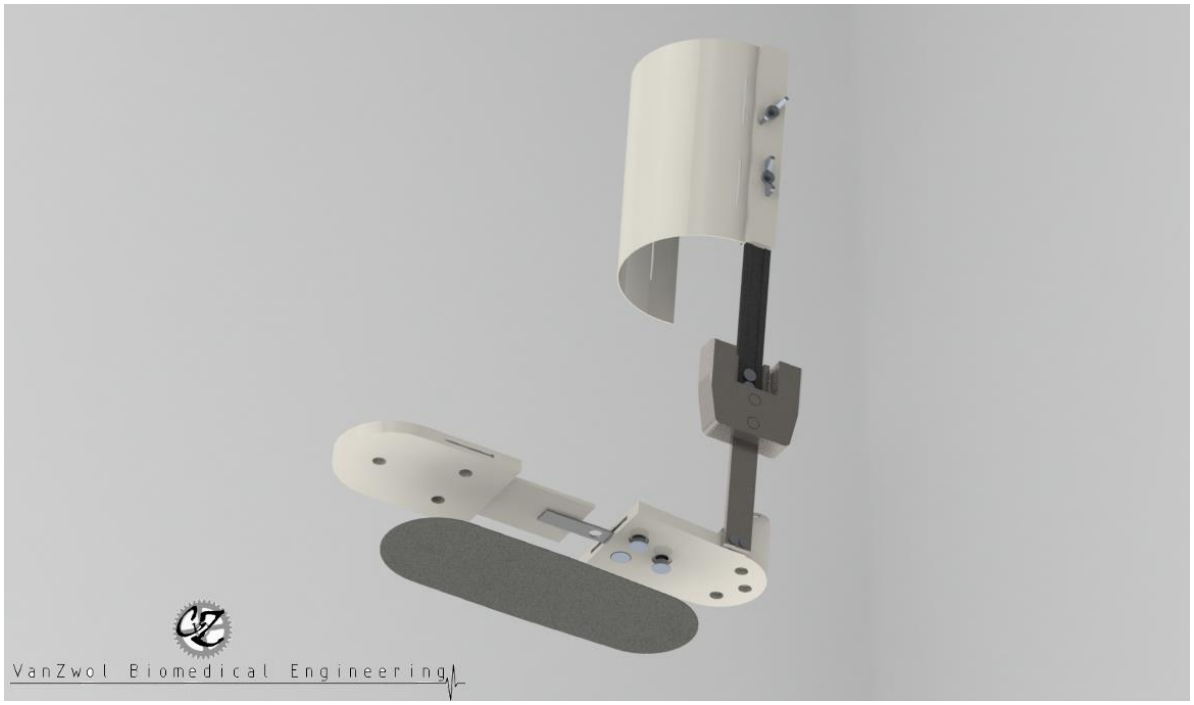
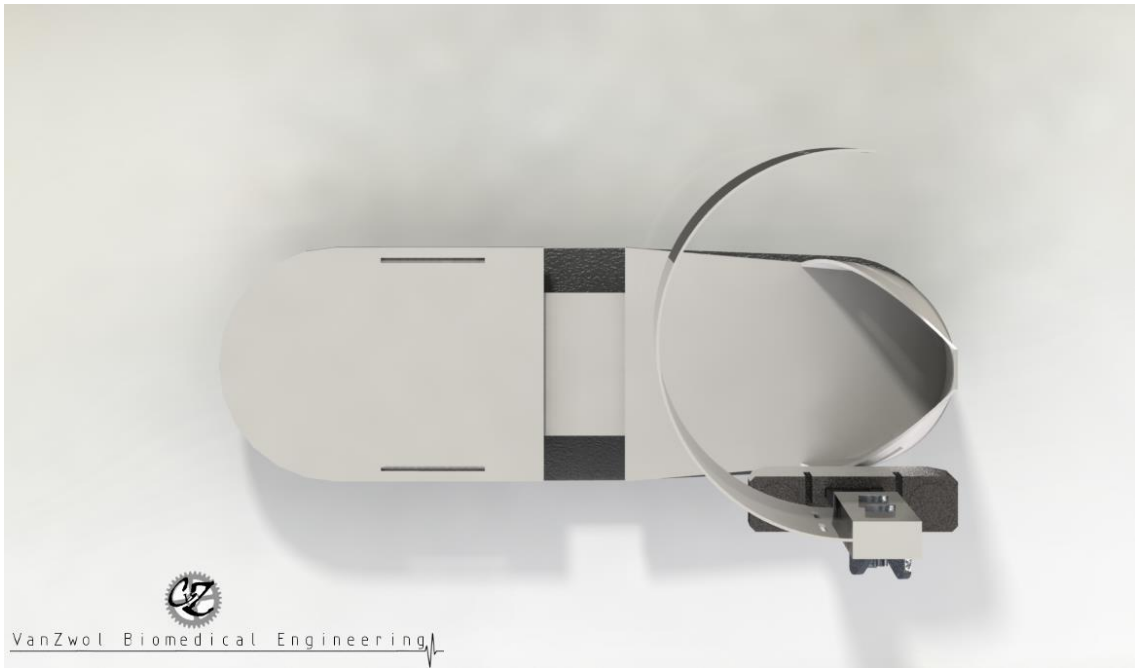
7-7-2015



SPRINT FINDING THE MISSING LINK



Finding a new design for the Adjustable Orthosis Prescription Tool in order to assist over 20.000 Ankle-Foot Orthosis assessments |

Charlotte van Zwol – s2367807

Abstract

Walking is a complex process, unfortunately not all people are able to perform this process as desired. In some cases and Ankle-Foot Orthoses (AFO) is prescribed. During the current process, there are situations where there is little to no availability of AFO's and their properties, making it very hard to prescribe the optimal orthosis. In this paper, the key aspect is solving the situation where there is little to no availability of available AFO's or AFO-sole combinations during assessment. The goal is to delete this limitation by designing an Adjustable Orthosis Prescription Tool (ADOPT), which will give unlimited trial and error with many adjustability's in both size and resistance during assessment so ensure the optimal AFO can be prescribed. Since there is an available prototype, the process is focussed on redesigning this prototype. Key aspects of the current prototype were needed improvements for the heel cup, the weight of the ADOPT, internal rotation of the two shafts and the range of calf circumferences that could fit in, while positive points were the adjustability, ankle axis alignment and the hinge used. In this paper is worked through three synthesis phases in order to make a design that will realise the goal as much as possible. In synthesis I many ideas get put on paper and rated at the end so only three concepts remain. In synthesis II the three chosen ideas are detailed and analysed more precisely, after which the final product is chosen and worked out in synthesis III.

Content

Introduction

As is elaborated in the analysis phase accompanying this report walking is an admirable process of multiple muscles of the leg and hips working together in order to bring the body forward with coordination of the central nervous system. Unfortunately, not all people are able to perform this process as desired. This can have multiple causes, for example congenital, disease or trauma, though for this paper focus lays on the resulting calf muscle deficiencies. In this case, an Ankle-Foot Orthoses (AFO) can be prescribed to some patients. During AFO assessment, patient gait is analysed in order to determine a suitable AFO and its benefits. Regrettably, this process does not necessarily give all information needed to prescribe the optimal AFO, as it does not involve properties of the AFO the patient will receive at the end of the process. As this process happens more than 20.000 times per year it is a serious aspect for improvement (1).

In this paper focus lays on designing an Adjustable Orthosis Prescription Tool in order to provide all AFO properties during assessment. As there is a prototype of an earlier design, the assignment is redesigning this concept. Good aspects of this prototype are its adjustability, ankle axis alignment and the hinge used, as it already was on the market making the prototype more feasible. Points for improvement are the internal rotation of the two shafts, weight, heel cup design and the range of calf circumferences that can fit into the prototype. From tests performed by Evelien van Zwol and Jeroen Toorn the issues addressed are the weight of the prototype and the missing information on which the spring unit choice could be based. A more detailed evaluation of this prototype can be found in the associated thesis.

First, in synthesis I multiple ideas are written down and morphological maps are composed. At the end of this phase, three concepts will be chosen in order to be examined further in synthesis II. During synthesis II the three concepts are detailed, the sterilization methods are written down and materials are defined. Also, risks are analysed through Failure Mode and Effect Analysis (FMEA) and TRIZ. For evaluation components are simulated for Finite Element Analysis (FEA). At the end of this phase, the concepts with their components are rated again as done at the end of synthesis I in order to get a final design. In synthesis III the final design is detailed and materials are defined as is the method of sterilization. Technical drawings are made in order to allow prototyping. Based on the detailing, technical drawings and materialisation a cost estimate can be made. Next to that, the design is evaluated by the essential requirements necessary for CE-marking, in order to allow distribution in the EEC. The benefits from the ADOPT are estimated through Technology assessment.

Synthesis I

To solve a problem, there are two approaches that can lead to a solution. Either the entire problem can be solved at once in a holistic approach, or it can be solved by a reductionistic approach; the problem is divided into sub problems, which then will be solved individually. Since the ADOPT has to be adjustable in multiple ways, the best way to make it is through the reductionistic approach. To achieve this the current prototype for the ADOPT is divided into main components: the sole-section, the joint and the tibia-compartment. The sole section can be subdivided into the sole itself and its adjustability, the addition of sole-combinations and fixation of the foot. The joint controls both the range of motion of the foot with respect to the lower leg and the assistance and resistance, together with alignment with the ankle axis. The tibia-compartment consists of the fixation of the lower leg, adjustability in length and calf circumferences. Per subdivision multiple solutions are offered in this phase. To oppose too much subdivision and thereby losing sight of the problem, the best rated components will be assigned into three whole concepts for further evaluation in synthesis II as part of a holistic approach. The best combination is taken to the final concept in synthesis III.
As a start, a morphological map of the function analyses is described to allow abstract thinking and therefore restricting limitations in the brainstorm process.

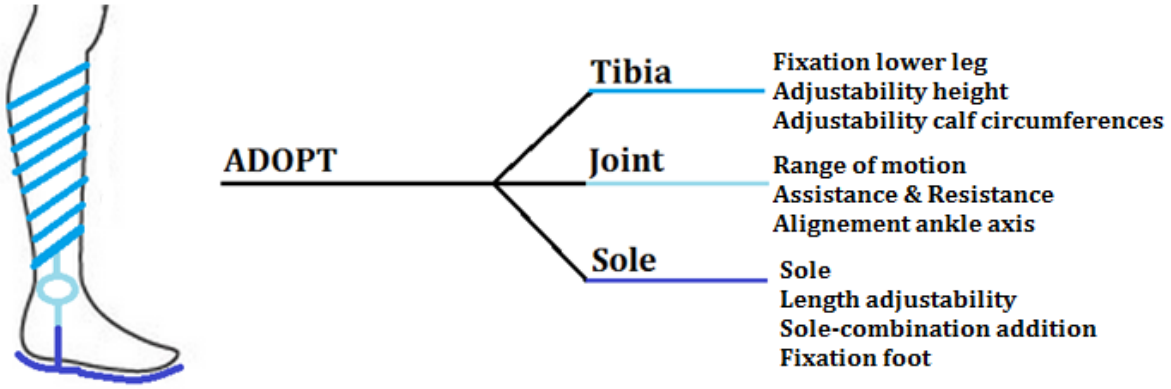
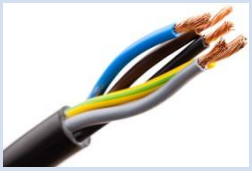
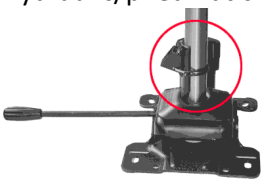
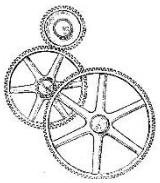
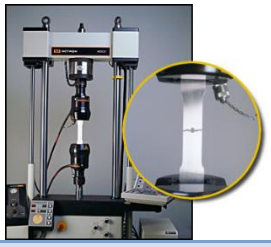


Figure 1

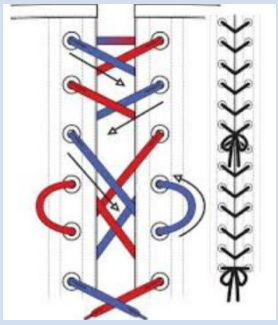
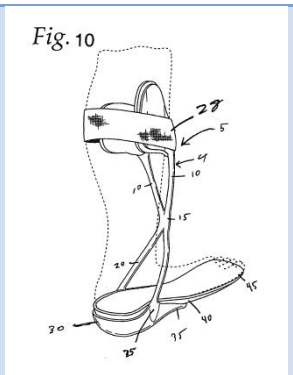
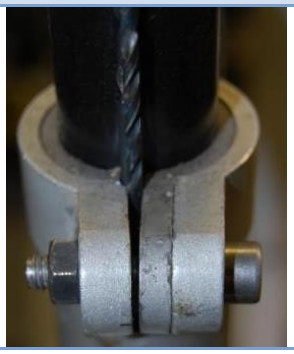
Morphological map Function analysis

To prevent any limitation in creativity, it may help to think about the problem as vague and abstract as possible. Therefore, the sub functions of the ADOPT are described first instead of directly focussing on the ADOPT. The sub functions described in the function analysis in the thesis are material connection, material transport, information transport, information storage and energy storage, of which the main function of the ADOPT is material transport as its length adjustability is a characteristic that distinguishes the ADOPT from an usual AFO (1). The table below shows first ideas to fit the sub functions.

Connect	Material Transport	Information transport	Information storage	Energy storage
Duct tape 	Rail system 	Electric wire 	Hard drive 	Battery 
Tyraps 	Hydraulic/pneumatic 	Mechanical 	USB 	Material strain 
Stitching 	Fishing rod mechanism 	Trial 	Reading device 	Convert into other energy 
Hook-and-loop fasteners 	Screw-thread 	Wireless signal 	Remember 	Spring compression 
Magnet 		External sensors 	Write it down 	Flywheel principle 
	Gears 	 Sound signals		

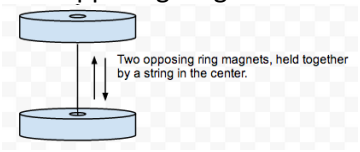
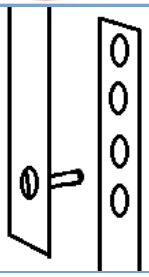
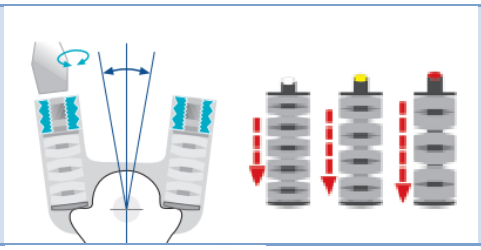
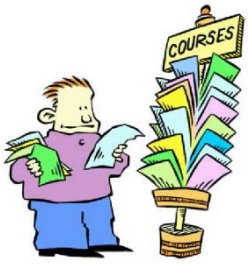
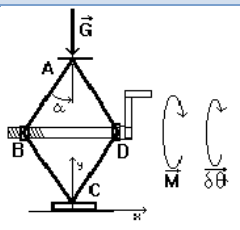
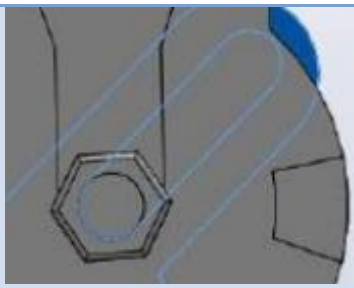
Tibia

Below is a morphological map describing the functions of the tibia component. It is divided into fixation of different calf circumferences, adjustability in height and its support for the tibia itself. Next to that they are numbered for later reference.

	Fixation of different calf circumferences	Adjustable Height	Tibia Support
1	Velcro straps 	 By separating the ventral support plate, it can be adjustable in height	
2	Skeeler mechanism 		
3	laces 	Making additional top parts that fit on top of each other like puzzle pieces 	
4			

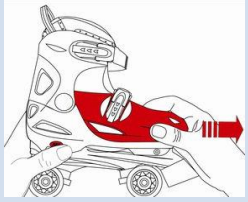
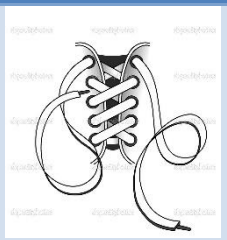
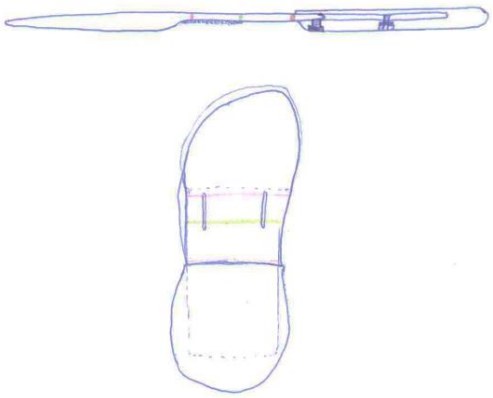
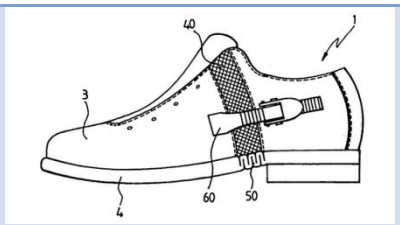
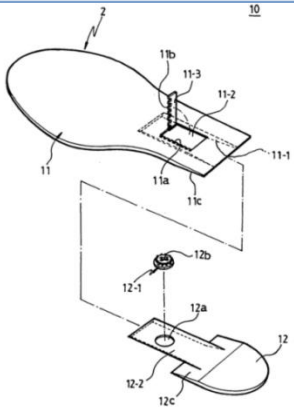
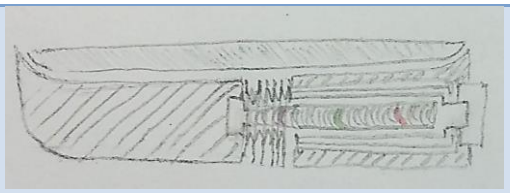
Joint

The joint is divided into range of motion, assistance resistance and the ankle alignment. To create multiple possibilities for each sub function, a morphological map is composed, as seen below. These are numbered as well for later identification.

	Range of motion	Assistance&Resistance	Ankle alignment
1	 This joint controls range of motion and is commonly used in knee braces	 Same joint used in prototype, acts on springs	Insoles of different thickness 
2	 Already in use for AFO's	Two opposing magnets 	
3			
4	 Special courses for the patient		
5			

Sole

Length adjustability, sole combination addition and foot fixation are the sub functions of the sole. They are displayed below in a morphological map together with numbering for later reference.

	Sole with length adjustability	Sole combination addition	Fixation
1			
2			Hook-and-loop fasteners 
3		Making a hook that can fit in a slot 	Skeeler mechanism 
4		Special sole pockets where additions can be slipped in 	External fixation 
5			Elastic straps 

Rating

Weighing factors

To review the concepts that have been made, they will be rated based on the requirements stated in the thesis (1). The requirements can be divided into sub groups, which are design, pricing, safety, functioning and use. These subgroups have been rated to evaluate the importance of the requirements in relation to each other. This rating was done by including each stakeholder to enclose all interests of those involved. Each stakeholder has a weighing factor according to his or her involvement with the key problem. The clinicians are given 7 votes because one clinician treats multiple patients. Next to this, the clinician is the specialist in the discipline where the problem occurs. The priorities of this group are safety, because the situation has to improve, use, since the clinicians have to work with it, and design, because if it does not give useful information it will not be used. The patient is given 6 votes because he or she has to live with the consequences of the given treatment. These stakeholders are most concerned with safety and design, as their priority is better healthcare. 5 Votes have been given to the manufacturing industry, since the production of the concept will not be realized without them. The priority of this industry is also safety, but pricing is an important factor too as otherwise it will not sell and therefore no profit. The biomedical engineers have 4 votes because they are the specialists in the discipline of how to achieve given goals by their design. Biomedical engineers have high priority for safety and design, but little for functioning because some maintenance is acceptable if the product is perfect in other key aspects. The hospital receives 3 votes because it will buy the design, but has little to do with the problem directly. Because of this, hospitals have high priority for safety and pricing. The next group of stakeholders is insurance. This is because not optimal care can result in other health problems which will be covered by insurance. However, other than these extra costs to cover extra health problems, the design has little consequences for the insurance since it still will pay for the patients AFO, thus resulting in 2 votes with most interest in safety and pricing, since otherwise it will not be bought and used. Society has only 1 vote because it is not directly in contact with the problem, although it cannot be left out because this group is essential for product acceptance. Priorities of the society are at safety and pricing, since indirectly society will also indirectly pay for the design because the hospital will charge the buying price of the ADOPT through higher healthcare costs.

The individual ratings for the weighing factors based on the described rating fashion above can be found in Annex 1 of which the results are shown in table 1. The ratings of the offered solutions can be found in Annex 2, of which the results are shown below per main section of the ADOPT.

Table 1

Design	Pricing	Safety	Functioning	Use
0,221851	0,169454	0,270903	0,133779	0,204013

Rating

Tibia

In this paragraph the rating for the solutions concerning the tibia section of the ADOPT are discussed. The complete rating can be found in annex 2 'Tibia' and the final results are listed in table2 below under their reference numbers.

Table 2

	1	2	3	4
Fixation	4,284195	3,689821	3,973416	3,014236
Adjustable height	4,401424	3,411972	3,28531	4,026584
Support	4,387702	4,387702	3,549095	4,558357

For fixation, Velcro straps are a commonly used fixation technique and can also be used for the ADOPT. Fixation like in rollerblades is a trickier to achieve but saves more time than the more achievable laces. The fourth option will be left out for the upcoming phases due the limited calf circumferences it can hold. Adjustability in height is most achieved by the first and fourth option. For the support of the tibia only the third option is left out because it is not unilateral while the other options do provide this key aspect, as bilateral has a tendency for internal rotation as seen in the current prototype .

Joint

The solutions for range of motion, assistance & resistance and ankle axis alignment are rated in annex 2 'Joint'. The end score of each solution is shown in table 3.

Table 3

	1	2	3	4	5
Range of motion	4,431953	4,104365	4,481434	2,472773	3,441643
Assistance & resistance	4,401424	3,027957	4,45545	4,325101	3,168082
Alignment ankle axis	4,415145	4,230769	3,932852	3,812623	4,558357

Because the joint used in the ADOPT prototype provided both range of motion and assistance & resistance without problems, it will also be used in this design. For alignment, the fourth option will be left out of further consideration due low achievability. The second option is a limited form of the fifth solution and therefore also left out.

Sole

The total rating of the solutions offered for the sole sub-functions can be found in annex 2 'Sole'. The end score is represented in table 4.

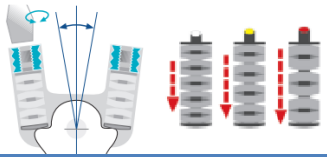
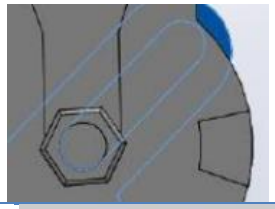
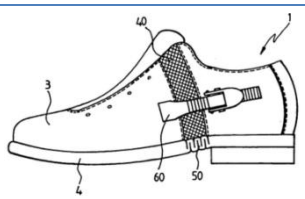
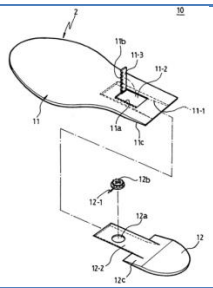
Table 4

	1	2	3	4	5
Length adjustability	3,706629	4,310779	4,170655	4,073836	3,729526
Sole combinations	4,558357	4,688706	4,103507	4,140125	4,544035
Fixation	4,230169	4,620958	3,946574	2,124262	4,688706

Due low achievability, the first and last and fifth option for length adjustability can be left out of further consideration, leaving the second, third and fourth option as possible solutions for length adjustability. For sole combination addition, the first and second are very similar. Because for the second option additional soles already exist, it is the option that will be used. The fourth option will not be evaluated further due limited addition possibilities. Lastly, foot fixation is most achievable by laces, Velcro straps or elastic straps.

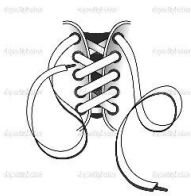
Concepts

Taking the ratings into account, the concepts described below will be taken to phase II of the synthesis. The three best rated solutions per main function are combined into three complete ADOPT designs. These three designs are candidates for replacing the design of the current ADOPT prototype. In the table below the components that will be combined are shown as they were in their morphological map. In the section following the morphological map, their complete design is drawn and explained.

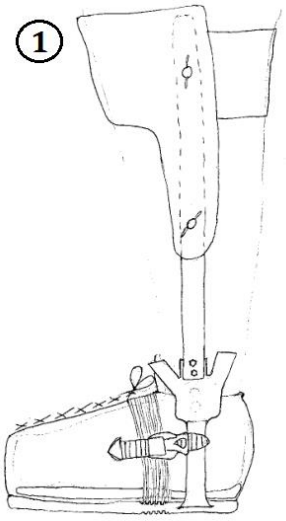
Concept:		1	2	3
Tibia	*Support*			
	Height adjustability	By separating the ventral support plate, it can be adjustable in height		
	Fixation	Velcro straps 		
Joint	*Range of motion*			
	Assistance& Resistance			
	Alignment	 Slipsoles		
Sole	*Length adjustability*			

Sole combinations

Fixation

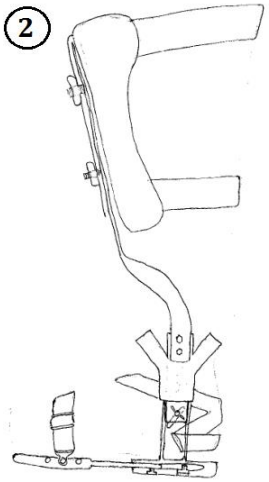


Concept 1



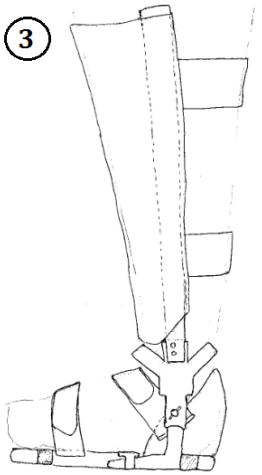
The ventral tibia support covers $^1/_4$ of the lower leg and part of the supporting rod. The lower leg is fixated in this support through a single Velcro strap. The tibia support can slide over the supporting rod and is fixated by butterfly nuts. The same hinge is used as done in the prototype, meaning the NeuroSwing is used for range of motion and resistance & assistance. The hinge itself is fixated at the height of the highest ankle axis. The alignment of the ankle is possible through insoles of multiple thicknesses. The foot compartment consists of a shoe, which fixates through laces. The sole is extendible through screw thread processed in the sole, together with a buckled section of the sole. By turning the screw, the buckles section allows sole elongation. Any addition concerning sole-combinations can be clicked on through clipping on the side of the sole.

Concept 2



The tibia support is placed ventral and covers $^1/_2$ of the lower leg with fixation through two Velcro straps. The supporting rod slides into a slot on the front of the tibia support and is fixated through butterfly nuts. This supporting rod is positioned ventral proximally and medial distally. It is attached to the NeuroSwing, as done in the ADOPT prototype. The ankle axis alignment is done in the same fashion chosen in the prototype design; a bolt and butterfly nut connect the lower bar to a rod connected to the sole. This rod contains a slot, allowing the joint to be adjustable in height and also some lateral shifting. The sole itself consists of two compartments of which one slides into another. Foot fixation onto the sole is chosen to be done through elastic straps. Any sole-combinations can be clicked on through gaps in the sole-bottom and fitting nods on the sole-additions.

Concept 3



The tibia support gives ventral support and covers $^4/_5$ of the lower leg. It is fixated to the lower leg by two Velcro straps. The supporting rod slides into the tibia support through a slot. The rod is attached to the NeuroSwing as well. The bottom beam of the NeuroSwing is curved to fit the allocated uni-rail attached to the sole, allowing adjustability in height to ensure alignment to the ankle axis. The

sole consists of two parts that fit like a puzzle with fixation through screws. The anterior part can be exchanged dependent on the needs of the patient. Fixation of the foot is made possible by a heel cup and Velcro straps. When necessary, sole-combinations can be added by sliding them into the allocated elastic straps surrounding the sole

Synthesis II

In this phase, the three concept are described in more detail, the dimensions and the minimal needed strength is calculated. Certain materials are allocated to the individual components and their sterilization methods are analysed, as it hygiene is an important factor. Failure Mode and Effect Analysis (FMEA) is performed: a list of risks is listed, together with the likelihood and its impact, making a priority score for each risk. Being able to analyse risks and think about future risks gives for better anticipation or even prevention of these risks. Also TRIZ is performed; it is a Russian acronym for "Theory of Inventive Problem Solving". This describes a method to solve risk-creating problems in a way that opposes 'psychological inertia'. Psychological inertia happens when assumptions are made about the problem, the solution or the resources and opposes creative thinking which is needed to solve the problem. For this theory over 2.8 million patents are studied in order to find patterns that predict breakthrough solutions. These solution of multiple industries and studies are put into general solutions that can be used for basic problems. In this paper, focus will be on TRIZ solutions for technical contradictions, which are most commonly engineering trade-offs. Next to TRIZ and FMEA, a Finite Element Analysis (FEA) is done for the tibia support and different designs for the supporting rod. This means the design is divided into a mesh for evaluation. Each element of this mesh is programmed to contain properties of selected material, like density and Young's modulus, which determines how the element will react to given stress. All the reactions of the elements combined give information about the reaction of whole design to an anticipated stress.
At the end of this phase, the three concepts will be rated again using the same method and weighing factors as done in synthesis I. The best composition will be taken into synthesis III.

Concept 1

Detailing

The supporting rod, displayed in orange in figure 2, should not come above the fibula head (2). Taking into account where the tibia ends in the ankle and where the supporting rod is fixated in the joint, the supporting rod has a maximum length of 29.78cm, see figure 3 on the following page. The width of the rod is 2cm to fit it in the joint (3). The thickness of the rod is not is not bigger than the supporting rod of the prototype; a 0.2cm rod in a 0.6cm shaft. Thus the supporting rod is maximal (0.2+0.6)/2= 0.4cm in thickness.

The bolts and butterfly nuts play a role in relaying the force created by the body. The bolts run through the rod and the tibia support, with their widening at the tibia side and the screw thread faced outward so they can be fastened by the butterfly nuts. The diameter of the widened section is 1.5cm, which is 75% of the supporting rod, to ensure good transfer of the acting

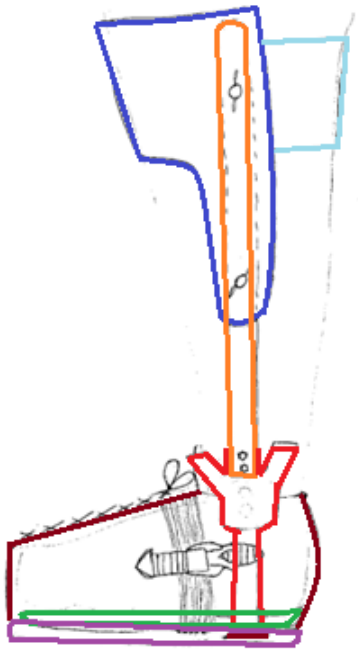


Figure 2

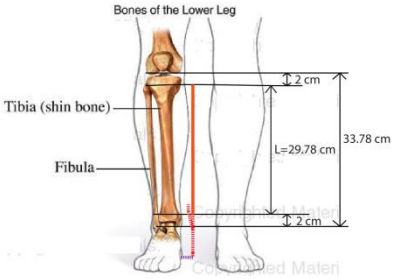


Figure 3

forces. The diameter of the section running through the rod and tibia support is 0.5cm.

The broad part of the support of the tibia, dark blue in figure 2, covers ¼ of the lower leg, making the height 8.45cm. It covers half of the biggest calf circumference, thus is 22.5cm in width (1). The thickness of this component is, as in the current prototype, 0.1cm. The longer section of the blue component covers 2/3 of the supporting rod, thus 19.85cm. For comfort, the lining with a pad is put over the tibia support section. This cover is 2cm bigger in length, height and width to ensure it fits over the rigid layer of the tibia support, but can be removed for cleaning.

The Velcro straps, light blue in figure 2, are 4cm wide (2). The length, given it goes through two slots on either side of the blue component which are 2cm from the edge, must completely overlap the smallest calf circumference of 35cm (1). This means that the length is 33cm. For the biggest calf circumference, 45cm (1), this would mean 3.25cm overlap on each side.

The joint, red in figure 2, can be fastened to the orange rod through 2 bolts, and to the shoe through the component shown in figure 4 in combination with screws which run through the sole with a length of 7cm and a diameter of 0.2cm. The length of the component shown in figure 4 is 7.4cm from the middle of the bore hole and its thickness 0.3cm (3).


Figure 4

The stretching compartment is made of Lycra, which can stretch 500% (4). The difference in foot length between the biggest and smallest foot size is 5.5 cm (1). The minimal length of the section made from lycra is the difference between the biggest and smallest size divided by its stretch capacity, thus the minimal length is 1.1cm. For the buckle, the restriction is that the minimum length of the strap is 5.5cm in order to be able to cover the compartment when fully stretched, plus 1cm to be still able to hold onto it, thus resulting in a total of 6.5cm.

The sole, see figure 5, is divided into three sections; the frontal section, the length adjustable section and the heel section. The length of the adjustable section consists of a slot with the cross section of a screw thread on either side with one side connected to the forefoot and the other to the heel section. In between is a screw as shown in figure 5. When the screw is turned, both sides of the slot are moved in opposing directions. The total length of this section is dependent on the amount of length that must be added, which is 5.5cm, and the radius of the screw used. Since motion of the screw moves both sides of the sloth in opposite directions, the length of this section is 5.5/2+screw diameter. Taking 0.5 cm as radius makes this section 3.25cm. The width of the sloth is 1cm screw radius plus 0.5cm for screw-thread on either side, thus 2cm. To make sure the screw does not fall from the sloth, the diameter of the broader section of the screw is 1.5cm. The sole material in this section is bulged. Taking two rounding's per centimetre gives a total of 6.5 rounding's and a maximum material thickness of 0.5cm.

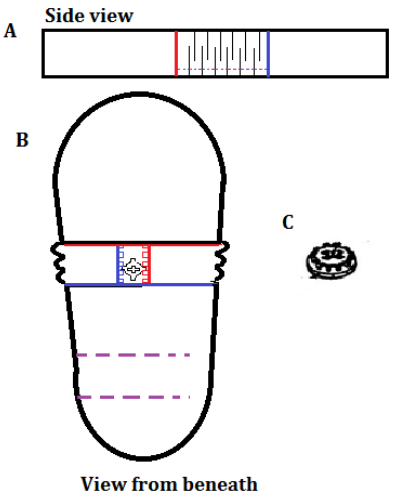


Figure 5

Concerning the frontal and heel section, it should give support to two times $^1/_3$ of a foot with a length of 29cm, making the minimal length of each section 9.67cm (5). In this case, the smallest size is 23.5cm (1) minus the adjustable section, which leaves $9.0cm$. This differs 0.67cm from the minimal needed length, which can be accepted. The thickness of the sole is

maximal 0.5cm, as determined by the adjustable section

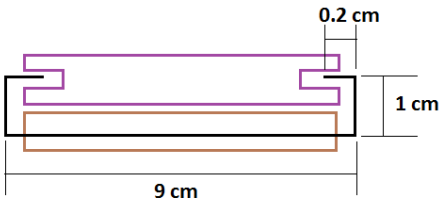


Figure 6

The sole additions can be clipped on, as seen in figure 6. The material connecting the sole and the sole addition is able to bend under force in order to fit the addition on top of the sole, but spring back into its original shape in order to keep the sole and its addition connected. This rod only connects sole additions to the outsole of the shoe and therefore must be able to carry the weight of the addition without bending and withstand the compressive forces but does not play a significant role in the processing of the forces created by the ankle momentum. The slot the rod clicks into is 2 cm wide, 1cm in depth and the height, given that the total height of the sole is 0.5cm, is 0.1cm, leaving 0.2cm at either side of the slot. These measurements make that the total length of the rod when pulled straight is 11.4cm, and 1cm in width.

For ankle axis alignment with the joint axis, insoles are used. These insoles have the same width as the sole itself, but differ in length. As the length is adjustable over 4cm, the length is in steps of 1cm.The height of the insoles is dependents on difference in height of the joint, which is set on the highest ankle, and the height of the actual ankle. As calculated in annex 12, the height of the outer malleolus is 0.0431 of the total body height. Using the heights used for tibia calculation, this means the height differs from 7.11cm to 8.19cm when using the same body lengths used for tibia calculation. Thus there is a total difference of 1.08 cm in malleolus heights (1). Distributing this over 8 sizes, this means insoles must be available in steps of 0.135cm. As this is very small, a thickness of at least 0.2cm is preferred. Given that the component shown in figure 4 is 7.4 cm and attached alongside the sole, which leaves a height of 6.4cm. This means the component should be custom made with a length of the highest malleolus plus the length of the part that covers the sole. Therefore, the component must be custom made to 8.69cm instead to ensure it can be set to fit the highest joint.

Determining Minimal Material Strength

As model for determining stress the supporting rod can be seen as a beam fixed onto the wall, seeing the foot as the fixed body. On the end of this beam a force is applied, causing the rod to bend by the created momentum. On the fixed end, the beam both is stretched on the plane on which the force is applied. This stretching force causes a momentum equal and opposite to the applied force and its momentum. A compressive force is generated on the face furthest form the applied force, which is equal and opposed to the tensile force but does not create a momentum as its arm goes directly through the pivot point. When the beam is relieved of the applied force it must form back to its original shape. For this reason the minimal needed Young's modulus is calculated for the supporting rod. As the forces are evaluated at the end of the rod, the moment of inertia is calculated for the end of the rod as well, meaning equation 1 will be for the calculation.

$$I = \frac{1}{3} * b * h^3 \qquad y = \frac{ML^2}{2EI} \qquad E = \frac{ML^2}{2*I*y}$$

Equation 1 Equation 2 Equation 3

The minimal Young's modulus can be calculated using equation 2, rewritten in the form of equation 3. Using a moment of M=188Nm and length L=0.2978m, Young's modulus E and the moment of inertia I with width b=0.004m and height h=0.02m. The maximal displacement will be y=0.005m. This makes that the minimal Young's modulus is 156.31 GPa.

For the tibia support different computations are made. As the material is stretched from the supporting rod and must afterwards spring back into place, also its Young's modulus must be defined.

$$\sigma = \frac{F}{A} \qquad \varepsilon = \frac{L' - L_0}{L_0} \qquad E = \frac{\sigma}{\varepsilon}$$

Equation 4 Equation 5 Equation 6

Taking the maximal displacement of 0.5cm in the sagittal plane means the new radius of the section becomes $\frac{45}{2\pi} + 0.5 = 7.66cm$ and the new circumference $7.66 * 2\pi = 48.14cm$. This means the new width of the section is 24.07cm as opposed to its original 22.5cm, making the strain 0.070, as calculated using equation 5. Using the strain and the stress, the Young's modulus of the material can be calculated by equation 5, resulting in a minimum Young's modulus of 0.11 GPa.

For calculation of the Young's modulus needed in the sole, it can be modelled as a beam fixed on one end, as the toes stand on this end fixating the sole, and the end of the forefoot can be viewed as a fixed support. In this model, the Young's modulus can be calculated using equation 3. The length L is the length of the forefoot , thus 1/3*0.235=0.07833m, and the total sole length is length a, making a=0.235m. The force acting perpendicular on the sole is F=215.91N, see annex 6. Calculating the moment of inertia with width b=0.005m and height h= 0.09m gives that I=1.22E-6 m^4. Computing the Young's modulus by using these values in equation 3 shows that the minimal needed Young's modulus is 13.43 Mpa.

$$E = \frac{Fa^3(L-a)^2(4L-a)}{12yIL^3}$$

Equation 7

In rest, accounting for the bearing of the heel, the forefoot and the side of the foot, the maximal compressive forces are $\frac{1470.998}{5/6 * 0.09 * 0.235} = 0.0835\ MPa$.

Materialisation

- ***Tibia support***

- Rigid layer; Low Density Polyethylene (LD-PE);
  With a minimal Young's modulus of 0.200 GPa LD-PE is able to easily hold the required 0.11 Gpa. It is cheap, 0.50€ per kg, and it is resistant to high impacts. Its glass temperature is 110°C and its density is 0.92 g/cm3 (6) (7).

- Lining; polyurethane foam
  The lining of the tibia support is soft to ensure patient comfort. This can be achieved by polyurethane foam; this foam is used for in mattresses, cushioning and comfort (8) (9). Because of its open-cell structure it is very breathable. The base of this foam is polyol, isocyanate and water mixed together. The density of the foam is 0.084 g/cm3. To hold the foam cushion into place it is placed in a cover made of Lycra. Lycra can stretch up to 5 times its length and is therefore able to easily keep up with the deformation of the foam (4).

- Butterfly nuts &bolts; Aluminium

  To not add more weight than necessary, the butterfly nuts and bolts are made from aluminium. Taking alloy 356.0, its density is 2.69 g/cm3 , its Young's modulus is 72.4 GPa and its shear strength is 120 GPa. The melting point of this alloy is 555°C (10).

- ***Tibia fixation***

- Velcro straps

  Velcro straps are made from a polyester/nylon mix (11). To not limit the adjustability, the straps are double sided. For patient comfort, the loops, of the hook-and-loop fasteners, are on the tibia side. As advantages Velcro straps are quick, strong and cheap, but their tendency to gather dust and alike is a disadvantage

- ***Supporting rod***

- Stainless Steel Alloy 17-7PH

  The supporting rod has a minimum Young's modulus of 156.32 GPa, ruling a lot of plastics out. Instead, steel can be used, in particular the stainless steel alloy 17-7PH in a TH 1050 state. This type of stainless steel has high strength and hardness. Next to that, it has good fatigue properties and good formability, making it a good choice for this rod with its custom shape and its endurance of repeated force . This alloy has a relatively high density of 7.65 g/cm3 and but a desirable Young's modulus of 204 GPa (12) (10). The melting point of this material is 1400°C, making it able to put the rod in the autoclave if necessary (13).

- Screws; Aluminium

  The screw is made from the same material as the butterfly nuts and bolts, meaning it is made from aluminium 356.

- ***Shoe***

- Upper shoe; cotton and Lycra

  The upper shoe is made from cotton. It is chosen because it does not stretch, it gives good fixation, it is already used in shoes and is washable. The extendible section is made from Lycra, because it is able to stretch up to five time its length but also shows resilience (4).

- Sole:

  Sole rigid sections; Polypropylene;

  The sole must have a Young's modulus of 16.23 MPa. Polypropylene co-polymer is a thermoplastic polymer which easily meets this requirement as it has a Young's modulus of 800 MPa. Its density is 0.902 g/cm3 and its melting point of 170°C, making the material autoclavable. Its costs are an advantage as it is relatively cheap (6) (14).

  Slot; Fibre Glass Reinforced Nylon 6-6;

  The material is best made of the material the supporting structure in between the insole and outsole. Originally it is made of steel, though this is durable and very rigid with a Young's modulus of 207 GPa, it can also add weight due its density of 7.85 g/cm3. A better candidate to replace steel is Fibre Glass Reinforced Nylon 6-6, as chosen here; its density is 1.35 g/cm3,

its Young's modulus is 7.6 GP which is higher than the required 16.23 MPa. The compressive yield strength is 140 MPa and its maximal temperature 90°C (15) (6).

Screw; Aluminium;

The screw is made from the same material as the butterfly nuts and bolts; aluminium 356.

Adjustable section; EthylVinylAcetate (EVA)

EVA is a very flexible material that has a strong tendency to move back in its original shape and is crack resistant. EVA also has a high friction coefficient, allowing grip for patients steps, and a soft touch like silicone (16) (17). Its density is 0.93g/cm^3, making this section 12.15g (17), and its absolute melting point 93°C.

Buckle; polypropylene

Because of its low pricing and low density, the buckle is also made from polypropylene.

- ***Insole***

  The insole is made from silicone. Silicone is already widely used in insoles to provide better pressure distribution, pain relief and shock absorbance. Its density is 1100 kg/m3.

Sterilization

To clean the concept, a number of actions is needed. The tibia support, its inner lining, the supporting rod, the joint and the shoe must be taken apart. The supporting rod can be sterilized in the autoclave together with the butterfly nuts, bolts and the screw used in the sole. If kept below 110°C the tibia support can also be put in the autoclave, though otherwise must be disinfected with alcohol. Because of the melting point of EVA, the shoe cannot be put in the autoclave. Instead, the shoe can be washed in a washing machine together with the Velcro straps. The inner lining must be washed manually and the joint as well. The insoles can be cleaned with alcohol.

Failure mode and Effect Analysis

For the total failure and effect analysis of concept 1, see the tab named 'Concept 1' of annex 9. The risks with a high rating are listed in table 5 below.

Table 5

ID number	Description	Likelihood	Impact	Priority Score
8.1	The expectations for supplier delivery are not defined	60	80	70
9.2	Customers do not accept the final deliverables of the project	50	80	65

The first risk is created by concept complexity, mainly because of its shoe and its many sections. Because the concept requires many custom made components and product adjustments, the likelihood of miscommunication rises. This could case either custom made products with the wrong dimensions causing the entire concept to not function, or rejection from manufacturers, causing the concept to not be made in the first place. To solve this, technical drawings can be made to specify every dimension of each component and simulations showing the strength needed in each compartment. The second risk is caused by the risk of clinicians not trusting the concept over their own experience. To overcome this, its benefits can be widely introduced and information can be distributed by marketing and education.

Concept 2

Detailing

The support of the tibia, blue in figure 7, must cover half of the circumference of the biggest calf ; 45 cm (1). This means that the width is 22.5cm. In length, it covers half of the tibia as well, resulting in 16.89 (1). The shaft for the supporting rod is also 16.89cm in length, and 2cm in width to ensure good fitting of the rod. The thickness of the slot is the same thickness of the supporting rod, which is maximal 0.4cm. The thickness of the tibia support and the layer forming the shaft is both 0.1cm. For comfort, there is an inner lining of which the dimensions are 2cm bigger to fit over the rigid layer and can be taken off for cleaning.

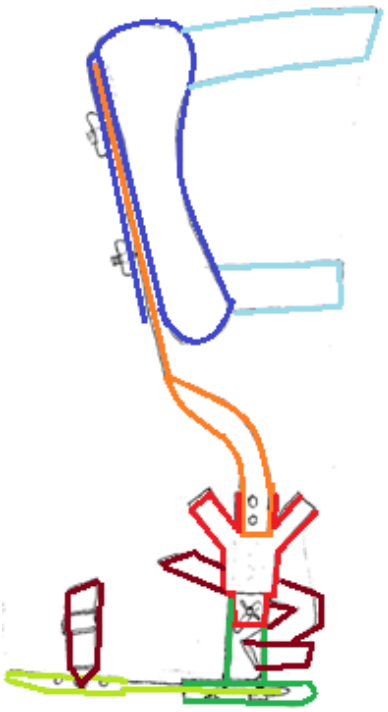


Figure 7

The Velcro straps run through slots on either side of the tibia supporting component. The upper Velcro strap must completely overlap at the smallest calf circumference, meaning its length is 33.0cm. For the biggest calf circumference this would mean 3.25cm overlap on both sides (1). For the lower one, taking 0.8 the calf circumference, it would mean 19cm, resulting in 1.08cm overlap on both sides for the biggest calf circumference.

The supporting rod, displayed in orange in the assembly in figure 7 and individually in figure 8, is 2cm in width to fit on the joint. It crosses over from medial to ventral with a 20° angle, see annex 3 (18). Taking the middle tibia circumference of 40cm, this would make the height of the twist 2.13cm (19). The total height of the rod is 29.78cm, and the length is calculated by adding 3.5 cm to fit the joint plus 6.219cm for the twist and 24.15cm for the straight ventral part, thus making the total length when pulled straight 33.87cm. The width of the supporting rod of the prototype is a 0.2cm rod in a 0.6cm shaft. Based on this, the maximal width of the support is 0.4cm.

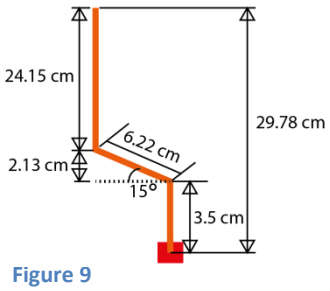


Figure 9

The two bolts run through the tibia support, the supporting rod and again through the tibia support, as the supporting rod is inside the shaft of the tibia support. At the tibia side the bolts are widened, at the outside they are secured with butterfly nuts that fit the same dimensions as the bolts. The diameter of the bolts is 0.5cm and the widened section of the bolts is 1.5cm to cover 75% of the width of the rod.

The joint is fastened to the tibia support rod through two bolts. The design of the bottom part of the joint is as shown in figure 9. This component is 7.5cm from the middle of the bore hole to the bottom, but should be 8.10cm since the maximal height of the rod is set by the minimal height of the ankle joint, which is 7.10cm and the sole thickness is 1cm. It will be fastened to the sole through a bolt that runs through a slot in the supporting rod of the sole and through this component, with a butterfly nut on the outside. The slot in the supporting rod of the sole is as wide as the bolt, which is 0.5cm, and 1.10cm high since the difference in height is 1.08cm, as calculated in concept 1. The total height of the supporting rod of the sole is 2.6cm due 1.10cm for the difference in height, plus 1 cm sole thickness and 0.5cm for slot closure.

Figure 8

The sole is consistent of two parts displayed in light and dark green in the figure 7. The heel

and the forefoot are each 1/3 of the entire foot, which will be the minimum lengths of the broad parts of the both compartments (5). Taking the biggest size, which is 45, gives that the length should be at least 9.67cm. Size 45 has a length of 29, while the smallest size, 39, has a length of 23.5cm, meaning only 5.5cm has to be extendible (1), resulting in a length of 11.75 cm for each broad part of the component. The extendible part should be at least 5.5cm, plus 3cm for overlap, thus 8.5 cm. The entire length of the dark green component is therefore 11.75 with a tunnel in it. This tunnel has the length of 8.5cm and 5.5cm in width. The length of the light green compartment is 20.25; 11.75cm plus an additional 8.5cm to fit the allocated slot in the heel section of the sole. Taking 1cm as thickness, the slot is 3mm, the bottom section is 0.3cm plus the thickness of the screw head, which is minimal 0.1cm, thus 0.4cm. The upper section therefore is the remaining 0.3cm. The circumference of the screws used to fixate the forefoot in the heel section is 1.0cm, of which there are three placed in a triangular fashion with a spacing of 2.5cm.

The sole additions stack in a Lego-like fashion. The dimensions of the three slot used have a depth of 0.5cm and have a radius of 1.0cm, positioned in a triangular fashion 2.4cm apart (20). The dimensions of the cylinders fitting in these slots are 0.5cm in height and have a 1.1cm radius. The friction caused by the volumetric strain due diameter differences of the cylinder and the sloth is able to withstand the gravitational pull on the additions, thus material with a higher coefficient of friction is desired on at least the outside of the cylinders.

The elastic straps must fit over both a foot with shoe size 37 and a foot with size 45. For the forefoot this means that it cover at least 60% of the circumference of the forefoot, in this case 13.70cm with a max of 15.75cm. Considering the fixation should be tight, the strap will cover 200% of the smallest foot when fully expanded. For a nylon strap, this results in the nylon being stretched for 190% at a length of 27.39cm. This means the length in a neutral situation is 14.42cm. For a foot with size 45, this translates to a length for the first cover being 15.75cm, which is stretched 190%, thus taking 8.29cm from the strap in a neutral situation and leaving 5.95cm that can stretch 11.31cm for a second cover of the foot. The strap fixating the heel is modelled like figure 10; connecting the instep of the foot, the sole and the heel, together with a heel strap. The length of the strap going over the instep and heel and through a slot in the supporting rod beneath the joint is the same length as the ankle circumference. For a tibia of 35cm, this is 14.78cm (1) (21). Giving that the elastic strap cover this twice when fully stretched, it means that the length in rest is $\frac{2*14.78}{1.9} = 15.56cm$. For a calf circumference of 45cm, this means the elastic strap covers the calf circumference for 127.8%. The height of the heel strap is 6.5cm, and the height of the strap fixating the strap around the ankle with the sole is 7 cm when fully stretched, thus 3.68cm. The width of all straps used is 4cm.

Figure 10

Determining Minimal Material Strength

The tensile strength acting on the tibia support is following equation 4, with F=628.89 N, see annex 5, and A= 0.001*0.1689. This results in a tensile stress of 3.72 MPa. Using same displacement in concept 1 and therefore the same strain, the Young's modulus of the material must be $0.053\ GPa$ as calculated by equation 6.

Seeing the dimensions of the supporting rod are the same as used in concept 1, the minimally needed Young's modulus to oppose generated forces is also the same. Thus, the minimal needed Young's modulus for the supporting rod is 156.31 GPa.

The Young's modulus necessary for the material used in the sole is found through the same model handled in the computations for concept 1 and thus also calculated by using equation 7. In this concept there is a force of 215.91 N, see annex 6, and the moment of inertia has a width of b=0.01m and a height of h=0.09m. This computation shows the minimal Young's modulus is 6.74 MPa. As calculated in concept 1 the maximal compressive force acting on the sole is 0.0835 MPa.

Considering the sole additions, volumetric strain and material friction make sure the sole-combinations do not break loose. To calculate the minimal needed relations, a computation is made in annex 8 of which the end result is shown in equation 8. For the sole-addition to not break loose, the material must fulfil this requirement.

$$\mu = \frac{4.58e6}{E}$$

Equation 8

Materialisation

- ***Tibia support***

- Rigid layer; PolyVinyl Chloride(PVC);
  PVC is a thermoplastic polymer made of a carbon and chloride blend. Though it is a lot stronger than required as its Young's modulus is 3.38 GPa for the required 0.053 GPa, it is very cheap, making it more achievable. PVC starts to decompose at 140°C and has a density of 1.58 g/cm3 (6).

- Lining; Cambrelle
  Cambrelle is a synthetic lining material that is generally used in leather outdoor shoes. It is able to absorb moisture; three and a half times its own weight. A very desirable feature is its prevention of bacterial growth and thus also odour (22).

- Butterfly nuts and bolts; aluminium
  The butterfly nuts and bolts used in concept 2 are the same as used in concept 1. Thus, these butterfly nuts and bolts are also made of aluminium 356, with its density of 2.69 g/cm3 , its Young's modulus is 72.4 GPa and its shear strength is 120 GPa and melting point 555°C (10).

- ***Tibia fixation***

- Velcro straps
  As in concept 1, the Velcro straps are form a nylon/polyester mix (11). To ensure patient comfort, the Velcro straps are one-sided, with the first $^1/_4$ of strap being loops, the next $^1/_2$ hooks and the last part loops again, making sure that when it overlaps on both sides, loops are pointed inward and not the hooks, which would be less comfortable.

- ***Supporting rod***

- Carbon Fiber
  Carbon fiber is a material made from thin strands of carbon twisted together like yarn. This yarn can be woven once again. This structure allows the carbon fiber to be light weight but still able to withstand a lot of stress (23). Carbon fiber with a standard modulus has a density

of just 1.78 g/cm3 and a Young's modulus of 230 GPa, making this a very desirable material for the supporting rod. The maximum temperature depends on the resign. When epoxy is chosen as resin, the rod could be heated up to 300°C. Key aspects to keep in mind with this material are high material and production costs, plus the material does not bend when yielding but suddenly snaps (23) (10).

- ***Sole***

- Posterior and anterior component; Polypropylene
  Both sole components can be made from polypropylene. It is cheap and is able to withstand the required 8.12 MPa as its Young's modulus is 800 MPa. The compressive strength is 41.37 MPa, thus it can easily carry the needed 0.0785 MPa. The melting temperature of 170°C creates the possibility to sterilize the component (6) (14).

- Screws
  The screws used in the sole are, as are the butterfly nuts and bolts, made of aluminium 356. Meaning the density of the screw is 2.69 g/cm3 , its Young's modulus is 72.4 GPa and its melting point 555°C (10).

- ***Fixation straps***

- Elastic straps; Nylon, polyester and rubber
  As elastic straps for shoes made from nylon, polyester and rubber, it is most feasible to select these materials for the elastic straps. They also are cheap : €0.10 per 0.65m (24).

- ***Sole additions***
  For sole additions, the conditions of equation 8 must be met. Styrene butadiene rubber (SBR) does, with its minimal Young's modulus being 2 Mpa, meaning its friction coefficient must be at least 2.29. Depending on finishing, rubber has a static friction coefficient reaching from 1.0-4.0 when tested on solids. Its density is 0.940 g/cm3. Its service temperature reaches from -30°C up to 100°C (25) (26).

Sterilization

To sterilize the design, it must be taken apart first. The butterfly nuts and bolts, together with the supporting rod, sole components and screws can be put in the autoclave. When kept below 140°C the rigid layer of the tibia support can also be put into the autoclave, otherwise has to be cleaned with alcohol. The elastic straps can be washed in the washing machine together with the Cambrelle lining and Velcro straps. The sole additions must be cleaned with alcohol.

Failure mode and Effect Analysis

The total rating of the failure mode and effect analysis can be found in annex 9 with the tab 'Concept 2'. The risks rated with a high priority score are listed below in table 6.

Table 6

ID number	Description	likelihood	impact	Priority score
4.1	The project exceeds the budget allocated	70	60	65
8.1	The expectations for supplier delivery are not defined	50	80	65

9.2	Customers do not accept the final deliverables of the project	50	80	65

The first risk is the concept being be too expensive to realize. This is mainly because of its Carbon Fiber Reinforced Epoxy used for the supporting rod. To solve this problem, the material could be replaced by a cheaper material that meets the same requirements. The second risk is that the requirements for the deliverables are not clearly specified. Even though the risk is lower than for concept 1, it cannot be left out. This is also due sole complexity, as it has many adjustments. This can be solved by making technical drawings specifying all dimensions and have regular meetings with the manufacturing personnel. The third risk is clinicians not accepting the final product. Because it is new and not used before, it is possible the final product is not trusted over own experience. To give the clinicians experience with the final product, information about the design can be widely spread and models can be distributed or showed during information fairs.

Concept 3

Detailing

The component supporting the tibia, displayed in blue in figure 11, covers 4/5 of the tibia, meaning its length is 27.02cm. At the top it is 22.5cm to cover half of a calf circumference of 45cm, meaning an exes 4.59cm when a calf has a circumference of 35cm. At the end it is 13.25cm, meaning an exes 6.75cm for a calf circumference of 35cm (1) (19). The thickness of the rigid layer is 0.1cm. The inner lining is done by foam inside a cover which stretches over the rigid layer.

The upper Velcro strap must completely overlap at the smallest calf circumference, meaning its length is 33.0cm. For the biggest calf circumference this would mean 3.25cm overlap on both sides (1). For the lower one, taking 19.75cm as circumference (19), it would mean the length of the Velcro strap is 21.0cm, resulting in 1.875cm overlap on both sides when the calf has the largest circumference.

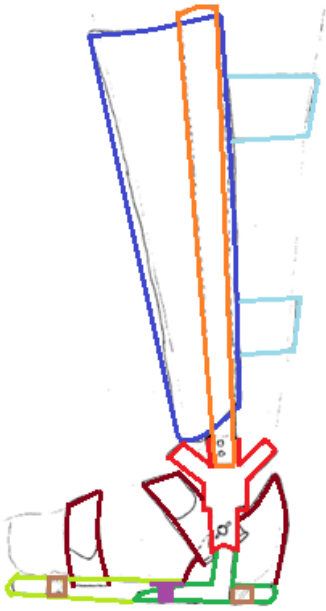


Figure 12

The supporting rod, shown in orange in figure 11, is 29.78cm, as calculated in the detailing of concept 1. The width is 2cm to fit the joint, and the thickness is, as is also determined in concept 1; 0.4cm.

The joint can be attached to the tibia supporting rod through two bolts. A uni-rail is made from the bottom section of the joint to connect it to the supporting rod that leads to the sole. To achieve this, the short version of the River Attachment Technique, see figure 12, is used to make it into custom rails as seen in figure 13, with a length of 1.08cm for the difference in ankle height plus a minimum overlap of 2cm, thus 3.08cm. The circumference of the arc is the width of the rod, which is 2 cm. This makes that the diameter of the sole supporting rod is $1.273cm$. The height of the supporting rod leading to the sole is 7.10cm, as that is the minimal height, to ensure good function of the rails.

Figure 11

The sole consists of two parts that fit on each other like a puzzle, showed in dark and light green in figure 11. Given the biggest foot with length 29cm (1), the two parts each are 14.5cm of which the outer 9.67cm is levelled and the overlapping is processed in the inner 4.83 cm. The smallest size would acquire the light green

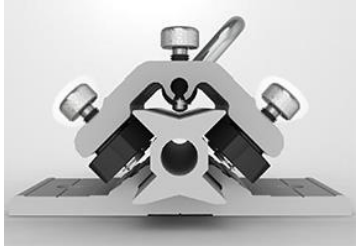


Figure 13

sole component to be in total length of 9cm of which the first posteanterior 4.83cm is made to fit the overlapping and the other 4.17cm is straight.

The straps fixating the sole additions, displayed as light brown in figure 11, cover the entire sole circumference in a relaxed state, meaning its length is 2*(9+0.3)=18.6cm. Making these straps from spandex would mean the possibility of adding a sole with a thickness of 1.5cm (4).

The heel cup is 7cm high and attaches to the levelled section of the anterior sole component, shown as green in figure 11, meaning the total length is 9.67cm (5). For the rounding shape of the heel, half of the width is taken, thus 4.5cm (5). This means that the total width of the heel cup when flattened is 24.4cm.

The Velcro strap fixating the forefoot covers 200% of the smallest foot, which translates in a length of 27.4cm in length, creating 174% overlap in case of a circumference of 15.75. For the strap fixating the heel, taking into account that it covers 200* of half the heel diagonal circumference; 31.50cm, which results in a 111.6% coverage in case of shoe size 45 with a heel diagonal circumference of 35.56 cm.

Determining Minimal Material Strength

The tibia support undergoes again tensile stress. Using equation 4 with F=628.89 N and area A= 0.001*0.2702 shows the magnitude of this stress is of 2.33 MPa. This means the Young's modulus is $0.033\ GPa$, as calculated with equation 6.

The supporting rod has the same dimensions as the supporting rod in concept 1 and thus the minimal needed Young's modulus can be calculated through the same computation. Therefore, the material needs to have a minimal Young's modulus of 156.31 GPa, as is the same for concept 1 and concept 2.

Calculating the minimal needed Young's modulus for the sole is done in the manner as used for the computations in concept 1, but for this concept the moment of inertia has width 0.003m and height 0.09m. This gives that the Young's modulus is 22.47 MPa. The pressure in rest is, as calculated in Concept 1, has a magnitude of $0.0835\ MPa$.

Materialisation

- ***Tibia support***

- Rigid layer; High Density PolyEthylene (HDPE)
  HDPE is a petroleum-based thermoplastic polymer with a high strength to density ratio with its Young's modulus being 600 MPa (7). This makes it tough material that shows good impact resistance. The high density makes also for very little water absorption, which is desirable in order to keep the component clean. The density is 0.96 g/cm3 and its maximal operating temperature 82 °C (10) (6) (27).

- Lining; latex foam, cotton
  Latex foam is a light weight soft foam of vulcanized rubber, commonly used in mattresses. Originally, it is made of latex coming from the trunk of rubber trees, which is a polymer of isoprene. It is structure is open-cell, making it very breathable. It is anti-microbial and also has resistance towards dust mites (28). One disadvantage is its cleaning: it must be done manually in order to not damage the foam (29). Another point for consideration are latex

allergies, though it is not very common, it cannot be overlooked. The cover, to keep the foam in place, is made of polyester.

- Butterfly nuts and bolts; aluminium
  The butterfly nuts and bolts used in concept 3 are the same as used in concept 1, meaning they are made of aluminium 356. The density of this alloy is 2.69 g/cm3 , its Young's modulus 72.4 GPa and melting point 555°C (10).

- ***Tibia fixation***

- Velcro straps; Nylon/Polyester
  As in concept 1, the Velcro straps are form a nylon/polyester mix (11). The first half of the strap are hooks and the second half are loops to ensure most hooks are pointed outward and most loops are pointed inwards, for patient comfort.

- ***Supporting rod***

- Cast Iron Grade 80-55-06
  Cast Irons are often used as a replacement for plain carbon steel which causes cost reduction for parts that need much processing. They contain very small round nodules of graphite in a solid metal matrix, which makes the material easier to process without adding of lead, sulphur, bismuth or phosphorus. The matrix of cast iron grade 80-55-06 is ferritic/pearlitic. The material has a Young's modulus of 172 GPa and a density of 7.10 g/cm3. Its melting point is 1120°C, making the rod easy to sterilize (30).

- ***Sole***

- Rigid layer; Ultra High Molecular Weight Polyethylene (UHMWPE)
  Polyethylene is a thermoplastic polymer that is most commonly used plastic. As UHMWPE the polyethylene contains very long molecules, making for the high molecular weight. These long chains make for strong Vander Waals binging which makes it tough and wear resistant. Its density is 0.93 g/cm3, its Young's modulus 551.6 MPa and its compressive strength 2.1 MPa. The melting temperature of UHMWPE is 130.56°C, though it is recommended to not work with it above 82.22°C (10) (6) (31).

- Screws; Ultra High Molecular Weight Polyethylene (UHMWPE)
  The screw is also made from UHMWPE, as it is tough and wear resistant (10) (6) (31).

- Heel cup; Rhenoflex Rx 3002
  The heelpiece in shoes is reinforced with stiffer material than the material used in the upper shoe. Making the heel cup of this concept from the same material would mimic normal shoes, which is desirable as patients encounter the same in normal shoe wear. Rhenoflex Rx 3002 is a thermoplastic material often used in orthopaedic footwear. It is easy to modulate and mouldable between 120-150 °C (32) (33).

- Heel cup lining; viscoelastic memory foam
  Viscoelastic memory foam is a specialised type of polyurethane foam focussed on slow recovery. When weight is applied, it wraps around this weight until it is released again, after which it will slowly recover into its original shape. Its structure is semi-closed, meaning it is

mostly open cell, but some cells are closed, making it less breathable. The material is very good in relieving pressure points and cushioning. The density of memory foam is 0.080 g/cm3. Disadvantages are its sensibility to humidity and temperature influences. Also, soaking in water damages the cell structure, making it not machine washable (34) (9).

- ***Straps***

- Velcro straps; Nylon/Polyester
  The Velcro straps used for fixation of the foot are made the same way as done for tibia fixation.

Sterilization

For the concept to be cleaned, it must be taken apart first. When kept under 120°C, the supporting rod can be put in the autoclave together with the butterfly nuts and bolts, otherwise it must be cleaned with alcohol. The tibia support, the sole, the screws and heel cup must be cleaned with alcohol. The Velcro straps and cotton cover can be machine washed, but the latex foam and viscoelastic memory foam must be washed manually.

Failure mode and Effect Analysis

The total rating of the failure mode and effect analysis can be found in annex 9 under the tab 'Concept 3'. The risks with the highest priority score are listed below.

Table 7

ID number	Description	likelihood	impact	Priority score
4.1	The project exceeds the budget allocated	70	60	65
9.2	Customers do not accept the final deliverables of the project	50	80	65

The first risk is the pricing of the final product. Because of the Fiberglass reinforced epoxy, the final product will be more expensive. To solve this, the material used for the supporting rod can be changed to a cheaper material. The acceptance of the final product by the clinicians is the second risk. Since it is new, it will be hard to make a habit of using the final product instead of the current method. To make the clinicians more familiar with the product, work should be put into advertising and distributing of models in lectures.

Finite Element Analysis

To compare the load baring components undergoing most force, which are the rigid layer of the tibia support and the supporting rod. For the tibia support the three current designs are used while for the supporting rod three new concepts are introduced in order to find optimal ADOPT stabilization. The designs are analysed in Solid works simulations and compared in order to find the optimal design. The results are discussed in the text below. In order to compare only the designs, the material is set to be the same, even though in the materialisation of each concept a different material was chosen. The tibia support is set to polypropylene copolymer and the supporting rod to plain carbon steel. Focus will be on comparing Von Mises stress, strain and displacement of the compared components. Von Mises stress is based on distortion energy: the energy required for shape deformation of the object. When the distortion energy is higher than the yield strength of a material, the construction

will fail. This form of stress is more favourable to compare as in this situation not only normal stress occurs but instead total deformation.

Supporting Rod

Because the supporting rod from concept 2 is dependent of the leg circumference, it is unfavourable for the ADOPT as it must be applied to a range of circumferences, therefore its design is left out of further consideration. Since a beam, as used in the other concepts, suffers from internal rotation, focus in this section lies on finding a better design for the rod. In order to do this, the three designs displayed in figure 14 have been analysed using Solid works. Starting on the left of figure 14, there is a cylindrical rod with a circumference of 4.8cm at the top to ensure smooth transition into a rectangular at the bottom with the dimensions to fit the joint. Next, in the middle, is an I beam configuration, with a u beam configuration at the end in order to fit the joint, with the dimensions of the slot being 0.1*1.0cm. The last rod is a U-beam with a 2mm groove with a width of 1cm. Images of the measurements together with the data points can be found in annex 11, the most important values are summarized table 8. For illustration, images of the evaluation of the I-beam under the applied force can be seen in figure 15.

Figure 14

Table 8

	Von Misses stress max (E8 N/m2)	Maximal strain (E-3)	Max deformation (mm)	Maximal stress during torque (N/m2)	Maximal displacement during torque (mm)
Cylinder	5,628	1,817	3,246	3,60E+09	3,182
I-Beam	6,535	2,309	3,371	1,70E+02	1,546
U-beam	7,93	2,59	3,46	5,07E+01	5,407

Under normal load, the maximal Von Mises stress can be found just above the joint, as the rod is fixated there and thus it is where the motion is relayed in fixation. The cylinder displays the least stress and the U-beam the most, the I-beam is right in between these values. Maximal strain is also found above the joint as that is where the material is pulled from its fixation. Like with the Von Mises stress, the cylinder performs best and the I-beam performs average. Concerning displacement, the maximum value can be found at the top as that is where most motion can occur since it is furthest from fixation. The cylinder has least deformation and the U-beam the most, although the values do not differ significantly. As internal rotation is a key aspect, it cannot be left out in this evaluation of the designs. When a torque with a moment of 188 Nm is applied, the cylinder has worst performance. This is because in the cylinder design the forces caught by the cylinder are still transferred to a rectangular rod, which is prone to show internal

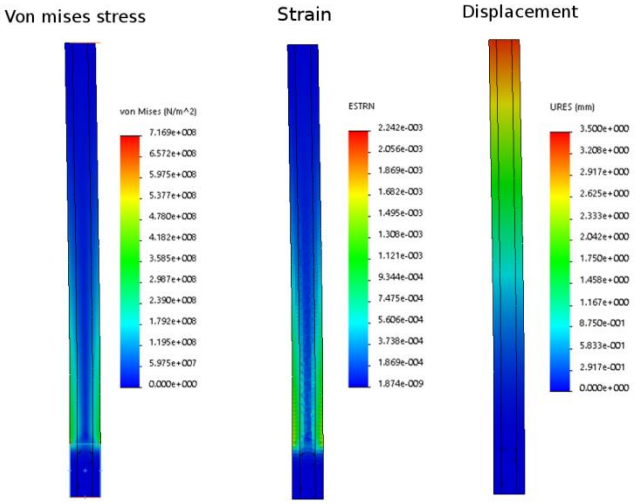


Figure 15

rotation. This causes the maximal stress to be very high when comparing to the U-beam and I-beam. Instead, the I-beam shows best performance under these conditions and the U-beam the worst. For displacement during torque, the U-beam shows worst performance and the I-beam showed best performance. Since torque is a key aspect and it did not underperform under normal stress, the I-beam is best used in the ADOPT. When choosing this design for the ADOPT, the new needed Young's modulus can be calculated by using formula 1 and 2. The new moment of inertia can be calculated by simply subtracting the momenta of inertia of the two grooves from the total beam. As the dimensions of the two grooves are 0.001m in width and 0.01m in height, the new moment of inertia is 1.0E-8. The necessary Young's modulus then becomes 166.72 GPa.

Tibia support

In this section the tibia support from each concept is evaluated using Solid works simulations. Once again Von Mises stress is used, together with strain and deformation. Their dimensions are as explained in the detailing of each concept and their fixation is through areas mimicking the Velcro straps and the fixation points to the supporting rod. The force applied is 628.89N, see annex 5. The values of the measurement can be found in annex 11, but are also listed below in table. For illustration, the evaluations of the tibia support of concept 1 with force appliance are showed in figure 17.

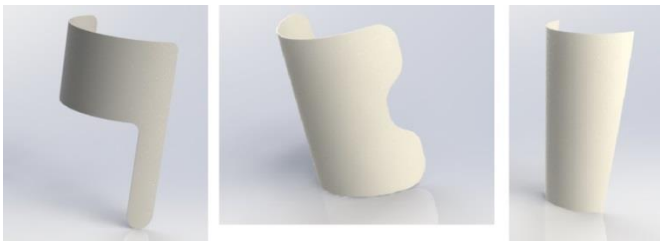


Figure 16

Table 9

	Max von Mises (E+007 N/m2)	Max strain (E-002)	Max deformation (mm)
concept1	2,518	1,879	2,326
concept2	1,612	1,244	1,511
concept3	3,485	2.493	6,389

The Von Mises stress is maximal around the fixation points as it is where the transference of forces happens. Concept 3 has the greatest stress in this comparison, as it has a long area for support, but the distance between the fixation points is high compared to the other two concepts. Concept 1 has the fixation points relatively close to each other, but a very small area over which the force is distributed. This causes for not as much stress as concept 3, but higher stress than concept 2, as concept 2 has a greater area than concept 1 but the fixation points are not as far apart as concept 3. The same can be seen in strain for all concepts: the strain is maximal around the fixation points, causing concept 3 to perform the worst and concept 2 to perform best. Because of the high distance between the fixation points, the simulation showed concept 3 to have a tendency to break loose, causing a

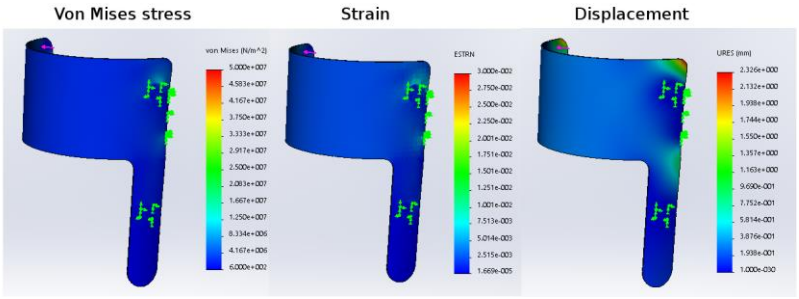


Figure 17

deformation of 6.389mm. Because of its relatively small area, concept 1 has a deformation of 2.326mm while concept 2 only shows a deformation of 1.511mm. Based on these evaluations, the tibia support of concept 2 is best used for the ADOPT. One adjustment can be made; the curves have showed to be very sensitive to stress and strain. Removing the curves from the design would strengthen the tibia support.

TRIZ

The ADOPT requirements cause design contradictions. As the concepts are very similar, their contradictions do not differ significantly, thus a general TRIZ analyzation is chosen for the complete ADOPT. In table 10 the contradictions accompanying the ADOPT design are listed together with the reference numbers of possible solutions. Each problem and the offered solutions are discussed below.

Table 10

	improving	worsening	Solutions
1	Area of stationary object	Weight of stationary object	30,2,14,18
2	Stress or pressure	Weight of stationary	13,29,18,10
3	Duration action of moving object	Strength	27,3,10
4	Stability of the objects composition	Use of energy by moving	19,13,17,24
5	Device complexity	Ease of operation	35,1,13,11
6	Adaptability or versatility	Device complexity	15,29,37,28
7	Device complexity	Ease of manufacturing	27,26,1,13
8	Ease to operate	Adaptability or versatility	1,16,7,4
9	Weight of stationary object	reliability	10,28,38
10	Area of stationary object	Device complexity	1,18,36
11	Strength	Weight of stationary object	40,26,27,1
12	Stability of the objects composition	Device complexity	2,22,26,35

1: Improving area of the stationary object VS worsening the weight of the stationary object:

The ADOPT should both be able to provide more area, in order to be able to be suitable for multiple sizes, but also must be light weight in order to not disturb patient gait in an undesired way. If the area of the ADOPT can be improved to fit a bigger size, it also means more material and thus weight is used. TRIZ offered the following solutions:

- 2: Extract; remove or separate a property form an object:
  This means for the ADOPT that the size adjustability can be separated from the ADOPT itself. For example this could be done by separating the ADOPT in a component next to the lower leg and the sole where the length adjustments must take place. This is already done in concept 3, but can be considered in concept 1 and 2.
- 14: Sphericality: replace linear parts or flat surfaces with curved ones or replace a linear motion with an rotating event:
  The sole could be made from a spring structure, making it easy to adjust length. The problem created would be device complexity, making this a non-viable solution for the ADOPT.

- 18: Mechanical vibration: set an object into oscillation
  By oscillating, material can elongate without use of more material. Difficulties with this is that the elongated area is constantly needed for support, thus oscillation is not an option.
- 30: Flexible membranes or thin films: replace traditional constructions with flexible membranes or thin films
  Replacing the sole with flexible membranes or thin films makes length adjustability more light weight, but would not provide the needed support for the foot. Since this is a key aspect of the ADOPT, this option does not provide a solution

2: Improving stress or pressure VS worsening the weight of the stationary object

To improve the stress the ADOPT can handle means using more material, resulting in more weight. Since weight is undesirable as it disturbs patient gait, improving stress too much would worsen ADOPT function. This can be said as improving stress while worsening the weight of the stationary object, as the ADOPT itself is stationary. The following solutions were offered:

- 10: Prior action: arrange objects so they can go into action in a timely matter and form a convenient position
  Certain preparations can be done to improve the amount of pressure per second in order to smoothen the process, for example teaching the patient how to walk cautiously. As AFO's are used in daily life where there are no preparations, this is also not an option for the ADOPT.
- 13: Inversion: make a moving part of the object or outside environment immovable and the non-moving part movable
  For the ADOPT, inverting the design would mean making the joint rigid and the sole and supporting rod flexible. This would provide a lot of properties given the all parts can be exchanged. The problem with this is limited storage to obtain the range of possible resistance and supporting properties and also the amount of settings per feature. This makes the solution not favourable.
- 18: Mechanical vibration: set an object into oscillation
  As described in the first contradiction, this is not a feasible solution for the ADOPT.
- 29: Pneumatic or hydraulic construction: replace solid parts of on object by gas or liquid, these parts can use air or water for inflation, or use air or hydrostatic cushions
  The spring can be replaced by a pneumatic construction. This would save weight, but add the problem of the linkage between resistance used and the actual prescribed AFO and worsen device complexity, making this a possible but unfavourable solution for the ADOPT.

3: Improving duration of moving object VS worsening the strength

The ADOPT prototype disturbs patient gait because of its weight, causing the patient to move with a reduced speed. To improve this duration, with other words to lessen weight, less material could be used. Use of lesser material causes the ADOPT to be weaker and thus perform less. Seeing the patient as a moving object and the weakening as worsening strength, these are the solutions offered by TRIZ:

- 3:Local Quality: have different parts of the object carry out different functions

By separating according to function makes specialisation of the components possible. This enhances their performance in each section. As the ADOPT already exists of many separate components, more separation is not feasible.

- 10: Prior action: arrange objects so they can go into action in a timely matter and form a convenient position
  This solution is described in the second trade-off and found not applicable for the ADOPT.
- 29: Pneumatic or hydraulic construction: replace solid parts of on object by gas or liquid, these parts can use air or water for inflation, or use air or hydrostatic cushions
  In the second design contradiction it is explained how this solution is a possibility but not favourable

4: Improving stability of the objects composition VS worsening energy used by moving

To oppose instability of the ADOPT, more material can be added in sections that undergo most stress. This, however, would case the weight of the ADOPT to increase and therefore the patient will need more energy in order to move the ADOPT. Translating this to a more general form makes this situation: improving stability of objects composition whilst worsening energy used by moving. The solutions offered are listed below:

- 13: Inversion: make a moving part of the object or outside environment immovable and the non-moving part movable
  As explained in the third contradiction, this solution is not favourable.
- 17: Moving to a new dimension: Use a multi-layered assembly of objects instead of a single layer
  By making the components of the ADOPT multi-layered it would contain different properties of used materials. The disadvantage in this is the ease with which the product can be manufactured, though it is not a solution to leave disregard.
- 19: Periodic actions: replace a continuous action with a periodic one
  By creating a periodic process from walking, the patient is able to take rests in between the periodic movements. However, even though the patient is able to withstand the weight longer, this makes analysing patient gait impossible and thus not applicable.
- 24: Mediator: temporarily connect an object an object to another one that is easy to remove
  By making a mediator that takes responsibility for the worsening factor, the improving factor remains. This could mean making a robot that walks alongside the patient to carry the ADOPT. As this would make analysing patient gait impossible, worsen device complexity and probably disturb patient gait in the process, this solution does not apply in this scene.

5: Improving device complexity VS worsening ease of operation

By applying many features and adjustability's to the ADOPT it would get many more properties that can mimic more types of AFO's. The downside to this is the ease of operation, as it would get too difficult to know what feature to adjust and to what it should be adjusted to in a given situation. Below is a description of the solutions offered by TRIZ:

- 1: Segmentation: increase the degree of objects segmentation
  Increasing the degree of segmentation could that for every adjustment another specific component can be addressed. As the ADOPT already is segmented with adjustments attributed to specific parts, this solution is already processed in the current concepts.

- 11: Cushion in advance: compensate for low reliability of an object by countermeasures in advance
  To oppose the worsening factor in advance, the features could be set to a default setting. This would ease the time spend of setting it to those settings during assessment, but however does not simplify the ease of operation in further adjustments during assessment, meaning the problem is not resolved with this method.
- 13: Inversion: make a moving part of the object or outside environment immovable and the non-moving part movable
  This solution is not favourable, as is explained in the second contradiction.
- 35: Transformation of the physical and chemical states of an object: change the objects density, distribution, degree of flexibility or temperature
  Choosing other densities causes a wide range of possible weights for the ADOPT. Since it has many components, each component can be chosen to have a different material with different densities according to their function. Choosing different materials to achieve this is already been done in all concepts. Distribution if the weight is also an important factor; the balance of the product is important in order to not disturb patient gait. No attention has been on this point and can be thought of in all concepts.

6: Improving adaptability or versatility VS worsening device complexity

By adding more adjustability's to the ADOPT, it is able to mimic a greater range of AFO's. By doing so, however, the device will become more complex, making its use harder and also manufacturing more difficult. Therefore there is a trade-off between improving the adaptability and device complexity. Solutions for this trade-off offered by TRIZ are described below:

- 15: Dynamicity: if an object is immovable, make it movable or interchangeable
  The immovable parts of the ADOPT are all components except the joint. Making different parts so they can be changed creates a wider range of properties that can be applied, which makes the opportunity for finding the optimal AFO bigger. This is already done for the sole in concept 3, but can be considered for the sole in concept 2 as well and the rod and tibia support in all concepts.
- 28: Replacement of an mechanical system: use an electrical or magnetic field for interaction with the object
  Electrical fields or magnetic fields are very adjustable considering strength. On the other hand, to build a mechanical system to evoke an electric field that interacts with the ADOPT creates more device complexity than it solves, and therefore cannot be applied to the ADOPT.
- 29: Pneumatic or hydraulic construction: replace solid parts of on object by gas or liquid, these parts can use air or water for inflation, or use air or hydrostatic cushions
  As explained in the second design trade-off this is not a favourable solution for the ADOPT.
- 37: Thermal expansion: use a material which expands or contracts with heat
  Using a sole that expands or shrinks under influence of temperature would be ideal, as it does not add any weight or device complexity itself. A disadvantage is whether this is feasible, as the temperature of function cannot be altered and there is a time limit restricting complete re-manufacturing of the sole components from the same material, thus is not a solution to improve adjustability when not worsening device complexity.

7: Improving device complexity VS worsening ease of manufacturing

Improving the amount of features on the ADOPT makes the product more complex. This complexity causes the ADOPT to mimic a greater range of AFO's and therefore makes describing the optimal AFO more feasible. Although this aligns with the goal of the ADOPT, it also greatly decreases the ease with which it can be manufactured. This is a serious problem, as with great manufacturing complexity the product will not be produced. Considering this problem TRIZ listed the following solutions:

- 1: segmentation: increase the degree of objects segmentation
  In the fifth contradiction it is explained how this is already being applied to all ADOPT concepts.
- 13: Inversion: make a moving part of the object or outside environment immovable and the non-moving part movable
  This solution is not favourable, as is explained in the third solution.
- 26: copying: use a simple and inexpensive copy instead of an object which is complex, expensive, fragile or inconvenient to operate
  By exchanging complex component with a cheap simple one, the ease of manufacturing is greatly increased as is the price. One thing to keep in mind when practicing this solution is whether the needed function is still performed on required level. When performance is the same, this is an option to keep in consideration.
- 27: Inexpensive short-lived object for expensive, durable one
  By changing form short-lived components to durable ones, the product is less dependent on manufacturing processes as its total life time is longer. This means more time can be taken per product to ensure the manufacturing process is completed as desired. As an end result, device can be more complex but still can be produced. As production is a key aspect, this is a solution to keep in mind. Though the opposite can be considered for the sole additions in concept 2. The sole additions are made from SBR, but can be replaced by short lived cork alternatives. Cork has a Young's modulus is 32 MPa and its friction, depending on opposing area, varies from 0.2 to 1.2, which is over the needed 0.14 that corresponds with the given Young's modulus. As its density is only 0.25g/cm3 instead of 0.940 g/cm3, resulting in lower weight for the same functioning. The same substitution can be made for the insoles as the density of silicone is 1.1 g/cm3 (35) (36) (37).

8: Improving ease to operate VS worsening adaptability or versatility

Having little adjustability's on the ADOPT increases the ease with which it is used, since only a few features have to be understood and less time is spend on adjusting the ADOPT. Opposing this advantage, there would be less adaptability and therefore a smaller range of AFO properties the ADOPT will contain. Struggling with this problem, TRIZ had offered the following solutions:

- 1: Segmentation: increase the degree of objects segmentation
  As is explained in the fifth contradiction this is already been done in all concepts.
- 4: Asymmetry: replace a symmetrical form with an asymmetrical form, or increase the degree of asymmetry if already asymmetric
  By making the product asymmetric, features can be distributed equally while each have their specific place, making it easy to tell different features apart. The amount of asymmetry in this case depends on the patient using the ADOPT. Since this is a range, it is not easy to find an asymmetry that fits all, making this solution not achievable for the ADOPT design.
- 7: Nesting: contain an object inside another which is in turn in a third object

By nesting, multiple features can be applied without losing sight of all features. In the ADOPT, to improve weight, dimensions are more favourable when small. When in these small dimensions are made hollow to fit features, the strength of the ADOPT is worsened. In order to preserve product strength, this solution is ruled out.

- 16: Partial or overdone action: if it is difficult to achieve 100% of the desired effect, reach for somewhat more or somewhat less to simplify the problem
  By improving the ease to operate, the amount of trials and errors is higher. Because there can be more trials, the best and worst results can be middle after which the optimal properties can be determined. As this is not very exact, it is not very desirable, though it covers a lot of properties and therefore not yet excluded.

9 Improving weight of stationary object VS worsening reliability

As the patient carries the ADOPT, it must not disturb patient gait. In the current prototype, the weight does cause a distortion. Using lighter material or smaller dimensions, the total weight of the product is improved. As a downside, changing material to lighter ones and making components smaller, the ADOPT can oppose less stress. This could case breakage of components, decreasing reliability. To go against this problem, solutions found through TRIZ are described below:

- 10: Prior action: arrange objects so they can go into action in a timely matter and form a convenient position
  This solution is not achievable in the ADOPT design, as concluded in the second design contradiction.
- 28: Replacement of an mechanical system: use an electrical or magnetic field for interaction with the object
  As is explained in the sixth design contradiction this solution cannot be applied to the ADOPT designs.
- 38: Use strong oxidizers: treat object in air or oxygen with ionizing radiation
  By oxidizing material, it will have different properties on the oxidized faces and in the non-oxidized sections. This would create a multi-layered component that combines the different properties. This could be used to lose low density materials while using strength at the surface, for example in the soles. It is possible to consider for ADOPT construction though it does increase product manufacturing complexity, therefore making this solution undesirable.

10: Improving area of stationary object VS Worsening device complexity

In order to apply the ADOPT on all patients it is necessary to be adjustable according to size and circumferences. Since they differ from person to person, the ADOPT must be adjustable concerning length and width. More adjustability's requires more constructions which makes the device more complex. Concerning this problem, the following solutions offered by TRIZ can be considered:

- 1: Segmentation: increase the degree of objects segmentation
  This solution has already been applied in all concepts, as is explained in the fifth contradiction.
- 18: Mechanical vibration: set an object into oscillation
  This is not a feasible solution for the ADOPT, which is explained in the first contradiction.
- 36: Phase transition: implement an effect developed during phase transition of a substance

As there is no phase transition, this is not feasible.

11: Improving strength VS worsening weight of stationary object

In order to improve the amount of applied forces and resulting stress a component can hold it can be made in bigger dimensions. Using bigger dimensions results in using more material, which of course causes for less stress in total, but also more weight for the patient to carry, which is undesirable as it disturbs patient gait. Solutions to fight this problem are described in the following enumeration.

- 1: Segmentation: increase the degree of objects segmentation
  In the fifth contradiction is described how this has already been done for all three concepts.
- 26: Copying: use a simple and inexpensive copy instead of an object which is complex, expensive, fragile or inconvenient to operate
  Explained in the seventh trade-off this is an option to keep in mind.
- 27: Inexpensive short-lived object for expensive, durable one
  This is an option for the ADOPT design, as explained in the seventh contradiction.
- 40: composite materials: replace homogenous material with a composite one
  Composite materials combine properties of the used materials. This makes for a wider range of materials that can be used. This is already done in concept 2 to combine strength but stay low on costs. This can also be applied in the other concepts in order to get the best combination of material properties for a given component.

12: Improving stability of the objects composition VS worsening device complexity

To oppose applied forces and internal rotations multiple shapes can be added in carrying bodies. As an example, the change of a straight rod to a more complex design. The danger in this is applying the right amount of shapes which also can be done in the surface of the sole, but too many causes the device to become too complex. In order to balance these two factors the following aspects can be considered:

- 2: Extract; remove or separate a property form an object
  In the second contradiction is described how this has already been done in concept 3 but could be considered for the other two concepts as well.
- 22: Convert harm into benefit: increase the amount of harmful action until it ceases to be harmful
  In this case, the harm is the device complexity. To solve device complexity that comes with stabilizing the ADOTP with more device complexity, the structures can be made that complex until a solid form is left. As this is not favourable considering weight, this solution is left from further consideration.
- 26: Copying: use a simple and inexpensive copy instead of an object which is complex, expensive, fragile or inconvenient to operate
  In the seventh design contradiction it is explained how this is an option to consider.
- 35: Transformation of the physical and chemical states of an object: change the objects density, distribution, degree of flexibility or temperature
  As explained in the fifth contradiction, it is applicable to change the density and weight distribution in order for maximal function.

The joint

Operation

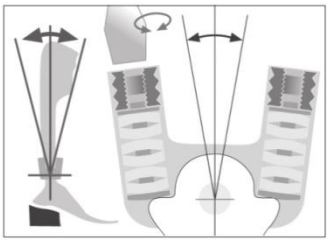


Figure 18

The joint can set range of motion, resistance and alignment with the ankle. This is through its operating mechanism shown in figure 18. Because the bottom rod is widened, it pushes on the spring unit in the joint. This spring unit is either with disc springs, number 3 in figure 19, or coil springs, number 4 in figure 19. These spring units can be changed by units of different strength, ranging from normal to extra strong. Each of these units its own range of motion limitation, see figure 20.

To further limit the range of motion, motion limiting screws can be used, number 2 in figure 19. To block motion, the screw is turned down in the spring unit. The more the screw is unscrewed, the more motion is possible. The maximum range of motion, however, is set by the used spring unit.

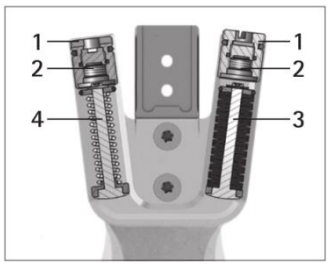


Figure 19

The alignment of the tibia component with respect to the foot component can be set using the alignment screws, see figure 18. To set it correctly, the alignment screw must be unscrewed until the required angle between the foot and the lower leg is acquired. After that the other screw is screwed in until it touches the stirrup. In other cases the sub-assembly is set too deep, the spring unit will get pre-loaded, limiting the range of motion in an unintended manner.

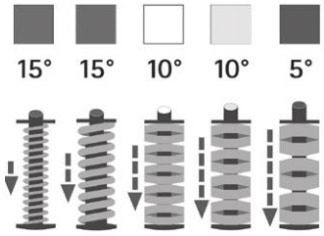


Figure 20

Point of interest

Though the joint is able to be adjusted in range of motion, assistance and alignment as desired, it has a drawback as well. The experiments of Evelien van Zwol and Jeroen Toorn brought forward the following problem; there is no link between the spring units and AFO properties. For them this meant picking two springs and assuming it were the right choices. In the future this would case the same problems for the clinicians using the ADOPT. This causes no acceptation of the final product, as it does not improve the current assessment.

Solution

Figure 22

Measuring the stiffness of the spring units and being able to compare it to the stiffness of other materials could offer a solution to this problem. Because the properties of the spring units could be compared to the properties of other materials, it causes better understanding of the behaviour of the spring units and better AFO assessment. The difficulty in this is the build of the spring units. In these spring units not only regular springs are used, in which case Young's modulus computation is easily done through the spring constant and the known applied force and elongation for which a set-up is seen in figure 21. Instead, disc springs are used. These springs consists of slightly bulged discs pressing together as a force is applied. For these units a custom made set-up must be arranged in order to determine Young's modulus. In a possible set-up, the force applied compresses the discs up to a certain length. As the force can be regulated, the length difference can be measured, giving a strain calculation. Using this strain calculation together with the known applied force and the area of the discs, the Young's modulus can be determined.

Figure 21

To be able to compare it to real AFO's, AFO's could undergo the same tests. To simplify this procedure hinges used in AFO's can also be used instead. An example is the piece in figure22 (38). This piece shows characteristics of the used material, but also of the shape it is moulded into. This makes the spring units can be compared to dorsal and ventral AFO's.

Rating

In this section the three concepts are rated again. Due to the difference in each component, they will be rated individually using the same requirements and weighing factors as done at the end of synthesis I. The individual rating can be found in annex 13. Table 11 summarizes the end scores of the components chosen in the three concepts for tibia support, foot fixation, ankle axis alignment, sole and sole-combinations. Table 12 represents the scores of the designs offered for the supporting rod.

Table 11

	Concept 1	Concept 2	Concept 3
Tibia support	3,555784	4,481434	2,876597
Foot fixation	3,913302	3,786553	4,404511
Ankle axis alignment	4,361118	4,350485	3,728925
Sole	3,782952	4,518052	3,932852
Sole combinations	4,127262	4,637767	4,036618

For tibia support, concept 2 is chosen as is explained in the Finite Element Analysis. It will be made from polypropylene, as the material is cheap, meets the requirements and had the lowest density of the evaluated plastics. The inner lining will be done from polyurethane foam with a polyester cover, as it is more achievable than Cambrelle and does not face allergies as is the case for the latex foam. Since laces, as done in concept 1, is overdone in this context and elastic straps do not fully fixate, Velcro straps are chosen as done in concept 3. The heel cup will be made from polypropylene to give a rigid fixation. Its lining is made from memory foam, as it will wrap around the patients heel giving good support and comfort. The alignment of the axis of the ankle is not feasible through the design of concept 3 due complexity. The design of concept 2 is applicable on all patients while the design of concept 1 needs additional parts for each patient. However, since the total difference is 1.08cm as calculated in concept 1 and the maximum distance is 0.5cm (1), it is overdone to make an entire construction as done in concept 2. Therefore, the insoles are used for ankle alignment. These insoles will be made from cork. Concerning the sole with length adjustability, it is not achievable through the design in concept 1, as it is too complex. Comparing the design in concept 2 and 3, they are very similar; the forefoot of both concepts can be exchanged for ones with different properties. Given the sole of concept 2 needs a lower Young's modulus than the sole of concept 3 as calculated in detailing plus the opportunities to create any additions in between the forefoot and heel components, the sole of concept 2 is chosen to be used in the ADOPT. The material used to make the soles will also be polypropylene, as it has the required strength and lowest density of considered materials for the sole components. For sole combinations, both the design of concept 1 and concept 3 offer limited possibilities, while the design of concept 2 offers a wide range of combinations that can be added. Therefore, sole combinations will be added through the design of concept 2 made from cork.

Table 12

Supporting rod	Cylinder	I-beam	U-beam

	3,46514	4,325615	4,10042

As explained in the Finite Element Analysis, the I-beam shows best performance under torque. Since this design also does not underperform under normal stress, the I-beam design is chosen to be used in the ADOPT. The material that will be used for the rod is Cast Iron Grade 80-55-06, as its density is lower than steel and it is easier to produce in the required shape than carbon fiber.

Synthesis III

Figure 23

In this synthesis, there is more focus on the final product chosen at the end of synthesis II, as seen in figure 23. It is fully detailed, materials are fully defined and a cost estimation is made of the material and production costs of the final product. The manufacturing and packaging methods are described, also testing procedures are set up and the technology assessment is analysed. Since the ADOPT is a medical device, it is bound to the CE marking, which will be discussed in this phase as well. In the appendix the technical drawings can be found.

Detailing

Individual parts

Tibia support

Figure 24

The tibia support is 16.89 cm in length, 22.5 cm in width with a thickness of 0.1cm. Seeing from the front, the first 2.2cm is formed into a shaft to hold the supporting rod into place. This shaft has an outer dimension of 2.2 cm in width and a thickness of 1.2cm. The cut going through the shaft has the same dimensions as the supporting rod. Four slots are placed in the straight surface in order to fasten the Velcro straps. Each slot is 4cm in length and 0.2cm in width. The Velcro straps themselves are 4 cm in width and their length is 33.0cm.The straight face is flexed along an arc with the diameter of 6.21cm. Important to note is as the straight face is flexed, the slot fitting the supporting rod is not. The middle points of the bolts securing the supporting rod within the tibia shaft are 5 cm apart and have a diameter of 0.5cm and the widened parts have a diameter of 1cm. The butterfly nuts have a hole fitting the bolts and at their widest section 2cm to ensure good grip.

The lining is made from a cover of polyester, with the dimensions of length 19.89cm and width 25.5cm, ensuring a 1.5cm overlap over the rigid layer. The polyurethane foam is 0.8cm in thickness, its width is 22.5cm and length 16.89, in order to cover the rigid layer. In the border of the cover an elastic thread is placed for the fixation of the lining.

Rod

The supporting is shown in figure 25. The dimensions are 2cm in width and 0.4cm in thickness, with a length of 29.58cm. Starting from the top, the first 26.58cm is shaped like an I-beam: the beam of 2cm in width and 0.4cm in thickness has two symmetric grooves of 1cm in width and 0.1cm in thickness. To fit the joint, the rod is shaped like an U-beam in the last 3cm: a beam with a width of 2cm and a thickness has a single groove of 1cm in width and 0.1cm in thickness. To be attached to the joint, two holes are made so screws can run through them. These holes have a diameter of 0.5cm are placed on

the middle line of the joint. From the bottom, the middle point of the first hole is at height 0.65cm and the second is at height 1.75cm. For height adjustability, it is ideal for the ADOPT to reach up to a tibia of 44.17cm (1). The height difference that must be bridged is 10.39cm (1). As the tibia support and the supporting rod are connected through two bolts, this would require two slots of 10.39cm. The rod is 29.78cm long and the upper bolt fixating the tibia is at height 24.15, it is not feasible to process two slots of the required length. A slot with a height of 10 cm containing both screws can be made instead. The middle point of the bolts are 5cm apart, meaning the height can be set from a tibia of 33.78cm to a tibia of 38.89cm.

Figure 25

Joint

The joint used is the NeuroSwing from Fior&Gentz, see figure 26. The unit used is the 20mm straight version, as it is most suited to carry the forces that are generated in the ADOPT. It has a height of 7.4 cm and at the bottom has a width of 7.2cm. The material used is steel, making the weight 226g. The system stirrup used is the Rivet attachment short and it is custom made to the length of 9.17cm. At the bottom there are two holes for attachment to the sole through screws. The centre point is 0.5cm from the bottom and they are 5.33cm apart in order to ensure equal spacing between each other and the rod boundaries. The screws connecting the rod and differ in length in length to avoid interaction with the slot. The posterior screw is 5.5cm and the anterior screws is 1 cm. Both screws have a diameter of 0.5cm. In between the rod of the joint and the sole is a rubber ring in order to leave space for the ankle and heel but leave no movement of the two components relative to each other. These rings have an outer diameter of 0.9cm with an inner diameter of 0.5cm and a height of 0.3mm.

Figure 26

Sole

The complete composition of the sole can be seen in figure 27. The sole is consistent of two major parts: the heel section and the forefoot section. The heel section is 12.5cm in length and 1cm in thickness. At the anterior side it has a width of 9cm and at the posterior side it has an arc with a radius of 3.75cm. It has a slot which starts at the anterior side with a depth of 8.5cm, height of 0.3cm and its width is 5.5cm. Below and connected to this main slot is another secondary slot with width 1.5cm and 0.2cm in height and depth 8.5cm. This slot can be used for additional support beams, but when this is not necessary it is filled with a beam with the same dimensions as the slot: 1.5cm in width, 8.5cm in depth and 0.2cm thickness. Seen from the bottom, there are three holes running through the lower section of the sole, including the filling beam of the lower slot, and end up in the main slot. Through these holes the forefoot can be fixated into the heel section. These holes have a circumference of 1cm and fit screws that have a 1cm diameter, a 1.5cm head and a length of 0.5cm for fixating functions and 0.8cm for supporting functions. In the posterior part of the bottom of the sole are three holes in order to attach the sole additions. These holes have a diameter of 1 cm, a depth of 0.5cm and are placed 1.303cm from each other. At the top of the heel section a heel cup is positioned. This heel cup runs along the arc with the radius of 3.75cm and reaches over on either side with 2cm. It is 5cm at its highest point and has a thickness of 0.15cm. It has two slots for Velcro

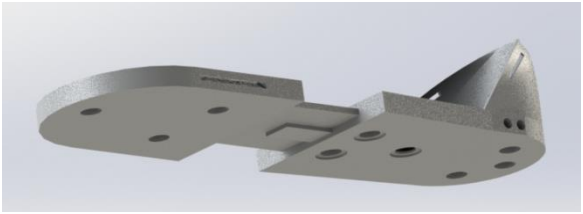


Figure 27

fixation on either side of 4cm in height and 0.2 cm in width, and is arced along the sides of the heel cup. The Velcro strap that runs through these slots is 4cm wide and 31.50cm long. Inside the heel cup there is a lining following the dimensions of the cup made from memory foam in a polyester cover. The design is made in a straight fashion, causing it to bend when used in the heel cup, and has a thickness of 0.8cm. Because of its tendency to go back to its original shape, it will push to the heel cup and thus minimizing movement.
The forefoot section of the sole is 11.0cm in length plus an additional part to fit in the slot of the heel section, which has a length of 8.5cm and a width of 5.5cm. The thickness of this section is 1cm, and the additional part that fits in the main slot of the heel section has a thickness of 0.3cm. Below the attachment of the additional part a small groove is placed in order to ensure any additional supporting beams can be fitted into both sole sections. The anterior section runs along an arc with a diameter of 4.5cm. Seen from the bottom, three holes are placed for sole addition in the same way as done for the heel section. For fixation of the Velcro strap fixating the forefoot there are two slots with a length of 4cm and a width of 0.2cm on the foot facing area and 0.3cm on the side. The Velcro strap is 4cm wide and 27.4cm long.

Insoles

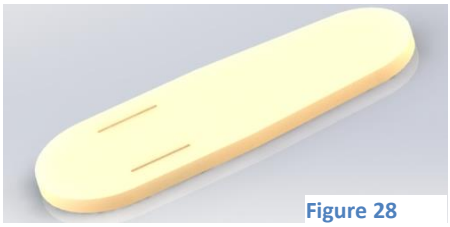


Figure 28

The insoles are available from 23.5 cm to 29cm with steps of 1.4 cm, meaning 4 sizes. The width of the insoles are the same as the width used for the heel sections, though they have small cuts of 4cm to overlap difference in width which differs for each size. In height, there are 5 types: 0.2cm, 0.4cm, 0.6 cm, 0.8 cm and 1cm. This results in a total of 20 insoles. As explained in TRIZ, the use of cork is favourable because of its low density and therefore substitutes the silicone based materials.

Additions

Sole additions have nobs on top to go into the allocated holes in the soles. These knobs have a diameter of 1.1 cm and a height of 0.4cm. They are made from cork and are in lengths available from 24cm-29cm in steps of 1 cm. The height depends on the shape of the addition: rockers are rounded with a radius of 2cm and additions for influencing the angle of inclination are made in a 2.5° and 5°, of which the height depends on the size. This results in a total of 10 sole additions.

The additions fitting in the secondary slot are beams with a thickness of 0.2cm and a hole matching the hole in the heel section bottom to allow the fixating screw to go through and thus fixating both the beam and the forefoot. Their length is available from 7.5cm to 12.5cm, in steps of 1 cm.

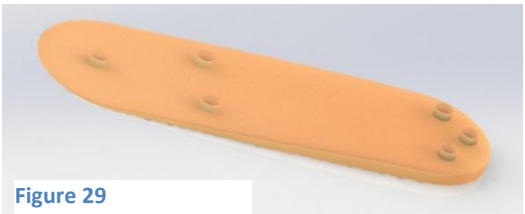


Figure 29

Databank

In order to compare found settings with AFO's, a databank must be set up. This databank contains information of the spring units as well as information about materials commonly used in AFO's, as described in synthesis II. As an addition, custom AFO testing can be arranged; by testing the resistance of different AFO's allows the ADOPT to give a better link between optimal found settings and AFO assessment. One possibility as testing set-up is a beam attached to a cylinder in a 90° angle, mimicking a lower leg and foot. By then decreasing the angle under a known force, the resistance can be measured. The minimal coverage of the databank is the stiffness of the spring units and four

AFO's, one of each type described in the associated thesis; flexible AFO's, anti-talus AFOS, rigid AFO and AFO's with a tamarack flexure joint.

Complete design

The new design can be set to fit the patient through sliding the tibia support over the supporting rod until it reaches the desired height, after which it is fastened with butterfly nuts. The ankle axis can be aligned to the joint by choosing a fitting insole. The sole can be extended by sliding the forefoot section outward and fixating it through screws located at the bottom of the heel section of the sole. If necessary, additional supporting beams can be placed into the secondary slot of the heel section whilst resting in the allocated groove in the forefoot section. If not, the secondary slot in the heel section is filled with a simple polypropylene beam fitting slot dimensions. When required any sole additions can be added by selecting an outsole and pressing its nods in the allocated gaps. The assistance & resistance together with range of motion can then be selected through a spring unit choice based on information given through the databank. The angle of the joint itself can also be aligned by unscrewing the allocated screws. Once ready, the patient can place his or her lower leg and foot into the ADOPT. The lower leg is fixated through two Velcro straps that run through their assigned slots in the tibia support and the foot through two Velcro straps of which one runs through slots in the heel cup and the other one through slots in the forefoot section. Once patient gait has been analysed with these settings, it can be changed to it reaches desired outcomes by changing the spring units or any other sole-additions, or both when necessary. Once the optimal spring unit has been found, it can be compared to other AFO's through the databank to find the AFO meeting the same requirements. This results in an AFO prescription with optimal results for the patient.

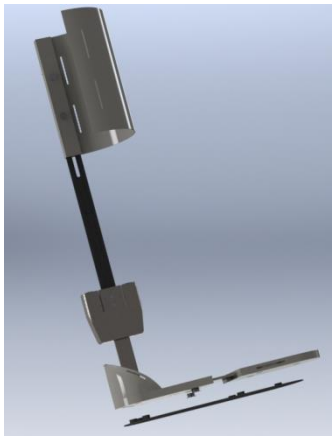


Figure 31

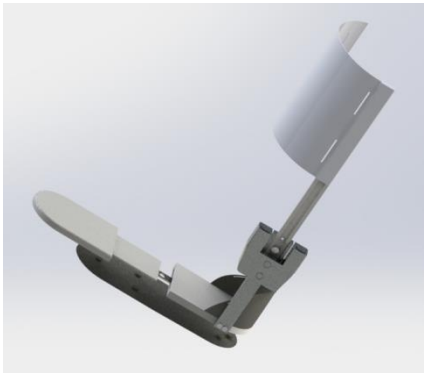


Figure 30

Sterilization

In order to clean the product, it can be taken apart. The tibia support and the supporting rod can be separated by loosening the butterfly nuts which secure the bolts and drawing out the rod. The rod can be separated from the joint by loosening the bolts that connect these two components. The sole and joint can be separated by unscrewing the screws. The heel section and forefoot can be separated by unscrewing the fixation screws located at the bottom. The lining from the tibia support can be removed from the rigid layer by loosening the elastic thread. The lining from the heel cup can be taken from the cup. The rigid layer of the tibia support, the supporting rod, the both sole sections, the rubber ring and the screws can be put into the autoclave, given the temperature stays below 170°C. The joint must be cleaned manually; the spring units have to be removed and cleaned with high air pressure and degreased. The outer sections can be cleaned with alcohol. The polyester covers of the lining can be machine washed together with the Velcro straps. Both the polyurethane foam and memory foam must be washed manually. The cork insoles and outsoles can be replaced by new cork units.

Cost estimation

The total weight of the heel section is 74.64 g plus 1.73 for the beam in the secondary slot 1.73g, the forefoot is 100.69g and the tibia support 60.65g as calculated by Solid works. In total, this means 237.71g of polypropylene is needed. The price of raw polypropylene is €1,44/kg (39), making the price for the material that must be used € 0,34.

The supporting rod weighs 119.93g. Iron cast metals with high machining needs costs €1,82/kg. Since the beam only weighs 119.93g, the costs of the beam are 0.11993*1.82= €0,22 per piece (40).

The aluminium needed is 3*1.27g for the screws fixating the forefoot, 1*3.02+1*0.63 for connecting the heel to the joint and 2* 0.79 to connect the joint to the supporting rod, 2*1.38g to connect the tibia support to the supporting rod and 2*1.79g for the butterfly nuts. This makes that the total weight of aluminium needed is 15.38g. The price of aluminium is €1,617/kg (41), thus the material costs for the aluminium components are €0,03.

For foam, 0.8*8.64*0.8= 34.56 cm3 memory foam is needed, resulting in a weight of 2.77g. Taking the price of a queen sized mattress, this comes down to $€6.77E-4$ per cubic centimetre (42), making the price for the heel cup cushion €0,03. Its polyester lining is 81.18cm2. The volume of polyurethane is 405.76cm3, times its density makes the weight of the polyurethane foam 34.12g. Using the price of €396,05/m3 gives that the price for the foam used in the lining for the tibia support is €0,16 (43). The elastic strap in the border of the tibia support is 90cm long, making the price for the used strap $€0{,}93$ (44). The lining polyester lining covering the polyurethane foam is 617.0 cm2. Thus the total surface needed for lining is 698.18 cm2. As the price for polyester is €0,65 per metre with a widths of 1.47m, the price for the total lining is €0,03 (45).

The total length of Velcro needed is 31.50+2*33.0=97.50cm and its width is 4cm. As the found price is €0,20 per metre, the price for the Velcro straps is €0,20 (46).

A simple sole addition with length 25cm and giving an inclination angle of 15° made from cork weighs 5.61g, opposing the 21.08g if it were made of SBR. Taking an insole with thickness of 1cm, the weight is 50.75g which significantly lighter than the 223.3g of an similar silicone insole. The costs of cork are €8,86 per kilogram, making the price for simple additional sole components €0,50 (37).

The rubber ring used in between the sole and joint is made from SBR and has a weight of 0.32g, thus a total of 0.64g. The price of raw SBR is €2,23 per kilogram (47), making the material costs for the rings $€0{,}001$.

Injection moulding, which is used for the polypropylene, requires the production of a mould as well, which ranges from €7.120 up to €17.800 (48). Taking €17800 as a price as the structures are more complex and predicting 70% of all hospitals in the Netherlands will buy an ADOPT reduces the price per product to $€164{,}10$. Sand casting for the supporting rod costs €0,60 per part (49). The foam must be cut to the desired dimensions, thus a saw machine must be bought. Accounting for the foam cushions and custom cutting for the cork soles results in a price per product of €3,28 when accounting for two machines of €178,00, together with 70% sell rate as used earlier (50). The covers for the foams must be custom made. Taking the average salary of the Netherlands in 2013 and accounting one cover per day (51), labour cost per ADOPT are $2 * \frac{22900}{365} = €125{,}48.$

Taking a new machine for the screws as well gives extra costs per product of $€90.23$ (52) when accounting for the earlier used selling rate. The rubber rings can be bought for €0,25, thus add up to a total of €0.50 (53). For the databank a whole new estimation must be made. Taking as a fundament two Dutch engineers work to make the databank and they will test at least four types of AFO, the

costs for the databank per ADOPT are $\frac{2*3074*12+4*339.64}{155*0.7} = €692{,}50$ (1) (54).

Summarizing all the costs, the price of one ADOPT is 1529,03, which resulted from €2,43 for material costs, €450 for the joint and €1076,69 as production costs. The total weight of the product is 470.86g plus 226g for the joint, thus 692.86g.

Manufacturing process

Polypropylene

The tibia support and both sections of the sole are made from polypropylene. This thermoplastic polymer is relatively easy to process in injection moulding, even though it has a semi-crystalline nature. In the process of injection moulding, raw material enters the injection barrel, it is driven forward by rotation of a screw. This screw has a growing diameter, causing the raw plastic to endure more and more friction. This friction causes heat and thus at the end of the injection barrel the plastic is molten and can be injected into the mould by pushing the screw forward. When sufficient material is injected, the screw withdraws to depressurize the material. The material in the mould is cooled and ejected from the mould after which the entire process is repeated. Moulding shrinking is usually around 1% although its precise value depends on design and moulding conditions. Because of the custom designs of the tibia support and sole components, a fitting mould must be made and the shrinking must be determined by a test run. These custom moulds must contain the shape of the components and the shafts in their design. The slots used for the Velcro straps can be either processed in the mould as well or can be laser cut through melt sharing: the material on the cut lines is melted after which the molten droplets are blown out of the cut. One disadvantage of using this laser technique is slight discoloration (58) (59) (60).

Cast Iron grade 80-55-06

Cast Iron is best shaped through sand moulding. In this process, a bottom layer of a sand box contains one half of the positive copy of the product and a matching second box contains the second half in the same fashion together with two bars for filling. These boxes are filled with sand, which is repeatedly compressed. They are then flipped upside down and the bottom layer is removed, leaving sand with a negative impression of the product copy and two holes in order to be able to pour in the metal. The two halves are combined and pinned together, after which the metal is poured in. When cooled, the sand boxes are removed, leaving the product with two feeder rods witch will be removed in post processing. As the sand takes over all the shapes, it is a good method to create the design of the supporting rod as it has multiple structures. A disadvantage is its relatively low production speed (61) (62).

Foam

Polyurethane is most commonly produced by a slab stock process; meaning that when the substances are mixed together, they are poured onto a conveyer belt. Within a few minutes, the foam has reached 0.60 to 1.20 meter thickness. At the end of the belt, it is cut into slabs and processed further (9). In further processing, the sheets needed for the ADOPT can be cut from the slabs.

Memory foam was originally made from polyurethane foam as well, although now it is made from polyol mixed with a dissocyanate and water. When the compounds are fully mixed they react with each other, resulting in cell-like structures, making its semi-closed structure. When fully rised, it is relayed into post processing. As the design for the lining is flat, the pattern can be cut from the

fabricated foam plates. If the design was not flat, the liquid mixture had to be poured into a Reaction Injection Moulding (RIM); the foam expands until it reaches the aluminium mould from which it is released later (63) (64) (65).

Aluminium

The screws are made from aluminium and have custom sizing. These custom sizes can be achieved by making small changes in the manufacturing process of the screws. The normal method is the processing of a thread until they are screws; the thread of the desired material, in this case aluminium, is cut at the desired length after which the screw head is created by punching a die to the head of the screw. After that, the screw is moved on to receive screw thread; either through a centreless cylindrical, where the screw blank is rolled between two round dies, through two dies, of which 1 is stationary in between which the screw is rolled, or planetary rotation process, in which the screw blank is fixated while die-cutting machines go around the blank. As with all three manners the material is impressed in the screw instead of removing material which contributes to screw strength (66). By adjusting the diameter of the processed thread and the cutting length the custom screws can be made.

Cork

Cork originally comes from the bark of cork oak trees. The bark is harvested from the tree after which these planks are stacked outdoors in order to cure due chemical reactions encouraged by sun and rain which improves cork quality. After that, the cork is cleaned from dirt and treated with water soluble components, like tannin, in order to make the cork more soft and flexible. Next the outer less valuable layer is removed and the stacks are stored in a dark cellar with controlled humidity in order to cure the material. After a few weeks, the stacks are trimmed into uniform slabs and their quality is checked: high quality will get used to produce wine bottle stoppers and lesser quality will be used to make agglomerated cork. Together with high quality left overs, the lesser quality is shredded into uniform particles of desired size. Pure agglomerated cork is made by packing the particles into a mould, for example tubular, and treating it with superheated steam, which is 315°C, or baking the mould at 260°C for six hours. Both mentioned methods activate natural resins. Afterwards the cork is cut for its intended use (67) (68). The insoles can be cut from sheets of cork by a simple cutting machine. However, as the sole additions are more complex it requires either a more complicated cutting machine or the knobs on top of the sole can already be integrated in the processing mould.

Packaging

In order to ensure good delivery of the ADOPT to the customer, packaging must be taken into consideration as well. The materials can be delivered to the manufacturer as is fit for the material; the aluminium rods can be stacked in scaffolds, the polypropylene pellets in plastic bags as well as the foam. The cork can be either transported in slabs or in plastic bags when fully shredded. After the materials are processed into the desired products, they must be sterilized using an autoclave when possible and sealed in plastic which is made vacuum to oppose bacterial growth. The components that cannot be sterilized this way must be disinfected and sealed in vacuum plastic bags as well. The components are then shipped to a central manufacturer that inspects the delivered products through random surveys. When the measured units meet the requirements, the remaining products can be put in a box. Note the different components are still in their plastic vacuum bag. The box is able to hold the weight of the ADOPT and withstand the weight applied when multiple boxes are stacked for

transport. Taking 30*10*15 cm for the measurements of the box and a transport crate with height 78cm (70), it results in stacking with 5 layers. This results in 2.79kg resting on the under most box plus 0.69686kg for its own ADOPT. Cardboard boxes with a single wave-structure are able to carry 10kg (69), making these fit for this application and even giving the possibility of using bigger crates to allow higher stacking. To oppose damage to the contents of the box, the products can be wrapped with bubble plastic as well or placed in fitting Styrofoam and filling the box with foam packing material for further cushioning. To ensure damage through high temperatures, the maximum temperature allowed during transport is set by the rubber rings as they have the lowest operating temperature. This means the temperature during transport of the completed ADOPT cannot exceed 100°C.

Failure method and effect analysis

For the final concept a list of risks has been analysed, similar to the analysis done in synthesis II. The complete list can be found in annex 15, the risks rated with a high priority score are listed below.

Table 13

ID number	Description	likelihood	impact	Priority score
4.1	The project exceeds the budget allocated	90	60	75
8.2	Suppliers do not meet the expectations defined	60	90	75
9.2	Customers do not accept the final deliverables of the project	50	80	65

As the cost estimation predicted an product price exceeding the budget, the likelihood of this risk happening is greatly increased when comparing to the concepts analysed in synthesis II. The biggest cause for this are the production costs, as it accounts for 70.40% of the total price per product. This can be solved by rising the budget or moving the processing to producers that are being able to manufacture beneath the cost estimation prices. The second risk is suppliers not meeting the expectations defined. As the product has many narrow dimensions, high quality is needed. When this is not provided, it causes less functioning of the ADOPT. To oppose this, multiple meetings must be held with the suppliers to ensure achievable manufacturing techniques meeting the needed requirements, plus exchanging of highly defined technical drawings give for better understanding of the dimensions of the design. Allocating more finances to the suppliers also gives them more opportunities to be able to provide better quality. As the budget is already above the stated maximum, a solution is to increase the budget. Another risk rated with a high priority score is customers do not accepting the final deliverables of the project. As with the concepts in synthesis II this was a repeated problem, as the clinicians are not familiar with other methods than the one currently in use. In order to create more trust towards the ADOPT, information must be freely available to all who show interest in the product. When releasing models in lectures, the starting clinicians can already get accustomed to using the ADOPT for AFO assessment, resulting in later use as well. Considering the hospital will buy the ADOPT it is important to approach this group as well next to the clinicians that will actually use the product. Different informational meetings can be held to show the benefits of ADOPT use to hospital management.

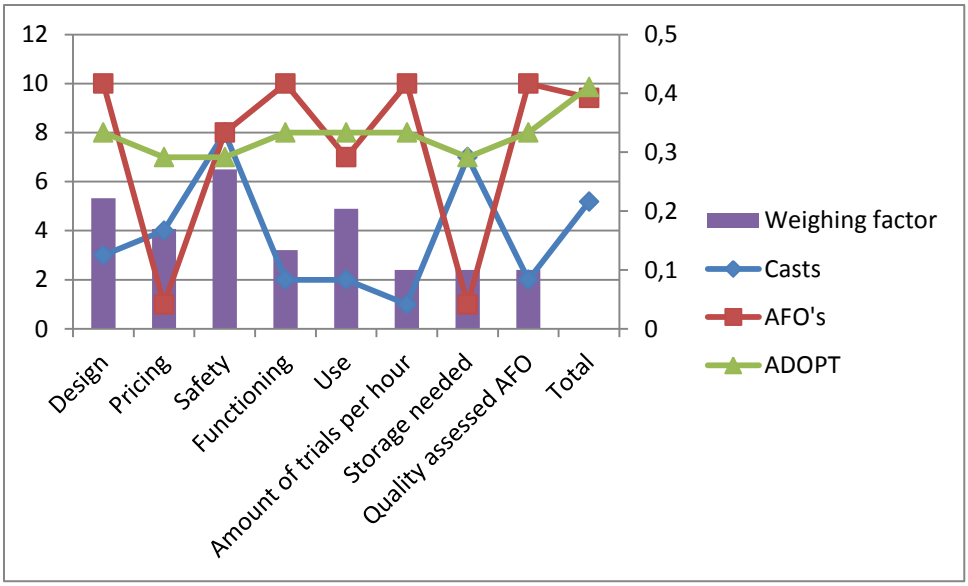
Technology assessment

The benefits of the ADOPT cannot be measured yet, but can be predicted. Under the assumption that the ADOPT will be bought in 70% of all hospitals in the Netherlands and improves 80% of all cases of AFO assessment, it will be bought 109 hospitals which will cost €166.705,69 and improves AFO prescription for 11556 people. This means the costs per helped patient are €14,43. For insurance however, there is no benefit that can be easily calculated, as still one AFO is prescribed as would have been before. The only benefit is prevented costs of extra healthcare due not optimal functioning patients when given a not optimal AFO. On a social level, the ADOPT will prove most beneficial, although this cannot be easily measured as it is expressed in happiness. Although there are certain scales for happiness, it is not easy to assess how much happiness comes from the optimal prescribed AFO as opposed to the happiness created by a not optimal AFO.

To get a better understanding of the effects of the ADOPT efficacy related studies can be done. These are randomized trials that focus on the clinical outcomes from which is determined if and how the ADOPT can improve the health of a patient. In later stages of clinical applications effectiveness studies can be done. These studies focus on whether including the ADOPT in hospital repertoire will improve patient healthcare.

In order to ensure functioning as required by the consumer, in this case the clinician, it is important to notify them of the designing process and value their opinion, as they know best what they will need from the ADOPT. This can also be applied to other stakeholders, making the designing and manufacturing process more complex but in the end more successful as it can be done before clinical application and thus minimizing postproduction adjustments.

Comparison of the ADOPT with other products is difficult as there is no ADOPT-like product on the market. Therefore, the ADOPT is compared to current solutions. Current solutions can be distinguished in two situations: one where a lot of AFO's are on site, for example in an orthopaedic institution, and another situation where only casts are used. These two situations have been compared to the ADOPT through rating of the requirements and their weighing factors. Because the amount of trials that can be performed, the quality of the AFO that is prescribed and the storage needed to retain the method are key aspects, they are taken into account as well. They have been given a weighing factor of 0.10, as they are single aspects and the requirements stand for multiple. At the end a total score is computed using the ratings and the weighing factors. The individual scores can be found in Annex 16, below is the graphic showing the results.



As can be seen, to mimic the properties of AFO's there is nothing better than actual AFO's. On the other hand, the cast shows very little AFO properties and therefore has a low score. The ADOPT can mimic certain features of AFO's, but not all, resulting in a lower score than the method using AFO's. The costs of the method used however are very high when using a lot of AFO's. Also, if multiple trials must be done, the price of casts runs higher. Because the ADOPT can be used for multiple trials with multiple settings, it is overall cheaper. Though, because of the great adjustability, the device is more complex than the other methods, creating more risks for safety. As the AFO's are put on and off easily, instead of having to cut it in order to remove it like is done with casts, it has the highest safety score. For functioning, the cast has lowest performance as it does not last long and cannot undergo maintenance when damaged. The ADOPT, as it is complex, is also more difficult in functioning. The AFO's used can undergo maintenance by local personnel and last long, making this method the best functioning method. Requirements regarding use are best fulfilled by the ADOPT as it has multiple settings with a databank remembering these. When using a lot of AFO's it is hard to keep check of all of their properties and even storage place. Using a cast eases the appliance, but is not comfortable for the patient nor can it be used multiple times. The ADOPT gives most trials per hour, as exchanging the spring units is faster than finding new appropriate AFO's. The cast takes too much time for one trial, making it perform worst. Though when using casts, the storage needed is limited, as only the precursors have to be stored. The ADOPT has a lot of additional soles and insoles, therefore needing more space. The most space will be occupied by storing all AFO's, resulting in this method to have the lowest score. At the end of the AFO assessment, the patient will receive an AFO of which the quality depends on whether the optimal AFO has been found or not. Using casts makes finding the optimal AFO the hardest, resulting in the lowest score. Using many AFO's results in the best score, as they contain all properties of the AFO the patient will receive. The ADOPT only has limited properties, but more than a cast, making it more favourable. The total score has been calculated by adding all the ratings times their weighing factor. It shows that for the given problem the ADOPT is best with using a lot of AFO's as runner up. An undesired solution is using the casts.

CE marking

The CE marking shows that the given product qualifies for the requirements stated by the law of the European Union for twenty product groups; Active implantable medical devices, Appliances burning gaseous fuels, Cableway installations designed to carry persons, Construction products, Eco-design of energy related products, Electromagnetic compatibility, Equipment and protective systems intended for use potentially explosive atmospheres, Explosives for civil uses, Hot-water boilers, In vitro diagnostic medical devices, Lifts, Low Voltage Devices, Machinery, Measuring Instruments, Medical devices, Noise emission in the environment, Non-automatic weighing instruments, Personal protective equipment, Pressure equipment, Pyrotechnics, Radio and telecommunications terminal equipment, Recreational craft, Restriction of Hazardous Substances in Electrical and Electronic Equipment, Safety of toys and Simple pressure vessels. Outside these groups it is illegal to carry a CE marking. When this mark is provided, it can be traded in the EER, which are the countries of the EU and the EVA-countries Iceland, Liechtenstein and Norway. Without meeting the requirements stated by the law the product cannot get the CE marking and it is illegal to distribute the product. If the product carries a CE marking while being unqualified, the producer is held responsible and has to take action: either make changes to his product in order to make it meet the requirements or remove his product from the market (55) (56). Even though it is the responsibility of the manufacturer, it is important to already take the requirements stated into account, as the manufacturer will simply decline if the product does not meet up to the requirements. Therefore, the ADOPT will be analysed by the Essential Requirements.

The ADOPT falls into the group of medical devices for which Directive 93/42/EEC is applied, as it satisfies the given definition as its goal is alleviation of a handicap:

Article 1:
2. For the purposes of this Directive, the following definitions shall apply:
(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of. conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

Next to that, the ADOPT is a Class 1 medical device, as it is non-invasive. The essential requirements are stated in 93/42/EEC Annex I (57). Points of particular interest are described below:

1 . The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

Concerning the safety of the product, many simulations can be done, but to truly test its capabilities and limits a prototype must be tested. Test procedures should focus on maximal forces as can be generated by patients, in particular heavier patients, and fatigue of the material used. This is important to do before clinical experiments and possible later use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

The design of the ADOPT is focussed to fulfil requirements to ensure optimal function. The manufacturing process is oriented to deliver components to achieve the design. The packaging can be an important factor as well since in some cases the product is damaged in either the packaging or storing process. Therefore, this is a key aspect to take into consideration.

8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.

As not all components can be sterilized, processing and the packaging must be done in manner minimizing bacterial growth and other impurities. This can be done by cleaning the ADOPT before packaging in a sterile environment. Using vacuum bags will decrease the amount of bacteria thus making this a possibility as well.

10.1 . Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

As the ADOPT measures the optimal resistance for the patient, this rule applies to the ADOPT as well. The accuracy of the ADOPT must be tested by performing young's modulus determining tests on both the used joint and AFO materials. This will have to be determined before the product is brought on the market.

Next to meeting all requirements stated in Annex X of Directive 93/42/EEC, it must be proven by clinical evaluation that the product meets the requirements concerning characteristics of the situation it is made to use in. The goal of this clinical evaluation is to prove product performance under normal circumstances and to determine any side effects that can occur. When doing this evaluation, there are instructions listed in Directive 93/42/EEC Annex X that need to be followed (57).

Testing

The performance of the ADOPT must be tested before clinical trial in order to ensure safety and gather information. The key points of these studies are on repeated pressure appliance on the different components as well as on the assembly. The rigid layer of the tibia can be tested by fixating the shaft as the supporting rod would and the slots through Velcro straps to mimic normal use. By applying a pressure of 631.29N on the layer with a cylinder of 35cm circumference, representing the

maximum forces this components will endure. By measuring the amount of cycles it takes for the material to yield gives valuable information about the lifetime of the ADOPT. The same can be done for the supporting rod. By fixating it through the bolts in a shaft with height 3cm as if it were in the joint, it can be bend repeatedly with a moment of 188Nm. This gives information about the fatigue, how many cycles the rod can endure and the signs accompanying yield. Applying these cycles with a torque is also important, as that happens during normal use as well. Testing the joint will be more complex than previously noted test procedures. One possibility is fixating the lower beam through the two screw holes and rocking the upper rod back and forth with a momentum of 188 Nm. Repeating these cycles with all spring units will give information about overall joint performance and lifetime, as well as spring unit fatigue. Testing the sole can be done by joining the combinations together while fixating anterior of the forefoot, creating a support on the top mimicking the end of the forefoot of a person. By applying a force of 215.91N repeatedly on the outer end, the sole is loaded as in normal use. Important in this procedure is to use the different lengths of the sole combinations, as well as the influence of supporting beams fitting in the secondary slot.

Clinical evaluation is restricted to requirements stated in Directive 93/42/EEC Annex X, of which the key points are discussed in this section. The goal of clinical evaluation is proving product performance and determine any possible side effects of which the severity can be evaluated. The directive states the procedures must be custom to the device, measuring relevant parameters as they occur in the situation the product will be used in. All negative events must be noted and be relevant authorities must be informed as well. This means the ADOPT can be tested using volunteers. These tests can focus on gait analysis and comparison of gait using the ADOPT, normal AFO's and no orthosis, as done in the experiments of Evelien van Zwol and Jeroen Toorn. These clinical evaluations will give information about ADOPT functioning and benefits of using the ADOPT instead of the current solutions.

Also, as the clinical trials require human subjects the clinical trials must be meet the requirements stated in the Medical Research Involving Human Subjects Act and/or the Embryos Act (WMO) and must be approved before starting clinical evaluations. The WMO states the committee can only grand approval when the research leads to new insights, there is no alternative for using human subjects, the significance is greater than the burden, it is supervised by qualified investigators and the study meets scientific criteria. The subjects must be over eighteen and must be independent of the research group. The subjects are fully aware of the protocols, their purpose and implications and are provided with sufficient time to reflect their decision. The clinicians participating in the trials must be independent and is available to give information about the research to the subjects. The study sponsor ensures direct insurance for the test subjects concerning damage done by the trials up until four years after the trials. When the study meets all requirements stated in the WMO an accredited medical research ethics committee (MREC) will give her approval and the clinical trials can be pursued (69).

Conclusion

Describing an AFO following current methods makes it hard for the clinician to find the optimal AFO for each patient due limited linkage of the properties of used materials and the properties of the prescribed AFO. To solve these situations with limited to no availability of the properties of the available AFO's and AFO-sole combinations, the ADOPT is introduced.
The final product can adjusted to fit a wide range of patients because of it offers the possibility to both extend the sole and the height at with the tibia support is fixated. Because of the length of the Velcro straps a wide range of circumferences of both calf and foot can be fixated. Following the fitting, the new ADOPT gives both assistance & resistance to the patient through both the spring units used in the joint as well as the additional supporting beams fitting in the secondary slot of the sole. Once the optimal settings have been found a databank comparison can be done resulting in the optimal AFO prescription. Therefore, the new ADOPT design is able to improve 20.540 AFO assessments per year in the Netherlands.

Discussion

In retrospect, the new for the ADOPT has good characteristics as well as points for further evaluation. Its weight has drastically improved compared to the prototype, as it went from 1.5kg to 0.69686kg. The costs for the used materials are also very low, making the product more feasible. Next, the method used for the sole additions gives for a wide range of possibilities, making the process of finding the optimal AFO-sole addition combination easier.

When comparing to all requirements stated in the corresponding thesis, the new ADOPT design does not meet all of them. It does meet the requirements regarding the generated forces, but the range of motion of the hinge used is not adjustable per degree. Also, the resistance given by the used hinge cannot be varied from none to completely rigid. Next to that, the design exceeds its allocated budget, which is mainly because €1142,50 is needed for the used joint. Whether the product meets the requirements regarding its lifetime can only be known through testing a prototype.

Regarding the alignment of the hinge and the ankle, it should be tested if the used method is necessary. As stated in the requirements, the joint axis is allowed to be in a 5mm radius of the ankle axis. As the maximal difference is 1.08 cm, it can be considered to attach the joint in to the sole without methods for alignment.

With regard to the hinge used, it is best replaced with a better fitting alternative hinge. Problems with the used hinge are its contribution to costs: 75% of the total price. When using another hinge, more expenses can go into lightweight materials. Next to that, unmet requirements are mainly caused by the used hinge, as noted in the second paragraph of this section. Next to this internal rotation is still prone to happen. This is because forces are relayed through the material and are processed when it meets fixation, meaning the I-beam profile relays the torque onto the rectangular beam, used in the lower section of the joint, where it will meet fixation in the sole. Therefore, the torque is still processed in a rectangular beam.

Concerning the use of the ADOPT, for patient comfort it can best be used on the left foot as some people tend to move their legs close to each other while walking, thus causing collision of the contralateral ankle with the joint when used on the right leg. As a solution can be considered running the holes used to attach the joint to the sole through the entire sole. This would allow the possibility

to attach the joint to both sides of the heel section, though would decrease sole stability. Further evaluation must prove whether this would be possible. Next to that, it can be reconsidered whether the build-up of the forefoot is optimal. As the used material has a very high Young's modulus compared to the minimal, it is possible the third rocker of patient gait is blocked by the used forefoot section. A solution can be to divide the forefoot section into two parts: a part for the toes and slightly extending them, ensuring limited blockage of the third rocker, and a rigid part supporting the other section of the forefoot to maintain foot support.

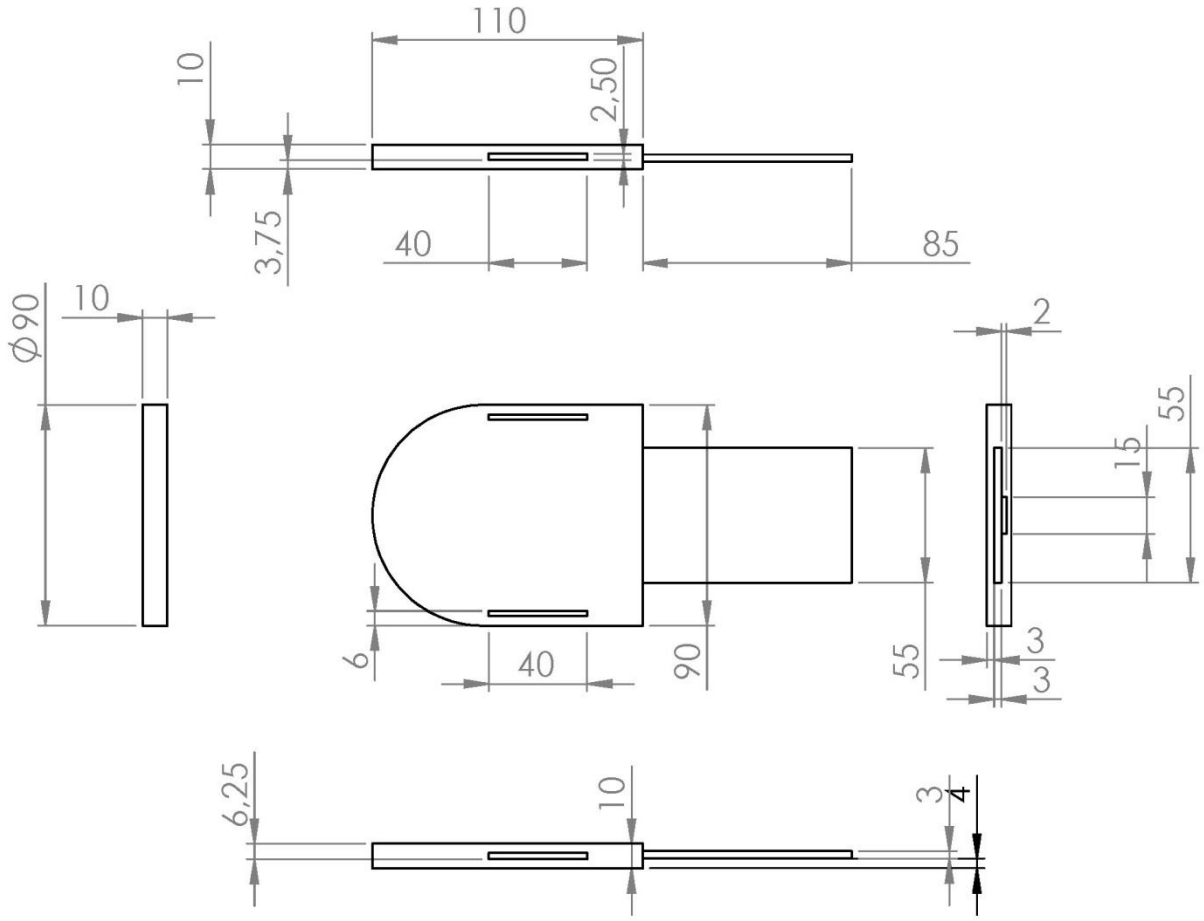
Acknowledgements

I would like to express my gratitude to J.M. Hijmans and D. van der Wilk for providing me with better patient insight and required information. Furthermore I would like to thank M. van der Heide for showing me orthopaedic assessment in practice and H. Loc for providing me with better orthopaedic insights for used measurements. Also I am grateful for the assistance provided by H.D. Oosterhuis, who has helped me through the 3D modelling process and providing information about the current prototype. For guiding me through this process I would like to thank H.M. Kuis as well as G.J. Verkerke who complemented where necessary.

Appendix I

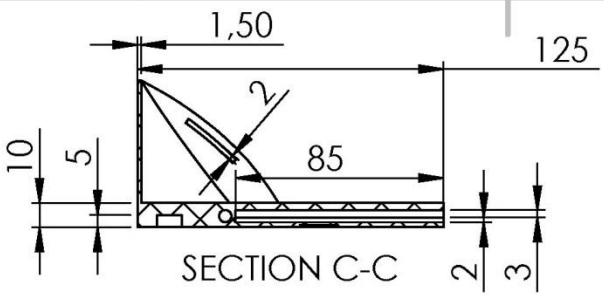
Technical Drawings

The following pages will show the technical drawings of the parts required to build the ADOPT. The dimensions are defined for each section, together with the materials.

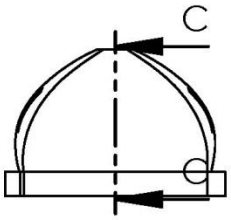


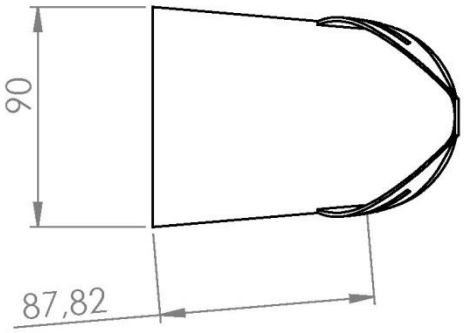
TITLE:FOREFOOT

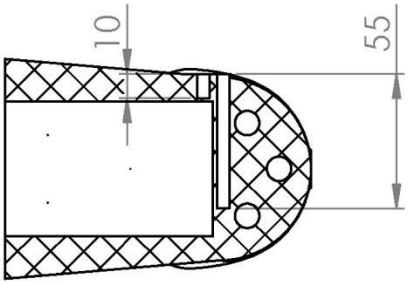
	MATERIAL: POLYPROPYLENE PROCESSING: INJECTION MOULDING	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SCALE:1:3	NAME: CHARLOTTE VAN ZWOL DATE:25-06-2015	SIZE A4



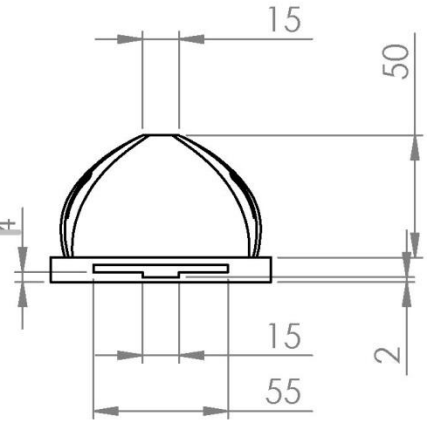
SECTION C-C

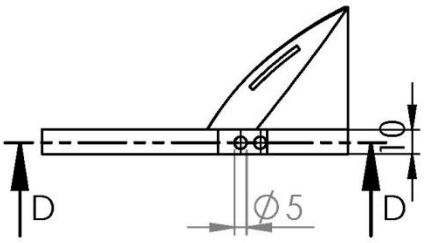


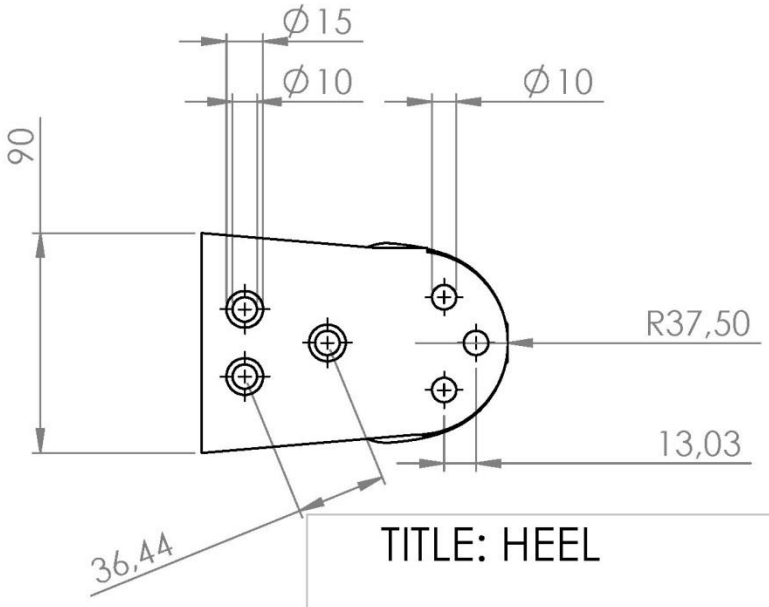




SECTION D-D

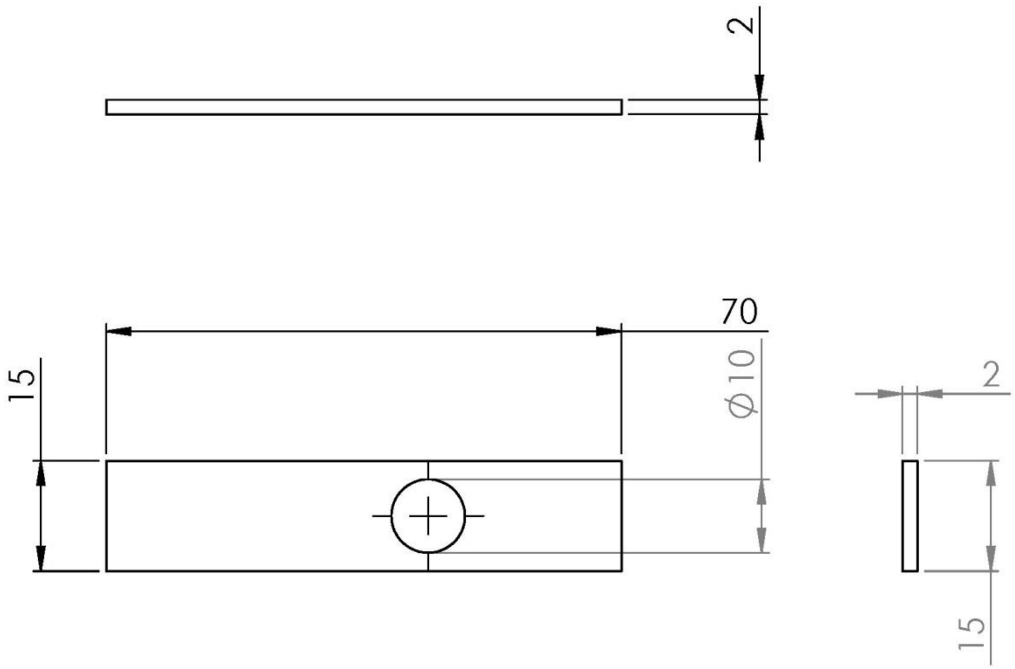


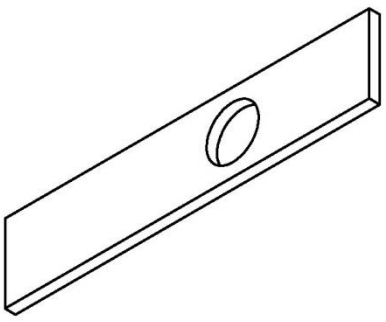




TITLE: HEEL

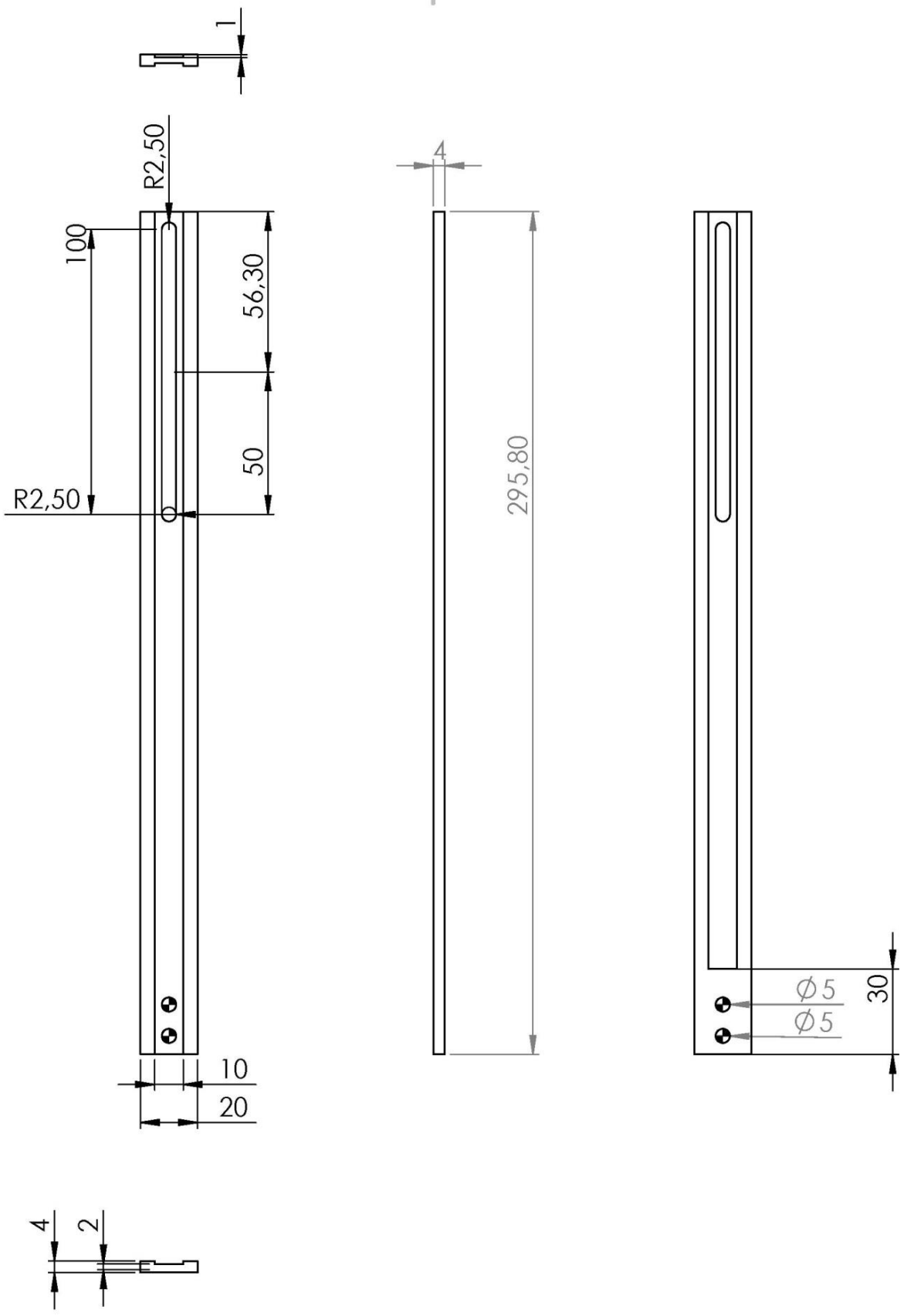
	MATERIAL: POLYPROPYLENE PROCESSING: INJECTION MOULDING	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SCALE:1:3	NAME: CHARLOTTE VAN ZWOL DATE:25-06-2015	SIZE A4





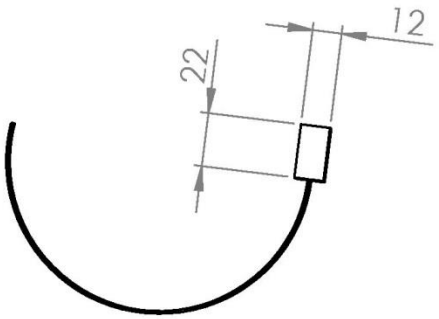
TITLE: INPART SECONDARY SLOT

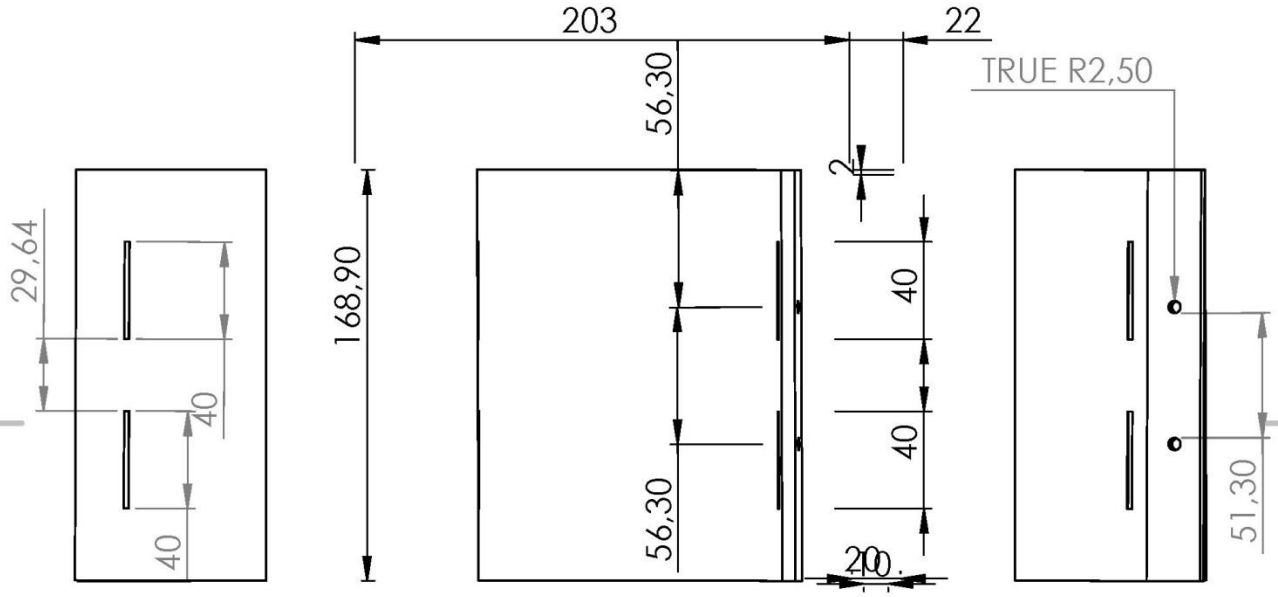
	MATERIAL: POLYPROPYLENE PROCESSING: INJECTION MOULDING	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SCALE:1:1	NAME: CHARLOTTE VAN ZWOL DATE:25-06-2015	SIZE A4

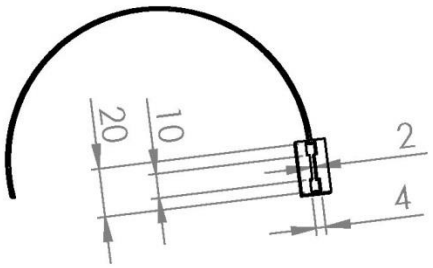


TITLE: SUPPORTING ROD

	MATERIAL: CAST IRON 80-55-06: PROCESSING: SAND CASTING	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SCALE:1:2	NAME: CHARLOTTE VAN ZWOL DATE:25-06-2015	SIZE A4

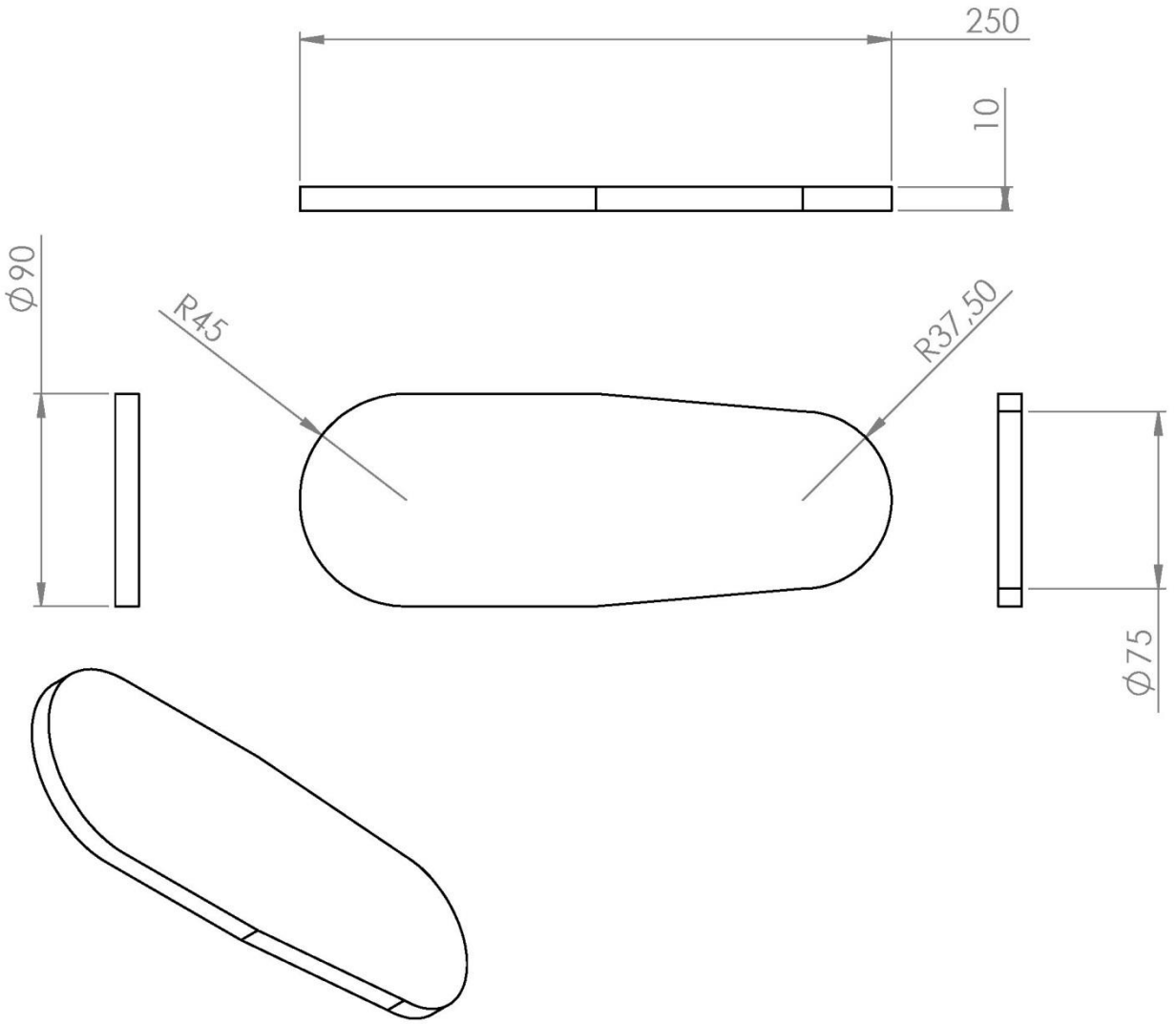






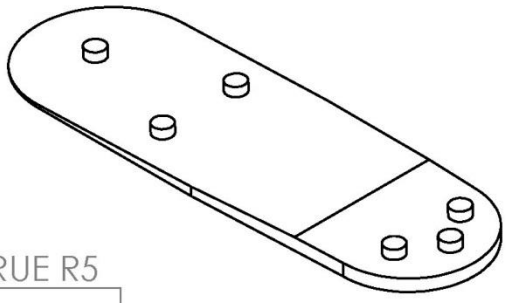
TITLE: TIBIA SUPPORT

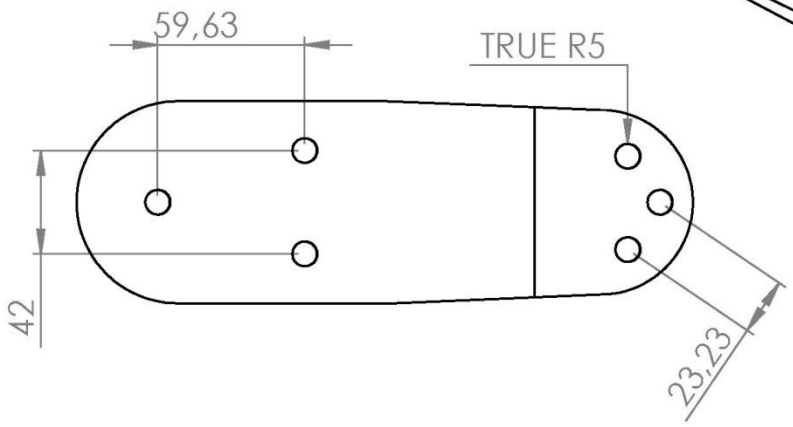
	MATERIAL: POLYPROPYLENE PROCESSING: INJECTOIN MOULDING	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SCALE:1:3	NAME: CHARLOTTE VAN ZWOL DATE:25-06-2015	SIZE A4

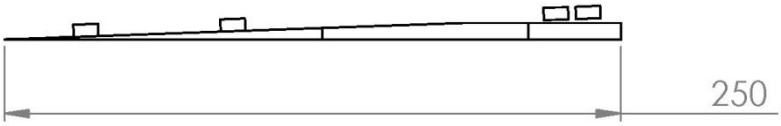


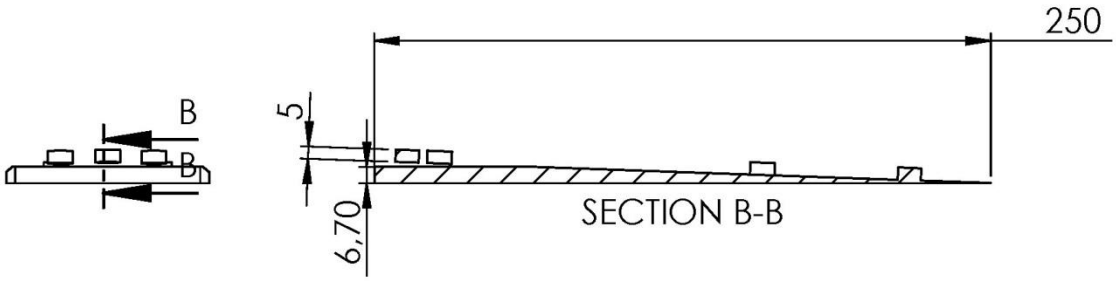
TITLE: INSOLE
LENGTH 25CM HEIGHT 1CM

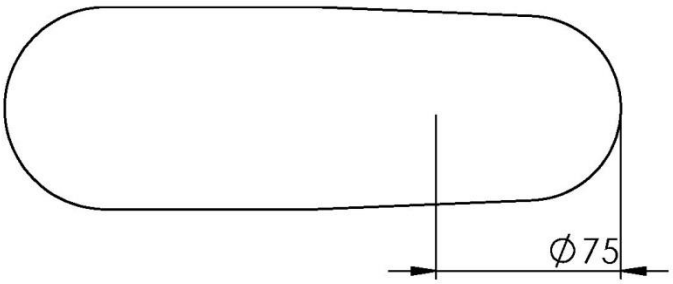
	MATERIAL: CORK PROCESSING: PRESSURE MOULDING/ POST PROCESSING CUTTING	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SCALE:1:3	NAME: CHARLOTTE VAN ZWOL DATE:25-06-2015	SIZE A4











TITLE: OUTSOLE
15° INCLINATION ANGLE

	MATERIAL: CORK PROCESSING: PRESSURE MOULDING/ POSTPROCESSING CUTTING	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SCALE:1:3	NAME: CHARLOTTE VAN ZWOL DATE:25-06-2015	SIZE A4

References

1. **Zwol, C. van.** Thesis: The missing link. 2015.

2. Manufacturing Guidelines, Ankle Foot Orthosis. *International Committee of the Red Cross.* [Online] https://www.icrc.org/eng/assets/files/other/eng-afo-2010.pdf.

3. Fior&Gentz. *Fior&Gentz.* [Online]

4. **How Products Are Made.** spandex. *how products are made.* [Online] http://www.madehow.com/Volume-4/Spandex.html.

5. **Zwol, C van.** Annex 4 Shoe measurements. 2015.

6. **BPI.** Sortable Materials Properties Table. *Boedeker.* [Online] http://www.boedeker.com/mtable.htm.

7. **MatBase.** LDPE. *MatBase.* [Online] http://www.matbase.com/material-categories/natural-and-synthetic-polymers/commodity-polymers/material-properties-of-low-density-polyethylene-ldpe.html#properties.

8. **American Chemistry Council.** Flexible Polyurethane Foam. *American Chemnistry.* [Online] 2005.

9. **Mattress To Go.** Beducation® Mattress Education Series. *matt-to-go.* [Online] 2010. http://www.matt-to-go.com/.

10. **William Callister, David Rethwisch.** *Materials Science and Engineering.* 2011.

11. **Shantex.** Velcro Straps. *Alibaba.* [Online]

12. **AK Steel.** 17-7PH Stainless Steel Data Sheet. 2007.

13. **ASM Aerospace Specification Metals Inc.** 17-7 PH Stainless Steel, TH1050, plate, sheet, and strip. *MatWeb.* [Online] http://asm.matweb.com/search/SpecificMaterial.asp?bassnum=MQM177F.

14. **Dynalab Corb.** Plastic Properties of Polypropylene (PP). *Dynalab Corb.* [Online] http://www.dynalabcorp.com/technical_info_polypropylene.asp.

15. Types of shanks used by different footwear manufacturers. *Reddit.* [Online] 2013.

16. **Britisch Plastic Federation.** Ethyl Vinyl Acetate. *BPF.* [Online] 2015.

17. **MakeItFrom.** Ethyl vinyl acetate. *Make It From .* [Online]

18. **Zwol, C. van.** Annex 3 Determining angle concept 2. 2015 : sn.

19. **Medical Stockings online.** Sizing and Measuring. *Medical Stockings online.* [Online] 2010. http://www.medicalstockingsonline.com/Juzo-stockings-fitting-chart-menu.php.

20. **Zwol, C. van.** Annex 5 Email contact with Dongguan Shine Way Shoes MaterialCO.,LTD. 2015.

21. **knittyblog.** Foot Sizing Surbey Results. *Knittyblog.* [Online]

22. **Camtex Fabrics.** How it works. *Cambrelle.* [Online] Camtex Fabrics, 2012. http://www.cambrelle.com/Products/.

23. **Johnson, Todd.** What is Carbon Fiber. *About Composits.* [Online] http://composite.about.com/od/aboutcarbon/a/What-Is-Carbon-Fiber.htm.

24. Rubber Black Elastic Straps Shoe Elastic Band. *Alibaba.* [Online] http://www.alibaba.com/product-detail/Rubber-Black-Elastic-Straps-Shoe-Elastic_60032212914.html?s=p.

25. **MatBase.** Styrenebutadiene rubber. *MatBase.* [Online] http://www.matbase.com/material-categories/natural-and-synthetic-polymers/elastomers/material-properties-of-styrenebutadiene-rubber-sbr.html#general.

26. **Egineer's Handbook.** Coefficient of friction. *Egineer's Handbook.* [Online] http://www.engineershandbook.com/Tables/frictioncoefficients.htm.

27. **Peninsula Plastics.** Thermoforming Materials & Blends. *Peninsula Plastics.* [Online] Peninsula Plastics, 2013. http://www.peninsulaplastics.com/thermoforming/thermoforming-materials/.

28. **The Mattress&Sleep Company.** Latex Foam Information. *tmasc.* [Online] The Mattress&Sleep Company.

29. Best way to wash a Latex Pillow. *Hubpages.* [Online] 2011. http://pillowsorg.hubpages.com/hub/Best-Way-To-Wash-A-Latex-Pillow.

30. **MatWeb.** Dura-Bar 80-55-06 Continuously Cast Ductile Iron Bar Stock ASTM A536. *Material Property Data.* [Online] http://www.matweb.com/search/datasheet.aspx?matguid=f9b0763303b04141a6ec67d0c1229470.

31. **Sterling Plastic Inc.** UHMW (ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE). *Sterling Plastics Inc.* [Online]

32. **Frecoma.** Rhenoflex Rx 3002 Serie. *Frecoma.* [Online] 2013. http://www.frecoma.nl/wp-content/uploads/2012/06/Frecoma-PDS-RX-3002-serie.pdf.

33. **Dumco.** Verstevigingen. *Dumco.* [Online] 2003. http://www.dumco.nl/pdf/Hoofdstuk%2003.pdf.

34. **Sitiala, Matt.** How to Clean a Memory Foam Mattress Topper. *Overstock.* [Online] http://www.overstock.com/guides/how-to-clean-a-memory-foam-mattress-topper.

35. **Engineering ToolBox.** Densities of Miscellaneous Solids. *Engineering ToolBox.* [Online] http://www.engineeringtoolbox.com/density-solids-d_1265.html.

36. *Friction properties of cork.* **M. Fatima VAZ, M.A. Fortes.** 1998.

37. **Massachusetts Institute of Technology.** *Mit Opn Courseware.* [Online] http://ocw.mit.edu/index.htm.

38. **Tamarack.** Tamarack Flexure Joints. *Tamarackhti.* [Online] Tamarack Habilitation Technologies Inc. http://www.tamarackhti.com/joints/dorsiflexion.asp.

39. **TAIZHOU HAILING YONGJIA TRADE CO.,LTD.** polypropylene raw material. *Alibaba.* [Online] TAIZHOU HAILING YONGJIA TRADE CO.,LTD. http://www.alibaba.com/product-detail/polypropylene-raw-material_60119677457.html.

40. CAST IRON PRICE PER POUND. *Ron Foundry.* [Online] http://www.iron-foundry.com/cast-iron-price-lb.html.

41. **Index Mundi.** Aluminum Monthly Price - Euro per Metric Ton. *Index Mundi.* [Online] http://www.indexmundi.com/commodities/?commodity=aluminum&currency=eur.

42. **Ikea.** MYRBACKA. *Ikea.* [Online] http://www.ikea.com/us/en/catalog/products/00272171/.

43. **Jilinew Sponge.** polyurethane foam type furniture, foam mattress, foam sofa. *Alibaba.* [Online] Jilinew Sponge,. http://www.alibaba.com/product-detail/polyurethane-foam-type-furniture-foam-mattress_60194505994.html?s=p.

44. Elastic Locking Shoelaces Shoe Laces Trainer Running/Jogging/Triathlon/Sporting. *Ebay.* [Online] http://www.ebay.com/itm/Elastic-Locking-Shoelaces-Shoe-Laces-Trainer-Running-Jogging-Triathlon-Sporting-/171772405656.

45. **Haining SHENGDAWEI Warp Knitting Co., Ltd.** Polyester Mesh Fabric. *Alibaba.* [Online] Haining SHENGDAWEI Warp Knitting Co., Ltd. http://www.alibaba.com/product-detail/Polyester-Mesh-Fabric_60025831611.html?s=p.

46. **Huizhou Dayawan Jianxing velcro Co., Ltd.** Good quality strong strength velcro strap. *Alibaba.* [Online] Huizhou Dayawan Jianxing velcro Co., Ltd. http://www.alibaba.com/product-detail/Good-quality-strong-strength-velcro-strap_60243502194.html.

47. **DaLian Bona Biological Technology Co.,Ltd.** SBS | Styrene Butadiene Styrene | High quality | Rubber Raw Material. *Alibaba.* [Online] DaLian Bona Biological Technology Co.,Ltd. http://www.alibaba.com/product-detail/SBS-Styrene-Butadiene-Styrene-High-quality_60132247104.html?s=p.

48. **Rex Plastics Inc.** FAQ. *Rex Plastics Inc.* [Online] Rex Plastics Inc. http://www.rexplastics.com/faq.php.

49. **Custom Part.** Sand Casting Cost Estimator. *Custom Part.* [Online] http://www.custompartnet.com/estimate/sand-casting/.

50. vertical band saw,wooden machine with high quality MJ344F. *Alibaba.* [Online] Weihai Hanvy Plywood Machinery Manufacturing Co., Ltd. http://www.alibaba.com/product-detail/vertical-band-saw-wooden-machine-with_2003816263.html?s=p.

51. **Gemiddeld Inkomen.** Modaal inkomen. *Gemiddeld Inkomen, Info over inkomens en salarissen.* [Online] http://www.gemiddeld-inkomen.nl/modaal-inkomen/.

52. **Harbin Rainbow Technology Co., Ltd.** automatic semi-tubular screw making machine 5mm. *Alibaba.* [Online] Harbin Rainbow Technology Co., Ltd. http://www.alibaba.com/product-detail/automatic-semi-tubular-screw-making-machine_60200906758.html?s=p.

53. **RubberShop.** Ringen op Maat. *Rubbershop.* [Online] http://rubber-shop.nl/producten/ringen/ringen-op-maat.

54. **LoonWijzer.** Salaris en Functie Ingenieur Maritieme Werktuigbouw, Vliegtuigbouw of Autotechniek. *LoonWijzer.* [Online] http://www.loonwijzer.nl/home/salaris/salarischeck?job-id=2144010000000.

55. **Synrad Application Lab.** Processing Plastic With CO2 Lasers. 2012.

56. **British Plastic Federation.** Plastic Processes. *British Plastic Federation.* [Online]

57. **Hindle, Colin.** Polypropylene. *British Plastic Federation.* [Online]

58. **Custom Part.** Sand Casting. *Custom Part.* [Online] 2009.

59. **Chuo Malleable Iron CO.,LTD.** Ductile Iron Casting. *Chuokatan.* [Online] Chuo Malleable Iron CO.,LTD, 2012.

60. **SleepTech.** How is Memory Foam manufactured? *SleepTech Magazine.* [Online] http://www.sleeptechmagazine.com/how-is-memory-foam-manufactured/.

61. **Loughnane, Chris.** Design guide: memory foam manufactoring. *Notebook, Product development.* [Online]

62. **Memory Foam Mattress.** How is Memory Foam made? *Memory Foam Mattress.* [Online] http://www.memoryfoammattress.org/how-is-memory-foam-made.htm.

63. *Screw.* **How Products are Made.** Volume 3,

64. **Amorim.** Perfect by Nature. *AmorimCork.* [Online] Amorim. http://www.amorimcork.com/en/natural-cork/raw-material-and-production-process/.

65. **How Products are Made.** Cork. *MadeHow.* [Online] http://www.madehow.com/Volume-5/Cork.html.

66. **RajaPack.** Exportkist Multiplex 6mm. *RajaPack.* [Online] RajaPack. http://www.rajapack.nl/kartonnen-dozen-verzenddozen-exportcontainers/exportdozen-kisten/exportkist-multiplex-6mm_PDT00360.html;pgid=.2FGArFvMT9SR0jfVT2rYsCB0000u-Z0H57N;sid=Bh2_00WZsqu-0xAUGcDwGriTh3UAxAERcvVijpAsHqChmUD8QoGg0sFZpQ_w-2Duix0cwQqxHqChmQ==.

67. **Xpack.** Kartonnen dozen. *Xpack.* [Online] Xpack.

68. Certificaten, keurmerken en meetinstrumenten. *rijksoverheid.* [Online] Rijskoverheid. http://www.rijksoverheid.nl/onderwerpen/certificaten-keurmerken-en-meetinstrumenten/vraag-en-antwoord/wat-is-een-ce-markering-en-wanneer-moet-ik-deze-op-mijn-product-aanbrengen.html.

69. CE-markering: Uitleg en veelgestelde vragen. *europa.* [Online] Europese Commissie. http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/about-ce-marking/index_nl.htm.

70. **Council Of The European Communities.** Council Directive 93/42/EEC. 1993.

71. **Central Committee on Research Involving Human Subjects.** Medical/scientific research and the WMO. *CCMO.* [Online] CCMO. http://www.ccmo.nl/en/accredited-mrecs.

72. **Hibbler, R.C.** *Statics and Mechanics of Materials.* 2011.

73. *Spring Force Constant Determination as a Learning Tool for Graphing and Modeling.* **Al, Newton I et.** 205, sl : NSCU Physics, 2002.

74. **Maine Maritime Academy.** Properties of Silicone. *Design Caltech.* [Online] http://www.design.caltech.edu/Research/MEMS/siliconprop.html.

75. **GoodFellow Group.** Carbon/Epoxy Composite - Material Information. *Goodfellow.* [Online] 2015. http://www.goodfellow.com/E/Carbon-Epoxy-Composite.html.

76. **Bregar, Bill.** Price keeping carbon fibre from mass adoption. *Plastics News.* [Online] 2014.

77. **Plasticon Composites.** GRE. *Plasticon Composites.* [Online] Plasticon Composites. http://www.plasticoncomposites.com/composites-material/gre.

78. **UL.** Epoxy Typical Properties Generic Epoxy - Glass Fiber. *UL.* [Online] UL. http://plastics.ulprospector.com/generics/13/c/t/epoxy-properties-processing/sp/4.