Design of a passive brace

Assisting elderly with the sit-to-stand transition

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TNO

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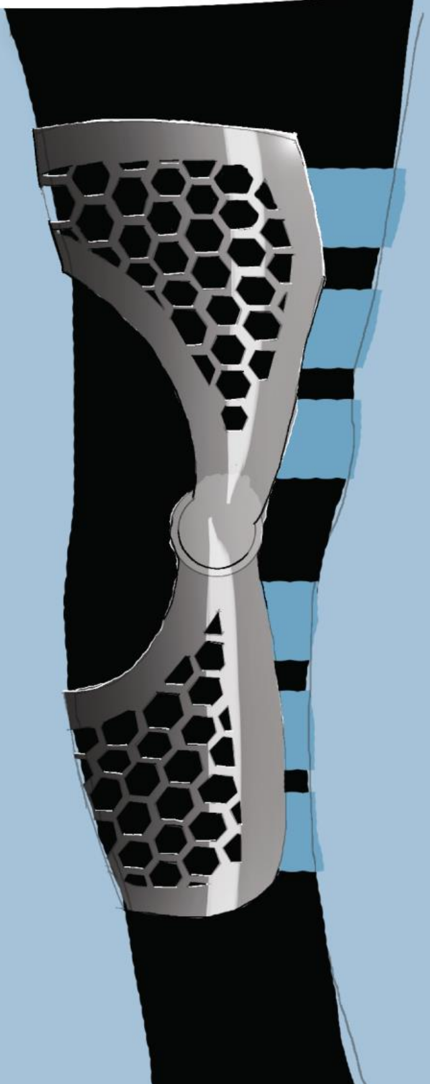
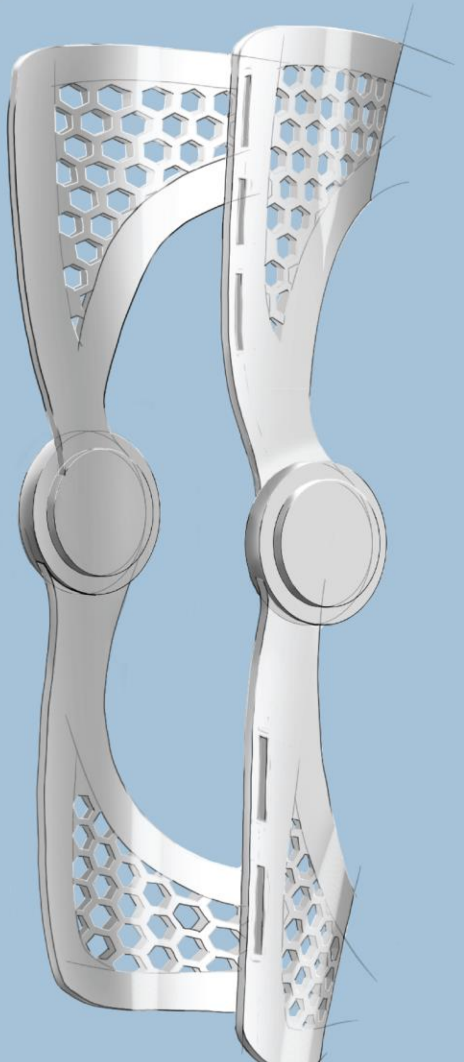
University of Twente

Bachelor Industrieel Ontwerpen





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Preface

When in search for a bachelor thesis I got in contact with Marc van Kleef who knew where I could do my bachelor thesis. This was at TNO in Eindhoven. I did not know much about this company at first, but after some research it seemed like a very interesting location for my bachelor thesis.

It was great to get the opportunity to work with such experienced people. I was able to join meetings and see how a large company like TNO works. My gratitude goes out to everyone at TNO who made me feel at home and helped me with difficulties I met on my way. I had much fun during the breaks at the coffee corner. The people in the EfAM department are very open and they involve interns as much as possible.

I would like to in particular thank my supervisors, Tom Vaneker and Mathijs de Schipper for giving me guidance through the assignment. I furthermore would like to thank my test persons Jan Bron and Leida Gassan for being so cooperative in evaluating the design.

Summary

Background

This report presents the process of a bachelor thesis of the study Industrial Design at the University of Twente. The assignment is executed commissioned by TNO at the department Equipment for Additive Manufacturing. TNO is targeting to take additive manufacturing to a higher level. The goal of the assignment is to make a conceptual prototype of an exoskeleton which is produced using additive manufacturing. The exoskeleton should assist elderly with the sit-to-stand transition.

Approach

The assignment is executed in four different phases. First the analysis phase in which market research is done, the stakeholders are analysed and literature research is done. The analysis phase results in a list of requirements. These requirements are used in the second phase, the concept phase. Three concepts have been developed and have been rated based on the requirements. The concepts have been improved into one final concept. This concepts is then turned into a prototype which brings us to the third phase. The validation phase, in this phase the concept is validated by a user test and theoretical evaluation. The points of improvement that are found in the validation phase are then used in the final phase, the final product design. In this phase a redesign is made which incorporates the points of improvement.

Results

An innovative solution was found that satisfies most requirements. The final product is a knee brace that helps elderly with the sit-to-stand transition. The product is a form fitting design with an incorporated hinge which can be 3D printed together with the product, which makes sure that an assembly step can be skipped.

Conclusion

By making the exoskeleton a form fitting knee orthosis all requirements set in the analysis phase are met or can be met with further development. Therefore the recommendations were drawn up which can be used in the continuation of the development process.

Samenvatting

Achtergrond

Dit verslag is geschreven naar aanleiding van de bachelor opdracht van de studie Industrieel Ontwerpen aan de Universiteit Twente. De opdracht is gedaan in opdracht van TNO bij de afdeling Equipment for Additive Manufacturing. TNO wil 3D printen naar een hoger niveau brengen. Daarom was het doel van de opdracht op een conceptueel prototype van een exoskelet te ontwerpen door middel van 3D printen wat ouderen helpt met de zit naar sta transitie.

Aanpak

De opdracht is uitgevoerd in vier ontwerpfasen. De eerste fase is de analyse fase waarin marktonderzoek en literatuur onderzoek is gedaan en de gebruikers zijn gedefinieerd. De analysefase resulteert in een programma van eisen. De eisen zijn gebruikt om in de tweede fase, de conceptfase, concepten te ontwikkelen. Er zijn drie concepten ontwikkeld die aan de hand van de eisen verbeterd tot een eindconcept. Van dit eindconcept is een prototype gemaakt wat gebruikt wordt in de derde fase, de validatie fase. Hier wordt het prototype getest in een gebruikerstest en in een theoretische evaluatie. In de vierde fase worden alle verbeterpunten uit de validatie fase toegepast en wordt het uiteindelijke concept ontwikkeld.

Resultaten

Een innovatieve oplossing was ontwikkeld die aan alle eisen voldoet. Het eindproduct is een knie brace die ouderen helpt met de zit-naar-sta transitie. De brace volgt de lichaamsvorm van de gebruiker en heeft een geintegreerd scharnier dat samen met de brace 3D-geprint wordt. Dit zorgt ervoor dat er minder assemblage stappen nodig zullen zijn.

Conclusie

Door het exoskelet het lichaam van de gebruiker te laten volgen wordt aan alle eisen voldaan of kan er aan voldaan worden door het product verder te ontwikkelen. Hieruit komen aanbevelingen voor het voortzetten van het ontwikkelen van het exoskelet voort.

Index

Definitions and abbreviations

	Term	Definition
1	AM	Additive manufacturing
2	BFP	Body fitting part
3	Body-fitting	Opposed to structural parts, these are the parts that will be personalized and made using AM
4	EfAM	Equipment for additive manufacturing
5	Form-fitting	A part that tightly follows the contours of the body
6	Orthosis	An externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal sytem. [1]
7	Passive	Unpowered, so without the use of any propulsion. It can be actuated by springs or dampers.
8	PA-12	Polyamide 12
9	Prosthetics	Externally applied device used to replace wholly, or in part, an absent or deficient limb segment. [1]
10	Structural part	Hinge of the exoskeleton.
11	STS	Sit-to-stand
12	SLS	Selective laser sintering
13	TPU	Thermoplastic polyurethane

01 Introduction

This report presents the process of a bachelor thesis of the study Industrial Design at the University of Twente. The assignment is executed by one student and the goal of the assignment is to apply the knowledge gathered during the education.

The assignment is executed commissioned by TNO. TNO is a knowledge organisation which enables business and government to apply knowledge. [2] The department that coordinates the assignment is the department Equipment for Additive Manufacturing (EfAM). This department is situated in Eindhoven. TNO is targeting to take additive manufacturing (AM) to a higher level. At present AM is mainly used for prototyping, TNO aims to drive the development in AM to develop world-class AM technology and products. [3] AM technology is still a new technology with lots of opportunities. It is a technology which can, when it is further developed create customised and sustainable products in a relatively cheap way. [4]

The goal of the assignment is to make a conceptual prototype of an exoskeleton, this exoskeleton is similar to an orthosis. Prostheses use similar techniques to orthoses therefore these will also be looked at. The state-of-the-art orthoses come in a limited amount of sizes and will not fit perfectly to anyone. To make them fit straps have to be very tight which causes a bad pressure distribution. For prosthetics the problems are worse, due to the bad pressure distribution the affected limb can be sore and the prosthetic will often not be worn. This problem shows the difficulty in producing form-fitting parts. AM can solve these problems. AM in combination with 3D scanning has the ability to get the exact dimensions of the limb and to produce a perfectly fitting orthosis.

To be able to create the design of the exoskeleton first a list of requirements is needed. The literature research which results in a list of requirements is presented in chapter two: Analysis. The third chapter uses the list of requirements to create three conceptual designs which are made into one final concept. Chapter four describes how this concept is validated using a prototype. Chapter five presents the redesign and final design. In chapter six the final design is evaluated in the conclusion and evaluation section.

1.1. Assignment description

To describe the assignment, first the central problem will be described. The population is aging rapidly, recent predictions indicate that by 2047 a majority of the people in the world will be over the age of 60. [5] This aging population brings new challenges, one of which is injuries related to falling. 30% of the people over 65 and 50% of the people over 80 fall each year. [6] Falls may lead to distress, pain, loss of confidence but also serious injuries leading to disabilities, loss of independence or, in the worst case, death. [7] Sit-to-stand (STS) transition is one of the critical activities for older people, since it is a pre-requisite for walking. [7] This is the reason why in this assignment the focus will be on designing an exoskeleton which will help with the STS transition.

There are presently no orthoses specifically designed to help with the STS motion. Other braces that exist are not form fitting and only come in a limited amount of sizes. Therefore these do not fit perfectly for everyone and since they are often heavy and non-breathable they will not be worn. AM could be a solution to this problem. This will be addressed in this report.

The assignment is part of a larger project: MovAiD. “MovAiD is a cross-disciplinary project gathering a consortium of 13 partners under the EU Horizon 2020 Research and Innovation Programme which aims at developing technologies assisting the manufacturing of intelligent, passive and highly personalised kineto-dynamic equipment to enhance or compensate human movements.” [8] The research institution TNO is developing a new AM machine that can make a passive exoskeleton which should follow the natural movement functionalities of the body to help elderly with the STS movement . The goal of this assignment is to create a prototype of the exoskeleton. The prototype will be used to explore the advantages of additive manufacturing in the comfort of body fitting parts. TNO is developing a machine which will be able to print this exoskeleton. For TNO the prototype will be used as a demonstrator, and a guideline for what the future AM machine should be able to make.

TNO has already defined the different parts which could be incorporated in the exoskeleton. Figure 1.1 shows the different parts. The exoskeleton will exist of body fitting parts (BFP) in which sensors will be embedded. The sensors will be connected by electrical connections. The electronics will not be present in the prototype but it has to be taken into account that it should be possible to incorporate them later. It also consists of a structural part which will be connected to the rigid body fitting part. Thus the prototype will consist of body fitting parts and structural parts. This is shown in figure 1.1.

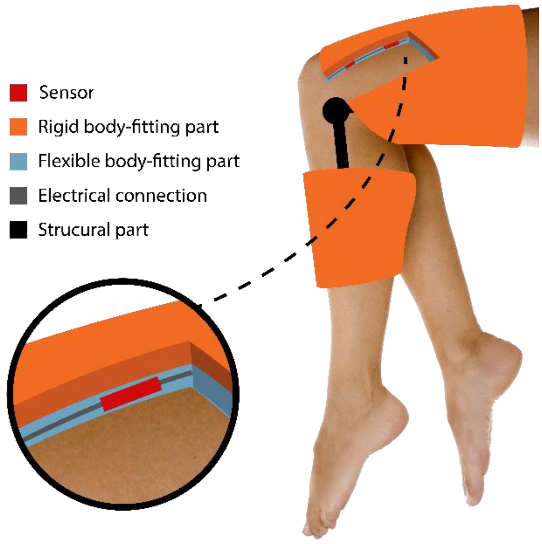


Fig. 1.1: schematic overview assignment

02 Analysis

The target of the analysis is to get enough information on the topic to be able to make conceptual designs. The gathering of information will be done in three steps. First of all the stakeholders will be defined. Secondly, the desk research in which similar products to the exoskeleton will be analysed. This is done to make sure the wheel will not be reinvented. It will furthermore point out the weak points which can be improved and the strong points which could be an inspiration. And lastly, after the market research there will be looked into different topics in scientific publications.

2.1 Stakeholders

To be able to design a product that suits the target group the target group should be analysed. The preferences and habits of the target group can be used to make sure the target group is able to use the product. Furthermore other stakeholders are analysed to make sure the product will suit the requirements of all people involved. From the user analysis the requirements concerning the use can be identified. The users are identified by looking into the lifecycle of the product to be designed and to identify all stakeholders throughout the whole process. The stakeholders are mapped in the context diagram in figure 2.6.

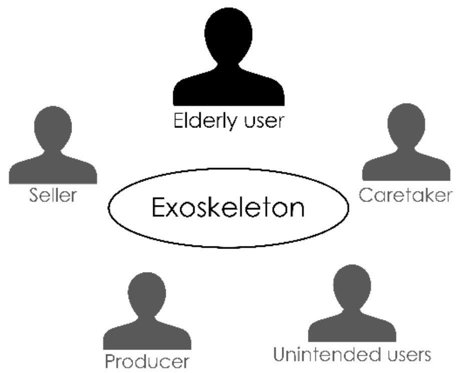


Fig. 2.6: context diagram

The specificities of these users will be elaborated in the next section.

2.1.1. Elderly user

Elderly users will be the primary users of the exoskeleton. Elderly are defined in this report as people who have an age above 65 years. Elderly users often have money and time. [9] They seek for a good service and product quality. They are very critical and conscious of the quality of a product. Elderly pay more attention to their health because their need for medical care rises while their mobility decreases.[9] The majority of elderly people want to keep living in their home as long as possible. [10] But this is hard since muscular strength declines with age. Increased joint stiffness and joint wear leads to reduce range of motion. [11] Hand strength also reduces with the years as well as visual functions which causes the hand-eye-coordination to reduce.

The user will use the product on a daily basis to make life easier. It will be worn at daytime but not at night. The product will be used in all situations. These contexts can be divided in at home, and outside. At home comfort and durability are very important while outside design and appearance are more important factors. Other important factors for the user are how easy the product can be cleaned and how easily it can be put on and taken off.

2.1.2. Seller

The seller is one of the secondary users of the product. Since the product should be made body fitting it is assumed that the seller is the person who is in direct contact with the customer. The seller will scan the customers limb and will sent this scan to the producer. The seller will also hand over the product to the customer once it is produced. The seller can be a podiatrist. For the seller it is important that the process is fast so he can help as many clients as possible. The sellers in this project are mostly interested in the reduction of the lead-time.

The seller will furthermore take care of the maintenance of the product. Therefore he would like the product to be easy to repair and would like it to be modular so if a part is broken only one small piece has to be replaced.

2.1.3. Producer

The producer is the company that produces the product based on the scan gained from the seller. The producer wants the lead-time to be low and the production costs to be low. The producer wants the product to be fast, easy and cheap to produce.

2.1.4. Caretaker

The caretaker would like the user to be able to put on and take off the product by him or herself. The caretaker will also find it important that the product is easily cleaned.

2.1.5. Unintended users

Unintended users are users for whom the product was not intended initially, for example injured people who would like some help with standing up, or people who have a muscular disease. These people will not be taken into account in the design process because they have conflicting values compared to the elderly, and elderly will be the largest target group. In the design these users will not be excluded either.

2.2. Market research

The market research aims to get insight in products which are similar to the product that is to be designed or which fulfil the same function. The first products that are examined are products that help elderly with the sit-to-stand movement, see figure 2.1. The second product group are medical products produced using AM. AM is not used in current clinical practice. [12] There are some clinical products produced on a small scale in which additive manufacturing is used, see figure 2.2.

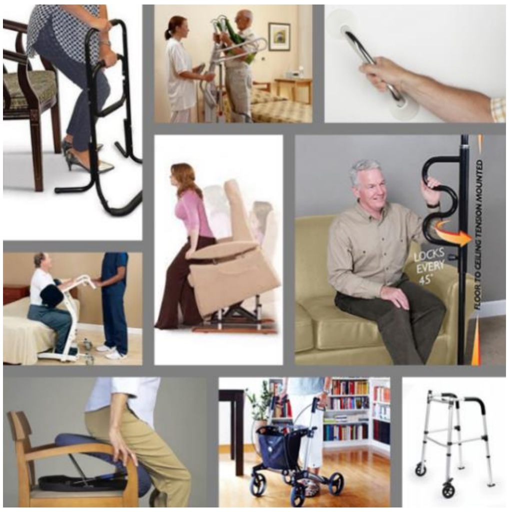
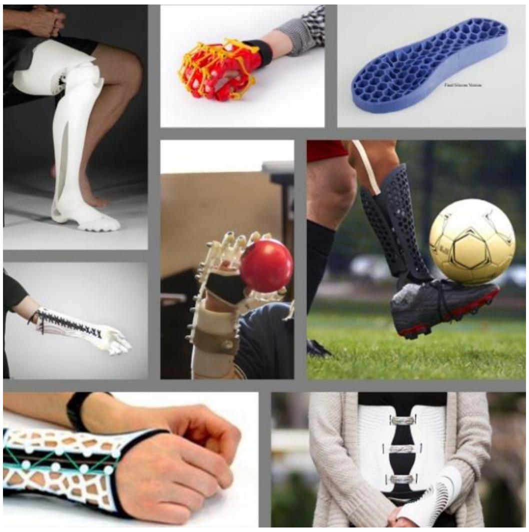


Fig. 2.1: similar products



2.2: clinical AM products

As can be seen from figure 2.1, sit-to-stand assisting products for elderly often compensate the lost muscular strength in the legs by using arm strength. The problem of this solution is that when the muscles deteriorate further this solution will not work anymore. Another disadvantage of these products is that they are bind to one chair or location and cannot be easily taken with you. Compared to the present products the designed product should be carried with you and the user should be able to use the product without the use of his arms.

In figure 2.2 you can see that these are customised products adapted to shape and taste of the user. These products are lightweight and easily carried with you. Clinical products that are most alike the product to be designed are prosthetics and orthoses. Prosthetics are products that replace a missing body part. The other products are orthoses which are used to support, align, prevent or correct function of movable parts of the body. A few examples will be scrutinized to see how they can be improved or which parts are good and should reoccur in the designed exoskeleton.

2.2.1. Arm orthosis

Figure 2.3 shows the first product to be looked at. This arm orthosis which is specifically designed for individuals with upper limb paralysis and to wear when riding a mountain bike. The parts of this product that can be used as an inspiration are the easily adapted strength of the spring and damper. Furthermore the use of two printed parts, a soft inside and a hard shell. These can make sure that the forces are distributed over a larger area of the arm. A miss in this design is that it is not form fitting. It is not adapted to the user's body shape. The comfort could be improved by personalising it further.

Fig. 2.3: arm orthosis [13]

2.2.2. Levitation

In figure 2.4 the next product is shown. This is the Levitation. A knee orthosis which passively stores energy when the leg is flexed and will release it with extension. This is very similar to the knee orthosis that will be designed. The only difference with this knee orthosis is that it is not form fitting. By making its shape more adjusted to the user it could be more easily worn underneath a pair of trousers and the pressure distribution could be optimised. In knee orthoses the balance between using a lot of material to distribute the pressure or using very little material to keep the temperature comfortable is a difficult challenge. This is something to pay attention to in the final product since elderly are prone to pressure sores.

Fig. 2.4: Levitation [14]

2.2.3. 3D printed leg orthosis

In figure 2.5 the design of a 3D printed orthosis is shown. This is a very aesthetic and slim design. The only problem is that the product has no fasteners which has the effect that it should be wide enough to put it over your foot. You have to step into it which will be no problem for younger people, but for elderly it will be hard to move their foot in the right position to get into the orthosis. This orthosis is furthermore worn over your clothing because it has no soft lining. Adding soft lining and fasteners could make this a very successful product. This orthosis cannot shift up because it has a foot pad. This is since the specific user for whom this product was designed cannot move his feet.

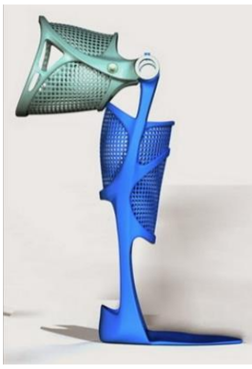


Fig. 2.5: knee orthosis AM[15]

2.2.4. Honda walk assist

Figure 2.6 shows the last product to be examined which is the Honda Walk Assist. This is a lightweight device that actively supports people with reduced walking ability. The product will support the lifting of the upper leg and the lower leg will follow. It is an actuated product and the battery lasts for 60 minutes. This product could help elderly stand up by stabilizing the hips, but as will be seen in the next chapter, stability is not the main problem with the STS movement.

Fig. 2.6: Honda Walk Assist [2.4]

This market research leads to a list of requirements which can be seen in the requirements section. It furthermore gives starting points for the conceptual design of the exoskeleton. During the market research no products were found that support the STS transition.

2.3. Additive manufacturing

For this project TNO set the requirement is that the product should be produced using AM, AM is the process of joining or adding materials with the intention to make a three-dimensional model using the layer-by-layer principle. [2.9] Within the project, TNO already decided that the product should be produced using selective laser sintering (SLS[2.1]). To be able to understand the process of additive manufacturing different AM techniques have been analysed. (Appendix A)

2.3.1. Making an AM product

When designing an AM product clear steps have to be taken. Gibson, I., Rosen, D. & Stucker, B. [16] give a very clear action plan of how to additive manufacture a product. This theory is used to write a step-wise action plan specifically for the to be designed product.

- The leg of the user will be scanned to gain a CAD model of the users leg.
- A CAD model of the body fitting part will be created based on the scan of the leg.
- The CAD model will be transformed into the right file for the AM machine to read. In this step the product can also be scaled and positioned so it has the right orientation for building.
- The fourth step is to actually build the product.
- Once the product is completed the parts must be removed from the machine. This step is different for different AM techniques.
- When the product is obtained it should be post-processed. Post-processing are all activities from the time a part is removed from the printer until it is ready for its use. [17] In the SLS process you first need to depowder the product, the surface can be post processed or the product can be heated to gain strength. This step can take a lot of time when the settings or the design was not optimised.

2.3.2. Possibilities within this assignment

As mentioned before, the product will be produced using SLS printing. SLS printing uses a high power laser to fuse a powder. The sintered material forms the part and the left over powder can be recycled. No support structures are needed and a great variety of materials can be used. [18] Within this project thermoplastic polyurethane (TPU[2.2]) and/or polyamide-12 (PA-12[2.3]) will be used. Both materials have high enough Vicat softening temperatures to be used in all temperatures. The lowest is that of TPU which lies at 90°C. [19, 20]

When using an SLS machine some design parameters have to be taken into account throughout the process. Stratasys and Shapeways have defined design rules that have to be followed when designing for SLS [21, 22]. These rules can be found in the list of the requirements. For the specific machine used at TNO some extra parameters have to be taken into account:

- The building volume is 300 x 300 x 300mm
- The z-resolution is 0.15 mm
- The wall thickness should be between 1mm and 3mm
- The product edges should have a radius of more than 0.4mm
- The bottom of the product should allow for 0.1mm additional material

2.4. Sit-to-stand movement

To be able to design an exoskeleton which supports elderly with the STS movement the problems in the STS should be analysed. To be able to effectively deal with the largest problems in the STS movement literature research has been done to identify the most important factors which can cause the difficulty in STS.

The most important in explaining a considerable part of the variance in STS performance between young people and elderly is the quadriceps strength. [23] During the STS movement the quadriceps cause the extension of the knees. [24] Muscle deterioration causes more problems in the STS movement than balance. [25] Other important factors that contribute to the decreased STS performance in elderly are the decrease in knee flexion strength and ankle dorsiflexion strength. [23]

1. Knee extension strength
2. Knee flexion strength
3. Ankle dorsiflexion strength

For this design the focus will be on the knee extension strength. This has been chosen since this is the main problem in the sit to stand movement.

2.4.1. Moment knee extension

To be able to calculate whether the exoskeleton is able to withstand all forces a maximum moment around the hinge is calculated. In STS the knee extends from 95 to 0 degrees. [26] Assuming the weight of the trunk of an elderly will not be higher than 100kg and assuming the length of the upper leg is 49.6cm [27] the maximum moment needed to lift the body of the elderly can be calculated. The moment is maximum when the angle is 90 degrees. It is assumed that the foot does not move because it has enough friction with the floor.

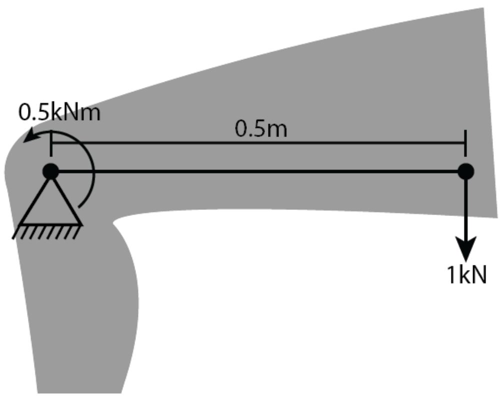


Fig. 2.7: Maximum moment

Figure 2.7 shows the maximum moment for both legs. This should be divided by two to get the maximum moment per leg.

Since the knee extensor muscles only decline with 39% for adults between 65 and 80 years old [28], the orthosis does not have to deliver the full moment. The elderly should be supported but he should not be moved by the orthosis. Therefore probably less than 39% is needed. But for the calculation of the maximum moment the calculation has been done with 50%. Therefore the maximum moment the orthosis should be able to deliver is 250Nm and 125Nm per leg. This is the maximum moment which is used to calculate the minimum material thickness.

2.4.2. Knee joint

To provide the right support the hinge in the orthosis should match the knee joint. It should not cause decreased mobility. The movements a healthy knee joint can make are listed below [29,30] and visualised in figure 2.8.

1. 160° to -5° flexion and extension
2. 6° to 11° varus-valgus in extension
3. 25° to 30° internal-external in flexion
4. 1 to 2 mm medio-lateral
5. 5 to 10 mm anterior-posterior
6. 2 to 5 mm compression

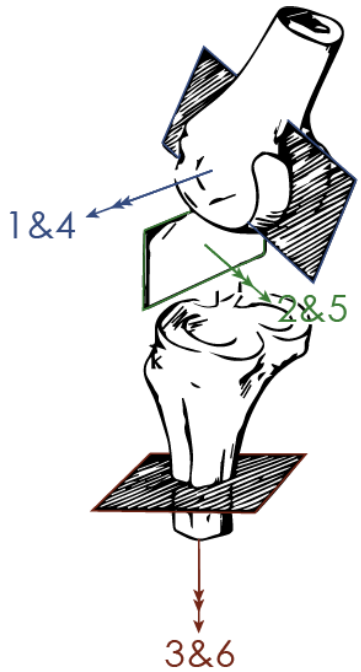


Fig. 2.8: Degrees of freedom knee

This amount of knee movement is not always necessary. According to Rowe, P. J., Myles, C. M., Walker, C., & Nutton, R. the knee joint requires an excursion of 135° of flexion from 0° flexion during functional activities. [31] The largest angle was needed when getting in and out of bath. When is assumed that the user does not go into bath with the orthosis the maximum excursion should be 100°.

These details help to set requirements for the movement of the orthosis. Because extension of the leg is supported it should be made sure that hyperextension is not enhanced. Hyperextension can cause problems such as excessive loading of structures of the knee joint which causes changes in these structures. [32] To give the user the freedom to make movements they normally make the internal-external rotation in flexion should be the least limited as possible.

The varus-valgus rotation does not necessarily have to be constrained. In arthrosis patients valgus knee bracing significantly reduces pain. [33] Since more than 27% of the people older than 65 suffer from arthritis and almost 14% suffers from knee arthritis. [34, 35] Therefore a requirement will be set to be able to add a strap which reduces the varus-valgus rotation for arthritis patients.

The different movements of the joint can be accounted for by compression of the material and laxity in the joint. Under conditions of light loading, the anterior-posterior laxity is 5-10mm and the rotational laxity is 20-30°. [36] Which is enough to allow for the movements of the joint.

The hinge will have to rotate around an axis, this axis has to be aligned with the axis around which the knee joint rotates to make sure ligaments are kept at normal length patterns as well as muscles and to prevent external forces. Since the knee joint is more complex than a one direction hinge the axis will not be in the same position when the leg is moved. Kurosawa, H., Walker, P. S., Abe, S., Garg, A., & Hunter, T. [36] have made a graphical representation of the axis which can be seen in figure 2.9.

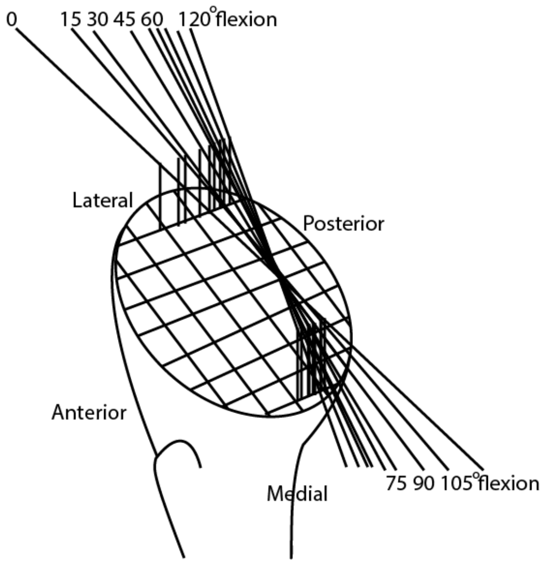


Fig 2.9: Axis knee

The rotation around the femoral axis (rotation 3 in figure 2.8) which also causes the shift of the axes, will have a maximum of 20.2 degrees when the leg is flexed 120°. The orthosis should allow for these movements. This can be done by not making the orthosis fully rigid.

2.5. Comfort

The target of this assignment is to design a comfortable exoskeleton. To be able to test whether the exoskeleton is comfortable comfort should be defined. Lastly present comfort solutions are analysed for prosthetics orthoses and exoskeletons.

2.5.1. Definition of comfort

Comfort of body fitting parts is mostly defined by the pressure. The contact pressure should not exceed the pain pressure threshold. [37] The pressure should also not exceed the ischemic level, which is the level at which the capillary vessels in the leg are unable to conduct blood [38], which is estimated at 30 mmHg [39], for more than two hours. [40] To maximize the comfort the interaction forces between the product and the user should be as low as possible. [41] It is furthermore important to make sure the external loads are in the proper areas of the lower limb. These areas are defined by Moreno, J.C.; Brunetti, F.J.; Pons, J.L.; Baydal, J.M.; Barberà, R. Next to these areas it is important not to apply loads on bony prominences. [42] Two other factors that can increase comfort is to make the exoskeleton as lightweight as possible [41] and to make the audible noise as low as possible. [43]

So to summarise, comfort in an exoskeleton is defined as:

1. Magnitude contact pressure
2. Location of contact pressure
3. Weight of the exoskeleton
4. Audible noise of the exoskeleton

2.5.2. Present comfort solutions

According to Erica B. et al. padding can improve the comfort of an orthosis. The drawbacks of padding are the increased heat and furthermore the increased size of the orthosis caused by the padding. The perfect solution would be to be able to personalise the amount of padding to the user. [44] Comfort of an orthosis is also achieved by making the design such that when the limb is in neutral position, no forces are applied. [45] A personalized orthosis with a perfect fit will also cause an increase in wearing comfort. [45] In prosthetics the main problem is the pressure distribution over the amputated limb. This can be solved by mapping the limb including the internal structures. Then a good pressure distribution can be achieved by using CAD software and additive manufacturing. [46]

2.5.3. Fastening

Comfort of an exoskeleton is also defined by whether the user can independently use the product. Therefore we will look at the extreme users within this category, the arthritis patients. Research from D. Cone shows that clothes for arthritis patients can be improved using Velcro fasteners. [47] Also Sperling, L. & Karlsson, M. made a list of functional demands for clothing fasteners for elderly patients. These demands can be used in the design of the exoskeleton. [48] The requirements can be found in the section requirements. A requirement added by Ramachandran, R. & Radhika, R. is that it should be possible to put the product on while being seated due to the loss in balance and muscle strength.

2.6 Requirements

A list of requirements has been made based on the analysis. The weight of the different requirements will be indicated using the MoSCoW model. [49] In which an M indicates a requirement that must be completed to make the product fulfil its main function. An S indicates a requirement that is important but not as urgent to meet as the must requirements. A C indicates that the requirement is desirable but not necessary. The last are the won’t have requirements. These have been agreed with the stakeholders to not execute but they could be reconsidered in future research.

The European Union has set a couple of targets for the MovAiD project. From these targets the following requirements are defined. TNO is a knowledge company. Therefore they want to gain new information about innovation through this project. They execute a project commissioned by the EU but parallel to this project they do their own innovations which they will be able to use in later projects. Therefore TNO adds some requirements. The next requirements will be named based on the different sections previously treated. An added section are requirements based on scenario analysis which can be found in Appendix B.

One requirement that arose from the scenario analysis are that the product should be used in all outside temperatures. Since the orthosis is located on your skin it will not be very cold. The skin temperature in winter is 29°C and 33°C in summer [50]. But since the orthosis will be stored in the house and will have the surrounding temperature when it is put on the range has been expanded to 19°C up to 43°C. It should not break between 48°C and -58.1°C [51] These are the highest and lowest temperatures measured in Europe. This requirement is set in case someone accidentally leaves the orthosis outside.

The second requirement that should be elaborated is that it should last for at least two years. From different websites which sell knee orthoses the warranty information is checked and found is that the soft parts which include straps and padding most of the time have a warranty of 6 months. The frame and hinge most of the time have a warranty up to two years. To be able to compete with these product the exoskeleton should also last at least two years.

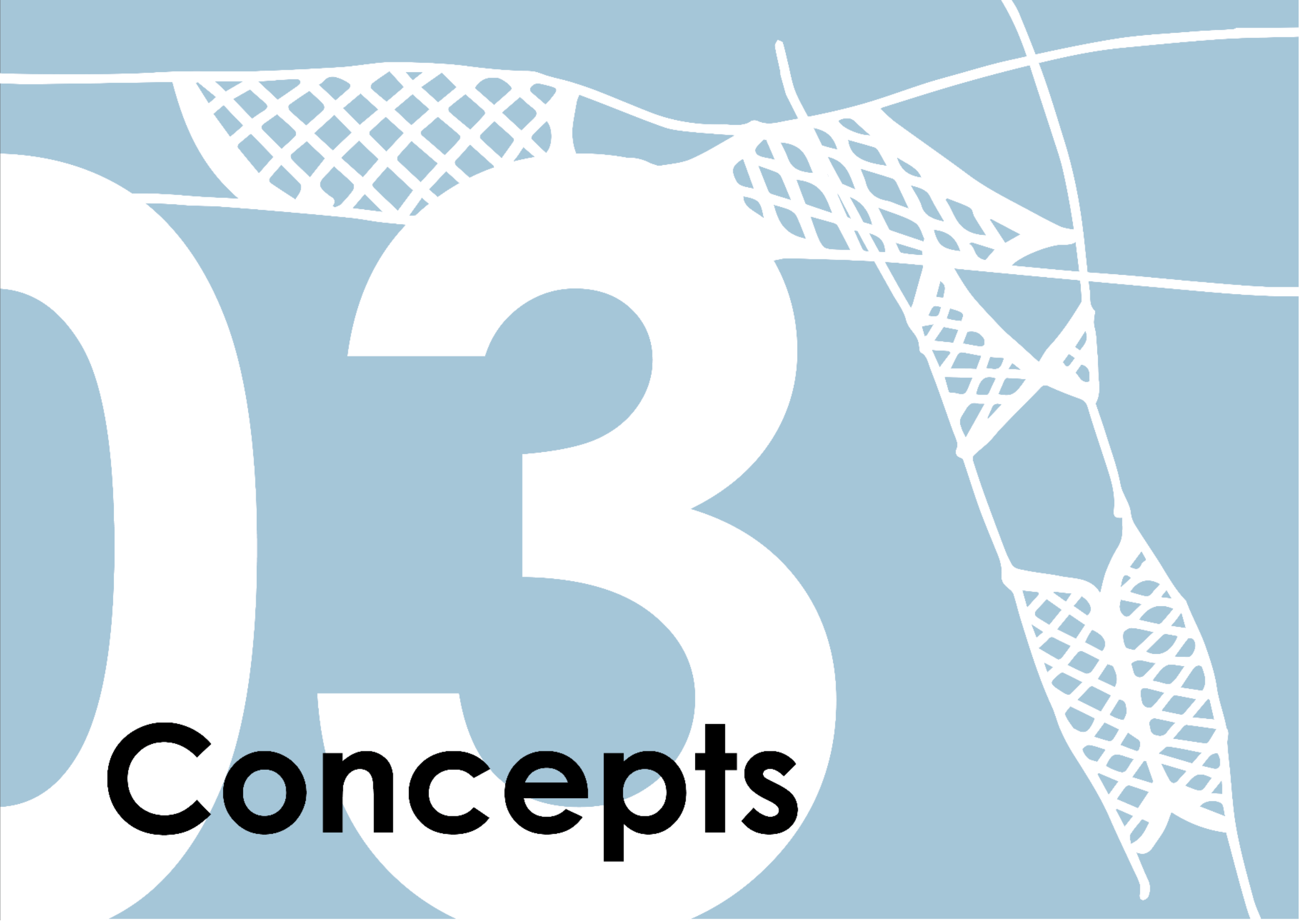
Requirements EU [52]		
1	The product must be made form-fitting for every individual user	M
2	The product must assist the user in a passive way	M
3	The product must assist with the sit-to-stand movement	M
4	The product should be 20% cheaper to manufacture than personal products that do not use AM	S
5	The product should allow for shape changes of the limb due to muscle contraction	S
6	The product could make use of multi material printing	C
Requirements TNO		
7	The material used must be TPU or PA-12	M
8	The product should be produced using selective laser sintering	S
Requirements market research		
9	The user should carry the product with him while using it	S
10	The user should be able to use the product without using his hands	S
11	The product could be personalisable aesthetically	C
Requirements users		
12	The user should be able to independently put the product on	S
13	The user should be able to independently take the product off	S
14	The product should be usable when it is raining	S
15	The user should be able to clean the product	S
16	The product should last at least 2 years.	S
17	The product should work at temperatures between 19°C and 43°C	S
18	The product should be able to withstand temperatures between -58°C and 48°C	S
19	It should be possible to replace broken or worn pieces of the product	S
20	It could be possible to wear the product under your clothing	C
Requirements of AM product		
21	The minimum wall thickness must be 1.0 mm	M
22	The product must have edges with a minimum radius of 0.4 mm	M
23	Feathered edges must taper to no less than 0.8 mm	M
24	The wall thickness should be less than 3.0 mm	S
25	The bottom side of the product should allow for 0.1 mm added material	S
26	Round shapes should be positioned around the z-axis	S
27	It should be possible to reach cavities to remove unsintered powder.	S
Requirements STS		
28	The product must support the extension of the knees during the STS movement	M
29	The product should be able to withstand a moment of 125Nm per leg	S
30	The user should be able to move its knee joint from 0° to 100°	S
31	The user could be able to move its knee joint from 0° to 135°	C
32	It could be possible to constraint the varus-valgus rotation of the knee	C

Requirements Comfort		
33	The forces on the body of the user should not exceed the PPT	S
34	The pressure should not exceed the ischemic level for more than two hours	S
35	The product should not be placed over bony prominences	S
Requirements fasteners		
36	The fasteners should be easy to understand and identify, visually and tactually	S
37	The fasteners should be possible to handle with one hand	S
38	The fastener should be easy to grip and hold	S
39	The fastener should not scratch or rub over the skin	S
40	The fastener should not cause pressure sores	S
41	The user should be able to put the product on while being seated	S
Requirements Scenario's		
42	The orthosis should be dry within 12 hours	S
43	The product should be used when using the bathroom	S
44	The orthosis could be water resistant	C

Table 1.1: Requirements

Objectives	
1	The interaction forces between the user and the product should be as low as possible
2	The product should be as lightweight as possible
3	The exoskeleton should make an as low as possible audible noise
4	The product should last as long as possible
5	The product should be as cheap as possible
6	Keep the size of the exoskeleton as low as possible
7	The internal-external rotation in flexion of the knee should be limited as little as possible
8	The varus-valgus rotation of the knee should be limited as little as possible

Table 1.2: Objectives



Concepts

To generate ideas a brainstorm session is done in which a vast amount of solutions is generated. Secondly this brainstorm is turned into visuals from which the best ideas can be chosen. These ideas are developed into concepts. Lastly these concepts are evaluated and improved.

3.1. Idea generation

For the brainstorming session a mind map is made. The mind map can be found in Appendix C. In the mind map different design challenges were mentioned. Solutions for these challenges were posed and these were later used to make sketches of the exoskeleton, these sketches also show possible designs of the exoskeleton. A selection of the sketches can be seen in Appendix D. From these ideas three directions were chosen and these are elaborated in the next section.

3.2 Concepts body fitting part

To develop the concepts a morphological matrix was made based on the mind map and the generated ideas. For the morphological matrix the functions of the exoskeleton have been identified and for every function different solutions are posed in the matrix. The morphological matrix can be found in Appendix E. To be able to evaluate which idea would best suit the function three potentially good concepts were generated. These are used to visualise the solutions. These will then be combined in to one final concept which combines all the best ideas into one. The three concepts only exist of the body fitting parts. The choice for the structural parts is made separately. For the structural parts also three concepts have been generated. The three BFP concepts are explained in the next section.

3.2.1 Concept 1: Closed shell

The first concept is shown in figure 3.1 and. This is a concept which is made of a closed rigid body fitting part. The rigid body fitting part will be lined with TPU to make it feel softer on the inside. It will furthermore have cut outs which can be seen in the figure. The rigid shell has a hinge on the outside of the leg and a click fastener in the front. The click fastener is embedded in the shell so it does not increase the pressure in these places.

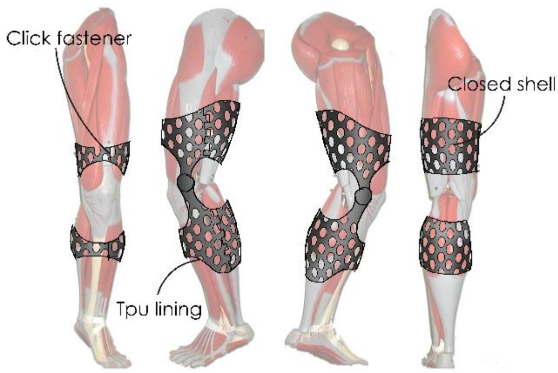


Fig. 3.1: concept 1, body fitting part

3.2.2 Concept 2: Shell with straps

In the second concept the choice has been made to not fully close the rigid shell. This is to make sure the muscles can extend. The exoskeleton can be put on using the Velcro straps. These are placed on top of the leg so elderly have least difficulty opening and closing them. The back of this concept does not have cut outs since the heat can escape through the front. This concept is visualised in figure 3.2.

Fig. 3.2: concept 2, body fitting part

3.2.3 Concept 3: Rigid skeleton

The last concept is a concept in which a limited amount of ribs carry the main loads. These loads are further distributed over the skin by a netting structure between the ribs. The advantage of this netting is that heat can easily be dissipated. This concept can be found in figure 3.3.

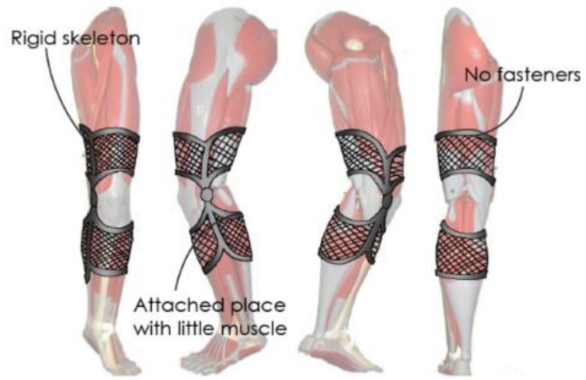


Fig. 3.3: concept 3, body fitting part

3.2.4. Concept choice

To make a well substantiated concept choice the concepts have been rated based on the list of requirements. For the requirements a prediction is made whether this concept will be able to meet the requirement. The list of requirements is not the full list, only requirements about which an estimation can be made are listed here. The choice matrix can be found in Appendix F. For this concept choice only the body fitting parts are scored. The choice of the structural part is made independently from the body fitting part.

Since all scores are fairly low a combination of concept 2 and concept 3 has been made to make a higher scoring concept. This concept will contain the backside of the third concept and will use the straps from concept 2 to attach it. This will combine the strength of both concepts. This concept has a significantly higher score. This concept is shown in figure 3.4.

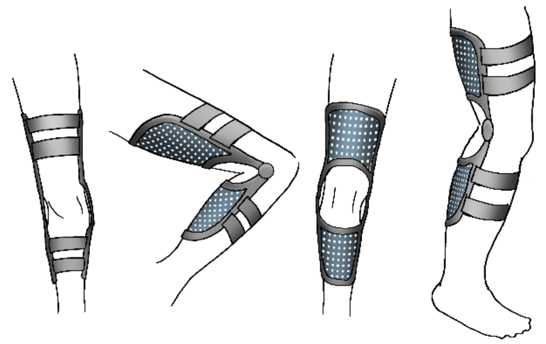


Fig. 3.4: Final concept

As can be seen in the concept choice the final concept can still be improved concerning two objectives. The size of the exoskeleton should be as low as possible. The interaction forces should also be as low as possible. These two points will be taken into account when detailing the final design.

3.3 Concepts structural part

To be able to develop a prototype also a choice needs to be made about which structural part will be used. Therefore also three concepts have been developed concerning the structural parts:

3.3.1. Concept 1: Torsion

The structural part has an embedded torsion spring to deliver the needed moment around the hinge. Figure 3.5 shows an image of this concept.

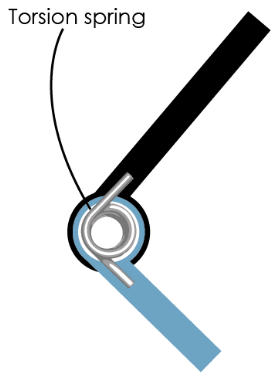


Fig. 3.5: concept 1, structural part

3.3.2. Concept 2: Compression

The structural part of this concept uses a pressure spring to transmit the force. By loosening or fastening the screw the force can be changed by the user. Concept 2 is shown in figure 3.6.

Fig. 3.6: concept 2, structural part

3.3.3. Concept 3: Elongation

The structural part in this concept uses an elastic to create a moment around the hinge. By changing the position of the hook the moment around the hinge can be changed. This is visualised in figure 3.7.

Fig. 3.7: concept 3, structural part

3.3.4. Concept choice

The concept choice of the structural part has been made based on the fact that it has to be developed into a prototype. Since the moment needed in the hinge is not yet known a funded choice cannot be made jet. The prototype will make use of the structural part in concept 3. In concept 3 the moment can easily be changed by using a different elastic or changing the hook in which it is attached. The complexity of the third design is also low and therefore easy to make.

After the analysis of the prototype a final choice will be made in the structural part.

3.4. Final concept

The details of the final concept have been determined based on the weak point found in the concept choice. The most important design choices can be seen in the following paragraphs. Other design choices can be seen from the drawing in figure 3.8.

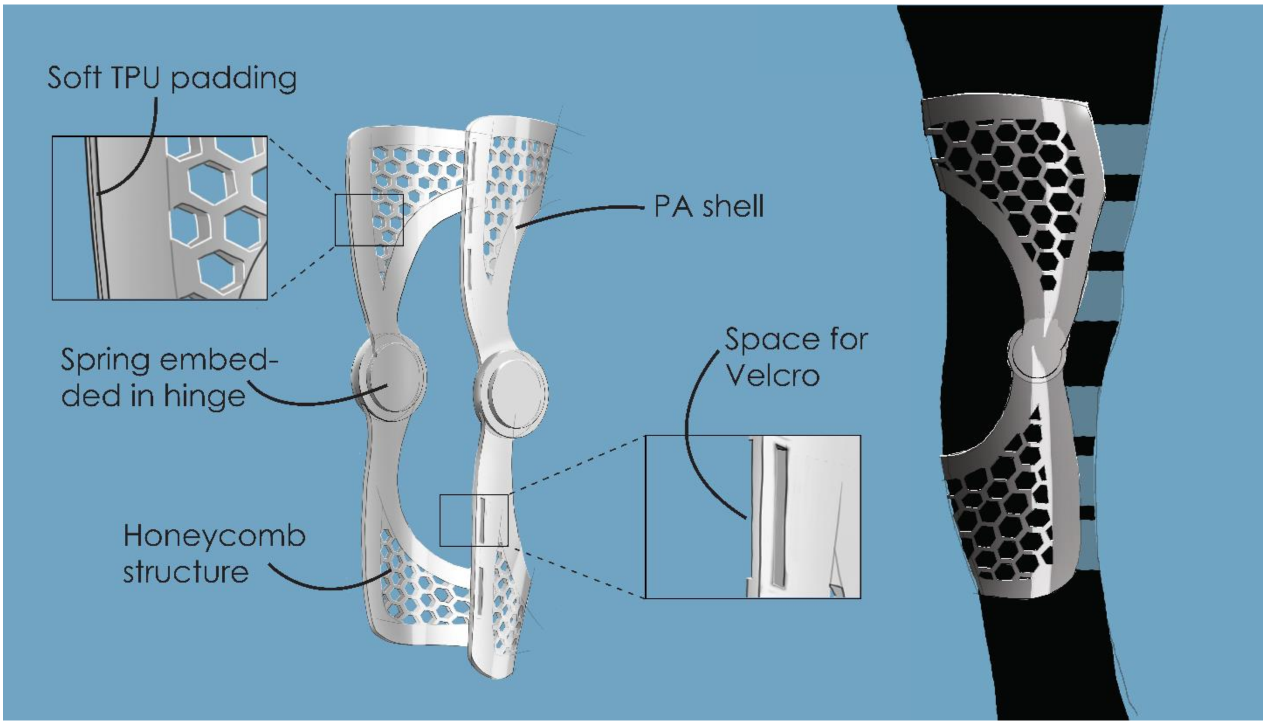


Fig. 3.8: Final concept details

3.4.1. Forces

The amount of force needed to help the elderly stand up was based on the amount of muscle degradation found in the literature analysis. The amount of muscle degradation is 39%. To compensate for this the orthosis could apply a force which corrects for these 39% but since you do not need the full 100% of your muscles to be able to STS lower values have been chosen.

During STS the user will probably prefer more force than during walking. A system in which the amount of force could be changed by the user would be ideal. This will be designed after the prototype test since then more will be known about the forces needed.

3.4.2. Shape of the BFP

The BFP are placed at the back of the users leg. Since the moment will cause the exoskeleton to apply a force on the back of the leg this will be the location where a good pressure distribution is needed. Therefore only at the back of the leg a body fitting part is needed.

The structure of the BFP is made out of ribs and out of a netting structure. The ribs are made to evenly distribute the forces from the hinge over the back of the leg. The netting structure is made so heat and sweat of the leg can evaporate. The netting furthermore makes the material more flexible which allows the muscles to change shape. Since the shape of the leg changes most where there are muscles the ribs are mostly placed on ligaments. Bony prominences have also been avoided since these have a lower pain to pressure ratio. The netting structure has larger holes in the back because the back of the leg deforms most.

The shape of the exoskeleton is also made in such a way that the leg still has the freedom to bend from 0° to 135° since this is the amount of freedom needed to be able to do daily activities. This bending is allowed by making a large cut-out at the popliteus to make sure the knee can bend without the upper and the bottom body fitting parts touching each other. This is illustrated in figure 3.7.

For the structure a honeycomb structure has been chosen. This decision was made since a honeycomb structure has a very good balance between strength and weight. The dimensions of the honeycomb have been estimated based on similar 3D printed designs. Based on the test the size and shape of the holes can be changed for the final design.

3.4.3. Shape of the hinge

The hinge has been designed in such a way that it has a large circumference which makes it possible to use a weaker spring to apply the force. Furthermore this hinge design will prevent hyperextension.

In the hinge it is very important to apply the design rules of SLS printing. The good thing of SLS is that moving parts can be printed at once. Parts of the hinge which are thicker than three millimetres have one or two unsintered layers between them to make sure the deformation of the product is minimised. Furthermore all moving parts have to have a clearance of half a millimetre.

3.4.4. Connection between the hinge and the BFP

The exoskeleton can be printed in one piece. The connection between the hinge and the BFP is estimated as the part where the highest force density is, therefore calculations have been done to make sure that the yield strength is not passed. This calculation results in a minimum thickness of the material of 0.64mm the calculation can be found in Appendix G. Since the yield strength of SLS printed material can vary a large safety factor is applied to make sure the prototype will not break when the spring is attached. The chosen material thickness is 3mm. This is chosen by looking at products which were SLS printed using the same material.

3.4.5. Fasteners exoskeleton

For the choice of the fasteners the target group is very important. Since research shows that Velcro is easily fastened and loosened by elderly this is a good fastener to be used in the prototype. It furthermore meets all requirements concerning the fasteners.

3.4.6. Padding

To improve the pressure distribution in the final design a layer of padding is added on the inside of the orthosis. To make sure this padding is also form fitting it will be made of TPU and will be 3D printed as well. TPU is an elastic plastic but is not very soft on its own. Therefore the TPU will be build up as a 1mm layer of TPU. Then a 4mm layer of TPU consisting of a bouncy structure will be added to give it the soft feel. It will be connected to the PA using connections or in the future it could probably be manufactured by using the multi-material printing process. A schematic picture of a section view of the padding can be seen in figure 3.8.

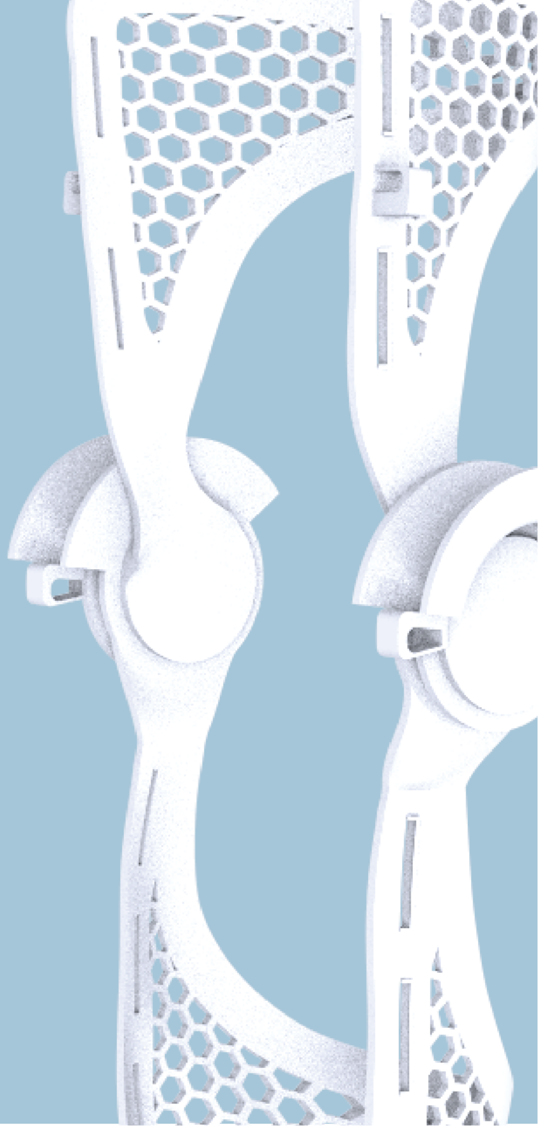
Fig. 3.8: Section view padding

The firmness of the padding will be determined after the prototype test. The PA shell will be created with a spacing of 5mm between the leg and the shell. This space can then be filled with the soft TPU layer. The TPU will be slightly thicker then 5mm because it will be compressed when the orthosis is being worn.

3.4.7. Assembly

For the final design it has been chosen to print the exoskeleton as one part. Only the Velcro and the spring have to be assembled. This can be an advantage as well as a disadvantage. The advantage is that the product does not have to be assembled. Connections between parts can be weak and could cause the product to fail. The disadvantage is that when one piece is broken the whole exoskeleton has to be replaced.

04 Prototype



The design of a complex product like an exoskeleton is a task including many uncertainties. To be able to make funded design choices for the final concept a prototype is made. This prototype is not meant to be perfect, but it is meant to give input for a perfect product. The prototype will be used to test certain important aspects in the design of the exoskeleton. The tested parameters will take a lot of time investigating by literature or simulations and a prototype can give a quick guideline.

This was the reason to make the first prototype. A prototype can also raise unexpected problems which would not have been raised based on calculations and literature.

4.1. Concept to prototype

The final concept cannot directly be made into a prototype. Some alterations in the design have been made to make a good prototype design.

4.1.1. Forces

To be able to change the force, a system has been made in which three different springs fit. These range from the weakest spring which would be able to lift 10% of the users body weight up until the strongest spring which could raise 35% of the users body weight. This will make it possible to test which percentage suits best. The calculations of the spring stiffness can be found in Appendix H.

4.1.2. Padding

The padding described in the concept will not be executed in the prototype. It is very costly to print these prototypes and to be able to determine what firmness is most comfortable it would be ideal to be able to try different padding. To be able to test differences in firmness Velcro will be attached to the inside of the shell and foams with different firmness's will be attached during the test.

4.1.3. Hinge

To make the hinge fit for printing the details had to be determined. For the hinge it is important that hyperextension is prevented. That it allows for a rotation from 0° to 135° and that it has a large circumference so the spring can be less strong. The final hinge design can be seen in figure 4.0.

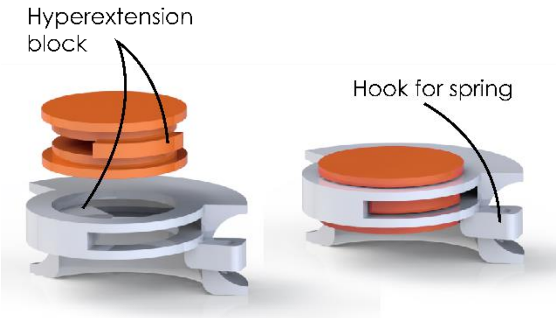


Fig.4.1: Exploded view hinge

4.2. Making the prototype

Making the prototype was done using the step by step plan created in the analysis.

4.2.1. 3D scan user

To be able to create a body fitting product the leg of the users had to be scanned. This is done using the handheld Sense scanner. The leg of the test persons were scanned with a slightly bended relaxed leg. The range in which the leg moves most of the time is between 90 and 0 degrees. Therefore the aim was to scan the leg slightly bended. This would make sure that the exoskeleton has to change the least shape to allow for shape changes of the leg. For test person 1 the leg was scanned in an angle of 33° and test person 2 in an angle of 43°. The results of the scans can be seen in figure 4.1 and 4.2.

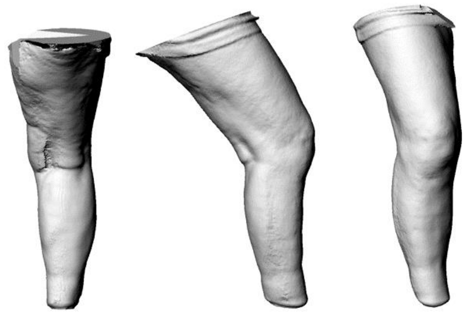


Fig. 4.1: Scan test person 1

Fig. 4.2: Scan test person 2

As can be seen from the figures the scans have some errors in the back of the legs. This is due to the lack of light in the back. This was partly solved during the scanning by placing an extra light directed to the leg. But for a next scan it would be best to use a room where there is more light. This will improve the quality of the scan. The resolution of the used scanner was 1mm.

4.2.2. Create CAD model

To create the CAD model two CAD programs were used. The first one is Rhinoceros which has as advance that it can work with large STL files. Rhinoceros was used to change the original STL file which was a mesh into a surface. This surface was then imported into SolidWorks in which the CAD model was finalised. In figure 4.3. and 4.4. The final CAD models are shown.

Fig. 4.3: CAD model test person 1

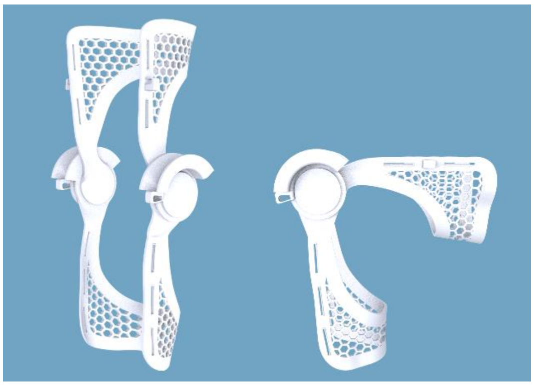


Fig. 4.4: CAD model test person 2

4.2.3. Make CAD model ready for printing

After the CAD model was finished it had to be changed to make it suitable for printing. The first step was to make an STL file of the product. Then the STL file had to be fixed. This was done using Magics. Magics is software that checks your STL file and can fix different faults in your STL including overlapping triangles, bad edges and flipped triangles. Magics fixed most of the faults in the model and in SolidWorks different fillets were added to the model to meet the requirements of an SLS product. Which needs a radius of at least 0.3mm.

4.2.4. Build the product

Before the actual product was built the most critical part of the product was printed. This is the hinge. All moving parts were molten together because the print job got too hot. A picture of the hinge can be seen in figure 4.5.

Fig. 4.5: SLS hinge

Even though the hinge did not move some conclusions could be drawn from this first print. First of all that when the printer is overheated the product will not work. Second of all that the thickness of the material is good. It does not break very easily. And last of all the distance between the moving parts could be increased to minimise chances of the hinge getting molten together.

Since the SLS printer at TNO was broken the making of the prototype was delayed a couple of weeks and instead of printing it at TNO it was ordered at Shapeways. A mistake was made in the order which caused the build direction to be off. The build direction was meant to be perpendicular to the hinges so the surfaces that slide over each other would be smooth. It furthermore caused the hinges to be stuck together. This was solved by first using a knife to open up all moving parts manually. Most of the parts were not molten together but were stuck due to the powder between the moving parts. This took quite long and could be improved by printing the hinge in the proper build direction and most importantly by making holes in the hinge so the powder will be able to escape from the hinge more easily. Making the clearance between the moving parts larger could also be a solution, but this is a trade-off between easy assemblage and space for motion in the hinges.

The second mistake made in the order was that the brace of test person 2 was ordered twice and the brace of test person 1 was not ordered at all. Due to a lack of time the second brace could not be printed anymore.

4.2.5. Assembly

The product is not fully 3D printed. The springs and the Velcro have to be attached before the product is ready for use. The schematic drawing of the Assembled design can be seen in figure 4.5.

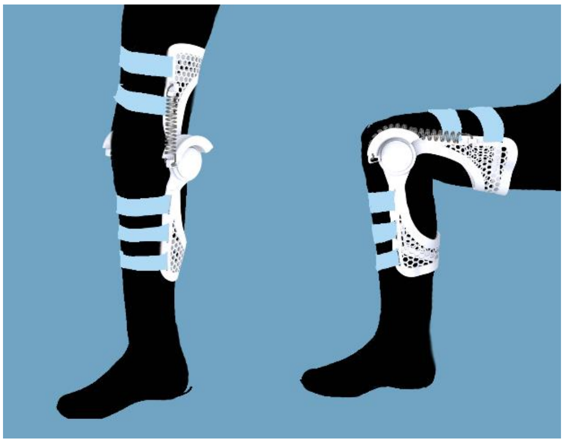


Fig. 4.6: Assembly prototype

The Velcro has been attached to the brace by sewing it to one side. Then the lining was attached using small pieces of Velcro so the lining can be changed during the test.

Finally the spring was attached. The loops at the end of the spring were too small to fit into the hooks printed on the brace, therefore they had to be bended open using pincers. The assembled brace can be seen in figure 4.6.

Fig. 4.7: Assembled exoskeleton

05 Validation

To validate whether the design is successful the design is evaluated theoretically. Then the prototype is used to do a user test.

5.1. Theoretical evaluation

The evaluation of the prototype has been done in two steps. One is a theoretical evaluation. This included making a failure mode and effect analysis (FMEA), doing an interaction evaluation, interviewing a physiotherapist and refelecting on society and technology. The second is a practical evaluation in which the prototype was tested.

5.1.1. FMEA

For the theoretical evaluation an FMEA was made. The FMEA can be found in appendix I. The failure modes were defined in a brainstorm session. Then the possible causes of the failure were mentioned. There were values assigned to the severity of the failure, the occurrence of the cause and the detectability. These were all multiplied and this gave a score : the Risk priority number (RPN).

High values of RPN mean that this point of the design should be improved. To get a clear view the FMEA was coloured acording to the RPN values. The highest 33% of the values are orange. The next 33% are blue and the lowest 33% are white. This makes clear what has to be improved. The points of improvement on the failures in the orange zone are:

- Provide a clear guidebook with the orthosis
- When the orthosis is tried on at the store, draw a line on the strap to indicate how tight the strap should be
- Check the product before it is delivered to the customer
- Coat product to make it watertight

- Check movement of the hinge before it is delivered to the customer
- Increase wall thickness for persons over 100kg
- Check users weight and height before producing

The points of improvement from the blue zone are:

- Locally increase wall thickness
- Check scan immediately after scanning
- Place spring in a protecting tube

Points of improvement from the white zone:

- Send customer e-mail after a year that says that the straps have to be replaced
- Check straps before delivery to customer

Overlapping points of improvement are noted only once. It is important in the redesign to include the points of improvement from the first section. The blue section could be considered but will only be processed when the payoff is low. The white points of improvement will only be processed when they are fairly easy.

5.1.2. Interaction evaluation

The knee orthosis is a product in which user experience plays a very important role. It has different interactions with the user which should be considered when designing the orthosis. This has partly been done in the scenario's but this section will describe the expected use whereas the scenario's defined the extreme cases which should be taken into account. The interaction has also been visualised and can be found in Appendix J.

The user will put on the product when sitting on a chair. The product will be put on by placing it on the back of the leg and then tightening the Velcro. Since the front of the orthosis can be opened completely the user does not have to step into the product and is able to put it on while being seated. When the orthosis is placed on the back of the leg he will push the Velcro straps through the opening on the opposite side of the orthosis. This will be done for all straps.

When the user wants to stand up he will stand up as he regularly does, but while standing up the orthosis will give him the extra support he needs. When standing the user can walk while having the orthosis on. When the user sits down again the orthosis will also support the quadriceps which will slow the user down so he can make sure he will land on the chair.

To adjust the force of the orthosis the spring can be changed. The user will sit down and grab the kit that has been delivered with the product. In this kit there are multiple springs. Ladled by their strengths. The user can hook the spring off that is presently on the orthosis and put a stronger or weaker spring onto it. When changing the spring the user should stretch its leg so the spring is relaxed.

The orthosis could be improved by making it easier to adjust the force. You cannot change the force of the orthosis for walking compared to sitting. It would be nice for the user to be able to adjust the force while standing. Maybe the force could also be taken off the orthosis when the user is seated. This will make sure the orthosis can be used when you are relaxing. Another point that should be addressed in the redesign is that the force should be taken off the orthosis when the user is seated.

5.1.3. Evaluation with physiotherapist

Because the product was designed by an industrial designer who has little knowledge about the human body, an expert in this field was consulted. This expert is a physiotherapist. In the consult he gave remarks about the prototype and named points of improvement or further research. In Appendix K the interview with the physiotherapist can be found. The points of improvement gained from this interview are listed below:

- Elderly have a very thin skin, therefore they have a bigger chance on Pressure ulcers. Make sure the product does not enhance these.
- The brace should stimulate movement.
- Make the orthosis strong enough to not exclude overweight people.
- Make sure the end extension is not limited.
- Make sure the varus-valgus rotation Is possible when the leg is flexed.

5.1.4. Reflection on society and technology

The focus up till now was on the product. To be able to fully reflect on the product it is also important to zoom out to see the bigger context of the product. This has been done in a separate report which can be found in Appendix L. The points of improvement and further research found in this report are listed below:

- A follow up study concerning the alignment of the exoskeleton with the human movement should be done to make sure the product is as transparent as possible and will enhance an embodiment relation between user and technology.
- A second recommended follow up study is into the aesthetics of the orthosis. This should enhance the image of the user.
- Before the product is sold a fitness test shoud be done or it should be proceeded by a doctor's note to make sure only people will user it who are unable to STS.
- The exoskeleton should come with an online society in which orthosis users can meet up to walk together.

5.2. User test

For the user test first a test plan was made. This test plan was then executed.

5.2.1. User test plan

The parameters that will be tested are a combination of comfort parameters and design parameters:

Comfort:

- Magnitude contact pressure
- Location of contact pressure
- Weight of the exoskeleton
- Audible noise of the exoskeleton

Design:

- The force needed to support STS
- The aesthetics
- The firmness of the padding

The test consists of three parts. The first part is the use test. This is where the test persons will do five repetitions of the STS transition. This will be done in five different situations. The first one is without a brace, the second one is with the brace on but without any spring attached. Then three different springs will be tested. To be able to compare the results the user will have to do the STS as fast as possible and this will be timed. The test persons will take turns doing the exercise to make sure they are fully rested when they start the next set.

The second part is a questionnaire. The questionnaire will be held in different round. After every round of STS the users are asked to write their experiences down. After the whole test the general experience will be asked. The questionnaire will make use of VAS [53, 54], which is a way of rating pain. This will be used to check whether the different springs have influence on the amount of pressure and to be able to compare the results.

The last part of the test is to try different linings. This is done last of all because the user will know how the brace feels and will be better at estimating which lining will be best for the long term. For the rest of the test the lining will be used that is not the hardest but also not the softest.

5.2.2. User test execution

Due to the mistake made in the order of the brace the product could not be tested as it was planned. Another fact that influenced the test was that test person two injured his ribs and kidney just before the test. Therefore he was unable to execute the repetitions of STS.

Because of this the test was slightly altered. Test person two tested the comfort of the brace. He was asked to stretch and bend his leg multiple times from a seated position and to comment on the comfort of the exoskeleton. Next the spring was attached and he first tried stretching and bending his leg again and then he did one STS. The situation can be seen in figure 4.6.

Fig. 5.1: Test with springs

When using the exoskeleton in combination with the spring it twisted around the hinge. It was therefore not possible to do tests with stronger springs than spring 2 since a stronger spring would only deform the brace more and would not add any force to the extension of the leg. The effect of the second spring can be seen in figure 4.7.

Fig. 5.2: Deformation caused by spring

The legs of test person 1 and test person 2 differed too much wherefore test person 1 did not fit into the knee brace and was unable to perform the STS transition with the brace on. The second test person was still able to comment on the aesthetics of the knee brace.

5.2.3. Results user test

The test did not go as it was planned. Instead of a test it turned out to be more of a co-design session in which the test persons advised on improvements of the exoskeleton.

The first part of the test was where test person 2 tried the brace on and tried whether he could stand up using the springs on the brace. Test person 2 takes the view that the orthosis can support the STS transition. The force of the springs is still quite low, but it could be just enough. The test person said that his movement were not limited by the orthosis. Clear points of improvement that arose from this user test were:

- The material should be thicker so that it does not twist when the springs are stretched.
- The hole in which the spring is positioned should be the same size as the spring so the spring is guided in the right direction.
- The Velcro straps should be of a stretch material to allow for shape changes of the muscles
- The Firmness of the lining is hard to determine after such a short period. It would be best if it was possible to let the user use the brace for a week with an average lining and then decide the firmness of the lining.
- Two braces would probably be better because it would give more support.
- The force of spring 1 was too low. Spring 2 could just be enough but slightly more would be better. Spring 3 was too strong to test on this prototype. Estimated was that when the brace would be worn on both legs a spring of 4 N/mm would be just enough to still be able to bend your legs when seated and to help you stand up.

After the test persons both tried the brace on a couple of questions and input was asked. During the test also some points of improvement were mentioned. The points of improvement are listed below.

- It should be possible to wear the brace under your clothing so it will not be visible to everyone.
- It would be nice when a pattern of flowers could be added to the exoskeleton.
- The audible noise of the exoskeleton is too loud.

The test also concluded that a couple of the tested requirements were already met. These are listed below.

- The user should be able to independently put the product on.
- The user should be able to independently take the product off.
- The forces on the body of the user should not exceed the PPT.
- The fasteners should be possible to handle with one hand.
- The fastener should not scratch or rub over the skin.
- The user should be able to put the product on while being seated.
- The product should be as lightweight as possible

06 Final design

The points of improvement from the validation phase are taken as a starting point for the redesign of the exoskeleton. In this section the final design will be presented with all design choices made. This will start with the actual design. Then the production and the use of the product will be elaborated. Lastly the price, incorporation of electronics and the expected lifetime are discussed.

6.1. Final design

In this section first the points of improvement from the result section are turned into a list of solutions to incorporate in the final product. Then the design of the final product will be presented piece by piece.

The validation section shows many points of improvement, here only the points of improvement that have to do with the design of the orthosis will be listed.

- The product should be coated to make it water resistant.
- Locally increase the wall thickness at connection between BFP and straps.
- Locally increase wall thickness at connection between BFP and hinge.
- Make holes in the hinge to let the powder escape.
- Change geometry at the hinge so they cannot twist due to the force of the spring.
- Make the Velcro straps from stretch material
- The springs should generate a moment which lifts 14% of the users body weight. Calculations can be found in Appendix M.
- The hinge design should be changed so the orthosis fits under your clothing.
- There should be multiple options for the pattern on the back of the orthosis.
- The colour and pattern of the orthosis should be chosen by the user.

- The audible noise of the exoskeleton should be lower by using the right build orientation and by making sure all unsintered powder can be removed.
- By redesigning the hinge the product should not limit nor enhance hyperextension.

These points of improvement have been incorporated in the redesign which can be seen in figure 6.1. Therefore the different parts of the product are listed below and the redesign is explained.

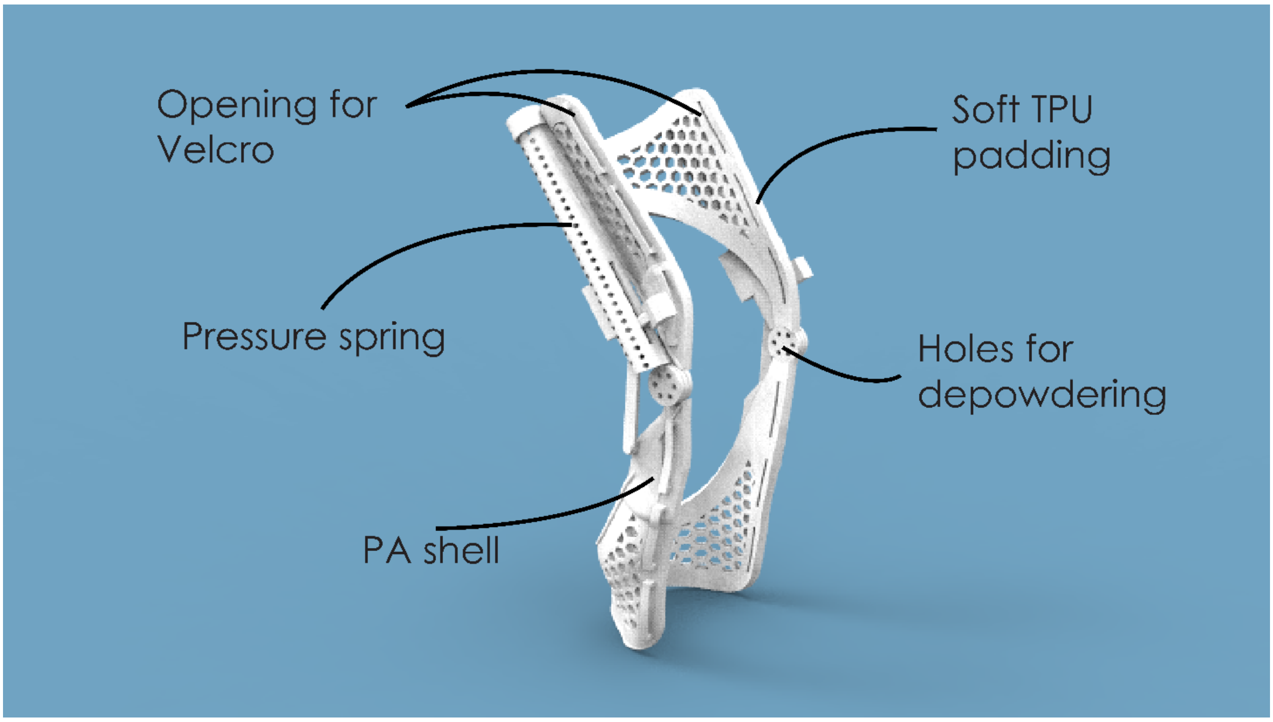


Figure 6.1: Final design

6.1.1. Coating

To improve the product on water tightness a coating is needed. Post processing to a watertight surface can be done by infiltration or vacuum infiltration. Water tightness of SLS printed PA with different dip-coatings was investigated by Schmid, Simon & Levy, (2009). The coatings that were best to make the material water tight were a double coating of silicon or a double coating of vinyl-acrylate. [55] There are many more possibilities in making the product water tight but this will not be investigated any further. This proofs that the requirements can be met when the right coating is used.

Post processing is also often used to make the product's surface smoother. If the same post processing step could make the surface watertight and make the surface smooth this would be ideal.

6.1.2. Hinge

The hinge is a very important part of the orthosis. The brace can to a great extend influence the comfort and the user experience. There are quite some points of improvements which could be addressed in the design of the hinge. To be able to make a good redesign of the hinge the use and wished performance of the hinge is elaborated.

As said before the hinge will not prevent hyperextension since this is not a big problem for elderly. The prevention of hyperextension can prevent the user from being able to fully extend the leg. The user does not have to be able to flex more than 100°. When standing up your legs will be in an angle of 90° as could be seen in the market research section most STS aids give support at an angle between 90° and 45°. The advantage of this is that the brace will not apply any force when walking. Therefore the user would be able to walk freely and will only be supported with the STS transition.

The only problem left is that when being seated the orthosis will still exert a force. This problem is overcome by using a click system. When seated the user can push a button on the side of the orthosis which locks the brace in place. When he wants to unlock it he should just bend its legs slightly further. This is a natural movement since when standing up someone will first sit up straight which will bend the legs further and then stand up. Another advantage of this system compared to a break put on the system is that the force will be applied gradually. The user first has to apply force to the system and bend its legs slightly further before he can stand up. Figure 6.1 shows a section view of the redesign of the hinge. The pressure spring makes sure the movement is only supported between 90° and 45°. The hooks inside the product make up the lock system. The different click systems considered can be seen in Appendix N.

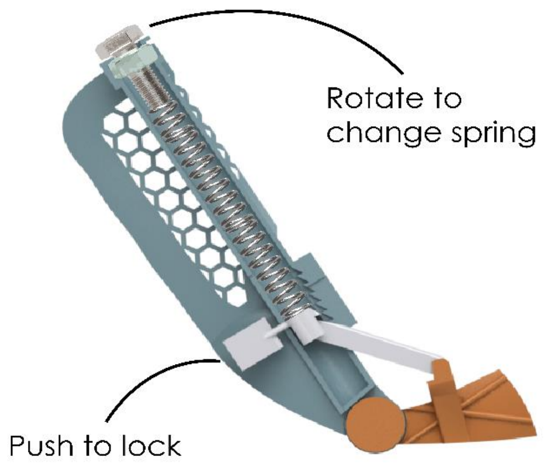


Figure 6.2: Cross section hinge

To be able to verify whether the new hinge design was successful it was printed. The printed part can be seen in figure X.

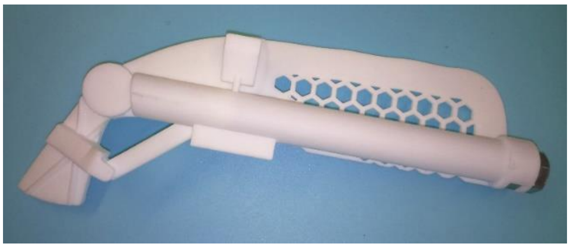


Fig. 6.3: Printed hinge

Sadly it did not move. This could be caused by the lack of holes through which the powder could escape. The part that is stuck is the piece that has to move through the shaft. This can be solved by adding three small ledges which guide the moving part. A cross section of the shaft can be seen in figure X.

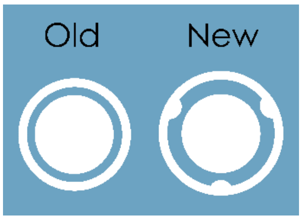


Fig. 6.4: Redesign shaft

Furthermore holes were added to the shaft to make it easier to remove excess powder. These can be seen in the image of the final concept in figure X.

This print also gave some positive feedback. It appeared that the ribs added to make the part stronger worked. The part with the ribs could not twist anymore. An extra rib could be added around the outside of the brace to make sure it cannot bend about the hinge.

6.1.3. Adapt aesthetics

Since the orthosis is custom made for the user it is a small effort to add a personal touch. This will increase the value of the product and the appreciation of the users. The user will be able to make two choices in the aesthetics of the product. First is the shape of the grid, a series of grids could be available. The grid has to be quite robust but will not carry very heavy loads. Therefore two options are available now: Hexagons and Flowers. This could be increased in the future. The second personalisation step is choosing the colour. These different options can be seen in Figure 6.3.

Figure 6.3: Aesthetics

6.1.4. Fasteners

The points of improvement concerning the fasteners was mostly that they should be of a stretch material. During the test the straps often sticked to other straps. This should be prevented by making the sticking end shorter and by making the straps shorter. It was furthermore hard to close the straps because when the orthosis was worn the holes were hard to reach. Therefore the opening through which the Velcro should be attached is now placed on the outside of the shell. The straps are also made slightly wider. This is to make the Velcro easier to handle. The new Velcro holes can be seen in figure 6.2.

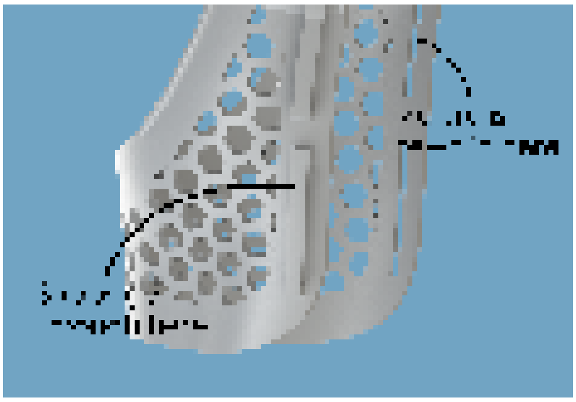


Figure 6.3: Velcro holes

In a follow up study research could be done to 3d printed fasteners. This could personalise the fasteners more. For example use larger fasteners for people with arthritis. There are also structures which can be 3D printed that can be closed and opened but can also very well distribute pressure. These structures are often very complex and it was not possible to investigate this further within this assignment.

6.1.5. Padding

To be able to decide on the padding a lengthy research needs to be done on the needed firmness. The padding used in the test was in the right range but to be able to make a funded decision the brace should be worn for a longer period of time. In figure 6.4 the padding is coloured blue. The padding will be produced using multi material printing from the material TPU.

Figure 6.4: Padding

6.1.6. Building box

Since the building box of the demonstrator SLS machine TNO is building is quite small TNO asked to change the design so that it can fit in the smaller building volume. This building box is only 330 x 140 x 60mm. [56] Since the orientation of the hinges should be in z-direction the thickness of the leg of the user defines how the product will be printed. Therefore the product should be split into four parts. Two parts including the hinges and two parts of the back. The parts will be connected using a snap fit system. This is because it should be assembled after production but it does not have to open again. Since the back part of the product does not include a hinge it can be orientated in an optimal way for the snap fit connection.

Advantages of the splitting are that the middle part could be made of a more flexible material than the other parts to make the orthosis more comfortable. This could give some difficulties with the fasteners between the parts but this could be investigated in future research. Another advantage is that when one part breaks not the whole brace has to be replaced but only part of it can be printed again.

6.1.7. Stiffness

The prototype was not stiff enough. This mostly showed in the rotation around the connection between the hinge and the body fitting part. Therefore two solutions were implemented. The thickness of the shell was increased in the thin part between the hinge and the BFP. Also ribs were added. 3D printing gives a lot of freedom. This is used when the ribs were made. Small hollow ribs are placed on this part, the ribs are hollow to form a torsion box. This is similar to the ribs they use in aircraft structures to prevent torsion in the wings of an aircraft. [57]

6.2. Procedure producer

The orthosis is designed especially for the user. Therefore buying the orthosis will be different from the present situation.

1. The first step is to scan the users legs . In this step it is important that there is enough light and that the leg is in a slightly bent position. The user can be seated on a high stool to prevent movement during the scan. During this step the height and weight of the user should also be written down.
2. The second step is to make a CAD model of the orthosis. In making the model the height and weight of the user should be used to define the thickness of the material.
3. The third step is to manufacture the orthosis using an SLS machine.
4. Then the orthosis should be checked on the following points:
   - Does the hinge move smoothly
   - Is the Velcro of good quality
   - Check visually whether all layers are sintered together.
5. The fifth step is to explain how the user should use the orthosis. The seller can assist the user to put it on and can show how tight the straps should be. When they agree on how tight they are the position of the straps can be marked on the Velcro using a marker.
6. The next step is to adjust the spring using the bolt on the bottom of the hinge. The user can try to STS a couple of times and the spring can then be adjusted by the seller.
7. The last step is to send a reminder to the user after a year that the straps should be replaced.

6.3. Use

Because of the new design the interactions have slightly changed. A visualisation of the use can be found in Figure 6.5.

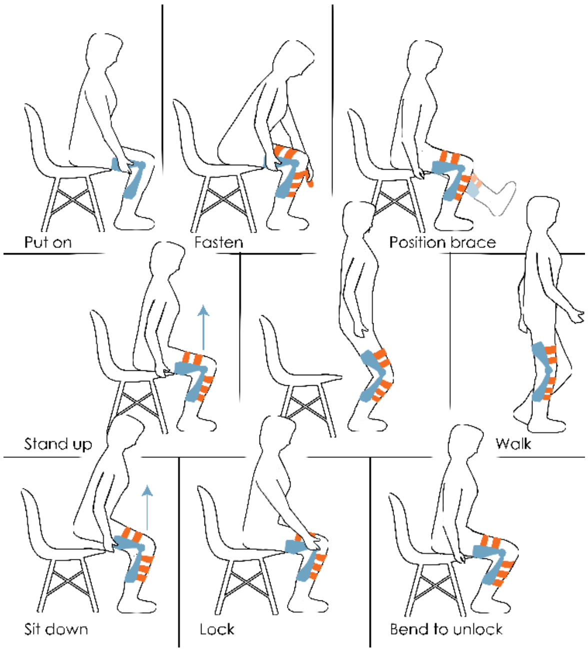


Figure 6.5: Use final design

The user will put the product on while being seated. The product will be put on by placing it on the back of the leg and then putting the Velcro in and fastening it. The user will then stretch and bend its leg to see whether the orthosis is in the right position. If it is not he will move it again.

When the user wants to stand up he will stand up as he regularly does, the orthosis will support the user for the first 45°. Then he can walk around freely. When the user wants to sit down again the orthosis will also slow down the last part of the movement. Which can prevent falls where the user sits down next to a chair.

When the user is seated he can push the button on the side of the orthosis to lock it in place. This is to make the user sit comfortably and not with stretched legs due to the force of the spring.

When the user wants to stand up again he first has to put force on the brace and bend its legs slightly further to unlock it. Then when it is unlocked it will support the user to stand up again.

6.4. Price

One of the advantages of 3D printing is that a personalised product is relatively cheap to produce. To be able to evaluate this factor the price of the product is estimated and is compared with a state of the art personal knee brace. The price of the SLS printed brace will be based on the price of the printing but also the price of attaching the Velcro and the wage of all people involved. When the orthosis was ordered at Shapeways it costed about €250 but the product still has to be assembled and the TPU was not printed. So to have a very pessimistic estimate it would be tripled to be €750. The state of the art custom orthoses range from €800 to €4000. So €750 is still a fairly cheap knee orthosis. This shows that the requirement that the product should be 20% cheaper than a state of the art personalized orthosis has been met.

6.5. Electronics

In the final exoskeleton electronics need to be incorporated. The idea is to integrate sensors to monitor the movement of elderly and to give feedback based on this information. As a follow up study it would be nice to look into the use of electrodes in the exoskeleton. Electrodes can activate muscles and therefore train your muscles to make them stronger. This could be a way to prevent muscle deterioration and to improve the fitness of elderly.

The largest component incorporated will be a inertial measurement unit (IMU) board on a printed circuit board (PCB). In figure 6.6 an IMU and its dimensions can be seen.

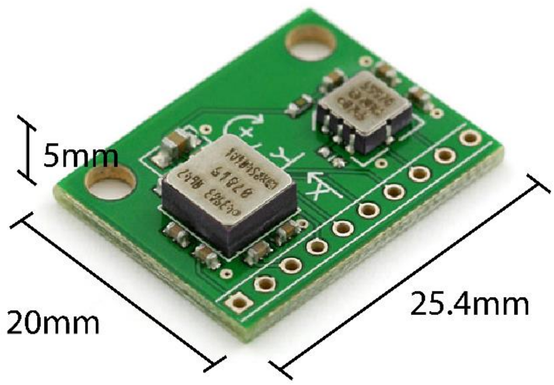


Fig. 6.6: IMU component

There is enough room left to fit this component in. It cannot be place within the hinge because in the project it is defined that every limb segments should have its own IMU. The cavity needed to place this component can disrupt the force distribution. Therefore it will be placed in the top corner of the limb segments where the stress in the material is the lowest.

An important founding in the prototype is that the rigid shell is not that rigid. Therefore the connections between the different electronic components should be able to withstand quite large deformations. This can also cause stress in and around the components itself which should be taken into account when this is developed further.

6.6. Lifetime

In the requirements it has been stated that the exoskeleton should have a lifetime of at least 2 years. Lifetime is defined as the ability of the product to work with the necessary interruptions for maintenance or repair. The main part of the orthosis that will wear out are the straps. This will be the first part to be replaced and this Is estimated to have a life time of 1 year. These can easily be replaced. The next part that could wear out are the hinges. TNO has done some tests with PA printed moving parts which could do 2.5 million repetitions and are still not broken and only show little wear marks. A picture of the tested part is shown in figure 6.7.

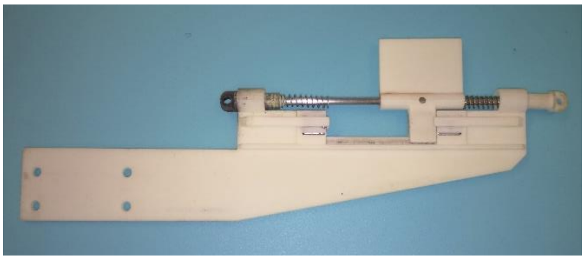


Fig. 6.7: Lifetime test part

The target group defined in this report are people that are older than 65 and have difficulty with the STS transition. Men aged 65 are the ones that take most steps per day which are 5499 steps per day on average. [58] This will be assumed when the life time of the product is tested. This will mean that to be sure that the product lasts 2 years the hinge should be able to withstand 4 million movements. Expected is that this is possible since the product at TNO was able to withstand more than half this many repetitions.

The prototype has been opened and closed 23 000 times. There were no external forces applied except from the opening and closing mechanism. After this test the product did not show any visual wear marks. To be sure a follow up study should be conducted to test it for 4 million cycles with forces that are expected when it is used.

07 Evaluation and conclusion

In the previous section all points of improvement gained from the prototype have been incorporated in a redesign. This redesign will now be evaluated based on the list of requirements. This will be followed with a list of recommendations and follow up studies. The section will end with the conclusion.

7.1 Evaluation

Table 6.1 shows the list of requirements. An extra column has been added in which the final design is compared to the requirement. When it meets the requirement it will get a check mark (✓) when it does not meet the requirements it gets a cross (**X**) and when it is unknown whether this requirement is met the letter u will be listed.

Requirements EU			
1	The product must be made form-fitting for every individual user	M	✓
2	The product must assist the user in a passive way	M	✓
3	The product should assist with the sit-to-stand movement	M	✓
4	The product should be 20% cheaper to manufacture than personal products that do not use AM	S	✓
5	The product should allow for shape changes of the limb due to muscle contraction	S	✓
6	The product could make use of multi material printing	C	✓
Requirements TNO			
7	The material used must be TPU or PA-12	M	✓

8	The product should be produced using selective laser sintering	S	✓
Requirements market research			
9	The user should carry the product with him while using it	S	✓
10	The user should be able to use the product without using his hands	S	✓
11	The product could be personalisable aesthetically	C	✓
Requirements users			
12	The user should be able to independently put the product on	S	✓
13	The user should be able to independently take the product off	S	✓
14	The product should be usable when it is raining	S	✓
15	The user should be able to clean the product	S	✓
16	The product should last at least 2 years.	S	✓
17	The product should work at temperatures between 19ºC and 43ºC	S	✓
18	The product should be able to withstand temperatures between -58ºC and 48ºC	S	✓
19	It should be possible to replace broken or worn pieces of the product	S	✓
20	It could be possible to wear the product under your clothing	C	U
Requirements of AM product			
21	The minimum wall thickness must be 1.0 mm	M	✓
22	The product must have edges with a minimum radius of 0.4 mm	M	✓
23	Feathered edges must taper to no less than 0.8 mm	M	✓
24	The wall thickness should be less than 3.0 mm	S	✓
25	The bottom side of the product should allow for 0.1 mm added material	S	✓
26	Round shapes should be positioned around the z-axis	S	✓
27	It should be possible to reach cavities to remove unsintered powder.	S	✓
Requirements STS			
28	The product must support the extension of the knees during the STS movement	M	✓
29	The product should be able to withstand a moment of 125Nm per leg	S	✓
30	The user should be able to move its knee joint from 0º to 100º	S	✓
31	The user could be able to move its knee joint from 0º to 135º	C	X
32	It could be possible to constraint the varus-valgus rotation of the knee	C	X
Requirements Comfort			
33	The forces on the body of the user should not exceed the PPT	S	✓
34	The pressure should not exceed the ischemic level for more than a minute	S	U
35	The product should not be placed over bony prominences	S	U
Requirements fasteners			
36	The fasteners should be easy to understand and identify, visually and tactually	S	✓
37	The fasteners should be possible to handle with one hand	S	O
38	The fastener should be easy to grip and hold	S	✓
39	The fastener should not scratch or rub over the skin	S	U
40	The fastener should not cause such pressure against the skin that might lead to pressure sores	S	U
41	The user should be able to put the product on while being seated	S	✓
Requirements Scenario's			
42	The orthosis should be dry within 12 hours	S	✓
43	The product should be used when using the bathroom	S	✓
44	The orthosis could be water resistant	C	✓

Table 7.1: Requirements

There are two requirements which are not met. These are the requirement that the user should be able to extend its knee from 0º to 135º. According to the study on which these angles are based the only daily activity when the user will need to flex between 100º and 135º is when he is taking a bath. Since the brace is not meant to be used when taking a bath it has been decided to make the hinge slightly less complex by only allowing for a flexion up to 100°.

The second requirement that is not met is that it is possible to constraint the varus-valgus rotation. This is to relieve pain from osteoarthritis patients. This feature has not been added due to a lack of time. Because of the misfortunate test not all requirements have been tested. This means that follow up studies are needed to make sure that all requirements are met.

7.2 recommendation

In the prototype section the final design section and the evaluation of the requirements already some recommendations have been raised. These and some additional recommendations are listed below.

- A detailed follow up study could be conducted to evaluate the alignment of the knee joint with the hinge of the orthosis.
- A co-design session could be held with a group of elderly in which the aesthetics of the product are evaluated and improved on.
- A follow up study concerning the coating could be done to investigate a coating which could not only improve water tightness but also aesthetics, the sliding behaviour and material stiffness.
- Further investigations into fasteners could improve the product. Due to the freedom 3D printing gives a 3D printed fastener could be an improvement.
- The padding has not been investigated in this project due to time. Therefore a follow up study is needed to define the firmness and structure of the padding.
- Also the connection between the different parts has not been investigated. A snap fit has been given as an option but different connections could be investigated in a follow up study.
- The production has not been investigated in this project but in the end a parametrical 3D model of the orthosis is needed which makes it fast to customise.
- The incorporation of electronics should be investigated and with that the use of electrodes.
- Furthermore a long term study needs to be done in which multiple users use the exoskeleton for a couple of weeks to see whether pressure sores form and to know how the comfort is on long term.
- A follow up study should also be done concerning muscle deterioration. It is very important to make sure no muscle deterioration will take place when the product is used since this will only worsen the problem.
- It would also be interesting to look into the material. In this study the material was given, but when the orthosis was made of another material it could be thinner and stronger.
- The next interesting thing to look into is whether gait could be improved by supporting the extension of the leg.

7.3. Conclusion

The main conclusion of this bachelor thesis is that the design of a knee orthosis is very complex. A lot of different factors take part in the design and specifically in the comfort. Due to a lack of time the final product could not be tested yet but the design looks promising. By making the exoskeleton a form-fitting knee orthosis all requirements set in the analysis phase are met or can be met with further development. Therefore the recommendations were drawn up which can be used in the continuation of the development process.

TNO will later on print the redesigned product. When this product meets the requirements it will be used to demonstrate the newly built 3D printer.

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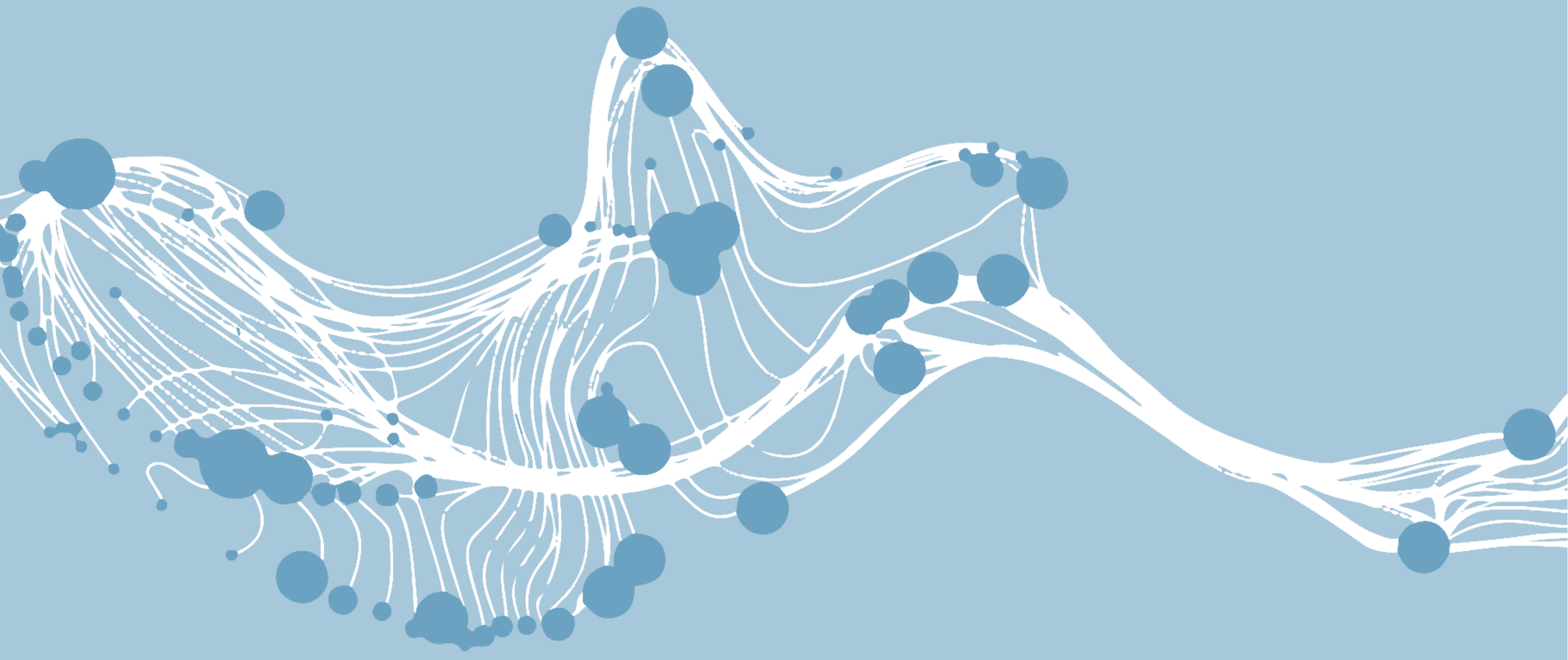

Appendices

Appendix A: AM technologies

Additive manufacturing processes can be subdivided in many ways. One of the ways is by looking at the state of the input material. As shown in figure 7.1. Most of these techniques are further examined in the next section.

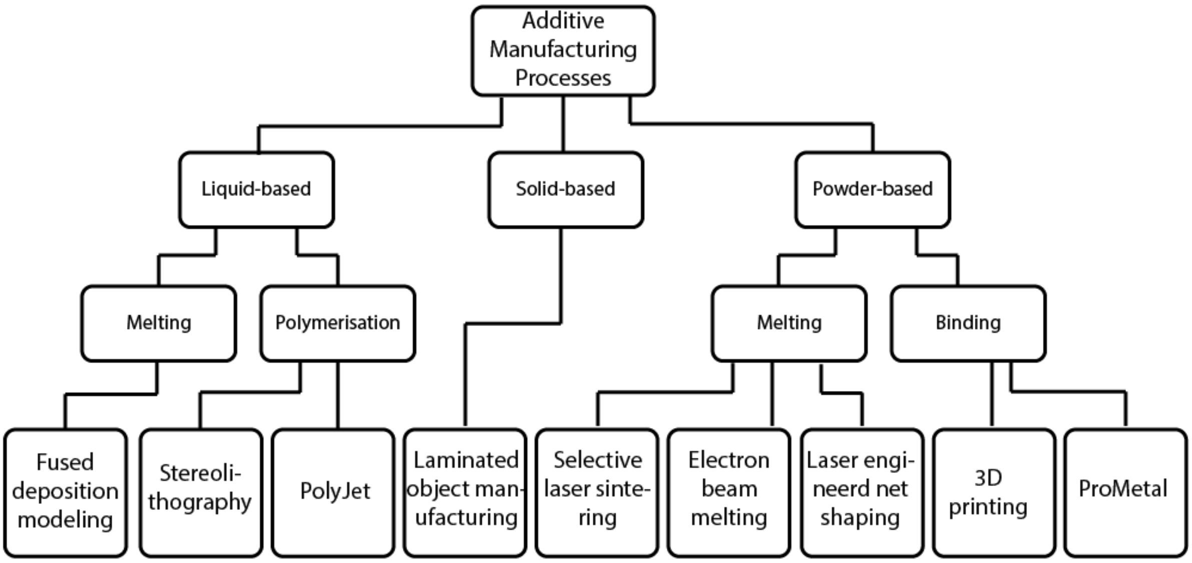

Fig. 7.1: AM subdivision[1]

Fused deposition modelling (FDM)

A movable head deposits liquid thermoplastic material in very thin layers. These layers solidify immediately since they were only heated one degree above their melting point and it also easily cold welds to the previous layers. Supports are needed to support overhanging geometry. There are visible seam lines between the layers which can delaminate over time. But the equipment is very cheap and the material is also cost effective it is furthermore easy to operate. [1, 2]

Stereolithography (SLA)

An ultraviolet laser makes contact with the liquid resin which cures the solidification of a photosensitive polymer. A support structure is needed when the geometry makes use of overhanging structures. Multiple material SLA is possible but only when the change of material happens fully between two layers. The product will be put in a bath of another material and the process will continue there. [1]

PolyJet

Layers of an acrylic-based photopolymer are jetted onto a build-tray via inkjet printing. The droplets are immediately cured with a ultraviolet lamp. The pro of this process is its ability to simultaneously jet multiple materials. [3]

Selective laser sintering (SLS)

A high power laser fuses a powder. The sintered material forms the part and the left over powder can be recycled. No support structures are needed and a great variety of materials can be used. [1]

Electron beam melting (EBM)

A high voltage electron laser fuses a powder. It is used extensively to build metal parts. It can be done in a vacuum so it could be used in outer space. [1]

3D printing (3DP)

A starch based power is treated by a print head which applies a binder to glue it together. The part can be heat treated to make it stronger. The surface finish is often rough and the sizes are limited, the post processing due to the surface quality makes the products expensive. [1]

ProMetal

ProMetal is a powder based process in which stainless steel is used. The printing process uses a liquid binder which is spurted onto the steel powder. The material should be hardened using heat. [4]

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Appendix B: Scenario’s

Scenario 1: in the home

Mary lives on a first floor apartment which she set up such that she can easily reach every room with her rollator. She has a very comfortable chair at the window, but she recently got trouble getting out of her chair which resulted in multiple falls due to balance loss. This resulted in regular visits of the personal carer to check on her. Since Marie is wearing the sit-to-stand exoskeleton she has had no trouble with standing up anymore. The exoskeleton made sure that her personal carer does not have to visit as regularly anymore. With her exoskeleton she can move around the house at ease.

Scenario 2: outside

Henk lives in a flat and because of the lack of a garden he likes to take a walk in the park. While walking Henk often gets tired and halfway his regular round is a bench on which he will sit for a while, until he is fully rested again. But after he once fell when getting up from the bench he does not dare to sit there again because he is afraid that he cannot get up anymore. He did not go out for a while but luckily he now possesses a sit-to-stand exoskeleton which gives him the security that he will be able to get up. Henk walks everyday again to keep fit, no matter the weather.

1. The orthosis should be used at all temperatures

Scenario 3: put on

Jeannet has reached an age at which her locomotion and sight are not as good as they have been. Furthermore her muscles have deteriorated which is not a irregularity when you are 85 years old. She uses the sit-to-stand exoskeleton which she will put on every morning. The exoskeleton has been made so she can independently put it on and take it off. Because of the exoskeleton Jeannet does not need help with getting out of her bed in the morning and to stand up from a chair throughout the day.

2. The user should be able to put the exoskeleton on and off, even with a decreased locomotion.
3. Someone with a decreased sight should be able to put the exoskeleton on and take it off independently.

Scenario 4: take off

Jean-Pierre just turned 65 but he is already troubled by old age problems which mostly show up when he has to stand up. Facing his friends he tries to hide his problems by standing up as fast as he can. This sadly often results in him losing his balance. Therefore he wears the sit-to-stand exoskeleton. He can wear it under his clothes which makes sure none of his friends know about it.

4. The user should be able to wear the exoskeleton under his clothing

Scenario 5: taking a shower

Linda’s muscles have deteriorated so much that it is impossible for her to stand up from a chair by herself. That is why she uses the sit-to-stand exoskeleton. When she takes a shower she also has trouble getting up from her shower chair, she therefore wears the exoskeleton while showering. When she is seated in the chair she often takes it off to clean it, and before she stands up again she will put on the exoskeleton again. After taking a shower she goes to bed so her orthosis can dry overnight.

5. The exoskeleton should be water resistant.
6. The exoskeleton should dry within 12 hours.

Scenario 6: visiting the bathroom

Herman lives in a small house in the middle of Amsterdam. The house is very small and it is hard to move through it with a rollator. As an alternative for such a large rollator Herman has a walking stick and a sit-to-stand exoskeleton so he can move through his house independently. When Herman visits the toilet he can stand up by himself and because of the design of the orthosis this does not cause unhygienic situation during or after going to the bathroom.

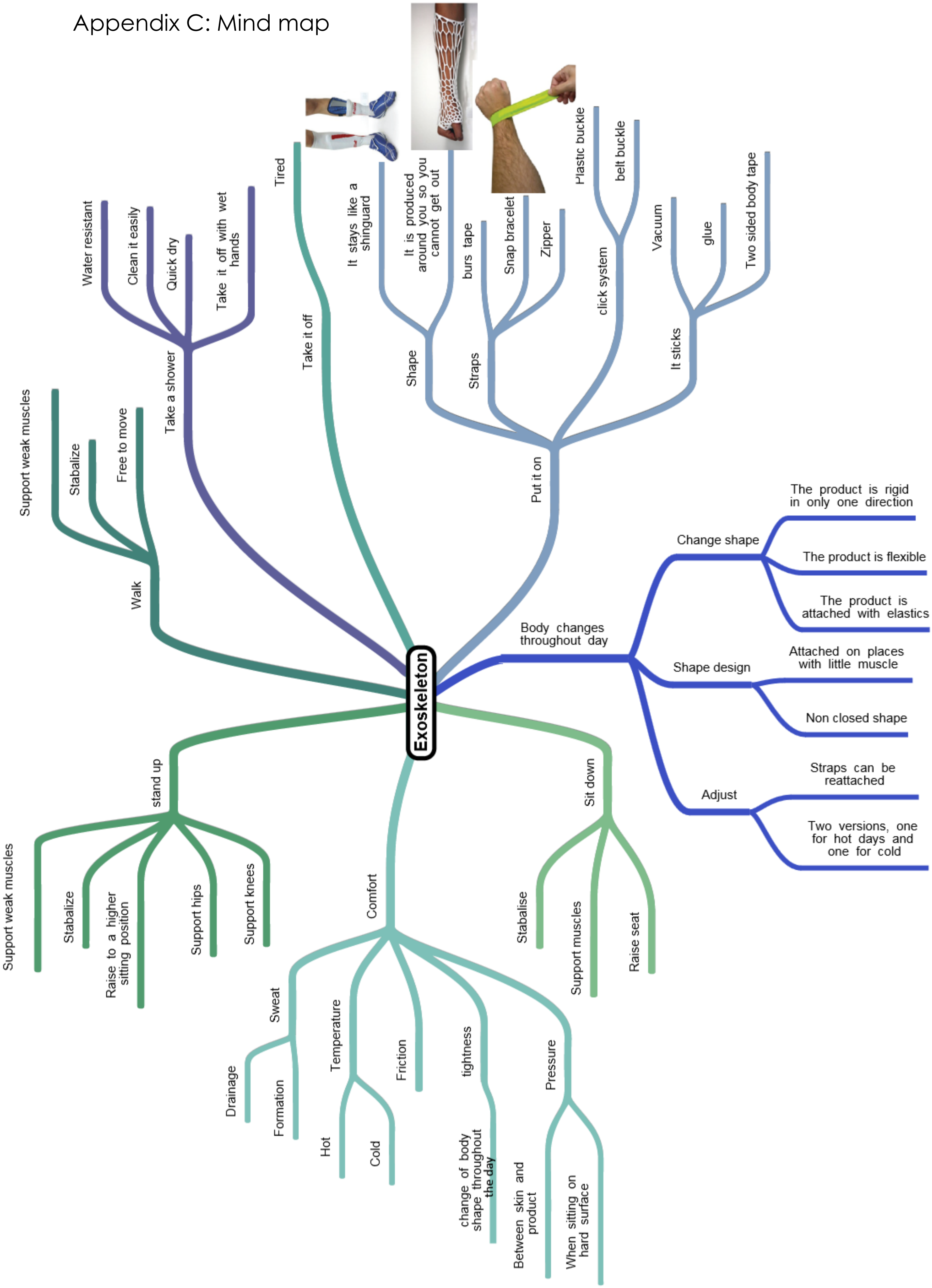
7. The user should be able to wear the orthosis while going to the bathroom.

Scenario 7: temperature

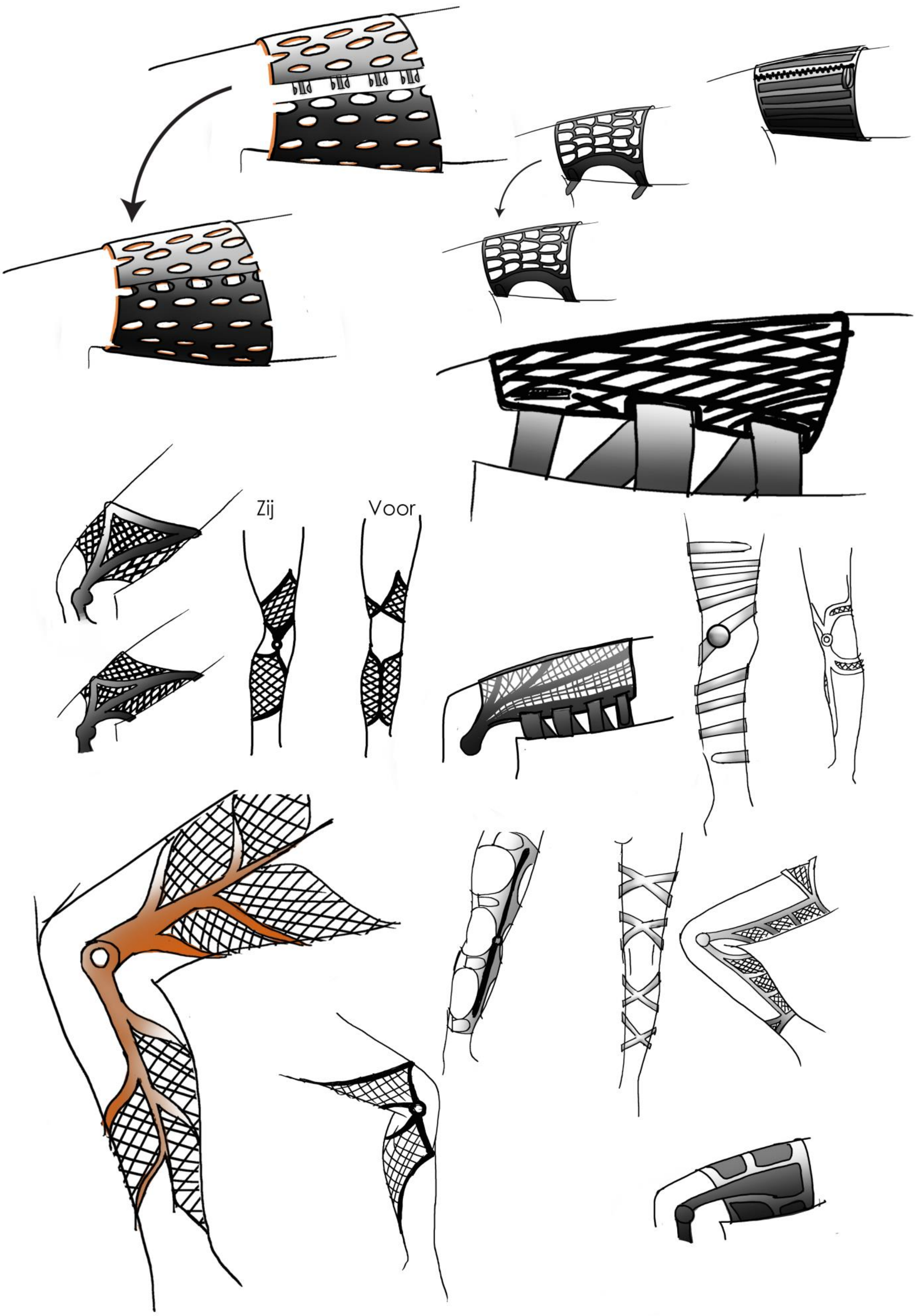
Lea lives in Franeker in a farmhouse in the countryside. She wakes up early in the morning when she immediately puts on her exoskeleton. It is very cold in the morning and since she just woke up her legs are still very thin. But throughout the day the temperature increases and because of her walking around her legs will increase in size. Because the design of the exoskeleton has taken this into account she is able to keep wearing it without it being too tight. And it will also give enough support and not start shifting when her legs decrease again.

8. The design of the orthosis should take the change of shape of the legs throughout the day into account.

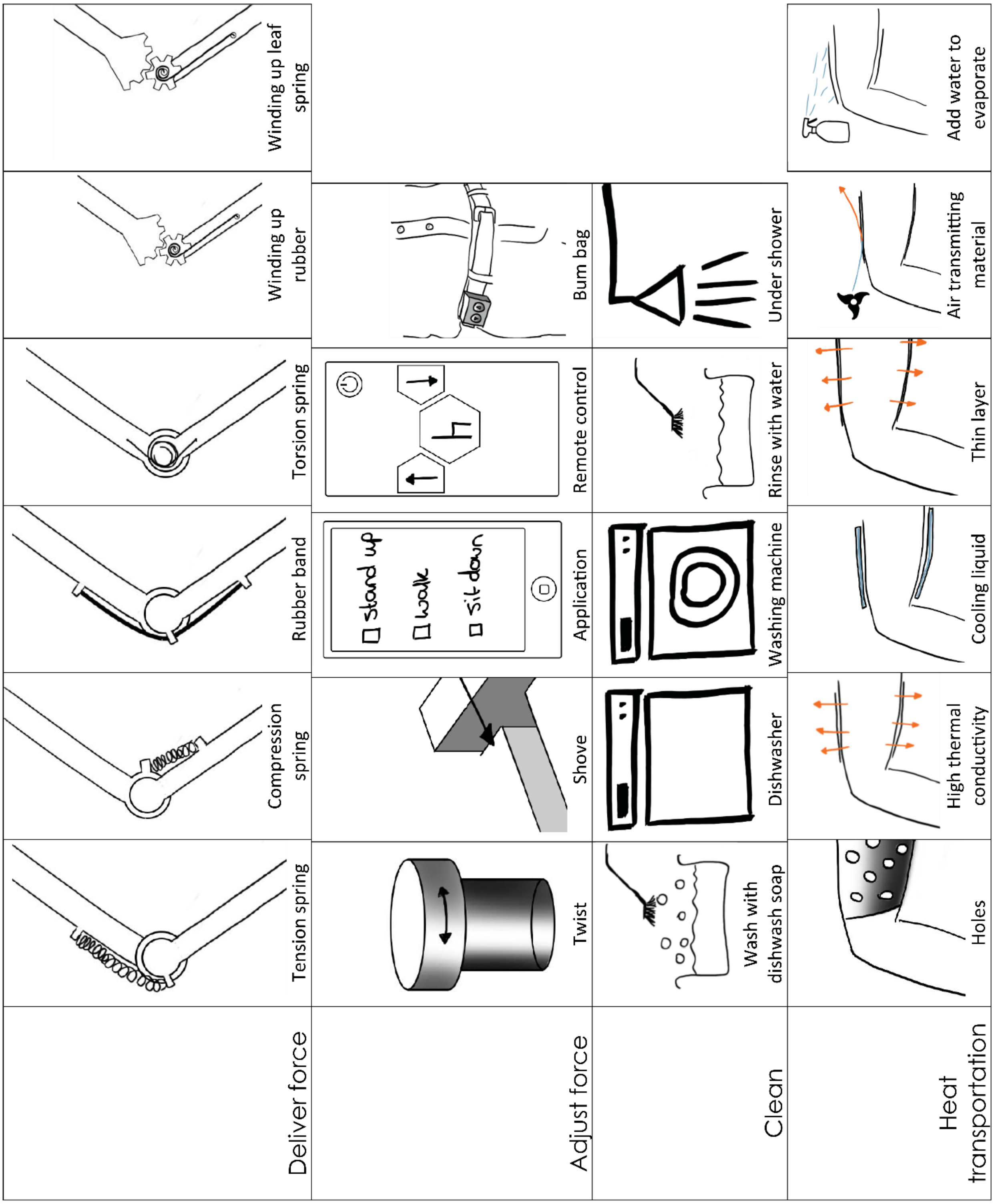
Appendix C: Mind map



Appendix D: Idea sketches



Appendix E: Morphological matrix



Facilitate end of life	Different materials can be split	One of the materials can be dissolved	Compostable	Burn	Partially reuse	Fully reusable				
Stay on	Clamp around body	Sticks	Can only move in one direction	Velcro	Clicks shut around limb	Like a snap bracelet	Zipper	Plastic buckle	Belt buckle	Vacuum
Allow for body changes	Soft back	Openings at muscles	Stretch material	Hinges on many places	Chain mail	Elastic closing in front	One direction stretch			
Distribute force	Large area	Body-fitting	Soft inside							
Adapt astatically	Colour coating	Personalised holes	Name inscription							

Appendix F: Concept choice

To make a well substantiated concept choice the concepts have been rated based on a reduced list of requirements. The list was reduced because not all requirements can be rated yet based on these concepts. Every requirement has a weight which is directly linked to the MoSCoW model used in the requirements. A must will have a weight of 3, a Should has a weight of 2 and a Could has a weight of 1. Then the concepts will get a score from 3 to 1 for every requirement. The concepts which meets the requirement best or has the potential to meet the requirement best will get a three. Then all scores are weight and added and the results are displayed below.

	Weight	Concept 1	Concept 2	Concept 3	Concept 4
The product must be form fitting	3	3	1	2	1
The product should allow for shape changes of the limb due to muscle contraction	2	1	3	2	3
The product should be personalisable aesthetically	2	2	1	3	3
The user should be able to independently put on and take off the product	2	2	3	1	3
It should be possible to replace broken or worn pieces of the product	2	2	3	1	3
It should be possible to wear the product under your clothing	2	2	1	3	3
Interaction forces should be as low as possible	2	3	1	2	2
The product should be as lightweight as possible	2	1	2	3	3
Keep the size of the exoskeleton as low as possible	2	3	2	1	1
Total		41	35	38	45

Appendix G: Calculations thickness material

Expected is that the connection between the hinge and the BFP will be where the largest forces will be seen. Therefore the minimal thickness will be calculated to be able to withstand these forces. The moment in the hinge has been calculated in the analysis section. This resulted in a maximum of 125Nm per leg so 62.5 Nm per hinge. To apply a safety factor of 2 a moment of 125Nm will be used in further calculations. Figure 7.5 shows the situation with the needed forces to create this moment in the hinge. The section view in which the forces will probably be critical is also shown in figure 7.5.

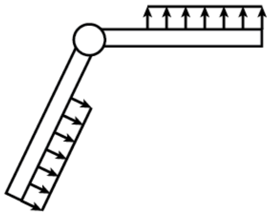


Fig. 7.5a: Forces hinge

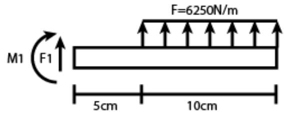


Fig. 7.5b: Forces hinge section

Fig. 7.5a: Section render

Used formulas:

$M = F \cdot a \qquad \frac{F}{L} = Distributed\ load \qquad \sigma_y = \frac{F}{A} \qquad A = W \cdot T$

Symbols:

M = Moment [Nm]
F = Force [N]
a = arm [m]
L = length [m]

σ_y = yield strength [Pa]
A = area of section [m^2]
W = width [m]
T = thickness [m]

To calculate the minimum thickness of the material that connects the hinge to the BFP the tensile stress will be calculated. The tensile stress should not exceed the yield strength of the material. The yield strength of SLS printed PA-12 is taken at 45^{o}C since the yield strength decreases with an increasing temperature and this will make sure it complies with the requirement that the product should work at temperatures between 19^{o}C and 43^{o}C. The yield strength is then 58MPa [1].

$$A = W \cdot T = 0.01667 \cdot T$$
$$F = L \cdot Distibuted\ load = 0.1 \cdot 6250 = 625N$$
$$\sigma_y = 58MPa = 58\ 000\ 000\ Pa$$
$$\sigma_y = \frac{F}{A} \qquad 58\ 000\ 000 = \frac{625}{0.01667 \cdot T} \qquad T = 0.64mm$$

Which concludes that the thickness of the material should be a minimum of 0.64mm.

Another possible weak spot are the holes to which the spring is attached. For these the minimum thickness is also calculated and a safety factor of three has been applied. This calculation is similar to the previous calculation. This results in a contact area between the hole and the body fitting part of 50mm^2.

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Appendix H: Calculations spring stiffness

Facts about the test persons can be found in table X.

Test person	Weight [kg]	Length [m]	Sex	Upper leg length [m]*	Weight upper body [kg]**
1	71	1.54	Female	0.383	42.0
2	67	1.75	Male	0.406	39.7

Table 7.3: Facts test persons

* Upperleg is for males 23.2% of their height and for women 24.9% [1]

** Upper body is 59.26% of the total weight [2]

The extension of the spring is caused by it winding around the hinge as can be seen in figure 7.6 and 7.7. The leg will be moved from a maximum of 135° to 0°. This will make the spring elongate up to 75mm. The force applied by the spring should generate a force which can lift 10% to 40% of the users body weight. The moment which should be generated in the hinge depends on the length of the upper leg of the user as can be seen in the analysis section.

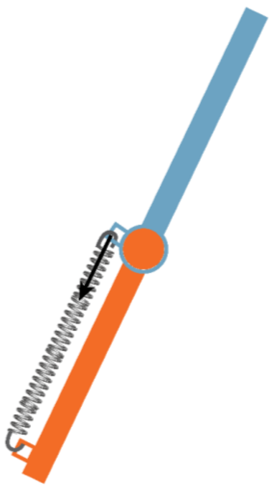

Fig. 7.6a: Spring hinge 0°

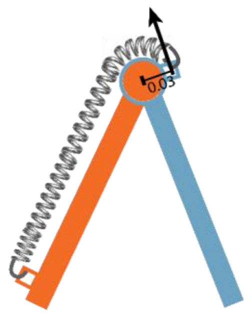

Fig. 7.6b: Spring hinge 135°

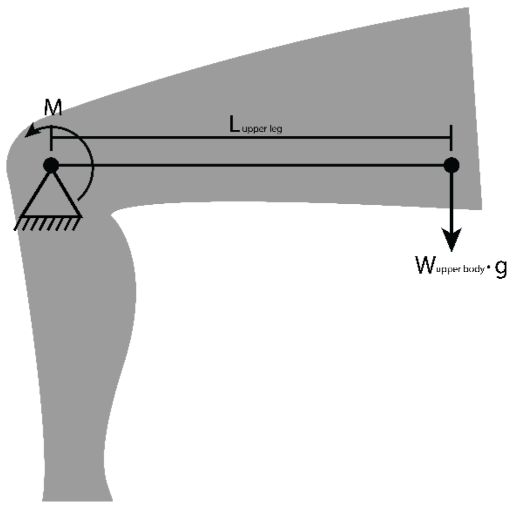

Fig. 7.7: Forces leg

$M = F \cdot a = W_{upper\ body} * g * L_{upper\ leg} \qquad M_1 = 158\ Nm \qquad M_2 = 158\ Nm \qquad M_1 = M_2 = M$

$$F_{total} = \frac{M}{a} = \frac{158}{0.03} = 5267\ N$$

The total force is the force needed to fully lift the user. Since this will be divided over 4 hinges and only 10% to 40% of the body weight needs to be lifted the needed force is less.

$$F_{needed,10\%} = \frac{F_{total}}{4} \cdot 0.1 = 132\ N \qquad F_{needed,40\%} = \frac{F_{total}}{4} \cdot 0.4 = 526.7\ N$$

The spring stiffness is determined by the force and the elongation of the spring.

$$k_{needed,10\%} = \frac{F}{u} = \frac{132}{75} = 1.76\ N/mm \qquad k_{needed,40\%} = \frac{F}{u} = \frac{526.7}{75} = 7.02\ N/mm$$

This means that for the prototype test three springs between 1.76 N/mm and 7.02 N/mm will be ordered. The springs ordered are shown in table 7.4

Percentage	k [N/mm]	L0 [mm]	Du [mm]	Sn [mm]

10.8%	1.9	123	9.6	86.49
17.55%	3.09	122	12	80.50
35.51%	6.25	122	25	86.08

Table. 7.4: Used springs

Sn is the maximum extension of the spring, this should be higher than 75mm.
Du is the outside diameter of the spring.
L0 is the length in mm which should be the same for all three springs.
k is the spring constant which should be between 1.76 and 7.02.

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Appendix I: FMEA

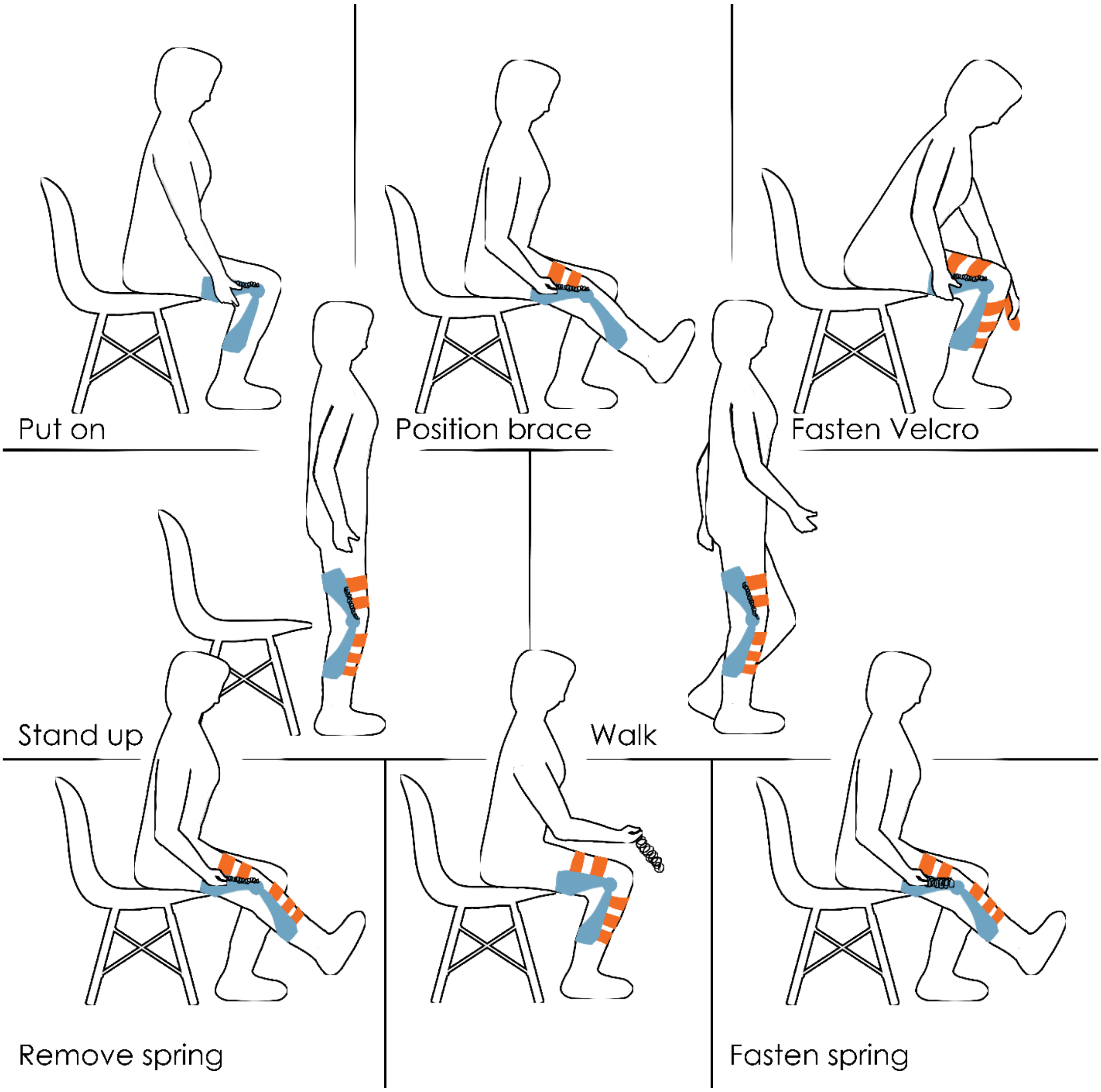
Failure	Effect	S	Cause	O (expected)	D	RPN	CRIT	#	Recommended action	Solution type
Strapping undoes or loosens	Brace shifts when moving which misaligns axis	6	Worn out Velcro	2	2	24	12	1	Send customer e-mail after a year that the straps have to be replaced	O
	Brace shifts when moving which irritates skin		Not properly closed straps	3	4	72	18	2	Draw a line on the strap to indicate how tight the strap should be	D
	Brace shifts when moving which causes heat		Bad quality Velcro	2	4	48	12	3	Check straps before deliver to customer	D
	User falls due to lost force and injures									
	User trips over loos strapping and injures									
Connection Strap and BFP breaks	Brace shifts when moving which misaligns axis	6	Material is too thin	2	4	48	12	4	Locally increase wall thickness	O
	Brace shifts when moving which irritates skin		Print job is under heated	2	6	72	12	5	Check product before it is delivered to customer	D
	Brace shifts when moving which causes heat		Material is worn out	3	4	72	18	6	Coat product	O
	Broken piece is sharp and injures user		Brace was used incorrectly	5	4	120	30	7	Provide a clear guidebook with the brace	O
	User falls and injures		Strap was on too tight	5	6	180	30	8	Draw a line on the strap to indicate how tight the strap should be	D
Strapping is not tight enough	Brace shifts when moving which misaligns axis	5	Strapping loosens when put on too tight	2	4	40	10	9	Draw a line on the strap to indicate how tight the strap should be	D
	Brace shifts when moving which irritates skin		Strap is too large	2	2	20	10	10	Check straps before deliver to customer	D
	Brace shifts when moving which causes heat		Strapping stretches	2	4	40	10	11	Check straps before deliver to customer	D
Strapping is too tight	Blood vessels are pinched off causing numbness	5	Strapping stretches	2	4	40	10	12	Check straps before deliver to customer	D
	Deforms brace which misaligns hinges		Straps are too small	2	2	20	10	13	Check straps before deliver to customer	D
	User is unable to open brace									
	Strapping irritates skin									
Connection hinge and BFP breaks	User falls and injures	8	Material is too thin	2	4	64	16	14	Locally increase wall thickness	O
	Sharp break edge injures user		Print job is under heated	2	6	96	16	15	Check product before it is delivered to customer	D
	Spring disconnects and injures user		Material is worn out	3	4	96	24	16	Coat product	O
			Brace was used incorrectly	5	4	160	40	17	Provide a clear guidebook with the brace	O
			Misalignment of axis	2	6	96	16	18	Check movement of the hinge before it is delivered to customer	D
Hinge gets stuck	Leg is not able to flex	7	Spacing between moving parts is too small	2	8	112	14	19	Check movement of the hinge before it is delivered to customer	D
	Leg is not able to extend		Dirt collects inside hinge	5	4	140	35	20	Coat material	O
	Leg is suddenly stopped causing knee injury		Material is too rough	2	8	112	14	21	Check movement of the hinge before it is delivered to customer	D
	Leg is suddenly stopped causing fall and injury		Opposite hinge axes are misaligned	2	6	84	14	22	Check movement of the hinge before it is delivered to customer	D
			Print job is overheated	2	6	84	14	23	Check product before it is delivered to customer	D
			Print job is under heated	2	6	84	14	24	Check product before it is delivered to customer	D
Hinge breaks	Leg is not able to be flexed	10	Hinge has a too small wall thickness	2	4	80	20	25	Check movement of the hinge before it is delivered to customer	D
	Leg flexes around wrong axis causing knee injury		Print job is under heated	2	6	120	20	26	Check product before it is delivered to customer	D
	Leg is not able to extend									
	Leg extends around wrong axis causing knee injury									
Hinge not aligned with knee joint	Leg is not able to be flexed	8	Knee joint axis is not (properly) marked in scan	1	8	64	8	27	Check scan immediately after scanning	D
	Leg flexes around wrong axis causing knee injury		Straps misalign the brace	2	4	64	16	28	Draw a line on the strap to indicate how tight the strap should be	D
	Leg is not able to be extended		System is overloaded due to overweight user	4	6	192	32	29	Wall thickness is increased when a person is over 100kg	O
	Leg extends around wrong axis causing knee injury		Print job is under heated	2	6	96	16	30	Check product before it is delivered to customer	D
			Print job is overheated	2	6	96	16	31	Check product before it is delivered to customer	D
Opposite hinge axes not aligned.	Hinges cannot move at all	8	Knee joint axis is not (properly) marked in scan	1	8	64	8	32	Check scan immediately after scanning	D
	Leg is not able to be flexed		System is overloaded due to overweight user	4	6	192	32	33	Wall thickness is increased when a person is over 100kg	O
	Leg is not able to be extended		Print job is overheated	2	6	96	16	34	Check product before it is delivered to customer	D
	Leg twists while flexing causing knee injury		Print job is under heated	2	6	96	16	35	Check product before it is delivered to customer	D
	Leg twists while extending causing knee injury									
Spring disconnects	Spring jumps away and injures someone	8	Connection spring and BFP breaks	3	1	24	24	36	Locally increase material thickness	O
	Sudden force makes user fall		Force hooks spring off	3	3	72	24	37	Place spring in a tube	S
	Force breaks the brace		Spring breaks	1	1	8	8	38	Place spring in a tube	S
Spring force is too stong	User cannot flex knee	8	Too strong spring is used	1	4	32	8	39	Check users weight and height before producing	O
	While seated users knee is extended		Spring is not adapted to weight of user	2	6	96	16	40	Check users weight and height before producing	O
	Spring cannot be hooked up to brace		Distance between hooks to connect spring is too large	1	4	32	8	41	Check users weight and height before producing	O
Spring force is too weak	User is still unable to STS	8	Too weak spring is used	1	4	32	8	42	Check users weight and height before producing	O
			Spring is not adapted to weight of user	2	6	96	16	43	Check users weight and height before producing	O
			Distance between hooks to connect spring is too small	1	4	32	8	44	Check users weight and height before producing	O

RPN > 95

96 > RPN > 47

47 > RPN

Appendix J: Interaction visualisation



Appendix K: Interview physiotherapist

What are the main problems you see with this orthosis?

- I think one of the main problems is that elderly have a very thin skin. Therefore they are way more prone to pressure ulcers.
- Furthermore a problem I see is that you have to be very certain that this brace will really get elderly to move. When it limits them it can indeed cause muscle deterioration and have the opposite effect.
- Also elderly who are unable to STS are often overweight. Make sure the orthosis can also support overweight people.

Do you think this orthosis gives the knee enough freedom and does not infringe with the natural movement of the knee joint.

- Make sure the flexion and extension of the knee is not limited. And especially make sure that in gait the end extension is not limited.
- The varus-valgus rotation should be possible when the leg is flexed. When it is stretched it does not necessarily have to be free.
- The internal-external rotation is only used in competitive sports and can give an advantage then. But since your target group is probably not playing competitive sports it is not a problem when this movement is constrained.

Do you have any other remarks on this knee orthosis?

- In elderly who cannot STS anymore balance is also a problem. Make sure that the spring does not push too hard or too sudden so the user will not lose its balance.

Appendix L: Reflection on society and technology

Introduction

In the bachelor thesis there was a lot of attention on the functional aspects of the product rather than the relation between human and technology and the points of contact of the technology with society. Therefore the question asked in this report is: What can be improved in the interaction between human and technology and between technology and society in the design of the 3D printed orthosis?

Analysis

To be able to answer this question all interactions should be analysed. Therefore the analysis will use the mediation theory to analyse the human-technology relation and Steven Dorrestijn's product impact tool to analyse the points of contact. The product impact tool is a good tool to get the full picture of all points of contact. The to-the-hand interaction zooms in on the product while the above-the-head interaction zooms out to see the interaction on a larger scale.

The risk of this conceptualisation is that needs that emerge from the use of a product are not taken into account. The relation between the elderly person and the exoskeleton can be investigated by looking at the relations defined by Peter-Paul Verbeek[1]. From his report on Materializing mortality it can be conducted that this orthosis has an embodiment relation with the user. In an embodiment relation the user establishes a different relation with the world through the use of this technology. The technology on itself is not perceived. This is the same relation as a pair of glasses has. Through this technology the world is perceived differently.

Not only the relation is important when reflecting on the product but also the influence it has. In the next section the points of contact will be analysed according to Steven Dorrestijn's impact tool.[2] Steven Dorrestijn's tool is very effective since it zooms into the product to find points of contact but also zooms out. This causes a full view of the points of contact of the technology.

The first point of contact is the to-the-hand interaction. This is the physical interaction between the user and the product. In the design of the exoskeleton the intention was to make this interaction as small as possible. Due to a form fitting design which causes the perfect pressure distribution the product should feel like a second skin. This form fitting design will also enhance the embodiment relation of the user with the product.

The second interaction is before-the-eye. The body fitting shape of the product already guides the user to the way it should be put on. It is visually clear how the product should be placed. The before-the-eye interaction can also influence someone's image. Since the product looks slightly like a knee brace the user's image will not benefit from the use of the exoskeleton. Therefore the exoskeleton can be placed under your clothes. This makes sure that this interaction will not have a negative influence. Though hiding of a certain problem as in his case the difficulty with the STS transition could also have a negative effect. Erving Goffman explains in his book that hiding can make people feel anxiety, depression and in the end can withhold them from going out in public.[3]

The third interaction is the behind-the-back interaction. One of the behind the back interactions of the exoskeleton could be that it can cause muscle deterioration. Since the exoskeleton supports the quadriceps muscles it could be that the muscles get even less movement and therefore get weaker. A background condition to be able to use the exoskeleton is that you have still some strength in your muscles. The user does not have to be able to STS independently anymore but an inflamed person will not get help from this product. Another behind-the-back interaction is that the product will help elderly to stay home independently for a longer time. This could be a positive effect but it can also make the user more lonely, where he was used to a visit of a carer twice a day he will now be alone all day. The problem of elderly becoming more and more lonely will be aggravated by the product. To shed light on the other side of this argument, the user will be able to STS independently again and therefore will be able to visit the neighbours again and go have a walk to meet people. This will increase the social contact of elderly instead of decrease it.

The last interaction defined by Steven Dorrestijn is above-the-head. This is about the larger scale. The exoskeleton can have influences on the larger scale. The exoskeleton could fit into a utopian society. This product shows that disability and becoming elderly and weaker is not a problem anymore. All disabilities can be solved. This product will fit into this utopian world and will also enhance it. But the downside is that this product will also enhance the dependence of society on technology. This could have several bad influences, technologies take away the need people have to help each other. This will diminish human interaction and could create a society of individuals living alongside each other.

Evaluation

When evaluating the points of contact between the user, society and the product, the mediation theory and Steven Dorrestijn's tool will be used again. All the different interactions have already been analysed in the analysis section, this section will evaluate how the product could be changed to improve the interactions.

The interactions between the user and the product are analysed as mostly embodiment relations. At first use, the interaction may be more an extension relationship since the user will be very aware of the technology. But after a while it should turn into an embodiment relation. The embodiment relation will be achieved when the exoskeleton and the user move as one. Therefore it would be good to make sure that the movement of the exoskeleton is perfectly aligned with the users movements. A follow up study can make sure this is the case. The same point of improvement is raised when looking at the to-the-hand interaction. Making the product more transparent will enhance these relations.

The before-the-eye relation could be extended. At present the affordances are very clear but the image of the user could be improved. The product is worn under clothing as if it is something to be ashamed of. If the product could be redesigned in such a way that it could be comfortably worn over your clothing it could improve the image. Then the design should be altered so the association with a knee brace will not be made. Image of elderly can be improved by making the product look very high-tech, as if it is a gadget. When it is marketed in the right way it could even be a product people want to wear.

To improve on the behind-the-back interaction between the product and society it should be made sure that the exoskeleton does not enhance muscle deterioration. This could be made sure by a long lasting study in which different subjects use the brace for a couple of years. An expected conclusion of this research is that a healthy elderly will not have any benefit from the brace. While elderly who are immobile due to their lack of the ability to independently STS will get stronger muscles when using the exoskeleton. This could be solved by for instance an insurance company only paying for the exoskeleton when the user has problems with STS. Or that the brace can only be bought after a certain level of fitness has been tested. The second behind-the-back interaction is that of the user getting lonely. By the time this product has come out all elderly are probably online. This can bring the solution to when you buy the brace you are added to a certain online society. The guidebook could encourage to join this society and to practice walking with the exoskeleton together with other users. This could provide the user with a walking buddy and make them less lonely.

The above-the-head interaction is very hard to improve. The society is changing inevitably. The best way to deal with it is to be aware of this change. A way of making the user less dependent on the product is by making sure the product will not only support STS but also enhance the reinforcement of the muscles of the users. This could be done by integrating electrodes in the design which can activate the muscles when the user is not using its muscles this can improve the muscle strength to such an extent that after a while the user will be able to STS by himself again. This could be a solution but will also raise more infringing values.

Conclusion

In the analysis the interactions and relations between the technology, user and society have been analysed. The evaluation section gives recommendations for follow up studies and points of improvement. The conclusion is that a follow up study should be done concerning the alignment of the exoskeleton and the human movements. The second follow up study is about the marketing and aesthetics of the exoskeleton, result of this study should be a brace that improves the image of the elderly. The third point of improvement is that the exoskeleton should only be sold to users who are unable to STS and not to fit users. The fourth point of evaluation found is that the exoskeleton should come together with an online society in which people can meet up to walk together. The last point of improvement could be to integrate electrodes in the product, but a follow up study is needed to be sure about the effects.

These points of improvement cannot be executed within this bachelor thesis anymore but they would be a very interesting topic of another bachelor thesis or maybe even my own master graduation project.

References

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Appendix M: Calculations spring final design

From the user test it appeared that when a spring of 4 N/mm would be used on both legs it would have the perfect strength. It will extend your leg enough to give support with the STS transition but it will not extend your legs while being seated.

$$2 \cdot \pi \cdot r \cdot \frac{1}{4} = 2 \cdot \pi \cdot 0.03 \cdot \frac{1}{4} = 47mm$$

During the user test the user extended his leg from 90° to 0° which gave the spring an extension of 47mm.

$$k \cdot u = F = 4 \cdot 47 = 188$$

When four springs of 4 N/mm were used this would generate a force of 188N per hinge and therefore 752N for the whole system.

$$M = F \cdot a = 752 \cdot 0.03 = 22.56\ Nm$$

The moment in the hinges all together would be 22.56 Nm.

$$W_{upper\ body} \cdot g \cdot L_{upper\ leg} \cdot percentage = M$$

$$39.7 \cdot 9.81 \cdot 0.406 \cdot percentage = 22.56 \qquad percentage = 0.14 = 14\%$$

Appendix N: Redesign hinge