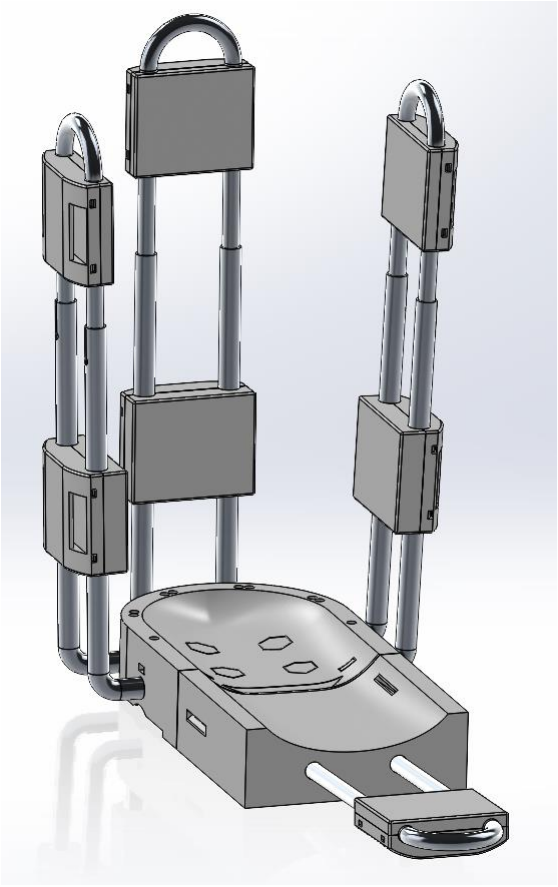
CHALMERS
UNIVERSITY OF TECHNOLOGY



Design and development of a bypass-socket for intact limb usage of a transfemoral prosthesis

Master's thesis in biomedical engineering

VICTOR ÖBERG

DEPARTMENT OF ELECTRICAL ENGINEERING

CHALMERS UNIVERSITY OF TECHNOLOGY

Gothenburg, Sweden 2020
www.chalmers.se

Master Thesis

Design and development of a bypass-socket for intact limb usage of a transfemoral prosthesis

VICTOR ÖBERG

Department of Electrical Engineering

CHALMERS UNIVERSITY OF TECHNOLOGY

Gothenburg, Sweden 2020

Design and development of a bypass-socket for intact limb usage of a transfemoral prosthesis

VICTOR ÖBERG

Supervisor: Alexander Thesleff, PhD Student, Chalmers University of Technology
Examiner: Max Ortiz Catalan, Associate Professor, Chalmers University of Technology

Department of Electrical Engineering
Chalmers University of Technology
SE-412 96 Gothenburg
Sweden
Telephone + 46 (0)31-772 1000

Cover: CAD-model of the bypass-socket made using SOLIDWORKS

Gothenburg, Sweden 2020

Acknowledgement

I would like to express much gratitude to my supervisor Alexander Thesleff for the guidance, commitment, support, and feedback throughout the project. I also thank my examiner Max Ortiz Catalan for the support and commitment.

I would like to specially thank CPO Tommy Svensson at Ottobock, Orthopaedic Engineer Joakim Engström at Ortopedteknik Sahlgrenska, and Christoffer Lindhe at Lindhe Xtend AB for counselling and lending me the necessary prosthetic components for evaluating the bypass-socket. I am grateful for the discussions and guidance from Professor Mikael Enelund and form Research Engineer Göran Stigler. I would also like to thank the people at Prototyplaboratoriet at Chalmers for providing the necessary materials for the On-the-side connector and for the use of the water jet cutter.

I express my appreciation to the people at the Biomechatronics & Neurorehabilitation Laboratory (BNL) for their support, viewpoints, and kindness throughout my time with them. A special thank you to Maria Munoz, Jan Zbinden and Andrew Smiles for participating in the evaluation of the prototype, as well as to Brett Musolf for being an additional user and giving important feedback.

Abstract

The evolution of prosthetic legs has gone from rigid to bendable robotic joints that recently can be controlled using microprocessors. Sophisticated powered prostheses can potentially restore more natural motions for the user. Some researchers use electromyographic signals in the control algorithms for the microprocessors that command the prosthesis. The evaluation of such control algorithms often requires an individual with lower limb amputation to wear the prosthesis.

This thesis aims to create a bypass-socket that enables able-bodied researchers to use a transfemoral prosthesis to do initial evaluations of new control algorithms. By conducting a literature review, important aspects regarding electrode placements, expected forces, and socket types were collected. Early concepts were sketched based on a requirement specification, and prominent concepts were further designed using computer aided design. The finite element method was used to reassure the durability for a 100 kg user. A bypass-socket was designed consisting of a 3D-printed plate of polylactic acid where the knee of a bended leg is placed, and 3 supporting struts of aluminium that fixates the thigh to the bypass socket. The prototype was made in a household environment with standard equipment available for the average person to increase accessibility.

A prosthetic leg with a mechanical passive knee joint and a prosthetic foot without an ankle joint was used for the user tests. The prototype of the bypass-socket was tested by three people and worn by additional three people to collect viewpoints. The bypass-socket was usable and enabled able-bodied people to walk with a prosthesis. The knee of the user was fixed in the bypass-socket but relative movement between the proximal end of the bypass-socket and the thigh occurred. Problems with instability occurred for all the users due to inexperience of using a prosthetic leg along with insufficient pressure at the proximal end of the supporting struts of the bypass-socket. Loads above 100 kg is not recommended in this design. Electrode placement allowing recording of EMG was observed possible. In summary, the bypass-socket developed in this work was found functional but not optimal.

Keywords: bypass-socket, able-bodied socket, transfemoral-socket, intact legs, transfemoral prosthesis, research evaluation.

Contents

1. Introduction

There are two major principles of how a prosthesis can be attached to the residual limb of an individual with an above-knee amputation, a so called transfemoral amputation [1], [2]. The most used principle is the use of a socket which the residual limb is positioned in [3]. Between the residual limb and the socket, is usually a liner that brings more comfort and suspension [3], [4]. The interface between the socket and the limb is crucial. Any discomfort may affect the skin and lead to blisters and pain [1], [5]. To get the appropriate fit, the socket is casted based on the residual limb and pressure sensitive points are avoided to not harm the skin [4]. According to Zhang pain and skin damage can be the result if the loads are not distributed correctly [6]. The tuberosity of the ischium is often used to transfer the load from the transfemoral prosthesis to the body according to Rajťúková *et al*. and that the distal end of the socket should transfer ideally a maximum of 10 % of the body weight to not damage soft tissues [2].

The other principle is direct skeletal attachment [3]. A titanium rod is fixed into the femur of the residual limb, enabling all the load from the prosthesis to be transferred directly to the femur via osseointegration. The phenomenon refers to the anchoring of the implant to the bone due to formation of bony tissue around the titanium rod [7]. The prosthetic leg is then attached to the titanium rod, meaning that no socket is needed. This type of attachment leads to a more comfortable use for the individual with an amputation [1], which results in more usage of the prosthesis. Since the forces are absorbed by the femur, there will be no load bearing on the skin. The process however, of attaching the titanium implant requires surgical procedures [1], [3], [7] and months of healing before full load bearing can be applied to the implant. In some cases, infections occur [8], usually at the skin-penetration area or superficial, but deep infections around the implant could also occur and can in rare cases result in implant removal.

The evolution of prostheses has gone from having knee joints that needed to be fully extended during the gait cycle [3], into being bendable and having microprocessors that control the movement of the knee [3], [9], [10]. Most of these are however passive, where the prosthesis can store or dissipate energy but not create net power during the gait cycle. Therefore, more energy is required for ambulation for a prosthetic user compared with an able-bodied individual [11]. Microprocessors enable safer gait for patient, since these prohibits unintentional bending of the knee and enable patients to more easily move on uneven ground [3]. Research has been done where the recordings of electromyography (EMG) signals in the residual limb have been used to control the prosthesis [9]–[13]. The patient can then move the joints intentionally, using muscle contraction and neural signals. This technology is however not yet commercially available for lower limb prostheses.

Researchers in the field of transfemoral prosthetics need participants with a transfemoral amputation to evaluate their research and control algorithms. As the research is an iterative process, this becomes time consuming for both the researchers and the participants. The process requires frequent evaluation which is inconvenient when using third party participants. There are however ways to test these control algorithms on able-bodied people as done in some studies [11], [14]. These studies used an able-bodied testing adaptor which made it possible to connect a lower-limb prosthesis to an intact leg. A testing adaptor of this type makes it possible to evaluate some of the research without the need of a participant with a lower-limb amputation. This saves time, money, and reduces the needed effort to get the appropriate clearance and compensation for participants since the researcher can perform evaluation and initial tests on themselves to a higher extent.

1.1. Aim and limitations

The aim of this master thesis is to produce a working modular, adjustable transfemoral socket for usage by an able-bodied person. The socket should be attachable to a standard lower limb prosthesis and preferably, but not necessarily, be usable by a person with transfemoral amputation.

The project is limited to transfemoral prostheses. The literature study will mention important parts of the entire prosthesis, both osseointegrated and socket prosthesis, but will have its focus on the socket and the socket adapter. This implies that the focus is proximal of the artificial knee.

For the design of the prototype to be achievable and available for researchers to build, the prototype should not rely on advanced manufacturing processes. Simple or easily accessible tools and material for people within the research community should be used.

The thesis is conducted during the time of the covid-19 pandemic which affects the possibilities to use the workshop at Chalmers for prototype production and get the appropriate parts when needed. This further stated in the report where needed.

2. Methods

The section presents the methodology of creating the bypass-socket which consisted of four parts. First design inputs were gathered through a literature review and consultation with different parties. Then conceptional designs were created through sketches and computer aided design. The designs were then evaluated and further developed using the finite element method. Lastly, prototypes were made and evaluated in user tests.

2.1. Inputs for the design

In the beginning of the project a literature review was conducted to get a background, and a foundation of the problem and understand what aspects that were important. This included reading literature and investigating existing solutions for ideas of what to do and if/how the problem had been solved by others. An important part was also to get ideas and inputs from other people and researchers to widen the frame of reference, get more ideas and see unknown problems. The most important things were concluded in a requirement specification before the start of the conceptual design.

2.1.1. Literature review, patents, and websites

Information was gathered from medical websites, company websites, and books. A literature review was conducted where papers and articles were read. Search engines used were Google scholar, PubMed and Mendeley with the keywords: socket development, able-bodied adapter, socket construction, transfemoral prosthesis, lower limb prosthesis, force sensor, transfemoral amputation and socket-adapter.

Espacenet was used to get inspirations from patents and existing solutions. Since the product is to be used for research purpose, a violation of a patent was not considered to be a crucial problem but should be avoided if possible.

Websites have been used to check products from different manufacturers and distributers to view existing solutions. They have been used to view standard prosthetic components and other components of interest in a lower limb prosthesis. Medical websites have been used to better understand the residual limb, and considerations and procedures of constructing a transfemoral socket.

2.1.2. Consultation with project group and specialists

A meeting was held to present the project, literature review and findings for the Biomechatronics & Neurorehabilitation Laboratory (BNL) research group at Chalmers University of Technology. Some early concepts were shown and discussed, and viewpoints and opinions from the group were collected. This discussion led to advices and provided new insights which were further considered in the project, along with more requirements for the prototype. Viewpoints and aspects were then continuously collected from the project group during the project.

Consultation with experts within relevant fields ensured that the appropriate aspects were considered. One professor and one research engineer both from the mechanical department was contacted to discuss the different designs. In the meeting with the professor, the amount of force, reasonable force distribution and design requirements regarding stiffness and strengths in the materials was in focus. In the meeting with the research engineer the focus regarded 3D-printing aspects. Prosthetic components and information were gathered by contacting an orthopaedic engineer from Ortopedteknik Sahlgrenska and a Certified Prosthetist Orthotist (CPO) from Ottobock.

2.1.3. Requirement specification

Based on the literature review, website information, aspects from the research group and consultation with the supervisor, a requirement specification was set. The requirement specification includes both requirements that needs to be fulfilled and request which are wanted for the final prototype. These requests have different values depending on to what degree they are wanted, which are based on the discussion with the BNL group, and to what degree physically possible to do.

2.2. Designing of the concepts

Based on the requirement specification, conceptual designs were sketched. The sketches were evaluated where the most prominent were kept for further designing. By using computer aided design (CAD), the concepts were more thoroughly designed, and errors were corrected. The CAD-models were first visually evaluated and later, the strength in some of the designs was evaluated using the finite element method (FEM). An iteration process between the CAD-modelling and the finite element analysis (FEA) ensured the fulfilment of the requirements.

2.2.1. Generating concept and concept evaluation

The conceptual design started with plain sketches on paper. Sketches were made for both able-bodied bypass-sockets and bypass-sockets compatible with a residual limb. It was assumed that the residual limb compatible sockets could be adapted for able-bodied usage, while the able-bodied sockets were optimized for usage with an intact leg. To get an appropriate sense of the dimensions for the socket designs, small paper models of a thigh and a residual limb was made. Solutions for different sub-functions were combined to get more concepts. The sketched designs were evaluated using evaluation matrices to conclude the ones most likely to preform best. Due to description complexity, both the method and result are presented in Concept evaluation.

2.2.2. Computer aided designs

The concluded designs were designed more accurate using CAD (SOLIDWORKS, Dassault systems). In this part dimensions were set, and more components and adjustments were made as problems occurred. The usage of CAD and FEM was decided as a preferable approach rather than doing a physical prototype directly, due to the uncertainty of the designs' durability. The drawback is the uncertainty of the designs' usability when assigning the dimensions in the CAD-model, hence a user test was done at the end of the project. An evaluation of the designs was conducted to narrow the necessary computations for the FEA, and to decide on a design that was assumed to be realistically achievable during the thesis period.

2.2.3. Mechanical strength evaluation using FEM

Using the FEM based software ANSYS, the structural strength and durability of the CAD-files was assessed. Only the crucial and most exposed structural elements were evaluated to reduce unnecessary calculations and data storage. The loading parameters in the tests were based on the requirement specification and inputs from the professor. An iteration process between the CAD-modelling and the FEA was made until the designs fulfilled the requirements. The FEA resulted in a construction that should meet the set requirements and thus be suitable as a prototype. The anticipated number of load cycles that the bypass-socket would be exposed to was considered sufficiently low to justify a replacement of fatigue bench test by using a safety factor of two for the applied forces.

2.3. Prototype

A prototype was made to evaluate the final design. The prototype was made using equipment and materials available for researchers. Parts that could be 3D-printed were printed at BNL, and parts that needed to be more durable and thereby made in steel or aluminium was planned to be made at the prototype lab of the mechanical department at Chalmers or by using general tools of the house-environment. Due to the stated pandemic, the prototype lab could not be used, and the prototype was built using only general tools of the household-environment.

2.3.1. User tests for prototype evaluation

An initial user test of the prototype attached to a transfemoral prosthesis was conducted to evaluate the initial alignment of the socket and obvious design flaws which could be easily corrected. Changes of the design were then made to correct the errors.

A final evaluation was conducted using three participants with intact legs. The participants were chosen based on height and mass to evaluate the usability of the bypass-socket and if the requirements were fulfilled. Participant 1 had a length of 167 cm, participant 2 had a mass of 80 kg and a length of 194 cm and participant 3 had a mass of 100 kg. To ensure safety, the tests were done on a treadmill and a safety harness was used if preferred by the participant. To evaluate the usability, it was investigated if the bypass-socket could be used when the participant supported him-/herself with both hands, with one hand and without any support. Three additional people used the bypass-socket for general feedback but with no intention of verifying the fulfilment of requirements.

The possibility of recording EMG was evaluated by placing electrodes at targeted muscle groups on the thigh while using the bypass-socket. Trials of extending and flexing the knee was then conducted while EMG was recorded to see the quality of the signal. This was done for one of the additional users.

An evaluation of the required forces and moments was needed to verify that the prototype was safe to use. Static loading of the maximum forces and moments was primarily done using body weight, which means that the safety factor could not be confirmed in the physical test.

3. Design inputs

The construction of a prosthesis is complex with many functions and components, from the socket down to the prosthetic foot. Since the bypass-socket is to be used with standard transfemoral prostheses, construction of the artificial knee joint and distal parts is not crucial for the success of the project, hence only components proximal of the knee joint will be studied.

3.1. Socket types

The residual limb must fit the socket in a way for the individual with an amputation to be able to use the prosthesis. This is complicated and not all sockets have an optimal fit, leading to unused prostheses or damages to the residual limbs [1]. The socket is usually created by first making a cast of the residual limb which is then filled with a plaster to create a model of the residuum, [4], [15]. Prosthetists can ensure a good fit by making modifications on the model [6], [15], which includes removing material from the model to create pressure zones and to ensure stability, and adding plaster where needed to make space for prominent parts. By laminating or using thermoplastic, the socket is created over the model [15]. Alternatively CAD and manufacturing systems can be used to create the socket [6], although problem occurs due to lack of knowledge of what socket shape that is the most comfortable for the user. The modifications made by the prosthetists are based on experience and user feedback, making each socket unique and individual [6].

A transfemoral socket can typically be divided into three parts: the seating face is located at the proximal end of the socket, the area of socket control and then the distal socket end [2]. The primary function of the seating face is to transfer loading from the prosthesis to the user. The load is typically transferred to the ischial tuberosity and gluteus maximus [2], [16]. The control of the prosthesis is ensured by the controlling area [2]. During the gait cycle when the user is moving the prosthesis, a firm fit in the controlling area ensures that the prosthesis remains stable. Depending on the socket type, load transfer can also occur in the controlling area [4], [16], reducing the localised pressure points, making the socket more comfortable for the user. At the distal end of the socket, minimum load bearing should occur. Rajťúková *et al.* states that in an ideal case a maximum of 10 % of the total body weight should be transferred at the distal socket end [2], while *Physiopedia* states that only contact, and no pressure is allowed in this region [4]. The reason for this is that the distal end of the stump is where the surgical scar is located which may be pressure sensitive, along with the distal end of the residual femur compressing the soft tissue against the socket wall if the distal end of the socket is subjected to loading.

Two kinds of sockets are commonly used, the quadrilateral and the ischial containment socket [4], [16]. The quadrilateral socket has been the most used socket type in the past [4], [16]. It uses the ischial tuberosity as the primary loading area, along with the gluteus maximus. Four walls surrounding the thigh enables control of the prosthesis during stride for the user. Since this socket type primarily uses one area for loading, the localized pressure may be high with a higher risk of discomfort for the user [4]. When using the ischial tuberosity for load transfer the centre of gravity of the body is slightly shifted [2]. The centre of gravity is moved further laterally to the sound leg, leaving a higher load bearing ratio transferred to the healthy leg. The deviating weight ratio consumes more energy from the user, than in a healthy person where the body weight is distributed evenly between the legs [2]. The benefits of the quadrilateral socket are stability and support when standing, but rotation of the socket can appear during the swing phase if the anterior-posterior dimensions are to narrow, due to muscle activity of the residual limb [16].

Another socket type that has becoming more popular is the ischial containment socket [4], [16]. In this socket the load bearing is spread across the entire limb [4]. This results in less pressure for the user and thereby it becomes more comfortable. The medial to lateral dimensions are narrower to give support for the femur and decreases the lost motion, which is an unwanted, relative motion between

the socket and the stump when the soft tissue is compressed against the socket wall. The socket includes the ischial tuberosity and parts of the ischial rasmus which stabilizes against lateral shifting [4], [16]. The slender dimensions in both the medial-lateral directions and the anterior-posterior directions gives stability to the user, but requires an exact volume determination [4].

These two socket types are made by a hard shell and are dependent on a tight fit around the residual limb and are thereby sensitive to volume changes of the stump. During the first 12 – 18 months after an amputation, the volume of the residual limb changes significantly [17]. After this period daily volume changes of the residual limb are common and depend, amongst others things, on the activity level [17]. The changing of the volume and shape has an impact on the fit, which might result in an uncomfortable socket, instability, and skin problems. To deal with these fluctuations, liners, socks and other materials can be used which are placed between the socket and the limb [17]. These inlays are often uniformly distributed while the change of the residual limb might not be, and the result is still an uncomfortable socket, but not as severe physical problems [17].

Another type of socket is the Compression/Release socket such as the High-Fidelity interface socket [15],[18]. The pressure around the thigh can be increased and decreased by turning a nob at the proximal end of the socket, thus making it possible to compensate for daily volumetric changes. If the fit is loose, the socket can be tightened, thus increasing the pressure; if the socket is too tight, the socket can be loosened, and the pressure is reduced. This principle of changing the volume can be utilized when creating a modular socket that can fit a variety of people.

3.2. Alignment

The alignment throughout the prosthesis is important to create a natural gait and proper stance. Without proper alignment the body needs to compensate for the deviation [19], thus more energy than optimal is consumed [2], [20]. For this an arbitrary vertical line from the proximal to the distal end of the prosthetic leg is used [2]. Prosthetic components are positioned with respect to this reference line and the procedure is done by professional prosthetists [2], [20]. Each alignment is individually configured to accommodate for structural variations between people, but manufacturers give recommendations as starting points for where the reference line should be relative to the component [19].

Balance and stability of the socket is evaluated in the static alignment procedure where the natural posture of the stump is studied in a standing position [20]. The socket adapter should be placed at the point where the frontal and sagittal planes of the residual limb coincides for the socket to be in equilibrium [20]. If the adapter is placed incorrectly, the distance between the point of equilibrium and the attachment point of the socket adapter where force is transferred to the socket, creates a lever resulting in rotational forces, tilting the socket. The body compensates by changing the posture and thereby putting stresses and strains on the muscles and joints [20]. The point of equilibrium is affected by physical variation, for instance the length of the stump or contracture of the hip joint [19], which is why individual alignment is a necessity. The length of the prosthesis is set to even the loading between the limbs and level the pelvis [2]. A dynamic alignment is done to ensure a natural gait and is the final part in the alignment of the socket [2], [20]. By investigating the gait cycle, prosthetists can detect deviations, construction errors and other problems that needs correction. The reference line is used for the remaining components as well, where certain points of the knee and foot should intersect with it [2], [21], [22]. This is however, not within the scope of this project and will not be discussed further.

3.3. Tissue considerations

Most of the residual limb is tolerant against pressure and can thereby bear loading from the socket [4], [15], as demonstrated in Figure 1. This is utilized in compression/release sockets where loading is applied on the surface of the residual limb, along the femur [15]. When load is applied to the surface of the skin, layers of soft tissue compresses until the pressure reaches the point where the underlaying bone and muscles prevent further compression [15]. For a residual limb encapsulated in a socket, with no precompression, this effect results in lost motion. The stump moves inside the socket as the soft tissue between the socket wall and the underlaying bone and muscles compresses, as the amputee initiates movement of the prosthesis, illustrated in Figure 2. Precompression can be applied to the stump by the socket, to prevent the lost motion and stabilize the femur [15]. Only a certain amount of stress is tolerated to bear throughout the day. Alley *et al*. measured the tissue displacement on the proximal forearm versus the applied force and state that this limit of tolerance for soft tissue is just below 5 MPa, corresponding to a strain of 60 % [15]. By having precompression areas at 3-4 places around the stump and along the bone, the load transfer will occur along the entire shaft of the bone and can be adjusted to be uniformly distributed [15]. The femur is fixed and cannot move relative to the socket in any direction, and thereby no ischial containment nor concern of the distal end of the stump is needed [15]. When an area of tissue is compressed, the local surrounding tissue expands due to tissue displacement. Between the areas of precompression, release areas must be included for the displaced tissue to freely expand.

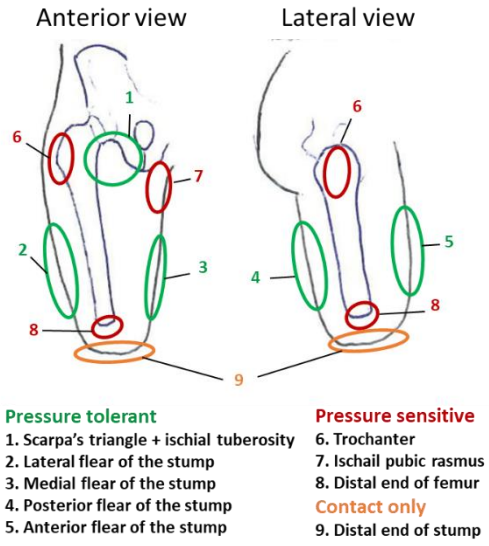


Figure 1: Pressure sensitive and tolerant areas of the residual limb. Image has been adapted with reference from figures in [4] and [23].

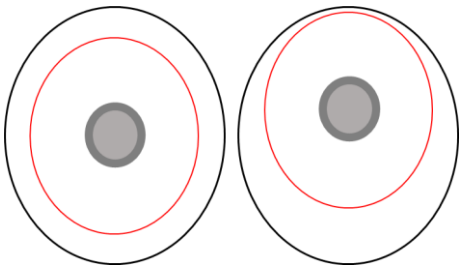


Figure 2: Lost motion occurs when layers of soft tissue is being compressed between the femur and the socket wall. Image has been adapted with reference from figure in [15].

Although much of the residual limb is tolerant against pressure, there are some sensitive areas, see Figure 1, and thus where pressure should be avoided [4], [5]. An unnatural environment is created within the socket and Arthur F.T. Mak *et al*. describes it due to a numerous of factors [5]. Firstly, are the loads transferred by the socket which produces pressures and shear forces to the stump generating stresses and deformations acting on the skin and the soft tissue beneath. This can obstruct the circulation within the blood vessels and the lymphatic drainage, decreasing the flow of oxygen, nutrients and wastes to and from the cells in the tissues, affecting the metabolism [5]. The cell function is negatively affected along with other biophysical processes and can lead to breakdown of the tissue if continued [5]. The tissue can however adapt to the new circumstances if the conditions and the repetitive loads are within acceptable boundaries for the individual [5].

Deformation of the skin and biomechanical irritations can be the result if the skin rubs against the socket edge, and abrasion of the skin and heat generation can occur if the relative movement is too substantial [5]. This slippage, along with instability, can be the cause of a too lose socket [5]. Too tight however, may give stability but can result in too high pressure at the socket interface. The slippage is

also affected by the interface friction which assists in supporting the loads. The coefficient of friction of skin varies between material and amount of perspiration, but is around 0.61 with silicon [24]. Tissue distortion is a consequence of the frictional forces and combined with pressure, friction can increase the skin damage [5]. It is the frictional force that assists in the supporting the loads and is a combination of the coefficient of friction and the normal force, thus a decrease in the coefficient of friction means that an increased normal force, i.e. pressure, is required to support the same ambulatory load. A tight socket gives higher pressure, but inhibits the circulation of air and traps the generated sweat inside, which creates an unnatural humid environment [5]. The materials of the socket and the conditions at the interface can cause irritations and allergic reactions of the skin [5]. Soars and blisters are also common [5]. Thus, an accurate fit of the socket is not the only factor to have in consideration when designing a socket. Many individual variations effect the comfort of the socket and if the socket can be used or not.

3.4. EMG measurement

The muscles of the thigh all play a part in the motion of the leg and by using surface electrodes, the EMG of the superficial muscles, Figure 3, can be measured and used to control a prosthesis [9], [10], [12], [13], [24]–[26]. Different muscles have been used, or mentioned for prosthetic control in different studies [9], [10], [12], [25], [27]. Common muscles to use are the *Vastus lateralis, Vastus medialis, Rectus femoris* and *Biceps femoris* [9], [10], [12], [25], [27]. These muscles are used in the extension and flexion of the knees [27], [28] and are thereby important when that motion is to be reproduced in an artificial knee joint.

If the socket contains the residual limb, the electrodes measuring the EMG needs to be implemented in the socket. Hefferman *et al*. studied four variations of electrode implementations within sockets, to get an understanding of the effects on signal quality and comfortability for the patient, depending on how the surface electrodes are implemented [26]. Some of the problems with electrode-socket interaction include motion artefacts caused by relative movement between the socket and the residual limb [9], [26], localized pressure zones caused by the electrodes [26], and irregular EMG potentials caused by perspiration within the socket [9]. A configuration where wireless electrodes were imbedded into an inner suction socket and a more rigid exterior socket, gave the least amount of motion artefact and was most comfortable of the variations in Hefferman's study [26]. In other configurations used in studies, the electrodes are embedded in a transparent suction socket [9] and placed on an experimental socket [12] with the electrodes penetrating the socket wall to ensure a

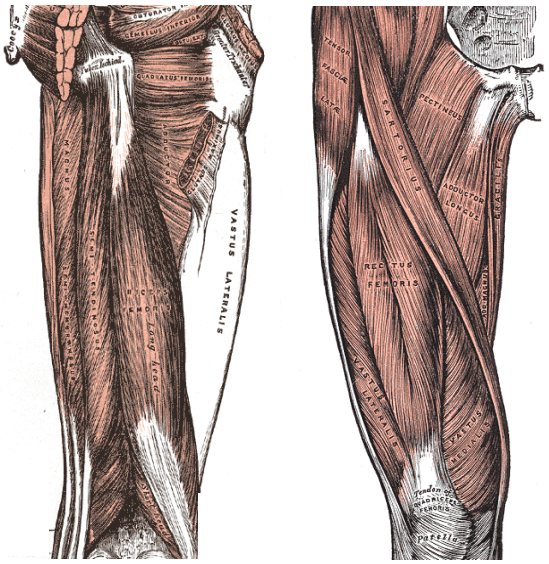


Figure 3: Posterior and anterior view of the superficial muscles of the thigh [56].

sufficient skin-electrode contact. Common for all the configurations of electrode-socket interaction in studies is that an additional custom-made socket, specifically designed to fit the test subject and to allow EMG signal acquisition was made for the study [9], [12], [25], [26], as mentioned by H. Huang *et al*. [12].

3.5. Force measurements

When a force is applied to a material, the material deforms. How much deformation is dependent on the elasticity and strength of the material. Metals can deform a lot before they break while some polymers are more fragile if they have high strength**.** Because the amount of deformation by a given force is depending on the characteristics of the material, an unknown force can be calculated using the deformation and the material characteristics. The deformation is commonly measured by strain gauges, where the strain gauges are attached to the material in where the load bearing will occur [11], [14], [29]. The deformation of the material will cause an elongation of the strain gauges, leading to a change in the resistance, thus causing a change in the voltage output of the strain gauges. The usage of strain gauges are also commonly for commercial transducers such as the Multi-Axis Force/Torque sensor from ATI [30], the Force/Torque sensor from JR3 [31] and the iPecs™ [32]. These voltage changes are very small and can thereby be difficult to measure. To make the changes more significant and more unsensitive, the strain gauges are often arranged in Wheatstone bridges. A transformation matrix allows the user to convert these voltage changes into applied forces and moments of forces to the measurement unit [14], [29].

The total number of forces and moment of forces which can be measured in a point are three forces and three moments. The number of forces and moments of interest depends on the controlling algorithm of the prosthesis. In two studies made by F. Sup *et al*. only the axial force and the moments in the frontal and sagittal plane was used [11], [14], and in L. Gabert and T. Lenzi only one force and one moment was used [33]. Other papers includes all the forces and moments [29], [34]–[37].

Table 1 shows the absolute values of forces and moments used or measured in different papers, corresponding to the magnitude of a walking subject. The largest force component is the axial force which is reasonable since it corresponds to the gravitational force acting on the body mass. For during activities such as running or falling, the forces and moments are higher. Thesleff *et al*. measures the ground reaction forces of an able-bodied person running on a treadmill [36]. Using a full body musculoskeletal model of an individual with a transfemoral amputation, the measurements are used to calculate the load exposure of an osseointegrated implant during running. The results were normalized to 15.0 N/kg, 5.58 N/kg and 18.3 N/kg for F_x, F_y and F_z respectively, and 1.45 Nm/kg, 1.84 Nm/kg and 1.59 Nm/kg for M_x, M_y and M_z respectively. The resultant force at the implant is 24.2 N/kg. Even though the results in the study are for an osseointegrated implant, they are assumed to be applicable for a normal transfemoral amputee as well. This since the hypothetical distance between the socket adapter and the adapter between the implant and the prosthesis, is similar. The forces occurring when falling is higher than that of a person running. Welke *et al*. reports peak resulting forces

Table 1: Limits and measurements of forces and moments used in papers, for walking subjects. X, y and z-directions corresponds to anterior/posterior, medial/lateral and proximal/distal-directions respectively.

PAPERS	F_X [N]	F_Y [N]	F_Z [N]	M_X [Nm]	M_Y [Nm]	M_Z [Nm]
[11], [14]	-	-	1000	100	100	-
[34]	180	60	800	30	50	10
[35]	283.1	50.3	777.3	32.5	139.1	15.1
[33]	-	-	800	-	120	-
[37]	200	50	600	23	45	10

of 43,7 N/kg and peak resulting moments of 2,46 Nm/kg in a study using a numerical model of a test subject [38]. Following this topic, Schwarze *et al*. compared the impact that the amputation height has on the reaction forces when falling [39]. They showed that for a lower amputation height, giving a long residual limb, the peak resultant force is about 41,6 N/kg and the peak resultant moment is 3,0 Nm/kg. Both studies are for osseointegrated implants but are as well assumed to be representable for conventional sockets.

3.6. Able-bodied bypass adapter

A number of studies have used bypass-adapters to enable the able-bodied researchers of the studies to evaluate their work [11], [13], [14], [33], [40]–[45]. Two types where used between these studies, both requiring the user to bend the knee of the leg using the adapter, however the exact construction of the adapters is not described. Figure 4 presents two early sketched concepts based on these types. One type positions the knee on the medial side of the prosthesis using a modified commercial knee-immobilizer [13], [14], [41]. This positions the real and artificial knees approximately at the same height but does not allow correct alignment of the reference line. The other type positions the prosthesis under the knee of the able-bodied subject [33], [42]–[45]. The alignment of the reference line can be made more correct, but the knees are not levelled. To avoid leg length discrepancies shoe elevation of the regular leg can be used [42]–[44], or the length of the prosthesis can be shortened [33], [45].

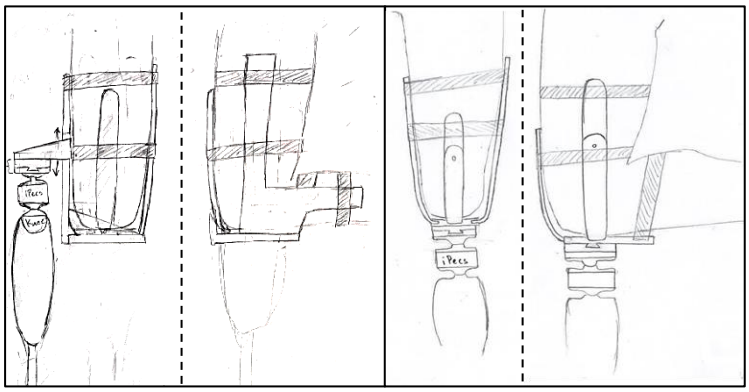


Figure 4: Early concepts based on the two bypass-adapters used in studies where the concept on the left is attached on the medial side of the prosthesis and the concept on the right is attached on top of the prosthesis.

3.7. Websites and patents

Ottobock and Össur are two major manufacturers of prosthetic components and were thereby investigated for prosthetic components which could be of interest. Ottobock has a sliding adapter 4R101 which allows ±11 mm continuous displacement in both the anterior/posterior and medial/lateral directions, with a system height of 25 mm without a pyramid adapter [46]. They also have a continuous adjustment adapter named 4R1 that allows for ±25 mm displacement in the anterior/posterior directions and ±15 mm displacement in the medial/lateral direction. This increase in displacement leads to an increase in the system height of the adapter, which is 68 mm. The 4R112 sliding adapter set allows more displacement in both medial/lateral and anterior/posterior directions with a maximum of 48 mm and 24 mm respectively. The displacement is done in 12 mm increments meaning that it does not allow a continuous displacement as the other two alternatives. The advantage is less system height, which is beneficial if the adapter is placed between the socket and the prosthesis. The system height is 32 mm plate including both pyramid adapter. All three adapters have a user limit of 100 kg. No alignment adapter of satisfaction or with the appropriate information was found at the websites of Össur nor Fillete, as the adapters needed to be adjustable in the horizontal plane and permanently usable. When talking to a CPO in a later part of the project it was found that a temporary

alignment adapter is usable in the purpose of research. This since the prosthesis is not subjected to daily usage, but for a few hours per month.

For the design of the prototype to be achievable and not require specific manufacturing processes, websites selling building materials were investigated and a perception of available materials and products was found. The companies were Biltema, Bauhaus, Hornbach and Slöjd-Detaljer and are available for the private user in Sweden. The product and material are therefore standard and easy to come by, implying that most research departments can access them without major concern or costs, and spare parts are widely accessible.

Espacenet was used to get inspirations from patents and existing solutions. Since the product is to be used for research purpose, a violation of a patent is not considered to be a major issue but is to be avoided if possible. To find appropriate patents, the keywords used were: socket, transfemoral amputation, socket adapter, lower limb, lower limb prosthetic socket.

3.8. Presenting the literature review to the project group

Initially, the requirements and requests were as presented in Table 2. The requirements were functions or aspects that were needed to be fulfilled by the prototype for the project to be considered successful. The requests were functions or aspects which were not required for the prototype to be successful but still desired and taken in consideration during the design. These were based on the collected information from the literature review and the research purpose of the bypass-socket. The researchers intended for the usage, have their major focus on osseointegrated implants which has a user weight limit of 100kg. The required load capacity of the bypass-socket was thereby set to 100 kg. The initial body lengths usable by the bypass was based on the average person in Sweden. Males have an average length of 180 cm, and females have an average length of 166 cm [47]. To increase the range of usability, the upper limit was set to 185 cm and the lower limit was set to 160 cm.

Table 2: Initial requirement list set on the bypass-socket.

FUNCTION	REQUIREMENT/REQUEST
sEMG compatible – At least four sites	Requirement
Adjustable in the horizontal plane	Requirement
Wearable for 160 – 185 cm long people	Requirement
100 kg person walking – 1000 N	Requirement
100 kg person falling 4000 N	Requirement
Fit standard prostheses	Requirement
Measure forces and moments (done using the iPecs™)	Requirement
100 kg person running – 2400 N	Request
Transfemoral amputee compatible	Request

The purpose of the research is mainly to test controlling algorithms for different parts of a prosthetic leg. This implies that the minimum amount of locomotion conducted, using the bypass-socket, is walking, leading to force requirements corresponding to that of a 100 kg person walking. As stated by Thesleff *et al*. the generated forces when running are roughly 246 % body weight [36]. As this is a secondary action of locomotion it was not set as a requirement, but a request. For safety aspect the bypass-socket also needed to hold if the user were to accidentally trip or fall with the bypass. This corresponds to a force of roughly 445 % body weight [38]. An iPecs™ is available at BNL and is therefore to be used to measure the reaction forces.

A meeting was held to present the project, literature review and findings for the research group of BNL. Some early concepts, see Figure 4, were shown and discussed, and viewpoints and opinions from the group were collected. Important aspect regarding the requirements and what is to be achieved with the project were presented by the group to add in the requirements for the prototype. The user weight limit was reasonable, but it was emphasised that it would be very beneficial if the bypass-socket could be made amputee compatible, for future research. The upper limit of the compatible body lengths was increased to 190 cm since some of the researchers at BNL are as tall, or taller than 185 cm. Winter states that the lengths of the thigh is somewhere of 20 % - 24.5 % of an individual's total height [28]. These measurements were used to decide a sufficient range for the height of the socket walls. The range of possible users leads to a length of the thighs from 32 cm – 47 cm. To give enough stability, the proximal support should be at 70 % of the thigh's length from the knee which was based on analysis and measurement of the author's thigh. The socket wall should be at most 22 cm when set to fit shortest users, and at least 32 cm when it is set to fit tallest users.

Another important input from the group was the possibility of using pneumatic support as support and protection between the bypass socket and the leg. The tips were based on the Roehampton pneumatic walking aid which is used in an early stage of amputee rehabilitation, when minimum load bearing can be tolerated by the residual limb [48]. This walking aid covers the whole stump, using a pneumatic sleeve, and thereby distributes the load bearing all over the stump and minimizes the pressure. A support frame, with a SACH foot at the distal end, is attached on the outside of the sleeve to transfer the ground reaction force to the pneumatic sleeve and ensure stability [48]. An air pressure of 40 mmHg is applied to the sleeve when the patient is in a seating position, which will increase to 60 mmHg or more when the patient starts walking [48]. These pressures correspond to approximately 5 330 Pa and 8 000 Pa, respectively.

3.9. Requirement specification

Based on the literature review, website information, aspects from the research group and consultation with the supervisor, a requirement specification was set. It contains both requirement and requests. The requests were weighted on a scale between 1-5 depending on their importance and how physically achievable they were assumed to be, where 5 had highest importance. The most important requirements and requests are presented in Table 3. The entire requirement specification can be viewed in Appendix A – Requirement specification.

To test the bypass-socket, components for a prosthetic leg were needed. These components were borrowed from Ortopedtekniska in Gothenburg during the last months of the project period, along with the 4R101 and 4R112 adapters from Ottobock in Sweden.

Table 3: Some of the most important requirements and requests as a compressed requirement specification. The requirements need to be fulfilled while the requests are weighted on a scale between 1-5 where 5 has highest importance.

	Criteria	Target value	Requirement/ Request	Weighting	Comments
1.	**sEMG compatible**				
1.1	Four sites	Quadriceps + biceps femoris	Requirement		Mainly used in knee motion
1.2	More than four sites	Quadriceps + biceps femoris + others	Request	5	
2.	**Durability**				
2.1	Static load	4 000N	Requirement		Falling
2.2	Repetitive load	1 000 N	Requirement		Walking
2.3	Repetitive load	2 400 N	Request	5	Running
2.4	Cycles	162 500	Requirement		Based on 5000 steps per leg and day, where 8 hours are effective. 1h/week for 5 years
3.	**Bypass compatibility**				
3.1	Fit able-bodied leg	Fit able-bodied between 160-190 cm	Requirement		
3.3	Under-the-knee	Prosthesis attached under the knee	Request	5	Either 3.3 or 3.4 is required to be fulfilled
3.4	On-the-side	Prosthesis attached on the knee side	Request	5	
4.	**Prosthetic compatibility**				
4.1	Fit standard components	4-hole pattern OR pyramid adapter/reci	Requirement		
5.	**Size**				
5.1	Highest minimum socket height	22.4 cm	Requirement		Highest allowed socket wall hight when adjusted for the shortest user.
5.2	Lowest maximum socket height	32.6 cm	Requirement		Lowest allowed socket wall hight when adjusted for the tallest user.

4. Conceptual designs

The bypass-socket was divided into six sub-functions to make the design phase easier. The sub-functions were: On-the-side connector, socket – Able-bodied, socket – Residual limb compatible, knee-plate, height adjustment and support structure/strap attachment. Firstly, concepts were sketched on paper during the concept generation. The concepts were evaluated, and the best were furthered developed using CAD. Lastly the CAD-models were evaluated.

4.1. Concept generation

Sketches were made for both able-bodied sockets and residual limb sockets. To get an appropriate sense of the dimensions for the socket designs, small paper models of a thigh and a residual limb with roughly the same sizes were made, see Figure 5. The model of the thigh, viewed in the sagittal plane, was based on figure 4.7 from Winter [28], while the anterior view was based on figure 2.7 from V. Gillis [27].

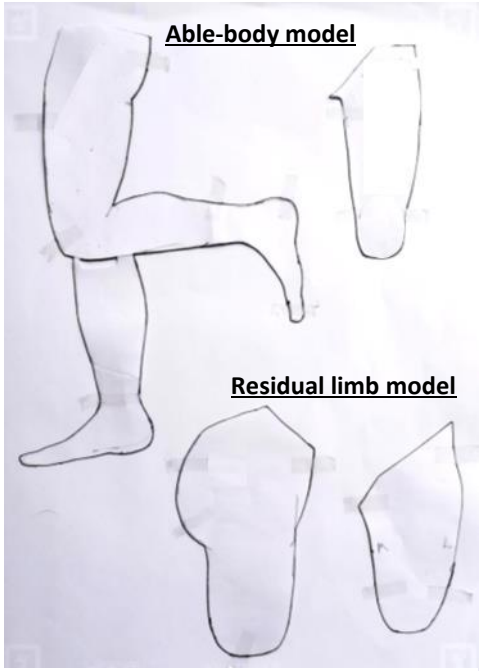


Figure 5: Paper models of able-bodied limb, sagittal view [28] *and anterior views* [27]*, and residual limb [4] sagittal and anterior view.*

4.1.1. On-the-side connector

The on-the-side connector enables the bypass-socket to be set on the side of the prosthesis. Vertical adjustment is needed to ensure that the prosthesis can be used with or without the iPecs™ load cell. The displacement adapter was however considered as permanent for simplicity. A continuous adjustment capability is optimum to compensate for individual variations between people. This can be made possible by two pipes of different dimensions sliding against each other and a screw that is tightened to fixate the pipes. This, either by decreasing the circumference of the outer pipe so that it pinches the inner pipe as the principle of a hose clamp, or by going through a hole of the outer pipe and then pushing the inner pipe against the inside of the outer pipe and thereby pinching it in place. The problem with both these options with a continuous adjustment is that with the high forces expected to be applied, a feeling of safety was not ensured, and an overall solution could not be invented. Instead the focus was directed on bolts and nuts that attaches a horizontal plate, where the socket is attached.

Figure 6 pictures the sketched versions of the on-the-side connector where each has been given a letter-number combination for simplicity. The first sketched version of the on-the-side connector, *A1*, can be attached to fit both right and left leg users. Both the horizontal plate attached to the prosthesis and the horizontal plate, which is attached to the socket and further called socket connector, has a 4-hole pattern to fit standard prosthetic components. A vertical, rectangular pipe is attached to the prosthesis connector plate and with some supporting component, should be able to withstand the forces and moments induced by the lever from the placement of the socket. The socket connector can be secured on different heights on the vertical pipe by fixating screws. The screws are subjected to shear force and the more fixating screws, the less shear force in each screw. The socket connector is wide to minimize the risk of interaction between the bypass-socket and the vertical pipe. The socket connector plate also has some supporting components to

withstand the moments induced by the lever. These supporting components could be reinforced angle brackets if they are able to withstand the forces and moments. *A2* has the same features as *A1* but where the socket connector is attached to the vertical pipe, which can be set to different lengths and secured to the prosthesis connector plate with fixation screws.

A3 and *A4* are based on *A1* and each has a rectangular pipe that crosses on the anterior side of the prosthesis to the lateral side of the prosthesis. The crossing pipe is believed to reduce the induced moment from the socket placement.

To use a hollow pipe instead of a solid rod for the designs are due to the mechanical properties where a pipe has higher moment of inertia than a solid rod which gives better strength to mass ratio.

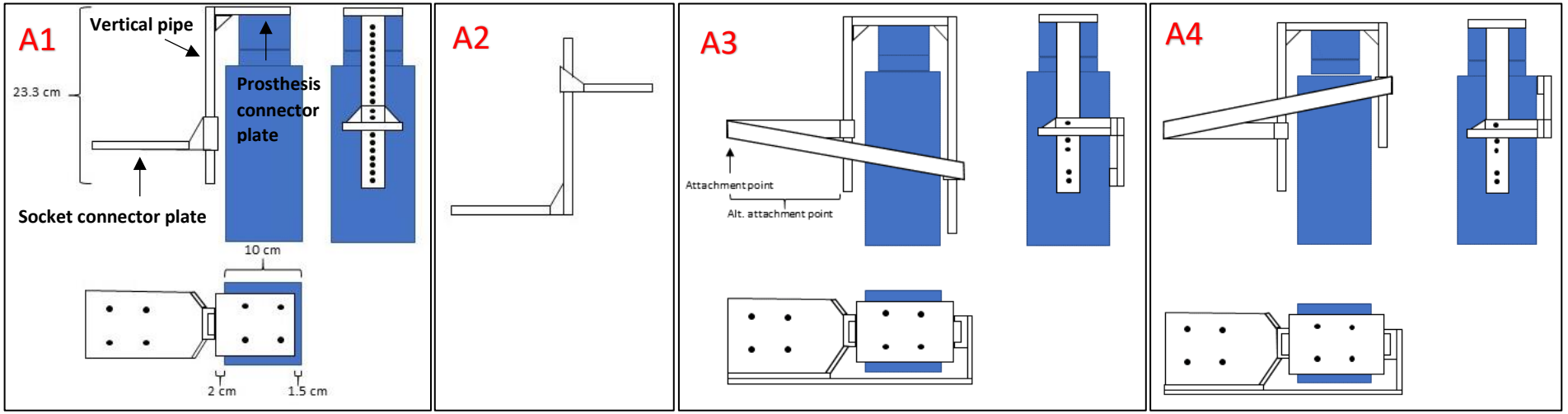


Figure 6: Sketches of the on-the-side connector.

4.1.2. Socket – Able-bodied

To make the socket EMG compatible, the walls of the socket could not cover the whole thigh but instead struts were designed to ensure stability of the socket during gait. The idea of the struts was inspired by a patent of an adaptable socket system for residual limbs [49]. In a pursuit to not violate the patent, two principle types of struts were designed. One design has flat struts, comparable with the ones in the patent, and the other design is made by bended pipes making the strut hollow. The first design principle is further referred to as flat-struts, *B1-5* in Figure 7, and the other design is further referred to as pin-struts, *B6* in Figure 7. The struts of the sketched sockets are mainly made by either two or three parts, to enable height adjustments to manage variations in lengths of the thighs. All the sockets use multiple straps around the thigh and shin to secure the leg to the socket. The knee is placed on what will be referred to as the knee-plate, which has a 4-hole pattern for the attachment of a standard prosthetic component for all the socket designs. Common for the socket designs

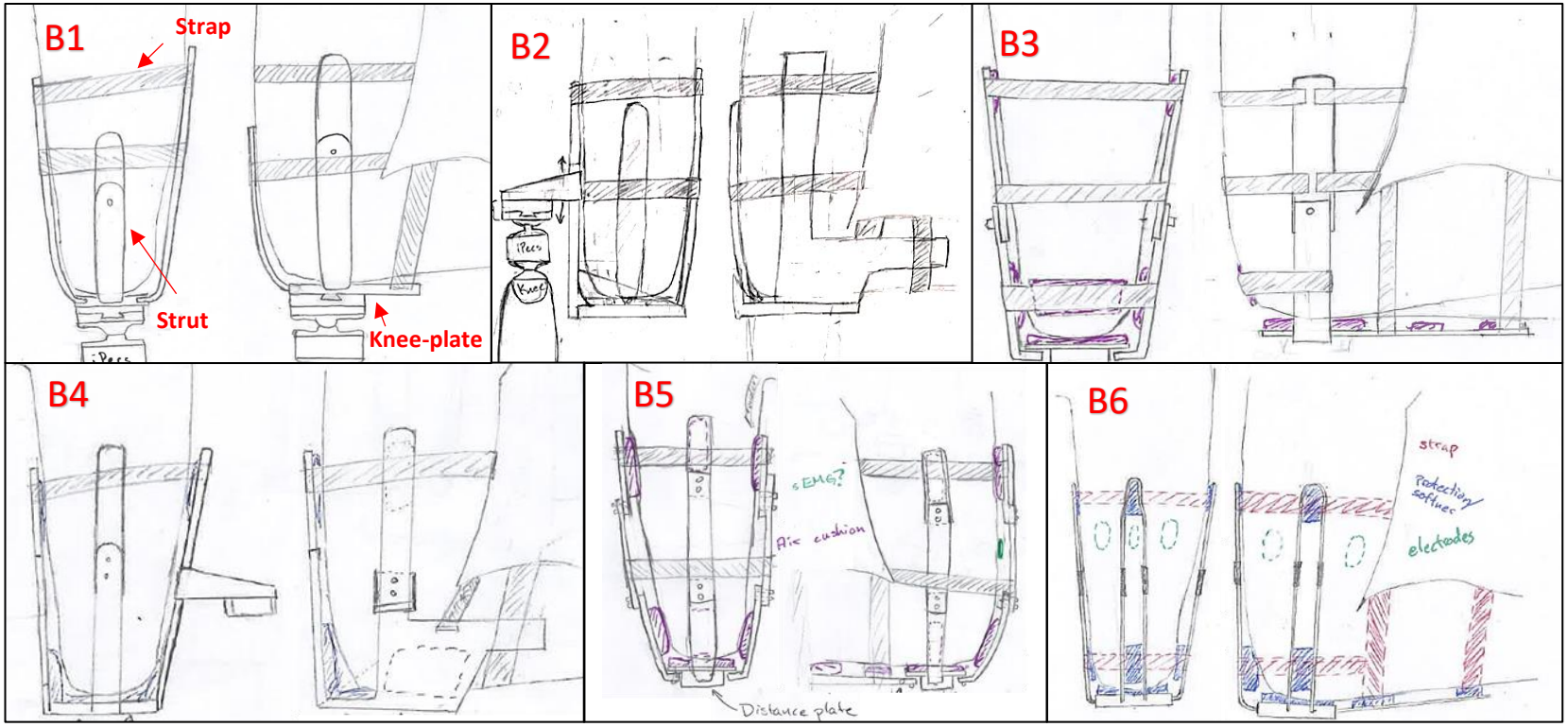


Figure 7: Sketches of the able-bodied bypass-sockets.

are the use of cushioning made by either foam or pneumatic support to increase the fit and comfortability. These are placed in the posterior and distal ends of the struts. All the sketches are viewed in Figure 7 with a letter-number combination.

Both *B1* and *B2* are the first versions of the able-bodied socket. In *B1*, the prosthesis is attached under the socket and the struts are made angular adjustable. For *B1,* B2 and *B4* the knee-plate is longer in the posterior direction to give support to the shin. *B2* is connected on the side. The anterior strut is not fixed to the knee-plate but can be detached and the angle in the sagittal plane can be adjusted to fit the user. The medial and lateral struts is fixed and does not allow angular adjustment in the coronal plane. This is to make the construction stronger and give more resistance against the moment induced by the lever when attached to the prosthesis. The distal parts on these struts have more material to increase support and a protruding part posteriorly to support the shin. The increased support and the strap at the popliteal makes the knee fit more firmly in the socket. The bypass socket can be attached either to the left or right side of the prosthesis. The connector which is attached to the prothesis, is attached directly to the socket using screws. This eliminated some of the sensitive connection joints. The connector can be attached on different heights on the lateral strut. The struts are not adjustable in height. The anterior strut is shorter than the struts on the medial and lateral side to make it possible to place an electrode on the rectus femoris. *B3* is the only socket with two struts and has an extra strap on the anterior side of the thigh to prevent anterior movement of the knee. The flat struts goes into the connection plate and can be positioned in different distances and tightened with bolts.

B4 is based on *B2*, but where each strut has two parts to enable height adjustment and the distal parts are fixed to the knee-plate, preferably using screws for easier construction. Fixing them in their position, preventing possibility of angular adjustments, makes the design stronger. *B5* has adjustable struts made by three parts and fixed relative to each other using screws. Each strut has two pressure points, one in the proximal end and one in the distal end. The anterior strut has a distance to the leg, where electrodes can be places to measure the rectus femoris. The struts on the medial and lateral side does not have this distance, mainly to not interfere with the other leg during stride since this would result in an unnatural gait. The posterior strut has a hinge close to the knee-plate allowing it to be horizontal to support the shin. A locking mechanism guarantees that the strut remains horizontal when used. The shin is secured to the strut with straps.

B6 has struts made by round tubes or preferably tube with a u-profile to withstand forces perpendicular to the leg and not flex. Since the struts are made of bended tubes, there is space in the middle of the strut where an electrode can be placed. This makes it easier to perform EMG measurements of the desired muscles. Three struts surrounds the thight and one strut is protruding to the posterior to support the shin.

4.1.3. Socket – Residual limb

Four sockets were sketched to fit the stump of a transfemoral amputee, see Figure 8. To fit a variety of people, adjustability of the socket walls or struts were in focus. Due to the research purpose and thereby temporary usage of the sockets, simplicity at the attachment point between the socket and the prosthesis was made. This implies that the attachment point is at the distal end of the socket without any angular or positional compensation to perfect the alignment.

As mentioned in section 3.2, misalignment is compensated by muscle movement to adjust the posture and is assumed to be temporarily possible by the user, even though this is not optimal.

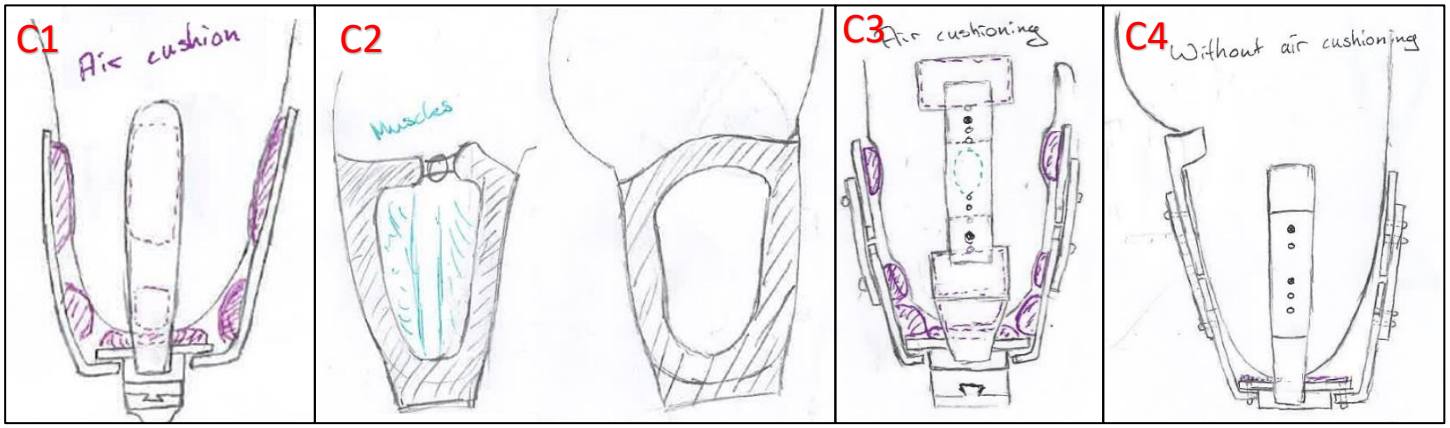


Figure 8: Sketches of the residual-limb compatible sockets.

Three of the sketches, *C1, C3* and *C4*, have four struts to support the residual limb and the ambulatory loads. The struts are positioned at the anterior, medial, posterior, and lateral side, respectively, of the stump. Although not included in the images, the struts are connected to each other by a strap that goes around the stump.

Both *C1* and *C3* use compression/release to secure the socket on the limb. The compression stabilizes the femur inside the stump and thereby reduces lost motion during stride. The compression is applied using the four struts, creating depression zones. For *C1* the compression is in a longitudinal direction along the femur, while the depression zones on *C3* are located at the proximal and distal end of the struts. To optimize the pressure at the depression zones and manage variations in the different shapes between residual limbs, the protection material between the struts and the stump should be pneumatic cushioning. Depending on the desired pressure, the cushioning can be inflated or deflated. A strap around the limb ensures that the pressure is keep over time and reduces the risk of buckling of the struts when the pressure is applied. For *C1*, the electrodes are placed above the anterior and posterior struts and between the struts at the release zones and in *C3* the electrodes can be placed on the inside of the middle part of the strut. The measurements might be affected because of the displacement of the soft tissue which is a consequence of the depression zones. *C2* is a recreation of the High-Fidelity socket, which also uses compression and release zones. The socket is made by a rigid material with socket walls that can be detached or individually adjusted, and the pressure is changed by turning a nob. To manage variations in the anterior/posterior and the medial/lateral dimensions between different stumps, the inside surface of the depression zones can be combined with pneumatic cushioning. This type of socket has a patent pending and is difficult to make able-body compatible.

C4 has all the load bearing using the ischial tuberosity and the gluteus maximus and has no compression zones. At the proximal and distal end of the socket are either pneumatic or foam cushioning at the interface between the socket and the stumb. A strap around the socket allows a tight fit and thereby control of the prosthesis. The height adjustments of the struts are similar to *C3*.

4.1.4. Knee-plate

The knee-plate is positioned at the distal end of the socket where the bended knee is placed and at which the struts, or socket walls, are connected. The circular shape on most of the plates, see Figure 9, makes it possible to attach the struts to different locations, depending on the muscles of interest for the EMG measurements. Rectus femoris is in the middle on the anterior side of the thigh, while the vastus lateralis and the vastus medialis sits on the lateral and medial side of the rectus femoris. By enabling multiple attachment-points for the struts, they can be rearranged to always have at least one muscle of interest uncovered. The plates have a width of 100 mm to minimize the risk of interference with the sound leg when using the bypass-socket. The struts are attached to *D1* and *D2* using screws.

To give more stability and comfort for the shin during able-body usage, two knee-plates, *D3* and *D4*, were designed with a protruding posterior part. This follows the shin roughly 10 cm extra to give better support. A special strut, or the top part of an ordinary struts, can be connected to follow the shin even further if necessary. Straps are connected to the protruding part to fasten the shin. Two designs, *D4* and *D5*, are specially made for the pin-strut configuration. The distal end of the struts is pushed into the side of the knee-plate and is secured by screws from underneath. Variations in the dimensions of the thighs, can be compensated by the distance of which the strut pins are pushed into the connector plate. *D6* was designed as the distal end of a flat strut, which could be connected to *D1* or *D2* but not *D3*. *D7* was designed to allow pin-struts to be connected to either *D1* or *D2* with a screw and the pin-struts are connected to either side of the attachements screw.

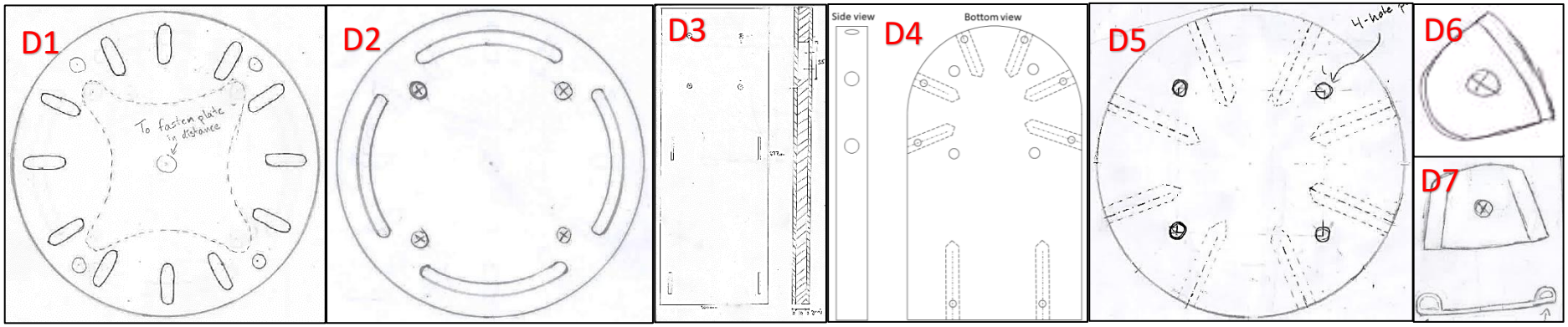


Figure 9: Sketches of the knee-plates.

4.1.5. Height adjustment and support structure/strap attachment

Height adjustment refers to the function of adjusting the length of the struts to fit a range of thigh lengths, where four versions were sketched, *E1-4* see Figure 10. *E1* is for a three-parted flat-strut, where the middle part can slide in the upper and lower part. Cut-outs on the side of the upper part allows attachment of straps. As mentioned in 4.1.2 the parts of the struts are secured and attached to each other using screws. In E2 one part of a flat-strut slides inside of another, made possible either by the entire rectangular pipe fitting inside of the other or using a dove tail shape. The parts are locked using screws, either by going through a hole both in the inner and outer pipe or by going through a threaded hole in the outer pipe, pinching the inner pipe in place. *E3* is a telescopic height adjustment for pin-struts. A tube with a small diameter fits inside of another tube with a slightly larger which can be reduced using a hose clamp to pinch the inner tube in place. *E4* is also for pin-struts where two lead screws are placed between the proximal and the distal part of the strut. The screws have threads with opposite directions that moves them into a threaded container when the container is rotated, decreasing the length of the struts.

At the proximal end of the struts are support structures which are the interfaces between the strut and the thigh, to increase the contact area to reduce the localized pressure, and to increase comfortability, see Figure 10. At the interface between the supporting structure and the thigh is soft padding using foam or pneumatic support. The structures have a space for the attachment strap. *F1* is slid over the strut and is made by fabric. It is easy to make and adjust, but might fit better for flat-struts than for pin-struts since the fabric is not rigid. *F2* and *F3* are support structures made by 3D-printed plastic. These are slid over the struts and fastened with screws. *F2* is specifically made to work with flat-struts and *F3* to work with pin-struts. On the surface facing the leg, cushioning is applied and on the outside of the socket is an attchement point for the strap. This ensures that the support plate stays in the right place, along with applying sufficient socket pressure.

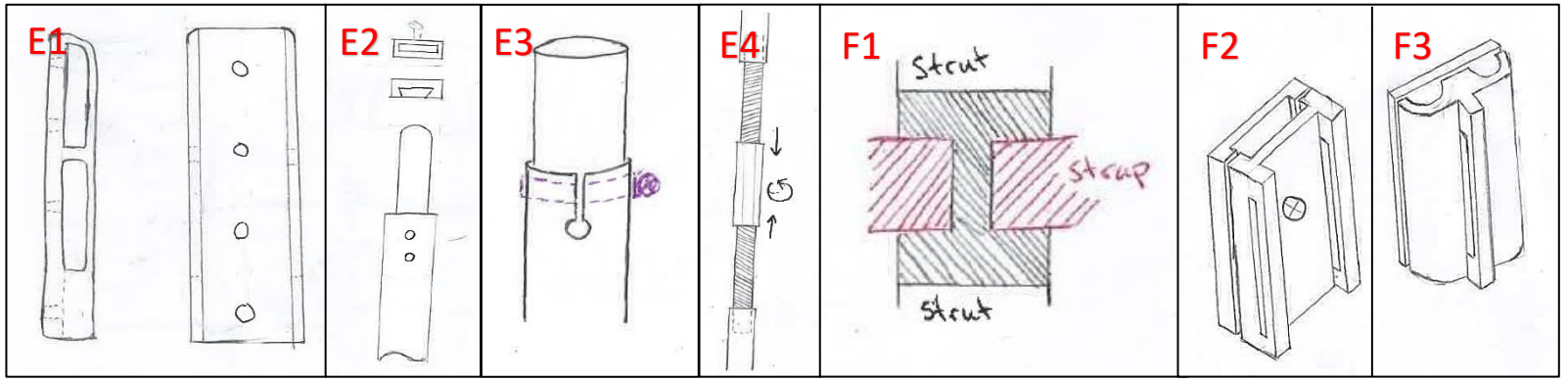


Figure 10: E1-2 are height adjustment for the flat-strut concepts and E3-4 are for pin-strut concepts. F1-3 enables fastening of the straps and act as a support structure between the socket and the limb.

4.2.Concept evaluation

The concept sketches in each sub-function were evaluated against each other to conclude the most prominent solutions. Motivation for the evaluation, along with the evaluation matrices corresponding to each sub-function are presented in Appendix B – Evaluation matrices. Presented in Table 4 are the primary consideration during the concept evaluation process.

Table 4: Primary considerations used during the evaluation of the concepts.

SUB-FUNCTION	PRIMARY CONSIDERATION
On-the-side connector	Strength and weight
Socket – Able-bodied	EMG compatibility, stability/strength and adjustment capabilities
Socket – Residual limb	Stability, force distribution, and adjustment capabilities
Knee-plate	Adjustability, strength, and stability
Height adjustment	Stability, strength, and functional intuition
Support structure/strap attachment	Given support

A new concept for the able-bodied bypass-socket was created by combining *B3* and *B5,* called *B3/5.* This resulted in a concept with three struts on the thigh and one strut supporting the shin, see Figure 11, as in *B5* but where the struts are made by two parts, as in *B3*.

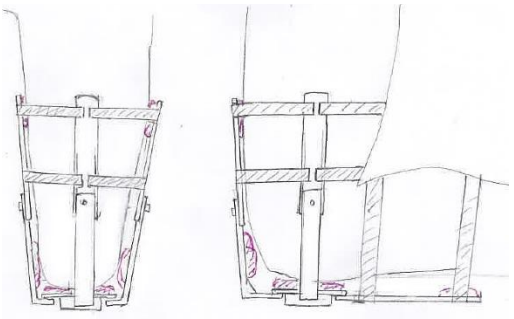


Figure 11: The concept B3/5, created during the evaluation phase by combining B3 with B5.

All the evaluation matrices with the total and weighted points are presented in Appendix B – Evaluation matrices. The concepts of using flat-struts and pin-struts were evaluated in the matrices as parallel paths to take, that is, each of the paths in the sub-functions, where applicable, has a design with a highest score. The designs with the highest scores are presented in Table 5. The highest scored knee-plate design for flat-struts was only compatible with struts on the medial and lateral side of the thigh. This was not compatible with the highest scored flat-strut design which consists of three struts supporting the thigh. The overall loss of functions choosing a two-strut configuration to comply with the highest rated knee-plate was considered as greater than that of choosing the second highest scored knee-plate to comply with the three-strut configuration. The second highest scored flat-strut knee-plate was thereby chosen along with the highest scored designs in the other sub-functions. These were combined to create four concepts, namely two for able-bodied bypass-sockets, with an on-the-side connector and two for bypass-sockets compatible with residual limbs.

Table 5: Sub-functional concepts with the highest scores.

	SUPPORTING SURFACE STRUCTURE	**HEIGHT ADJUSTMENT**	**SOCKET – ABLE-BODIED**	**KNEE-PLATE**	**ON-THE-SIDE CONNECTOR**	**SOCKET – RESIDUAL LIMB COMPATIBLE**
FLAT-STRUTS	F2	E2	B3/5	~~D3~~ D1	A1	C4 C3
PIN-STRUTS	F3	E3	B6	D4	A1	-

4.3. Computer aided designs

The concepts with the highest scores were further designed. The CAD-models were more detailed with reasonable or exact dimensions.

4.3.1. On-the-side connector

Two on-the-side connectors were designed, one to be manufactured by existing parts which can be bought at the local hardware store, and one thought to be customized for the task at hand, requiring more advanced manufacturing. The designs presented here are the initial designs from the sketches to the computer. These were redesigned after evaluation using the finite element analysis presented in section 5.

4.3.1.1. Customized concept

A customized concept was designed with the purpose to deal with the high forces in an optimal way, Figure 12 pictures the first version. The plan was to, based on that custom design, investigate the market to create an equivalent design with part existing on the market. From the horizontal prosthesis connector plate, a vertical rectangular pipe is placed and allows attachment of the socket connector plate which fastened in the intended position using bolts. The socket connector has brims at the fastening point to support with the loading and decrease the stresses at the 90° angle. The socket connector has a thickness of 5 mm, a total width of 153 mm and a depth of 85 mm. The width was set for the struts of the bypass-socket to not interfere with the vertical pipe. The plate can be fastened to the vertical rectangular pipe at two locations, with or without the iPecs™ load cell. This is to level the real knee with the artificial knee.

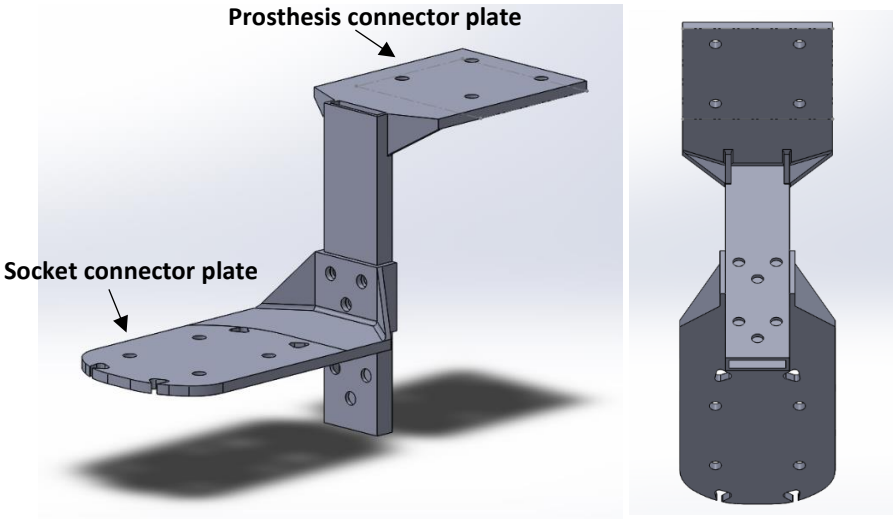


Figure 12: The first version of the customized on-the-side connector.

Both the socket connector and the prosthesis connector plate have a 4-hole pattern that can be attached to standard prosthetic components. At this stage, no exact dimensions of the 4-hole pattern was known. At Bulldog Tools, a M6 65-mm 4-hole pattern was stated for a male pyramid adapter and was assumed to be the standard dimensions, where 65-mm was measured across the diagonal [50]. This was later changed to the accurate dimensions of 36 mm between the holes and not the diagonal.

Brims are also included to decrease the stresses at the prosthesis connector plate. The prosthesis connector plate has a thickness of 5 mm, a width of 107 mm and a depth of 82 m. The depth is as deep as the load cell and the width are as wide as the load cell plus 35 mm to allow medial/lateral displacement of the prosthesis.

4.3.1.2. Made by existing parts

The author is inexperienced with welding and to not depend on more advanced manufacturing, the configuration of existing parts was made by bolt-and-nut joints as much as possible.

To know what materials and components that exists on the market, a search on Google was made using *building angle* and *rectangular pipes* as keywords. *Building angle* is referring to an angle bracket. This led to the Bauhaus' website. An angle bracket was to connect the vertical pipe with the horizontal prosthesis connector plate. Another was also used to attach the socket connector to the vertical pipe. The angle bracket "JOMA 2.5x90x90x65mm", see Figure 13, was chosen because of its thickness, length and reinforced structure [51]. The length allows multiple fastening points to distribute the load transfer and the supporting structure make it durable against bending, which is to be expected at the 90° angles between the horizontal and vertical parts. When loading is applied during gait, the lever between the attachment point at the prosthesis and the location of the applied load generates a moment of force, resulting in a bending motion of the vertical pipe towards the prosthesis. As seen in Figure 14 this creates tension and compression areas. The angle bracket was fastened on the outside of the 90° angle to better withstand the tension since the horizontal and vertical pipes gives support to each other. Through the horizontal pipes are 5 mm holes corresponding to the ones in the angle bracket. Due to the pandemic, a physical angle bracket was not available for the exact dimensions of the part. What was known was the width, height, depth, and thickness, and the other dimensions were estimated by measuring an image and using proportions [51]. The dimensions were later updated when a physical bracket was available.

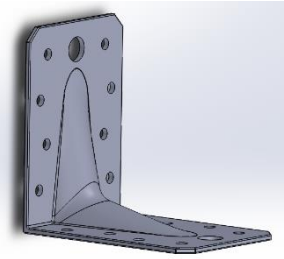


Figure 13: Angle bracket JOMA 2.5x90x90x65mm. Reproduced using CAD.

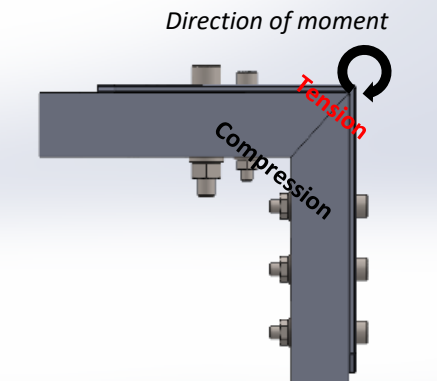


Figure 14: Tension and compression areas due to bending when load is applied.

The structural support on the angle bracket was not compatible with one central pipe, or building block, as in the customized case, but instead two rectangular pipes were used with smaller dimension. Rectangular pipes of dimensions 15x15 mm with a thickness of 1 mm exists in the hardware store which were used as a start-off point. After a primary design based on the customized case, the dimensions were changed into using 20x20 mm rectangular pipes. The design will be considered version 1 and viewed in Figure 15. The prosthesis connector plate from the customized case was replaced with two horizontal, rectangular pipes with a length of 108 mm which are connected to two vertical pipes via a 45° cut, see Figure 14. The horizontal pipes have M6 holes in a 65-mm 4-hole pattern. The vertical pipes have a length of 256 mm. The socket connector is to be connected at two locations on the vertical pipes, which were initially at 80 mm and 119.5 mm distally of the attachment point to the prosthesis. The angle brackets where placed respectively and the corresponding attachment holes of the angle brackets where translated onto the vertical pipes. At this stage, only the dimensions of the iPecs™ was known and not the exact dimensions of the adjustment

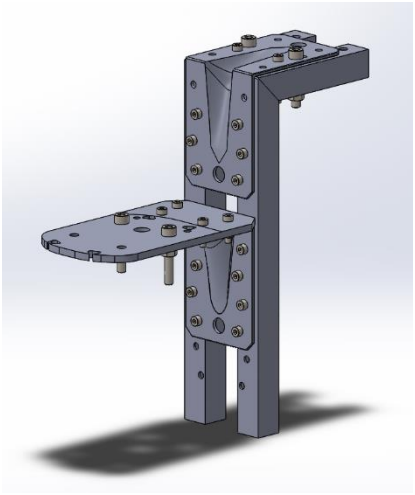


Figure 15: The first version of the On-the-side connector where the primary attachment is done using bolts and nuts.

adapter nor the pyramid adapter, which are supposed to be between the prosthesis and bypass adapter.

The socket connector, Figure 16, is made by a 5 mm thick steel plate and is attached to the vertical pipe via an angle bracket. A 65-mm 4-hole pattern allows the bypass-socket to be connected and is placed at a centre distance of 97 mm from the vertical pipe, so that the struts does not interfere with the vertical pipe. Holes were made for the attachment bolt for the struts in the pin-configuration and the corners of the plates were rounded off for safety reasons.

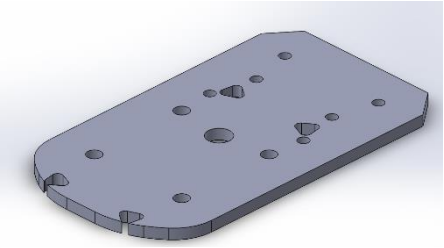


Figure 16: First version of the socket connector plate.

4.3.2. Able-bodied sockets

The hardware store was checked for dimensions for the struts of the sockets. In contrast to the struts of a socket compatible with the residual limb, the able-bodied struts are not meant to support body weight. The struts need to be strong enough to give stability and control over the prosthesis and be able to bear the weight of the bypass-socket with the prosthetic components during stride. The forces were not considered to be very high which was why smaller dimensions were of interest to make the socket lighter.

4.3.2.1. Flat struts

The flat-strut socket, Figure 17, consists of a distance plate, knee-plate, 3 flat struts for the thigh and 1 flat strut supporting the shin. Each strut for the thigh consists of a bottom part, a top part, a distal and a proximal support and a scratch protection at the proximal end of the top part. The strut for the shin consists of a top part, two supports and a scratch protection.

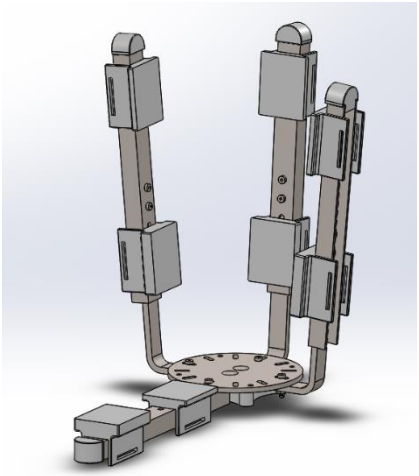


Figure 17: Posterior view of the flat-socket with the lateral side to the left. The upper edge of the proximal support is 236 mm

The top part has a cross-sectional shape of a U with a width of 19.9 mm, depth of 15 mm, thickness of 2 mm and a length of 200 mm [52]. 6 4.5 mm-holes are positioned along the part with a centre-centre distance of 15 mm. These are to connect the top part with the bottom part of the strut using M4 bolts and nuts. The bottom part, Figure 18a, is made by a 15x5 mm flat bar with a height of 200 mm [53]. At the distal end is a 95° bend and a 4.5 mm hole for attachment to the knee-plate using a M4 bolt and nut. The distal end is rounded with a radius of 7.5 mm to not interfere with the distance plate if some rotation round the vertical axis is needed.

The distal and proximal support, see Figure 18b, have a width and height of 40x50 mm and is placed at the interface between the thigh and the strut. The function is to create a comfortable contact point between the socket and the limb, and to create an attachment point for the strap and thereby increase stability. The supports have an internal width to fit the top part of a strut. The distal support has more material to the frontside, than the

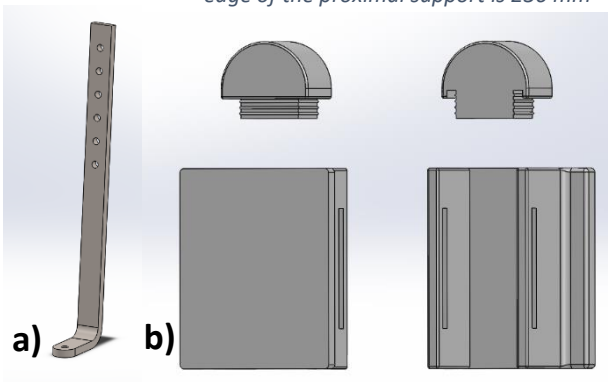


*Figure 18: **a)** Bottom part of a strut, **b)** Front- and backside of the proximal support and of the scratch protection.*

proximal support, to better manage the slimmer dimension of the distal part of the thigh. The supports have the shape of a U and are placed on the inside of the struts, facing the thigh, and the walls of the supports are protruding to the outside of the struts. The straps around the thigh are connected through the vertical openings on the backside of the supports. The total depth of the proximal and distal support is 29 mm and 34 mm, respectively.

A protection against scratches was designed and placed at the proximal end of the top part, see Figure 18. This part has no structural significance but protects the user against the edge of the top part, which might become or appear sharp during dynamic circumstances.

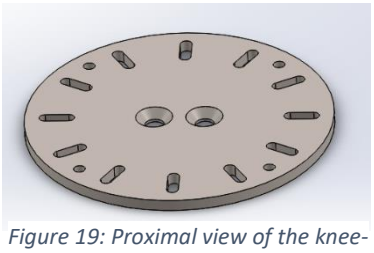


Figure 19: Proximal view of the knee-plate.

The struts are attached to the knee-plate using M4 bolts and nuts. The knee-plate, see Figure 19, has a diameter of 105 mm and thickness of 4 mm. 12 capsule-shaped holes are symmetrically distributed round the plate and allows dimensional adjustments of the socket width. The attachment screws of the struts can be attached at 7-15 mm from the border of the plate to manage variations between thighs. Depending on the distance to the border of the plate, ± 41° - ± 66° of rotation round the vertical axis of the struts are possible, to enable adjustment possibilities to compensate for the varying shapes of the thigh. Between every third of the capsule-shape holes, is a single M4 hole to make space for the distance plate at the distal side of the connection plate but still allow flexibility for the attachment of the struts. In the centre of the plate are two M6 countersunk holes to connect to the distal plate.

The distance plate is attached to the distal side of the knee-plate and has the primary function of creating space between the knee-plate and the socket connector on the on-the-side connector, for the attachment screws of the struts. The plate has a height of 15 mm and is made of steel, see Figure 20. In the centre of the proximal side are two threaded M6 for connection to the knee-plate. On the distal side is a 65-mm 4-hole pattern with M6 threaded holes for connection to the on-the-side connector or to a standard prosthesis.

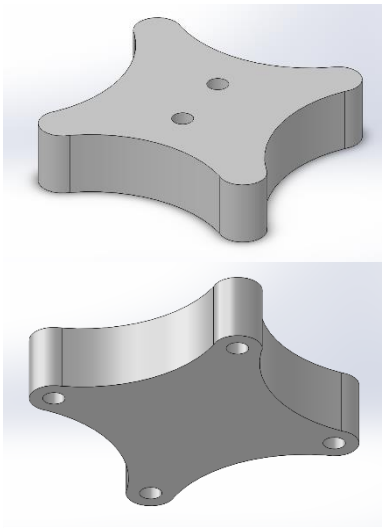


Figure 20: Distance plate where the two M6 (upper) and the 4-hole pattern (lower) can be seen.

4.3.2.2. Pin-struts

The pin-strut socket, Figure 21a, consists of a knee-plate, 3 pin-struts for the thigh, 1 pin-strut supporting the shin and 7 supports for the interface with the limb. The struts for the thigh are made by one bended top-part and two bottom- parts, each connecting to one end of the bended top-part. The top-part is made of one 8 mm in diameter aluminium tube with a wall thickness of 1 mm, a height of 180 mm and internal width of 27 mm. The bottom-parts are each made by one 10 mm in diameter aluminium tube with a wall thickness of 1 mm. At the proximal end of a bottom-part is a special cut, see Figure 21b, to allow for a temporary reduction of the circumference to fasten the top-part to set the height of the strut, using a hose clamp. At the distal end of a bottom part is a 92° bend to make the dimensions of the distal end of the socket tighter than the proximal end of the socket. The bended distal end is connected to the knee-plate.

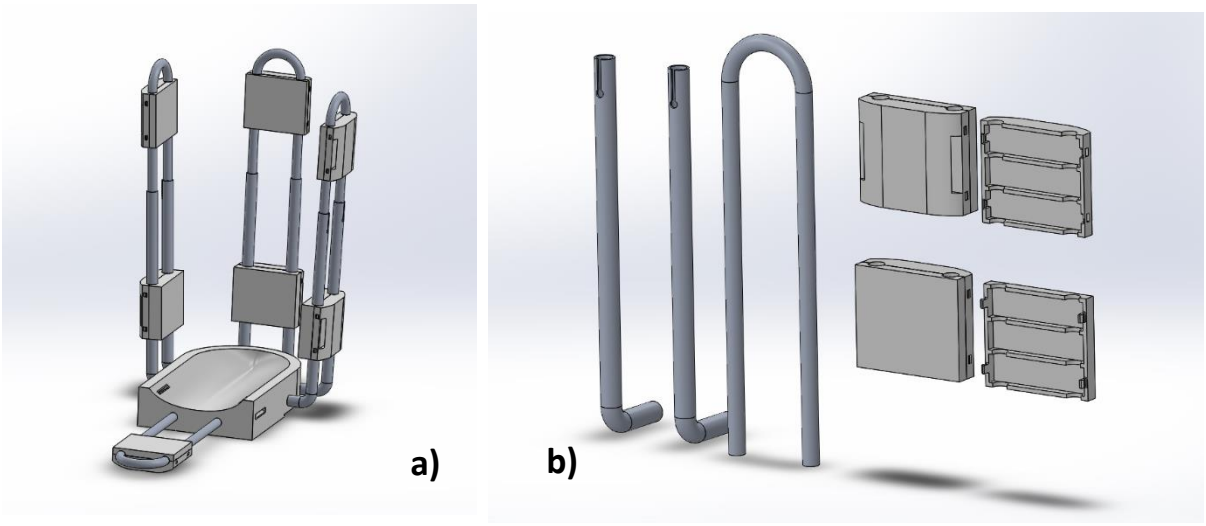


*Figure 21: **a)** Posterior view of the pin-socket with the medial side to the right. **b)** Parts of the pin-strut from the left: Two bottom-parts, bended top-part, top support (backside upper, frontside lower) and the inside of the back- and frontside of the support.*

A secondary type of pin-struts was made with the purpose to be 3D-printed using polylactic acid (PLA). The parts have the same shapes and lengths, but different diameter with thicker walls. The top-part is 7 mm in diameter and a solid rod, while the bottom-part is 10.5 mm in diameter with a varying wall thickness. From the proximal end of the bottom-part, the wall thickness is 1.5 mm for 150 mm and is then designed as a solid rod down to the distal end, see Figure 22. This is to give more stability and strength at the attachment point to the knee-plate, but still allowing the top-part to slide within the bottom-part for height adjustment.

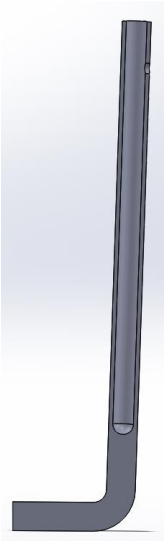


Figure 22: Section view of a 3D-printable bottom-part of a strut version 1.

Each of the struts for the thigh has a proximal and a distal support, comparable to the ones for the flat-strut socket, while the posterior strut supporting the shin only has one support. The designed support is made to be 3D-printed, see Figure 21b. The support was divided into two parts, frontside for the interface between the thigh and the support, and a backside. When the two parts are connected, two holes are visible going through the proximal to the distal end of the support. The two parts of the support is connected around the strut with the pins going through these holes. The support for the proximal end of the strut has 8.2 mm holes for the pins while the support on the distal end of the strut has 10.2 mm holes to fit the pins. The frontside of the support is flat and the backside of the support has a curvature for appearance, reduction of unnecessary material and not to have any sharp edges. On the backside is a vertical space for the fastening strap. After analysis of the socket dimensions, the support for the distal end of the socket was made with more material on the frontside to compensate for the slimmer dimensions closer to the knee.

The pin-socket has a knee-plate, Figure 23, where the knee rests and which is connected to the socket connector on the on-the-side connector. The knee-plate has a 4-hole pattern, allowing it to be attached to either the on-the-side connector or directly to the prosthesis. The first version of the CAD-model is based on the sketches made on paper with the same dimensions. After analysis of the dimensions and comfortability, the model was changed and a bowl-shape was added to the proximal side to make a more comfortable interface between the plate and the knee, Figure 23d. The width of the plate was increased to 110 mm to further widen the socket to fit the required thigh dimensions. The holes for the anterior, medial, and lateral struts are 10.2 mm in diameter and 25 mm deep, which are each

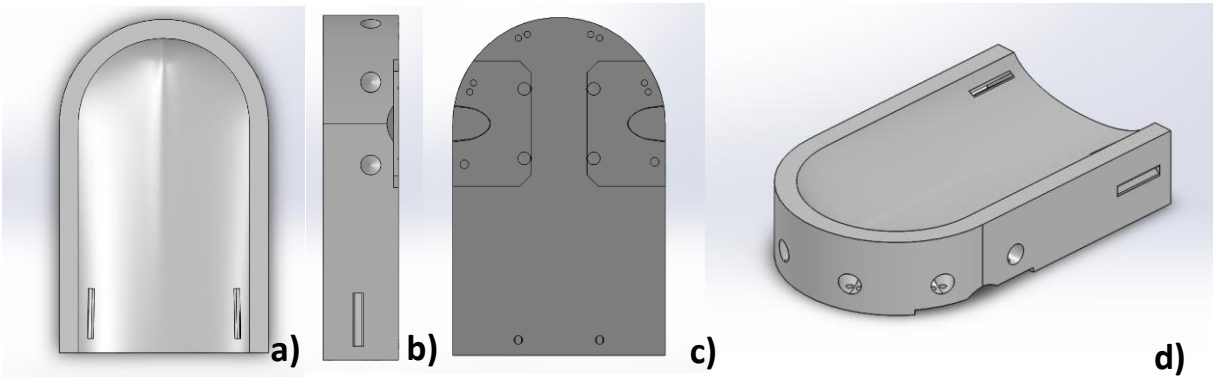


Figure 23: Knee-plate version 3, a) proximal-distal view, b) medial-later view, c) distal-proximal view and d) isometric view.

fastened by one M4 screw on the distal side of the plate. The holes for the M4 screws are visible in Figure 23c. At the posterior end, proximal side of the plate are two horizontal holes for straps that goes around the shin to keep it in place. Two 8.2 mm holes with a depth of 40 mm on the posterior side of the plate allows a top-part of the pin-struts to be connected, to give more support to the shin.

In order for the on-the-side connector to withstand the ambulatory loads an angle bracket was added to the proximal side of the socket connector plate in section 5.1.2. This affected the design of the knee-plate and some material on the distal side of the knee-plate had to be removed to not interfere with the angle bracket, see Figure 23b-d. To make the plate usable for both knees, material was removed symmetrically. A compensational "filling" was designed, Figure 24, to ensure that both spaces are filled during usage, for more pressure distribution between the knee-plate and the socket connector plate.

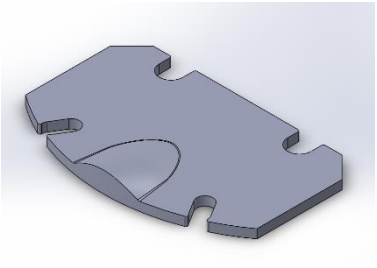


Figure 24: Compensational piece due to the space for the proximal angle bracket.

4.3.3. Residual limb-compatible sockets

Two socket concepts compatible with the residual limb were further designed, one with the primary load bearing occurring through the ischial tuberosity and gluteus maximus, and one using compression/release to transfer the load from the socket. Both have their advantages and disadvantages and to get a better and more fair understanding of the concepts, they were both designed. The plate where the struts are connected will still be referred to as the knee-plate for simplicity even though the socket is residual limb compatible.

4.3.3.1. Ischial support

The medial, anterior, and lateral struts of the socket are the same as for the able-bodied socket with flat struts. The posterior strut was designed with an ordinary bottom part and a custom-made top-part. At the proximal end of the top-part is a rounded shape for more comfort as this is the primary loading area giving a high-pressure zone, seen Figure 25a. The load transfer is meant to be through the ischial tuberosity and the gluteus maximus and will be referend to as ischial support. The height of the seat itself, responsible for the ischial support, is approximately 25 mm with a rounding of 15 mm, and the width of the seat is 100 mm with a radius of 91 mm giving an arc length of 106 mm.

Under the posterior strut is a holder for the attachment strap round the stump. This holder has no support on the inside of the socket to not interfere with the residuum as it is resting on the ischial support. As with the other sockets, the other holders are integrated holder and support. The holder and supports are kept in place using spikes, see Figure 26, which goes through matching holes on the top-parts of the struts, partly visible in Figure 25a.

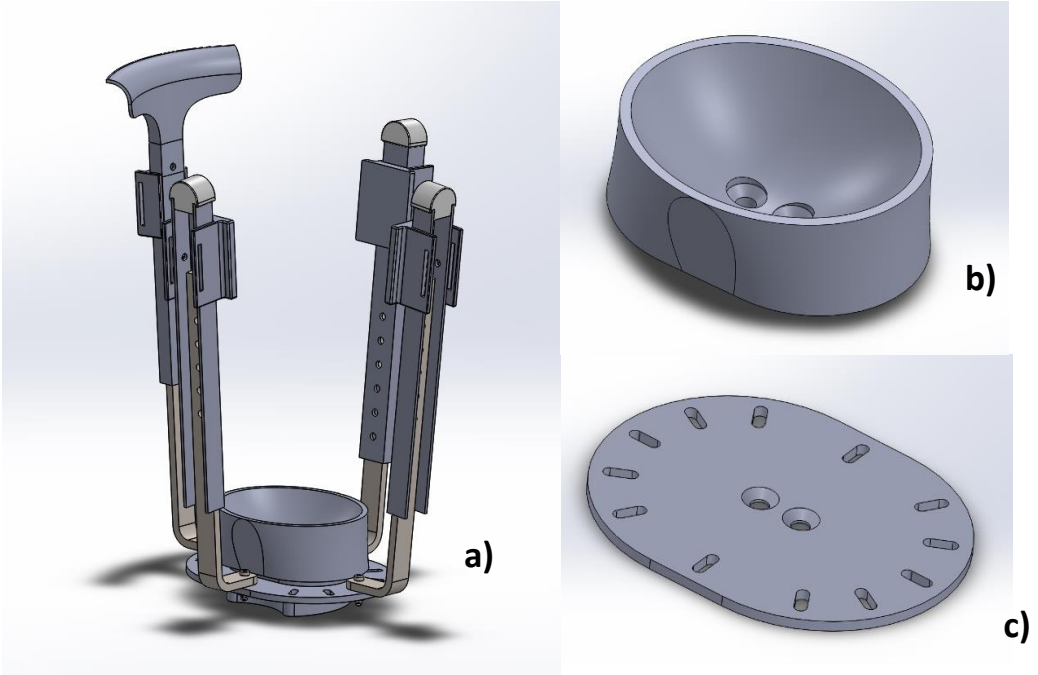


Figure 25: a) residual limb compatible socket with the primary load transfer through an ischial support, b) housing for the distal end of the stump, c) knee-plate for the stump-compatible sockets.

At the proximal side of the knee-plate, is a housing for the distal end of the residual limb, Figure 25b. This is to prevent some movement of the stump during stride and as a possible protection against the screw heads on the knee-plate. The housing has an ellipsoid shape with an anterior-posterior dimension of 93 mm, a medial-lateral dimension of 79 mm and a depth of 30 mm. In the centre of the protection are two M6 countersunk holes for connection to the knee-plate and to the distance plate.

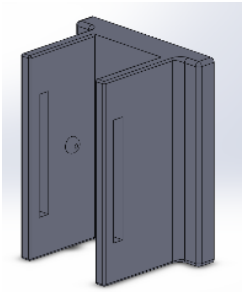


Figure 26: The supports are kept in place using spikes on the inside its' walls.

The initial knee-plate was the same as describe for the able-bodied flat-strut socket but was later updated to a capsule-shape to increase the anterior-posterior dimensions of the socket, and thereby better fit a residual limb. The new plate, Figure 25c, is 105 mm wide and 135 mm in the anterior-posterior direction. As for the flat-strut socket, a distance plate is attached on the distal side of the knee-plate with a greater anterior-posterior dimension. This is to support the knee-plate against the moment induced by the greater distance of the anterior and posterior struts.

4.3.3.2. Compression/Release

The socket, Figure 27, is made by a distance plate, a knee-plate, housing for the stump, four struts and straps round the stump. The struts are made by a bottom part, a middle part, a top part, and a proximal support.

The bottom-part, Figure 28a-b, of the struts were custom made with supporting beams to better deal with the high ambulatory forces, which will result in high stresses on the distal end of the bottom-parts. The function of supporting the distal end of the limb is integrated with the bottom-parts for better strength, in contrast to the support for the able-bodied sockets. A pneumatic support is to be placed on these supporting structures and by inflating this pneumatic support, compression against the limb is created to transfer some of the loads from the socket to the residual limb. On the outside

of the bottom-parts are two protruding M6 threads, allowing attachment to the middle-parts. A 95° angle at the distal end of the bottom-part of the strut is to increase the anterior-posterior and the medial-lateral dimensions of the most proximal part of the socket.

The middle-part of the struts is made by 50x10 mm rectangular pipes with a thickness of 1 mm and a length of 156 mm. 13 M6 clearance holes, with an intermediate distance of 12 mm allows attachment to the bottom- and top-part for height adjustments of the struts. The rectangular pipes prevent buckling of the part when subjected to high vertical loads, if compared to a rectangular rod with the same mass due to the pipes' higher moment of inertia.

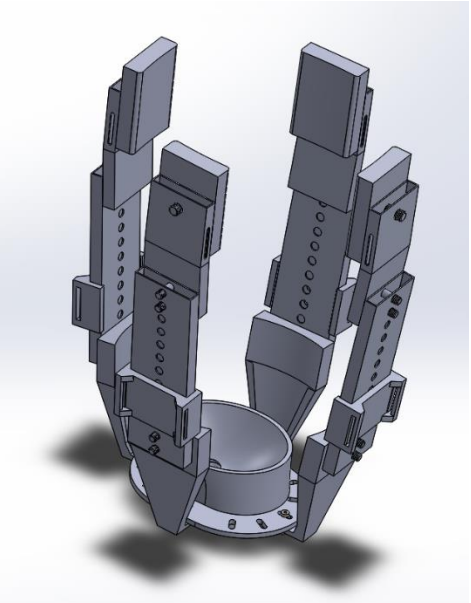


Figure 27: Socket using compression of the proximal part of the thigh as the primary load bearing area to reduce localized pressure points.

The top-part, Figure 28c, consists of a rectangular pipe and has a 5° angle in the centre to compensate for the increased angle at the bottom-part of the strut. The oblong hole on the sides of the top-part is for connection of an attachment strap. The proximal support, Figure 28d, is attached to the top-part using a M8 thread. The support can be rotated to be used either as horizontal or vertical depending on what is convenient for the user. At the interface between the support and the residual limb, a pneumatic inflated support is to be used to create compression against the limb, as done with the support structure on the bottom-part. By using the pneumatic support, the pressure against the tissue can be controlled and ensured to be within of what is tolerant by the soft tissue and the user. The housing for the distal end of the residual limb, the knee-plate, and the distance plate are the same as for the residual limb compatible socket with ischial support.

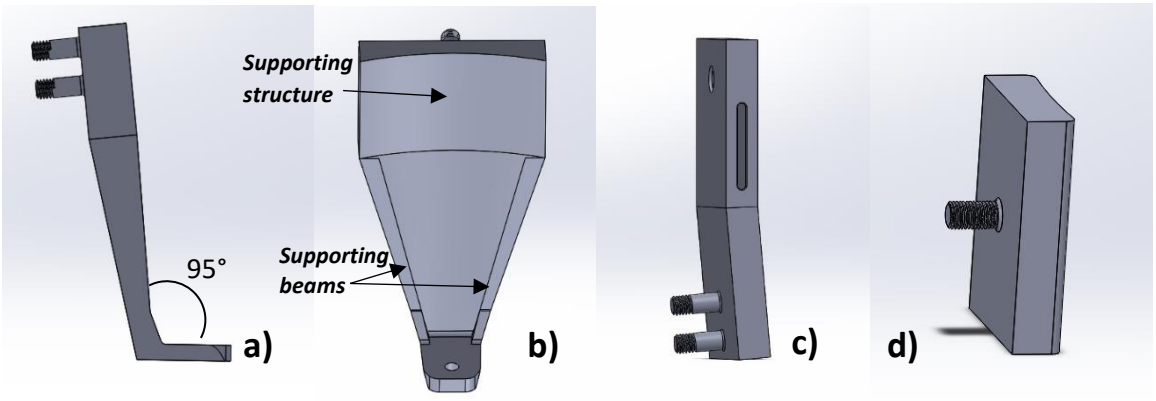


Figure 28: a) side view of a bottom part of a strut b) frontal view of a bottom part c) top part of a strut d) proximal support.

4.4.CAD evaluation

The primary function of the adapter is to allow an able-bodied subject to use a prosthesis and not to create a socket that is usable by an individual with amputation as well. As mentioned in section 3 Design inputs, the creation of a socket that is usable by an individual with a transfemoral amputation is complex and is to be developed by a professional prosthetist to ensure that no tissue damage occurs. The residual limb compatible sockets were therefore not further developed. The other designs were partly evaluated using the finite element method.

5. Finite element method to evaluate the strength

To evaluate the durability of the designs, the program ANSYS was used to conduct the finite element analysis, using the coordinate system in Table 6. After consultation with a professor in the field of mechanical engineering, the forces on the able-bodied sockets were assumed to be low enough for the body of the struts to hold without concern. This since they should not support any ambulatory load. The weak spots were in the attachment point between the struts and the knee-plate due to the angular shape of the strut's distal end and the applied moment to the knee-plate.

Table 6: Anatomical directions and the corresponding coordinate system for right leg usage.

ANATOMICAL DIRECTIONS	COORDINATE SYSTEM
Posterior-Anterior	X-axis
Medial-Lateral	Y-axis
Proximal-Distal	Z-axis

When applying force to a structural component, areas with stress concentration are to be expected. These stress concentrations depend among others on the design of the structural component and on the applied load. According to the professor in the fields of mechanics, the high stresses occurring at these stress concentrations can to some degree be neglected since the stresses will be more distributed than what is calculated by the program. The stress concentrations should be viewed as weak parts of the design that might need to be improved.

The comparative results in consideration during the evaluation were the equivalent stresses in the finite element model during the applied load, which indicates possible stress magnitudes in the physical model. The equivalent stresses were compared against the yield strength and the ultimate tensile strength of the material. The properties of the material are assumed to be linear up until the yield strength is reached, after that the region of plasticity occurs where linearity no longer applies and some of the deformation of the material is irreversible. This is not desirable and was therefore the evaluation parameter for normal usage. To ensure that the design is safe to use and endures the repetitive loading occurring during the locomotion action, a factor 2 of was used. This implies that if the required possible loading force was 1000 N, the applied force in the evaluation was 2000 N.

The ultimate tensile strength was used to evaluate the scenario of maximum loading and is the maximum stress the material can withstand before breakage. Maximum loading can occur if the user where to fall with the prosthesis and is not meant to be a recurring scenario. For safety reason the adapter should be able to withstand this force without breakage, but plastic deformation was acceptable to simplify the designing parameters, and because this is not the purpose of use for the adapter. A safety factor of 2 was not used for the maximum case.

For the structural components found in the local hardware store, the specific alloys were not stated. The rectangular pipes were simply stated as steel, the angle brackets as galvanized steel and the circular pipes for the pin-struts as aluminium. Structural steel was assumed to be equivalent to the unspecified steel from the hardware store and was chosen in ANSYS for the steel components.

5.1. On-the-side connector

The evaluation of the on-the-side connectors were initiated with applying a 1000 N in the proximal-distal direction to investigate if the first versions of the designs were prominent or not. 1000 N corresponds to the largest used force limits presented in the literature review, in Table 1. If the equivalent stress results were less than the yield strength of the material, the required repetitive forces and moments corresponding to walking with a safety factor were applied. These loads came from a study by Dumas [37]. The next step was to evaluate if the design endured the scenario of falling where

the parameters were collected from Welke *et al*. [38]. The loads from the studies were normalized to acquire the corresponding load for 100 kg user which are presented in Table 7.

The material properties were set by the standards found in ANSYS for the respective material. For the evaluation of both designs, structural steel was used. The material has a yield strength of 2.5e+8 Pa and an ultimate tensile strength of 4.6e+8 Pa. The parameters used in the evaluation are presented in Table 7.

Table 7: Parameters used in the FEA.

PARAMETER	VALUES
Meshing	Nonlinear Mechanical
Element size	5 mm, curvature capturing
Connections	Bounded, frictional 0.2
Force, Walking (F_x, F_y, F_z)	(640, 160, 1920) N
Safety Factor	
Moment, Walking (M_x, M_y, M_z)	(-64, -128, -32) Nm
Safety Factor	
Force, Falling (F_x, F_y, F_z)	(-639, -606, -4272) N
No Safety Factor	
Moment, Falling (M_x, M_y, M_z)	(-147, -165, 42.7) Nm
No Safety Factor	
Structural steel	2.5e+8 Pa
Yield strength	
Structural steel	4.6e+8 Pa
Ultimate tensile strength	
PLA	5.41e+7 Pa
Yield strength	
PLA	5.92e+7 Pa
Ultimate tensile strength	

Although the results were assumed to be within the linear region of the material properties, the calculations were set to include nonlinear behaviour as well as the mesh was set to nonlinear mechanical. The element size of the mesh was set to 5 mm with a curvature capturing. Bolts and nuts are difficult to simulate when using the evaluation tools as a pretension is applied and for simplicity the connections between the bolt-and-nut were set to bounded contacts. For the interfaces with surface contacts, but with no applied pretension force, a frictional contact was set with a coefficient of 0.2.

5.1.1. Customized case

When applying 1000 N in the proximal-distal direction, the first version of the custom-made connector showed plastically deformed regions as seen in Figure 29. The connection plate which is attached to the prosthesis appeared to be too thin and could not endure the bending motion. The stress concentrations occurring at the sharp edges indicated more rounding to create a larger radius to reduce the localized stresses. The stresses on the socket connector plate were larger than 50 % of the yield strength and the stresses have even passed the yield strength at some localized points. More material and better structure was needed, and therefore the connector was redesigned.

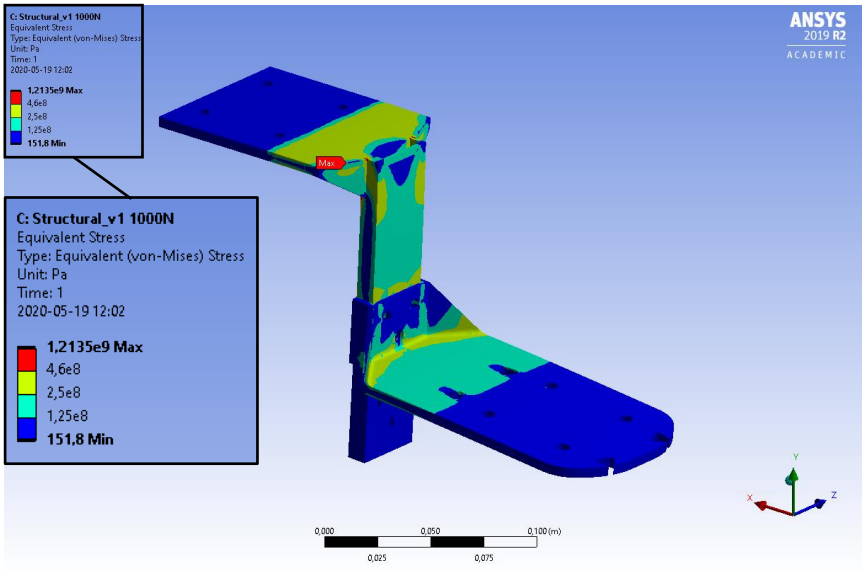


Figure 29: The equivalent stresses of the first version of the special on-the-side connector. Light blue > 50 % of yield strength. Yellow > yield strength. Red > ultimate tensile strength.

All the new designs were based on the first version with small differences and more material was added where needed. In total 5 version were made where the fifth is presented in Figure 30. The design uses a shell-based construction to minimize the weight but still be durable. The vertical pipe and the prosthesis connector plate are constructed together with a shell of 3 mm. The socket connector plate has a thickness of 10 mm and with a shell thickness of 4 mm. The supporting brims were reinforced and are protruding further into the plate to dissipate the loads. The weight of the total on-the-side connector is 1.34 kg when made by stainless steel which has a density of 7800 kg/m^3. Stainless steel was chosen since structural steel was not available in SOLIDWORKS but has roughly the same density.

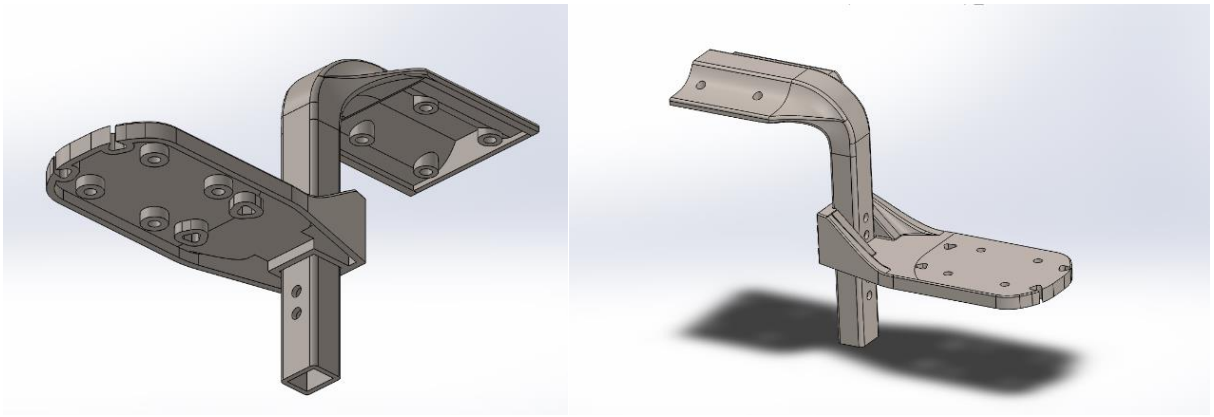


Figure 30: The fifth version of the customized On-the-side connector.

The version could withstand a force of 1000 N in the proximal-distal direction but when applying the requested amount of force, the material was plastically deformed, and some local fractures occurred as presented in Figure 31, where the red indicates that the ultimate tensile strength has been exceeded. These local fractures appeared in areas where stress concentrations could be expected and could therefore to some degree be neglected. The stresses in the connector were however too large on the vertical pipe and on the centre of the knee plate to be acceptable and the connector was considered to not fulfil the requirements. No further development of this custom case was conducted due to limited time and the advanced manufacturing process that this connector requires.

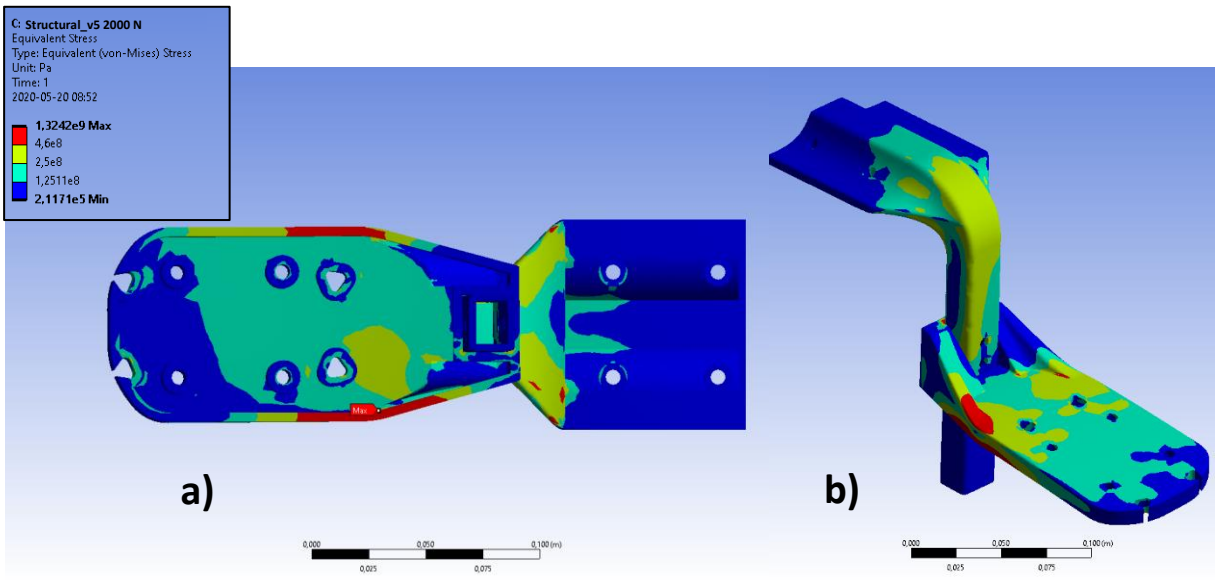


Figure 31: On-the-side connector version 5 applied with required forces with a safety factor of 2 where a) is distal-proximal view and b) is isometric view. Light blue > 50% of yield strength. Yellow > yield strength. Red > ultimate tensile strength.

5.1.2. Existing parts

For the first version, a small region exceeded the yield strength of the material during the initial evaluation when 1000 N was used. Since this area was primary in the region where stress concentration is a possibility, the required repetitive forces and moments corresponding to walking with a safety factor were applied.

The result, presented in Figure 32, indicated permanent deformation of the first version of the on-the-side connector made by existing parts. As seen in the distal-proximal view, Figure 32b, some regions at risk of fracture were at the areas where stress concentrations were expected. The simulation

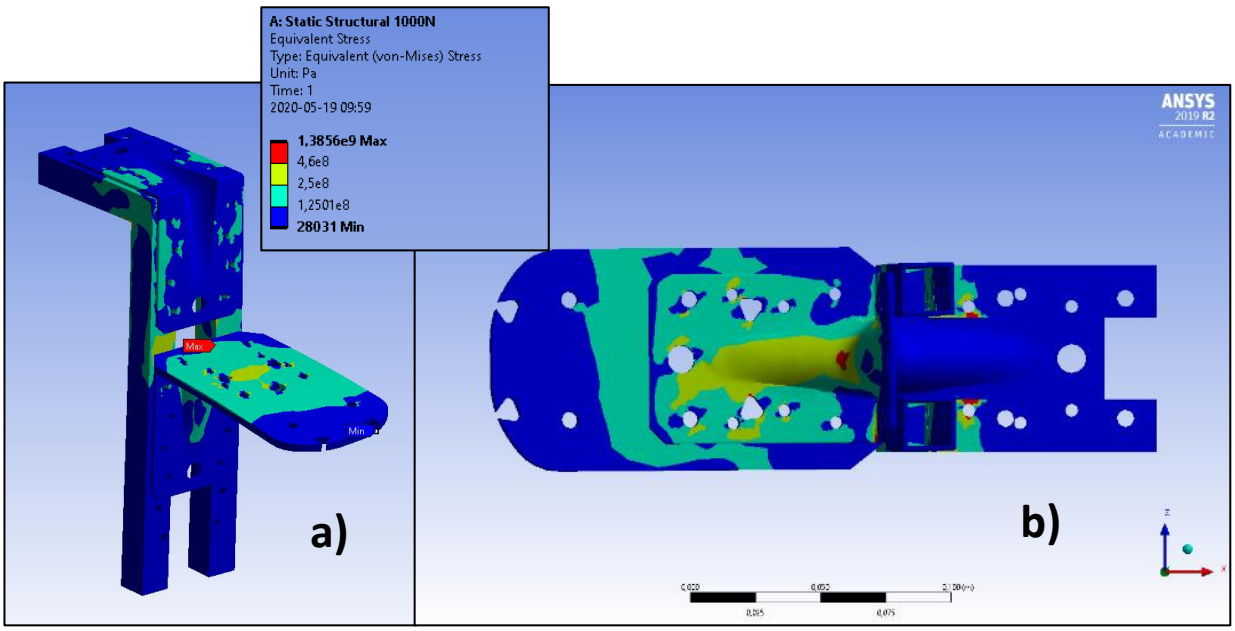


Figure 32: Results for the evaluation of the first version of the on-the-side adapter where the yellow and red areas indicated that the yield strength and the absolute yield strength has been reached viewing a) isometric view and b) the distal-proximal view.

indicated that the angle bracket would suffer from extensive deformation and stress levels that surpassed the yield strength. Therefore, and the connector was redesigned.

In total five designs were constructed with small changes between each design. The changes were done through changing the dimensions of the square pipes as well as adding supporting structures which could be manufactured by simple tools. In the first version the horizontal and the vertical pipes are connected as one part, as would be an ideal case and could be compared to if the parts where welded together. To add manufacturing simplicity, this was removed and the horizontal and the vertical pipes were constructed as individual parts, being in contact with each other at a 45° angle. The final version is seen in Figure 33 and is made by 25x25x1.5 mm rectangular pipes and weighs approximately 2.08 kg without bolts and nuts added to the model. An angle bracket was added to the proximal side of the socket connector. Two supporting beams were added to the distal side of the socket connector. These were made by 10 mm aluminium pipes, the same as the bottom-part of a pin-strut. At this stage, the correct measurements of the 4-hole pattern was known and was changed in the design. The horizontal pipes, serving as the prosthesis connector, had to be angled in the horizontal plane to fit the new 4-hole pattern, visible in Figure 33. Holes were made in the distal and proximal angle bracket corresponding to the 4-hole pattern. Drawings of version five are found in Appendix C – Drawings for the on-the-side connector.

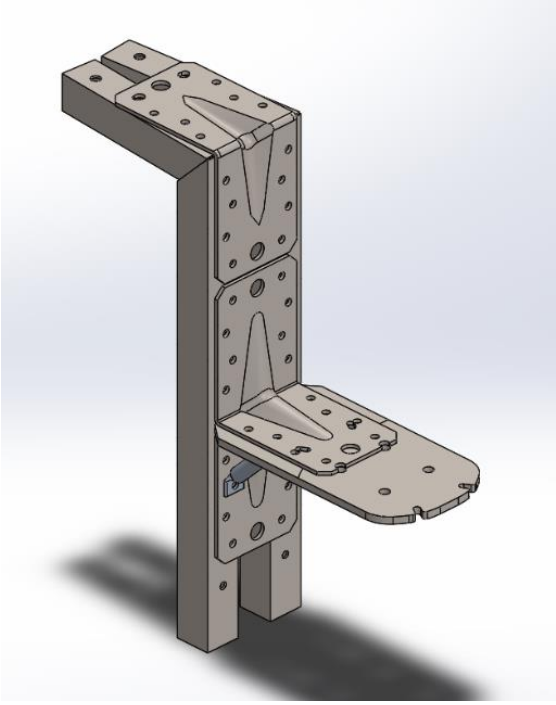


Figure 33: CAD-model of final version of the On-the-side connector, positioned for the use without the iPecs load cell.

Figure 34 pictures the result when applying the required load of walking. The result indicated the risk of the angle bracket on the distal side of the socket connector to suffer from stresses that exceeded the yield strength for the material. The area where the yield strength was exceeded is small and since a safety factor was used for the applied load, the version was considered to fulfil the requirements.

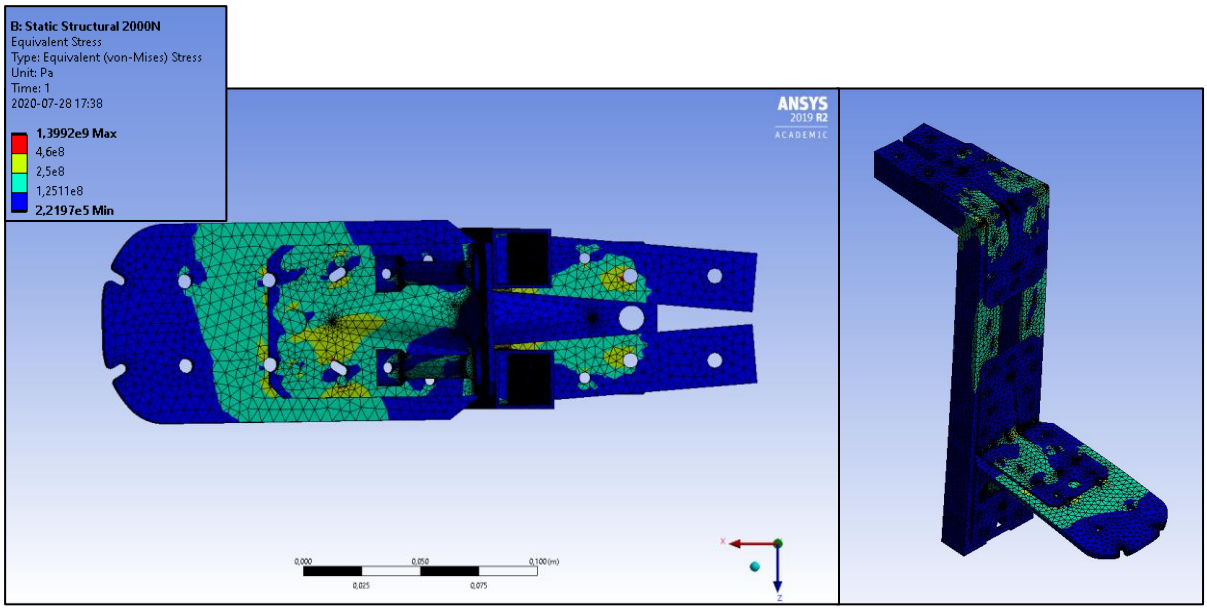


Figure 34: Test results of version five for the required walking loads including a safety factor of 2, distal-proximal view to the left and an isometric view to the right. Light blue > 50% of yield strength. Yellow > yield strength. Red > ultimate tensile strength

When applying the required loads corresponding to the scenario of falling with the prosthesis, the yield strength was exceeded in multiple places as seen in Figure 35. As mentioned previously this was considered acceptable since it is a worst-case scenario. The ultimate tensile strength was exceeded on the angle bracket on the distal side of the socket connector, indicating fracture of the angle bracket. For the angle bracket on the proximal side of the socket connector, the ultimate tensile strength had not been reached, indicating the risk permanent deformation but not fracture. The result was considered acceptable since the ultimate tensile strength had not been exceeded for both angle brackets on the socket connector.

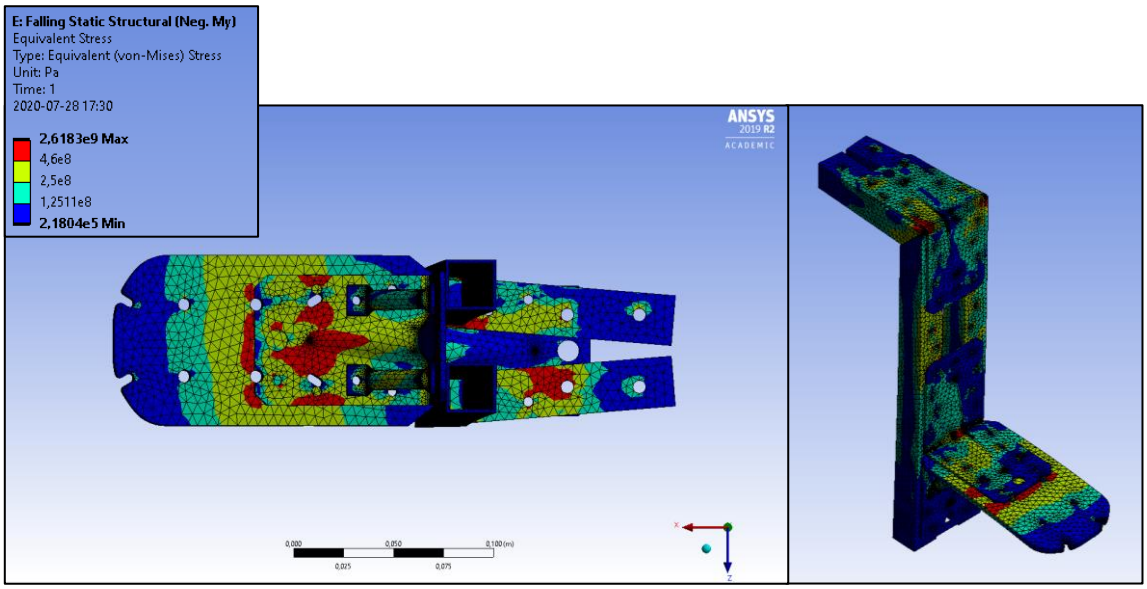


Figure 35: Test results of version five when applying the required loads in the scenario of falling. Light blue > 50% of yield strength. Yellow > yield strength. Red > ultimate tensile strength.

5.2.Socket evaluation

An investigation of the forces applied to the socket was done in section 3.5. The walls of the socket were subjected to these forces due to the load bearing conditions involving an individual with a transfemoral amputation. This is not the case for the bypass socket, where all the load transfer occurs at the interface where the knee interacts with the knee-plate. Thereby only the knee-plate was evaluated for a full-loading scenario. As seen in Figure 36a, the loading scenario of walking, including a safety factor, was applied to the proximal side of the plate as done previously for the on-the-side connector, and a fixation was applied to the holes of the 4-hole pattern on the distal side of the plate. The material properties were set to PLA since the plate was assumed to be 3D-printed. The durability of 3D-printing is depending on the settings for the 3D-printer during the printing process. The finite element analysis gave an indication if 3D-printing was a possibility as it indicated if PLA itself was strong enough or not. Figure 36b shows the results of the evaluation for the knee-plate of the pin-strut concept. Local high stresses, indicating fracture, occurred at the connections holes where stress concentrations can be expected, and the high stresses were therefore assumed to be neglectable. PLA was assumed to be usable to create the component.

The loading conditions subjected to the struts were difficult to anticipate, since they were not meant to carry any ambulatory load during the locomotion action but merely give stability. The anticipated loading of the struts occurs during the motion of lifting the prosthesis and should therefore not be more than 10 kg. The struts were evaluated in a scenario where a force of 200 N was applied in the proximal-distal direction to the knee-plate. To save computational space, the top-part of the struts were excluded in the evaluation. The evaluation was done using both aluminium and PLA as materials for the struts and the struts showed no indication of fracture for both the evaluated materials. Through the evaluations it was noticeable that the concept of a pin-socket had potential to be produced using only 3D-printing. This simplifies the production and minimizes the risk of failure in the manufacturing process. The flat-strut socket relies on more metallic parts, among them a circular knee-plate, which requires more advanced manufacturing processes and increased risks of failure if manufactured manually. Therefore, the pin-socket was chosen as the most prominent concept and is the design on which the prototype was based.

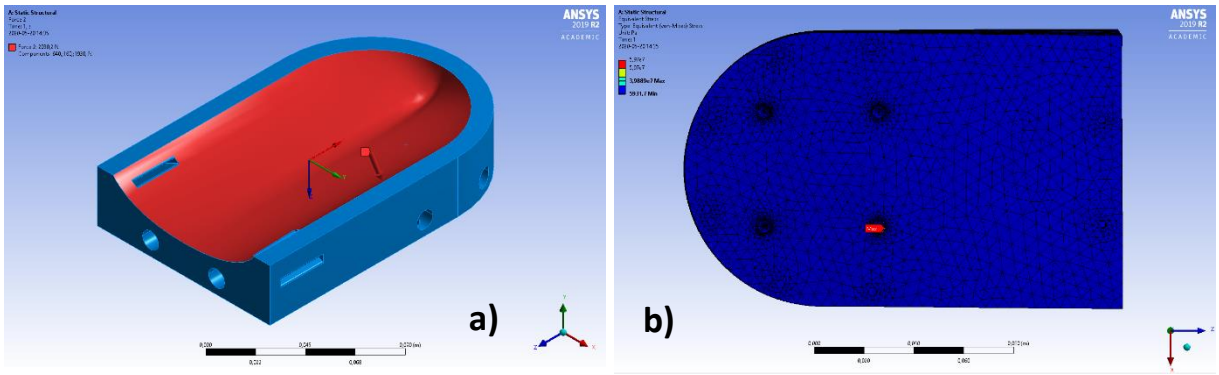


*Figure 36: FEM-images of the knee-plate where **a)** 2030.2 N and 146.64 Nm is applied and **b)** the results were local pressure points.*

6. Prototyping and user tests

A prototype of the entire bypass-socket was made based on the fifth version of the on-the-side connector made by existing parts and the pin-socket concept. An iteration was made for the parts which were 3D-printed to correct errors in the design. These errors were expected due to shrinkage of the PLA when printing and durability properties which were unknown during the design part.

6.1. Building process of the On-the-side connector prototype

As the dimensions of the CAD-model for the angle bracket was based on the information on the seller's webpage the width of the model is constant 65 mm [51]. This was not the case due to the reinforcement on the bracket where the width decreases as the metal deforms. The placements of the holes on the model were measured from the border of the bracket when a physical bracket was accessible. This means that the distance between the holes on the model was not sufficiently large and an error of 0.5 – 1 mm per hole existed in the model. Drawings, including the error, were done for the on-the-side connector before the manufacturing process of the prototype.

The initial plan for the construction of the prototype was to manufacture it in the prototyping lab at Chalmers. Due to the pandemic, the access to the lab was restricted and the plan was thereby changed. The on-the-side connector was manufactured by tools applicable in a household-environment except for the socket connector plate which was cut using the water jet cutter at Chalmers. The part was made from a 5 mm thick 7075 aluminium plate, as structural steel was unavailable at the time. The strength of 7075 aluminium is equivalent to structural steel and has less density and was considered as a suitable substitute. An evaluation of the design with the new material was done to reassure durability. The results indicated that the material was acceptable, Figure 37a.

Errors which occurred during the building process, affected by the error in the drawing and manual errors, were compensated as much as possible. The building process can be viewed in Appendix D – Building process of the on-the-side connector. The prototype is presented in Figure 37b and was made of rectangular steel pipes and reinforced angle brackets with the possibility of positioning the socket connector plate at the distances of 156 mm and 202mm. The supporting beams on the distal side of the socket connector plate was made by AlMgSi0.5 aluminium pipes [54]. All the parts of the prototype were connected using M5 bolts and nuts.

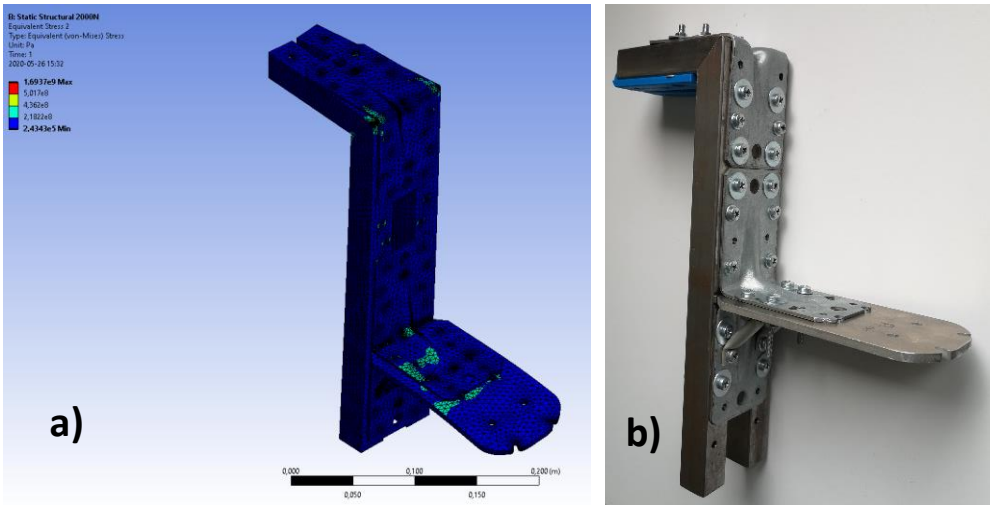


Figure 37: a) Evaluation of the connector with aluminium 7075 as material for the socket connector plate. Light blue indicates that the stresses does not reach the yield strength of the material. b) the final prototype of the on-the-side connector.

6.2. Bypass-socket prototypes

Due to shrinkage of the 3D-printed material, errors in the design, and limitations in the 3D printer capabilities, an iterative process was done to achieve a desirable design outcome. The different parts were printed parallel and design changes of one component could imply a design change needed for another component.

The main testing of the 3D-printed pin-struts was to get the correct dimensions for screw-clearance, for the compartments of the nuts and for the inner and outer diameter for the struts. To get enough support and strength in the material, the walls of the bottom-parts of the struts were set to a minimum of 1.5 mm. The outer diameter of the bottom-part was set to 10.5 mm and the inner diameter was set to 7.5 mm. The outer diameter of the top-part was set to 7 mm. The proximal part was prone to bending and was further investigated during an initial user test. On both the bottom-part and the top-part, a small protruding part was constructed for the resting of the support, see in Figure 38. This is to simplify the placement of the supports during the donning of the socket and prosthesis.

Figure 38: Two versions of the 3D-printable strut, with direct screw fixation on the left and decrease of circumference to the right

The holes of the supports were changed to match the changed diameters of the struts and were set to have 0.5 mm of clearance. The pins locking the bottom and the top parts of the supports together were prone to break, due to the brittle PLA. The supports were changed during three versions where the final version, Figure 39, has spacing between the pins and the wall of the support to allow some bending of the pins. The pins are still weak, but the support can be used even if one of the pins breaks. Table 8 presents the parameters used during the 3D-printing part.

The third version of the knee-plate was printed for early evaluation. The radius of the surface at the anterior interaction point with the knee was considered too small to fit a wider knee variation. Version five was made 110 mm wide. After consultation with a mechanical research engineer at the prototype lab at Chalmers, 3D-printed threads were considered inappropriate for the intended use of the knee-plate. Printed threads are difficult to print and are easily worn, instead nuts were incorporated for attachment of the bolts. Material was added to the distal side of the plate to incorporate M6 nuts to the 4-hole pattern. The nuts were positioned from the proximal side of the plate, and the holes were covered with plugs, seen on the side of the isometric view in Figure 40d.

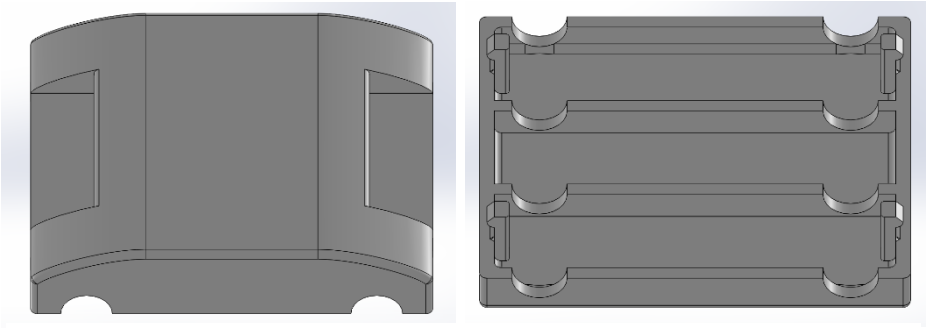


Figure 39: Version 3 of the supports allows some bending of the pins as seen on the right image of the proximal support.

*Table 8: MakerBot print settings for the 3D-printed parts. *Knee-plate used for inital evaluation and initial user tests.*

PRINT SETTINGS	KNEE-PLATE*	STRUTS	SUPPORT/PROTECTION
EXTRUDER TYPE	Smart Extruder+		
PRINT MODE	Balanced		
BASE LAYER	Raft		
EXTRUDER PRINT SPEED	90 mm/s		
INFILL DENSITY	15 %	95 % / 70 %	40 %
INFILL PATTERN	Diamond Fill		
LAYER HEIGHT	0.2	0.15	0.2
NUMBER OF SHELLS	5 Shells	5 Shells	3 Shells
SUPPORT ANGLE	68°		
SUPPORT DENSITY	16 %		
SUPPORT TO MODEL SPACING	0.4 mm		
SUPPORT TYPE	Breakaway Support		
SUPPORT UNDER BRIDGES	No	Yes	No

M4 nuts were incorporated in the knee-plate for the fastening screws which attaches the bottom-parts of the struts. In the third version of the knee-plate, each hole for the strut-placement has a M4-fastening screw, which was removed in later versions due to interference of the incorporated nuts. In version 5, the two interfering holes were combined to one, see Figure 41, which resulted in the fastening screws being uncentered. The holes for the struts were lengthened to 28 mm. Each strut is capable of 15 mm of displacement, resulting in the range of the medial-lateral dimension for the socket to 115 - 145mm at 91 mm from the surface of the knee-plate. At 230 mm the range of the medial-lateral dimension is 136 - 166 mm and at 320 mm the range is 143-173 mm. The two posterior holes for the struts were lengthened to 50 mm. The holes for the struts in the version with aluminium struts were set to 10.5 mm and 8.5 mm, and in the version with 3D-printed struts was set to 11 mm and 7.5 mm.

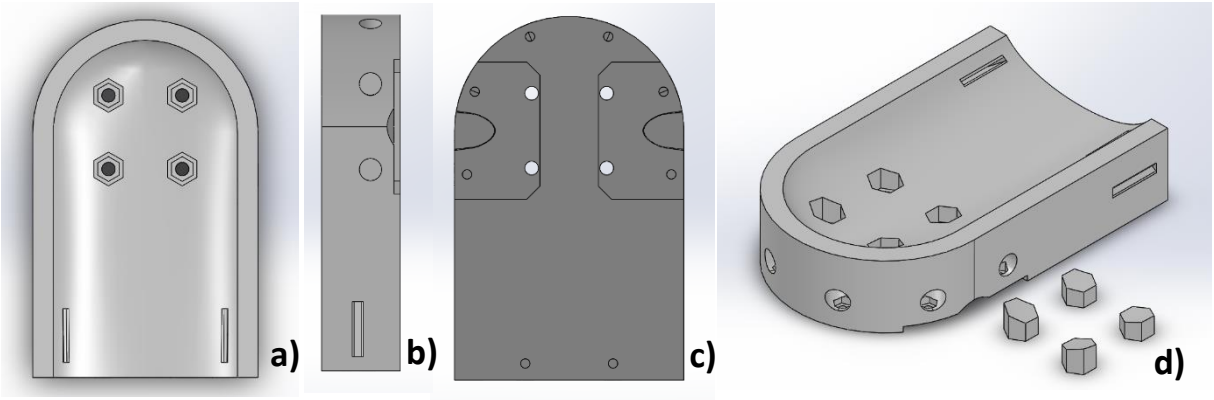


Figure 40: Knee-plate version 5, a) proximal-distal view, b) medial-later view, c) distal-proximal view and d) isometric view.

Four custom straps were manufactured where two straps are attached around the thigh and two straps are attached around the shin. Protective foam was glued to the supports and onto the knee-plate. This serves as cushioning, protection against sharp or pointy edges and increases the friction at the interface between the socket and the limb.

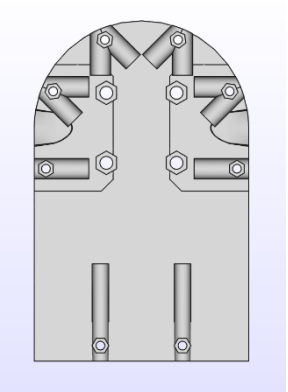


Figure 41: Transected view of the knee-plate version five, picturing the uncentered fastening screws for the struts.

6.3.Initial user test

An initial user test was conducted to evaluate the durability of the 3D-printed struts and the placement of the 4-hole pattern on the knee-plate, indicated by alignment issues. These initial tests were conducted without the on-the-side connector. A correct alignment of the prosthetic components was not considered necessary for this test since the intention of the test was not a definite evaluation but to investigate problems with the socket design. As seen in Figure 42 the prosthetic foot was positioned to far anteriorly in natural standing position. This indicates that the 4-hole pattern on the knee-plate should be placed further posteriorly.

The socket was usable but had stability issues. The printed struts were too flexible and resulted in no support for the shin as intended by the posterior, horizontal strut. The knee-plate gave insufficient support for the shin and was considered too short in the posterior dimension. To investigate the supportability of the shin, a strap was attached between the proximal strap of the thigh to the posterior strap of the shin to prevent extension more than 90°. This correction increased the stability of the socket.

Figure 42: Initial user tests of the bypass-socket, indicating alignment issues.

The M4-bolts fixating the struts to the knee-plate did not have a centred connection point with regards to the strut. The 3D-printed knee-plate had 15 % infill material since the intend of the print was to do preliminary evaluation of the shape. This, in combination with the uncentred M4-bolts, resulted in the inability to create enough normal force to the struts to fixate them. When the bolts were tightened too much, the plastic gave in. However, enough force could be applied such that the struts could not be pulled from the knee-plate with reasonable hand force. During usage, rotation of the medial and lateral struts occurred towards the anterior strut. It was suggested to attach a strap between the medial and lateral struts, going on the posterior side of the thigh, to prevent rotation.

The knee-plate was redesigned, see Figure 43. Complementary, centred fastening screws were added on the proximal side of the knee-plate, to fixate the struts from two directions. The posterior dimension was lengthened with 50 mm and the posterior part of the knee-plate was made hollow to remove weight, see Figure 43c. The plate was divided in an anterior and a posterior part, to reduce the necessary continuous time of printing. The 4-hole pattern was moved 20 mm posteriorly. This moved the space for the proximal angle bracket of the on-the-side connector further posteriorly on the knee-plate. The compensational piece to fill the space was redesigned to fit the new design of the knee-plate. The new knee-plate was printed with the parameters from Table 8, but with 70 % infill instead of 15 %.

For the final user tests, struts of aluminium (AlMgSi0.5) pipes were manufactured to decrease the flexibility and increase stability. The pipes for the top-parts were bent around a custom-made wooden

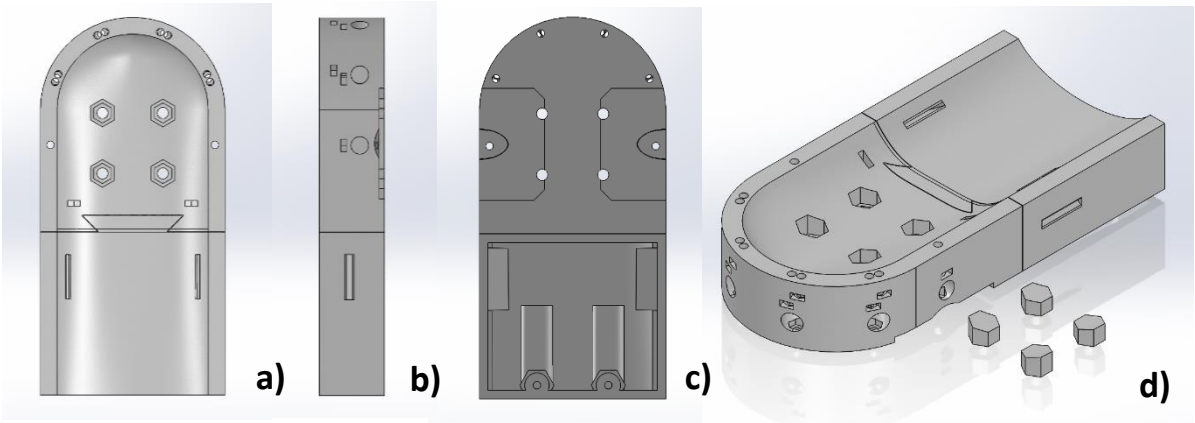


Figure 43: Knee-plate version 7, a) proximal-distal view, b) medial-later view, c) distal-proximal view and d) isometric view.

object with a diameter of 41 mm and the pipes for the bottom-parts were bent around an object with roughly 1 cm in diameter. To reduce the risk of cracks of the pipes during the process of bending, the material was heated with a torch. The interior of the area exposed to the bending process of the top-part was filled with sand to demote yielding. Yielding was unavoidable for the bottom-parts of the pipe due to the slim radius. Due to dimension tolerances, some sanding of the top-part was necessary for it to fit inside the bottom-part of the struts. The drawings for the parts of the struts are presented in Appendix E – Drawings for the struts.

An initial user test was performed on a treadmill with the on-the-side connector, at a speed of 1.5 km/h. A natural gait was not possible due to the twisting moment induced by the placement on the side. To overcome the moment and not fall during the locomotion action, the body shifted the weight over to the prosthesis, causing a limp. It was not possible to walk with the on-the-side connector without using both hands as support which reduced the weight on the prosthesis. The requirement of normal locomotion was considered to not be fulfilled and the research usability was questionable when support was needed that most likely reduced the forces in the prosthesis. The on-the-side connector was regarded as unsuccessful and was not evaluated in the final testing.

6.4. Final user testing

Participant 1 was able to walk with the bypass-socket using one hand for support but unable to walk without using support. Participant 2 was able to walk without using support and participant 3 was temporarily able to walk without using support but needed at least one hand for support most of the time. All participants were able to walk at 1-2 km/h and participant 3 could walk at 2.5 km/h which resulted in a more natural walk, but support was still needed. A limping motion was present for all participants, resulting in an unnatural locomotion action. Participant 2 showed a twisting of the hip as a compensation while walking with the prosthesis and participant 3 stated problems with control. As seen in Figure 44, both feet of the participants are evenly placed.

The bypass-socket was perceived as being attached to the leg with the knee fixed in relative position. Instability occurred for all the participants while walking with a lateral bending of the prosthetic leg and socket. A small, relative movement between the proximal end of the socket and the thigh was visible during this bending motion. Instability was always present but became less severe with time of use.

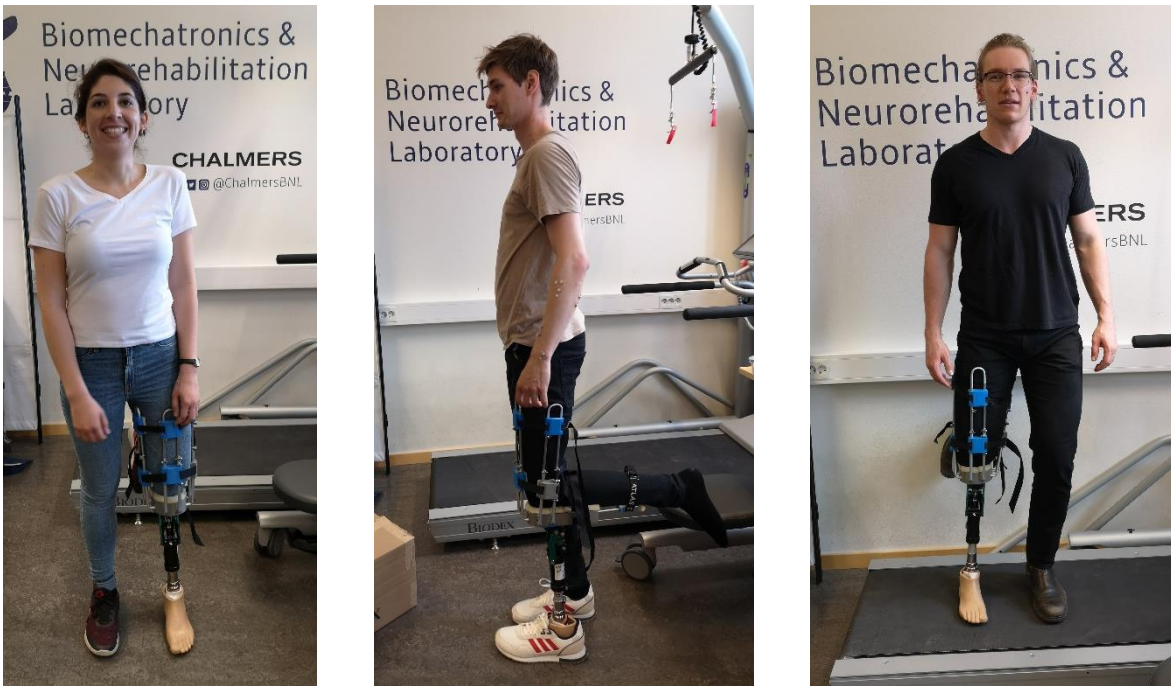


Figure 44: Participant 1, 2 and 3 respectively, for the final evaluation.

Participant 3 and two of the additional users became sore in the fold of the knee due to one of the distal straps around the thigh. Participant 2 and 3 perceived the padding foam insufficient, causing pain to the patella during usage.

During usage, the socket seemed to withstand the stresses well for participant 1 and 2, with no feeling of concern for the durability. For participant 3, the stresses were noticeable as a bending was present in the joint between the posterior and the anterior part of the knee-plate, and the struts had a difficulty to withstand the bending motion. As partly seen in Figure 44, after the test the knee-plate for participant 3 is not perpendicular to the central line of the thigh, but slightly angled while this is not the case for participant 1 and 2.

Additional user 3 walked with the bypass-socket after the use of participant 3. No safety harness was used during the initial trial of additional user 3 where the user walked with and without support. During the non-supporting walk, the prosthetic leg was not entirely extended when a new step was conducted, causing the user to fall. The user was not injured and no obvious, exterior sign of failure to the bypass-socket was discovered and the trail was continued, using a safety harness. The socket was analysed after the trail with additional user 3. As seen in Figure 45, fractures on both lower parts of the medial strut was discovered along with a relative twist between the knee-plate and the struts, causing the central line of the thigh and the face of the knee-plate to not be perpendicular. The socket was not analysed between the participants and it is not clear if the fractures and relative twist were present before the use of the additional user 3 or not.

The targeted muscle groups for the electrode placement were the quadriceps and the hamstrings. 7 channels could be positioned, and EMG signals was detected both for extending and flexing the knee.

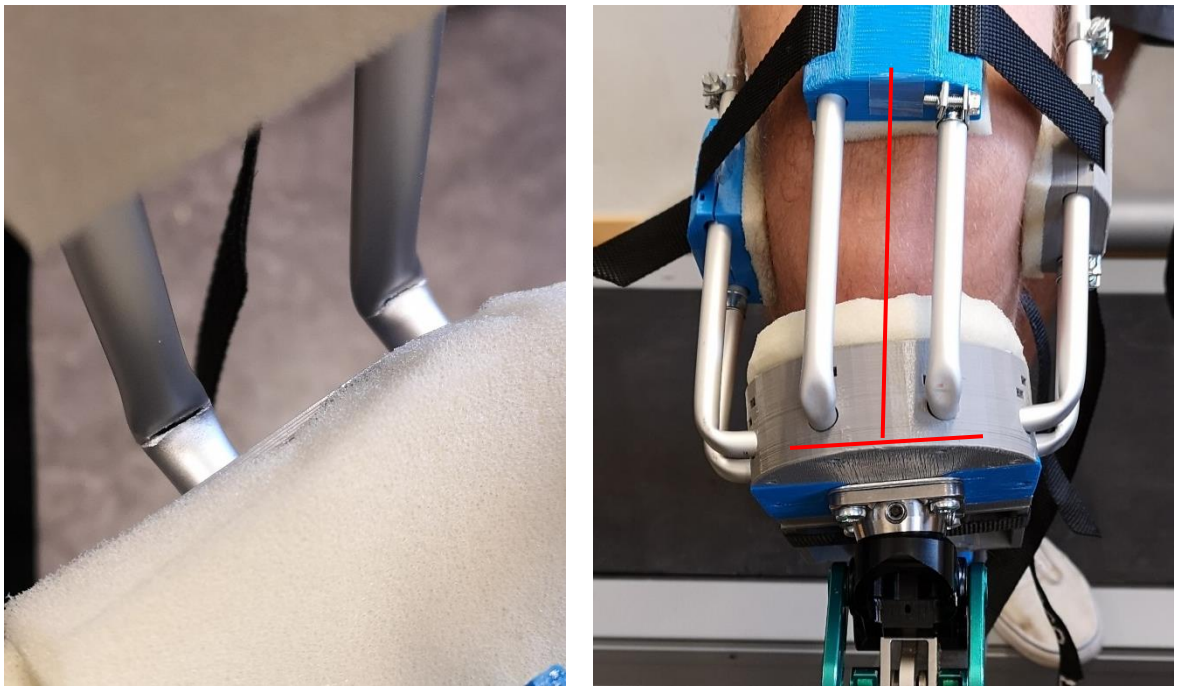


Figure 45: Examination of the bypass-socket after the final tests showed fractures at the distal angle of a strut along with a relative twist between the struts and the knee-plate, causing the central line of the thigh and the face of the knee-plate to not be perpendicular.

7. Discussion

The discussion is divided in Residual limb compatible sockets, On-the-side connector, and Bypass-socket. The first part discusses the potential of the CAD-models regarding the bypass-sockets compatible with the residual limbs. The second part discusses the on-the-side connector, both the CAD-model of the custom made and the prototype. The last part discusses the prototype of the bypass-socket, with problems, potentials, and further development.

7.1. Residual limb compatible sockets

The sockets compatible with the residual limb, needs to be discussed with a proper orthopaedist to evaluate their potential. Misplaced pressure can have a serious impact on the user, but since the socket is to be used for research purpose and therefore a short amount of time, the impact will not be of the same magnitude as if the socket was for permanent use. Some misplaced pressure can be tolerated before causing damage to the participant, but this is to be decided by a professional within the field.

The concept using compression/release is the concept that most likely will be the most stable as the lost motion is minimized, and also more comfortable for the user as the load is distributed over a larger area. A tighter fit however makes the socket more difficult to design as the shape of the stump differs between people. The socket presented in the report would for instance have problem with stump shaped more as a cylinder while it would fit better for an ellipsoid shape. The length of the stump is also to be taken in consideration as a contact point at both the proximal and distal end is needed for stability. The concept using ischial support could be easier to design as the primary loading is transferred at one point. The posterior strut can be made adjustable to fit a variety of stump shapes, mainly by changing the length. By using pneumatic support at the interface between the other struts and the stump, the final contact for an acceptable fit and sufficient pressure can be made by inflating these supports.

The struts of the socket using ischial support should be made thicker for them to work and would preferably be made by rectangular pipes to reduce the risk of buckling. The angle at the distal end of the struts should be reinforced and the knee-plate on both concepts should probably be made thicker to better withstand the ambulatory loads.

7.2. On-the-side connector

As mentioned previously, an unnatural moment of force is induced by placing the bypass-socket on the side of the prosthesis. If all the degrees of freedom are measured in the prosthetic knee, it is questionable if the measurements when using the connector could be of use. Partly because the forces would not represent reality meaning that a compensation is needed in the code to transform the measured forces on the side to something which would represent a normal connection on top of the prosthesis. Another important factor is the measurement range of the loadcell in the prosthetic knee. If for example the distance between the attachment point of the prosthesis and the socket is 0.15 m and the user weighs 100 kg the induced moment can be up to around 150 Nm during the gait cycle, which might not be within the measurable range of the load cell. This is of course if all the weight of the user is transferred to the prosthetic leg, which would not be the case during stance, but will be the case during walking. If all the degrees of freedom are measured and used in controlling the prosthesis, this is important to keep in mind.

Although the customized design for the on-the-side connector could not withstand the required forces, it has some important features which affect the strength to weight ratio in a positive way. By making some parts hollow, as done with socket connector plate, the parts can be made with less material but still be strong enough to withstand the forces. One of the weakest parts is the 90° angle between the prothesis connector and the vertical rod as seen in Figure 31. The vertical rod could be divided into

two parts and done with the design using existing parts, to distribute the weight. More material could also be added at this bend and somewhat redesigned to reduce the stresses. The customized design enables a better weight-to-strength ratio and easier usage as the vertical placement is fixed using 2 screws instead of 12 as for the existing one.

During the initial test of the on-the-side connector prototype, the induced moment was severe, and the prosthesis was unusable without using both hands as support and taking some of the ambulatory loads. This most likely reduces the forces in the prosthesis. The usability in research is thereby questionable since the measurement does not represent the real scenario. It is doubtful that the connector would be used since it was easier to walk with the prosthesis directly under the bypass-socket which would give more realistic measurements. The locomotion action was not natural and during the test, a small skipping motion towards the prothesis was needed to overcome the moment and not fall. Even though the locomotion action was not natural when using the bypass-socket placed on top of the prosthesis either, it was still more natural than when using the on-the-side connector. Therefore, the on-the-side connector in the report was regarded as unsuccessful. The use of a socket on the side is also questionable when compared to using a socket attached on top.

7.3. Bypass-socket

When using the bypass-socket the leg is fixed at a 90° angle and it was questionable if this affected the muscle activation and thereby limiting EMG signal that could be recorded. Electrodes where placed on one additional user which showed that appropriate signals could be recorded. More user tests are needed to verify that the bypass-socket is surface EMG compatible and that this test was not an exception. However, surface EMG compatibility is considered as plausible. If more user test would conclude that the signals are insufficient due to limited muscle activation, the prosthesis could be placed on the side of the leg, hanging freely in the air by using just the lateral strut and turning it 180°, facing it outwards. The prosthesis should not support any weight. This would allow for the leg to be fully flexed and extended, and correct muscle activity could be recorded and used to control the prosthesis. A risk however with the prosthesis attached with this lateral contraption is gait distortion due to inertial forces as the prosthetic joints starts to move. It is probably better to attach the prosthesis to a test bench instead and record the movement of the prosthetic leg and the limb simultaneously.

The cause of instability when using the bypass-socket was difficult to determine and many factors play a part. Inexperience of using a prothesis will cause instability, and it was observed that the participants became better at using the prosthesis with time. Incorrect alignment of the prosthesis is also to be taken in consideration, as no person with proper training regarding alignment was present at the time. The alignment and settings of the prosthetic components was done as what visually seemed to be correct in the eyes of inexperienced people. The prosthetic leg had a fixed ankle and a passive, mechanical knee joint which flexed when a certain moment threshold was surpassed. Until that point in the gait cycle, the leg was straight, which is unnatural and causes a limp. Since the joint is mechanical, there is no active power that holds the knee flexed as the prosthetic leg is moved in a posterior-anterior motion as a new step is taken. A spring-behaviour causes the knee to extend and thereby causes the prosthetic foot to be dragged along the ground. If the knee is not fully extended when the next step is taken, the mechanical knee joint can flex as soon as the prosthesis bears ambulatory load. As this is not intended by the user, it can cause a fall, which is what happened to additional user 3. To ensure that the prosthetic foot does not drag before the new step, the body leans more to the sound leg and rises the hip of the simulated, impaired leg as a compensation. This causes an unnatural gait. Further evaluation is needed in the presence of a properly trained prosthetist to evaluate if the unnatural locomotion is caused by the bypass-socket or the use of the prosthesis. The bypass-socket is

considered usable but not optimal, as the requirement of natural locomotion could not be fulfilled nor with certainty unfulfilled.

Even though the participants perceived the socket to be fairly stable, it was noticed that some relative motion between the proximal end of the socket and the thigh occurred during the lateral bending motion. The relative motion can occur if the proximal strap around the thigh is not firmly tightened. It can also be caused due to compression of soft tissue as in lost motion. The straps where tightened by hand force which made the thigh firmly attached to the bypass-socket during normal stance. During the gait cycle however, the lateral bending increased the pressure between the proximal end of the socket and the thigh which caused compression of the soft tissue, and thereby a relative motion causing instability for the user. A way to improve this is to use pneumatic support between the bypass-socket and the thigh instead of the currently used foam. After the strap is tightened, the pneumatic support is inflated to increase the pressure and thereby reducing the lost motion, making the socket more stable.

The pipes used in the project had the same outer diameter for the top-part as the inner diameter for the bottom-part of the struts. Depending on the tolerances, this can be possible and was checked in a hardware store in the beginning of the project. The pipes were later bought from another store since that store specified the aluminium alloy in the pipes. However, these pipes seemed to use a different tolerance and could not fit inside one another. Material was removed from the top-part until it fitted inside the bottom-part. It was necessary for both surfaces to be smooth and clean for the parts to slide smoothly. If dirt or grain exists on either surface, the parts would not slide smoothly and material from the inside of the bottom-part could be scratched and be piling up on the inside between the pipes of the bottom- and top-parts. This could result in the top-part becoming lodged in place within the bottom-part, removing the ability to change the length of the that strut. It is thereby advisable to order custom telescopic tubing with the appropriate clearance between the pipes to minimize the work and risk of error. If this is not possible, 3D-printed struts could be used but with greater dimensions than used in the project to make the struts stronger and distribute the stresses within.

The anterior side of the thigh in the sagittal plane has a slight convex shape when the knee is bent 90°, while the struts are straight. As a compensation, the aluminium struts are bended and plastically deformed when the proximal part of the socket is tightened. The deformation occurs primarily for the top-part and as a result, it is difficult to decrease the height of the strut since the lower-part is straight while the top-part is slightly curved. A solution is to increase the dimension of the frontside, facing the thigh of the proximal support. This decreases the dimensions of the proximal end of the socket while keeping the dimensions in between the distal and proximal end. The diameter of the aluminium struts should be increased, alternatively changed to a strong material. The used aluminium alloy is of AlMgSi0.5 with an unknown temper designation, since this was the only kind of aluminium specified at the hardware store. It has a yield strength of 60-160 MPa depending on the temper designation [55] while some other aluminium alloys have higher yield strengths and should be more suitable. Another alternative is to use stainless steel as this also has higher yield strength and might be more easily accessible.

The bypass-socket was not thoroughly evaluated between the use of each participant and additional user and it is therefore impossible to know if the fracture of the strut was due to the usage of participant 3 or to the fall of additional user 3. Participant 3 was the heaviest user and were to evaluate if the socket could fulfil the requirement of 100 kg user. If the fracture occurred with the use of participant 3, the requirement of durability is considered as unfulfilled and if the fracture occurred due to the fall, the requirement could be considered fulfilled. This since falling subjects the socket to higher forces than for the intended use. Only one strut was broken after the fall and not the entire socket,

which is good from a safety perspective and no damage of user was recorded. However, during the evaluation of participant 3, the aluminium struts appeared too weak to withstand some of the bending motions and the stresses on the socket appeared substantial, rising a concern for the durability. Since a proper evaluation of the durability was not conducted, the bypass-socket should not be used without a safety harness for users between 80-100 kg even if the users are supporting themselves with their hands.

The reason for the fracture can also be due to fatigue in the bend. As buckling occurred due to the slim radius of the 90° bend, this area of the strut was weak and could not withstand the bending forces. As the participants and additional users walking with the socket perceived instability, causing a bending motion as mentioned, this could have caused the struts to bend slightly back and forth. The weak area could thereby have suffered a fracture due to fatigue or was weaker due to fatigue and broke more easily at the occurrence of the fall. To increase the strength at this 90° bend, a larger radius is necessary so that the lower part of the strut does not suffer from buckling. A pipe elbow could also be used which eliminates the risk of buckling.

The required range of use for the bypass-socket was 160 – 190 cm which is considered to be fulfilled. Participant 2 was 194 cm and could be fitted with the socket well, implying that the upper limit is greater could be greater than required. Participant 1 as 167 cm and is thereby taller than the lower user limit. During the usage, the lengths of the struts were not set to their minimum but had approximately 4 cm of which they could be shortened. This indicates that shorter people should be able to use it as well, fulfilling the range of user height requirement.

8. Conclusion

The purpose of the thesis was to design a bypass-socket which could be attached to a standard lower limb prosthesis to enable researchers with intact legs to do initial evaluation and testing of prosthetic control algorithms. The bypass should be adjustable to fit a wide range of users, be EMG compatible, not cause unnatural locomotion, and be reproducible without using advanced manufacturing processes.

By using an on-the-side connector, placing the bypass-socket on the side of the prosthesis to level the knees, a moment is induced and imbalance occurs as the placement of the prosthesis is further lateral than normal. As compensation, limping was noted during initial trials, resulting in an unnatural locomotion. Gain in such design will most likely be unrealistic due to the induced moment. The on-the-side connector was thereby considered unusable in this work.

The bypass-socket design on-top, rather than on-the-side, was found usable by people between 167-194 cm, and potentially by people around 160 cm tall. EMG recording for extending and flexing the knee was considered plausible. The socket is durable enough to be used by people up to 80 kg. The durability is questionable when used by people weighing 100 kg and safety harness should always be used for people between 80-100 kg. The knee was found stable in the bypass-socket but some relative movement between the proximal end of the socket and the thigh was observed. Training was needed before proper usage of a prosthetic leg was possible, and all participants had problems with instability, most likely as a combination of inexperience with prosthetic use and the bypass-socket. A limping was present causing an unnatural locomotion, but not as severe as with the on-the-side connector. An evaluation with a prosthetist is required for correct placement of the prosthetic components to evaluate the effect of the bypass-socket. A stronger material or larger diameter is needed for the struts, and the 90° bend at the distal end of the struts needs to be improved. For research purpose, the bypass-socket was considered usable and useful.

References

[1] H. Van De Meent, M. T. Hopman, and J. P. Frölke, “Walking ability and quality of life in subjects with transfemoral amputation: A comparison of osseointegration with socket prostheses,” *Arch. Phys. Med. Rehabil.*, vol. 94, no. 11, pp. 2174–2178, 2013.

[2] V. Rajťúková, M. Michalíková, L. Bednarcíková, A. Balogová, and J. Živčák, “Biomechanics of lower limb prostheses,” *Procedia Eng.*, vol. 96, no. February 2015, pp. 382–391, 2014.

[3] L. J. Marks and J. W. Michael, “Artificial limbs,” *Sensors (Peterborough, NH)*, vol. 323, no. September, pp. 732–735, 2001.

[4] P. Contributors, “Lower Limb Prosthetic Sockets and Suspensions Systems,” *Physiopedia*, 2020. [Online]. Available: https://www.physio-pedia.com/index.php?title=Lower_Limb_Prosthetic_Sockets_and_Suspension_Systems&oldid=229830. [Accessed: 03-May-2020].

[5] A. F. T. Mak, M. Zhang, and D. A. Boone, “State-of-the-art research in lower-limb prosthetic biomechanics- socket interface : A review,” vol. 38, no. 2, pp. 161–174, 2001.

[6] M. Zhang, A. F. T. Mak, and V. C. Roberts, “Finite element modelling of a residual lower-limb in a prosthetic socket: A survey of the development in the first decade,” *Med. Eng. Phys.*, vol. 20, no. 5, pp. 360–373, 1998.

[7] K. Hagberg, R. Brånemark, B. Gunterberg, and B. Rydevik, “Osseointegrated trans-femoral amputation prostheses: Prospective results of general and condition-specific quality of life in 18 patients at 2-year follow-up,” *Prosthet. Orthot. Int.*, vol. 32, no. 1, pp. 29–41, 2008.

[8] J. Tillander, K. Hagberg, L. Hagberg, and R. Brånemark, “Osseointegrated titanium implants for limb prostheses attachments: Infectious complications,” *Clin. Orthop. Relat. Res.*, vol. 468, no. 10, pp. 2781–2788, 2010.

[9] C. D. Hoover, G. D. Fulk, and K. B. Fite, “The Design and Initial Experimental Validation of an Active Myoelectric Transfemoral Prosthesis,” *J. Med. Devices, Trans. ASME*, vol. 6, no. 1, pp. 1–12, 2012.

[10] B. Laschowski and J. Andrysek, “Electromechanical design of robotic transfemoral prostheses,” *Proc. ASME Des. Eng. Tech. Conf.*, vol. 5A-2018, pp. 1–10, 2018.

[11] F. Sup, A. Bohara, and M. Goldfarb, “Design and control of a powered transfemoral prosthesis,” *Int. J. Rob. Res.*, vol. 27, no. 2, pp. 263–273, 2008.

[12] H. Huang, T. A. Kuiken, and R. D. Lipschutz, “A strategy for identifying locomotion modes using surface electromyography,” *IEEE Trans. Biomed. Eng.*, vol. 56, no. 1, pp. 65–73, Jan. 2009.

[13] S. K. Wu, G. Waycaster, and X. Shen, “Electromyography-based control of active above-knee prostheses,” *Control Eng. Pract.*, vol. 19, no. 8, pp. 875–882, 2011.

[14] F. C. Sup and M. Goldfarb, “Design of a pneumatically actuated transfemoral prosthesis,” *Am. Soc. Mech. Eng. Dyn. Syst. Control Div. DSC*, no. January 2006, 2006.

[15] R. D. Alley, T. W. Williams, M. J. Albuquerque, and D. E. Altobelli, “Prosthetic sockets stabilized by alternating areas of tissue compression and release,” *J. Rehabil. Res. Dev.*, vol. 48, no. 6, pp. 679–696, 2011.

[16] B. C. Wehe, “An Overview of Transfemoral Socket Designs,” vol. 463, 1993.

[17] J. E. Sanders and S. Fatone, “Residual limb volume change: Systematic review of measurement and management,” *J. Rehabil. Res. Dev.*, vol. 48, no. 8, pp. 949–986, 2011.

[18] “HiFi Socket Interface Casting - Cornerstone Prosthetics - YouTube.” [Online]. Available: https://www.youtube.com/watch?time_continue=28&v=CPbNrOcCyh4&feature=emb_logo. [Accessed: 04-May-2020].

[19] artlimb, “Prosthetic Alignment: Part1. The Basics.” [Online]. Available: http://www.artlimb.com/more-details/lower-limb-articles/prosthetic-alignment-part1-basics/. [Accessed: 06-May-2020].

[20] artlimb, “Prosthetic Alignment: Part2. The Socket.” [Online]. Available: http://www.artlimb.com/more-details/lower-limb-articles/prosthetic-alignment-part2/. [Accessed: 06-May-2020].

[21] artlimb, “Prosthetic Alignment: Part3. The Foot.” [Online]. Available: http://www.artlimb.com/more-details/lower-limb-articles/prosthetic-alignment-part3/. [Accessed: 07-May-2020].

[22] artlimb, “Prosthetic Alignment Part 4. Joints.” [Online]. Available: http://www.artlimb.com/more-details/lower-limb-articles/prosthetic-alignment-part-4-joints/. [Accessed: 07-May-2020].

[23] M. Buzzi, G. Colombo, G. Facoetti, S. Gabbiadini, and C. Rizzi, “3D modelling and knowledge: Tools to automate prosthesis development process,” *Int. J. Interact. Des. Manuf.*, vol. 6, no. 1, pp. 41–53, 2012.

[24] M. Zhang and A. F. T. Mak, “In vivo friction properties of human skin,” *Prosthet. Orthot. Int.*, vol. 23, no. 2, pp. 135–141, 1999.

[25] C. D. Hoover, G. D. Fulk, and K. B. Fite, “Stair ascent with a powered transfemoral prosthesis under direct myoelectric control,” *IEEE/ASME Trans. Mechatronics*, vol. 18, no. 3, pp. 1191–1200, 2013.

[26] G. M. Hefferman, F. Zhang, he Huang, and M. J. Nunnery, “Integration of surface electromyographic sensors with the transfemoral amputee socket: A comparison of four differing configurations,” *Prosthet. Orthot. Int.*, vol. 39, no. 2, pp. 166–173, 2015.

[27] V. Gillis, “Real-time intention detection of locomotion modes using Electromyography,” 2019.

[28] D. A. Winter, *Biomechanics and Motor Control of Human Movement: Fourth Edition*. 2009.

[29] J. E. Sanders, R. A. Miller, D. N. Berglund, and S. G. Zachariah, “A modular six-directional force sensor for prosthetic assessment: A technical note,” *J. Rehabil. Res. Dev.*, vol. 34, no. 2, pp. 195–202, 1997.

[30] “ATI Industrial Automation: Multi-Axis Force / Torque Sensors.” [Online]. Available: https://www.ati-ia.com/products/ft/sensors.aspx. [Accessed: 30-Aug-2020].

[31] JR3 Inc, “Force-Torque Sensors.” [Online]. Available: https://www.jr3.com/products/force-torque-sensors. [Accessed: 30-Aug-2020].

[32] G. Fiedler, B. Slavens, R. O. Smith, D. Briggs, and B. J. Hafner, “Criterion and construct validity of prosthesis-integrated measurement of joint moment data in persons with transtibial amputation,” *J. Appl. Biomech.*, 2014.

[33] L. Gabert and T. Lenzi, “Instrumented Pyramid Adapter for Amputee Gait Analysis and Powered Prosthesis Control,” *IEEE Sens. J.*, vol. 19, no. 18, pp. 8272–8282, 2019.

[34] L. Frossard, J. Beck, M. Dillon, and J. Evans, “Development and Preliminary Testing of a Device for the Direct Measurement of Forces and Moments in the Prosthetic Limb of Transfemoral Amputees during Activities of Daily Living,” *J. Prosthetics Orthot.*, vol. 15, no. 4, pp. 135–142, 2003.

[35] P. Stephenson and B. B. Seedhom, “Estimation of forces at the interface between an artificial limb and an implant directly fixed into the femur in above-knee amputees,” *J. Orthop. Sci.*, vol. 7, no. 3, pp. 292–297, 2002.

[36] A. Thesleff, S. Ludvigsson, E. Ohr, and M. Ortiz-Catalan, “Load exposure of osseointegrated implants for transfemoral limb prosthesis during running,” *Proc. Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. EMBS*, vol. 2018-July, pp. 1743–1746, 2018.

[37] R. Dumas, L. Cheze, and L. Frossard, “Loading applied on prosthetic knee of transfemoral amputee: Comparison of inverse dynamics and direct measurements,” *Gait Posture*, vol. 30, no. 4, pp. 560–562, 2009.

[38] B. Welke, M. Schwarze, C. Hurschler, T. Calliess, and F. Seehaus, “Multi-body simulation of various falling scenarios for determining resulting loads at the prosthesis interface of transfemoral amputees with osseointegrated fixation,” *J. Orthop. Res.*, vol. 31, no. 7, pp. 1123–1129, 2013.

[39] M. Schwarze, C. Hurschler, F. Seehaus, T. Correa, and B. Welke, “Influence of transfemoral amputation length on resulting loads at the osseointegrated prosthesis fixation during walking and falling,” *Clin. Biomech.*, vol. 29, no. 3, pp. 272–276, 2014.

[40] F. Sup, H. A. Varol, J. Mitchell, T. Withrow, and M. Goldfarb, “Design and control of an active electrical knee and ankle prosthesis,” *Proc. 2nd Bienn. IEEE/RAS-EMBS Int. Conf. Biomed. Robot. Biomechatronics, BioRob 2008*, pp. 523–528, 2008.

[41] K. Fite, J. Mitchell, F. Sup, and M. Goldfarb, “Design and control of an electrically powered knee prosthesis,” *2007 IEEE 10th Int. Conf. Rehabil. Robot. ICORR’07*, pp. 902–905, 2007.

[42] M. Liu, F. Zhang, P. Datseris, and H. (Helen) Huang, “Improving Finite State Impedance Control of Active-Transfemoral Prosthesis Using Dempster-Shafer Based State Transition Rules,” *J. Intell. Robot. Syst. Theory Appl.*, vol. 76, no. 3–4, pp. 461–474, 2014.

[43] R. D. Gregg, T. Lenzi, N. P. Fey, L. J. Hargrove, and J. W. Sensinger, “Experimental effective shape control of a powered transfemoral prosthesis,” *IEEE Int. Conf. Rehabil. Robot.*, pp. 1–7, 2013.

[44] T. Lenzi, L. J. Hargrove, and J. W. Sensinger, “Preliminary evaluation of a new control approach to achieve speed adaptation in robotic transfemoral prostheses,” *IEEE Int. Conf. Intell. Robot. Syst.*, no. Iros, pp. 2049–2054, 2014.

[45] D. Quintero, D. J. Villarreal, and R. D. Gregg, “Preliminary experiments with a unified controller for a powered knee-ankle prosthetic leg across walking speeds,” *IEEE Int. Conf. Intell. Robot. Syst.*, vol. 2016-Novem, pp. 5427–5433, 2016.

[46] Ottobock, “Prosthetics - Lower limbs.”

[47] SCB, “Varannan svensk har övervikt eller fetma,” 09-Oct-2018. [Online]. Available: https://www.scb.se/hitta-statistik/artiklar/2018/varannan-svensk-har-overvikt-eller-fetma/. [Accessed: 16-Sep-2020].

[48] R. G. Redhead, “The early rehabilitation of lower limb amputees using a pneumatic walking aid,” *Prosthet. Orthot. Int.*, vol. 7, no. 2, pp. 88–90, 1983.

[49] A. Randall, “Adaptable socket system, method, and kit,” US10369027B2, 06-Aug-2019.

[50] Bulldog Tools, “Titanium 4-Hole Base + Titanium Male Adapter.” [Online]. Available: http://www.bulldogtools.com/prosthetic/titanium-hole-base-titanium-male-hole_p_6966.html. [Accessed: 16-Sep-2020].

[51] Bauhaus, “VINKEL JOMA 2,5X90X90X65MM STÅLPLÅT.” [Online]. Available: https://www.bauhaus.se/vinkel-2-5x90x90x65. [Accessed: 22-Mar-2020].

[52] Bauhaus, “U-PROFIL ALUMINIUM 15X19,9X15X2MM 2M.” [Online]. Available: https://www.bauhaus.se/u-profil-aluminium-15x19-9x15x2mm-2m. [Accessed: 18-Mar-2020].

[53] Hornbach, “Plattstav KAISERTHAL stål 15x5 mm 1 m - köp.” [Online]. Available: https://www.hornbach.se/shop/Plattstav-KAISERTHAL-stal-15x5-mm-1-m/8829113/artikel-detaljer.html. [Accessed: 24-Jul-2020].

[54] Slöjd-Detaljer, “Aluminiumrör - Längd 1 m.” [Online]. Available: https://www.slojd-detaljer.se/sortiment/tra-metallslojd/ror-stanger/aluminium/aluminiumror-8740. [Accessed: 17-Sep-2020].

[55] Nedal, “Alloy data sheet EN AW 6060,” 2017. [Online]. Available: https://www.nedal.com/wp-content/uploads/2017/11/Nedal-alloy-Datasheet-EN-AW-6060.pdf. [Accessed: 29-Aug-2020].

[56] H. Gray, “The Muscles and Fasciæ of the Thigh,” in *Anatomy of the human body, by Henry Gray. 20th ed., thoroughly rev. and re-edited by Warren H. Lewis.*, 1918.

Appendix A – Requirement specification

Requirement specification: Bypass adapter							
Issuer: Victor Öberg		***Created: 2020-02-28*** ***Modified: 2020-05-26***					
	Criteria	***Target value***	***Requirement/Request***	***Weighting***	***Verification***	***Reference***	***Comments***
1.	**sEMG compatible**						
1.1	Four sites	Quadriceps + biceps femoris	Requirement				Mainly used in knee motion
1.2	More than four sites	Quadriceps + biceps femoris + others	Request	5			
2.	**Durability**						
2.1	Static load	4 000N	Requirement		Finite Element Analysis		Falling
2.2	Repetitive load	1 000 N	Requirement		Static test with weights		Walking
2.3	Repetitive load	2 400 N	Request	5	Finite Element Analysis		Running
2.4	Cycles	162 500	Requirement		Finite Element Analysis		Based on 5000 steps per leg and day, where 8 hours are effective. 1h/week for 5 years
2.5	Cycles	325 000	Request	3	Finite Element Analysis		1h/week for 10 years
3.	**Bypass compatibility**						
3.1	Fit able-bodied leg	Fit able-bodied between 160-190 cm	Requirement		User test	BNL group	
3.2	Fit transfemoral stumb	short - normal stumb lengths	Request	3			Usable by amputee patients
3.3	Under-the-knee	Prosthesis attached under the knee	Request	5	User test		Either 3.3 or 3.4 is required to be fulfilled
3.4	On-the-side	Prosthesis attached on the knee side	Request	5			
4.	**Prosthetic compatibility**						
4.1	Fit standard components	4-hole pattern OR pyramid adapter/reciever	Requirement				
5.	**Manufacturing**						
5.1	Standard processes	Widely used processes	Request	4	Prototype	Chalmers	3D-printing and/or mashines and materials in ordinary workshops and hardware stores.
5.2	Primitive processes	Not requiring expensive/advanced tools	Request	4	Prototype	Chalmers	
6.	**Size**						
6.1	Highest minimum socket height	22.4 cm	Requirement		Concept analysis		Highest allowed socket wall hight when adjusted for the shortest user.
6.2	Lowest maximum socket height	32.6 cm	Requirement		Concept analysis		Lowest allowed socket wall hight when adjusted for the tallest user.
6.3	Adjustable socket height	4 lengths	Requirement		Concept analysis		
6.4	Adjustable socket height	< 4 lengths	Request	5	Concept analysis		

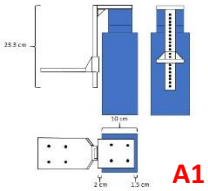
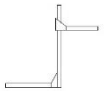
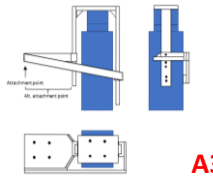
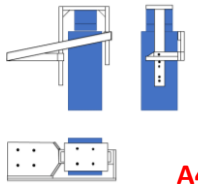
7.	**Weight**						
7.1	Maximum weight		Requirement				
8.	**Material**						
8.1	Polymer	3D-printed	Request	4	Prototype		Widely used and accessible in BNL.
8.2	Metal	Light weight	Request	4	Prototype		
8.3	Accessible	Sold in hardware stores	Request	5	Prototype	Public hardware stores	Easy to buy and widely accessible.
10.	**Ergonomics**						
10.1	Comfortable	No tissue damage < 1h	Requirement		User test	BNL group	Protective padding
10.2	Comfortable	No tissue damage > 1h	Request	3	User test	BNL group	
10.3	Normal locomotion	During gait	Requirement		User test	BNL group	Should not produce unnatural motions
10.4	Normal locomotion	During running	Request	3	User test	BNL group	
10.5	Alignment	Correct construction line	Requirement				
11.	**Quality**						
12.	**Safety**						
	Stable		Requirement		User test	BNL group	
13.	**Patent and literature**						
13.1	Unpatented	Not vaildate patents	Request	3	Concept analysis		

Appendix B – Evaluation matrices

The designs are assessed using an evaluation matrix for each sub-function. The criterions in the matrices are different, depending on the sub-function and what is most critical. The more complex the circumstances for the sub-function is, the more criterions are needed in the matrix to give a fair judgement of the design. The criterions are based upon the requirement specification, and a few are based upon usage intuition, and are weighted from 1 – 5 to set aside the most important, for instance safety-related, from the less important, for instance visual intuition. The higher the weighting, the more important is the criteria. Points are then given to the designs from 1 – 5, based on how well they are presumed to fulfil each criterion. The points are given individually, meaning that multiple designs can get the same points. In the sub-functions of the knee-plate, the criteria of amputee compatibility can only be given points from 1 – 3 since the plates are either compatible or not. For each design, the criteria score is the weight of the criteria multiplied by the given points for the design, and the final score is the sum of the criteria score. The best solutions in each sub-function is marked with green. The designs are referred to as the letter-number combination given in Figure 6-Figure 10.

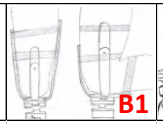
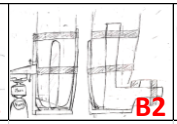
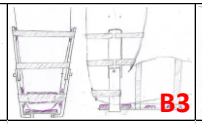
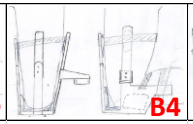
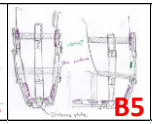
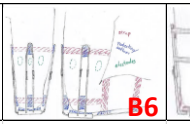
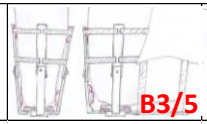
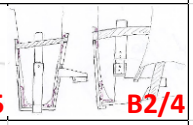
A1 is attached directly to the longitudinal beam, leaving that the distance between the end of the beam and the knee will change and minimizing the risk of the beam interfering with the socket. When the entire length of the beam is not needed the 4-hole pattern could be moved in closer to the prosthesis to minimize the effect of the lever. In *A2* the distance between the end of the beam and the knee is fixed to the greatest distance and might interfere with the socket. The evaluation matrix is presented in Table 9.

Table 9: Evaluation matrix for the on-the-side-connector.

On-the-side connector							
Criterias	**Weighting**	**Max. points**	 A1	 A2	 A3	 A4	
Manufactor complexity	4	5	5	5	3	3	How difficult it is to manufactor, in terms of the shape, low point => complex
Material access	4	5	4	4	4	4	What material it's made from and the accessability
Stability	5	5	3	3	4	4	The stability for the connected strut
Moment resistance	5	5	3	3	4	4	How well it can withstand the moments from the struts
Axial force resistance	5	5	3	3	4	4	How good it can handle axial force
Initial moment neutralization	5	5	1	1	2	2	How well the induced moment due to the lever can be "neutralized"
Socket interference risk	4	5	4	3	4	4	Risk of the longitudinal beam interfereing with the socket
Visual intuitivity	3	5	5	5	4	4	How easy it is to see how to fasten the strut
Functional intuitivity	5	5	5	5	4	4	How easy it is to actually fasten the strut
Mass	4	5	5	5	3	3	How much it weighs.
Total points		50	38	37	36	36	
Weighted points		220	162	158	158	158	

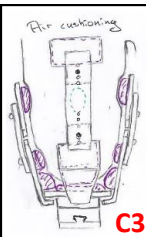
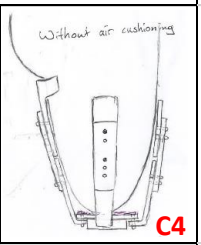
The able-bodied sockets are evaluated based mainly on the EMG compatibility, stability/strength and capability of adjusting. *B1* has different sizes on the front struts compared to the medial and lateral struts which makes it difficult if the struts are to be moved to other locations around the leg. The support is then non-symmetric and might result in an unnatural gait. *B5* has a rather non-complex design but cannot be amputee compatible. For an able-bodied design, it has potential. *B3* has many joints in the struts, which makes the design complex and risk of being unstable. The design should be combined with the struts from *B5* to reduce complexity and risk of instability. This design can be made amputee compatible and gets a high score. Designs *B2* and *B4* are similar in design with the exception that *B4* is fixed to the connection plate while *B2* can be moved and detached but cannot be adjusted in height. This means that a combination between *B4* and *B2* gets a higher score than what they get individually. The highest score is the combination between *B5* and *B3* since this can be made amputee compatible. *B6* is the only concept with pin-struts and will be further evaluated. The evaluation matrix is seen in Table 10.

Table 10: Evaluation matrix for the able-bodied struts.

Socket - Able bodied											
Criterias	**Weighting**	**Max. points**	 **B1**	 **B2**	 **B3**	 **B4**	 **B5**	 **B6**	 **B3/5**	 **B2/4**	
Manufactor complexity	4	5	3	4	5	4	3	4	4	3	How difficult it is to manufactor, in terms of the shape
Material access	4	5	4	4	5	4	4	4	4	4	What material it's made from and the accessability
Stability/control	5	5	4	4	4	5	5	4	5	5	Stability of the able-body's leg
Horizontal forces	5	5	3	4	2	5	3	4	4	4	horizontal forces on the struts. Many joints, now that heigh frontal strut, detachable struts gives lower score
Shin support	4	5	4	4	4	4	3	3	3	4	Capability of supporting the shin
EMG capability	5	5	4	2	5	3	4	5	4	3	How well the muscles can be "reached"
Angular adjustment	5	5	5	3	2	1	5	4	5	3	Angular adjustment around the central axis of the socket
Height adjustment	5	5	4	1	4	4	5	4	4	4	Ability to change the length of the struts to fit different dimensions of thighs
Residual limb compability	4	3	2	1	1	1	3	3	3	1	Ability to be desgined in such a way that it can be made to fit a residual limb as well
Visual intuitivity	3	5	4	5	4	4	3	4	4	4	How easy it is to see how to fasten the strut
Functional intuitivity	4	5	4	5	5	5	4	4	5	5	How easy it is to actually fasten the strut
Total points		53	41	37	41	40	42	43	45	40	
Weighted points		125	180	157	177	174	187	189	198	175	

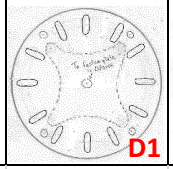
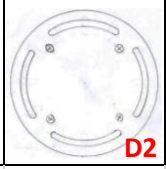
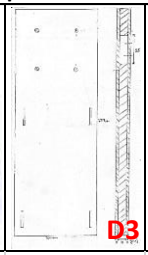
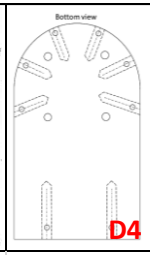
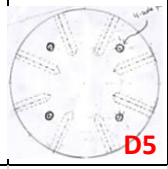
Stability, force distribution, and adjustment capabilities are the primary focuses for the evaluation of the residual limb compatible sockets. *C2* is not suitable for adjustments in different variations in the lengths of the residual limbs and can only be adjusted to a small degree in the anterior/posterior and the medial/lateral directions. Making this not that adjustable compared to the other designs and is therefore eliminated. *C3* has a complex structure due to the compression zones being horizontal and in the top part of the socket. They can though be made to support the ischial tuberosity instead of compression. If the horizontal compression zones are made rotatable, the areas of compression can either be longitudinal along the femur or horizontal, making this the best design for residual limbs. This is even though it has a complex construction and rely on air cushioning for adequate compression for varying stump shapes. *C4* is the only design that does not rely on compression and release zone to operate. Since compression zones might obstruct the EMG recordings, this design is necessary to evaluate as an alternative. *C1* has longitudinal compression only and thereby gets a lower score than *C3* even though the design is less complex. The best design compatible for an individual with a transfemoral amputation is *C3* and *C4.* The evaluation matrix is presented in Table 11.

Table 11: Evaluation matrix for the residual limb compatible struts.

Socket - Residual limb							
Criterias	**Weighting**	**Max. points**	 **C1**	 **C2**	 **C3**	 **C4**	
Manufactor complexity	4	5	4	2	3	4	How difficult it is to manufactor, in terms of the shape
Material access	4	5	3	2	3	4	What material it's made from and the accessability
Socket stability	5	5	4	5	4	3	Stability of the residual limb
Force distribution	5	5	4	5	4	2	How much the force is distributed (leading to better comfort)
EMG placement	5	5	3	3	4	4	How well the muscles can be "reached"
EMG readings	5	5	3	3	4	5	How good the muscles signals are, discuss with maria?
Angular adjustment	5	5	4	2	4	3	Angular adjustment around the central axis of the socket
Height adjustment	5	5	4	1	5	4	Ability to change the length of the struts to fit different dimensions of thighs
Stump variation	5	5	4	1	4	3	Ability to adjust depending on the shape of the stump
Visual intuitivity	3	5	3	5	3	5	How easy it is to see how to use
Functional intuitivity	4	5	4	5	4	5	How easy it is to actually use
Total points		55	40	34	42	42	
Weighted points		225	183	151	198	192	

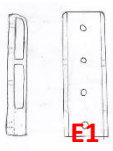
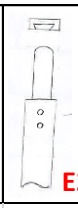
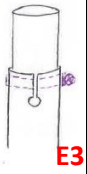
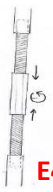
The knee-plates are evaluated based on the adjustability, strength, stability. *D1* allows less angular adjustment than *D2* but allows some adjustments in the medial/lateral and anterior/posterior directions. Both need some distance plate to make room for attachment of the prosthesis component. *D1* gets a higher score than *D2*. *D3* can only fit two flat struts and is not amputee compatible but is simple to build and gives good support for the shin. The struts are firmly attached giving the socket stability and can easily be adjusted in both the medial and lateral directions. *D3* gets a high score. *D4* and *D5* are both for pin-struts, but *D5* is amputee compatible while *D4* is not. In that category, *D4* gets a higher score since it gives better support for the shin and is assumed to be easier to build. *D6* can be combined with connections plate such as *D1* and *D2* but does not allow as good connections as *D4*, this since the connection involves more parts. For pins-struts, *D4* gets higher score than *D6. D7* is the connection point of the flat strut and is thereby needed. The evaluation matrix is presented in Table 12.

Table 12: Evaluation matrix for the knee-plates.

Knee-plate										
Criterias	**Weighting**	**Max. points**	 D1	 D2	 D3	 D4	 D5	 D6	 D7	
Manufactor complexity	4	5	3	3	5	5	4	5	5	How difficult it is to manufactor, in terms of the shape
Material access	4	5	4	4	5	5	5	4	4	What material it's made from and the accessability
Number of parts	2	5	4	4	3	5	5	4	4	How many parts that the connection plate is made of or requires to opperate e.g. distance plate
Stability, strut	5	5	4	4	5	5	5	4	4	The stability for the connected strut
Strut compatibility	5	5	5	5	3	4	4	4	4	What type of truts that fits, eg. flat/pin and the number of pins.
Moment resistance	5	5	3	3	5	4	4	4	4	How well it can withstand the moments from the struts
Axial force resistance	5	5	4	4	5	5	5	3	3	How good it can handle axial force
Shin support capability	4	5	3	3	5	5	4			Capability of supporting the shin
Ampute compability	2	3	3	3	1	1	3			How easy it is to make amputee compatible, 1-3 in grade in it is or isn't since they are round or not
Angular adjustment	5	5	5	4	1	3	3			Angular adjustment around the central axis of the socket
Dimension adjustment	5	5	4	2	5	5	5	1	5	Ability to adjust due to anterior/posterior and medial/lateral changes
Visual intuitivity	3	5	4	3	5	3	3	5	3	How easy it is to see how to fasten the strut
Functional intuitivity	5	5	5	5	5	5	5	5	4	How easy it is to actually fasten the strut
Total points		63	51	47	53	55	55	39	40	
Weighted points		130	216	198	228	236	232	164	173	

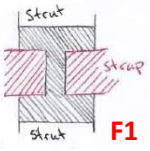
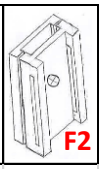
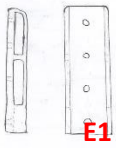
The height adjustments are mainly evaluated based on stability, strength and functional intuition. *E4* and *E3* are both made for pin-shaped struts. *E4* uses two lead screws and should probably be made by metal. Since lead screws are standard, the complicated part is to connect the lead screws to the connector in the middle. This height adjustment requires two joints where movement occurs (at the ends where the lead screws moves), which risk instability. *E3* has only one joint that moves, leading to a lower risk of instability. By fixing the telescopic function with a hose clamp, this solution is slightly easier than *E4* and therefor also better. *E2* and *E1* are only suitable for flat struts. *E2* has a less complex structure than *E1* and thereby gets a higher score. Both types are suitable for metallic material, but since *E2* has a larger cross section area and thereby greater strength, 3D-printing can be considered for this part making it easier to manufacture for researchers. The best height adjustment designs are *E3* and *E2*. The evaluation matrix is presented in Table 13.

Table 13: Evaluation matrix for the height adjustments.

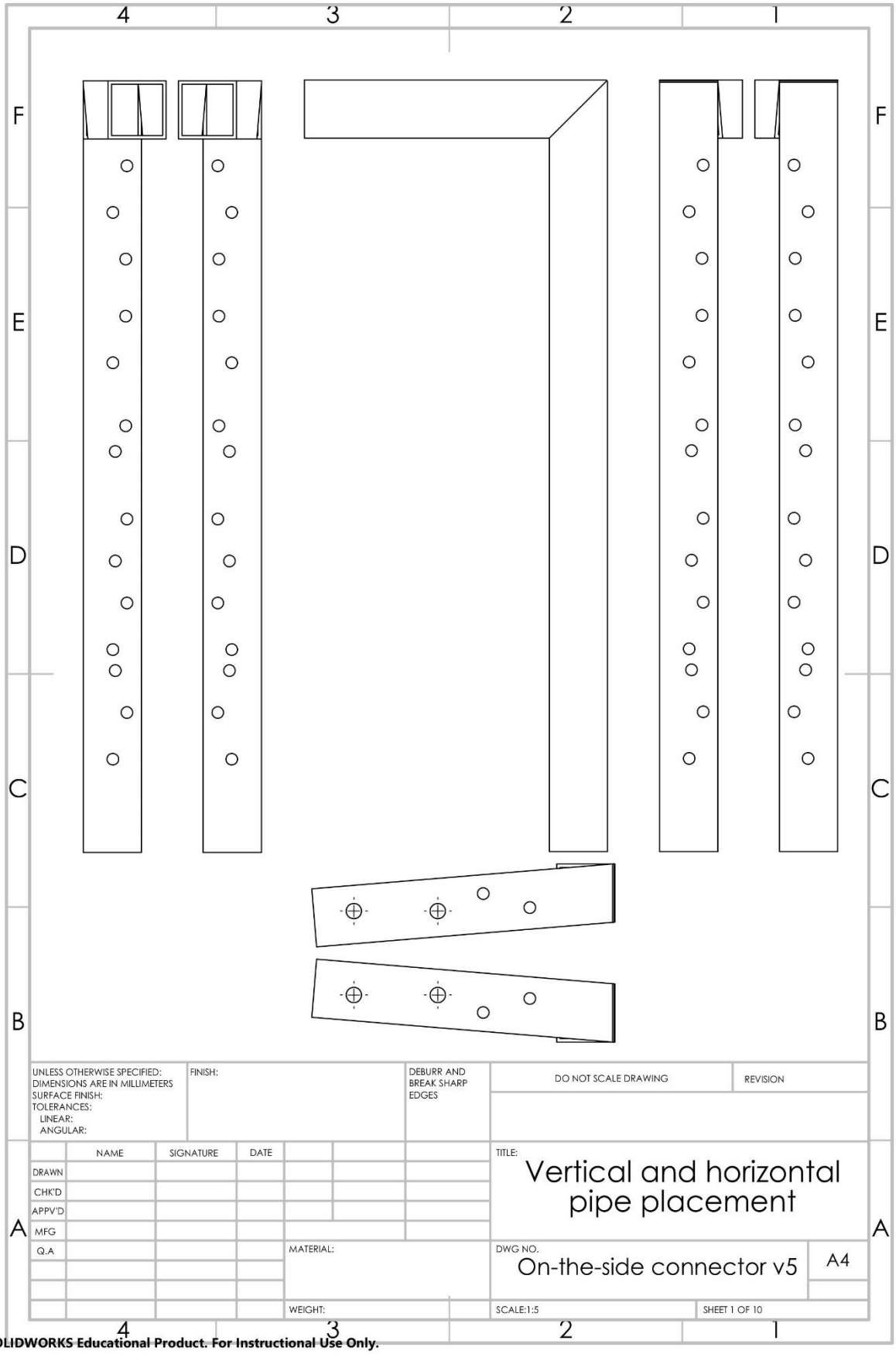
Height adjustment							
Criterias	**Weighting**	**Max. points**	 E1	 E2	 E3	 E4	
Manufactor complexity	4	5	2	5	4	3	How it is t be produced
Material access	4	5	4	4	4	3	What material it can be made of, not known if the right dimensions are accessable
Stability	5	5	5	5	4	4	Stability affected by joints
Strength	5	5	4	5	4	3	The strength in the design, cross sectional shape
Visual intuitivity	3	5	3	4	4	5	How intuitiv the usage is when looking at it
Functional intuitivity	5	5	4	5	4	5	How hard it is to use
Total points		30	22	28	24	23	
Weighted points		130	98	123	104	99	

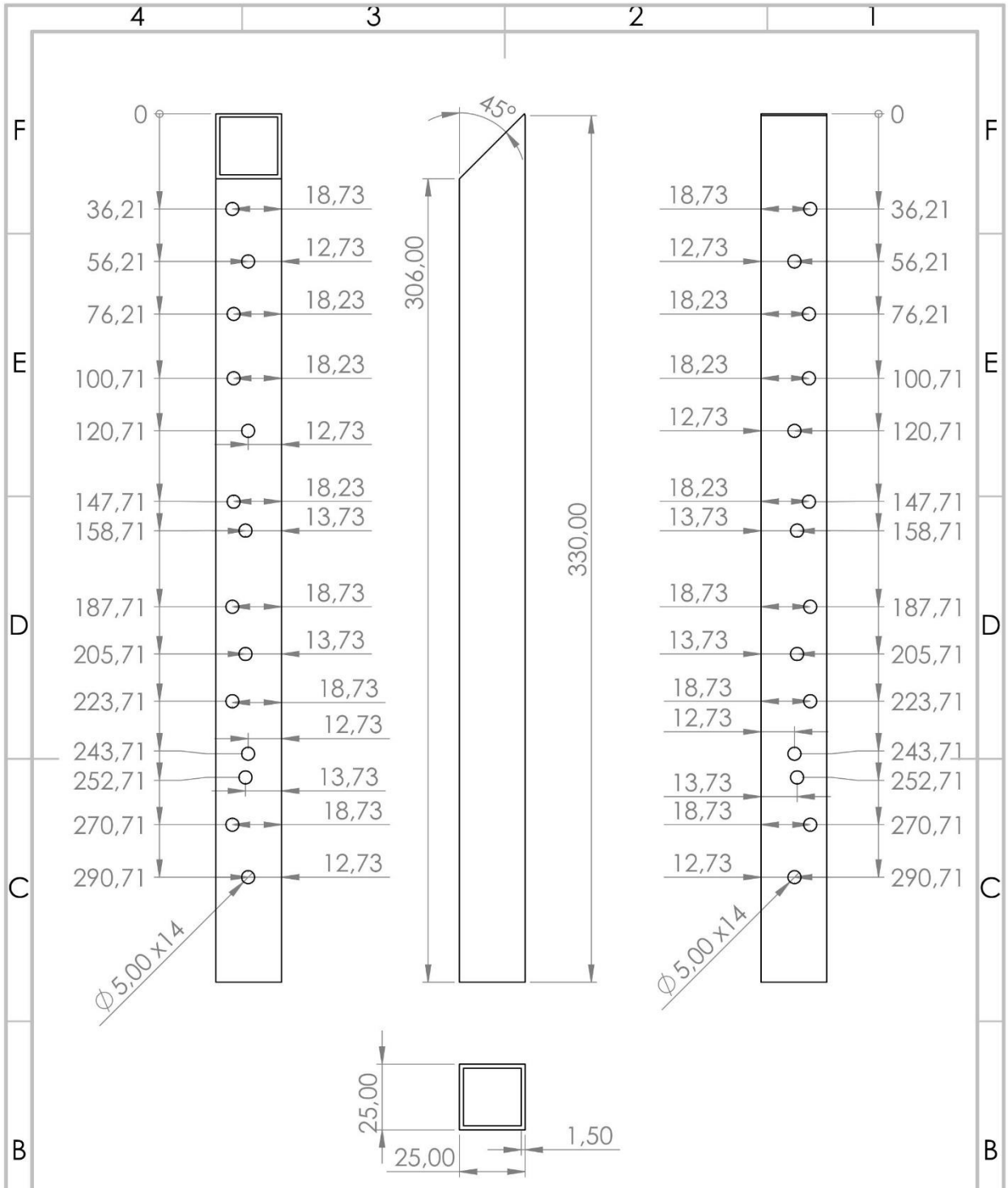
The main evaluation criteria for the supporting structure is the given support. *F1* is easy to make and can be made by fabric and foam. It is soft and might need some more support to not give in too much for the strut, if the strut is made by bended tubes. For flat struts, no more support is probably needed. *F2* is preferably made by 3D-printing and attached to a flat strut. The outer part might not be needed it the loops for the strap is attached to the inner side. Since both *F1* and *F2* are made for flat struts, *F2* gets the higher grade since it provides better support. *F3* can only fit pin-struts and is preferably 3D-printed. Since *F1* is made by fabric *F3* is better for pin-struts. *E1* is combined with height adjustment and holder for the strap. This implies a complex shape and since it is going to take load as it is part of the strut, this might not be 3D-printed but instead made by steel or aluminium. This makes it harder to fabricate and thereby gets the lowest score. The evaluation matrix is presented in Table 14.

Table 14: Evaluation matrix for the supporting surface structure.

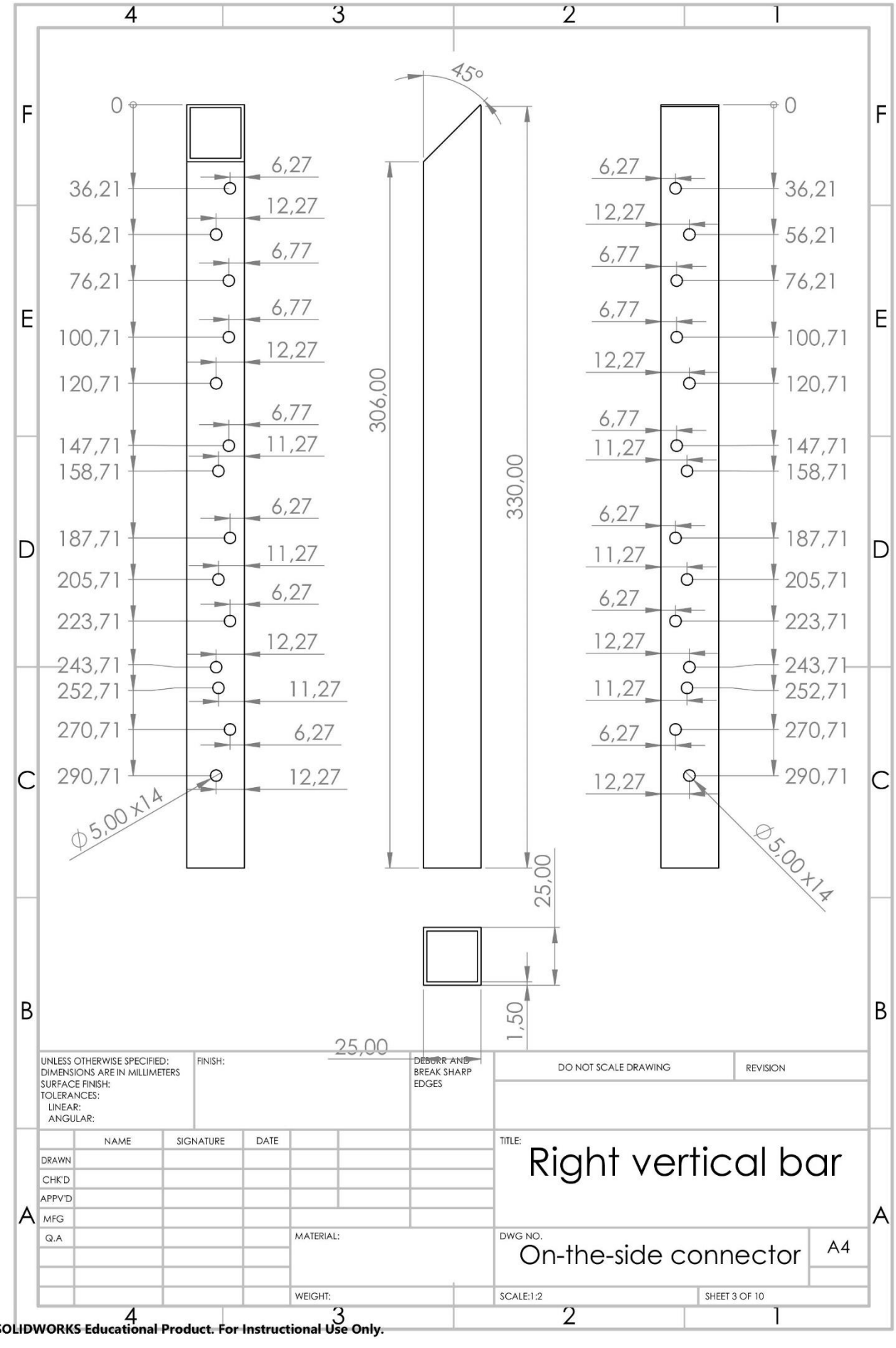
Supporting surface structure						
Criterias	**Weighting**	**Max. points**	 F1	 F2	 F3	 E1
Manufactor complexity	4	5	5	3	3	2
Support	5	5	2	5	5	5
Material access	4	5	5	4	4	3
Total points		15	12	12	12	10
Weighted points		65	50	53	53	45

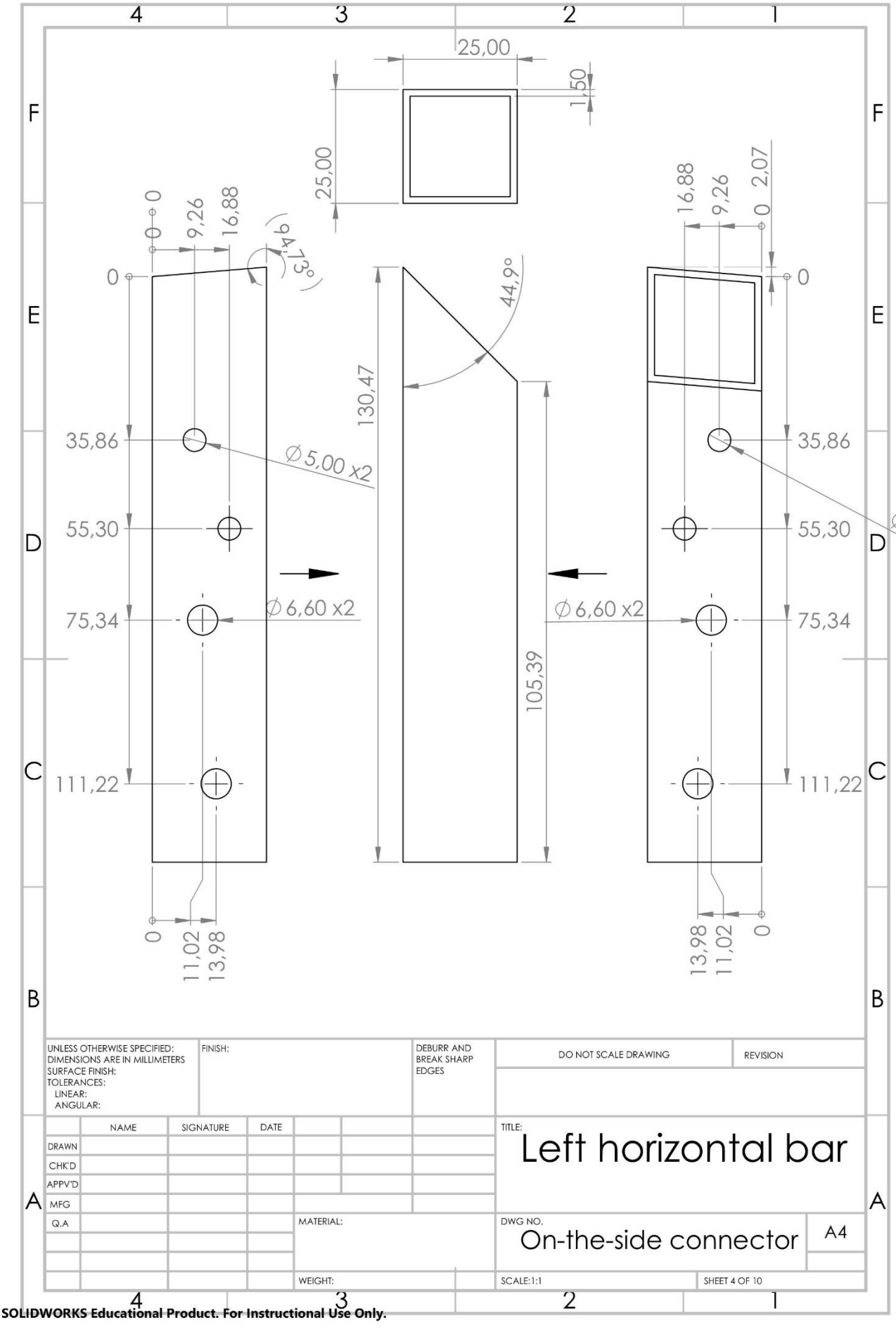
Appendix C – Drawings for the on-the-side connector





UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:		DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION		
	NAME	SIGNATURE	DATE	TITLE:			
DRAWN				Left vertical bar			
CHK'D							
APPV'D							
MFG							
Q.A				MATERIAL:	DWG NO.	A4	
					On-the-side connector		
				WEIGHT:	SCALE:1:2	SHEET 2 OF 10	





UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:	DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING / REVISION

	NAME	SIGNATURE	DATE
DRAWN			
CHK'D			
APPV'D			
MFG			
Q.A			

TITLE: Left horizontal bar

MATERIAL:

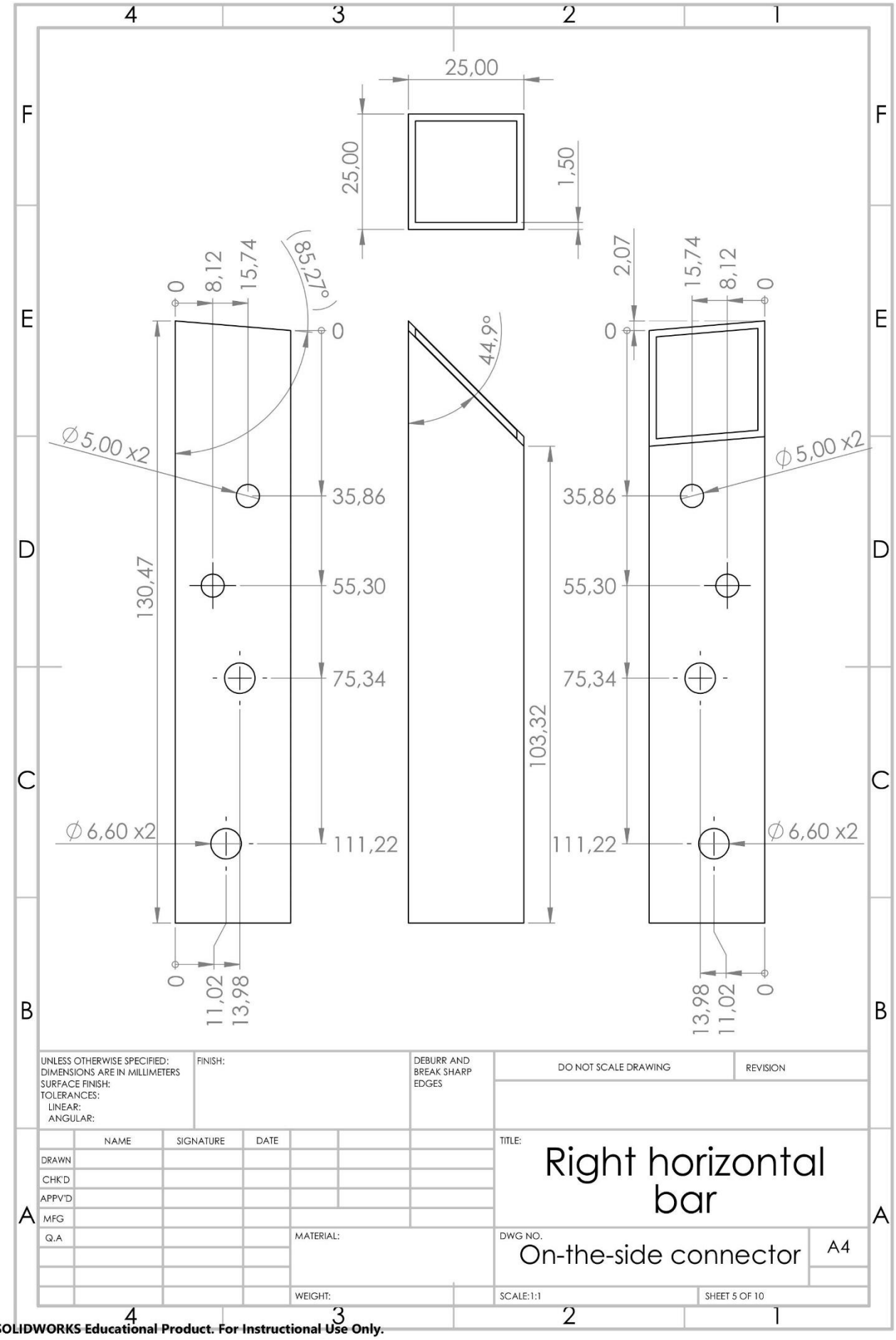
DWG NO. On-the-side connector

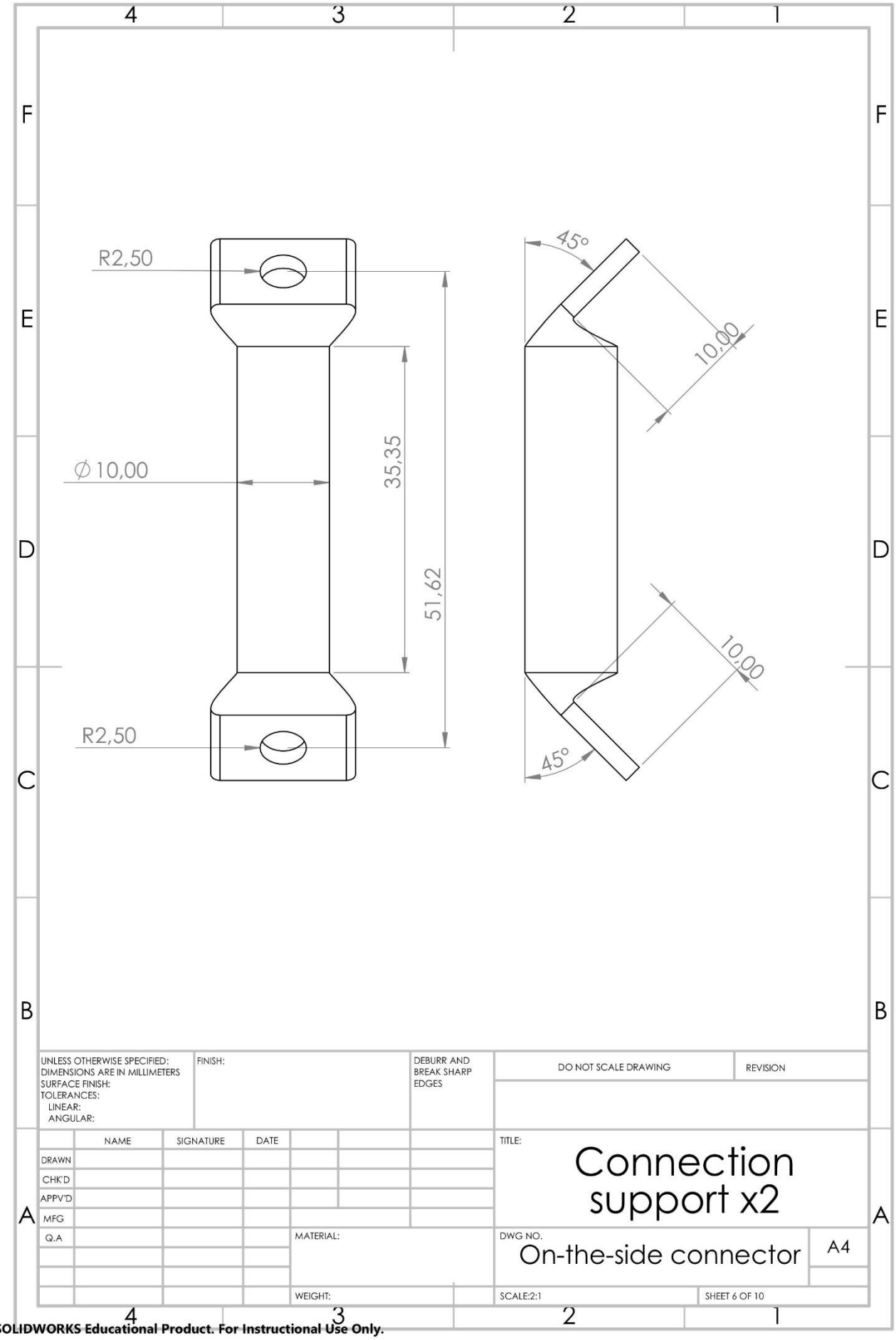
A4

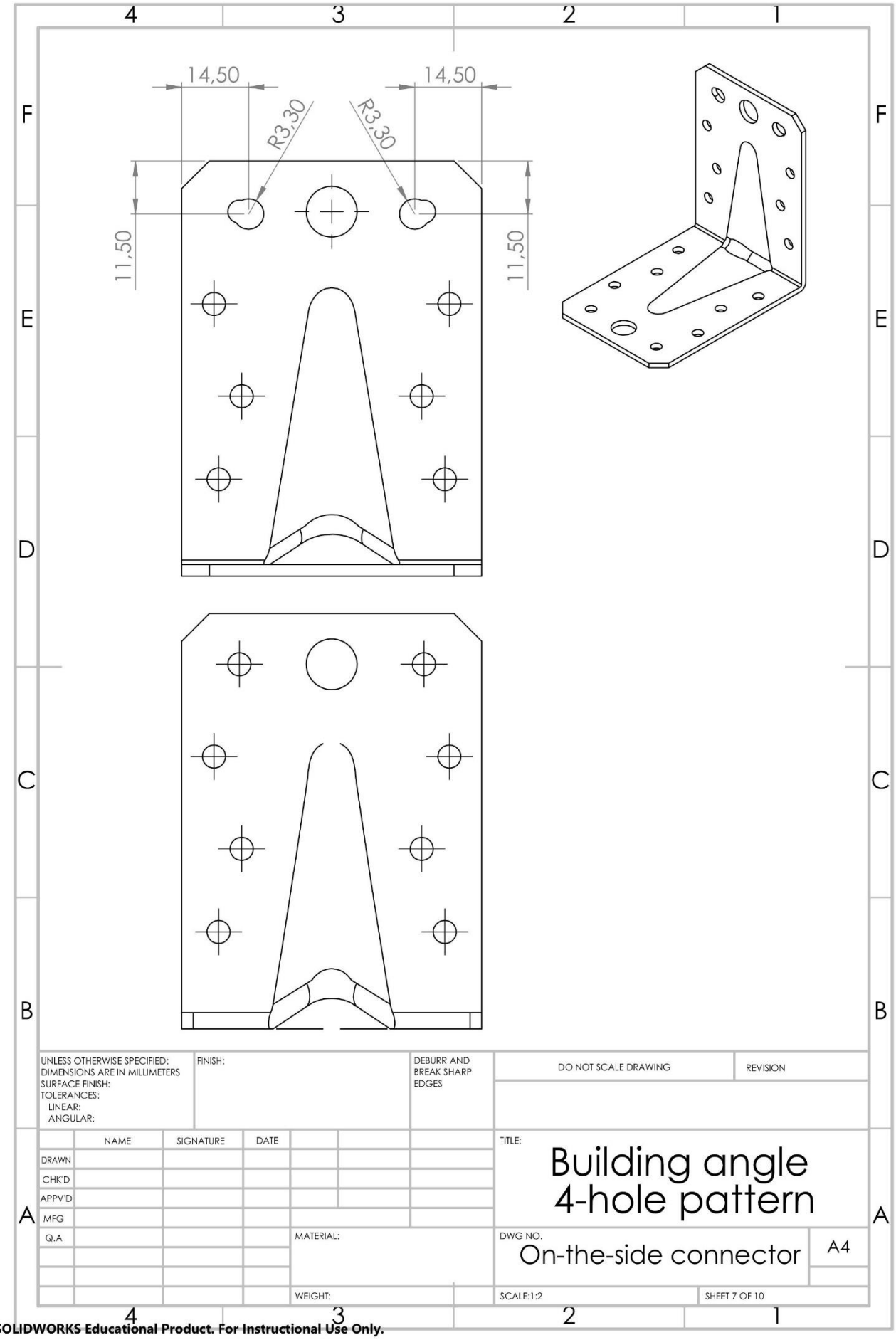
WEIGHT:

SCALE:1:1

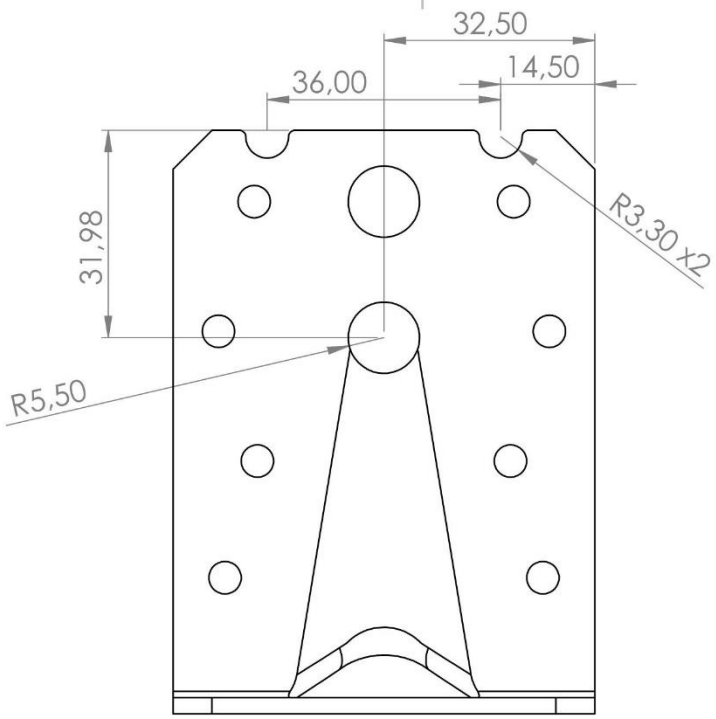
SHEET 4 OF 10

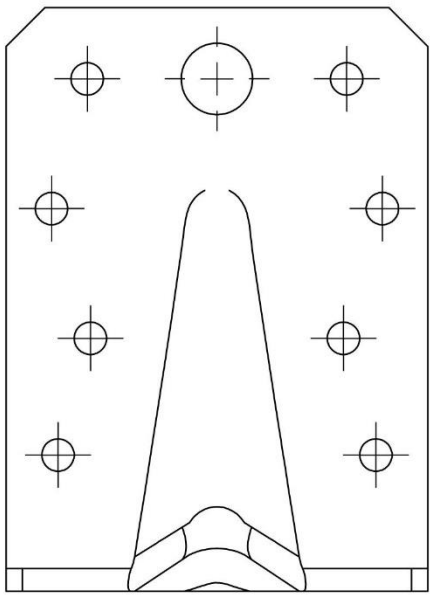






UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:		DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION	
	NAME	SIGNATURE	DATE	TITLE:		
DRAWN				Building angle 4-hole pattern		
CHK'D						
APPV'D						
MFG						
Q.A			MATERIAL:	DWG NO.	A4	
				On-the-side connector		
			WEIGHT:	SCALE:1:2	SHEET 7 OF 10	





UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:	DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING / REVISION

	NAME	SIGNATURE	DATE
DRAWN			
CHK'D			
APPV'D			
MFG			
Q.A			

TITLE: Angle bracket - socket connector plate x2

MATERIAL:

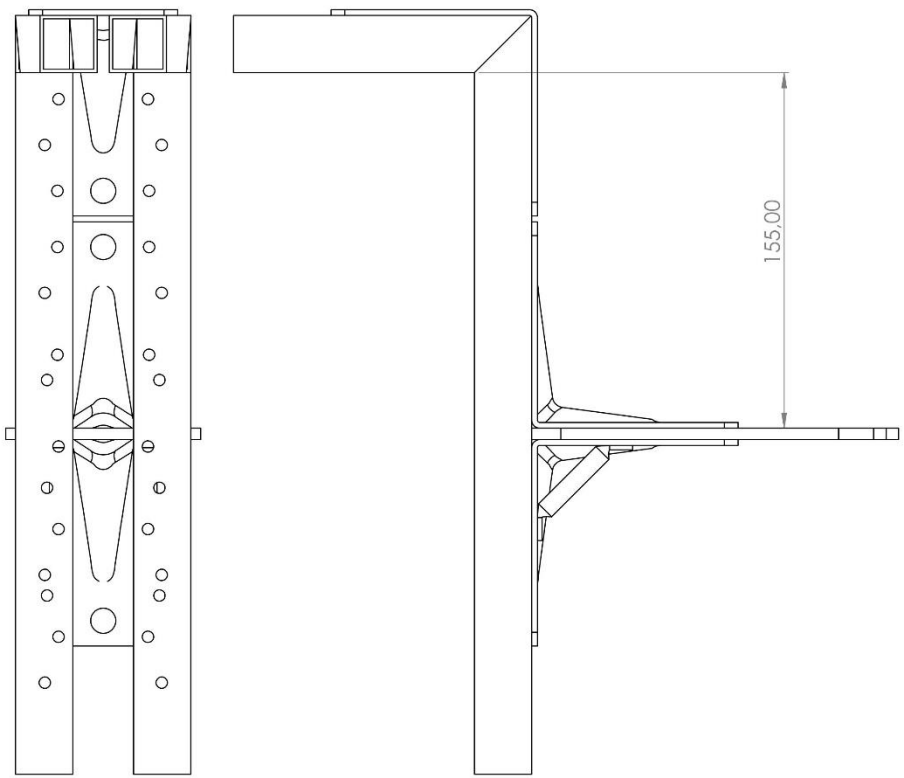
DWG NO. On-the-side connector

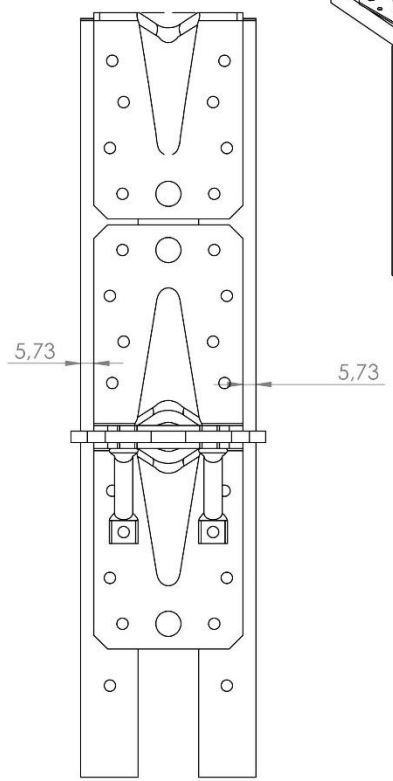
A4

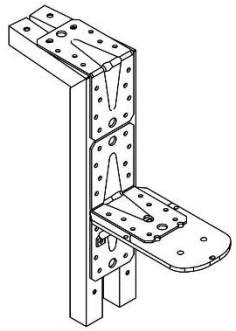
WEIGHT:

SCALE:1:2

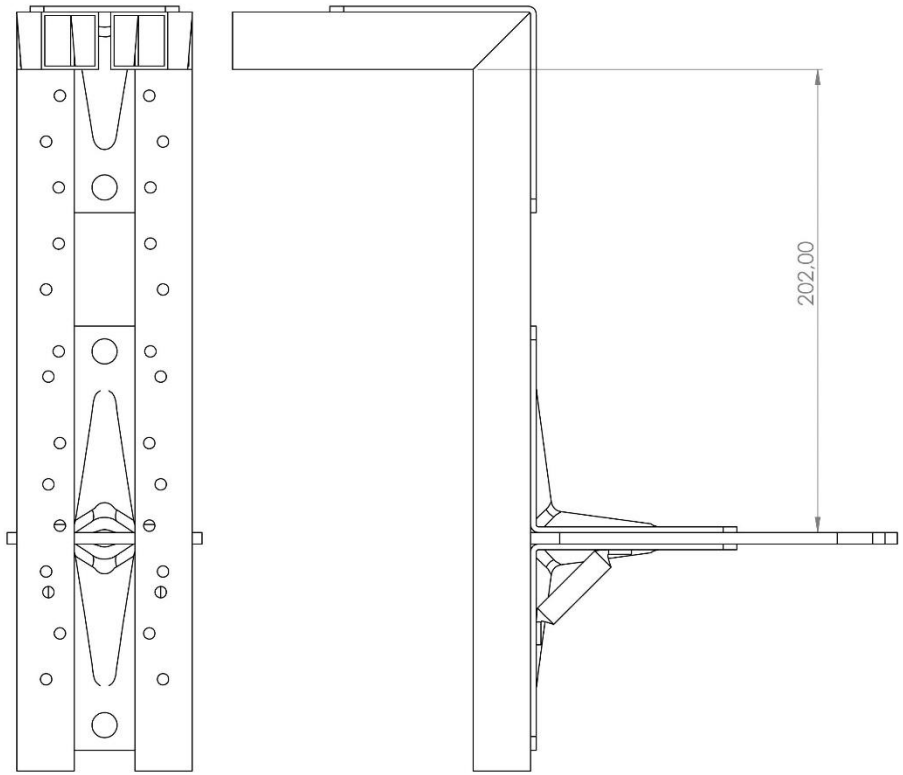
SHEET 8 OF 10

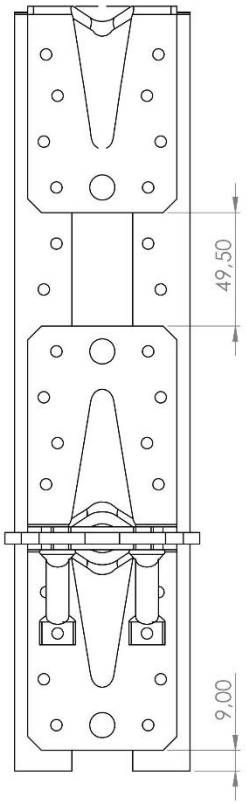


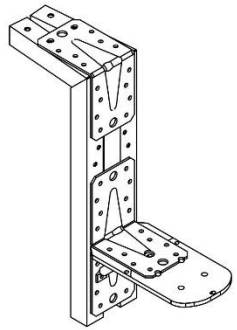


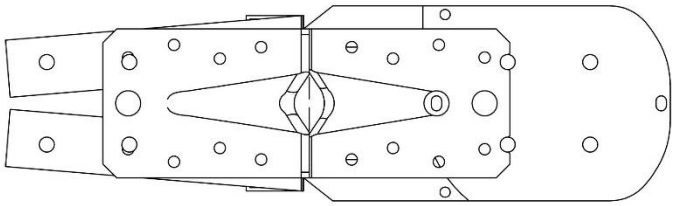


UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:			FINISH:			DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION
	NAME	SIGNATURE	DATE				TITLE: Overview - No iPecs	
DRAWN								
CHK'D								
APPV'D								
MFG								
Q.A				MATERIAL:			DWG NO. On-the-side Connector	A3
				WEIGHT:			SCALE:1:2	SHEET 9 OF 10









UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:		FINISH:			DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION
	NAME	SIGNATURE	DATE			TITLE: Overview - with iPecs	
DRAWN							
CHK'D							
APPV'D							
MFG							
Q.A				MATERIAL:		DWG NO. On-the-side connector	A3
				WEIGHT:		SCALE:1:2	SHEET 10 OF 10

Appendix D – Building process of the on-the-side connector

The rectangular pipes are manually cut using a hacksaw. The result is imperfect due to the manual errors when cutting. The pipes are not perfectly angled and slightly shorter than according to the drawing. The radius of the 90° bend of the angle bracket, and the dimensions of its supporting structure are measured using a calliper when correcting the CAD-model. Due to difficulty, the measurements cannot be done exact and manual corrections are needed when creating the prototype. To get a satisfactory result, see Figure 46, the corrections are done manually using a file. The interaction between the vertical and horizontal pipes on the left-hand side in Figure 46a, was considered unsatisfactory during a later inspection and the horizontal pipe was remade for a better interaction as seen in Figure 46b.

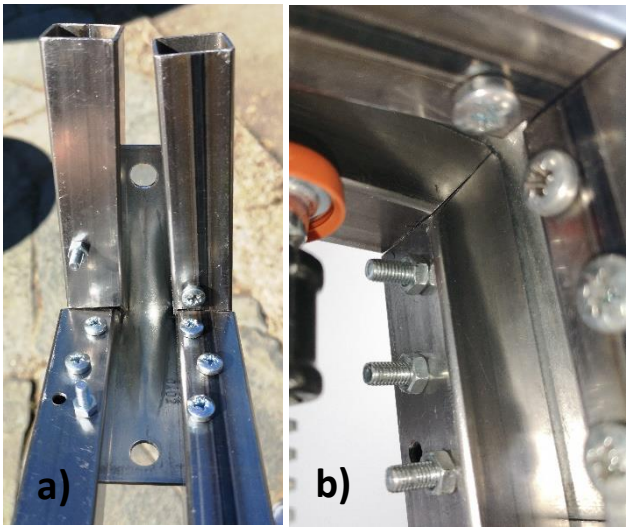


Figure 46: a) Satisfactory interactions between the rectangular pipes on the right-hand side b) and satisfactory interaction between the pipes on the left-hand side after reconstruction.

As seen in Figure 47, the initial measurements for holes of the vertical pipes are referenced from the bottom, while they should be referenced from the top of the pipes. The first drilled hole is placed according to the initial drawing of the connector which resulted in a placement of the angle bracket too far from the proximal end of the vertical pipe. Due to the errors in the drawing, the holes are positioned by placing the angle bracket in its correct place and marking the placement of the corresponding holes. The first hole was re-drilled with the further used method.

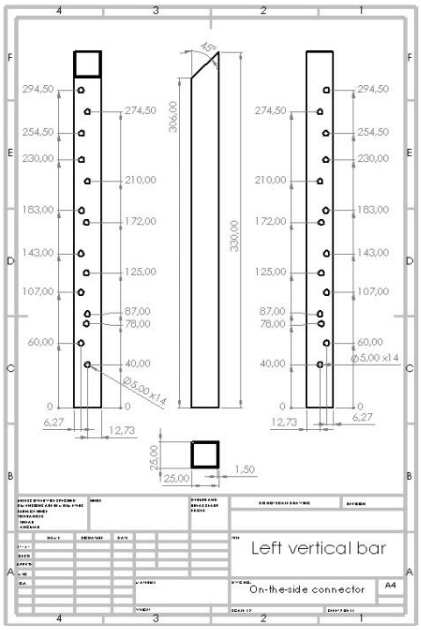


Figure 47: Initial drawing of the on-the-side connector used for the prototype manufacturing, where the measurements are referred from the wrong end.

The distal face of the proximal angle bracket for the socket connector plate is placed at approximately 156 mm from the distal face of the horizontal pipes. To reassure that the socket connector plate is levelled to minimize the initiated moments to the prosthesis, a spirit level is placed on the proximal face of the angle bracket, see Figure 48a. The position of the holes is marked on the vertical pipes and drilled with a simple kind of pillar drill. The same procedure is done when positioning the angle bracket at 202mm to enable the usage of a load cell. The socket connector plate and the distal angle bracket is attached to mark the position of the holes for the distal angle bracket on the vertical pipes. As secondary failures to the errors in the drawing and the following manual positioning, the distal angle bracket cannot be centred and parallel to the edge of the vertical pipes, see Figure 48b. The holes are positioned near the edge of the pipes and on the border of what can be viewed as acceptable. Since the wall of the pipe parallel with the bolt is not damaged during the drilling procedure, the result is considered as acceptable. After the attachment of the distal bracket, the levelling of the socket connector plate is measured again for reassuring purposes.

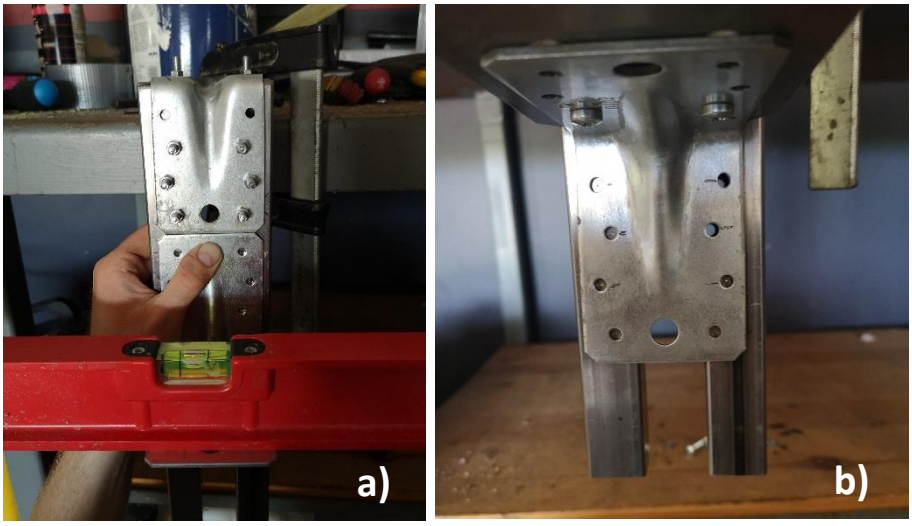


Figure 48: a) placement of the proximal angle bracket for the knee-plate using a spirit level. b) an oblique placement of the distal angle bracket.

Two holes for the 4 -hole pattern are needed on the angle bracket which attaches the horizontal and the vertical pipes. The holes are positioned on the brim of two of the existing 5 mm holes. This is problematic from a drilling perspective since the drill is pulled towards the existing hole. The existing holes are filled with a nail fastened in a piece of wood and the position of the new holes are marked and finally drilled with a 6 mm drill, see Figure 49. The positioning of the two holes are checked against an existing 4-hole pattern of a prosthetic component and some misalignment exist and is corrected using a file.

Figure 49: Existing holes are plugged with nails to simplify the drilling procedure.

The supporting tubes on the distal side of the socket connector plate are made using 10x1mm circular, aluminium pipes as would be used for the bottom-parts of the struts in the pin-strut bypass-socket. Both edges are flattened and bent using an anvil as seen in Figure 50a. Cracks occur on the sides when the pipes are flattened due to the stresses. The tubes are attached to the distal side of the socket connector plate, see Figure 50b.

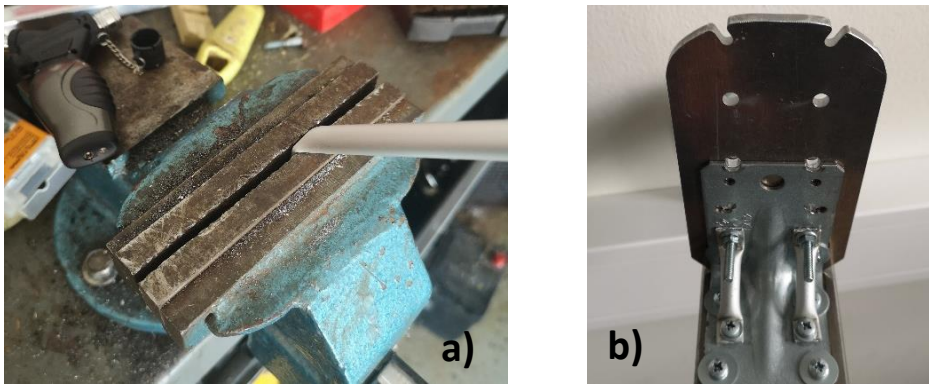
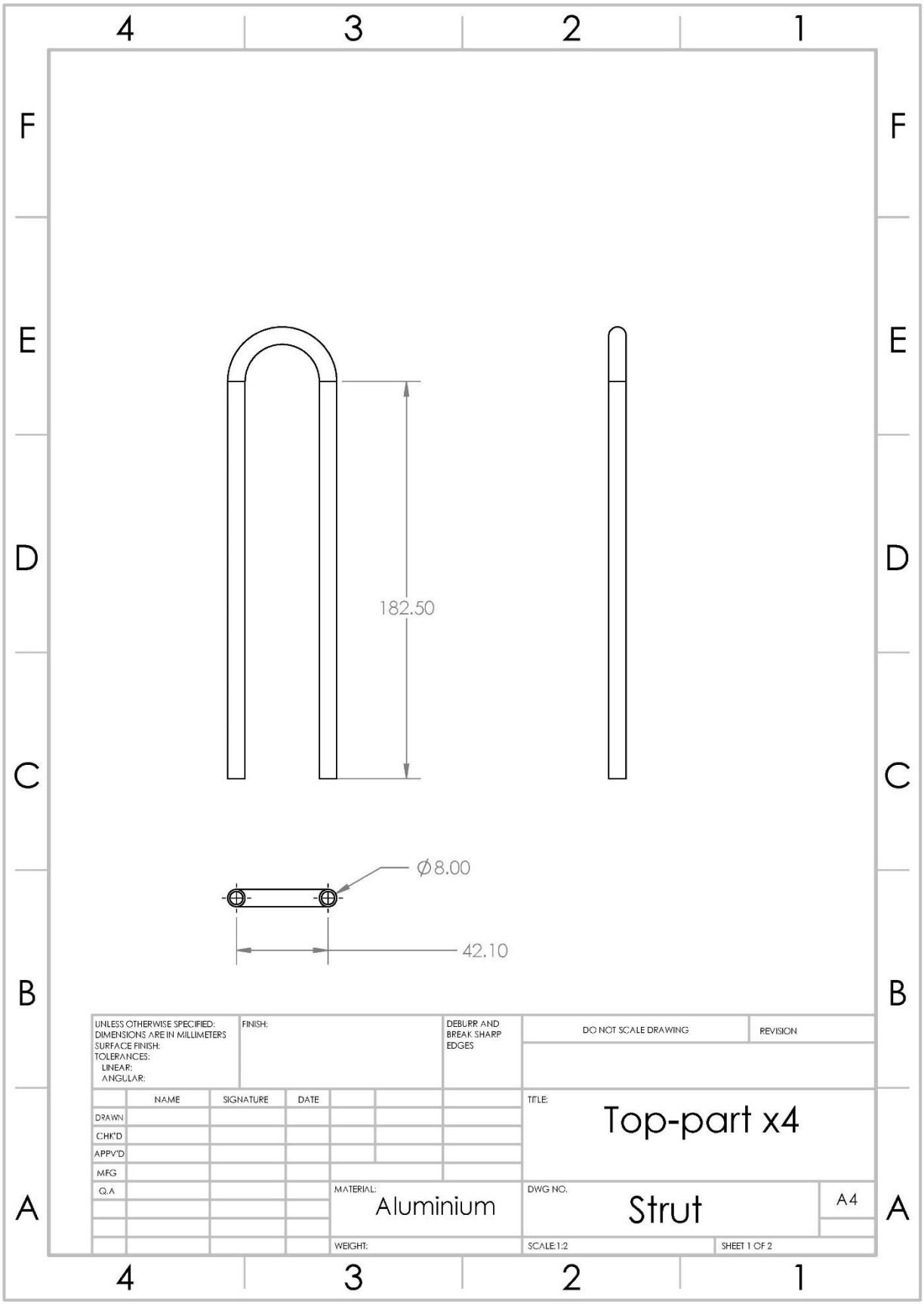
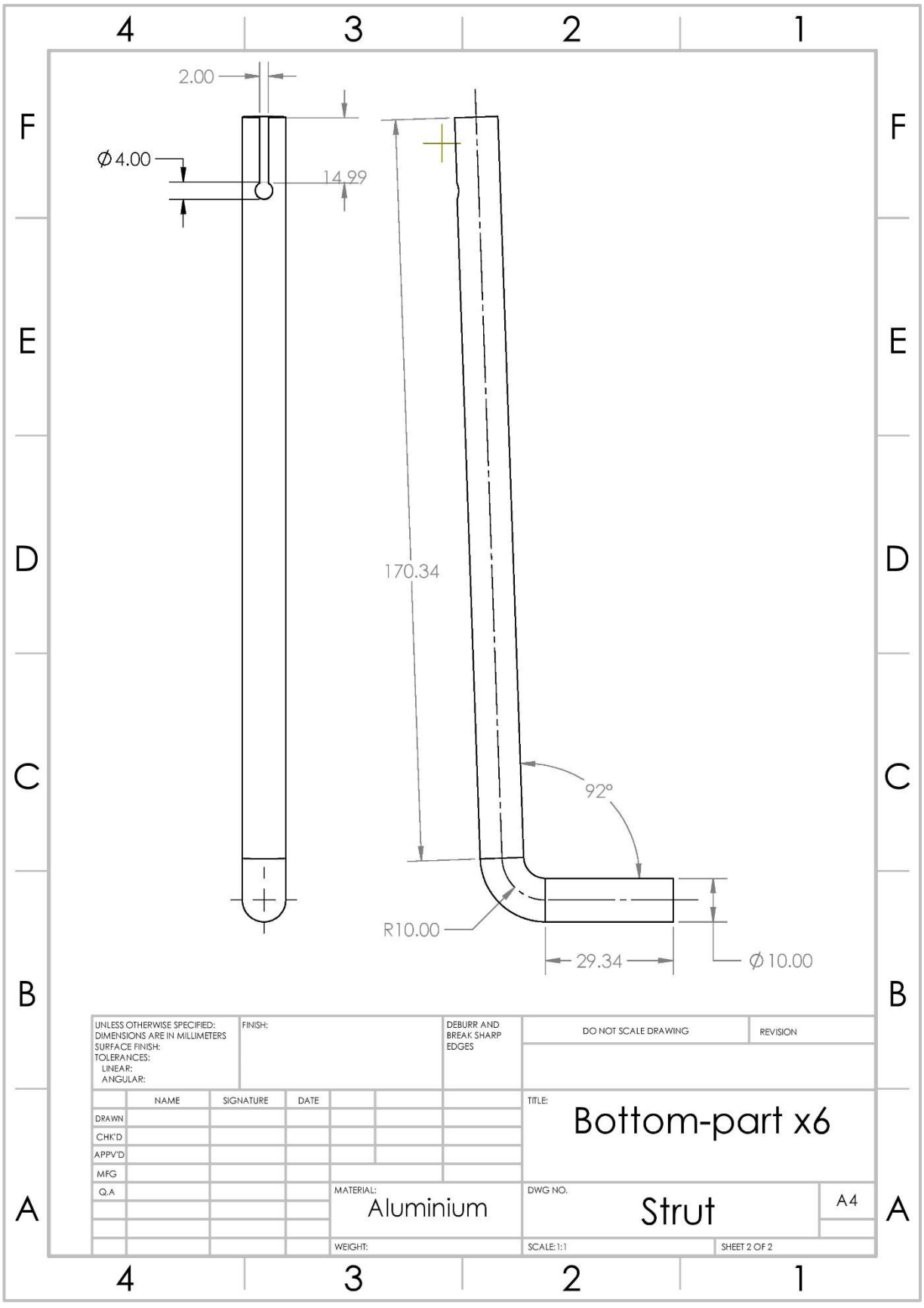


Figure 50: a) the supporting tube is flattened and bent using an anvil and b) the supporting tubes are attached under the knee-plate.

Appendix E – Drawings for the struts




4
3
2
1
F
E
D
C
B
A
2.00
Ø4.00
14.99
170.34
92°
R10.00
29.34
Ø10.00
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES:
LINEAR:
ANGULAR:
FINISH:
DEBURR AND BREAK SHARP EDGES
DO NOT SCALE DRAWING
REVISION
NAME
SIGNATURE
DATE
DRAWN
CHK'D
APPV'D
MFG
Q.A
TITLE:
Bottom-part x6
MATERIAL:
Aluminium
DWG NO.
Strut
A4
WEIGHT:
SCALE:1:1
SHEET 2 OF 2

DEPARTMENT OF ELECTRICAL ENGINEERING
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden
www.chalmers.se

CHALMERS
UNIVERSITY OF TECHNOLOGY