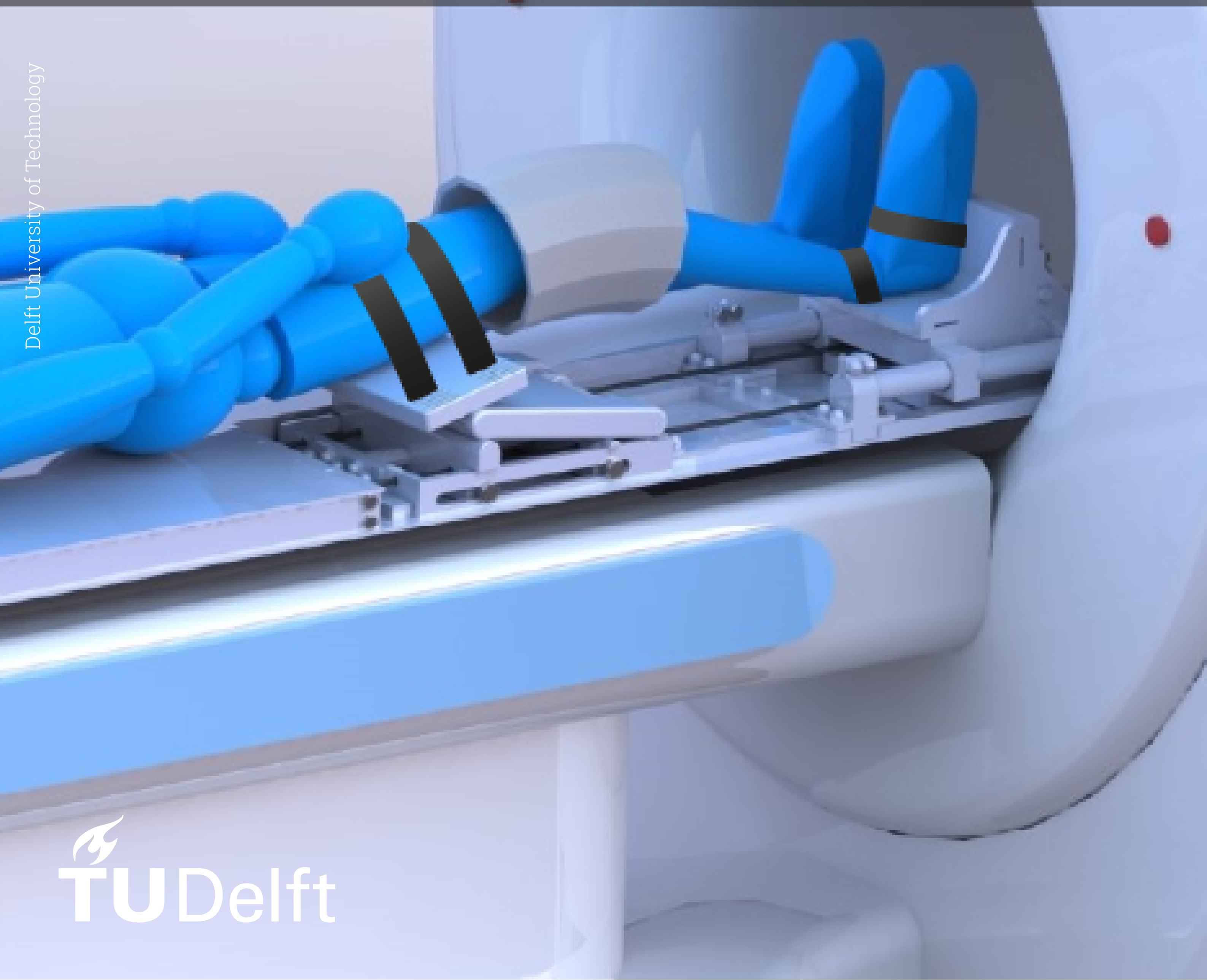
The design of a MRI-compatible knee loading device

Evaluating soft tissue responses indicating early osteoarthritis

Esther Buur



Delft University of Technology

TU Delft

The design of a MRI-compatible knee loading device

Evaluating soft tissue responses indicating early osteoarthritis

by

Esther Buur

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TU Delft

Preface

This master thesis marks the end of my time as a student. My academic path started with a bachelor's in Industrial Design Engineering, where I have learned to systematically address design challenges. I always preferred the concrete, technical challenges where the end product's desirability was clear, compared to designing more abstract visions or strategies. The minor in Biomedical Engineering inspired me to continue my studies in medical technologies.

Although I chose to redeem the faculty of Industrial Design Engineering, I never stopped loving designing and creating physical products. I would like to show my gratitude towards Jaap Harlaar, Edwin Oei and Jos Runhaar for finding a thesis project that perfectly aligned with my interests and learning objectives.

I would like to thank Jaap Harlaar and Mariska Wesseling for their close guidance throughout the project. Their guidance has been inspiring, and I am grateful for all their expertise, assistance, feedback, and patience. I also would like to thank Erin Macri, Niels Dur, Edwin Oei and Jos Runhaar their valuable input during the validation steps of my design. Moreover, I would like to thank the entire Clinical Biomechanics group who always listened to me and helped me with my issues the during process. I enjoyed our update meetings and the mutual motivation we shared.

Furthermore, I would like to thank Luud Rijnen, MRI laboratory assistant at Erasmus MC, for all his valuable insights regarding the MRI workflow and the insightful feedback on the design solutions. Special thanks to Jan van Frankenhuyzen for all his guidance through the embodiment design phase, the final design would not have reached the same level without him. I believe he saved me a lot of time and plastic with the ability to foresee some beginner mistakes. I am also thankful to Reinier van Antwerpen, Damian de Nijs, and everyone else in the IWS and IWM workplaces for their assistance in producing the parts required for the physical prototype.

Last but not least, I want to thank my family and friends for their support and belief in me throughout the entire journey. Special thanks to my roommate Rolien, who was kind enough to lend her laptop when mine broke down, trusting me not to spill coffee on it.

Esther Buur
Delft, June 2024

Abstract

The knee is the most common joint affected by osteoarthritis (OA). Evaluating knee cartilage in MRI is usually done under non-loading conditions. However, load-bearing is a key capacity of cartilage, so using compression may be a tool for clinicians to identify early OA. A loading device could simulate weight-bearing conditions in a supine position. This report presents the development of an MRI-compatible knee loading device, following the double diamond method and the V-model.

The most important requirement are that the device must apply an axial, accurate, and adjustable load through the foot to the patient's knee in a supine position. The device should be able to apply different small knee flexion angles. Existing loading devices, MRI procedures, knee biomechanics, and potential risks were analyzed to establish a comprehensive set of requirements. A knee loading device has been developed where a balance needed to be found between feasibility, functionality and complexity, with feasibility as the main priority to ensure a working foundation for further enhancements.

A biomechanical analysis was conducted to understand the impact of applying compression to the knee in a supine position on the internal joint moments, which reflects the effort that needs to be provided by the patient. Adjustments in knee flexion angle and the height of the applied load at the foot were made to evaluate their effect. The results showed that a 10° knee flexion with a load application through the ankle requires the least effort from the patient, making it the most feasible loading condition to maintain stable for several minutes. For the design, this meant that the height of the footplate was set twice the distance between the bottom of the calcaneus and the position where the load goes through the ankle. Although 10° knee flexion might the most feasible loading condition, it does not necessarily mean it is the best indicator for early OA. Therefore, the device still needs to enable different knee flexion angles.

The load is applied at the foot through a footplate, which slides along axes. To generate the load, elongating elastic material was chosen because of its practicality and safety. Suspended weights were excluded, as they require an inconvenient set-up and are not safe in case of emergency. Since a setup with suspended weights requires more space and covers both the patient bed and MRI table, it is not possible to disconnect the MRI table from the MRI scanner rapidly. The final design of the MRI knee loader ensures the patient can be positioned, and the load could be applied without having to change the position. To make the load generation feasible for radiology laboratory personnel, a driving wheel and pulley systems were incorporated to reduce the force required at the wheel. Additionally, a knee support is implemented to apply a knee flexion angle to the patient.

A prototype has been manufactured to evaluate the functional application of the applied load and knee flexion angle, as well as patient compatibility. It included the essential functional components: the footplate, knee support and the plates they are connected to. The prototype demonstrated the capability of applying a load to the foot in an experimental set-up. A linear relation was found between the input force and the measured force at the footplate, mimicking the load that is applied at the foot. Unfortunately, the measured force was not sufficiently accurate and the variation between the repeated measurements was found substantial. It was argued that this was due to the friction in the current design.

Further design improvements are required to overcome the limitations of this design. Compromises were done to improve feasibility, but it could be analysed how the functionality and accuracy could be improved. A starting point could be to find a better fit between the bearings in the footplate and the axes, to reduce friction and ensure a more accurate application of the load. The footplate should be redesigned so it does not clamp. Moreover, the complete final design of the MRI knee loader (including the footplate, knee support and their connection plate, as manufactured in the prototype, as well as the driving wheel and the table with the double bottom embedding the cable and elastic) must be produced to verify and validate the device's overall functionality, patient compatibility, suitability within the MRI environment and workflows, and operational ability by the MRI laboratory personnel.

Contents

1 Introduction

Osteoarthritis (OA) is a major cause of pain and disability in the adult population. Where it was thought to be a primary disorder of articular cartilage, OA is a slowly progressive degenerative joint disorder characterized by cartilage damage, changes in subchondral bone, osteophyte formation, muscle weakness, and inflammation of the synovium tissue and tendon [22]. The disease reflects a complex interplay of biochemical, biomechanical, metabolic and genetic factors [5]. It mostly affects weight-bearing joints and disrupts the normal structure of cartilage, consisting of proteoglycan, water, and collagen. This results in a reduced load-bearing capacity [34].

The knee is one of the most common joints affected by osteoarthritis [9]. Standard knee imaging with magnetic resonance imaging (MRI) is usually done with a patient in non-weight-bearing conditions. However, using weight-bearing MRI could be useful to understand the biomechanics of the knee and identify structural changes not detected in supine, non-weight-bearing position [3]. The biomechanical properties of the cartilage are exposed under loading conditions, and using compression may be a tool for clinicians to identify cartilage disease. Using a loading device could simulate weight-bearing conditions in the supine position. An example of using a loading device in a clinical setting can be seen in figure 1.1.

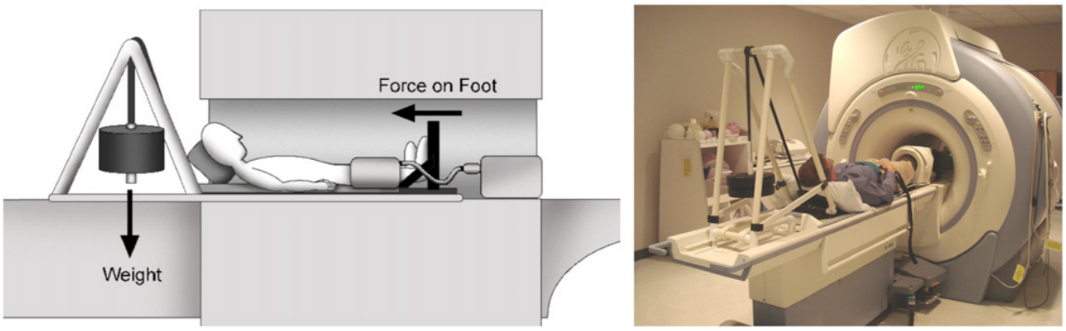


Figure 1.1: Schematic and photo of a loading device [33].

A literature study had been conducted and studies have been found where patient's knees were loaded under the MRI. These studies used different values for knee flexion and loading magnitudes. No direct comparisons between the effects of knee flexion angles and loading magnitudes have been made, therefore their combined impact remains uncertain. The aim of this work is to design an MRI compatible knee loading device, which is able to apply an axial, accurate load, facilitating the evaluation of soft tissue responses in the knee of a patient in supine position. It should be adjustable for each patient and be easy to use. Moreover, it should be capable of flexing the knee into a desired angle.

2
Project approach

2.1. Project partners

This project was executed at the TU Delft, led by Esther Buur. It was supervised by Jaap Harlaar, Mariska Wesseling, and Erin Macri within the Clinical Biomechanics group. Jan van Frankenhuyzen and Reinier van Antwerpen provided guidance in the feasibility of the design embodiment and how a student could produce a high-quality prototype.

Besides the TU Delft, Erasmus MC had an important role in providing the knowledge necessary to make the loading device applicable in the right clinical context. This collaboration involved close co-operation with Jos Runhaar and Edwin Oei, experts in musculoskeletal disorders and radiology. They have profound insights into the progression and treatment of OA and contributed to defining the next steps in our research efforts. Moreover, MRI laboratory worker Luud Rijnen was involved in providing context of the workflow of patients undergoing MRI procedures.

All people involved regularly provided input throughout the process. Important steps in the process are discussed and validated with them.

2.2. Design methods

The objective of this project was to design an MRI-compatible knee loading device to indicate early OA. The process was executed following two design methods.

The first method used was the double diamond method (figure 2.1). These diamonds represent the process of diverging and converging twice. This process involved four main steps: discover, define, develop and deliver. The ‘discover’ phase represented gaining insights into the problem. Specifically, for this thesis this included analyzing literature, existing loading devices, MRI procedures and workflow, knee biomechanics, and identifying risks. The ‘define’ phase represented narrowing down the analysis to a comprehensive set of requirements. Based on these two phases, a problem definition/design brief was created outlining the relevant context, design guidelines, and prerequisites of the project. The ‘develop’ phase involved generating concepts and refining them into a final design embodiment. The ‘deliver’ phase included prototyping, testing and evaluating the device using the set requirements.

The second method used during this design process was the V-model (figure 2.2). This model illustrates how validation and verification connect the activities across the phases in the design process. Validation is an objective set to demonstrate that the product meets the original intent, while verification is done to test if the product meets the metrics of the requirements [11]. This method was used as a guide to meet the requirements of the medical device regulation (MDR).

The outcome of this thesis project was a prototype, demonstrating a ‘proof of concept’ of a MRI-compatible knee loading device. However, as the project progresses towards clinical testing and

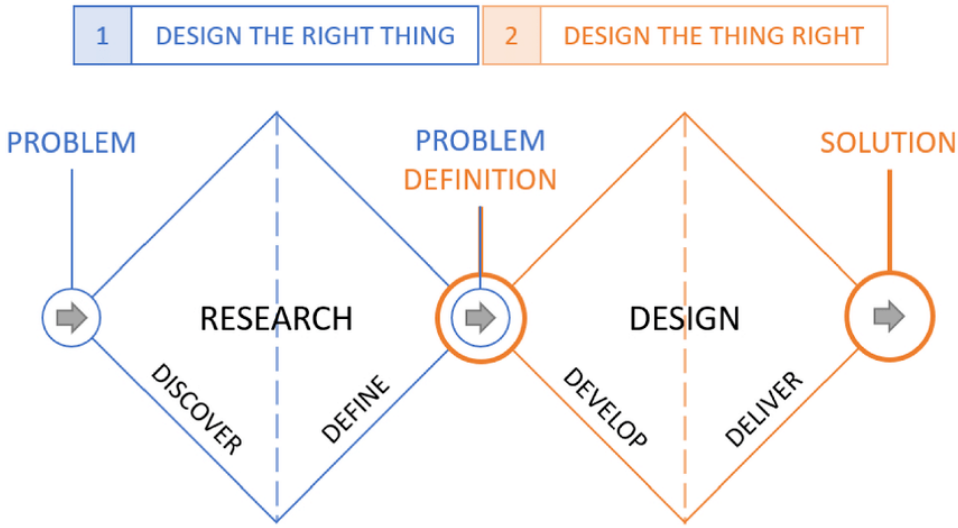


Figure 2.1: The double diamond design method, *retrieved from [1]*

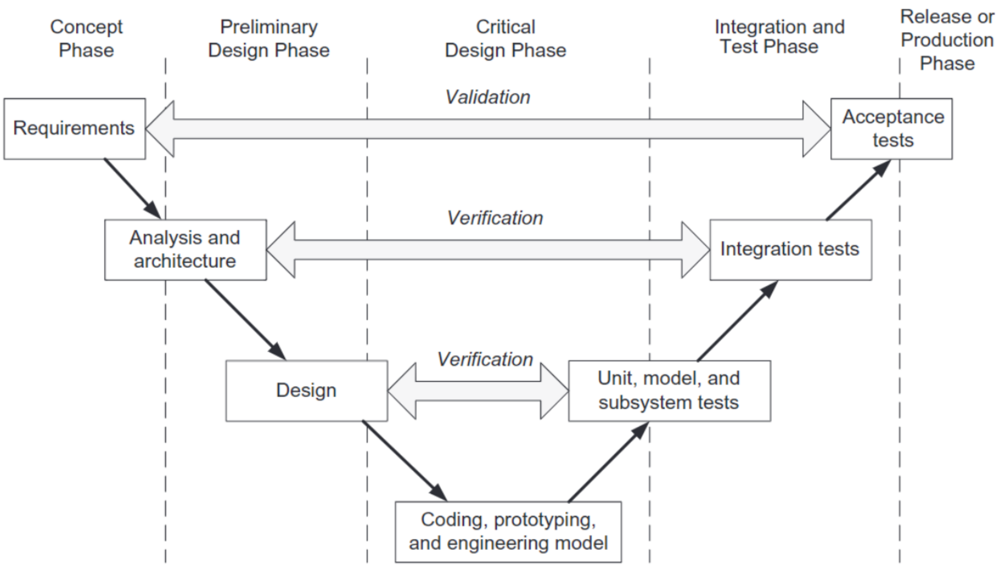


Figure 2.2: The V-model, *retrieved from [11]*

potential CE-marking it needs to be considered that it should comply with several guidelines. For a non-commercial device used in clinical testing, working according to an IMDD file is relevant to cover all relevant applications. MDR is required to obtain CE-marking for medical devices. Devices must be validated and must comply to essential requirements of safety and performance for the patient and user. MDR compliance should be considered to facilitate transitions between pre-clinical and clinical research. For my thesis, all stages of the process had to undergo validation and verification. Reviewing the design cycle steps were documented in a Design History File (appendix B), ensuring thorough documentation. Additionally, risk management procedures were conducted by ISO 14971:2019 – Medical Devices Risk Management. This included risk analysis and evaluation in alignment with established guidelines.

Part I

Discover

3 Analysis

3.1. Literature

A literature study was conducted which aimed to determine the effect of knee loading to evaluate soft tissue responses indicating osteoarthritis using MRI. The loading devices used were analyzed to identify the advantages and disadvantages of existing solutions. They were evaluated on ease of set up, stability, accuracy, complexity and availability 3.1. A recommendation for further research based on their studies is documented.

MRI knee loading devices found in literature

First, with a pulley/cable device (figure 3.1), a load is created by gravity acting on suspended weights behind the patient. This load is transmitted through a sliding footplate against the lower extremity [4][7][23][24][25][26][29][32][33][34][36][37][35].These devices are relatively simple to produce and have great availability. However, the setup is bulky and requires significant time in the setup.

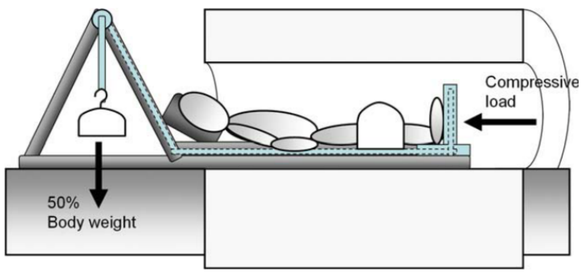


Figure 3.1: Pulley system device in MRI acquisition set-up [32].

Second, another system uses a harness with rubber bands attached (figure 3.2), the extended rubber band exerts a load on the foot sole [2][17][18]. A pre-determined extension value is used to apply a determined load. The setup of this device is relatively fast. The net external force on the body is zero, which reduces the potential of the motion artefacts. However, calibration of the rubber bands is needed, and the exerted force could not be read [18].

Thrid, Wang et al. (2015) [40] used a displacement control apparatus (figure 3.3). A compressive load was applied by using a ratcheting mechanism which drives the load cell against the foot.

Fourth, several studies used active systems to load the knee [6][20][38]. Chan et al. (2016) [6], Lange et al. (2017) [20] and Szomolanyi et al. (2017) [38] have used pneumatic loading devices (figure 3.4). A force was applied at the foot through a piston providing pressure at a footplate. These active systems

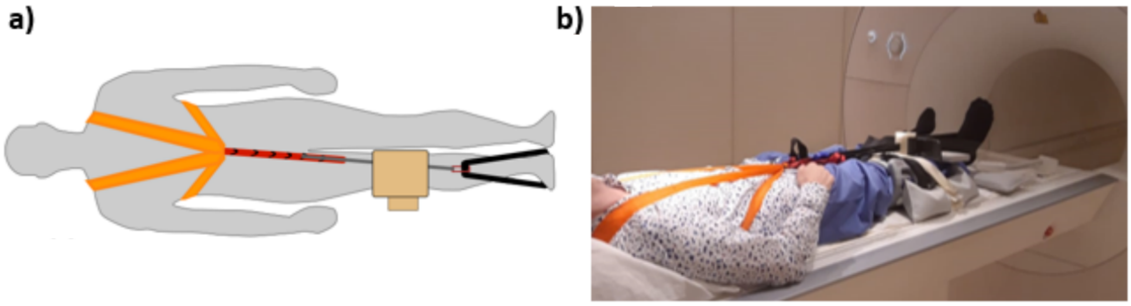


Figure 3.2: A: schematic illustration of the harness with extended rubber band device, B: a device worn by a participant in the MRI [2].

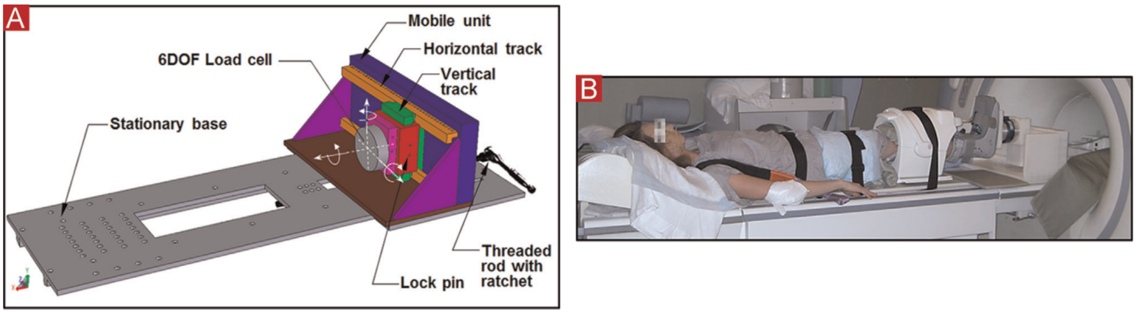


Figure 3.3: A: CAD drawing of the device with load cell and ratchet mechanism, B: device with participant undergoing axial load in the MRI [40].

have more precise control over the applied force but are more expensive and less available [18].

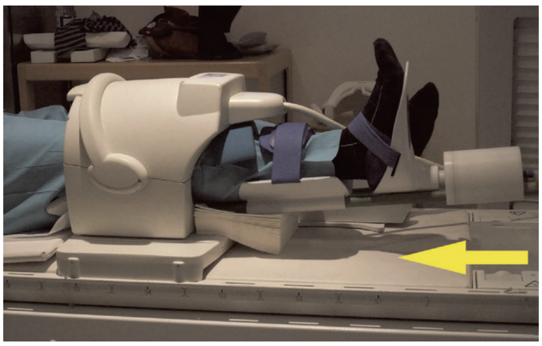


Figure 3.4: A pneumic compression device, a piston providing pressure [38]

Recommendation from the literature study

Based on the literature study, it was recommended to evaluate the effect of loading the knee in different flexion angles, since none of the studies have done this within the same experiment. It could be hypothesized that angles loaded in daily functional movements show greater reaction to load and, as a result, may reveal early signs of degradation, as OA may be mechanically driven [7]. Therefore, small knee flexion angles until 20° could be evaluated as these occur during the stance phase of gait.

It was discussed that applying greater load results in greater soft tissue responses. However, using a greater load also increase the risk of instabilities. It could be further researched to what extend a greater load is the more relevant in identifing early OA. For example, a study could be conducted to compare the responses of applying a 25% or a 50% body weight to the knees of healthy and OA participants. Moreover, feasibility tests should be done, to determine which position could be loaded under what magnitude for what time.

Pulley system device				
	- -	-	+	++
ease of setup		■		
stability		■		
accuracy			■	
complexity			■	■
availability			■	■

Harness with rubber band				
	- -	-	+	++
ease of setup			■	■
stability			■	
accuracy	■	■		
complexity			■	
availability			■	

Pneumic compression device				
	- -	-	+	++
ease of setup		■		
stability			■	
accuracy			■	■
complexity	■	■		
availability	■	■		

Displacement control device				
	- -	-	+	++
ease of setup		■		
stability			■	
accuracy			■	■
complexity		■		
availability		■		

Table 3.1: Harris profiles of different design strategies

These recommendations will be used as input for the MRI knee loading device's functional requirements.

3.2. MRI procedures

To gain an understanding of the workflow of both MRI technicians and patients undergoing MRI procedures, I visited MRI technician Luud Rijnen at Erasmus MC. The most important insights concerning the design requirements of the MRI loading device are reported in this section. The full interview is documented in appendix A.

Workflow

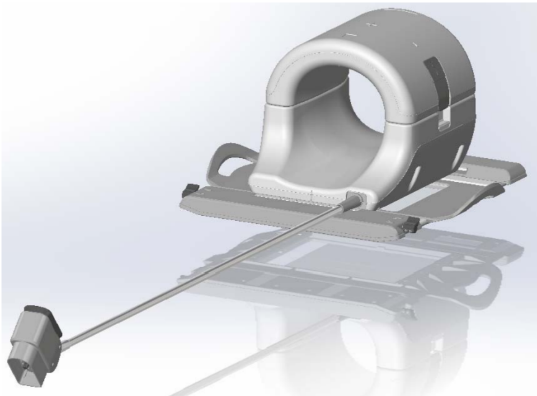
The knee MRI scanning process is divided into five phases: screening, changing attire, preparing the MRI room, positioning the patient on the table, scanning and the patient leaving the table and MRI room. MRI time can be costly, therefore the processes related to changing patients for scanning need to be executed rapidly. The MRI equipment can be handled quite rough and requires the design of the MRI knee loading device to be robust. An opportunity for enhancing efficiency is to prepare the next patient while the previous patient's scan is in progress. This is an important opportunity to optimize efficiency and save time.

MRI compatibility

The MRI knee loader should be compatible with MRI scanners used in the Erasmus MC. They use the GE artist (1.5 T) and the GE premier (3.0 T), so the MRI knee loader will be designed to be compatible with these MRI scanners.

Knee coils

MRI coils are used to send and receive radiofrequency signals during MRI scans. There are three options for knee coils: standard, flexible and air coils, as could be seen in figure 3.5. The standard knee coil is used for most patients, offering better signal and extra stability compared to the other two. However, it is only usable in one determined angle and is not suitable for all patients. The flexible coil allows various knee flexion angles and is usable for all patients. While it provides a signal quality slightly lower than that of the standard knee coil, it remains adequate for knee imaging. The air coil covers the knee like a blanket, providing the highest level of flexibility. However, the signal strength is the lowest.



(a) Standard coil [27].

(b) Flexible coil [39].

(c) Air coil [15].

Figure 3.5: Different MRI knee coils

Location and orientation of the knee coil

The signal is most robust at the centre of the MRI bore, both in terms of height and width within the circular field. The signal strength is at its peak when the knee coil is precisely aligned with the magnetic field.

Emergency levers and buttons

In figure 3.6 the emergency levers and buttons that should not be obstructed by the MRI loading device are illustrated (1, 3, 4 and 5 in figure 3.6). Using the device should not result in accidentally bumping into the levers. Moreover, the surface of the table outside the bore should remain clear so the bed with the patient can slide over it (2). A full description of the functions of the levers can be found in appendix A.

Fitting in the MRI

Normally, the patient lies on the patient bed (figure 3.7). A device can be connected to the patient bed in multiple ways. In figure 3.7, at point 1, a compartment can be removed, creating a gap. This gap provides an opportunity for protrusions from a base plate, allowing for horizontal positioning. At point 2, a groove is present, facilitating the attachment of a fixation band.

The patient table has an inner width of 40 cm. Positioned 1 cm above this surface, a width of 50 cm is available. If a base plate with a width of 50 cm is used, it could only be supported under the central 40 cm, so it does not interfere with the patient bed. This is visualized in figure 3.8

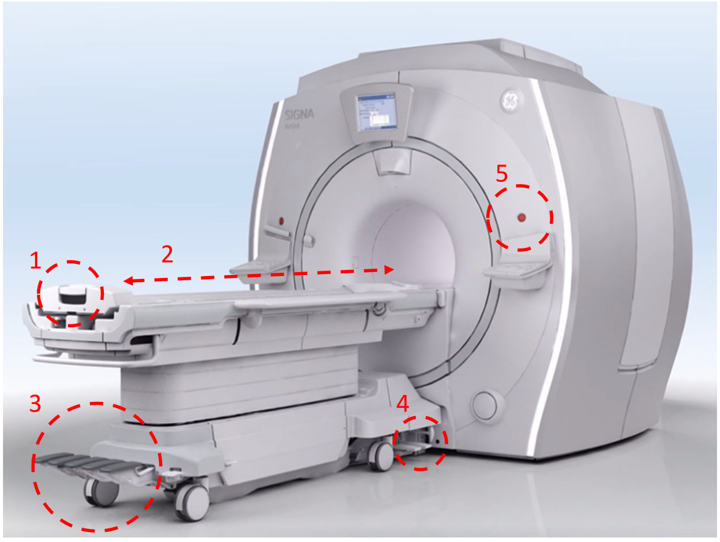


Figure 3.6: Emergency levers and buttons on the MRI which should not be obstructed by the loading device. *1. Lever used to quickly slide the patient out of the bore, 2. Surface of the table outside the bore, 3. Foot pedals used to lower the table and disconnect it from the tunnel, 4. Back-up for 3, 5. Emergency buttons*

Figure 3.7: Patient bed

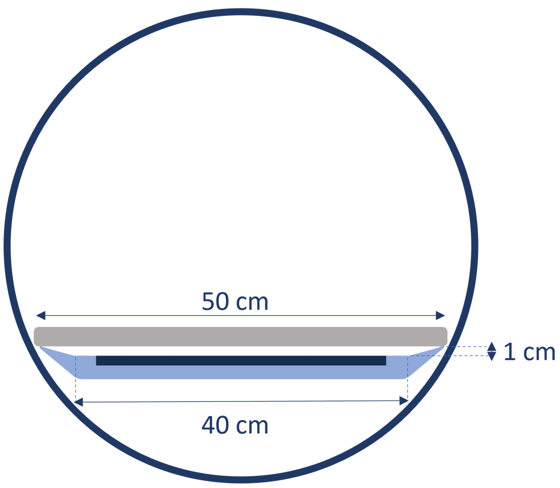


Figure 3.8: Schematic figure of MRI bore, illustrating a support opportunity for the base plate (grey) on the patient bed (blue), in the 40 x 1 cm in between. The removable compartment is illustrated in dark blue.

Use of non-ferromagnetic metals

Using a non-ferromagnetic material like aluminium could be a great opportunity in a loading device because of it's strength, as ferromagnetic materials could per definition not be used. Non-ferromagnetic materials might be used the MRI room, but ideally not within the MRI itself. Their presence could cause image disruptions and should be kept from direct contact with the patient to prevent from warming the skin. It is advised to do feasibility tests first if their use is desired.

3.3. Biomechanical analysis

Literature

Since the progression of OA might be mechanically driven [7], it is hypothesized that early signs of degradation are exposed when the knees are loaded in flexion angles that correspond to daily functional movements. Therefore, analyzing the gait cycle might help to determine relevant knee flexion angles indicating early OA, as it reflects at which knee flexion the ground reaction force is the largest. Figure 3.9 shows that ground reaction forces are greatest around 20% and 50% of the gait cycle, corresponding with knee flexion angles between 0° and 20°. Therefore, the MRI knee loader should be able to apply these angles to the knee.

The knee can be loaded statically or cyclically. While walking, the knee is loaded cyclically. However, it should be questioned whether the most physiological loading condition is the most suitable loading condition for using the MRI knee loader. Since it is not clear what loading condition has more predictive value for early OA, the feasibility of the loading condition will be prioritized, and static loading will be used as a starting point. Cyclic loading produces lower-quality images compared to static loading. While cyclic loading may be more physiologically relevant, it is not necessarily a superior option.

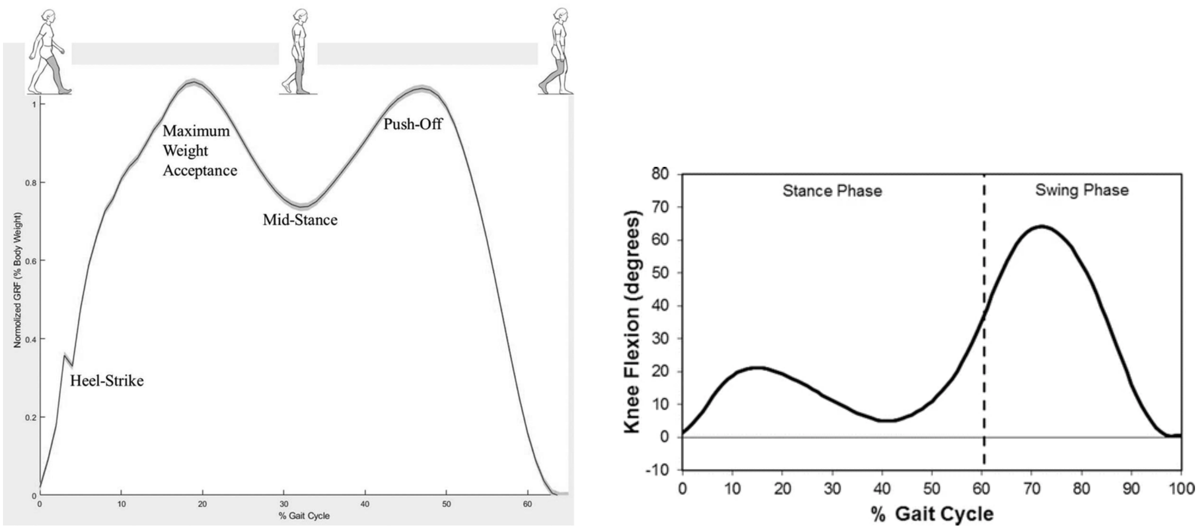


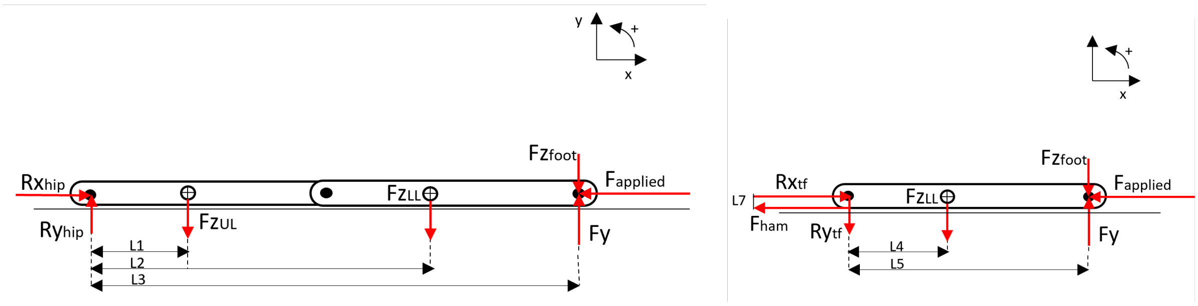
Figure 3.9: Ground reaction force and Knee flexion angle over the gait cycle [13][14].

Dynamic simulations

A biomechanical analysis was conducted to understand what effort is demanded from a patient when the knee is loaded in a certain loading condition. Initially, a free-body diagram was used to obtain insights into what effect varying the knee flexion angle has on the knee moment, muscle forces, and joint reaction forces. Subsequently, OpenSim was used to simulate the loading response induced by the knee loader, which allows to easily make changes within the loading conditions and evaluate what the effect is. The impact of adjusting the knee flexion angle and the location of the applied force will be assessed. The moments around the ankle and knee will be considered, as well as the force in the quadriceps and the reaction forces in the ankle and knee joints.

Free-body diagrams of the patient laying supine with an axial load applied at the foot with 0° and 20° knee flexion are created (figures 3.10 and 3.11). Since a static leg is desired, the sum of the moments around the hip joint should be equal to zero. Using equation 3.1, the vertical reaction force (Fy) could be calculated.

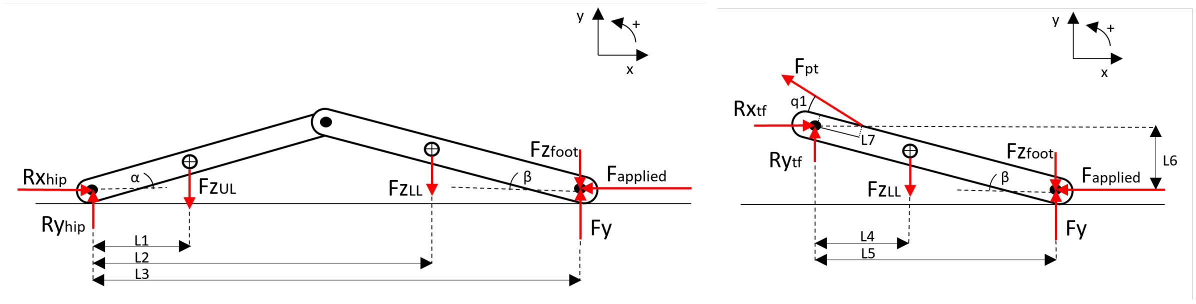
With a free body diagram of the lower leg (figures 3.10b and 3.11b) the knee joint reaction forces of the femur on the tibia and the effect on the quadriceps and patellar tendon were considered. An upper



(a) The applied horizontal force at the foot (F_{applied}) is a simplified representation of the ground reaction force during gait. The gravitational forces of the upper leg, lower leg, and foot are included (Fz_{UL}, Fz_{LL}, Fz_{foot}). The vertical reaction force F_{y}) could be determined using the moment equation (3.1) around the hip.

(b) FBD of the lower leg. Joint reaction forces (Rx_{tf}, Ry_{tf}) and muscle forces (F_{ham}) in the knee joint could be determined using equations (3.2, 3.3 and 3.4)

Figure 3.10: FBD of external and internal loads at the extended knee.



(a) The applied horizontal force at the foot (F_{applied}) is a simplified representation of the ground reaction force during gait. The gravitational forces of the upper leg, lower leg, and foot are included (Fz_{UL}, Fz_{LL}, Fz_{foot}). The vertical reaction force F_{y}) could be determined using the moment equation (3.1) around the hip.

(b) FBD of the lower leg. Joint reaction forces (Rx_{tf}, Ry_{tf}) and muscle forces (F_{pt}) in the knee joint could be determined using equations (3.2, 3.3 and 3.4)

Figure 3.11: FBD of external and internal loads at the 20° flexed knee.

leg support should be provided as feedback for the knee flexion angle. Since the support is not taken into account in the FBD, it should not push or pull at the upper leg. This should be requested from the patient during the knee loading.

$$\sum_{M_{\text{hip}}} = -Fz_{\text{UL}} \cdot L_1 - Fz_{\text{LL}} \cdot L_2 - Fz_{\text{foot}} \cdot L_3 + Fy \cdot L_3 - F_{\text{applied}} \cdot L_6 = 0 \tag{3.1}$$

$$\sum_{M_{\text{knee}}} = F_{\text{pt}} \cdot \sin(q_1) \cdot L_7 - Fz_{\text{LL}} \cdot L_4 + Fy \cdot L_5 - Fz_{\text{foot}} \cdot L_5 - F_{\text{applied}} \cdot L_6 = 0 \tag{3.2}$$

$$\sum_{Fx} = Rx_{\text{tf}} - \cos(\beta + q_1) \cdot F_{\text{pt}} - F_{\text{applied}} = 0 \tag{3.3}$$

$$\sum_{Fy} = Ry_{\text{tf}} + \sin(\beta + q_1) \cdot F_{\text{pt}} - Fz_{\text{LL}} - Fz_{\text{foot}} + Fy = 0 \tag{3.4}$$

The '3DGaitModel2392' was used in OpenSim (height of 1.8 m, mass of 75 kg). The model consists of 13 rigid body segments and includes the lines of action of 92 muscles. To simulate a static position, constant joint angles and constant forces for Fx and Fy are applied (figure 3.12). Fx is pre-determined (50% body weight) and Fy is calculated from equation 3.1. Six simulations have been executed, including three knee flexion angles (0°, 10° and 20° with a load applied through the top of the calcaneus) and three different heights in load application (through the bottom and top of the calcaneus, and through the toes, all in 10° knee flexion). In the full extension loading condition, an extra normal force is applied at the upper leg, assuming the upper leg rests on the knee support. The internal joint moments and joint reaction forces were evaluated. The joint reaction forces were expressed in the anterior-posterior, medial-lateral and seperior-inferior directions.

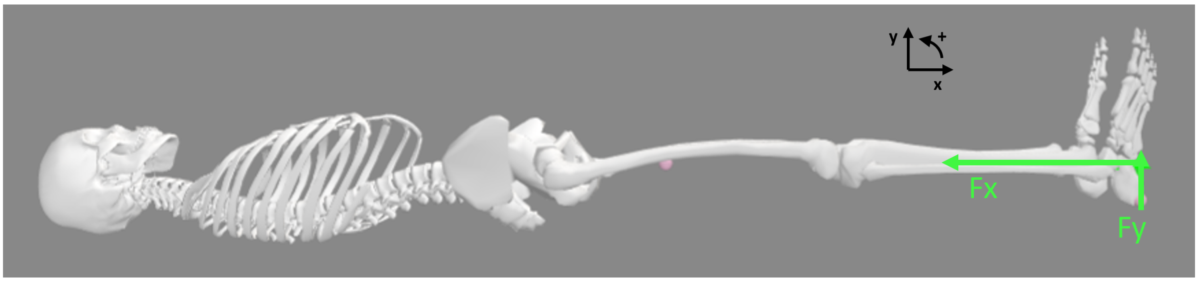


Figure 3.12: Opensim model '3DGaitModel2392' in full extension. The applied forces are manually positioned in this illustration because they are not fully visible within the model, given that they go through the bodies.

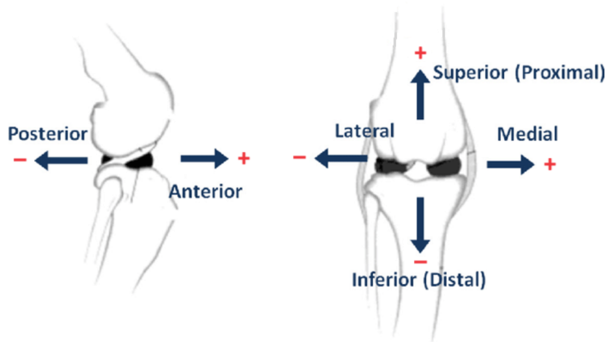


Figure 3.13: The six degree of knee motion freedom for human right knee, adapted from [19]. The plus signs resonate with the positive direction of the reaction forces.

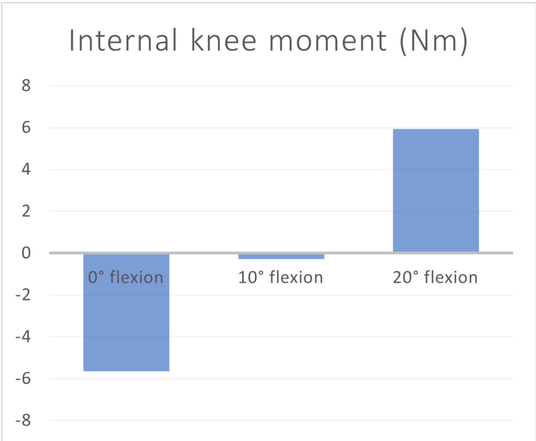


Figure 3.14: Internal knee moments in different loading conditions

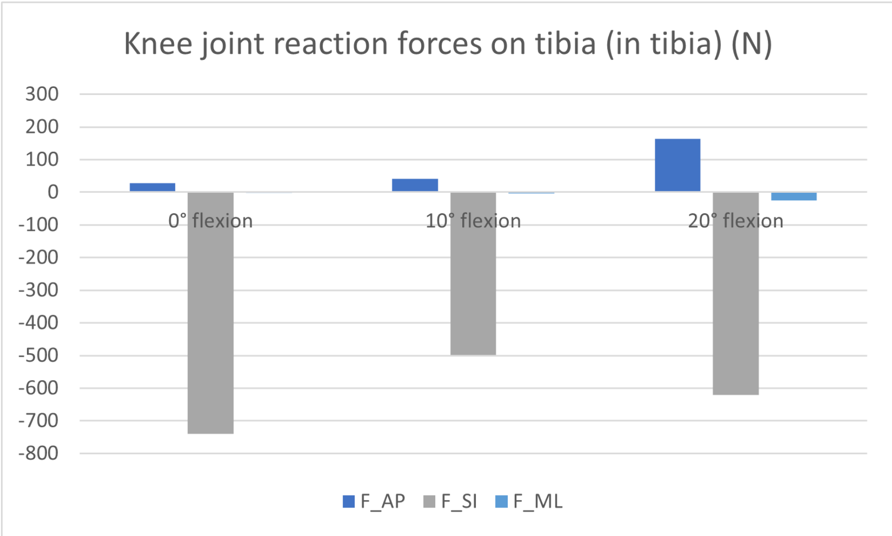


Figure 3.15: Knee joint reaction forces in tibia (on tibia) (N). F_{AP} is the reaction force in the anterior/posterior direction, F_{SI} in the superior/inferior direction, F_{ML} in the medial/lateral directions (figure 3.13).

Results and Discussion

The largest internal knee moments were in the extended knee, see figure 3.14. This was unexpected, as under normal standing conditions, internal knee moments are generated by moment arms between the GRF and the knee joint, which are larger in flexion compared to extension. When a patient is lying down, such as during an MRI, the gravitational force affects the mechanics of the knee differently. A normal force under the foot in the vertical direction, Fy, catches the weight of the leg. Figure 3.10a shows Fy can be calculated from solving the moment equation (3.1) around the hip. Fy has a larger magnitude than Fz_{LL}. In figure 3.10b could be seen that Fz_{LL} creates a negative moment around the knee joint. Fy has a larger magnitude and a larger moment arm, and therefore a resulting positive moment around the knee joint. Therefore, with an extended knee the hamstrings are engaged to maintain knee stability, while in 20° flexion the quadriceps are engaged. At 10° flexion, the net moment is nearly zero, requiring the least effort from the patient. Engaging the quadriceps and/or hamstrings increases joint reaction forces. Since these muscle forces are minimal in 10° flexion, the joint reaction forces are lowest as well. This could be seen in figure 3.15

In addition to varying the flexion angle, adjustments to the height of the applied force are done as well (figure 3.18). 3.16 shows that the magnitude of the experienced joint moments is highest with the highest force application at the toes. This is caused by the relatively large moment arm between the force application and top of the calcaneus, which is the location where the internal knee moment equals zero. As the applied force operates in front of the knee, it generates an extending moment at the knee, having the same direction as the dorsiflexion moment exerted at the ankle.

Relatively large joint reaction forces are experienced with the load applied at the bottom of the calcaneus and the toes (figure 3.17). This could be explained since external moments around the ankle are created when the applied load does not go right through the ankle. For example, in the ‘high’ loading condition a large force needs to be provided by the triceps surae to prevent dorsiflexion and results in large reaction forces in the ankle and knee. The ‘low’ loading condition has a similar effect, with a reduced magnitude of the applied external moment due to the distance between the bottom of the calcaneus and the center of the ankle.

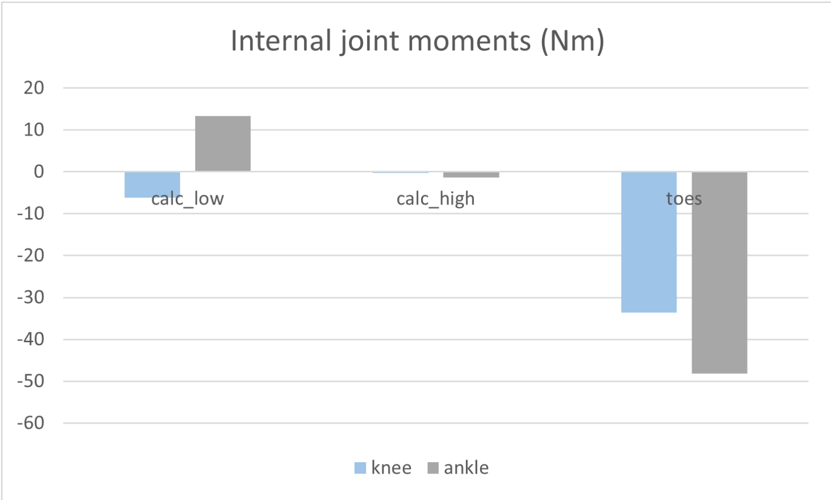


Figure 3.16: Internal joint moments with height adjustment of applied force (Nm)

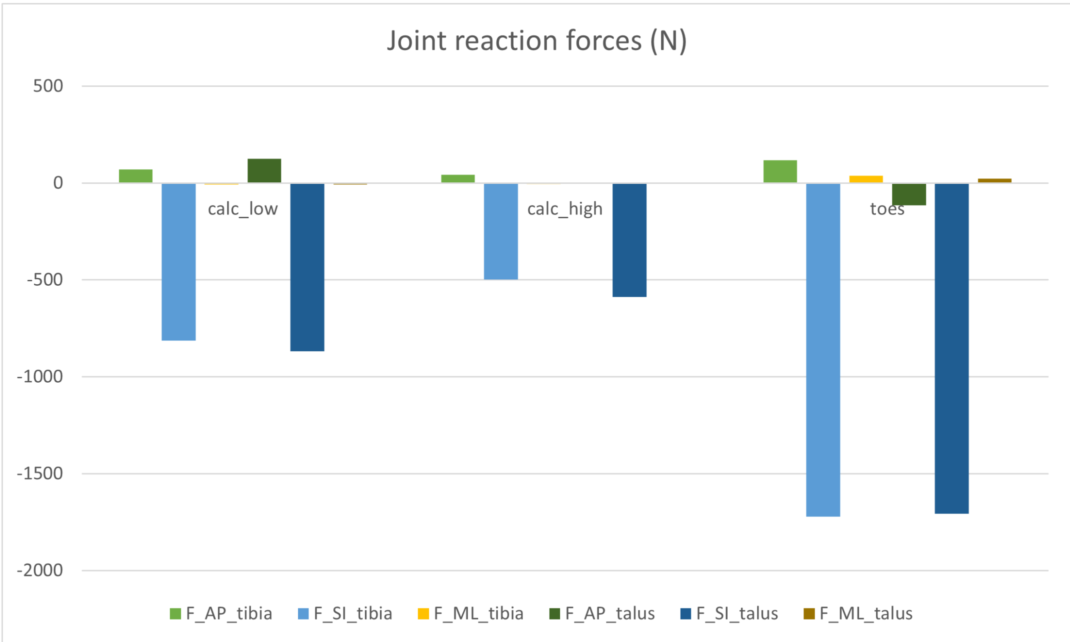


Figure 3.17: Joint reaction forces at the tibia and talus with height adjustments in applied force (N). F_{AP} is the reaction force in the anterior/posterior direction, F_{SI} in the superior/inferior direction, F_{ML} in the medial/lateral directions (figure 3.13).

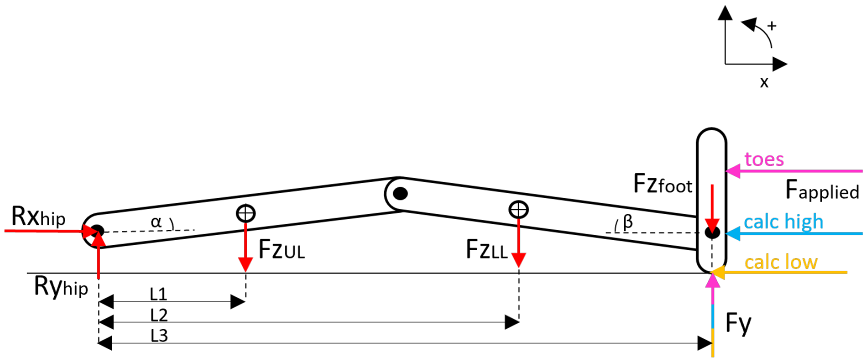


Figure 3.18: FBD including the different heights where the forces are applied at the foot in different loading conditions including their effect on the magnitude of Fy.

Concluding from this analysis, the effect of knee flexion angle and the location of the applied force have been investigated. It was found that 10° flexion with the force applied right through the ankle ('normal height') would be the loading condition requiring the least effort from the patient to maintain stable. Therefore the MRI knee loading device should provide loading at the height of the ankle joint. Although 10 deg flexion requires least effort from the patient, the ability to vary the flexion angle is still important to be able to investigate which position is the most accurate predictor for early OA. The MRI knee loading device should therefore enable loading the knee in 0°, 5°, 10°, 15° and 20°.

3.4. Risk management

Risk management has been done based on the templates provided by the Medtech Innovation Support Office (MISO), which are in accordance with ISO NEN-EN-ISO 14971:2019. Risk management consists of several steps: risk analysis, risk evaluation and risk control.

The risk analysis helps identify potential hazards, assess their severity, and determine the likelihood of occurrence. The intended use of the device needs to be clear to be able to do this. In the risk evaluation phase probability and severity are multiplied resulting in the risk level. Risks are evaluated in 'unacceptable' (red), 'reduced as much as possible' (orange)' and 'acceptable' (green). This assessment is documented in table 3.2. After risk evaluation, mitigation measures are explored to reduce the risks as much as possible. Risk mitigation could be done by: inheriting safety by design, protective measures in the actual medical device and/or manufacturing process or information for safety, such as labeling and instructions for use.

The main hazard identified creating potential risks was 'energy risks', including mechanical forces (with regard to the patient and the design) and unintended movements. These risk could be mitigated by biomechanical analyses considering the effort required by the patient when the knee is loaded and doing pilot tests to check test the feasibility. The risk of mechanical forces in the design is mitigated through several design principles: overdimensioning parts to achieve a safety factor, employing smart construction techniques to ensure loads are properly transmitted within the design, minimizing reliance on nylon fastener connections, and conducting strength tests on a prototype before involving any persons. Use risks are mitigated by providing clear instructions, ensuring intuitive handling of the device and ensuring a robust design without fragile connections.

	Risk analysis			Risk evaluation			Risk control
	Hazard	Foreseeable sequence of events	Possible injury or consequence	Probability	Severity	Risk level	Mitigation measures
Energy risks							
1	Mechanical forces	Knee will be loaded for too long	Patient experiences pain caused by applied force	4	2	8	Searching the literature beforehand and conducting experiments to determine which forces are tolerable for the target audience, for how long, at which knee flexion angle. Ensuring there is a possibility to remove the load directly.
		Patient is attached to the MRI environment/knee loader for stability.	Patient experiences discomfort.	4	2	8	Attempting to distribute the force as evenly as possible over the body, enlarging the contact surface. Additionally, introducing a slight incline to create a horizontal normal force component that pushes the person back slightly.
		The patient becomes tired, movement in de legs	Motion artifacts	4	2	8	Searching in literature beforehand and conducting experiments to determine which forces are tolerable for the patient, for how long, and at which knee flexion angle.
		The device is not properly secured and falls	The device can get damaged	1	2	2	
		Forces are too large for the device	The device may break. It could happen that a part moves towards the patient.	2	3	6	Using safety factors in the calculation of components. Do not rely on nylon fasteners for strength, but design in a way the construction absorbes the load. Testing connections between components in verification tests before it is used on the patient.
2	Unintended movements	Footplate detaches from the foot and movestowards the patient.	Footplate moves with velocity towards the patient.	2	3	6	Ensure proper fitting of the footplate to the patient and use fixation bands.
Biological risks							
1	Biological contamination hazard	Bacteria or fungi haven't been thoroughly cleaned.	Infection	1	3	3	Using material that can be effectively disinfected. Furthermore, the device should also be disassembled for proper sterilization.
2	Allergic reaction	Patient may be allergic to materials or cleaning products.	Allergic reaction	2	3	6	Screening patient on allegies
Environmental risks							
1	Devices which need to coorporate are not alligned with each other	The knee loader could not be used together with the knee coil or the patient bed.	The knee loader could not be used properly	2	3	6	Analyse how the device could interact with the existing devices by consulting labarotory workers and technicians.
2	Magnetical field MRI	The magnetic field could heat up non-ferrous metals.	When these components are located at the skin surface, this could lead to burns. Moreover, non-ferrous metals could distrub images.	2	3	6	Do not use ferrous metals. Preferably, also avoid using non-ferrous metals. If it's necessary, they should not be in contact with the skin surface. Moreover, if they are used it should be tested if it is feasible and does not cause image disturbtion.
		It's possible that during the production process, a piece of ferrous metal accidentally got into the device. This will be pulled out by the magnetic field.	This could lead to severe injuries or damage to the equipment	2	4	8	Use a metal detector before introducing the deviceto the MRI room.

Table 3.2: Risk matrix

	Risk analysis			Risk evaluation			Risk control
	Hazard	**Foreseeable sequence of events**	**Possible injury or consequence**	**Probability**	**Severity**	**Risk level**	**Mitigation measures**
Use risks							
1	Sharp edges, points and protruding parts	The device contains sharp edges, points, and protruding parts.	The patient could hurt himself or herself.	1	2	2	During the design process, ensure that angular components have rounded edges and that no parts protrude.
2	Uncareful use of the device	The user acts quickly, resulting in rough handling of the device.	The device may be damaged.	3	2	6	Design the device as robustly as possible. Avoid adding fragile components and/or connections.
Inappropriate, inadequate, or overly complicated user interface, man/machine communication.							
1	Complex or confusing operation of the device	The intended use of adjustments is not interpreted correctly by the technician, leading to incorrect adjustment of the device.	The patient might experience discomfort if the device is not properly adjusted.	2	2	4	During the design phase, the settings should be designed in a way that makes them easy to use and understand. Moreover, the users should be trained and instructed to use the device properly.
Risks due to defects, maintenance, and aging							
1	Decreased functionality due to frequent use	The device may no longer perform its functions correctly within thespecified tolerances: force magnitude and knee flexion angle	The knee is not loaded in the intended manner. The outcomes of the experiments will be less reliable.	2	2	4	Frequent verification tests, depending on the final design

Risk matrix (continued)

Part II

Define

4 Requirements

The list of requirements of the MRI knee loading device is based on existing literature, expert knowledge and the analyses presented in chapter 3.

Functional requirements

Performance requirements:

- The loading device should be able to apply a static, axial load through the foot at the patient's knee while in supine a position. *This load should induce a response in the knee joint which could be assessed to evaluate the load-bearing capacity while ensuring the stability of the patient's knee and a high-quality MRI scan. This includes taking into account factors such as the loading magnitude, location of the applied load, direction of the applied load, and the knee flexion angle.*

Specifications:

- The loading device should be able to load the knee at different angles ranging from 0° to 20° in steps of 5°. *Based on recommendation from the literature study and validated with Jaap, Jos and Mariska. These angles loaded heaviest during the stance phase and therefore likely represent an insightful loading condition for assessing OA. It is not necessary to adjust in every single degree because it would add limited clinical value and in practice it would be hard to validate whether it is exactly that amount of flexion.*

- The loading device should be able to provide an accurate force, with an allowed error of 3.33%. (Depending on the loading strategy. If possible, a smaller error is preferred.) Measuring this force digitally is the preferred option. *Discussed with Erin Macri. 3.33% is based on the load perception of a person, assuming that a person of 60 kg would not experience a large difference in tolerance holding a 2 kg weight.*

- The loading device should be able to provide different magnitudes of forces. The applied force is a percentage of someone's body weight (25% or 50% body weight patients) and therefore the device should be adjustable to be suitable for multiple patients. The load range should be between 13.9 kg and 48.5 kg. The magnitude should be adjustable in steps of at least 0.5 kg. *25% or 50% of body weight is based on the literature study recommendation, so the effect of using different magnitudes of forces could be evaluated. The weights are based on DINED [8] using the P5 and P95 values of the population Dutch adults 30-60 years old. 0.5 kg fits safely within the difference in 'participant tolerance'.*

- The load should be applied at the foot. It should be applied at a height where limited joint moment is created around the ankle ($\pm$ 3 Nm). *Within the range of flexion angles between 0° and 20°, the ground reaction force acts between the heel and the middle of the foot. Applying the load through* *the ankle prevents burdening the patient with a high moment around the ankle, which costs more effort to maintain and is not required for loading the knee. +/- 3 Nm is based on that it is half the effect of what $\pm$ 10° (with respect to 10° knee flexion) has on the effort required.*

- The loading device should fit or be adjustable to the dimensions of different participants (within P5 and P95 of the population of Dutch adults 30-60 years old based on DINED [8]).

- The loading device should prevent creating motions/instabilities. The participant should be constrained in all directions. The position of the knee should be guided by the set-up and the participant should actively maintain the position. The upper leg should be supported and the ankle should be stabilized to prevent rotation of the knee. (If the lower leg would be supported, the loading device would absorb the load intend for the knee joint.)

Constraints:

- The loading device should fit in the MRI environment and within the dimensions of the MRI scanner. Diameter MRI bore: 60 cm. Measure range: 50 cm. The measure range specifies the area within the bore where tissues can effectively be imaged.

- The loading device will be used in an MRI scanner and should not contain magnetic metal components. Non-ferrous metals like aluminum can be used in the MRI room (for preparations) but should not be used under the MRI scanner. *source: Luud Rijnen. Ferrous metals are magnetic and should therefore not be used in the MRI, as they are attracted by the magnetic field. Non-ferrous metals could cause disruptions in the image. Moreover, it could get warm and therefore should not be in direct contact with the patient during the scan. Edwin Oei: aluminum should not give problems. It should be tested in the MRI if it is desired to use.)*

- The loading device should be compatible with the flexible knee coil. *source: Luud Rijnen. The flexible knee coil can be used for all patients. The standard knee coil cannot be used for everyone, but gives a better signal and more stability)*.

- The loading device should be used with the 'feet first position', where the patient's head is outside the MRI bore.

- The knee should be located in the middle of the bore. *source: Luud Rijnen. Because the signal is weaker at the outlying areas, in the width and height of the bore.*

- The knee should located in the middle of the bore and the knee coil should be aligned with the magnetic field (which translates to alignment within the bore). *source: Luud Rijnen. Under these circumstances, the signal is best.*

Use requirements

- Using the loading device should not result in discomfort for the participant.

- Laboratory personnel should find it feasible to use the loading device, indicating that they can execute the necessary actions. This also implies that the MRI loading device should be user-friendly and straightforward to operate effectively. After training, the required operations should be easily remembered and integrated into the workflow.

- The set-up time of applying the force to the patient's knee should be as quick as possible. The total procedure may not exceed 45 minutes (including screening, patient changing clothes, room preparations/loading device set-up, patient positioning on the table, scanning) *source: Luud Rijnen. Check if it is possible to do parts of the set-up outside the MRI to shorten the set-up time. For example, measure load. These preparations may not include the patient bed, as this is used by the previous patient.)*

- It is desirable that the device does not have many adjustments. The benefits of any adjustments will be evaluated based on the effort and time required to set them.

- It is desirable for the device to be compact, easy to replace and have an easy set-up.

Safety

The loading device should be safe to use. Risk management will be executed in all phases of the design. Risks will be reduced as much as possible, without having a negative influence on the risk-benefit ratio. Mitigation measures to control the risks are also described in table 3.2.

Set up:

- The connection between the knee coil, patient bed and the MRI loading device should be safe and not negatively influence the performance of any component.

- The loading device must be designed and manufactured in such a way that adjustment, calibration, and maintenance can be performed safely and effectively.

Design:

- The loading device should not have sharp parts sticking out.

- The design of the loading device should consider the mechanical properties of materials such as strength, deformability, fracture toughness, wear resistance, and fatigue strength.

- The loading device should be as robust as possible. This requires the device to not fail when it is used by laboratory personnel.
  (Laboratory personnel typically act very fast with setting up the patient, they might not be careful with the products they use.)

- The loading device should be able to apply forces to the participant without failing. The device should have enough stiffness to withstand the forces, which could be secured by using safety factors in the dimensions of the parts and using secure connections.

- The device should stand stable and not fall during use.

- If the loading device contains moving parts, the risks of them harming the patient should be reduced as much as possible.

- Precautions should be taken to minimize the conversion of potential energy into kinetic energy, which could pose a risk to the patient when using the loading device.

- The loading device should be modular, it should be possible to take all components of the device apart. *(In case of an infection, the device should be cleaned thoroughly. Moreover, if one of the components breaks, it should be repairable).*

Use:

- There should be a possibility to quickly remove the load if needed. *(Based on examples in literature).*

- The loading device should be cleanable, and therefore should be resistant to water, alcohol and chlorine. The device should be modular and surfaces should not have textures which have negative effect on the ability to clean. *(In the normal routine the parts which interact with the body should be cleaned with alcohol. However, if a patient has an infection, everything needs to be cleaned with chlorine as well.)*

Material selection:

- The materials used should be non-toxic.
- The materials used should not be flammable when used in an MRI scanner.
- The use of materials that contain phthalates should be reduced as much as possible.

Production

- The device's production should be achievable by a TU Delft student using the universities' facilities.

Maintenance

- Inspection and preventive maintenance (1), including all activity necessary to ensure a piece of medical equipment is functioning correctly and is well maintained, and corrective maintenance (2), to restore the physical integrity, safety, and/or performance of a device after a failure [28], should be executable for the technical team of Erasmus MC.

Standard, rules and regulations

- The loading device should comply with medical device regulations (MDR). *This includes product verification and validation. Choices in design need to be documented. Risk-benefit considerations should be done.*

5

Problem definition/design brief

Following the double diamond method, after ‘discovering’ insights into the problem and ‘defining’ the area to focus on, a problem definition/design brief is stated outlining the relevant context, design guidelines and prerequisites of the project.

The knee is the most common joint affected by OA. Early detection of OA helps for timely intervening the disease, to slow down the progression and reduce the impact on the patient’s life. Standard knee imaging with MRI is usually done with a patient in non-weight-bearing conditions. However, using weight-bearing MRI is useful to understand the biomechanics of the knee and identify conditions not diagnosed in supine, non-weight-bearing position. Using a loading device could simulate weight-bearing conditions in supine position.

These devices are currently not used in the clinic. They require a lot of time to develop which is costly over the limited evidence of clinical benefit and feasibility. Moreover, using a MRI knee loading device requires more time, which can be costly, and requires adjustments to workflow, schedules, and the training of MRI personnel.

A literature study was conducted which established the functional requirements for the design: it must apply an axial, accurate, and adjustable load through the foot to the patient’s knee in a supine position. The biomechanical analysis provided insights in the effect of loading on the internal joint moments, which reflect the effort that needs to be provided by the patient. The results showed that a load application through the ankle requires the least effort from the patient, making it most feasible loading condition to maintain stable for several minutes. The loading device should be able to apply different flexion angles at the knee, as more research is needed to determine the best loading condition to evaluate early OA.

The MRI loading device should possess adjustable features accommodating patients’ dimensions, including adjustable knee flexion angle and load magnitude. The primary focus for innovation lies in ensuring that the load is applied correctly, minimizing setup time, and ensuring feasibility. A balance needs to be found between functionality, complexity and feasibility. The mitigation measures should be considered to inherit safety by design. While the device will initially serve research purposes, future consideration will be given to its potential application in patient care.

Part III

Develop

6
Conceptual design

6.1. Morphological chart

The conceptual design phase started with creating a morphological chart, where concepts were found by integrating subsolutions that addressed subproblems (figure 6.1). These ideas were found by brainstorming and exploring existing products and mechanisms.

6.2. Design concepts

An iterative process was conducted with different combinations of subsolutions. This process resulted in three concepts, which were evaluated using a Harris profile. These concepts and the evaluation were discussed with experts to ensure validation. It was discussed with Jaap Harlaar, Mariska Wesseling, Erin Macri, Niels Dur, Jos Runhaar, Edwin Oei, Luud Rijnen and Jan van Frankenhuyzen.

Concept 1:
The first concept (figure 6.2) includes a mechanism supporting the leg with rotating linkages, with an adjustable knee flexion angle, achieved by adjusting the length of the rope between the linkages. A load is generated by elongating an elastic material. Before positioning, force is generated by the patient extending his leg against the footplate. To secure the load magnitude, a pin is inserted into the elastic band. The leg can be appropriately positioned and the pin can be removed, allowing the force to be applied to the foot.

Concept 2:
The second concept (figure 6.3) consists of two parts supporting the leg. The angles of the supporting elements are adjustable, allowing for precise positioning of the knee at the desired angle. An elastic band wrapped around the lower leg support, with a rope attached to lower and the upper leg support. The part supporting the upper leg has multiple connection points for the rope, enabling the elastic band to stretch to varying lengths. First, the length of the rope will be adjusted so it reaches the position corresponding to zero force. Next, the rope will be attached to the upper leg support element at the desired elongation of the elastic band from the zero force position. This leads to the distal part sliding proximal, since the band is not extended. The leg is positioned correctly again when the patient extends his leg, simultaneously applying the appropriate amount of load to the knee.

Concept 3:
The third concept (figure 6.4) has a leg support consisting of two linkages with an adjustable angle supporting the leg, so the knee flexion angle could be applied precisely. The linkages are adaptable to the patient's dimensions by a pin-through-hole connection. A footplate sliding over one of the linkages is pulled at with an elastic band, with cables connecting the band to a harness worn by the patient. These cables can be shortened to elongate the elastic band. By adjusting the length of the ropes, the load magnitude can be varied. The ropes traverse pulleys, so they do not cut into the patient's skin.

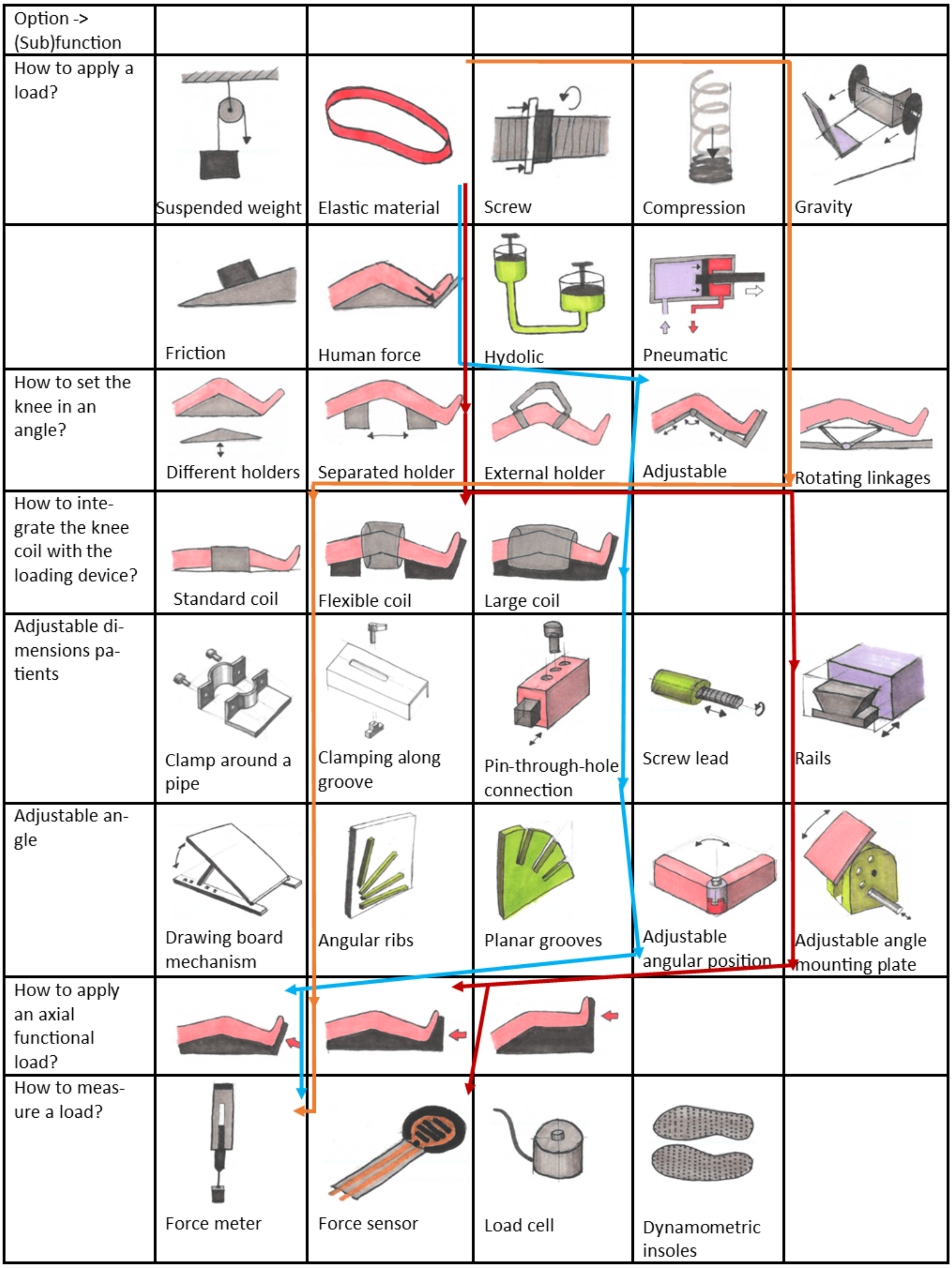
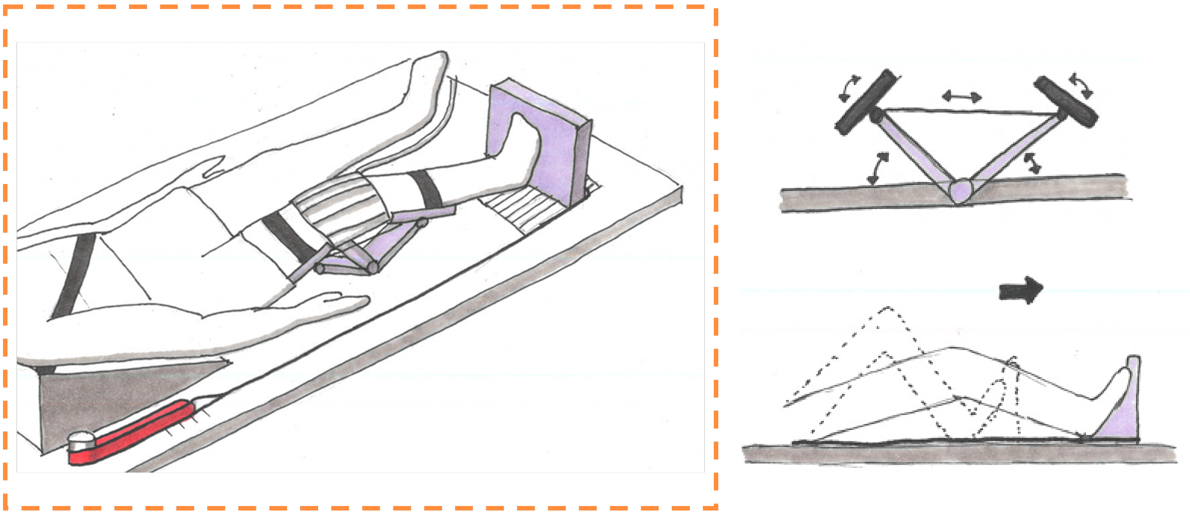
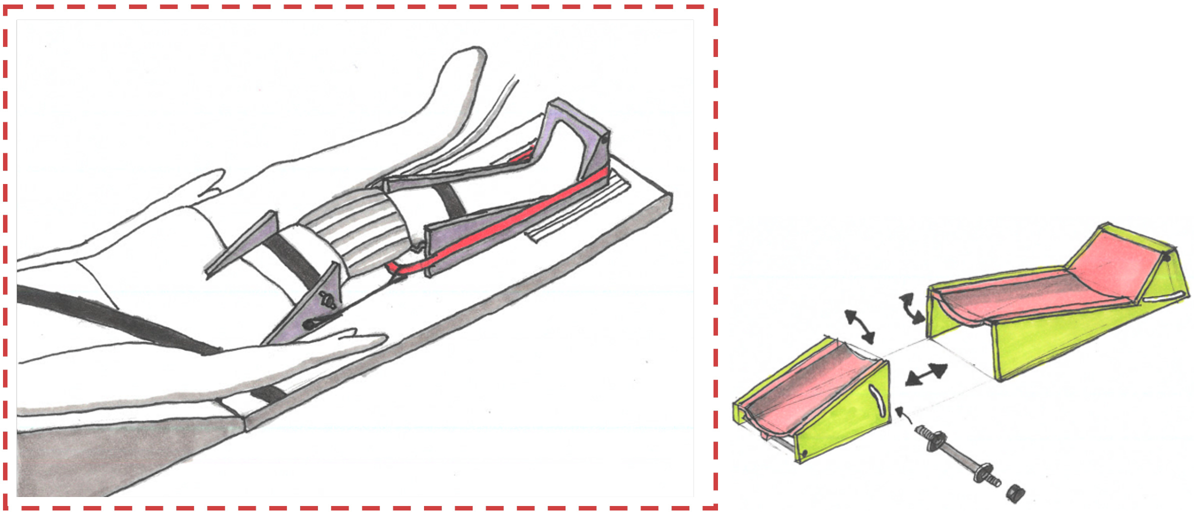


Figure 6.1: Morphological chart. Colours indicating the concepts are corresponding with figures 6.2, 6.3 and 6.4.

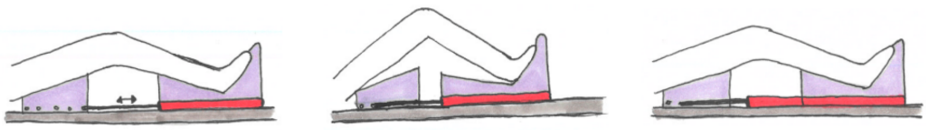


(a) Patient interaction **(b)** Product interaction

Figure 6.2: Concept 1

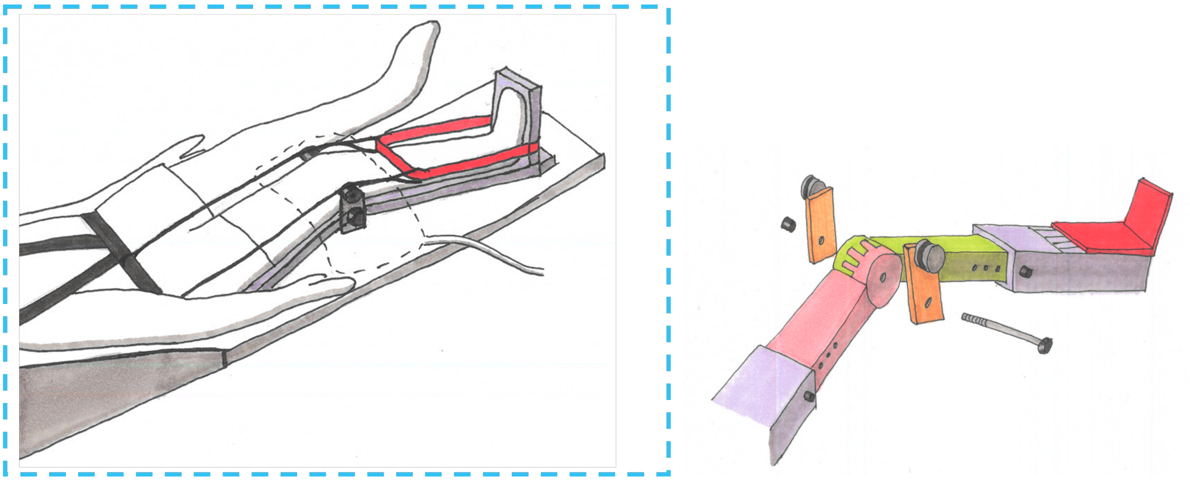


(a) Patient interaction **(b)** Detailed product



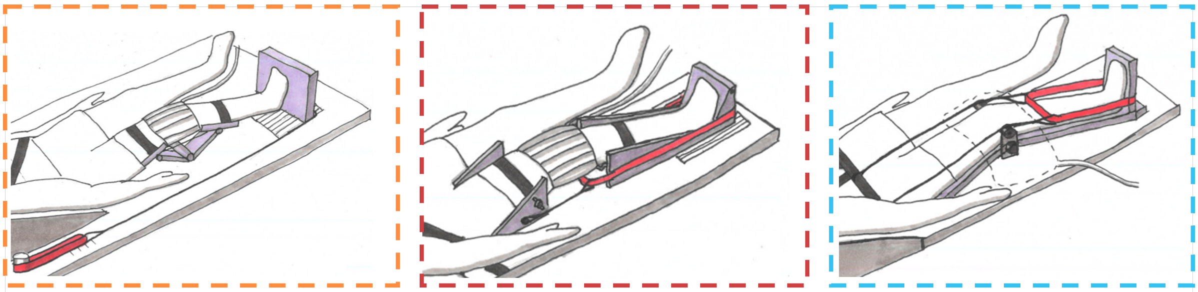
(c) Product interaction

Figure 6.3: Concept 2



(a) Patient interaction (b) Detailed product

Figure 6.4: Concept 3



Concept 1	-2	-1	1	2
Safety			■	■
Stability			■	
User friendly			■	■
Feasibility			■	
Signal			■	
Precision/accuracy			■	
Complexity			■	

Concept 2	-2	-1	1	2
Safety		■		
Stability		■		
User friendly			■	
Feasibility		■		
Signal			■	
Precision/accuracy		■		
Complexity			■	

Concept 3	-2	-1	1	2
Safety			■	
Stability			■	
User friendly		■		
Feasibility			■	
Signal	■	■		
Precision/accuracy			■	
Complexity		■		

Figure 6.5: Harris profile evaluating the three established concepts

The concepts were evaluated on several aspects, prioritized in sequence of importance: safety, stability, user-friendliness, feasibility, precision/accuracy, and complexity. This is visualized in figure 6.5. The Harris-profile decision-making approach involves summing up the black compartments on both the negative and positive sides of the table. The concept that leans most convincingly toward the positive side may be determined as the most suitable concept for the requirements.

Everyone agreed on concept 1 to meet the requirements best. The amount of adjustment is minimal, making it more user-friendly than the other two concepts. Additionally, the elastic band is positioned away from the knee and can be covered in an iterated concept, enhancing safety compared to other alternatives. The main reason for concept 2 to be excluded was that a rig for positioning needs to be separate from the force plate to be more user-friendly. Concept 3 could not be used in combination with a flexible knee coil, which has a strong preference over the other coils.

For concept 1, several crucial points were raised that were considered for the final design. The points below were considered during the next steps in the design process. The design iterations until the final design is reported in appendix B.

- The most important aspect is that the leg extension required to create the loading is too complex. It would be better if the patient is positioned, and then the load is applied without having to change the position of the patient.
- Investigate further how to apply the load at the desired position at the foot.
- The amount of friction in the footplate and whether the patient is moving during scanning needs to be factored in since this can results in a varying load magnitude which is applied at the knee.
- Placing the cable directly on the plate surface is not viable, as it should avoid contact with the patient. Moreover, if the cable or elastic snaps, this should not be close to the patient.

6.3. Detailed design

Throughout the design process, several principles were identified and considered for the feasibility of the prototype to be developed.

- Given the constraint of not using metal in the design, plastic bolts, screws, and nuts should be used. Since these have lower strength than metal ones and no specifications were given, the device was designed to use bolts and screws for connections they do not need to withstand high tensile or shear forces.
- Components can be purchased, 3D printed, or made from PMMA plates. It is preferred to purchase pre-made parts rather than manufacturing them myself. When deciding on the manufacturing method for each part, it is important to prioritize either enhanced flexibility in shape or strength. 3D printing offers greater flexibility in shapes but comes with its limitations. While the strength is generally lower compared to PMMA plates, it is also influenced by the printed orientation and the tolerances are greater. Opting for PMMA plates enhances strength, but improving shape flexibility necessitates the establishment of connections that may adversely affect the part's integrity.
- Functionality will be integrated into one single part as much as possible. However, the components must have sufficient thickness to ensure enough stiffness, and integrating all features into one part may result in oversized components that demand excessive 3D printing time.
- Considering manufacturing tolerances in the design is crucial. For instance, in 3D printing it's necessary to incorporate tolerances into the part's design, anticipating potential issues with a perfect fit. There are parts where the fit needs to be exactly right. In such cases, it becomes essential to produce multiple versions of the part with slight dimensional variations and determine the best-fitting one through practical testing.
- There is a critical importance of aligning components that move along a specific axis. Consequently, when two parts are intended to slide along the same axis, it is essential that they are not integrated into a single component. If one of them deviates from the specified dimensions, it could disrupt the alignment along the axis. Therefore, it is advisable to have them as separate parts. This approach allows them to slide independently along the axis before being connected seamlessly.
- Bolts will be used rather than countersunk screws. Bolts provide greater flexibility in positioning, although they may be less convenient for the design since they have large heads. On the other hand, countersunk screws are self-centering but lack the flexibility in positioning. Therefore, it should be considered whether the flexibility of positioning or the shape of the fasteners should be prioritized.

- Finally, the use of pulleys should be reduced as much as possible. Each pulley represents a potential ‘problem zone’, as there is a risk of the cable slipping out of the wheel when it is not under load. Moreover, high stresses are created at the axes and in connecting them to the environment, which increases the opportunity for the device to fail.

7
Final design

7.1. Final design
The final design of the ‘MRI knee loader’ is visualized in figure 7.1, 7.2 and 7.3.

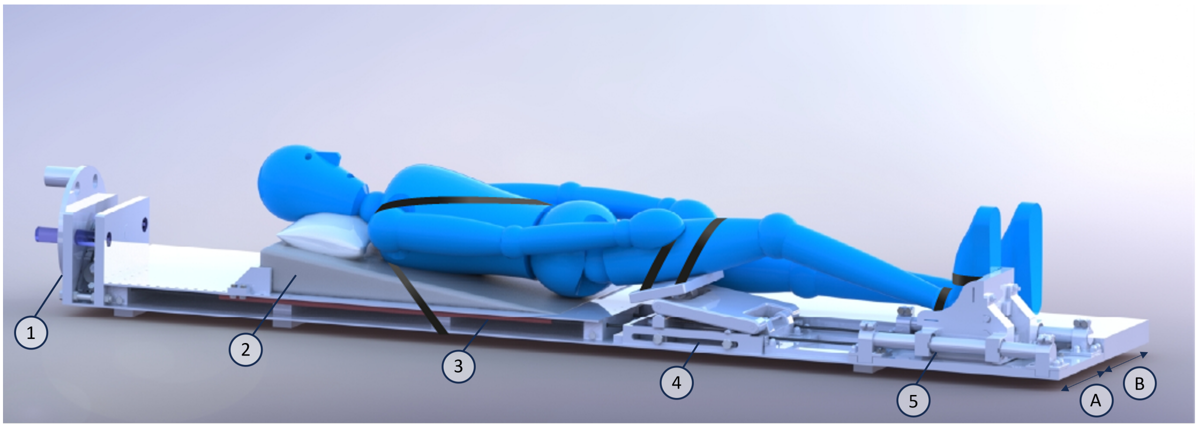


Figure 7.1: Final design of the MRI loading device with a patient.
1: drive wheel, 2: back support, 3: elastic spring, 4: knee support, 5: footplate
A: knee loading section, B: support section

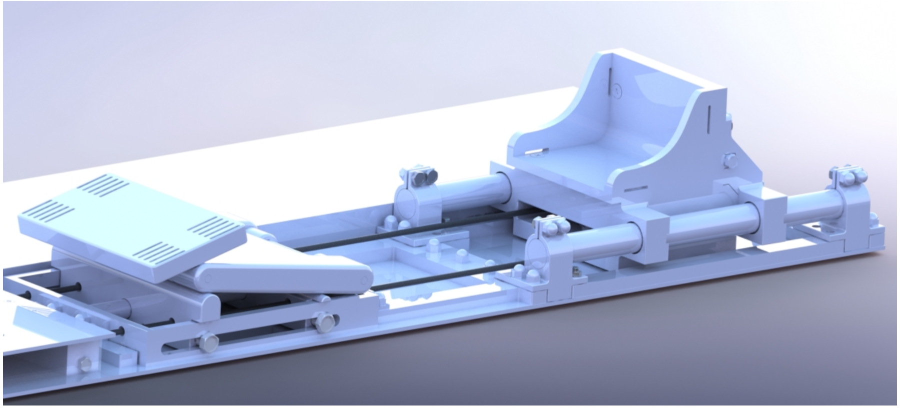


Figure 7.2: Detailed view of the knee support and the footplate.

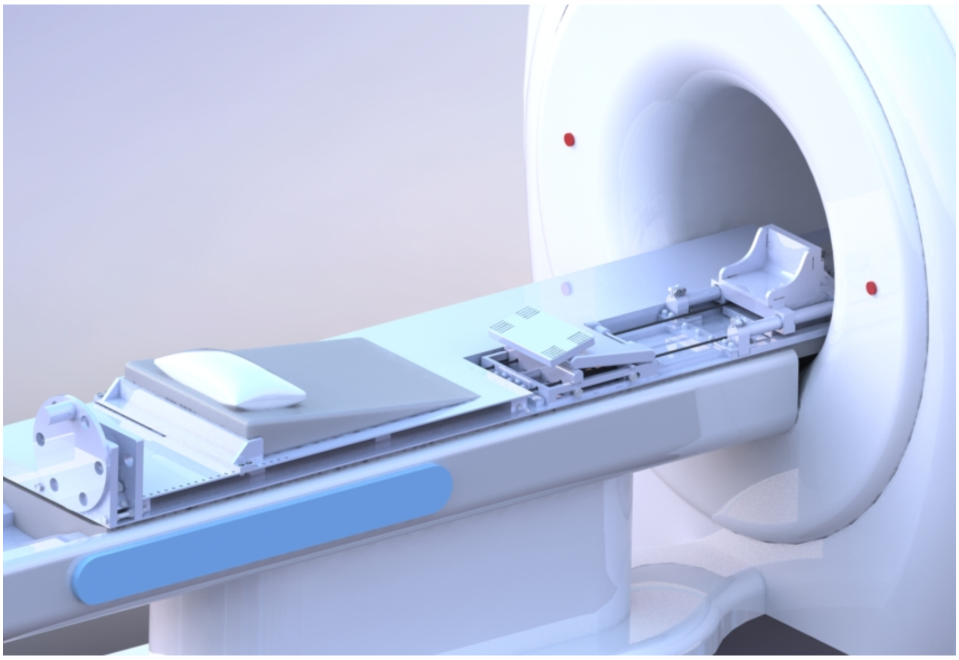


Figure 7.3: Final design of the 'MRI knee loading device' located on the patient bed, in the MRI.

In the final design a load is generated by elongating an elastic component connected to a cable threaded through a pulley system positioned beneath a footplate. Through this footplate, a load is exerted on the foot and transmitted through the knee. The knee support ensures the knee could be supported in the desired knee flexion angle. The device consists of two longitudinal sections: the knee loading part and the support part. The design of the MRI knee loading device is fully symmetrical, so it could be used for the left and the right knee.

Foot plate

The foot is positioned at the base of the footplate (figure 7.2) and could be fixated to the sides of the footplate with fixation bands. In that way, the ankle is stabilized as much as possible and prevented from rotating.

Since the footplate is a highly complex part (figure 7.4), 3D printing was the preferred manufacturing method. 3D printing (FDM) the entire footplate is not recommended, as it would take a around two days. With this relatively long printing time, the risk that the printer could stop resulting in a failed print was increased. Therefore, it was divided into multiple parts, figure 7.4. This was being done a manner that minimized the impact on the strength: avoid splitting the part at high-stress points and separate material which is not loaded. A finite element analysis was performed on the footplate, where the stresses and deformations were between acceptable limits (appendix C).

Load magnitude

According to the requirements, the applied load should be 25% or 50% of a person's body weight. This load can be achieved by rotating the drive wheel and elongating the elastic material. The elastic material should be calibrated, and the desired load can be applied by elongating the spring to the corresponding length. As shown in figure 7.1, the side of the table is transparent, allowing the elongation of the elastic material to be measured.

The load is locked by applying a thick pin through the holes of the driving wheel and the plates the driving wheel is connected to (figure 7.6). To release the load, the pin can be removed, allowing the elastic material to return to its resting length.

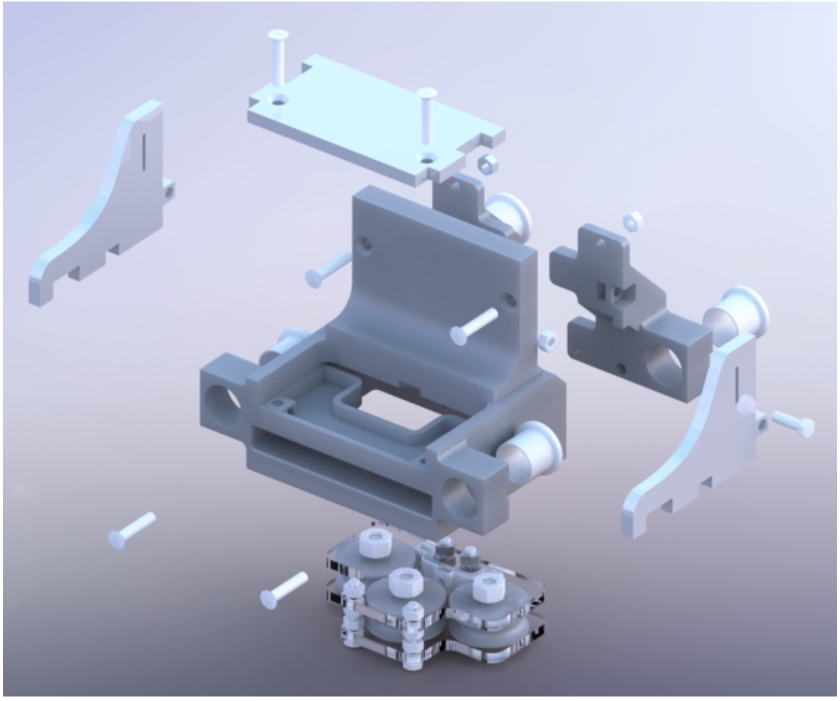
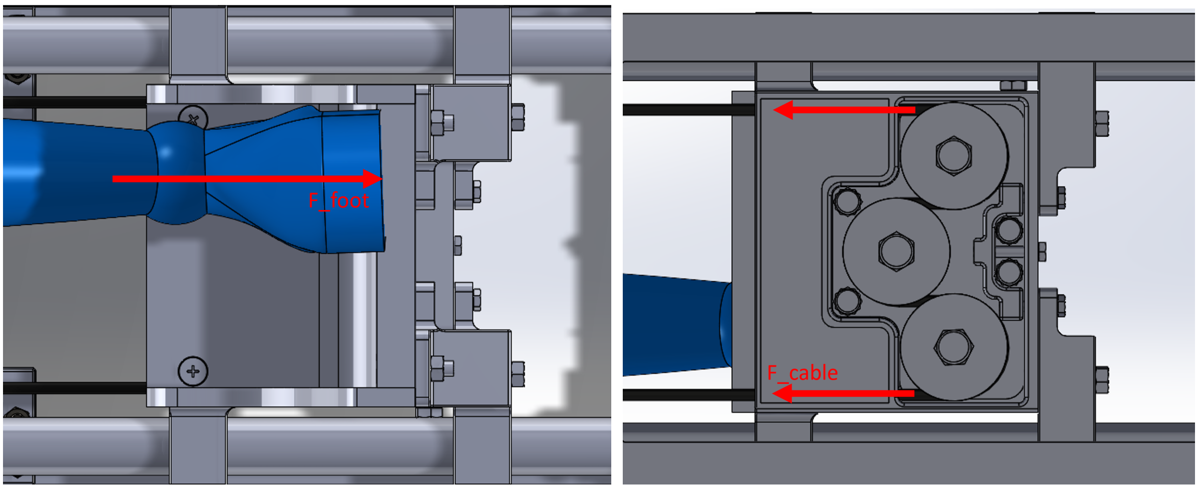


Figure 7.4: Exploded view of the footplate, illustrating all parts. The high gloss white appearance plates as well as the clear plates (in the pulley block) are made of PMMA. The soft grey plastic appearance parts are 3D print parts.

Force transmission

A pulley system is integrated at the bottom of the footplate to ensure a force transmission between the force applied on the foot and the force in the cable (figure 7.5b). At the drive wheel, force transmission is achieved by creating a distance between the handle and the axis of rotation (figure 7.7). These transmissions are related in equations 7.1 and 7.2.



(a) Top view of the footplate interacting with the patient's foot, illustrating the reaction force of the foot on the footplate.

(b) Bottom view of the footplate, illustrating the cable force in the pulley system.

Figure 7.5: Force transmission through pulley system.

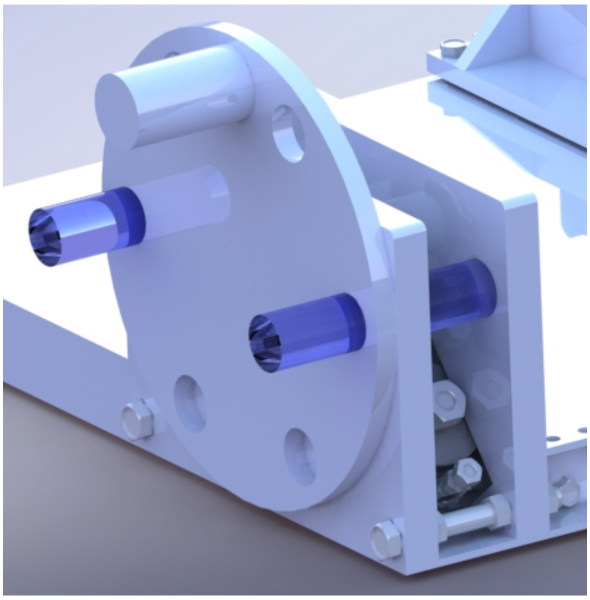


Figure 7.6: Driving wheel with two blue axes through it, securing the wheel's position and locking the length of the elastic material.

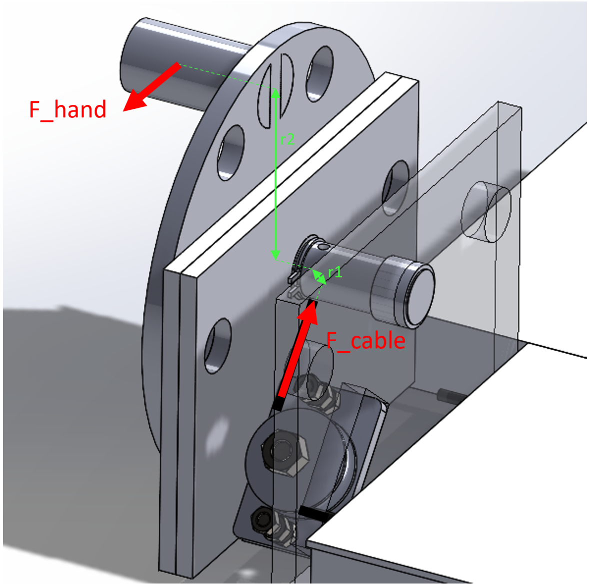


Figure 7.7: Force transmission at the driving wheel, using the principle of torques around the axis.

$$F_{\text{foot}} = 2 \cdot F_{\text{cable}} \tag{7.1}$$

$$F_{\text{cable}} \cdot r_1 = F_{\text{hand}} \cdot r_2 \tag{7.2}$$

F_{cable} is a factor two smaller than F_{foot}, since the mechanical advantage (ratio of the output force to the input force) is equal to the number of ropes with variable length in the pulley system in an ideal situation without friction [16] (figure 7.5b). 1 cm change in the position of the footplate relates to 2 cm of displacement in the cable. Therefore, the force in the cable is 2 times smaller. The transmission described in equation 7.2 is based on the torques which should be equal around the axis at both sides of the equation.

It was anticipated that the transmission would not be ideal and that static friction would negatively impact its efficiency. No friction static coefficient was found between nylon (bearings) and PMMA (axes) in literature, and it must be considered that the friction coefficient is also depended on factors like surface roughness and environmental conditions. Moreover, the friction coefficient of PMMA was found to increase under compressive stress [21]. The amount of friction will be evaluated through verification tests conducted with a prototype.

Knee support

In this design it was required to be able to load the knee in flexion angles between 0° and 20°. This requirement is met by a system illustrated in figure 7.8. Figure 7.9 and 7.10 illustrate the extreme positions of the supporting block with a small patient in small flexion and a larger patient in large flexion, as they determine the extreme positions of the support blocks. A comprehensive explanation of dimensions in relation to measurements is provided in appendix D.

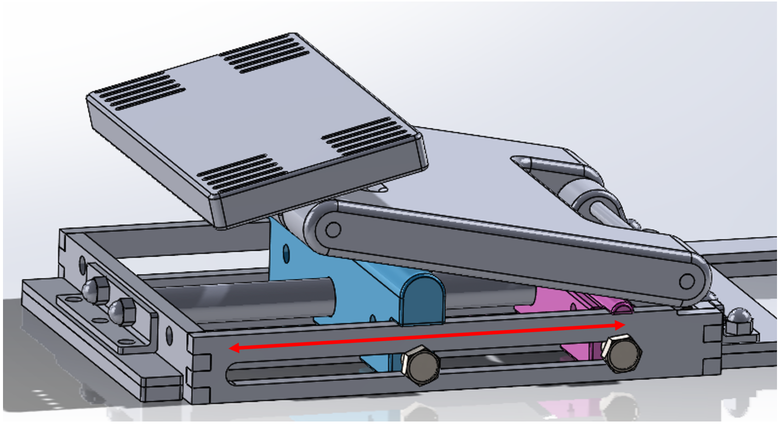


Figure 7.8: Knee support allowing the patient's knee to flex in angles between 0° and 20°. The small support block (pink) could slide along the length of the 'box', as indicated with the red arrow, and be clamped in its place at every desired position. The function of the large support block (blue) is to offer extra support to the H-part, particularly in situations involving greater flexion angles when the small block is positioned closer to the hinge.

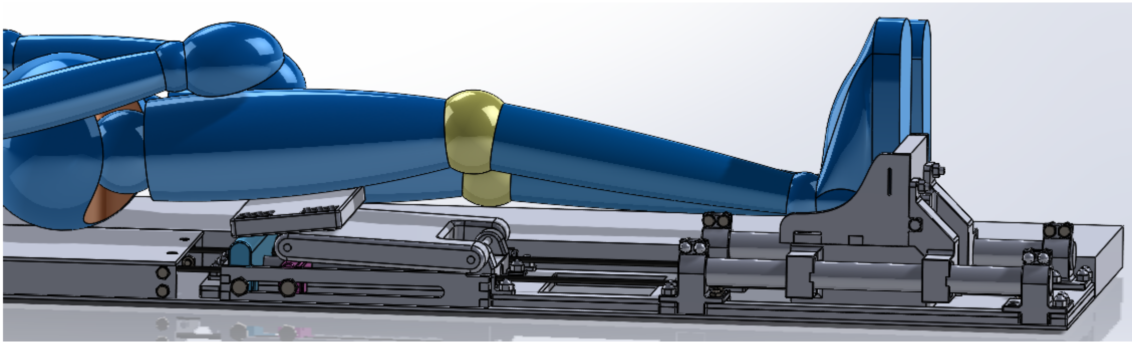


Figure 7.9: Knee support providing support to a relatively small (160 mm) patient in small (∼5°) knee flexion.

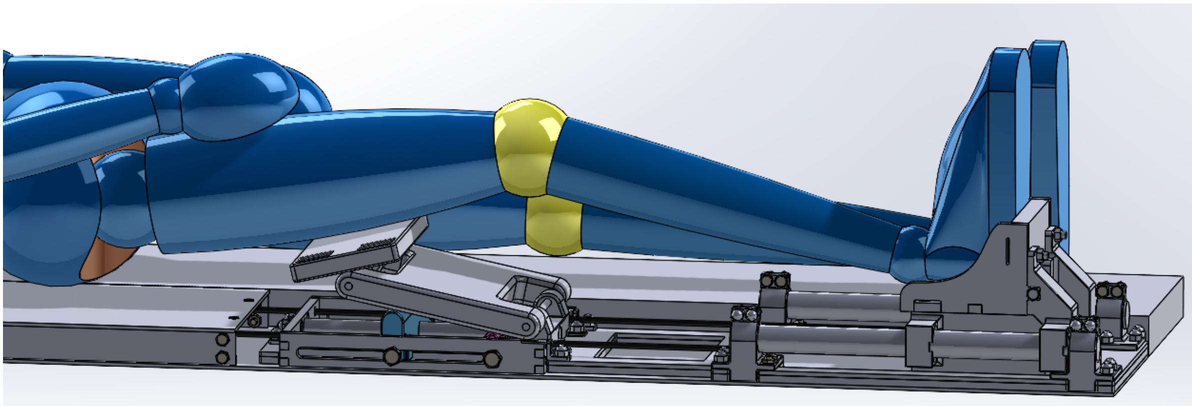


Figure 7.10: Knee support providing support to a relatively large (185 mm) patient in larger (∼20°) knee flexion.

Fixation of the patient

The applied load at the foot will cause the patient to be pushed in the direction of the driving wheel. A back support with an 8° incline, which is adjustable in position, is integrated into the device (figure 7.11). The normal force resulting from the weight of the upper body will be under an angle. This results in it having a horizontal component, opposing the movement direction and creating extra resistance against moving. The resulting force driving the patient to move will be restrained by securing the patient with fixation bands, which are connected to grooves in the patient bed.

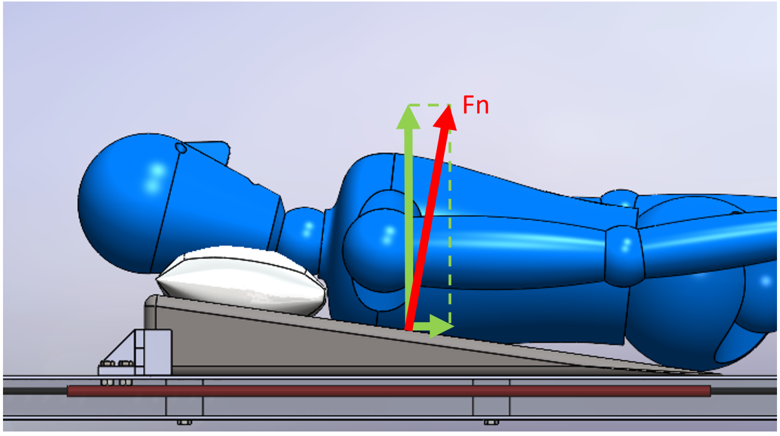


Figure 7.11: Back support resulting in a horizontal component opposing the movement direction.

Fitting in MRI

As described in section 3.2, the patient bed contains removable compartments, creating an opportunity to constrain the potential movement of the loading device. The bottom of the 'MRI knee loading device' has protruding bars spaced to correspond with the length of the removable compartment (figure 7.12). The fixation bands are connected to the patient bed, so when tension is applied to the fixation band when the patient's knee is loaded, the 'MRI knee loading device' is secured in postion.

The footplate and knee support are mounted at two connection plates (figure 7.13). As shown in figure **??**, the outer 5 cm of the plates should not have bolt heads sticking out at the bottom, as the patient bed has raised edges. The base plate could rest in the middle: on bolts when there is no gap from a removed compartment (figure 7.14a) and a protruding bar when there is an open compartment (figure 7.14).

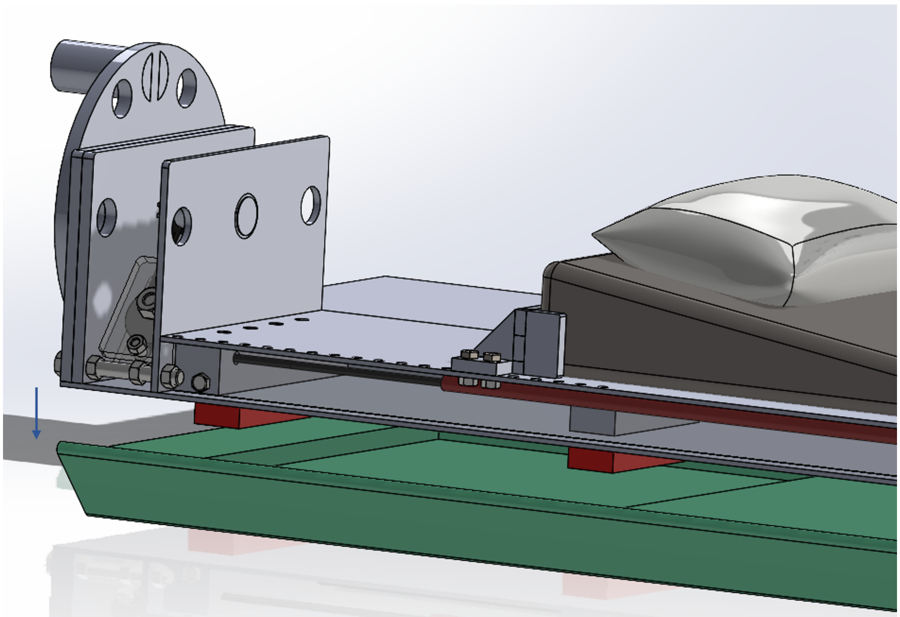


Figure 7.12: Protruding bars at the bottom of the base plate secure the 'MRI knee loading device' in position.

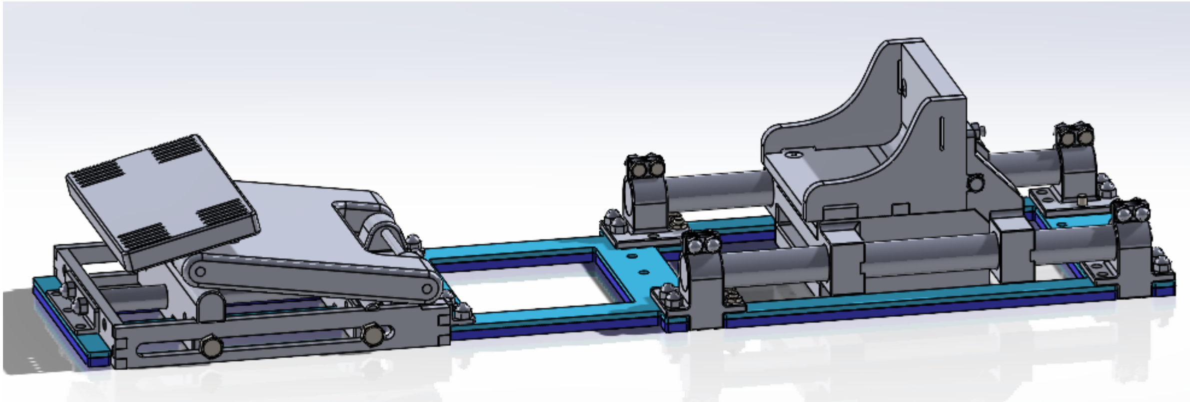
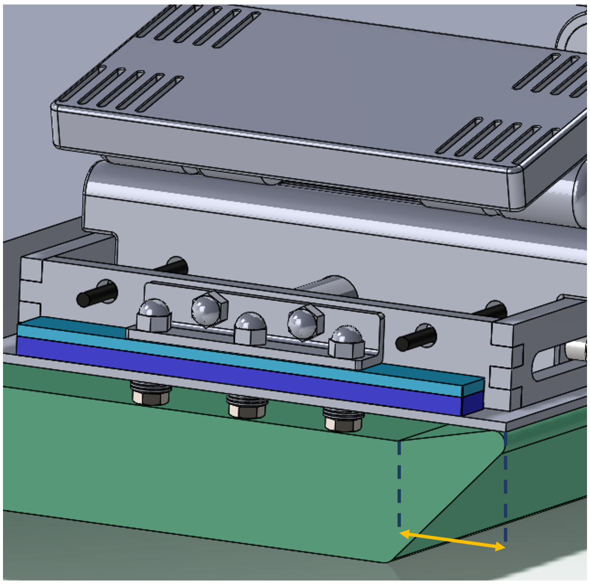
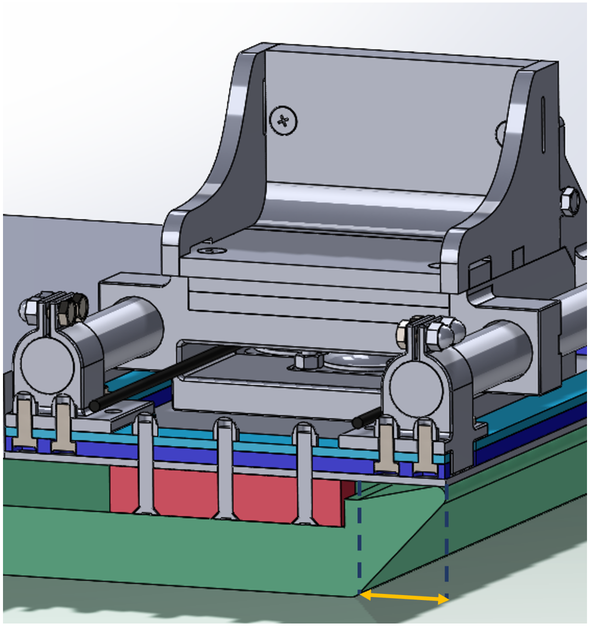


Figure 7.13: Connection plates that connect the knee support and the footplate to the base plate.



(a) Section view of the loading device resting on bolts.



(b) Section view at a open compartment, where the loading device rests on protruded bars.

Figure 7.14: Section views of the 'MRI knee loading device' positioned at the patient bed. The outer parts of the baseplate are not rested on, as that would interfere with the raised edges of the patient bed.

Part IV

Deliver

8 Prototyping and Evaluation

8.1. Prototyping

A prototype has been manufactured to demonstrate a ‘proof of concept’ of applying a constant load to the knee with the MRI knee loading device. An image of this prototype can be seen in figure 8.1.

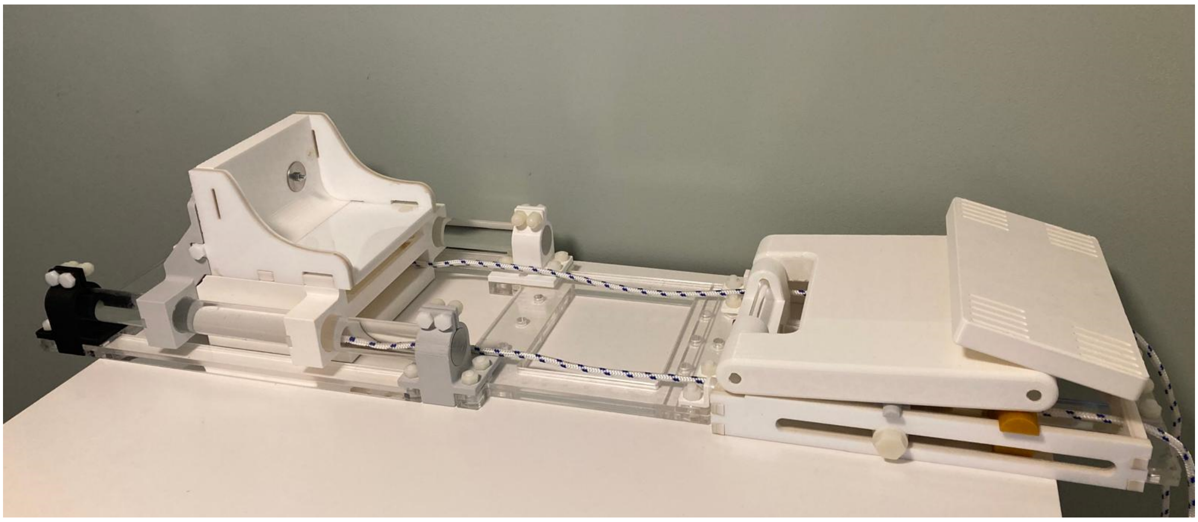


Figure 8.1: Picture of the developed prototype, including the footplate, knee support and the connection plates.

Various components in the prototype were manufactured using 3D printing (fused deposition modeling, standard infill from Cura-slicer 3D printing software: 20%) with PLA and laser cutting for PMMA plates (5, 8 and 10 mm thickness). This was done at the TU Delft at the ME faculty, in the IWS and IWM workplaces. All other components, like nylon fasteners or fixation bands, were purchased.

Because the CAD model was extensive, the prototype highly resembled the product embodiment design. No major design errors were found during the prototyping process. However, the prototyping process required some trial and error about the parts’ tolerances and working principles. Since most components are relatively large, 3D printing was a time-consuming process. The three largest 3D-prints (base footplate, H-rotating-part and the supporting surface in the knee support) took more then three days to print and did not succeed the first time.

8.2. Verification and functional evaluation

Method

The experiment aimed to evaluate the functional application of the load at the footplate, functional application on the knee flexion angle and patient compatibility with the MRI loading device. An experimental set-up was created to test the prototype, see figure 8.2.

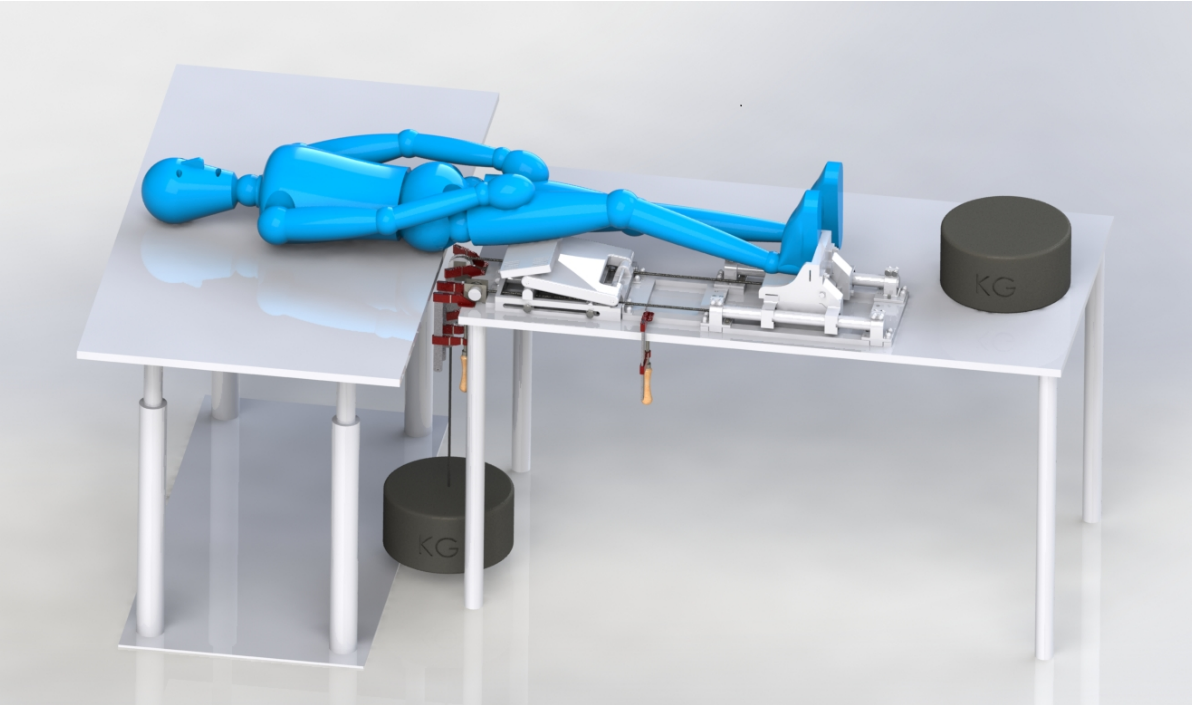


Figure 8.2: The experimental set-up for testing the prototype.

In the experimental set-up, suspended weights were used to create a load. In the final design, the load is generated by elongating elastic material. Using suspended weights, the force in the cable does not need to be measured, since it is equal to the gravitational force acting on the weight. It does not need to be calibrated, in contrast to using elastic material.

The connection plate is connected to the table with clamps. Two custom made sheet metal parts were used to fixate the cable at the desired height at the table and to guide the cable over a pulley.

Functional and performance testing of application of the load on the footplate

An eye screw was inserted at the position where the patient's foot would be located when using the MRI knee loading device. First of all, the static friction coefficient between the footplate and the axes was determined, without any suspended weights. Then, the applied load at the footplate was measured by pulling at the eye screw with a digital spring scale connected to the environment, while the cable exerted force on the pulley block at the bottom of the footplate caused by suspended weights (figure 8.3). The position where the digital spring scale pulls at the footplate replicates the location of the patient's foot when using the MRI knee loading device.

Then, experiments were done with suspended weights of 1.5, 7.5, 15, 22.5 and 30 kg, evaluating the force which need to be applied at the footplate to prevent it from moving. For each weight, accuracy and repeatability were evaluated by applying the weight and measure the load at the footplate three times. Moreover, tests were conducted to evaluate the force before and after five minutes, as well as to determine the force range required to maintain the footplate in a fixed position.

Figure 8.3: The experimental set-up for evaluating the functionality and performance of the load application at the footplate.

Functional and performance testing of application of a knee flexion angle

The functionality and performance of the knee support was evaluated to ensure it was possible to apply different knee flexion angles and to validate the support block to ensure a desired knee flexion angle. With the knee support at the determined position, the actual knee flexion angle was measured with a goniometer (figure 8.4).

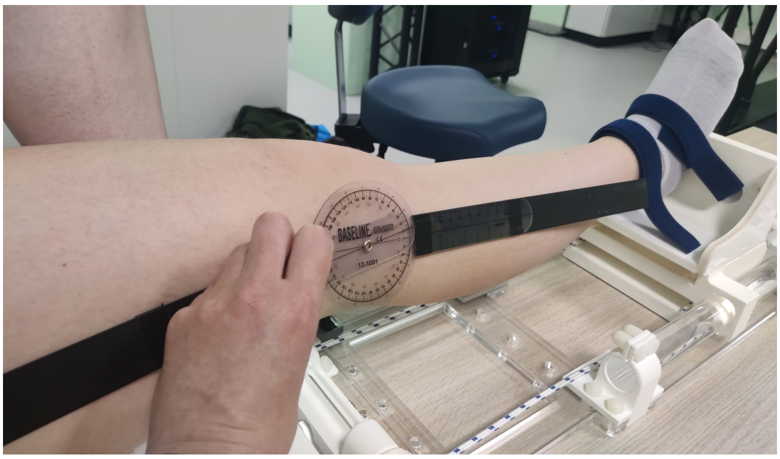


Figure 8.4: Knee flexion angle measured using a goniometer. The major trochanter (femur) and thelateral maleolous (tibia) were identified as the endpoints for aligning the goniometer.

Patient interaction with the loading device

Evaluating the 'MRI knee loading device' with a participant required an additional table, as the final design of the MRI knee loader positions the patient slightly higher than the base plate, ensuring they lie above the pulleys and cables. A suspended weight of 15 kg was used while applying a load to the participant, to evaluate the experience of interacting with the MRI knee loading device. Load experience, ergonomics and usability were evaluated qualitatively. Moreover, the conclusions of the biomechanical analysis regarding the effort required from a participant were validated.

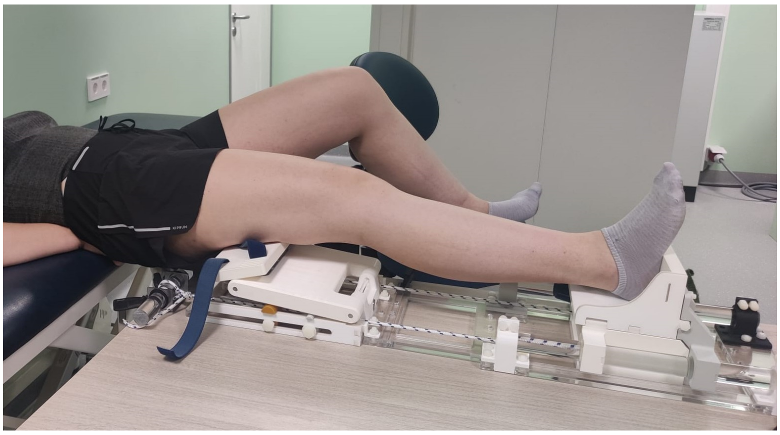


Figure 8.5: Patient compatibility testing: the knee is loaded with the knee loading device.

Results

Functional and performance testing of application of the load on the footplate

The footplate weighed 1.46 kg and it needed 0.50 kg force to initiate movement over the axes, resulting in a static friction coefficient of 0.34.

A linear relationship was found between the measured force at the footplate and the suspended weights (figure 8.6). During the experiments, it was observed that the measured force was not constant. In most cases, the measured force was initially higher and stabilized within approximately 5 to 15 seconds. All measured forces are compared to their expected forces (table 8.1), based on the line in figure 8.6. The absolute errors range between 0.54 - 1.9 kg and the absolute percentual errors between 1.4 - 54.0%.

Weight (kg)	Measured force (kg)	Expected force (kg)	Error (kg)	Percentual error (%)
1.5	1.54	1	0.54	54.0
1.5	1.54	1	0.54	54.0
1.5	1.54	1	0.54	54.0
7.5	9.21	9	0.21	2.3
7.5	9.30	9	0.30	3.3
7.5	9.30	9	0.30	3.3
15	18.8	20.5	-1.70	-8.3
15	19.5	20.5	-1.00	-4.9
15	19.4	20.5	-1.10	-5.4
22.5	29.6	31.5	-1.90	-6.0
22.5	31.1	31.5	-0.40	-1.3
22.5	32.0	31.5	0.50	1.6
30	43.9	42	1.90	4.5
30	42.6	42	0.60	1.4
30	43.7	42	1.70	4.0

Table 8.1: Measured forces compared to expected forces. The expected forces are read from figure 8.6.

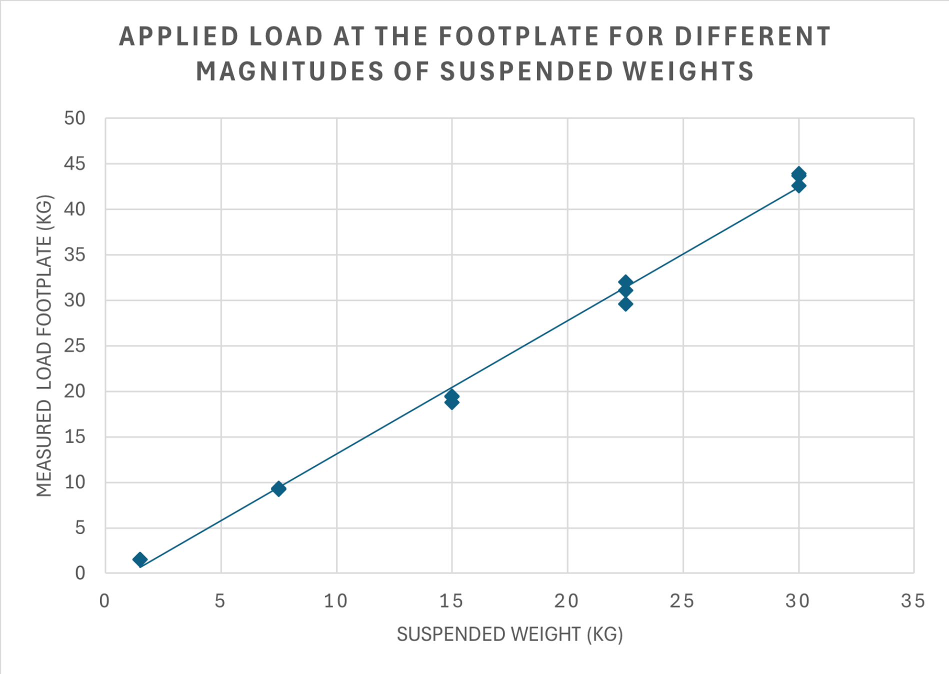


Figure 8.6: Applied load at the footplate for different magnitudes of suspended weights (1.5, 7.5, 15, 22.5, 30 kg) evaluated for three repetitions.

Two tests were done by adding weights (1.5 kg and 3.0 kg) at the footplate (see figure 8.7), using 15 kg suspended weight. This setup mimics the effect of the vertical force of the foot. The measured force at the footplate had increased from an average of 19.2 kg over three repetitions without added weight at the footplate to 20.9 kg and 21.3 kg with the addition of 1.5 and 3.0 kg to the footplate respectively.

The effect of loading over five minutes was evaluated using 15 kg suspended weights (figure 8.8). In all three repetitions the applied load at the footplate decreased slightly by 0.2 to 0.8 kg.

The range of force magnitudes required to move the footplate was evaluated. Using a suspended weight of 7.5 kg, pulling with a maximum force of 9.3 kg was required to initiate sliding of the footplate along the axes. To change direction, a minimum force of 20.6 kg was necessary. Pulling with a force somewhere between these values, the footplate remains in the same position.

Functional and performance testing of application of a knee flexion angle

The final functional test involved evaluating the accuracy of the knee flexion angle when the leg is supported by the knee support. For one person (167 cm, 64 kg) the position of the support block with respect to the hinge was determined using the established model (appendix E). The small support block should be positioned at 16.6 cm, 8.35 cm, 5.60 cm, 4.23 cm for 5°, 10°, 15° and 20° respectively. Figure 8.10 shows that every measured angle deviates 5° from the estimated angle, and therefore has a constant offset.

Patient interaction with the loading device

It was confirmed that the MRI knee loader is capable of applying a load at the foot, which is transmitted to the knee. Using a 15 kg suspended weight, the load was experienced as comfortable and required less effort than standing. Additionally, it was confirmed that with a knee flexion angle greater than 10°, the quadriceps were engaged, while with an extended leg, the hamstrings were engaged.

Figure 8.7: Footplate with 1.5 kg the force mimicking the vertical force of the foot resting on the footplate.

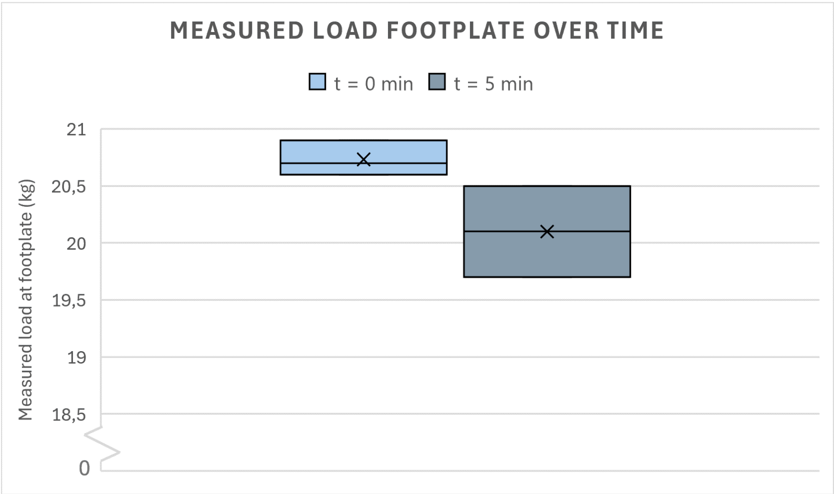


Figure 8.8: Applied load at the footplate initially and after 5 minutes for three repetitions.

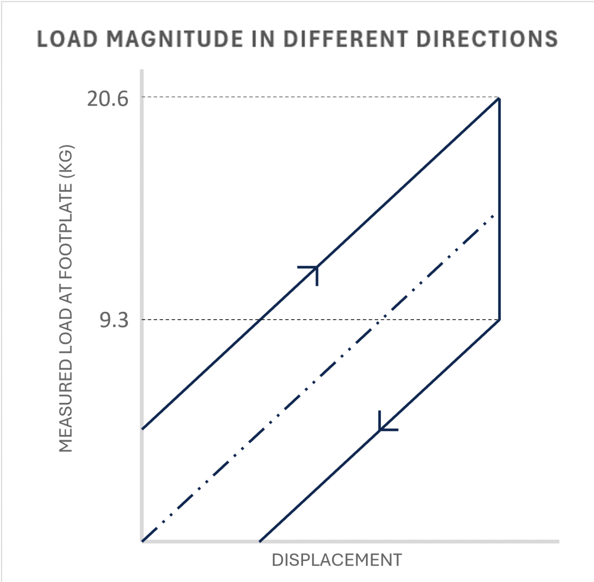


Figure 8.9: Load measured at the footplate in different directions, with a suspended weight of 7.5 kg

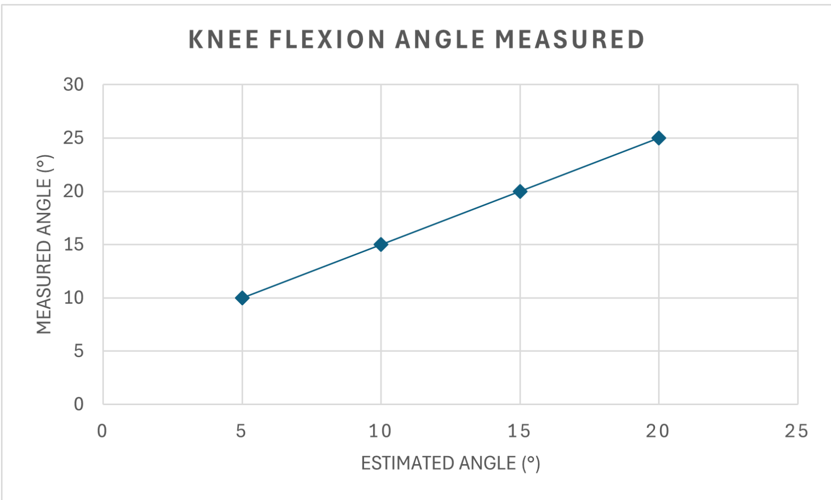


Figure 8.10: Measured knee flexion angle compared to the estimated angle determined using the person's measurements.

9

Fulfillment of requirements

Functional requirements:

Performance requirements:

- The loading device should be able to apply a static, axial load through the foot at the patient's knee while in a supine position.
  Fulfilled. It was verified that the prototype was able to apply a load through the footplate.

Specifications:

- The loading device should be able to load the knee at different angles ranging from 0° to 20° in steps of 5°.
  Fulfilled. *- The knee support proved to be able to apply different knee flexions. The adjustment is not sensitive and therefore practical. For example, for a person of 167 cm length, the model calculated that the small support block could be positioned 16.6, 8.35, 5.60 and 4.23 from the hinge to realize angles of 5°, 10°, 15° and 20° respectively. In practice, this was achievable. However, this is a simplified model and without MRI images is was not possible to validate the knee flexion angle.*

- The loading device should be able to provide an accurate force, with an allowed error of 3.33%. (Depending on the loading strategy. If possible, a smaller error is preferred.) Measuring this force digitally is the preferred option.
  Not fulfilled. *- In figure 8.6, a linear relationship between the measured force in the footplate and the suspended weight was found. The absolute percental errors between the measured and expected forces based on the linear relationship ranged between 1.4 - 54.0%. Although 54.0% is found with a suspended weight of 1.5 kg and is not relevant, as this is lower than the loads the device need to provide, errors above 3.33% are found with greater suspended weights as well (table 8.1.)*

- The loading device should be able to provide different magnitudes of forces. The applied force is a percentage of someone's body weight (25% or 50% body weight patients) and therefore the device should be adjustable to be suitable for multiple patients. The load range should be between 13.9 and 48.5 kg. The magnitude should be adjustable in steps of at least 0.5 kg.
  Not tested. *- The maximum measured force at the footplate was 43.9 kg during the experiments, using 30 kg suspended weight. For the final design, an elastic material generating forces within this range should be selected. The sensitivity of the elastic material should be chosen such that each 1/6 rotation of the driving wheel, given that there are 6 locking positions per rotation, results in an elongation of the elastic material resonating with less than 0.5 kg load increase.*

- The load should be applied at the foot. It should be applied at a height where limited joint moment is created around the ankle($\pm$ 3 Nm).

Fulfilled. - *The height of the footplate is twice as high as the distance between the bottom of the calcaneus and the position where the load needs to be applied to create minimal joint moments for the average person. To evaluate the knee moments for people who deviate from the average dimensions, it was calculated at what ratio from the bottom of the foot the load application is positioned with respect to their foot length 9.1. In Opensim, the load is applied at this ratio of the Opensim model's foot to evaluate the joint moments (figure 9.2), they do not exceed (± 3 Nm). It could be researched further whether it is worth the extra complexity to make it adjustable to the dimensions of different patients, so for every person the effort required could be minimized.*

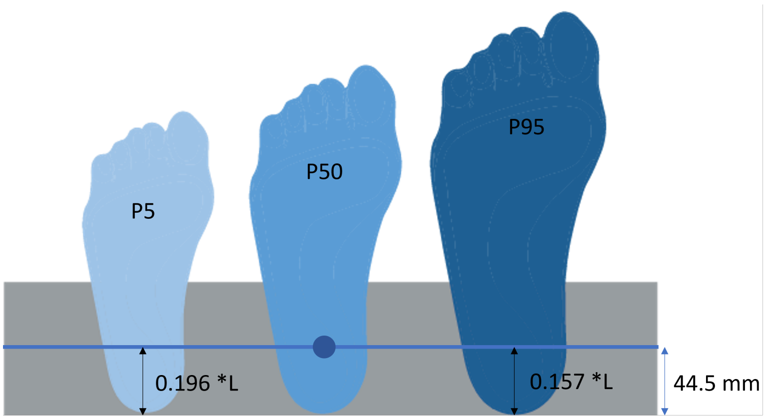


Figure 9.1: The ratio of the distance between the bottom of the calcaneus and the location of the applied load to the length of the entire foot, for P5-P95 (Dutch adults 30-60 years [8]).

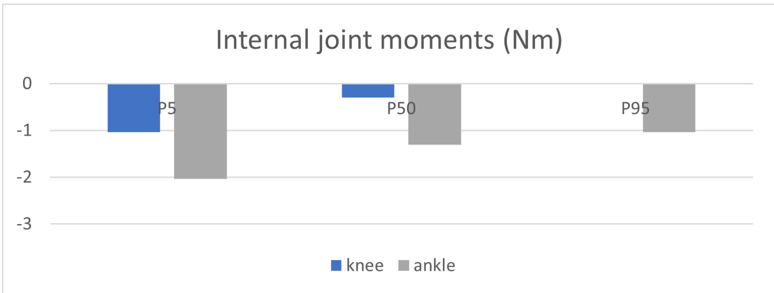


Figure 9.2: Internal joint moments when the load is applied with the footplate on P5-P95 patients (Dutch adults 30-60 years [8])

- The loading device should fit or be adjustable to the dimensions of different participants (within P5 and P95 of the population of Dutch adults 30-60 years old).
  Fulfilled. - *During the design process, the anthropometrical measurements of this population are taken into account when setting dimensions.*

- The loading device should prevent creating motions/instabilities. The participant should be constrained in all directions. The position of the knee should be guided by the set-up and the participant should actively maintain the position. The upper leg should be supported and the ankle should be stabilized to prevent rotation of the knee.
  Not tested - *Although fixation bands and back supports are used to prevent motions/instabilities, it is not verified whether in experiments since clinical trials with multiple subjects (since instabilities are patient-dependent) are needed to evaluate this requirement.*

Constraints:

- The loading device should fit in the MRI environment and within the dimensions of the MRI scanner. Diameter MRI bore: 60 cm. Measure range: 50 cm. The measure range specifies the area

within the bore where tissues can effectively be imaged.
Fulfilled - *In the design process, the measurements of the MRI are used as strict guidelines which should not be passed.*

- The loading device will be used in an MRI scanner and should not contain magnetic metal components. Non-ferrous metals like aluminum can be used in the MRI room (for preparations) but should not be used under the MRI scanner.
  Fulfilled - *The final design does not contain metal compontents.*

- The loading device should be compatible with the flexible knee coil.
  Not tested - *The knee support is designed to leave the knee area open, allowing the flexible coil to fit around it. However, testing with the complete final design should be done to ensure full compatibility*.

- The loading device should be used with the 'feet first position', where the patient's head is outside the MRI bore.
  Fulfilled - *The driving wheel, the part where the laboratory worker interacts with the device to generate the load, is located at the side of the head, so the feet can go in first.*

- The knee should located in the middle of the bore and the knee coil should be aligned with the magnetic field (which translates to alignment within the bore).
  Partially fulfilled *The knee coil is aligned with the bore in all loading conditions. From the top plane, when observing the patient on the loading device, the knee is located close to the middle, as it would be without the knee loading device. However, from a side view, the patient lies a little higher compared to without using the loading device (45 mm - thickness padding patient bed). The knee is further outside the middle in deeper flexion. It should be evaluated further with the radiology experts to what extent this affects the signal strength.*

Use requirements:

- Using the loading device should not result in discomfort for the participant.
  Not tested. - *During the patient compatibility test no pain was experienced by using the loading device. It should be noted that the test with a person was shorter than the time it would take to scan and use the device in an MRI. The knee support was experienced to be not ergonomic. It should be further researched how to improve ergonomics without adding to many complexities.*

- Laboratory personnel should find it feasible to use the loading device, indicating that they can execute the necessary actions. This also implies that the MRI loading device should be user-friendly and straightforward to operate effectively. After training, the required operations should be easily remembered and integrated into the workflow.
  Fulfilled - *The knee loading device is designed to be user-friendly and straightforward to operate effectively. This was validated with Luud Rijnen. However, he mentioned that re-adjusting the knee flexion angle will be hard if the weight of the patient's leg is already on it.*

- The set-up time of applying the force to the patient's knee should be as quick as possible. The total procedure may not exceed 45 minutes (including screening, patient changing clothes, room preparations/loading device set-up, patient positioning on the table, scanning).
  Not tested - *The total procedure of setting up the device in the MRI room and scanning the knee should not exceed 45 minutes, this is validated with Luud Rijnen. However, it is not tested in practice*

- It is desirable that the device does not have many adjustments. The benefits of additional adjustments will be evaluated based on the effort/time required to set them.
  Fulfilled - *The device having little adjustments was prioritized during the concept generation. The only adjustments necessary are the positioning of the knee support block and generation of the*

load by rotating the driving wheel.

- It is desirable for the device to be compact, easy to replace and have an easy set-up.
  Partially fulfilled - *While the design allows for an easy setup, it only requires placing the device on the patient bed, the large dimensions of the base plates make it inconvenient to use. It would be worth investigating whether the device could be divided into more modular parts without significantly compromising functionality, setup time, strength, or complexity. However, Luud Rijnen preferred it to be a single robust unit, as multiple separate components could become disorganized in the storage area with the MRI accessories.*

Safety:

Set up:

- The connection between the knee coil, patient bed and the MRI loading device should be safe and not negatively influence the performance of any component.
  Not tested - *The knee loading device is designed to fit on the patient bed. However, it could only be evaluated in compatibilty tests with the final design.*

- The loading device must be designed and manufactured in such a way that adjustment, calibration, and maintenance can be performed safely and effectively.
  Not tested - *The only adjustment that could be evaluated was the positioning of the blocks in the knee support, which proved to be safe. Calibration and maintenance are also considered safe, as the modular design allows individual parts to be handled separately. However, since the design consists of many parts (275, most of them being fasteners), cleaning the entire device thoroughly requires substantial effort.*

Design:

- The loading device should not have sharp parts sticking out.
  Fulfilled

- The design of the loading device should consider the mechanical properties of materials such as strength, deformability, fracture toughness, wear resistance, and fatigue strength.
  Fulfilled - *The mechanical properties of the device have been carefully considered. Highly loaded 3D-printed parts have thick dimensions, and preferably, high-loaded parts are made from PMMA plates. Reliance on fastener connections is minimized. The loading device has undergone tests without breaking. Finite element analyses confirm that the footplate does not fail under the applied loads (appendix C). However, additional strength testing over an extended period is necessary to ensure safety.*

- The loading device should be as robust as possible.
  Fulfilled - *Luud Rijnen, a laboratory worker, played around with the prototype and confirmed it would be robust enough for the rough handling of his colleagues. The prototype did not break during the experiments and was able to withstand the high loads. During transport, the prototype fell accidentally from a 1-meter height. One glue connection between PMMA plates failed, but that was easy to repair, resulting in minimal damage.*

- The loading device should be able to apply forces to the participant without failing. The device should have enough stiffness to withstand the forces, which could be secured by using safety factors in the dimensions of the parts and using secure connections.
  Not tested - *During the experiments the prototype did not fail. However, additional strength testing over an extended period is necessary to ensure safety.*

- The device should stand stable and not fall during use.
  Not tested - *Fulfilled for the prototype, but this should be evaluated with the final design used in the MRI patient bed.*

- If the loading device contains moving parts, the risks of them harming the patient should be reduced as much as possible. Precautions should be taken to minimize the conversion of potential energy into kinetic energy, which can pose a risk to the patient when using the loading device.
  Fulfilled - *The footplate is a moving part, but the risk of harming the patient is reduced as it is fixated to the foot/ankle of the patient and therefore could not slip underneath the foot and accelerate. Winding up the driving wheel stores potential energy, as elastic material is elongated. It can be 'fixed' by inserting a pin in trough the wheel and the plate it is connected to, but before it is secured, it could turn into kinetic energy if the wheel slips out of the laboratory worker's hand. This is not considered unsafe because it only reduces the load. However, a mechanism such as a ratchet would be more user-friendly, because the force is locked when the handle is released. However, this is more complex to implement.*

- The loading device should be modular, it should be possible to take all components of the device apart.
  Fulfilled - *The device is modular. In the footplate and the knee support a few perpendicular joints between PMMA plates were glued to increase the strength of the joint. To ensure it still could be cleaned properly, possible gaps should be sealed.*

Use:

- There should be a possibility to quickly remove the load if needed.
  Fulfilled - *The pin that locks the position of the driving wheel, and consequently the length of the elastic material and the load could, be removed at all times.*

- The loading device should be cleanable, and therefore should be resistant to water, alcohol and chlorine. The device should be modular and surfaces should not have textures which have negative effect on the ability to clean.
  Partially fulfilled - *Some surfaces in the prototype could not be properly cleaned, caused by uneven surfaces due to removal of support. Other 3D printing techniques, where for example a powder bed is used as support structure, should be considered to prevent this.*

Material selection:

- The materials used should be non-toxic.
  Fulfilled

- The materials used should not be flammable when used in an MRI scanner.
  Fulfilled - *No metals are used, ensuring the materials do not heat up during scanning.*

- The use of materials that contain phthalates should be reduced as much as possible.
  Fulfilled - *Phthalates are most commenly used as softeners to make plastics more flexible and durable [10]. In the prototype, only PLA (for 3D printing), PMMA (plates) and nylon (fasteners) are used. These require to be stiff and do not contain phthalates.*

Production:

- The device's production should be achievable by a TU Delft student using the universities' facilities.
  Fulfilled

Maintenance:

Inspection and preventive maintenance (1), all activity necessary to ensure a piece of medical equipment is functioning correctly and is well maintained, and corrective maintenance (2), to restore the physical integrity, safety, and/or performance of a device after a failure [28], should be executable for the technical team of Erasmus MC.
Not tested. - *This is not tested by the technical team of Erasmus MC. However, since verification tests were done by a student and her supervisor, it could be assumed that the activities (verification, calibration and safety testing) could be executed by the technical team of Erasmus MC as well. Since the production of the device is relatively easy, it should be feasible for the technical team of Erasmus MC to do reparations. The frequency of inspection and preventive maintenance could not be determined yet, since the performance and durability of the device should be tested over a longer period.*

Standard, rules and regulations:

- The loading device should comply with medical device regulations (MDR).
  Fulfilled - *During the design process, the list of requirements is set-up using the 'General Safety and Performance Requirements' every medical device must meet. An important requirement was that no unnecessary risks were taken, therefore, risk management has been incorporated. Additionally, design control and validation were conducted throughout the process to ensure quality management (documented in section 6.2 and appendix B.)*

10 Discussion

During the design of the MRI knee loader, finding a balance between functionality, complexity, and feasibility in the design was a great challenge. Since this was the first prototype of this design concept, the focus was on feasibility rather than complexity, which included some sacrifices for the design. From a working prototype, it could be further evaluated what would be the next steps to improve the design.

10.1. Interpretation of the test results

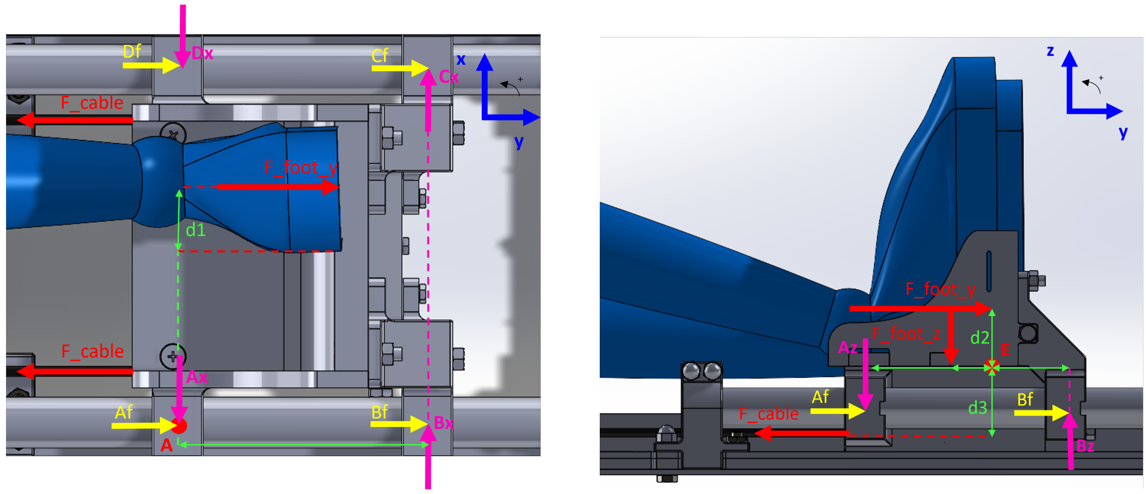
Functional evaluation of the applied load at the footplate

The system proved to be capable of applying a load at the foot. A linear relationship was found between the suspended weights and the measured force at the footplate. In the results of section 8.2, it could be observed that the measured force at the footplate is greater than the suspended weight, which is desirable. However, since the used pulley transmission was ideally 1:2, and the ratio between measured force at the footplate and was around 1:(1.3-1.4), quite some energy is lost in the system.

The footplate had a substantial weight, 1.46 kg, therefore static friction ($\mu = 0.34$) caused energy loss and had an effect on the measured force at the footplate. A water film was applied at the axes, in an attempt to reduce the friction, but this did not have an effect on the measured force at the footplate.

The foot being positioned off center results in a moment around the vertical axis (z-axis, figure 10.1a). Pushing against the footplate and pulling at the pulley block tends to rotate the footplate backward around the depth axis (x-axis, figure 10.1b). Since there is some play between the bearing and the axis (this was hard to prevent, since both parts are purchased and are not designed to interact specifically with each other), this resulted in the footplate clamping around the axes. The bearing blocks create extra normal forces to counteract this moment, which creates friction forces in the opposite direction of the movement as friction is equal to a constant times the normal force.

All measured forces at the footplate are compared to their expected forces, originating from the linear relationship found between the data points. The absolute errors range between 0.54 - 1.9 kg and the absolute percentual errors between 1.4 - 54.0%, causing the accuracy to not meet its requirement. When a suspended weight pulled at the footplate, a 'range' of forces applied at the footplate was present to keep the footplate clamped around the axes at the same position. The force-displacement curves varied depending on the direction of the footplate movement. This phenomenon is called hysteresis. The difference between these force-displacement curves enclose a surface (figure 8.9), which equals the loss of energy caused by friction [30]. With a suspended weight of 7.5 kg, the applied load is somewhere between 9.3 and 20.6 kg. When the load was applied at the foot, initiating movement in the footplate required a substantial increase in effort by the participant. This makes it unlikely that the load which was already on the foot was close to 20.6 kg. However, these results indicate the load could not be applied accurately. It should be noted that this was only measured in an experimental set-up, using



(a) Top view of the forces experienced by the footplate. Since the foot is off-centred, a moment equal to $F_{\text{foot}_y} \cdot d_1$ is created around point A.

(b) Side view of the forces experienced by the footplate. $F_{\text{foot}_y} \cdot d_2$ and $F_{\text{cable}} \cdot d_3$ create a negative moment around point E.

Figure 10.1: Forces experienced by the footplate; red: applied forces, pink: normal forces counteracting the moment created by the applied forces, yellow: friction forces in the movement direction caused by normal forces.

suspended weights. In the final design, an elastic material is introduced to generate the load, which could even lead to larger errors.

Although the executed experiment provided valuable insights into the load applied to the foot through the footplate, the experiments could be improved. A load cell could incorporated into the footplate to measure the force directly under the foot of the participant. This approach enables continuous data logging over time, but it is more susceptible to measurement errors if the load cell is loaded in a different direction, and the sensor would require proper calibration. Although this would get a more precise insight on the force applied at the foot, it is unlike it will change the finding that the force could not be applied accurately.

Functional evaluation of application of the knee flexion angles

When evaluating the knee flexion angle, an error of 5° was found between the measured and desired angles. Before the evaluation, it was already clear that the model is a simplified version of reality and precise estimation of the location of the supporting block would be challenging. The leg was modeled as a triangle, however, the effect of (variance in) thicknesses of upper legs is not incorporated. Despite this lack of precision, it was verified that the system is able to apply flexion angles between 0° and 20°. The positioning of the support block could be used as a guide. MRI images are needed to measure the knee flexion accurately. It should be further researched how the knee flexion application could be standardized. However, some deviations from the desired knee flexion angle is acceptable for the application in research as is seen now, if it will not alter the amount of required effort too much.

10.2. Final design

Design methods

During this project, two design methods were used: the double diamond method and the V-model, which guided through the process.

From my perspective, the double diamond method encouraged me to explore and use creativity to come up with innovative ideas and solutions. While converging, you are ensured you will diverge and come up with concrete outcomes. Although this is a clear guide to give the project some structure, this design method was quite general and did not provide many new insights to me.

The V-model encouraged structured and systematic verification and validation of the design and its requirements. This method was new to me and was a valuable approach to managing the project ensuring quality and risk mitigation. At important steps during the process, the design choices were verified or validated together with the involved experts in this project. This included requirement validation, validation of the concept choice, verification test of the functional requirements, and validation of the final design.

Design principles

This design aimed to be as simple as possible. This ensured the design to be user-friendly without requiring unnecessary adjustments and feasible to produce. The use experience of interacting with the prototype was confirmed to be user-friendly by Luud Rijnen.

In the final design of the MRI knee loader, MRI compatibility is ensured through using components manufactured from 3D-printed PLA or laser-cut PMMA plates. This combination worked well in designing: 3D printed parts are preferred when flexibility in shape was required and PMMA plate material was used when stiffness was required. In situations where both shape flexibility and stiffness were required, extra-thick dimensions with 3D printed parts were were used. Relying on nylon fasteners was reduced as much as possible. It has been demonstrated that it is feasible to construct a heavily loaded device using MRI-compatible materials. However, the device should be tested longer, to be able to ensure safe use.

The entire device is fully mechanical and only uses easily accessible materials and common manufacturing methods, making the design relatively easy to produce and implement.

Final design compared to other devices

Compared to MRI knee loading devices using suspended weights, this device has a relatively easy and quick set-up. However, the device is still large and not convenient to move. Safety is improved by ensuring the device does not obstruct the process of sliding the patient bed onto the MRI table, facilitating rapid disconnection in emergencies. The cables and elastic materials are concealed beneath the upper surface, preventing any interaction with the patient.

The 'MRI knee loader' enables the knee to be loaded in flexion angles between 0° and 20°, which is unique compared to other devices. Other devices do not enable adjustments to the knee flexion angle. This capability allows for research to identify the most informative knee flexion angle for indicating early OA, facilitating direct comparison.

10.3. Limitations

Time constraint

The main constraint of this project was the time limitations within the master thesis, which made it unfeasible to fully prototype the entire MRI knee loader. The focus shifted to producing a 'proof of concept' for applying a load with the footplate. Although evaluating this concept provided insights regarding the force which is applied at the footplate, it was not feasible to validate the complete design.

Concept generation

From early on in the process, discussions with experts on feasibility and functionality provided many valuable insights. However, the initial brainstorming sessions and the establishment of a morphological chart were done by one person. While many adaptations have since been made in collaboration with experts, more diverse ideas might have emerged if the early brainstorming sessions had been done in a team. Given this master thesis is an individual project, this approach is understandable.

Prototyping

Since this prototype was developed as a 'proof of concept', the device has been manufactured for low cost using the university's facilities. An important consideration when manufacturing a CE-certified product is ensuring that the surfaces of the 3D-printed parts can be cleaned properly. Using FDM, support structures are necessary to prevent excessive overhangs in structures. When these are removed, uneven surfaces remain visible. While post-processing can address this in most instances, it may not be feasible in all cases, particularly when dealing with hard-to-reach areas. A solution could be using a more advanced additive manufacturing method like SLS (selective laser sintering) where small parts of thermoplastic material are melted together. Since the powder bed supports the parts during printing, there is no need for dedicated support structures making it more suitable for complex parts.

Another challenging aspectin cleaning the device is the modularity. In some scenarios, the fit between two parts must be tight, so the connection is strong, such as the connection between the bearing and its holder or the footplate and the pulley block (figure 10.2 and 10.3). However, they can be hard to separate. In an iteration, it should be further investigated how to improve the ability to assemble and disassemble the product, without reducing the product's integrity or strength by using fasteners in critical parts.

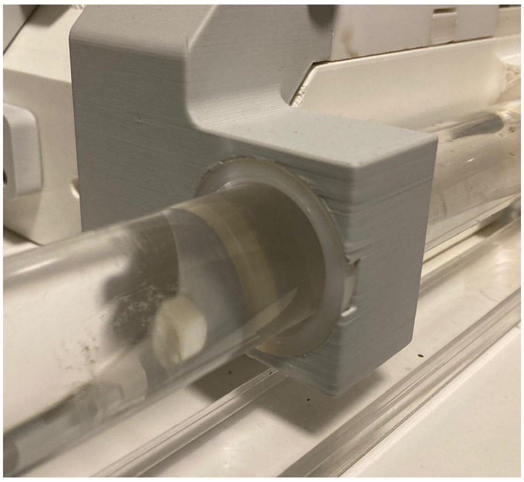


Figure 10.2: Bearing and footplate with a tight fit.

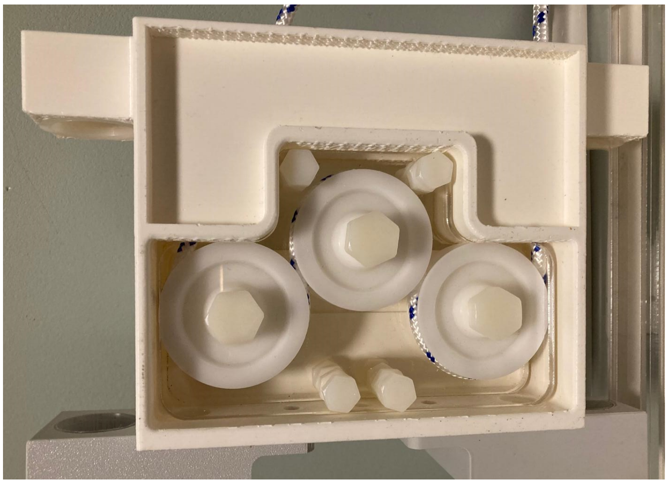


Figure 10.3: Pulleyblock and footplate with a tight fit.

Biomechanical validation

A biomechanical analysis has been conducted to evaluate what effort is required from a patient when a load is applied to the knee joint. The Opensim simulations could give a clear representation of the internal joint moments, muscle forces and joint reaction forces. The biomechanical analysis showed least effort is required with a 10° flexion. With a full extension, hamstrings are engaged, and in knee flexion larger than 10° quadriceps are engaged. This is validated qualitatively by one person. This could be further evaluated quantitatively by using EMG measurements.

In the Opensim simulations, the force is applied at points. However, a distributed load is more realistic. The effect of this simplification has not been evaluated and remains unclear. No substantial effect is expected, since it is quite common to model distributed loads (like ground reaction forces during gait) as point applications.

10.4. Future design recommendations

Reducing friction in the system

Although a lot of energy is lost in the system, there is still a greater measured force at the footplate compared to the suspended weights, indicating a positive transmission. A starting point could be to evaluate the effect of a better fit between the bearing and axes. Further improvements could be obtained if a cable could go behind the footplate instead of under the footplate, as was suggested in an earlier version of the design (figure 10.4. However, this results in a more complex system since four extra pulleys are required to guide the cables under the surface the patient lies on.

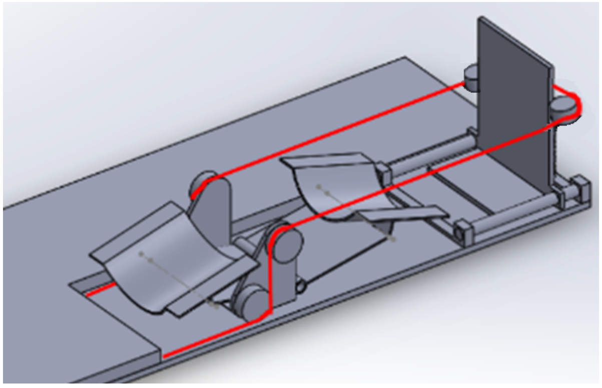


Figure 10.4: Previous version of the design that should experience less friction between the bearings and the axes, as the force from the cable causes a moment counteracting the moment created by the foot on the footplate.

Strenght/stiffness

During the experiments, no parts failed under loading. However, the upper plate bent due to the moment on the footplate pushing the axis upward, see figure 10.5. It should be noted that during the experiment, the connection plates were clamped to one side of the table instead of being fastened to a base plate as in the final design. Fastening all plates together should enhance bending resistance, as the stiffness of all plates is combined. However, it is important to note that this area experiences high loads, and precautions should be taken to prevent excessive tension on the bolts. Therefore, it is recommended to improve the upper plate's strength, which can be easily achieved by increasing its thickness and adjusting its geometry.

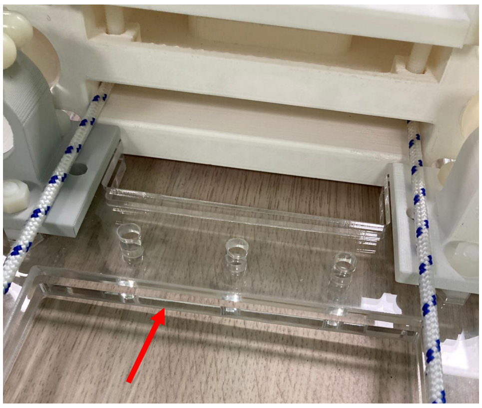


Figure 10.5: Slit between the two connection plates, indicating lacking bending resistance in the upper connection plate.

Ergonomics

This design is created so it is feasible to produce with a maximum ration between functionality and complexity. For example, the plate the upper leg rests on the knee support is flat, which allows for support of people with every hip width. As could be seen in figure 10.6, this supporting surface cuts in the skin of the patient. Although this supporting surface could not be made too large, as it should not interfere with the flexible knee coil, it should be further researched how it could be ergonomically improved.

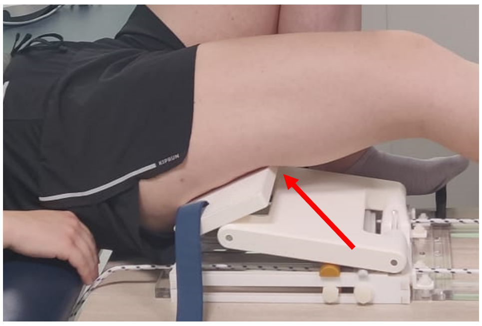


Figure 10.6: Uncomfortable knee support.

Other recommendations

It would be recommended to re investigate the possibilities of reading the elongation of the elastic spring. In the current design, this is done by reading at the side of the table. It would be more user-friendly and safe (since potential energy is stored which could be released into kinetic energy) to read this elongation at the driving wheel. However, this requires insight into what cable length winds around the axis per 360° rotation, which might not be constant as the cable goes over each other.

The materials used were easily accessible and cost effectively for a prototype. However, for further implementations of the design it should be further researched what would be most suitable for a durable medical device.

It would be interesting to further research how the design could be adapted to load knee flexion angles up to 40°, allowing the patellofemoral joint to be loaded as well. This adaptation would require the footplate's loading section to be adjustable and capable of rotating, ensuring that the ankle maintains a standardized angle. Creating an adjustment mechanism that is easy to use yet strong enough to withstand high loads could be challenging. While it presents a great opportunity for future design iterations, it should still be considered whether it is still feasible for the patient to maintain stable and to fit within the MRI bore.

11
Conclusion

This project aimed to design an MRI-compatible loading device to evaluate soft tissue responses indicating early OA. This device should be able to apply a load to the foot of the patient, support the knee in different knee flexion angles, and be adjustable to different patients. This report describes the analysis, design process, prototyping, and evaluation of the design concept.

During the design phase, the between feasibility, complexity, and functionality were balanced. Feasibility was the first priority, providing a working basis for further improvements. The prototype of the MRI knee loader, including the essential functional components, was evaluated and found capable of applying a load to the foot in an experimental set-up. For further research, it is recommended to find ways to reduce friction in the system, allowing the knee to be loaded efficiently and accurately. The final design should be produced and further evaluated to be able to validate all set requirements.

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A

Interview laboratory worker: Luud Rijnen

MRI procedure:

- What does a regular MRI procedure look like for a knee scan? How much time does this take in total compared to the scan time?

  The process starts with an orthopedist's request, is signed off by a radiologist.
  1. Screening: questions about possible wearing of metal
  2. Changing clothes (while other patient is being scanned).
  3. Room is prepared (knee coil, flexible coil, abdominal coil)
  4. Patient on table
  5. Scanning

  Total time: set-up + scanning
  Total knee: 30 minutes
  Trauma: 20 minutes (shorter because with trauma it is often much more specific what needs to be imaged)
  For loaded knee it should take about 45 minutes

- What does the full procedure look like (in the workflow)?

  During the scan of patient X some preparations can be made for scan Y, but outside the MRI room and without the patient bed (because it will still be used for person X).

- What components are involved in a knee scan?

  1. Coil: (knee coil, flexor coil, abdominal coil). For signal, but also for stability (with knee coil). The knee coil can slide sideways, so it can be used for left as well as right leg. Type: QED 18ch TiR Knee Coil. Foam inserts to make fit good.
  2. Support pad other leg.
  3. Foam, towels
  4. Patient table. In it parts are removable, with a kind of rectangular cutouts.

- How to measure a knee at an angle, can you do that with the coil?

  Measuring at an angle different from the angle in the knee coil (15 degrees?) can only be done with the flexible coil.

- What positions are common, lying on your back or side? Feet first or head first?

Always feet first, laying on the back. Knee comes in the middle of the tunnel (in the longitudinal tunnel).

- What are the possible risks/obstacles during a normal MRI procedure?
  1. Not fitting into the knee coil
  2. Positioning, how mobile is a person? Movement restrictions
  3. Metal can burn the skin of the patient when it heats up

- How long should it take to set up the patient and device? What is normal?

  Not keen on extending the time. But possibly the scan time can be shorter with OA if a specific sequence can be run.

- Would it be cost-effective to do part of the set-up/procedure outside the MRI room?

  Yes, when the previous patient is scanned, preparations can already be made for the next one (outside the MRI room!)

- Which biomarkers are mainly used in knee examination, in which specific situations?

  3T is better for measuring knees than 1.5T, but is more sensitive to interference and artifacts. Length of scan depends on number of photos/sequences

- What is possible in terms of metals? What are the possibilities?

  Non-ferrous metals can enter the chamber. They can interfere with images in the scanner and get warm. The further out, the better.

- Now what are knee flexion angles applied? Or only extension? What postures, are there supports?

  The angle of the knee flexion (small angle, about 15 degrees)

- Are points of contact with the body disinfected?

  Device should be able to be disinfected with alcohol and water. If an infection is present (e.g. mrsa) everything should be cleaned with chlorine. It must be able to be taken apart.

MRI constraints:

- What type of MRI scanner is used at Erasmus MC? Which manufacturer, what exactly does the coil look like?

  GE devices, 1.5T: artist and 3T: premier

- What are the dimensions of the ”bore” of an MRI scanner? Diameter, height from patient bed to top.
  Diameter: 60 cm
  Width of measurement range: 50 cm
  The further off-center, quality decreases. This applies to both width and height.

- Is the use of metal completely inadvisable? Even if it cannot ”move” in any direction? (Risk/benefit)

  Can still give image distortions. Should not be on the contact surface, as it can get hot.

- Assumption: aluminum could be used.

  See question above. Could be in the room, preferably not in the device, or it should be tested.

- What are the options for storing the device? Are there any restrictions on this?

  There is quite a bit of storage space. This should not be a big problem.

- What else should you consider when designing for MRI?

  That it fits, for people of different sizes
  MRI signal is strongest when the coil is in line with the tunnel

- Is there a possibility of materials getting hot at the skin/product contact points?

  This applies to metals, plastic is not a problem.

MRI opportunities:

- What are possible attachment points with the MRI patient table? Are other devices/accessories sometimes attached to it? May also be totally different application (brain scan oid).

  Cutouts in MRI patient bed. Grooves where fixation straps can be slid in.

- What other devices are used in the MRI? What are the experiences with these?

  1. Blood pressure monitors (with a long tube getting outside the room)
  2. Masks (radiotherapy)
  3. Temperature measurements (equipment at substantial distance)

- What devices that you already own could be used in combination with/ as part of the 'knee loader'? For example, an orthopedic shoe or support for the knee?

  Fixation straps, pads. Orthopedic boot with a foot flexor.

Use:

- What defines ease of use for a lab technician?

  Speed, not being fragile/ easily replaceable

- What is the main requirement from the user side? Is that as fast as possible, or rather easy to use in terms of settings, or not having to make adjustments in the MRI room?

  Time number one

- What would be most comfortable for the patient? (loading strategies, side or supine, head first feet first)

  Feet fist

Other:

- Are there other devices 'loading devices' on the market, suitable for joints other than the knee? To validate clinically. Spine, herniated disc? Knee loading device from telos, for X-ray

Full description of the emergency levers and buttons

Emergency lever 1 used to quickly slide the patient out of the bore, as illustrated in figure A.1. This lever moves along with the patient as they enter, and can be used to urgently remove the patient, by sliding it back out over the table. This lever should be easily accessible, and the surface of the table outside the bore (2) should also remain clear so that the bed with the patient can slide over it.

The foot pedals (3) are used to lower the table and disconnect it from the tunnel to quickly move the patient out of the MRI room. During resuscitation, nothing can be brought inside the MRI room, therefore the patient needs to exit the room quickly.

If disconnecting with the pedal does not work, there is a backup emergency lever at 4 that allows physical disconnecting the table from the tunnel.

The red buttons on the MRI (5) are of less importance because they are also located in other places in the MRI room and on the control panel. However, they should not be touched or bumped into.

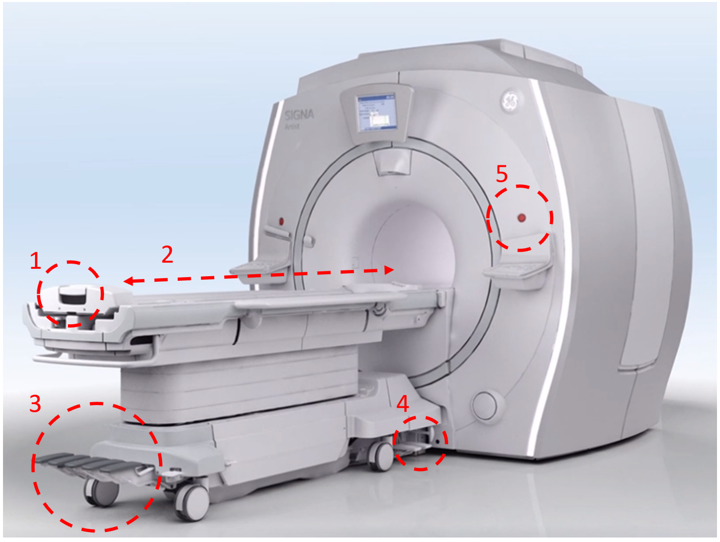


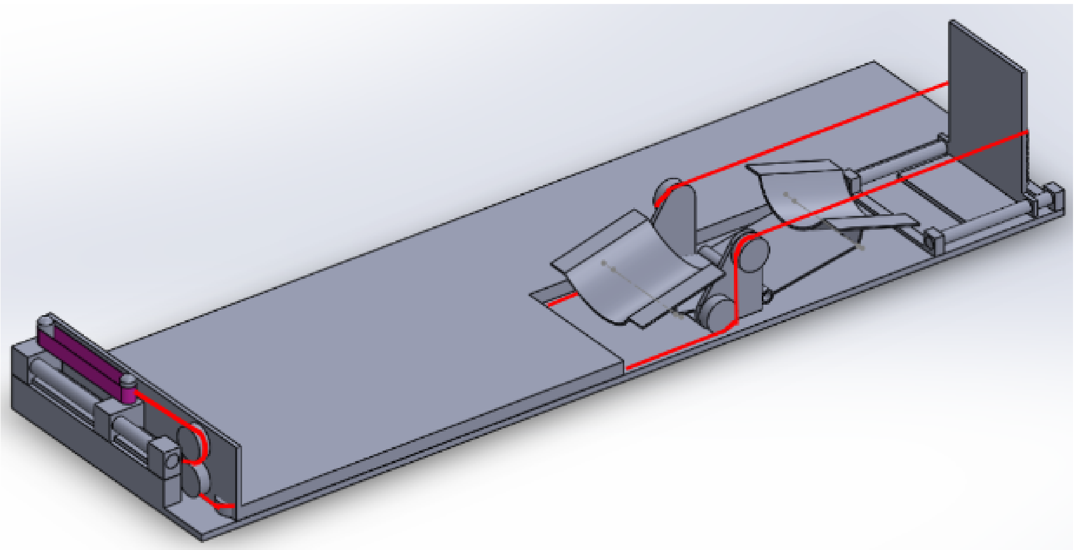
Figure A.1: Emergency levers and buttons on the MRI which should not be obstructed by the loading device. *1. Lever used to quickly slide the patient out of the bore, 2. Surface of the table outside the bore, 3. Foot pedals used to lower the table and disconnect it from the tunnel, 4. Back-up for 3, 5. Emergency buttons*

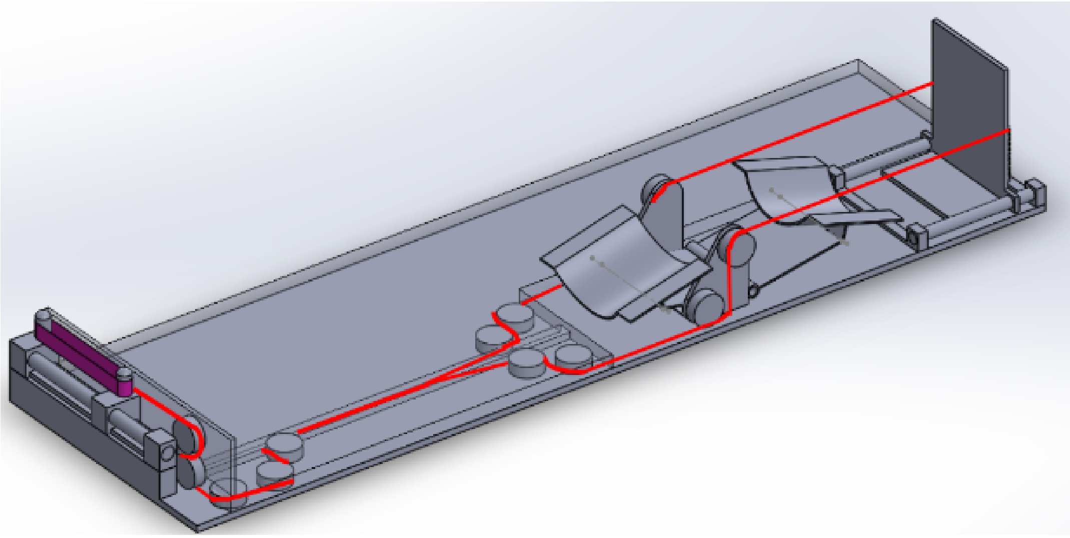
B

Design history

Considerations 28-8-2023:
Although using leg extension to create a load may be more/too complex, using suspended weight is not ideal either. The suspended weight needs to be coupled to the patient bed, because the laborant should asses the knee after the load is applied. However, building a construction behind the patient bed might obstruct the laborant being able to reach the emergency lever. This is linked to the patient bed. The surface outside the bore needs to remain clear to make sure the patient can slide over it. As this 'MRI knee loader' is a device iterated from 'research device' into 'research device taking into consideration that maybe one day it will be used in practice, it is important to include this consideration.

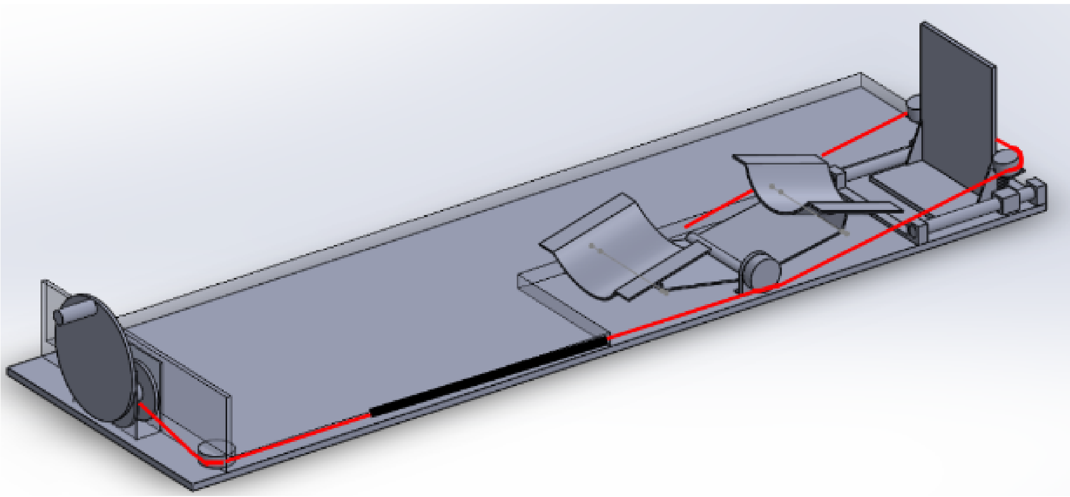
As 'concept 1' is designed right now, the force is applied at the heel. The moment around the knee joint will be too large in this way (and is less physiology-relevant). Therefore, a system with pulleys will be designed to enable force direction.



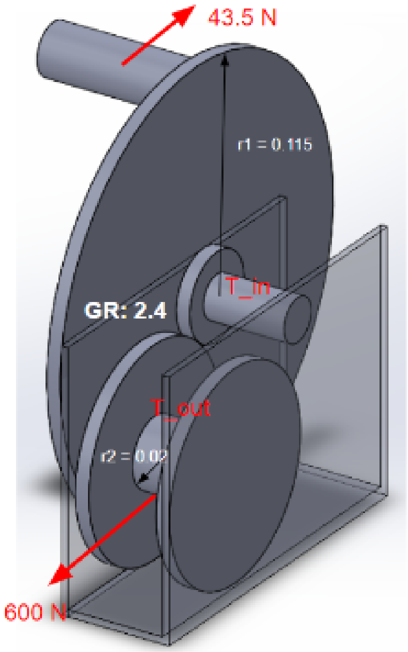


Then this concept came along. A double layer is formed in the base board, so the cables are underneath the patient and are not in contact with his/her upper body. The height of the cables at the footplate is adjustable. Moreover, the cable/pulley system is symmetrical, which means the cable does not experience friction at the footplate.

However, this setup becomes very complex with all the pulleys. Especially the pulley which needs to be adjustable in height is a problem, as it experiences great forces, but needs to be adjustable at the same time. Moreover, asking the patient to extend his knee, then position the knee, and apply the force is complex and could be more use-friendly. However, asking the laboratory worker to generate these high forces is not ideal either.



Therefore, an iteration was made to simplify the concept. There is no symmetry in the pulley cable system, which provides simplicity. The pulleys at the footplate enable the cable to move. A winch mechanism is introduced to reduce the applied force by using transmissions.



H = T * ω

T_out = 600 * 0.02 = 12 Nm

Gear ratio = 2.4 = T_out/T_in
T_in = 12/2.4 = 5 Nm

F_hand = T_in/r1 = 43.5 N

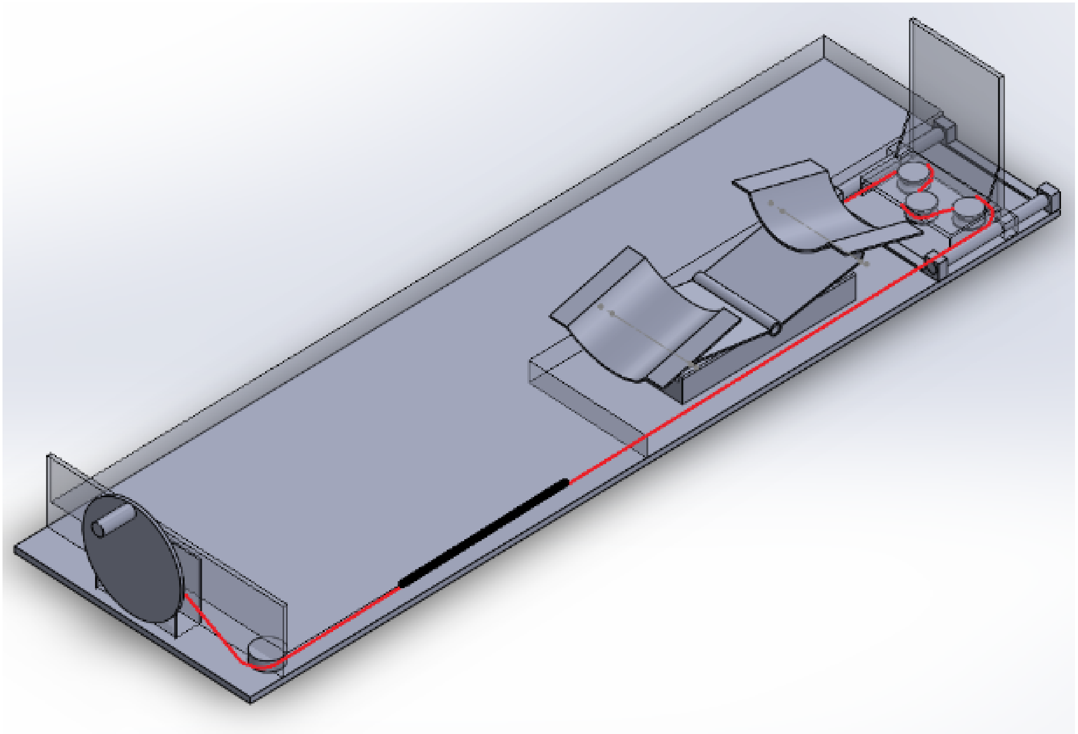
4-10-2023

Unfortunately, the production of the ‘mechanical winch part’ is relatively complex, especially concerning the gear section. Since robust gears are necessary, 3D printing is not a viable option. While purchasing gears is possible, ensuring an exact fit is a challange. In theory this approach seems to be promising, but to make it feasible to produce as a student, another solution would be better.

Another approach would be to make a pulley at the corner of the baseboard, and ask the laboratory worker to generate the load by putting the foot through a cable connected through an elastic band. However, this could still be a task which requires physical effort and coordination of the laboratory worker. Another option to create a force transmission is to attach pulleys under the footplate. The gears will be eliminated, but the cable will still be wound up with the wheel. By applying the force over a considerable distance, the design minimizes the effort to counterbalance the moment generated by extending the elastic band.

It is important to consider that the amount of pulleys needs to be reduced as few as possible, since every pulley could be a ‘problem area’. It is important that they are enclosed, so the cable could not escape when the cable is not under tension.

This results into the following concept:

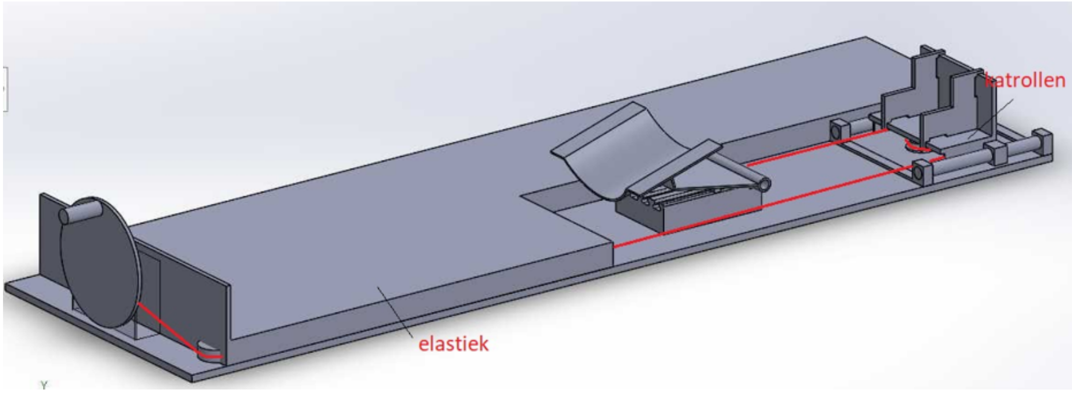


To support the knee in a chosen flexion angle, the approach by connecting the supports with a cable is not suitable. The minimal changes in cable length make it unsuitable for precise adjustments. Therefore, a new component is designed where the support rests on a block which could slide along a rail. This modification results in a less sensitive adjustment process, allowing for a more dependable and precise setting.

Meeting 4-10-2023

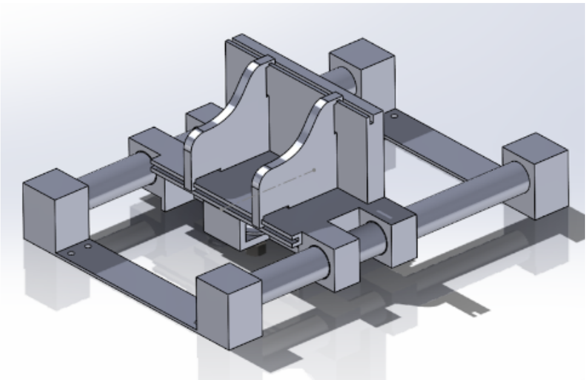
Esther, Jaap, Mariska, Erin, and Niels had a discussion regarding how to ensure that the load is exclusively applied to the desired part of the foot, specifically through the ankle. When there is a surface behind the entire length of the foot, there's a risk that force might also be applied to unintended areas, such as the toes, potentially creating undesirable moments around the ankle. Therefore, we have decided to remove the upper part of the footplate.

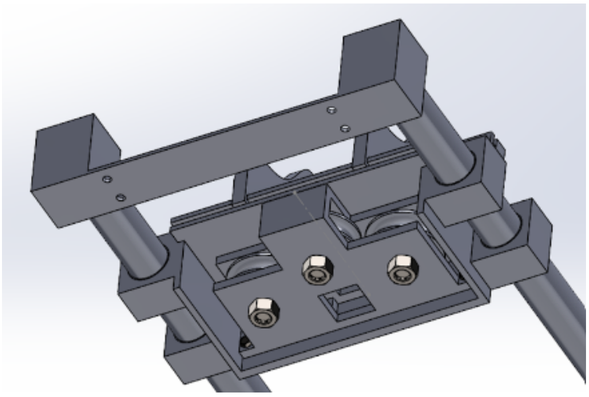
Moreover, Jaap mentioned that the lower leg support is redundant. We had a discussion that it is not necessary to have the lower leg support to maintain the flexion angle. I (Esther) said that it might be necessary for the stability of the knee joint. Moreover, that support would have resulted into dissipating the applied load. Therefore, we came to the conclusion to pay some extra attention to the design of the footplate, so the ankle will be stabilized and the tibia will not rotate around the knee joint.



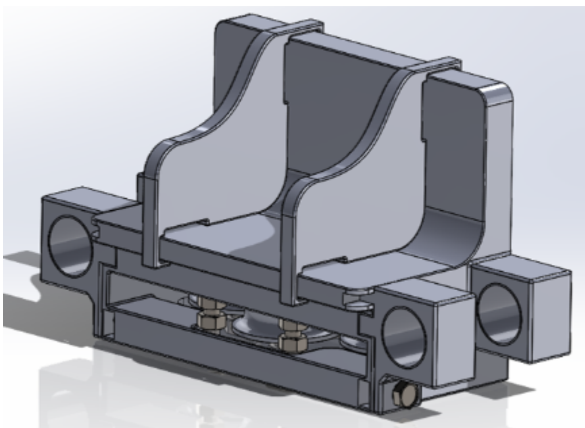
December 2023
Further detailed design:

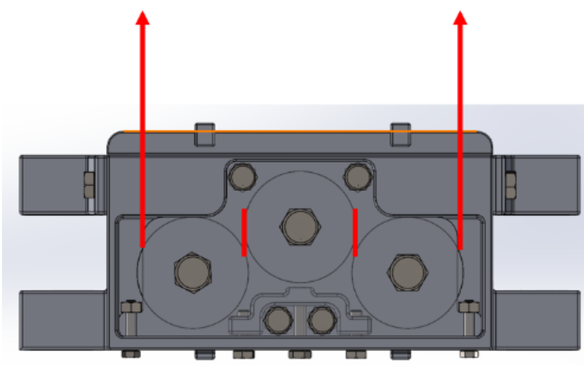
Footplate





This version of the footplate has a 3D printed block with pulleys, which could rotate around M12 nylon bolts. The ankle clamb parts could slide along rails, and be pushed towards each other with fixation bands. Two bearing ‘blocks’ are added, to catch the moment created on the base part and reduce the stresses in the material.

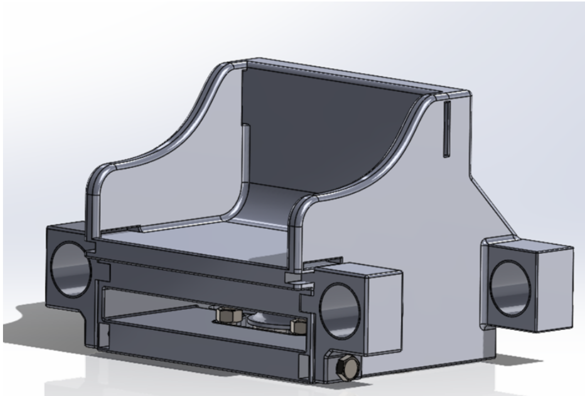
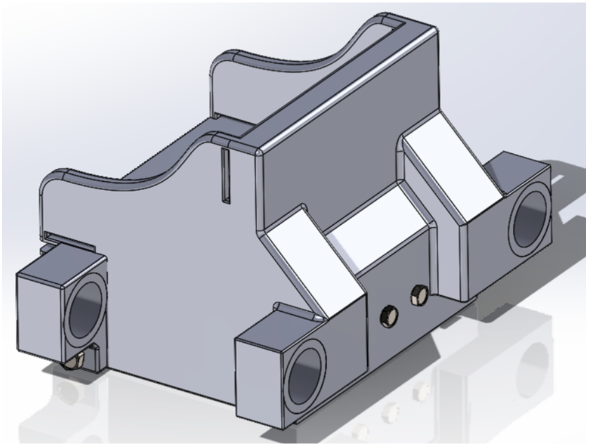




In this version, the slide mechanism of the ankle clamb plates is adapted in a way that ‘schranken’ is prevended.

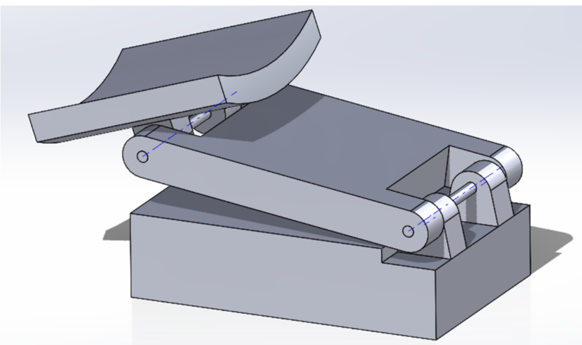
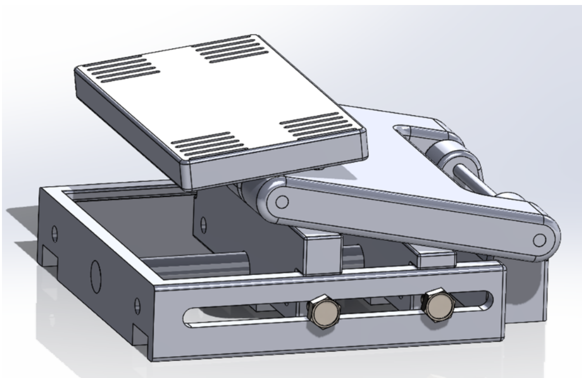
Another adaption is that two of the 'bearing blocks' have become separate parts, which could be connected to the base footplate. This is done since they slide along an axis and there are no tight tolerances guaranteed with 3D printing. Therefore the rod needs to be put through both of the bearing blocks, and then the separated bearing blocks could be fixated to the base part.

Another aspect which has been changed since the previous version is that the 'pulleyblock' has become a 'sandwhich' made of PMMA plates which are separated by bolts and nuts. In between the pulleys are located. In the base part, an edge is added where the block is pulled to, so the block is not only resisted from moving by the bolts which are pulled at. An extra part is added to make sure the block could be fixated in the Z-direction from the outside.

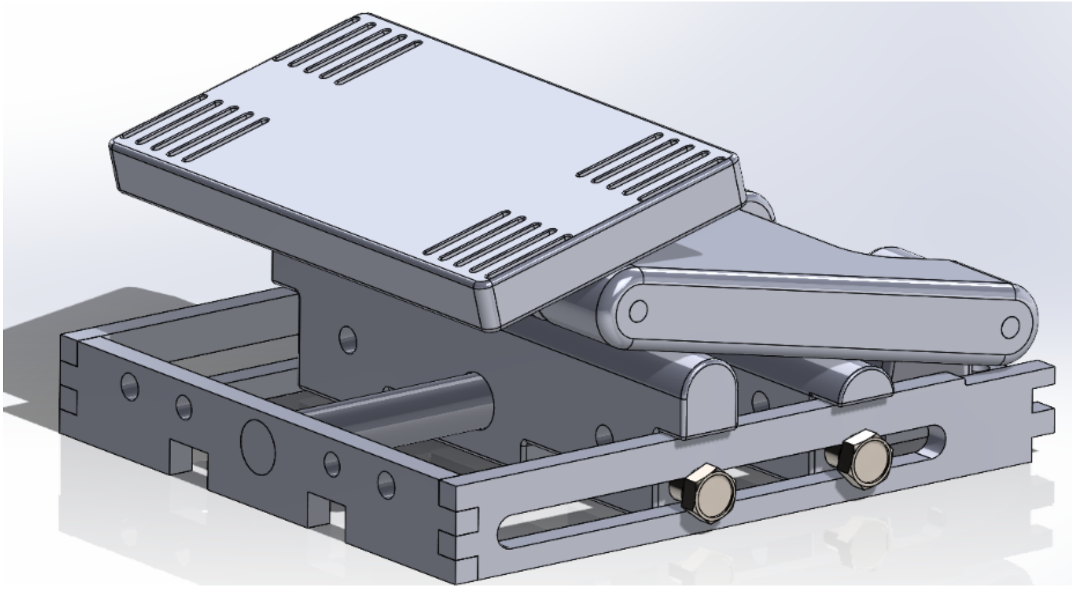
The following adaptions are that the gliding clamping anke plates are integrated in the base part. The 'gliding' function was not really an addition, and integrating them in the footplate could give the whole part an increased integrity. Moreover, the basepart has more 'body' at the back, and 'triangles' are added to catch the bending moment.

Knee support

The knee support has been made flat, to ensure that the knee could be supported at every width position. It is fully symmetrical, and therefore could be used for both knees.

Two support blocks are used, to make sure the 'H-part' is not flexing too much in relatively larger knee flexion angles. In the support block a nut is hidden, so the block could be pulled and it could be clamped in the right position.

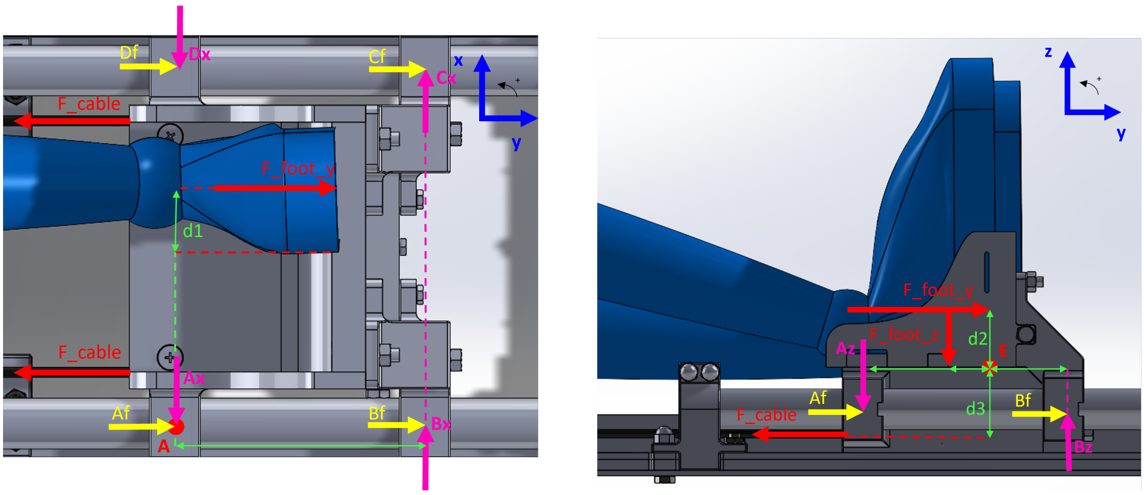


The previous version was made of a 3D-printed ‘housing’. However, this is not really necessary and could be made of PMMA plates as well.

C

Finate Element Analysis footplate

To assess the feasibility of the footplate, a finite element analysis (FEA) was executed. The applied loads are based on figure C.1. The set-up of the static static study could be seen in figure C.2 and C.3. A custom material was added to the study, representing 3D printed PLA material with tri-hexagonal infill pattern and 25% infill density [31].



(a) Top view of the forces experienced by the footplate. Since the foot is off-centred, a moment equal to $F_{\text{foot}_y} \cdot d_1$ is created around point A.

(b) Side view of the forces experienced by the footplate. $F_{\text{foot}_y} \cdot d_2$ and $F_{\text{cable}} \cdot d_3$ create a negative moment around point E.

Figure C.1: Forces experienced by the footplate; red: applied forces, pink: normal forces counteracting the moment created by the applied forces, yellow: friction forces in the movement direction caused by normal forces.

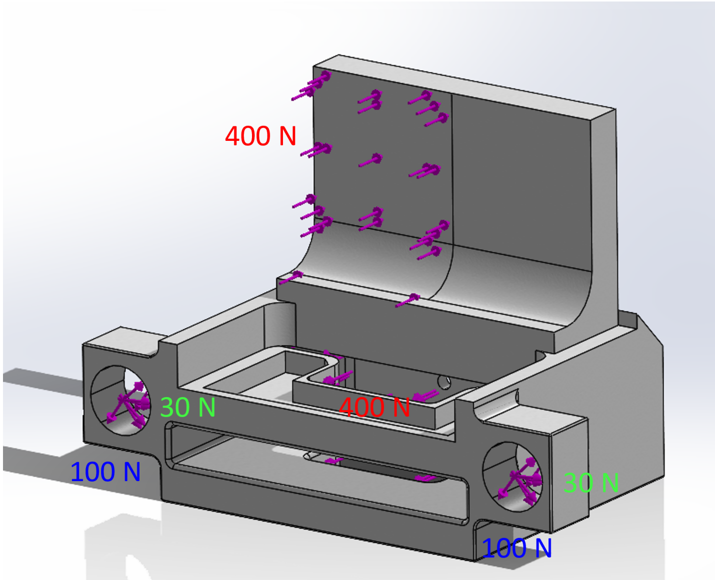


Figure C.2: Front view of the set-up of the FEA. The load magnitude where the foot is positioned is calculated based on the weight of an 80 kg patient (50% body weight). The forces at the bearings follow from figure C.1, where $A_z \approx \frac{1}{4} F_{\text{foot}_y}$ and $A_x \approx \frac{1}{12} F_{\text{foot}_y}$

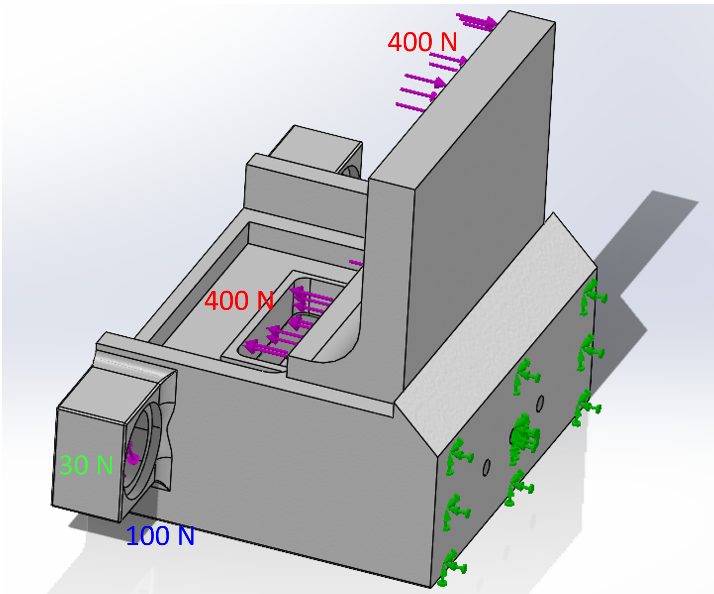


Figure C.3: Back view of the set-up of the FEA. The load magnitude where the foot is positioned is calculated based on the weight of an 80 kg patient (50% body weight). The forces at the bearings follow from figure C.1, where $A_z \approx \frac{1}{4} F_{\text{foot}_y}$ and $A_x \approx \frac{1}{12} F_{\text{foot}_y}$. The fixed geometry at the back represents the bearing blocks which are attached there.

The maximum von Mises stress reaches 4.236 MPa (figure C.4), which is well under the yield strenght of 25.50 MPa. The maximum displacement at the footplate reaches 0.2936 mm.

Although these analyses say the design is stiff and strong enough, it should be considered that using experimental data of the Young's modulus and yield strength is a simplification of reality. The strength and stiffness are also dependent on other factors, like the print orientation and the layer thickness.

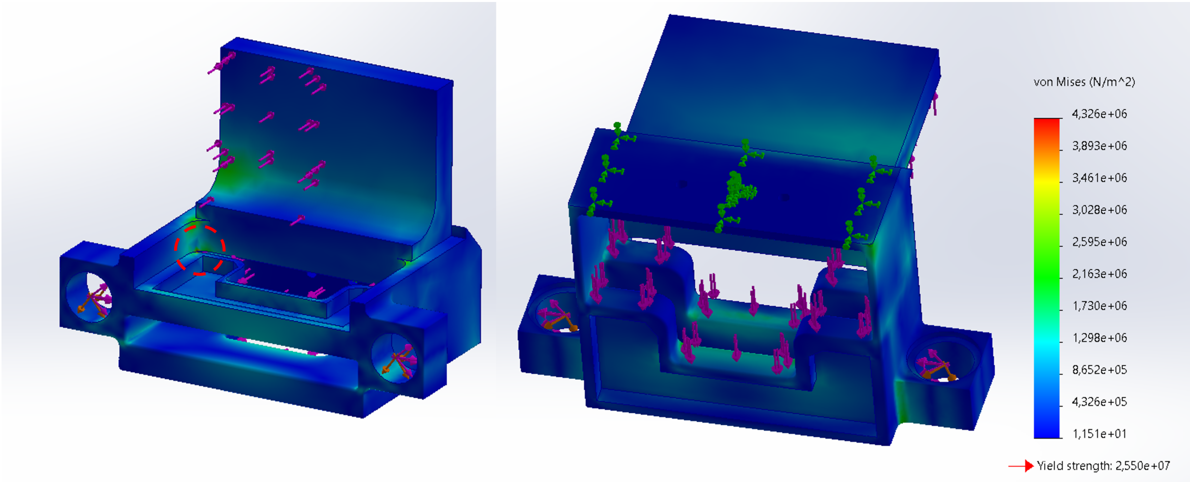


Figure C.4: Front and back view of the von Mises stresses plotted on the footplate. The red striped circle indicates the location where the stress is highest.

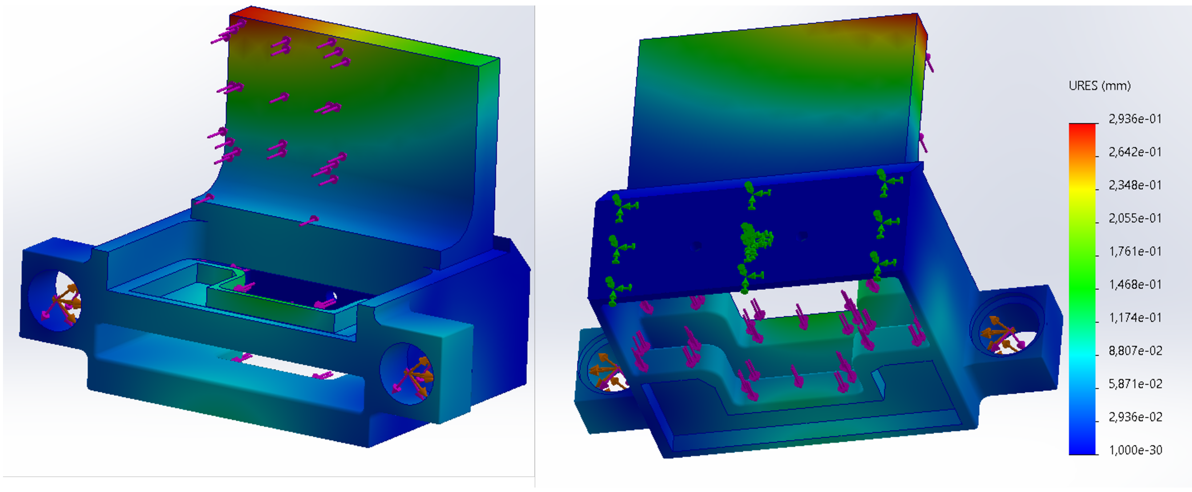


Figure C.5: Front and back view of the displacements plotted on the footplate.

D
Dimensional design

To ensure that the MRI knee loader will have the appropiate dimensions for the population, its sizing is determined by anthropometric data sourced from DINED [8], specifically focusing on adults aged 30-60 years. All the used data is summarized in table D.1. The dimensions used in the table are illustrated in figure D.1 and D.2.

	P5 female	**P5 mixed**	**P95 mixed**	**P95 male**
Stature	1558	1562	1854	1895
Popliteal height	391	395	517	534
Upper leg (UL)	337	338	401	410
Lower leg (LL)	369	370	439	449

Table D.1: Anthropometric measurements by percentile and gender. Upper and lower leg are measurements taken as percentage of stature.

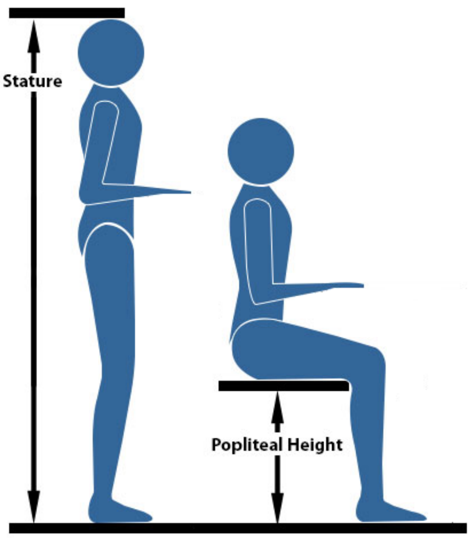


Figure D.1: Stature and popliteal height illustrated, adapted from [12]

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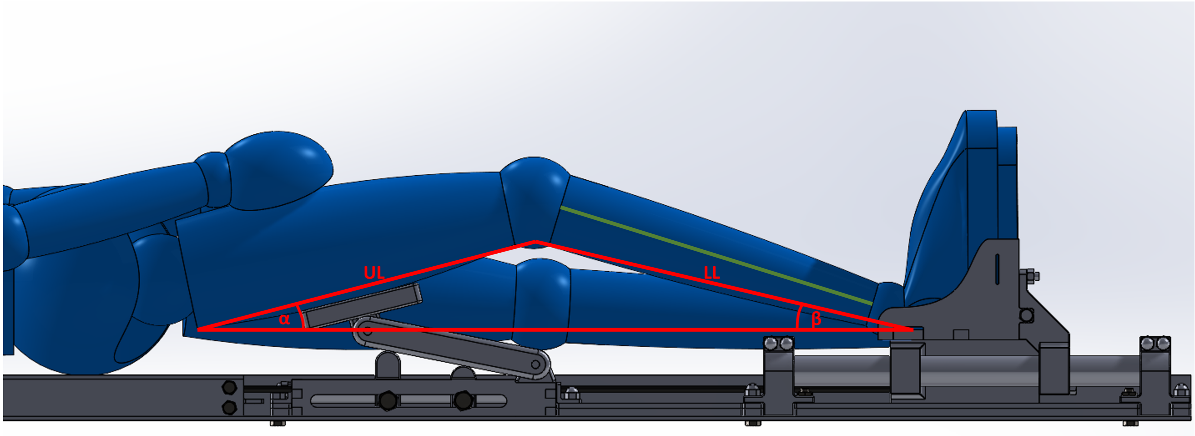

Figure D.2: Distance between hip and knee (UL) and knee and ankle (LL) illustrated in flexed knee. The knee is aligned above the hinge.

A standard rule of thumb is to include the dimensions of P5-P95 in the design. However, when opting for the mixed category, this choice may disproportionately exclude (taller) men and (shorter) women. Therefore, population dimensions between P5 females and P95 men are considered.

First of all, the length of the patient is considered, as they need to fit between the footplate and the back of the propulsion wheel assembly. This could be seen in figure D.3.

Moreover, the popliteal height of the patients is used to determine the distance between the axis of the knee support and the footplate. This is done because the knee is aligned to be exactly above this axis. This could be seen in figure D.4 and D.5. Patients whose dimensions are out of this range could still be supported if the upper body is slid backward or forward. However, then the knee could not be aligned with the axis and this makes it challenging to do the right adjustments for the flexion angle. In this case, the position of the supporting blocks to enable the right flexion angle needs to be determined manually.

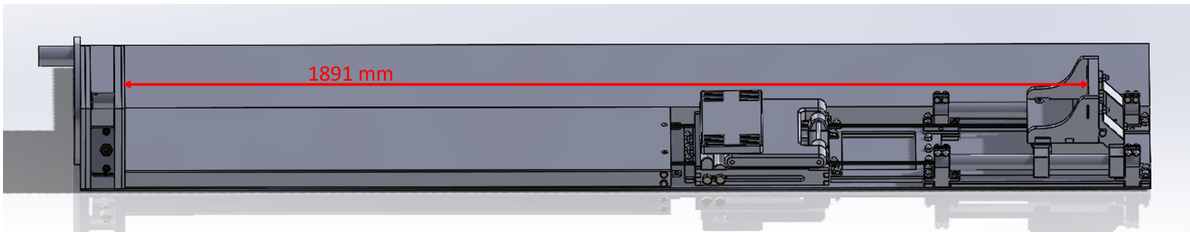

Figure D.3: Maximum length patient in device

To determine the right position for the support block in the knee support, the distance between the hip and the knee (UL) and the knee and the ankle (LL) are needed (figure figure D.2). These dimensions are hard to measure precisely and are not reported in the DINED database. Therefore, a Solidworks model, sourced from DINED and based on their anthropometric data, is used to obtain the required measurements. To determine UL and LL, these dimensions were measured in the CAD model and related to the stature measure of the model. Using this ratio and DINED's P5 woman - P95 men stature lengths (figure D.1), UL and LL were determined for the desired population.

Footplate

The height of the footplate is determined based on the location where the force needs to be applied at the ankle, multiplied with a factor 2 (figure D.6). In the section labeled 3.3, the location where there is no moment around the ankle is described. The '3DGaitModel2392' has been used, wherein the force must be applied at a distance of 4.56 cm from the bottom of the foot to obtain a zero moment around the ankle. The ratio between the foot length of the Opensim model (26 cm) and the average foot length

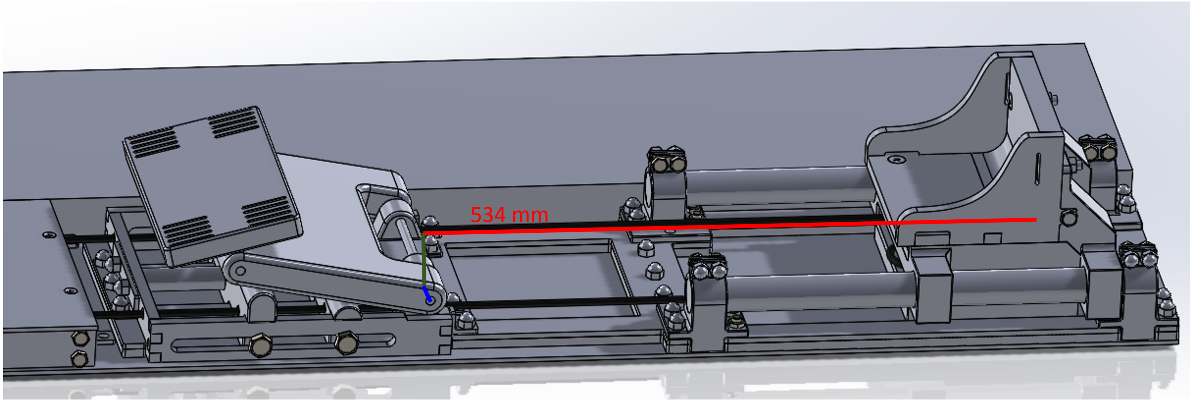

Figure D.4: Minimum length between knee and footplate

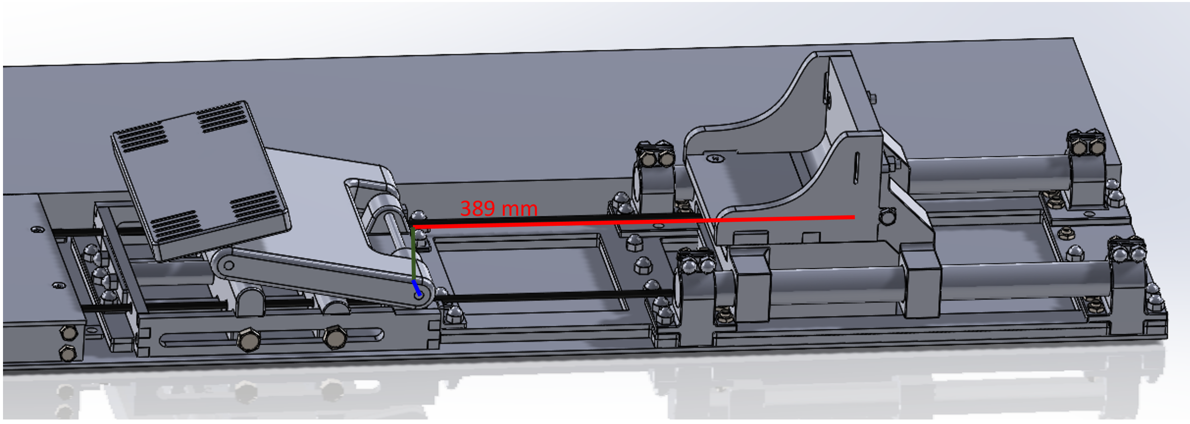

Figure D.5: Maximum length between knee and footplate

of the DINED 30-60 adult population (25.4 cm) is calculated, and this value is multiplied by 4.56 cm. This calculation results in a total footplate height of 8.9 cm.

Knee support

The dimensions of the H-part's length and the height of the small support block are tailored to accommodate individuals ranging from P5 women to P95 men, within a knee flexion angle of 5° to 20°. When the upper and lower leg lengths are measured, the angles alpha and beta could be calculated. This could be seen in figure D.2. In this model, the knee should be aligned above the hinge. A model was established to determine the position of the small support block for a patient with his/her unique dimensions in a desired knee flexion angle. Since the design consists of thick plastic parts, they could not be modeled as lines and an offset should be incorporated. An in-depth description of this model could be found in appendix E.

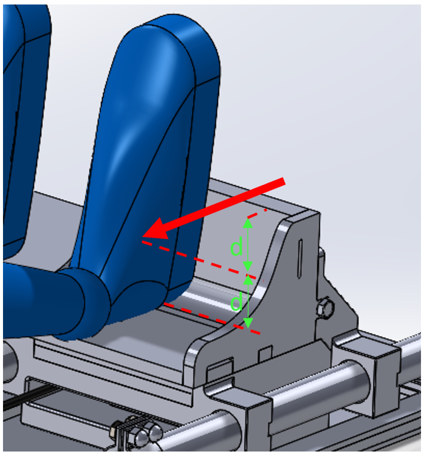

Figure D.6: Height of the footplate equals two times the distance between the bottom of the foot and the desired position for load application.

E

Calculation position supporting block

A model has been created to determine where the supporting block needs to be positioned, to support a leg with unique dimensions (UL and LL, figure E.1) in a desired flexion angle. Angles α and ϕ need to be calculated by solving sets of equations originating from goniometric triangles. The relationship between these triangles is illustrated in figure E.2

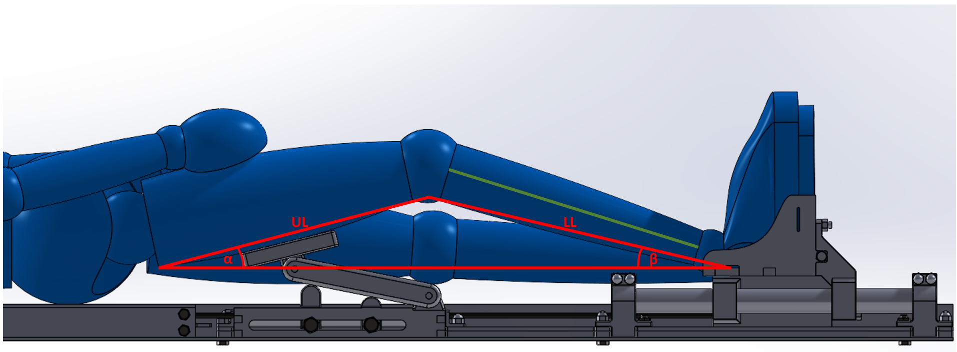

Figure E.1: UL and LL in relation to the design.

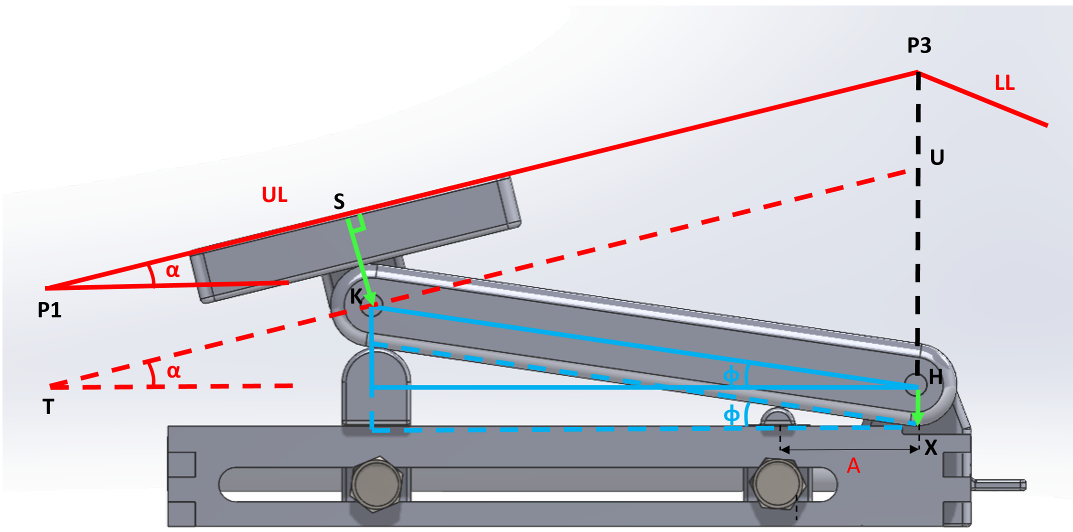

Figure E.2: Knee support overview on how to calculate the distance between the middle of the support block and the hinge (A).

The values of α and β are calculated using UL, LL and the desired flexion angle, see figure E.3 and equations B.1 - B.5. ϕ is calculated by solving equations B.6-B.8, illustrated in figure E.4

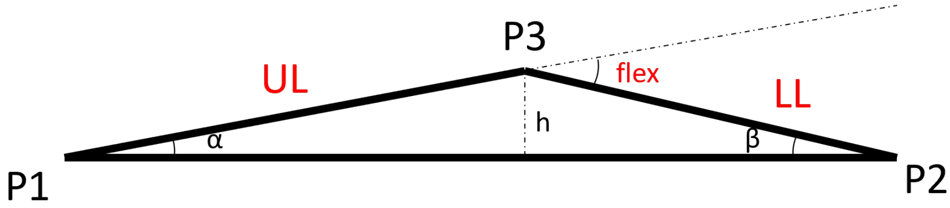

Figure E.3: Illustration on the relationships how to determine α and β

$$h = \sin(\alpha) \cdot \text{UL} \tag{E.1}$$

$$h = \sin(\beta) \cdot \text{LL} \tag{E.2}$$

$$\sin(\alpha) \cdot \text{UL} = \sin(\beta) \cdot \text{LL} \tag{E.3}$$

$$\alpha + \beta = \text{flex} \tag{E.4}$$

$$\sin(\alpha) = \frac{\text{LL}}{\text{UL}} \cdot \sin(\text{flex} - \alpha) \tag{E.5}$$

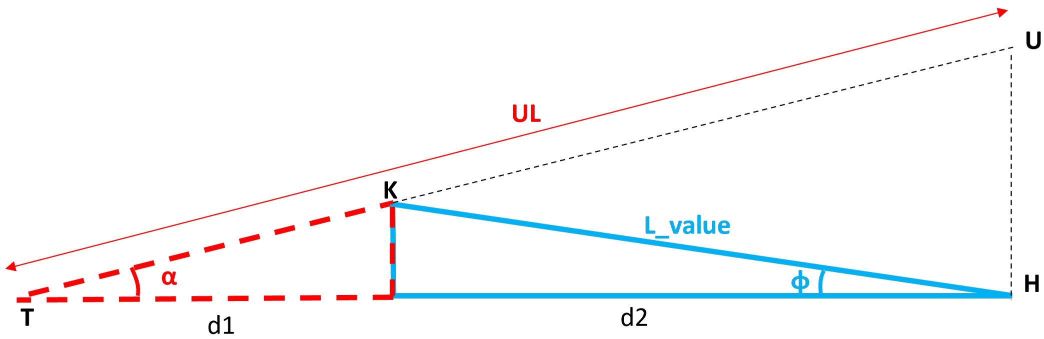

Figure E.4: Illustration on the relationships how to determine ϕ

$$\tan(\alpha) \cdot d_1 = \tan(\phi) \cdot d_2 \tag{E.6}$$

$$\cos(\alpha) = \frac{d_1 + d_2}{\text{UL}} \tag{E.7}$$

$$\cos(\phi) \cdot L_{\text{value}} = d_2 \tag{E.8}$$

The H-part of the design is supported by the block, which does not have a flat top to prevent from wear. The H-part will not be supported exactly at the middle of the block. To ensure adjustability and proper placement, a calculation has been performed, illustrated in figure E.5. With the given values of angle ϕ and the radius of the support fillet, the calculation for determining the midpoint of the circle involves using the right angle formed by the radius and the tangent line of the circle within a right-angled triangle.

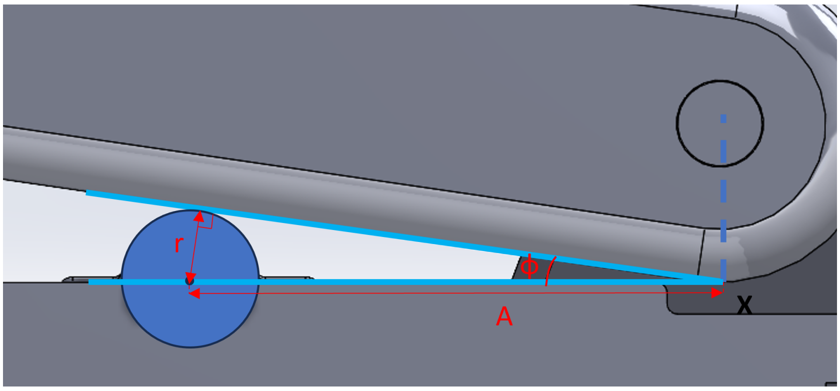

Figure E.5: Distance between the middle of the support block and the hinge

$$A = \frac{r}{\sin(\phi)} \tag{E.9}$$

The positions of the points referenced in the figures are modeled in the Jupiter Notebook scripts. In figure E.6 and E.7 could be seen that the support block is positioned at both extreme sides of the H-part, supporting relatively small women in small flexion angles and relatively great men in greater flexion angles.

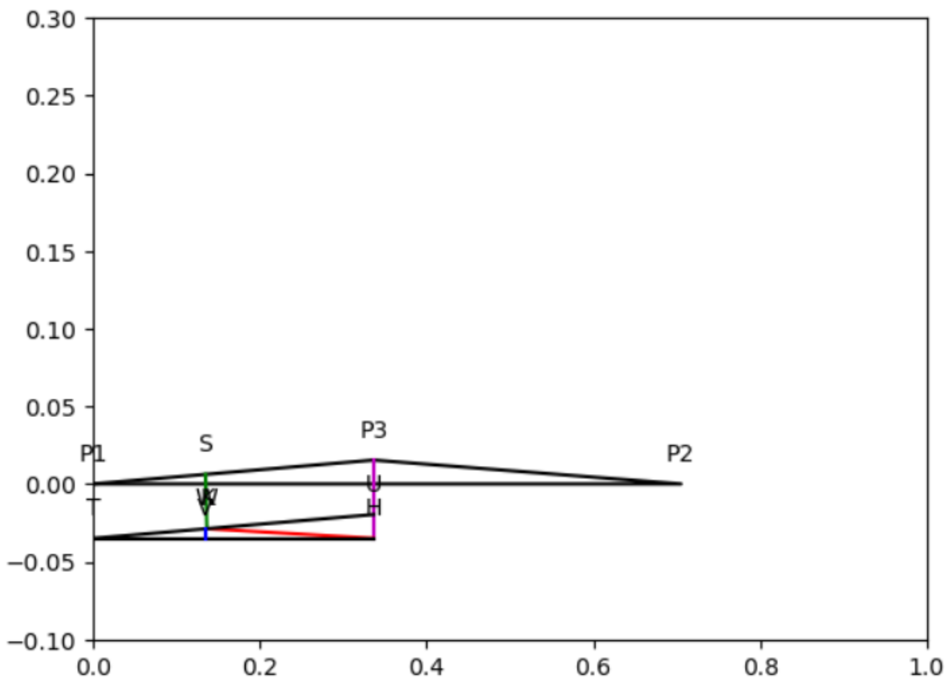

Figure E.6: Position of the support block for P5 woman in 5° flexion.

```python
import sympy as sp
from scipy.optimize import fsolve
import math

# Define the symbolic variables
alpha, beta, UL, LL, flex_ang = sp.symbols('alpha beta UL LL flex_ang')

# Define values for UL LL and flex_ang
UL_value = 0.361
LL_value = 0.421
```

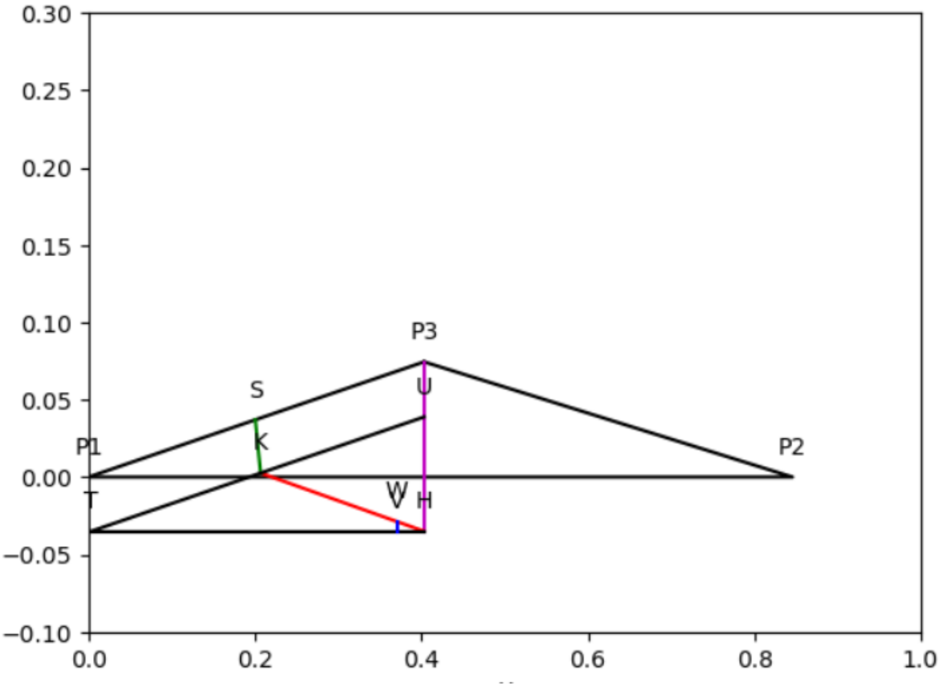

Figure E.7: Position of the support block for P95 man in 20° flexion.

```
flex_ang_value = sp.rad(20)
L_value = 0.20
h_block = 0.00625

# Define the equations
eq1 = sp.Eq(sp.sin(alpha), LL/UL*sp.sin(flex_ang-alpha))
eq2 = sp.Eq(alpha + beta, flex_ang)

# Define an initial guess for the solution
initial_guess = (0.1, 0.1)

# Substitute the values of alpha and beta into the equations
eq1_substituted = eq1.subs({UL: UL_value, LL: LL_value, flex_ang: flex_ang_value})
eq2_substituted = eq2.subs({UL: UL_value, LL: LL_value, flex_ang: flex_ang_value})

# Convert the equations to functions for numerical solving
func1 = sp.lambdify((alpha, beta), eq1_substituted.rhs - eq1_substituted.lhs)
func2 = sp.lambdify((alpha, beta), eq2_substituted.rhs - eq2_substituted.lhs)

# Use fsolve with a relaxed tolerance to find numerical solutions
numerical_solutions1 = fsolve(lambda x: [func1(*x), func2(*x)], initial_guess, xtol=1e-4)

alpha_radians = numerical_solutions1[0]
beta_radians = numerical_solutions1[1]

# Convert the solutions from radians to degrees
alpha_degrees = math.degrees(numerical_solutions1[0])
beta_degrees = math.degrees(numerical_solutions1[1])

print("Numerical solutions1:")
print("alpha =", alpha_degrees, "degrees")
print("beta =", beta_degrees, "degrees")

d_S_K = 0.035
h_triangle_leg = sp.sin(numerical_solutions1[0])*UL_value
h_triangle_hinge = h_triangle_leg - d_S_K/sp.cos(alpha_radians) + d_S_K
h_triangle_hinge

d1, d2, phi = sp.symbols('d1 d2 phi')
```

```

# Define the equations

eq3 = sp.Eq(sp.tan(alpha_radians)*d1, sp.tan(phi)*d2)
eq4 = sp.Eq(d1 + d2, h_triangle_hinge/sp.tan(alpha_radians))
eq5 = sp.Eq(sp.cos(phi)*L_value, d2)

# Define an initial guess for the solution
initial_guess2 = (0.1, 0.1, 0.1)

func3 = sp.lambdify((phi, d1, d2), eq3.rhs - eq3.lhs)
func4 = sp.lambdify((phi, d1, d2), eq4.rhs - eq4.lhs)
func5 = sp.lambdify((phi, d1, d2), eq5.rhs - eq5.lhs)

# Use fsolve with a relaxed tolerance to find numerical solutions
numerical_solutions2 = fsolve(lambda x: [func3(*x), func4(*x), func5(*x)], initial_guess2,
    xtol=1e-5)

print("Numerical␣solutions2:")
print("phi␣=", numerical_solutions2[0], "radians")
print("d1␣=", numerical_solutions2[1], "m")
print("d2␣=", numerical_solutions2[2], "m")

d1 = numerical_solutions2[1]
d2 = numerical_solutions2[2]
phi_radians = numerical_solutions2[0]
phi_degrees = math.degrees(numerical_solutions2[0])
phi_degrees

distance_from_hinge = h_block/sp.tan(numerical_solutions2[0])
distance_from_hinge

from IPython.display import HTML
from matplotlib.animation import FuncAnimation
from scipy.integrate import solve_ivp
import matplotlib.pyplot as plt
import numpy as np
import sympy as sm
import sympy.physics.mechanics as me

me.init_vprinting(use_latex='mathjax')

N = me.ReferenceFrame('N')
A = me.ReferenceFrame('A')
B = me.ReferenceFrame('B')
E = me.ReferenceFrame('E')
F = me.ReferenceFrame('F')

A.orient_axis(N, (0.5*math.pi-math.radians(beta_degrees)), N.z)
B.orient_axis(A, (flex_ang_value), A.z)
E.orient_axis(N, -(math.pi+phi_radians), N.z)
F.orient_axis(N, alpha_radians, N.z)

P1 = me.Point('P1')
P2 = me.Point('P2')
P3 = me.Point('P3')
H = me.Point('H')
K = me.Point('K')
S = me.Point('S')
T = me.Point('T')
U = me.Point('U')
V = me.Point('V')
W = me.Point('W')

d3 = sp.cos(alpha_radians)*UL_value + sp.cos(beta_radians)*LL_value
d4 = sp.sin(alpha_radians)*UL_value + d_S_K

P2.set_pos(P1, d3*N.x)
P3.set_pos(P2, LL_value*A.y)
H.set_pos(P3, d4*-N.y)
K.set_pos(H, L_value*E.x)
```

```
S.set_pos(K, d_S_K*F.y)
T.set_pos(H, (d1+d2)*-N.x)
U.set_pos(H, h_triangle_hinge*N.y)
V.set_pos(H, distance_from_hinge*-N.x)
W.set_pos(V, h_block*N.y)

# Create a figure and axis for the plot
fig, ax = plt.subplots()

# Define points
points = [P1, P2, P3, H, K, S, T, U, V, W]

# Initialize empty lists for X and Y coordinates
x_coords = []
y_coords = []

# Labels for the points
point_labels = ["P1", "P2", "P3", "H", "K", "S", "T", "U", "V", "W"]

# Loop through the points and extract their coordinates
for point in points:
    coordinates = point.pos_from(P1).to_matrix(N)
    x_coords.append(float(coordinates[0]))
    y_coords.append(float(coordinates[1]))

# Append the first point to close the loop
x_coords.append(x_coords[0])
y_coords.append(y_coords[0])

# Plot black lines between P1, P2, P3, and back to P1
ax.plot(x_coords[0:3], y_coords[0:3], 'k-')
ax.plot([x_coords[0], x_coords[2]], [y_coords[0], y_coords[2]], 'k-')

# Plot pink lines between H and P3
ax.plot([x_coords[2], x_coords[3]], [y_coords[2], y_coords[3]], 'm-')

# Plot red lines between H and K
ax.plot([x_coords[3], x_coords[4]], [y_coords[3], y_coords[4]], 'r-')

# Plot green lines between H and K
ax.plot([x_coords[4], x_coords[5]], [y_coords[4], y_coords[5]], 'g-')

# Plot black lines between S and T
ax.plot([x_coords[3], x_coords[6]], [y_coords[3], y_coords[6]], 'k-')
ax.plot([x_coords[6], x_coords[7]], [y_coords[6], y_coords[7]], 'k-')

# Plot blue lines between V and W
ax.plot([x_coords[8], x_coords[9]], [y_coords[8], y_coords[9]], 'b-')

# Annotate points with labels
for i, label in enumerate(point_labels):
    ax.annotate(label, (x_coords[i], y_coords[i]), textcoords="offset points", xytext=(0, 10)
        , ha='center')

# Set axis limits
ax.set_xlim(0, 1.0)
ax.set_ylim(-0.1, 0.3)

# Set axis labels
ax.set_xlabel('X')
ax.set_ylabel('Y')
```