The development of a non-migrating knee orthosis

D.A. Boiten
Faculty of Engineering Technology
Department of Biomechanical Engineering

Examination committee:
prof. dr. ir. G.J. Verkerke
ir. E.E.G. Hekman
ir. M.P. Zwier
R. Endert

Document number
BE-750

Summary

The use of knee orthoses has seen a large rise since the 70's, since their use for sport related injuries became more accustomed. A frequent problem all orthoses share is that they have the tendency to slide down, however, the position of the orthosis is critical for it to fulfill its function correctly.

The two causes of this migration of an orthosis are the conical shape of the leg and a mismatch between the hinges used in orthoses and the knee joint. The knee joint is a very complex joint which rotates using a combined rolling and gliding motion. The combination of these two motions causes the rotation axis of the knee joint to move along a pathway of rotation, primarily in the sagittal plane.

In this project it was tried to create a non-migrating knee orthosis for anterior cruciate ligament injuries firstly by designing a suspension system to solve the conical shape of the leg and secondly by creating a new hinge that follows the natural pathway of rotation to eliminate any mismatch with the knee joint.

A suspension system was created by developing multiple concepts which were produced into prototypes. These prototypes were used to evaluate all the possible designs. After the first prototype evaluation some prototypes were improved and reevaluated. A final suspension system was chosen from these improved prototypes. The chosen system avoids any migration of the orthosis and also supports the correct positioning of the orthosis.

The biggest challenge in designing a hinge that follows the natural pathway of rotation of the knee was that this pathway is unknown. Literature is very divided on this topic, so there does not exist a generally accepted pathway. In an attempt to find the correct pathway motion tracking experiments were conducted. The results of these experiments showed that the used method was not precise enough to be able to determine a reliable rotation pathway. The method was, however, used to compare the pathway of the knee motion of different hinge prototype with the natural situation.

Two final hinge designs were created. The first imposes a rotation pathway on the knee and allows some variation from this pathway to adjust to individual pathways. The motion tracking comparison showed a slight deviation from the natural motion pathway, but the hinge could provide the needed support to the knee. The second design that was created left the rotation free. The motion tracking of this prototype showed that the natural motion pathway was followed, however, less support was provided to the knee. Each design performs well in different categories and would be suitable for different client types, since a client is not yet known no final choice between the two hinges was made.

Samenvatting

Het gebruik van knie ortheses is sterk toegenomen sinds de jaren 70, wanneer het gebruik hiervan gebruikelijk werd voor sportblessures. Een veel voorkomend probleem van knie ortheses is dat deze de neiging hebben om af te zakken terwijl de juiste positie van de orthese erg belangrijk is om correct te kunnen functioneren.

De twee oorzaken van deze migratie van de orthese zijn de conische vorm van de benen en een mismatch tussen de scharnieren die gebruikt worden in de huidige ortheses en het kniegewricht. Het kniegewricht is een erg complex gewricht die roteert door een gecombineerde rollende en glijdende beweging. De combinatie van deze twee bewegingen zorgt ervoor dat de rotatie-as van het kniegewricht beweegt langs een zogeheten rotatiepad, deze beweging vindt voornamelijk plaats in het sagittale vlak.

Het doel van dit project was om een niet migrerende knie orthese voor voorste kruisband letsel te maken door eerst een suspensiesysteem te ontwerpen dat het probleem van de conische vorm van de benen oplost en door dan een nieuw scharnier te creëren dat het natuurlijke rotatiepad volgt om de mismatch met het kniegewricht op te lossen.

Meerdere concepten zijn ontwikkeld om een suspensie systeem te ontwerpen, deze concepten zijn tot prototypes gemaakt. Deze prototypes zijn gebruikt om de verschillende ontwerpen te evalueren. Na de eerste prototype evaluatie zijn sommige prototypes verbeterd en opnieuw geëvalueerd. Uit deze verbeterde prototypes is een eindontwerp gekozen. Dit suspensiesysteem vermijdt elke vorm van migratie van de orthese en zorgt er ook voor dat de orthese juist gepositioneerd wordt.

De grootste uitdaging in het ontwerpen van een scharnier dat het natuurlijke rotatiepad volgt was dat dit pad niet bekend is. De literatuur is erg verdeeld over dit onderwerp en daarom is er geen rotatiepad dat algemeen geaccepteerd is. In een poging om het juiste rotatiepad te vinden zijn motion tracking experimenten uitgevoerd. De resultaten van deze experimenten lieten zien dat de gebruikte methode niet precies genoeg is om betrouwbare rotatiepaden vast te stellen, maar de methode kon wel gebruikt worden om het pad van de beweging van de knie van verschillende scharnierprototypes te vergelijken met de natuurlijk situatie.

Voor het scharnier zijn twee eindontwerpen gemaakt. Het eerste ontwerp legt een rotatiepad op maar staat wat variatie toe aan de knie om af te wijken van dit opgelegde pad om aan het persoonlijke pad van de gebruiker te kunnen aanpassen. Een vergelijking met behulp van motion tracking liet zien dat het gevolgde pad licht afweek van het natuurlijk gevolgde bewegingspad, maar het scharnier was wel in staat om voldoende ondersteuning te bieden aan de knie. Het tweede ontwerp liet de rotatie vrij. Met motion tracking werd gezien dat het prototype het natuurlijke bewegingspad volgde, maar het bood minder ondersteuning aan de knie. De beide ontwerpen presteren beter in verschillende categorieën en zouden daardoor geschikt zijn voor verschillende soorten klanten, aangezien de klant nu niet bekend is wordt er geen keuze gemaakt tussen de twee scharnierontwerpen.

Table of contents

1. Introduction

1.1 BACKGROUND

The use of knee orthoses has seen a significant rise since the 70's. Before this they were only used for patients with an abnormal knee position. However, starting from the 70's the use of knee orthoses for sport related injuries started to become accustomed [1]. The present market offers many different knee orthoses meant for different purposes. A frequent problem all of these orthoses share is that they have the tendency to slide down, however, the position of the orthosis is critical for it to fulfill its function correctly [2].

While reviewing the currently available orthoses it can be seen that most have a simple hinge design, either single axis or dual axis. If you would compare this to the hinge of the knee, i.e. the knee joint, it becomes clear that there exists a mismatch. This is due to the complicated center of rotation of the knee. The rotation axis is not fixed but moving during flexion of the knee. This movement of the axis is caused by a combined rolling and sliding movement of the knee joint [3]. This motion causes the center of rotation to follow a pathway that is curved into a shape similar to a J [2]. Combining this complicated pathway of the center of rotation of the knee joint with a simple single or dual axis hinge in an orthosis clearly results in a mismatch.

A mismatch between the orthosis hinge and the knee joint can cause multiple problems such as chafing and stressed ligaments. Additionally, it causes the orthosis to migrate which combined with the conical shape of the leg results in the common problem of the orthosis sliding down [2, 4, 5]. This and the other mentioned problems can prevent or slow down the intended healing process of the patient.

To solve this problem orthoses were designed to mimic the J-curve of the knee joint. These designs have not been a clear success [2]. What must be realized to understand this is that these designs try to perfectly mimic the prescribed pathway of the instantaneous center of rotation, while, in reality, this pathway differs per person [2]. This deviation would still cause a mismatch between the knee joint and the hinge if the theoretical pathway of the center of rotation would be followed. This shows that there is a need for a knee orthosis that allows the user to rotate their knee according to their own pathway of rotation.

1.2 BAAT MEDICAL

BAAT medical is a medical product development company located in Hengelo. It started as a spin-off out of the University of Twente in 1999. BAAT medical develops products for their clients. These developed products are orthoses, implants and instruments. Besides the development of these products BAAT can also organize the production of medical products for their clients. If preferred BAAT can also become the legal manufacturer of the product. This means, that they are responsible for the delivered products and therefore take care of their certifications and quality among other things. So over time BAAT has developed itself to a development company that can facilitate the entire product development process, from idea to bringing the product to the market and beyond.

1.3 ASSIGNMENT

The assignment is to develop an orthosis which will not migrate and slide down by designing a brace that allows the patient's own natural pathway of rotation to be followed. The orthosis must facilitate the rehabilitation of the patient by limiting unnatural movements. The final orthosis design should be supported by tests performed on prototypes of the orthosis. To protect the final results of these assignment the design will be confidential, therefore not all parts of the design process can be described in this report or will only be vaguely described.

1.4 SCOPE

The focus of this assignment will be on designing a knee orthosis that will not slide down. This will partly be achieved by focusing on a design which allows the rotation of the knee joint to follow the natural pathway of the center of rotation and partly by focusing on solutions for the conical shape of the leg. Additionally, it must also be ensured that the final brace design results in a brace that will contribute to the rehabilitation process of the patient.

It is very difficult to create an orthosis that is suitable for all the conditions which could require an orthosis to be worn, so this design will be focused on orthoses meant for patients with a cruciate ligament injury. Other applications of the orthosis will also be considered if possible.

To realize the most optimal orthosis, discussions and interviews will be performed with the stakeholders.

1.5 PROCESS

The process, pictured in figure 1, starts with a literature study which focusses on the knee joint, its rotation and possible injuries. The subsequent analyses investigate the current orthosis market, expert opinions and the user experience. Using motion tracking experiments the rotation pathway is investigated. The information gathered from this is used to develop a solution for the migration due to the conical shape of the leg and is tested using prototypes. Subsequently, a solution is developed for a hinge that follows the correct rotation pathway. This solution is also tested using prototypes. Finally, the two chosen solutions are combined to form the final design.

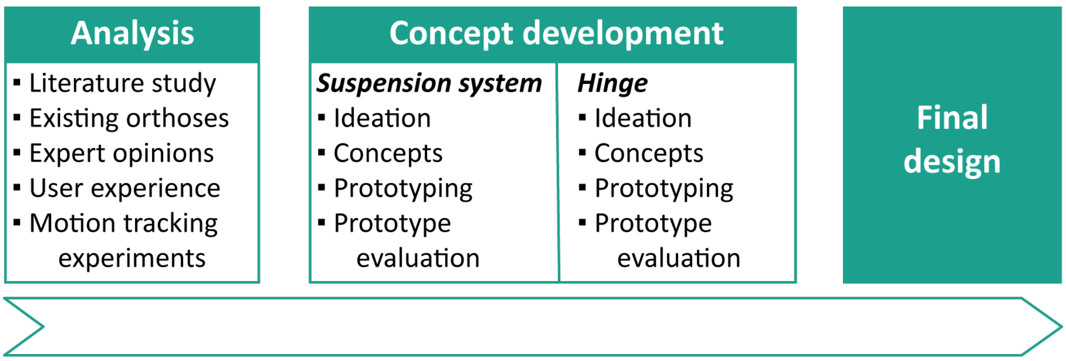


Figure 1: Depiction of the process followed

2. Theory

This chapter will elaborate on the relevant theory for this design process. Firstly, the anatomy and the movement of the knee joint in general will be discussed. Then the pathway of the center of rotation of the knee joint will be treated in more detail. Furthermore, common knee injuries which are treated using an orthosis are discussed. Lastly, the knee orthosis itself will be addressed.

2.1 KNEE JOINT

The knee, as pictured in figure 2, connects the femur and the tibia and fibula. The knee actually consists of two joints: the patellofemoral joint and the tibiofemoral joint [6]. The patella is placed in front of the tibiofemoral joint and forms the patellofemoral joint with the femur. In this joint the patella acts as a pulley to redirect the forces from the quadriceps, placed on the patella with the quadriceps tendon, correctly to the lower leg via the patellar tendon [5]. However, the amount of force the patella can transfer is dependent on the angle of flexion [3]. So while the patellofemoral joint functions as an extension mechanism the tibiofemoral joint limits the range of motion of the knee and is therefore also the joint that is influenced by an orthosis [6].

The joint is connected by ligaments. The anterior and posterior cruciate ligaments connect the femur with the tibia. Just as the medial collateral ligament, while the lateral collateral ligament connects the femur with the fibula. These

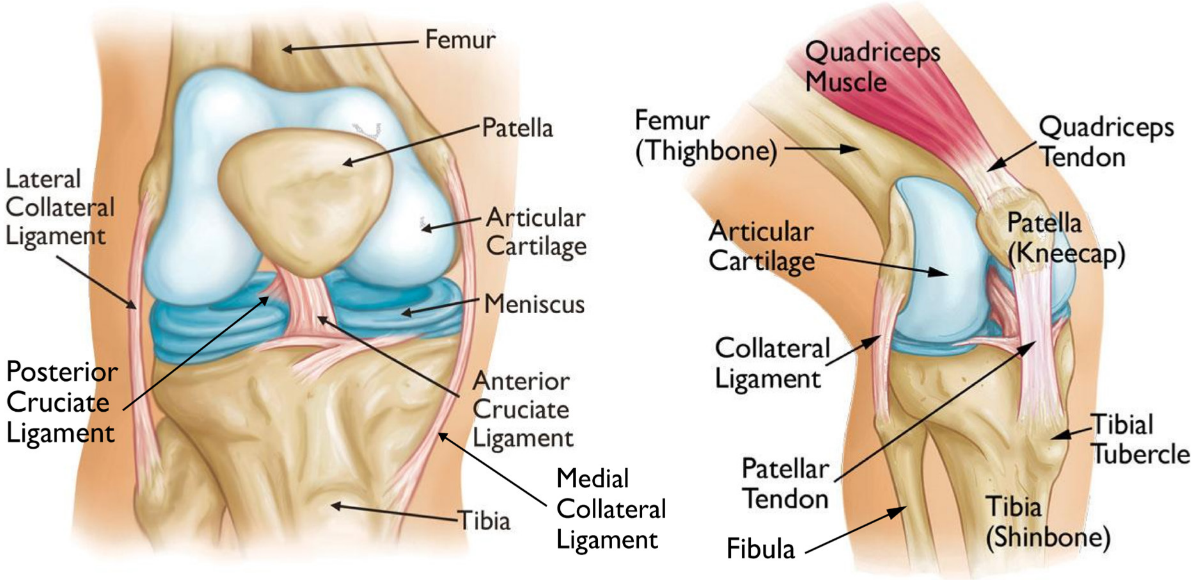


Figure 2: Anatomy of the knee joint [9, 10]

ligaments provide the stability of the knee joint and also restrain unwanted motions [5, 7]. Therefore, the stability of the knee is dependent on the integrity of the ligaments [8]. The femoral condyles, which are located at the end of the femur, are protected from damage inflicted by the joint by articular cartilage [5]. Lastly, where the condyles contact the tibia the menisci are placed. These deform when the joint moves to ensure that the load placed by the femur on the tibia is distributed evenly. Furthermore, the menisci also act as shock absorbers [5].

2.1.1 DEGREES OF FREEDOM

The knee joint has six degrees of freedom, three translations and three rotations [5]. The three rotational axes are shown in figure 3. The largest range of motion of the knee joint is around the flexion-extension axis, making this the primary movement [3]. Here the joint can rotate from 0°, when the knee is fully extended, up to 160°. Small rotations, 6°-8°, are also possible around the varus-valgus axis. Around the last axis, the internal-external axis, a rotation of 25°-30° is possible. Translations also occur in the knee joint albeit small. Medial-lateral translation is possible up to 1-2 mm, anterior-posterior up to 5-10 mm and proximal-distal up to 2-5 mm [5].

2.1.2 JOINT MOVEMENT

Flexion of the knee joint is a combination of two different movements in the joint. These movements are the rolling of the femur on the tibia and the sliding of the femur over the tibial plateaus. In the initial stages of flexion the rolling movement is dominant, while in the later stages the sliding movement is dominant [3]. The left side of figure 4 shows the motion if only the rolling movement would occur and the middle if only the sliding would occur. This shows the need for the combination of these movements which is shown in the right side of the figure. This rolling causes the contact point of the femur and tibia to

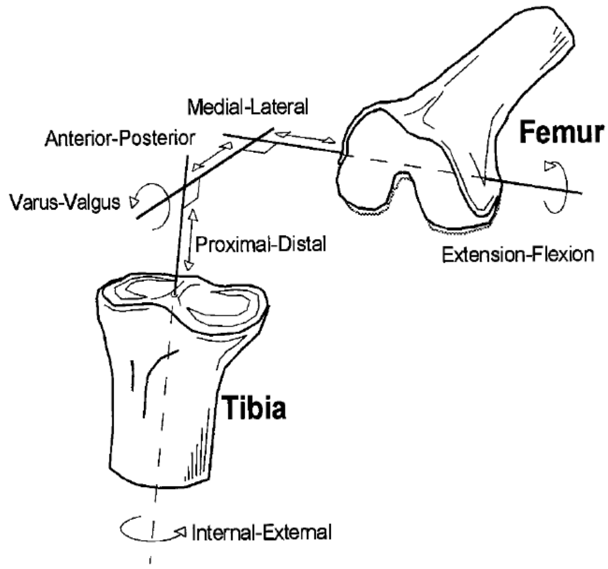


Figure 3: Rotational axis of the knee joint [7]

move backwards. This helps to reduce the wear of the joint since the load is carried by different parts during flexion [11].

During flexion and extension not only movement in the sagittal plane occurs [7]. Due to the shape of the femoral condyles also an internal-external rotation of the tibia takes place. This rotation is known as the screw-home mechanism [5]. This rotation is caused by an asymmetry in the knee joint. The medial femoral condyle has a larger radius of curvature than the lateral femoral condyle causing internal rotation of the tibia during flexion due to the rolling of the femur on the tibial plateau [1, 3]. During extension this results in an external rotation of the tibia. Lastly, the radius of curvature of the femoral condyles differs depending on the location. During a flexed position the radius of curvature is short, as can also be seen in the right part of figure 4, this results in a lax anterior cruciate ligament and collateral ligaments. Whereas a knee in

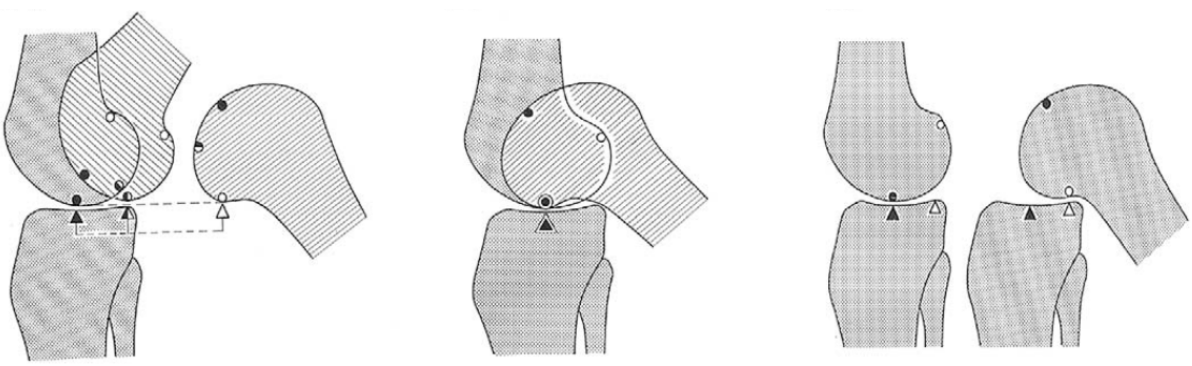


Figure 4: The actual rolling and sliding movement of the knee joint during flexion (right), a theoretical pure sliding movement (middle) and a theoretical pure rolling movement (left) [8]

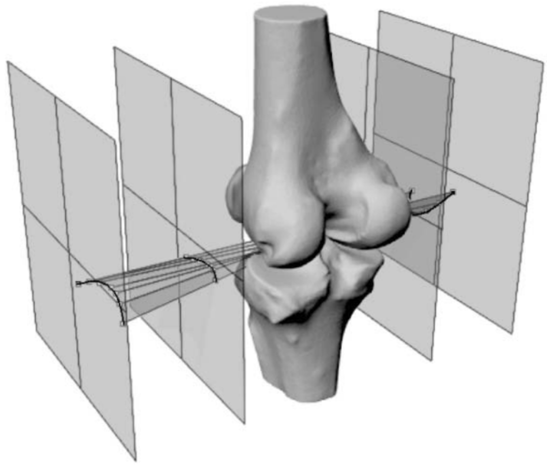


Figure 5: Pathway of the theoretical axis of rotation [2]

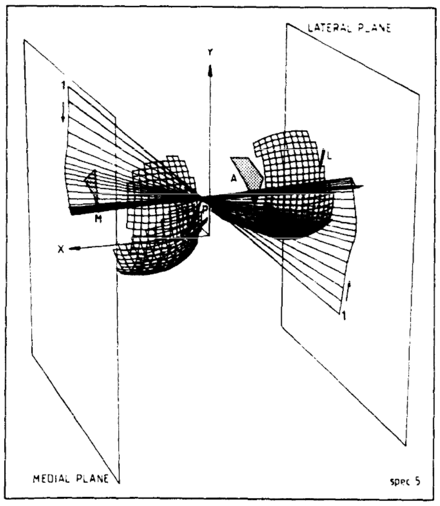


Figure 6: Measured pathway of the axis of rotation [15]

extension results in an anterior cruciate ligament and collateral ligaments in tension because here the radius of curvature of the femoral condyles is larger. Due to all three of these ligaments being in tension during extension this is the most stable position [8].

2.1.3 CENTER OF ROTATION

Due to the combined rolling and sliding movement the knee joint does not function as a simple hinge with a fixed point of rotation. The transition from rolling to sliding causes the instantaneous center of rotation to move. Since the largest movement in the knee joint is in the sagittal plane, the largest displacement of the instantaneous center of rotation is also in the sagittal plane [5]. In this plane the instantaneous center of rotation is located at the point where the anterior and posterior cruciate ligaments cross, which is vertically above the point of contact between the femur and the tibia [12].

However, the instantaneous center of motion does not exclusively move in the sagittal plane, it also moves in other directions due to the screw-home movement [13]. The majority of this movement takes place near full extension. This makes a pure sagittal view of the instantaneous center of rotation pathway reasonably accurate except near full extension [14].

A 3D image of the theoretical movement of the axis of rotation during flexion can be seen in figure 5. Figure 6 shows a pathway of the axis of rotation that was based on measurements. The intersection of this pathway with the sagittal plane is shown in figure 7. The figures show that the instantaneous center of rotation follows a curled-up pathway. This shape of pathway is known as a J-curve. The figures also show that the pathway of the medial and lateral side is mirrored vertically. This is due to the tilting of the rotation axis which can be clearly seen in figure 6. Furthermore, figure 7 also show that the pathway of the instantaneous center of rotation can differ between individuals, although the general shape is the same. This is due to the differences of individual bodies such as body weight and height [2]. The pathway does not only differ per person but can also alter due to damage in the knee joint. This is since the pathway of the instantaneous center of rotation is determined by the ligaments, so damage to these ligaments will alter the pathway. This is demonstrated in figure 8.

The difficulty with determining the pathway of the instantaneous center of rotation is that it is hard to accurately measure the location of the instantaneous center of rotation. This low

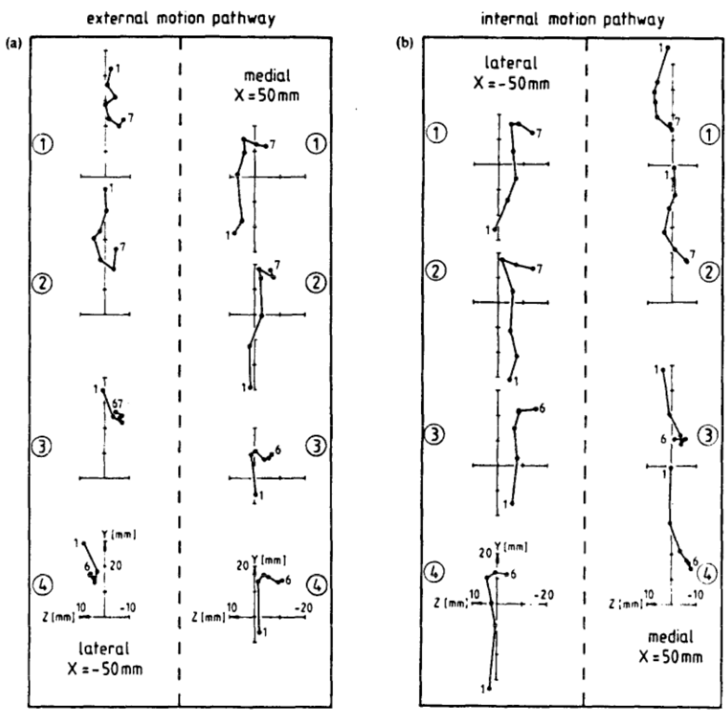


Figure 7: Intersection of the pathway of the instantaneous center of rotation with the sagittal plane [15]

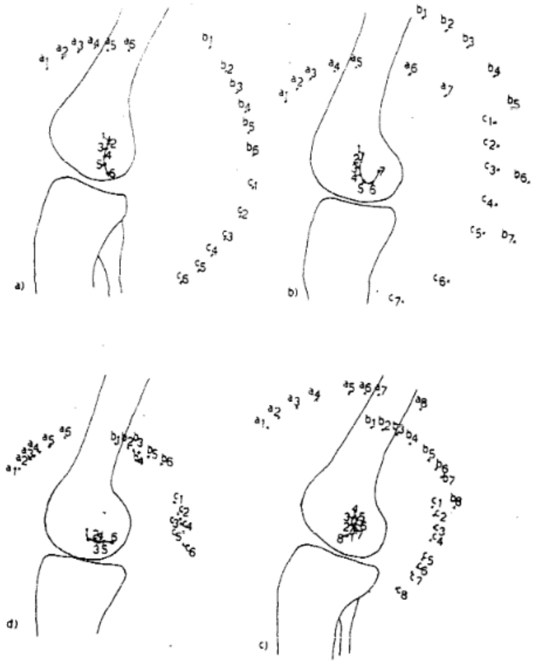


Figure 8: Pathway of the instantaneous center of rotation; a) For a normal knee, b) For a knee with a torn meniscus, c) For a knee with an ACL tear, d) For a knee with a meniscectomy [13]

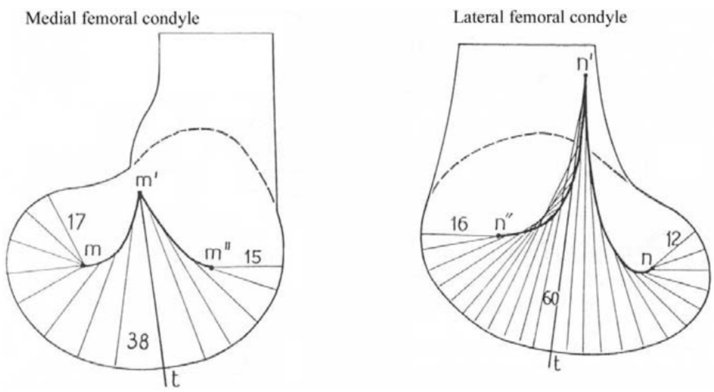


Figure 9: Possible pathway of the instantaneous center of rotation of the knee joint [8]

accuracy gives a wide range of found results for the pathway of the instantaneous center of rotation. This causes a wide range of opinions on the exact shape and location of the pathway. This is demonstrated in the pathways that were found in literature. None of the pathways shown in figures 5, 7, 8 and 9 are completely similar and all vary in different ways.

Figure 10 shows a summary of the pathways that were found in the literature. The irregularities that exist between these pathways can most likely be attributed to the difference in methods used to determine the pathways. The pathway found in figure 5 which is pictured in figure 10a, for example, was based on a model and not directly on measurements such as in figures 7 and 8, pictured in figure 10b, 10d and 10e, while the method used in figure 9, which is pictured in figure 10c is unclear.

Lastly, it can be seen that figure 7 shows two contradictory pathways: one indicated as an external motion pathway and one as an internal motion pathway. The difference between these two pathways is the applied load during the experiment. To obtain these pathways a torque was placed on the tibia. In one experiment this torque was directed externally and in the other internally. Figure 7 shows that this results in reversed pathways for the two situations. From this it could be concluded that the pathway not only differs per person but also per applied load, however it must be noted that this situation with applied torque is not a natural situation. This conclusion could therefore be incorrect or only partially true. If true, this would mean that one person can have multiple natural pathways of the center of rotation.

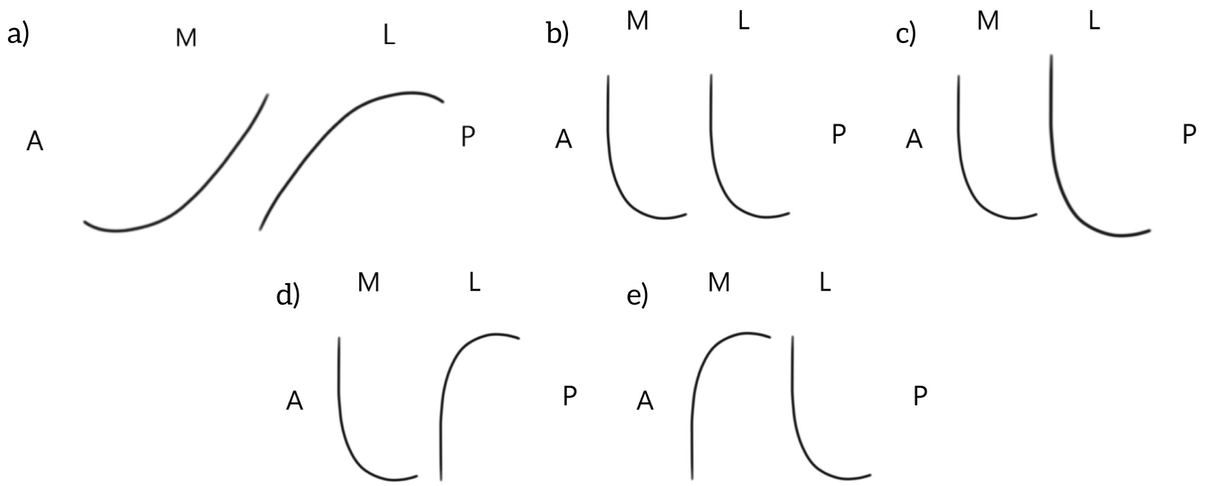


Figure 10: Rotation pathways presented in literature

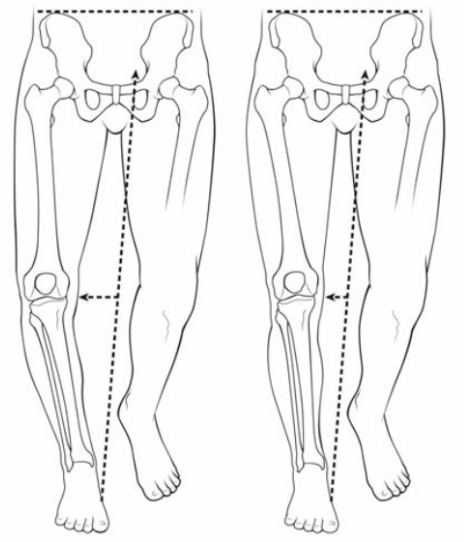


Figure 11: Adduction moment on the knee with and without varus [16]

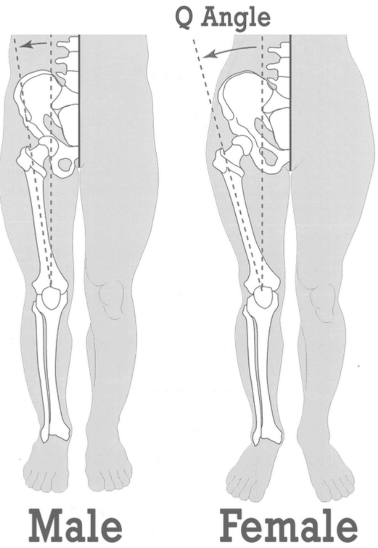


Figure 12: Q-angle of a typical male and female [17]

2.1.4 BIOMECHANICS OF THE KNEE JOINT

The forces which are placed on the knee can be divided into internal and external forces. The external forces are forces such as the ground reaction force, forces due to the weight of the body and due to the movements of limbs. Internal forces are forces in the knee joint by the muscles and tendons to counteract the external forces placed on the knee [3].

These external forces can also cause moments to be placed on the knee joint. The size of the moment can be dependent on the specific built of the body. For example, an adduction moment is caused due to the location of the foot not being under the center of mass. In patients with varus, meaning an outwards angulation of the knee, this adduction moment is larger due to a larger arm, as can be seen in figure 11 [3].

The Q-angle is the angle between the quadriceps and the patellar tendon [5]. Since woman typically have wider hips than men the Q-angle is also larger for them, as shown in figure 12. Due to the existence of this angle between the quadriceps and the patellar tendon the quadriceps not only places a downwards force on the patella but also a lateral force which is larger for females due to the larger q-angle [5].

These forces that act on the knee joint are generally relatively large since the knee is located at the two longest levers that exist in the human body [18]. However, the size of these forces can differ much between different activities [19]. For example, squatting can exert a compressive load of 5.6 times the body weight on the tibia while cycling only exerts a force of 1.2 times the body weight [5]. Evaluating these forces in normal knees and injured knees can be useful during treatments of injured knees to determine its success [7].

2.1.5 KINEMATICS

During gait the primary motion of the knee is flexion-extension rotation. However, due to the complexity of the knee joint its movement is also complex and is not simply limited to this rotation. Figure 13 shows the extend of movement in each of the six degrees of freedom of the knee during the stance phase of gait. The solid lines indicate the average values and the dashed lines the minimum and maximum values. The stance phase is the period in normal gait in which the leg of the concerning knee is in contact with the ground and thus the time the knee is weightbearing. The figures show that flexion-extension rotation is the primary motion, but motion also takes place in all other degrees of freedom. Of these other DOF's the internal-external rotation is the largest and the distal-proximal translation the smallest. The distal-proximal motion might appear large due to the values indicated on the y-axis of the graph, but these values indicate the position of the femur relative to the tibia so the difference between the minimal and maximal number is the total motion that occurs.

2.1.6 CONCLUSION

It can be concluded that the knee joint is a complicated joint. Although the movement is primarily a rotation around the flexion-extension axis, movements in all other directions also take place. To complicate matters even further this primary movement is comprised out of two different motions causing the knee joint to

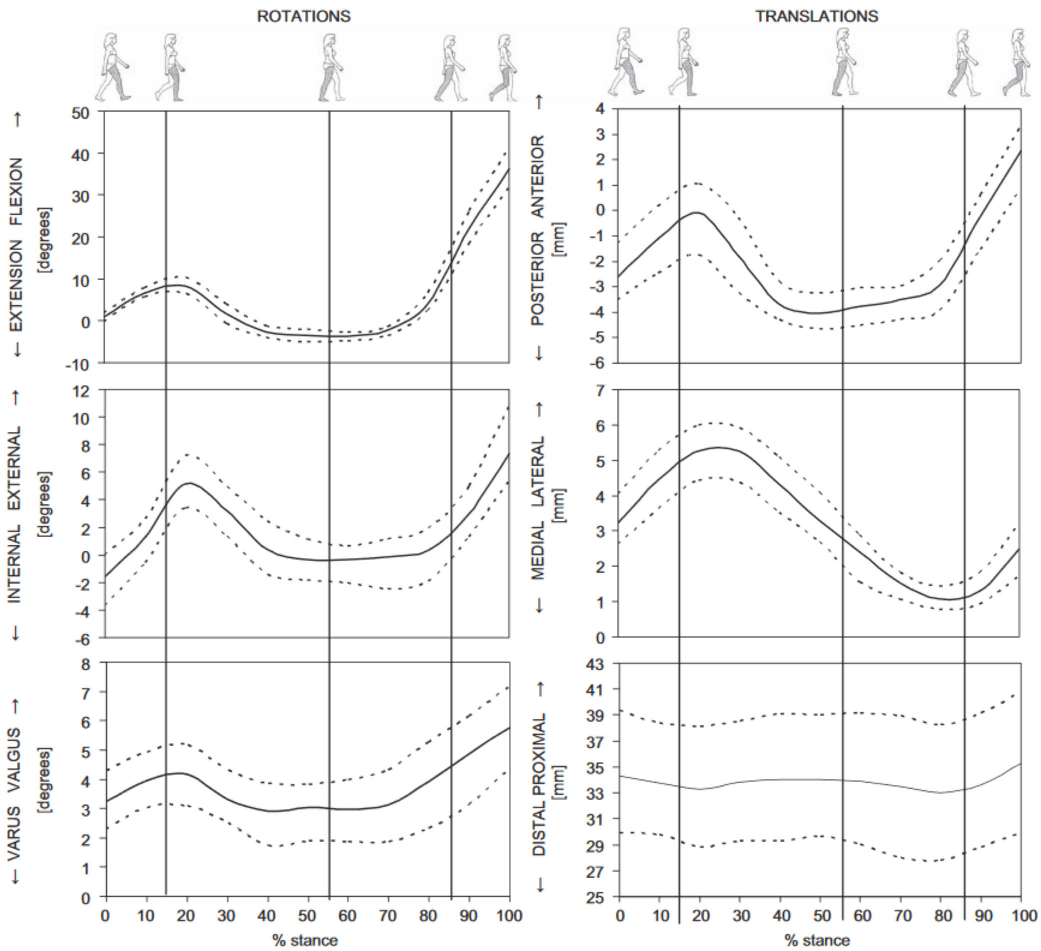


Figure 13: The occurring movements in the knee joint during the stance phase of gait [20]

have a moving axis of rotation during flexion-extension. How this axis moves has been up for debate and many different pathways have been proposed. The accuracy of these pathways can differ considerably based on the method with which the pathway is determined. However, there is an agreement that this pathway is curved in a J-shape. It might also be possible that the pathway could differ depending on the way the knee is loaded. This would mean that an orthosis that attempts to follow the natural pathway of the center of rotation must be able to follow these varying pathways under different loading situations. Lastly, a difficult characteristic of the knee joint is that the forces and moments which act on it are relatively large due to their placement.

2.2 CRUCIATE LIGAMENTS

2.2.1 ANTERIOR CRUCIATE LIGAMENT

The anterior cruciate ligament (ACL) is connected to the femur at the posterior part of the inner surface of the lateral femoral condyle and to the tibia at the anterior part between the two menisci, this can be seen in figure 14. The shape of the ACL changes with the flexion angle and is larger at the tibia than at the femur [22]. The ACL can be split up into two bundles, the anteromedial bundle (AMB) and the posterolateral bundle (PLB). During extension these bundles are parallel, but during flexion the AMB start to rotate around the PLB [22].

The function of the ACL is to provide stability to the knee joint by restraining anterior translation of the tibia. Besides this primary function the ACL also helps to restrain internal rotation of the knee and to a lesser extend to restrain external rotation and varus-valgus rotation [22]. When the ACL is damaged it is not able to perform these functions or can only perform them partially.

2.2.2 POSTERIOR CRUCIATE LIGAMENT

The posterior cruciate ligament (PCL) is attached to the femur to the roof and medial side of the femoral intercondylar notch and to the tibia posteriorly between the horns of the menisci going over the edge of the tibial plateau [23], this can be seen in figure 14. Similar to the ACL the PCL can also be split into two bundles, the anterolateral bundle (ALB) and the posteromedial bundle (PMB). However, there exist some discussion if this is the best way to

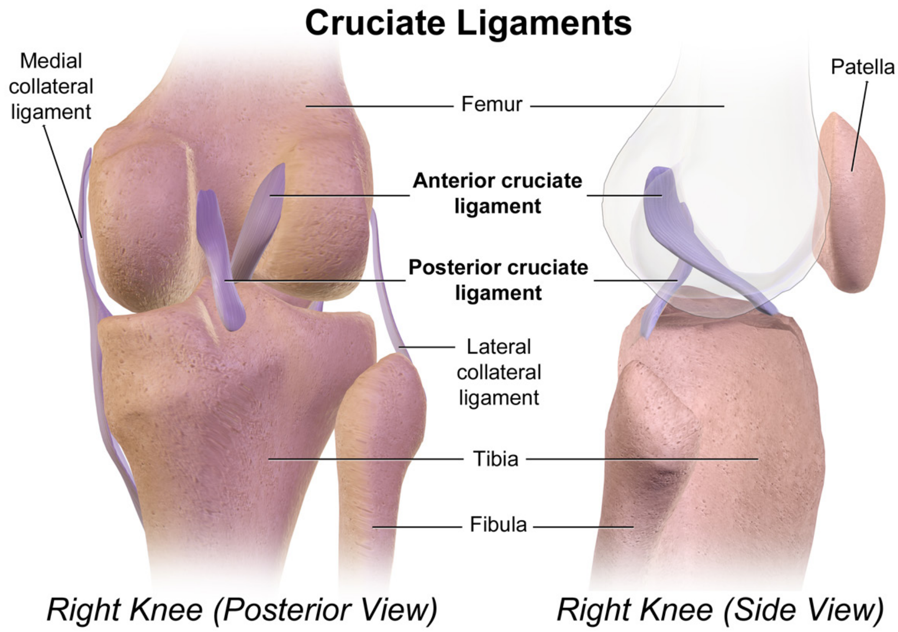


Figure 14: Anatomy of the knee with the cruciate ligaments indicated [21]

describe the PCL or if a one bundle description would be more accurate [24].

The function of the PCL is to provide stability to the knee by restraining posterior tibial translation [24]. However, due to the orientation and tightening of the bundles of the PCL they are not able to withstand posterior tibial translation during full extension. So during full extension other parts of the knee joint must provide this stability. Therefore, a PCL injury leads to less instability than for example an ACL injury [23].

2.3 KNEE INJURIES

Since it is such a complex and heavily loaded joint the knee is the most commonly injured joint [25]. Since the use of the orthosis will be focused on cruciate ligament injuries this section will also focus on these injuries. However, cruciate ligament injuries can occur in combination with other knee injuries and therefore other common injuries will also be briefly mentioned.

2.3.1 LIGAMENT INJURIES

Injuries to the ligaments, both the cruciate and the collateral ligaments, are the most occurring knee injuries together with injuries to the menisci [1]. Since the ligaments provide the stability to the knee joint a rupture or other injury to a ligament can cause instability and laxity of the knee joint [11]. Also, when a ligament is injured it cannot carry its usual load, therefore the other ligaments must carry the residual load which heightens the risk for further injury to these other ligaments [7]. Treatment of a ligament injury can be a surgical repair of the ligament or nonsurgical by firstly immobilizing the knee and by physical therapy [26]. Orthoses are used for ligaments injuries to stabilize the knee and by limiting the range of motion. This helps to prevent reoccurrence, but also prevents the knee, which is more lax now, to hyperextend [27].

ACL injuries are reported to occur when the knee is near full extension and mostly occur during non-contact and weight-bearing situations. The injury takes place when the person suddenly decelerates. This can for example be while running by coming to a stop or a sudden change of running direction or it can be when landing from a jump [28].

PCL injuries have two likely ways of occurring. The first is when a large force is anteriorly placed on the top of the tibia. Forcing the tibia

Figure 15: Situation that can cause a PCL injury [30]

backwards and thereby injuring the PCL. The second scenario which can cause an injury to the PCL is when a person falls on their knee while it is flexed and the foot is in a plantarflexion position, an example of this is shown in figure 15. Another situation which is less common but which can also cause a PCL injury is when the knee is hyperextended [29].

As said a ligament injury leads to instability of the knee joint. This can cause the motion pattern of the knee to change, which could cause osteoarthritis [31]. It is not always possible for the knee to make a full recovery after a ligament injury. However, it can be possible for patients to return to their sport, but possibly at a lower level than before [31].

2.3.2 OTHER KNEE INJURIES

Meniscal tears can occur when the upper leg suddenly rotates while the lower leg stays in place [5]. If the tear of the meniscus is small and located on a convenient location it can be treated with rest and anti-inflammatory medicine. In other cases the meniscus must be surgically repaired [26]. After this an orthosis can be used to again create stability, prevent hyperextension, but also to reduce the pressure from the body of the lower leg and thus of the meniscus [32].

In a similar way as the ligaments the tendons can also be injured. Since tendons connect the muscles to the bone, a rupture of the quadriceps tendon can cause the patella to dislocate due to it not being fixed in its place by the quadriceps tendon [26]. A tendon tear is often treated by surgically repairing the tendon, but can in a few cases be solved non-surgically by immobilizing the joint [26]. An orthosis is used for this to support healing of the tendon. After a first stage of total immobilization, the range of motion can gradually be increased [33].

Other injuries that can occur are a fracture of the patella, which can also be treated by immobilizing the joint with an orthosis [34], joint instability and chondromalacia, where the articular cartilage of the kneecap has softened [5]. Another, non-sports related, injury to the knee joint is osteoarthritis. Here the articular cartilage of the joint has gradually worn, which exposes the underlying bone. This can cause great discomfort during movement and damage to these bones. Osteoarthritis is mainly caused by old age and by the patient being overweight [5]. Osteoarthritis can also be helped with the use of an orthosis, which helps to shift the load of the damaged section of the joint and provides extra stability [35].

2.3.3 CONCLUSION

Due to the complex nature of the knee joint and its many elements many possible injuries exist. Most of these injuries can be repaired using surgery. However, the need for this depends on the extent of the injury. In all these cases, surgical or not, an orthosis can be used to help treat the injury. However, the functioning of the orthosis depends on the type of injury.

2.4 PROBLEM DEFINITION

Since the use of orthoses in knee rehabilitation has become more common in the past decennia the issues with the use of these orthoses have become more apparent and of importance. The main problem experienced during the use of an orthosis is migration of the orthosis. This problem has two main causes: the conical shape of the legs and the mismatch between the hinges that are currently used in the orthoses and the knee joint.

Gravity is pulling downwards on the orthosis causing migration. Since the leg have a conical shape which is pointing downwards there is no suspension point on the leg which could help keep the orthosis in place to counter the force put on the orthosis by the gravity.

The knee is a complex joint that is influenced by many different parts and factors resulting in a complex movement. The combined rolling and sliding movement and the shape of the femoral condyles causes a J-shaped pathway that the instantaneous center of rotation of the knee follows. In current hinges for knee orthoses this complexity is not represented. Most of the commonly used orthoses with hinges use either a single or dual axis hinge. The use of these hinges causes a mismatch between the way the orthosis rotates and the way the knee rotates.

This mismatch causes unwanted forces which causes problems such as chafing, misalignment and stress on the ligaments. The goal of an orthosis for cruciate ligament injuries is to avoid stress on the injured cruciate ligaments. This mismatch between the knee joint and the orthosis hinge undermines this. Furthermore, adequate support depends on the correct placement of the orthosis and misalignment compromises the ability of the orthosis to correctly guide the movement.

It is shown that the functioning of the orthosis is highly dependent on its alignment. Therefore, it must be tried to avoid migration of the orthosis. Since there are two causes of the migration both must be addressed. So firstly it must be tried to overcome or compensate for the conical shape of the leg and secondly the current hinge design must be altered to avoid the existing mismatch.

3. Analysis

This chapter presents the research done in preparation for the design process. The target group, stakeholders, user experience and the current market are researched. Furthermore, interviews are performed with experts and the requirements are composed.

3.1 TARGET GROUP

The orthosis is meant for patients with cruciate ligament injuries, so either the ACL or PCL. So to understand the target group it must be understood in which situations such injuries occur and which persons are likely to sustain such injuries.

Of the cruciate ligament injuries only a small amount are to the PCL. The majority are ACL injuries. In 95% of the trauma cases to the PCL the patient is also suffering other ligament injuries in the knee, such as an ACL injury [29]. However, this does not mean that cases with isolated PCL injuries do not exist, but these are only 1.6% of the cases where patients suffered a ligament injury to the knee [36]. Similar to the PCL when a patient suffers from an ACL injury they likely also suffer from other injuries to the knee, such as meniscus lesions and/or medial collateral ligament lesions. However, while it is likely for a patient to also have other injuries with an ACL injury the occurrence rate of a multiple ligament injury is with 80% not as high as with PCL injuries [37].

Most patients with an ACL injury are male although women have a higher risk of an ACL injury. The difference between these two facts can be explained by the fact that many ACL injuries take place during sports and more males participate in these sports [38]. A study in the occurrence of ACL and PCL injuries in US collegiate (American) football and basketball shows that the incidence rate of an ACL injury for men is 0.12 per thousand athletes for football and 0.1 for basketball. For women the same rates are 0.33 for football and 0.29 for basketball. This clearly shows the higher likelihood for women to sustain an ACL injury. These rates are much lower for PCL injuries: for both men and women 0.04 for football and 0.01 for basketball [39]. These numbers indeed show that the risk to sustain a PCL injury is much lower than an ACL injury. Furthermore, it can be seen that PCL injuries do not have the same higher risk for women that ACL injuries have. Another study shows that high risk ages for sport related ACL injuries are 20 to 39 and 55 to 59 [38]. While another study even states that 50% of the ACL injuries are in persons aged 15-25 [40].

Most of the ACL injuries take place during sports activities. A study of ACL injuries in New Zealand showed that of the nonsurgical ACL injuries 32.5% took place at a recreation or sport location, while this number was 65.1% for surgical ACL injuries [38]. ACL injuries mainly occur in ball sports that requiring running such as football, volleyball, basketball and squash [38, 39].

A common case where a PCL injury occurs is during a car crash when a person is hit in the knee by the dashboard. This causes the anterior force on the top of the tibia that causes a PCL injury. However, PCL injuries can also occur during sports, for example when a person is kicked or falls.

3.1.1 CONCLUSION
For the target group this information means that the patients will most likely have an ACL injury. However, isolated PCL injuries are also possible. The injury to the ACL or PCL will most likely be combined with other injuries to the knee, such as meniscus and MCL damage. Furthermore, the users will most likely be involved in sports and male, but the number of female users could increase due to the higher risk and increase of females in athletic activities. The users will most likely not be young children or elderly and range from the ages of 15 to 60. Moreover, the user group will most likely be dominated with young users between the ages of 15 to 25.

3.2 STAKEHOLDERS
To understand which parties have interest in this design project and how they could possibly influence it a stakeholder analysis was performed. The stakeholders that were defined are BAAT medical, the future client, orthopedic surgeons, rehabilitation physicians, orthopedic technicians, physical therapist, users, insurance companies and manufacturers. All these stakeholders are reasonably well defined except for the future client. BAAT medical develops medical products for their clients, but a client that would want to develop an orthosis as presented in this project has not been found yet. This causes it to be unclear what type of company is pictured as the future client. The possibilities for the future client range from an orthosis manufacturer to a shop chain, since it is possible to sell the concept to a manufacturer but also to directly provide the braces to relevant shops. The analysis is shown in table 1.

3.2.1 CONCLUSION
While multiple stakeholders exist only a limited number have real influence on the project. However, these stakeholders with low influence on the project can be of high value due to the knowledge they possess. Therefore, this must be considered and taken advantage of during the design process.

3.3 EXPERT INTERVIEWS
To gather useful information for the development of the orthosis interviews were conducted with relevant experts. These experts were the managing director of BAAT medical, a human movement scientist at ‘OCON’ which is an orthopedic clinic, a rehabilitation physician at ‘Roessingh research and development’, an orthopedic technician at ‘Roessingh revalidatie techniek’ and a physical therapist at ‘Fysiocentrum Kamminga’. The gathered relevant information from these interviews is summarized below.

3.3.1 BAAT MEDICAL
The current market for knee orthosis is very large but is not innovative. This is illustrated with the problem of the orthosis sliding down and the mismatch between the current hinges and the knee joint. These problems are simply accepted as unsolvable and it is generally not tried to fix this because of it. The idea for this project is to try and fix these problems.

Furthermore, current orthosis designs are driven by the needs of product managers and manufacturers while the needs of patients are considered of lower importance. The goal is to design this orthosis with the needs and problems of patients and their treating physicians as a driving force.

Besides trying to fix the migration and hinge problem with a new orthosis the design should focus on providing stability to the patient. Furthermore, it must be possible to both have a flexible flexion and extension stop.

3.3.2 ORTHOPEDIC CLINIC
Patients are referred to the orthopedic clinic by their primary physician. At the clinic the extend of the injury is assessed. When a tear of the ligament is suspected an MRI is made to confirm this. Based on the age and the ambition of the patient it is decided to use a surgical treatment or to train the leg to compensate for the damaged ligament. To be able to qualify for a surgical treatment the difference in performance between the injured and uninjured leg must be no larger than 20%. This is to avoid reinjury or injuries to the healthy leg due to overcompensation.

Currently there are two surgical treatment methods used in this specific clinic. The first is the established method in which the ligament is replaced by another ligament. The second is an experimental method where the damaged ligament is sutured. These methods take place at different moments after the injury. When the first method is used the knee must recover from the swelling and trauma the injury has caused before the repair is done. This is done to avoid the new ligament to be affected by the still present damage in the knee. With the second method the suture repair must be done as soon as possible. When the established method is used no brace is used, but with the experimental method a brace is used right after the repair. The brace is put on in the operation room after the

Table 1: Stakeholder analysis

Stakeholder	Interest	Influence	Expectations	Potential	Implication
BAAT medical	High	High	Obtain a detailed knee orthosis design to sell to interested parties	Provide wishes and expertise on development of such a knee orthosis	Have close contact to ensure satisfaction with the project and acquire present knowledge
Future client	High	Low	Obtain a unique design which will have an advantage with respect to other knee orthoses	Bring the knee orthosis to the market	Consider their possible needs during design
Orthopedic surgeon	Medium	Low	A knee orthosis which will improve the rehabilitation of patients	Provide insight on the knee joint, the process of rehabilitation and knee orthoses	Meet to understand point of view and acquire knowledge
Rehabilitation physician	Medium	Low	A knee orthosis which will improve the rehabilitation of patients	Provide insight on the knee joint, the process of rehabilitation and knee orthoses	Meet to understand point of view and acquire knowledge
Orthopedic technician	Medium	Low	A knee orthosis which will improve the rehabilitation of patients	Provide insight on the knee joint, the process of rehabilitation and knee orthoses	Meet to understand point of view and acquire knowledge
Physical therapist	Medium	Low	A knee orthosis which will improve the rehabilitation of patients	Provide insight on the knee joint, the process of rehabilitation and knee orthoses	Meet to understand point of view and acquire knowledge
User	High	Medium	A knee orthosis which improves rehabilitation and comfort	Provide insight on daily use of knee orthoses	Involve to ensure user-centered design
Insurance companies	Low	Low	A knee orthosis which will improve the rehabilitation of clients and that is priced in such a way that they are cheap, but effective without major complications	Potentially enabling the distribution of the knee orthosis	Consider during design
Manufacturers	Low	Low	A knee orthosis that is manufacturable and manufacturable on the available machinery	Provide production possibilities and produce orthosis	Consider manufacturing possibilities during design

repair and must be worn for one or two weeks continuously except when in bed. This is done to help the patients to be mobile right away to reduce complications but without straining the still weak ligament.

An orthosis that would follow the knee's natural movement could possibly be helpful for an orthopedic clinic to use as a testing device. If it could be used to measure the torques placed on the knee during actual sport situations this would greatly improve the value of the performance tests. The current tests are performed in a laboratory setup and are thus not a very accurate representation of real scenarios.

At the moment sport physicians do not use orthoses since they limit too much of the degrees of freedom of the knee. When this would not be the case they would possibly reconsider the use of orthoses since they could help the users to return to sports sooner. This could be aided by creating a brace for which it is possible to reduce the amount of support it gives. Ideally the brace gives full support at the beginning of the rehabilitation process, but as the strength of the knee increases the amount of support delivered by the brace should decrease to give the knee the opportunity to gain more strength.

3.3.3 REHABILITATION PHYSICIAN

Functional braces are typically used in two scenarios. The first is for people who are not treated surgically for their cruciate ligament injury and therefore have instability in the knee joint. These persons can wear an orthosis during active situation to help provide stability to the injured knee. The other scenario is for people who are treated surgically but lack the confidence in their repaired knee. They can wear an orthosis during activities such as sports to increase their confidence and make sure they remain active.

The choice between a surgical or nonsurgical treatment is based on a few factors. The first is the extent of the injury. Is the ligament completely torn or partially? The second is the age of the patient and the third is the level of activeness of the patient. If the patient is not active it is not worth it to do a surgical repair, while it can be favorable to repair a ligament if the patient actively participates in sports even if the ligament is only partially torn.

Cruciate ligament injuries mainly occur in young patient and in combination with other knee injuries. Mostly this is an injury to the MCL. The goal of an orthosis for cruciate ligament injuries should be to avoid anterior-posterior translation of the femur.

Orthoses cannot help and prevent reinjury, since they are not capable of stopping the large forces which cause cruciate ligament injuries. Instead their function is to provide confidence to the patient, guide the movement of the knee in normal motion patterns and provide stability. To provide this stability orthoses meant for cruciate ligament injuries generally have rigid frames. This causes these orthoses to be relatively expensive. Therefore, insurances tend to only reimburse one orthosis since this completely uses the budget. So users do not switch to other braces later in the treatment process.

When considering the found results from literature studies about the knee joint one must be careful. This is since cadaver knees can act differently than normal knees. This is caused by degraded menisci in cadaver knees and due to the fact that they are not weightbearing. Therefore, conclusions of studies with cadaver knees should not necessarily be assumed to be true for normal knees.

The biggest problem with current orthoses is the migration problem. The two main causes for this are the conical shape of the leg and the mismatch between the hinge and the knee joint. This makes this project to design a hinge which resembles the knee joint relevant. This is not only due to the migration problem, but also since this mismatch is bad for the rehabilitating knee.

3.3.4 ORTHOPEDIC TECHNICIAN

Generally speaking there exist two kinds of orthoses for cruciate ligament injuries: light sleeves or rigid heavier full orthoses. The sleeve type orthosis only supplies minimal support while the rigid type orthoses supply much more support. Therefore, the rigid types are meant for more serious injuries while the sleeve types are meant for only mild injuries. Within these categories all the existing orthoses are very similar in functioning and design. The only regularly used orthosis with a different design is the CTi from Össur. This has a deviating hinge design that is more similar to the knee joint. Therefore, this orthosis is considered to be the best in its field and to be the benchmark. Lastly, it was again confirmed that the sliding down of the orthoses is the biggest current problem.

3.3.5 PHYSICAL THERAPIST

A physical therapist is closely involved with the rehabilitation process of a patient. After injury the patient comes to the physical therapist or is referred by a general practitioner. The physical therapist assesses the injury and refers the patients to an orthopedic surgeon when necessary. Physical therapy is started immediately to strengthen the patient for surgery and is continued after surgery to help rehabilitate the patient. The total rehabilitation process normally takes 9-12 months. Where the patient slowly returns to sports around 7-8 months post-surgery.

In the east of the Netherlands orthoses are not used for exclusive ACL injuries. This is since the surgical reconstruction have become better over time. This does not leave the reconstructed areas as vulnerable as they used to be after reconstruction causing an orthosis to be unnecessary. Orthoses are used if the ACL is injured in combination with the MCL or a meniscus. Furthermore, they are also used for PCL injuries. The goal for the orthosis with MCL injuries is to avoid valgus rotation and for meniscus is to limit flexion to avoid too large loads on the recovering meniscus. These braces are used for 24 hours a day over a longer time period.

A common problem encountered with the use of orthoses is that they do not support complete extension correctly. What is meant to be full extension is actually around 5° flexion. This could lead to patients not being able to fully extend their knee.

3.4 USER EXPERIENCE

A small online study was done to gather A small online study was done to gather experiences users had with the use of orthoses for knee injuries.

A common discussion online under users is regarding the effectiveness of the orthoses [41]. Similar discussion can also be found in literature. Opinions on this topic vary quite drastically from passionate opponents to supporters and all levels in between. The most commonly voiced counter argument references studies that show that orthoses do not contribute to the recovery of knee injuries. In contrast the commonly voiced arguments in favor of wearing orthoses are increased confidence and it creates visibility of the injury in public. This helps to alert bystanders to the injury which makes them more patient and careful with the person wearing the orthosis.

Another often seen discussed topic is the problem of the orthosis sliding down [41, 42]. Some individuals even complain of the orthosis completely sliding down within taking a few steps. That this topic is so much discussed on user message board also shows that it is either not solved effectively in the design or the users are not correctly informed on how to wear the orthosis. The online discussion show that the problem occurs frequently due to both these causes. This results in users informing each other on how to properly wear the orthosis and also proposing their own concocted solutions to the problem. These solutions range from always gripping the top of the orthosis to prevent it from sliding, adding suspenders and to adding adhesive bandages.

Lastly, an often talked about topic is if the orthosis should be worn over or under clothes [41, 42]. The majority of the users seem to prefer to wear the orthosis on the skin, stating that wearing it over clothes is uncomfortable by the material creasing due to the tight orthosis and causing indentations and irritations. Some people overcome this problem by wearing tight and stretchy clothes under the orthosis. However, this can contribute to the orthosis sliding down due to decreasing the friction with the orthosis.

3.5 KNEE ORTHOSES

Three groups of knee orthoses exist: prophylactic, which are used to prevent injury, functional, which are used to provide stability and substitute for a damaged ligament [43] and rehabilitative orthoses, which are used during post-operative rehabilitation and protect the range of motion [1]. This thesis will focus, as indicated earlier, on the functional orthoses.

3.5.1 FUNCTIONING OF THE ORTHOSIS

A perfect orthosis should be able to allow a full range of motion and should only constrain the knee joint when the limits of the range of motion are reached [44]. A common problem with knee orthoses is the point at which the orthosis will apply forces to the joint to resist unwanted movement. The wanted position of this point might differ per injury, but generally this point is located at soft tissue making it difficult to apply the needed force to the correct position [45]. This soft tissue also creates another much occurring problem with the use of knee orthoses. Since this tissue is compressible it can allow the orthosis to move downwards causing the hinge of the orthosis to be wrongly aligned with the actual knee joint [1]. The functioning of the orthosis is strongly dependent on the correct placement of

Figure 16: Single axis orthotic knee joint [46]

Figure 17: Polycentric axis orthotic knee joint [46]

the hinge of the orthosis [1, 4]. The accuracy of the placement of the hinge must be within a few millimeters to ensure good performance of the orthosis [4]. So this tendency of the orthosis to slide, also caused by the forces that are placed on the orthosis, endangers the performance of it [45].

3.5.2 HINGE

The simplest hinge, which is commonly used, is a single axis hinge. An example of such a hinge can be seen in figure 16. Since this hinge grossly oversimplifies the kinematics of the actual knee joint, which were presented earlier, another frequently used hinge is the polycentric hinge, depicted in figure 17. This hinge resembles the actual knee joint more closely, but still differs considerably. This hinge contains two rotation points: one connected to the part of the orthosis on the upper leg and one for the part of the lower leg. These rotation points are connected by a small component. This construction results in a moving rotation point for the rotation of the upper part with respect to the lower part.

Oversimplifying the joint of the knee can cause serious damage to the knee joint and would therefore worsen the situation of the patient [2]. This damage is inflicted by unwanted forces which are induced by this mismatch between the orthosis hinge and the joint [44]. These forces stress the ligaments in the joint which causes them to become lax [1]. Furthermore, this mismatch can also unintentionally limit the range of motion [1] and cause the orthosis to misalign [2]. Lastly, the remaining difference between the joint and the hinge which is not carried by the ligaments causes deformation of the soft tissue around the joint, which can cause chafing between the brace and the skin [4]. This shows the importance of creating a hinge which accurately resembles the knee joint. The difficulty here is that the pathway of the instantaneous center of rotation differs per individual, as mentioned earlier. Therefore, for a knee orthosis to correctly resemble an individual's knee joint kinematics it must be custom made to their instantaneous center of rotation pathway or it must be possible for the hinge of the orthosis to adjust to the user that is wearing it.

3.5.3 CONCLUSION

This thesis will focus on the functional orthoses. The task of these orthoses is to stabilize the knee joint while allowing for the natural range of motion. An important factor in this is the correct placement of the hinge. The placement of the hinge can be compromised because it is possible for the orthosis to move or slide down due to the soft tissue around the knee joint. Incorrect placement can cause damage to the knee joint and is therefore unwanted. To solve this migration of the orthosis must be avoided and it should resemble the kinematics of the knee joint to eliminate the difference between the orthosis and the knee joint as best as possible.

3.6 EXISTING KNEE ORTHOSIS HINGES

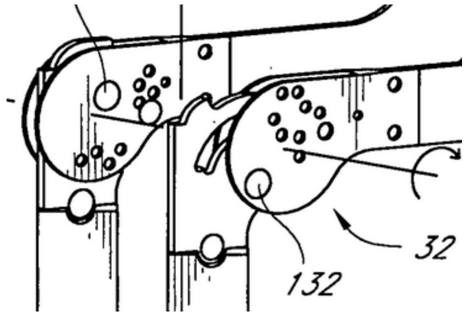
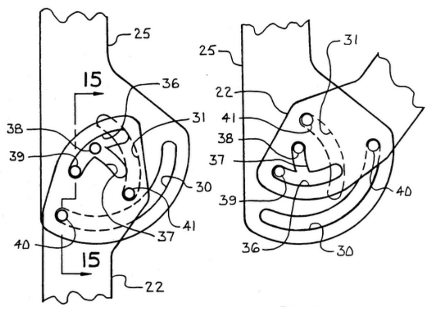
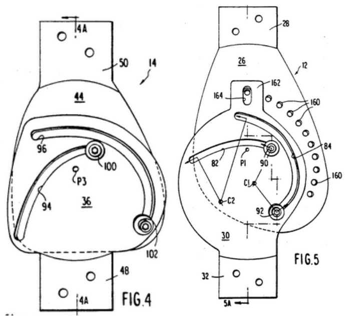
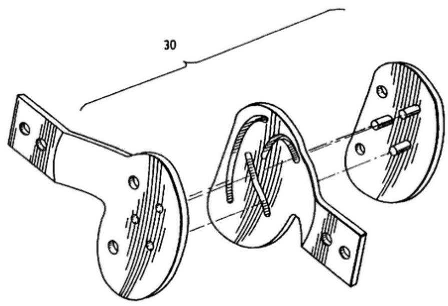
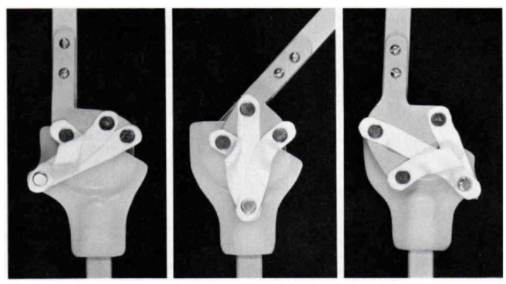
Table 2 shows different hinge designs that all try to resemble the natural pathway of the knee joint, what must be noted for these hinges is that as far as could be determined none of these hinges are currently on the market. It can clearly be seen that the polycentric hinge is simplistic in comparison to the other shown designs. This also indicates that although it is designed to better resemble the natural knee joint motion the difference is still considerably.

It can also be noticed that many of the other designs use slots to guide the rotational axis along a pathway. However, the number of slots used differs. The 'internal-external rotation hinge' design uses a single slot. This helps to resemble the natural pathway, but would only rotate the rotational axis creating a C-curve instead of a J-curve. The big advantage of this designs is that it includes the internal-external rotation the knee joint experiences during flexion. This is possible since a little leeway was created at the connection point of the hinge and the lower leg rod.

The ‘double slot hinge’ has two slots which guide the rotation point along its pathway. Having two slots allows the curve of the pathway to not be a perfect circle and thus helps to better resemble the natural pathway.

The other designs which use slots to guide the

Table 2: Existing hinge designs

Hinge	**Polycentric hinge**	**Internal-external rotation**
Picture	 Figure 18: Polycentric hinge [46]	 Figure 19: Internal-external rotation hinge [47]
Functioning	Dual axis is used to resemble the dynamic rotation axis of the knee	Hinge follows a pathway through a slot
Specifics	Rotation axis is static	It is also possible for the hinge to make small internal-external rotations
Hinge	**Double slot**	**Limited ROM**
Picture	 Figure 20: Double slot hinge [48]	 Figure 21: Limited ROM hinge [49]
Functioning	The two slots should follow the pathway of the knee joint	Two slots that follow the pathway of the knee joint
Specifics		Rotation can be limited with holes
Hinge	**Triple slot**	**Ligaments imitation**
Picture	 Figure 22: Triple slot hinge[50]	 Figure 23: Ligament imitation hinge [44]
Functioning	Three slots that must follow the natural pathway of the knee joint	Textile bands guide the rotation of the hinge
Specifics	Medial and lateral hinge each have their own pathway	Imitates the ligaments of the knee joint

pathway of the rotational axis do not differ much, but some small difference exist. For example, the 'limited ROM hinge' has the possibility of limiting the range of motion by blocking the rotation with the use of holes. The other slot-based hinge design, the 'triple slot hinge' has different slots for the medial and lateral hinge. This accounts for the different pathway the instantaneous center of rotation follows on each side of the knee joint.

The last hinge design is the 'ligament imitation hinge' design. This design did not try to create the natural pathway of the instantaneous center of rotation but tried to resemble the anatomy of the knee by creating artificial ligaments on the hinge. Three artificial ligaments are placed on the hinge to compensate for the length differences that occur in the cruciate ligaments during flexion. By imitating the anatomy of the knee joint it was tried to also make the hinge imitate the natural pathway of the rotational axis.

3.6.1 CONCLUSION

Multiple different orthoses exist which try to mimic the motion of the natural knee joint. Most of these orthoses function by guiding the rotation point along one or multiple slots, although other methods also exist. These orthoses differ in how closely they try to resemble the knee joint. While some try to exactly mimic the joint others only adjust their design slightly.

3.7 EXISTING KNEE ORTHOSES

As previously stated not many existing orthoses have hinges that try to resemble the knee joint. However, this does not mean that it is not beneficial to research existing orthoses for the development of the current orthosis. Therefore, table 3 shows an overview of existing orthoses used for cruciate ligament injuries.

It can be seen in the table that all orthoses have a rigid frame. These frames are either made from carbon fiber or aluminum to minimize the weight of the orthosis. This is done since a higher weight could cause extra migration of the orthosis and could be uncomfortable or awkward for the user. Although the shape of the rigid frame is very similar for all the designs there are some differences in application. For example, the Donjoy Defiance III and the M.4s orthoses both use a rigid frame that is located at the front on the upper leg and at the back on the lower leg. Conversely, the other braces use a frame that is located at the front for both the upper and the lower leg. Furthermore, the Compact X2K orthosis has a small variation on the frame design since it includes frame parts running from the middle of the frame to the hinges. Breg states these parts are added to improve the varus-valgus stiffness of the frame [51]. Lastly, all the orthoses are supplied in set sizes except for the Rebound DUAL. The frame of this orthosis is adjustable in height.

Furthermore, it can be seen that the current orthoses are not only similar with respect to the used frames but also other aspects of the design. All the orthoses use the mentioned rigid frame, Velcro straps and padding to protect the user from the rigid parts. What does deviate is the used hinge. The first three orthoses shown in table 3 use polycentric hinges. This research showed that almost all orthoses used for ligament injuries use these hinges. The last two orthosis in the table deviate from this trend. They both use their own patented hinge system that tries to resemble the rolling and gliding motion of the knee joint. Of these two braces the M.4s is relatively unknown while the CTi is much more accepted. As mentioned earlier the orthopedic adviser described this orthosis as the benchmark in the sector.

The CTi brace uses excentre gears in its hinge to mimic the rolling and sliding motion. Furthermore, it can be seen that the rigid horizontal parts of the frame are not used to attach the Velcro straps and close the orthosis as the other shown examples due. Instead, a more flexible appearing padded part is added which fulfills this function.

All these braces are meant for both ACL and PCL injuries. To support with ACL injuries the anterior translation of the tibia must be resisted and with PCL injuries the posterior translation of the tibia. How these braces handle this double function differs per brace. All braces have a rigid part only on one side of the lower leg. Some have this part on the front, making it more ideal for ACL injuries, and some on the back, making it more ideal for PCL injuries. Most of the braces accommodate the other type of injury simply by having Velcro straps resist movement in the non-rigid directions. The brace that differs in this aspect is the CTi brace. This brace provides an extra PCL kit which can be added to the brace when necessary. The kit consists of a hard pad which is placed on top of the calf to apply pressure at this point and help to alleviate the load on the PCL.

Table 3: Existing knee orthosis

Hinge	**Donjoy Defiance III**	**Rebound DUAL**
Picture	 Figure 24: Donjoy Defiance III knee orthosis [52]	 Figure 25: Rebound DUAL knee orthosis [53]
Manufacturer	Donjoy	Össur
Specifics	Functional knee brace for ACL and PCL injuries. Rigid carbon fiber frame.	Functional knee brace for ligament instability. Rigid frame adjustable in height.
Hinge	**Compact X2K**	**M.4s**
Picture	 Figure 26: Compact X2K knee orthosis [51]	 Figure 27: M.4s knee orthosis [54]
Manufacturer	Breg	Medi
Specifics	Functional knee brace for ACL, PCL and collateral ligament injuries. Rigid frame in diamond shape for varus and valgus stiffness.	Functional knee brace for cruciate and collateral ligaments injuries. Rigid aluminum frame combined with Physioglide hinges that imitate the rolling and gliding motion of the knee joint.
Hinge	**CTi**	
Picture	 Figure 28: CTi knee orthosis [55]	
Manufacturer	Össur	
Specifics	Functional knee brace for ACL, PCL, MCL and LCL instability. Rigid carbon fiber frame combined with Accutrac hinges that imitate the rolling and gliding motion of the knee joint.	

3.7.1 CONCLUSION

Many different orthoses for cruciate ligament injuries are available in the current market. These braces are, however, in most cases very similar. Only a few stand out by having a slightly different design, which in the case of the CTi brace causes it to be preferred.

3.8 DESIGN ASSIGNMENT

The aim of this design is to obtain an orthosis which does not migrate and is still able to fulfill its rehabilitating functions without the risk of doing unwanted damage to the joint. To achieve this the hinge must allow the natural pathway of the center or rotation of the individual to be followed.

3.8.1 BOUNDARIES

The final product developed in this assignment will be a prototype and not a completed product. The orthosis will be designed for adults. It was chosen to focus the design of the orthosis for anterior cruciate ligament injuries since these are the most common cruciate ligament injuries. Since these injuries predominantly occur during sports the orthosis will not have to be able to accommodate obese patients.

3.9 FUNCTIONS

Based on the theory and the analysis functions for the to be developed orthosis can be defined. These are listed below:

- Fix to the upper and lower leg and avoid migration
- Adjust to leg shape of the user
- Indicate the correct position to users
- Indicate the presence of an injury to other people
- Allow flexion-extension of the knee
- Limit anterior-posterior translation
- Limit varus-valgus rotation
- Be able to limit flexion-extension to individual preference
- Allow the rotation of the knee to freely follow the user's natural pathway
- Constrain abnormal movements
- Provide feedback for natural movements
- The orthosis does not have to actively apply load to unload certain parts of the knee joint

3.10 REQUIREMENTS

3.10.1 HINGE MOVEMENT

TThe hinge must allow the natural pathway of the center or rotation of the individual to be followed. This must be true for all possible users, so the hinge must be able to allow the rotation point to follow each of their personal pathways.

The hinge must be able to allow the normal motion of the knee joint. The normal motion of the knee joint occurs in six degrees of freedom as mentioned previously. The largest motion is the flexion-extension movement, followed by the internal-external rotation, the anterior-posterior translation and the proximal-distal translation. The varus-valgus rotation and the medial-lateral translation are the smallest movements. Therefore, movement of the hinge must be possible in the first four degrees of freedom and ideally in all six. This movement must be limited to the natural range of motion. Therefore, the hinge must allow for 0-120° of flexion and extension and 10° of internal external rotation, since this amount of internal-external rotation takes place during flexion and extension [14].

The end points of the range of motion and thus the pathway must be fixed to avoid movement of the knee joint that are not part of the normal range of motion. The hinge does not have to be fixated when the ends of the range of motion are reached, but that the flexibility that is present during the movement of the knee joint is not present for the end points.

For some rehabilitation processes it is needed to be able to limit the range of motion of flexion-extension. So it must be possible to set the maximum flexion and extension angles. This must be possible in steps of 10°, where it must be clear for the user, either the patient or the physician, at what angle the hinge is set and how to change this angle. Lastly, during use it must not be possible that these maximum angles have unwanted changes.

3.10.2 HINGE DIMENSIONS

For the comfort and aesthetics of the orthosis the hinge cannot be too large, the dimensions are restricted to 100 mm, this could cause the user to feel uncomfortable wearing the orthosis or they could, for example, bump the orthosis into their other leg or onto their surroundings causing discomfort. Lastly, the orthosis cannot weigh more than comparable orthoses on the market, which weigh 0.5-1 kg.

3.10.3 ORTHOSIS POSITIONING

For the orthosis to function properly the hinge must be placed in correct alignment with the knee joint within 5 mm. The orthosis must facilitate the correct placement of the hinge and it must maintain its position on the leg during use. Furthermore, it must also be clear how to put the orthosis on. It should be possible to finish within 60 seconds.

3.10.4 STABILITY

The orthosis must provide stability to the user. It must do this by avoiding unnatural movements by restricting the degrees of freedom as mentioned previously. Furthermore, it must provide stiffness, primarily in the anterior-posterior direction, to help provide the stability, since the ACL is not providing its normal stiffness in this direction, and create a sense of security for the user.

3.10.5 USER COMFORT

The orthosis must be as comfortable for the user to wear as possible. Injuries or discomfort due to harder parts of the orthosis must be avoided. The parts that come into contact with the skin must be cleanable and be removable to facilitate this. Furthermore, the materials used in the orthosis must not be irritating for the skin. This must also be the case during sport activities which will cause higher temperature and moist conditions due to sweating. This also means that the material must be breathable to avoid excessive sweating under these parts. Lastly the orthosis and the hinge must not be able to injure the user during use but also during transportation or while putting the orthosis on.

3.10.6 LIFETIME

The orthosis must have a lifetime that is longer than the time needed by the user for rehabilitation, which is 12 months. During this time the user will use the orthosis during walking and other activities. This causes repetitive movements in the hinge. Therefore, the hinge must be able to withstand these movements for the length of the lifetime. The average amount of steps taken per day for a person is around 5000 depending on the country. This amount can vary much depending on the occupation of the person [56]. For this case an amount of 16000 steps per day is taken. This to be sure that the hinge will be able to function during the entire lifetime of the orthosis, even for the users that take an above average number of steps per day. To further ensure the durability of the orthosis it must be made with materials that do not deteriorate due to substances that one is likely to encounter during normal use of the orthosis, for example water and sweat.

The full list of resulting requirements can be seen in table 4.

Table 4: Requirements

Requirement	**Ideal**
Hinge	
Hinge must allow the rotation to follow the pathway of the instantaneous center of rotation of the joint: • Flexion-extension rolling combined with anterior-posterior sliding • Pathway must be flexible to adjust to different individual pathways • Begin and end point of pathway must be fixed	
Hinge must allow four degrees of freedom: flexion-extension rotation, anterior-posterior translation, proximal-distal translation and internal-external rotation	Hinge must allow six degrees of freedom: flexion-extension rotation, anterior-posterior translation, proximal-distal translation, internal-external rotation, varus-valgus rotation and medial-lateral translation
Unnatural movements must be constrained • Hyperextension must be avoided • Flexion must be constrained above 120° • Anterior-posterior translation must be constrained above 10 mm • Proximal-distal translation must be constrained above 5 mm • Internal-external rotation above 10 degrees must be constrained • Varus-valgus rotation must be constrained • Medial-lateral translation must be constrained	Unnatural movements must be constrained • Hyperextension must be avoided • Flexion must be constrained above 120° • Anterior-posterior translation must be constrained above 10 mm • Proximal-distal translation must be constrained above 5 mm • Internal-external rotation above 10 degrees must be constrained • Varus-valgus rotation above 8 degrees must be constrained • Medial-lateral translation above 2 mm must be constrained

Table 4: Requirements

Requirement	**Ideal**
Hinge	
• It must be possible to individually set maximum flexion and extension angles • Adjustments should be possible in steps of 10° • Adjustment method must be straightforward and easy (Must be comparable in ease with current orthoses) • Orthosis must clearly show at what angles the hinge is fixed • It must not be possible to have unwanted adjustments of the fixed flexion and extension angles	
The hinge must be able to withstand the repetitive movements of 16000 steps per day • In total almost 600000 movements	
The hinge cannot be larger than 100 mm in diameter	The hinge cannot be larger than 70 mm in diameter
General orthosis	
The orthosis should maintain its position on the leg • It should not migrate more than 5 mm • It must not rotate more than 10°	The orthosis should maintain its position on the leg • It should not migrate • It must not rotate
The orthosis must facilitate the correct placement of the hinge with respect to the knee joint within 5 mm	
The orthosis must provide stability to the knee joint	
Lifetime of the orthosis must be 12 months	
Orthosis must avoid discomfort of the user	
Parts in contact with the skin must be easy to remove	
Parts in contact with the skin must be machine washable at 30 °C	Parts in contact with the skin must be machine washable at 40 °C
Parts in contact with the skin must be made of breathing material to avoid excessive sweating	
It must be clear how to put on the orthosis	
Material of the orthosis must not be irritating for the skin	
The material of the orthosis must not deteriorate due to substances encountered during normal use of the orthosis	
The user must not be able to hurt themselves on the orthosis or the hinge	
Orthosis should not weigh more than 1 kg	Orthosis should not weigh more than 0.5 kg
Final selling price must be lower than €1000	

3.10.7 WISHES

To conclude there are also a few wishes for the orthosis. These are not required to be fulfilled but when fulfilled would result in a better orthosis.

- Firstly, it must be tried to make the orthosis easy to transport. Meaning that the user can easily put the orthosis in a bag. Factors to consider for this are the size of the orthosis and the space it takes up while not in use.
- Secondly, as was seen in the online survey it was a big discussion points among users whether to wear orthoses under or over clothes. A considerable amount of the users indicated that they wear the orthosis over clothes even though manufacturers and physicians indicate that direct skin contact is necessary. Therefore, it would be favorable to design an orthosis which can be worn both over and under clothes.

3.11 RISK ANALYSIS

To help minimize the risks of the to be developed orthosis a risk analysis was performed. This was done by performing a DFMEA (Design Failure Modes and Effects Analysis) and AFMEA (Application FMEA). It is expected that it is not necessary (yet) to perform a PFMEA (Process FMEA) for this project since this analysis covers the production, distribution, storage, etc. of the product and this will not be covered in this project.

In the DFMEA each part of the future product and their function(s) are considered and the possible risks with these functions are evaluated. The initial DFMEA can be seen in Appendix I: Risk analysis in Table 10. In this table it can be seen that a significant amount of the established risks have a substantial risk level, therefore these risks must be considered during the design of the orthosis to ensure that these risk levels decrease. The DFMEA will be updated during the entire design process to reflect the new risk levels and taken measurements.

In the AFMEA the phases the user goes through during the entire lifetime of the product and their steps are considered and the possible risks with these steps are evaluated. The AFMEA can be seen in Appendix I: Risk analysis in Table 11. Similar as with the DFMEA some risk have a substantial risk level which must be decreased. This will be documented in the AFMEA table.

4. Rotation pathway

The literature review showed that there is not much research available regarding the pathway of the instantaneous center of rotation and that the results of the research that is available are very inconsistent. It was concluded that the literature presented four plausible pathways, which are all J-shaped but orientated differently and also differ in size. These pathways are shown in figure 29. To be able to resemble the natural pathway with the new hinge it must be known which is the correct pathway. Based on the information gathered from the literature review this would just be a guess between the four pathways, therefore it was decided to perform experiments of which the results can be used to make a choice for one of the pathways.

4.1 ARUCO MARKERS

It was tried to map the rotation pathway using motion tracking. To accomplish this Aruco markers were used [57-59]. Aruco markers are squared fiducial markers and look very similar to QR codes, an example is shown in figure 30. These markers can be detected in images or videos and with the use of the calibration info of the camera used to caption the motion their relative position with respect to the camera can be determined. This way the position of the markers can be detected in different images or video frames to determine the translation and rotation of the marker. Experiments with these markers are relatively simple since only the cardboard markers and a camera are required.

4.2 EXPERIMENT SETUP

4.2.1 TEST MOTION

To determine the rotation pathway the tracked knee must rotate from extension to complete flexion (around 120°). Therefore, a suitable motion must be selected to use as a basis for the

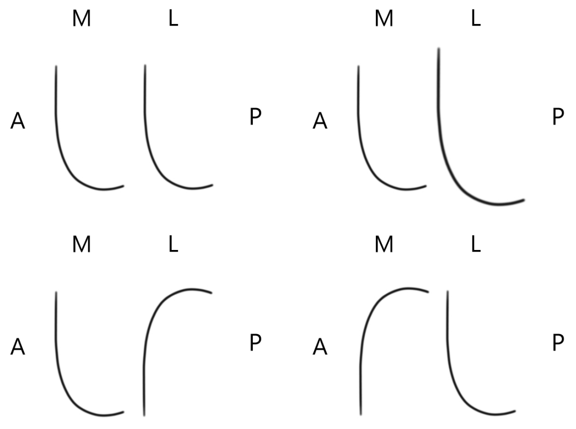


Figure 29: Possible rotation pathways

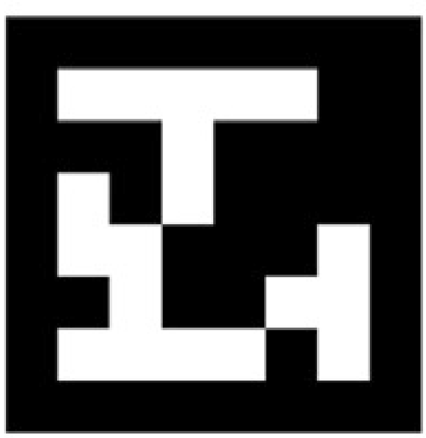


Figure 30: Example of an Aruco marker [58]

Figure 31: Placement of the markers on the leg

motion tracking. Walking only reaches flexion angles of 60° and can therefore not be used. It would also be convenient if the motion does not involve a translation with respect to the ground, since this would require the use of a treadmill or some kind of system that would move the camera. Considering these factors it was chosen to use a squad motion, since high flexion angles are reached and the feet remain static.

4.2.2 MARKER PLACEMENT

Since the level of detection of the markers can vary considerably between images six markers are used for one measurement. This way the markers with the highest level of detection can be used to determine the pathway. Three markers are placed on the upper leg and three markers on the lower leg, as shown in figure 31. To ensure that datapoints are collected for all flexion angles it is asked of the test subjects to perform twenty squads.

4.2.3 CAMERA CALIBRATION

The camera used for this experiment was a mobile phone camera, but any camera that can lock the focus used would be suitable. It was placed on a table to ensure that it remained static during the experiment. The camera was recalibrated for each session. The calibration was performed using the MATLAB camera calibrator app [60]. Using this app the focal length and optical center of the camera were found and stored in an intrinsic matrix. Also, the distortion coefficients of the camera were determined and stored in a vector.

4.2.4 TEST SUBJECTS

The goal was to perform the experiment with twenty test subjects. However due to the COVID-19 virus outbreak at the start of the experiment it could only be conducted with five test subjects to comply to social-distancing standards.

4.2.5 DATA PROCESSING

The results of all twenty squads were used to create one rotation pathway per test subject. One squad motion shows the complete flexion range twice. Once for the downwards parts of the squad and once for the upwards part of the squad. Since the upwards part of the motion is smoother than the downwards part it was chosen to only use this part of the squad motion.

For both the upper and the lower leg the marker with the highest level of detection is chosen to use for the data processing. The parameters obtained from the calibration are used to find the translation and rotation of the markers with respect to the camera to determine their position. This is done using code provided by the Aruco library [57-59]. The positions of the markers are transformed with a transformation matrix in such a way that the position of the upper marker becomes fixed and the position of the lower marker shows its movement with respect to the upper marker. Furthermore, clear outliers are removed. An example of this is shown in figure 32. For the clarity of the figure only the side of the upper leg marker and the top of the lower leg marker are plotted.

The gathered data has quite some variation. This causes the rotation points to be all over the place, since a clear rotation pathway is very dependent on a smooth pathway of the rotated body. Therefore two curves were fitted through the measured position of the two used

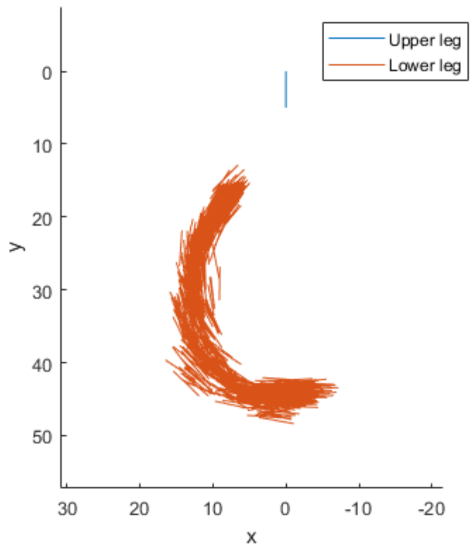


Figure 32: Example of processed marker position

corners of the lower marker and subsequently the corresponding marker positioning was determined. This created a smoothened path of the marker. These fitted marker positions were used to determine the corresponding rotation points.

4.3 RESULTS

The results for each test subject are shown in figures 33 up to 37. The measured location of the top corners of the lower marker are shown in red and blue dots. The fitted curves are indicated on top of these locations and the corresponding marker positions is shown in purple lines. The resulting rotation pathway is shown in purple asterisks.

It can be seen that the pathways differ profoundly between test subjects. While some of the pathways show a distinguishable shape for a part of the pathway, the pathway of test subject 3 does not show this and merely shows a cloud of rotation points around the knee.

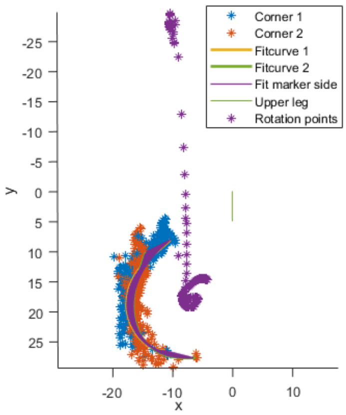


Figure 33: Rotation pathway for test subject 1

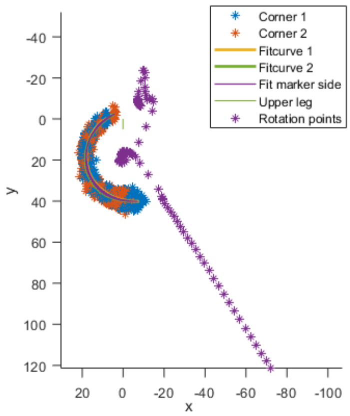


Figure 34: Rotation pathway for test subject 2

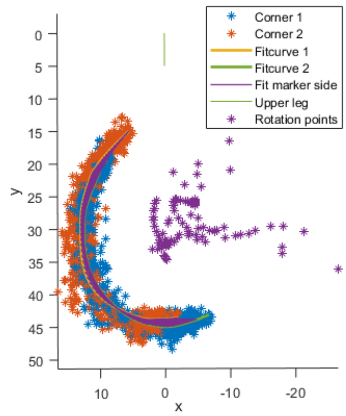


Figure 35: Rotation pathway for test subject 3

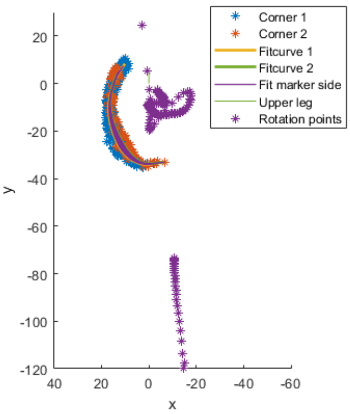


Figure 36: Rotation pathway for test subject 4

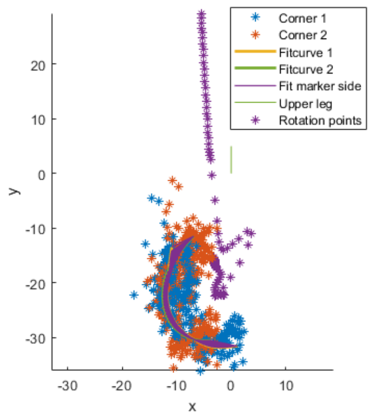


Figure 37: Rotation pathway for test subject 5

4.4 DISCUSSION

It was discovered during the data processing that a small variation in the fitted curves could cause a large variation in the rotation pathway. Due to the large variation in the position of the corners it was difficult to fit a curve through these points and other curves might be possible as well. Even though the variations between these possible curves are not very large, these variations lead to large variations in the rotation pathway, therefore these results are not very accurate.

4.5 CONCLUSION

Since the accuracy of this method for determining the rotation pathway is low these results should not be used to draw a conclusion on the shape of the rotation pathway. However, this method can show the pathway of the rotated body. In this case the position of the corners of the lower marker. Since the noise from the measurements is not as amplified for the marker position as it is for the rotation pathway these values are more accurate and could possibly be used for a comparison between different orthosis concepts and the natural situation. That way the rotation pathway is not known, but it is known if the legs motions is equal or similar to the natural situation. If the motion would be equal to the natural situation it could be concluded that since an identical motion is followed the resulting followed rotation pathway is also identical.

5. Suspension system

5.1 APPROACH

The design process for this orthosis is divided into two sections, a design that compensates for the conical shape of the leg and a hinge design that follows the natural knee motion, as mentioned earlier. This first section will focus on the design of a suspension system to solve the problem of the conical shape of the leg. After this a hinge design will be developed.

There are multiple factors which are accepted to contribute to a better suspension of the orthosis. These are a good fit of the orthosis, friction between the orthosis and the user and a point on the user that can be used to suspend the orthosis on. A suspension system can consist and probably should consist of a combination of these factors. These factors will be used as a starting point to develop a suspension system.

When trying to design a system that provides a good fit for the user there are several points of attention. The first is that what shape would be considered a good fit differs per person since people have different body shapes. The second is that it must be considered that the person wearing the orthosis has an injury to their knee which in many cases is treated surgically. This leads to swelling of the knee which changes the body shape of the person. This swelling can in extreme cases continue even 7 months post-surgery [61]. Furthermore, the change from an often active lifestyle can cause the muscles in the leg to weaken which reduces the size of the leg. Thus, what could be a good fit at the start of the usage of an orthosis could be a bad fit later on.

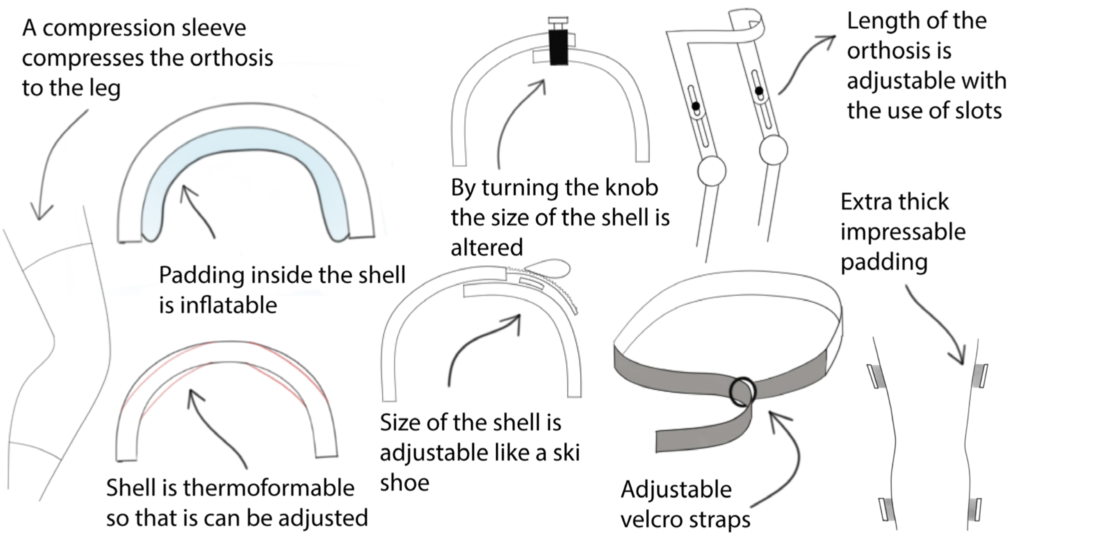


Figure 38: Ideas to help improve the fit of the orthosis

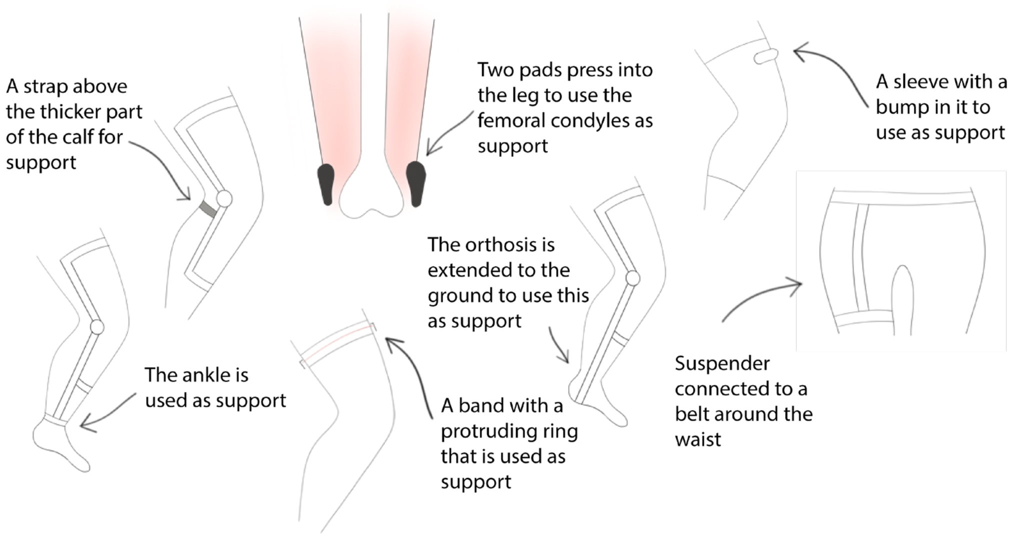


Figure 39: Ideas for a suspension point

This means that it would be ideal to use a system which can change the fit throughout the recovery process to assure a good fit over the entire duration.

5.2 IDEATION

Ideas were generated per presented function of the suspension system. These ideas can be seen in figures 38 and 39. Not all ideas and subsequent parts in this chapter are complete, since they could not be shared due to confidentiality.

The ideas presented in these figures can be combined to create concepts for a suspension system. For the concepts the idea of a suspension point on the femoral condyles will not be used, this is since this idea has a few disadvantages. Firstly, when the leg is extended and muscles are contracted it is difficult for the system to push into the leg as far as is needed to use the femoral condyles as a suspension point. Secondly, the pressure that is needed to push into the leg can be uncomfortable for the user. For this reason, this idea is generally only used in custom braces where the system can be tailored to the specific user. Additionally, the idea for the support on the ground will not be used as well. This is since such a system can be difficult to combine with certain shoes and the hard rigid parts needed for the support can be uncomfortable around the moving ankle. Also the idea to use extra thick padding will not be further developed since this would lead to too much tolerance for unwanted movements. The other ideas were all used to create multiple possible concepts for the suspension system.

5.3 CONCEPTS

The selected ideas were combined into four different concepts. The first concept can be seen in figure 40. The details of this concept are left out due to confidentiality. The main part of the concept consists out of a sleeve that is worn over the leg. On this sleeve arrangements are made to improve the stability of the orthosis and to help the user to correctly position the orthosis. Lastly, straps are used to secure the orthosis and to provide the correct fit. Altering the fit by altering the straps can only minimally change the fit of the orthosis, therefore the orthosis should be supplied in different sizes to provide a correct fit for the user.

The second concept can be seen in figure 41 and an alternative version can be seen in figure 42. In this concept a small strap is placed above the knee. On this strap a small ledge is placed. This ledge fits into a recess of the rigid shell of

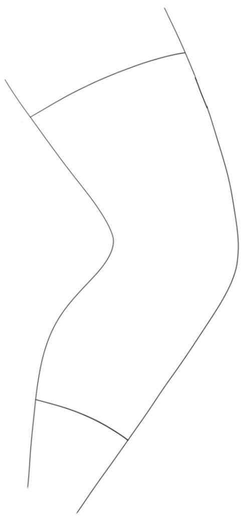


Figure 40: Drawing of the sleeve concept

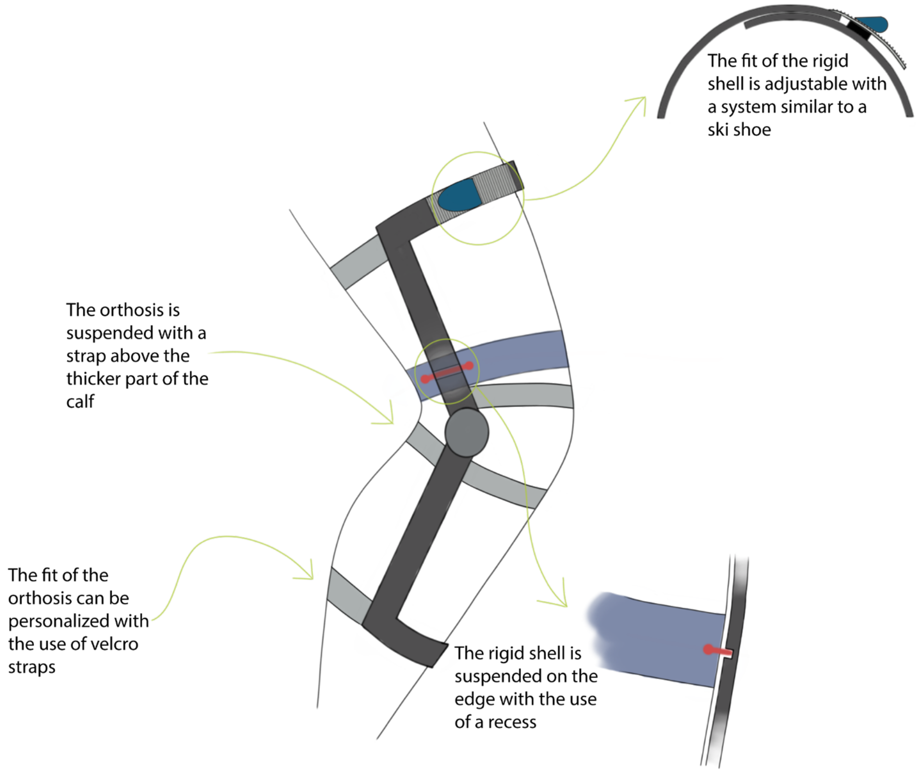


Figure 41: Drawing of the strap concept with the ski shoe system

the orthosis and is used to suspend it. To avoid unwanted rotations of the orthosis the edges of the ledge are thicker. To provide a good fit the size of the rigid shell is adjustable. In the first version of this concept, concept 2a, this is done with a system that is similar to one used to tighten a ski shoe. A small cantilever is placed on top of a ribbed strap. This strap is attached to one part of the rigid shell and pulls this part closer or further away when the strap is adjusted using the cantilever. In this way the size of the shell can be adjusted. In the second version of the concept, concept 2b, this is done with another mechanism. This mechanism is similar to a mechanism used in helmets. Again, the rigid shell is separated into two parts which can

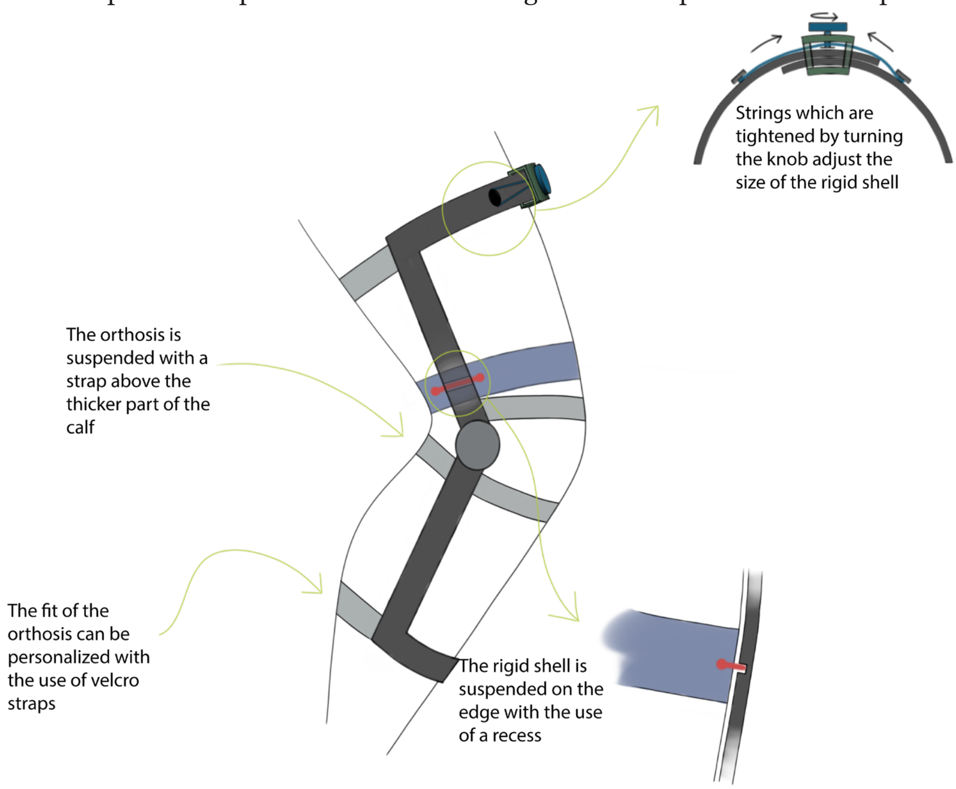


Figure 42: Drawing of the strap concept with the knob system

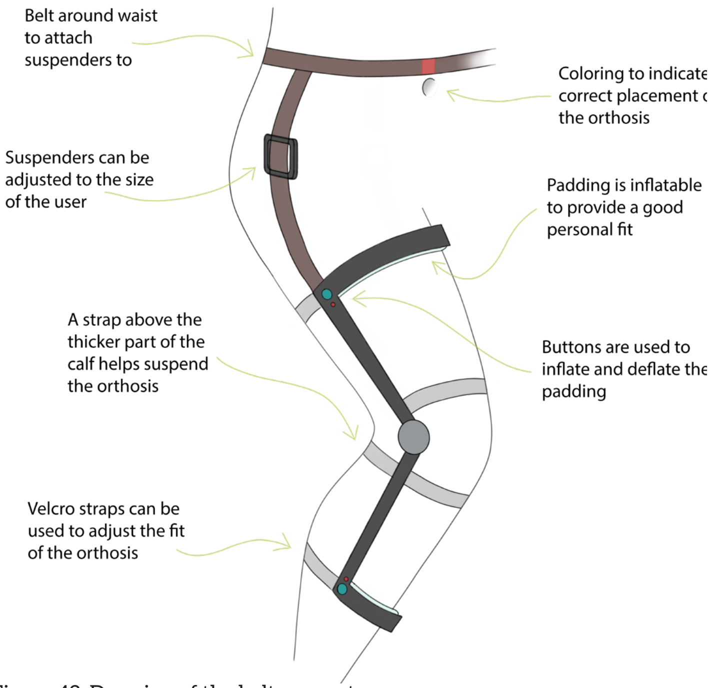


Figure 43: Drawing of the belt concept

slide to adjust the size. On each part of the shell a string is attached which leads to a knob. By turning this knob the strings are either tightened or loosened allowing the parts of the shell to extend or slide over each other.

The third concept is shown in figure 43. The idea of this concept is that the orthosis is suspended with the use of suspenders which are attached to a belt. The belt is placed around the waist of the user and is suspended in this location on the hips. On the side of the belt a suspender is attached which can be adjusted in length. This suspender is attached to the top of the orthosis. This way the belt is used to suspend the orthosis. Furthermore, the padding of the orthosis is inflatable. With the use of buttons the user can inflate or deflate the padding to create a perfect fit with the leg. This padding consists of different compartments to avoid the air in the padding to move to one side under a load and in this way allow unwanted movement of the brace.

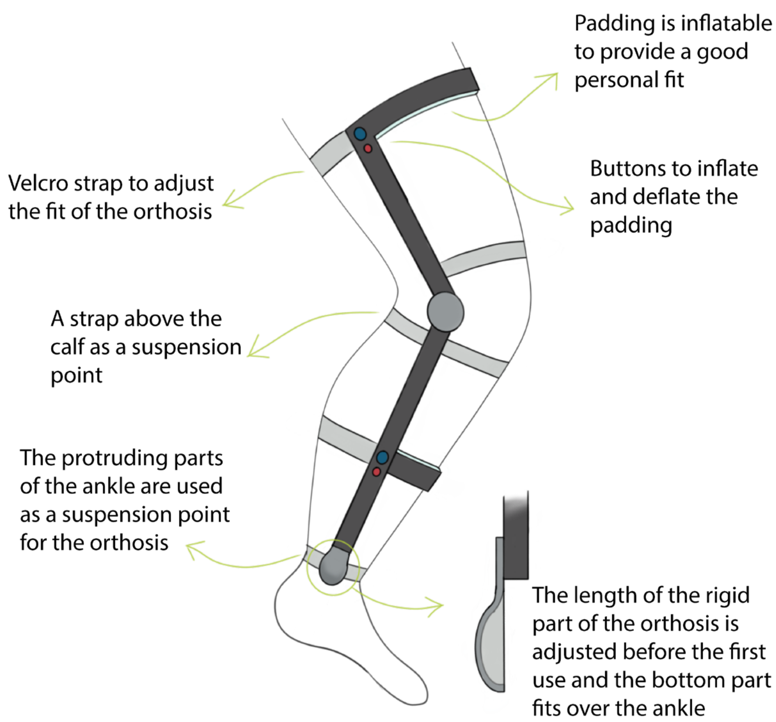


Figure 44: Drawing of the ankle concept

The last and fourth concept can be seen in figure 44. This concept is very similar to the third concept. The concept also uses inflatable padding to create a personal fit, but instead of suspenders the orthosis is suspended on the ankle. The rigid part of the orthosis on the lower leg is extended downwards. On the end of this rigid part another part is placed which is shaped like the inner bump on the ankle. Since not all users will have the same lower leg length the lower rigid part must be adjusted in length before the first used after which the cup shaped part can be attached. This cup fits over the bump on the ankle and is fastened with a strap. This way the orthosis is suspended on this bump on the ankle.

5.3.1 ADVANTAGES AND DISADVANTAGES OF THE DIFFERENT CONCEPTS

As a preliminary evaluation it was tried to determine the advantages and disadvantages of each concept. These can be seen in table 5.

5.4 PROTOTYPING

To evaluate the concepts it was tried to build the concepts into quick prototypes. To be able to fully understand the effect of the prototypes it was tried to test each function separately when possible. It was not possible to easily recreate the size adjustment systems of the strap concept. Since these are not primary suspension points

Table 5: Advantages and disadvantages of the suspension system concepts

Concept	**Advantages**	**Disadvantages**
Sleeve	• It is possible to wear above and underneath clothes • Correct position of the orthosis is supported • Sleeve helps to avoid chafing • The orthosis itself remains simple which helps to keep costs low	• The system is entirely dependent on the correct placement of the sleeve • The sleeve could possibly cause excessive sweating • Multiple sizes are needed for the orthosis
Strap	• Strap causes the orthosis to be placed correctly • Only one size needed	• Brace is more complicated indicating higher costs • The system is entirely dependent on the correct placement of the strap
Belt	• Causes a very good personal fit • One (or only a few) sizes needed • Correct position of the belt is indicated • Belt and suspenders are adjustable	• Brace is complicated indicating higher costs • Quite large and eye-catching which could inhibit users from wearing it • Correct position and size of the belt and suspenders must be set each time by the user
Ankle	• Causes a very good personal fit • One (or only a few) sizes are needed • Correct position of the orthosis is caused by the cup over the ankle	• Cup over the ankle might be uncomfortable • Could be difficult to combine with shoes • Brace is complicated indicating higher costs • Quite large and eye-catching which could inhibit users from wearing it • A serious adjustment is needed before the first use which might not be possible for users to do themselves

Figure 45: Prototype of the strap concept

they will only be judged on their advantages and disadvantages. Each concept function was judged in five different categories: the way it must be put on, the level of attention it will draw, how foolproof it is, its comfort and last and most importantly the amount of migration. To be able to create a more realistic evaluation of the migration of the orthosis this was evaluated after several energetic movements, such as rising from sitting, swinging, fast repetitive flexing and extending and jumping. The following section will quickly evaluate these categories for each concept function and will show the created prototypes. The results from this evaluation led to an iteration for some of the prototypes. A more elaborate explanation can be found in Appendix II: Suspension concepts evaluation.

5.4.1 SLEEVE CONCEPT

The prototype of the sleeve concept cannot be shown due to confidentiality. A possible problem found during the evaluation with this concept could be that it might be difficult to put on the sleeve in combination with a knee injury. Small migrations were possible, but were eliminated by slightly altering the prototype.

Figure 47: Revised prototype of the ankle concept

Figure 46: Prototype of the ankle concept

5.4.2 STRAP CONCEPT

The prototype for the strap concept is shown in figure 45. For the prototype the ledge was replaced by Velcro which is attached between two protruding parts of the orthosis and a sleeve instead of a strap was used. No migration was possible with this concept. To test if this was caused by the sleeve or the Velcro the migration was also evaluated without closing the Velcro straps. This did show migration which indicates the effectiveness of this concept.

5.4.3 ANKLE CONCEPT

In figure 46 the ankle suspension concept is shown. The orthosis was extended using a wooden piece and foam was added to the end of this for comfort around the ankle. However it was necessary to fasten this ankle piece very tightly for it to function as a suspension point causing great discomfort. With the iteration it was tried to improve this by replacing the large piece of foam with a custom made cup with a thin foam lining in between the cup and the skin. Despite this alteration the ankle part still had to be put on very tightly for it to function. This iteration can be seen in figure 47.

5.4.4 INFLATABLE PADDING FUNCTION

The inflatable padding prototype is shown in figure 48. The prototype was put on with the inflatable parts complete filled and these were deflated until a good fit was achieved. A piece of fabric was added between the inflatable parts and the skin since the plastic in combination with the skin was too slippery.

Figure 48: Prototype of the inflatable padding function

5.4.5 BELT CONCEPT

The belt concept is shown in figure 49. The force that had to be put on the belt made the concept very uncomfortable and the vertical belt became too loose during flexion of the hip because it did not stay in the same place relatively to the leg. It was tried to solve this with an iteration, which can be seen in figure 50. A second belt was added at hip height to help the suspenders keep in line with the leg. Also, a wider belt was used at the waist and the suspenders were sewn to the belt to avoid wrinkling and add comfort. This did however create a very stiff system.

5.5 PROTOTYPE EVALUATION

All prototypes were evaluated on the predefined criteria and the results of this are shown in table 6. The same was done for the prototype iterations, this can be seen in table 7.

5.6 CONCLUSION

The goal of these concepts was to ensure a good suspension of the orthosis. Since the inflatable padding system fails to create a good suspension it will no longer be considered for this use. The concept did improve the comfort of the orthosis and will therefore still be considered for this use.

The strap and sleeve concept performed similarly in the evaluation and therefore only one was chosen for further consideration. If the functionality of the concepts is considered

Figure 49: Prototype of the belt concept

Figure 50: Revised prototype of the belt concept

Table 6: Results of the evaluation of the prototypes

Concept	Sleeve	Strap	Inflatable padding	Belt	Ankle
Easy to put on	+	+	-	-	+
Comfort	+	+	+	-	-
Foolproof	±	±	-	-	+
Noticeability	+	+	+	-	±
Migration	+	+	--	-	-

Table 7: Results of the evaluation of the altered prototypes

Concept	Sleeve	Belt	Ankle
Easy to put on	+	-	-
Comfort	+	±	-
Foolproof	+	-	+
Noticeability	+	-	±
Migration	+	+	-

it becomes clear that the sleeve concept has an extra function compared to the strap concept. For the strap concept the orthosis must be placed directly on the strap to be able to secure the orthosis. For the sleeve concept this is not necessary and the orthosis can be worn over clothing. In the analysis it was determined that it is a wish to be able to wear clothes under the orthosis, therefore the sleeve concept is chosen for further consideration.

It must be determined if the size adjustability of the second concept should be used based on their advantages and disadvantages. Using such a system would reduce the need for multiple sizes of the orthosis, however it would make the orthosis more complicated which would increase the costs. Additionally, the two potential systems both have protruding parts which would make it possible for things to get stuck on the orthosis. So ultimately such a system might not even reduce the cost since the production cost of a single orthosis would be higher and it introduces extra disadvantages. Therefore, it is chosen not to use such a system for the orthosis.

The evaluation of the ankle prototypes showed that the addition of a cup shaped to the ankle did not improve the suspension of the ankle suspension point. Still a significant amount of migration could be observed, therefore it was decided to not use this concept as a final suspension system.

This meant that a final choice had to be made between the sleeve concept and the belt concept. After the alteration to the prototypes both prototypes prevented all noticeable migration, therefore the other evaluation criteria are used to make a choice.

The sleeve concept scored well in all criteria. It was stated that it might be difficult to put on a sleeve after a knee injury or surgery. To put on such a sleeve some flexion of the knee is needed. In a description of the rehabilitation after ACL surgery it is stated that patients could ‘gently ride a stationary bike’ directly after surgery to improve the rehabilitation [62]. The flexion angles that are needed to accomplish this are more than what is needed to put on a sleeve and therefore it can be concluded that this must be possible.

The belt concept showed a few downsides during the evaluation. Even though the level of comfort was improved with the iteration of the prototype, the system was still not as comfortable as desired. Additionally, the concept is very noticeable since so many parts are needed for it to properly function as a suspension system and it is relatively large. This could prevent possible users from wanting to use this system to avoid unwanted attention. Due to these downsides, which are not present in the sleeve concept, it is chosen to not choose this concept but to use the sleeve concept.

6. Hinge system

6.1 IDEATION

The final hinge solution must have certain features to be a suitable alternative for the currently available hinges. Firstly, it must allow rotation of the orthosis. Additionally, it must allow the rotation point to follow the natural pathway of the center of rotation of the knee joint of each individual user. To obtain this the hinge must allow the J-curve to be followed while also allowing for a small amount of internal-external rotation. To solve this problem the initial focus will be on designing concepts that can follow this J-curve. Later the internal-external rotation will be added to these concepts.

Attempting to follow the natural pathway of the center of rotation for each individual can be done in two ways. It can either be done by making the rotation point of the orthosis follow the theoretical pathway of the center of rotation with a certain flexibility to adjust to individual pathways or by letting the rotation point of the orthosis be free, possibly within certain bounds. Ideas were generated for both ways and sketches of this can be seen in figures 51 and 52. Again not all ideas and details are included in this chapter due to confidentiality.

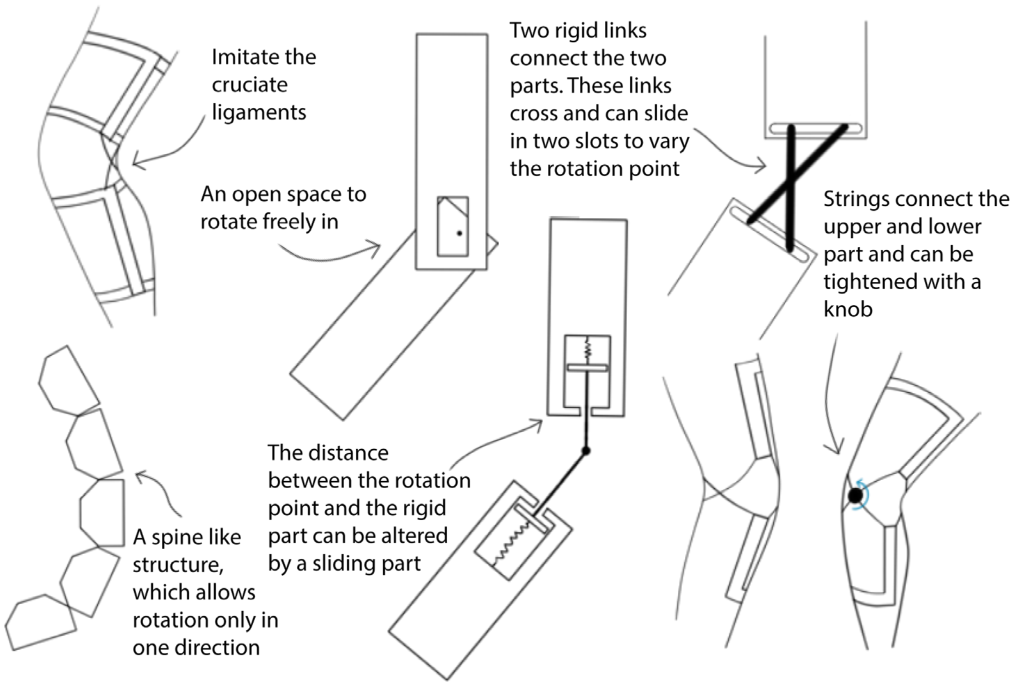


Figure 51: Ideas for a hinge without imposing a rotation point or pathway

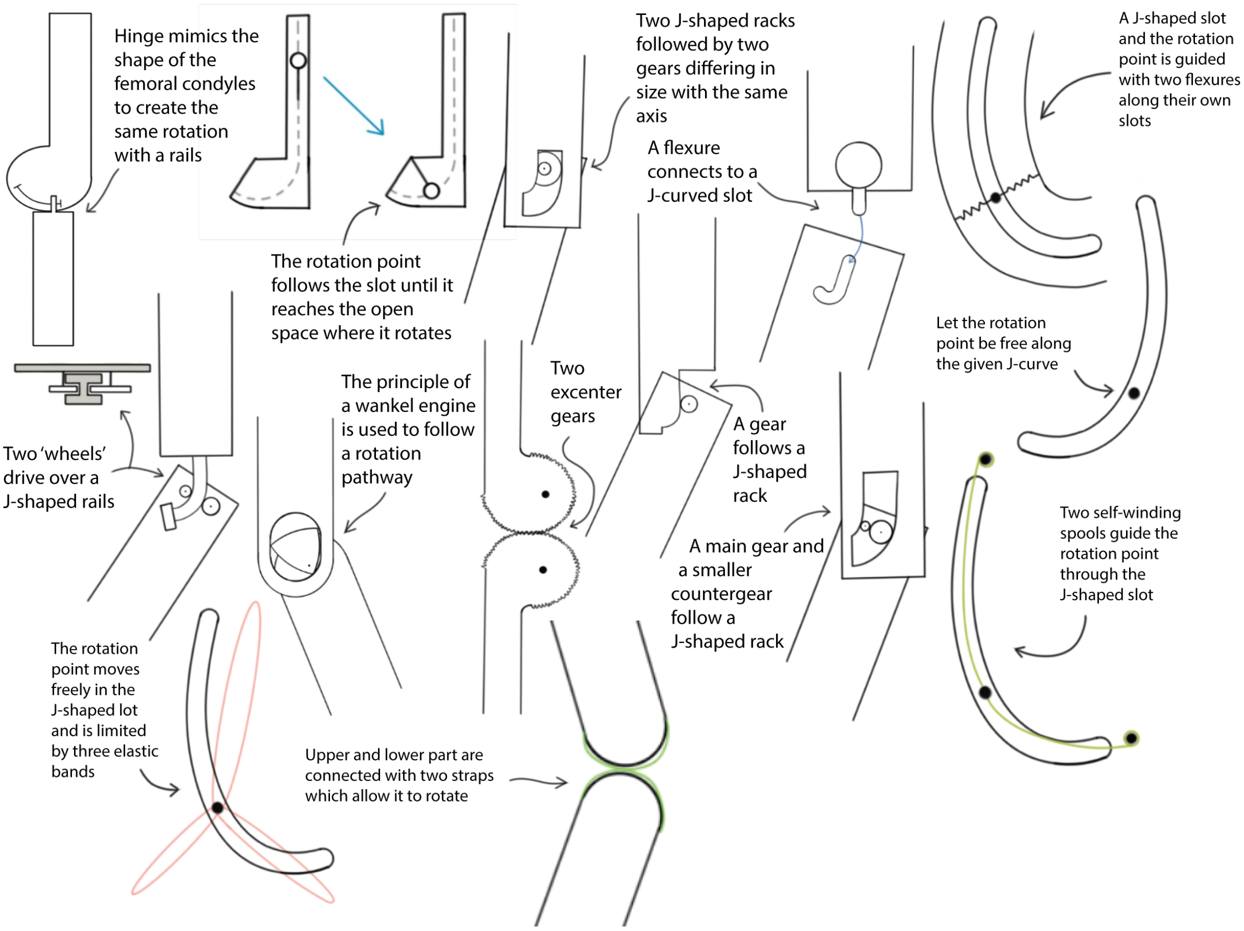
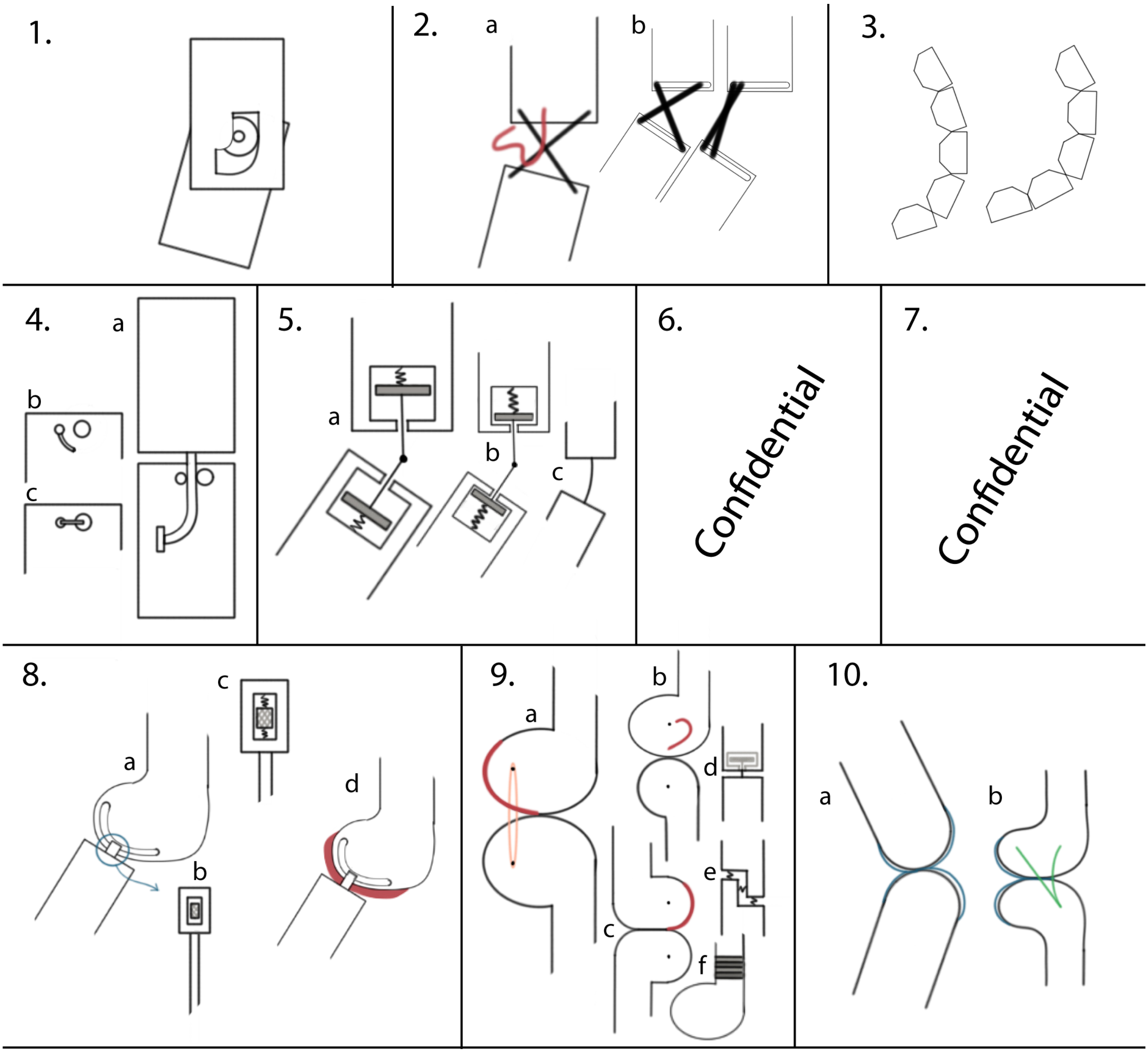


Figure 52: Ideas a hinge that impose a rotation point or pathway

Ten interesting and promising ideas were selected and elaborated on to make a final decision on which of these ideas would be used as a basis for the orthosis concepts. These ten elaborated ideas can be seen in figure 53. Of these ideas it was decided that ideas 2,3 and 5 would be eliminated since it was not possible to limit the anterior-posterior translation as needed for these ideas. Idea 4 was also eliminated since this provided too much technical difficulties. This left ideas 1, 6, 7, 8, 9 and 10, but since ideas 9 and 10 are similar only idea 9 was chosen to be developed into a concept. So to conclude ideas 1, 6, 7, 8 and 9 were chosen to be developed further.



1. a) The lower part rotates due to two gears and J-shaped racks.

2. a) The lower part rotates due to a moving mechanism of two rigid bars. The rotation path is indicated in red. b) Allowing the bars to slide would also allow unwanted larger translations.

3. Blocks positioned as in a spine allow for rotation. However, the spine also allows unwanted large translations.

4. a) The lower part rotates along a J-shaped rails. First there would, however, be no rotation due to the straight part of the J, so the wheels must be able to turn. Either through a slot (b) or by joining the two wheels and only attach one to the lower part (c).

5. a) The ends of the lower and upper part can extend allowing the rotation point to vary. This also allows unwanted large translations (b). Some of these translations can be stopped by adding a leaf spring (c).

6. A hinge that imposes the rotation pathway, but allows some variation from this pathway.

7. A hinge that leaves the rotation free.

8. a) The upper part is shaped as a femoral condyle along which the lower parts rotates. b) The lower part is attached around a slot in the upper part. To allow for variations and translations springs could be added to the attachment (c), or elastic material could be added between the parts (d).

9. a) Two oval excenter gears allow for rotation and are kept together using an elastic band. Red indicates the rotation pathway. b) The lower part is replaced with a normal gear resulting in a J-shaped pathway. c) Both gears are replaced with non-excenter flattened ovals. Variations could be added by attaching to parts while leaving room to translate (d), the use of flexures (e) or extendable material (f).

10. a) The upper and lower part can rotate by rolling over each other and are kept together using two stringes which also allow for variation. b) To improve the pathway the parts should be shaped as femoral condyles. Extra strings could be attached to stop rotation at the correct angle.

 Figure 53: Ideas chosen for further consideration

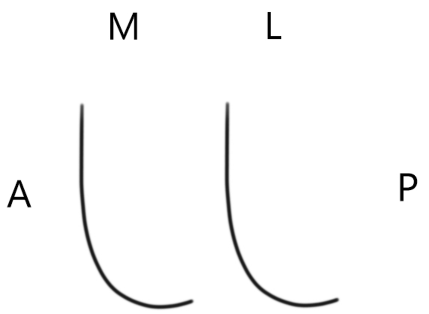


Figure 54: Pathway chosen for the design of the slot concept

6.2 CONCEPTS

6.2.1 GEAR CONCEPT

Since it is not clear which presented pathway by the literature is the natural rotation pathway, one pathway was selected to design this concept and other concepts that impose a rotation pathway. It could, however, also be designed for the other possible pathways. The chosen pathway is shown in figure 54.

The initial idea was to guide the rotation point of the lower leg part through a J-shaped slot while two gears and a rack ensure that the bottom part of the orthosis has the correct angle corresponding to the location in the slot. While calculating the needed size of the two gears two problems became apparent. The first was that one of the gears needed to be very large if only two gears were used. This would result in a very large hinge. To avoid this it was decided to add an extra gear which would allow for a smaller hinge although it would add an extra vulnerability.

The second problem that arose was that that even though the lower part of the J-shape is curved in the same direction the lower leg must rotate in, the curvature is so high that the relative rotation of the lower leg to this part of the slot is in opposite direction. The same is not the case for the upper part of the J-shaped slot since the curvature of this part is much lower. This means that the direction of the rotation of the lower leg relative to the J-shaped slot must be reversed when the curvature of the shape changes. To support this two different racks are needed and two extra gears must be added. Not only do the two extra gears increase the risk of failure for the hinge, but the part of the hinge where the gears must switch racks is very critical.

The final concept can be seen in figure 55. To allow small translation the lower leg part will be attached to the hinge using elastic material (in line with idea 1b). Internal-external rotation is allowed for small rotation by attaching the upper leg part with an axis and the shape of the hinge limits the rotation above 5° in both directions, as can be seen in figure 55.

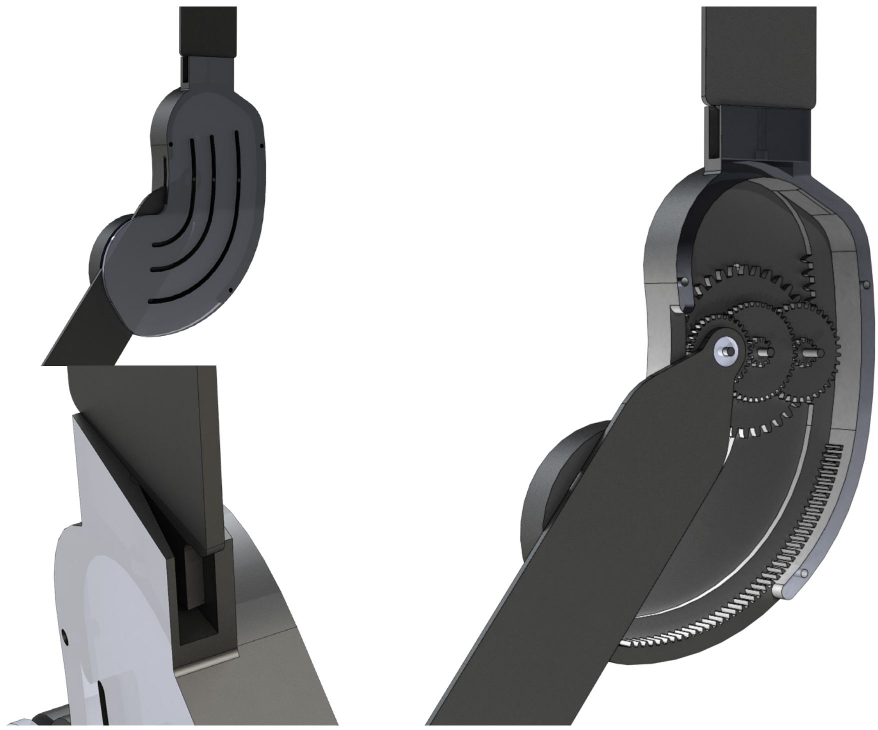


Figure 55: Gear concept (top left), its rotation part (bottom left) and details of the gears and variation (right)

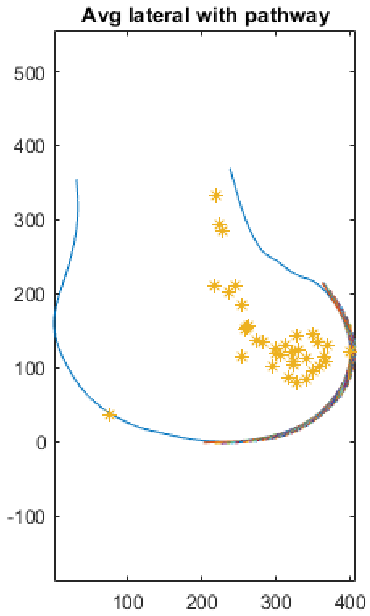


Figure 56: The average shape of a femoral condyle with the resultant rotation pathway (yellow)

6.2.2 IMPOSING ROTATION PATHWAY CONCEPT

Another concept was created that also imposes a rotation pathway. The details of this concept cannot be shared due to confidentiality. The concept allows some variation from the imposed pathway to adjust to individual pathways.

To determine a configuration of the pathway that imposes the chosen rotation pathway a MATLAB [63] program was written. This program runs an interior-point optimization to optimize the resultant rotation pathway of the concept to the given ideal pathway. The difference between the two pathways is calculated using two parts. The first is done by determining the discrete Frechet distance. This determines the similarity of two curves by calculating the distance between the points of each curve. The second is the difference between the begin and endpoints of the actual pathway and the ideal pathway. The differences resulting from the two different methods are added to each other and each have their own weight. The result of this optimization is a configuration that has a rotation pathway that is the closest match to the given ideal pathway.

6.2.3 CONDYLE CONCEPT

The idea of this concept was to let the lower leg follow the hinge which is shaped as a femoral condyle which should theoretically lead to a motion similar to the natural motion of the leg. To shape the concept to a femoral condyle multiple x-rays were used to trace the shape of the femoral condyle. These traces were used to create an average shape of a femoral condyle. The resultant rotation pathway was also calculated. This can be seen in figure 56. Subsequently, the created condylar shape was scaled to have the average size of a femoral condyle, which was found in literature [64].

The final concept can be seen in figure 57. To the condylar shape a slot was added to allow flexion from 0° to 120°. The lower leg is connected to this shape with two rods. To allow for anterior-posterior translation the lower leg can slide within the connecting part. Internal-external rotation is again implemented as in the other concepts. The axis that allows the internal-external rotation is able to slide up and down to allow proximal-distal translation.

6.2.4 MOVED POLYCENTRIC CONCEPT

The underlying thought of this concept is that although the hinge does not resemble the natural pathway of the instantaneous center of rotation it is located in the right spot relative to the knee joint and the shape somewhat resembles the correct shape. By allowing small variations the rotation pathway can then adjust to the correct pathway. The big advantage of this is that the design of the hinge can be kept relatively simple.

The model of the final concept can be seen in figure 58. The hinge is very similar to a polycentric hinge, but the big difference is that the two gears of the hinge are placed backwards to try and match the location of the natural pathway. Internal-external rotation is introduced in the same way as in the other concepts. Small translations are allowed in the sagittal plane by connecting the axis that is providing the internal-external rotation in a ‘chamber’ in the lower leg part where it is free to translate within the limits of the chamber, as can be seen in figure 58.

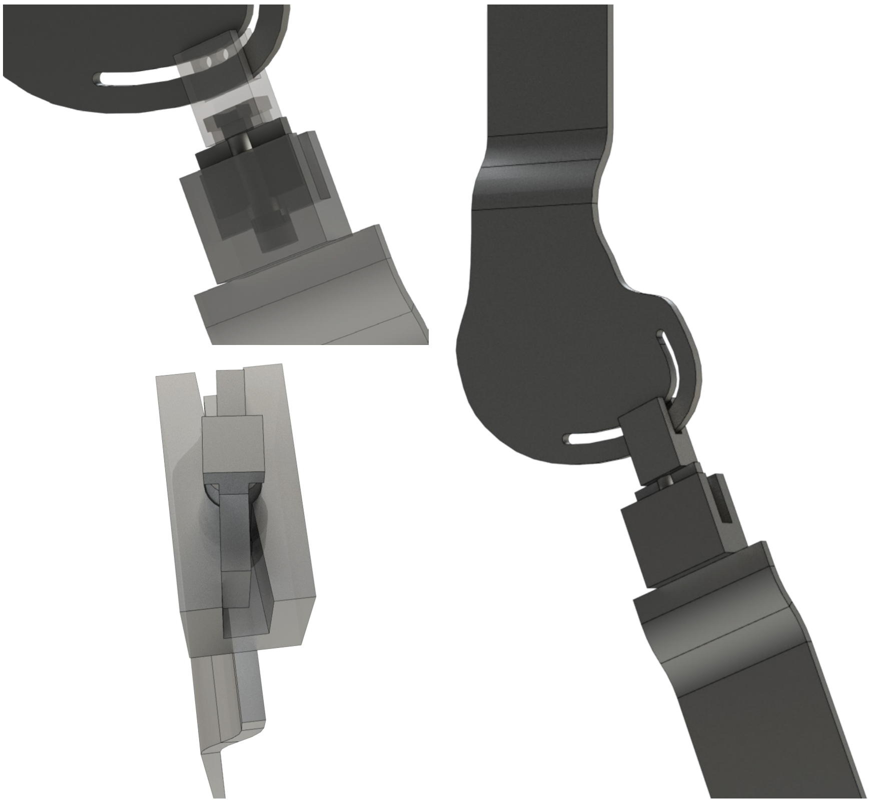


Figure 57: Condyle concept, detail showing the rotation (top right), detail showing the rotation and translation (bottom right)

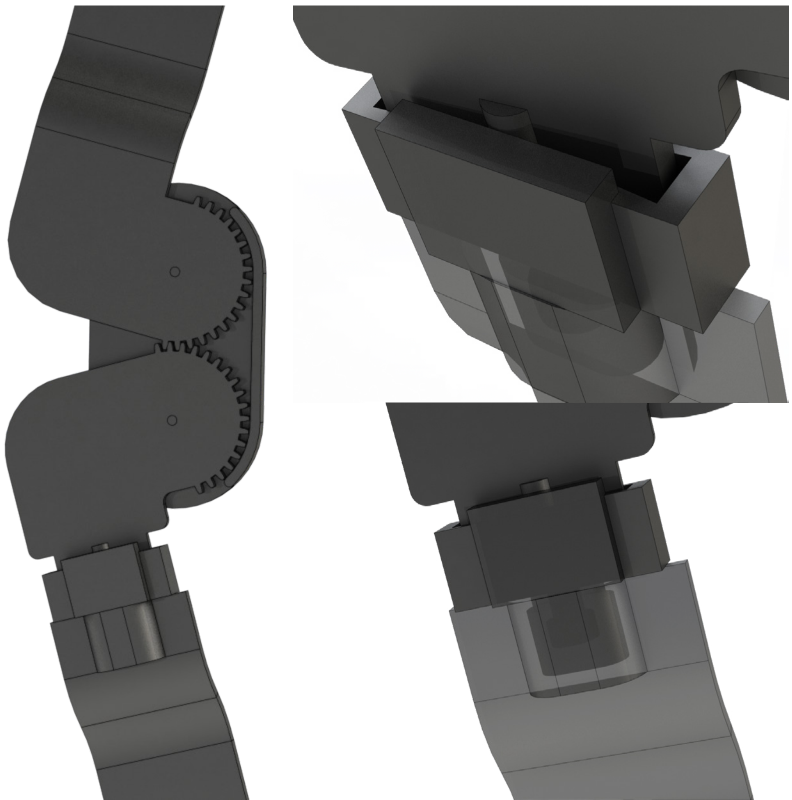


Figure 58: Moved polycentric concept, with detail of the translation and rotation (top right) and detail of the rotation (bottom right)

6.2.5 FREE ROTATION CONCEPT

This concept is different than the other concepts since it does not impose a pathway to the user. It is not tried to resemble the motion of a healthy knee, but to take over for the damaged ACL. The details of the concept can again not be shared due to confidentiality.

Since the rotation pathway is not imposed by this concept it is not necessary to introduce any variation possibilities since the pathway is free to follow the personal pathway of the user. The difficulty with this concept is to have a free rotation pathway but simultaneously restrict movements to provide the necessary support for the injured ACL.

6.3 CONCEPT CHOICE

Due to the large amount of gears needed for the gear concept it became a relatively vulnerable construction. The transition between the two racks increased the risk of failure even more, therefore it was decided that this concept was eliminated.

The moved polycentric concept was eliminated as well, since it only slightly differs from existing orthoses and would therefore likely have the same problems (albeit probably in a lesser amount). This would also mean that it would be harder to present the orthosis as distinguishing from the other available orthoses on the market.

It was decided to produce a prototype of the remaining three concepts and perform tests with these prototypes to determine which concept will be chosen to develop into the final product.

6.4 PROTOTYPING

For each of the remaining concept a prototype was developed in such a way that the prototypes could be attached to the frame of an existing orthosis. This simplifies and speeds up the prototyping process. All three prototypes were designed to be produced by laser cutting. To keep the design of the prototypes relatively simple only the part of the concepts that is responsible for the flexion-extension rotation, which is the primary knee motion, was used to design the prototypes.

6.4.1 CONDYLE PROTOTYPE

The prototype for the condyle concept, which can be seen in figure 59, consists of three plates. One plate is shaped and scaled like a femoral condyle and has a slot for the lower part to move through. This plate is connected to the upper part of the orthosis frame with three bolts. The remaining two parts are identical and placed on either side of the lower part of the orthosis frame with two bolts. The two plates also have four holes for four bolts to go through. The upper two bolts will move through the slot of the condyle plate and the lower two bolts are used for reinforcement and alignment.

Figure 59: Model of the prototype of the condyle concept

When the prototype was constructed the bottom part of the orthosis was not able to move freely through the slot in the condylar shape as was intended. This was because the bottom part got jammed in the slot. To hopefully solve this the condylar shape and the small plates attached to the bottom part of the orthosis were taped over to smoothen the surface. Furthermore, the bottom part was connected to the condylar shape with the lower two holes of the attachment instead of the upper holes to hopefully avoid torsion between these parts. Lastly, grease was added to the hinge. These improvements made it possible for the hinge to move freely through a part of the slot, but for the most part of the slot the bottom part still got jammed. Figure 60

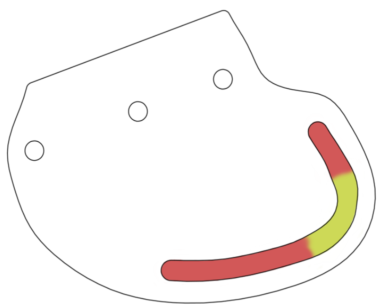


Figure 60: Part of the slot that allows free movement

shows in green the parts of the slot in which the prototype was able to move and in red the parts where the hinge was blocked. The hinge was able to move through the red parts of the slot if it was guided but not when a normal flexion motion with the orthosis was attempted. It is speculated that this is caused by the low curvature of the slots in the red parts. This causes the bottom part of the orthosis to jam when it is trying to rotate at the current position by pushing the connecting bolts into the sides of the slot instead of moving through the slot. Since the prototype was not able to function even after alteration it was chosen to not consider this prototype for further development.

6.4.2 IMPOSING ROTATION PATHWAY PROTOTYPE

This prototype was also produced using laser cutting and initially also had some difficulties to move smoothly. Similar to the previous prototype tape was put on the surfaces of the hinge to smoothen them and grease was added. This was sufficient for the prototype to be able to move smoothly.

6.4.3 FREE ROTATION PROTOTYPE

While building this prototype it became clear that some migration of the orthosis was still possible while wearing the orthosis. Therefore some alterations had to be made to the previously designed suspension system and the prototype itself. After these alterations the prototype was able to remain static.

6.5 TESTS

The prototypes were tested on two important aspects: if unnatural movements were possible and if the natural motion of the knee could be achieved. The prototypes could not be tested on their ability to allow unnatural movements on test subjects since their healthy ligaments would restrain these movements. To solve this two leg molds were built out of Styrofoam, one extended version and a version in 90° flexion. While the prototypes were placed on these molds it was

Table 8: Results of the unnatural movements tests

Motion	Slot	Obser-vations	Slot 90°	Obser-vations	Spring	Obser-vations	Spring 90°	Obser-vations	Accep-ted
AP	4 mm	Orthosis is static, leg mold translates within orthosis	2 mm	Orthosis is static, leg mold translates within orthosis	7 mm	Requires quite some force	28 mm	Extension stop is slacker allowing more translation	10 mm
ML	4 mm	Bending of orthosis frame causes translation	3 mm	Bending of orthosis frame causes translation	7 mm	Requires quite some force	4 mm		2 mm
PD	0 mm		0 mm		4 mm		7 mm	Easily	5 mm
Ext	0°				-5°	Requires a lot of force			0°
Flexion			120°				110°	Extension stop stops further flexion	120°
VV	0°		0°		2°	Barely	5°		8°
IE	-2°/2°	Orthosis itself is static, the leg mold rotates within the orthosis.	-2°/2°	Orthosis itself is static, the leg mold rotates within the orthosis.	5°-10°	In each direction	I:5°+, E:5°-		-5°/5°

attempted to perform unnatural movements. The movements that were determined to be unnatural are: anterior-posterior translation above 10 mm, medial-lateral translation above 2 mm, proximal-distal translation above 5 mm, extension below 0°, flexion above 120°, varus-valgus rotation above 8°, internal-external rotation below -5° and above 5°. The results of these tests can be seen in table 8.

These results show that the rotation imposing prototype performs well, both in the extended and the bended version. Only the medial-lateral translation exceeds the allowable movement and this is with only 1-2 mm. Moreover, this translation is not caused by the hinge but by the frame of the orthosis bending. A second thing that can be noticed is that internal-external rotation was possible with the rotation imposing prototype even though this function was not yet incorporated into the prototype design. This was since the leg could rotate slightly with respect to the orthosis, since only small rotations are allowed in this direction it can be concluded that adding such a rotation function would be unnecessary since this is already possible.

The free rotation prototype performed only slightly poorer than the rotation imposing prototype in the extended test. The allowable medial-lateral translation was exceeded with 5 mm and internal-external rotation up to 5°. However, what must be noted with these unnatural movements is that it required quite some force for most of these movements to be performed, so even though the unnatural movements were not completely stopped they were dampened. The test for the free rotation prototype in flexion shows different results. Large anterior-posterior translation was possible since the extension stop did not limit this motion as it did during extension. Also, larger proximal-distal translation was possible and this translation was not dampened as in the extended case. Lastly, the extension stop limited the flexion to 110°.

To improve the results of the free rotation prototype the prototype was altered. Again it was tried to perform the unnatural motions with the altered prototype at 90° flexion. The new results are shown in table 9. It can be seen that the anterior-posterior translation was completely stopped. However, the alterations also stopped any further flexion. Since it was determined that anterior-posterior translation was allowed up to 10 mm this could be approved slightly by adjusting the prototype slightly. This would allow for more flexion and would allow small anterior-posterior translations, but this will be limited and possibly a maximum of 100° flexion could be achieved.

Secondly, the motion of the leg was compared to the natural movement. This was done by tracking the motion of the leg while the prototypes were being worn and without the prototypes. For this motion tracking 20 squad motions were performed per situation. The results for the rotation imposing prototype can be seen in figure 61. Two markers were placed on the lower leg and two on the upper leg. In the figure the motion is transformed to show the motion of the upper leg around the lower leg. The first lower marker is located at (0,0) and the second lower marker is located around (0,65). The pathway of the two upper markers is shown in the figure. The red asterisks show the pathway of the prototype and the blue asterisks of the natural motion, so without a prototype. It can be seen in the figure that the curves from the upper markers in both situations are very similar, however they do deviate. The upper markers of the prototype tracking start slightly lower than the natural situation at extension, but end slightly higher (relatively) to the natural situation at full flexion.

Table 9: Results of the updated unnatural movements test

Motion	Spring 90°	Obser-vations	Accep-ted
AP	0 mm		10 mm
ML	4 mm		2 mm
PD	10 mm		5 mm
Ext			0°
Flexion	90°	AP translation stop also stops further flexion	120°
VV	5°		8°
IE	-5°/5°		-5°/5°

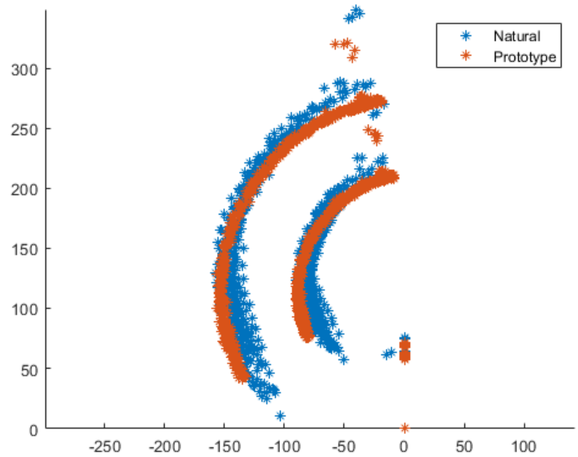


Figure 61: Comparison of the natural motion pathway (blue) to the pathway of the rotation imposing concept (red)

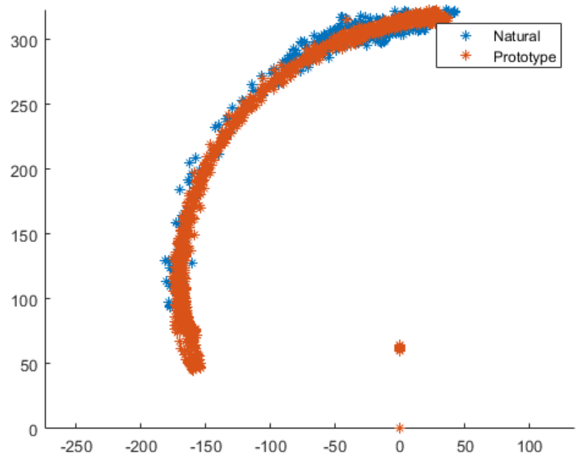


Figure 62: Comparison of the natural motion pathway (blue) to the pathway of the free rotation concept (red)

Figure 62 shows the results of the same test for the free rotation prototype. Again the results for the prototype are shown in red and the natural situation is shown in blue. The figure shows that the motion pathway of both situations are almost identical.

6.6 CONCLUSION

The prototyping tests showed that the rotation imposing concept performed good in resisting the unnatural movements, while the free rotation concept performed considerably worse. However its performance was increased by altering the prototyping, but this was at the expense of the flexion range.

The second test, which tested the ability for the prototype to follow the natural movement showed that the free rotation concept was capable of following the natural movement while the rotation imposing concept deviated slightly. The intended possible variation which was incorporated in the design of the rotation imposing concept was not incorporated into the prototype. If this variation would be added it could make it possible for the motion of the orthosis to slightly alter and become identical to the natural motion pathway.

Other aspects of the concepts that must be considered are that the free rotation concept leaves the rotation pathway free for the user to define while the rotation imposing concept predefines the followed rotation pathway although it is possible to slightly deviate from this. Secondly, the rotation imposing concept had no migration when it was used in combination with the chosen suspension system while alterations had to be made to the free rotation prototype for the concept to stay in place.

During the analysis phase it was determined that an orthosis that would be able to alter the amount of given support over time could be very interesting for possible clients. This would be possible for the free rotation concept.

It was determined that both concepts have different advantages and disadvantages. While the rotation imposing concept has fewer technical difficulties, the free rotation concept is more innovative. Which of these two concepts would be best would therefore be dependent on the situation, such as the future client and intended market. Since these are both not known at the moment it is chosen to keep both the concepts as a final concept to be able to make a suitable choice when these factors would be known.

7. Concept detailing

The chosen concepts were further detailed to two full orthosis designs. During this detailing it was tried to include all the functions that were described in the requirements. Furthermore, the needed lifetime of the orthosis was considered for the design choices that were made.

7.1 ROTATION IMPOSING CONCEPT

In the final design of this concept a foam layer is placed between the frame and the leg to support a better fit and comfort for the user. The hinge itself is placed at a small distance to the leg and is therefore not in contact with the user to avoid chafing. Furthermore the hinge is covered both on the inside and outside with a plastic cover. This would make it possible to add grease to the hinge if necessary without this getting on the clothing of the user and avoids possible harm to the user. Connection points for the Velcro straps are added to the frame. The locations of these connection points are chosen to facilitate a good suspension. These connection points are attached with one pivot point. This way the connection point can rotate which causes the angle of the Velcro strap with respect to the frame to change which makes it possible for the strap to adjust slightly for individual leg shapes.

The variation that is possible for this design is not included when the hinge reached the limits of flexion and extension. This is done to avoid unnatural movements beyond these limits. Furthermore, a flexion and extension stop are added to the design.

The existing AFMEA and DFMEA are elaborated on specifically for the rotation imposing design, these could, however, not be included due to confidentiality.

7.1.1 FEM ANALYSIS

The most delicate part of this design, which is responsible for the variation was researched using a FEM analysis to determine a suitable design and material. Six different designs were analyzed with seven different materials. The FEM analysis evaluated the maximum stress when the maximum variations was applied. The requirements state that the orthosis must withstand approximately 600000 cycles. It is possible to reach 106 cycles if the stress in a part is lower than one third of the yield, therefore the maximum stresses were compared to this value. Only one design could withstand the 600000 cycles and was therefore chosen for the final design. This was for the combinations with PA6 reinforced with glass fiber, PP and titanium. Of these materials it is recommended to choose PP since this is a relatively cheap material which can be easily manufactured.

7.1.2 COST ESTIMATION

To determine the production costs of the slot design it was split into parts and the costs to manufacture each part was evaluated and added to the total production costs. The resultant production costs for this design were €93,50. A detailed breakdown of these costs cannot be shared due to confidentiality. Along with the costs the weight was also determined for each part and the total weight of the orthosis is 598 grams.

7.2 FREE ROTATION DESIGN

Again a foam layer is placed between the frame and the leg to support a better fit and comfort for the user. Also the same connection points are used. The alterations that had to be made to the prototype to ensure that it remained static were also included in this final design.

Some additional alterations had to be made to the design to make it easier to put on the orthosis. These alterations also made it possible to adjust the level of support the orthosis provides during the use of the orthosis. The expert interviews showed that this would be attractive for physicians. This way the support could be decreased during the rehabilitation while the strength of the patients ACL recovers. As with the previous design a flexion and extension stop was added to the design and the existing AFMEA and DFMEA were also elaborated on specifically for this design.

7.2.1 FATIGUE CALCULATIONS

The most delicate part of this design is the spring. To ensure that the spring will not show fatigue a fatigue spring calculator was used to determine if the spring was strong enough [67]. The design parameters of the spring were used for this as well as the determined maximum and minimum force (57.5 and 37.5 N). This calculator showed that the spring would be able to handle this loading dynamically without showing fatigue.

7.2.2 COST ESTIMATION

The costs of the free rotation design were also evaluated to find the production costs. The found production costs for this design were €95,92. A detailed breakdown of these costs cannot be shared due to confidentiality. Along with the costs the weight was also determined for each part and the total weight of the orthosis is 722 grams.

7.3 CE MARKING

A knee orthosis is a medical device and to be able to manufacture and distribute medical devices within the European union the device must have a CE-marking, which shows that they comply with the essential requirements set by the EU. The devices are divided into four classes for this CE marking based on their risk level. The here presented knee orthoses belong to class I, which is the lowest class, since they are non-invasive and do not come into contact with open wounds [65].

8. Recommendations

If it was decided to develop one or both of the current designs further it is recommended that tests with users are performed. These tests should focus on the ease of use of the orthoses and if the way the orthosis should be used is intuitive. It should also be tested by users if the orthoses deliver the amount of support that is needed while being able to perform normal daily activities.

Secondly, of course the possible production of the products must be researched and suitable materials, which should comply with the requirements, should be chosen. Also mechanical testing must be performed to confirm the findings of the FEM analysis and the fatigue calculations.

During the prototyping of the suspension systems it was found that the inflatable padding prototype did not help to improve the suspension of the system, however it did improve the level of comfort of the orthosis. When the orthosis would be developed further the use of this system as padding should therefore be considered.

Lastly, new published literature should be monitored to know if new research is being published about the rotation pathway of the knee which could give a definitive answer on the correct pathway and should be used to update the slot design.

9. Discussion & Conclusion

9.1 DISCUSSION

The goal of this project was to develop an orthosis for cruciate ligament injuries which would not migrate or slide down, by allowing the patient's own natural pathway of rotation to be followed. The orthosis that was to be developed had to facilitate the rehabilitation of the patient by limiting unnatural movements.

During the analysis phase it became clear that designing an orthosis that would follow the natural rotation pathway would be very challenging for the simple fact that it is unclear what this pathway looks like. This became one of the largest challenges of the project. Literature was very unclear about the shape of the pathway and multiple different pathways were presented without one of these being the clear true pathway. Experimental research could also not help in determining what could be the correct pathway, therefore the project had to continue without knowing the shape of the natural pathway. This also makes it difficult to determine if the final designs meet the set goal of following the natural pathway. Since the free rotation design leaves the rotation of the knee free, this design will be able to follow the natural pathway. In contrast to the free rotation design, the rotation imposing does impose a rotation pathway so we cannot say if this design follows the natural pathway. However, the pathway that is imposed can be changed so if better research is published and reveals the correct natural pathway the design can be adjusted by changing the slots to follow the correct pathway. Until this time the current pathway can be used, which is one of the possible presented rotation pathways. Furthermore, the motion tracking study performed showed that the natural motion pathway was closely followed, but not completely similar.

The most important aspect of the orthosis design was to create an orthosis that would not migrate and slide down. The sleeve that was created showed no migration during the prototype tests and would therefore meet the goal. When the sleeve was used in combination with the free rotation prototype migration was again observed. These migrations were resolved by altering the design of the sleeve and the free rotation concept. So the final designs both did not show migration and therefore met the goal.

The last goal was to limit the unnatural movements possible when the cruciate ligaments are injured. The prototyping tests showed that all unnatural movements were constrained for the rotation imposing design within the set limits except for the medial-lateral translation which was 4 mm which exceeded the limit with 2 mm. Therefore, the goal is not completely met, but since the medial-lateral translation is not the translation that is affected by cruciate ligament damage the slight exceedance is not expected to cause problems. The same is true for the free rotation design, since this also exceeds the limit for the medial-lateral translation with exactly 2 mm. The proximal-distal translation was exceeded as well during flexion with 5 mm. Similar to the medial-lateral translation this is not the translation that is most effected by cruciate ligament damage. Another remark concerning the unnatural movements for the free rotation design is that in order to limit the anterior-posterior translation, which is the translation most effected by cruciate ligament damage, the maximum flexion angle is limited to just above 90°. The lower flexion limit will most likely not be a problem since such high flexion angles are rarely reached during normal activities. To confirm this test with the orthosis should be performed while the user performs their normal activities, such as sports.

9.1.1 REQUIREMENTS

To determine the success of the two final designs they were compared to the requirements. Only the requirements that were incorporated into the design will be used for this comparison, so requirement such as that the parts in contact with the skin must be machine washable at 30 °C will not be used since a material is not yet chosen for these parts. The comparison showed that the rotation imposing design fulfilled all the relevant requirements except that as discussed above the limit for the medial-lateral translation was slightly exceeded.

The free rotation design also fulfills almost all relevant requirements. Again, the medial-lateral translation was slightly exceeded and during flexion the proximal-distal translation also exceeded the allowed proximal-distal translation with a few millimeters. Furthermore, the adjustment method for the flexion and extension stops might not be as straight forward as desired. Lastly, it might not be completely clear how to put on the orthosis. To determine if these requirements are met or not user tests should be performed.

9.2 CONCLUSION

So, to conclude it is found that both designs do not completely fulfill all the relevant requirements but most requirements and the important requirements are met, therefore it can be said that the designs are relatively successful. Further development could also help to improve the current issues. The designs perform well in different requirements, therefore they are suitable for different types of clients and their possible success would also be dependent on a fitting client choice for each design.

10. Acknowledgements

I would like to thank BAAT medical for giving me the opportunity to graduate and providing me with a very interesting and diverse assignment. I would also like to thank all the people from BAAT for providing a very nice work environment for me to perform my assignment. I would like to thank Ryelle Endert in particular for mentoring me during this assignment and all the insight she has given me.

From the University of Twente I would like to thank Bart Verkerke and Edsko Hekman for mentoring me the past year. Your different points of view were always very helpful for me to improve my project.

Furthermore, I would like to thank JohnJohn de Koning, Hans Rietman, Robert Dull and Rianne Huis in ‘t Veld for allowing me to interview them and sharing their knowledge and experience with me.

Lastly, I would like to thank my family and Thomas for being my test subjects when I could not perform my experiments due to the coronavirus outbreak.

11. References

1. Hsu, J.D., J. Michael, and J. Fisk, AAOS atlas of orthoses and assistive devices E-Book. 2008: Elsevier Health Sciences.
2. Bertomeu, J.M.B., et al., Development of a hinge compatible with the kinematics of the knee joint. Prosthetics and orthotics international, 2007. 31(4): p. 371-383.
3. Andriacchi, T.P., T.S. Stanwyck, and J.O. Galante, Knee biomechanics and total knee replacement. The Journal of arthroplasty, 1986. 1(3): p. 211-219.
4. Walker, P., et al., External knee joint design based on normal motion. J Rehabil Res Dev, 1985. 22(1): p. 9-22.
5. Pääsuke, M. Biomechanics of the knee joint. 2011 Juni 2011 [cited 2019 29 August]; Available from: http://seltsft.eu/wp-content/uploads/2011/06/Mati_Pääsuke_põlveliigese_biomehaanika.pdf.
6. Fleming, B.C., B.D. Beynnon, and M.H. Pope, Functional anatomy and biomechanics of the anterior cruciate ligament. Operative Techniques in Sports Medicine, 1993. 1(1): p. 1-9.
7. Woo, S.L., et al., Biomechanics of knee ligaments. The American journal of sports medicine, 1999. 27(4): p. 533-543.
8. Smith, P.N., K.M. Refshauge, and J.M. Scarvell, Development of the concepts of knee kinematics. Archives of physical medicine and rehabilitation, 2003. 84(12): p. 1895-1902.
9. Hettrich, C.M. and D. Liechti. Patellofemoral Pain Syndrome. 2015 02/2015 [cited 2019 8 October]; Available from: https://orthoinfo.aaos.org/en/diseases--conditions/patellofemoral-pain-syndrome.
10. Foran, J.R.H. Total Knee Replacement. 2015 08/2015 [cited 2018 8 October]; Available from: https://orthoinfo.aaos.org/en/treatment/total-knee-replacement.
11. Moorehead, J.D., D.M. Harvey, and S.C. Montgomery, A surface-marker imaging system to measure a moving knee's rotational axis pathway in the sagittal plane. IEEE transactions on biomedical engineering, 2001. 48(3): p. 384-393.
12. Montgomery, S., et al., A new technique for measuring the rotational axis pathway of a moving knee. The Knee, 1998. 5(4): p. 289-295.
13. Soudan, K., R. Van Audekercke, and M. Martens, Methods, difficulties and inaccuracies in the study of human joint kinematics and pathokinematics by the instant axis concept. Example: the knee joint. Journal of Biomechanics, 1979. 12(1): p. 27-33.
14. Yamaguchi, G.T. and F.E. Zajac, A planar model of the knee joint to characterize the knee extensor mechanism. Journal of biomechanics, 1989. 22(1): p. 1-10.
15. Blankevoort, L., R. Huiskes, and A. De Lange, Helical axes of passive knee joint motions. Journal of biomechanics, 1990. 23(12): p. 1219-1229.
16. Thorp, L., et al., The biomechanical effects of focused muscle training on medial knee loads in OA of the knee: a pilot, proof of concept study. J Musculoskelet Neuronal Interact, 2010. 10(2): p. 166-73.
17. Phillips, M. Understanding The Q Angle And Its Role With Injuries. 2017 14/08/2017 [cited 2019 5 September]; Available from:

https://runnersconnect.net/understanding-q-angle-and-role-with-injuries.
18. Biščević, M., et al., Gender differences in knee kinematics and its possible consequences. Croat med J, 2005. 46(2): p. 253-260.
19. Koo, S. and T.P. Andriacchi, The knee joint center of rotation is predominantly on the lateral side during normal walking. Journal of biomechanics, 2008. 41(6): p. 1269-1273.
20. Kozanek, M., et al., Tibiofemoral kinematics and condylar motion during the stance phase of gait. Journal of biomechanics, 2009. 42(12): p. 1877-1884.
21. BruceBlaus. Cruciate Ligaments. 2020/05/26 [cited 2020 15 Jul]; Available from: https://en.wikipedia.org/w/index.php?title=Cruciate_ligament&oldid=958994964.
22. Duthon, V., et al., Anatomy of the anterior cruciate ligament. Knee surgery, sports traumatology, arthroscopy, 2006. 14(3): p. 204-213.
23. Amis, A., et al., Anatomy of the posterior cruciate ligament and the meniscofemoral ligaments. Knee surgery, sports traumatology, arthroscopy, 2006. 14(3): p. 257-263.
24. Voos, J.E., et al., Posterior cruciate ligament: anatomy, biomechanics, and outcomes. The American journal of sports medicine, 2012. 40(1): p. 222-231.
25. Gage, B.E., et al., Epidemiology of 6.6 million knee injuries presenting to United States emergency departments from 1999 through 2008. Academic emergency medicine, 2012. 19(4): p. 378-385.
26. OrthoInfo. Common Knee Injuries. 2014 March 2014 [cited 2019 30 August]; Available from: https://orthoinfo.aaos.org/en/diseases--conditions/common-knee-injuries.
27. Physioroom. Best Knee Braces for Recovering from an ACL Injury. 2018 19/07/2018 [cited 2019 30 August]; Available from: https://www.physioroom.com/info/best-knee-braces-recovering-acl-injury.
28. Shimokochi, Y. and S.J. Shultz, Mechanisms of noncontact anterior cruciate ligament injury. Journal of athletic training, 2008. 43(4): p. 396-408.
29. Allen, C.R., et al., Posterior cruciate ligament injuries. Current opinion in rheumatology, 2002. 14(2): p. 142-149.
30. Masnad health clinic. Posterior Cruciate Ligament Injury - Masnad Health Clinic. [cited 2019 11 October]; Available from: https://masnad.com.au/injury-hub/knee/posterior-cruciate-ligament-injury.
31. Kvist, J., Rehabilitation following anterior cruciate ligament injury. Sports Medicine, 2004. 34(4): p. 269-280.
32. McDavid. Can Knee Braces Help You Recover from a Torn Meniscus Injury? 2019 11/03/2019 [cited 2019 30 August]; Available from: https://www.mcdavidusa.com/blogs/posts/can-knee-braces-help-you-recover-torn-meniscus-injury.
33. Grillo, J. Every Guy's Guide to Healing Your Torn Knee Tendon. 2015 03/06/2015 [cited 2019 30 August]; Available from: https://www.webmd.com/men/features/patellar-tendon-recovery#2.
34. Physiopedia, Patellar Fractures. 2019.
35. Clinic, M. Knee braces for osteoarthritis. 2019 18/07/2019 [cited 2019 30 August]; Available from: https://www.mayoclinic.org/tests-procedures/knee-braces/about/pac-20384791.
36. Barba, D., L. Barker, and A. Chhabra, Anatomy and biomechanics of the posterior cruciate ligament and posterolateral corner. Operative Techniques in Sports Medicine, 2015. 23(4): p. 256-268.
37. Dargel, J., et al., Biomechanics of the anterior cruciate ligament and implications for surgical reconstruction. Strategies in Trauma and Limb Reconstruction, 2007. 2(1): p. 1-12.
38. Gianotti, S.M., et al., Incidence of anterior cruciate ligament injury and other knee ligament injuries: a national population-based study. Journal of Science and Medicine in Sport, 2009. 12(6): p. 622-627.
39. Arendt, E.A., J. Agel, and R. Dick, Anterior cruciate ligament injury patterns among collegiate men and women. Journal of athletic training, 1999. 34(2): p. 86.
40. Griffin, L.Y., et al., Understanding and preventing noncontact anterior cruciate ligament injuries: a review of the Hunt Valley II meeting, January 2005. The American journal of sports medicine, 2006. 34(9): p. 1512-1532.
41. Reddit. r/ACL. 2019/10/29/ [cited 2019 29 Oct]; Available from: https://www.reddit.com/r/ACL.
42. Kneeguru. KNEEtalk. 2019/10/29/ [cited 2019 29 Oct]; Available from: https://www.kneeguru.co.uk/KNEEtalk/index.php.
43. Cluett, J. Types of Knee Braces for Support and Injury Prevention. 2019 12/04/2019 [cited 2019 06 September]; Available from: https://www.verywellhealth.com/knee-braces-support-2549604.

44. Lewis, J.L., et al., A new concept in orthotics joint design-the Northwestern University knee orthosis system. Orthotics Prosthet, 1983. 37(4): p. 15-23.
45. Rose, G.K., Orthotics: Principles & Practice. 1986, London: William Heinemann Medical Books.
46. Becker. Knee Joints. 2019 06/09/2019 [cited 2019 06 September]; Available from: https://www.beckerorthopedic.com/Product/KneeJoints.
47. Nathanson, J.J. and R.E. Gildersleeve, Knee brace hinges having dual axes of rotation. 2011, Google Patents.
48. DeFonce, M.A., Variable axis knee brace. 1991, Google Patents.
49. Rogers, M.M. and L.L. Rogers, Anatomically correct knee brace hinge. 1992, Google Patents.
50. Bleau, J.-C., et al., Neurophysiologically designed knee orthosis with three dimensional joint. 1998, Google Patents.
51. Breg. Compact X2K® Knee Brace. [cited 2019 11 Nov]; Available from: https://www.breg.com/products/knee-bracing/functional-ligament/compact-x2k.
52. DJO Global. Defiance III Knee Brace. [cited 2019 11 Nov]; Available from: https://www.djoglobal.com/products/donjoy/defiance-iii-knee-brace.
53. Össur. Rebound DUAL. [cited 2019 11 Nov]; Available from: https://www.ossur.com/injury-solutions/products/knee/ligament-braces/rebound-dual.
54. Medi. M.4s® comfort knee brace. [cited 2019 11 Nov]; Available from: https://www.mediusa.com/m-4s-comfort-knee-brace.html#itemTabs.
55. Össur. CTi. [cited 2019 11 Nov]; Available from: https://www.ossur.com/injury-solutions/products/knee/ligament-braces/cti.
56. Santos-Longhurst, A. How Many Steps Do People Take Per Day on Average? 2018 27/11/2018 [cited 2019 23 September]; Available from: https://www.healthline.com/health/average-steps-per-day#guidelines.
57. Garrido-Jurado, S., et al., Automatic generation and detection of highly reliable fiducial markers under occlusion. Pattern Recognition, 2014. 47(6): p. 2280-2292.
58. Garrido-Jurado, S., et al., Generation of fiducial marker dictionaries using mixed integer linear programming. Pattern Recognition, 2016. 51: p. 481-491.
59. Romero-Ramirez, F.J., R. Muñoz-Salinas, and R. Medina-Carnicer, Speeded up detection of squared fiducial markers. Image and vision Computing, 2018. 76: p. 38-47.
60. Mathworks, MATLAB Camera Calibrator app. 2018.
61. Reddit. ACL survey. 2017 [cited 2019 13 Nov]; Available from: https://imgur.com/a/2PBz4.
62. Ability rehabilitation. What Happens After an ACL Tear Surgery? 2016/09/23 [cited 2019 18 December]; Available from: https://abilityrehabilitation.com/physical-therapy/acl-tear-surgery.
63. Mathworks, MATLAB. 2018.
64. Terzidis, I., et al., Gender and side-to-side differences of femoral condyles morphology: osteometric data from 360 Caucasian dried femori. Anatomy research international, 2012. 2012.
65. European Union, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. 1993.

12. Appendix I: Risk Analysis

Table 10: DFMEA

Part	Function	Hazard	Potential harm	Cause of failure	Current risk control measures	Sever-ity	Oc-cur-rence	Risk level
Rigid upper leg shell	Provide stability	Unstable knee joint	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material	5	1	5
	Limit anterior translation	Unnaturally large anterior translation	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material	5	1	5
	Limit var-us - valgus rotation	Unnaturally large varus - valgus rotation	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material	5	1	5
Rigid lower leg shell	Provide stability	Unstable knee joint	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material	5	1	5
	Limit anterior translation	Unnaturally large anterior translation	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material	5	1	5
	Limit var-us-valgus rotation	Unnaturally large varus - valgus rotation	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material	5	1	5
Hinge	Connect rigid upper and lower part	Upper and lower part can move freely	Reinjury of the knee	Connec-tion of rigid part to hinge breaks or comes loose	Use of rigid and strong connecting material	5	1	5
	Allow flexion-ex-tension rotation	Knee joint can-not move	User can-not use the orthosis	Connec-tion of rigid part to hinge breaks or comes loose	Use of rigid and strong connecting material	2	1	2

Table 10: DFMEA

Part	Function	Hazard	Potential harm	Cause of failure	Current risk control measures	Sever-ity	Oc-cur-rence	Risk level
Hinge	Indicate correct position	Orthosis is se-cured in wrong location	Knee joint cannot rotate	Location of hinge in the ortho-sis is not clear	Different shape and material used for hinge	2	1	2
				Patient is not instructed clearly about posi-tioning	Physician explains use	2	1	2
	Limit anterior translation	Unnaturally large anterior translation	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material Rev1: Lim-it DOFs of the hinge	5 Rev1: 5	1 Rev1: 1	5 Rev1: 5
	Limit var-us-valgus rotation	Unnaturally large varus-val-gus rotation	Reinjury of the knee	Rigid part fracturing or bending	Use of rigid and strong material Rev1: Lim-it DOFs of the hinge	5 Rev1: 5	1 Rev1: 1	5 Rev1: 5
Velcro straps	Keep the orthosis in the correct position	Orthosis mi-grates	User can-not use the orthosis	Velcro straps loosen	Non-elas-tic materi-al is used	2	1	2
				Velcro straps lose fastening ability		2	3	6
				Connect-ing part for the straps comes loose	Use of rigid and strong material	2	1	2
	Limit an-terior-pos-terior translation	Unnaturally large anteri-or-posterior translation	Reinjury of the knee	Velcro straps loosen	Non-elas-tic materi-al is used	5	1	5
				Velcro straps lose fastening ability		5	2	10
				Connect-ing part for the straps comes loose	Use of rigid and strong material	5	1	5

Table 10: DFMEA

Part	**Function**	**Hazard**	**Potential harm**	**Cause of failure**	**Current risk control measures**	**Sever-ity**	**Oc-cur-rence**	**Risk level**
Padding	Provide a comforta-ble fit	The orthosis causes the user discomfort	Orthosis causes bruising or puncture the skin	Padding comes loose		2	1	2
				Padding degrades	Rev1: Test material on deg-radation before making final mate-rial choice	2 Rev1: 2	2 Rev1: 1	4 Rev1: 2
Flexion/ Exten-sion angle setting mecha-nism	Limit flexion/ extension angle	Full range of flexion and extension is possible	Reinjury of the knee	Parts of the angle setting mecha-nism have broken off	Use of rigid and strong material	5	1	5
		A too small range of flexion and extension is allowed	Knee will not be able to reach full flexion and extension without orthosis	Angle set-ting mech-anism is stuck in position		4	2	8

Table 11: AFMEA

#	Phase	Step	Potential failure	Hazard	Potential harm	Cause of failure	Current risk control measures	Severity	Occurrence	Risk level
1	Unpacking orthosis	Removing orthosis from box	Damaging orthosis while cutting open box	Strap of orthosis is cut	Orthosis can no longer be used	Box is too difficult to open	- Rev1: Use packaging that is easy to open and where no tape is used and place orthosis in such away it cannot be cut in the package	3 Rev1: 1	1 Rev1: 1	3 Rev1: 1
2		Removing packaging material from orthosis								
3	First use of the orthosis	Receiving instructions from the physician	User does not pay attention	Orthosis slides down	Orthosis does not provide the needed support	Physician does not make sure the user is listening	- Rev1: Instruct physicians to ask if the use is clear Rev2: Include information folder in packaging	3 Rev1: 3 Rev2: 3	1 Rev1: 1 Rev2: 3	3 Rev1: 3 Rev2: 3
4		Setting flexion and extension angles	Wrong flexion and extension angles are set	Too small flexion and extension angles are allowed	Users ability to reach larger angles is lost	Physician does not pay attention while setting the flexion/extension angles	- Rev1: Instruct physicians to test the set angles Rev2: Angles are clearly indicated on orthosis	4 Rev1: 4 Rev1: 4	2 Rev1: 1 Rev2: 1	8 Rev1: 4 Rev1: 4

Table 11: AFMEA

#	Phase	Step	Potential failure	Hazard	Potential harm	Cause of failure	Current risk control measures	Severity	Occurrence	Risk level
5				Too large flexion and extension angles are allowed	Reinjury of the knee	Physician does not pay attention while setting the flexion/extension angles	- Rev1: Instruct physicians to test the set angles Rev2: Angles are clearly indicated on orthosis	5 Rev1: 5 Rev2: 5	2 Rev1: 1 Rev2: 1	10 Rev1: 5 Rev2: 5
6		Putting the orthosis on under supervision of the physician	Orthosis is put on incorrectly	Orthosis slides down	Orthosis does not provide the needed support	Physician does not pay attention while putting on the orthosis	- Rev1: Instruct physicians to let the user test the orthosis in their presence	3 Rev1: 3	2 Rev1: 1	6 Rev1: 3
7	Use	Positioning the orthosis on the leg	Orthosis is positioned incorrectly	Large stresses and forces are put on the knee joint	Reinjury of the knee	User was not properly instructed on how to put on the orthosis	- Rev1: Instruct physicians to ask if the use is clear Rev2: Include information folder in packaging	5 Rev1: 5 Rev2: 5	2 Rev1: 1 Rev2: 1	10 Rev1: 5 Rev2: 5
8		Fastening the straps	Straps are fastened in the wrong way or not tight enough	Orthosis slides down	Orthosis does not provide the needed support	User was not properly instructed on how to put on the orthosis	- Rev1: Instruct physicians to ask if the use is clear	3 Rev1: 3	3 Rev1: 2	9 Rev1: 6
9		Walking with the orthosis during normal daily activities	Users bumps the orthosis into obstacles	The orthosis is damaged	Orthosis can start to rust	User is not careful while using the orthosis	- Rev1: Use material that is not able to rust	1 Rev1: 1	3 Rev1: 1	3 Rev1: 1

Table 11: AFMEA

#	Phase	Step	Potential failure	Hazard	Potential harm	Cause of failure	Current risk control measures	Severity	Occurrence	Risk level
10		Sporting with orthosis	User collides with another person	Protruding parts of the orthosis comes into contact with another person	Injury to another person	User is not careful while using the orthosis	- Rev1: Avoid protruding parts of the orthosis Rev2: Round all parts on the outside of the orthosis	3 Rev1: 3 Rev2: 3	2 Rev1: 1 Rev2: 1	6 Rev1: 3 Rev2: 3
11			User falls with orthosis	The orthosis is damaged	Orthosis can start to rust	User is not careful while using the orthosis	- Rev1: Use material that is not able to rust	1 Rev1: 1	2 Rev1: 1	2 Rev1: 1
12				Parts of the orthosis bump into the user	Orthosis bruises the user	User is not careful while using the orthosis	- Rev1: Avoid protruding parts of the orthosis Rev2: Round all parts on the outside of the orthosis	2 Rev1: 2 Rev2:2	3 Rev1: 1 Rev2: 1	6 Rev1: 2 Rev2: 2
13		Unfastening the straps	Not all straps are opened	Straps remain fastened	Orthosis cannot be taken off	User does not pay attention		1	1	1
14		Removing orthosis from leg	User trips over orthosis	User must step out of the brace due to its shape	Reinjury of the knee	User loses its balance	- Rev1: Have both the rigid parts of the orthosis on the same side of the leg	5 Rev1: 5	3 Rev1: 1	15 Rev1: 5
15	Storage		Orthosis is not put away in a safe place	Persons could step on the orthosis	Person could injure their ankle	User is not careful with orthosis	- Rev1: Instruct users to not leave orthosis on the floor	3 Rev1: 3	2 Rev1: 1	6 Rev1: 3

Table 11: AFMEA

#	Phase	Step	Potential failure	Hazard	Potential harm	Cause of failure	Current risk control measures	Severity	Occurrence	Risk level
16				Objects could damage orthosis	Orthosis can start to rust	User is not careful with orthosis	- Rev1: Use material that is not able to rust	1 Rev1: 1	2 Rev1: 1	2 Rev1: 1
17		Transporting orthosis in a bag	User can drop bag	Orthosis can be damaged in fall	Orthosis can start to rust	User is not careful with orthosis	- Rev1: Use material that is not able to rust	1 Rev1: 1	1 Rev1: 1	1 Rev1: 1
18			Potentially damaging objects are also stored in bag	Orthosis is damaged by objects	Orthosis can start to rust	User is not careful with orthosis	- Rev1: Use material that is not able to rust	1 Rev1: 1	2 Rev1: 1	2 Rev1: 1
19			User holds the orthosis by the hinge while putting it in a bag	User pinches themselves between parts of the orthosis while putting it in bag	User's skin is bruised by getting pinched	Parts of the orthosis touch when bend	- Rev1: Ensure an opening between the parts at the hinge when fully bend	3 Rev1: 3	2 Rev1: 1	6 Rev1: 3

13. APPENDIX II: SUSPENSION CONCEPTS EVALUATION

13.1 FIRST ITERATION

13.1.1 SLEEVE

The details of this prototype cannot be shared due to confidentiality.

The way this concept idea must be put on is very similar to the way current braces must be put on. One extra step of putting on the sleeve is necessary. If it is clear to the user in what location the sleeve must be worn this can be very easy. However, what must be considered is that the people that will use the orthosis will have an injured knee. This could make it difficult for them to put on such a sleeve. Therefore, it must be researched what the exact abilities are of the users after their injury and if it is possible to put on a knee sleeve.

The sleeve itself must be quite large and cover at least the area from the top of the orthosis to below the knee. This could draw the attention of the environment. However (almost) the entire sleeve will be covered by the orthosis and would therefore not draw any more unwanted attention to the user as current braces do.

In theory this could be a very easy system to use and would guide the user into wearing the orthosis in the correct way. Firstly, by showing the correct location of the top of the orthosis since this part must be placed on top of the bumps and secondly by the magnets on the sleeve that will connect to the magnets on the orthosis. The problem that arises here is that this is all dependent on the correct location of the sleeve. So if the change of color indicating the physical markers is sufficient to ensure a correct placement of the sleeve then this concept idea is very foolproof.

Although no large migrations take place when actively using this system there still are some smaller migrations during the movements. Alterations were made to the prototype to try and resolve this. This did indeed improve the amount of migration of the orthosis, which was not noticeable after this improvement.

13.1.2 LEDGE

The prototype used to evaluate the ledge concept idea is shown in figure 63. Instead of a strap a full knee sleeve was used since this was easily available and a strap was not. Since the relevant part of the idea should be the ledge the size of the sleeve/strap should not be significant for the results of the evaluation. Since a recess could not be easily created in the available orthosis with the possible resources an alternative solution was

Figure 63: Prototype of the ledge on a strap concept function

found to recreate the effect of the ledge-recess combination. On each side of the sleeve small Velcro straps were sewn. When closed over the brace these were kept into place on the top by the connections of the straps of the orthosis and below by the hinge of the orthosis.

In comparison with current orthosis two extra steps are needed to put on the orthosis: the strap must be put on and the Velcro straps must be fastened around the brace. These steps are relatively simple and should not be a problem.

Similar to the previous idea the sleeve does not draw any more attention than the orthosis itself would do. Moreover, if not a sleeve but only a strap, as was initially intended, would be used this would also decrease the chance of drawing unwanted attention since it would be less prominent.

How foolproof the system is is again dependent on if it is clear how to correctly place the sleeve. If this is done correctly the system is relatively foolproof since only the Velcro straps have to be closed which can only be done around the overlapping part of the orthosis which should due to the correct placement of the sleeve be the correct part of the orthosis.

This concept idea scores well for the level of migration. No migration could be noticed.

To determine if the improved level of migration of this concept idea and the previous were caused by the created system or simply by the wearing of the sleeve the same movements were performed with the orthosis and the sleeve on only without securing the Velcro straps. This did cause quite a bit migration: close to 2 centimeters downwards migration after a small amount of intense movements. This shows that the systems do have an effect.

13.1.3 INFLATABLE PADDING

Creating a prototype for inflatable padding was a bit more difficult than the previous ideas. To do this the original padding of the orthosis was removed and these were replaced with swimming armbands, as can be seen in figure 64. The difficulty with this is that the size cannot be altered otherwise the armbands would not be inflatable anymore. This caused the width of the new padding to be correct, but the height was too large for the rigid parts of the orthosis. Secondly, the armbands only consist out of one compartment while the padding, if actually implemented in the brace, would be split up

Figure 64: Prototype of the inflatable padding concept function

into multiple compartments. However, these armbands were still used to evaluate the concept idea to have some information to judge it on.

If compared to the other concept ideas this idea has multiple extra steps which are needed to put on the orthosis. Firstly, the padding must be inflated after which the level of inflation must be adjusted to create the perfect fit with the leg. This can take a few tries of adding and releasing air. This makes it relatively complicated and lengthy to put on this system.

Since this concept idea would replace the padding present in orthoses no extra element is added and therefore the orthosis would not draw any extra attention.

The inflatable padding creates a surprisingly comfortable fit for the orthosis due to the padding shaping to the leg. This makes it more comfortable than the original padding.

The migration during the performed movements was large and made it impossible to finish all movements. It was thought that the plastic material of the armbands possible was too smooth causing the orthosis to slide down. To test this two pieces of fabric were placed between each inflatable armband and the skin. This did decrease the amount of migration, however the level of migration was still significant.

13.1.4 SUSPENDERS AND BELT

Large Velcro straps were used to create a belt and suspenders which can be seen in figure 65. Two types of suspenders were used. Firstly, one single suspender was used attached to the strap of the orthosis next to the rigid part of the orthosis. Secondly, an extra suspender was added crosswise to the rigid part of the orthosis. This can both be seen in figure 65.

Figure 65: Prototype of the suspenders and belt concept function

This system can be more difficult to put on than some of the other concepts. Extra steps are required to put on the belt and the suspenders. Additionally, it could be complicated for the users to determine the correct height and tightness of the belt and suspenders which could cause them to need multiple tries to correctly put on the system.

This concept idea can draw significant attention to the person wearing it. The full system with the orthosis takes up a considerable amount of space on the body due to the belt being worn around the waist and the orthosis continuing to the lower leg. The system drawing this extra attention to its user might inhibit possible users from wanting to wear the orthosis in combination with this system.

Additionally, the concept is not foolproof. The user must determine the correct size and tension of the belt and the suspenders each time when putting the orthosis on. The user could be helped by having a physician indicating the correct tightness when first providing the user with the orthosis but would still have to determine the correct tightness each time. Another problem would be that even if the belt and suspenders were worn with the correct tightness the functionality of the system is fully dependent on the user placing the belt at the correct height around the waist. This is also made more difficult due to the belt being pulled askew by the suspenders.

The concept is not very comfortable. The belt does not have to be worn very tight since it is hold up by the hips, however the suspenders must be under tension and therefore pull hard on the belt. This causes the belt to dig into the flank and hip of the person wearing it.

While wearing this system the orthosis can still migrate considerably. This is because the suspender can only stop the migration of the brace when it is under tension. When the hip flexes during movements this removes the tension on the suspenders, therefore it is possible for the brace to migrate if the hip is not extended. This causes the brace to migrate during movements. When the leg returns to an extended position after this the suspenders become tensioned again, however due to the brace being migrated this tension causes an uncomfortable pull on the orthosis. Adding the second suspender delays the moment of the suspenders losing tension, but only minimally and therefore does not improve the situation.

13.1.5 ANKLE SUSPENSION

To create a prototype of the concept idea that uses the ankle as a suspension point a wooden bar was used to extend the rigid part of the orthosis as shown in figure 66. This bar was fixed to the inside of the orthosis with Velcro to be able to adjust the length of the extension. To the end

Figure 66: Prototype of the ankle suspension concept function

Table 12: Scores of the concept on the evaluation criteria

Concept	Bump	Strap	Inflatable padding	Belt	Ankle
Easy to put on	+	+	-	-	+
Comfort	+	+	+	-	-
Foolproof	±	±	-	-	+
Noticeability	+	+	+	-	±
Migration	+	+	--	-	-

of the extension a strap is connected to secure the system to the ankle. The system was tested both as is and with a foam part to try and add comfort for the ankle.

If the correct length of the extension part is predetermined by a physician as was intended, it is easy to put on this system. The orthosis should be put on as normal, the only extra strap would be fastening the strap around the ankle. This also makes the system relatively foolproof if the length of the extension is not altered.

To ensure that the concept functions correctly and thus can use the ankle as a suspension point the extension must be secured very tightly. This is because the protruding part of the ankle is not very large and the skin there is very mobile. This causes the system to be quite uncomfortable. The added foam does not change this situation since the foam is completely compressed due to the pressure needed to secure the extension.

The system does draw some extra attention due to the added parts, however the extra attention is relatively small.

If the system is secured with a normal pressure it does not help to reduce the migration of the brace. Securing the system very tightly does help to reduce the level of migration, however it does not prevent all migration so still some migration is present.

Table 12 shows the scores of each concept.

13.2 SECOND ITERATION

13.2.1 SLEEVE

Some alterations were done to the prototype to improve its functionality. The evaluation of the altered prototype showed that the concept still scored the same on all factors but the level of migration as with the unaltered prototype. The alterations were successful and no migration of the orthosis was observed.

13.2.2 SUSPENDERS AND BELT

The altered prototype for the suspenders and belt concept can be seen in figure 67. As shown in the figure an extra belt like part was added to the prototype at the height of the hip joint. This part was added to try and hold the suspenders in its place relative to the leg in the hope that it would help to keep the suspenders under tension and therefore active as a suspension point. The

Figure 67: The altered prototype of the belt and suspenders concept

other alteration that was done to the concept was the use of a wider belt to try and better divide the pressure on the hips.

The big problem with this concept during the initial evaluation was that the suspenders would only support the orthosis when the hip was extended. The new evaluation showed that the extra belt that was added helped to solve this problem. The extra belt kept the suspenders in its place which caused it to remain in tension. This can also be seen in the figure. The preserved tension made it possible for the suspenders to hold the orthosis up during all movements. Due to this improvement no migration could be observed during the performed activities.

The second problem that was found in the previous evaluation was the discomfort caused by the belt due the tension of the suspenders. To try and solve this a wider belt was used. As can be seen in the figure the belt was still compressed, however the lower part of the belt is no longer digging into the skin above the hips. This improved the level of comfort, but the system was still not as comfortable as desired. It was attempted to avoid the compression of the belt by sewing the suspenders to the belt. The results of this are shown in figure 67 on the right side. It can be seen that the belt still creases but these creases are very minor and no folds arise from this. This solved the discomfort of the belt, but since this construction is quite stiff and wide it could also not be described as comfortable.

The previous evaluation determined that putting on this system could be difficult. By adding the extra belt to keep the suspenders under tension an extra part must be put on. This only adds to the difficulty of putting on this concept and also increases the chance of users putting the system on incorrectly and thus further reduces how foolproof this concept is.

Widening the belt helped to improve the level of discomfort the concept caused, however this wider belt can make the system attract more attention along with the added extra belt. This could stop people from using this system.

13.2.3 ANKLE SUSPENSION

The improved ankle suspension prototype can be seen in figure 68. The problem with the original prototype was that it would only functions as a suspension system if an uncomfortable amount of pressure was used to secure the part around the ankle. To try and avoid this a new part was created with casting material shaped to the ankle. Since casting material can be very uncomfortable when placed directly on the skin a layer of foam material was added, but to ensure that the part kept the correct shape only a thin layer was used.

The first thing that could be noticed while evaluating the prototype was that it was more difficult to position the orthosis correctly when putting it on. Normally when putting on the orthosis the main focus would be on positioning the hinge correctly, but now also the part around the ankle had to be positioned with care to ensure the correct position. Since these parts are relatively far apart it can be difficult to keep both parts positioned correctly while fastening the straps.

The bump of the protruding part of the ankle is small, as can be seen in figure 68. This is what made it difficult to use this point as a suspension point in the first prototype. Since the part of the system placed on the ankle is shaped to the ankle the curve in this part is also small. To ensure that it functions as a suspension point a precise and tight fit is needed. When fastening the Velcro strap around the ankle relatively tight, as is done in the figure, the orthosis immediately starts to migrate when any movement takes place. To try and limit the amount of migration the ‘cup’ on the ankle must be pressed tighter to the skin. To do this the strap must be fastened more tightly, but due to this pressure the strap would press so hard into the skin around the ankle that it would pinch off the parts of the leg below it. The evaluation showed that due to the performed movements the orthosis immediately started to migrate significantly. Due to the high level of mi-

Figure 90: Altered prototype of the ankle suspension concept

Table 13: Scores of the final suspension concepts

Concept	**Bump**	**Belt**	**Ankle**
Easy to put on	+	-	-
Comfort	+	±	-
Foolproof	+	-	+
Noticeability	+	-	±
Migration	+	+	-

gration and the difficulty of the small protruding part it would only be possible to improve the level of migration to a certain degree. Eliminating the migration would be a farfetched goal using this system and would certainly be combined with a high level of discomfort for the user.

Table 13 shows the final scores of the altered prototypes.