LVATE BRACE: A TOOL TO DELAY SURGERY FOR PATIENTS WITH KNEE ARTHRITIS

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LVATE BRACE AS A TOOL TO DELAY TOTAL KNEE REPLACEMENT SURGERY FOR PATIENTS WITH KNEE ARTHRITIS

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PREFACE

This thesis is the final project that closes off my time as a student at the TU Delft. During the course of this project, I received a lot of support and encouragement for which I'd like to thank everyone.

I want to express gratitude to my supervisory team that guided me through the project. I want to thank Armaĝan for the positive and encouraging meetings after which I always felt new loads of energy to tackle my project. When I encountered a problem, she helped me to make it manageable. Arjen, I want to thank you for keeping me with both feet on the ground, which I needed every now and then. Where I sometimes wanted to tackle everything, I was encouraged not to, which gave me room to breathe. I also want to thank Iemkje for stepping into the project at the end with an open mind. I appreciate that the entire team treated me as an equal and let me experience my mistakes instead of preventing them from happening. This often led to a breakthrough.

From Orthobroker BV, I want to thank Patrick for giving me the freedom to explore this project and for supporting me with his knowledge and experience within the field of orthoses. Roel, I want to thank as well for both the formal and informal meetings related to the project. I do not take it for granted that even during the weekend, there was time to meet up or to discuss the occurring problems.

I'd like to express special thanks to my girlfriend, Sanne, for the unlimited support, feedback and advise. Together, in a single room studio during lockdown, every high and every low is shared with each other. Having a buddy on this rollercoaster ride has been very valuable for me.

A few of my dear friends played a big role in letting off some steam and being able to relax. I am grateful for the many sport sessions with Robbie where we could discuss our projects or distract our minds. Charlotte and Daphne, I like to thank for the virtual lunch meetings, that eventually became entire afternoon meetings, where we could work apart together and chat every now and then. I'd like to thank Tom for reading my report and providing me with valuable feedback over a cup of tea.

Last but not least, I thank my parents and brothers for being there for me and for hearing me out when I tried to get my head around a problem. I highly appreciate the help they provided with reading the report, being my test victims, taking pictures and participating in brainstorms.

EXECUTIVE SUMMARY

During the course of this thesis, the design of a knee brace that improves the quality of life for people with arthritis in the knee, is being researched.

The knee joint is covered with articular cartilage which protects the bones from being damaged. Arthritis of the knee is a pathology where this cartilage is damaged potentially even to the extent that direct bone-to-bone contact occurs. The most common symptoms for the patient are pain and inflammation, affecting their mobility and quality of life.

This project is completed in collaboration with Orthobroker BV, a company situated in Belgium that develops orthopaedic products. Orthobroker is researching the benefits of additive manufacturing in the orthopaedic field of custom devices.

Firstly, research is conducted on the arthritis knee disorder, the patients and their interests, and the technical aspect of a knee brace in relation with the knee kinematics. The following main insights are revealed by the analyses:

- Arthritis in the knee is wear and tear of the articular cartilage caused by loading. This can be the result of extensive sports, overweight, incorrect alignment of the joint or aging.

- There are no treatments available that cure the damaged cartilage tissue. It is therefore in the patient's interest to slow down the deterioration process. When the disorder impacts the quality of life too much, replacement surgery can be opted for.

- Replacement surgery is the last resort option due to its invasiveness, possible complications and high rate of dissatisfied patients. It is therefore in the patient's interest to delay the need for a surgery if possible.

- The deterioration process can be slowed down by applying less load on the knee joint. Partially unloading the joint can be beneficial during demanding activities or even daily activities, depending on the stage of arthritis.

- A knee brace could help the patient to partially unload the affected knee. For this, a customized fit is preferred for increased comfort and effectiveness.

Secondly, during the development phase of this thesis, two main challenges are explored, being the custom fit of the brace and the unloading mechanism. In order to make a perfectly fitting brace design, many mock-ups are created directly on the leg and evaluated on their comfort and secure fit. The insights are later on translated into a standard model that can be shaped around the patient's 3D scan of the leg. The same method of creating and evaluating mock-ups is also applied to find an unloading mechanism that can be integrated in the brace. The concepts are tested by attaching them to the brace mock-ups that were created when exploring the perfect fit.

Thirdly, a design proposal is created, resulting in the LVATE brace that can be integrated in Orthobroker's product-service platform. During the patient's appointment with an orthotist, a 3D scan of the leg is made and uploaded to a digital platform. The platform morphs the LVATE brace around the 3D scan in such a way that it distributes pressure and only applies it in tolerant zones of the leg. The brace can then be ordered right away. The unloading mechanism is activated by rotating a knob that is positioned on the lateral side of the brace.

Finally, the brace is evaluated on its feasibility, desirability, and viability. A conclusion is derived from the evaluation feedback and recommendations are prepared for a further development of the design proposal.

GLOSSARY

ACRONYMS

AAOS	American Academy of Orthopaedic Surgeons
OA	Osteoarthritis
NSAID	Nonsteroidal anti-inflammatory drugs
TKA	Total knee arthroplasty
GP	General practitioner
TF	Tibiofemoral
PF	Patellofemoral
BW	Bodyweight
GRF	Ground reaction force
PT	Patellar tendon
MT	Muscle tendon force
ACL	Anterior cruciate ligament
PCL	Posterior cruciate ligament
MCL	Medial cruciate ligament
LCL	Lateral cruciate ligament
ACI	Autologous chondrocyte implantation
OAT	Osteochondral autograft transplantation
UKA	Unicompartmental knee arthroplasty
WBL	Weight bearing line

TERMS

This report uses the standard orientation and directions of the human body as shown in figure 1, figure 2 and figure 3.

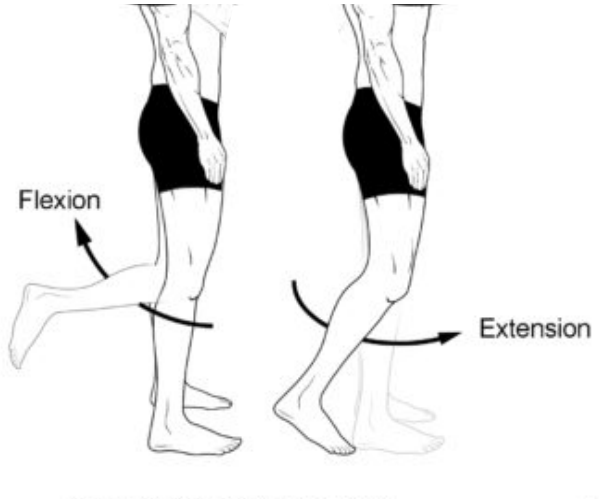

Figure 1. Flexion and extension of the knee joint (Lumen, n.d.).

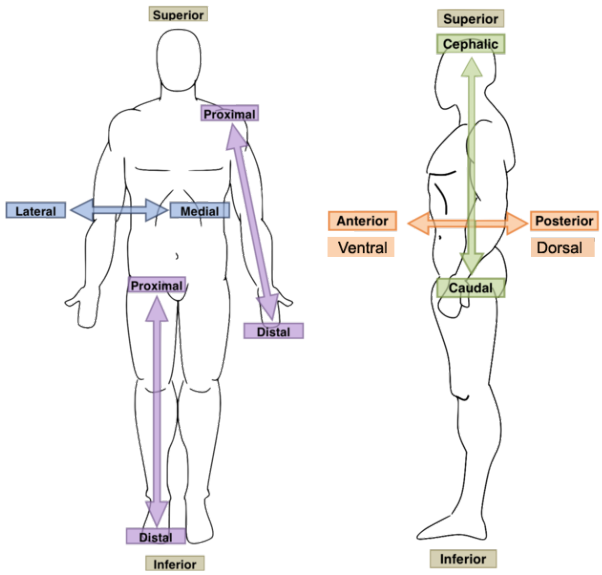

Figure 2. Anatomical orientation and directions (Lumen, n.d.).

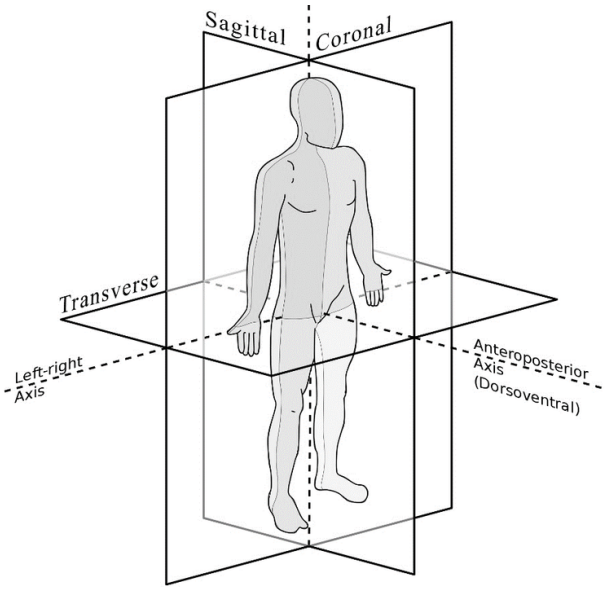

Figure 3. Anatomical planes (Pelkey, 2018).

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INTRODUCTION

The aim of my graduation project is to develop a load bearing knee brace that enhances functioning of the knee joint and improves the patient's mobility. The design process of this project exists out of three main phases, which are covered in this report. Firstly, research was conducted to gather all the information necessary for defining and substantiating the project scope with its user and functional needs. This information is summarized in criteria and serves as design input for the second phase, which includes the conceptualization and embodiment of the product. The evaluation of the design is covered during the last phase. The initial project brief can be found in appendix A.

COLLABORATION

This graduation project is done in collaboration with Orthobroker BV, which is a company specialized in orthopaedic braces and post-operative bandages. Their objective is to develop more effective and customized braces using 3D scanning and additive manufacturing. Orthobroker provides orthotists and prosthetists with the right software and tools for accurate analysis of the patient. This makes fully customized products more accessible while decreasing manufacturing time.

PROBLEM DEFINITION

Injured or damaged body parts often require rest in order to heal or prevent worsening. For the knee in particular, many braces are on the market to immobilize or stabilise the joints. Although these joints have to withstand a lot of pressure when moving around, only few options are provided to unload it.

The force (N) applied on one knee is 1,5 times the bodyweight (kg) while walking and up to 5 times the bodyweight when squatting to reach something on the ground (Harvard Medical School, n.d.). Shifting part of the bodyweight away from the knee joint can be done by using crutches or avoiding certain movements and activities. Both solutions, however, intervene with the patient's mobility and are not suitable as long-term solutions for patients with a chronic disorder.

SCOPE

The scope of this project is to develop a device that reduces loading on the knee joint. It is hereby aimed to deliver a product that is complementary with the patient's level of activity. To reach this goal, the amount of support delivered by the device should be adjustable simultaneously with the patient's need.

A knee brace will be developed in the course of this project and should fit the user's leg perfectly. This should ensure correct alignment of the brace hinge in reference to the knee joint and enhance the patient's comfort.

APPROACH

This thesis is split into four main parts: discover, define, develop and deliver. This follows the double-diamond design process (Design Council, n.d.) to which the graduation planning is applied, see figure 4.

At the kick-off meeting, a problem statement is presented with which the project takes off. To guide the reader through the process, each chapter in this thesis report covers a part of the double-diamond as follows.

PART I

In the first chapter, the entire research phase is covered. This entails diverging research to gain insights into the problem, and the conversion of these insights into a focussed problem definition. The explorative analysis combines desk research and interviews with different stakeholders to compare scientific based information with real experiences.

PART II

The design phase is covered in the second chapter where potential solutions are created. Due to the character of this project, where the form is subordinate to the function of the product, this is mainly achieved by making and testing numerous mock-ups. Iterations are made based on the results and feedback from the evaluative tests, until a final design is proposed.

PART III

The third chapter evaluates the final design that is resulted from part II in order to define its feasibility and viability. These evaluations assess the manufacturability, functioning and business case.

PART IV

In the final part, a conclusion is derived from the entire process and the final design outcome. Based on this, recommendations are prepared for further iterations and development of the proposed product.

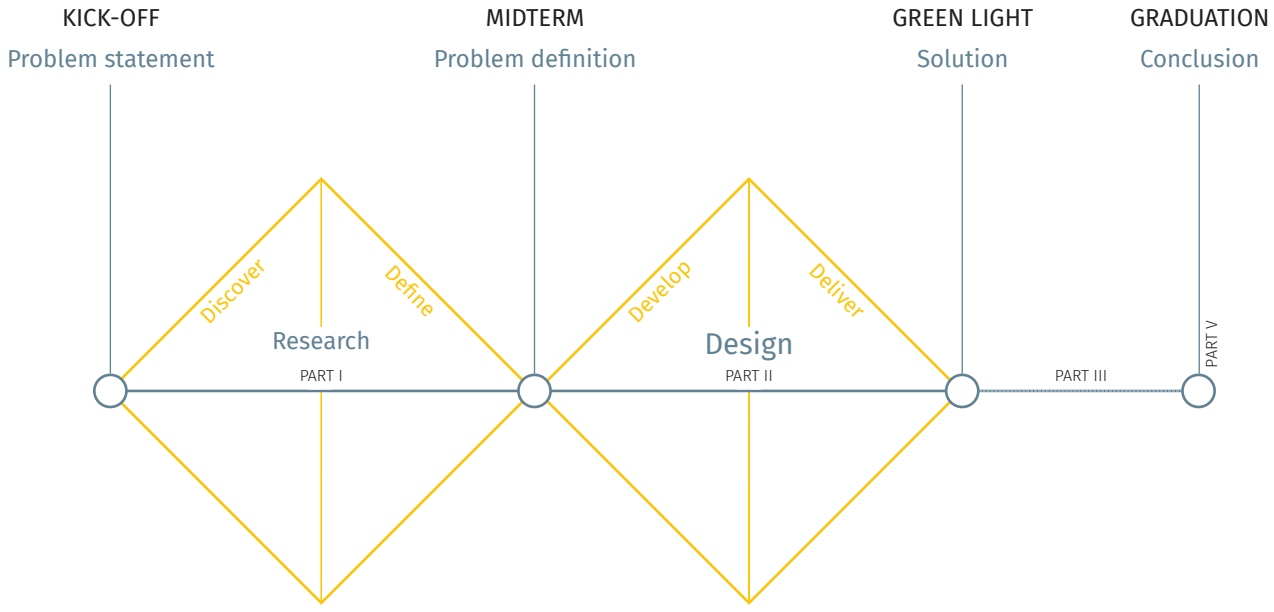


Figure 4. The double-diamond design process (Design Council, n.d.).

PART I

RESEARCH

Three research domains are explored in this report. The first one is the medical analysis where the anatomy of the knee is explained, and a target group is defined based on possible pathologies of the knee. Secondly, a human-centred analysis is conducted including more information on the human aspect of this project. The final analysis covers technical research, which covers knee kinematics and support mechanisms. The information gathered in these three domains leads to a refined project brief and a list of requirements, which acts as the starting point for the design phase.

1. MEDICAL ANALYSIS

During the medical analysis, research on the anatomy of the knee is conducted in order to gain a better understanding of the structures and their functioning. Based on this information, the possible disorders and surgeries for each structure are collected as well as their treatment. The need for unloading the knee joint during treatment for each pathology is analysed in order to find the target group for the brace. Desk research is used as approach for this analysis in order to gain scientific based information.

1.1. ANATOMY OF THE KNEE

The majority of joint injuries are located at the knee, which is the biggest and most complex joint of the human body. Its functioning relies on a complex collaboration between different structures including the bones, muscles, ligaments, cartilage and meniscus (Meyler, 2018).
The anatomy of the knee as described by Martini and Bartholomew (2012) and Paulsen and Waschke (2011) is summarized in this chapter.

1.1.1. BONES

There are four bones in the knee joint, as shown in figure 5. The femur and tibia are the weight-bearing bones of the knee joint and transfer the forces across the femoral and tibial heads, which are respectively called the femoral condyles and tibial plateau. The fibula helps to stabilize the ankle joint but does not help with weight-bearing. The patella or kneecap slides across the femur, which helps creating a momentum for extending the leg.

1.1.2. CARTILAGE AND MENISCUS

Articular cartilage covers the femoral condyles, the tibial plateau and the posterior side of the patella in order to protect the bones from getting damaged. As the femoral and tibial heads have to withstand a lot of pressure, an extra cushion of fibrous cartilage, called the meniscus, helps to absorb shocks and enlarges the contact area in order to increase pressure distribution. The position of the articular cartilage and meniscus are shown in figure 6.

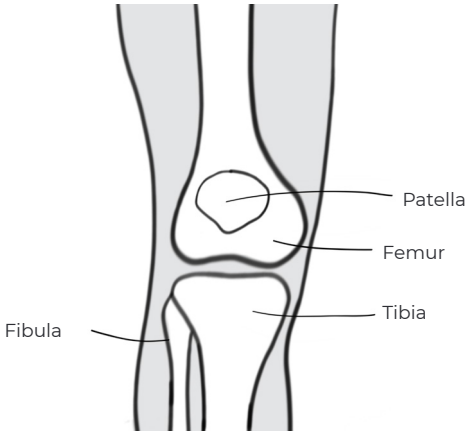


Figure 5. The four bones in the knee.

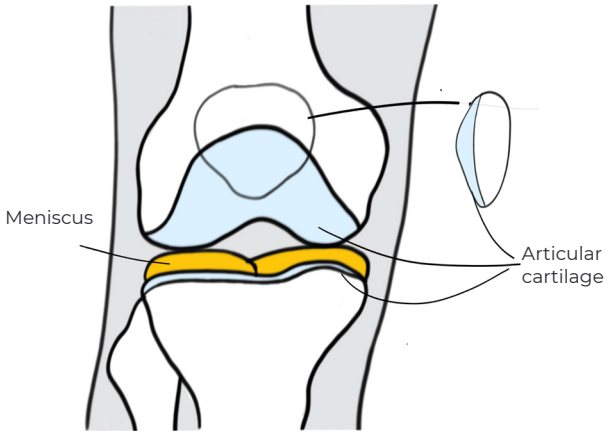


Figure 6. Articular cartilage and meniscus in the knee joint.

1.1.3. MUSCLES

The muscles that enable flexion and extension of the knee joint, include:

- The hamstrings
- The quadriceps
- The patellar tendon
- The popliteus muscle

Flexion of the knee occurs by contracting the flexors, which are muscles grouped as the hamstrings and are attached to the tibia on the posterior side of the leg. The quadriceps is a muscle group of four muscles, which are used for extending the leg and have their insertion on the patella, which is attached to the tibia via the patellar tendon. When the leg is fully extended, a small rotation of the tibia locks the knee. In order to allow flexion again, the popliteus muscle, which runs from de lateral condyle to the medial side of the tibia, "unlocks" the joint by rotating the tibia. The muscles are illustrated in figure 7.

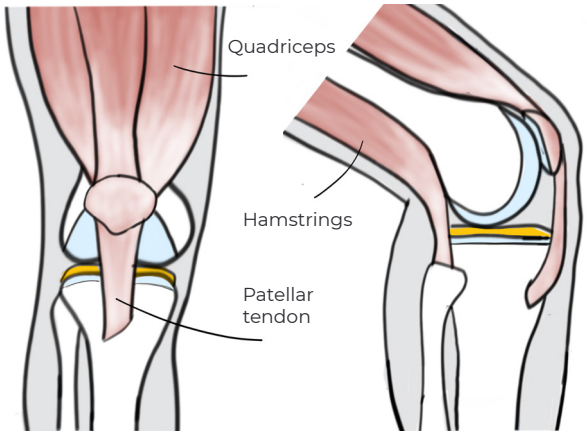


Figure 7. Muscle groups necessary for flexion and extension of the knee.

1.1.4. LIGAMENTS

Ligaments are connective tissue attached from bone to bone with the function to stabilise the knee and hold it together. The knee joint contains four ligaments, see figure 8. The fibular and tibial collateral ligament prevent the joint from moving too much along the transversal axis while the anterior and posterior cruciate ligaments do the same for the sagittal direction.

1.1.5. BURSAE AND SYNOVIAL FLUID

The bursae serve as shock absorbers and are small sacs filled with fluid. The synovial membrane surrounding the joint produces synovial fluid, which is then contained in the cartilage. When pressure is applied to the cartilage, the nutritious fluid is squeezed out and serves as a natural lubricant, which means that using the leg enhances lubrication and keeps the joint healthy due to the circulation of nutrients in the joint. Both the bursae and the synovial fluid decrease friction.

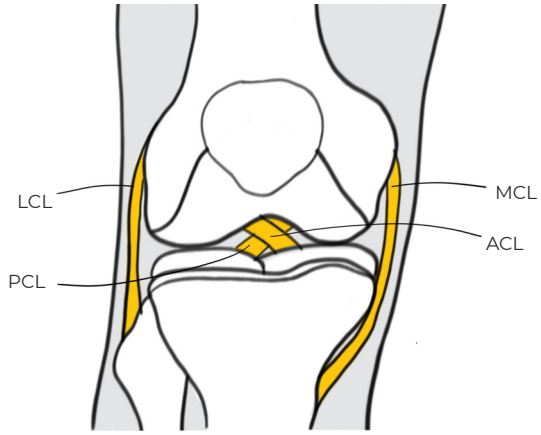


Figure 8. The four ligaments of the knee joint.

1.2. TARGET GROUP

To determine the target group for this project, extensive research has been conducted regarding the nature, cause and treatment of knee problems, which can be found in appendix B. Large forces act on the structures involved in the knee joint mechanism, which leads to a lot of possible injuries and disorders. From this research is concluded that patients with arthritis of the knee would benefit the most from a product as defined in the project scope.

1.2.1. ARTHRITIS OF THE KNEE

According to American Academy of Orthopaedic Surgeons or AAOS (2014) the three main types of arthritis are osteoarthritis (OA), rheumatoid arthritis and post-traumatic arthritis. They all lead to damaged cartilage but have a different root cause.

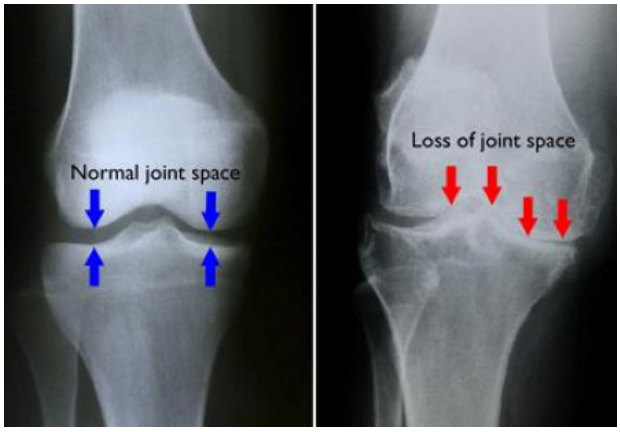


Figure 9. X-ray of a normal knee (left) and a knee affected by OA (right) AAOS (2014).

The target group for this project is patients with OA and post-traumatic arthritis. When using the term osteoarthritis or its abbreviation OA in this report, it refers to both categories. Rheumatoid is not relevant for this project because unloading the joint does not slow down the deterioration process and can therefore not be used as treatment method.

1

OSTEOARTHRITIS

Osteoarthritis (OA) is the most common type of arthritis and is caused by wear and tear of the articular cartilage. The AAOS (2013) states that osteoarthritis is the result of an imbalance between the breakdown and repair of the articular cartilage. The deterioration of cartilage leads to a decrease in cushioning and joint space, which may result in direct bone to bone contact of the femur and tibia as shown in figure 9. This causes pain and inflammation of the joint.

2

RHEUMATOID ARTHRITIS

Rheumatoid arthritis is an autoimmune disease where the immune system attacks own body structures such as cartilage, ligaments and bones in multiple joints. Unlike the other two types, the deterioration process cannot be slowed down by unloading the joint because the disease is not subject to weight-bearing. Rheumatoid is a symmetric disorder and therefore often occurs in both knee joints.

3

POST-TRAUMATIC ARTHRITIS

A subcategory of OA is post-traumatic arthritis. People who have had a knee injury have an increased probability of developing this type of arthritis. Injuries such as ligament or meniscus tears can lead to instability and therefore a larger exposure to wear and tear in certain areas of the condyles. Other relevant injuries are the osteochondral femur fracture and tibial plateau fracture, which affect the quality of the articular cartilage and may therefore cause a lower resistance against weight-bearing.

1.3. OSTEOARTHRITIS

Further research on the pathology of the target group is conducted in this chapter in order to get more insight in the relevance of this project. Osteoarthritis, whether caused due to wear and tear or a trauma, is influenced by many factors. Firstly, a few relevant facts and figures are collected on this disorder. Secondly, the symptoms and treatment options are examined. Lastly, more information is gathered on knee replacement surgery and why this is defined as the last resort solution.

1.3.1. FACTS AND FIGURES

Arthritis in the knee joint is one of the most common muscular skeletal disorders. The high incidence rate of this disorder in the population is illustrated in figure 10 which indicates that a sustainable treatment option is relevant for a large group of people.

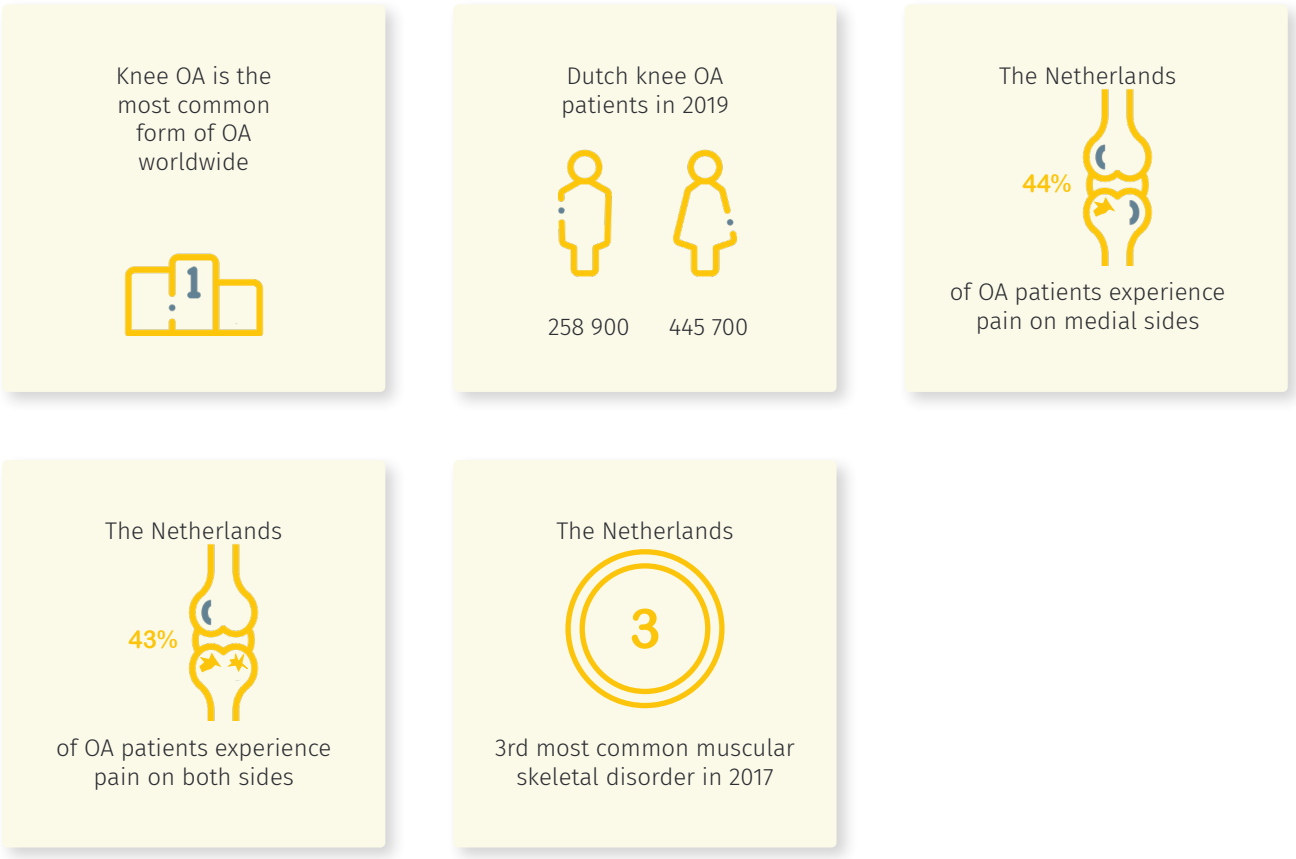


Figure 10. Facts and figures about OA of the knee (RIVM, 2019; 2020).

1.3.2. SYMPTOMS

The main symptoms as defined by AAOS (2014) are:

- Knee pain, which usually worsens over time.
- Inflammation in the knee that can be influences by the burden put on the knee.
- Swelling and stiffness of the knee joint, which could cause limitation in the patients' range of motion both during passive and active movements.
- Buckling in the knee may occur.
- Loose fragments of the cartilage may occur and cause limitation in the range of motion as well or even "lock" the knee during certain movements.
- Symptoms may be worse in the morning or after a period of rest.
- Patients often experience more pain with rainy weather.

There are four stages of radiographic OA as shown in figure 11. It can occur that a patient with stage four radiographic OA has no symptoms while another person with stage one has severe pain. This is called an imbalance of radiographic OA and symptomatic OA (Arden & Nevitt, 2006).

Arthritis in the knee can occur in three compartments (tricompartmental), namely the lateral and medial tibiofemoral compartment and the patellofemoral compartment, but depending on the condition this requires a different treatment. This project focusses on bicompartmental arthritis, which is when deterioration occurs in the two tibiofemoral compartments. However, patients with tricompartmental OA may benefit from the brace as well. This is further elaborated upon in chapter 2.2.

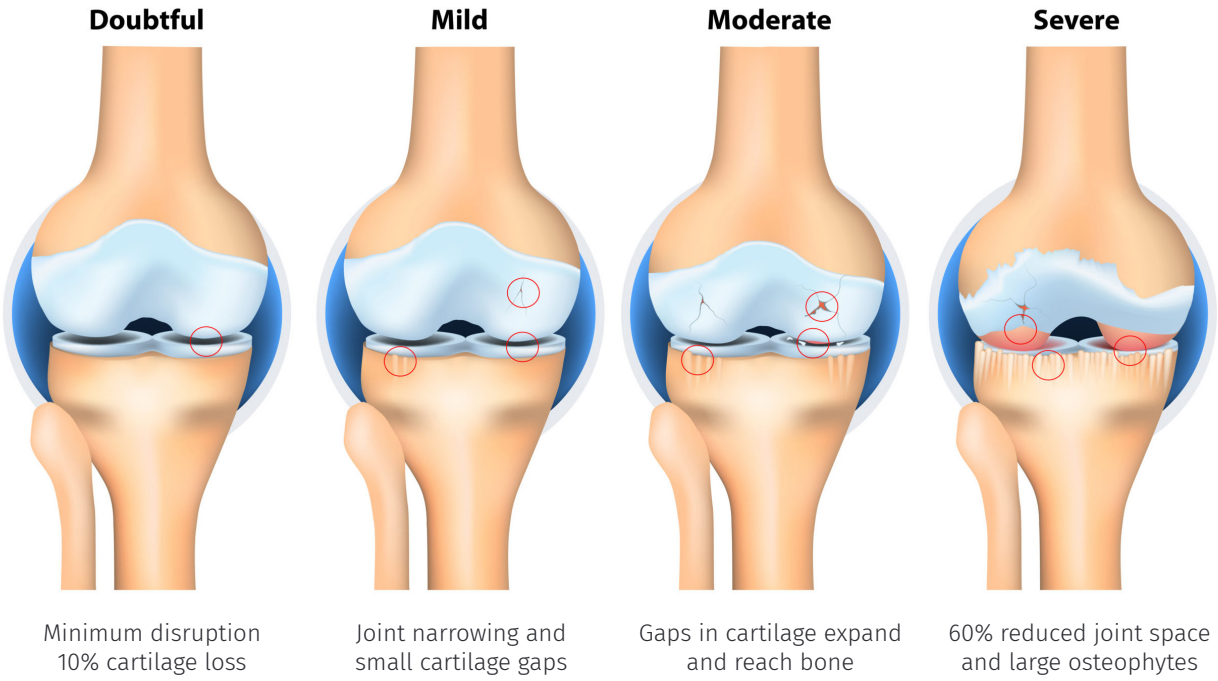


Figure 11. Stages of radiographic knee osteoarthritis (Arthritis research Canada, n.d.).

1.3.3. TREATMENT

GUIDELINES AAOS

An evidence-based guideline has been developed by the AAOS (2013) which provides orthopaedics and general practitioners with recommendations on knee OA treatment that is less invasive than a knee replacement. Both conservative and surgical options are included in the guidelines from which the relevant treatments are shown table 1. The strength of the recommendation depends on the evidence about the balance between possible benefits and potential harm of the treatment.

- **Strong**: There is high-quality evidence on the benefits.
- **Moderate**: Benefits exceed the potential harm but its evidence is less qualitative.
- **Inconclusive**: The evidence is ambiguous and on the balance between benefits and harm.
- **Limited**: The evidence is not convincing or shows little benefits.

It can be concluded that the recommendations mainly focus on symptom relief but do not cure the deterioration. The muscles can be strengthened with physiotherapy in order to absorb loading, and aerobic exercises ensure circulation of nutrients, which decreases pain and stiffness. Losing weight or solving malalignment of the knee joint can help to unload the damaged compartment. Lateral wedge insoles can help with malalignment because it repositions the weight bearing area on the condyles and therefore decreases pain. There is no strong recommendation for surgical treatment such as partial meniscus removal and osteotomy.

There is currently no cure for OA, and worsening of the defects in the cartilage is caused by applying too much load on the knee joint. By actively unloading the knee joint, the deterioration process may be slowed down, which could help prevent the need for knee replacement surgery. However, the current treatment recommendations of the AAOS are lacking effective methods for unloading the condyles. Bracing therapy could fill this gap.

NON-SURGICAL TREATMENT	RECOMMENDATION
Physiotherapy: strength training, low-impact aerobics and neuromuscular exercises	**Strong**
Weight loss for patients with BMI ≥ 25	**Moderate**
Lateral wedge insoles	**Moderate**
Use of nonsteroidal anti-inflammatory drugs (NSAIDs)	**Strong**
SURGICAL TREATMENT	**RECOMMENDATION**
Cannot recommend arthroscopy in patients with a primary diagnosis	**Strong**
Partial removal of a torn meniscus	**Inconclusive**
Osteotomy for unicompartmental knee OA caused in patients with valgus	**Limited**

Table 1. Recommendations on treatment methods for OA (AAOS, 2013).

KNEE REPLACEMENT SURGERY

Total knee arthroplasty (TKA), or in other words total knee replacement surgery, is the most common form of definitive management of knee OA but is still considered a last resort option due to the invasiveness, cost and potential complications. It is a surgical procedure that demands for a long rehabilitation period and causes muscle atrophy, which is a weakening of the muscles. Additionally, one out of five patients is unhappy with the results of a primary TKA, see figure 12. Revision surgery is most commonly needed after 15 to 20 years or when implications occur. During revision, the old prosthesis is extracted, and the bone is cleaned from cement and freshly cut into shape before the new prosthesis can be placed. The holes and cuts in the bone have to become larger every revision in order to create clean and reliable surfaces to which the prosthesis can be attached (Gohal et al, 2018).

The aim of the bracing therapy, in addition to pain relief, is slowing down the deterioration process and thereby delaying the possible need for a surgical treatment. The estimated increase in the number of TKA by 2030 shows the potential of patients interested in the bracing therapy, see figure 12. This would enable the patient to delay the TKA and therefore also minimize the need for revision surgery.

Both the patient's and surgeon's point of view are described in order to gain a better understanding of the relevance of delaying the TKA.

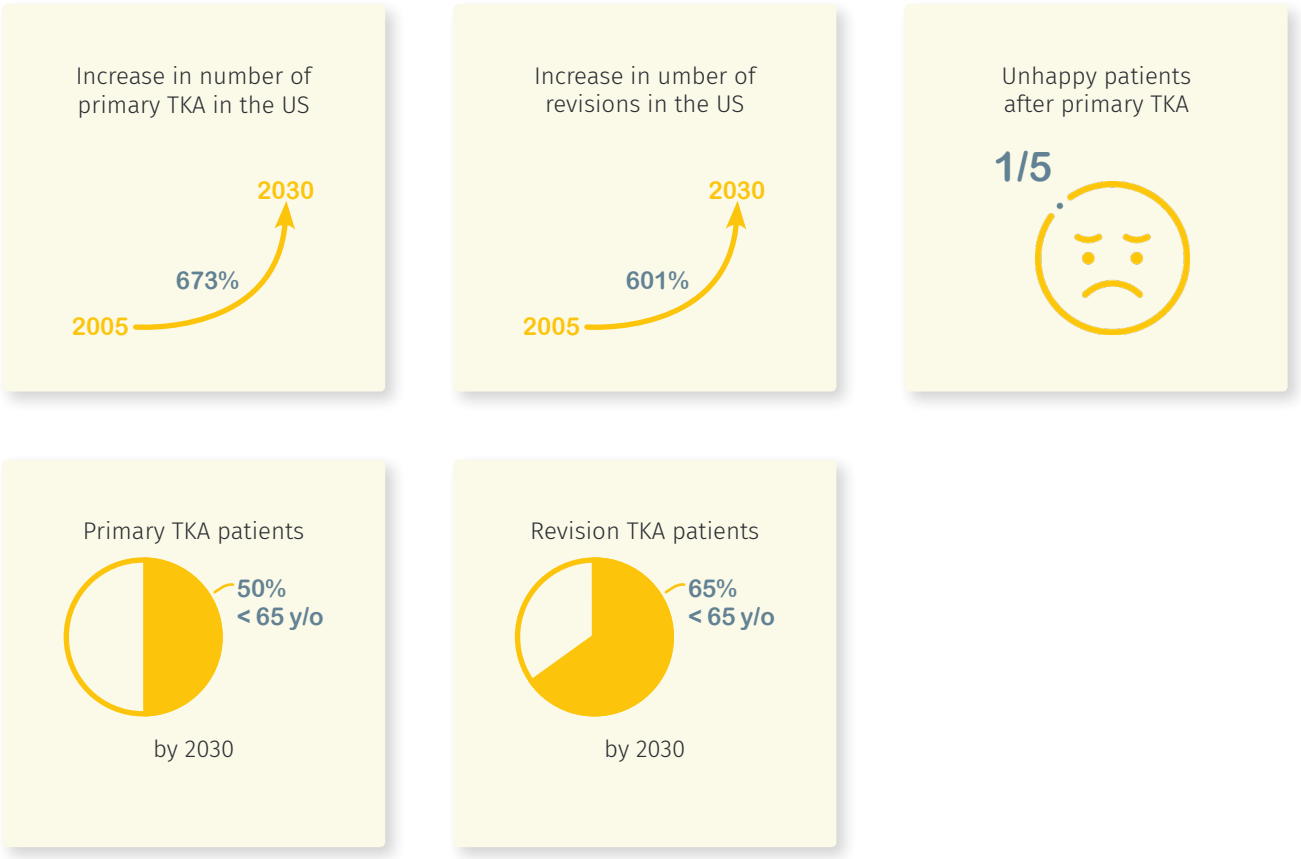


Figure 12. Facts and figures TKA in the United States (Kurtz, Ong, Lau, Mowat, & Halpern, 2007; Kurtz, Ong, Lau, Kelly, & Bozic, 2009; Gohal et al, 2018) .

MEDICAL PERSPECTIVE

An orthopaedic surgeon (appendix D) and a former employee at Zimmer Biomet, a company that produces knee implants among other things, were interviewed. They confirmed that surgery should be delayed, if possible, for a few reasons. One reason is that a knee implant has a limited lifetime. This influences the choice for postponing surgery for a younger patient because they will need more revisions. On average, a knee implant lasts about 20 years.

Another important aspect is that one in five (19%) patients with a knee implant, is unsatisfied with the results (Gohal et al, 2018). According to the orthopaedic surgeon, this even increases to one in three for younger patients. He expects that this can be explained by the imbalance of expectations and results. The patient may experience some side effects after surgery, which might be harder to take for a young and active person who thought to regain their full mobility. The implant mimics the knee kinematics, but there is a noticeable difference. It is therefore always preferred to save the patient's knee joint or part of it, instead of replacing it with an implant.

The interviewed surgeon tries to delay surgery as long as possible. However, in Belgium in general, many people experience, that surgeons advise a surgical procedure rather quickly, in comparison to other countries, such as The Netherlands. This is probably caused by the financial benefits for the surgeon when performing surgeries.

PATIENT'S PERSPECTIVE

Jacobson et al. (2008) states that many patients first choose to delay surgery even though their pain and knee function worsen. This acceptance process can take several months to years, which goes to show the patient's resistance towards undergoing a TKA. A lot of stress arises when they finally agree to proceed with a knee replacement because they do not know what to expect. On top of that, the patient might experience difficulties after surgery with accepting the new knee, and postoperative pain is often reported. Based on this, it can be assumed that patients would rather choose for a non-surgical treatment that enables them to delay the TKA while providing pain relief and increasing mobility. The majority of the interviewed OA patients appendix D) indicated that they would prefer a bracing therapy over a surgical procedure as long as it significantly improves their pain and supports them during activities.

1.4. CONCLUSION

1.4.1. PROBLEM DEFINITION

Patients with osteoarthritis or post-traumatic arthritis in the knee are the target group of this project. The damaged cartilage cannot be cured but non-surgical treatments are first advised to the patient in order to decrease the symptoms. When the pain symptoms are too prominent and the quality of life is affected too much, a surgical treatment may be opted where the knee joint is replaced by an implant. However, due to the invasiveness of the surgical procedure, it is in de patient's interest to delay this, if possible.

Physiotherapy is the main focus in current conservative treatments with the aim to strengthen the quadriceps and hamstrings and use aerobics for decreasing stiffness. Patients might be advised to wear insoles, lose weight or use nonsteroidal anti-inflammatory drugs (NSAID) when found necessary. However, this does not cure or slow down the deterioration but decreases the symptoms.

Although the cause of pain and further progression of wear and tear is related to the loading of the knee joint, there are no conservative treatments available in the guidelines from the AAOS that take away part of the load.

1.4.2. RELEVANCE

Osteoarthritis is one of the leading causes for immobility worldwide and a sustained increase of incidences is expected in the future. Knee replacement surgery is the last resort option and should be delayed, if possible, due to its invasiveness and possible complications, the 20% rate of unhappy patients and the probable need for one or more revision surgeries.

A sustainable non-invasive solution for unloading the knee joint in order to delay surgery, is therefore of great relevance.

1.5. MAIN TAKEAWAYS

- OA cannot be cured and therefore needs treatment for a long period of time, if not for the rest of the patient's life.
- Moving the knee without overloading it, enhances the circulation of nutrients by the synovial fluid, which is important for a healthy knee joint.
- Symptoms of OA can be reduced by decreasing the tibiofemoral contact forces.
- 20% of people who underwent TKA are unhappy with the result.
- There is no treatment in the guidelines from the AAOS that actively unloads the tibiofemoral knee compartment.

2. HUMAN-CENTRED ANALYSIS

In this analysis domain, research is conducted on the human aspect of the project. This includes the patients themselves, who are represented by a persona, as well as all the medical parties involved in the patients' journey. The effectiveness of bracing therapy and therefore the potential of this treatment method, is examined.

2.1. STAKEHOLDERS

The stakeholders are the parties that influence the project and/or would be interested in the envisioned product. They are all shortly described below in order to get a better understanding of who they are.

As shown in figure 13, each stakeholder is positioned along two axes representing their influence and interest. They are also divided into three categories (human-centred, technical and economic) based on which domain they influence most. Further research on the part each stakeholder takes in this project, is conducted in the analysis corresponding to their domain. The stakeholders that are positioned in the first quadrant of the chart are involved in the project using interviews or expertise meetings. The stakeholders in the second and third quadrant influence the requirements of the product, which are taken into account during the design process and business case based on desk research.

Figure 13. Graph showing all the stakeholders and their interest and power regarding this project.

2.1.1. ORTHOBROKER

As producer of the envisioned knee orthoses, they participate in the design and decision-making process. The product should fit within their portfolio, be manufacturable given Orthobroker's resources and be profitable.

2.1.2. PATIENT

Patient compliance is of large influence on the effectiveness of the bracing therapy. Therefore, the patient is of great importance when defining the design specifications that enhance a good customer journey and increase the compliance and comfort of this treatment. Interviews are conducted with OA patients during the course of this project, see appendix D

2.1.3. GENERAL PRACTITIONER

The general practitioner (GP) is the centre of primary care and often the first person consulted by the patient. Because they are not specialised in orthopaedics, they do not influence the design of the brace but are important in providing the patient with the right treatment. How well the GP is informed about the knee orthoses, will influence their advice given to the patient. A GP with an additional expertise a sports doctor is interviewed during this project, see appendix D.

2.1.4. PHYSIOTHERAPIST

A physiotherapist focuses on strengthening exercises and aerobic activities in order to create better conditions for the knee joint to function. They influence the design decisions related to the functioning of the brace and its potential effect on the musculoskeletal system. The brace might bring added value to the physiotherapy when it can be used as a tool. The interview with the physiotherapist can be found in appendix D.

2.1.5. ORTHOTIST

The orthotist or orthopaedic technician measures the patient and chooses an off-the-shelf brace model or produces a custom fitting one. Therefore, they influence the customization process and provide information on currently used hinges and brace designs. This information is collected during an interview (appendix D).

2.1.6. ORTHOPAEDIC SURGEON

The most important stakeholder, when it comes to decisions on the functioning of the brace, is the orthopaedic surgeon. They are well informed about OA thanks to their education and experience. They can best estimate the effect of the brace on the progression of the disorder. The orthopaedic surgeons' point of view is gathered during an interview, see appendix D.

2.1.7. RELATIVES & FRIENDS

The patient's environment will show a small interest in the brace as they want the best treatment for their friend or relative. The brace might enhance the patient's participation in joint activities.

2.1.8. UNIVERSITIES

Universities might be interested in the project for further research on the progression of OA. The mentor and chair of this project are related to the TU Delft and influence the design decisions.

2.1.9. GOVERNMENT

The government determines how the insurance system of a country works and which standards should be met for the orthopaedic devices to be released on the market.

2.1.10. INSURANCE

A reimbursement may apply to the brace depending on the standards of the insurance companies and the regulations of the government. These standards affect the design itself as it influences whether patients receive reimbursement on the product.

2.1.11. MANUFACTURER

It is important to analyse the manufacturing options and production techniques that are suitable for the brace. These come with design restrictions that are taken into account.

2.2. MEDICAL PROCESS

Research is conducted on the relevant part of the patient's journey in the OA process which starts with the first complaints and stops with the decision for a surgical treatment. All key players in this process are interviewed in order to gain more insights. The interviews can be found in appendix D.

2.2.1. KEY PLAYERS

The information gathered from the interviews is summarised below for a better understanding of the key player's role in the process.

PATIENT

The deterioration process and symptoms, highly affects the decision on the kind of medical care that should be provided to the patient. The best treatment is chosen in consultation with the patient. However, the patients are always dependent on the experience and capability of the doctor, physiotherapist or surgeon for receiving the right recommendations for each individual situation.

GENERAL PRACTITIONER

The intention is that the GP is the first person to be consulted by people with knee pain. A first clinical examination is conducted, and the most appropriate treatment is advised. The GP also decides whether to refer a patient to a physiotherapist or orthopaedic surgeon. Before considering this decision, a radiograph can be made.

However, unlike in The Netherlands, people in Belgium can go directly to the next person in line, such as the surgeon, without being referred by their GP.

PHYSIOTHERAPIST

The physiotherapist is primarily an executive branch where the symptoms are treated by providing the patient with strengthening and aerobic exercises. The therapist may advise the patient to seek their GP again when they think this would be beneficial. They can also recommend for a referral to the orthopaedic surgeon but cannot forward the patient themselves.

ORTHOPAEDIC SURGEON

Patients in a more severe stage of OA should seek advice from an orthopaedic surgeon. Most of the conservative treatment options should already have been tried before making an appointment. The surgeon refers the patient to a radiologist for a radiographic examination of the knee joint. Based on the results and the severity of the symptoms, the surgeon will advise a non-surgical or surgical treatment going from hyaluronic injections to total knee replacement surgery.

ORTHOTIST

The orthotist takes the patient's measures in order to provide them with a correct fitting off-the-shelf or custom brace. The orthotist often chooses which brace would be the best option for each patient. Reimbursement of the device is only possible when it is prescribed by the GP or surgeon in The Netherlands and the physio or surgeon in Belgium.

2.2.2. PATIENT JOURNEY

The patient journey is mapped out in figure 14 based on information received from the interviews in appendix D. The yellow arrows visualise the optimal scenario and how the journey should evolve in theory. In reality, however, shortcuts are sometimes taken, depending on the situation. These are indicated with grey arrows.

YELLOW PATHWAY

Osteoarthritis of the knee is often not a singular problem but may be caused by or may affect other musculoskeletal issues. Once a patient experiences pain, they try to compensate by using their body in a different way in order to avoid the painful movements. However, this causes a different way of burdening the body structures, which often leads to other injuries.

A patient often seeks to see a GP when the complaints start interfering with their daily life. The symptomatic and radiographic stage of OA when making this first appointment, highly differs between patients. This depends on the patient's pain limits and on how fast they generally ask for medical help. The GP will perform a clinical examination before recommending a particular treatment such as a period of rest, pain medication, NSAID's and a referral to the physiotherapist. Multiple types of treatment can take place simultaneously.

The physiotherapist supports the patient by giving them physical exercises to primarily strengthen the quadriceps. This could help to manage the symptoms such as pain and loss of function as the muscles will be more engaged and give a better support to the knee joint. Inflammation and stiffness could decrease by aerobic activities that don't put a lot of pressure on the condyles, such as cycling with a high bicycle saddle. However, deterioration of the articular cartilage will not be stopped with physiotherapy. When the symptoms worsen and exercises do not seem to cover the problems, the patient is advised to make a new appointment with the GP who can refer them to the orthopaedic surgeon.

The orthopaedic surgeon most commonly sends the patient to a radiologist in order to examine the stage of radiographic OA. This can support the treatment decision, although the symptoms that are experienced by the patient are leading. When a lot of pain and immobility is experienced, but radiographically the articular cartilage is not too severe, surgery might still be opted for and vice versa. Surgeries can include osteotomy for varus or valgus and partial or total knee replacement. Non-surgical options next to physiotherapy and pain- or anti-inflammatory medication are for example hyaluronic injections, bracing and platelet-rich plasma (PRP) therapy.

As mentioned, in Belgium, physiotherapists and surgeons are able to prescribe a brace in order for the patient to receive reimbursement. The same goes for a prescription from a GP and surgeon in The Netherlands. However, the interviews showed that only one out of the five patients I interviewed wore a preoperative brace. In the orthopaedic surgeon's experience, most of the braces prescribed to OA patients end up collecting dust rather than being worn. When a brace is prescribed to the patient, they make an appointment with the orthotist. This person chooses the optimal brace depending on the characteristics of the patient, their preferences and pathologies. The brace can be prefabricated or custom made.

GREY PATHWAY

The patient journey can differ in each individual situation. Some people wait very long before making an appointment with the GP. In this case, they might be directly forwarded to an orthopaedic surgeon without trying physiotherapy or other conservative treatments. The surgeon might try non-surgical options, but it also happens that they recommend surgery right away. From the interviewed patients, three out of five never went to the physiotherapist before they got the total knee replacement. A fourth patient was told to be needing TKA within five years but instead neglected this advice and follows physiotherapy since then, which by now was fifteen years ago (appendix D).

Whether a conservative treatment would have helped the three patients who underwent surgery is unknown. However, two of them stated to have preferred a conservative treatment if it would have been available and could have helped them in a similar way surgery did (appendix D).

In Belgium, the GP and physiotherapist can be skipped entirely. Whether this increases the chance of receiving a recommendation for a TKA, has not been researched in this report. However, multiple parties state in their interview that surgeons overall tend to advise a TKA faster in Belgium compared to The Netherlands (appendix D).

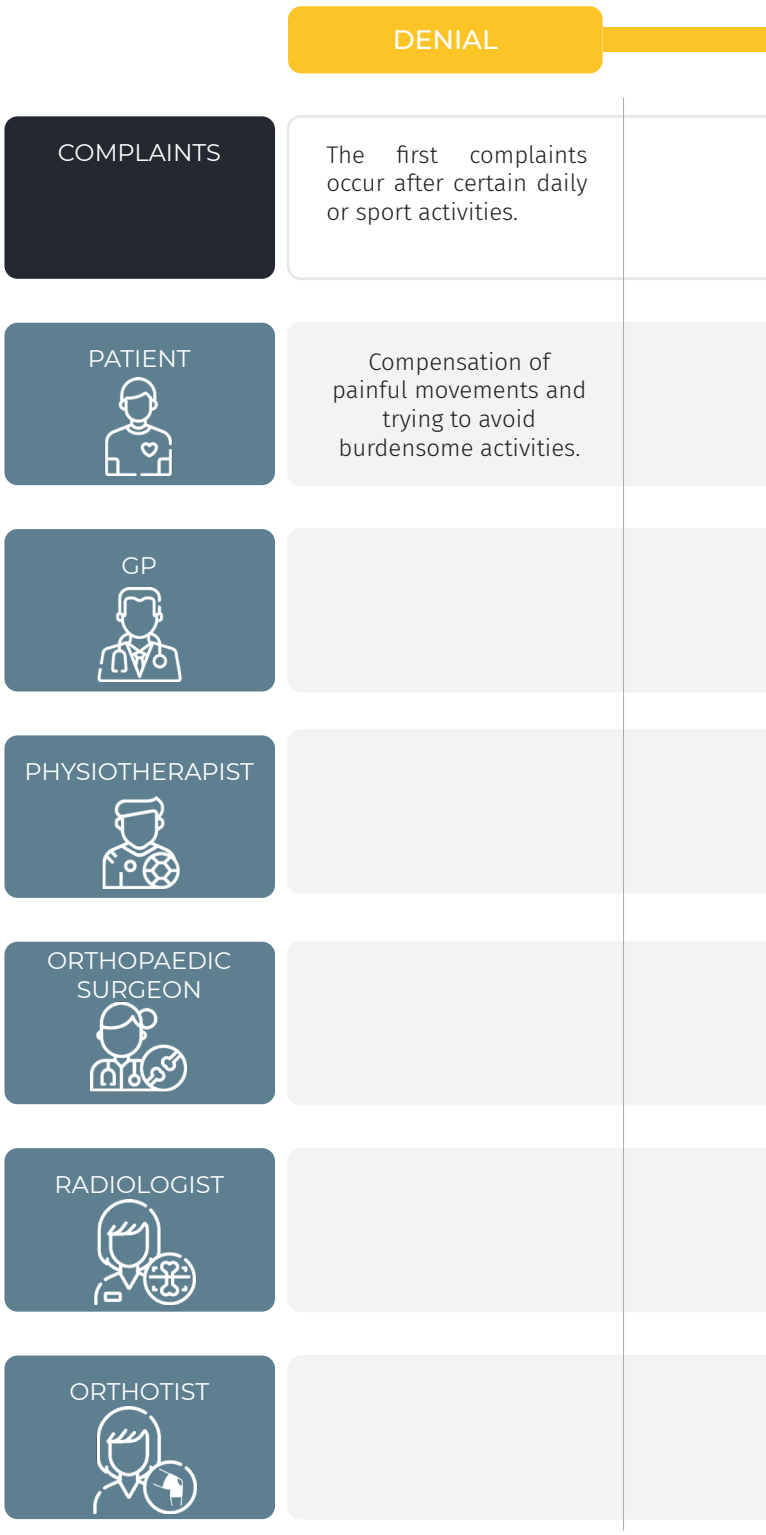
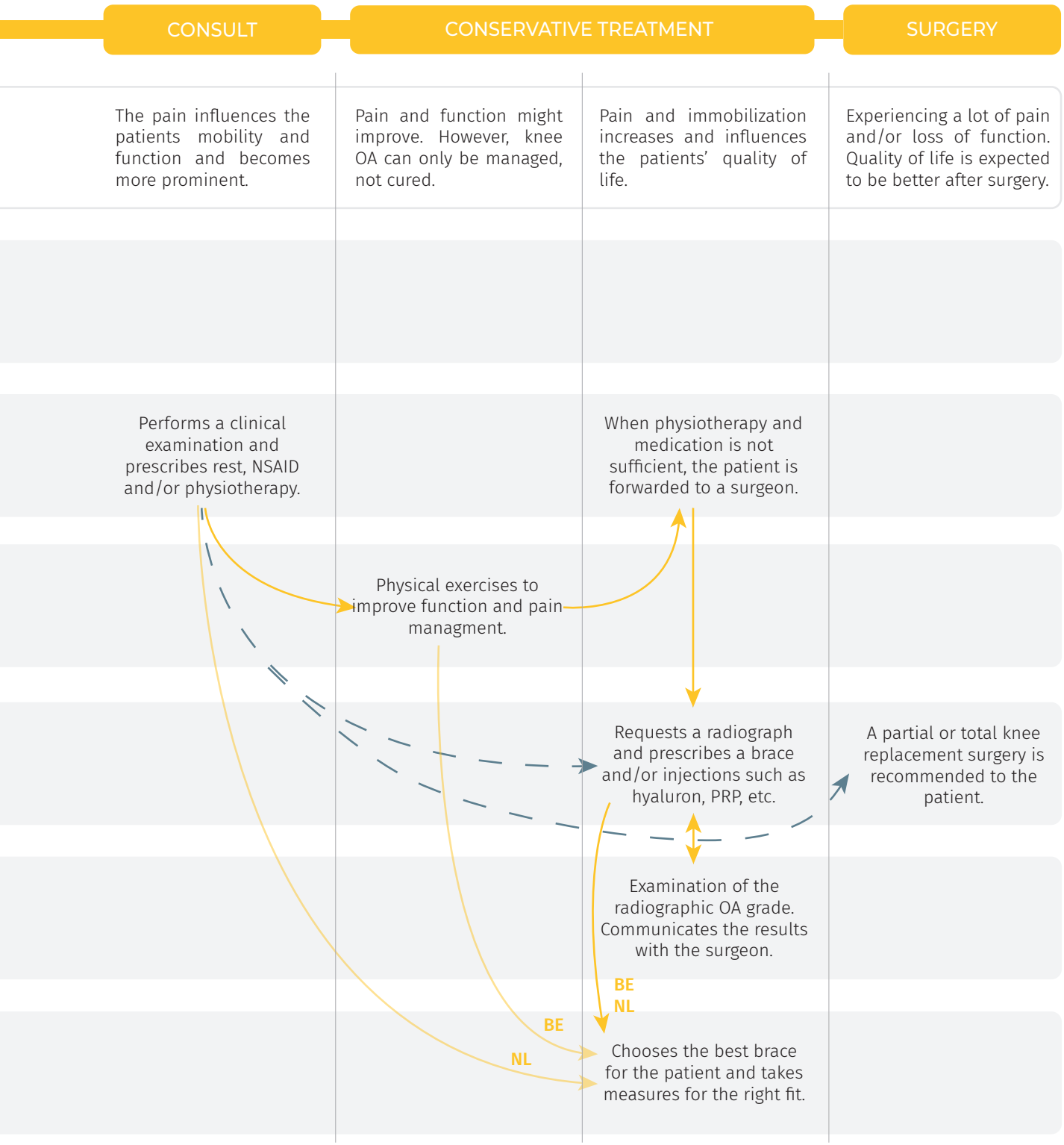


Figure 14. Patient journey from first complaints to a total knee replacer


CONSULT
CONSERVATIVE TREATMENT
SURGERY
The pain influences the patients mobility and function and becomes more prominent.
Pain and function might improve. However, knee OA can only be managed, not cured.
Pain and immobilization increases and influences the patients' quality of life.
Experiencing a lot of pain and/or loss of function. Quality of life is expected to be better after surgery.
Performs a clinical examination and prescribes rest, NSAID and/or physiotherapy.
When physiotherapy and medication is not sufficient, the patient is forwarded to a surgeon.
Physical exercises to improve function and pain managment.
Requests a radiograph and prescribes a brace and/or injections such as hyaluron, PRP, etc.
A partial or total knee replacement surgery is recommended to the patient.
Examination of the radiographic OA grade. Communicates the results with the surgeon.
BE
NL
BE
NL
Chooses the best brace for the patient and takes measures for the right fit.

ment.

2.3. TARGET GROUP

Based on the medical analysis, it is concluded that patients with OA are the target group of this project. However, a large variety of people suffer from this pathology. The target group is therefore further converged based on the personas and their acceptance towards bracing therapy.

2.3.1. PERSONAS

Two personas are created based on the risk factors defined by Arden and Nevitt (2006) and the interviews with an orthopaedic surgeon, a physiotherapist, a general practitioner and OA patients that are conducted during this project. The risk factors can be found in appendix C and the full interviews in appendix D.

OSTEOARTHRITIS

Christine
Sex: Female
Age: 62 years old
Length: 168 cm
Weight: 95 kg
BMI: 33,6

Context
Christine has been a teacher for 40 years at the high school in her town. She has never been the most active person but goes for a walk every now and then and swims with a friend once per week. Keeping her weight under a 3-digit number is a struggle.

Complaints
She experiences a lot of knee pain, and it restricts her in her daily activities. Walking for more than a couple of hundred meters or coming down the stairs is not possible without being in serious pain. The complaints sometimes keep her awake at night.

Treatment
She is under treatment, which involves weekly sessions at the physiotherapist, a hyaluronic injection and NSAID's.

Objective
Christine wants to perform her daily tasks and activities without pain. Surgery might be an option but is invasive and brings along possible implications. Christine would prefer a non-surgical treatment, if possible.

POST-TRAUMATIC ARTHRITIS

Thomas
Sex: Male
Age: 30 years old
Length: 186 cm
Weight: 77 kg
BMI: 22,2

Context
Thomas has been playing soccer since he was a little kid. He recovered from ligament injuries and still trains every week. Due to the many hours on the soccer field, Thomas developed constitutional varus.

Complaints
Pain is experienced every time after soccer training, a match or other activities that put a lot of load on his knees. The pain started on the medial side of the knee but affects the whole knee by now. Daily activities cause no problems at the moment.

Treatment
The weekly trainings are now supported with physiotherapy and extensive warming ups. He also tapes his knee before trainings.

Objective
Thomas wants to keep playing soccer and live an active life. This will not be possible after an osteotomy. He is too young for knee replacement surgery as still has a long life ahead of him, and the lifetime of a prosthesis is around 20 years.

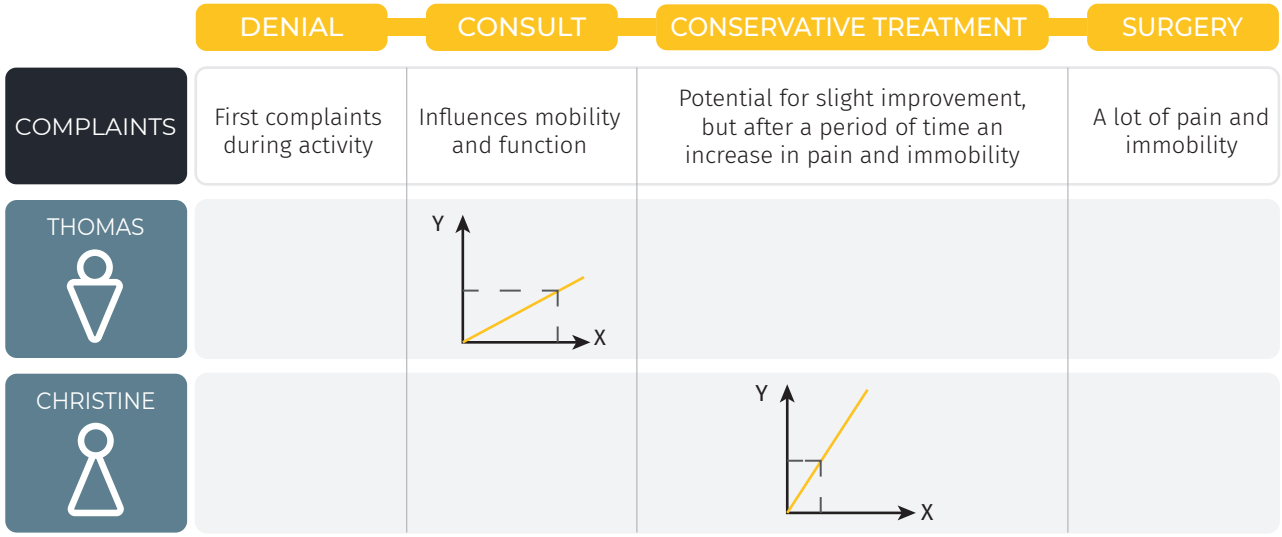
The personas function as a representation of the possible users of the brace, which makes the target group more tangible. The choice for one persona impacts the requirements and specific needs for the brace.

One group of patients suffers from OA due to wear and tear to which the knee is exposed over the years, as represented by the persona Christine. They experience symptoms when getting older. The main risk factors here are her age, her gender and being overweight. Another group of patients might experience early OA due to trauma or extraordinary use of the knee joint as represented by the persona of a young sportsman named Thomas. The number of patients in this situation is smaller but they have a longer life ahead of them with increased pain and possibly limited function.

2.3.2. TREATMENT ACCEPTANCE

Squyer et al (2013) state that comfort and effectiveness of the brace are amongst the most important factors for patient compliance. As with any other treatment, the benefits should exceed the disadvantages. It can be assumed that the more pain and loss of function a person experiences, the more discomfort they are willing to withstand from an effective treatment. However, this balance is different for each individual. Thomas is expected to be less averse towards the brace than Christine. This assumption is confirmed in the interview with the orthopaedic surgeon (appendix D).

The expected scenario for each persona is shown in figure 15. The young and active patient, represented by persona Thomas, will be more interested in using the brace as a prevention method. It is assumed that they will consult a GP when the arthritis starts influencing their sports activities. To be able to continue their active lifestyle, they could be advised to wear the brace during these demanding activities, which will prevent extreme impacts on the articular cartilage. Due to the fear for immobility at an early age, they are expected to accept more discomfort during treatment for less severe symptoms than persona Christine. This balance between tolerated discomfort of the treatment and the severity of the complaints is illustrated by the graphs in figure 15. Patients that suffer from OA as a result of aging, may wait too long before taking serious measures and consult a doctor or surgeon. Deterioration is a continuous process, and a brace seems like an “overkill” to their problems, as stated by the interviewees (appendix D). Therefore, this group of people may tend to accept a brace only when symptoms are severe and cause disfunction during daily life activities, as shown in in figure 15. Before this time, the complaints are not experienced serious enough for such measures.



X = Severity of the complaints
Y = Discomfort the patient is willing to withstand during (effective) treatment

Figure 15. Acceptance of a brace during the patient journey.

2.3.3. OPPORTUNITY

The target group focus of this project is the active patients, represented by the persona Thomas. This group includes both sexes, a P5 – P95 body length and an age ranging from 18 to 35 years old, which is between the end of the growth spurt and the retirement age of professional athletes. The target group excludes patients who are categorised as obese, meaning they have a BMI above 30. This decision is made because the extensive amount of soft tissue among patients with obesity may cause a significant difference in the interaction with the brace compared to people with a BMI lower than 30. A BMI lower than 30 is chosen as focus because it matches with the persona description of Thomas.

The active patient is preferred for this project because firstly, they are assumed to be more acceptant towards bracing therapy earlier in the deterioration process. Secondly, the relevance of delaying a TKA increases when the age of the patient decreases. These two factors raise the expectation of a larger impact of the bracing therapy among younger and more active patients compared to older patients who suffer from wear and tear OA.

2.4. BRACING THERAPY POTENTIAL

Whether bracing therapy has the potential of being an effective treatment to decrease pain and delay the need for surgery, depends on various factors. Firstly, the working principle of the brace should help to achieve the desired medical effect. The second important variable is patient compliance and lastly the type of brace. The findings on these variables are discussed in this chapter.

2.4.1. BRACING THERAPY

A recent study by Gohal, Shanmugaraj, Bedi, Adili, & Khan (2018) states that the use of a valgus unloader brace for treating OA of the medial compartment of the knee is effective in improving pain and function. The unloader brace corrects malalignment of the knee by applying a sideway force to the knee, as shown in figure 16. In this way, pressure is relieved from the medial condyle and shifted to the lateral. However, the unloader does not absorb part of the loading but shifts it. This way it decreases the load on the affected condyle while increasing load on the other one (Prestige Healthcare, n.d.).

Results about the effect of the unloader brace on stiffness are shown to be heterogeneous and positive. Some studies developed the theory that an increase in function would cause the patient to use the affected knee more. As earlier mentioned, cartilage acts as a sponge during movements and squeezes out the synovial fluid, which keeps the joint healthy and decreases stiffness. However, other studies argue that the patients feel as if the braced leg is weak and are therefore hesitant to use the affected leg. Overcompensation by using the unaffected leg causes more stiffness and increased chances in developing other injuries in other joints (Gohal et al, 2018).

Figure 9. Working principle of the unloader brace from Össur (Prestige Healthcare, n.d.).

The unloader brace can only provide effective relief for one knee compartment for patients with unicompartmental OA. However, Heekin and Fokin (2014) state that the majority of people that go for total knee surgery have bi- or tricompartmental osteoarthritis, as shown in figure 17.

Based on the results on the effectiveness of the unloader brace, it can be assumed that a brace, which unloads both tibiofemoral compartments, will be an effective method to improve pain relief and targets the majority of TKA patients.

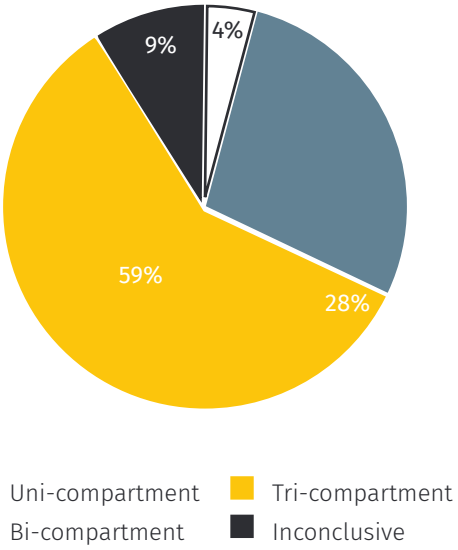


Figure 16. Prevalence of knee OA per compartment (Heekin & Fokin, 2014).

2.4.2. PATIENT COMPLIANCE

A recent study has shown that poor patient compliance is the biggest problem when it comes to unloader bracing therapy. After one year, only 28% of the correspondents was still using the brace. There was no link found between the discontinuation and variables such as BMI, age, radiographic OA, etc. However, it seemed that patients, who experience a significant increase in their function and mobility, are more likely to stick with the brace as a treatment rather than those who did not experience this amount of improved functioning. The self-reported issues that influenced the correspondent's compliance, are shown in table 2. These aspects are taken into account in the new brace design of this project (Squyer, Stamper, Hamilton, Sabin, & Leopold, 2013).

	BRACE USED > 1 YEAR	
BRACE ASPECT	NO	YES
Skin irritation or swelling	17 (40%)	4 (20%)
Bad fit or uncomfortable	25 (60%)	2 (10%)
Not helping symptoms enough	21 (50%)	2 (10%)
Hard to put on/take off	7 (17%)	0
Hard to wear with clothes	13 (31%)	6 (30%)
Heavy and bulky	14 (33%)	4 (20%)

Table 2. Complaints reported by the patient that influence their compliance (Squyer et al, 2013).

The orthotist stated during the interview that the most common complaints about a brace are that it slides down, is bulky and heavy, and that it causes irritations to the skin. Custom made braces are more likely to cause fewer complaints (appendix D).

2.4.3 PREFAB VERSUS CUSTOM

In a study conducted by Draganich et al (2006) two braces from Donjoy were compared, namely the off-the-self OAdjuster and the custom OA Defiance. There was found to be a significant effect on the pain, function and stiffness experienced by the patient with both unloaders compared to wearing no brace at all, as shown in figure 18. The closeness of fit from this custom unloader brace had an even more positive effect on these three factors as well as on the malalignment of the knee joint than the prefabricated brace. According to the interviewed orthotist, the effectiveness of the brace decreases significantly when it is worn incorrectly. Generally, patients are better able to align the hinge correctly with the knee joint when the brace is a more custom fit.

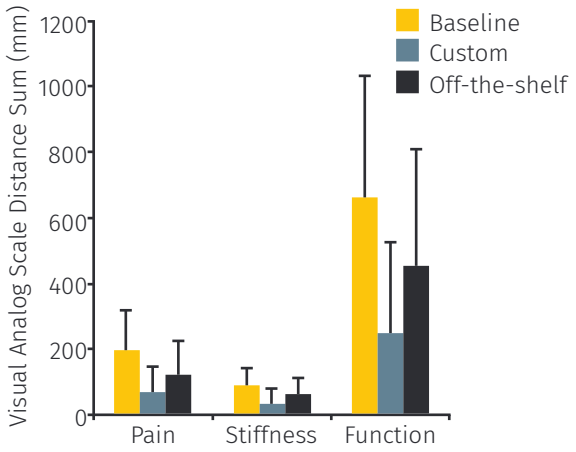


Figure 18. The effect of a custom and prefab brace on the pain, stiffness and function in patients with OA primarily on the medial condyle compared to no brace (Draganich, et al., 2006).

2.5. CONCLUSION

From the human-centred analysis it can be concluded that two relevant categories of OA patients can be distinguished. On the one hand, the younger persona Thomas with early arthritis due to extensive use of the knee and potentially a trauma. On the other hand, the persona Christine with an age above 50 years old and arthritis caused by wear and tear over the years. The first category is expected to use the brace earlier in the patient journey in order to prevent loss of function and with the main intention to stay active. The second group of patients will use the brace later in the process when arthritis influences daily life and wearing a brace during certain daily activities causes more benefits than disadvantages. The impact of the brace is assumed to be larger for this subgroup due to the early age when prognosed with OA and their acceptance towards wearing a brace. Therefore, this project focusses on one persona Thomas, representing patients between 18 and 35 years old with a body length in the P5-P95 range and a BMI lower than 30. This BMI limit is chosen because the amount of soft tissue influences the design of the brace due to the difference in how the soft tissue behaves. Although, it is assumed that when an iteration will be made to include this part of the target group as well, the function and architecture of the brace will be the same but the design to fit and the aesthetics will differ.

The existing unloader knee brace repositions the weight bearing area from the medial to the lateral condyle. This technique decreases pain end enhances function for patients with unicompartmental OA, which goes to show the effectiveness of unloading the damaged articular cartilage areas. However, there are no bracing solutions currently provided for patients with bi- or tricompartmental OA. Hence the need for a new bracing solution

.

Patient compliance has a large impact on the effectiveness of the bracing therapy. Therefore, a fully customized brace is preferred in order to increase comfort. On top of that, more positive effects on the symptoms are experienced in a closely fitted brace instead of an off-the-shelf model.

2.6. MAIN TAKEAWAYS

- The majority of OA patients is older than 50 but is expected to be more averse towards the brace. Young patients with early OA or post-traumatic arthritis are with less but might be more interested.

- Delaying surgery is of higher relevance in younger patients because of its invasiveness and the need for revision surgery every ±20 years, with each surgery coming with the risk of complications.

- Conservative measures are preferred over surgical treatment. If pain is relieved and the functionality is improved, a conservative treatment is preferred by both the medical staff and the patient.

- It is important for the patient's compliance to develop a compact, well-fitting and comfortable brace that doesn't slide down and helps to decrease the symptoms.

- A customised brace has better effect on the patient's symptoms than the same model but prefabricated.

- The GP, physio and surgeon should be well informed about the existence of the brace in order to reach the patient.

- The patient should be able to use pre-sets, which increases treatment effectiveness due to the decreased chance for incorrect wearing.

- 89% of patients who choose for a TKA suffer from bi- or tricompartmental OA.

3. TECHNICAL ANALYSIS

A technical analysis of the project is conducted in order to gain better insights in the possibilities and restrictions that apply to the brace design. Firstly, information is gathered on the knee kinematics and the recreation of this mechanism within a hinge design. Secondly, further research is conducted on the support system and what the desired function is for effectively unloading the knee joint. These two aspects define the function of the envisioned brace. Lastly, the technology used for this support system in existing braces is analysed.

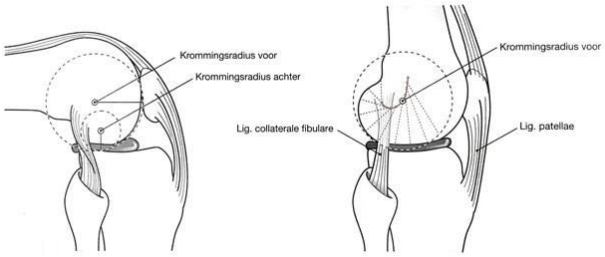


Figure 19. Knee kinematics axis and radius of curvature (Paulsen & Waschke, 2011).

3.1. KNEE KINEMATICS

The femoral condyles rotate on the tibial plateau and have a smaller radius of curvature on the posterior side, compared to the anterior side. Therefore, the location of the transversal axis, around which the femur rotates, is not constantly in the same position but moves along a bend line as shown in figure 19. This is called femoral rollback. The femoral condyles are not equal to each other, causing a lateral rotation of the knee joint. This leads to a primary use of the lateral condyle during the first 20 degrees of flexion. From then onwards, the femur further rotates mainly using the medial condyle (Paulsen & Waschke, 2011).

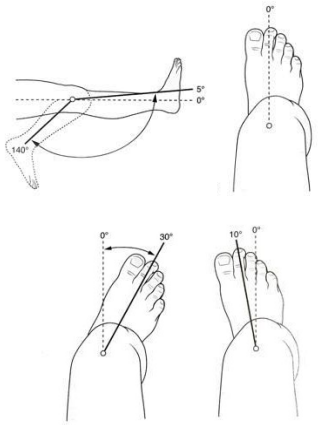


Figure 20. Flexion, extension and rotation angles of the knee joint (Paulsen & Waschke, 2011).

The ligaments stabilize the knee and keep everything in place but do allow a small rotation of the tibia as shown in figure 20. The maximum angle the foot can rotate inwards is smaller than outwards because of the cruciate ligaments that wrap around each other, due to the way they cross each other.

The hinge of a brace should allow and support polycentric rotation and femoral rollback of the knee joint, during flexion and extension. A polycentric hinge, see figure 21, is most commonly used for functional or unloader braces, instead of a monocentric design, as it more closely recreates the joint movement (Larazo & Dec, 2019).

Figure 21. Functional brace with a polycentric hinge (Rebel sport, n.d.).

Another schematic model of the knee joint movement along the sagittal plane can be created with use of a four-bar hinge mechanism, as shown in figure 22. This is an even better representation than the polycentric model (Smith, Refshauge, & Scarvell, 2003). Both models are taken into account during the development of the hinge design.

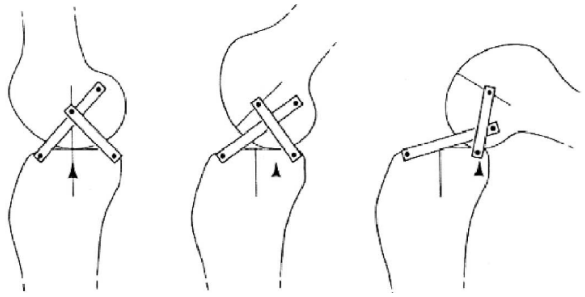


Figure 22. Four-bar mechanism of the knee joint (Smith, Refshauge, & Scarvell, 2003).

According to Larazo and Dec (2019), optimal bracing relies mainly on the correct placement of the hinge related to the femoral condyles instead of a particular hinge design as long as it simulates the movement close enough and does not restrict it. This is confirmed during the interview with an orthotist (appendix D). For a polycentric brace, the centre between the two gears should be aligned with the centre of the patella in the coronal plane and on a 4/6 posterior-anterior ratio in the sagittal plane. However, the posterior-anterior ratio can differ depending on the patient's pathology. The fitting and positioning of the brace is done by an orthopaedic technician. The downside is that patients can change the settings afterwards reducing the effectiveness of the brace.

Aside from the movement in the sagittal plane, a tibial rotation occurs during flexion-extension. This phenomenon is called the "screw home rotation" and allows the leg to fully extend. This lateral rotation of around 10° occurs during the first 30° of flexion and rotates back in the medial direction during the last 30° of extension. Although it seems to be a small angle, it is important for a healthy movement and full range of motion (NASM, 2015).

3.2. SUPPORT SYSTEM

In order to get a better understanding of the forces acting on the knee joint, a diagram is created as shown in figure 23. Tibiofemoral (TF) force reduction is relevant in patients with bicompartmental arthritis. In case of tricompartmental OA, the patellofemoral (PF) force should be decreased as well. When rising from a chair, 50% of the bodyweight (BW) is carried by each leg and applied to the foot as the ground reaction force (GRF). At 90° flexion, the horizontal distance between the point to which GRF is applied, and the knee joint centre is approximately 200 mm, causing a momentum. In order to get a moment equilibrium, the patellar tendon (PT) force, with a moment arm of approximately 35 mm, creates a counteracting momentum with the same magnitude. The PT force at a flexion angle above 70° is approximately the same as 70% of the force delivered by the quadriceps (Q). The PF and TF can be derived using vertices (Masouros, Bull, & Amis, 2010).

The magnitude of these forces during the two daily activities walking and squatting, are further described.

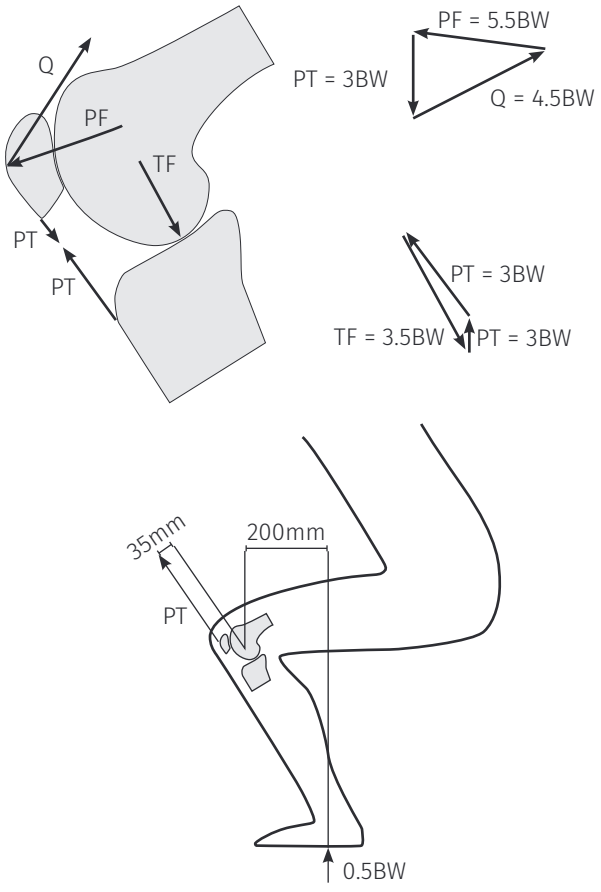


Figure 23. Simplification of the joint forces diagram of the knee (Masouros, Bull, & Amis, 2010).

3.2.1. GAIT ANALYSIS

The largest pressure in the TF contact area occurs during the stance phase when the bodyweight is carried on one leg. During this phase, the leg is almost fully extended and remains under a flexion angle of 20°, as shown in figure 24. Therefore, the pressure on the TF compartment is caused by the vertical GRF as a result of bodyweight and gravity, instead of the quadriceps muscle causing momentum. In order to relieve the TF contact area, force transfer between the femoral condyles and the tibial plateau should be prevented. A possible solution is to use a brace that pulls the femur and tibia away from each other, which is referred to as traction (figure 25) and absorbs the vertical forces.

Figure 25. Traction of the knee joint (DDS, n.d. a).

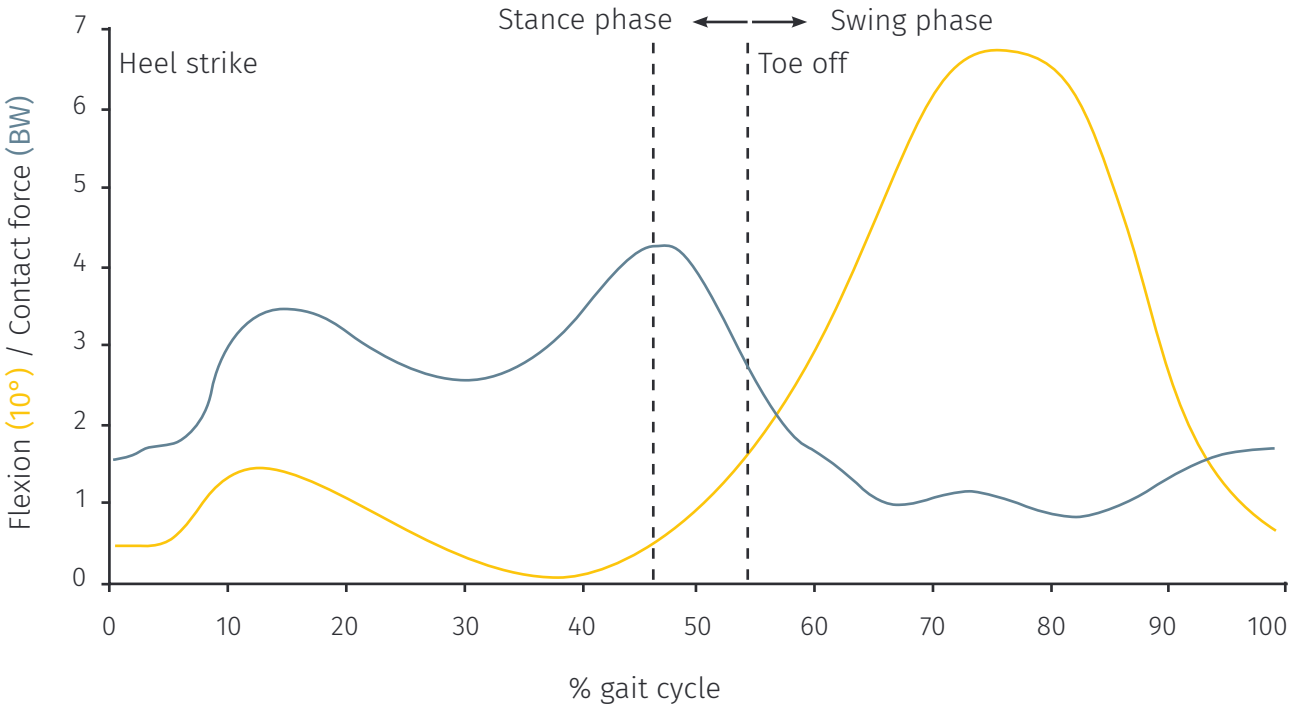


Figure 24. Magnitude of the TF contact force during the gait cycle (Lenton, et al., 2018).

3.2.2. SQUAT ANALYSIS

McGibbon and Mohamed (n.d.) researched the effect of three different energy storing mechanisms in knee braces on the PT and TF contact forces during a deep-knee bend. The impacting forces were simulated by applying a force anterior to the tibia and 20 cm below the knee in order to analyse the effect on the other joint forces during a deep knee bend. The brace that was found to be most effective, as shown in figure 26, applies a linear force proportional to the flexion angle of the knee.

The contact force is a result from the momentum created by the GRF and the patellar tendon. An energy storing mechanism creates a momentum in the same direction as the PT force does, leading to a reduction of quadriceps force and thus PT force. This support system can be referred to as external muscle-tendon (MT) force.

The graphs show that at the start and at the end of the deep-bend, when the leg is near extension, the brace has almost no effect on the PT and TF forces. This makes the energy storing mechanism less beneficial during gait, where the largest contact forces are present at a flexion angle <20°.

3.2.3. OPPORTUNITY

Different knee brace mechanisms are necessary for unloading the tibiofemoral contact areas during the entire flexion range. During gait, the main focus is the absorption of the vertical force as a result of carried weight and gravity. When squatting, a counter momentum around the joint centre should be created by the brace in order to unload the TF contact area. By doing so, the PF contact forces will also be reduced. Both mechanisms can be combined, or a choice can be made in correlation with the intended use of the brace.

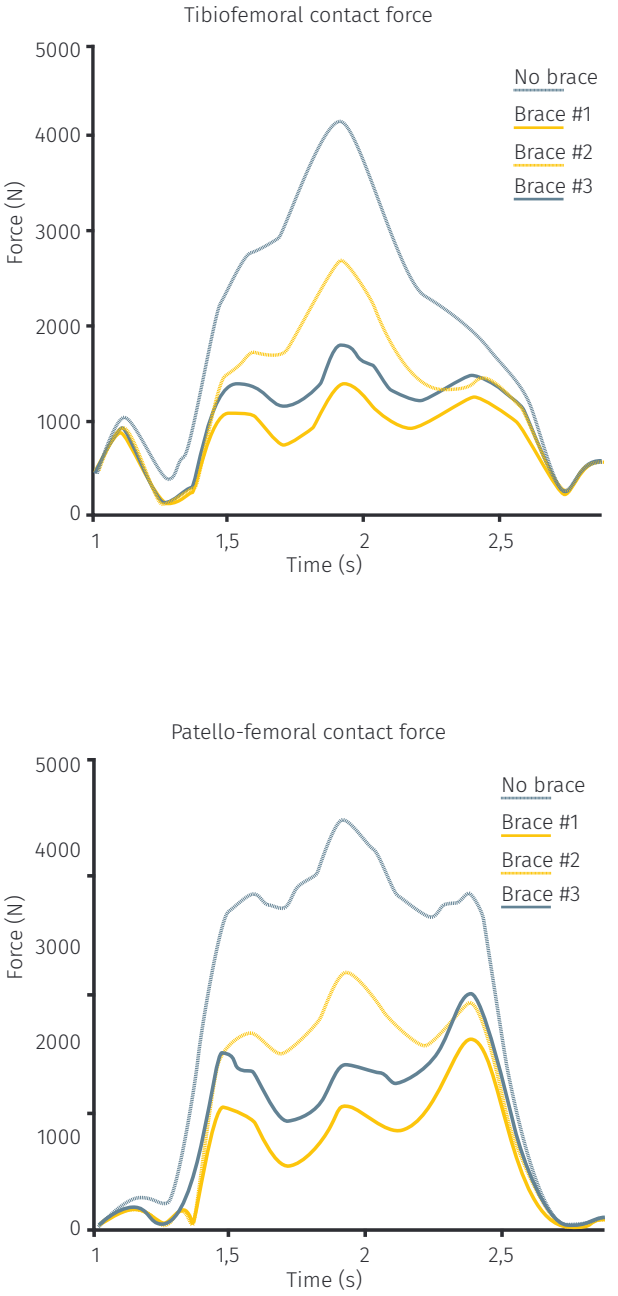


Figure 26. Effect of three different energy storing braces on PT and TF forces (McGibbon & Mohamed, n.d.).

3.3. PRODUCT COMPETITORS

The braces that are currently on the market and unload at least two compartments of the knee joint can be found in table 3. Unloader braces that apply force sideways on the joint, are not included as they shift the weight from one compartment to another, instead of unloading both. The braces are categorised by their function and ordered by price. The technology used by the competitor products and their selling price is analysed as well.

The braces are categorized by the support mechanism that is used and based on whether they are off-the-shelf or custom designs. The first support system is traction of the knee joint, which creates space between the femur and tibia. The second mechanism is external muscle-tendon (MT) force, which assists to extend the leg. A custom traction brace is currently not available and is therefore seen as an opportunity for this project.

FUNCTION	PREFAB	CUSTOM
External MT force	- Push Med brace - Levitation 2 - Icarus Ascender - Icarus Aspen	-Icarus Ascender -Icarus Aspen
Traction	- Kneetrac lite - DDS OA Kneetrac	Opportunity

Table 3. Braces on the market and their function (DDS, n.d. a; n.d. b; Push braces, n.d.; Springloaded, n.d.; Icarus, n.d. b).

3.3.1. TECHNOLOGY ON THE MARKET

The technology used in OA-braces that are available on the market, are analysed and described below. The technologies are arranged by their support mechanism as stated before.

DISC DISEASE SOLUTIONS

One brace is currently on the market with an integrated traction mechanism. Disc disease solutions (DDS) designed a special hinge that acts as a lever and pulls away the bodyweight from the knee joint during extension, see figure 27. The femur is pushed upwards, and the brace therefore lifts part of the weight. It is questionable how the brace clamps around the leg using off-the-shelf standard sizes in order to engage traction without slipping (DDS, n.d. a; n.d. b).

PUSH

The Push Med Knee brace uses a leaf spring instead of a hinge design in order to apply an external MT force. The compression of the spring increases with the flexion angle and therefore delivers more counterforce the deeper the user bends, see figure 28. Further research is required in order to define the effect of a spring design instead of a hinge that recreates the polycentric rotation and femoral rollback of the knee (Push braces, n.d.).

SPRINGLOADED

The Levitation 2 unloader from Springloaded uses a liquid spring in order to store the kinetic energy during flexion and releasing it again during extension, see figure 29. The spring makes bending harder when the flexion angle increases because it then delivers more counterforce in the hinge. The brace is an off-the-shelf external MT force design (Springloaded, n.d.).

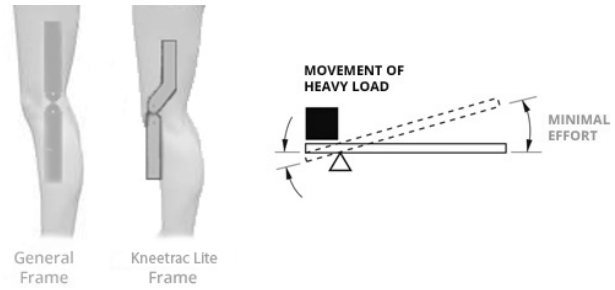


Figure 27. DDS traction hinge design (DDS, n.d. a; n.d. b).

ICARUS

The Ascender and Aspen brace from Icarus use one or more elastic bands that run through the hinge and can be tightened with a Boa® system, see figure 30 and figure 31. The counterforce increases when more or stiffer bands are used, creating an external MT force. This system as well provides the user with extra support during flexion and increases along with the flexion angle. The amount of counterforce can easily be managed with the Boa® knob. In this way, the user can quickly adjust or turn off the mechanism when not needing it, allowing for an increased range of motion (US Patent No. US10.806.619 B1, 2020).

Figure 28. Push Med knee brace leaf spring mechanism (Push braces, n.d.).

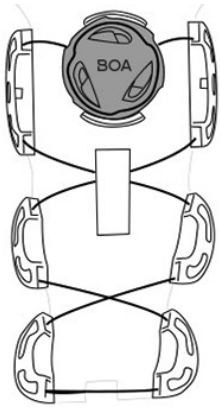


Figure 30. BOA technology (FTG safety shoes, n.d.).

Figure 29. Levitation 2 unloader system (Springloaded, n.d.).

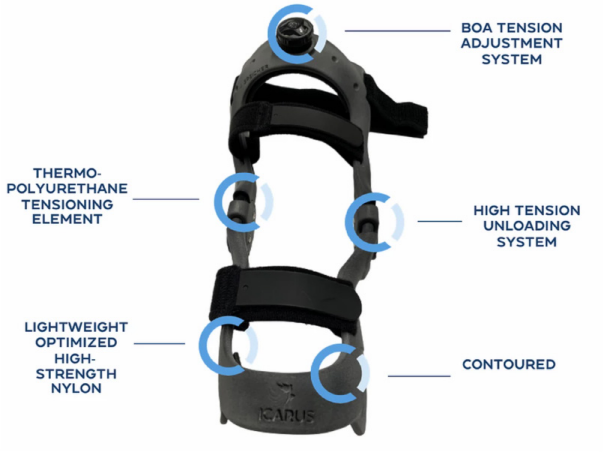


Figure 31. Ascender knee brace technology (Icarus, n.d.b).

3.3.2. MARKET PRICE

The price of the prefabricated braces varies between €139 and €2969. This is in direct relation to the complexity of the technology used, starting from a mechanical hinge design on the low end to a liquid spring on the high end of the price range. The customized braces that are created using a 3D scan of the patient's leg, are both from Icarus and cost around €1200. The only brace that is available via Belgian orthotists is the Push Med knee brace.

COMPANY	BRACE NAME	CUSTOM /PREFAB	PRICE
DDS	Kneetrac lite	P	€139
Push	Push Med	P	€146
DDS	OA Kneetrac	P	€326
Icarus	Ascender	P	€788
Icarus	Aspen	P	€907
Icarus	Ascender	C	€1.151
Icarus	Aspen	C	€1.237
Sprinloader	Levitation 2	P	€2.969

Table 4. Price of the levitation and MT force braces currently on the market (DDS, n.d. c; DDS, n.d. d; Goed thuiszorgwinkel, n.d.; Icarus, n.d. a; Knee clinic, n.d.).

3.4. CONCLUSION

A lot of research can be conducted on the hinge design of the brace. It is most important that the polycentric rotation, femoral rollback and screw home rotation are not limited by the brace. More comfort and better results are observed when a polycentric hinge is used instead of a monocentric hinge, because it better recreates the sagittal replacement of the knee joint. Another option is the use of a four-bar linkage. The effectiveness of the brace highly depends on the correct positioning of the hinge in relation to the knee joint, rather than the hinge design itself.

The focus of this project is to design a brace that causes traction in order to support the patient by partially unloading the tibiofemoral compartment. The traction mechanism is most effective during near extension, for example, during walking and running, which covers a large portion of activities.

3.5. MAIN TAKEAWAYS

- Polycentric rotation and femoral rollback should not be restricted by to the hinge design.
- Screw home rotation should not be restricted by to the brace.
- Decreasing the TF contact forces during gait would require traction of the knee joint.
- Decreasing the TF contact forces during squats would require an external MT force, which is created by a counteracting momentum around the joint centre. This also decreases PF force.
- A polycentric hinge or four-bar linkage mechanism can be used to simulate knee joint rotation.
- Default position of a polycentric hinge is at 4/6 anterior-posterior ratio. This may differ depending on the pathology of the patient.
- Based on the bicompartmental unloader braces from competitors that are available on the market, it is concluded that the opportunity of this project is to design a custom traction brace.

4. CRITERIA

A refined project brief is derived from the analysis phase and provides information on the exact design goal, the requirements and the design vision. The final product is again assessed on the same criteria in order to compare the initial relevance with the achieved relevance.

4.1. PRODUCT DEFINITION

The new knee brace design will distinguish itself from other braces on the market due to its hinge design and the ability for patient specific adjustments. The brace is a customized product that is generated by the orthotist.

The support system of the brace will provide traction between the femoral condyles and the tibial plateau. This means that the brace carries a part of the patient's bodyweight, which reduces the load on the knee joint. The brace slides in the correct position due to the custom fit of the design and the anatomical interaction with the patient.

4.2. DESIGN DRIVERS

The design drivers, see table 5, are the design wishes that will distinguish the product from its competitors. The full list of requirements can be found in appendix E.

4.3. VISION

The vision is to design a customized brace that perfectly fits the patient, which enhances comfort and increases the chance for continuation of the treatment. The brace clamps around the leg and only applies pressure on pressure tolerant areas of the leg. Due to the perfect fit, it is easy to position the brace correctly for a good alignment of the hinge with the knee joint, which increases effectiveness. The hinge mechanism creates traction between the tibia and femur, which unloads the tibiofemoral compartment.

DESIGN DRIVERS	DOMAIN
The brace enhances pain relief and increases mobility by creating traction.	Medical
Unloads both medial and lateral tibiofemoral compartments using traction.	Medical
The brace is designed to limit mistakes made by the user that would lead to incorrect activation. Receiving an explanation on how to use the brace from the orthotist one time, should be sufficient.	Human-centred
The hinge design does not interfere with the mobility of the knee and mimics the knee joint for increased comfort and effectiveness.	Human-centred
The brace is a slim fit that is less bulky than existing models and can be worn under straight trousers.	Human-centred
The brace doesn't slide down and is therefore more comfortable to wear than alternatives.	Human-centred
Slides into position in order to prevent malalignment and increase effectiveness.	Human-centred
The brace can be manufactured using 3D printing and standard parts.	Technical
The assembly of the different parts can easily be done.	Technical
The support mechanism can be deactivated without having to take off the brace.	Technical
The production cost of the brace is lower than the current alternative of manually producing a custom brace using cast.	Economic

Table 5. Design drivers for the envisioned knee brace.

1
Ratchet Buckle
2
Non-circular hinge
3.a
4.
5
screwing
6.b
6.a
7

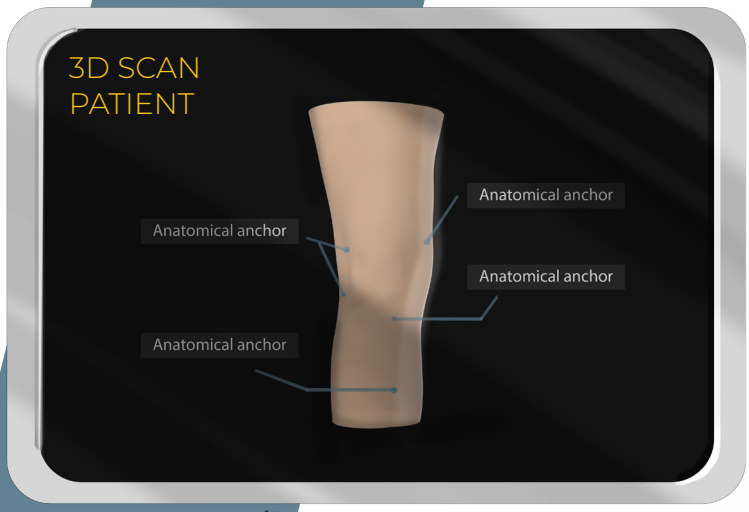
PART II

DESIGN

In this chapter, an overview of the final brace design and the framework in which it operates are provided. The entire process that leads to this final design is divided in three main aspects, which are covered in this chapter. The first aspect includes the preparations that are necessary for a customized design, which involves manipulation of the 3D scan from the patient's leg. The two following main aspects cover the actual design of the brace and are divided in its fit and function. The design is evaluated on the extent to which it meets the list of requirements.

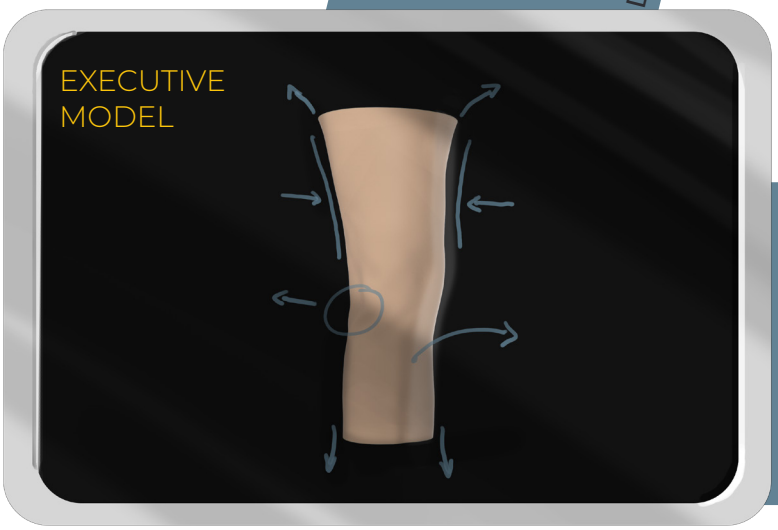
Orthotist scans patient

1 3D SCANNING



GACP PROTOCOL

2 DEFORMING



3 MORPHING

Figure 32. The LVATE brace and the general automated customization process (GACP), which serves as a framework to facilitate customization of the brace to the patient's specific 3D scan.

5. LVATE SOLUTION

5.1. SOLUTION

The LVATE brace, derived from the English term ‘elevation’, is developed to carry part of the patient’s bodyweight while providing a perfect fit. The upper cuff of the brace is pushed upwards by rotating the knob on the lateral side of the brace. The knob is connected to a pulley, which winds a cord that is attached to the hinge bars. Winding the cord around the pulley would pull the hinge bars downwards, but instead the upper cuffs, to which the pulley is attached, is pushed upwards due to the fixation of the hinge bars in the lower cuffs. In this way, traction is created between the upper and lower part of the brace hereby providing more support to the patient. The amount of traction is variable and depends on how much the patient winds the pulley. More information on the name and logo can be found in appendix F.

5.2. FRAMEWORK

The design of the brace is custom fit for enhanced comfort and effectiveness, as defined in chapter 2.4. Shaping the brace to each patient individually, would be too time consuming if this is done manually. Therefore, the brace is integrated in the general automated customization process (GACP), which serves as a framework to generate the individual braces.

Three main steps are distinguished in the GACP as shown in figure 32. Firstly, when the patient comes to the orthotist, a 3D scan of the affected leg is made and uploaded to the OrthoSOLID® platform. This platform is the overarching software from Orthobroker in which the brace is created and ordered for the specific patient (Orthobroker BV, n.d. b). In order to provide a perfect fit, the brace is shaped around the scan. Doing this directly on the original scan, however, would result in gaps and irregularities. Therefore, the second step is to deform the original scan model into an executive model. Deformations and corrections are applied to the original model by the software to ensure a perfect fit and pressure distribution. The third step is to morph the LVATE brace design around the executive model, which results in a custom version that can be ordered on the platform. The LVATE brace is designed with consideration for the fit of the cuffs and the function of the hinge and traction mechanism.

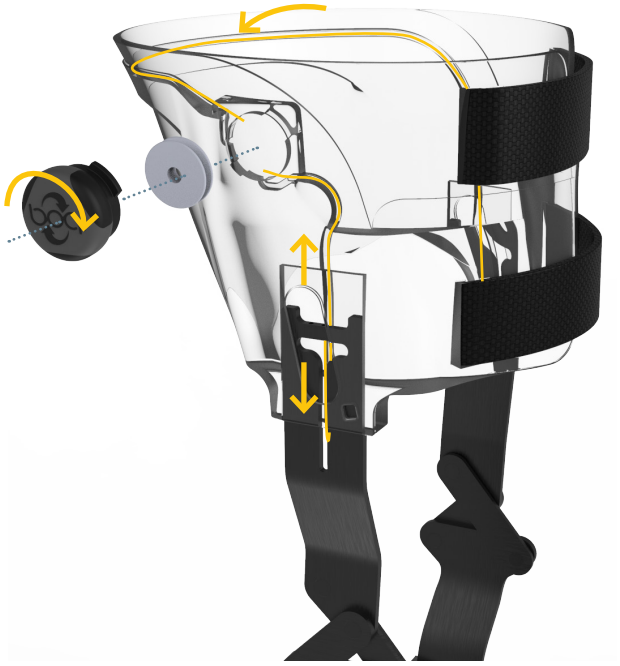


Figure 33. Working principle of the LVATE brace.

This chapter first defines the protocols that are used in the GACP in order to properly integrate the brace and provide a generalised process. Secondly, the design of the LVATE brace itself is described. The protocols are executed manually during the course of this project but are intended to serve as base for the software code in the OrthoSOLID® platform.

6. MAKING IT CUSTOM

Two GACP protocols are defined, which allows for a general processing of the patient's 3D scan towards the executive model. The first protocol describes the scan requirements and how they are interpreted. Secondly, the deformation protocol is defined in order to manipulate the data from the interpretation of the scan. This results in the executive model around which the LVATE brace is morphed. Both protocols are developed in a generalised way so that it can be applied to all patients. An experimental approach is chosen to find the protocols, in combination with scientific based information around pressure tolerance.

6.1. SCAN PROTOCOL

The 3D scan of the patient's leg will be made by the orthotist. Deformation of the leg occurs depending on how the leg is positioned, which leads to a different shape of the 3D scan. In order to provide the best fitting product, the effects of the scan position on the shape of the brace are researched. The scan is afterwards interpreted and aligned using anatomical anchor points, which is used as a basis for the executive model.

6.1.1. POSITION

Both a seated and standing scan position are assessed using two methods. Firstly, the scans are compared to each other using modelling software, which allows to visualise the differences. Secondly, simple 3D designs of brace cuffs are made for both scan positions and are assessed on their fit. The full assessment using these two methods can be found in appendix G. The preferred scan position is selected based on the advantages of each scan position, defined in the full analysis and summarized below.

ADVANTAGES OF FLEXION SCAN

- The patient puts on the brace when seated. Therefore, it can be argued that the best fit should be provided during flexion as this will enhance the right positioning of the brace.
- It is more comfortable for the patient to be seated during the scan.
- The quadriceps expands during flexion. Using this as scan position leads to a design that is not overly tight during flexion.

ADVANTAGES OF EXTENSION SCAN

- The creation of traction is most relevant during extension. It can therefore be concluded that a more reliable fit of the brace is more important during this 'operational' phase rather than during flexion.
- Scanning a patient in stance position is a more general guideline than seated. No extra information on what the angle of flexion should be, has to be provided to the orthotist. This results in an easier process and a more accurate 3D scan.
- The scanning in a standing position is less prone to mistakes as it is easier for the orthotist to reach around the leg leading to higher accuracy.
- Defining the necessary cut-out in the upper cuff in order to not interfere with the patella, is easier during extension as the patella comes closest to the cuff while standing.
- The tendons in the back of the knee are not visible during extension, which makes the scan more reliable.
- A tight fit is provided during extension, which decreases the chance of slipping down.

A semi-flexible print is required for a good fit of the brace due to the large deformation of the upper leg between extension and flexion. For this project, it is preferred to design on the extension scan position as this produces a more universal and reliable scan than in the flexed position. The method is more straightforward, and it is easy to reach around the leg while scanning. The extension or stance phase is also the “operational” phase where unloading the tibiofemoral compartment from vertical forces is the most relevant. Therefore, the brace should fit perfectly during this phase.

6.1.2. INTERPRETATION

After the scan is uploaded on the platform, an algorithm is defined to translate the scan into a general aligned SolidWorks model that is easy to manipulate for customization. This algorithm enhances uniformity among all scans. The 3D-model uses a x,y,z-axis coordinate system, which is positioned on the scan, as shown in figure 34.

- Z-axis: Runs parallel to the tibia and through the tuberositas tibiae.

- X-axis: Can be placed perpendicular to the z-axis and in the coronal plane. The axes intersect in the tibia tuberositas tibiae.

- Y-axis: Runs through this same anatomical anchor point and is perpendicular to the z-axis in the sagittal plane. The z-axis runs vertically through the fibula head when lookingto the sagittal plane.

A point cloud is created from the leg scan and is used for morphing the brace, see figure 35. A value is linked to each reference point of the cloud, which represents its location and therefore differs for each patient individually. The algorithm that is used for creating the point cloud is described in appendix H.

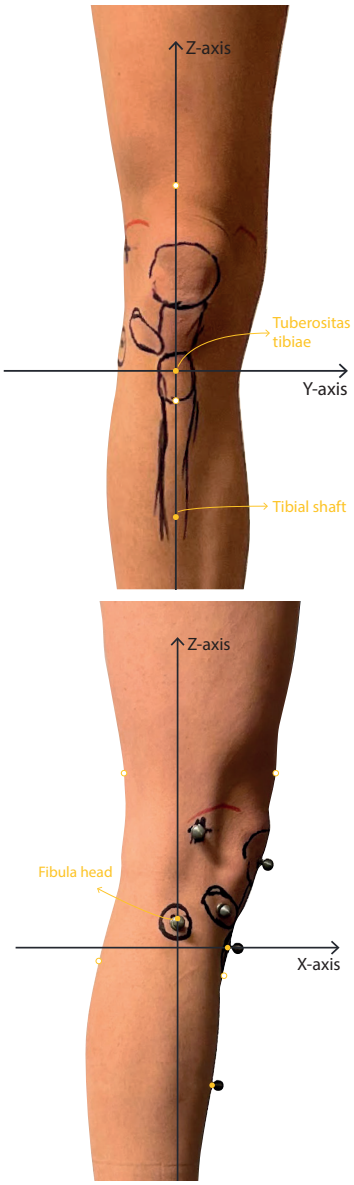


Figure 34. Position of the leg scan in reference to the coordinate system.

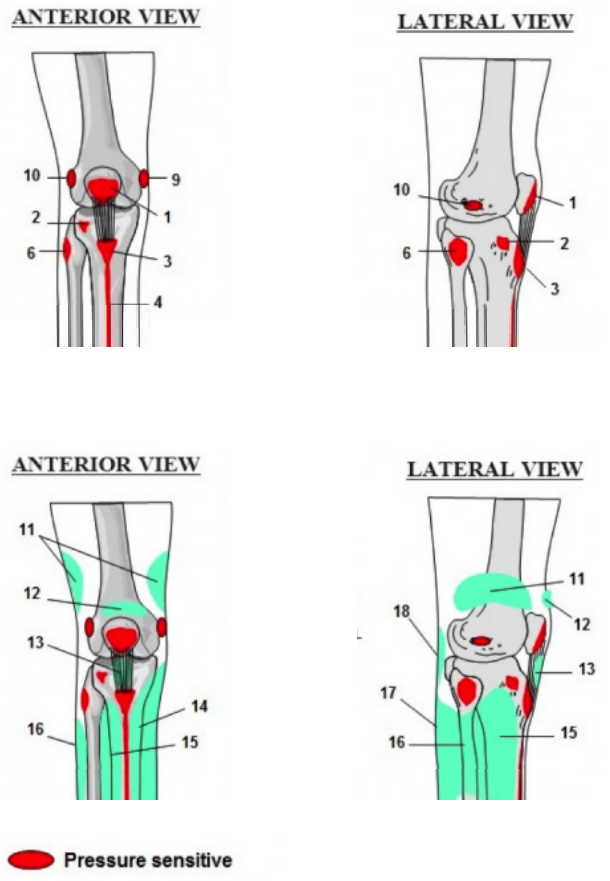
Figure 35. Reference points for the 3D scan of the leg.

6.2. DEFORMATION PROTOCOL

The deformation protocol serves as a guideline, which is followed when adjusting the shape of the original leg scan. The adjustments are applied in order to avoid pressure in the intolerant areas and control the pressure distribution in the tolerant zones, as shown in figure 36. The general rule of thumb is that direct pressure on the bones and tendons is experienced as uncomfortable.

The most relevant pressure intolerant areas are located on both condyles, the patella, the tuberositas tibiae, the fibular head and the tibial shaft. This information is transferred to the point cloud of the leg scan. The values that define the location of the reference points are changed so that thickenings and recesses are created. Morphing the brace around this model results in more pressure on the leg where the recesses are located and less pressure in the thickened areas. The detailed deformation protocol as well as an application example can be found in appendix H.

The scan and deformation protocol are applied to two participants. The difference between the original scan and the executive model is shown in figure 37.



1. Patella
3. Tuberositas tibiae
4. Tibial shaft
6. Fibular head

Figure 36. Pressure tolerance chart of the leg (Cahill, 2016).

Figure 37. The original scan (left) and executive model (right) of two subjects.

7. MAKING IT FIT

The design of the cuffs depends highly on the function of the hinge and traction mechanism. This chapter describes the overall shape and fit of the brace, which is created as a base model in which the functions are integrated. The results are achieved with an experimental approach, where several iterations of mock-ups are created. Due to the nature of the design challenge, this approach is preferred because comfort, feel and the way the cuffs interact with the leg cannot be predicted easily without a database of experience.

7.1. BASIC SHAPE

Nine mock-ups of cuffs (figure 38) are created during the iterative process in order to find the right shape and characteristics for the final cuffs. Each cuff focuses on another technique or aspect, which leads to unique advantages or disadvantages for every cuff.

Fused deposition modelling (FDM) is a material extrusion printing technique, which is used for the first cuff models in polylactic acid (PLA) material. These prints research the pressure distribution on the leg as well as the influence on fixation. Additionally, cuffs are manually created using polymorph, which is a thermoplastic material. The material can be deformed a number of times and is therefore used to research the shape. Based on the findings, a polyamide (PA) cuff is printed using multi jet fusion (MJF). MJF is a powder bed 3D printing technique that delivers accurate prints with excellent mechanical properties. The polyamide MJF prints have a higher yield strength than the PLA, which allows deformation of the muscles during movements without breaking the cuffs. All mock-ups are evaluated on the eight aspects summed up below, which are derived from the list of requirements.

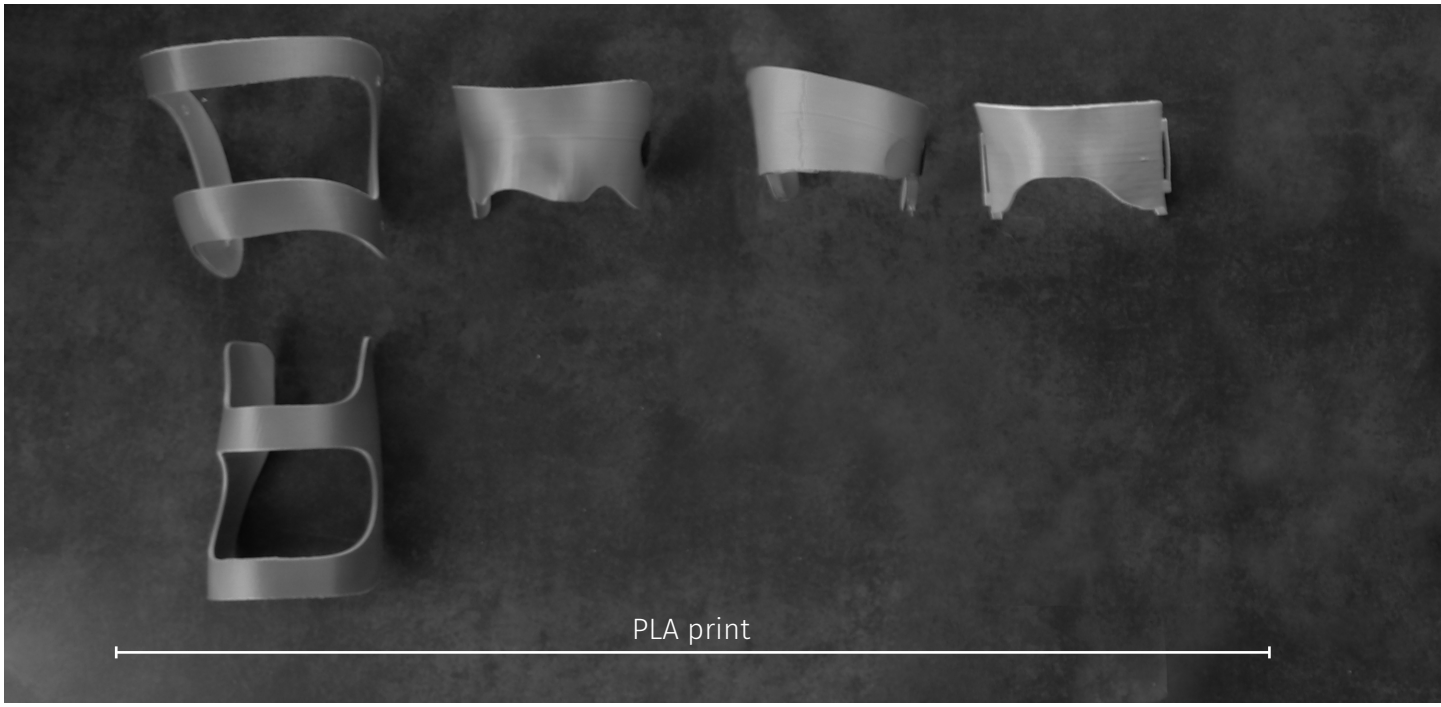


Figure 38. Cuff mock-ups for researching the final cuff design and characteristics.

1. **Pressure tolerance**
   Pressure distribution and pressure relief on intolerant areas are important for user comfort. Pressure points should be avoided at all costs as this would start to irritate and eventually hurt.

2. **Freedom of motion**
   The brace should not interfere with the leg or other parts of the brace and decrease the range of motion of the user.

3. **Fixation**
   A good fixation of the cuffs around the leg is important to make sure that the brace stays in place at the correct positioning. This enhances the effectiveness of the brace.

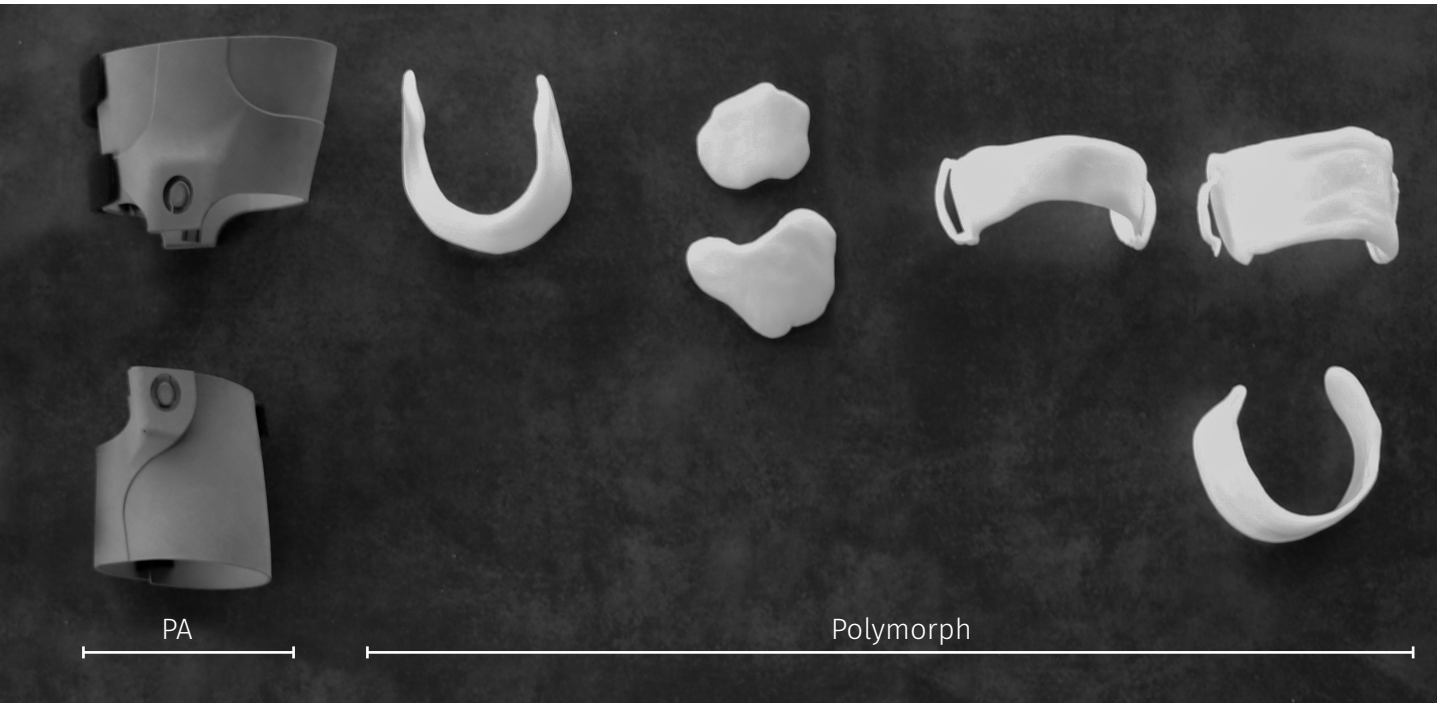
4. **Tightening**
   Tightness of the brace directly influences the fixation. It should therefore be comfortable and easy to tighten the cuff correctly.

5. **Positioning**
   Correct positioning of the cuff is important as this affects the alignment of the hinge and therefore its functionality and effectiveness. Positioning the cuff correctly should be intuitive to the user.

6. **Overall comfort**
   The overall comfort covers aspects related to comfort that do not fall under previously mentioned aspects. In this way, nothing is overlooked.

7. **Unique advantage**
   The advantages that are a result of a specific feature in the mock-up. This leads to overall insights for further iterations.

8. **Unique disadvantage**
   The disadvantages unique for a certain mock-up, leads to a better understanding of what to avoid.



An extensive evaluation of the cuff mock-ups can be found in appendix I. The main takeaways from this evaluation are collected in table 6.

Main takeaways	
Pressure tolerance	All edges should be rounded in order to avoid pressure points.
Freedom of motion	When the cuff is positioned too close to the patella, this is perceived as uncomfortable and even threatening. When the cuff would slide down, it would rest on the patella, which may cause irritation and even injuries. The possibility to bend the leg is limited when the material of the cuff is not flexible and therefore cannot deform along with the upper leg. The posterior trimline of the lower cuff has to be low enough in order to prevent interference with the upper cuff during flexion.
Fixation	Fixation of the cuff is mainly realised by tightening the cuff and by friction instead of pressure points or customized shape. A tighter fit can be enhanced by making the circumference of the cuff a little smaller than the circumference of the leg. It is important to apply this all the way around the leg as otherwise the brace would push itself away because it cannot get a good grip. The gap situated under the straps allows for circulation.
Tightening	Skin is not pinched or drawn between the straps and cuffs when the straps run underneath the cuff.
Positioning	The correct position can be retrieved due to a customized design around the 3D scan and has a slightly smaller circumference than the original scan. Positioning is easiest for the lower leg.
Overall comfort	The upper leg expands significantly during flexion, which is why cuffs tend to get too tight in this phase or even break due to the inflexibility of the materials.

Table 6. Main takeaways from the evaluation of the cuff mock-ups.

7.2. LVATE CUFF

The cuffs of a knee brace are often designed to cover the posterior or anterior side of the leg and are fixated with straps that run around the other side. This makes it possible to create a few sizes that cover a large part of the population but compromises on comfort and effectiveness, as stated in chapter 2.4.3.

The LVATE cuffs are therefore designed to cover the leg as much as possible, creating an almost closed design, see figure 39. As the cuffs are morphed around the executive model, a comfortable fit is created, which loses its benefit when a large part would be replaced by straps. However, a fully closed design is not beneficial either because of the changes in circumference of the leg during movements.

A small gap is positioned on both cuffs on the anterior side. This allows the patient to tighten the brace as preferred in a place that is comfortable to reach. The position of the gap in the lower cuff corresponds with the location of the tibial shaft, which is a very pressure intolerant area. Doing so enables to only cover the tibia with straps, which is more flexible and softer than the cuff itself. Extra cushioning can be applied to the straps if necessary. The outer edges of the brace are bend outwards, which prevents pressure points and cutting the skin. In this way, load is applied on the inner side of the brace instead of on the edge.

Figure 39. The upper (left) and lower (right) cuff of the LVATE brace.

From the mock-ups is concluded that a larger contact surface between the cuffs and skin, contributes to a more comfortable pressure distribution. Therefore, the size of the LVATE cuffs is in proportion with the patient's posture, which is experimentally defined, see figure 40. It is found that the upper cuff's height should equal the patient's crotch height divided by seven and start at one patella height above the top of the patella. This provides enough space above the patella in order to make sure that there is no interference with the brace regardless of the activity. The lower cuff starts 20 mm under the tuberositas tibiae to prevent interference with the back of the knee. The height of this cuff should equal an eighth of the crotch height in order to fixate on top and below the calf. This subdivision is also used in the deformation protocol, see appendix H.

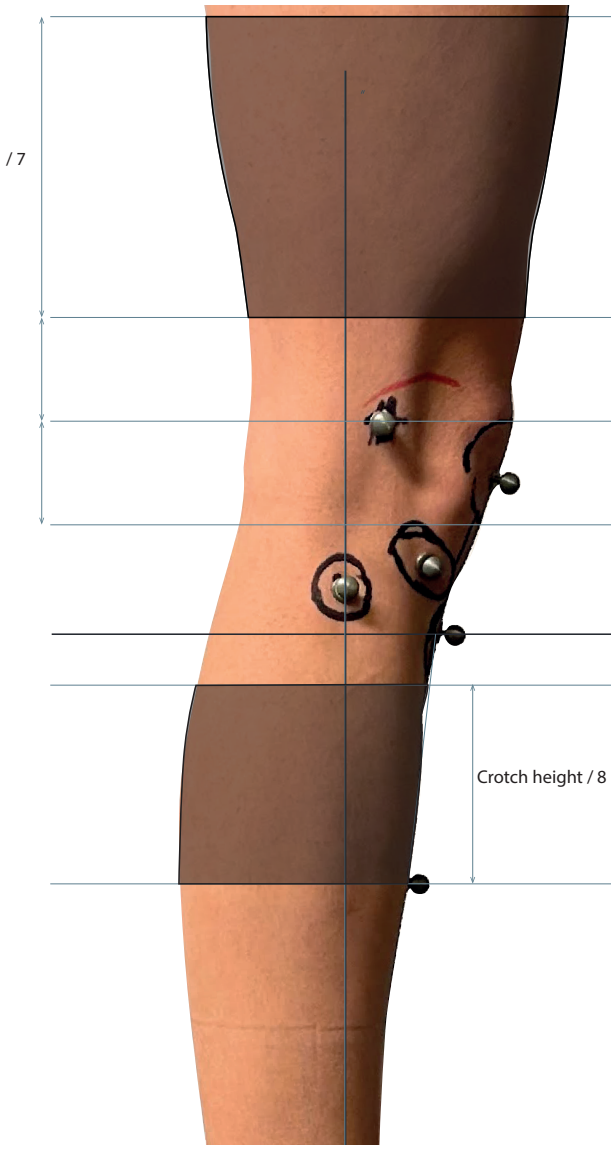


Figure 40. Parameters of the cuff in relation to the patient's leg and posture.

8. MAKING IT FUNCTION

The hinge design includes both the knee hinge and the traction mechanism. The design process is performed in three main phases. Firstly, the challenges are defined and translated into requirements in order to create a clear goal and selection criteria. Secondly, ideas are generated and evaluated. In the last phase the best ideas are further developed into a concept. Here as well, an experimental approach is utilized in order to test the effect of the mechanisms on the knee kinematics and whether the concepts are experienced as a support or rather as an obstruction.

8.1. CHALLENGES

The problem is further specified in order to get a better understanding of the challenges that are faced when designing the hinge. The problem definition methodology is used and summarized in this chapter.

The target group exists of younger patients that have their femur and tibia exposed to a lot of pressure due to extensive sports or a past knee injury. The peak pressure during gait is measured between heel strike and toe off, which correlates to a knee flexion angle under 20 degrees, as defined in chapter 3.2.

The goal is to decrease the exposure of the femur and tibia to pressure during walking and running. This should be reached using passive mechanisms so that an external energy source is not needed.

The side effects to be avoided are:

- Pressure points that are caused by the creation of traction.
- Skin irritation as a result of the brace sliding down.
- Applied traction when lying down with a flexion angle <20 degrees.
- That the patient has to take off the brace completely in order to relief traction.
- A bulky hinge design.

The three main actions required to reach the goal are formulated as the following 'How to-statements'. The brainwriting (diverging), clustering (reverging) and hits-and-dots (converging) methods are the base for the drawn morphological chart that can be seen in figure 41. An extended version of the brainstorm results for the statements can be found in appendix J.

- How to create a distance between two rigid objects? (traction)

- How to relief traction? (on/off system)

- How to switch between different modes of tension/traction? (modes)

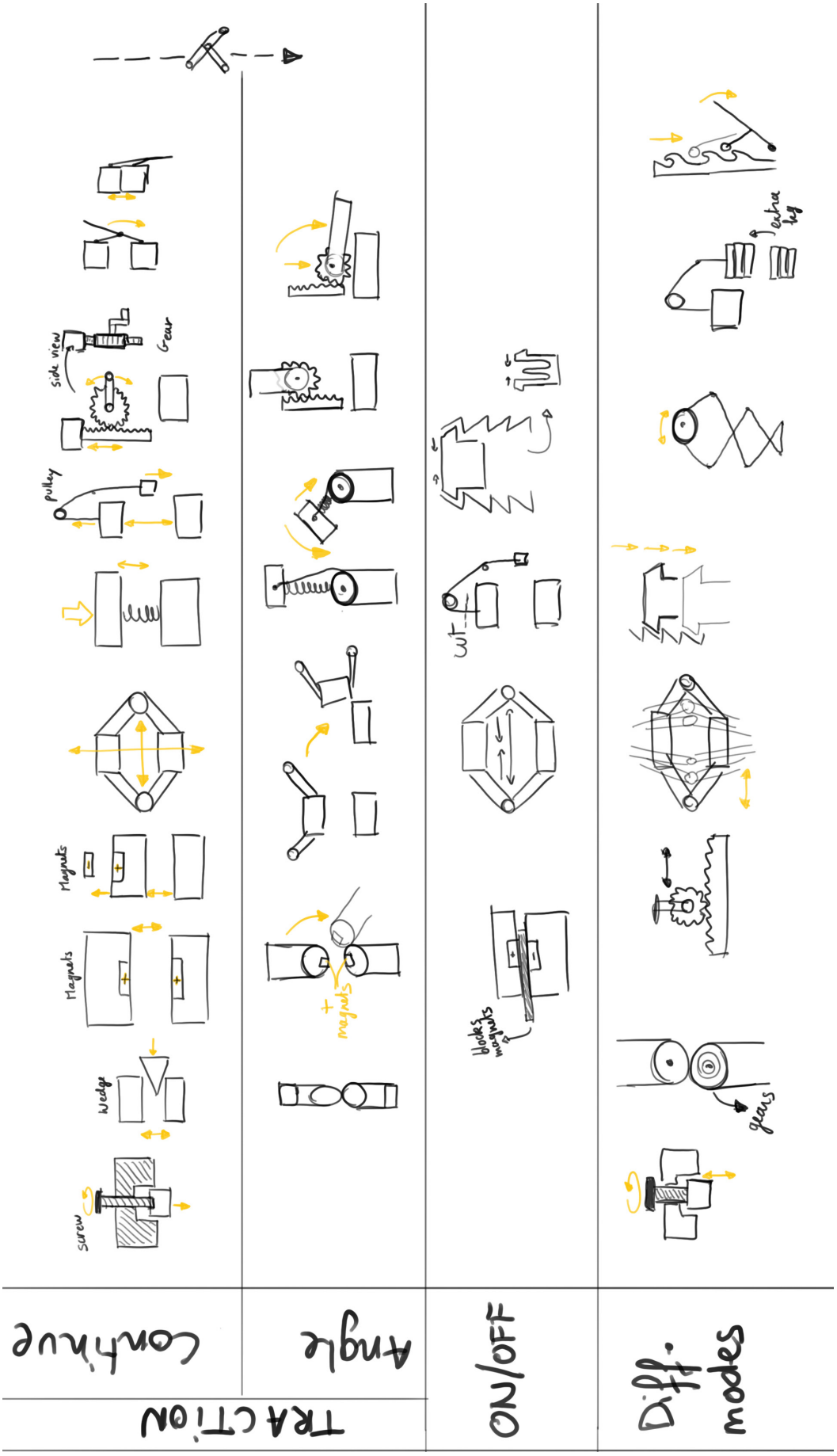


Figure 41. Morphological chart for the traction mechanism.

8.2. REQUIREMENTS

More extensive research is performed in this chapter in order to get a more focused understanding of the requirements regarding the traction mechanism. The preferred location and type of traction mechanism is analysed first. Afterwards the optimal mimicry of the knee kinematics is defined.

8.2.1. TRACTION TYPE

The hinge ideas that create traction can be divided into three categories, as shown in figure 42. The first category causes traction in the hinge itself thereby driving the cuffs apart from each other. The amount of traction can be variable depending on the flexion angle. A second category uses standard hinges for each user and implements the traction mechanism in or near the upper cuff. This method provides a traction force independent of the flexion angle. Thirdly, metamaterial mechanisms can be used in order to change the material's properties, causing traction during extension.

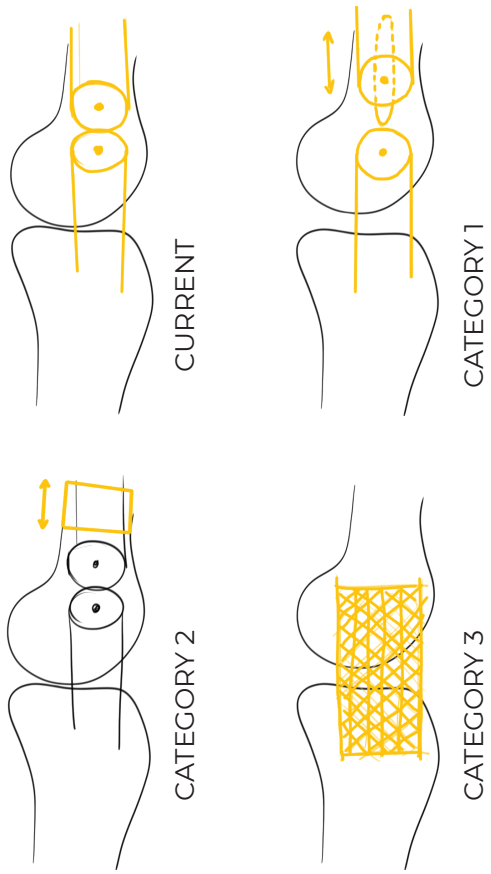


Figure 42. Three categories of traction types that can be used in the brace design.

After consulting experts in the field of metamaterials and 3D printing structures (M. Chae, Z. Doubrovski, S. Ghodrat) it is concluded to exclude the third category from further analysis as a separate research would be necessary to develop a 3D printed structure that changes the material properties in the required way. Whether it is preferred to create traction in the hinge or above the hinge, depends mostly on the comfort of both options. A mock-up that fits in the MJF cuffs is created for both categories in order to test how they interact with the knee, as shown in figure 43.

Two conclusions are drawn from this test. Firstly, the location of traction is preferred to be above the hinge instead of integrated in the hinge itself. This can be explained by the pathway of the hinge in comparison to the pathway of the knee joint. As described in chapter 3.1, the kinematics of the knee is best mimicked by a polycentric hinge or a four-bar linkage system. However, integrating a traction mechanism in the hinge itself changes its pathway, which leads to a larger difference between the knee kinematics and the mimicry. This difference is experienced as an obstruction rather than an aid, because it counteracts the natural movement of the joint, decreasing the freedom of motion.

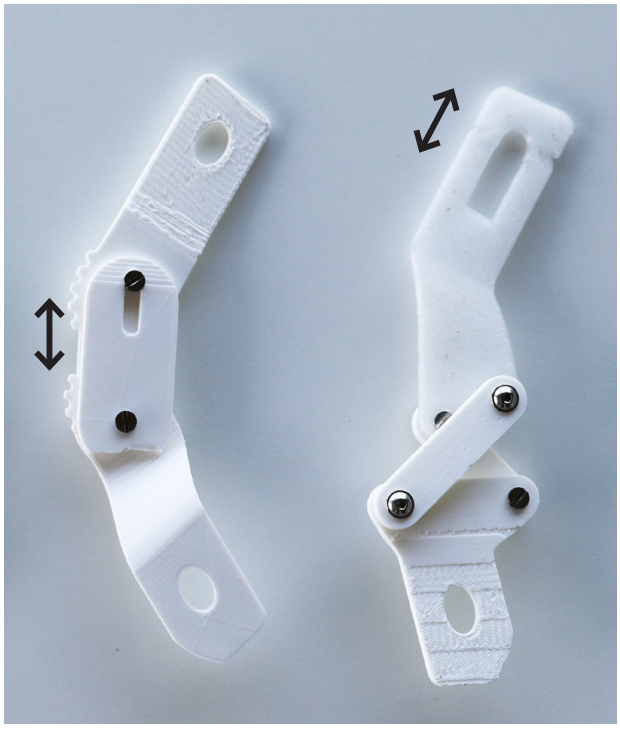


Figure 43. Mechanisms with traction in the hinge (left) and traction near the cuff (right).

Secondly, it can be argued that applying a continuous traction force on the knee, regardless of the flexion angle, may be less user-friendly for daily use. The brace can be worn during sports or high demanding activities, where it is beneficial to use a constant traction force to continuously unload the knee from large impact. However, when the patient uses a brace with the same mechanism during a regular day, traction force is also applied when seated, which can cause discomfort. Irrelevant activation of the brace during rest positions are expected to occur more often during daily use compared to during sports-related use.

As stated, the target group of this project are active patients who want to unload the tibiofemoral compartment during demanding activities. Therefore, a hinge design with a continuous traction force above the hinge itself is preferred. A deactivation mechanism is designed with the intention to allow for releasing traction force during periods of rest that are too short to take off the brace.

8.2.2. HINGE TYPE

As concluded, it is of great relevance for the patient's comfort, to opt for a hinge design that closely mimics the natural movement of the knee joint. This will decrease the chance that the brace counteracts knee joint movements and would be experienced as a burden. Both the polycentric hinge and the four-bar linkage system are 3D printed so that they can be inserted in the MJF cuffs. The hinges are tested during walking, running and sitting (see figure 44).

Figure 55. Polycentric hinge (left) and four bar linkage (right) printed compatible with PA cuff.

The test concludes that the four-bar linkage system is preferred for the final product based on the following two main findings regarding comfort and positioning.

1) Comfort
The polycentric hinge feels more like an obstruction because it slightly limits the patient's range of motion. The four-bar linkage system on the other hand, is experienced as a copy of the actual knee joint movement and feels more natural overall. This finding issupported by Etoundi, Vaidyanathan and Burgess (2012).

2) Position
The accuracy of the knee joint mimicry is not only defined by the hinge design but also by the position of the mechanism. Both mock-ups are created in reference to the 3D scan of the leg. However, during the research phase, the position of the polycentric hinge is found in relation to a flexed leg while the four-bar linkage system can be created on an extended leg scan based on the research results. This last mechanism will therefore be more reliable as the extended leg scan is chosen as protocol for this project (see chapter 6.1).

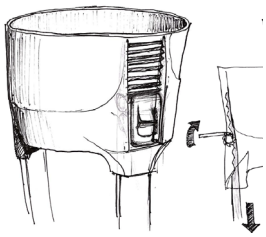
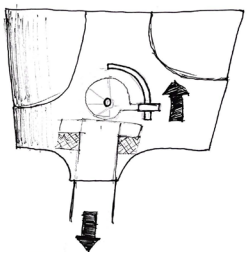
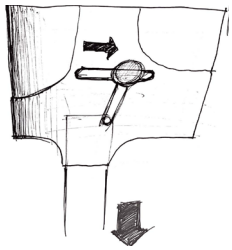
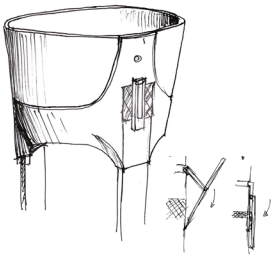
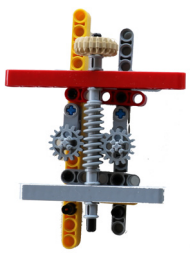
8.3. DEVELOPMENT

Ideas are generated for the traction mechanism and evaluated to select the most feasible ones. The selected ideas are modelled and printed in order to get a better understanding of the working principles as well as the bottlenecks. The models are again evaluated, and the most promising ones are further developed and tested with the brace cuffs. This test provides additional information on the comfort of the system and is used to select the final mechanism.

8.3.1. IDEATION

Eight traction mechanisms are derived from the morphological chart, shown in chapter 8.1, see table 7. A mock-up in LEGO technic is created from the most promising ideas to evaluate and iterate on them.

As defined in the requirements in chapter 8.2, traction should be applied continuously, independent of the flexion angle and a deactivation system should be integrated to increase user comfort. The ideas are evaluated on the extent to which they meet these requirements and their feasibility, see table 7.

	IDEA	PRINCIPLE	FEASIBILITY	TRACTION FORCE	FAST DEACTIVATION	MODES
1		A ratchet buckle is used to create traction. This type of buckle is also found on snowboard bindings and is developed for tightening instead of creating traction. This impacts the feasibility in a negative way in terms of strength and stiffness. The system is also rather large compared to other ideas. An example of a ratchet buckle can be found in appendix K.	-	Contstant	Yes	Yes, no pre-sets
2		A can creates traction that increases when the hinge is rotated more. This system is straightforward and simple. A rotary knob can be integrated and translates the linear traction force to a momentum. The system can fit inside the cuff so that only the knob protrudes.	++	Contstant	Yes	Yes, with pre-sets
3		The linear traction force is not translated in a momentum but is created by changing the angle of the bar, increasing the traction distance. The main concerns are how to make a linear movement possible in a double curved cuff shape and the force accumulation in the connection around which the bar rotates.	+	Contstant	Yes	Yes, with pre-sets
4		A spring mechanism is integrated, which causes traction when it is extended. In order to deactivate the system, the patient can compress the spring using a toggle latch that can be found on ski boots as well. The main concern with this idea is the spring mechanism, which should be stiff enough to carry part of the bodyweight but still be manually compressible with the latch. An example of a toggle latch can be found in appendix K.	--	Contstant	Yes	Yes, with pre-sets
5		The most simplistic idea is one where a bolt is inserted in the cuff and moves it up and down using the thread during rotation. The concern with this mechanism is that the patient should turn a lot in order to create traction and that deactivating is not possible in a fast and easy manner. The big upside, however, is the simplicity and compactness of the idea.	+	Contstant	No	Yes, no pre-sets

The second and sixth idea score best on feasibility and meet the requirements, namely a constant traction force independent of the flexion angle of the knee and the possibility for fast deactivation. It is possible, in both cases, to implement predefined magnitudes of traction between which the patient can easily switch.

A variant of the ninth idea is further developed as well because of the main advantage that both medial and lateral sides can be connected to one central control unit, in this case the knob.

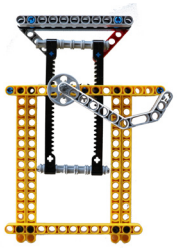
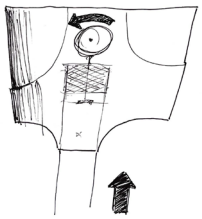
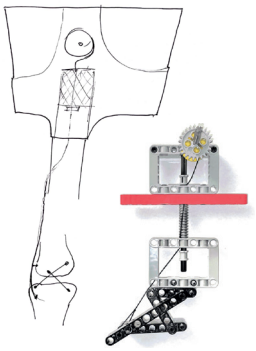
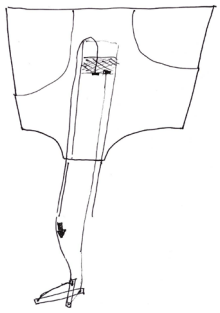
IDEA		PRINCIPLE	FEASIBILITY	TRACTION FORCE	FAST DEACTIVATION	MODES
6		In this iteration on idea five, the bolt is replaced by a gear rack and cylindrical spur gears. Depending on the size of the spur gear, a sufficient amount of traction can be generated after a 90 degrees rotation of the handle. This variant of the original idea enables the possibility for fast deactivation.	++	Contstant	Yes	Yes, with pre-sets
7		A variant of idea four is created by using a reel knob lacing system to contract the spring mechanism. The lacing system, also known as a Boa®, is for example used on motorcycle boots or snowboard boots. The main concern here is the stiffness of the spring necessary for traction, compared to the force that is needed to rotate the knob for contraction. An advantage of this system is that both medial and lateral sides of the cuff can be connected to one knob and thus move simultaneously. An example of a reel knob lacing system can be found in appendix K.	--	Constant	Yes	Yes, with pre-sets
8		The previous mechanism can be taken one step further by connecting the lace to the four-bar linkage system. The two rotation axes of the linkage on the anterior side are further away from each other during flexion compared to extension of the knee. After tightening the lacing system, hereby creating the preferred amount of traction, the lace is locked and not variable in length anymore. When bending the knee, more lace is required to cover the increased distance between the anterior rotation axes, which causes the spring to compress. An additional advantage of this system is that bending the knee is supported because of the counter momentum created by the lace.	--	Variable	Yes	Yes, no pre-sets
9		The distance between the posterior two axes of the four-bar linkage system decreases when the distance between the two anterior axes increases during flexion. This is the case during flexion and the opposite occurs during extension of the knee. That implies that a traction mechanism can be made variable depending on the flexion angle of the knee. The downside of this system is that it is more complex and not easy to customize or deactivate.	--	Variable	No	Fixed

Table 7. Evaluation of the traction system design ideas.

8.3.2. MOCK-UPS

The three ideas that are further developed result in four mock-ups, which are lined up in figure 45 and described below.

The first concept is an alternative version of the geared mechanism idea, see number 6 in table 7. The rectangular upper part is a representation of the cuff to which the gear axes are connected, and the lower rectangular part is the connection to the four-bar linkage. The user can switch between three pre-sets each resulting in a different traction magnitude. The mechanism is locked with a small snap hook, as shown in figure 46. A variant of this system is used in all concepts in a slightly different manner.

The second and third concept are variants of idea numbertwo in table 7. Traction is created by using a can, a non-cylindrical rotation piece, that pushes the four-bar linkage and upper cuff away from each other. The main difference is that the second concept uses a two-sided traction method which moves both cuff and linkage, while the third concept uses a one-sided traction method. This last one can therefore be fixed to the cuff, which is not the case for the first variant.

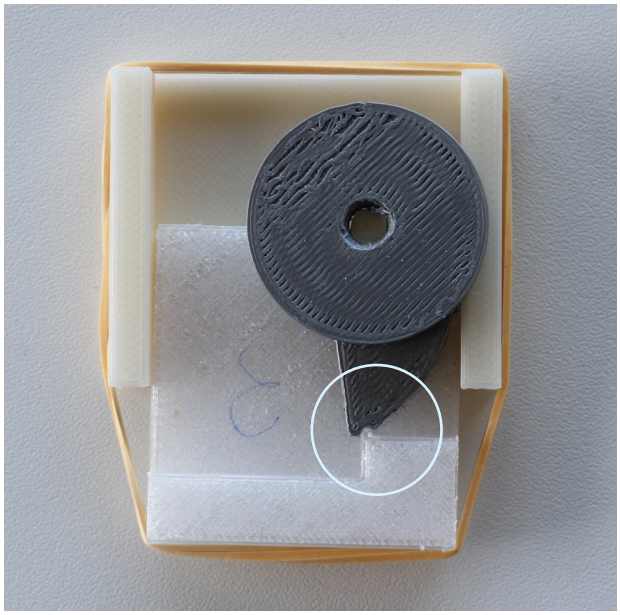


Figure 46. Lock system for the mechanisms which relates to a pre-set traction magnitude

A reel knob is used for the fourth concept, which is attached to the cuff. In order to be able to pull the hinge bar downwards, the lace should run through the cuff underneath it, run back upwards outside the cuff and be attached to the hinge bar. Both medial and lateral mechanisms can be connected to one knob, if preferred.

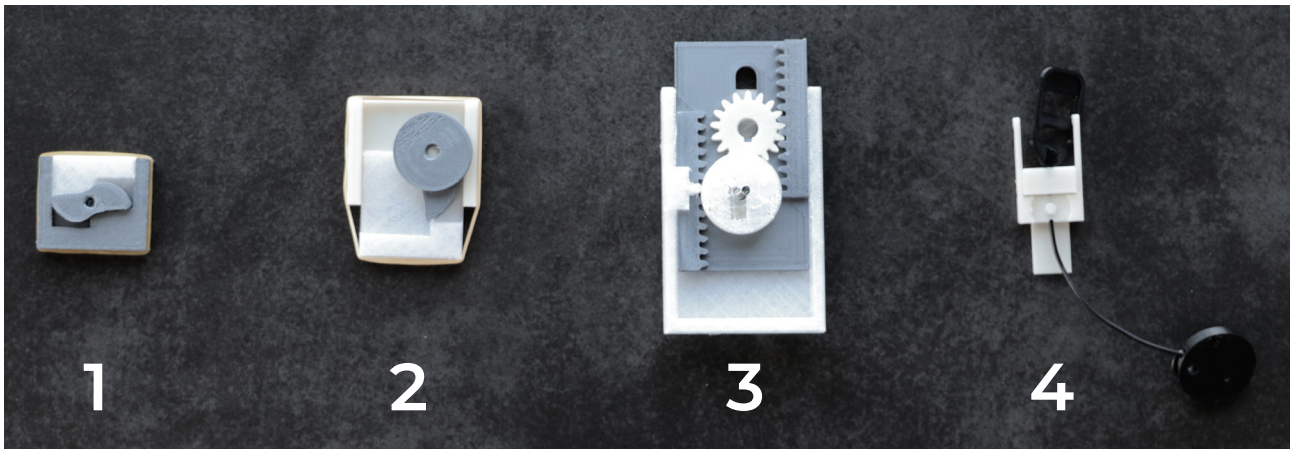


Figure 45. Line-up of the concept mock-ups from traction mechanisms

8.3.3. EVALUATION

The concepts are evaluated using six weighted objectives derived from the design drivers and defined as follows.

- Manufacturability
Can the mechanism be manufactured using a combination of 3D printing and standard parts?

- Ergonomic fit
Is it possible to shape the mechanism to fit the cuff without changing its ergonomics?

- Complexity
How fast and easy is the assembling procedure?

- Size
Can the mechanism be worn under straight trousers in terms of bulkiness?

- Usability
Is the mechanism susceptible to mistakes made by the user leading to incorrect activation?

- Production cost
How high are the estimated production cost?

The score per objective ranges from one to four. Alternative to the general evaluation method is that every rate can only be given once per objective, which means that the concepts are ranked from best (rate 4) to worst (rate 1). The result of the evaluation is shown in table 8.

OBJECTIVE	WEIGHT	CONCEPT 1	CONCEPT 2	CONCEPT 3	CONCEPT 4
Usability	8	1	3	2	4
Manufacturability	7	3	4	1	2
Ergonomic fit	7	2	3	1	4
Complexity	5	1	4	2	3
Size	4	3	2	1	4
Production cost	2	2	3	4	1
Total		**64**	**107**	**52**	**107**

Table 8. Evaluation of the concepts using weighted objectives.

As both concept two and four score best, add-ons for the cuffs are created based on these concepts, to be able to evaluate them when implemented in the brace, as shown in figure 47 and figure 48. Both mechanisms fit in an equal sized add-on to make sure that evaluation is performed based on the experience of the mechanism rather than on the implementation.

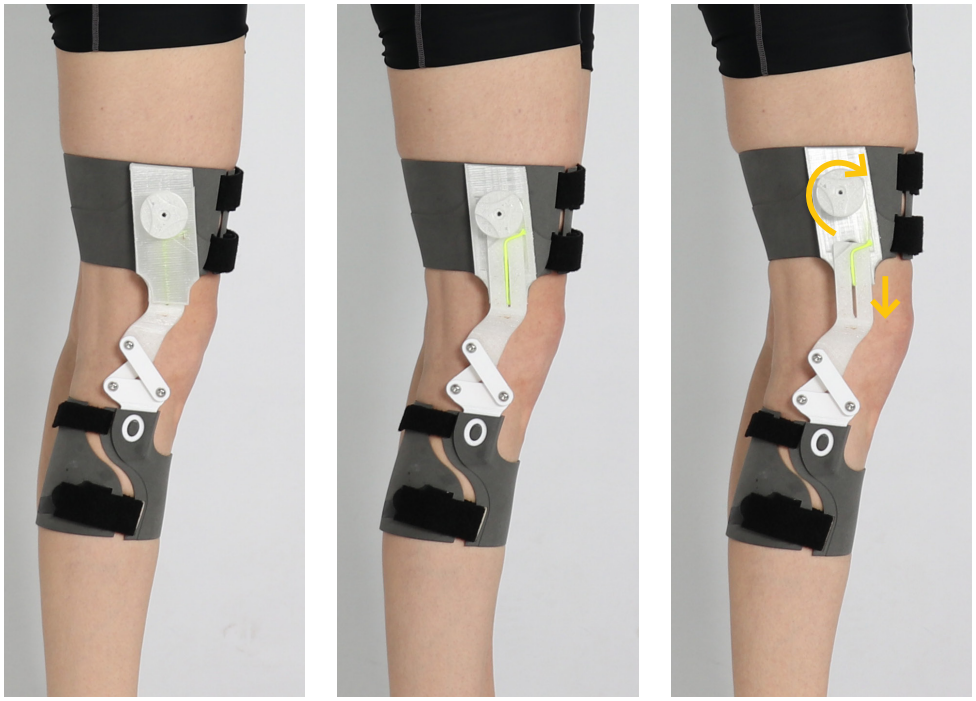


Figure 47. Working prototype of the pulley mechanism attached to the cuffs.

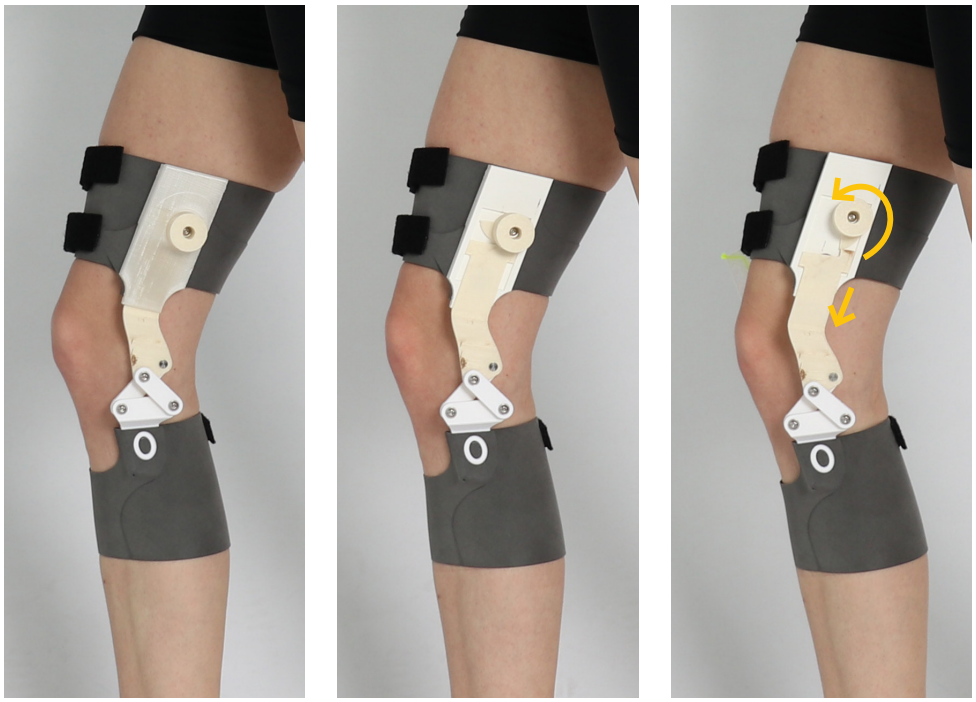


Figure 48. Working prototype of the can mechanism attached to the cuffs.

In the pulley design, the hinge bar is pulled downwards with the cord, by rotating the knob that winds the cord. The knob rotates freely when pushed in the medial direction and snaps into one of the pre-sets when pulled in the lateral direction. When the knob is fixated, the pulley to which it is connected remains in its position, keeping the length of the cord constant. The magnitude of traction depends on the length of the cord an thus the chosen pre-set.

In the other design, the hinge bar is pushed downwards, due to the shape of the can during rotation. The can is provided with three grooves in which the hinge bar snaps in position. Each groove results in a different traction magnitude, which means that the user can switch between these pre-sets.

The pre-sets in both prototypes fixate the downwards movement of the hinge bar at 0, 1 or 2 cm.

Although the working principle differs, the handling of both mechanisms is similar. The user rotates the knob, which causes a downwards movement of the hinge bar, driving the cuffs apart. From the test is concluded that the pulley mechanism required less force from the user to rotate the knob, which indicates a better force transmission. This conclusion is plausible because the force from the can is applied on the hinge bar under an angle instead of vertically such as with the pulley mechanism, see figure 49. Applying the force under and angel leads to a partial loss of force in the horizontal direction, which pushes the hinge bar against the edges instead of downwards. The pulley mechanism is therefore preffered as final traction mechanism design.

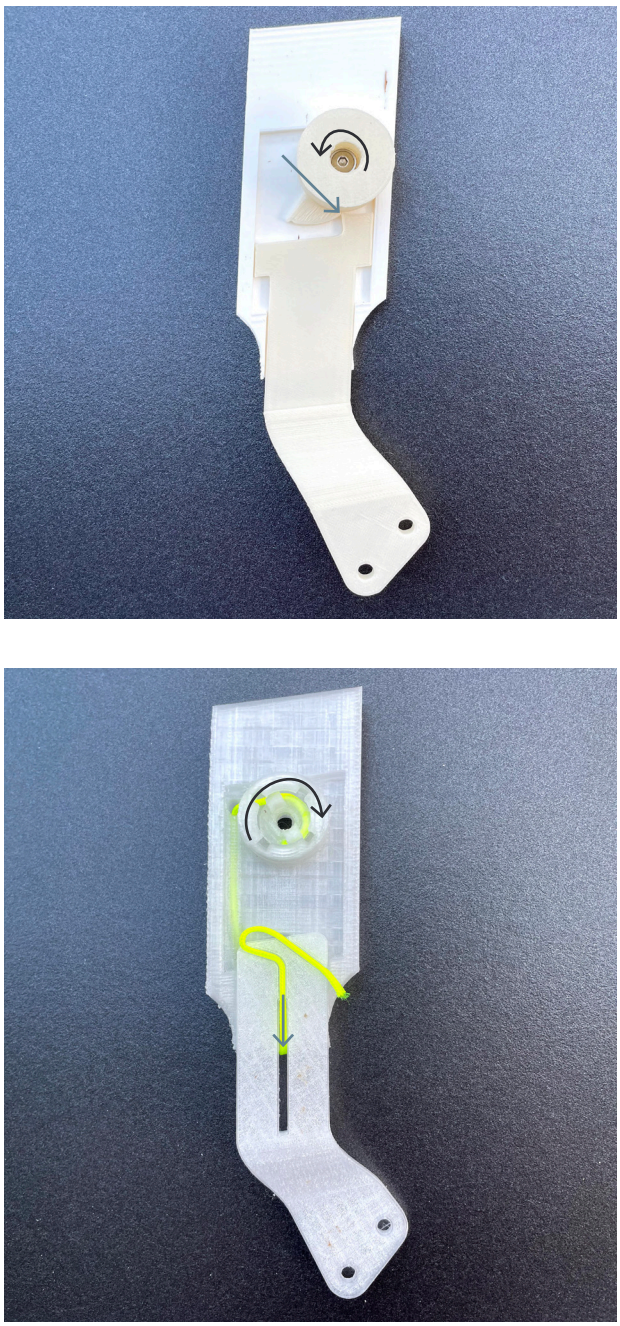


Figure 49. The applied pull force from the pulley design (bottom) and push force from the can design (top) on the hinge bar.

PART III

EVALUATION

A prototype is created from the LVATE brace design and evaluated on the extent to which it fits the design drivers. Four categories are distinguished, each related to a different assessment. The medical design drivers are difficult to assess with the limited access of professional measurement tools. However, a traction test is performed to indicate which forces act on the brace and what can be concluded from it. A user test is set up to gain more insight on the human-centred design drivers. This includes comfort, bulkiness and how easy it is to handle the brace. The functioning of the brace is also assessed during this user test, which relates to the technical design drivers together with its manufacturability. The economic design drivers are covered in a business case. A green, orange or red light is assigned to each design driver, to summarize whether the requirement is met, partially met or not met, respectively. Unmet design drivers are the base for recommendations for future research.

9. MANUFACTURING

●	The brace can be manufactured using 3D printing and standard parts.	Technical
●	The assembly of the different parts can easily be done.	Technical
●	The support mechanism can be deactivated without having to take off the brace.	Technical

This chapter defines the manufacturing method and material of the different parts that are used in the brace and assesses their mechanical properties. More research and testing need to be conducted on the actual percentage of bodyweight that is elevated by the brace and how to maximize this. Therefore, the load resulting from the full bodyweight is used as a threshold for choosing manufacturing techniques and materials to ensure the functioning of the brace. A maximum vertical force of 1622 N applied on one leg is therefore used, based on the P5-P95 stature percentile and a maximum BMI of 30 as calculated in appendix L.

9.1. CORD

In order to make a compact brace design, the cord of the traction system should be as thin as possible, without compromising on reliability. A metal cable with a diameter of 1 mm is used in the first concept but seemed too stiff for the sharp turns that it has to make, which causes kinks in the cable.

Further research is conducted on cords used in extreme sports such as kitesurfing, sailing, parachuting and climbing where the sporter's life relies on a variety of cords and cables used in their gear. The most suitable fibre type is selected based on the knowledge derived from these sports and the CES EduPack software, as shown in appendix M.

Further research is conducted on cords used in extreme sports such as kitesurfing, sailing, parachuting and climbing where the sporter's life relies on a variety of cords and cables used in their gear. The most suitable fibre type is selected based on the knowledge derived from these sports and the CES EduPack software, as shown in appendix M.

The LVATE brace uses a Dyneema SK99® cord, which is a trademark name for ultra-high-molecular-weight polyethylene (UHMWPE) fibre. UHMWPE is a cutting resistant and self-lubricating material causing less friction which distinguishes this fibre from the other high-performance fibres (Alpha Ropes, n.d.; Granta Design Limited, 2009). The general properties of UHMWPE are shown in table 9.

The specific cord used for the prototype is the Dyneema® "Powerline SK99" from Premium Ropes with a diameter of 1,6 mm and a tensile strength of approximately 2049 MPa (Lijnenspecialist, n.d.). This meets the required tensile strength of 811 MPa (= N/mm²) which is derived from the maximum vertical force of 1622 N applied to the cross-section surface of 2 mm² from the cord. The cord has a safety factor of 2,5 for the heaviest patient in the target group with a P95 posture and a BMI of 30.

Fibre	Trademark name	Tensile strength (GPa)	Elongation at break (avg. %)	Friction coefficient	Resistance to abrasion	Weather resistance	Price(€/kg)
UHMWPE	Dyneema SK99	2,5 - 3,3	3,5	0,05 - 0,07	Excellent	Excellent	76,1 - 128

Table 9. Material properties of polyamid, polyethylene and aramid (Alpha Ropes, n.d.; Granta Design Limited, 2009).

9.2. HINGE

The four-bar mechanism of the brace is designed to cut and fold from a metal plate. For the prototype a 3 mm aluminium plate is used because of the cord that needs to easily run through the plate and be attached to it. An FEM analysis performed on the hinge can be found in appendix N.

The hinge is assumed to be a standard part of the LVATE brace. The cuffs are adapted accordingly in the 3D model, in order to maintain the correct position. For the final product, it might be preferred to opt for laser cutting instead of water jet cutting due to its higher precision, higher speed, no waste besides metal residues and lower cost, as shown in table 10. In addition, water jet cutting is not ideal due to the force of the water and the small size of the components. Because of its higher tolerance, the holes in which the bolts are placed, have to be drilled afterwards which causes an additional step in the manufacturing process.

9.3. CUFFS

Additive manufacturing is preferred as production technique for the cuffs due to the unique character of the product and the beneficial price/quantity ratio of this technique. Extensive research on the polymer 3D printing techniques is conducted in appendix O. The cuffs are also challenged during the FEM analysis, see appendix N.

The final cuffs are printed with multi jet fusion (MJF), which is a powder bed fusion printing technique that is suitable for end-use parts. Each layer of powder particles is cured with a high energy source creating isotropic mechanical properties. This leads to a strong connection between particles and is built up layer by layer.

The mechanical properties of the products can be compared to those of injection moulding. Other polymer printing techniques produce more brittle parts and are therefore less suitable for the cuffs. MJF is preferred instead of other powder bed fusion options because it is faster, cheaper and has a higher recyclability. The design guidelines can be found in appendix O and are taken into account in the design of the cuffs (3D Hubs, n.d. b).

Polyamide (PA) and thermoplastic polyurethane (TPU) are the materials that are generally available for MJF printing. TPU is not suitable for the cuffs due to its flexible character and low tensile strength. Strong products can be produced with PA12, which is used for functional parts. The material is resistant to water, strong and durable. The stiffness of the material allows the thin-walled cuff to plastically deform during movements for a better fit, without sacrificing the functionality of the brace. The biocompatibility certifications ensure it to be skin safe. PA11 would be suitable as well but is not as commonly available as PA12. A more extensive description of the available materials can be found in (HP, 2019).

Post-processing of the parts includes removing loose powder, sandblasting the parts and curing it in a vapor fusion machine, which creates a polished finish. This last procedure ensures a very smooth finish and no loose powder particles, which could otherwise lead to skin irritation (Materialise, n.d. d).

	Tolerance (mm)	Speed(mm/min)	Waste	Cost (€/h)
Laser cutting	0,13	500 -1778	Dust	11 - 17
Water jet cutting	0,5	76 - 355	Mix of water and abrasive waste	17 - 33

Table 10. Properties of laser and water jet cutting (McHone Industries, 2019).

9.4. PULLEY

The pulley that is used to create traction is positioned on the lateral side of the upper cuff where it is easy to reach and does not interfere with the legs. A Boa® dial is integrated in the prototype, as shown in figure 50. This is a lacing system designed for various applications and according to the company “gives you the freedom to dial in fit” (Boa fit, n.d. a). In the long term, it might be more beneficial for Orthobroker to design their own integrated pulley system when this is used in multiple of their products. However, for now it is preferred to opt for the existing Boa®, which is the market leader in its field of expertise. This Boa® Fit System is used in workwear and sports gear such as helmets, boots and shoes as well as braces, among which the Unloader from Össur that is described in chapter 2.4.1. The pulley is designed to minimize friction and withstand a lot of force. The attachment to the brace is realised with a snap connection (Boa fit, n.d. a).

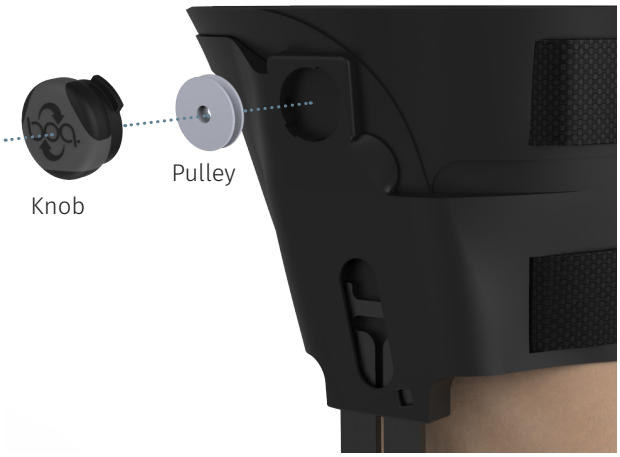


Figure 50. The Boa® dial integrated in the LVATE brace.

10. TRACTION TEST

- The brace enhances pain relief and increases mobility by creating traction. Medical
- Unloads both medial and lateral tibiofemoral compartments using traction. Medical

The traction test is performed on one subject in order to get an indication of the forces that act on the brace during stance. The Dyneema® cord is attached to the hinge bars and pulled upwards using a force gauge, see figure 51. The cord runs along the inside of the cuff, instead of through the cord canal in order to minimize friction. The maximum force measured, is captured by the tool and displayed on the screen. An assistant indicates when the desired traction distance is reached and notes the maximum force displayed on the force gauge. The distance is marked on the hinge bar every 5 mm, as shown in figure 52.

One test exists of six repetitions, each corresponding with a different traction distance. Between each repetition, the brace is returned to its default position with no tension on the cord and a traction distance of zero. This way, the results of the repetitions are not influenced by each other. The test is performed three times so that errors are averaged out a little. The forces needed for the displacements are plotted in figure 53 and can also be found in appendix P.

Figure 51. Traction test setup.

Figure 52. Marks for the different traction distances that are tested.

In the graph it can be seen that the relation between the force necessary to cause the traction distance and the distance itself, is not linear. The force needed in the first part of the traction distance is largely influenced by the soft tissue displacement that occurs as reaction. The actual unloading happens in the higher modes of traction distance when the soft tissue is under tension and is not displaced as much anymore. Therefore, it should be further researched what part of the traction force magnitude causes soft tissue displacement and what part affects the tibiofemoral contact forces.

No significant difference in traction force is measured when all bodyweight is shifted to the braced leg. This means that regardless the pressure on the tibiofemoral compartment, the traction force remains constant. This can be explained by the fact that the displacement of soft tissue around which the brace is fixated, depends on the velocity of an impact rather than the magnitude of a static force. Therefore, when calmly shifting the bodyweight to one leg, no displacement of soft tissue occurs, and the difference in load bearing solely impacts the internal structures of the leg. What the effect of the brace is during impact where displacement of soft tissue occurs, such as with running, cannot be concluded from this static test as it requires a dynamic setup.

It should be noted that this traction test only serves as an indication of the forces acting on the brace. Too many factors such as friction and human errors can influence the results. The test also does not provide insight on the effect of the brace on the tibiofemoral compartment. In order to analyse the relation between the traction force and the tibiofemoral contact forces, multiple tests on cadaver legs are needed or tests on a large number of participants over a long period of time.

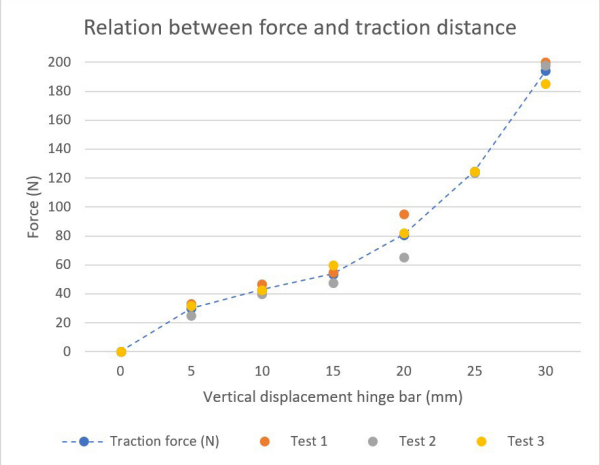


Figure 53. Graph showing the relation between traction distance and the necessary force to create this distance.

11. USER TEST

The hinge design does not interfere with the mobility of the knee and mimics the knee joint for increased comfort and effectiveness.	Human-centred
The brace is a slim fit that is less bulky than existing models and can be worn under straight trousers.	Human-centred
The brace doesn't slide down and is therefore more comfortable to wear than alternatives.	Human-centred
Slides into position in order to prevent malalignment and increase effectiveness.	Human-centred
The brace is designed to limit mistakes made by the user that would lead to incorrect activation. Receiving an explanation on how to use the brace from the orthotist one time, should be sufficient.	Human-centred

A user test is performed on participant one in order to receive an indication of the interaction between the user and the LVATE brace. The user test mainly focusses on the design drivers that are associated with comfort. How comfortable a product is, depends on numerous factors and is not a measurable variable. However, by comparing the LVATE brace to the unloader brace from Orthobroker, a relative difference in comfort can be determined.

The first aspect is the bulkiness of the brace, which is compared to the unloader, as shown in figure 54. The cuffs of the LVATE brace are much thinner than the unloader and fit under trousers, which can clearly be seen in figure 55. The hinges on the other hand are wider in the LVATE brace. A future solution could be to apply cushioning on the inside of the hinge, so that it can be positioned closer to the knee, as with the unloader.

Figure 55. Wearing the unloader on the left leg and LVATE brace on the right leg under trousers to compare their bulkiness.

Figure 54. Comparison bulkiness of the unloader brace from Orthobroker BV (left) and the LVATE brace (right).

The second aspect of the test is the correct positioning of the hinge in relation to the knee joint. A test with the unloader brace is performed during the research phase of this project and can be found in appendix R. The main complaint from the participants that is revealed by this test, is that there is no clear feedback while putting on the brace that indicates a correct or incorrect position. After performing some movements, the participants noticed obstruction by the brace in case of incorrect positioning. However, they were often unable to change this correctly. A wrong approach was often chosen such as putting the brace on like a sleeve or tightening the straps in the wrong order.

A similar test is performed to test the LVATE brace. Participant one is seated on a chair during this test and let's a second participant put on the brace. This second participant has, unlike participant one, no knowledge about either of these braces. The results are shown in figure 56.

Both braces are put on in the correct position. However, the time used for this is approximately one minute for the LVATE brace and three minutes for the unloader. Both braces are applied as if they are sleeve, although this is not the correct process for the unloader brace. Participant two stated that positioning the LVATE brace felt intuitive because of the way that the lower cuff slides over the calf into its position.

The last test performed, challenges the comfort of both braces. The participant runs up and down two staircases and jogs a tour of approximately five minutes, see figure 57. During this test, a traction distance of 1 cm is applied in the LVATE brace. The lower and upper edge of the brace is indicated on the leg with a black line in order to analyse whether the brace slides down. The pressure marks on the leg left by the brace are analysed together with the feedback of the participant.

Figure 56. Position of the hinge for the LVATE (left) and unloader (right) brace when put on for the first time.

Figure 57. Testing both braces on their comfort during a short run.

Both braces remain their position and do not interfere with the movements. The resulting pressure marks from the test are shown in figure 58 and figure 59. To a certain extent, it is normal and not uncomfortable that the brace leaves marks. However, when too much pressure is applied on a small contact surface with the leg, this will cause discomfort and potentially even cut off proper circulation.

This is the case for the upper edge of the lower cuff from the LVATE brace because this edge is not conical, like the lower edge of the lower cuff. This causes cutting when traction is activated. An iterative process is therefore recommended, to solve the sharpness of the edges without losing the benefits of the customized fit.

Figure 58. Pressure marks from the unloader brace after the sport test.

Figure 59. Pressure marks of the LVATE brace after the sport test.

12. BUSINESS CASE

- The production cost of the brace is lower than the current alternative of manually producing a custom brace using cast. — Economic

This business case describes the current orthopaedic market and the competitors. Information is gathered on where Orthobroker should be positioned in the market, in order to reach the patient and which relevant braces are currently on the market worldwide. The second part of this chapter is about the reimbursement system for this type of products and the estimated cost price. Lastly, the sales market is described in order to create different scenarios and profit estimations.

12.1. CURRENT MARKET

An analysis of the market is made in order to gain more insight in the position of Orthobroker and the target group. Before a brace reaches the patient, several steps need to be followed, as shown in figure 60.

The journey of the brace starts at the producer who designs, develops and manufactures the brace in collaboration with its partners. The most common brands are listed in figure 60, from which Ottobock and Aqtor are the biggest in Belgium. The product is then passed on to the distributor. Some of the bigger brands own a distributor company, which is indicated with a black arrow in figure 60. These companies first try to sell their own brand before choosing for another brand. However, almost all distributors sell braces from many different brands.

The patient is not directly connected to the distributor. Depending on the country specific regulations, a prescription might be needed from the orthopaedic surgeon, physiotherapist or general practitioner in order to receive a reimbursement. The patient is then referred to an orthotist. The referral is often based on an informal collaboration between the medical staff and the orthotist.

The orthotist may work in an affiliate from a distributor company or independently, although the independent orthotists are often affiliated with a producer or distributor as well. The prescription commonly includes the patient's pathologies and the type of brace they need. It is then the orthotist's responsibility to choose the best fitting brace for each patient individually, from all the types and brands that exist.

The biggest brands are the ones who have a share in almost every step of the process. Vigo is the distributor from Ottobock and has his own affiliates and orthotists. Some of these orthotists are located in the hospital and therefore easily referred to by surgeons and doctors that work in this hospital. The same goes for Aqtor. This leads to a share for them in every step of the distribution process, causing them to be the leading market players.

In order to reach the patient, Orthobroker should directly collaborate with orthotists, orthopaedic surgeons, GP's and physiotherapists. When the medical staff is convinced about the brace, they offer it to the patient. Orthobroker is expected to reach the largest number of patients with this strategy instead of trying to sell the product to another distributor as it will then be invisible among the other distributed products.

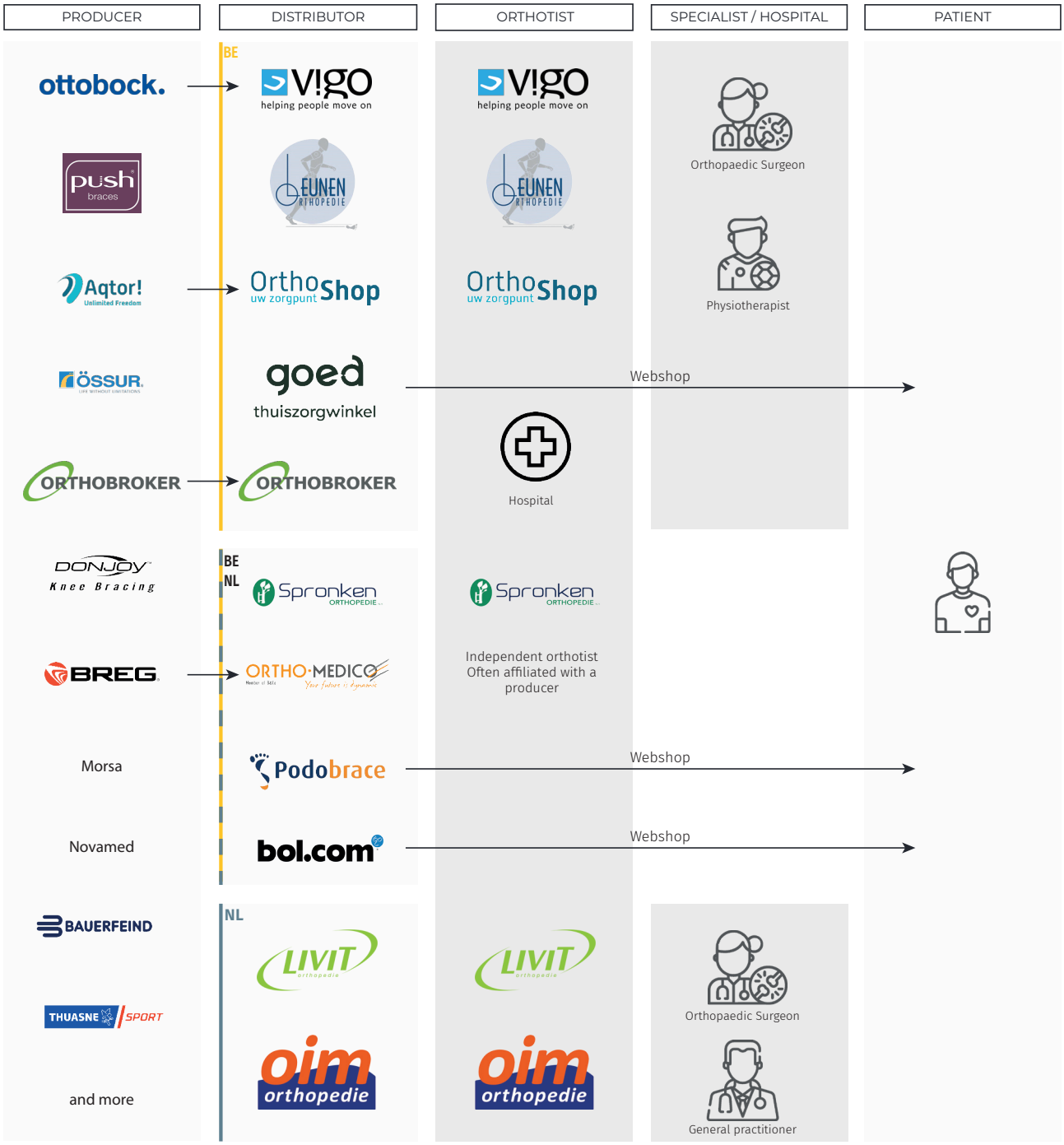


Figure 60. Overview market players in Belgium and The Netherlands.

12.2. SALES

In order to gain more insight in the cost and profit margin, a cost estimation is first performed. The estimation is compared to the traditional production method of custom braces in order to research the difference. This chapter describes the conclusions derived from this analysis and the effect of the reimbursement system on the purchase price and profit margin.

12.2.1. COST ESTIMATION

The cost analysis includes the production price of the brace, medical care and required equipment, which can be found in appendix S. The results are summarized in table 11.

It can be concluded from the cost estimation that creating a similar brace design manually results in a significantly higher production cost compared to using additive manufacturing. The difference is not the material cost but the labour intensiveness of the technique. A manual method requires a significant amount of working hours in order to deliver a finished product. Automating this process cuts back in production cost.

	3D printed LVATE brace (€)	Custom brace casting process (€)
Cuffs	112	122
Hinge	5,5	5,5
Cord	0,3	0,3
Boa® L6	15	15
Orthotist	80	432
Software	35	0
Development	6,22	6,22
Total	**254**	**581**

Table 11. Comparison of the cost estimation for additive manufacturing and the casting production method (Lijnenspecialist, n.d.; Rose bikes, n.d.; R. Vanstiphout, personal communication 2020, 2021).

12.2.2. PURCHASE PRICE

The selling price of medical products depends on the production price, profit margin and reimbursement system. Belgium and The Netherlands act by different reimbursement systems which was studied by Simoens et al. (2007) and summarised in table 12.

FEATURES	BE	NL
REIMBURSEMENT		
Reimbursement based on (cost-)effectiveness		
- Yes		●
- No	●	
Reimbursement level		
- Full reimbursement		●
- Full or partial reimbursement	●	
- Partial reimbursement		
Reimbursement linked to medical indication / chronic condition		
- Yes		●
- No	●	
PRESCRIBING PROCESS		
First prescription by		
- Specialist physician	●	●
- General practitioner		●
Prescription by		
- Brand name	●	
- Generic name	●	●

Table 12. Reimbursement system of orthotic devices (Simoens, et al., 2007).

Whether a knee brace is fully reimbursed in The Netherlands or not at all, depends on the health insurance of the patient. The health insurer assesses whether a (new) medical device meets the legal criterion “state of the art and practise ”, in other words, whether the product has been proven to be effective. This leads to a reimbursement system linked to the medical indication and based on the cost-effectiveness of the product.

On the other hand, in Belgium, a standardised system is used by the government in order to define the refund tariff for each product category. The device does not have to be proven effective neither should it be linked to a medical issue; it only has to fit a certain category in order to define the reimbursement.

The envisioned brace design of this project is a customized hinge brace with or without a lock system in the hinge. The reimbursement tariff is calculated by multiplying the T-value and the key value for customized orthoses, which are both defined by the RIZIV nomenclature.

The key value changes along with indexation and is currently set on 3,262247 for customized orthoses by the RIZIV nomenclature. Applying this on the project, results in a tariff of €1308,81, as shown in table 13. Because of the customization of the orthoses, the renewal period is shorter for younger patients, as shown in table 14.

The reimbursement sum should be divided by 2,4 in order to estimate the price of the product without the orthotist's profit (R. Vanstiphout, personal communication, 26 November 2020). This results in a purchase price of €545,34 for the orthotists. This is again divided by 2,4 in order to deduct Orthobroker's optimal profit, resulting in a production cost of €227, which is close to the estimated €254.

12.3 SALES MARKET

The year prevalence of knee arthritis in The Netherlands in 2019 equals 704.600 patients or 4,05% of the Dutch population (Volksgezondheid en zorg, 2020). This percentage can be applied to the Belgian population leading to 466.026 knee arthritis patients in Belgium (StatBel, 2020). The potential sales are calculated based on the 0,28% of new cases in The Netherlands in 2019 (Volksgezondheid en zorg, 2020). This is again applied to Belgium.

The LVATE brace will first be available on the Belgian market because of the standardised reimbursement system. In The Netherlands, one must be able to prove the cost-effectiveness of the brace in order to convince health insurers to provide patients with a reimbursement. Data can therefore be collected from Belgian patients over the course of their treatment that supports the cost-effectiveness of the brace. The data can also be used for iterations and further elaborations to improve the brace design.

Depending on the market share, the profit is estimated to be between €468.210 and €1.872.841 in Belgium and between €709.185 and €2.836.740 in The Netherlands, as shown in table 15.

NOMENCLATURE NUMBER		CUSTOMIZED ORTHOSES			
AMBIENT	HOSPITALIZED	DESCRIPTION	T-VALUE	KEY VALUE	REIMBURSEMENT (€)
647356	647360	Device thigh and leg	283,20	3,262247	923,87
647496	647500	Additional knee guidance	188	3,262247	384,95
					TOTAL: 1308,81

Table 13. Riziv nomenclature (Riziv, 2020a; 2020b).

RENEWAL PERIOD		
<14 Y/O	>14 AND <21 Y/O	>21 Y/O
1 year	2 years	5 years

Table 14. Riziv renewal period (Riziv, 2020a).

POPULATION BY COUNTRY IN MILLION			
		11.4	17
		Belgium	The Netherlands
POTENTIAL PATIENTS			
Annual percentage of arthritis patiënts		←	0.28%
Annual amount of arthritis patiënts		**32 179**	**48 741**
Market share	5%	1 609	2 437
	10%	3 218	4 874
	15%	4 827	7 311
	20%	6 436	9 748
POTENTIAL SALES			
Selling price (excl. VAT 21%)	€ 545		
Estimated production cost (excl. VAT 21%)	€ 254		
Profit margin per product	€ 291		
Revenue at market share	5%	€ 876 889	€ 1 328 199
	10%	€ 1 753 777	€ 2 656 397
	15%	€ 2 630 666	€ 3 984 596
	20%	€ 3 507 554	€ 5 312 795
Profit at market share	5%	€ 468 210	€ 709 185
	10%	€ 936 420	€ 1 418 370
	15%	€ 1 404 631	€ 2 127 555
	20%	€ 1 872 841	€ 2 836 740

Table 15. Estimated annual profit (StatBel, 2020; Volksgezondheid en zorg, 2020).

12.4 RISKS

The LVATE brace is in the first place designed to wear only during activities, as it causes a significant amount of strain on the leg. It should be further researched whether the strain causes discomfort or irritation when wearing the brace more regularly or on a daily basis. When this appears to be no problem, the estimation of the sales market and business case as described above, can be applied. However, there are two options when the brace does seem to be too demanding for daily use.

On the one hand, the product can be marketed as a sports related product. This decreases the number of potential buyers and therefore drives up the selling price. On the other hand, a variant can be designed that meets the needs for daily use. The standardised parts such as the hinge and Boa® can be used for both variants, if the adaptations are only made to the cuff design. The variant that best suits the patient's needs can then be ordered on the OrthoSOLID® platform.

PART IV

FINAL STATEMENT

The final statement of this thesis report describes the overarching conclusion of this project, the recommendations for future development of the product and a reflection on the process.

13. CONCLUSION

The goal of this thesis was to create a proof of concept for a brace that enhances pain relief and mobility for patients with arthritis in the knee. With the final prototype of the LVATE brace, this goal was achieved to the utmost extend. The working principle, the interaction with the user and the comfort of the brace were proven to meet the requirements as intended in the design. During the traction test, it was demonstrated that a substantial amount of force is transferred through the brace when the traction distance increases. However, the question regarding the eventual effect on the pain and mobility of the patient, remains unanswered, due to the complexity of the tests that are necessary to research this.

This conclusion is further elaborated upon in the three main evaluation topics, being desirability, feasibility and viability of the product.

13.1. DESIRABILITY

Pain and limited mobility of OA patients is caused by weight-bearing in the tibiofemoral compartment of the knee joint. Unloading this compartment leads to pressure relief of the damaged articular cartilage, decreasing pain and immobility.

The design of a brace that unloads both tibiofemoral compartments is desired both from medical and patient perspective. The patients' main need is to relief pain symptoms and gain back their mobility. In an early stage of OA, this may be achieved by physiotherapy and NSAID's. However, as the arthritis evolves, more effective treatments are needed but not available. Eventually, a surgical treatment will be offered to the patient, although the majority of patients prefers a non-surgical treatment, if possible. There is currently no treatment available to fill the gap between physiotherapy and surgery. This is where the potential of this project is situated. By providing a brace that unloads both tibiofemoral compartments, both pain relief and mobility improve, and the deterioration process is slowed down due to decreased weight bearing. This means that the need for surgery can potentially be delayed by wearing the LVATE brace.

Additionally, this project is also desired from a medical perspective. One out of five patients that undergo knee replacement surgery, are unsatisfied with the result. Due to the limited lifespan of implants and the increased risk for infections, revision surgeries might be needed. It is therefore medically preferred to prevent the need for surgery in the first place, using non-surgical treatments as this involves less risks and possible implications.

13.2. FEASIBILITY

Concluded from the research phase was that a customized fit enhances the effectiveness and comfort of the brace. Therefore, this design uses a combination of 3D scanning and additive manufacturing to make it possible to perfectly fit the brace to each patient individually. Opting for powder bed fusion as 3D printing technique delivers a finished product and thus enables the possibility to produce a highly customized and unique products within an affordable price margin.

Designing the LVATE brace for each patient specifically, is too labour intensive and would add many hours to the production time. It is therefore important that the design is ensured to be compatible with the OrthoSOLID® platform from Orthobroker. This software is able to manipulate the product to a perfect fitting version for each patient based on their unique 3D scan. This implementation in the platform is ensured due to the GACP protocols that were defined in this thesis. These protocols can be transformed into software codes and added to the platform.

In order to ensure affordability of the brace, all patient specific adaptations and deformations can only be applied to the cuffs because of the individual production process. The hinges, on the other hand, are standardized and thus can be produced in masses. This enables the possibility to create metal parts and manipulate the cuffs in such a patient specific way that the hinges are positioned correctly.

13.3. VIABILITY

Arthritis is one of the most common muscular skeletal disorders with a high incidence rate in the knee joint. Research in the United States shows that the number of patients that will need a primary TKA in 2030, is estimated to increase with 673% compared to the year 2005 (Kurtz et al., 2007). This goes to show the expected increase of the target group, leading to an even higher demand for alternative non-invasive treatments in the future. The integration of additive manufacturing as a reliable production technique is expected to further improve in the future. This will create more production opportunities and supports the balance in supply and demand.

The combination of 3D scanning and additive manufacturing enables a new approach of creating highly customized products. In the cost estimation it was shown that the economic benefit of using these techniques compared to current manual production, is substantial and results in a profitable product. Additionally, there are currently no competitors that offer a customized traction knee brace, regardless of the desirability and large target group for this treatment.

14. RECOMMENDATIONS

Multiple iterations are necessary to transform this proof of concept into a market-ready product. In this chapter, recommendations are prepared that describe the way forward, when the product proposal is further developed.

- A general deformation protocol that deforms the leg scan in such a way that pressure is applied only in tolerant zones, is developed in this thesis. However, this protocol should be further elaborated upon, in order to integrate patient-specific parameters that may influence the magnitude of the pressure applied by the brace. Such parameters can be the mobility level of the patient, sensitive scar tissue, amount of soft tissue, and so on.

- The design of the hinge itself fell out of the scope of this project. Although, the hinge is functioning as intended and thus proves the concept, the design itself is bulky and not optimized. It is therefore recommended to run the hinge through the design process in order to create a slim, aesthetic and functioning four bar hinge mechanism.

- The Boa® knob is integrated in the cuffs to wind the cord and create traction. The force transmission should be further optimized so that minimal force is needed to rotate the knob.

- In the course of this project, a prototype is created for two subjects. To properly assess user comfort and functioning of the brace, a larger group of participants should be subjected to tests.

- One of the design drivers is the easy assembly of the brace by the orthotist. This requirement is not met with the final prototype due to the attachment method of the cord. The length of the cord defines the amount of traction that is created. When the cord is fully unwinded, the traction distance should be zero. The necessary length of the cord differs for each patient and should therefore be measured out by the orthotist. However, the way this is done in the final prototype, leaves room for human errors which, highly impacts the effectiveness of the brace. Therefore, it is recommended to further elaborate on a solution to attach the cord to the hinge, while ensuring the correct length of the cord.

- Due to the nature of this project, where form follows function, further elaboration on the aesthetics is recommended. Research should first be conducted on the perception of brace design characteristics, and what matches the intensions of the LVATE brace. Secondly, the insights from this analysis should be applied to the brace.

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