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Design of a transradial socket

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Abstract

Sometimes children are born with (part of) an arm missing. Next to congenital loss, children or adults can loose their arm due to an accident or illness. The missing arm can be replaced with a prosthesis, connected to the arm remnant by a socket. Existing sockets tend to have a hot and humid climate and some sockets are difficult to don and doff. The WILMER open socket is adjustable but looks bulky. All these disadvantages result in reduced wearing of the prosthesis. After the current prostheses are evaluated, the existing patents and available literature are investigated, a list of requirements was made for a new design. A new socket should fulfil the following requirements: the socket should fit closely around the arm remnant, be lightweight, provide a smooth transition between the remnant and the prosthesis, be easy to don and doff, provide self-suspension, provide optimal fixation of the prosthesis, load the skin with normal forces only, do not interfere with perspiration, be made of comfortable materials (no allergic reaction, no absorption of perspiration, smooth, strong and easy to clean), weather-proof (no oxidation, endure sand and dirt), have possibility to be fitted in a standard prosthetic facility, should not hinder the movement of the remnant, be adjustable, cost effective, have adaptive fitting and preferably have a soft outside shell. With the requirements, the problem can be solved by improving a current socket and designing new sockets.

The application of new materials in prosthetics is evaluated, resulting in several new designs. The WILMER open socket is improved, resulting in another design. From these designs one concept is chosen and detailed. The chosen concept is made of stainless steel wire mesh, with an adjustable condyle brace and a standard forearm shell over the mesh.

Keywords: prosthesis (fitting), upper extremity, prosthetic socket design, transradial.

Contents

Chapter 1

Introduction

Transradial amputation is the transverse loss of a part of the forearm. The remaining length of the forearm varies, the loss can be due to an accident, illness or congenital, see Figure 1.1. A prosthesis can be used to replace the function and/or appearance of the missing limb. The prosthesis can assist in two handed tasks, like opening a jar or stabilising the union to be cut. Simple tasks like tieing one's shoelaces, turn into difficult tasks when having only one arm, here a prosthesis can provide a solution.
A normal human arm has many degrees of freedom and it is therefore difficult to restore all the function. The socket connects the prosthesis to the remnant of the arm. Existing sockets tend to have a hot and humid climate, due to the impermeable full contact socket. The socket is often rigid, resulting in difficult donning and doffing. The only positive exception is the WILMER open socket design of Delft University of Technology [1]. The design consists of soft covered steel tubes which leave 75% of the skin uncovered. It is easy to don and doff the socket, on the down side it is too conspicuous and bulky, see Figure 1.2(a). The patients indicate that they would like to have a socket that fits closer to the skin and is more aesthetically pleasing [2]. In order to solve this problem, Wong has made a new design more aesthetically pleasing, with stainless steel foam, see Figure 1.2(b). The improvement of the WILMER open socket can result in another solution, or a whole new design can be made.

The goal of this thesis is the design of a novel socket for transradial amputees, as the current sockets all have one or more down sides. Before a new design is made, the existing patents and literature are investigated. With this information, a list of requirements for the new design is derived (Chapter 2). Then, in Chapter 3, the problem is analysed: when is the user content and when is he/she unsatisfied? With the known requirements several possibilities are investigated (Chapter 4): improving the WILMER open socket, continue with the design of Wong or designing a whole new socket. In Chapter 5 the chosen concept is detailed.

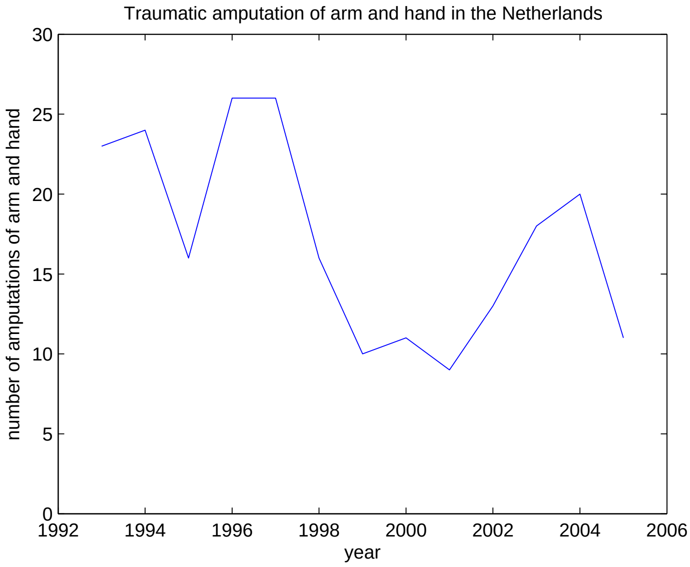
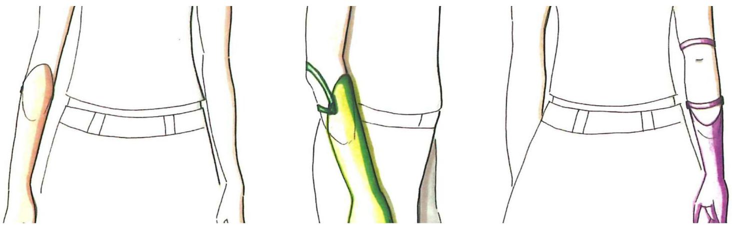


Figure 1.1: Number of traumatic arm and hand amputations per year in the Netherlands [3]

(a) The WILMER open socket design of Delft University of Technology [4]



(b) The design of Wong, the socket is made of open pored metal foam [2]

Figure 1.2: Examples of sockets

Chapter 2

Literature survey and design problem

This chapter starts with a brief overview of the history of arm prostheses. In the second section the literature on prosthetic design will be discussed. It contains information on patents, socket designs, patient surveys and prosthetic safety standards. The last two sections concern the problems of existing socket designs and requirements of a new socket design.

2.1 History of arm prostheses

For centuries people have tried to replace missing limbs [5]. One of the oldest examples is the prosthesis found on an Egyptian mummy dated 330 B.C., which was placed to restore the outward appearance of the wearer.
No prosthetics have been found dating between 330 B.C and the 15^{th} century, probably because they were made of wood and the prosthesis did not survive the wear of time [6]. A hand replacement from the second half of the 15^{th} century has an immobile thumb, which could be opposed to the mobile fingers by applying the sound hand, and was likely designed to hold the reins whilst horse-riding but otherwise had limited function (Stibbert Museum in Florence (Italy) [6]). Another passive hand prosthesis (dated 1509) can be moved with the help of the fingers of the other hand and was made for the German knight Götz von Berlichingen, see Figure 2.1. From the mediaeval time several examples of passive hands remain, most are made entirely of steel.
In the 19^{th} century the design of actively operated prostheses began. These prostheses were controlled by the harnessing of body movements. The movement tightens a cable which opens and closes the terminal device (the part that replaces the function of the hand). This type is called body-powered. In addition to body-power, a prosthesis can be powered by carbon dioxide gas (pneumatic) or battery packs (electrical). The use of electronics in 1960, results in myo-electrical controlled prostheses. The terminal device can be opened and closed by muscle activation. When the muscle is activated, a small electric signal leaves the muscle and can be measured at the skin of the patient, this signal is used to control an electric motor. Another kind is the mechanomyography controlled prosthesis. This kind of control measures the low-frequency sounds of the muscle in order to operate the prosthesis [7].

2.2 Overview of literature

To find currently available prosthetics and the opinion of patients, a literature review was performed by searing Scopus [8], the library of Delft University of Technology [9], Scholar Google [10], PubMed [11], ISI Web of Knowledge [12] and espacenet [13]. As search terms combinations of prosthes*, prothe*, limb, upper, socket, suspension, extremity, suction, silicone, fitting, review

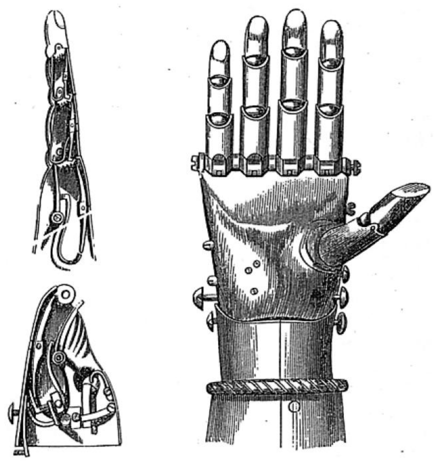
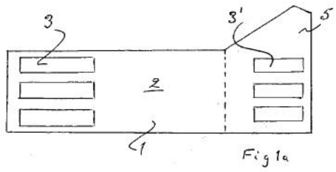


Figure 2.1: The prosthesis of Götz von Berlichingen [6]

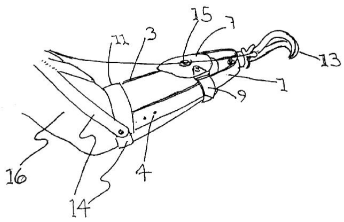
and amputee* have been used.
The ultimate goal of an engineer designing prostheses is the design of fully functional artificial arm and hand substitutes with a physical power and response, which can be controlled almost without thinking. All this of course in the space and shape of a natural arm. The problem is the number of lost joints (∼ the number of degrees of freedom) and the number of control possibilities. The human arm is comparable with an arm of a mechanical digger, but the operator uses hands and feet to control the digger arm. Then there is the issue of the weight of the artificial arm. Kutz [14] assumes that a normal arm weights about 10kg, but no one wants to think about carrying a laptop the whole day on one shoulder strap [14]. A simple math sum rises the conclusion that 10kg could be a little bit to heavy for a normal arm (arms 2*10+legs 2*15 = 50 kg and then the head and trunk have been left out). Dean Kamen estimates the weight of the human arm at 3.6kg [15], which seems a better estimation. Patients want feedback of the forces the artificial arm exerts. With the receiving of feedback and a lot of training, the patient knows how much force the terminal device is exerting, resulting in less concentration (less mental load) on the terminal device when gripping objects. Giving feedback is most simple with a body-powered prosthesis, but a pneumatic prosthesis with (limited) feedback has also been build [16]. Myo-electrical prostheses have been build with feedback (in the form of a buzzer), unfortunately with limited success [17].

2.2.1 Patents

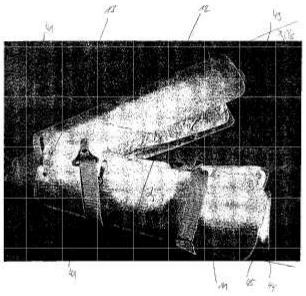
To find patents on prosthetics, espacenet [13] has been searched with the help of European classification codes. The codes used were A61F2/78 and A61F2/80, which is the class of means for protecting prostheses or attaching them to the body and the class of sockets. All patents filed till the eighth December of 2008 have been reviewed. Most of the approximately 400 patents are about silicone suspension (liners) or vacuum suction (sockets). Exceptions are the following patents on arms and legs sockets accompanied with a short description. Care must be taken in regard of the difference in fitting technique between an arm and a leg socket. A leg prosthesis is made for the transfer of mechanical forces of the body to the floor and the opposite way. The pull and centrifugal forces in the swing phase should be transferred as well. An arm prosthesis is made for the pull and centrifugal forces, but should also be able to cope with the transfer of mechanical forces of the body to the surroundings and the other way around [18]. Smith [19] brings this as follows to the point: “With lower-limb prostheses, the ‘connection’ between the person and the device - the ‘man/machine interface’ - is reinforced when the person steps down into the socket, pushing the prosthesis onto the residual limb. It feels more securely attached. On the other hand, since an upper-limb prosthesis pulls away from the limb when lifting something, it can actually



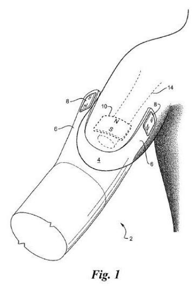
(a) GB2435216a, a padded socket shaft, which is adjustable via straps and a closure



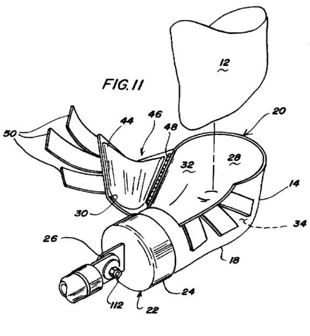
(b) CA2304743A1, a metal U-frame used as the socket, the stump is kept in place with additional straps and buckles. In this way the socket is open, and the problem of ventilation solved



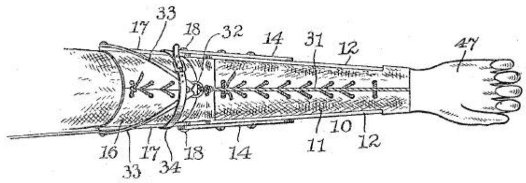
(c) WO2006066951A2, two plastic shells between which the stump can be fastened with Velcro, the shaft is designed for the period directly after the amputation when the limp is changing considerably in size and shape



(d) EP1743602a1, one set of magnets is placed in the prosthetic socket and the other is implanted into the patient



(e) US5800572, socket design with Velcro fastenings



(f) US1277747A, socket made of leather and straps

Figure 2.2: Impressions of the patents

feel disconnected." This means that a leg socket design cannot simply be transferred to the arm. An overview of the found patents can be seen in Figure 2.2 and in Appendix A, Figure A.1. A series of patents not in the figures (US1247710A, US1277747A, US1293478A, US1299756A and US1464842A) is old (∼1920) with sockets made of leather and straps. A bit newer is US1572318A which has a leather corset with straps kept in place by metal buckles.

Silicone suspension

There are different kinds of suspension of the prosthesis: with straps, enveloping prominent bones (e.g. the Münstertype socket, see Section 2.2.3, which is self-suspending), osseointegration, silicone suspension and vacuum suspension. Before the development of the Münstertype socket, straps were used as suspension systems. Nowadays straps are no longer used in suspension of transradial sockets. In the next sections, silicone suspension, vacuum suspension and osseointegration are evaluated.
Silicone suspension uses a silicone liner whereon the prosthesis is connected. The liner is rolled around the remnant and 'sticks' on the skin. The patents on silicone suspension have not been reviewed because silicone has a poor thermal conductivity. As all normal mechanisms to cool the body (convection, radiation, vapourisation and conduction) are hindered by the prosthesis, the socket design problem is challenging. Arterial convection is compromised by the eventual vascular disease of the amputee, convection by air is blocked by the prosthesis around the limb and convection of the whole body is compromised by the amputation of a limp resulting in a declination of body surface. Radiation is decreased by physical barriers (garments and stockings), evaporation by the low moisture permeability of the prosthesis wall and the conductive heat transfer by the unfavourable thermal conductivity of most materials used for sockets and liners in prostheses. This thermal conductivity of liner materials is most of the time even poorer than the conductivity of air (k_{air}=0.24W/mK [20] and k_{liner}=0.085-0.266W/mK [21]). Lowering of the skin temperature with only a few degrees, can result in a better socket climate: the patient is less sensitive to an increase in temperature [21].
Besides the problem of conductivity of silicone, there is a problem with skin irritations due to the silicone liner [22, 23]. Meulenbelt [24] states that due to the socket multiple skin diseases occur, and since the newer socket designs (the socket is in closer contact with the skin), a new problem has arisen: hyperhidrosis. This is an unbalance between production and evacuation of sweat leading to a humid climate where bacteria, yeasts and mycoses have an ideal culture medium. Meulenbelt also described patients having contact allergy wearing ICEROSS (ICElandic Roll-On Silicone Socket), due to a component in the silicone. Lake and Supan [25] describe a whole range of problems users experience when wearing a silicone liner. They found that the use of sheaths decreases the level of skin problems, as the sheath acts as a wick to remove moisture, allows a small amount of air to circulate around the stump and facilitates the removal of direct contact of the liner with the skin. Moreover, the use of a sheath reduces shear forces on the skin at the proximal trimline of the liner.

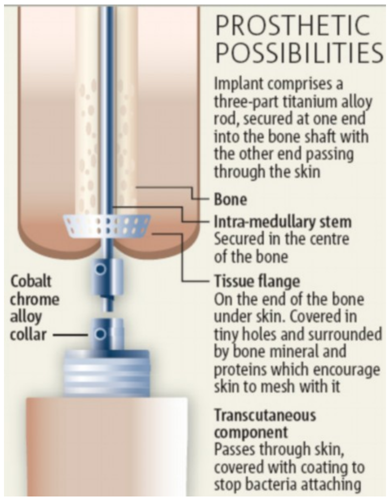
Vacuum suspension

Vacuum suspension uses vacuum to connect the socket to the limp. The limp is placed in the socket, now vacuum is applied and the socket is connected. Due to the kind of suspension, vacuum suspension allows no evaporation through the socket wall, this results in a humid socket climate for the patient. A hot, humid climate combined with shear stress on the skin is ideal for the development of pressure ulcers [26]. This is highly undesirable for the patient, as the prosthesis cannot be worn, therefore vacuum suspension was ignored.

2.2.2 Osseointegration

Instead of using a socket, the prosthesis can be connected directly to a metal pin in the bone. This technique is called osseointegration. First, a titanium plate is implanted to the bone, three to six months later a pin is screwed into the plate during a second operation, see Figure 2.3(a). The training with the new prosthesis starts after wound healing. Osseointegration has the following advantages: stable fixation of the prosthesis, better proprioception, elimination of skin problems and pressure problems and a better control of the prosthesis [27]. There is, however, also a disadvantage: infection of the skin and bone around the titanium implant [28]. This problem may be solved with the Intraosseous Transcutaneous Amputation Prosthesis (ITAP), but as only one human has received this kind of osseointegration in the arm [29] (see Figure 2.3(b)), prospects are unknown.

(a) Osseointegration: the pin screwed in the bone whereon the prosthesis is fixed [27]



(b) ITAP implant [30]

Figure 2.3: Implantation methods

2.2.3 Socket designs

An older socket design is the Münstertype socket. This kind of socket is self-suspending by a supra-condylar rim enveloping the epicondyles of the humerus [5]. The NorthWestern University (NWU) made their own socket design similar to the Münstertype socket (see Figure 2.4(a)), this socket is moreover suitable for a longer underarm stump [31]. In 1964, the Münstertype socket was compared with the users own prosthesis. The Münstertype socket felt better, but experts saw no difference in dexterity during using. An interesting fact is, that they used a porous material for the production of the Münstertype sockets [32]. When a impermeable material is used, the problem of perspiration can be addressed via windows in the socket [33].
A novel socket design (by Greenwald et al.) is filled with bags with water (see Figure 2.4(b)). During walking the pressure remains constant even when the volume of the stump is changing during the day. The socket needs no external power source, but a lot of control engineering [34].
A socket based on the Münstertype socket and the NorthWestern University socket is the Transradial Anatomically Contoured (TRAC) Interface [35], see Figure 2.4(c). The advantages of this socket are the decrease of the displacement of radius and ulna when the socket is loaded and the more stable relationship between the radial and ulnar angle in relationship to the posterior plane of the interface. The socket looks like the Münstertype socket, but the fitting technique is different, as the inner shell of the socket is made of flexible material. The range of motion of the elbow is increased compared to the Münstertype and NWU socket due to the special fitting technique and the flexible inner shell. When having a long forearm stump, rotation of the radius and ulna is not possible due to the skeletal lock build into the socket design.

A socket designed for active transradial prosthesis users is the High Performance Variable Suspension (HPVS) socket, see Figure 2.4(d). The socked is fitted with a more stretched arm compared to the normal fitting of a Münstertype socket. In this way sporting becomes easier, but reaching the face is more difficult. This seems no problem for unilateral amputees. When using the prosthesis in normal life, a normal liner is used, when using the prosthesis for sporting activities a silicone liner with lock is used, providing superior suspension [36].
Delft University of Technology created its own socket design [1]. This design, made of soft-covered steel tubes, supports the arm only at the minimal fitting areas, those areas that are required for a good fixation of the socket, see Figure 2.4(e). The socket can easily be put on and removed and is continuously adjustable during the day. Due to the steel tubes, the resulting construction is open, providing good ventilation.
Bennet [37] describes a socket with no shear forces. When the wall of the socket is shaped thinning when heading towards the rim (tapered flexibility), the socket exerts less shear forces on the skin at the rim. Sockets with flexible brims made of plastic laminate were tested in a limited clinical trial. These sockets appeared to be helpful for patients previously troubled by chronic or recurrent cysts, but the mechanical durability of the laminate was so poor that the sockets often lasted only six months [38].
Instead of making the socket with help of a mould, the socket could be manufactured using rapid prototyping. As this technique forms the socket layer by layer, the structural integrity is different than the socket made with the usual way of manufacturing. The socket made with rapid prototyping is 13-23 percent weaker in tensile strength, after correcting for this, the socket successfully completed a cyclic test with no observable failure (test according to ISO 10328 with load case II for a leg prosthesis) [39].
In Figure 2.4(f) a low-cost socket made from an ordinary soda bottle can be seen. The socket is made by putting a PET bottle over the plaster model of the stump and applying heat with a heat gun. The bottle conforms to the shape of the plaster model [40].
Deka Research & Development Corp., in Manchester, New Hampshire developed via funding money of the American government (DARPA, Defense Advanced Research Projects Agency, Revolutionising Prosthetics Project) also an open socket design. The socket consists of a harness-like support with silicone padding, see Figure 2.4(g). The stump is surrounded with multiple finger like extensions in which the stump is allowed to move freely. The free space is filled with inflatable bladders, the pressure inside the bladders responds to the different levels of stress, controlled by a microprocessor. A patient with a test socket was able to lift the prosthesis over his head, which was impossible with other designs. The socket should be in the clinical trials phase in 2008 and available on the market in 2010 [41, 42].

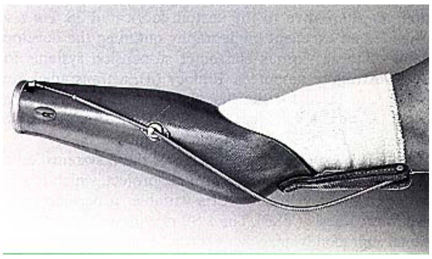
2.2.4 Patient surveys

Now that the different existing sockets are evaluated, the opinion of the user is discussed.
Kejlaa [44] found that most problems with body-powered prostheses are due to socket climate, strap irritation, wear of clothes and wire failure. When patients are asked what should be improved in the future, the answer is new socket designs and reconstruction of suspensions. Biddiss [45] also asked what the patient desires and found that complaints related to body-driven prostheses generally include excessive wear temperatures, abrasion of clothes, wire failure, unattractive appearance, with the most commonly recounted hindrance being harness discomfort and/or breakage. Another survey [46] pointed that, the longer the patients have a prosthesis, the more complaints they have, especially about comfort. Atkins [47] found similar research priorities for users of body-powered and electric prostheses: additional wrist movement, better control mechanisms that require less visual attention and the ability to make coordinated motions of two joints. Desired near-term improvements for body-powered prostheses include better cables and harness comfort, whereas those for electric prostheses include better gloving material, better batteries and charging units, and improved reliability for the hand and its electrodes. Although he found many complaints, he found none about the socket: patients were not questioned on this matter. The outcome of the last survey is particularly interesting in the light of the survey of Davidson [48]. Davidson

(a) The socket from the NorthWestern University [32]

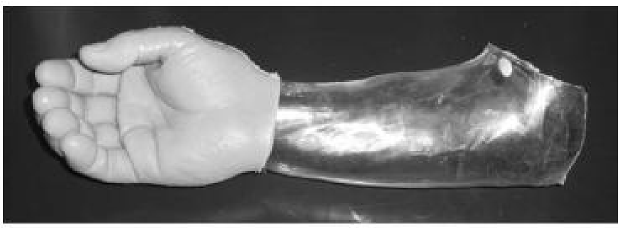
(b) The constant pressure socket [34]

(c) The Transradial Anatomically Contoured (TRAC) socket with window [35]



(d) The High Performance Variable Suspension socket [36]

(e) The WILMER open socket design [4]



(f) The low-cost socket made of a soda bottle [40]

(g) The socket designed by Deka [43]

Figure 2.4: Impressions of the existing sockets

based her survey on the survey of Atkins, but for the Australian upper limp amputee. She found that 55% of the amputees think the sweating in the prosthesis not acceptable and 34% find the comfort of the arm in the prosthesis insufficient. On the other hand 60% of the amputees rated the comfort of the socket good or well. Lake [49] found that the most determining factor whether patients wear the prosthesis or not, is the socket design. Another study confirms this: Miguelez [50] studied the effect on a newly fitted prosthesis in 4 cases. By looking again at the socket and prosthesis and giving the patient a new prosthesis with socket, the use of the prosthesis increases and the complaints decrease.
Good socket comfort is important, because when patients experience pain, this is often due to tissue degeneration [51], which is of course unwanted in the residual limb. The article states that pain is not only physical but also psychological, because more pain can be experienced even when the pain sensor firing rate to the brain does not change. Pain at the surface is better recognised and placed then pain in the body [51].
A well-fitting socket is important to prevent RSI. When the prosthesis is abandoned, the sound arm is overused which can lead to RSI [49, 52, 53, 54, 55].
A survey of ten hospitals for children in the United States and Canada [56] revealed that 49% of 110 non wearers of prostheses found the prosthesis uncomfortable. They gave comments as the prosthesis was too hot, sweaty, or heavy; it was uncomfortable in every way; also the harness was uncomfortable. The principal reasons for rejection of a prosthesis were lack of function, including some cases in which the device impaired function, and lack of comfort. Because children develop compensatory skills and 90 percent of all activities of daily living can be performed with only one hand [57], the primary focus for fitting a prosthesis should not be the need for function for daily activities, but rather as a tool to assist with the performance of specific tasks.
Biddiss [58] investigated the design priorities of children and adults. For body-powered prosthesis the design priorities of children were weight, comfort/appearance/function, size, reliability, life-like/fit/usefulness/harness comfort/ease of control and heat/grip strength. The priorities of adults were comfort of harness or straps, weight, cost, wrist movement or control, grip strength/fit, reliability, heat, sensory feedback, ability to manoeuvre in awkward positions and donning of doffing/physical effort needed to use.

2.2.5 Standards

Wearing a prosthesis should be safe for the user, to enhance this safety, standards have been developed. The main standards are:

NEN-EN 12182 Technical aids for disabled persons - General requirements and test methods. NEN-EN 12182 describes general requirements aids for disabled persons should fulfil. Demands concerning prostheses are the absence of single use closures, recyclable and fire retarding materials, bio-compatibility, include description with cleaning method of device, safety of movable parts, safety after wear, no danger of fingers/hands stuck between movable parts, no sharp edges and a risk analysis of forces on weak body parts (the pressure should not be inadmissible).

NEN-EN-ISO 22523 External limb prostheses and external orthoses - Requirements and test methods. NEN-EN-ISO 22523 describes the specific requirements of prostheses and the loads the prostheses should be able to endure. Demands are that the performance (strength and durability) should be described in the technical documentation, the risk of the propagation of flames and the production of toxic gases should be minimised, the forces on tissue should be small (risks: cell necrosis due to restricted nutrition and oxygen supply, tissue breakdown due to mechanical overload, tissue breakdown due to fatigue, tissue wear due to abrasion and cell destruction due to thermal coagulation) and appendix A contains load modes which the upper limb prosthesis should be able to bear.

NEN-EN-ISO 14971 Medical devices - Application of risk management to medical devices. NEN-EN-ISO 14971 describes in appendix B a scheme with the risk management process.

When documenting precisely the steps taken in this process, later failures of the product endangering the user, may be easier to cope with. Risk management is thinking about which risks a device can produce and which risks are inherent in the device. When these risks are known, an estimation has to be made about the probability of the occurrence and how severe it's consequences are. This estimation helps making a decision about what should be done with the risk: warn the user, make the device inherent safe or implement protective measures. The residual risk should be analysed again, a risk/benefit analysis should be made and the risks arising from control measures should be estimated. The process should be iterative, every time involving new risks and new estimations.

NEN-EN-ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing. NEN-EN-ISO 10993 is intended for the protection of humans, the standard describes tests that should be taken to discover whether a new device is bio-compatible or not. A prosthesis falls within the category surface contacting devices with permanent contact duration. This implies that the following test should be conducted before the prosthesis may be used by patients: cyto-toxicity (NEN-EN-ISO 10993-5), sensitisation (NEN-EN-ISO 10993-10) and irritation or intra-cutaneous reactivity (NEN-EN-ISO 10993-10).

2.3 Design problem

Each socket described in Section 2.2 has some drawbacks. The sockets of the patents are either made of leather (not hygienic), difficult to don, need an operation, use liners or have airtight sockets. Of patent WO2008040286a1 (see Figure A.1(f)), it is unsure whether the socket is stiff enough to suspend the limb functionally and it is difficult to manufacture. The Münstertype and NorthWestern University sockets all have more or less the same disadvantages: the socket is a compromise between fitting and the ease of donning and doffing, the fitting requires a highly skilled prothetist and due to the plastic socket perspiration and skin problems arise [4]. Baumgartner and Botta [18] on the other hand, do not see these drawbacks. They state that the best solution is a full contact socket, because then the forces are equally divided on the largest surface possible, the adhesion between stump and socket is better, the sensor properties of the skin are used advantageously (no perspiration) and no disturbance of the circulation.
Besides the silicone and vacuum suspension sockets provoke perspiration and skin problems. The drawbacks of the socket designed by Walta are the non-aesthetic look [2] and the difficult manufacturing technique reported by rehabilitation centres (see Appendix B compared to Appendix C). Osseointegration is not an option until the problem of infection is solved. In conclusion, a new socket design is needed.

2.4 Requirements of the new design

To come to a new socket design, requirements are needed. Klopsteg & Wilson [59], Childress & Billock [60] and Walta & Ariese [1, 61] give a list of requirements of a prosthetic socket. Baumgartner and Botta [18] state the socket as the centre of the prosthesis. When a compromise is made at function, quality and ease of wearing of the socket, the immediate result is decrease of acceptance by the prosthesis user. Amazeen and Turvey [62] show that human perception of weight is a function of the inertia tensor. This is important when designing a socket: not only the mass matters, but also the mass distribution. This conclusion states the obvious: by placing the mass farther from the stump, the moment (arm) on the stump increases and so the perceived weight. Coren describes in his book [63], that the sensation is also dependant on the adaptation level: something is heavy or light compared to the adaptation level.

With the above, a list of requirements can be made for the new socket design. To check whether the requirements are met in the new design, some numbers are defined. The new design should:
- **Fit closely around the arm remnant**

The distance between the socket and the remnant should not exceed 1mm.

• **Provide a smooth transition between the prosthesis and the body**

A maximal step of 5mm from skin to outside of the prosthesis socket when the prosthesis is worn.

• **Provide self-suspension**

Safe attachment to the arm, even when the user does not contract any muscles.

• **Low surface pressure on skin and load the skin with normal forces only**

The surface pressure on the forearm may not exceed 30mmHg (4.0kPa) pressure [64], because then blood flow is occluded. Flow occlusion may not be a good parameter to measure skin damage [65, 66], but as no agreement is reached and all agree with a safe pressure of 4kPa, this value is used. Another paper [67] finds that with an surface pressure of 13-23mmHg, the blood flow in the forearm is doubled. When the blood flow is occluded occasionally e.g. when lifting something heavy with the prosthesis, the blood occlusion is not a problem for the cells lying behind the occlusion when the flow is restored quick enough.

• **Not interfere with perspiration**

The skin functions normally, even when wearing the prosthesis. As the existing standard prosthesis do not breathe at all, the goal for the new design is either designing a prosthesis socket that has a breathable shell or a socket which leaves a 75 percent of the skin uncovered. As the existing WILMER open socket leaves 75 percent of the skin uncovered, and still users complain about the heat and itchy character of the socket [2], the use of breathable materials is always recommended.

• **Be possible to be fitted in a standard prosthetic facility**

• **Be lightweight, low inertia**

The WILMER open socket prosthesis for children weights 100-200g [2]. The weight of the new design should be in the same order of magnitude. When the weight of the prosthesis is kept around the stump, the inertia is low.

• **Be weather-proof**

The socket should not oxidise and should endure sand and dirt.

• **Be made of comfortable materials**

The material should not provoke an allergic reaction, should not absorb perspiration, should be smooth, sanitary, strong, easy to clean and nonflammable.

• **Not hinder the movement of the remnant**

• **Preferably have a soft outside shell**

The shell should feel like a normal arm by use of a soft outside shell.

• **Provide optimal fixation of the prosthesis**

• **Be easy to don and doff**

• **Be adjustable**

So that the prosthesis grows along with the child and eventual volume changes in the course of the day.

• **Be cost effective**

The costs of the current WILMER open socket can only be estimated. A well experienced prosthesis fitter needs about 25 hours to finish the open socket (information from personal communication with F. Peters from Pom Nijmegen, the Netherlands). When he charges €75 per hour, and the materials cost about €250, then the total costs are around €2125.

• **control of terminal device**

The socket should be able to cope with all possible control ways of the terminal device, e.g. harness of body movements, WILMER elbow control, myo-electrical control.

• **The socket should not disturb the information passed through the nerves**

• **Have adaptive fitting**

When using adaptive fitting, the contact pressures are more evenly distributed without sudden changes in magnitude. The adaptive fitting should be suspended in the centre, then the fitting adjust itself automatically in full contact with the skin. This is results in more comfortable wearing of the prosthesis [5].

An overview of the requirements with its definitions can be found in Table 2.1.

Table 2.1: Overview of the requirements

The new design should:

Requirement	Definition
fit closely around the arm remnant	< 1mm
provide a smooth transition	step < 5mm
provide optimal self-suspension	attachment without muscle contraction
low pressure on skin	< 4kPa
not interfere with perspiration	75% uncovered skin/evaporation possible
fitting in standard prosthetic facility	
be lightweight, low inertia	< 200g
be weather-proof	e.g. no oxidation, endure sand/dirt
be made of comfortable materials	e.g. no allergic reaction, easy to clean and sanitary
not hinder the movement of the remnant	preservation of 90 % of movement without prosthesis
preferably have a soft outside shell	
be easy to don and doff	
be adjustable	
be cost effective	<€~2200
cope with different ways of control	
no disturbance of circulation and innervation	
have adaptive fitting	

Chapter 3

Problem analysis

To come to an acceptable and optimal design for the users, the requirements have to be investigated. In order to find a relation between the design requirements and if the existing sockets meet these requirements, a house of quality has been made, see Tables 3.1, 3.2 and 3.3. An example of making such a table can be found in the book of Ullman [68].

3.1 The centre of the house of quality

In Table 3.1, the first column contains the demands of the prosthesis wearer and the prosthesis fitter.
In the first row several ways of achieving these demands are placed, the second row states in which direction this demand has to be developed to result in an improvement. The third row contains the units of these demands. At the intersection of the rows and columns, the relation between the demand and ways of achieving these demands are listed. Following symbols are used: $\odot$ strong relationship, $\ominus$ medium relationship, $\triangle$ weak relationship and *blank* means no relationship. The explanation can be found in Appendix D.1.
In the last column the existing sockets are compared via grades from one (bad) to five (very good). The following symbols are used for the existing sockets: *M* Münster type socket, *T* the TRAC socket (see Figure 2.4(c)), *N* NorthWestern University (NWU) socket (see Figure 2.4(a)), *H* High Performance Variable Suspension (HPVS) socket (see Figure 2.4(d)) and *D* Delft (the WILMER open socket design, see Figure 2.4(e)). The explanation of these comparisons can be found in Appendix D.2.
In the last four rows the demands are rated: which values have example sockets, at which values the prosthesis wearer is content and when is he/she unsatisfied?

Table 3.1: The centre of the house of quality

	HOW										NOW				
	smooth transition and close fit	self-suspension, fixation and adaptive fitting	shear forces and light weight	uncovered skin and evaporation	weather /dirt proof	no allergic reaction and soft material	no hindrance of movement	quick fitting	divisible and adjustable socket	cost effective	M: münster, T: TRAC, N: NWU, H: HPVS, D: Delft				
direction of improvement	↓	↑	↓	↑	↑	↑	↑	↓	↓	↓	1	2	3	4	5
units, relationship: ⊙ strong, ⊖ medium, △ weak and *blank* no	[mm] [mm]	[N]	[N/m^2] [g]	[%] [%]	[-]	[-]	[%]	[hours]	[Y/N] [mm]	[€]					
no perspiration problems	⊙	⊖	⊙	⊙	⊖	⊖					MH TN			D	
easy to wear	⊖	⊙	⊙			⊖	⊖		⊖				MN	HT	D
no blisters		⊖	⊙	⊖								MN		HT	D
comfortable materials	⊖	⊖	△	△	△	⊖				△	MN		HT		D
easy donning and doffing	△	△						△	⊙	△	MH TN				D
good fitting	⊙	⊙	⊖				⊖	⊙	△	△	MN H		T		D
not bulky	⊙	⊖	△	△					⊖			D		MH TN	
outside feels natural				⊖	△	⊙					MH TN	D			
easy to fit	△	△						⊙	⊙	⊖	MH TN	D			
no problems with water	△	△	△	△	⊙	⊙	△	△	⊖						MH TND
price								⊙		⊙	HTD	MN			
Delft	[8] [0]	[-]	[] [200]	[75] [75]	[-]	[-]	[70]	[25.5] App B	[YY] [1.5]	[]					
Münster	[~3] []	[-]	[] [240]	[0] [0]	[-]	[-]	[61]	[21.5] App C	[NN] [-]	[]					
target (delighted)	[] []	[-]	[200]	[] [100]	[-]	[-]	[90]	[]	[YY] [1.5]	[]					
target (disgusted)	[] []	[-]	[] [300]	[] [75]	[-]	[-]	[50]	[]	[NN] [-]	[]					

3.2 Dependence of ways of achieving the demands

When the ways of achieving the demands of the prosthesis wearer are not dependant on each other, optimising the design is simple. But when the ways are dependant on each other, the generation of an optimal design is complicated. To investigate the dependence Table 3.2 has been made. The following symbols are used: $\ominus$ a strong dependence, $-$ dependence, $\times$ independence, $\otimes$ strong independence and *blank* no dependence. The explanation of the ratings can be found in Appendix D.3.

Table 3.2: Dependence of the ways of achieving the demands of the prosthesis wearer

	cost effective	divisible and adjustable socket	quick fitting	no hindrance of movement	no allergic reaction and soft material	weather /dirt proof	uncovered skin and evaporation	shear forces and light weight	self-suspension, fixation and adaptive fitting	smooth transition and close fit
smooth transition and close fit				$\otimes$			$-$		$\ominus$	
self-suspension, fixation and adaptive fitting				$\times$				$\ominus$		
shear forces and light weight										
uncovered skin and evaporation		$\ominus$			$-$	$-$				
weather /dirt proof										
no allergic reaction and soft material										
no hindrance of movement		$\ominus$								
quick fitting	$-$	$-$								
divisible and adjustable socket	$-$									
cost effective										

3.3 Importance of requirements

Besides the relations, it is also important to know the importance of the different requirements. When the new socket is put into use, two groups will have intensive contact with the socket: the prosthesis fitter and the prosthesis wearer. Both groups prioritise the requirements different, to investigate this the requirements are graded. 1 point means the requirement is very important, 10 points means the requirement is the least important. The result is shown in Table 3.3. The opinion of the wearer was derived with the help of Biddiss et al [58] and the opinion of the fitter was derived through personal communication with F. Peters from Pom Nijmegen, the Netherlands.

3.4 Conclusions

Now that all the requirements are investigated some conclusions can be drawn. From the house of quality, the following possible conflicting demands can be identified: *smooth transition and close fit* conflicts with *no perspiration problems*, *good fitting* can be in conflict with *quick fitting* and *easy to fit* conflicts with *divisible and adjustable socket*. These conflicts can arise when a strong

Table 3.3: The importance of the requirements

	prosthesis wearer	prosthesis fitter
no perspiration problems	2	3
easy to wear	3	2
no blisters	4	4
comfortable materials	2	4
easy donning and doffing	4	6
good fitting	1	1
not bulky	2	5
outside feels natural	8	7
easy to fit	10	8
no problems with water	5	9
price	6	10

relationship exists and when the demands are contradicting.
From the dependence of ways of achieving the demands a possible problem with *smooth transition and close fit* with *self-suspension, fixation and adaptive fitting* can arise, because with adaptive fitting a smooth transition is difficult.
From the importance of the different demands the following conclusions can be drawn. The prosthesis wearer rates the no perspiration problems, easy to wear, not bulky and easy donning and doffing as important. The prosthesis fitter on the other hand rates the easy of fitting and having no blisters when wearing the prosthesis as important. Both groups need to be satisfied with the new socket design, so both important factors should be taken into account during the design phase.

Chapter 4

Concept solutions for a transradial socket

4.1 Materials

First, an overview of (new) materials applicable in the field of prosthetics is given. The engineering of new materials has developed rapidly the last 5 years and most materials can be useful in socket development. The materials eventually applicable in prosthetic sockets are subdivided in groups and discussed in the next sections: textiles, foams and metals.

4.1.1 Textiles

In this section an overview of the different possibilities with textiles is given, the following textiles are discussed: Spacer Fabric, 3XDRY, MTEX, Comfortemp and Evolon.
3D knitted fabric (no 1048 on inventables website, [69]), or Spacer Fabric, is a two layer breathable fabric with vertical threads in between, this makes the gap between the layers flexible. The gap also provides ventilation. The material is available in different thicknesses, compression characteristics and yarn combinations [70, 71]. Most interesting type of Spacer Fabric is cross-woven Spacer Fabric [71, 72], this type does not 'collapse' under pressure, but spreads the force equally over the surface and could in this way provide adaptive fitting. A disadvantage of this kind of Spacer Fabric is the rough-textured surface, when applied on the skin, an extra layer of fabric is needed to prevent abrasion of the skin.
In the book of Stattmann [73] new materials are introduced, textiles that can be useful in the field of prosthetics are 3XDRY (outside: waterproof, inside: sweat permeable and freshplus property, [74]), MTEX (metal connected to textile, but isolates well [75]), Comfortemp (dynamical climate control with phase change materials, [74]) and nano-sphere (repels water and dirt still breathable, [76]). These textiles are useful e.g. as cover over Spacer Fabric.
Evolon [77] is an isotropic fabric made of 70% polyester and 30% polyamide. The fabric is strong, breathable (29 mm/s, DIN EN ISO 9237: =1,5 mm/s [78]), dries fast, anti-mite (not permeable for 99.7% of 1μm-parts with velocity of 50cm/s, the allergens of mites are larger than 3μm, so Evolon is not permeable for mites, [78]), provides thermal insulation, is flame-retardant, provides UV protection, has no fibre release, is absorbent, washable (at 95°C) and environmentally-friendly. The material is permeable to water damp (4874 g/m^2 24h, [78]) The fabric can be thermoformed and can be processed with the traditional textile processes. It can be dyed, printed, finished, be cut and sewn as other fabrics. With non fraying edges, Evolon also provides the advantage of easier converting, making over stitching useless. A disadvantage of Evolon is the getting caught of the fabric on rough skin, which does not feel nice.

4.1.2 Foams

Via the website of inventables [69] several foams have been found. Brock foam (no 413 on the website) is a kind of polystyrene foam that is non-absorptive and breathable. At this moment the foam is used as base layer for football fields in the USA. A disadvantage is the good insulation capacities of the foam. StructUre poly-urethane foam (no 1557) is a foam that can be made rigid at desired places with an electron beam process, the rigidity can be customised by variation of the electron dose. A foam of this kind could be used to replace the WILMER open socket with foam, the current stainless steel tubes are simply made of rigid foam. As a electron beam is needed to cure the foam, the foam can not be processed in a standard prosthetic facility.
Dimer [79] is a company in Germany that makes different kinds of foam. Foams suitable for the socket are DIM RG 30, DIM RG 40 and Collar 2203, these are open-celled soft poly-urethane foams. But when bringing those foams in contact with water, the foams act like a sponge which makes them useless in the field of prosthetics.
M.pore is a company also in Germany, which developed LUPO, an open pored stiffened PUR foam. LUPO is a new material, not on sale yet, the information was obtained through personal communication.
From FXI foamex innovations, a custom felt with flame retardant was ordered. The felt has hardness 6 (on a scale from one (soft) to twenty (hard)) and has an open-pored structure. The felt has a permeability of 43 cfm/ft2, which is 13.10 $\frac{m^3 min}{m^2}$. But when applying water on the felt, the water is only reluctantly passed through the felt, but the stiffness of the felt doesn't change. The felt is permeable for water damp.

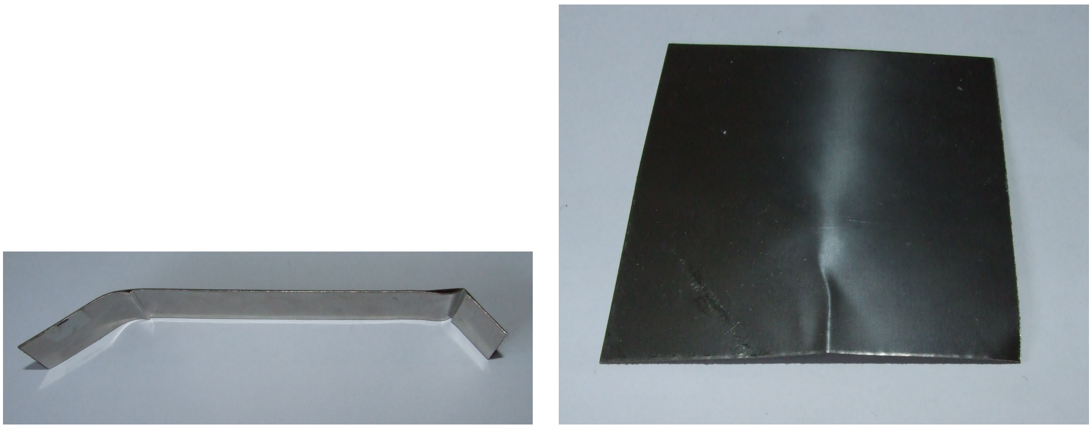
4.1.3 Metals

Hybrix

Hybrix [80] is a strong, thin and formable sandwich material. The core consist of microscopic stainless steel fibres vertically oriented against the stainless steel face plates. Hybrix can be drilled, sawed, bend, press formed, roll bend, screwed, coated (with Sandvik Decorex coating among others) and many other processes. Hybrix costs around 100-200 €/m^2 depending on the version (plate thickness and thickness of fibres). To invest the bend ability of the material a bending experiment was conducted by molding the material around a wooden sphere with a wooden hammer (see Figure 4.1). After a bending experiment is was concluded that hybrix is not bend able. The firm send a guide for forming hybrix and according to this guide, hybrix can be formed by pressing taking the following guidelines in account: use optimal blank geometry (constant flange of 3cm outside the pressed shape), use of a blank holder with enough force and lubrication or thin plastic films and the tool must have just enough space for the material. This means that the bend ability of hybrix can not be simply tested by forming hybrix around a sphere. Because the difficult bending properties of hybrix, the material is not suitable for use in prosthetics, as each prosthesis is different and would need a different blank. Surprisingly, hybrix is a wonderful material for rubber pad forming [81], see Figure 4.2, when taking the spring back of the material into account.

Stainless steel wire mesh

A rather old material is stainless steel wire mesh. A sample from Costacurta [82], Vico meshscreen with 1.9mm mesh width and 0.6mm wire diameter, was obtained. In order to use the wire mesh as prosthesis socket, it has to be bend in the right shape. To explore the bending possibilities of wire mesh, it has be shaped around a sphere. The result can be seen in Figure 4.3. The material shows a lot of rebound during forming, when manufacturing a socket, this has to be taken into account. Stainless steel wire mesh is easy obtainable (in different mesh widths and wire diameters) and does not provoke skin reactions.

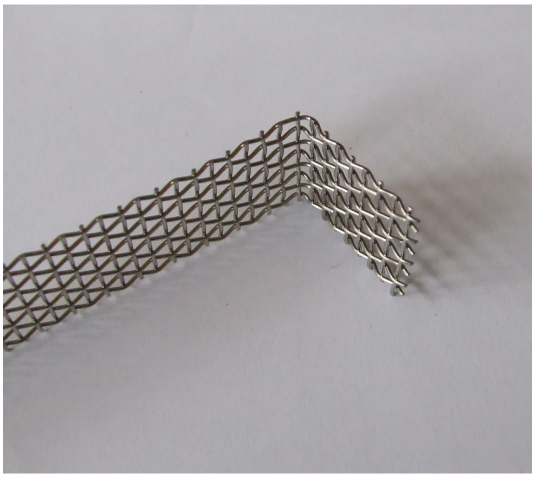


(a) Hybrix bend in a sharp edge bending machine

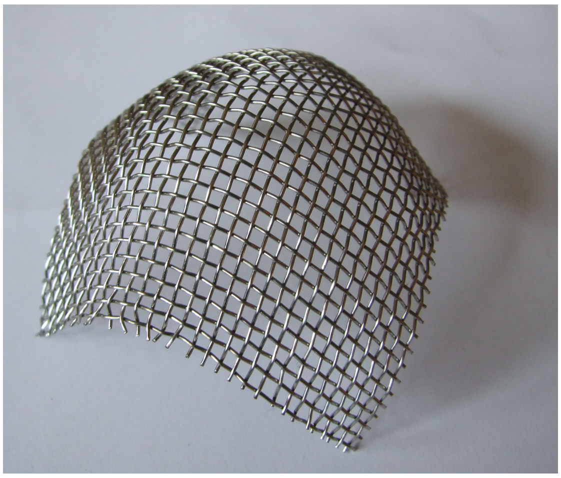
(b) Hybrix after it was molded around a wooden sphere of 6cm in diameter

Figure 4.1: The bending properties of Hybrix

Figure 4.2: Hybrix after rubber pad forming



(a) Stainless steel wire mesh bend in a sharp edge bending machine

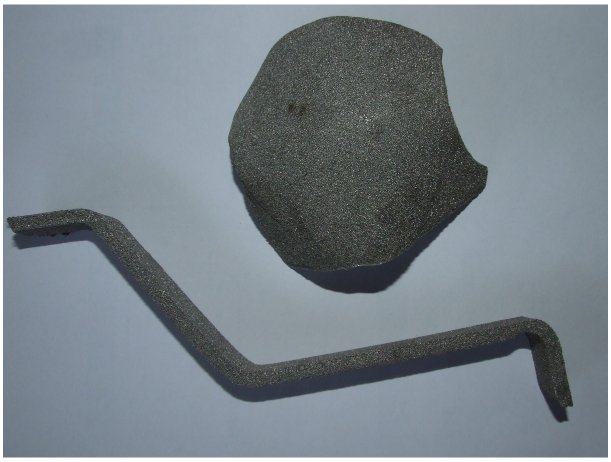


(b) Stainless steel wire mesh after it was molded around a wooden sphere of 6cm in diameter

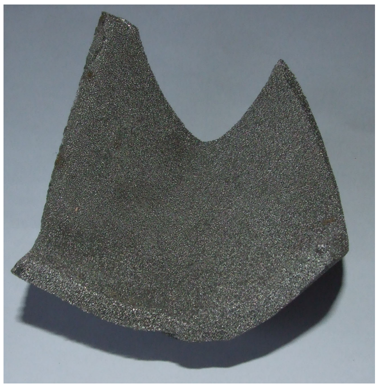
Figure 4.3: The bending properties of stainless steel wire mesh

Metal foams

As there are several types of metal foam [83] the possibilities of the different types have to be investigated, therefore samples of several types of this material were gathered. From the company Gleich [84] in Germany an ALPORAS aluminium foam sample was received. The alloy consists of Al, 1.5% Ca and 1.5% Ti. When trying to bend the material around a cylinder of 55 mm diameter, the sheet started to break. From the company ERG [85] in the USA a Duocel aluminium foam sample was received. The alloy consists of Al 97.6%, B 0.060%, Cr 0.030%, Cu 0.10%, Fe 0.50%, Mg 0.35-0.80%, Mn 0.030%, Si 0.30-0.70% and Zn 0.10%. Duocel has reticulated (open) pores and Alporas closed pores, this means Duocel is better permeable to sweat and water. But Duocel also breaks when trying to bend around a 55 mm diameter cylinder. In stead of trying to bend the material, it is also possible to mill and turn the socket out of a block of material. On the ERG-site, accessed on 6 March 2009, the price of a cubic inch of material was found. One cubic inch costs about US$1.50, which is €70 000 per m^3 (19 March 2009). When starting from a cylindrical block of material, diameter 10 cm and height 30 cm, the volume is around 2500 cm^3, the material costs are then €175. Wong [2] recommended stainless steel metal foam from the company Porvair Advanced Materials. The costs for a 207.37*185.85*6.6mm sheet with 11.3% pore density are US$76.31 on 28 February 2008 (€58.12 on 19 March 2009), which is €230 000 per m^3. For a prosthetic socket a volume of about $30*10\pi*1$cm=942 cm^3 is needed, the material costs are then €215. Unfortunately the company has suspended the manufacturing of metal foam due to the current economic conditions (last contact 29 October 2009). Mitsubishi [86] in Japan also manufactures reticulated stainless steel metal foam, a sheet of 150×100×6.0mm with pore size 300μm costs €735 (6 April 2009), which is too expensive. Now the company Recemat in the Netherlands has been contacted [87]. The company only produces nickel and nickel alloy metal foams, but stated a coating is possible. But before a coating can be applied, the metal foam has to be in the right shape. Recemat advised to bend the material first, then apply a chrome coating to harden the material and then apply another coating. In order to get an idea of the bend ability of nickel foam, the material was bend around a wooden sphere with the help of a wooden hammer. A picture of this experiment can be seen in Figure 4.4.



(a) Nickel metal foam after it was shaped around a wooden sphere of 6cm in diameter, the strip has been bend in a sharp edge bending machine



(b) Nickel metal foam after it was shaped around a wooden sphere

Figure 4.4: The bending properties of nickel metal foam

4.2 Improving the existing WILMER open socket

There are various options to come to a new socket design: improving the existing WILMER open socket, continuing with the socket of Wong [2] or designing a new socket. At this moment it is unclear which will result in the best socket, therefore all possibilities will be explored.

The first option, improving the WILMER open socket, will be discussed first. The main problem of the WILMER open socket is the non-aesthetic look (see Figure 4.5) and the difficult manufacturing technique. To improve the look, the space between the soft-covered steel tubes may be filled with a breathable material (e.g. the materials mentioned in Sections 4.1.1 and 4.1.2). In this way the socket is more one entity and not several connected steel tubes, this results in a less bulky and more aesthetic look. The bulky look can be further reduced by making the steel tubes flatter, converging more with the skin surface. Besides this the clamping method of the adjustable brace can be improved by making it flatter and smaller. The appearance of the tubes can be made flatter by substituting the foam around the tubes with a material under the tubes, e.g. spacer fabric. To solve the problem of the difficult manufacturing technique, the socket design is reconsidered. The main advantages of the WILMER open socket are the open structure (the skin is free to breath), the contact of the elbow with its surroundings and the easy donning and doffing. This advantages should be kept in the redesign.
The material between the steel tubes should be soft, breathable, not act like a sponge, let sweat pass trough, be lightweight and should not induce contact allergy. The material that fits the requirements best is spacer fabric. Spacer fabric could be used to substitute the soft foam around the steel tubes, simplifying the design.

4.2.1 Other steel tube cross sections

The steel tubes transmit the forces of the prosthesis to the arm remnant, therefore these tubes should have a high second moment of area, but not too high because they have to be bend in order to fit exactly around the arm remnant. The socket's weight should be as low as possible. In short this means the second moment of area should be as high as possible and the area should be as low as possible (this is comparable to a low weight). In the current WILMER open socket, a hollow circular cross section is used. An overview of possible cross sections can be found in Appendix E,

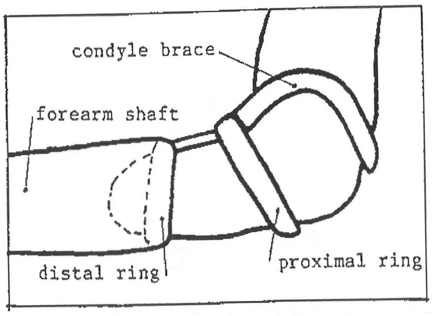


Figure 4.5: The current WILMER open socket [1]

Table E.1 [88, 89].
Susan van den Berg [90] made a redesign of the WILMER open socket, see Figure 4.6. The tubes of the open socket have been replaced by flattened tubes and straps. The condyle brace has been replaced by two short tubes (reach to the condyles) and a strap. All the straps are adjustable via Velcro. The socket has never been made except of two prototypes because the redesign still does not look aesthetically pleasing and the socket does not give enough control of the prosthesis. The manufacturer of the open socket, Ambroise [91], gives the following reasons: the design is not finished yet (there are a lot of snags) and the group of patients is too small for recouping the investment.

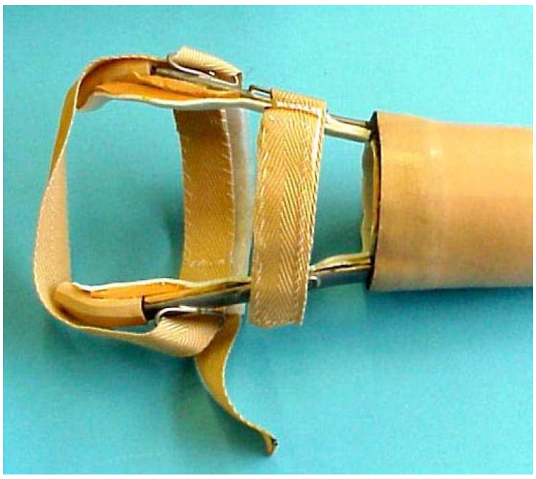


Figure 4.6: The redesign of Van den Berg of the open socket [90]

4.2.2 Clamping method

In the existing WILMER open socket, a ratchet with pawl fastener is used (see Figure 4.7) to clamp the brace around the upper arm. In this design the fastener is fairly high and as it is placed on the stump, this results in a bulge on the top of the prosthesis, even worse when the patient has a long forearm stump. The total height of the fastener is around 25mm, this includes the height of the socket wall.
In the book of Rosielle [92] two other solutions are provided. The first is the use of a belt around the adjustable brace, when the belt is tightened, the brace is clamped. The second is the use of a spring wrapped several times around the brace. When moving the brace in one way, no hindrance

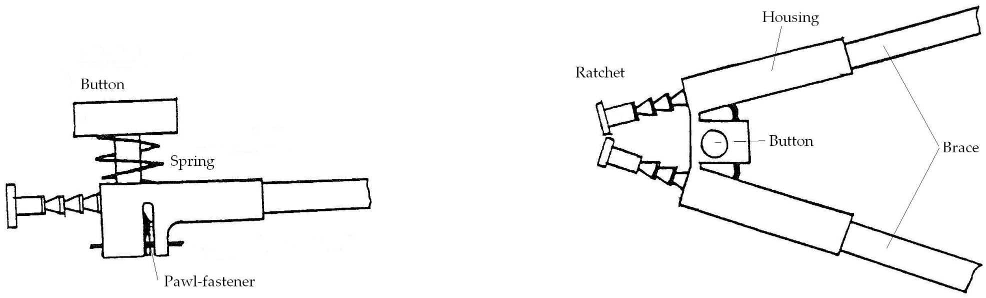


Figure 4.7: The current fastener of the WILMER open socket [61]

is encountered, when trying to move the brace the other way, the spring brakes the brace unless the spring is released.
In Appendix E, Figures E.2 and E.1, several suggestions for other clamping methods are shown. Chironis wrote several books about mechanisms, linkages and mechanical devices [93, 94]. In Appendix E, Figure E.3 suggestions from these books applicable as fixation method for the brace are shown. Other possibilities are the closure of an inline skate boot, a baseball cap or a type of Velcro closure used in shoes.

4.3 Continue the socket design of Wong

The second option to come to a new design, continuing the design of Wong, is discussed in this section. The design of Wong [2] can be seen in Figure 4.8. The socket is made of stainless steel metal foam, and coated to create a nice surface. The distal ring of the WILMER open socket is replaced by the metal foam cone. The metal foam is together the forearm shell and the socket, therefore an extra support is needed when the arm remnant is not shaped exactly conical. The support is a metal band shaped in the form of the arm remnant, the brace is attached to the metal foam.

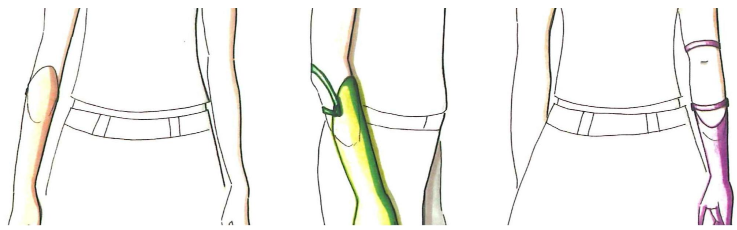


Figure 4.8: The socket design of Wong [2]

4.3.1 Metal foams

In the report of Wong [2], metal foam is suggested as material for a prosthetic socket. As the metal foam will be directly on the skin, allergic reactions are possible. Hostýnek et al [95] has investigated the reaction of the skin on several metals, he also looked at the rate on with the skin absorbs these metals. In Section 4.1.3 an overview of existing metal foams was already given. As nickel foam is the only remaining possibility, the allergy problem has to be solved. A coating could be applied, but Flint [96] on the other hand says that "Often the nickel plate is provided with a top coat, such as chromium, silver or gold, that, at conventional thicknesses, will reduce but is unlikely to eliminate formation of nickel ions when in contact with sweat." This means, allergy reactions are possible even when a coating is applied.

4.3.2 Adaptive fitting

In the existing WILMER open socket, the adaptive fitting is no problem: the place where the transmission of the forces occurs is well defined, and a well-thought design results in the absence of shear forces. In the metal foam socket this transmission place is not well defined, therefore something else is needed to counterbalance the shear forces, for example adaptive fitting. Adaptive fitting can be achieved by the introduction of small faces each supported in the middle via an elastic hinge, in this way the face will always be in full contact with the skin and shear forces are absent. An other way to achieve the absence of shear forces is to use a pressure spreading intermediate layer. Examples of such layers are Spacer Fabric [70, 71], film based honeycomb (the walls of the honeycomb collapse in such a way that all walls carry the same amount of force) [97] and pressure absorbing matrix (honey comb of soft plastic) [98].

4.3.3 Clamping of the brace

As clamping for the condyle brace a wedging clutch with a cylindrical roller is proposed. This clamping method is not convenient for children as after clamping and loading a high threshold value has to be overcome before the brace can be moved [92]. Via personal communication with Ambroise, another disadvantage came forward: the theoretical solution is nice, but the right angle of the wedge is difficult to reach when making a prototype. The angle should be smaller than the angle of friction, but large enough to prevent simple rolling. The coefficient of friction has to be high, for the best possible grip on the condyle brace. The hardness of the wedge should also be high, as deformation in combination with a high coefficient of friction could result in an immovable brace. A high hardness and coefficient of friction is difficult to unite in one material, so altogether it is difficult to fabricate a working prototype.

4.4 Designing a new socket

The last option is the design of a whole new socket, the advantage of this is that the materials and the design can be chosen freely, but with respect to the standards this can require extra attention as the new materials have to be tested on bio-compatibility. In Appendix E, Figure E.4 and Figure E.5 some new designs can be seen.

4.5 Concepts

The ideas presented above can be combined resulting in different concepts. The three most promising concepts are described in this section: a socket made of nickel foam, a redesign of the WILMER open socket and a socket made of stainless steel wire mesh.

4.5.1 Nickel foam

The first concept uses a structural porous material, nickel foam, which is probably permeable to water and air. Now that the sweat is released from the socket, it is possible to cover more skin with the material, resulting in a less bulky socket. But adaptive fitting is still a problem. This may be solved by using spacer fabric (around 8 €/m^2) or another force spreading material between the skin and the nickel foam. The risk of allergy is then also minimised. To reduce this risk further, a chrome coating is applied followed by another coating. The smallest pore size in nickel foam Recemat can fabricate is an average pore size of 0.4mm. In order to keep the metal foam and spacer fabric clean, an additional layer can be added. An example of such a layer is Evolon (an

isotropic fabric made of 70% polyester and 30% polyamide [77], see Section 4.1.1).
The metal foam has to be bend or milled in the right form. A relative simple way of bending material is rubber pad forming [81] as only one blank is needed. The blank was made of OBO (brand name) wood (see Figure 4.9(a)), and pressed with a 400 tonne press. The outer layer of rubber (20mm) had a hardness of 90 Shore A and the inner block (120mm) a hardness of 70 Shore A. The problem with this manufacturing method is that not only the foam is formed, but also compressed and cracked, see Figure 4.9(c).
Plate roll bending is another production method of cylinders and cones, this method maybe

(a) The blank used for rubber pad forming

(b) The blank cracked during the forming process

(c) The nickel foam after rubber pad forming

(d) A close up of the nickel foam after rubber pad forming

Figure 4.9: Rubber pad forming

applicable on nickel foam. Todd [99] provides and overview of manufacturing processes including plate roll bending. According to him nickel has fair to good roll bending form ability ratings, cones are possible and the thickness range of the plates is 0.03-10inch. As the nickel foam is 5mm=0.19inch, plate roll bending should be possible. The edges can be glued (with a flexible connection), screwed or clamped together.

4.5.2 Wilmer

The second concept is a redesign of the WILMER open socket. In the following paragraph the most optimal dimensions of the braces are calculated.
The WILMER open socket has two different tubes: for the condyle brace a 5mm diameter tube with a wall thickness of 0.5mm is used, for all other braces 4mm diameter tubes with wall thickness 0.5mm are used. When substituting this tube with circular cross section with a flatter tube with oval cross section, the second moment of area should be the same. Before the dimensions of the ellipse can be calculated, a premise has to be made: the long edge of the ellipse is twice as long as the short edge. R is the radius of the circular cross section of the WILMER open socket, t is the wall thickness, a is the half-length of the short edge of the oval cross section, b is the half-length of the long edge of the oval cross section (see Figure 4.10) and I is the second moment of area of the respective cross sections. The second moment of area of the hollow ellipse is taken from M.C. O'Neill and C.B. Ruff [89] and simplified by leaving higher order terms of t out.

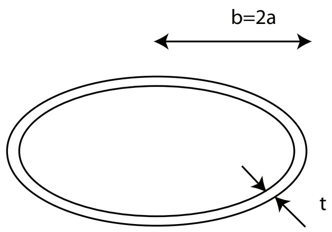


Figure 4.10: The dimensions of the elliptical cross section

$$I_{\text{circle}} = \pi R^3 t \tag{4.1}$$

$$\begin{aligned} I_{\text{oval short edge}} &= \frac{\pi}{4} a^3 t (1 + \frac{3b}{a}) \\ &= \frac{\pi}{4} a^3 t (1 + \frac{3(2a)}{a}) \\ &= \frac{\pi}{4} a^3 t (1 + 6) \end{aligned} \tag{4.2}$$

$$\begin{aligned} I_{\text{circle}} &= I_{\text{oval short edge}} \\ \pi R^3 t &= \frac{\pi}{4} a^3 t (1 + 6) \\ a^3 &= \frac{4}{7} R^3 \\ a &= \sqrt[3]{\frac{4}{7} R^3} \end{aligned} \tag{4.3}$$

This results in dimensions of a=2.07mm (condyle brace) and a=1.66mm (other braces).
In order to calculate the difference in force needed for bending of the tubes another, more accurate,

formula for the oval cross section is used [88].

$$\frac{F_{\text{circle}}}{I_{\text{circle}}} = \frac{F_{\text{oval}}}{I_{\text{oval}}}$$
$$F_{\text{oval}} = \frac{F_{\text{circle}} I_{\text{oval}}}{I_{\text{circle}}} \tag{4.4}$$
$$I_{\text{oval long edge}} = \frac{\pi}{4} t b^2 (b+3a)[1 + K_2 (\frac{b-a}{b+a})^2] + \frac{\pi}{10} t^3 (3b+a)[1 + K_3 (\frac{b-a}{b+a})^2]$$
$$K_2 = 0.1349 + 0.1279\frac{b}{a} - 0.01284(\frac{b}{a})^2$$
$$K_3 = 0.1349 + 0.1279\frac{a}{b} - 0.01284(\frac{a}{b})^2$$

Thus when substituting the figures in Equation (4.4), this results in:

$$F_{\text{oval}} = 3F_{\text{circle}} \tag{4.5}$$

When using an oval cross section in stead of the current circular cross section, the force needed for bending is over the long edge 3 times higher.
In stead of an oval cross section, a rectangular cross section can also be used. In this case it is also assumed that the long edge is twice the short edge, to simplify calculating the length of the edge when the same stiffness should be achieved as in the WILMER open socket tube. R is the radius of the circular cross section of the WILMER open socket, t is the thickness of the tube, d is the length of the short edge, $b = 2d$ is the length of the long edge, $b_i = b - 2t = 2d - 2t$ is the inner length of the long edge, $d_i = d - 2t$ is the inner length of the short edge, see Figure 4.11.

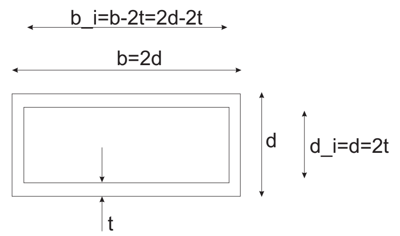


Figure 4.11: The dimensions of the rectangular cross section

$$I_{\text{rectangle}} = \frac{bd^3 - b_i d_i^3}{12}$$
$$I_{\text{circle}} = \pi R^3 t$$
$$\frac{bd^3 - b_i d_i^3}{12} = \pi R^3 t \tag{4.6}$$

Equation (4.6) has been implemented in Maple and solved, resulting in a value of 3.19 for d.
When comparing the force needed for bending of rectangular cross section to the circular cross section, the next equation is needed:

$$F_{\text{rectangle}} = F_{\text{circle}} \frac{I_{\text{rectangle}}}{I_{\text{circle}}} \tag{4.7}$$

which results in:

$$F_{\text{rectangle}} = 3.24 F_{\text{circle}} \tag{4.8}$$

From Equations (4.4), (4.8) it can be concluded that the use of a oval cross section is more feasible than the use of a rectangular cross section, as the force needed to bend the tube over the long edge is lower, the oval cross section has no sharp edges and the area of the cross section is smaller which means a lighter construction.

4.5.3 Stainless steel wire mesh

The socket of the third concept is made stainless steel wire mesh. This mesh has to be formed in the right shape. The desired shape could be obtained by press forming, but then the placement of the mesh is important. The optimal mesh placement is discussed in this section.
When using stainless steel wire mesh, the placement of the mesh during forming is important to keep the mesh from wrinkling. Delft University of Technology developed a program, Drape, to calculate how fibre reinforced laminate should be placed in the mould. This program can also be used to calculate how stainless steel mesh should be placed. The most suitable placement is found through trial and error. In the program several options can be chosen. The starting point and orientation of the mesh can be chosen and the way of expanding this mesh. The mesh can also be applied via press forming. The mesh width and the kind of mesh can be chosen as well. In Figure 4.12 the best placement can be seen. The result of wrong placement can be seen in Figure 4.13.
Besides the correct placement, the type of stainless steel is also important. There are many different kinds of stainless steels, every one with a different chemical composition. Some kinds are more prone to induce allergic reaction to nickel in humans than others. Haudrechy [100] found that low sulphur ($S \leq 0.03\%$) stainless steels (e.g. AISI304, 316L, 430) should not elicit nickel contact dermatitis and that high sulphur ($S > 0.1\%$) stainless steels (e.g. AISI303) or nickel plated stainless steels should be avoided.
The stainless steel wire mesh has also been bent with rubber pad forming. The wire mesh was held

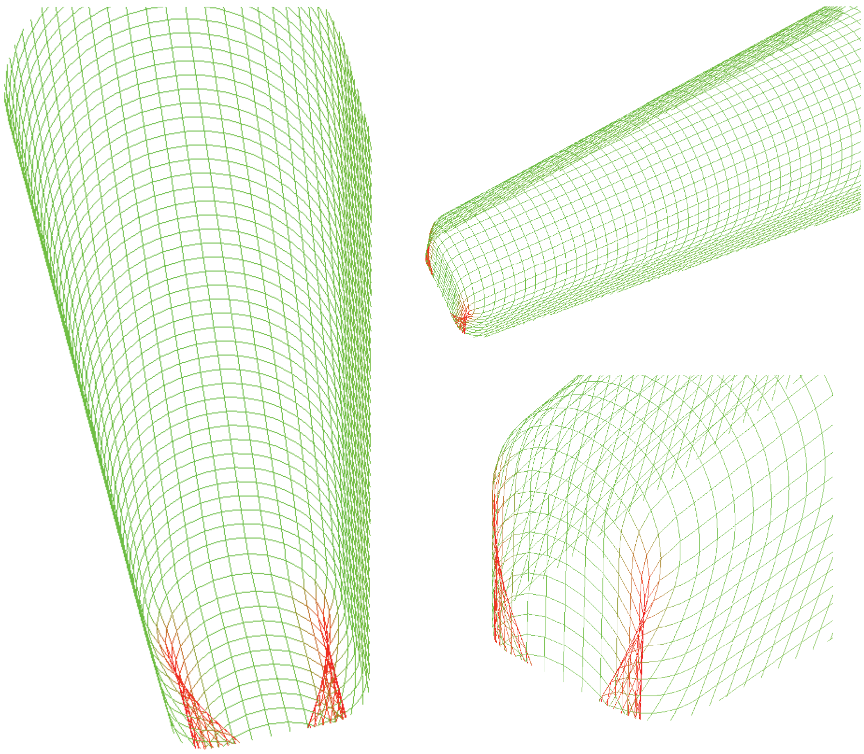


Figure 4.12: The best placement of the mesh. The wrinkles occur at the top of the cone, the place without direct skin contact

too tightly between the blank and the rubber, resulting in tearing of the mesh, see Figure 4.14. Tearing may be prevented by sandwiching the material between two metal sheets, accommodating slip between the mesh and the rubber.
Via plate roll bending, cones and cylinders can be made. In Figure 4.15 the result can be seen. The cone can be adapted to fit the various arm remnants.

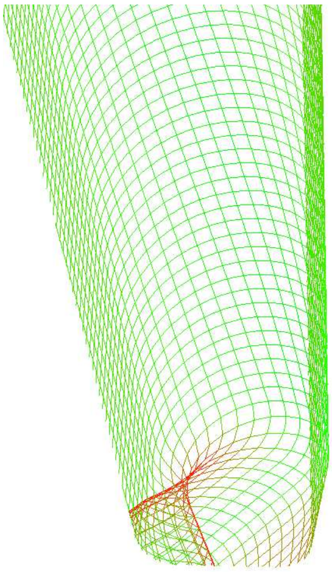
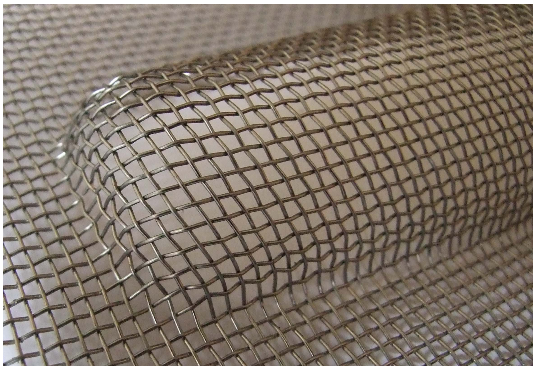
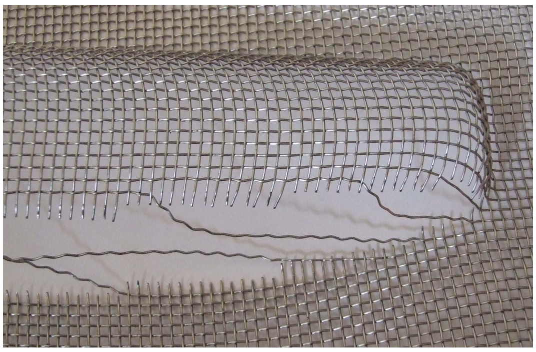


Figure 4.13: An example of wrong mesh placement, wrinkles can be seen at the top and at the side of the top of the cone



(a) The top of the mesh



(b) The teared mesh

Figure 4.14: Stainless steel wire mesh after rubber pad forming

Now that the mesh has the right form, the sharp edges have to be concealed. Examples of

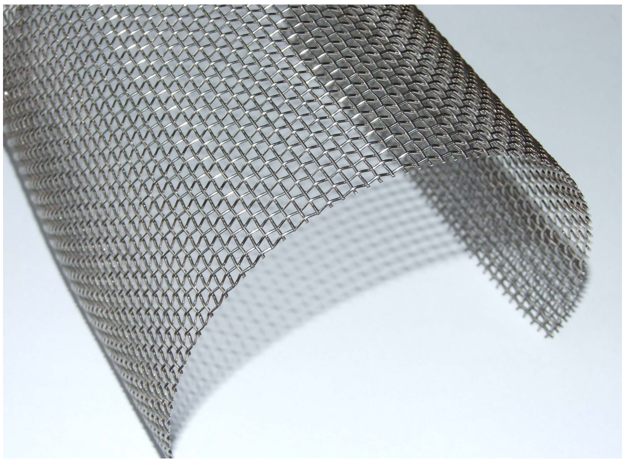


Figure 4.15: Stainless steel wire mesh after plate roll bending

concealing methods are a plastic strip which is put around the edge and secured, a plastic strip melted around the edges, a plastic strip glued around the edges, a kind of baseball cap closure with the mesh in between, screws with washers through the mesh and soldering each wire onto a frame, also the overlapping mesh can be soldered together.

Stiffness calculation of stainless steel mesh

When applying a stainless steel mesh as socket material, it should be stiff enough to transfer the forces of the environment to the arm remnant and the other way around. In this paragraph is therefore a stiffness calculation conducted. The second moment of area of one wire with radius r of the mesh is [88]:

$$I_{\text{wire}} = \frac{\pi r^4}{4}. \tag{4.9}$$

The Steiner rule [101] can be applied to calculate the second moment of area of socket with radius d and wire cross section A:

$$I_x = I + Ad^2. \tag{4.10}$$

The distance from wire to wire is 1.6mm and the radius of a wire is 0.3mm, the radius of the socket is 20mm, from this it can be calculated that there are around 66 wires in the socket. Now, the total second moment of area is:

$$I = 66(\frac{\pi r^4}{4} + Ad^2). \tag{4.11}$$

The deflection f at the end of a socket with length l 0.1m under a force F is and Young's modulus E [102]:

$$f = \frac{Fl^3}{3EI} \tag{4.12}$$

which results in a deflection of $1.07 * 10^{-5}$m under a force of 50N and a Young's modulus of 207GPa. This should be stiff enough for a socket design, especially because there are a lot of different stainless steel wire meshes with different wires and spaces between the wires.
Rosielle [92] gives a general rule when using a plate rolled into a tube, resulting in a low torsional stiffness. Clamping one cross section the stiffness equals a cylindrical tube of the same dimensions. When the tube is relatively long (longer than 5D, with D the diameter of the tube), the cross section should be repeated every 5D, which is here not the case.

4.6 Selection

Having generated a number of concepts, the next step is to choose a concept for further elaboration. To make a well-founded choice, the use of a technique to compare the concepts is inevitable. As there are many useful techniques, a choice has to be made. The technique should be easy and quick in use and the results should be conveniently arranged. In this study a Harris profile and Kesselring diagrams are used, as Kroonenberg [103] values them most. First, the most feasible socket concept is chosen, in the next section the most feasible closure for the condyle brace is chosen.

4.6.1 Selection of a socket design

Harris profile

The Harris profile can be seen in Table 4.1. The different concepts are given a mark from 1 to 4 (best) for each requirement. The total sum of marks for each concept is compared to the other concepts. The higher the total sum, the better the concept fulfils the requirements. The choice of one out of an even number of marks forces the user in doubtful cases to choose, between in this case two and three, in stead of taking the mean mark. By also giving the sum of maximal marks, it is convenient to see how much the concept deviates from the ideal solution. No weight-factors are used, as the influence of the factors is limited when having more requirements than the largest weight-factor [103].
Instead of putting the marks in a table, the marks can be visualised in a graph, see Figure 4.16. The marks of a concept of each requirement are represented in a bar diagram. In this way it is convenient to see where a certain concept lags behind at other concepts. The requirements *not hinder the movement of the remnant*, *cost effective*, *easy to don and doff*, *adjustable* and *different ways of control* are ignored, as they are merely design problems that can easily be solved in the next design phase.

Table 4.1: Harris profile of the different concepts, Concept 1: nickel foam, 2: redesign of open socket and 3: stainless steel wire mesh

No	Requirement	1	2	3
1	Fit closely around arm remnant	3	3	4
2	Provide smooth transition	2	2	4
3	Provide optimal suspension	2	4	3
4	Low pressure on skin	3	2	3
5	Load skin with normal forces only	2	3	2
6	Not interfere with perspiration	2	3	4
7	Be lightweight	3	3	4
8	Be weatherproof	4	4	4
9	Made of comfortable materials	2	3	3
10	Fitted in standard prosthetic facility	2	3	3
11	Soft outside shell	1	3	3
12	No disturbance of circulation and innervation	3	2	3
13	Have adaptive fitting	4	3	4
	total (max 44)	33	38	44
	total percentage	63%	73%	85%

Kesselring diagram

A Kesselring diagram is a two dimensional comparison of the different concepts. The requirements are divided into two groups, the sum of scores per concept per group is placed in the graph, see Figure 4.17. The first group contains the following requirements: fit closely around arm remnant,

provide optimal suspension, low pressure on the skin, loads skin with normal forces only, not interfere with perspiration, lightweight, no disturbance of circulation or innervation and adaptive fitting (this group contains comfort requirements that are dealt with all time during wearing of the prosthesis). The second group contains: provide smooth transition, be weatherproof, made of comfortable materials, fitted in standard prosthetic facility and soft outside shell, (the group of requirements that aren't dealt with all time during wearing of the prosthesis). The Kesselring diagram also helps improving the concepts: from the graph it can be immediately seen which group of requirements needs improvement.
From Figures 4.16, 4.17 and Table 4.1 can be concluded that stainless steel wire mesh offers the best possibilities to result in a comfortable and wearable socket design.

4.6.2 Selection of a clamping mechanism

In this section a clamping mechanism is chosen. In order to choose a mechanism, requirements should be known. These requirements are:

- flatter and smaller than the current WILMER mechanism.
- a low noise level
- different angles between the condyle brace possible
- lightweight
- capable of withstanding 2*250N pull force (two mechanisms the current WILMER mechanism can withstand a pull force of 250N per bar)
- stain proof
- dirt proof
- water proof
- no slack even after wear
- finger safe
- facilitates easy dressing
- maintenance possible
- easy one hand operating
- no extruding parts
- reliable.

Simulation of the clamping mechanisms

To check whether the requirement of the pull force is met, the different mechanisms were modelled in SolidWorks. In this section the modelling is described. Once a closure is modelled (an example can be found in Figure 4.18), the assemblies can be tested on strength in a static contact problem in SolidWorks Simulation. When solving multi-area contact problems, a particular set up has to be used, this set up is explained in Appendix F.
The results of the different studies of the mechanisms can be seen in Figures 4.19, 4.20, 4.21 and 4.22. In these figures the mechanism, the load case of each mechanism can be seen, the stresses in the mechanism and the eventual exceeding of the stresses over the tensile strength.
When a material is not available in SolidWorks, the data sheet can be exported from CES and placed in the material database of SolidWorks.

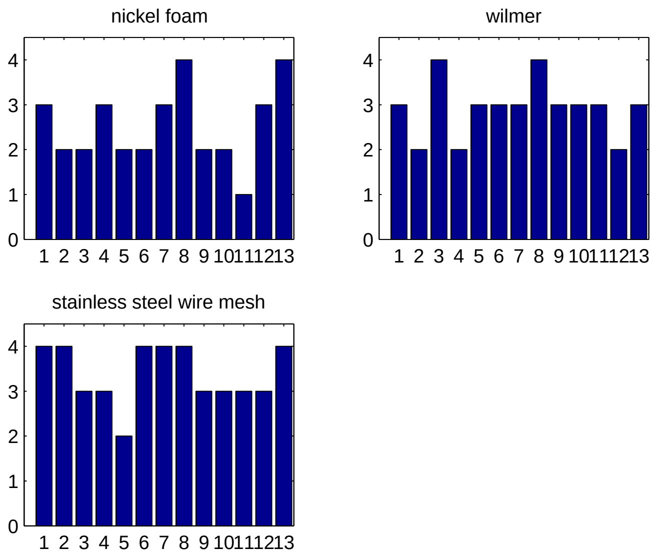


Figure 4.16: The marks of the Harris profile visualised in graphs, on the x-axis are the requirements numbered, on the y-axis contains the mark for each requirement

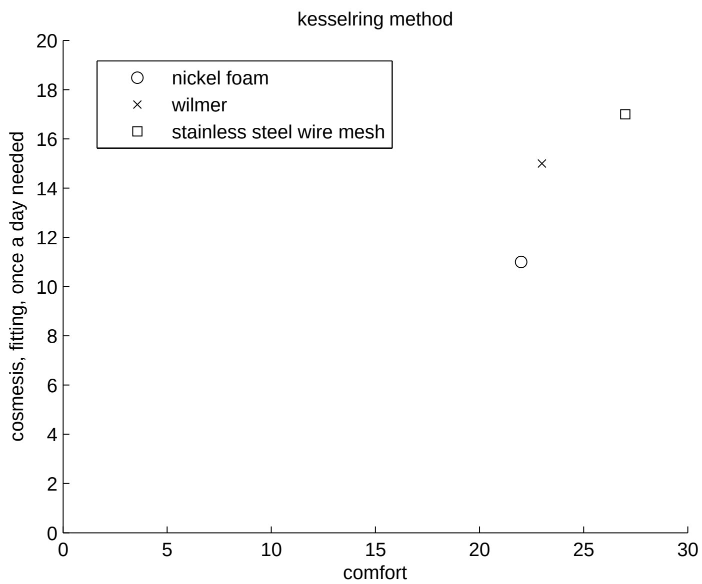


Figure 4.17: Kesselring diagram, the requirements are divided into two groups (comfort and cosmesis, fitting & once a day needed), the marks per concept per group are summed and put in the graph. Each group has a maximum of 36 points

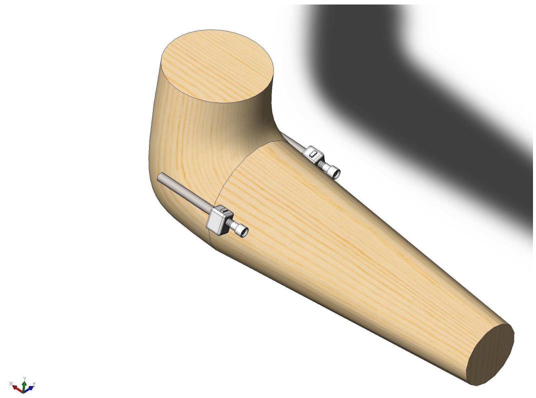


Figure 4.18: An example of a closure modelled in SolidWorks and placed on a stump which is also modelled in SolidWorks

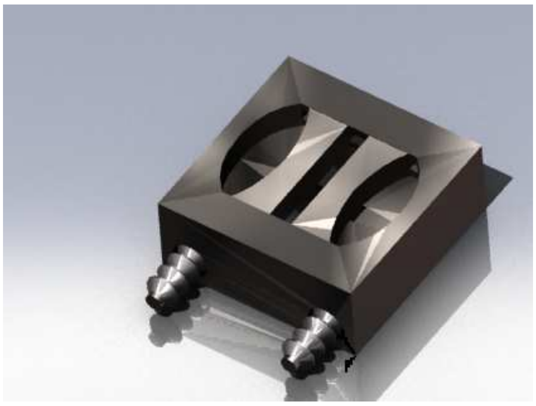
It is difficult to tell how reliable the results of SolidWorks Simulation are. Simple load cases can easily be checked by a calculation on paper, but the load case of the whole mechanism is more difficult to verify. Some results must be false as there are parts under stress which are unloaded, other simulations seem quite reliable. When taking this into account, the mechanism should be rather over- than underdimensioned. Mechanisms exported to Ansys could not be analysed due to constraints on the number of elements, resulting in a too coarse mesh and unreliable outcomes. The chosen clamping mechanism is simulated in SolidWorks part by part, which is more time consuming but results in more reliable results. Each part has been fixed and loaded, just as in the load case of the whole mechanism. This ensures that the mechanism is strong enough for the intended use.

Harris Profile

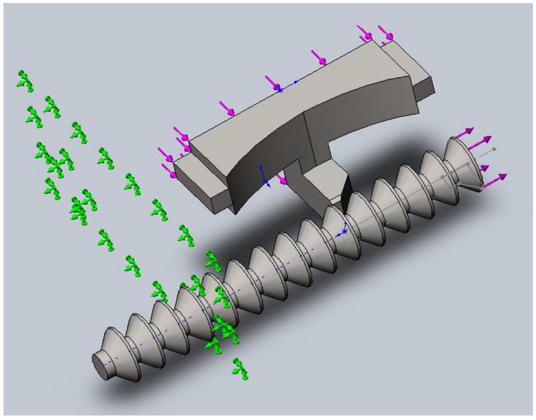
Now the SolidWork models have been made, all requirements can be assessed. In Table 4.2 an overview of the designs and the score on the requirements can be found. For each requirement a mark from 1 to 4 (best) is given. The total sum of marks per mechanism is compared with other concepts. The mechanisms can be represented in a bar diagram, just like the socket concepts. The bar diagram can be seen in Figure 4.23.

Kesselring diagram

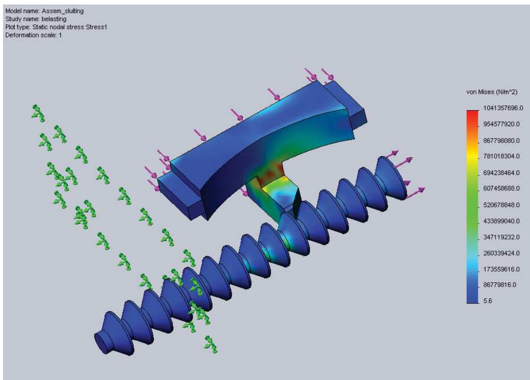
Here, again the requirements are divided into tow groups and plotted per mechanism, see Figure 4.24. The comfort group contains: flatter&smaller, low noise level, lightweight, stain proof, dirt proof, water proof, finger safe and easy one hand operating. The fitting & once a day needed group contains: different angles between the braces, 2*250N pull force (stress depends on mechanism), no slack, easy dressing, maintenance possible, no extruding parts and reliable.
With help of Figures 4.23, 4.24 and Table 4.2, it is concluded that the sliding mechanism is the best mechanism in prosthetic use.



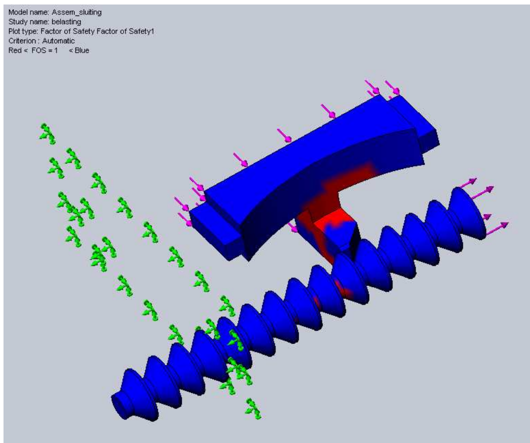
(a) The mechanism in SolidWorks



(b) The forces on the mechanism: 400N pull force on the brace and 50N on the clamp, the area with green arrows is fixed



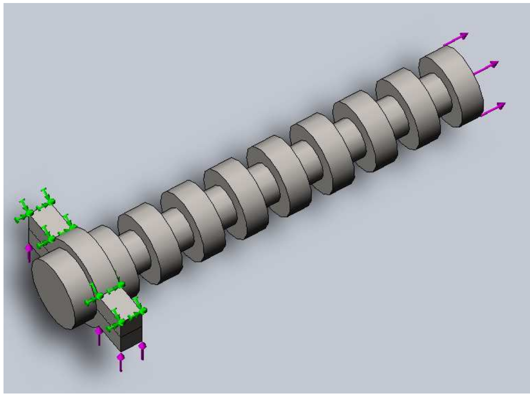
(c) A plot of the von mises stresses on the device



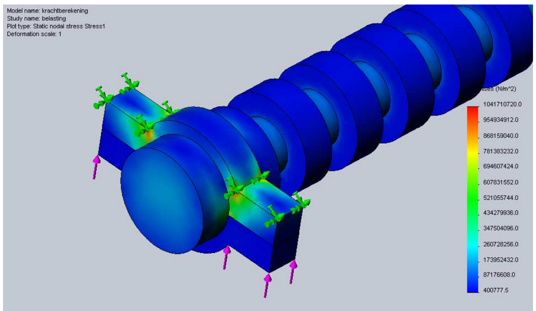
(d) The safety factor plot: when the stress is bigger than the material strength, the area is coloured red

Figure 4.19: The flatter WILMER open fitting clamping mechanism

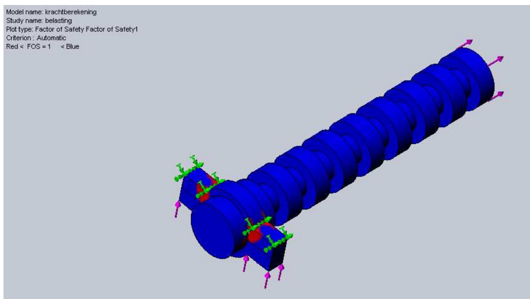
(a) The mechanism in SolidWorks



(b) The forces applied on the mechanism: 400N on the brace and 10N on the clamp, the area with green arrows is fixed

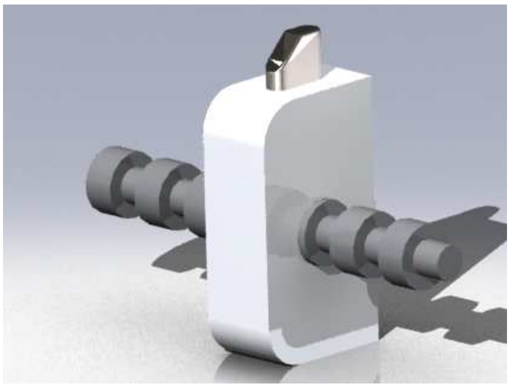


(c) The von mises stresses in the mechanism

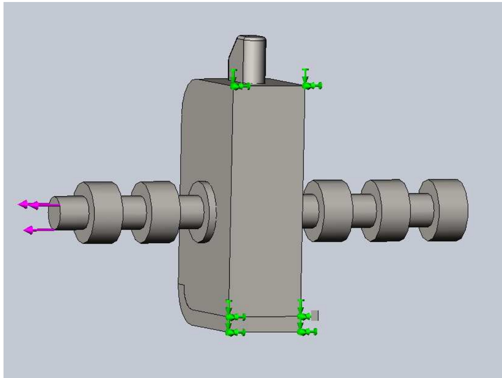


(d) The safety factor plot: when the stress is bigger than the material strength, the area is coloured red

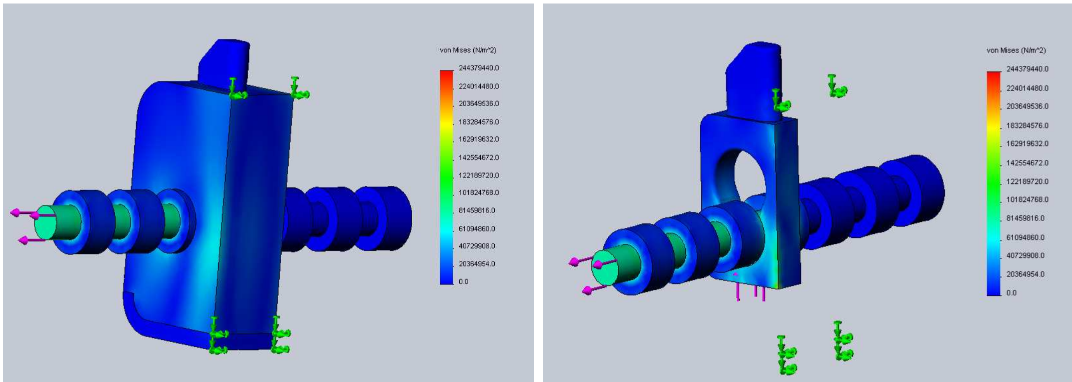
Figure 4.20: A simple clamping mechanism



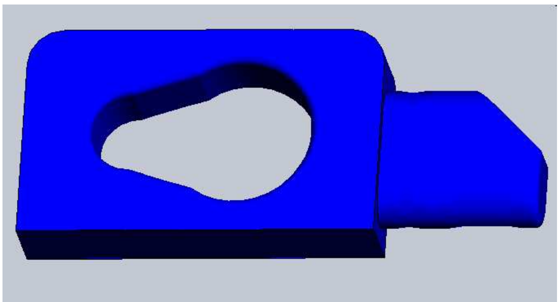
(a) The mechanism in SolidWorks



(b) The forces applied on the mechanism: 400N pull force on the brace, the area with green arrows is fixed



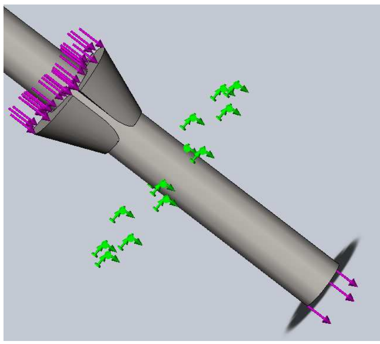
(c) The von mises stresses in the clamp and brace



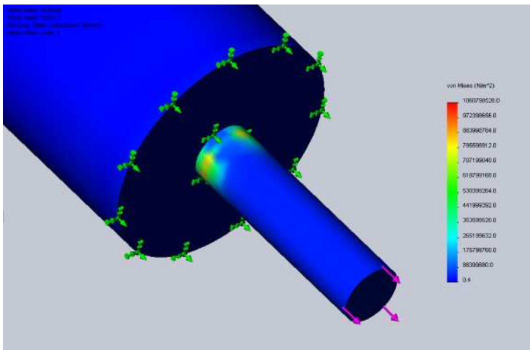
(d) The safety factor plot: when the stress is bigger than the material strength, the area is coloured red

Figure 4.21: A sliding mechanism to clamp the brace

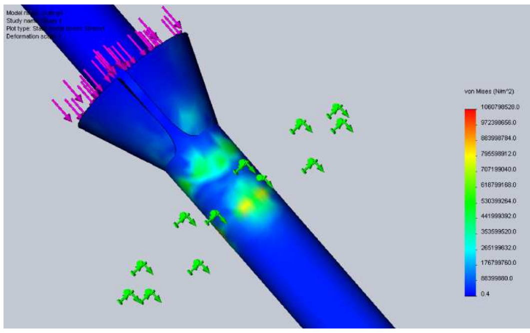
(a) The mechanism in SolidWorks



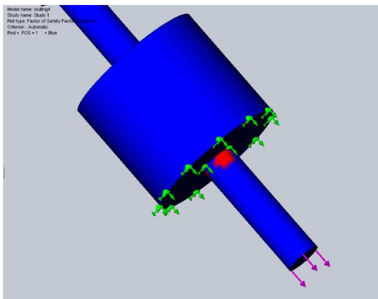
(b) The forces applied on the mechanism: 400N on the brace and 50N on each clamp, the area with green arrows is fixed



(c) The von mises stresses in the mechanism



(d) A close up of the von mises stresses in the mechanism



(e) The safety factor plot: when the stress is bigger than the material strength, the area is coloured red

Figure 4.22: The mechanism of a propelling pencil

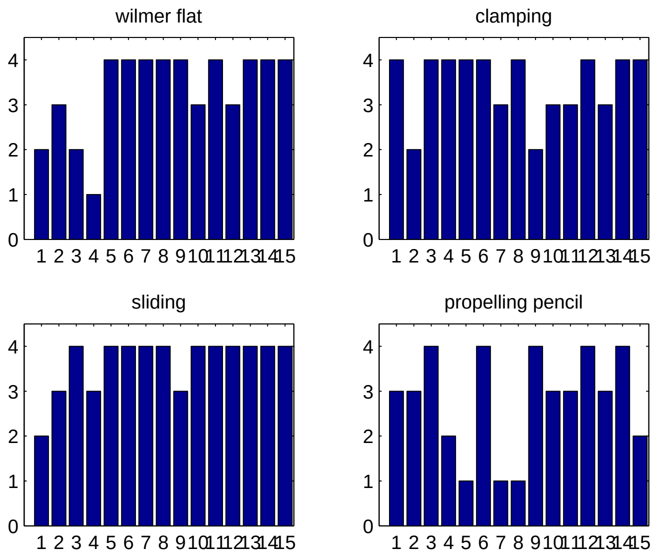


Figure 4.23: The marks of the Harris profile visualised in graphs, on the x-axis are the requirements numbered, on the y-axis contains the mark for each requirement

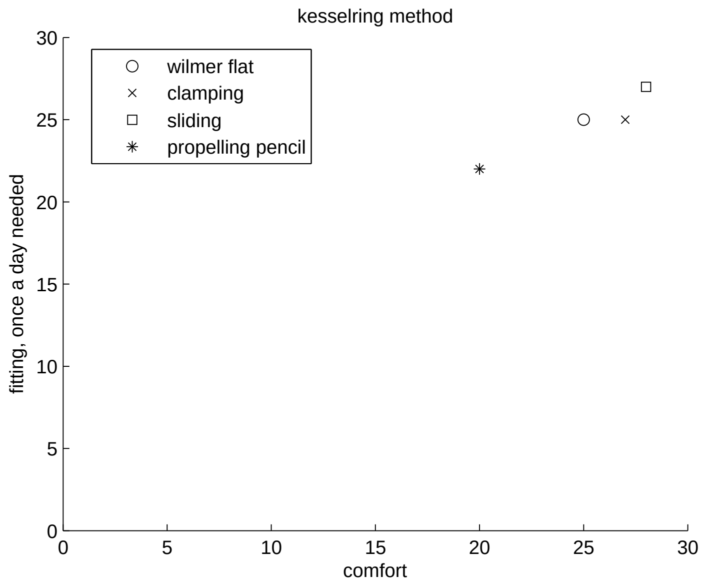


Figure 4.24: Kesselring diagram, the requirements are divided into two groups (comfort (max 32 points) and fitting & once a day needed (max 36 points)), the marks per concept per group are summed and put in the graph.

Table 4.2: Harris profile of the different clamping methods, Concept 1: flatter WILMER mechanism, 2: simple clamping mechanism, 3: sliding mechanism and 4: propelling pencil mechanism

No	Requirement Mechanism	1	2	3	4
1	flatter & smaller	2	4	2	3
2	low noise level	3	2	3	3
3	different angles between brace	2	4	4	4
4	lightweight	1	4	3	2
5	2*250N pull force	4	4	4	1
6	stain proof	4	4	4	4
7	dirt proof	4	3	4	1
8	water proof	4	4	4	1
9	no slack	4	2	3	4
10	finger safe	3	3	4	3
11	easy dressing	4	3	4	3
12	maintenance possible	3	4	4	4
13	easy one hand operating	4	3	4	3
14	no extruding parts	4	4	4	4
15	reliable	4	4	4	2
	total (max 60)	50	52	55	42
	total percentage	83	87	92	70

Chapter 5

Design of a transradial socket

In this chapter the chosen concepts of the socket and the closure are elaborated. First the finishing of the mesh edges is tested on feasibility, then a right plastic is chosen for the connection of the mesh edges. With the kind of plastic known, the adhesive can be chosen. Now the designs of the closure and socket are detailed.

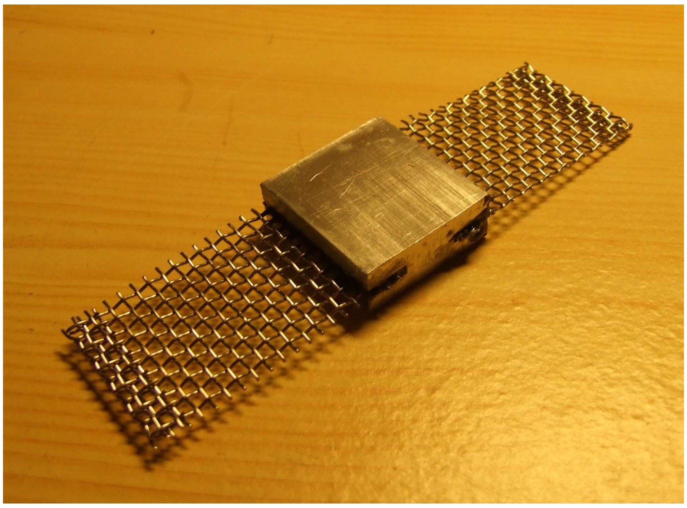
5.1 Testing stainless steel wire mesh connections on the tensile tester

The stainless steel wire mesh edges need to be joined. The most easy solution is a H-profile in which the wire mesh is glued. To test the feasibility of the idea a test is conducted. First, the edge of the mesh is bend 180 degrees to prevent fraying. The profile (aluminium) and the wire mesh are cleaned in isopropyl alcohol. Now Araldite resin AV138M and hardener HV998 are mixed (weight ratio 100:40) and applied in the profile. The wire mesh is positioned in the profile and the whole is placed for an hour in an oven at 60℃, the result can be seen in Figure 5.1. The parts are tested on a Zwick Z010 tensile tester, the results can be seen in Figure 5.2. When using enough adhesive (all holes in the mesh filled with adhesive) and a large enough adhesion area, the connection is strong enough to be used in prosthetic use.

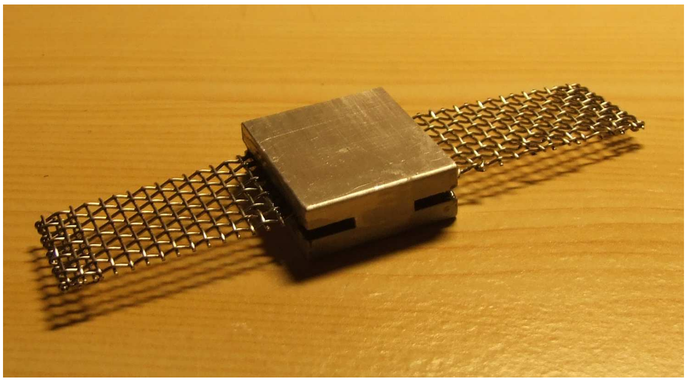
5.2 Choosing plastic for the connection of mesh edges

As the idea is feasible, a plastic must be chosen for the connection of the mesh edges. With the help of Cambridge Engineering Select (CES) EduPack [104] 2009 it is fairly easy to choose between the abundant stock of polymers. By simply putting constraints on several properties of the different polymers, the number of polymers is smaller. The following constraints were applied:

- yield strength minimal 50 MPa
- Young's modulus minimal 0.1 GPa
- elongation maximal 10%
- minimal service temperature: max -20 ℃(freeze)
- melting point above 100 ℃(sunshine)
- UV radiation (sunshine): good or excellent
- price below €50,-/kg
- flammability: self-extinguishing of non-flammable (safety)



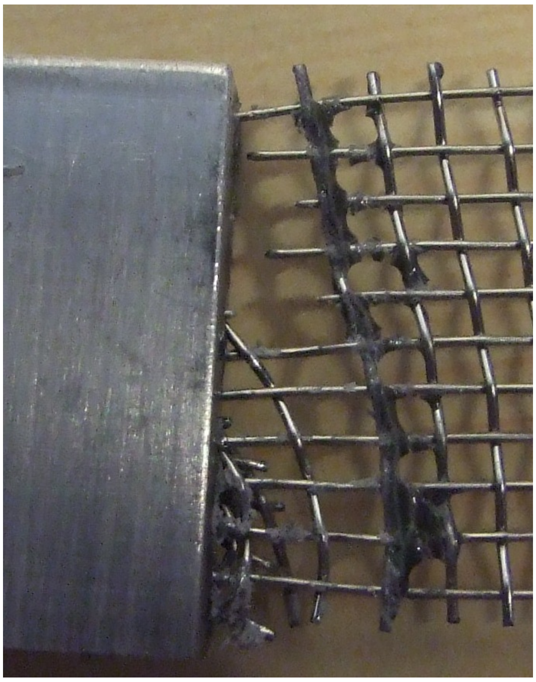
(a) Specimen with aluminium H-profile



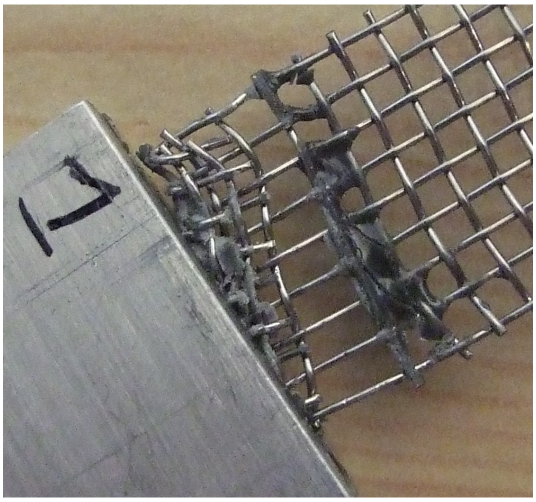
(b) Specimen with aluminium H-profile, less adhesive used then Figure 5.1(a)

(c) Specimen with two aluminium L-profiles

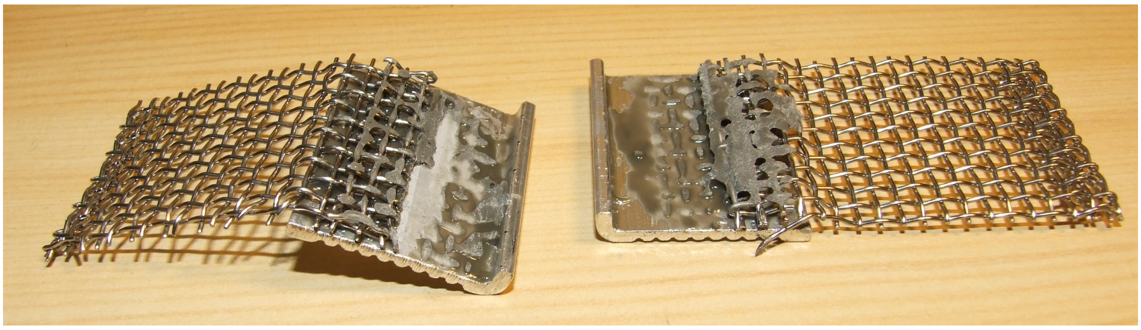
Figure 5.1: The specimens to be tested on the tensile tester



(a) Specimen with aluminium H-profile, maximum tensile strength 1.8kN, mesh is broken in stead of glue



(b) Specimen with aluminium H-profile, less adhesive used than Figure 5.1(a), maximum tensile strength 1.2kN



(c) Specimen with two aluminium L-profiles, maximum tensile strength 0.5kN

Figure 5.2: The specimens after testing them on the tensile tester

- salt water (sweat): acceptable or excellent
- fresh water (washing hands): acceptable or excellent
- weak acids (vinegar): acceptable or excellent
- weak alkalis (soap): acceptable or excellent

resulting in a pool of 50 polymers. After communicating with experts polyurethane is chosen, which is not in the pool of polymers, but with a fire retardant, a suitable material.

5.3 Adhesive

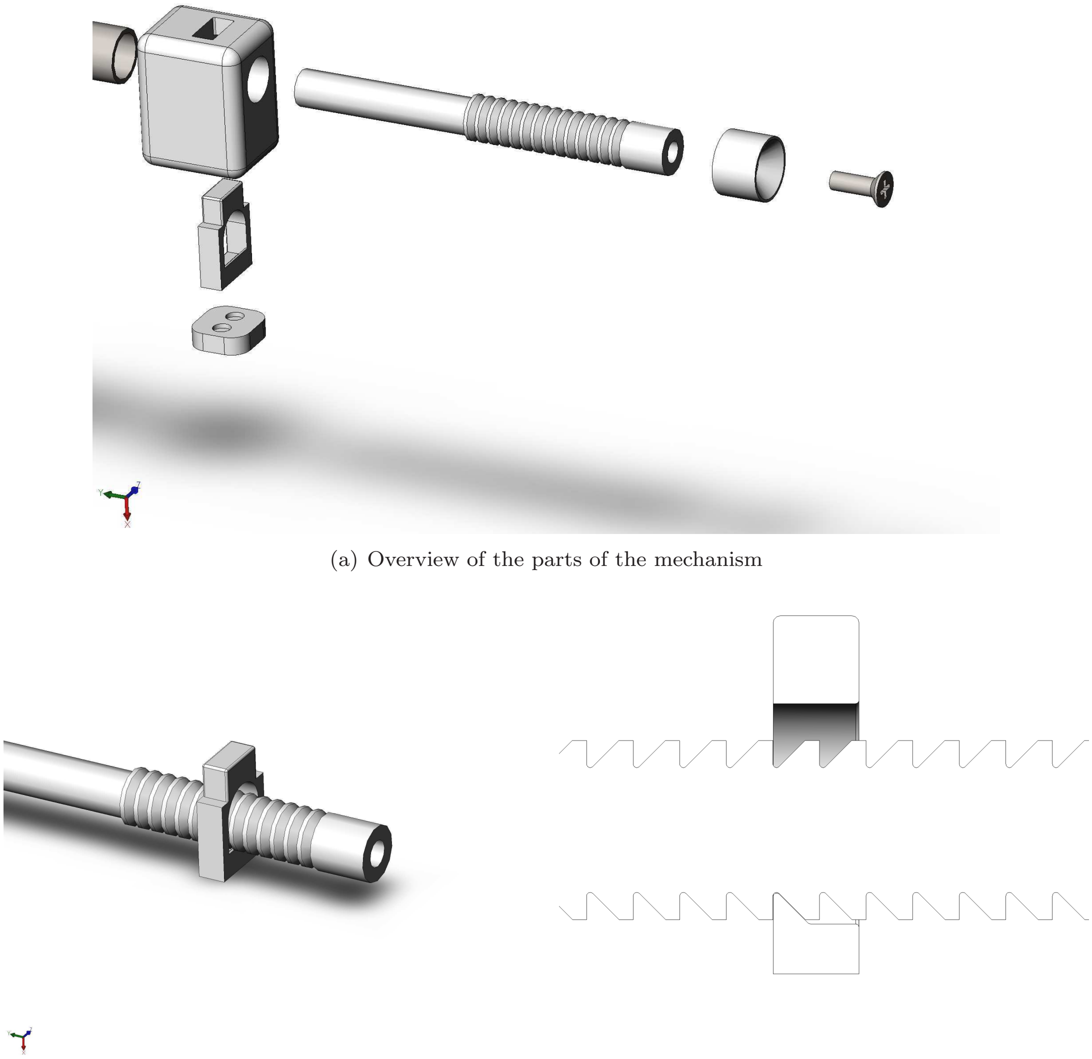
As the profile in the prototype is not made of aluminium but of polyurethane, the right adhesive has to be found. The adhesive has to fill the gaps of the stainless steel wire mesh, has to join stainless steel to polyurethane and should not provoke skin irritation. Masterbond (USA) [105] advises to use EP42HT-2ND2Med Black, the wire mesh must be roughened before the adhesive is applied. Viba (The Netherlands) [106] advises to apply Araldite resin AV138M and hardener HV998 after properly cleaning of the parts. The information sheets of the adhesives can be found at the end of this thesis.

5.4 Design of the closure

In the design of the closure, the tube is clamped by a sliding mechanism. The mechanism is operated by the thumb and the index finger. According to Marras [107], the maximal force the index finger can exert is 5N, so the maximal force of the mechanism should be 5N. The forces in the mechanism consist of a spring (the keep the clamp clamped when not operating the mechanism) and the friction.
The mechanism of Section 4.6.2 is altered in a way slack is removed from the mechanism. The result can be seen in figure 5.3. The mechanism is now a combination of the current WILMER closure with the chosen mechanism. The design unites now the advantages of both designs. The mass of the mechanism is around 5 grams, the parts and the materials can be found in Table 5.1. The total size of the mechanism is 12*16*10mm. The engineering drawings can be found in Appendix G. The ratchet in the tube is circular, as the current WILMER closure experiences problems due to the one sided ratchet.
Other materials, next to rigid PVC, feasible for the housing and cover plate of the housing are Polyphenylene Sulfide (PPS) and polyester liquid crystal (unfilled). These materials fall in the same pool of polymers as the polymers selected for the connection of the wire mesh edges and can be recycled. The recycle ability of these materials is important, as the housing is glued together and can only be opened for maintenance with brute force.
The skin is shielded from the ratchet by an tube around the ratchet. The tube is glued in the housing. In order to connect the housing to the wire mesh and the forearm shaft, a bonding area enlargement is screwed to the housing and then glued to the wire mesh and forearm shaft.
The condyle brace is, at the side in contact with skin, cushioned with spacer fabric covered with evolon. The cushion is attached with Velcro to the condyle brace, see Figure 5.7. Spacer fabric is chosen because of the optimal force spreading capacities, evolon because it can be easily cleaned, even at high temperatures. The tube around the condyles is sawn in the back middle, in this way the tube can hinge when the adjusting the brace. These parts are connected with a ball joint, just like the current WILMER open socket, see Appendix B.

5.5 Design of the socket

The socket is made of stainless steel wire mesh and bent in the right shape with plate roll bending. Stainless steel wire mesh has an advantage compared to the soft covered tubes of the current

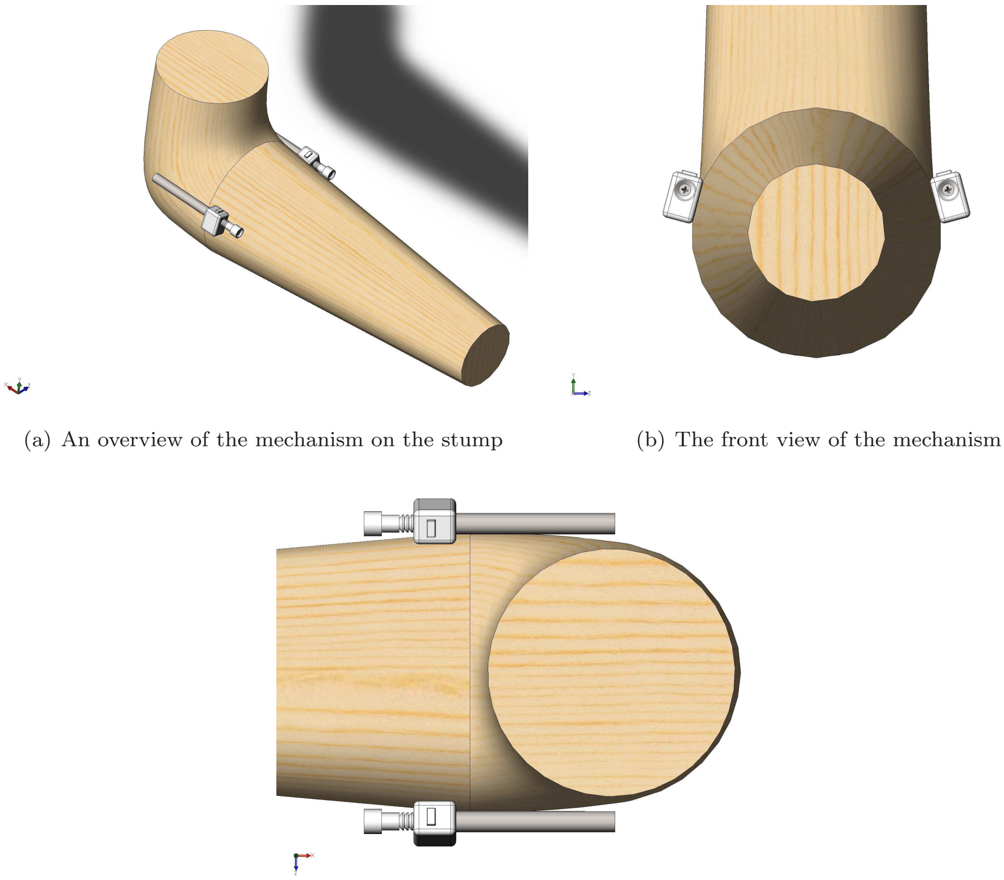


(a) Overview of the parts of the mechanism

(b) Mechanism with housing removed

(c) Cross cut of the mechanism

Figure 5.3: The design of the mechanism, a close up



(a) An overview of the mechanism on the stump

(b) The front view of the mechanism

(c) The top view of the mechanism

Figure 5.4: The design of the mechanism placed on the stump for size comparison

WILMER open socket: the width of continuous area of covered skin is smaller. Patients indicated the covered tubes of the open socket as hot and sweaty, especially during summer [2]. The edges are concealed by gluing them in a polyurethane strip (H profile). The forearm shell is the same as used in the Münster type socket, see Appendix C. This shell is used as it is a flat and skin-coloured solution, and available at standard prosthetic facilities. The mesh is connected to the forearm shell with glue and a polyurethane strip (U profile), in this way the last edge of the mesh is also covered to protect the skin. The closure is also glued to the mesh with plates to enlarge the surface for adhesion. Using glue prevents using bolts and nuts which would be in contact with the skin and reduce the comfort of wearing.
An impression of the socket can be seen in Figure 5.5. The socket and arm remnant have been build in SolidWorks, see Figure 5.6, from these pictures the appearance of the socket and the aesthetics can be evaluated.
The parts list of the socket can be found in Table 5.2 and the engineering drawings can be found in Appendix H. In the parts list the weight, price and fabrication method is also included.

5.6 Prototype

Due to time constraints a real prototype has not been build. In Figure 5.8, some kind of prototype can be seen. The stainless steel wire mesh is bent in conical shape and placed in the H profile. The material of the profile is not polyurethane, as this material was not available within the time left. The ends of the cone have not been covered as the forearm shell has not been placed.

5.7 Socket design and requirements

Now a socket design has been realised, the design should be checked with the requirements. Therefore the requirements of the socket are listed below, together with an explanation whether or not this requirement has been met.

fit closely around the arm remnant specification of the requirement was that the maximal distance between the socket and the skin should be smaller than 1mm. Stainless steel wire mesh can be formed in a cone and then, with help of the plaster cast model, further formed in the shape of the arm remnant. So the distance between skin and socket should be smaller than 1mm.

provide a smooth transition the total socket is maximal 5.5mm thick, which is at the rim of the socket. This requirement has not been met, but yet almost.

provide optimal self-suspension the suspension of the socket is secured by the condyle brace, keeping the socket safely attached to the remnant.

low pressure on skin (<4kPa) due to the large contact area of the socket, the forces are spread over a quite large area, resulting in low pressure on the skin.

load the skin with normal forces only shear forces on the skin are possible.

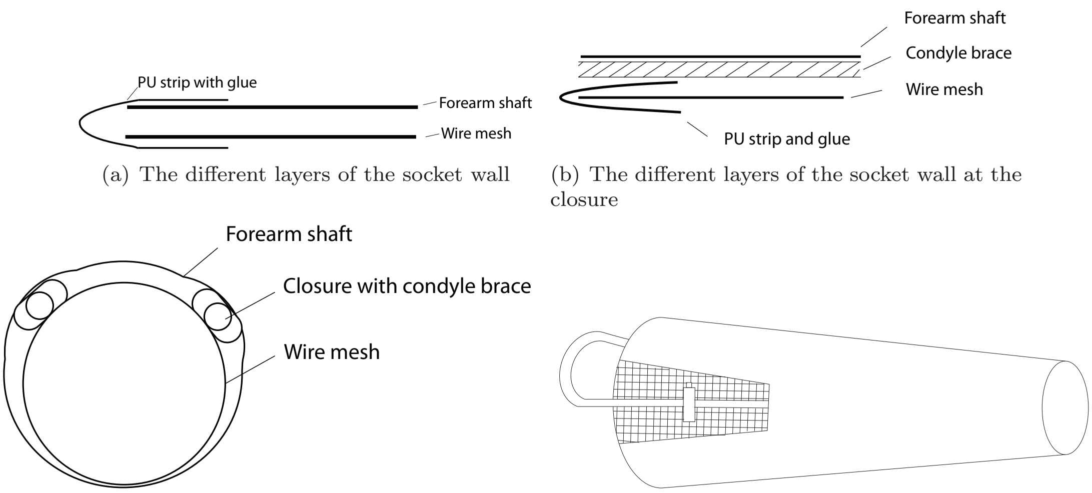
not interfere with perspiration one of the most important requirements, the aspect of sweat permeability of the prosthesis, could not be investigated, as this is user dependent and can only be tested in a longer trial period (>3 months, warm and cold weather). When the socket is still hot and sweaty, the forearm shell should be substituted with stainless steel wire mesh, the mesh can be covered with fabric. On the other hand is the wire mesh an open structure, which is optimal for the evaporation from sweat from the skin.

be lightweight the weight of the socket is estimated on 180g, which is within the requirement of a maximum weight of 200g.

be weather-proof in the socket are only materials used, that are weather-proof.

Table 5.1: Overview of parts used in the mechanism

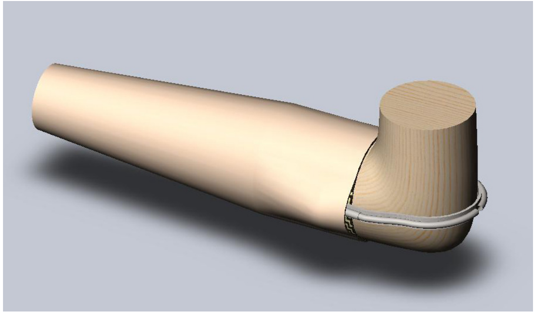
Part	material	weight (grams)	material price (€)	fabrication method
housing	rigid PVC	1.6	0.01	plate: saw, drill and mill
housing: cover plate	rigid PVC	0.1	0	plate: saw and drill
housing: glue				order at e.g. viba [106]
bonding area enlargement	stainless steel	5	0.20	plate: drilling and sawing
clamp	stainless steel	1	0.01	plate: drilling and sawing
tube to be clamped	stainless steel	5	0.20	tube, cutted and turned
spring	stainless steel	1	1.84 pp	order: nr DR430 [108]
tube around ratchet	stainless steel	3	0.15	order
stop	stainless steel	1.2	0.05	rod: saw and turn
screw for stop	stainless steel	0.03	0.10pp (250pieces)	order: e.g. skiffy nr 050 0108 000 02 [109]



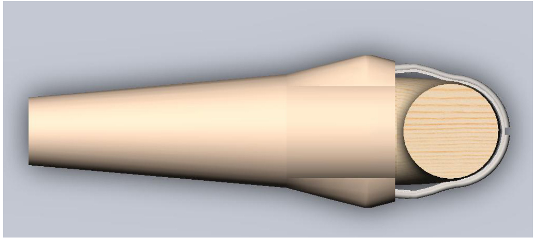
(a) The different layers of the socket wall (b) The different layers of the socket wall at the closure

(c) Cross section of the socket wall (d) Overview of the socket with cut out

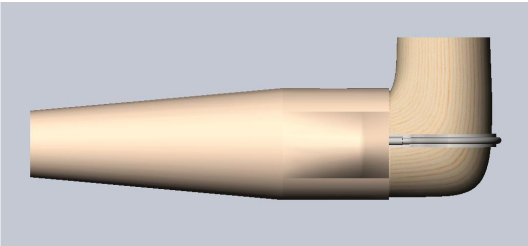
Figure 5.5: The design of the socket



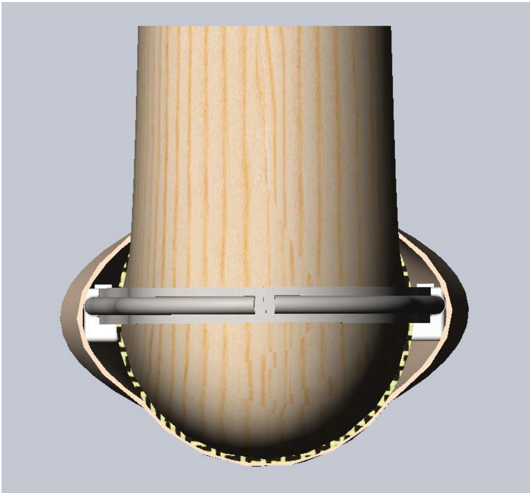
(a) Overview of the total socket with mechanism and cushion



(b) The top view

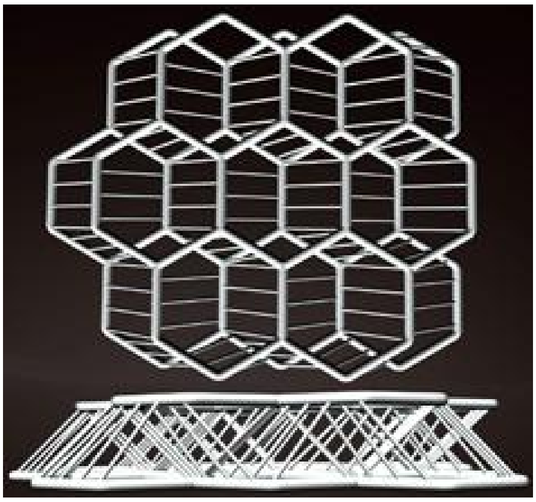


(c) The side view



(d) The back view, the two condyle braces have to be connected with a ball joint

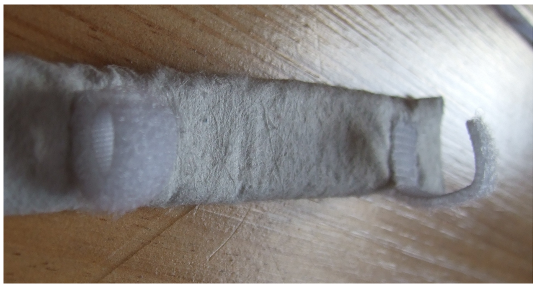
Figure 5.6: The design of the socket in SolidWorks, when placing the closure at a more suitable place, the design can be made flatter.



(a) An impression of the spacer fabric cushion

(b) A picture of the spacer fabric cushion covered with evolon.

(c) A close up of the picture with the spacer fabric cushion covered with evolon.

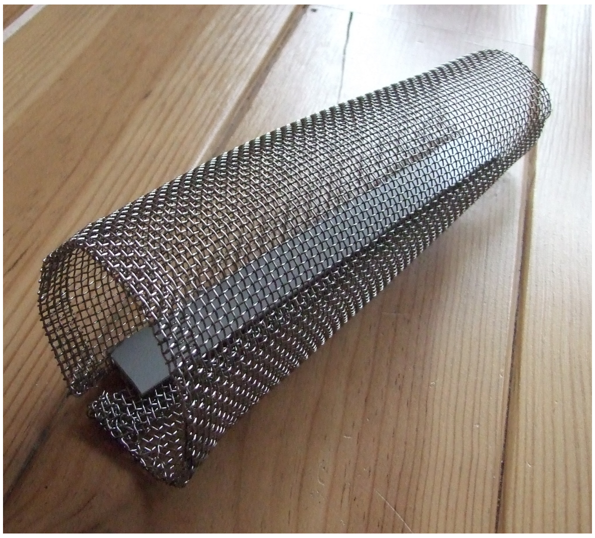


(d) The cushioning of the condyle tube with Velcro fastening

Figure 5.7: The cushioning of the condyle tube

Table 5.2: Overview of parts used in the socket design

Part	material	weight (grams)	material price (€)	fabrication method
H profile	polyurethane	21	1	extrusion
U profile	polyurethane	11	0,5	extrusion
glue				order at e.g. viba [106]
condyle tube	stainless steel 321	10	0.01	order
covering condyle tube	spacer fabric	1	0.10	order [71] and cut
covering spacer fabric	evolon	0.3	0.80 €/m^2	cut and sew
connection covering to tube	Velcro	1	0.25	cut and sew
wire mesh	stainless steel	77	2.70	order: [82] Vico meshscreen mesh: 1.9mm, wire 0.6mm
forearm shell	laminated fabric	40	12	make in prosthetic facility



(a) Overview of the mesh placed in the H profile

(b) Close up of the mesh and the profile

Figure 5.8: Stainless steel wire mesh, bent in conical shape and placed into a H profile

be made of comfortable materials the materials used in the socket are unlikely to induce allergic reaction, do not absorption perspiration, are smooth, sanitary, strong, easy to clean and nonflammable.

not hinder the movement of the remnant the design is such, that the movement of the remnant is hindered as less as possible.

be cost effective (<€∼2200) the cost of the materials is estimated on €20, in addition to this costs come the costs of the extrusion mould and the pay of the prosthetist.

fitting in standard prosthetic facility it is likely possible that the fitting and fabrication of the socket can be done in a standard prosthetic facility.

preferably have a soft outside shell the outside of the shell is not soft, but as laminated plastic is used, it feels 'warm'.

be easy to don and doff the condyle brace can be pulled out, resulting in convenient donning and doffing.

be adjustable the condyle brace is adjustable and can be fixed with an 1.3mm increment, over a total length of almost 20mm.

cope with different ways of control different kind of controls are possible, it may be that the socket wall increases in thickness.

no disturbance of circulation and innervation as the forces on the remnant are spread on a large area, the disturbance of circulation or innervation is improbable.

have adaptive fitting the socket has no adaptive fitting.

Summarised, 14 of 18 requirements have been met.

5.8 Closure design and requirements

Having rounded off the design of the closure, the design has to be compared with the requirements. The requirements of the closure are listed below, together with an explanation whether this requirement has been met.

flatter & smaller the new mechanism is flatter and smaller than the current WILMER mechanism.

low noise level the noise level is equal to the current WILMER mechanism.

different angles between brace is possible, a separate mechanism for each side of the brace.

lightweight the total weight of the mechanism is around 12g.

2*250N pull force The mechanism of the closure is supposed to be strong enough to withstand a pull force of 250N. The simulations of the mechanism as a whole may not be reliable, the separate parts have also been tested in simulations and has sufficient strength to endure the force. The only exception is the clamp, but as this kind of part is already in use, the strength is also thought sufficient.

stain proof the mechanism is made of stainless steel and plastics, which are stain proof.

dirt proof the mechanism is the same as the current WILMER mechanism, which functions fine, this mechanism probably also works fine.

water proof the mechanism is assumed to function still when in water.

no slack the mechanism has no slack, as the slack is pushed out of the system by the spring.

finger safe fingers can not reach the mechanism.

easy dressing the mechanisms can be operated with one hand, which facilitates easy dressing.

maintenance possible maintenance is possible, but the housing and the cover plate need to be replaced, as when opening the housing, the glue between the cover plate and the housing damages the housing.

easy one hand operating the mechanisms can be operated with one hand.

no extruding parts the mechanism is wholly covered by the housing, except the button which extrudes the housing about 1-2mm.

reliable the brace is clamped by a mechanical locking mechanism, which is reliable.

Summarised, 15 of 15 requirements have been met.

Chapter 6

Discussion and recommendations

A design of a transradial socket has been made, satisfying most of the requirements. Due to time constraints, an actual prototype has not been built. The separate components of the design have been tested. The gluing of the mesh in a aluminium profile was strong enough to be used in a prosthetic socket. The fitting of stainless steel wire mesh has been build. The forearm shell is already a standard element in the Münstersocket. In conclusion, the socket should be realisable. The closure of the socket has not been built, but as the working principle is already applied and used in the current WILMER closure, the mechanism functions undoubtedly.

The simulations of mechanisms is a new add-in in Simulation and the knowledge about this part of SolidWorks is small. Therefore the simulations of the mechanisms in SolidWorks could not be evaluated on reliability. The chosen mechanism is simulated part by part and these simulations are reliable.

The connection of stainless steel wire mesh glued in aluminium profiles was tested, but the mesh glued in the polyurethane profile was not tested, as the profiles were not available on time. Therefore the most feasible glue could not be chosen. Two companies have been contacted with the question which adhesive to use in this case, both companies could recommend a adhesive. There are many different kinds of adhesives and companies, so an arbitrary choice was made for the two companies.

The material choice for e.g. the profiles and housing of the mechanism was difficult as the knowledge on material properties was inadequate. For example the materials choice of the housing: the material should slide easily on stainless steel, but also be strong enough to cope with the stresses on the mechanism.

The cushion of the condyle brace consists of spacer fabric covered with evolon. Loose vertical threads between the two layers of fabric protruded the layer of evolon. When producing this cushion, the loose threads should be removed, before covering it with evolon.

During thinking and asking about fabrication methods, rubber pad forming appeared as possibility. The press used for this process is quite impressive, but unfortunately rubber pad forming of stainless steel wire mesh was not a success, the mesh teared. This may be prevented by sandwiching the mesh between two metal plates before the forming takes place. Or the mesh could be formed with help of a wooden hammer. The first methods uses special equipment not available in a standard prosthetic facility and the second methods is time consuming (making the mould and forming the mesh), so both methods were not tested.

During the search for materials applicable in the socket, many companies were contacted and many materials were found. The fabrication of some materials, like the stainless steel foam of Porvair, was suspended. Therefore this foam could not be tested on the feasibility as socket material, which is a pity as the material seems to have optimal qualities for this use. It was difficult to find an obtainable open-pored plastic foam. Several experts at Delft University of Technology have been consulted and the Internet has been searched, but a such a foam was not found. The use of a plastic foam seems feasible, as plastics are cheap and lightweight.

At this moment neither a prototype has been made, nor the closure has been tested. Therefore it is recommended that first the closure is made and tested on strength. Now the whole socket can be made and evaluated on a group of patients. Important aspects in this evaluation should be the comfort of the forearm shaft (should it be replaced by a sweat permeable stainless steel wire mesh shaft), the ease of operation of the closure, the opinion of the patients on the design (bulky design?), the aesthetics of the condyle brace, the need of an other kind of wire mesh and other up popping snags.

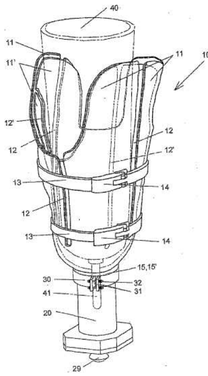
Chapter 7

Conclusion

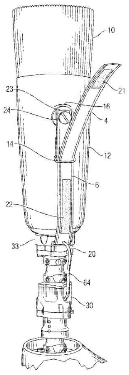
The goal of this study was the design of a socket for transradial amputees. The design is completed, but due to time constraints the realization of a prototype has not been achieved. The socket design fulfils most of the requirements and the design of the closure all of the requirements. It is concluded that the socket design is a successful mixing of existing sockets and new aspects, as the advantages of the Münstersocket and of the WILMER open socket are combined in this design. These advantages are the transition of remnant to socket and the adjustable condyle brace, easy donning& doffing, free elbow and sweat permeability. New aspects in the design are the use of stainless steel wire mesh, spacer fabric and evolon.
The overall conclusion of this work is that the new socket design offers possibilities for comfortable wearing of a prosthesis and should be tested further by creation of a prototype.

Appendix A

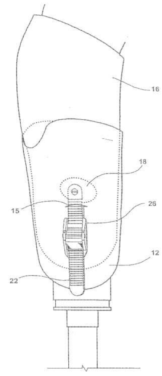
Patents on leg socket designs



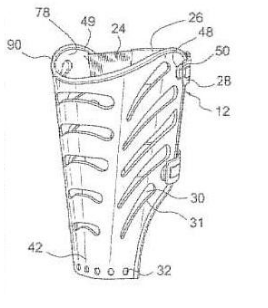
(a) US2004158332A1, two adjustable plastic shafts, assembled in such a way the opening of each of the shaft is not at the same place as the other



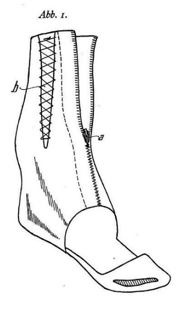
(b) US2007032883A1, incorporates a drainage system to remove perspiration from the leg and uses a gel liner for suspension



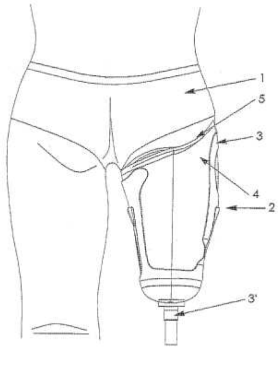
(c) US2007055384A1, silicone liner with two straps, which can be fastened on the prosthesis to prevent turning of the prosthesis mutually to the leg



(d) WO2007111971A2, a ventilated prosthesis shaft for the leg. The shaft is made of plastic with holes for the ventilation. An extra spacer element is needed between the shaft and the leg for cushioning



(e) DE457390C, a leather shaft with zipper and laces, in this way the shaft is adjustable and easy to don and doff



(f) WO2008040286a1, a design for a shaft for the upper leg. The shaft is made of two plastic frames with large holes for ventilation, the frames should keep the leg stabilised

Figure A.1: Impressions of the patents

Appendix B

Production of the WILMER open socket [90]

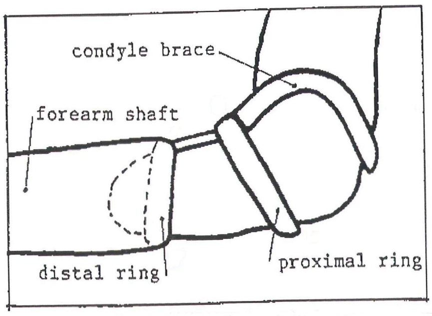


Figure B.1: The current WILMER open socket [1]

The WILMER open socket is produced in two stages. The first stage is at the supplier, who gathers and makes the building blocks of the socket. The tubes have to be sawn in the right length, the housing for the closure has to be made, the foam has to be cut and a hole has to be made for the tubes. The pawl plate, button, spring, ratchet and the plate to fixate the whole in the socket have to be gathered.
The fitting of the socket, see Figure B.1, starts with the determination of the angle between the condyle tubes, which are fixated in the closure described in Section 4.2.2. The housing is heated with a hair dryer and can now be bend until the right angle between the tubes is reached, once cooled the angle is fixed. Now two adjustable rings are placed around the stump, one at the elbow (proximal) and one at the end of the stump (distal). The position between the rings is secured. The ring at the elbow is now replaced with a tube that has been bend in the right shape. The tubes around the ratchet are also fixated at this ring. Now the tube around the condyles is bend, during bending the form is constantly checked on the patient. All the parts are fixed together and the patient has to try the frame on. When the fitting is correct, the patient can go home. During the whole process the foam is positioned and removed from the tubes.
The proximal ring is filed down on the places where the tubes of the ratchet where fixated, in this way the whole is flatter. Now the connection between the tubes is hard soldered. The tube around the condyles is sawn at the right length and hard soldered on the ratchet. The pawl plate has to be formed in the same angle as the housing, otherwise the closure does not run smoothly. The tube around the condyles is sawn in the back middle, in this way the tube can hinge when the adjusting the brace. These parts are connected either with a ball joint (St. Maartenskliniek Nijmegen, the Netherlands) or by pulling a cable through and solder it at the ends of the tube

(De Hoogstraat Utrecht, the Netherlands). Now the rest of the socket (forearm shell) is moulded with reinforced resin just like a Münster socket. When the shell is ready, the tubes around the ratchet are connected with a plate soldered in between. This plate is now glued with the help of carbon fibres and siegelhars. The socket is finished by gluing foam at the rim on the inside. After the patient has tried the prosthesis on, and the fitting is correct, the irathane coating over the foam can be applied by spraying or dipping. Now the prosthesis has to dry and air for two weeks, so that the scent of irathane is faded away. The total fitting and producing time is 25.5 hours (personal communication with F. Peters, St Maartenskliniek Nijmegen, the Netherlands).

Appendix C

Production of the Münster socket [90]

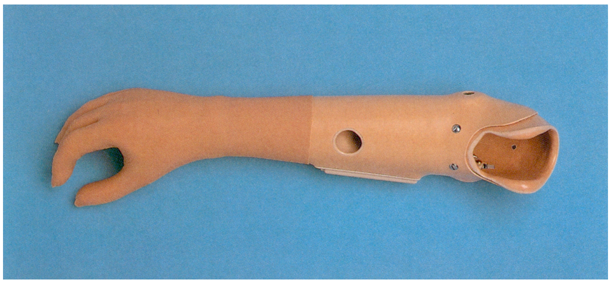


Figure C.1: The Münster socket [110]

The Münster socket is a full contact socket, enveloping both epicondyles. The socket is fixed by muscle tension, when the muscles are relaxed, the weak parts of the arm give way to don and doff the socket. If the socket is a little to big, the muscles can not fixate the socket which results in a loose and uncontrollable socket. If the socket is a little to small, the donning and doffing is difficult, maybe even impossible for the patient.
The Münster socket consists of two parts: a socket and plastic forearm shell. The socket fits exactly around the arm remnant of the patient. The shell restores the appearance of a normal underarm.
When making the socket, the stump of the patient is copied with the help of a plaster cast. During hardening of the plaster, it is also formed to emphasise particular marks of the stump. When the plaster is hardened, it is removed from the stump and filled with plaster. The outer plaster cast is removed and the copy of the stump remains. This copy is adapted with plaster, some spots need extra pressure, here the plaster is somewhat removed and other spots need extra relief, here some plaster is added. The adapted plaster model is used as mould for the fabrication of the socket, which is moulded with reinforced resin. The shell is sized with the help of the outer diameter of the socket and the size of the wrist and also moulded with reinforced resin. Now the socket and shell are fixed together.
A hole is often made at the end of the socket to facilitate donning and doffing. The patient puts on a sock, then over the sock his prosthesis and pulls the sock through the hole off his arm. In this way weak body parts that have been deformed during donning are pulled back in place.
The total fitting and producing time is 21.5 hours for a body-powered prosthesis and 32.5 hours for an myo-electrical prosthesis (personal communication with F. Peters, St Maartenskliniek Nijmegen, the Netherlands).

Appendix D

House of quality

In this section the realisation of the house of quality is explained. First the relation of the demands and the ways of achieving these demands is elucidated, then the current sockets are compared. Now the different ways of achieving the demands of the prosthesis wearer and the fitter are examined: how dependent are they on each other?

D.1 The relation demands and the ways of achieving these demands

The relationships appear not out of thin air, the explanation is as followed (explained per line, all the rows down). When a prosthesis fits close to the skin, the perspiration can not evaporate as when no prosthesis is worn, this means a strong relation exists between *no perspiration problems* and *smooth transition and close fit.* Adaptive fitting is the equal spreading of a force on a surface, in order to transfer the force to the skin, the skin must be covered in some way, so here a relationship exists between *no perspiration problems* and *self-suspension, fixation and adaptive fitting.* As the absence of shear forces requires a clear transfer point of the forces of the prosthesis on the skin, a larger fixed surface to transfer the forces, is not convenient. This is of no concern when adaptive fitting is used! The relationship between *no perspiration problems* and *shear forces and light weight* is strong. When the *skin is uncovered and evaporation* from the skin is possible, *no perspiration problem* exist, so the relationship is strong. *No perspiration problem* means an open-structure or a pored-structure, in this case dirt (*weather/dirt proof*) can easily enter the socket, so a relationship exists. Soft material is not by definition breathable, a relation between *no perspiration problem* and *no allergic reaction and soft material* exists. *No hindrance of movement* and *no perspiration problem* have no relation, as the hindrance of movement is dependant on where the force-transfer structure is and not how it is realised. *Quick fitting* and *no perspiration problem* have no relation as the fitting time is chiefly dependent on the fitting parameters and not on the material. *Divisible and adjustable socket* have no relation to *no perspiration problem*, because the divisibility of the socket merely depends on the way of designing. *Cost effective* is not related to *no perspiration problem* as the price is chiefly dependent on the number of man-hours put into the fitting and making the socket.

Easy to wear and *smooth transition and close fit* are related, as a close fit results in a better transfer of forces on the stump and better control of the prosthesis. *Easy to wear* is strongly related to *self-suspension, fixation and adaptive fitting* for the same reasons as mentioned at smooth transition and close fit. *Easy to wear* and *shear forces and light weight* have a strong relationship, for when shear forces occur, blisters are raised and this results in an uncomfortable wearing of the prosthesis. *Easy to wear* relates not to *uncovered skin and evaporation* because, sweat can also be drained away, resulting also in an easy-to-wear prosthesis. *Easy tot wear* and *weather/dirt proof* have no relationship as the problem of dirt starts at the wish of cleaning the socket after wearing. *Easy to wear* and *no allergic reaction and soft material* are related, for when wearing a

socket which provokes skin reaction and itching the socket is not comfortable. *Easy to wear* and *no hindrance of movement* are related, as when reaching for something, hindered by the prosthesis results not in wearing comfort of the prosthesis. *Easy to wear* and *quick fitting* are not related: the fitting procedure is ended when the wearing of the prosthesis starts. *Easy to wear* and *divisible and adjustable socket* are related for the comfort increases when it is possible to adjust the socket to the e.g increased volume of an arm in the summer. *Easy to wear* is not related to *cost effective*, the comfort of wearing is merely a problem of good design.
No blisters is not related *smooth transition and close fit*, as blisters arise when in a humid environment shear forces on the skin are exerted. *No blisters* is related to *self-suspension, fixation and adaptive fitting* because the goal of adaptive fitting is the equal spreading of forces on the skin, resulting in a decrease of shear forces. *No blisters* and *shear forces and light weight* are strongly related as the formation of blisters occur under influence of shear forces. *No blisters* and *uncovered skin and evaporation* are related, as when evaporation is possible, the climate in the socket is less humid. *Weather/dirt proof*, *no allergic reaction and soft material*, *no hindrance of movement*, *quick fitting*, *divisible and adjustable socket* and *cost effective* are not related to *no blisters*, because they have nothing to do with the occurrence of blisters.
Comfortable materials and *smooth transition and close fit* are related as the choice of a comfortable material such as foam is difficult to combine with a smooth transition. *Comfortable materials* and *self-suspension, fixation and adaptive fitting* are related for adaptive fitting requires a material that can transfer forces to a larger surface of the skin when only supported in the middle of the surface. *Comfortable materials* and *shear forces and light weight* have a weak relationship, using the right materials can result in a light construction. *Comfortable materials* and *uncovered skin and evaporation* are weakly connected, when choosing a breathable material, evaporation is possible through the material, so a special design is not necessary. *Comfortable materials* and *weather/dirt proof* have a weak relationship, as when using e.g. stainless steel the socket is weatherproof but possibly not comfortable. *Comfortable materials* and *no allergic reaction and soft material* have a relationship for comfortable most of the times means soft. *Comfortable materials* and *no hindrance of movement* have no relationship, as hindrance of movement merely depends on the design. *Comfortable materials* and *quick fitting* have no relationship, the fitting time merely depends on the fitting parameters. *Comfortable materials* and *divisible and adjustable socket* are not connected, the divisibility of the socket merely depends on the design. *Comfortable materials* and *cost effective* are not related, as the price of the prosthesis chiefly depends on the fitting time and production time and only minor on the material choice.
Easy donning and doffing is weakly related to *smooth transition and close fit* and *self-suspension, fixation and adaptive fitting* as all three are constructive properties, and are thus connected. *Shear forces and light weight*, *uncovered skin and evaporation*, *weather/dirt proof*, *no allergic reaction and soft material* and *no hindrance of movement* are not related with *easy donning and doffing* because easy donning and doffing is merely a construction property. *Easy donning and doffing* and *quick fitting*, *cost effective* are weakly connected as a divide able socket introduces another fitting parameter, and when the fitting time increases, the costs do also increase. *Easy donning and doffing* and *divisible and adjustable socket* are strongly related, as a divide able socket readily enhances the ease of donning and doffing.
Good fitting and *smooth transition and close fit* and *self-suspension, fixation and adaptive fitting* are strongly connected for good fitting depends on close fit (no movement of the prosthesis when the arm remnant is held still) and for good fitting could depend on adaptive fitting (adaptive fitting is the best possible method of transferring forces). *Good fitting* and *shear forces and light weight* have a weak connection, as the heavier the prosthesis is, the better the fitting should be otherwise pressure ulcers can develop. *Good fitting* and *uncovered skin and evaporation*, *weather/dirt proof* and *no allergic reaction and soft material* are not connected as the fitting is more a construction issue. *Good fitting* and *no hindrance of movement* are connected, when a fitting is good, movement is not hindered. *Good fitting* and *quick fitting* is strongly related, when a fitting should be good, the fitting should be done with great care and this takes time. *Good fitting* and *divisible and adjustable socket* and *cost effective* are weakly connected as an adjustable socket, when not entirely fitted correctly can be adjusted and as good fitting requires time, the costs increase.

Not bulky and *smooth transition and close fit* are strongly related, when a smooth transition from the skin to the socket is realised, the whole looks less bulky, but the design is also an important factor whether a socket is bulky or not. *Not bulky* and *self-suspension, fixation and adaptive fitting* are related for adaptive fitting is a bigger mechanism than just a bar to transfer the forces to the skin. *Not bulky* and *shear forces and light weight* are weakly connected, for when a socket is constructed light weight, with high density materials, it cannot be bulky. *Not bulky* and *uncovered skin and evaporation* are weakly related, when parts of the skin are uncovered and other parts are covered with tubes, the whole looks bulky as the user of the current WILMER open socket say. *Weather/dirt proof*, *no allergic reaction and soft material* and *quick fitting* have no relationship with *not bulky*, whether a socket is bulky or not depends on the design. *Not bulky* and *no hindrance of movement* are not connected, bulky is an appearance and hindrance of movement a measurable variable. *Not bulky* and *divisible and adjustable socket* are weakly related, for a divisible socket, needs some kind of mechanism which needs also space. *Not bulky* and *cost effective* are not connected, as the costs merely depend on the man-hours needed to fit and make the prosthesis and the bulkiness is mostly a design problem.
Outside feels natural is not related to *smooth transition and close fit*, *self-suspension, fixation and adaptive fitting* and *shear forces and light weight*, for the demand easily be met by e.g. a soft glove over the prosthesis. *Outside feels natural* and *uncovered skin and evaporation* are connected, when the wearers skin is not covered, the wearer feels his/her own skin, which should feel natural. *Outside feels natural* and *weather/dirt proof* are weakly related, as the weather proof material, may not feel natural, e.g. stainless steel. *Outside feels natural* and *no allergic reaction and soft material* are strongly connected, for a soft material feels more natural than e.g. stainless steel. *No hindrance of movement*, *quick fitting*, *divisible and adjustable socket* and *cost effective* have no relationship with *outside feels natural*, for these are design problems, and the demand can met e.g. by a special coating or glove.
Easy to fit has a weak relation with *smooth transition and close fit* and *self-suspension, fixation and adaptive fitting*. The closer the socket is to the skin, the more difficult the fitting is: the arm remnant exists of soft tissue with underlying bone, the soft tissue can move when the bone does not. For this reason self-suspension is also difficult. *Easy to fit* has no connection with *uncovered skin and evaporation*, *weather/dirt proof*, *no allergic reaction and soft material* and *no hindrance of movement*, as the fitting ease and time merely depend on the number of fitting parameters. *Easy to fit* has a strong relation with *quick fitting*, *divisible and adjustable socket* and *cost effective*, easy fitting means less fitting parameters, which results in quick fitting, but a divisible socket is more difficult to fit, as it has more fitting parameters. The costs of a socket merely depend on the man-hours need for fitting and making of the socket, when a socket is fitted easy, less man-hours are required and the costs of the socket are decreased.
No problems with water is weakly related to *smooth transition and close fit*, *self-suspension, fixation and adaptive fitting*, *shear forces and light weight*, *uncovered skin and evaporation*, *no hindrance of movement* and *quick fitting*, as these ways of archiving the demand are constructional problems and no problems with water is also a constructional problem. *No problems with water* and *no allergic reaction and soft material* and *weather/dirt proof* are strongly related, weather proof also includes rain proof, so the socket must be waterproof and a soft material may absorb the water. *No problems with water* has a relation with *divisible and adjustable socket* because a divisible socket needs a mechanism and mechanisms could be sensitive to water. *No problems with water* has no connection with *cost effective* as cost effective merely depends on the man-hours put into the fitting and production of the socket.
Price has a strong relation to *quick fitting* and *cost effective*, for the costs of a prosthesis merely depend on the hours of work put into the fitting and production. *Price* has no relation to *smooth transition and close fit*, *self-suspension, fixation and adaptive fitting*, *shear forces and light weight*, *uncovered skin and evaporation*, *weather/dirt proof*, *no allergic reaction and soft material*, *no hindrance of movement* and *divisible and adjustable socket*, for these are constructional problems, when solved properly in the design phase, the cost can be kept low.

D.2 Comparison current sockets

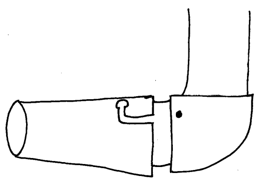
The comparison of the current sockets is firmed on the following considerations. For the demand *no perspiration problems*, all sockets except the WILMER open socket score badly: all these sockets are made of non-breathable materials and have no windows of some kind to make the evaporation of sweat possible. The WILMER open socket scores not all points, as users complain about the sweet trapped under the tubes. Demand *easy to wear* reveals more distinction in the sockets. The Münster type socket and the NWU socket score moderate, the sockets have a close fit, provide self-suspension and are dirt-proof. The HPVS socket adds to these properties the absence of shear forces, and scores better. The TRAC socket adds more stability of the stump in the socket and scores better than the Münster type and NWU socket. The WILMER open socket scores best as it adds also uncovered skin and a divisible socket. Demand *no blisters* shows a greater spreading, the Münster type socket and the NWU socket score under moderate, as due to the presence of shear forces, blister raise, using a silicone liner solves this problem partly (HPVS socket and TRAC socket) but a more elegant solution is providing a dry skin through which blistering decreases even more. Demand *comfortable materials* increases the spreading of the sockets: the Münster type socket and the NWU socket lag further behind, as the use of hard, non-breathable materials does not result in comfortable materials. By using a silicone liner, some cushioning is introduced (HPVS and TRAC socket), but still the WILMER open socket provides the best solution: soft foam around steel tubes for soft cushioning. Demands *easy donning and doffing* and *good fitting* can only be united by introducing a divisible socket, so even the HPVS and TRAC socket lag now behind. Demand *not bulky* finally shows one of the drawbacks of the WILMER open socket: it looks bulky. The Münster type socket, the TRAC socket, the NWU socket and the HPVS socket are less bulky by the use of laminated carbon fibre. Demand *outside feels natural* shows an shift of the Münster type socket, the TRAC socket, the NWU socket and the HPVS socket from a good score to a bad score: hard plastics are used, in stead of a soft material. The WILMER open socket scores a bit better by the use of soft foam. Demand *easy to fit* restores the WILMER open socket a bit, as the use of plaster cast is not necessary. Demand *no problems with water* reveals no difference between the sockets, all score good on this demand. Demand *price* on the other hand shows a difference between the sockets, the HPVS and the TRAC socket are expensive as multiple liners are provided, then the Münster type socket and the NWU socket follow. The WILMER open socket has a bad score, the prosthesis fitter requires 4 hours more for fitting and production compared to the Münster type socket.

D.3 Dependence ways of achieving the demands

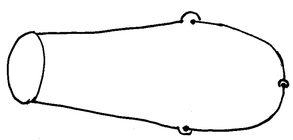
The ways of achieving the demands which are not dependant are not explained. The rest is explained from left to right and top to bottom. *Smooth transition and close fit* is strongly independent of *no hindrance of movement* for hindrance of movement is determined by the location of the socket on the arm remnant and not by the fit. *Smooth transition and close fit* is dependant on *uncovered skin and evaporation*, because when parts of the skin are uncovered a lot of transitions are needed. *Smooth transition and close fit* is strong dependant on *self-suspension, fixation and adaptive fitting*, when using adaptive fitting, the fit is perfectly close. *Self-suspension, fixation and adaptive fitting* is independent of *no hindrance of movement* for hindrance of movement is determined by the location of the socket on the arm remnant and not by the fit. *Self-suspension, fixation and adaptive fitting* is strongly dependant on *shear forces and light weight* as shear forces are eliminated by adaptive fitting. *Uncovered skin and evaporation* is strong dependant on *divisible and adjustable socket* for a divisible and adjustable socket is easier realised when an open structure is used. *Uncovered skin and evaporation* is dependant on *no allergic reaction and soft material*, e.g. with material choice: breathable material may induce skin irritation. *Uncovered skin and evaporation* is dependent of *weather/dirt proof* when evaporation through a porous material is possible, dirt easily becomes trapped in the pores. *No hindrance of movement* is strongly dependant on *divisible and adjustable socket*, when the prosthesis is hindering the movement and it is adjustable, the hindrance may be lessened. *Quick fitting* is dependant on *cost effective* and *divisible and adjustable socket*, fitting and producing of the prosthesis are most costly, so quick fitting has a positive effect on the costs. A divisible socket on the other hand introduces another fitting parameter which prolongs the fitting time. *Divisible and adjustable socket* is dependant on *cost effective*, for when the fitting time prolongs due to the extra fitting parameter, the costs also increase due to the increased man-hours.

Appendix E

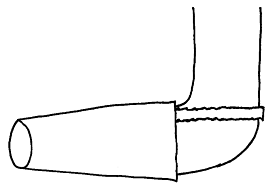
Concept solutions



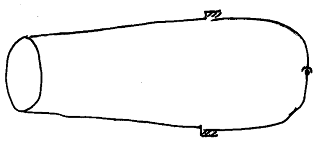
(a) Bayonet lock is shown, applied on a prosthetic socket



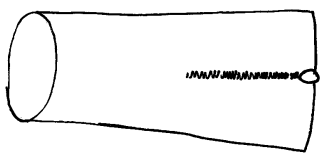
(b) The socket is divisible, the parts are placed around the remnant and then clicked together, the part around the elbow has a joint



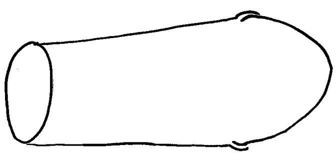
(c) Socket with an elastic band to keep it in place



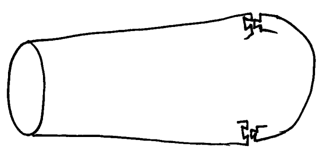
(d) The socket is divisible and connected together with the help of Velcro. The divisibility of the socket assures easy donning and doffing of the prosthesis



(e) A zipper is used to close the socket, resulting in easy donning and doffing

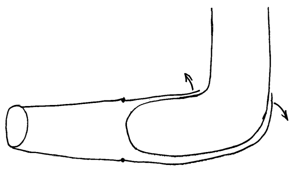


(f) The same mechanism as in Figure E.1(b), but now without the joint in the part around the elbow

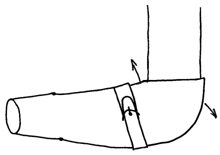


(g) The both parts are connected by a puzzle structure, but this needs an extra fixation

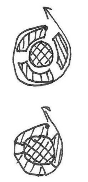
Figure E.1: Impressions of the new fixations



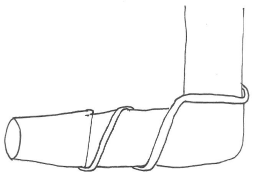
(a) A clamp is used to fixate the prosthesis to the arm



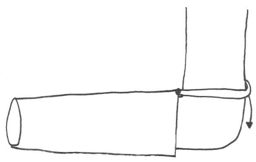
(b) A clamp with an extra fixation is shown,the fixation could be a band from a watch (metal or leather)



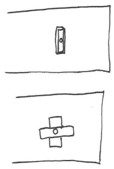
(c) The brace can be clamped with semi-circular clamping elements



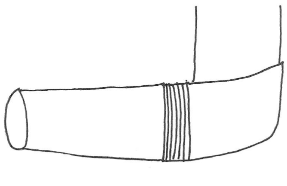
(d) Steel tube with soft covering bend around the arm remnant



(e) The brace behind the elbow can be turned away for donning and doffing

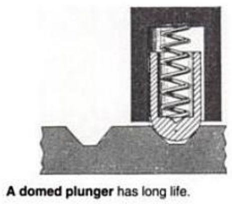


(f) When twisting the knob a half turn, the prosthesis is locked

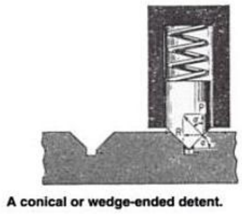


(g) Just like screw down a jar, the prosthesis can be screwed down on the socket

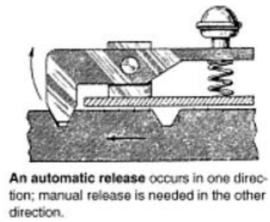
Figure E.2: Impressions of the new fixations



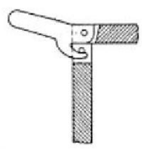
(a) Domed plunger with spring [93] when a knob is added, the plunger can be released



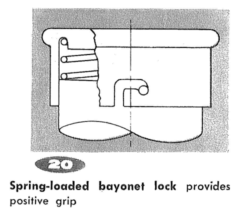
(b) Conical or wedge-ended plunger with spring [93] when a knob is added, the plunger can be released



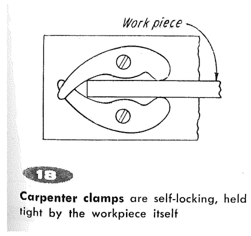
(c) Plunger with automatic release in one direction and manual release in the other direction [93]



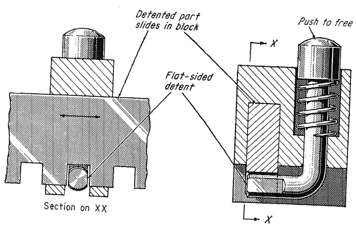
(d) Cam cover catch, movement of the handle locks the cover tightly [93]



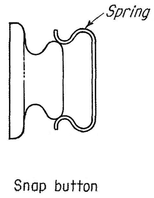
(e) Spring-loaded bayonet lock [94], the chance of releasing accidentally is smaller than with an usual bayonet lock



(f) Carpenter clamps, self locking [94]

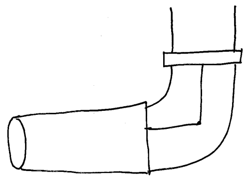


(g) Positive detent with push release [94], this mechanism resembles the original WILMER lock in the open socket

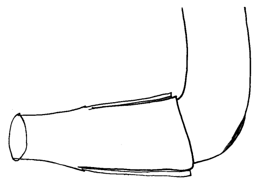


(h) (Simple) snap button [94]

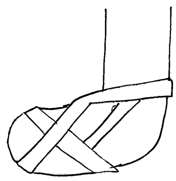
Figure E.3: Fixation methods eventually applicable for brace fixation



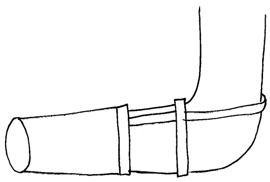
(a) Socket suspension via a corset around the upper arm, a bar with joint at the elbow connects the corset with the socket. In this way the suspension is less visible when wearing a t-shirt



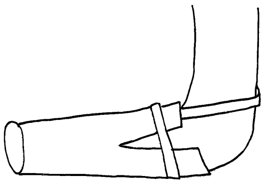
(b) Socket with a kind of TRAC interface: a soft material covering the skin and a harder material as outside shell. The soft material spreads the forces equally over the stump. There may be a problem with shear forces on the skin, as the soft material probably adheres to the skin and transfers in this way shear forces



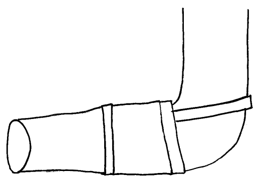
(c) Socket of a textile band wrapped around the arm, in this way the socket is open and close to the skin



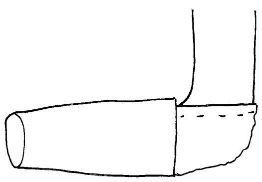
(d) Socket of a construction of metal tubes, the socket is kept in place by an elastic band, assisting donning and doffing



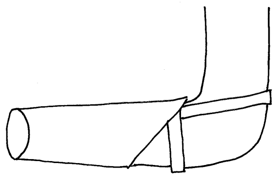
(e) Socket is in more ways adjustable, but this results in a more bulky structure than the current WILMER open socket



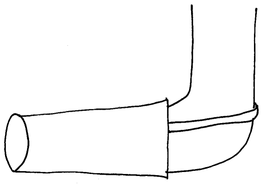
(f) The open socket design of WILMER, but now with foam filled between the two rings around the arm remnant, in this way the socket is more one entity



(g) Socket with a textile cover over the elbow, to make the socket more one entity

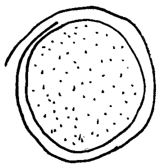


(h) The socket design of Wong

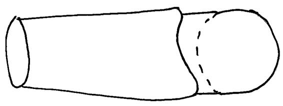


(i) Socket is less bulky, but has then less ways of adjusting the socket

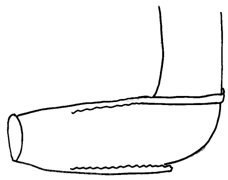
Figure E.4: Impressions of the new designs



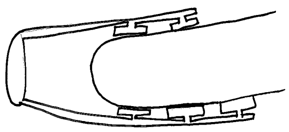
(a) The socket is rolled around the arm remnant, the socket is as close as possible to the skin resulting in a less bulky socket



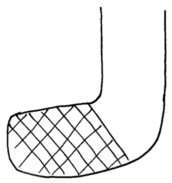
(b) The socket is shaped more streamlined and ergonomic, resulting in increased wearing comfort



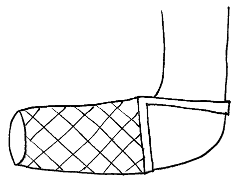
(c) The Socket is made of a special foam which can be made rigid at desired places (see Section 4.1.2), together with the metal tube around the upper arm suspension of the prosthesis is secured



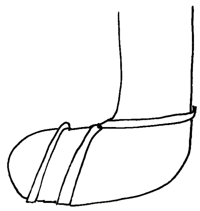
(d) Socket with adaptive fitting



(e) A special fabric is used for the suspension of the prosthesis, when trying to pull the remnant out of the socket, the fabric tightens and the remnant can not be released from the socket. It is a kind of Chinese finger trap, also investigated by The Open Prosthesis Project [111]



(f) Socket with a new material, LUPO is an open pored (breathable and sweat permeable) PUR foam. LUPO is a kind of metal foam, but than made of PUR, therefore it is not strong enough when used alone, so it is combined with wire mesh



(g) A textile band wrapped around the arm remnant

Figure E.5: Impressions of the new designs

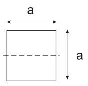
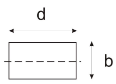
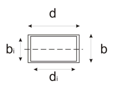
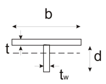
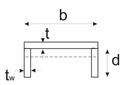
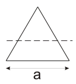
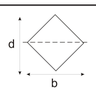
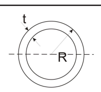
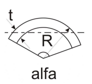
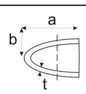
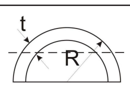
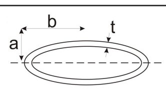
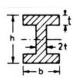
cross section	graphic	second moment of area	area
square		$I_x = \frac{1}{12}a^4$	$A = a^2$
rectangle		$I_x = \frac{1}{12}db^3$	$A = db$
hollow rectangle		$I_x = \frac{db^3 - d_i b_i^3}{12}$	$A = db - d_i b_i$
T frame		$y_c = \frac{bt^2 + t_w d(2t+d)}{2(tb+t_w d)}$ $I_x = \frac{b}{3}(d+t)^3 - \frac{d^3}{3}(b - t_w) - A(d+t-y_c)^2$	$A = tb + t_w d$
U frame		$y_c = \frac{bt^2 + 2t_w d(2t+d)}{2(tb+2t_w d)}$ $I_x = \frac{b}{3}(b+t)^3 - \frac{d^3}{3}(b - 2t_w) - A(d+t-y_c)^2$	$A = tb + 2t_w d$
triangle		$I_x = 0.01804a^4$	$A = 0.433a^2$
diamond		$I_x = \frac{1}{48}bd^3$	$A = \frac{bd}{2}$
hollow circle		$I_x = \pi R^3 t$	$A = 2\pi 2Rt$
part of circle		$I_x = R^3 t[(1 - \frac{3t}{2R} + \frac{t^2}{R^2} - \frac{t^3}{4R^3}) \times (\alpha + \sin(\alpha)\cos(\alpha) - \frac{2\sin^2(\alpha)}{\alpha}) + \frac{t^2 \sin^2(\alpha)}{3R^2\alpha(2-\frac{t}{R})}(1 - \frac{t}{R} + \frac{t^2}{6R^2})]$	$A = \alpha t(2R - t)$
semi ellipse		$a = 1.5$ $b = 2.5$ $t = 0.5$ $y_c = 1.31$ $I_x = \frac{\pi}{8}a^3 t(1+\frac{3b}{a}) - \frac{1}{2}\pi(a+b)t * {y_c}^2$	$A = \frac{1}{2}\pi(a+b)t$
semi circle		$I_x = \frac{\pi}{8}(R^4 - R_i^4) - \frac{8}{9\pi}\frac{(R^3 - R_i^3)^2}{R^2 - R_i^2}$	$A = \frac{\pi}{2}(R^2 - R_i^2)$
hollow ellipse		$I_x = \frac{\pi}{4}a^3 t(1 + \frac{3b}{a})$	$A = \pi(a+b)t$
I frame		$I_x = \frac{1}{6}h^3 t(1 + \frac{3b}{h})$	$A = 4t^2 - 2t(b+h)$

Table E.1: Overview of different cross sections and their second moment of area and the area.

Appendix F

SolidWorks Simulation settings

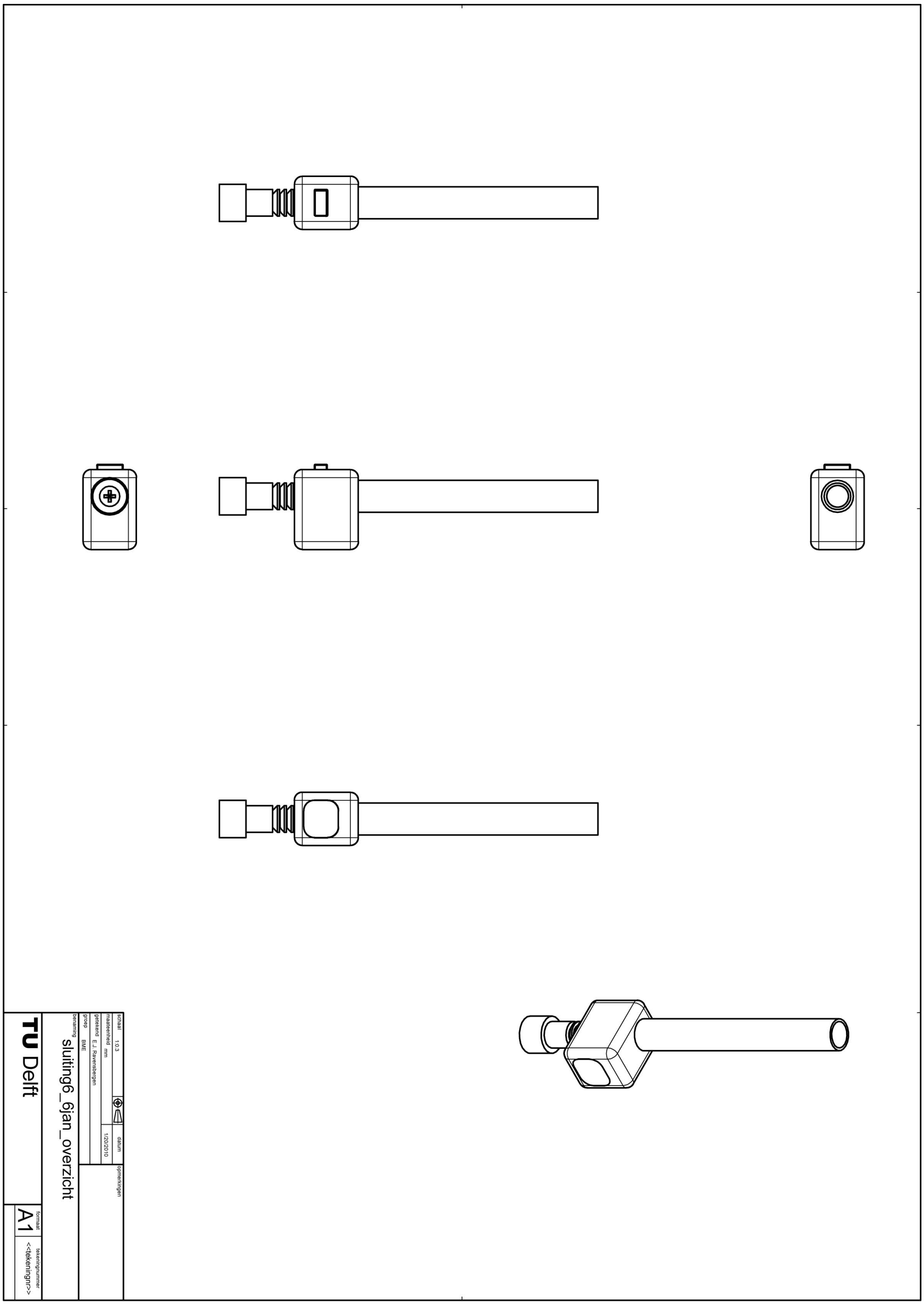
In a SolidWorks Simulation study the following settings should be checked off in the property manager of the study (right-click the name of the study and choose properties):

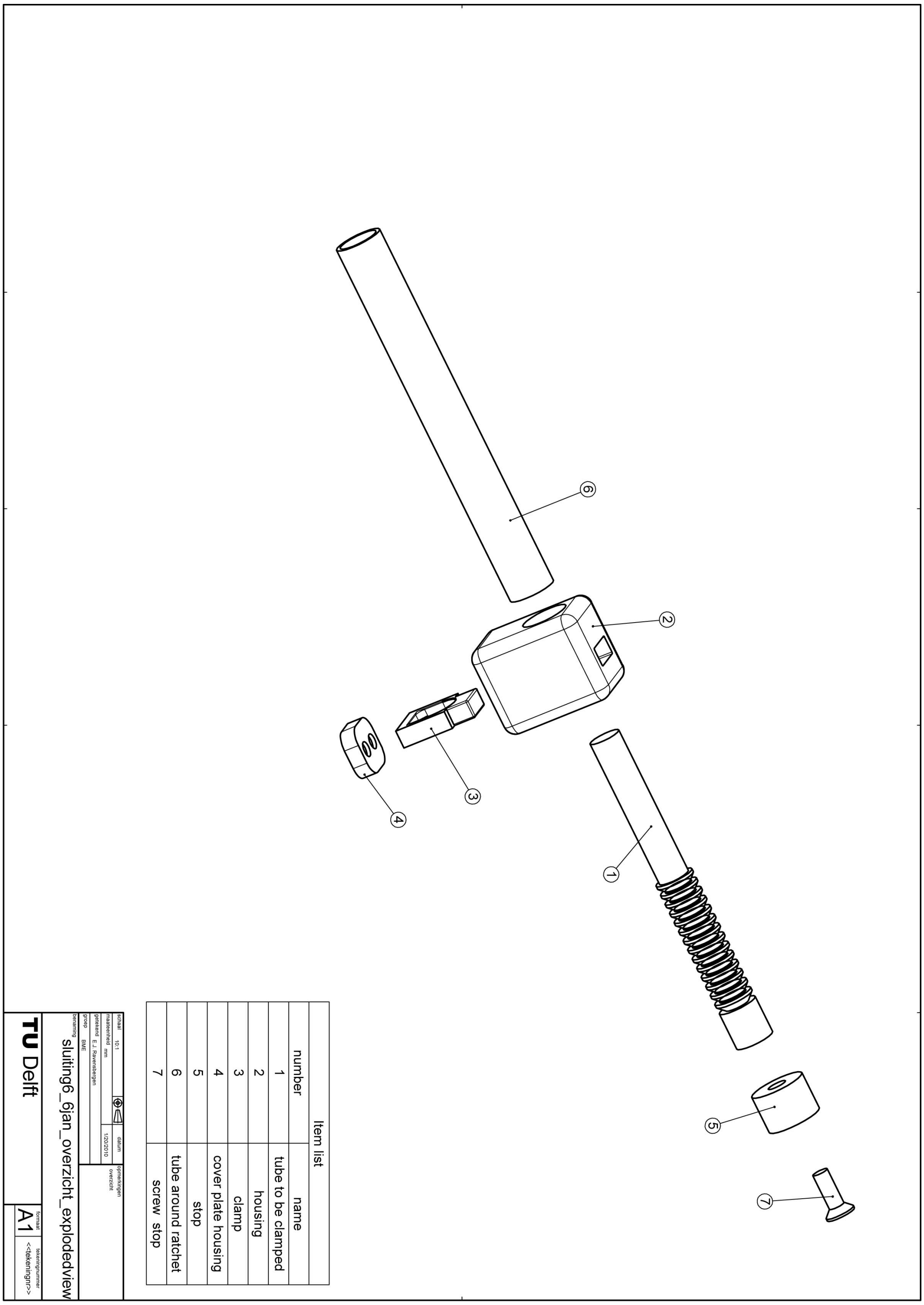
- improve accuracy for contacting surfaces with incompatible mesh (slower, this method produces continuous and more accurate stresses in regions with definitions of no penetration contact)
- friction mechanism: include global friction; the friction coefficient can be filled in
- calculating the stresses of the different parts: compute free body forces
- solver: direct sparse solver (multi-area contact problems where the area of contact is found via multiple iterations)

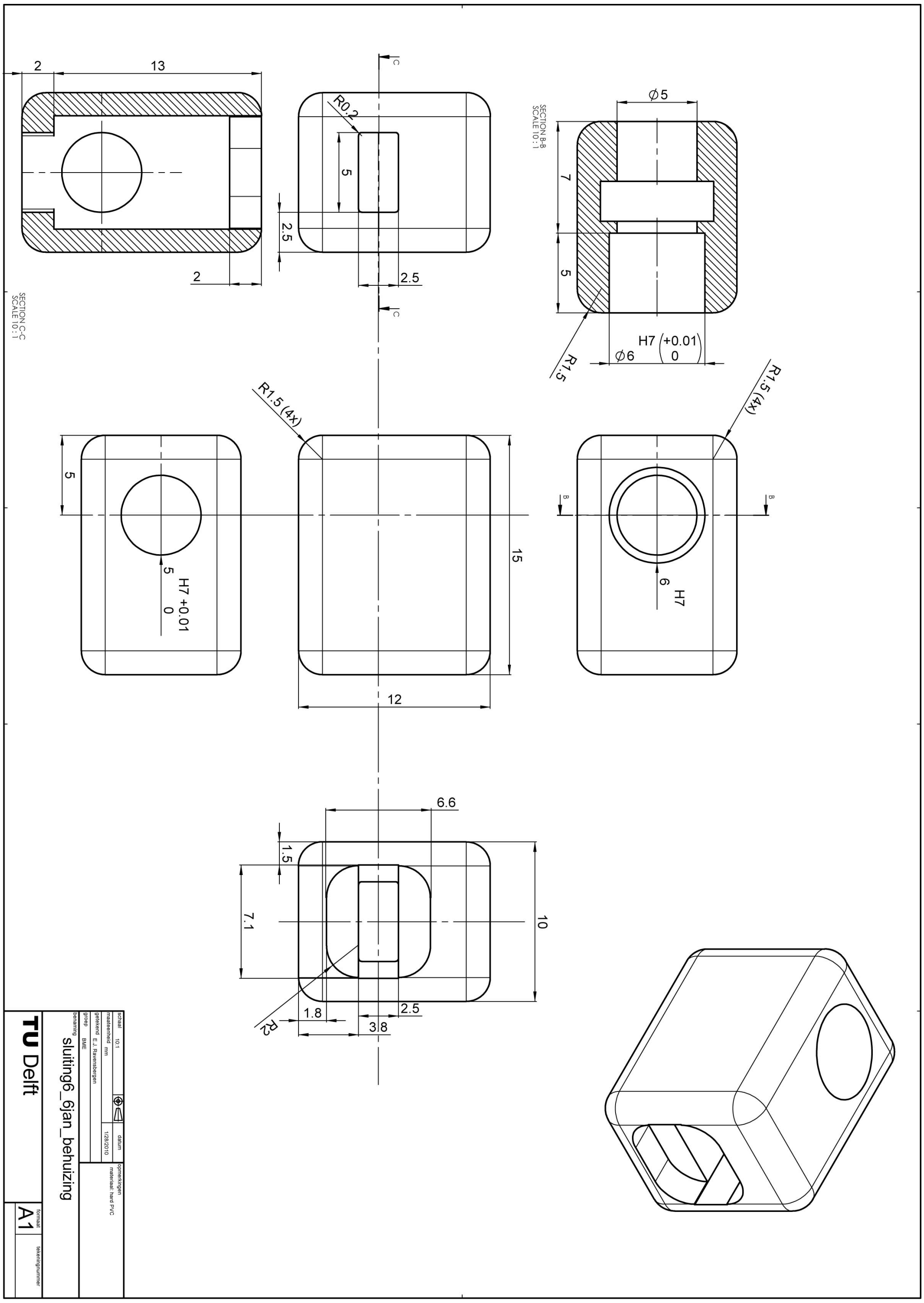
The results folder in the property manager should be changed to e.g. a folder in the folder of the mechanism to keep SolidWorks from overwriting them.
In the study connection settings can be defined. The global contact definition should be no penetration, and eventual extra contact sets with no penetration and surface to surface or node to surface as advanced settings. The extra contact sets are used when after simulation objects penetrate into each other. Surface to surface is more accurate than node to surface which is more accurate than node to node. The first two can be used when the loading causes sliding of the contacting areas, but take longer to solve. Sometimes the contacting area of the surface to surface contact set becomes too small and the simulation does not converge, in this case the node to surface offers a solution. Fixtures must be used, to keep the assembly from flying trough the simulation space under load. By applying forces, the load of the patient on the prosthesis can be simulated. In these studies a force of 400N is used, as there are two mechanisms and one person of 80kg that should be restrained in the worst case.
When objects of the mechanism interfere with each other, the simulation fails, so interference in the assembly should be checked before running the simulation. Another cause for a failing simulation are short edges which can raise mesh problems, therefore the presence of short edges should also be checked before simulating.
When finished with the set up above, the simulation can be run by right-clicking mesh and choose ‘mesh and run’. After the simulation is finished, results can be displayed by right-clicking results and choose from the menu (e.g. a stress plot). Sometimes the housing of a mechanism is in line of sight, the housing can be made invisible by right-clicking the housing and choose hide. By redrawing the plot, the housing is removed.

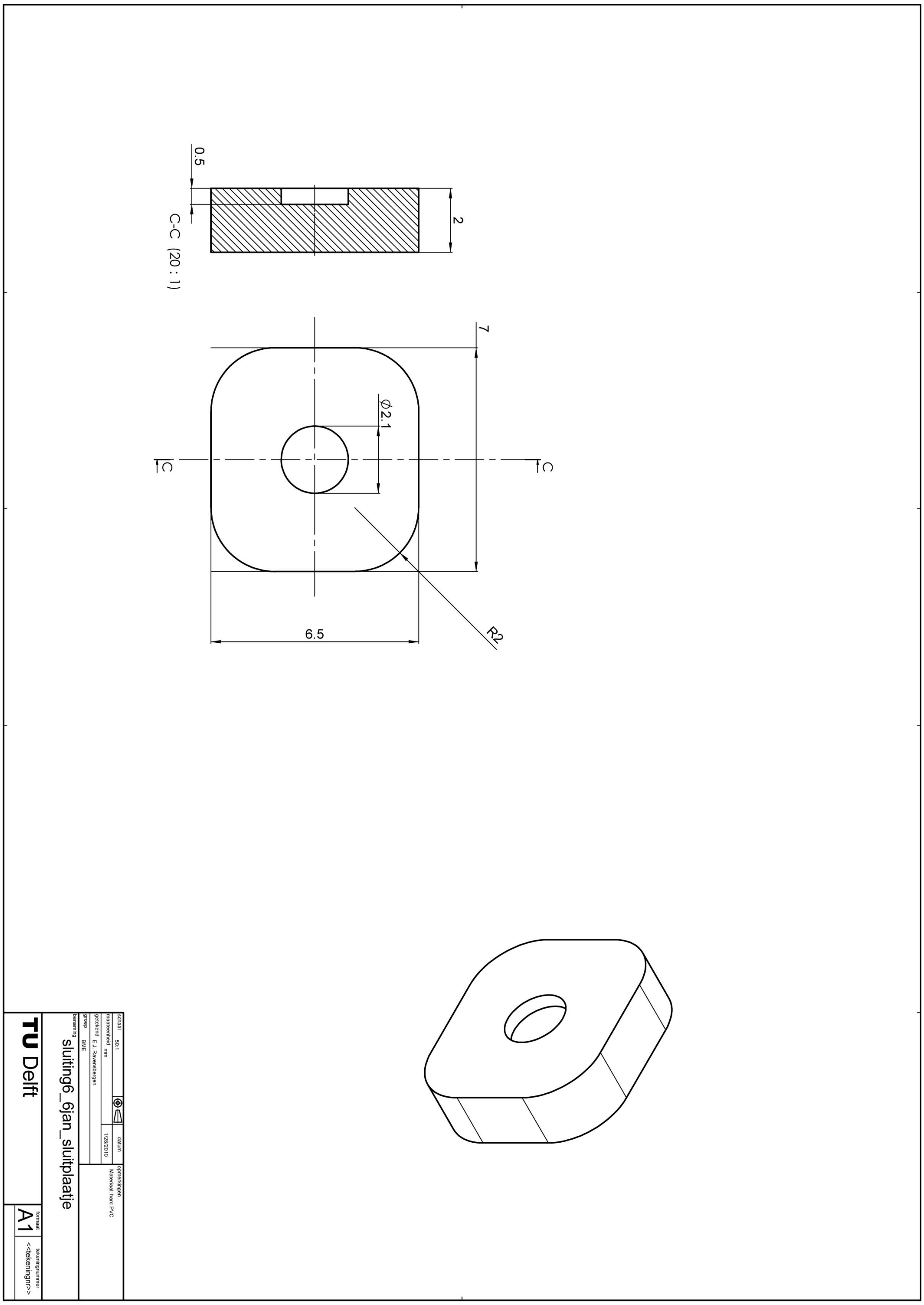
Appendix G

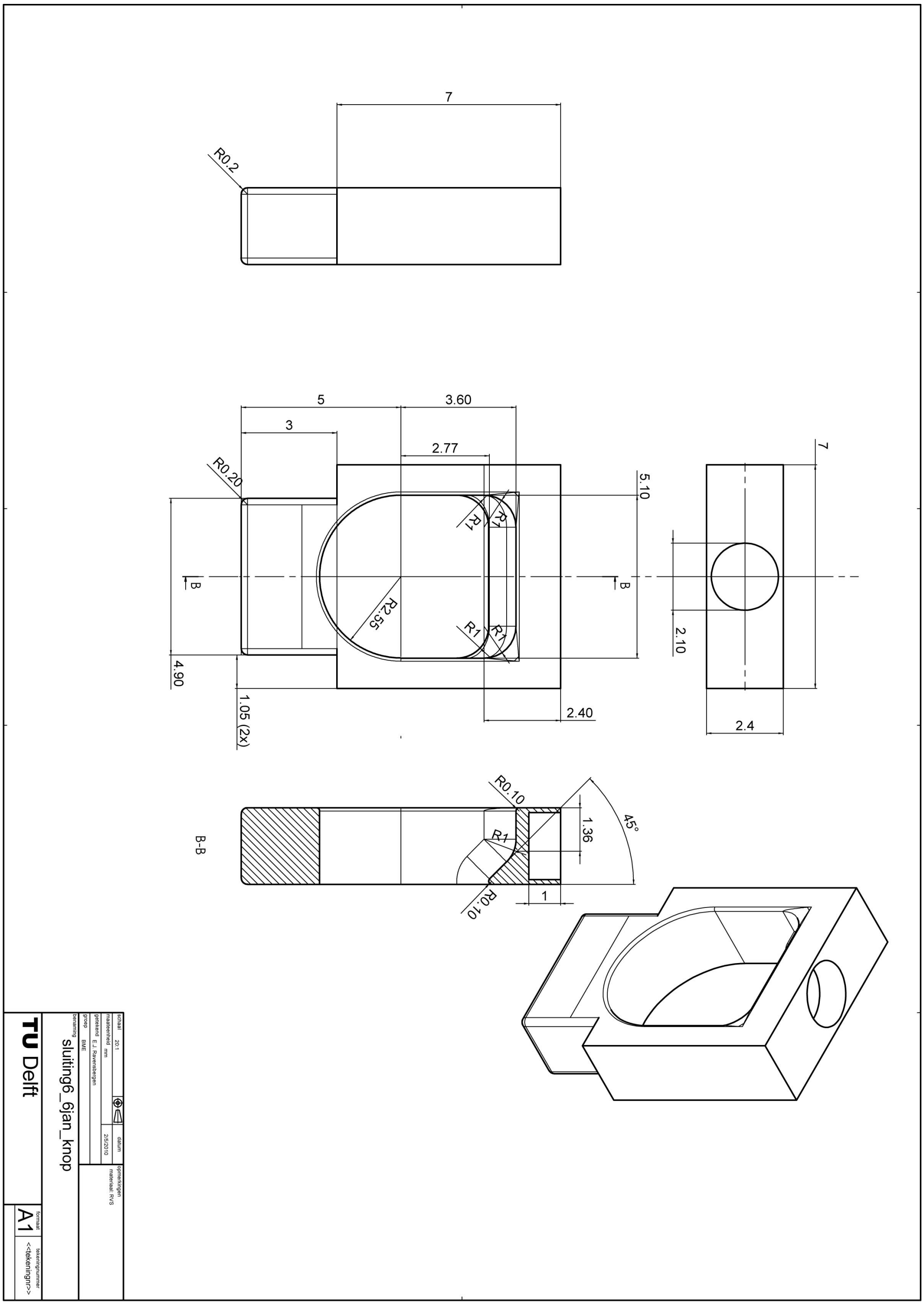
Engineering drawings closure

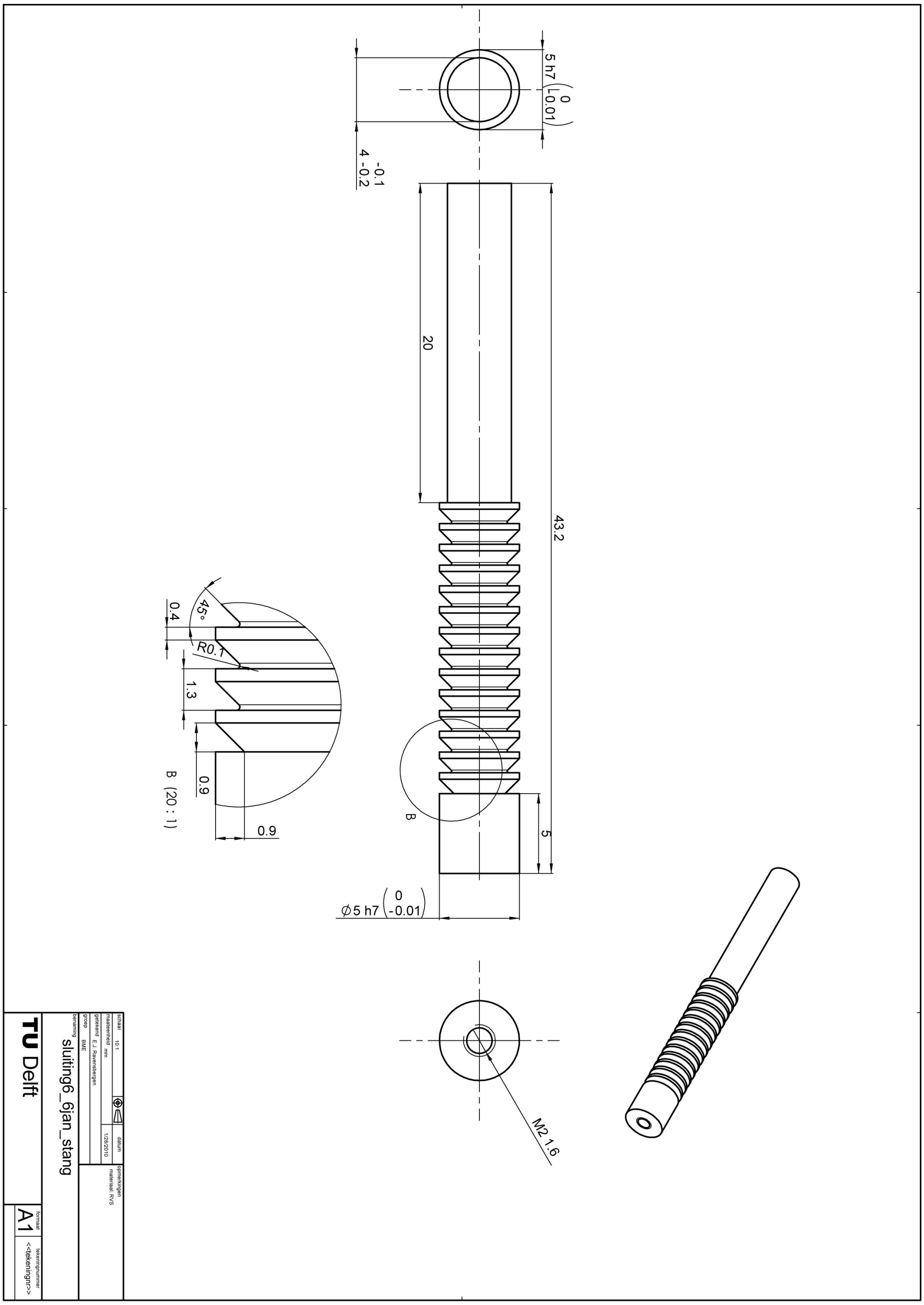

schaal 1:0.3
maateenheid mm
getekend E.J. Ravensbergen
groep BME
datum 1/20/2010
opmerkingen
benaming
sluiting6_6jan_overzicht
TU Delft
formaat A1
tekeningnummer
<<tekeningnr>>

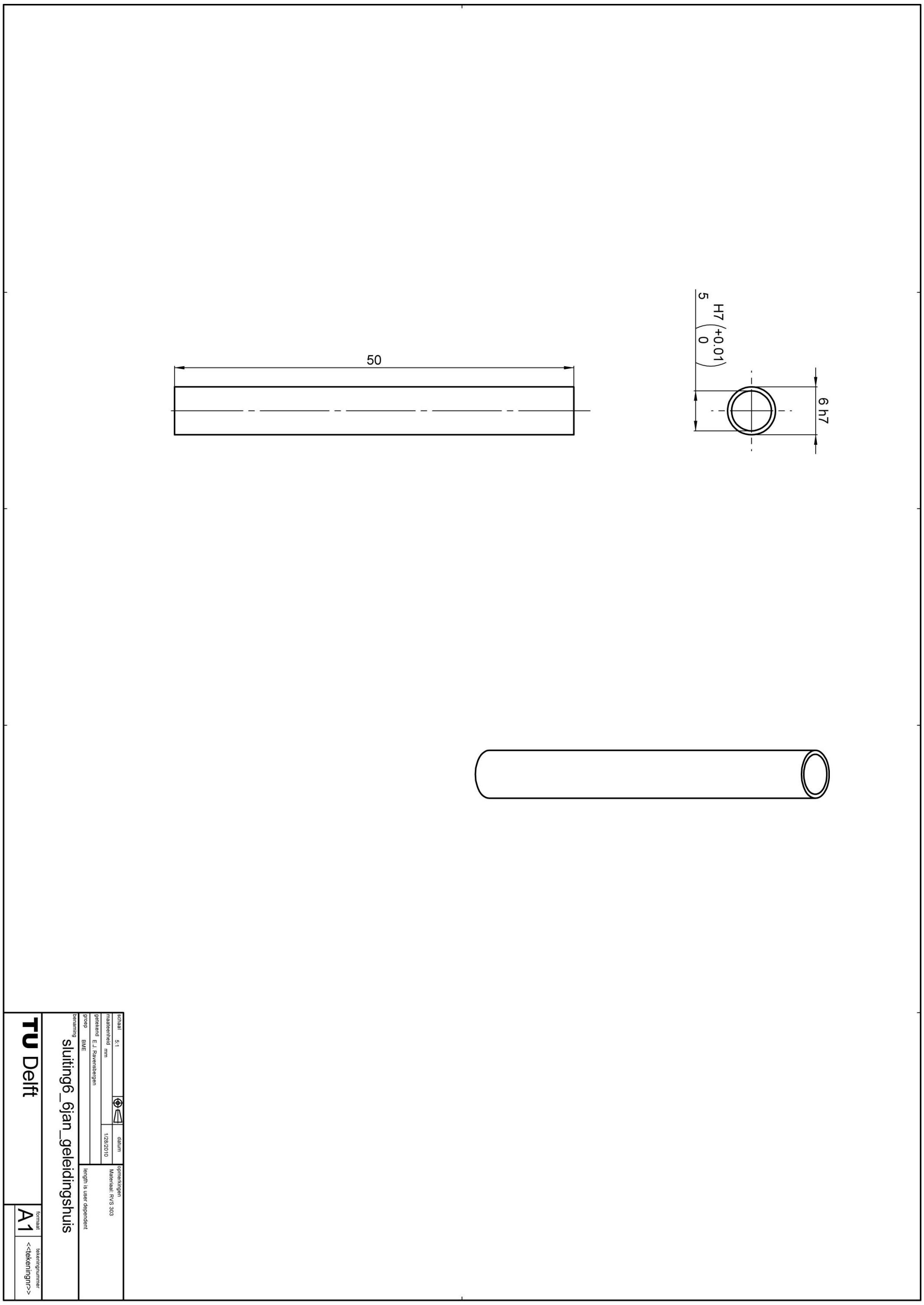

1
2
3
4
5
6
7
Item list
number
name
1 tube to be clamped
2 housing
3 clamp
4 cover plate housing
5 stop
6 tube around ratchet
7 screw stop
schaal 10:1
maateenheid mm
getekend E.J. Ravensbergen
groep BME
datum 1/20/2010
opmerkingen overzicht
benaming
sluiting6_6jan_overzicht_explodedview
TU Delft
formaat A1
tekeningnummer <<tekeningnr>>

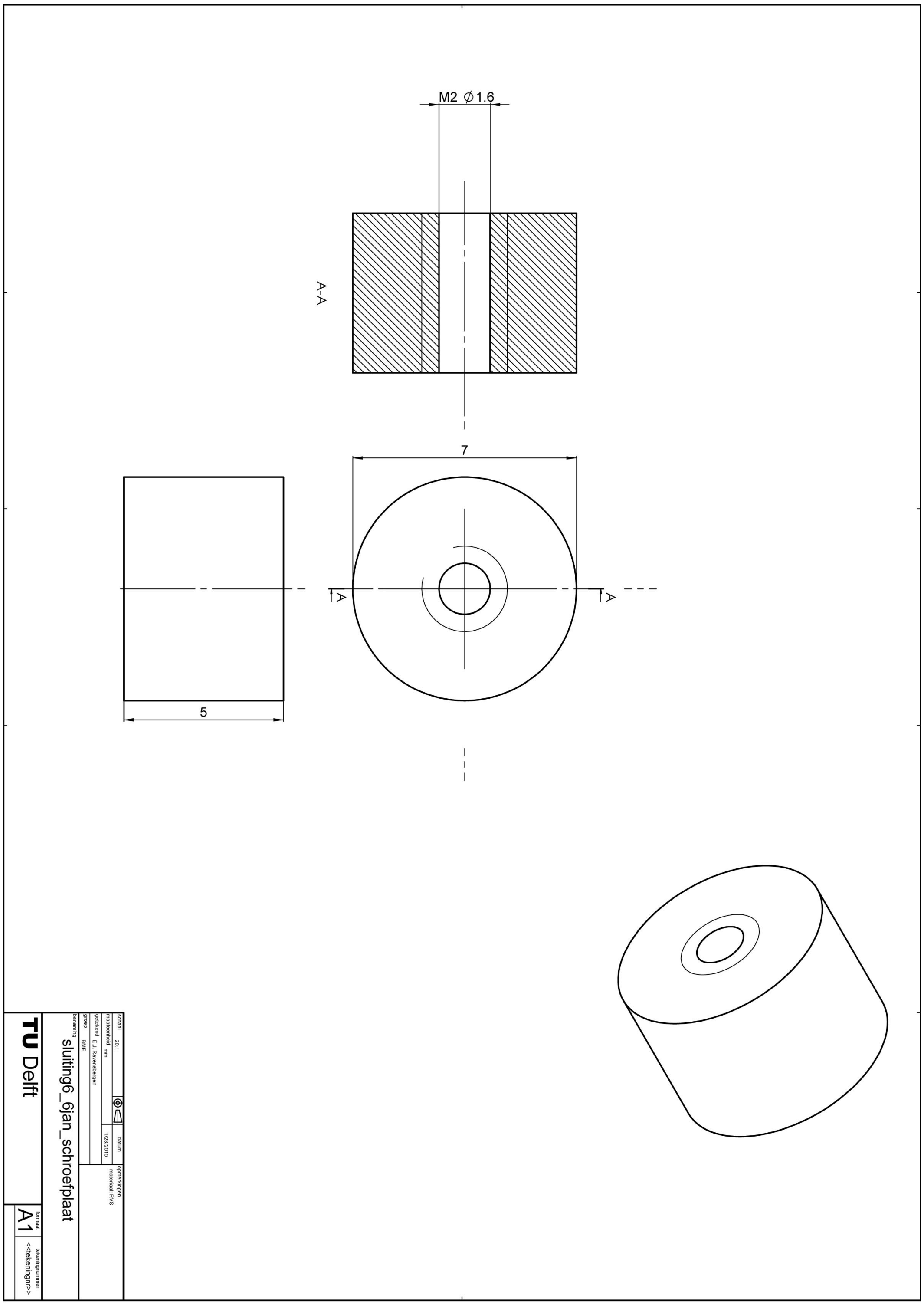

SECTION C-C
SCALE 10 : 1
SECTION B-B
SCALE 10 : 1
R0.2
R1.5
R1.5 (4x)
H7 +0.01 0
H7
R2
TU Delft
sluiting6_6jan_behuizing
A1


0.5
2
C-C (20 : 1)
7
⌀2.1
C
C
6.5
R2
sluiting6_6jan_sluitplaatje
TU Delft
A1
<<tekeningnr>>


7
R0.2
5
3.60
3
2.77
R0.20
5.10
7
R1
R2.55
B
4.90
1.05 (2x)
2.40
2.10
2.4
R0.10
45°
1.36
B-B
1
TU Delft
sluiting6_6jan_knop
A1
2/5/2010
E.J. Ravensbergen
BME
<<tekeningnr>>

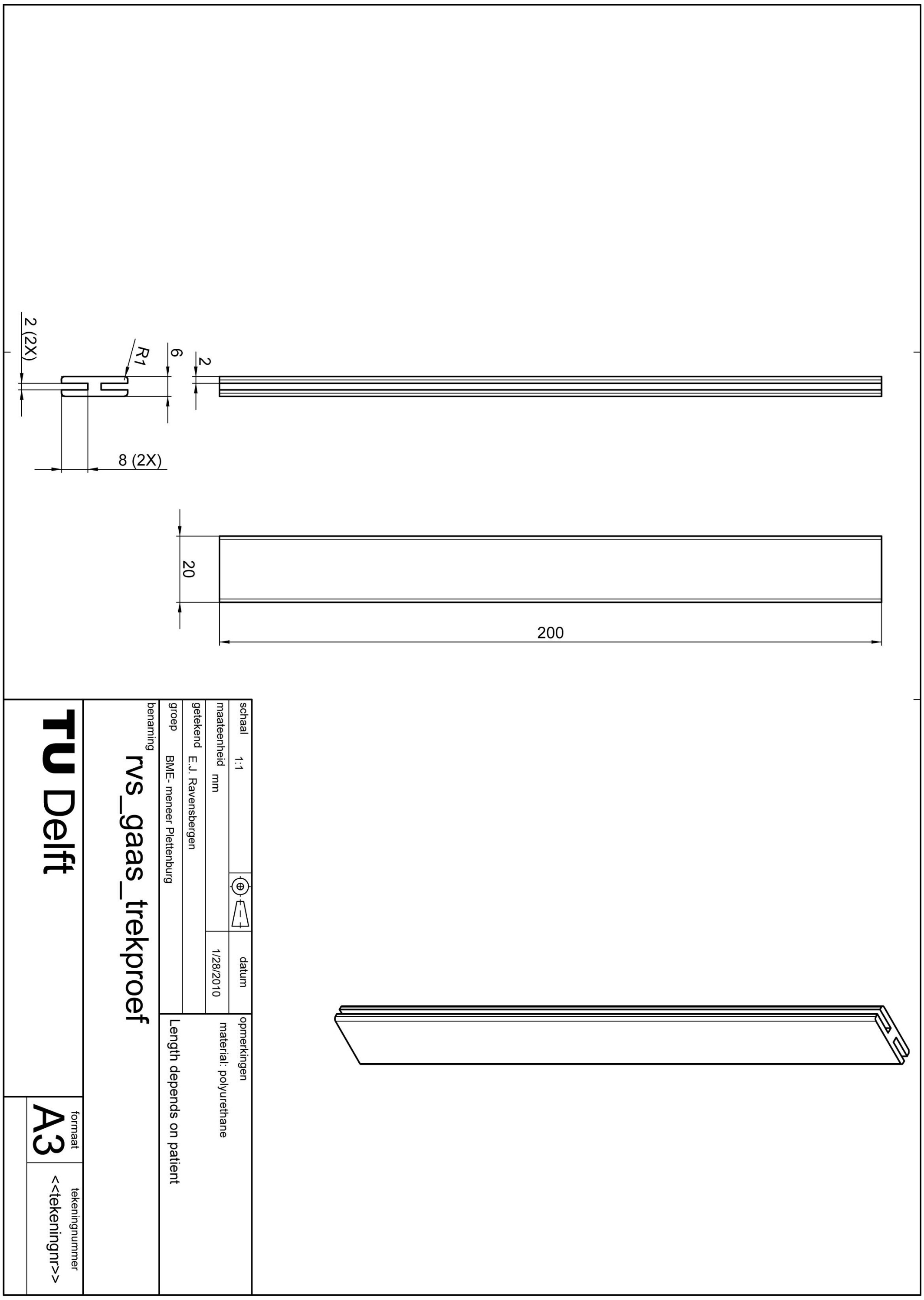

5 h7 (0 / -0.01)
4 -0.1 / -0.2
20
43.2
5
⌀5 h7 (0 / -0.01)
45°
0.4
R0.1
1.3
0.9
0.9
B (20 : 1)
B
M2 1.6
TU Delft
sluiting6_6jan_stang
A1

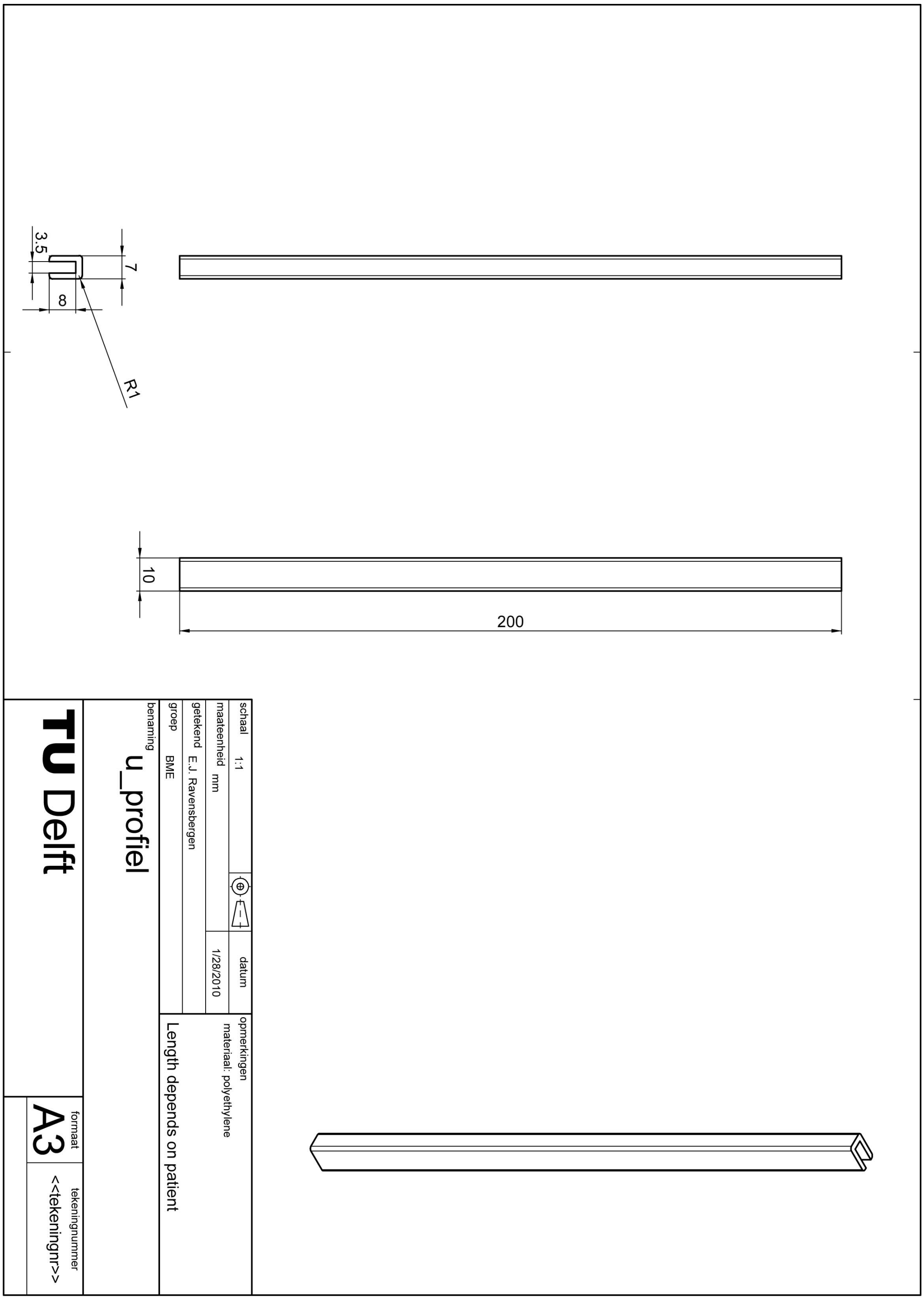

50
5 H7 (+0.01 0)
6 h7
schaal 5:1
maateenheid mm
getekend E.J. Ravensbergen
groep BME
datum 1/28/2010
opmerkingen
Materiaal: RVS 303
length is user dependent
benaming
sluiting6_6jan_geleidingshuis
TU Delft
formaat A1
tekeningnummer
<<tekeningnr>>

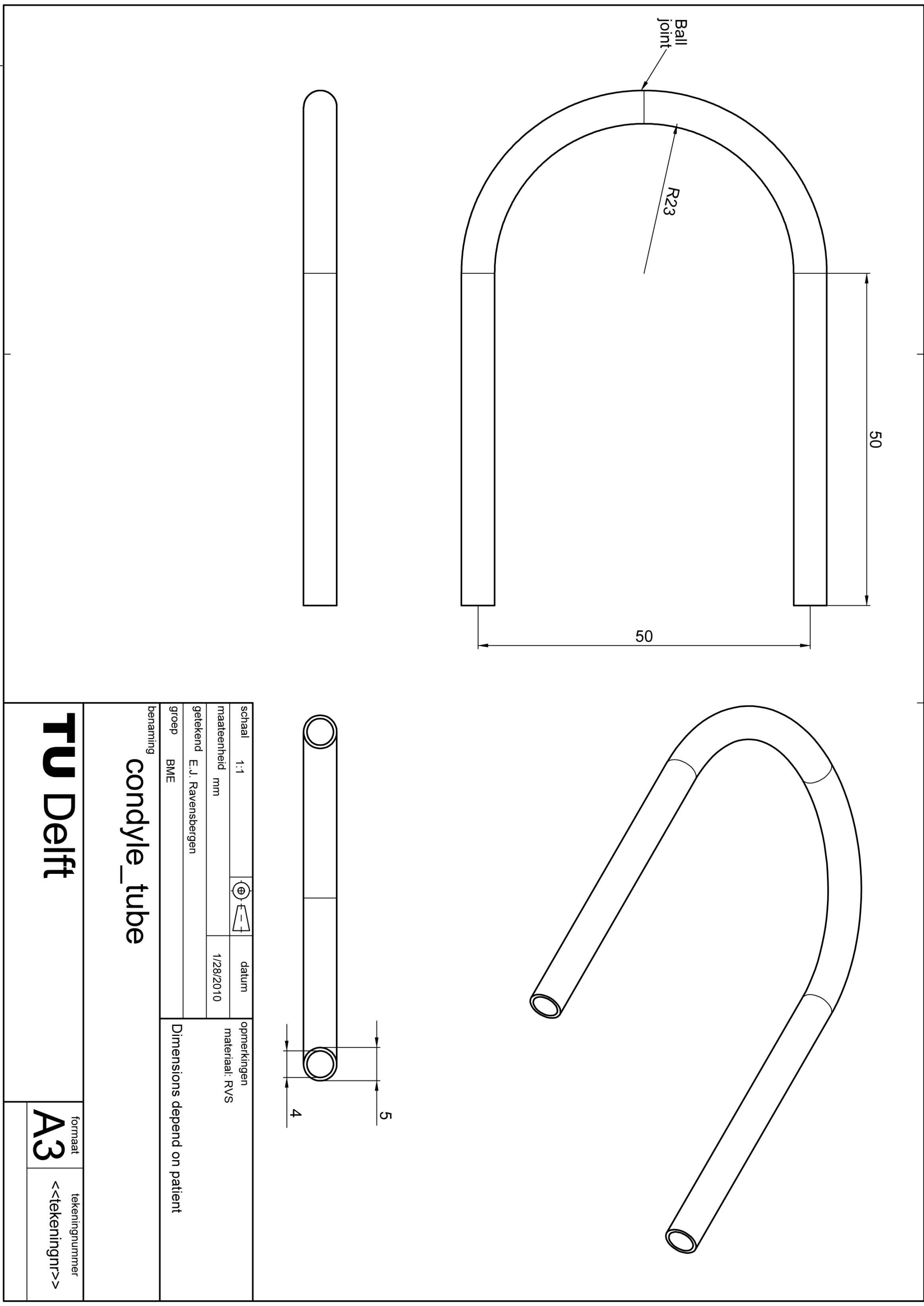

M2 ∅1.6
A-A
7
5
A
A
schaal 20:1
maateenheid mm
getekend E.J. Ravensbergen
groep BME
datum 1/28/2010
opmerkingen
materiaal: RVS
benaming
sluiting6_6jan_schroefplaat
TU Delft
formaat
A1
tekeningnummer
<<tekeningnr>>

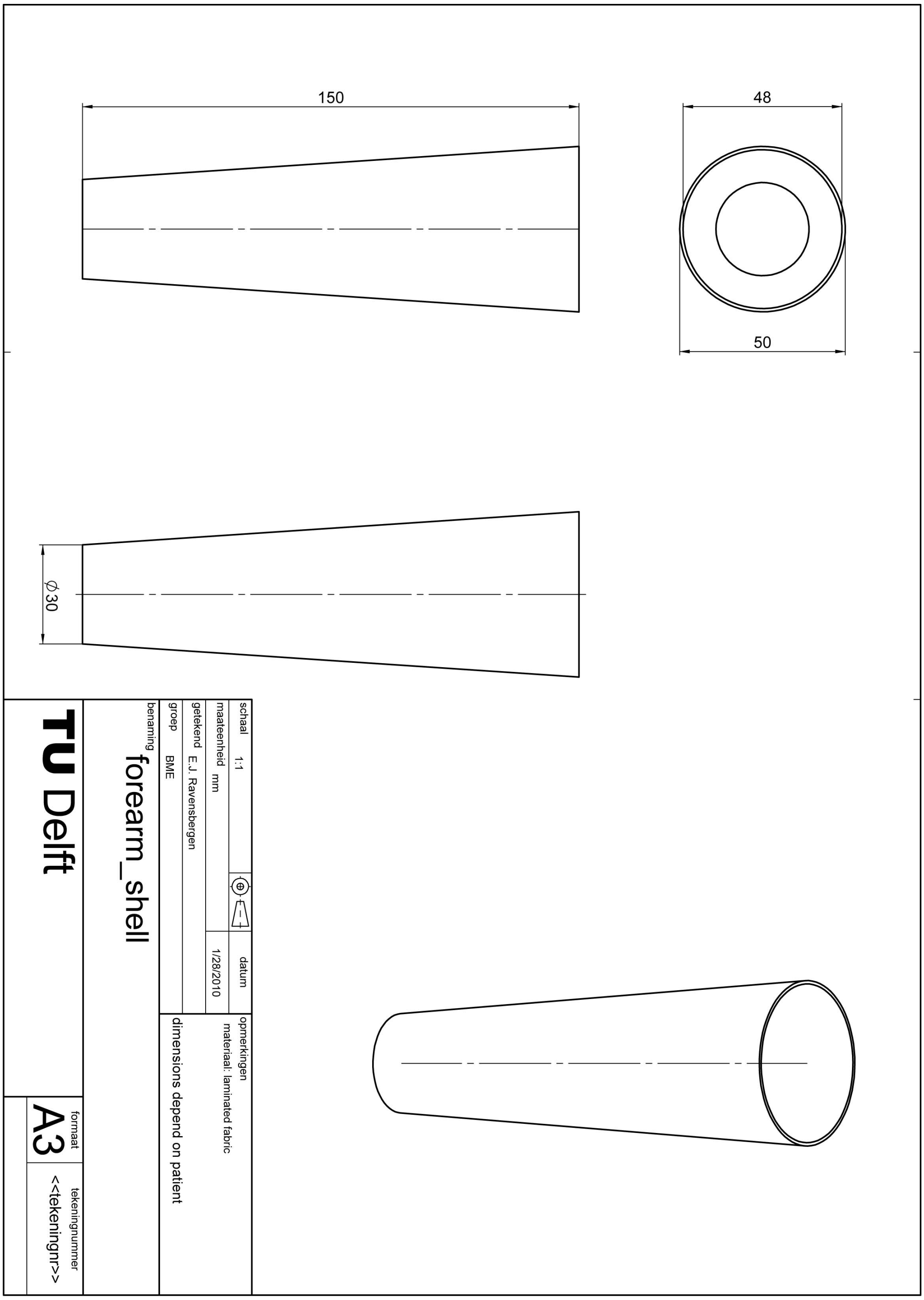
Appendix H

Engineering drawings socket


2 (2X)
R1
6
2
8 (2X)
20
200
schaal 1:1
maateenheid mm
getekend E.J. Ravensbergen
groep BME- meneer Plettenburg
benaming
rvs_gaas_trekproef
datum 1/28/2010
opmerkingen
material: polyurethane
Length depends on patient
TU Delft
formaat
A3
tekeningnummer
<<tekeningnr>>


3.5
7
8
R1
10
200
schaal 1:1
maateenheid mm
getekend E.J. Ravensbergen
groep BME
benaming
u_profiel
datum
1/28/2010
opmerkingen
materiaal: polyethylene
Length depends on patient
TU Delft
formaat
A3
tekeningnummer
<<tekeningnr>>


Ball joint
R23
50
50
4
5
schaal 1:1
maateenheid mm
getekend E.J. Ravensbergen
groep BME
datum 1/28/2010
benaming
condyle_tube
TU Delft
opmerkingen
materiaal: RVS
Dimensions depend on patient
formaat A3
tekeningnummer
<<tekeningnr>>


150
48
50
Ø30
schaal 1:1
maateenheid mm
getekend E.J. Ravensbergen
groep BME
benaming
forearm_shell
datum
1/28/2010
opmerkingen
materiaal: laminated fabric
dimensions depend on patient
TU Delft
formaat
A3
tekeningnummer
<<tekeningnr>>

Appendix I

Acknowledgements

The finishing of this graduation project would not have been possible without the support of the following people:
Dimer (Germany), *Gleich* (Germany), *Erg* (United Kingdom), *Recemat* (The Netherlands), *Lamera* (Sweden), *FXI foamex innovations* (United States of America), *Freudenberg Evolon* (France) *Costacurta* (Italy) and *Heathcoat* (United Kingdom) for answering a great many questions and sending samples.
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Prof Plettenburg for all his enthusiastic input and making it possible to do my master graduation project at Delft University of Technology.
Prof Steinbuch for the help with the transfer of biomedical engineering to mechanical engineering and his enthusiastic support during the master graduation tract.

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Product Data

ARALDITE® AV 138M Resin Hardener HV 998

EPOXY ADHESIVE

DESCRIPTION: Araldite AV 138M resin/Hardener HV 998 epoxy adhesive is a two-component, room-temperature curing paste with high strength and toughness. The cured epoxy adhesive performs well at elevated temperatures and features high chemical resistance. Araldite AV 138M resin/Hardener HV 998 epoxy adhesive is designed for bonding a wide variety of substrates including metals, ceramics, glass, rubbers and rigid plastics. The system is well suited for industrial applications requiring resistance to aggressive and/or warm environments. Araldite AV 138M resin/Hardener HV 998 epoxy adhesive also is a low out-gassing material that is suitable for use in specialized electronic telecommunication and aerospace applications.

ADVANTAGES:

- Low out-gassing/volatile loss
- Good chemical resistance
- Temperature resistant to 248°F (120°C)
- Cures at temperatures as low as 41°F (5°C)
- Thixotropic, gap-filling

TYPICAL PROPERTIES:

Property	Test Method	Test Values[1] Resin	Hardener	Mixed
Color/appearance	Visual	Beige	Gray	Gray
Specific Gravity	ASTM D-792	1.7	1.7	1.7
Viscosity (cP) at 77°F (25°C)	ASTM D-2393	Paste	Paste	Paste
Pot Life, minutes at 77°F (25°C), 100 gm mass	ASTM D-2471	--	--	35

PROCESSING:

Pretreatment

The strength and durability of a joint depend on the proper treatment of the surfaces to be bonded. At a minimum, joint surfaces should be cleaned with a good-quality degreasing agent such as acetone, trichloroethylene or a proprietary formulation to ensure the complete removal of oil, grease and dirt. Alcohol, gasoline or paint thinners should **never** be used.

For added joint strength, degreased surfaces should be mechanically abraded or chemically etched (pickled). After abrasion, surfaces should be degreased again.

MIX RATIO

Resin/hardener (by weight)	100R/40H
Resin/hardener (by volume)	100R/40H

Resin and hardener should be blended until they are homogeneously mixed.

Adhesive Application

The mixed epoxy adhesive should be applied with a spatula to the pretreated, dry joint surfaces.

A layer of adhesive 0.002 to 0.004-inches (0.05 to 0.10-mm) thick will normally impart the greatest lap shear strength to a joint.

Joint components should be assembled and clamped as soon as the adhesive has been applied. Even contact pressure throughout the joint area will ensure proper cure.

Mechanical Processing

For bulk processing, metering, mixing and spreading equipment is available. Consult your Huntsman Advanced Materials representative for more information about equipment to meet specific requirements.

Equipment Maintenance

All tools should be cleaned with hot water and soap before adhesive residues cure. (The removal of cured residues is a difficult and time-consuming process.) If solvents such as acetone are used for cleaning, technicians should take the appropriate precautions to avoid skin and eye contact.

RECOMMENDED CURE SCHEDULES:

Temperature	Minimum Cure Time	Lap Shear Strength at 75°F (23°C), psi (MPa)
50ºF (10ºC)	48 hours	1,450 (10)
59ºF (15ºC)	36 hours	1,595 (11)
75ºF (23ºC)	24 hours	1,885 (13)
104ºF (40ºC)	16 hours	2,030 (14)
140ºF (60ºC)	1 hour	2,175 (15)
176°F (80°C)	15 minutes	2,320 (16)
212ºF (100ºC)	10 minutes	2,610 (18)

TYPICAL CURED PROPERTIES:

Unless otherwise stated, the figures given below were determined by testing standard specimens made by lap-jointing 6.5-inch x 1-inch x 0.06-inch (170-mm x 25-mm x 1.5-mm) strips of aluminum. The joint area was 0.5 inch x 1 inch (12.5 mm x 25 mm) in each case. The figures were determined with typical production batches using standard testing methods. They are provided solely as technical information and do not constitute a product specification.

Lap Shear Strength, psi (MPa)
Metal-to-Metal Substrates ISO 4587
(Cured 16 hours at 104ºF/40ºC) (typical average values)
Pretreatment: Sand blasting

Metal	**Shear Strength, psi (MPa)**
Aluminum	2,030 (14)
Steel 37/11	2,175 (15)
Stainless Steel V4A	2,900 (20)
Galvanized Steel	2,320 (16)
Copper	2,320 (16)
Brass	2,175 (15)

Shear Modulus (DIN 53445)
(Cured 16 hours at 104ºF/40ºC)

Temperature	**Modulus, psi (MPa)**
77°F (25°C)	435,000 (3,000)
122°F (50°C)	290,000 (2,000)
167°F (75°C)	58,000 (400)
212°F (100°C)	14,500 (100)
257°F (125°C)	435 (3)
302°F (150°C)	290 (2)

Lap Shear Strength, psi (MPa)	ISO 4587 (typical average values)	
Effects of Test Temperature		
Cured 16 hours at 104ºF (40ºC)	**Test Temp.**	**Test Values**
	-76ºF (-60ºC)	1,812 (12.5)
	-40°F (-40°C)	1,812 (12.5)
	-4ºF (-20ºC)	1,885 (13)
	32ºF (0ºC)	1,958 (13.5)
	68ºF (20ºC)	2,030 (14)
	104ºF (40ºC)	2,175 (15)
	140ºF (60ºC)	2,204 (15.2)
	176ºF (80ºC)	2,320 (16)
	212°F (100°C)	1,885 (13)
	248°F (120°C)	1,232 (8.5)
	284°F (140°C)	870 (6)

Lap Shear Strength, psi (MPa)
Effect of Immersion (typical average values)
(Cured 16 hours at 104ºF/40ºC). Immersion for 90 days at 73°F/23°C in media listed.)

Properties	Test Values
Standard - As prepared	2,030 (14)
Methanol	1,885 (13)
Gasoline	2,320 (16)
Ethyl Acetate	2,030 (14)
Acetic Acid, 10%	1,740 (12)
Trichloroethylene	2,030 (14)
Lubricating Oil	2,030 (14)
Kerosene	2,030 (14)
Water @ 73°F (23°C)	2,175 (15)
Water @ 194°F (90°C)	2,320 (16)

Property	Test Method	Test Values[(1)]
Roller Peel[2], pli (N/mm)	ISO 4578	(1.8)
Hardness, Shore D		84-86
Elongation at break, %		1.2
Tensile Strength[2], psi (MPa)		(43)
Tensile Modulus, psi (MPa)		(4,700)
Coefficient of Thermal Expansion[2], in/in/°C (64°F – 200°F/18°C – 93°C)	VSM 77110	67×10^{-6}
Fatigue Test[2], simple lap joints @ 90-130 Hz	DIN 532852	
25% of static failing load, cycles to failure		$>10^{7}$
30% of static failing load, cycles to failure		$10^{5} – 10^{6}$
Volume Resistivity, ohms-cm @ 50 Hz	VSDE 0303	1.8×10^{17}
Electric Strength, kV (instantaneous value)	VSM 7710	45.8
Electrolytic Corrosion[2], after 4 days at 104ºF/40ºC/92% RH	DIN 53489	Rated AN1

[1]At 73°F (23°C) unless otherwise noted.
[2]Cured 16 hours at 104ºF/40ºC

Lap Shear Strength, psi (MPa) DIN 50015
Effect of Tropical Exposure (typical average values)
(Cured 16 hours at 104ºF/40ºC/92% R.H.)

Exposure Time	Test Values [(1)]
Standard - As prepared	2,030 (14)
30 days	2,175 (15)
60 days	2,320 (16)
90 days	2,465 (17)

[1]At 73°F (23°C)

Lap Shear Strength, psi (MPa)
Effect of Heat Aging
(Cured 16 hours @ 104ºF/40ºC)

Exposure Time	Test Values
Standard - As prepared	2,030 (14)
5 years at 104ºF(40ºC)	2,030 (14)
5 years at 176ºF(80ºC)	2,465 (17)
60 days at 302ºF(150ºC)	2,465 (17)

CAUTION:

Huntsman Advanced Materials Americas Inc. maintains up–to-date Material Safety Data Sheets (MSDS) on all of its products. These sheets contain pertinent information that you may need to protect your employees and customers against any known health or safety hazards associated with our products. Users should review the latest MSDS to determine possible health hazards and appropriate precautions to implement prior to using this material. Copies of the latest MSDS may be requested by calling our customer service group at 800-367-8793 or emailing your request to adhesives_group@huntsman.com.

FIRST AID!

Eyes and skin: Flush eyes with water for 15 minutes. Contact a physician if irritation persists. Wash skin thoroughly with soap and water. Remove and wash contaminated clothing before reuse.
Inhalation: Remove subject to fresh air.
Swallowing: Dilute by giving water to drink and contact a physician promptly. Never give anything to drink to an unconscious person.

KEEP OUT OF REACH OF CHILDREN

FOR PROFESSIONAL AND INDUSTRIAL USE ONLY

Technical Data Sheet

MASTER BOND POLYMER SYSTEM EP42HT-2ND2 MED BLACK

Two Component, Room Temperature Curable, Heat Resistant Medical Grade Epoxy Adhesive, Sealant & Coating Featuring Resistance to Repeated Sterilization Including Radiation, Chemicals and Steam. Meets USP Class VI Requirements.

Product Description

Master Bond Polymer System EP42HT-2ND2 MED BLACK is a room temperature curable two component epoxy, adhesive and sealant featuring high temperature resistance along with outstanding chemical resistance. It is widely used in medical devices because of its capability of withstanding repeated sterilizations, including radiation, ethylene oxide, chemical sterilants, and steam. In addition, it fully complies with the testing requirements of USP Class VI plastics. It has a paste consistency and minimal flow when applied. The color is black. EP42HT-2ND2 MED BLACK cures readily at ambient or more quickly at elevated temperatures. One particularly popular cure schedule is "overnight" at room temperature followed by 2-4 hours at 150-200℉.
It has an easy to use 100:40 mix ratio by weight or 100:50 by volume. The cured epoxy compound is resistant to various types of sterilizations, inorganic and organic acids, alkalis, organic solvents and aromatic hydrocarbons. EP42HT-2ND2 MED BLACK is an excellent electrical insulator. Especially noteworthy is its serviceability from -60℉ up to 4 50℉, combined with resistance to steam, chemicals and radiation. To optimize physical properties including heat resistance, a post cure of 100-130℃ for 1 hour is recommended.

Product Advantages

- Convenient non-critical 100:40 mix ratio by weight or 100:50 by volume.
- Contains no solvents.
- Convenient cure schedules at both ambient and elevated temperatures.
- Outstanding resistance to medical sterilants, radiation, ETO, chemicals and steam.
- Excellent chemical resistance to acids, alkalis and many solvents.
- Superior thermal stability; serviceable up to 450°F.
- Paste consistency; minimal flow.
- Conforms to the requirements for a USP Class VI plastic.
- Service temperature -60℉ - 450℉

Typical Product Properties

- Mix ratio, by weight, part A to part B 100/40
- Mix ratio, by volume, part A to part B 100/50
- Viscosity, Part A, cps, 25℃ .... >250,000
- Viscosity, Part B, cps, 25℃ .... >250,000
- Working life after mixing, 100 gram mass, 25℃, mi nutes 45-75
- Cure schedule
  - 25℃, ... 24-48 hrs
  - 200℉ .... 2-3 hrs
- Tensile strength, 77℉, psi .... >12,000
- Elongation, 77℉, %. .... <3
- Tensile lap shear, Al/Al, 77℉, psi ....>2000
- Tensile modulus psi .... >450,000
- Coefficient of thermal expansion, in/in x 10^{-6}/℃ 35-40
- Volume resistivity, 77℉, ohm-cm .... $>10^{12}$
- Dielectric constant, 77℉ (60Hz) 3.8
- Service temperature range, ℉ .... -60 to 450℉
- Hardness, Shore D .... >75
- Shelf life at 75℉, in unopened containers
  - Medical Grade .... 6 months
  - Commercial Grade .... 1 year
- Parts A and B available in syringes, ½ pints, pints, quarts, gallons and five gallon containers.

Special Chemical Resistance Data
Resistant at Room Temperature, 77°F (immersion): Acetic acid (10%), Ammonium hydroxide (29%), Butyl alcohol, Calcium hypochlorite (5%), Citric acid (10%), Cottonseed oil, Distilled water, Ethylene glycol, Formaldehyde (37%), Gasoline (98% octane), Hydrochloric acid (10%), Hydrogen peroxide (20%), Lard, Linseed oil, Mineral oil, Phosphoric acid (10%), Propylene glycol, Sea water, Sodium hydroxide (20%), Sodium hydroxide (50%), Sodium sulfite (1%), Sour crude oil, Sulfuric acid (10%), Tap water, Toluene, Zinc hydrosulfite (1%).

Resistant at 200°F (immersion): Citric acid (10%), Ethylene glycol, Hydrochloric acid (10%), Mineral oil, Phosphoric acid (10%), Propylene glycol.

Satisfactory Resistance to Spillage Above 200°F: Carbon tetrachloride, Ethyl alcohol, Gasoline, Hydrochloric acid (10%), O-dichlorobenzene (10%), Sodium hydroxide (10%), Sulfuric acid (10%), Tap water, Xylene.

Preparation of Compound and Bond Surfaces
Master Bond Polymer System EP42HT-2ND2 MED BLACK is prepared for use by thoroughly mixing part A with part B in a noncritical 100 to 40 mix ratio by weight or 100 to 50 by volume. Mixing should be done slowly to avoid entrapping air. The working life of a mixed 100 gm batch is 45-75 minutes. It can be further lengthened by using shallow mixing vessels or mixing smaller size batches. All bonding surfaces should be carefully cleaned, degreased and dried to obtain maximum bond strength. Certain metal or plastic surfaces should be mechanically or chemically etched in order to maximize bond strength. Castings can be accomplished in rubber, plastic or metal molds after application of appropriate mold releases. When casting, vacuum degassing may be necessary to eliminate all air bubbles.

Application and Assembly
For bonding or sealing, EP42HT-2ND2 MED BLACK can be conveniently applied with a spatula or knife. Enough mixed adhesive should be applied to obtain a final adhesive bond line thickness of 4-6 mils. This can be accomplished by coating one surface with an adhesive film 4-6 mils thick or by coating the two surfaces, each with a 2 to 3 mil thick layer of adhesive. Porous surfaces may require somewhat more adhesive to fill the voids than non-porous ones. Thicker glue lines do not increase the strength of a joint but do not necessarily give lower results since EP42HT-2ND2 MED BLACK does not contain any volatiles. The parts to be bonded should then be pressed together with just enough pressure to maintain intimate contact during cure.

Cure
Master Bond Polymer System EP42HT-2ND2 MED BLACK can be cured at room temperature or at elevated temperatures as desired. At room temperature, Master Bond Polymer System EP42HT-2ND2 MED BLACK develops 85% of its maximum bond strength within 24-48 hours. The bond strength then increases continuously for another 2-3 days. Faster cures can be realized at elevated temperatures, 2-3 hours at 200°F for full strength.

Handling and Storage
All epoxy resins should be used with good ventilation. Skin contact should be minimized. To remove resin or hardener from skin, use mild solvent then wash with soap and water. If material enters the eyes, flood with water and consult a physician. Optimum storage is at or below 75°F in closed containers. No special storage conditions are necessary. Containers should however be kept closed when not in use to avoid contamination. Cleanup of spills and equipment is readily achieved with acetone or xylene employing proper precautions of ventilation and flammability.

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