, taking the schranking effect into account.

The device can be made smaller by decreasing the diameter of the distraction device. If this diameter is smaller the device can be less tall and still not jam. The rule to take into account to prevent schranking is length= 2* diameter. Furthermore, the device would look smaller if there is more distance between the pins in the talus and the pins in the tibia, which would allow the distraction mechanism to be below the tibia clamps instead of next to it. Furthermore, if the diameter is smaller, the width of the hexagon can also be smaller. This means that the distraction does not have to be performed using a 34mm wrench, but a smaller, more common size, would be sufficient.

Lastly, the current indication for the location of the device, inside or outside of the leg, is done by engraving inside and outside on the model. A better way to prevent wrong placement of the device is needed. This could be done by creating a mark somewhere on the clamps, so it becomes clear which side is the front, the back, the inside and the outside of the device. So, it can easily be placed in the correct position. This mark could be for instance a number or a symbol such as a stripe.

Further development

In order for the current design to work, some extra features still need to be developed. The first one is to create a drilling guide that can be used during the pin placement surgery. This guide helps the surgeon to place the pins in the tibia parallel to each other at a fixed distance. This guide should also provide a minimal distance to the bottom of the foot, so that there is enough room to place the distraction mechanism between the lowest tibia pin and the rotation axis of the patient.
Currently, the prototypes and models were tailor-made for the cadaver leg, but the final design should fit on everyone. Therefore, some parts of the design still need to be developed. This includes a sizing system for the lower part that includes the rotation axis and the talus pins. This sizing should be made using the ankle circumference and the ankle height (medial and lateral) of the patient. Furthermore, a system should be developed for the springs based on the weight of the patient.

If the design is more finalised, a digital workflow should be developed, including a design algorithm and software. The goal of the software is to create a design based on different parameters in the scan, such as pin placement and the rotation axis of the patient. With this software it becomes easier to create personalized designs.

Testing

The ankle distractor is a medical device, which requires extensive testing and should fulfil the medical devices regulations (MDR) before it can be implemented as a new alternative treatment. The main goal of these tests and the MDR is to prove that the device is safe to use and that there is reason to believe that it can work. Therefore, a risk analysis and a proof of principle test have to be performed to show that the device works as intended. Only after these tests and fulfilling other needed documentation on the manufacturing of the device a clinical study can be set-up to examine the working of the treatment in AOA patients.

14

CONCLUSION

CHAPTER FOURTEEN

Ankle distraction arthroplasty can be a new promising joint sacrificing treatment if the distraction device allows for movement within the joint and can be adjusted per patient. Furthermore, the device should be easy to use and allow for a minimum of human error.

In the current design, a hinge and damping are included that enable movement of the joint to prevent stiffness and maintain intermittent fluid pressure during the distraction period. For the pin placement a drilling guide is used, to be able to use standardized clamps of the tibia pins. The placement of the pins in the talus needs more freedom and therefore the clamps around these pins need to be personalized. The location of the rotation axis differs per patient and therefore also need to be adjusted per patient. Both the clamps around the pins in the talus and the rotation axis, are designed based on a CT-scan of the patient.

This current design holds great promise for the future in treating young active people with AOA who are looking for a new type of treatment!

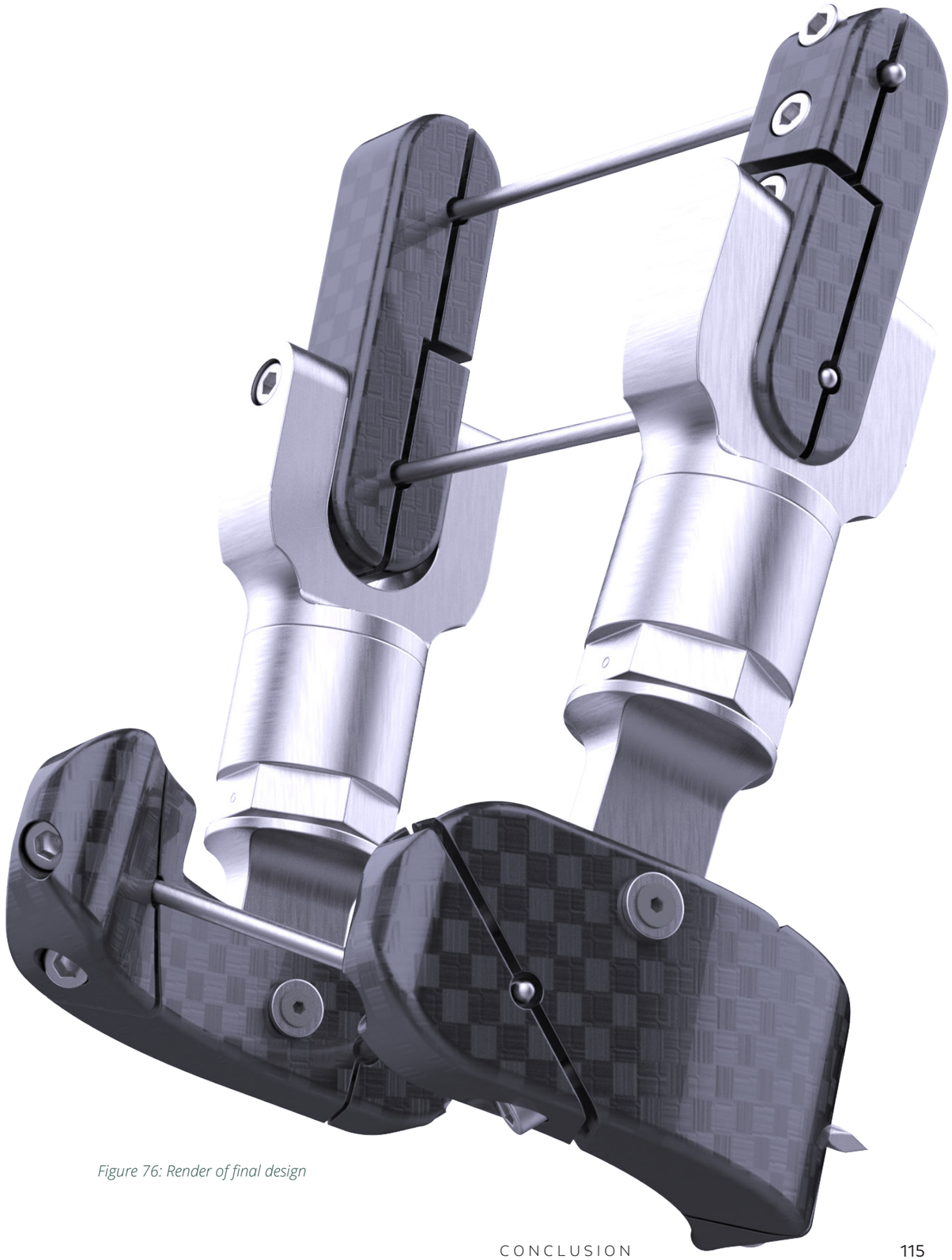


Figure 76: Render of final design

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