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Design of a Clubfoot Orthosis: A Valid Alternative for the Ponseti Method?

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Abstract

Clubfoot is a congenital disorder where one or both of the babies feet are pointed in and the soles are turned upward. The current treatment method is known as the Ponseti method, which treats clubfoot by gradually stretching of the soft tissues of the foot, followed by a cast. The rotation of the foot is done by putting pressure on the first metatarsal and giving counterpressure on the talus head. This process is repeated 5-6 times and afterwards an achilles tenotomy is performed. The clubfoot is placed in a brace for the next 3-4 years, finishing the treatment. There are some significant downsides to the Ponseti method. Firstly, the parents have to go to the hospital every week, the cast can cause pressure sores and irritation and the child can only be bathed once a week.

In this project, an alternative method is proposed. This is an orthosis designed to replace the casting phase of the Ponseti method. The orthosis consists of a 3D printed brace which provides pressure on the talus head. An elastic band is used to slowly pull the foot in the correct position. Measuring the angles of the clubfoot model when applying tension to the elastic bands indicated that the prototype worked. Force measurements were performed to investigate the safety of the orthosis. These measurements showed a high force on the talus head (highest = 26.8 N) and a very low force on the first metatarsal (highest = 1.92 N). The forces increased when more tension was applied to the elastic band. This suggest that the orthosis functions, but too much pressure is placed on the talus head without any tension on the elastic band. There were significant disadvantages and limitations of the force sensor used. While the prototype demonstrated in the report gives a good basis, future research and improvements are necessary before clinical trials can be performed.

Acknowledgments

During this project, I received a lot of help, for which I am very grateful.

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My gratitude also goes to the people from the UMCG casting room, where I was shown how the Ponseti method worked, which helped a lot with my understanding of the method.

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Contents

1 Introduction

1.1 What is Clubfoot

Clubfoot, also known as congenital talipes equinovarus (CTEV), is a birth defect where one or both of the baby's feet are pointed in and the soles are turned upward, as shown in Figure 1. The tendons of babies with clubfoot are shorter than usual, pulling the foot out of position. Untreated, children will walk on the sides and top of their feet. This can result in callus formation, skin and bone infections, limitations in mobility and the inability to wear standard shoes[1].

Figure 1: Congenital idiopathic clubfoot. Image from [2]

The condition can be diagnosed during prenatal ultrasonography [3]. CTEV is one of the most common congenital abnormalities in the lower limbs, affecting 1-2 per 1000 live births [4]. In around 50% of the cases, both feet are affected [2]. Clubfoot can be divided in several sub categories, most commonly described as congenital idiopathic clubfoot, syndromic clubfoot and neurogenic clubfoot. The last two occur as a part of a syndrome or neurological condition, respectively, whereas congenital idiopathic clubfoot is isolated and occurs in otherwise healthy infants [3][4]. In this report, the focus will be on the treatment of *congenital idiopathic clubfoot*.
Congenital idiopathic clubfoot can be caused by several factors. As nearly 25% of all cases are familial, it is strongly suggested that genetics play a role. Environmental factors, as exposure to cigarette smoke in utero, also increase the probability of the development of clubfoot [3]. In utero position of the fetus is also suggested as a possible cause. However, none of these theories have been proven and thus the cause is still unknown [5]. The condition is also more common in males than females, with a 2:1 ratio [3].
In CTEV, 4 anomalies can be detected, which can be remembered with the mnemonic ***CAVE***, explained in Table 1 [2][3]. These anomalies are also shown in Figure 2. Babies with clubfoot have a shortened Achilles tendon, which directly causes the equinus [6]. Furthermore, their calf is thinner, and due to the different forces from tendons and muscles, the bones of the foot and ankle are misaligned [6][7].

Table 1: Anomalies in CTEV [3][2]

Name	**Location**	**Deformity**
Cavus	Midfoot	High arch
Adductus	Forefoot	Turned in
Varus	Heel	Turned in
Equinus	Hindfoot	Pointed down

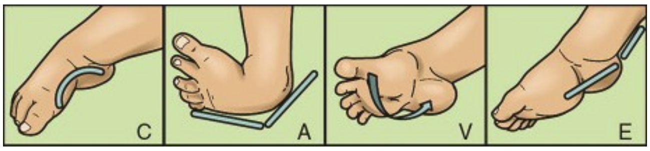


Figure 2: CAVE mnemonic visually explained. Image from [3]

The severity of this deformation can vary, and two classification systems are currently mostly used to evaluate the deformities. Both systems are based on a point-score system, namely the Pirani score and Dimeglio score [8].
For the Pirani score, six signs are classified with a score of 0 (normal), 0.5 (mildly abnormal), or 1 (severely abnormal) [9]. This measurement system can be seen in Figure 3.
The Dimeglio score is based on the angle of the foot. The angles will result in individual points, amongst other parameters. These points are added together result in the final classification (I-IV)[11]. This can be seen in Figure 4.

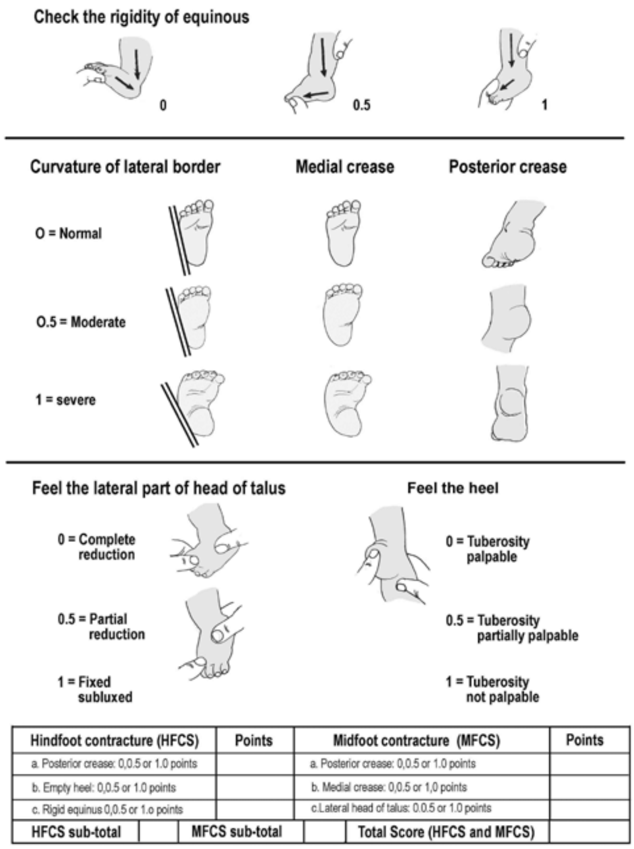


Figure 3: Pirani scoring sheet. Image from [10]

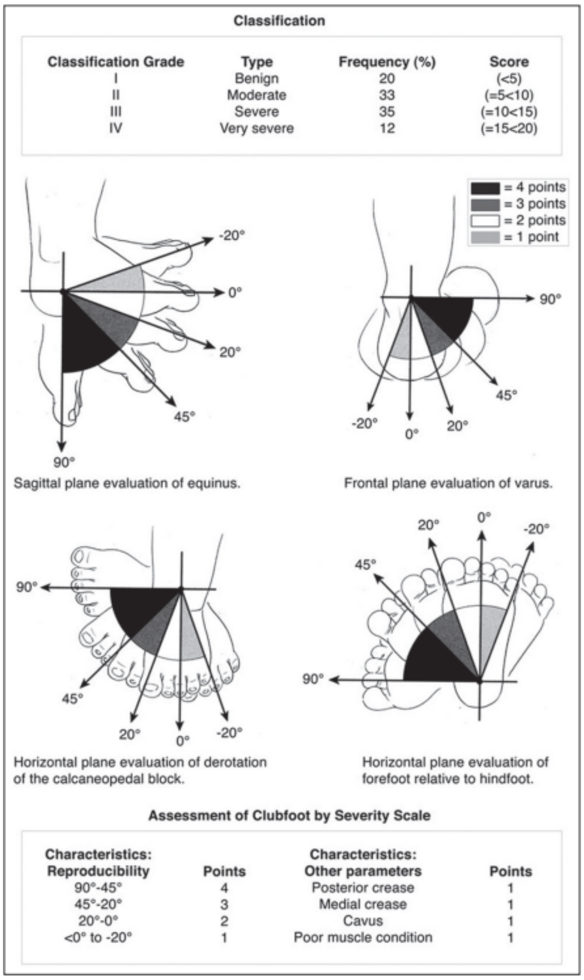


Figure 4: Dimeglio scoring sheet. Image from [11]

1.2 Current treatment methods

Several treatment options are used for CTEV. Non-operative methods include the Ponseti method and the French method, where the Ponseti method is most commonly used [12]. These methods will be explained in more detail below. However, usually non-surgical methods are not able to treat clubfoot to its full extend. In these cases, additional surgery is needed. This is a non-ideal situation, and therefore non-surgical methods are tried first to treat the deformity as good as possible [13].

The Ponseti method
The Ponseti method has become the primary treatment option for CTEV. The technique relies on the gradual stretching of the soft tissues. This is done in the order of CAVE [14].
It consists of three phases. First, using a series of casts, the cavus, adductus, and varus are treated in usually 5-6 weeks. This can be seen in Figure 5. After the casting period, the foot should be corrected into maximal normal abduction [7][9]. Every week, the foot is manipulated by the physician, as can be seen in Figure 6. It is important to note that the the foot should be rotated by putting pressure on the first metatarsal, while putting counterpressure on the lateral point of the talus, to prevent it from rotating in the ankle. This is also illustrated in Figure 5 [9].

Figure 5: Series of casts following the Ponseti method. Image from [9]

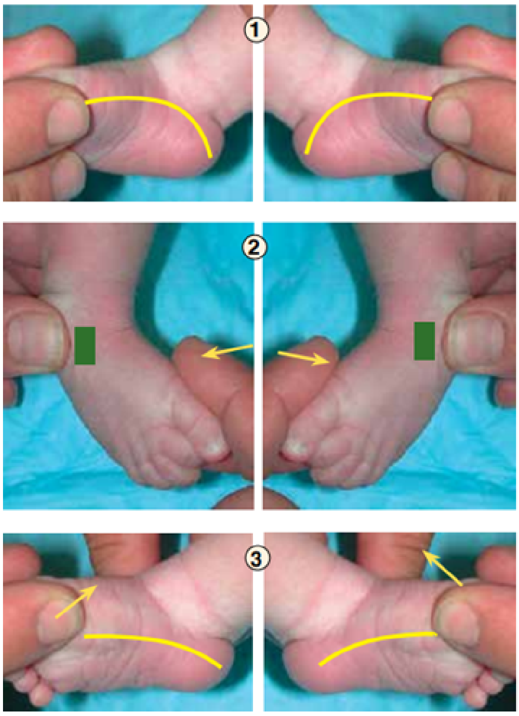


Figure 6: Manipulation of tissue following the Ponseti method. Image from [9]

The second step is usually an Achilles tenotomy. This is required in around 90% of the cases, and treats the equinus [7]. After the tenotomy, a cast is applied for 3 weeks [7].
Lastly, the feet are placed in a Dennis Browne brace for 3-4 years. For the first 3 months, it should be worn full time, after that, it should be worn for 14-16 hours per 24 hour period. The brace can be seen in Figure 7 [9].

Figure 7: Dennis Browne Brace following the Ponseti method. Image from [9]

The French method
The French method is also based on the stretching and manipulation of soft tissue. Instead of applying a cast every week, daily taping and splinting is used to maintain the correction. The treatment is

usually performed in a timespan from 3-5 months, by a professional. After this, the parents continue the treatment until the infant can walk. A splint is applied until the child is 2-3 years old [12].

1.3 This project

The objective of this project was to design an orthosis to replace the first part of the Ponseti method. This was done in collaboration with the UMCG. The casting room of the UMCG was visited to observe the Ponseti casting method. In the analysis phase, the main downsides of the Ponseti method are explained, together with the requirements for a functioning orthosis. Synthesis phase I describes the pre-concepts created, and the final pre-concept is made into a prototype during Synthesis phase III. Synthesis phase II was combined into both Synthesis phase I and Synthesis phase III. Using a force sensor, the force the orthosis exerts on the clubfoot model was measured in order to assess the safety and functionality of the prototype.

2 Analysis Phase

2.1 Problem definition

2.1.1 Background

As mentioned in the introduction, the Ponseti method is one of the most commonly used treatment options for CTEV [12]. However, there are several disadvantages regarding this method.

Research from Chatupon et al. [15] showed that complications are observed in 13 out of 73 feet. Eleven complications were the result of the cast, in the other two cases wound infections were found following the tenotomy. These complications included cast loosening, cast-associated skin irritation and cast-associated pressure sores. All the complications in this study were found in the first two years of using the Ponseti method in the hospital the study was performed in. This suggests that a lack of experience is a major cause of complications within using the Ponseti method [15].
Other research showed an incidence rate of 3% in 883 patients over five years in a CURE clubfoot clinic in a low income country. The complications found were moisture lesions, hematoma, dermatitis due to occlusion, pressure sores, and fractures [16]. Overall, the most common complications are skin lesions and pressure sores [17].

Clubfoot tissues behave viscoelastic. Part of the deformation is permanent (viscous), part is recovered after removal of the load (elastic). Over time, tissues adapt to the applied force, which causes the clubfoot to not immediately return to the old position after cast removal. A study using force sensors showed that clubfoot tissues reached a mechanical equilibrium within two hours [18]. Other studies have shown that changing the cast interval to two or three times a week, instead of once a week, did not show any adverse effects [18]. This suggests that the treatment time could be shortened significantly.

The excess water of the plaster needs to dry in order for the cast to harden. This is an endothermic process, causing it to remove heat from its surroundings, and thus cooling the patient. While it is highly unlikely that casting induces moderate or severe hypothermia, having cold feet for twelve hours is uncomfortable and can affect the infants mood [18]. This can also add extra stress for the parents.
Only one study was found on this topic, and this included 29 measurements on 10 clubfeet. The measurements in the study were also only done locally, no core temperature was measured. Lastly, the study did not meet the WMO (wet medisch-wetenschappelijk onderzoek) criteria [18]. While it can be assumed that the temperature of the clubfoot goes down as the cast dries, it is not possible to determine the true extend and consequences of this from this study.

As the cast has to be replaced every week, the parents and infant have to travel to and from the hospital every week. During a visitation to the cast room, parents explained that this takes a lot of time and energy, on top on the struggles of being the parent of a newborn. In the Netherlands, there are only thirteen clubfoot centres. Only one of them is located on the ABC islands (Horacio Oduber Hospital (Aruba)), the distribution of the other twelve can be seen on the map shown in figure 8 [19].

Another issue with the Ponseti method is the social stigma parents feel when other people see their baby with casted legs. People associate the casts with broken bones, causing outsiders to think the parents have dropped, or even abused, their child [20].

Figure 8: Clubfoot centers in the Netherlands [19]

It can also happen that the infant accidentally soils the cast, which is very unpleasant for both infant and parents and can lead to infections. Lastly, due to the cast, the parents are unable to bathe their child. As this is quite an intimate procedure for parents, and currently the only option is to bathe their baby during the hospital visit, improvements can be made on this area.

Overall, there are quite some disadvantages with the current treatment method for clubfoot, that could be improved, in order to improve the quality of life for both the parent and baby.

2.1.2 Market research

Several attempts have been made in order to improve the serial casting phase of the Ponseti method. These attempts will be explained in this section.

UNFO While the UNFO brace is not used to treat CTEV, it is used to treat a similar condition. In order to treat Matatarsus Adductus (MTA, also known as forefoot adductus), UNFO has developed an orthosis that can be worn below the ankle. According to their own website, the brace can treat all severity levels of forefoot adduction. The brace consists of a rigid plastic insert to correct and support the foot. A soft, thermoplastic material covers the entire insert to prevent pressure sores. The brace can be adjusted by a physician by adjusting a Velcro strap. A singular brace costs $325 and is a lot more comfortable for the parents and patients than serial casting [22][23][24].

Figure 9: UNFO brace on infants feet. Copied from [21]

However, there are several side effects and disadvantages of this product for the treatment of clubfoot. This brace only treats the adductus. A study comparing the UNFO foot brace to casting and splinting in order to treat MTA also showed a complication rate of 0.17 for the brace, namely mild skin irritation and superficial pressure sores. This study, with a test pool of 147 feet (95 casted and splinted, 52 in the UNFO brace), showed comparable results between both treatment options [21].

Figure 10: Dynamic CTEV orthosis. Image from [25]

Dynamic CTEV orthosis Chanu et al. [25] conducted research testing a dynamic CTEV orthosis, made from polypropylene plastic sheet. This product was tested on idiopathic CTEV with a Dimeglio score of III or lower. The baby's foot had to be manipulated at least 3 times a day by a caregiver, and the brace was worn the entire day except during manipulation and bathing. 1 out of 21 feet developed blisters and erythema. The conclusion of this research was that the orthosis was an effective method of treating CTEV [25]. However, no follow up research has been found, and this work has only been cited once.

Figure 11: Cunningham Clubfoot Brace. Image from [26]

Cunningham Clubfoot Brace The Cunningham Clubfoot Brace, or Newborn Dynamic Torsion Knee-Ankle-Foot Orthosis (Newborn DTKAFO) is a brace developed to correct CTEV in 4 stages. This can be done within 1 brace by using different forces. First, the strongest force will act on the foot. As tissue relaxes and moves with the brace, the force decreases and the next strongest force acts on the foot, and so forth until the foot is correctly aligned.

However, this brace is seen as an alternative to the Dennis Brown brace, and not the serial casting phase. So while it is an interesting technique, using this brace to replace the serial casting phase will not work. Afterwards, a second orthosis is used to prevent regression [26][27].
A study reported after a mean follow-up time of 31 months, 88% of the caregivers reported compliance and 8% recurrence. It also showed significant improvements in the range of motion of the foot and ankle. However, the sample size was 26 patients, and only 1 study was done [28]. While the self-reported results are positive, in order to determine the effectiveness of this brace, more research needs to be done.

Figure 12: Hybrid cast/brace. Image from [18]

Hybrid cast/brace Shortly suggested in Giesberts' PHD thesis, casting the lower part of the clubfoot and using a brace to connect the cast to the upper leg can prevent soiling of the brace [18]. However, this method does not solve the problems of cold feet, weekly hospital visits, or the inability to bathe the child.

Soft Robotics Giesberts also proposed a concept based on soft robotics, where a fluid puts pressure on a flexible finger, that changes the position of the clubfoot. This idea is only prototyped and no further research has been done on this concept. Other limitations of this product are that there is slow development and a limited range of motion for the foot [18].

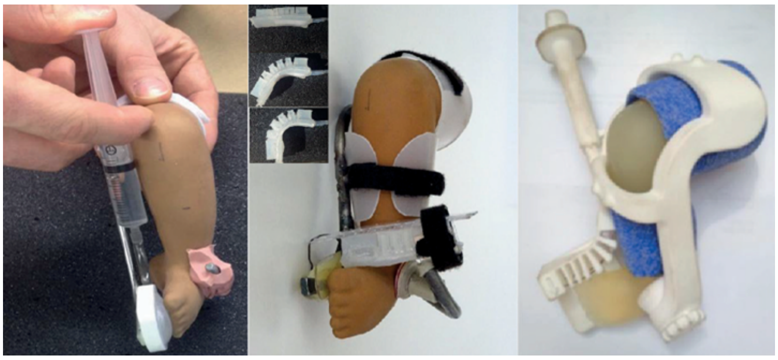


Figure 13: Orthosis based on soft robotics. Prototyping by Esther Keulers and Baat Medical. Image from [18]

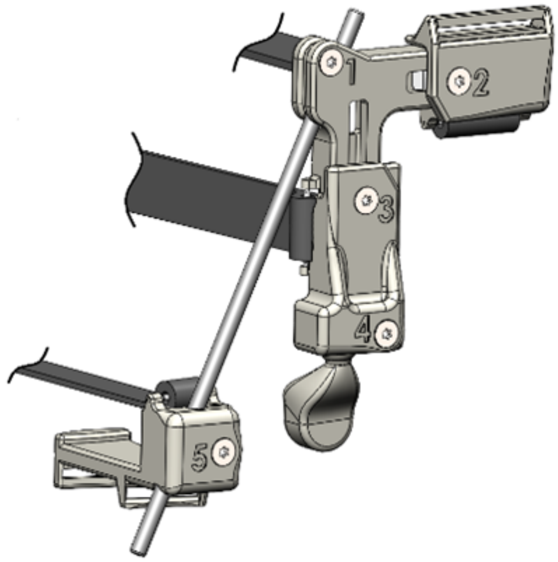


Figure 14: Clubfoot orthosis proposed by Thijs Vogelzang. Image from [29]

Clubfoot orthosis Bachelor project Thijs Vogelzang proposed an orthosis for a project in which a spring steel rod bends the clubfoot in the preferred position. According to the recommendations in the report, more knowledge should be gained about the forces that act on the various components of the brace [29].
This design was fitted on 2 baby feet, in order to evaluate the design. Furthermore, when Renske Biewenga tried to prototype a variation of this concept, several parts broke off during assembly [30], making it impossible to assess the possible functionality of this idea, as no functional prototype has been made.

2.1.3 Stakeholders

In chapter 2.1.1, the limitations and complications of the current serial casting phase of the Ponseti method are described. The following Stakeholders analysis (Table 2) has been made to show the different parties that would be affected by a newly designed clubfoot brace. This is done with the input of several involved parties.
A conversation with the parents of a child with clubfoot showed the importance of less hospital visits. The parents explained that the hospital visits took a lot of their time. Furthermore, the view of their child wearing the cast was also very unpleasant for the parents.
The casting room employees and the doctor treating the patient were quite content with the current method. However, it was shown that several employees were necessary for the casting process. An easier method that only requires one employee would be preferred.
Using this input, Table 2 has been made.

Table 2: Stakeholders analysis

Stakeholder	Characteristics	Expectations	Potentials and deficiencies	Implications and conclusions for the project
Patient	Diagnosed with clubfoot.	Pain-free, long-term treatment that does not hinder mobility.	Newborns have difficulty expressing themselves. Different severities of clubfoot and sizes of infants.	Solution needs to fit all patients.
Parents	Takes patient to and from hospital, takes care of patient.	Strives for good, fast, low-stress treatment of patient. Wants to be able to bathe patient during treatment. Wants fewer hospital visits.	Social stigma on wearing braces/-casts. Responsible for care of patient outside the hospital, so need to be trained in using solution.	Less hospital visits required. Easy solution so parents can use it themselves.
Hospital employees	Strives for best treatment of patient.	Easy, but qualitative treatment.	Will only use easy-to-use solution. Lacks technical knowledge.	Essential for implementing solution in healthcare.
Insurance	Strives to provide good healthcare at low cost.	Lower treatment costs.	Needs product to be cost-effective with no complications.	Essential for implementing solution in healthcare.
Society	Demands low healthcare costs, but high quality solution.	Sustainable and permanent solution.	Can be very critical of failures. Huge pool of consumers.	Patient groups can be asked for input to enhance social acceptance.
Industry	Strives for cheap, scalable product.	Profit.	Solution has to be profitable and manufacturable.	Knowledge of market potential, necessary for manufacturing.

2.1.4 Cause-effect diagram

The relation between the problems described in Section 2.1.1 can be seen in Figure 15. This diagram shows how the Ponseti method causes problems that in return cause a reduced quality of life, of both patient and family.

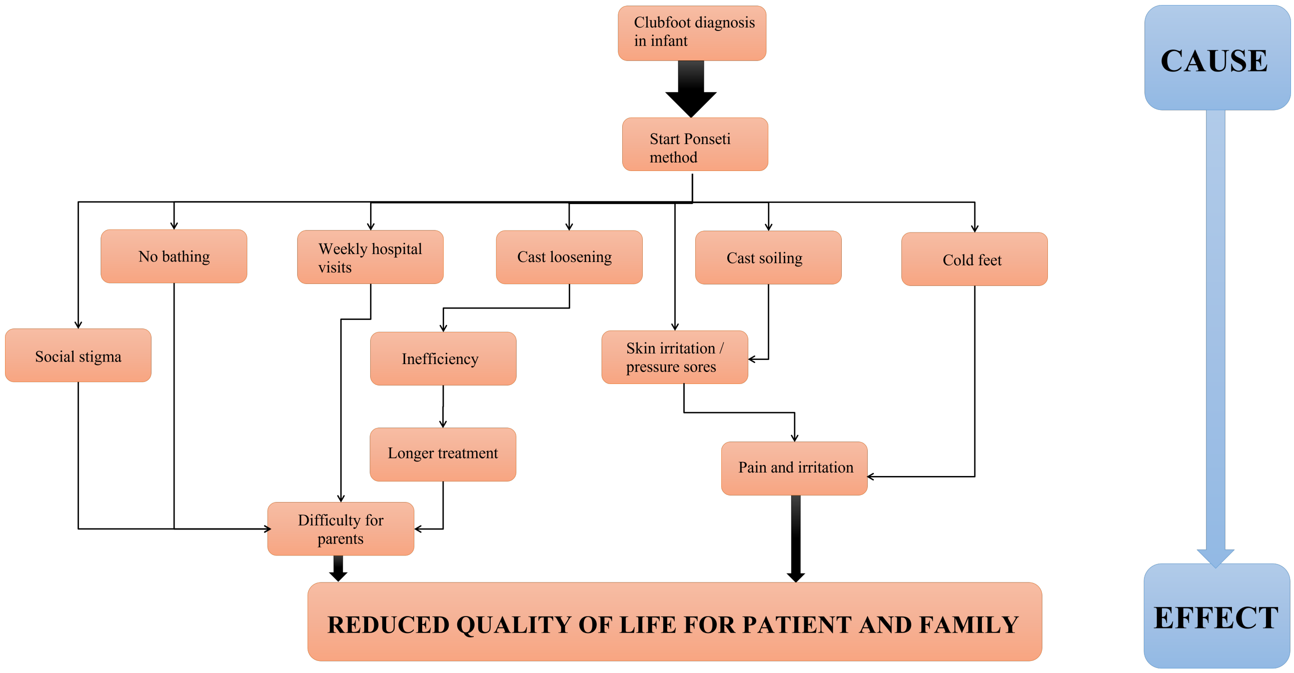


Figure 15: Cause-effect diagram of the problem

2.2 Goals

In Figure 16, the cause-effect diagram of the solution is shown. The goal of the product is to improve the quality of life of the clubfoot patient and their family. This should be achieved by preventing pain and irritation in the patient, caused by cast soiling, pressure sores and skin irritation, and cold feet. Another goal is to decrease the amount of hospital visits, as this is a a big issue for the parents. A more efficient design and the prevention of cast loosening should be able to achieve this goal. The parents should be able to bathe their child on a regular basis. The product should be easily cleanable and resistant to wear and tear. Lastly, social stigma is also one of the factors decreasing the quality of life for the patients' parents. The final product should show that the reason of wearing the device is not because of abuse or negligence.

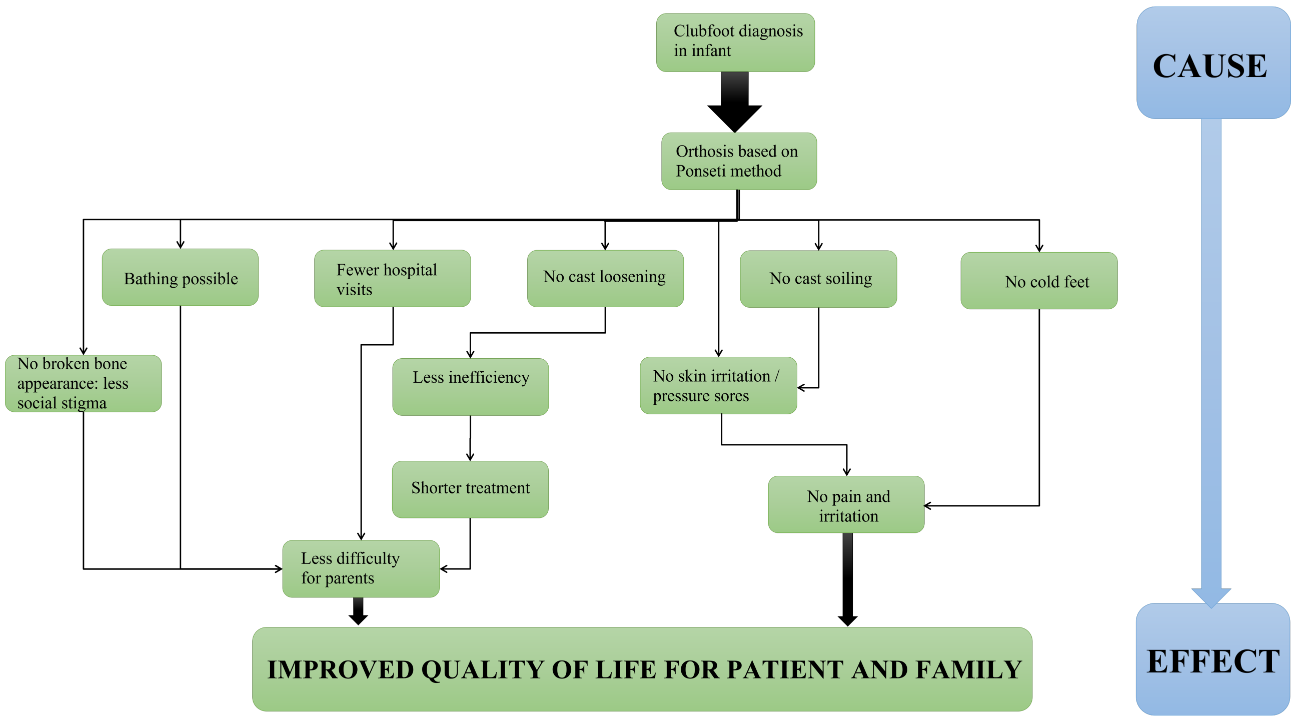


Figure 16: Cause effect diagram of the goal

2.3 Design assignment

The design assignment is to design an orthosis that is capable of replacing (part of) the serial casting phase of the Ponseti method, in order to treat clubfoot. This orthosis has to be safe, it has to work based on the Ponseti principles and it should improve the quality of life of the patient and his/her family.

2.3.1 Strategy to realize the goal

Several strategies can be chosen in order to achieve the design assignment described above. The orthosis should be able to rotate the clubfoot by putting pressure on the first metatarsal bone and counterpressure on the talus. This is a boundary condition for every strategy described below.
A first strategy would be to improve a current design. Another possibility is to create a new design from scratch. The orthosis could be applied to either the entire deformation (Cavus, Adductus, Varus, Equinus), or it is possible to only look at CAV, or even only AV, when in the first 1-2 weeks of treatment the casting method is used, and then later on replaced with an orthosis.
The strategies proposed above can use different techniques.
The orthosis could be adjusted every couple of days by parents or physicians. It could be adjusted in position using motors as well. The brace can be fully mechanical. Pressure sensors could be used to notice when the position of the orthosis should be adjusted. The orthosis could use elastic material to move the foot into the correct position, or use gears to rotate the foot step by step.
All the strategies suggested above have up- and downsides to them.

During synthesis phase I, these up and downsides will be explored and ideas will be proposed to treat the entire CAVE sequence, but also for just CAV and AV. It will be then decided which strategy is most feasible, and that is the strategy that will be finalized.

2.3.2 Limitations

There are several limitations to this project. One of the biggest limitations is time. There are approximately 10 weeks to finish this project. In this short time span, the research and analysis have to be conducted, a poster has to be made, the design has to be determined and preferably prototyped more than once, the prototype has to be tested, the report has to be written, and a presentation has to be prepared and given. Secondly, the prototyping has to be done using 3D-printers. While this method gives a lot of flexibility in creating the design, the printing takes time that has to be taken into account. Furthermore, the budget of this project is around €50, so this has to be taken into account when the materials of the prototype are chosen.

2.3.3 Demarcation

This project will focus on newborns born with idiopathic clubfoot in the Netherlands. The product will focus on replacing the serial casting phase of the Ponseti method. It should be remembered that the design is made for infants, so the patient cannot be instructed about what to do or not to do when wearing the design. The project should improve the quality of life for both patient and their family, but the patients safety should be the primary concern.

2.4 Requirements and Wishes

1. **Use requirements**
    (a) The product <u>must</u> be suitable to be applied by physicians
    (b) The product <u>must</u> be able to correct adductus (abduction of 60 degrees of foot [30])
    (c) The product <u>must</u> be able to correct varus (35 degrees into valgus [31])
    (d) The product <u>should</u> correct cavus (pronation of 50 degrees of forefoot [30])
    (e) The product <u>should</u> be suitable to be applied and removed by trained parents or caregivers
    (f) The product <u>should</u> be easy to clean with IPA (isopropylalcohol)
    (g) The product <u>should</u> allow bathing at least twice a week
2. **Functional requirements**
    (a) The product <u>must</u> apply force on the first metatarsal (3-10 N [18])
    (b) The product <u>must</u> apply counterforce on the talus head
    (c) The product <u>must</u> cause eversion and abduction in the coronal plane of the clubfoot
    (d) The product <u>must</u> cause supination in the transverse plane
    (e) The product <u>should</u> cause dorsiflexion in the saggital plane
3. **Safety requirements**
    (a) The product <u>must</u> have smooth edges
    (b) The product <u>must</u> have adequate ventilation to prevent moisture lesions

(c) The product must not cause pressure sores
(d) The product must not cause skin irritations
(e) The product must be non-toxic
(f) The product must not exert a force greater than 15 N on the clubfoot [18]
(g) The product must be impact resistant

4. **Ergonomics requirements**

(a) The product must fit 95% of newborn babies aged 1-10 weeks
(b) The product must be able to be mirrored to fit both legs
(c) Two products must be suitable to fit on both legs at the same time
(d) The product must have a 90 degree angle between upper and lower leg
(e) The product should be one size fits all

5. **Space requirements**

(a) The product must allow both legs to move separately
(b) The product should allow diaper changes
(c) The product should fit under or over normal clothes

6. **Time requirements**

(a) The product must correct clubfoot equally as fast or faster than the current serial casting method
(b) The product must be applicable within 10 minutes
(c) The product must be removable within 10 minutes
(d) The product must reduce the amount of hospital visits (less than 6 visits)
(e) The time to train caregivers in the application and removal of the product should be less than 30 minutes
(f) The product must be able to apply force until clubfoot is in final position
(g) The product should last at least 3 years

7. **Financial requirements**

(a) The product should cost less than 300 euros for hospitals to buy

8. **Wishes** (Could)

(a) The product could be reusable
(b) The product could (partially) correct equinus (dorsiflexion of 20 degrees of foot)

2.5 Function analysis

The final product has to perform a number of functions in order to be successful. In the function analysis these functions, or steps, are explored. For the clubfoot orthosis, the function analysis is described below.

1. Connect material: The material is attached to the clubfoot.
2. Transport energy: The orthosis exerts energy on the clubfoot.
3. Transform energy: The energy the orthosis exerts is transformed into movement.
4. Transform material: The material and clubfoot adapt to new shape over time.
5. Material transport: Adapations are made to the orthosis and functions 2-5 are repeated.
6. Material separation: The material and clubfoot are separated.

This function analysis is also placed in a block scheme, as shown in Figure 18. The legend for this scheme is shown in Figure 17.

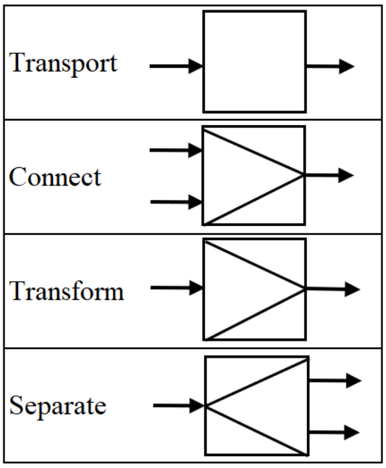


Figure 17: Legend symbols of function analysis

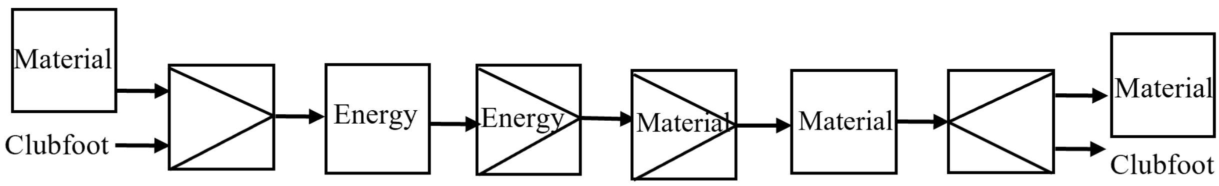


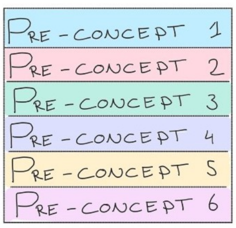
Figure 18: Block scheme of the function analysis

3 Synthesis I

In this Chapter, the finding and selection of the concept used for the final design is explained.

3.1 Morphological map

For each of the main subfunctions (connect materials, transport energy and transform energy), several solutions have been found during a brainstorm session. These solutions are shown in the morphological map below. Several routes have been taken through these different solutions, becoming the pre-concepts of a solution.



(a) Legend

(b) Morphological map

Figure 19: Results of brainstorm session

3.2 Pre-concepts

In this section, each pre-concept will be shortly described. All these pre-concepts are based on the morphological map shown in Section 3.1.

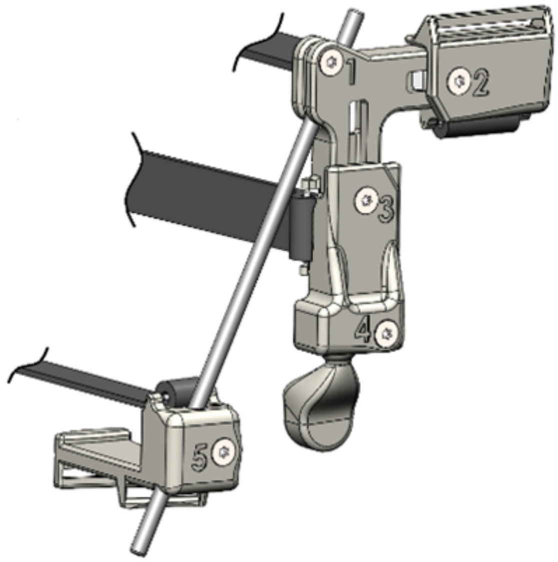


Figure 20: Pre-concept 1: Clubfoot orthosis proposed by Thijs Vogelzang. Image from [29]

3.2.1 Pre-concept 1

The first pre-concept is an improvement of the current design made by Thijs Vogelzang [29].The current design consists of an outer frame and a rod, which is bent when applied, and slowly bends back in place, correcting the clubfoot. However, this design only treats Adductus and Varus. An addition to this design is a second, shorter rod, that only treats Cavus. Also, the "shoe" of this design should be redesigned, making it fit more naturally around the foot. Lastly, the current design has lots of edges and sharp parts. These parts should be smoothened or put in a soft cover.

3.2.2 Pre-concept 2

Based on the soft-robotics concept in [18], the second pre-concept uses a robotic "finger" that will slowly stretch when a fluid is added. A pressure point is placed on the talus to make sure the rotation is correct. The tube through which the fluid is inserted can be closed fully. The parents can add the fluid using a syringe every day, up to every four hours. A second tube is applied at the bottom of the foot. This will push the toes upwards, causing dorsiflexion in the saggital plane.

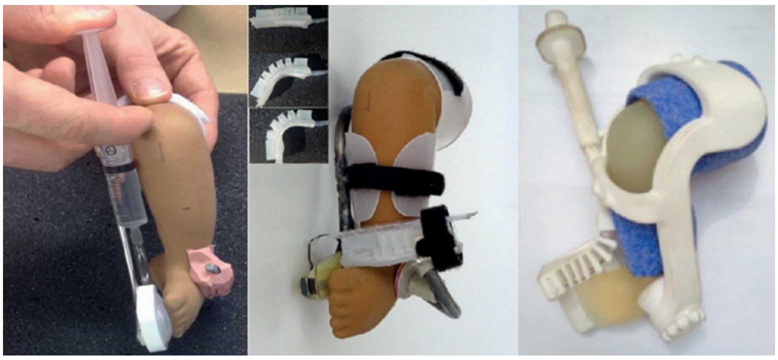
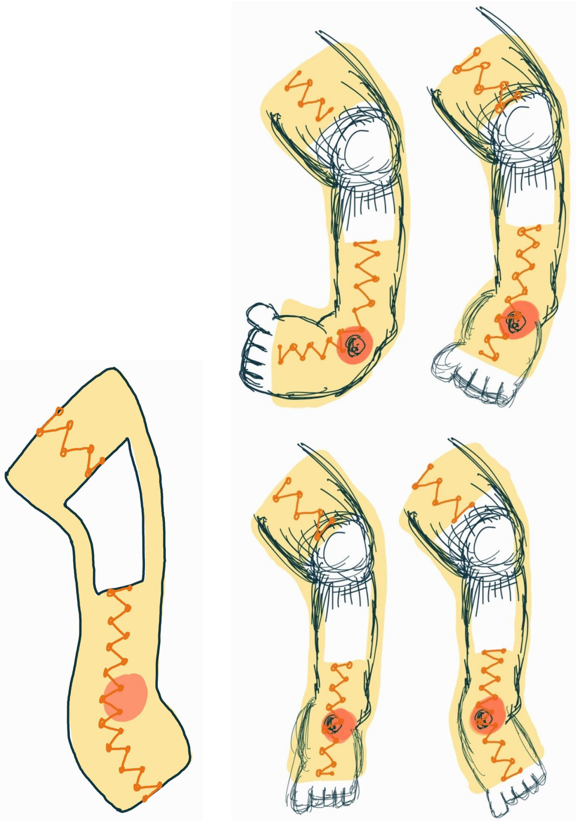


Figure 21: Pre-concept 2: Orthosis based on soft robotics. Prototyping by Esther Keulers and Baat Medical. Image from [18]



(a) Natural position brace

(b) Correction of Adductus and Varus

Figure 22: Pre-concept 3: Silicon sock

3.2.3 Pre-concept 3

A sock-like brace is made from an elastic material, like silicone. It can be attached to the clubfoot by laces. The natural shape of this brace is comparable to the last cast of the Ponseti method, as illustrated in Figure 22a. As the clubfoot tissue relaxes, it slowly moves with the brace to that final position (see Figure 22b). A hard part is inserted around the talus head, to make sure the clubfoot does not rotate over the ankle.

Figure 23: Pre-concept 4: Cunningham Clubfoot Brace. Image from [26]

3.2.4 Pre-concept 4

Pre-concept 4 is based on the Cunningham Clubfoot Brace [26]. This brace is developed as an alternative for the Dennis Brown brace, but the method could be used to replace the Ponseti method as well. A spiral and "shoe" will be made of tough plastic. When applied to a clubfoot, the spiral will rotate the shoe into the final position. A pressure point on the talus is necessary as well. The brace can be applied using Velcro tape, and soft padding has to be added on the inside of the spiral to make sure it does not scratch the baby.

3.2.5 Pre-concept 5

This pre-concept is based on an ankle brace used for sporters. A brace is made of a breathable fabric, which can be attached to the clubfoot using laces. A plastic pressure point is sewn into the fabric on the place of the talus, and a plastic toe cover extends over all toes and goes towards the inner foot over the first metatarsal. Velcro tape extends over the plastic toe cover, the talus head and the in- and outside of the lower leg, up to the knee. Two fabric bands with Velcro tape at the bottom, and partially on the top, are attached to the first metatarsal. The first band will be used to correct Cavus. The band will be put under tension by attaching it to the Velcro on the first metatarsal, over the toe cover, and tightening it up to the talus. Then it will be loosely applied to the Velcro on the inner side of the leg. This is also illustrated in Figure 24. The Velcro tape can be reapplied and tightened every four hours up to every day, until the Cavus has been removed. At this moment, the Velcro will stay in the final position.
After the Cavus has been removed, the Adductus and Varus will be treated in a similar method, as illustrated in Figure 24.

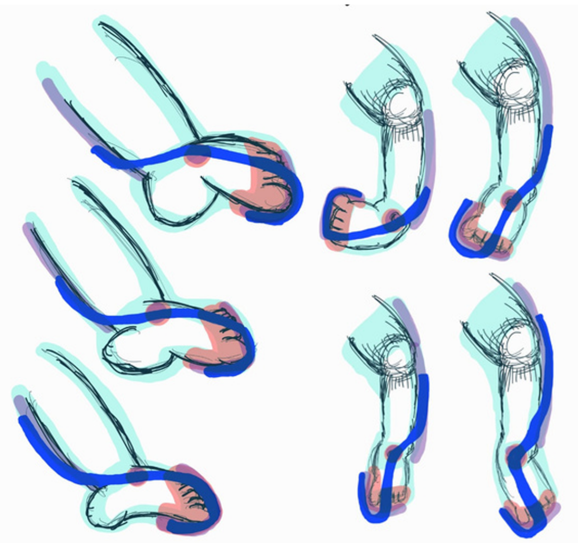


Figure 24: Pre-concept 5: Correction based on a fabric sportsbrace

3.2.6 Pre-concept 6

The last pre-concept uses springs to correct clubfoot. A hard cover is placed around the toes and first metatarsal. A pressure point is placed on the talus head. A stretched out spring is placed from the toes to the talus head. As the force from the spring pulls it back, the forefoot will follow in order to treat Cavus, as can be seen in Figure 25. A hard strip is attached from the first metatarsal to the talus head. A second stretched out spring is attached from the talus head to the knee. As this spring relaxes, the foot will be forced in an outward position, treating Adductus and Varus (Figure 25). The brace will be attached using a clicking system.

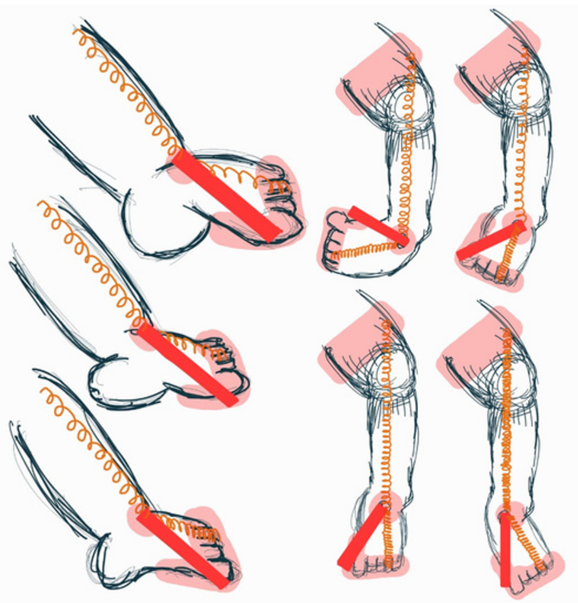


Figure 25: Pre-concept 6: Correction based on springs

3.3 Pre-concept selection

The pre-concepts described in chapter 3.2 all have pro's and cons attached to them. In order to determine the best pre-concept, they have to be ranked.

3.3.1 Requirements scoring

The requirements and wishes explained in chapter 2.4 where divided in the must haves, should haves and could haves. The should have requirements were assigned a weight, ranging from 2-6 based on importance, as seen in Table 3. The most important requirements are correcting the Cavus, allowing bathing and allowing diaper changes. The Could haves were all assigned a weight of one.

Table 3: Weight per requirement

Should haves:	Weight:
1.d	6
1.e	2
1.f	4
1.g	5
2.e	6
4.e	3
5.b	5
5.c	3
6.e	2
7.a	3
Could haves:	
8.a	1
8.b	1
8.c	1

Table 4: Scoring of each pre-concept

(a) Must-have scoring

	Pre-concept:					
Must haves:	1	2	3	4	5	6
1.a						
1.b						
1.c						
2.a						
2.b						
2.c						
2.d						
3.a						
3.b						
3.c						
3.d						
3.e						
3.f						
3.g						
4.a						
4.b						
4.c						
4.d						
5.a						
6.a						
6.b						
6.c						
6.d						

(b) Should-have scoring

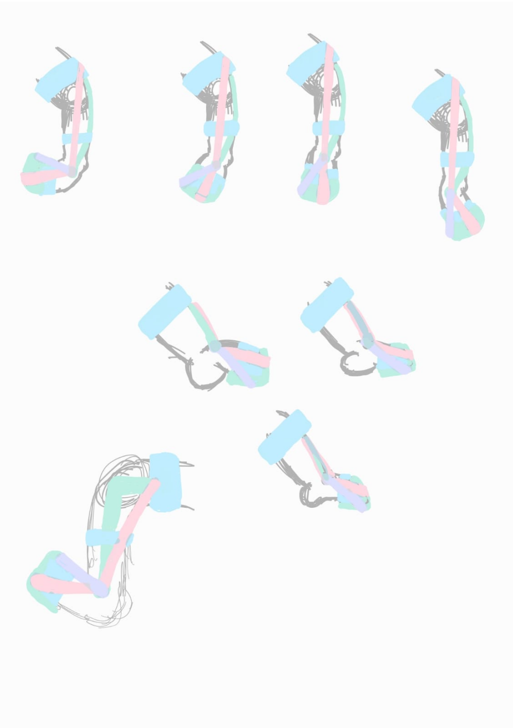
	Pre-concept:						Weight:
Should haves:	1	2	3	4	5	6	
1.d	4	4	2	3	5	5	6
1.e	5	5	4	5	5	5	2
1.f	3	4	5	4	2	3	4
1.g	5	5	4	5	5	5	5
2.e	4	4	2	3	5	5	6
4.e	4	2	2	4	4	4	3
5.b	4	3	5	4	5	5	5
5.c	3	1	5	3	4	3	3
6.e	5	5	5	5	5	5	2
7.a	5	5	5	5	5	5	3
Could haves:							
8.a	5	5	4	5	5	5	1
8.b	1	1	2	2	2	2	1
8.c	5	2	2	3	4	4	1
Weighed score:	172	156	151	163	188	189	

3.3.2 Pre-concept scoring

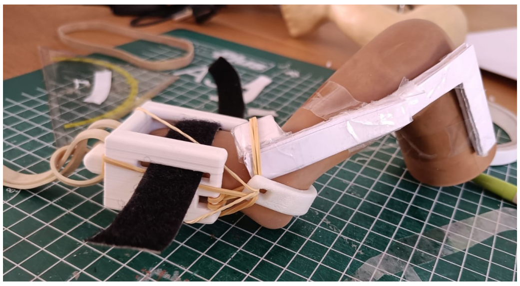
Each pre-concept was assigned a True or False value for the must have requirements, as can be seen in Table 4a. This showed that pre-concept 1, 2 and 6 missed 1 must have, pre-concept 3 missed 2 must haves and pre-concept 4 and 5 fulfilled all must have requirements. For every requirement that is not a must have, each pre-concept was assigned a score ranging from 1-5, where 1 means that the requirement is not fulfilled at all and 5 means the requirement is fulfilled perfectly. These scores were multiplied with the corresponding weight factor and all scores were added together in order to find the weighed score of the entire pre-concept. This can be seen in Table 4b.

3.3.3 Selection

As can be seen in Figure 4, pre-concept 5 and 6 have obtained the highest scores. Pre-concept 1 also has a high score, and the scores of pre-concept 2, 3 and 4 are significantly lower. In order to find a final design, a closer look has to be taken to pre-concept 1, 5 and 6.
All of these pre-concepts have different flaws. Combining the pro's of each concept can give a better pre-concept.
Combining the bands and the springs of pre-concept 5 and 6 gives elastic bands. This reduces the amount of sharp materials or sharp edges present in the pre-concept. Furthermore, the talus pressure point of pre-concept 1 stays in place better than the sewn in pressure point of pre-concept 5.
These combinations give a final, new, pre-concept, explained below.
A hard plastic "shoe" over the first metatarsal and the front of the toes is connected to the foot using a breathable fabric. Inside of the "shoe", soft padding is placed in order to protect the babies toes. A hard brace is connected to the babies upper leg and shin, and has a pressure point that can be placed on the talus head. An elastic band with thickened parts on even lengths connects the shoe from the toes to the brace around the leg in order to treat Cavus. A second elastic band with the same properties as the first band is placed from the first metatarsal to the brace to treat Adductus and Varus.
The drawings of this concept can be seen in Figure 26a, a very simplified prototype can be seen in Figure 26b.
This last pre-concept fulfilled all must-have requirements, and it has been given a score in the same manner as pre-concept 1-6. Table 5 shows that the new pre-concept scores significantly higher than the previous ones.
The new pre-concept, together with pre-concept 1, 5 and 6, were discussed with Dr. Moerman. She agreed that the new pre-concept was better than the others, and thus, this is the concept that will be explored further.



(a) Drawing of final pre-concept



(b) First prototype of final pre-concept

Figure 26: Scoring of each pre-concept

Table 5: Final scoring of best pre-concepts, including the new pre-concept

	Pre-concept:			
Should haves:	1	5	6	NEW
1.d	4	5	5	5
1.e	5	5	5	5
1.f	3	2	3	4
1.g	5	5	5	5
2.e	4	5	5	5
4.e	4	4	4	4
5.b	4	5	5	5
5.c	3	4	3	4
6.e	5	5	5	5
7.a	5	5	5	5
Could haves:				
8.a	5	5	5	5
8.b	1	2	2	2
8.c	5	4	4	5
Weighed score:	172	188	189	197

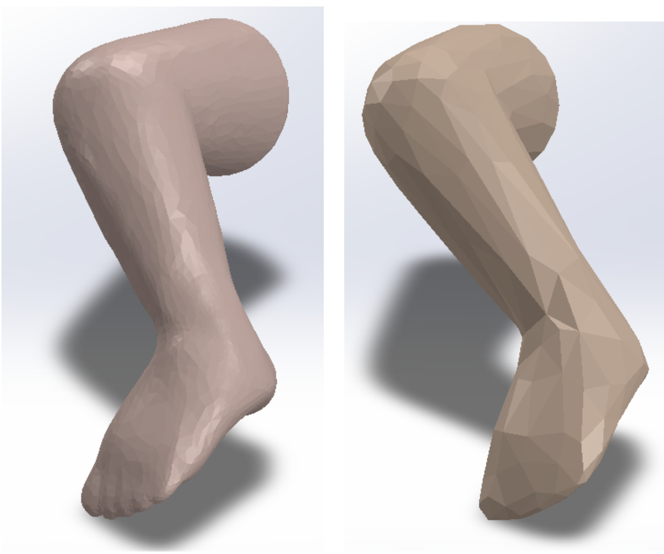
4 Synthesis III

A final pre-concept was chosen in Chapter 3, after merging 3 pre-concepts. As this process is usually part of Synthesis phase II, it was decided to distribute Synthesis phase II over Synthesis phase I and III.

4.1 Clubfoot model

In order to fit and test a prototype, a model of a clubfoot was provided (see Figure 27). This model was taken to the UMCG 3D lab. Using a Cone Beam CT scanner, the foot was scanned and an STL mesh was created. This mesh was reduced in size and later used during the creation of the SolidWorks Images. The original and reduced mesh can be found in Figure 28.

Figure 27: Images of clubfoot model



(a) Original mesh created from clubfoot model (b) Reduced mesh created from clubfoot model

Figure 28: Meshes created from clubfoot modes

5 Synthesis III - SPRINT 1

The first SPRINT of Synthesis III was used to quickly create a prototype and identify points of interest in the final design.

5.1 Concept overview

5.1.1 General overview

As explained in Section 1.2, the Ponseti method treats clubfoot by providing pressure on the first metatarsal and the talus head, slowly rotating the foot in the correct position. It is crucial that the orthosis works like this as well. The concept consists out of 3 parts, a toe part to place pressure on the first metatarsal, a heel part to provide stability, and a leg part to place pressure on the talus and provide a direction for the force. The force in this iteration is provided by rubber bands, and the orthosis is connected to the leg using Velcro tape.
As this prototype is the direct result of the final concept proposed in Section 3.3.3, the general overview of this prototype is the same as the description of the final concept.

5.1.2 Assembly of parts

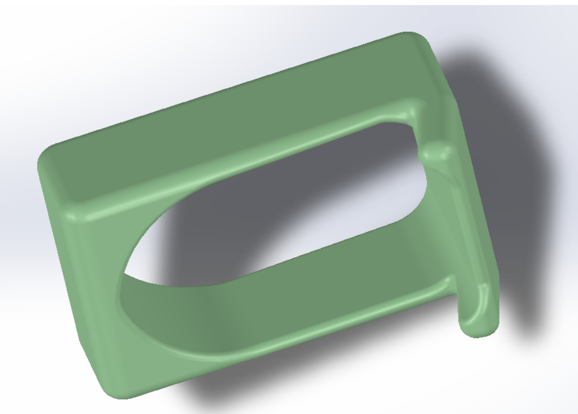


Figure 29: SolidWorks image of the toe part of the shoe

Toe part shoe The shoe consists of 2 3D printed parts, a toe part and a heel part. The toe part has to provide pressure on the first metatarsal, and fit snugly around the foot, without causing pressure sores. Furthermore, the elastic bands need to start from the toes, so they need to be able to be attached here.
The 3D drawing of the first toe shoe can be seen in Figure 29. The elastic bands can be bound around the upper part of the shoe. The medial side of the shoe is lengthened, to provide pressure on the first metatarsal.
This part is made of extrusion printed PLA, with a soft fabric on the inside. There are several issues with this first design. Firstly, by binding the elastic bands around the toes, this can cause friction sores on the baby's foot. Secondly, in order to stay on the foot, the model has to be a tight fit. This would not leave any room for growing. The product would only fit a very select group of infants.

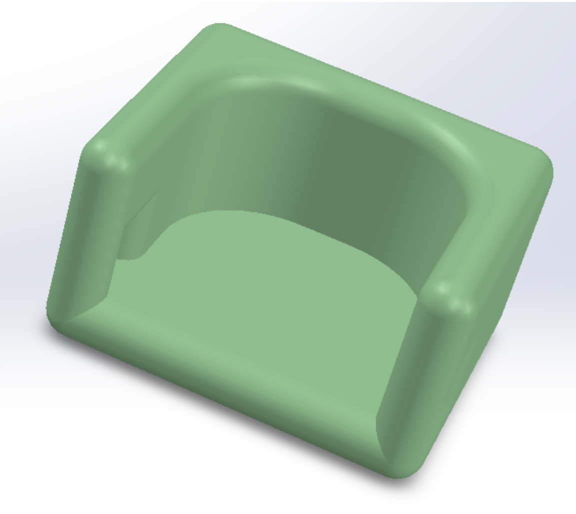


Figure 30: SolidWorks image of the heel part of the shoe

Heel part shoe The model for the heel of the shoe can be seen in Figure 30. This part is made of PLA as well and provides stability in the orthosis. The heel is placed in the U-shaped basket. Bands can be attached to the two holes on the sides to attach the heel part to the toe part.

Due to the height of the sides and depth of the part, this design is not applicable to 95% of the babies with clubfoot. Furthermore, due to the fact that the holes are placed at the bottom of the design, pulling the bands can result in the part 'tipping' over, loosing all function.

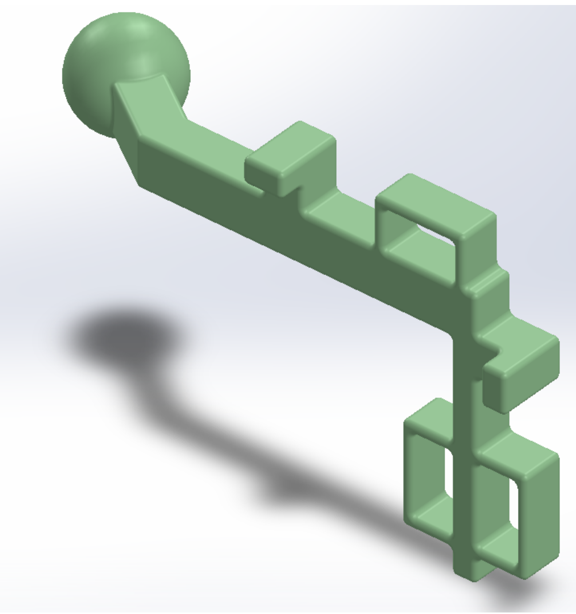


Figure 31: SolidWorks image of the leg part

Leg part The leg part of this iteration consists of one extrusion printed PLA part, the 3D drawing can be seen in Figure 31. The sphere seen in this figure provides pressure on the talus. The part can be applied to the leg by adding Velcro tape through the holes made in the model. The elastic bands can be attached to the two hooks.

This model cannot be changed in size, making it not applicable for at least 95% of the babies. The hooks do not allow a change in length of the elastic band, so the force cannot be changed over time. The shape of the design is also not applicable to the clubfoot model. The lower Velcro strap is attached to high, causing friction in the baby's popliteal area.

Figure 32: Prototype created in SPRINT 1

5.2 Prototype

As can be seen in Figure 32, there are several issues with this design. The heel does not fit, the toe part is too loose, and the talus pressure point is not placed correctly on the talus. The shape of the leg part does not follow the leg, leaving a large gap. The lower Velcro tape is located too high, and the elastic bands cannot be attached to the toe part correctly.

5.2.1 Prototype Creation

The prototype was created using an extrusion 3D printer to print PLA. The different parts were connected to the clubfoot model using Velcro and rubber bands.

6 Synthesis III - SPRINT 2

During the second SPRINT, the second design was created. This design formed the basis of the final product, which will be shown in Chapter 7.

6.1 Concept overview

The main problems found in Chapter 3 were the shape of the toe and heel part of the shoe, the inability to adjust the size, the location of the pressure point, the shape of the leg part, and the location of the attachment of the Velcro strap. These problems will be addressed in the second SPRINT.

6.1.1 General overview

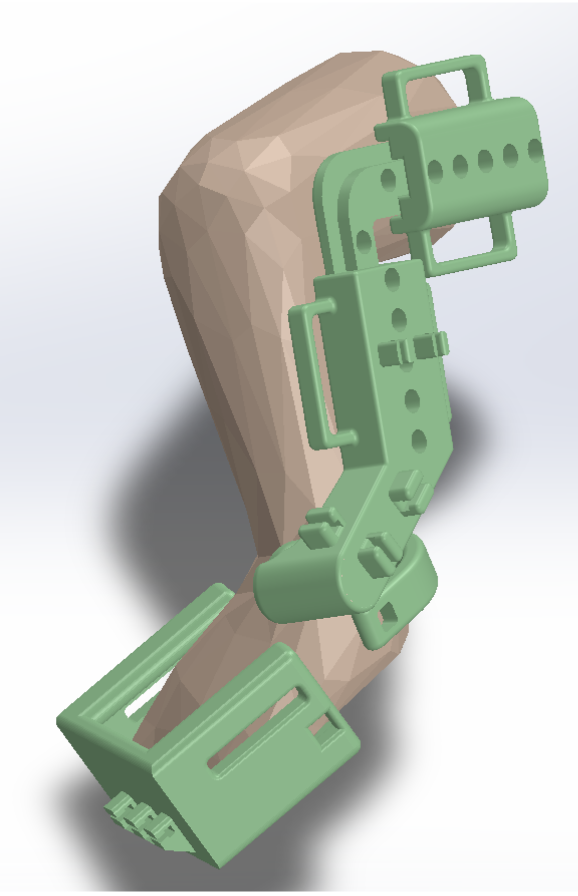


Figure 33: SolidWorks assembly of second prototype

This design consists of 6 parts: a toe part, heel part, lower leg part, knee part, upper leg part and an elastic part. The knee part, lower leg part and upper leg part are connected together with bolts. The upper and lower leg part can be connected to the knee part on different positions, adjusting the size of the orthosis. This connected part creates the leg part of the brace, which provides a pressure point on the talus head to ensure rotation over that point. The upper and lower leg parts have slots to which Velcro band can be connected. This Velcro band is used to connect the leg part to the childs leg. The toe part provides an attachment point for the elastic band and a pressure point on the first metatarsal. The elastic part is attached to the first metatarsal, and is laid around the toe part towards the lower leg part. Tension is applied to the elastic part and it is connected to the clamps of the lower leg part. The tension of the elastic band pulls the foot outward, treating Adductus and Varus.
The assembly picture without elastic bands is shown in Figure 33.

6.1.2 Assembly of parts

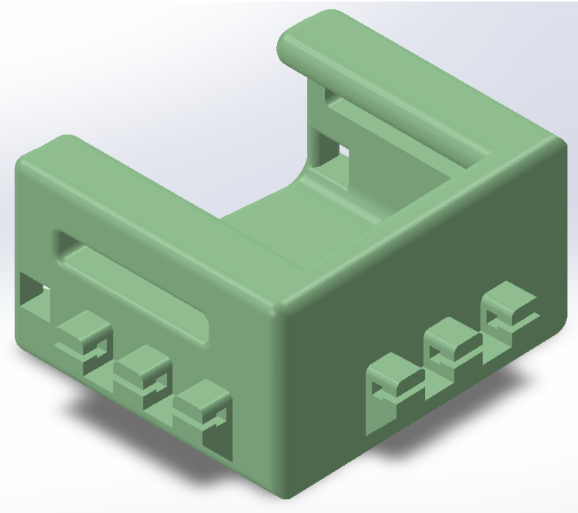


Figure 34: SolidWorks image of the toe part of the shoe

Toe part shoe The toe part consists of an PLA extrusion printed open box in which the forefoot of the baby is placed. Two holes are made to connect the toe part to the to the heel part. Clamps are attached to the medial and anterior sides of the part. These clamps can hold the elastic part. A slit on the medial and lateral side of the part are placed to provide space for Velcro band. The SolidWorks model can be seen in Figure 34.

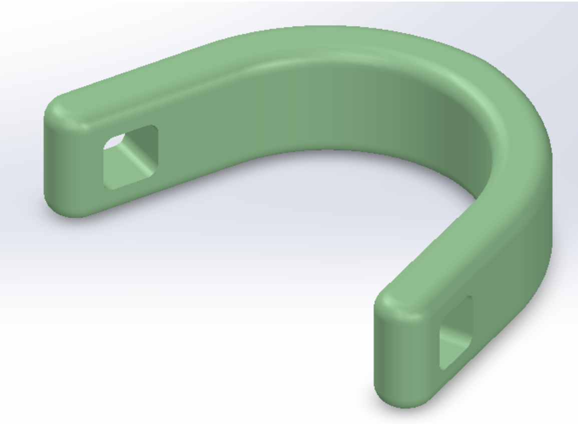


Figure 35: SolidWorks image of the heel part of the shoe

Heel part shoe The heel part is extrusion printed from TPU90a to provide flexibility and to prevent it from scraping into the skin. The model can be seen in Figure 35. It is placed around the Achilles heel. Two holes are made to connect the heel part to the toe part.

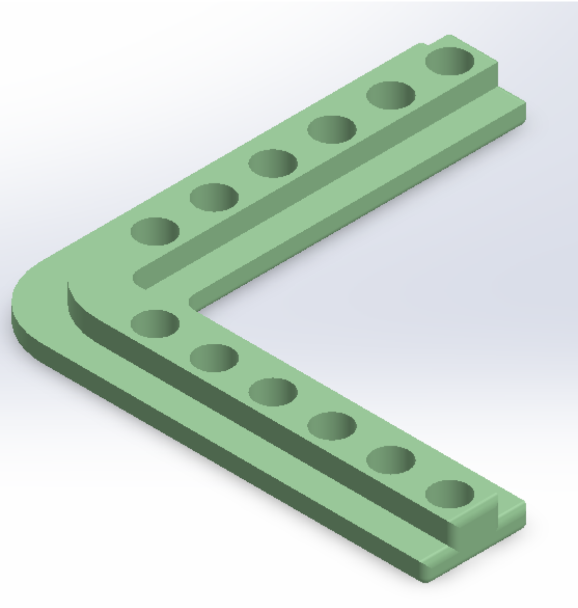


Figure 36: SolidWorks image of the knee part

Knee part The knee part is extrusion printed from PLA and consists of a strip at a 90 degree angle, which can be seen in Figure 36. The upper leg part and the lower leg part can be attached to the knee part at various places due to the screw holes in the knee part. The part where the strip bends is placed on the knee. The “legs” are placed over the upper and lower leg.

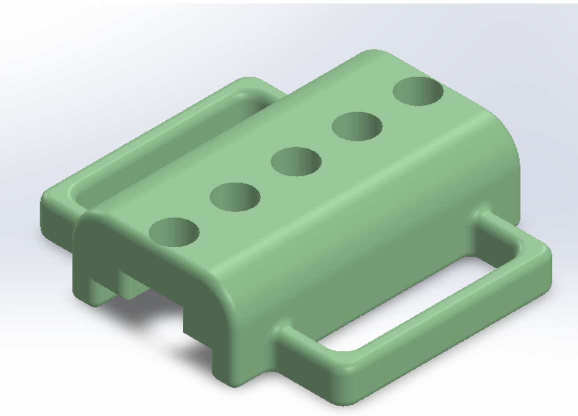


Figure 37: SolidWorks image of the upper leg part

Upper leg part The upper leg part is extrusion printed from PLA and consists of an open bottom where the knee parts fits in, screw holes to connect the upper leg part with the knee part. Two handles are attached to the upper leg part. Here, Velcro band can be connected to the part to fit it tightly around the upper leg. The SolidWorks model can be seen in Figure 37.

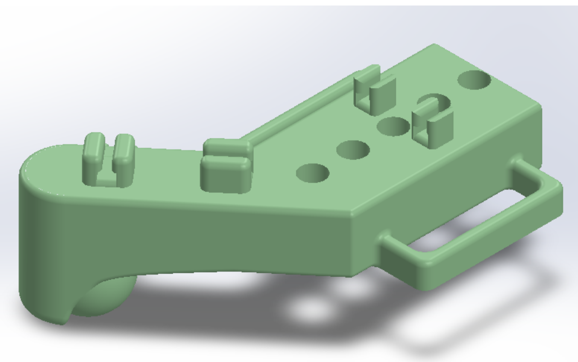


Figure 38: SolidWorks image of the lower leg part

Lower leg part The lower leg part consists of the same connection method as the upper leg part (screw holes and Velcro band). At the inferior side, an extrusion is made in the medial and posterior direction, to provide a pressure point on the talus. Several “clips” are placed on the part to provide place for the elastic band to be attached. The part is extrusion printed from PLA. The model can be seen in Figure 38.

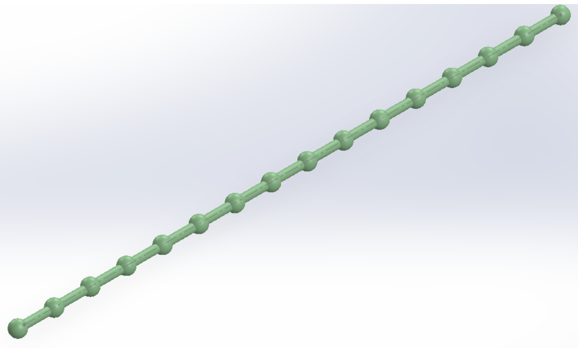


Figure 39: SolidWorks image of the elastic part

Elastic part The elastic part is extrusion printed from TPU90a to provide a flexible method to provide the force needed to correct clubfoot. It consists of a long cylinder with every 10 mm a thicker sphere. This way the force can be adjusted over time. The model can be seen in Figure 39.

6.2 Prototype

The second prototype can be seen in Figure 40. The prototype has improved significantly since the previous iteration. However, there are still significant downsides to this model.
Firstly, it does not correct Cavus, as the elastic band is only pulled outwards, and not upwards. Secondly, the upper and lower leg parts do not connect tightly enough to the leg, causing the elastic band to pull the orthosis down instead of correcting clubfoot.
The shoe is too big, causing the side to touch the talus pressure point when correcting. The slits for the Velcro band over the top is located too high, putting little pressure on the babies forefoot. The clips were also easy to break, and the heel was still connected to the toe part using rubber bands. The shoe is also quite pointy, giving a hostile look.
The pressure point on the talus is is not placed correctly and cannot be adapted to the babies size.
The elastic part gives a lot of flexibility and was strong, but showed plastic deformation when a high force was applied.

6.2.1 Prototype Creation

The second prototype was created by 3D printing the upper leg part, lower leg part, knee part and the toe part using PLA. The heel part and elastic part were printed with TPU90a to ensure flexibility. In the period this prototype was made, screw inserts were not available, so the upper and lower leg part were attached to the knee part using tape. The orthosis was attached to the clubfoot using Velcro band, and the heel part was attached to the toe part and leg part using an elastic band.

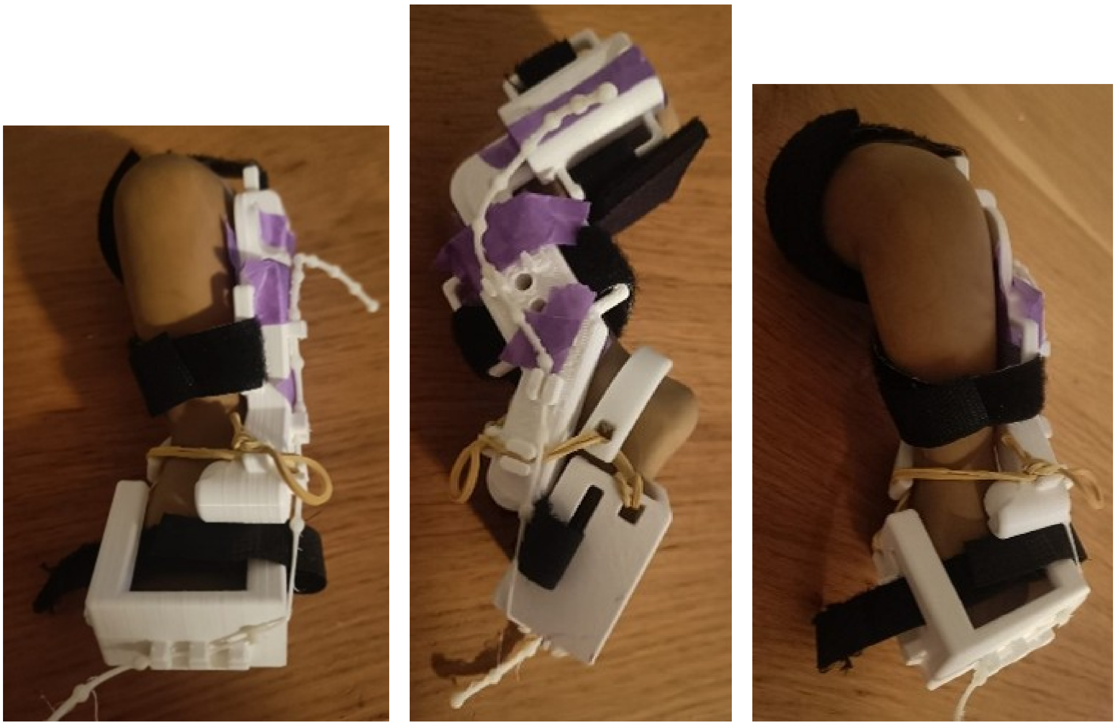


Figure 40: Prototype created in SPRINT 2

7 Synthesis III - SPRINT 3

The last SPRINT was performed to improve the prototype created in SPRINT 2.

7.1 Concept overview

The main problems observed during SPRINT 2 were the size of the shoe, the lack of Cavus treatment, and the attachment of the orthosis. This problems are adressed in SPRINT 3.

7.1.1 General overview

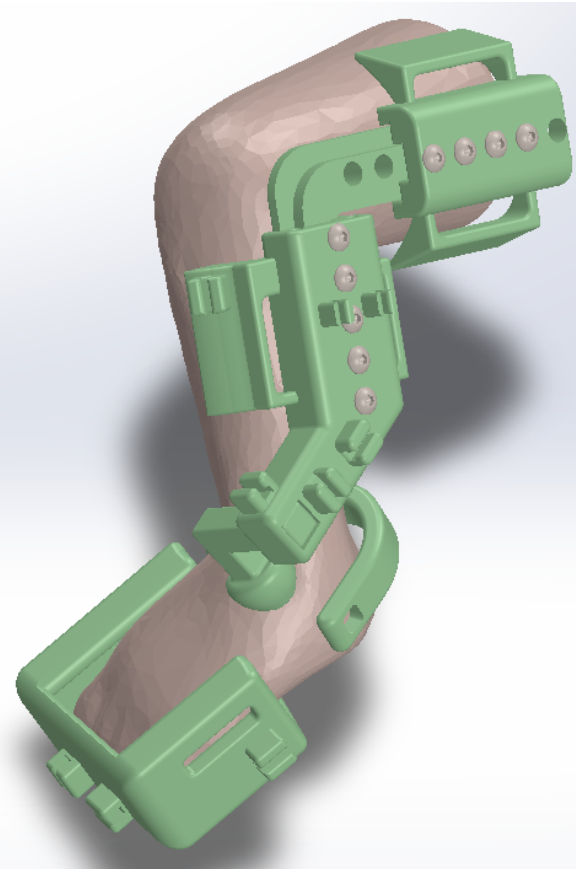


Figure 41: SolidWorks image of the assembly

The concept created in SPRINT 3 is shown in Figure 41. The general mechanism is similar to that of SPRINT 2. However, several improvements have been made. First of all, an extra elastic band has been added. The elastic band starts at the front part of the shoe and moves over the shoe part in order to treat Cavus. An extra clamp is added to the lower leg part to provide an endpoint for this elastic band. The heel part is attached to the toe part using another elastic part. This elastic band is also connected to the lower leg part, to provide stability and extra pressure on the talus head. The slots for the Velcro tape are bended in the new design, providing a smoother design and a more fast connection to the leg. The pressure point for the talus was removed from the lower leg part, and several sized inserts were created. This provides an extra method of adjusting the size of the orthosis to each infant. This insert can also be replaced with a different size during treatment, if necessary. Furthermore, small changes were made in the size of the shoe part, knee part and the Velcro slots to improve fitting. The technical drawing is shown in Figure 42. The SolidWorks file of this drawing can be found in Appendix F.

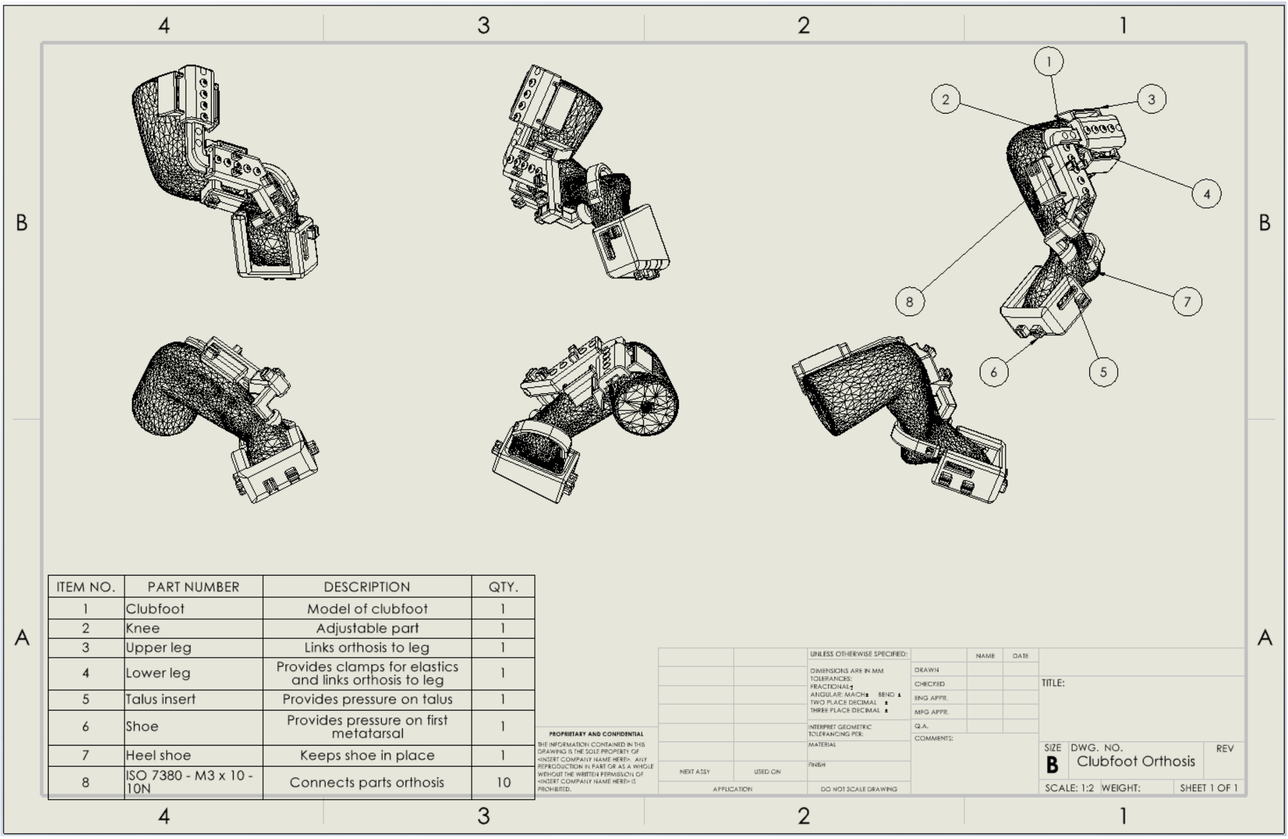


Figure 42: Technical drawing of final prototype

7.1.2 Assembly of parts

Improvements compared to SPRINT 2 are shown per part.

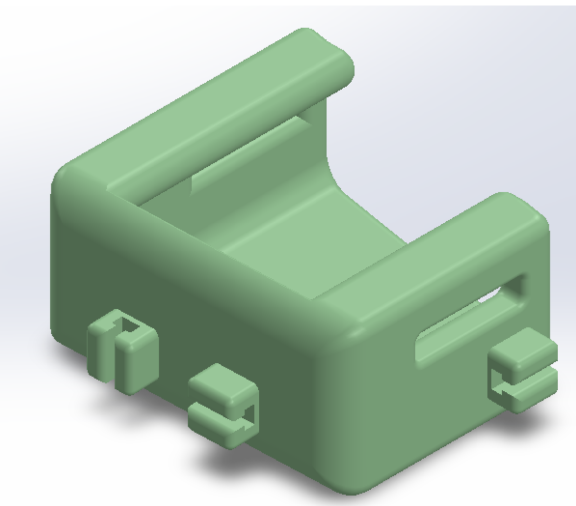


Figure 43: SolidWorks image of the toe part of the shoe

Toe part shoe The toe part of the shoe was improved on several fronts. Firstly, the shoe was made a bit smaller, in order to fit around the foot better. The slits for the Velcro tape are placed more towards the heel, in order to place the tape more over the bridge of the foot. The slits were also placed lower to cause more pressure and ensure a tight fit. One of the clamps was rotated 90 degrees with the aim of treating Cavus. The outer edges were smoothened, giving the part a less hostile look. The new design is shown in Figure 43.

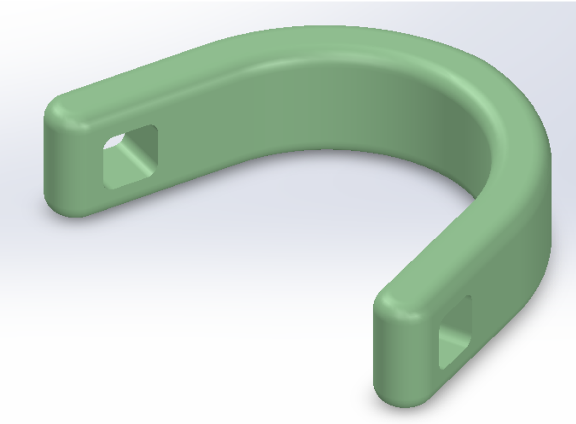


Figure 44: SolidWorks image of the heel part of the shoe

Heel part shoe No changes were made to the heel part of the shoe. See Figure 44.

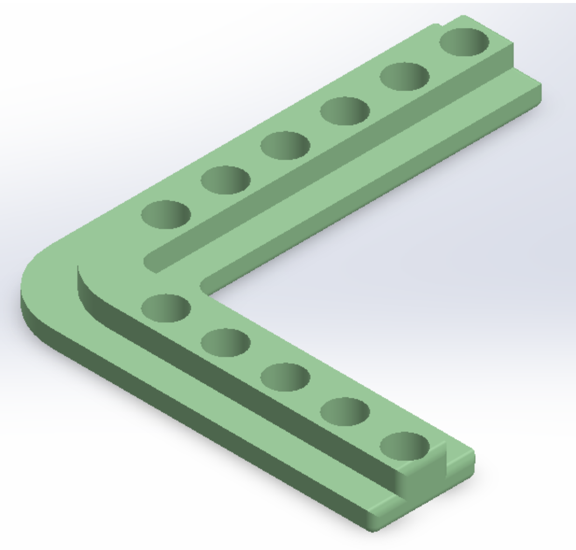


Figure 45: SolidWorks image of the knee part

Knee part One improvement was made to the knee part of the orthosis. The part that connects to the lower leg part was shortened, making it possible to move the lower leg part more upwards and shortening the entire orthosis. The improved part is shown in Figure 45.

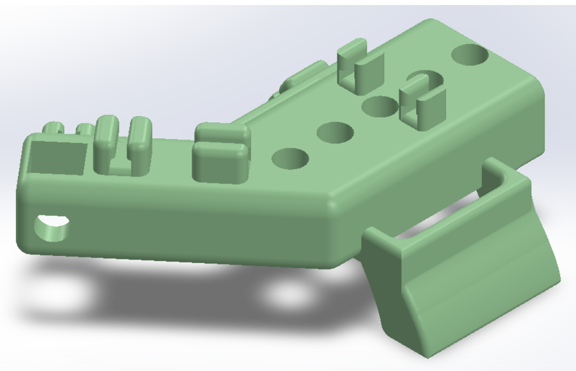


Figure 46: SolidWorks image of the lower leg part

Lower leg part Several improvements were made to the lower leg part. Similar to the improvements of the upper leg part, the attachment part was sized down and put under an angle to improve the fit. A clamp was attached to the inner side of the part, providing a place where the Cavus elastic part can be attached. The talus pressure point was removed and a hole was placed where the Talus insert can be placed. A screwhole was placed next to this hole so the talus insert can be easily secured. The rest of the part was the same as the part in SPRINT 2. The new design is shown in Figure 46.

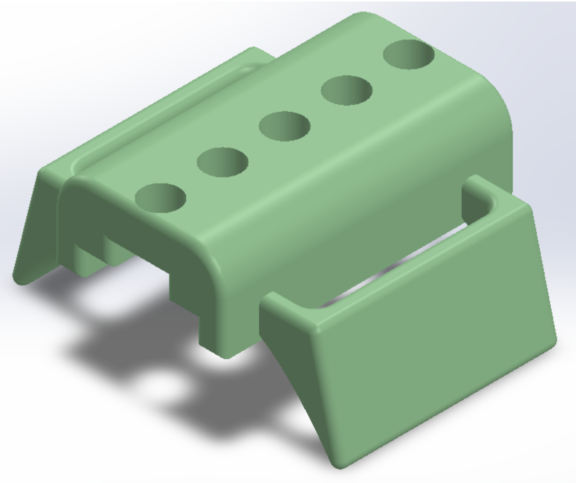


Figure 47: SolidWorks image of the upper leg part

Upper leg part The attachment part of the Velcro straps was decreased in size. Furthermore, the attachment part was rounded on the inside and put under a downwards angle so that the part encloses the upper leg better. This ensures a tight fit and keeps the orthosis better in its place. The part is shown in Figure 47.

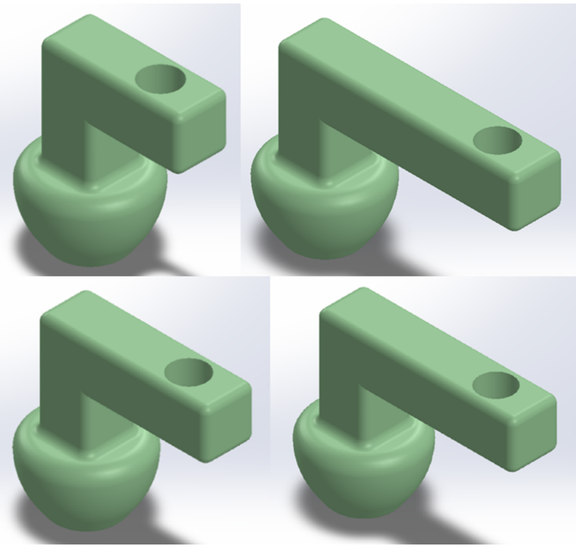


Figure 48: SolidWorks image of the talus insert part

Talus insert The talus inserts can be placed in the insert hole of the lower leg part. The insert comes in 4 different sizes, that can be chosen by a physician depending on the childs size and the severity of the clubfoot. The choice to have several inserts instead of using the same mechanism as for the upper and lower leg is to prevent an protruding part that could potentially harm the child. The pressure point is rounded, but has a flat bottom to spread the forces acting on the talus. The four inserts can be seen in Figure 48.

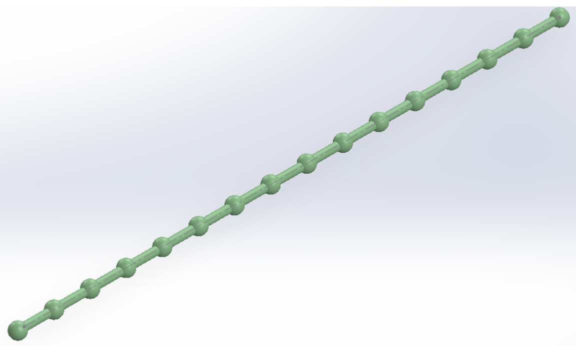


Figure 49: SolidWorks image of the elastic part

Elastic part No improvements were made on the elastic part. This part is used three times in the prototype in order to correct Cavus, Adductus/Varus and in order to connect the heel part to the toe part. For the last application, the elastic part was connected to the shoe, heel part and lower leg part on the lateral side, then the elastic part was cut and the process was repeated on the medial side of the leg. The elastic part is shown in Figure 49.

7.2 Prototype

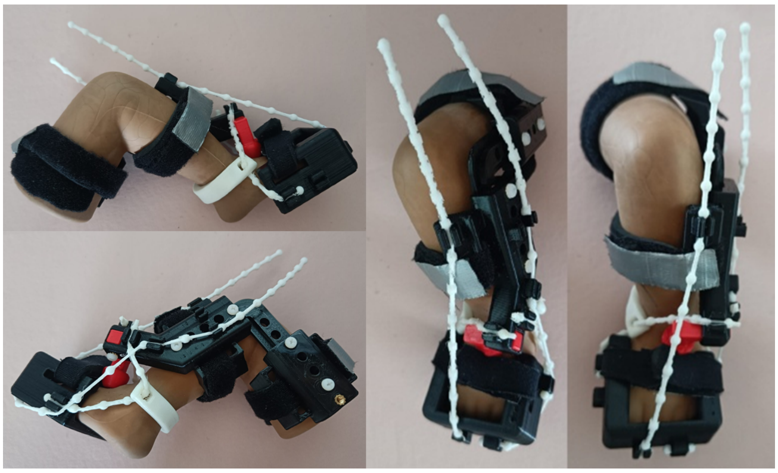


Figure 50: Final Prototype

The prototype is shown in Figure 50. This prototype gives the opportunity to treat both Cavus and Adductus/Varus. It fits around the leg and clubfoot better than the prototype designed in SPRINT 2. The testing and usage of this prototype are described in Section 7.2.2 and Section 7.6, respectively.

7.2.1 Prototype Creation

The prototype was created using an extrusion 3D printer. The upper leg part, knee part, lower leg part, talus inserts and toe part were printed with PLA. The heel part was printed with TPU90a.
The elastic parts were attempted to be printed with a resin printer using elastic resin. However, during the cleaning of the printed part before curing, the elastic band snapped. This was seen as an indication that the material would not work, and the elastics were printed using TPU90a.
M3 screw inserts were placed in the screw holes by placing the inserts on top of the screw hole, and inserting a hot soldering iron in the screw insert. This process heated the insert so that the plastic around it would melt, causing the insert to slowly sink into the screw hole. The prototype was set together using plastic bolts. Velcro felt was cut into straps and used to attach the prototype to the clubfoot model. In order to connect the toe part to the heel part, one of the elastic parts was halved and each part was used to connect one side of the toe part to the heel part and lower leg part. The Cavus elastic part and the Adductus/Varus part were simply clicked in the clamps.

7.2.2 Prototype Testing

Fitting First, the prototype was tested by fitting the different parts on the provided clubfoot model. All talus inserts were tested in order to find the right fit for this model. The elastic parts were attached to the toe part and put under various amounts of tension. Pictures were taken and angles were measured using ImageJ. The results can be found in Table 6. The Figures used to find the angles can be found in Appendix A.
Table 6 clearly shows that an increasing angle corresponds with an increasing tension for the Cavus treatment. This is a first indication that the prototype works. The Adductus angle decreases with increasing tension. This shows that the clubfoot is less severe when a higher tension is applied. Looking at the Dimeglio scoring system in Figure 4 in Section 1.1, no tension and 50 mm excess elastic band

length give the clubfoot model a score of 4. 70 mm and 80 mm both receive a score of 3. So while both the angle and Dimeglio score decrease, the clubfoot does not reach the final position necessary to continue to the second step of the Ponseti treatment.
One possible explanation for the inability to reduce the clubfoot further is the material the clubfoot model is made from. This silicon model is stiffer than an actual clubfoot and the material shows no plastic deformation or viscoelastic behaviour after pressure is applied, which is a fundamental step in the treatment of clubfoot. Due to the lack of plastic deformation, very high forces had to be applied in order to reach the final position of the elastic band. Nevertheless, new testing has to be done on a more realistic model in order to prove this theory.

Table 6: Angle of clubfoot model dependent on tension of elastic band

(a) **Cavus**

Excess elastic length [mm]	**Angle [degrees]**
No tension	148.6
60	167.8
80	179.3

(b) **Adductus/Varus**

Excess elastic length [mm]	**Angle [degrees]**
No tension	60.4
50	48.7
70	32.9
80	21.3

Force measurements Secondly, force measurements on the talus head and first metatarsals were performed using a non-linear piezoelectric force sensor. The force sensor was attached to an Arduino board as shown in Figure 51. The resistor shown in Figure 51 has a resistance of 10 kΩ. The bigger the force applied on the sensor, the higher the output voltage. In order to calibrate the sensor, 'boxes' had to be made to place weights in. The boxes needed to have a bottom with a diameter of 7 mm, as that was the diameter of the measuring part of the force sensor. These boxes can be found in Figure 52. The weights were placed on the sensor and the output voltages were obtained using the code found in Appendix B.

The force put on the sensor was calculated using the following formula:

$$F = m \times a$$

Where F is force in Newton, m is mass in kg and a is acceleration in m/s^2. The acceleration is in this case the gravitational constant, so 9.81 m/s^2. The calculations used to go from mass to force can be found in Appendix C. The force and the output voltages were plotted together. This can be seen in Figure 53. The graph clearly shows an increasing Voltage with an increasing Force, which was expected. Furthermore, the higher the force, the lower the difference in output voltage. The graph also shows some outliers, which indicates a low accuracy of the force sensor. This will have to be taken in to account when applying this calibration to the final results.

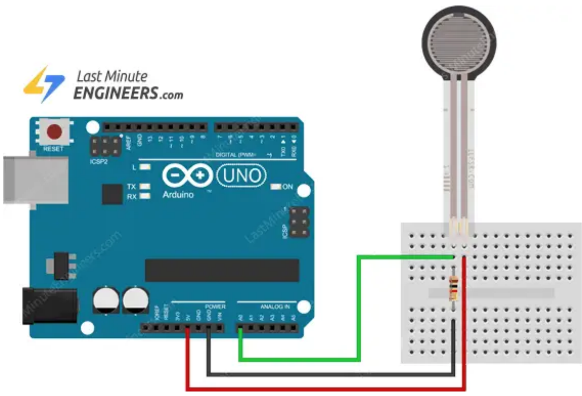
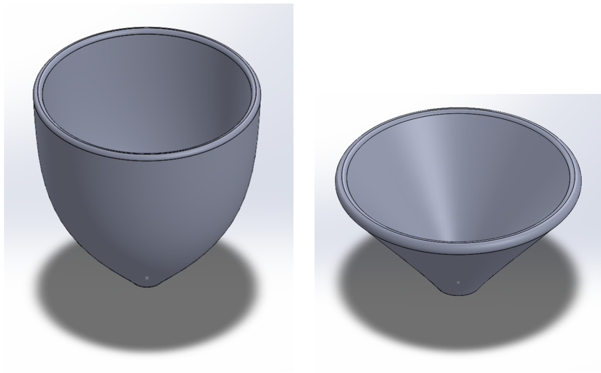


Figure 51: Force sensor Arduino set-up [32]



(a) Natural position brace

(b) Correction of Adductus and Varus

Figure 52: SolidWorks drawing of weight boxes for on top of the force sensor.

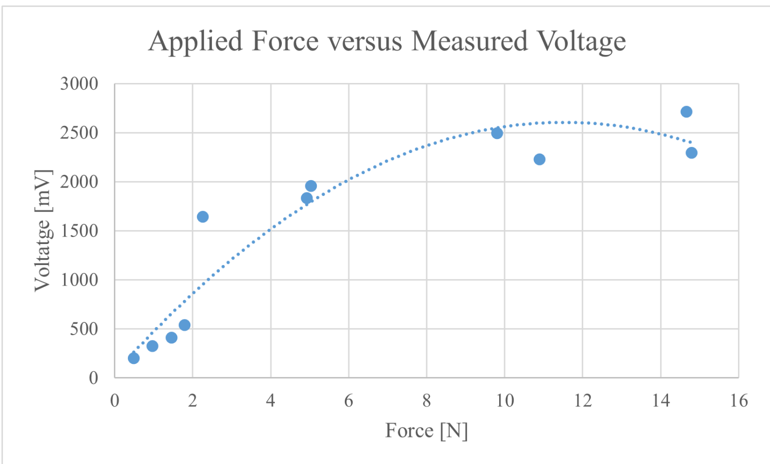


Figure 53: Graph showing the output voltage over the applied force

In order to make the finding of the final forces easier, the graph in Figure 53 had to be inverted. This can be seen in Figure 54.

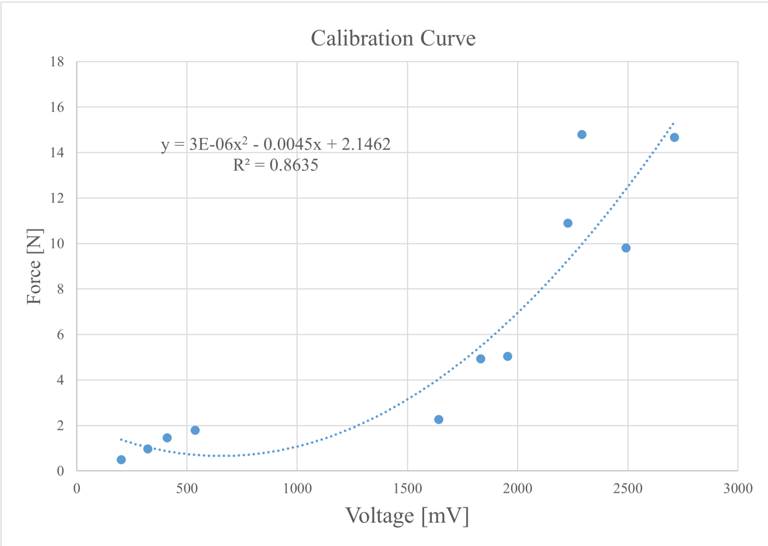


Figure 54: Calibration curve. The formula of the trendline is shown

A notion has to be made about the forces in between 250 and 1000 mV. A trough can be observed in this domain. This was not expected and shows the inaccuracy of the force sensor again. This trough needs to be taken into account when analyzing the results.
Lastly, during the calibration process, it was noticed that with equal force, the output voltage slowly increased. When the load was removed and placed again on the sensor, the output voltage would start low again and slowly increase over time. This occurence can be explained by the creep of the sensor, as the material slowly adjusts to the pressure and gets pressed together more closely [33]. As the load cannot be removed during the measurements, the results of the last measurements will be overestimated whereas the results of the first measurements will be underestimated.

With the aim of distributing the forces equally over the sensor, a plate with a diameter of 7 mm and a depth of 1 mm was 3D printed and attached to the sensor using double-sided tape. The sensor was placed on the talus under the head of the talus insert of the orthosis. The output voltage was measured without any elastic bands on tension, and on various stands of the elastics. Using the formula of the trend-line shown in Figure 54, the amount of force per measurement was calculated. The results can be found in Table 7. C0 means that the Cavus elastic band was loose, C4 means that there was 4 cm of elastic band above the clamp, C5 means that there was 5 cm of elastic band above the clamp. The same goes for AV0 (Adductus/Varus elastic band was loose), AV4, AV5, etc.

Table 7: Results of the force measurements on the talus head and first metatarsal

Talus measurements					
AV=0	**Voltage [mV]**	**Force [N]**	**C=7**	**Voltage [mV]**	**Force [N]**
C0	2693	11.8	AV0	3271	19.5
C4	2722	12.1	AV4	3475	22.7
C5	3128	17.4	AV5	3323	20.3
C6	3137	17.6	AV6	3401	21.5
C7	3271	19.5	AV7	3406	21.6
			AV8	3714	26.8
First metatarsal measurements					
AV=0	**Voltage [mV]**	**Force [N]**	**C=7**	**Voltage [mV]**	**Force [N]**
C0	53	1.92	AV0	327	1.00
C4	97	1.74	AV4	503	0.64
C5	361	0.91	AV5	444	0.74
C6	288	1.10	AV6	483	0.67
C7	327	1.00	AV7	527	0.61
			AV8	855	0.49

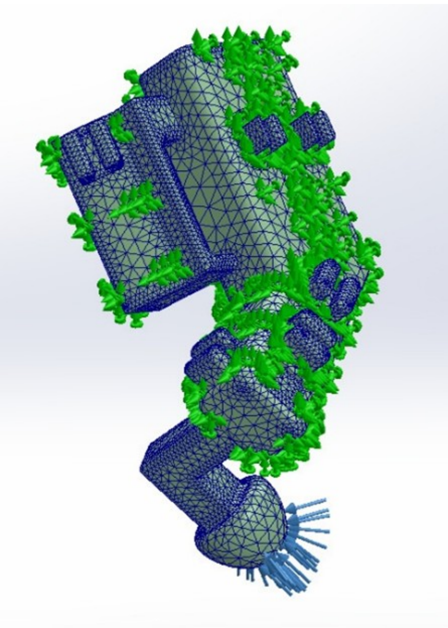
Talus measurements A force much larger than the 15 N proposed in Section 2.4 can be observed on the talus head. The data shows that for both an increase in tension of the Cavus elastic band as the Adductus/Varus elastic band, the force on the talus head increases. As the clubfoot model has not the same viscoelastic properties as an actual clubfoot, this increase in force was expected. The results also show that without any tension on the elastics, the force on the talus head is still 11.8 N. The highest force measured is 26.8 N. Both these values are higher than expected, and could be caused by the size of the orthosis. The talus insert gives too much pressure on the talus head on it's own, meaning that it is located too low regarding the rest of the orthosis. Moving the entire orthosis slightly upwards or reducing the height of the talus insert would reduce this force. Furthermore, when used on actual babies, the elastic band would not be moved until the force has significantly decreased due to the relaxation of the tissue. This means that the higher forces would never be reached.

First metatarsal measurements The results of the first metatarsal measurements differ significantly from the talus measurements. According to the force calculations, an increase of tension shows a decrease of force. However, the voltage measurements do show an increase with an increase of tension. As explained in paragraph 7.2.2, a trough can be observed in the trendline. This trough makes the force calculations incorrect, and the only notion that should be taken is that for all measurements, the force is significantly lower on the first metatarsal than on the talus head.
A couple of explanations can be given for this observation. Firstly, the foot is placed loosely in the shoe. Contrary to the talus insert, the shoe does not provide any pressure on its own on the first metatarsals, considerably reducing the force applied compared to the talus measurements.
A second explanation is the size of the force sensor. While the 7 mm diameter was perfect for the talus measurements, the length of the first metatarsal was a lot larger than that. This caused that the force

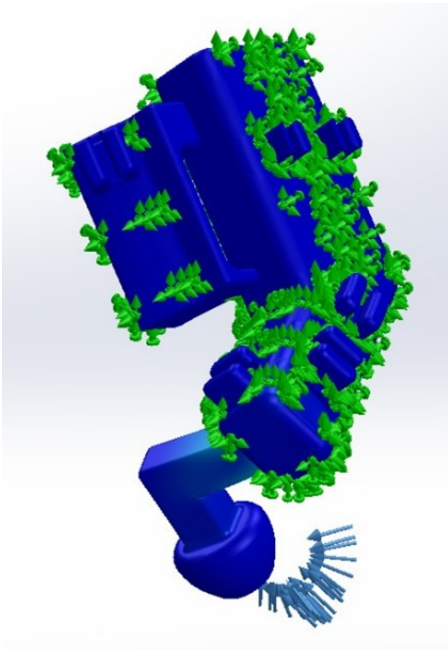
over the entire metatarsal could not be measured, but only on a specific part of the first metatarsal. This point correlates with the last explanation, namely the design of the shoe. The prototype shoe is a black, non-transparent PLA printed shoe. Because of this, the location of the force sensor could not be put exactly on the point where the force was exerted. This could have resulted in the force sensor being put on a part of the foot with very little contact with the shoe, resulting in a low force measurement.
What can be seen in Table 7, is that the voltage increases with increasing tension. This suggest that the force on the first metatarsal increased as well, regardless of the results of the force calculations.

7.3 Finite Element Modeling (FEM)

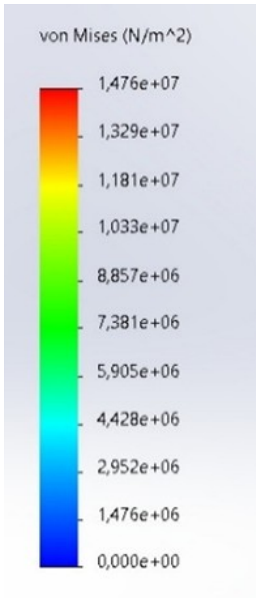
Using the results of the measurements shown in Section 7.2.2, a FEM analysis can be performed of the weakest part of the prototype, namely the talus insert. This analysis shows whether or not the materials and design chosen are strong enough to withstand the forces applied to it. This analysis was performed in SolidWorks. For the bolts, Stainless Steel 316L was chosen as the material. For the talus insert and the lower leg part, a high viscosity polycarbonate was chosen. This choice will be further explained in Section 7.4. The force applied was chosen to be 26.8 N, as this was the highest measured force in Section 7.2.2. The results of the analysis is shown in Figure 55.



(a) Mesh created for FEM



(b) Von Mises stresses acting on talus insert



(c) Legend Von Mises stresses

Figure 55: FEM analysis

Figures 55b and 55c show that the most stress is located where the talus insert is placed in the lower leg part of the orthosis. A slight deformation of the insert part can be observed as well.
The stresses are important, but in order to know wether or not the part will break when used, the factor of safety (FOS) has to be known. This can be seen in Figure 56. If the FOS is below 1, the part will break. The higher the FOS, the less likely the part is to fracture or fail. Usually, a high safety factor is chosen in order to safely use the part.

A FEM analysis was performed on the talus insert. The von Mises stresses are shown in Figure 56. The material chosen is PC. However, due to SolidWorks not having a Yield/Ultimate strength defined, the FOS could not be determined. Changing the material to PET, the FOS could be determined. The Von Mises stresses and the FOS are shown in Figure 57. The Von Mises stresses are comparable, and the minimal FOS is 7.2. This number also an acceptable safety factor, making PET a suitable material for the product. The material choices are explained in Section 7.4.

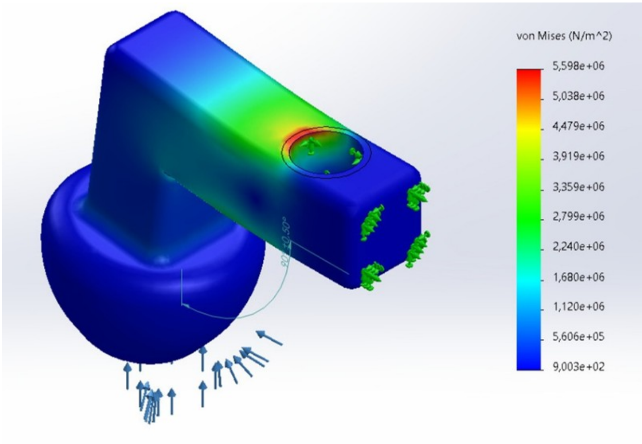
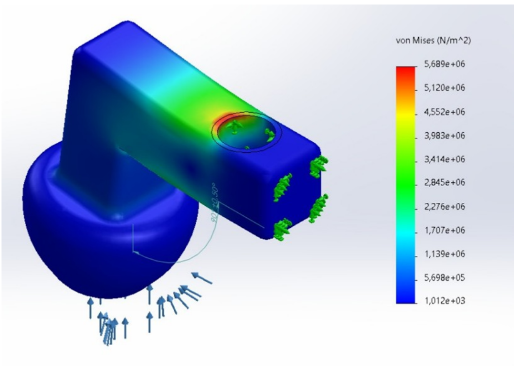
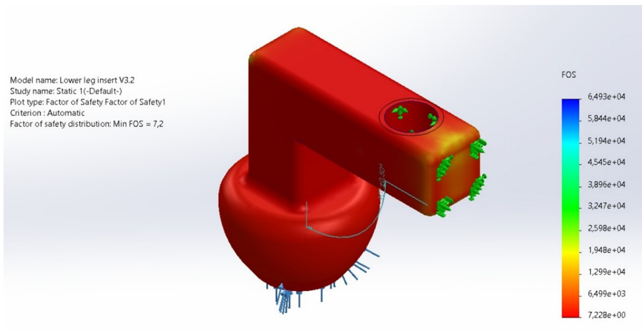


Figure 56: Von Mises stresses on the PC talus insert



(a) Von Mises stresses on the PET talus insert



(b) Factor of Safety of the PET talus insert

Figure 57: FEM analysis of PET talus insert

7.4 Materials & Manufacturing

One to two babies are born with clubfoot every thousand live births [4]. In 2022, there were 167 504 live births in the Netherlands. This means that around 168-336 babies with clubfoot were born. As in 50% of the cases both feet are affected [2], a good estimate of the amount of clubfeet that need to be treated per year in the Netherlands is around 350.
According to Besselaar et al. [34], around 200 infants are born with clubfoot every year in the Netherlands. Both this number and the one calculated above indicate that there is no need for mass manufacturing.
There are several requirements attached to the materials. All materials have to be non-toxic. No small parts should be able to break off, as that could suffocate a baby. The materials shouldn't provoke an allergic reaction and should also not feel uncomfortable on the skin. They should be easy to round off to prevent sharp edges, and be available in several colours. The colour is important for the final product, as the child has to wear the orthosis for several weeks, and nice colours look a lot friendlier to parents than a brace that is just black or white.
The heel part should be flexible. The elastic bands should be flexible as well, but also elastic and able to withstand force without plastic deformation. The other parts have to be strong.
Taking these requirements into account, for the toe part, upper and lower leg parts, and knee part, a hard, strong plastic would be advised. This is available in many colours, is easy to round of the edges and feels a lot more comfortable on the skin than for example stainless steel.
Regarding physical properties, the best options would be either polycarbonate (PC), PETG or Co-Polyester (CPE) [35][36].
Of these materials, there are food safe PETGs and CPEs on the market. BPA free PC filament is also an option [37][38][39]. Regarding the heel part, nylon, polypropylene (PP) or TPU have the correct physical properties. While food safe options are available for all these materials, PP is the only one that is completely non-toxic [35][36][37].
The elastic parts of the prototype were made from TPU90a. This material showed the right properties when tested. As shown above, TPU can be used safely for this product, so TPU is a possible option for the elastic part.
Furthermore, it is important that the materials are printed using a stainless steel nozzle, as brass can be poisonous [37].
The parts should be printed with full infill, to improve strength and lower the chance of parts braking off. If the 3D printer is also used to print with other materials, the nozzle should be cleaned in between prints using cleaning filament.
An advantage of 3D printing is that the scale of the orthosis can be managed per print. For a premature infant, the entire brace can be scaled down and still used with minimal effort.
Printing a singular brace can be done within a day. As for the Ponseti method the first cast is usually applied after the first week, giving the hospital plenty of time printing a brace before that period.
Soft Velcro tape or Velcro felt can be used to attach the orthosis to the clubfoot. A thick, soft fabric should be attached on the inside of the toe part, to make sure not too much pressure is put on the infants toes.
Threaded screw inserts have to be put in the designated holes of the orthosis. The knee part is attached to the upper and lower leg parts using plastic M3 bolts with a round head and flat bottom.

7.5 Cleaning & maintenance

During treatment, the orthosis can be removed by the parents or caregivers once or twice a week and the plastic parts can be cleaned using water and soap. The Velcro and soft fabric can be detached from the orthosis and put in the washing machine, if necessary.
When removed, the orthosis should be inspected by the caregivers for wear and tear, cracks and abnormalities. The Velcro tape should be inspected as well to assure the stability of the orthosis on the leg. Any observed abnormalities should be reported to the physician immediately, who then can decide if replacement is necessary.
After treatment, the orthosis should be cleaned and inspected thoroughly by hospital personnel. The soft fabric on the inside of the toe part and the Velcro felt should be replaced after every patient. The "hard" Velcro tape and the plastic parts can be reused, if there are no clear signs of wear and tear.

7.6 Product usage

A patient specific treatment plan has to be made by the physician in consultation with the parents, depending on the severity of the clubfoot. A shell of a treatment plan has to be made with a physician, but an example could be the following:
Corresponding with the Ponseti method, the Cavus will be addressed first. During the first consultation the orthosis is fitted and put together by the physician. The orthosis is put on the infant, and the first elastic band is placed on the orthosis. The physician also teaches the parents/caregivers how they can do this, and demonstrates how tight the elastic band can be.
The parents/caregivers take home their child and adjust the elastic band when necessary. They check whether or not it is necessary every night. The orthosis can be removed twice a week to allow bathing and cleaning of the orthosis.
After a week, the child is taken back to the hospital so that the physician can judge if the treatment is working and if the parents managed to apply and remove the orthosis correctly. The physician tracks the improvement and makes an estimate of when the treatment of Adductus and Varus can start.
A week after the second elastic band is added in order to treat Adductus and Varus, a new appointment is made, to check up on the parents and the progress of the treatment. If everything is going according to plan, the next appointment will be held two to three weeks later to monitor the progress. If the parents and/or physician are not comfortable with the low amount of appointments, an online appointment could be held every week to check up on the progress.
When the treatment of Adductus and Varus is complete, an Achilles tenotomy will be performed to treat equines. From that point on, the Ponseti method is followed.

7.7 Risk management

There are risks attached to every product, as every product can fail. Risk management identifies and quantifies those risks, in order to create a risk plan. This plan includes actions that must be taken to avoid or minimize those risks. This can be done in a Failure Mode & Effect Analysis (FMEA).

7.7.1 Failure Mode and Effects Analysis

The following definition of a risk was used in the reader "Designing of Biomedical Products" [40]:

"A risk is defined as any event which is likely to adversely affect the ability of the product to achieve the defined objectives"

This definition can be used to identify the risks of the designed product.

Categories The following categories were used to identify the risks. The category number corresponds with the first number of each risk's personal identification number (ID).

1. Manufacturing
2. Assembling
3. Transportation
4. Functioning
5. Use
6. Maintenance

Risk Identification All risks in each category were identified and given an ID number. This can be seen in the Table 8.

Table 8: Risk identification of the various categories

ID	Risk Description
Manufacturing	
1.1	The 3D printer malfunctions causing an inability to produce the parts.
1.2	The filaments can be out of stock and need to be ordered.
1.3	Low accuracy of the 3D printer caused by printer settings.
1.4	Human error regarding the 3D printer usage caused by insufficient training or experience.
1.5	Filament can be stored in a humid area causing low quality prints.
1.6	Low bed adhesion can cause the print to fail.
Assembly	
2.1	Human error can cause an incorrect assembly of the product.
2.2	Parts can break during assembly.
2.3	Necessary screw inserts, bolts or Velcro tape can be out of stock, delaying the assembly process.
2.4	Bolts can be screwed in too loose, resulting in failure of the orthosis.
2.5	Components can be misaligned, causing incorrect assembly of the product.
Transportation	
3.1	During transportation, products can be inadequately protected causing damage.
3.2	Transportation personnel can mishandle the product causing damage.
3.3	Excessive heat or humidity during transportation can compromise the structural integrity of the components.
3.4	Transport companies can lose the product.
Function	
4.1	The Velcro tape is not capable of providing a tight enough fit of the orthosis to the clubfoot.
4.2	Structural failure of the Cavus elastic band can cause injury or a delayed treatment.
4.3	Structural failure of the Adductus/Varus elastic band can cause injury or a delayed treatment.
Use	
5.1	Orthosis can be misplaced on the leg and/or foot by the physician or parents, reducing functionality.
5.2	Parents can misinterpret the instructions given regarding the elastic parts, reducing functionality and potentially harming the child.
5.3	Product materials can cause skin sensitivity, skin irritations or allergic reactions.
5.4	The product can break due to the baby's foot/leg hitting a hard object.
Maintenance	
6.1	Lack of sanitation during treatment period can cause skin irritation and/or bad odor.
6.2	Lack of sanitation in between 2 patients results in an unhygienic situation.
6.3	Lack of inspection to wear and tear signs can cause a lack of functionality in the product.
6.4	No spare parts being available can delay the treatment.
6.5	Cleaning the worn materials can compromise the structural integrity of the components.

Risk quantification Each of the risks described in paragraph 7.7.1 has a certain probability of it happening (P), a severity of the consequences when it happens (S) and a probability of it not being detected in time (D). Each risk can be given a score from 1-10 for P, S and D, where 1 means very low (P), possibly no consequences (S) and detected immediately (D). A score of 10 means certain (P), catastrophic (S) and not detected in time (D). The explanations of each number per risk factor can be seen in Appendix D.
A total risk score (R) can be calculated using these risk factors. This is done by using formula the following formula:

$$R = P \times S \times D$$

For all risks that have a total risk score > 20, a risk action plan has to be made. The P, S, D and R scores of each risk can be found in Table 9.

Table 9: Risk score calculations of each risk

ID	P	S	D	X	Status
1.1	4	4	1	16	OK
1.2	3	3	1	9	OK
1.3	2	2	2	8	OK
1.4	3	2	3	18	OK
1.5	2	3	3	18	OK
1.6	4	2	3	24	NOT OK
2.1	4	2	2	16	OK
2.2	1	2	1	2	OK
2.3	3	2	1	6	OK
2.4	2	4	2	16	OK
2.5	2	3	2	12	OK
3.1	2	3	4	24	NOT OK
3.2	1	3	4	12	OK
3.3	1	3	4	12	OK
3.4	1	3	4	12	OK
4.1	3	5	2	30	NOT OK
4.2	1	6	2	12	OK
4.3	1	6	2	12	OK
5.1	2	5	2	20	NOT OK
5.2	1	6	4	24	NOT OK
5.3	1	6	3	18	OK
5.4	2	4	1	8	OK
6.1	2	6	3	36	NOT OK
6.2	1	5	2	10	OK
6.3	2	5	2	20	NOT OK
6.4	1	4	1	4	OK
6.5	2	4	2	16	OK

Table 9 shows that the status of risk 1.6, 2.4, 3.1, 4.1, 4.2, 4.3, 5.1, 5.2, 5.5, 6.1 and 6.3 are NOT OK. This means that for these risks, an risk action plan has to be made.

7.7.2 Risk action plan

For all the risks whose risk score rated higher than the threshold, a risk action plan is described below. If followed, the risks will reduce significantly or even mitigate, improving the production and making the usage of the product safer.

1.6 Low bed adhesion can cause the print to fail. Low bed adhesion can be caused by both wrong printer settings due to human error as by a faulty printbed. In order to prevent this risk, several steps should be taken. First, the printbed should be from a high adhesion quality. The user of the 3D printer should check the state of the printbed after every print, and order a new one immediately when damage to the printbed is observed or the adhesion seems to be lowered. Using a closed 3D printer will help keep the climate inside the 3D printer stable, reducing the risk of the print deattaching from the printbed.
To reduce the probability of an human error occurring, a manual has to be written. While every 3D printer comes with a manual of their own, printer settings depend on printbed and filament as well. With trial and error, the right settings have to be found per material. These settings should be written down in an easy to use manual to reduce the chances of error.

3.1 During transportation, products can be inadequately protected causing damage. Damage caused by inadequate protection can delay the start of the treatment. The easiest way to prevent this is by keeping the 3D printers in the same hospital as where the treatment is given. The necessary screw inserts, bolts and Velcro tape will have to be transported by outside parties, but these parts are less vulnerable and should be in stock at the hospital at all times. If it is not possible to keep the 3D printer in the hospital, an employee at the 3D printer site should make sure that all parts are individually wrapped in bubble wrap and carefully packed in boxes, ensuring that even if the delivery driver is not careful with the package, the parts will arrive without damage to the hospital.

4.1 The Velcro tape is not capable of providing a tight enough fit of the orthosis to the clubfoot. Velcro tape can become less sticky over time, reducing it's ability to keep the orthosis on it's place. The risk of this negatively impacting treatment can be reduced by providing parents with spare Velcro parts, so they can decide to replace the Velcro when necessary.

5.1 Orthosis can be misplaced on the leg and/or foot by the physician or parents, reducing functionality. The only way to reduce this risk is by practice. The physician should have practiced placing the orthosis on a clubfoot witnessed by a more experienced physician. At the hospital, the parents should apply and remove the orthosis at least twice in front of the physician, to ensure all parties involved understand how it works. If the parents are dependent on another family member or babysitter in the care of the child, this person should receive the same instructions regarding to the orthosis *from the physician*. Furthermore, clear instructions online and on paper should be provided to the parents. These instructions should include both right and wrong examples of how the orthosis is placed, making it easier for the parents to compare. Video instructions of how to apply the orthosis should also be provided to the parents.

5.2 Parents can misinterpret the instructions given regarding the elastic parts, reducing functionality and potentially harming the child Reducing this risk follows the same steps as risk 5.1. Practice at the physicians office, clear instructions with images, explanations and videos should significantly reduce the probability of this risk happening.

6.1 Lack of sanitation during treatment period can cause skin irritation and/or bad odor. During the treatment period, the parents are primarily responsible for the cleaning of the orthosis. In order to reduce this risk of lack of cleaning, the parents should be instructed to clean the brace every time the child takes a bath. Providing a soft soap would encourage the parents to clean the orthosis regularly.

6.3 Lack of inspection to wear and tear signs can cause a lack of functionality in the product. Parents should be provided with examples of wear and tear signs, and pictures of the orthosis they take home should be made so a comparision can be made every week. These actions should prevent that an unfit orthosis is worn.

When taken into account, the risk action plan described above should provide a safe and useful method to use the orthosis as an alternative for the first part of the Ponseti method.

7.8 Testing protocol

Before the orthosis can be used in practice, it has to be tested.
First, the materials have to undergo testing. The elastic parts should be tested on their tensile strength, plastic deformation, and fracture point. As plastic deformation reduces the functionality, and a fracture during treatment could result in injury, it is very important that forces acting on the elastic bands are well below the thresholds of these properties. The materials of the other parts of the orthosis should be tested for their strength as well.
A realistic model of a clubfoot should be made. The silicon model used in this project has very different properties than an actual clubfoot. This influences the force measurements, making it impossible to obtain the actual forces applied to the first metatarsal and talus head when using the orthosis. Using this correct model, accurate force measurements should be made to test the force acting on the talus head and first metatarsal. These measurements should be performed with an accurate sensor designed for this purpose, for example the force sensor proposed by Dr. Giesberts [18]. This way the relaxation can be measured as well, and it can be tested when the tension of the elastic bands should be adjusted. The exact location of the talus pressure point should be decided as well. This can be done by placing the pressure point on top and on the lateral side of the talus head, and several places in between those sides. The angle of the foot should be measured over time of these different placements, in order to find the most effective place to put the pressure point.
When the testing on models is finished, a testing protocol should be made for testing on infants. For the first phase, the orthosis should only be tested on very mild cases of clubfoot. Contrary to the amount of hospital visits after the testing phase, the parents should take their child to the hospital at least once a week. If the method is proven effective, the testing should be expanded to also include more severe cases.

8 Future recommandations

While this project created a stable basis for a clubfoot orthosis, a lot of improvements are still necessary. As explained in Section 7.4 and Section 7.8, additional materials should be tested and considered.
The pressure point on the talus should be improved as well. Currently, it provides too much pressure on top of the talus head, and not enough on the lateral side. This makes Cavus easier to treat, but makes it harder to treat the final stages of Adductus/Varus.
The orthosis created during this project is based on the provided clubfoot model. This model is bigger than a newborns leg and foot, and the severity of the clubfoot is mild. The orthosis should be decreased in size to fit on at least 95% of the newborns with clubfoot.
The orthosis created during this project has a lot of extending parts, and sharp angles. This makes it harder to print with a 3D printer, which reduces the producibility of the product. Improving the printability by reducing the amount of overhang should improve the model. This will also reduce the amount of support needed during printing, giving the product a smoother feel.
The toe part of the shoe is connected to the foot using Velcro. A possible improvement could be a connection method that provides more pressure to the top of the foot. This would make it possible to remove the Cavus elastic band after the Cavus is treated. Parents would have to take less factors into account when removing and placing the orthosis from and on the leg, making it easier to use.
There should also be added another clamp on the toe part. This clamp should be located as low as possible on the lateral side of the toe part, in order to guide the Adductus/Varus elastic band better upwards.
The slots of the upper and lower legs are currently made from the same material as the rest of those parts. Making the slots from a softer, bendable material would ensure a tighter fit and the orthosis should stay in its place better. This can be achieved by making the slots "insertable" in the upper and lower leg parts, so that they can be printed separately.
The elastic bands are currently extended pretty far from the leg and orthosis. This can cause the orthosis to get stuck, providing a very uncomfortable situation for both child and parents. Finding a method to "hide" the elastics better or lead them closer to the foot itself would significantly improve this prototype.
The elastics are currently easily removable from the clamps. If the infant hits something, the elastic bands can get loose. This would delay the treatment, and the child could put the elastic bands in his/her mouth, possibly suffocating on it. Therefore, the most important recommendation for future research is to find a safety mechanism to protect the elastic bands from being removed easily. A possible option for this could be a stretchable cover surrounding the entire orthosis. If something goes wrong and the elastic band is removed from the clamps, it will stay inside the cover and not endanger the child.
Lastly, research should be done on what exactly causes the Ponseti method to function. The orthosis proposed in this report uses a continuous force to correct clubfoot, but another option could be that maintaining the correct position (without exerting any force), could be of great value as well. If this is the case, next to the elastic band, a non-elastic rope should be added as well. The treatment would be slightly elongated, and a time period in which no extra force by the elastic band is exerted, but the position is maintained by the rope, should be added in between adjusting the elastic band to a new position. This would ensure that the clubfoot has enough time to adjust to its new position.

9 Conclusion

The design assignment, described in Section 2.3, states that the orthosis should replace (part of) the serial casting phase of the Ponseti method, in order to treat clubfoot. Furthermore, the orthosis should be safe, be based on the Ponseti principles and should improve the quality of life of the patient and family.
The design fulfills all use requirements except for the cleanability with IPA (1.f). However, it can be cleaned with mild soap.
The functional requirement regarding force (2.a), was not proven to be obtained. However, wether this is due to the lack of pressure on the first metatarsal, or due to the pressure sensor is not known, and should be investigated in the future.
Safety requirement 3.f states that no force greater than 15 N can be applied on the clubfoot. This requirement was not realized. Redesigning the talus insert as described in Section 8 should make it possible to realize this requirement.
The product fulfills all ergonomics, space and financial requirements. Time requirement 6.g states that the product should last at least 3 years. In order to be certain wether or not this requirement is obtained, more testing has to be done. The other time requirements were realized.
In conclusion, the design presented in this report shows potential, and most of the requirements have been met, but still has a lot of testing and improvements needed before clinical trials could be attempted.

10 Ethical Considerations

As explained in Section 9, this project aimed to replace part of the Ponseti method, a medical procedure aimed at young infants. In research, ethics always need to be taken into consideration.
Biomedical Engineering is a combination of research, medicine and engineering. The ethics regarding Biomedical Engineering stem from these fields as well. The primary responsibilities are to prevent harm to the patient, and to *only* come up with improvements regarding the prevention of harm [41][42][43].
This project is morally and ethically acceptable because it fits under the two responsibilities proposed above. The goal was to improve a medical procedure, improving the treatment and thus reducing harm to the patient. As the prototype was not tested on any patients, the ethics regarding medical testing did not have to be taken into account.
ChatGPT was used in this project to find synonyms for certain words to make the report more easily readable. As this falls under language correction, the usage of ChatGPT was not unethical [44]. The AI Declaration Form can be found in Appendix E.

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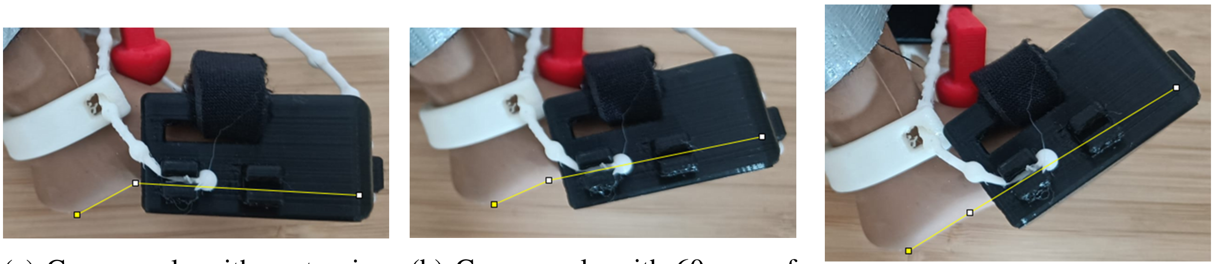
Appendices

A Angle measurements

The Adductus/Varus angles in Figure 59 show the outer angles The results are shown in Table 10. However, in the Dimeglio scoring system, the inner angles are used. To fix this, the following formula was used:

$$180 - measured\_angle = Dimeglio\_angle$$

The calculated Dimeglio angles are shown in Table 6 in Section 7.2.2



(a) Cavus angle with no tension on the elastic band

(b) Cavus angle with 60 mm of excess elastic length

(c) Cavus angle with 80 mm of excess elastic length

Figure 58: The change in angle of the forefoot with respect to the heel, depending on tension applied to the Cavus elastic band

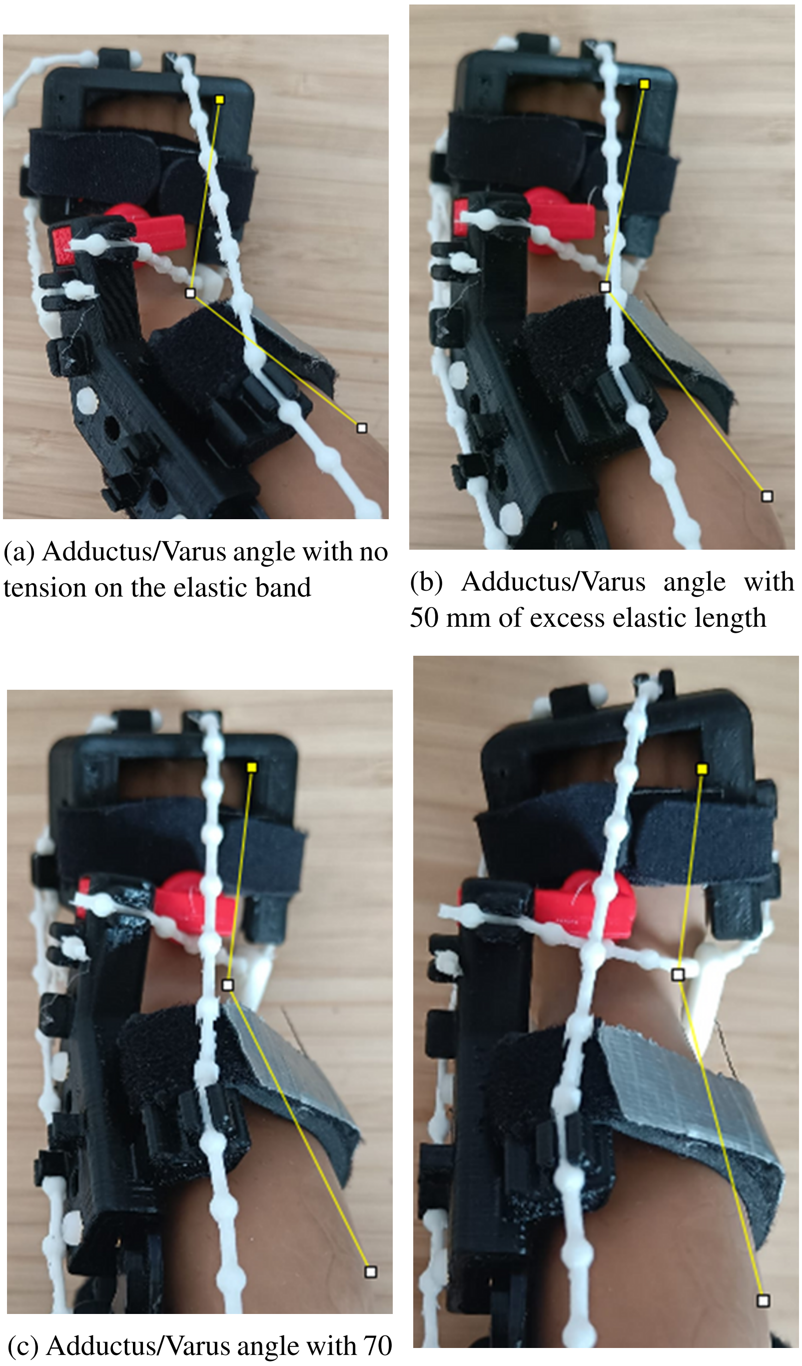
Table 10: Measured angle of clubfoot model dependent on tension of elastic band

(a) **Cavus**

Excess elastic length [mm]	Angle [degrees]
No tension	148.6
60	167.8
80	179.3

(b) **Adductus/Varus**

Excess elastic length [mm]	Angle [degrees]
No tension	119.6
50	131.3
70	147.1
80	158.7



(a) Adductus/Varus angle with no tension on the elastic band

(b) Adductus/Varus angle with 50 mm of excess elastic length

(c) Adductus/Varus angle with 70 mm of excess elastic length

(d) Adductus/Varus angle with 80 mm of excess elastic length

Figure 59: The change in angle of the foot with respect to the lower leg, depending on tension applied to the Adductus/Varus elastic band

B Arduino code

```
int fsrPin = 0;      // the FSR and 10K pulldown are connected to a0
int fsrReading;      // the analog reading from the FSR resistor divider
int fsrVoltage;      // the analog reading converted to voltage

void setup(void) {
  Serial.begin(112500);   // We'll send debugging information via the Serial
      monitor
}

void loop(void) {
  fsrReading = analogRead(fsrPin);

  // analog voltage reading ranges from about 0 to 1023 which maps to 0V to 5V
      (= 5000mV)
  fsrVoltage = map(fsrReading, 0, 1023, 0, 5000);
  Serial.print("Voltage reading in mV = ");
  Serial.println(fsrVoltage);
  delay(1000);
}
```

Listing 1: Arduino code used for the force sensor, adapted from [32]

C Force calculations

In Table 11, the raw data from the calibration is shown. The force is calculated from the weight using the Formula:

$$F = m \times a$$

Where a is the gravitational constant g, namely 9.91 m/s^2.

Table 11: Weight to Force calculations with the measured Analog and Voltage values

Weight [g]	**Force [N]**	**Measured Analog value**	**Measured Voltage [mV]**
50	0.4905	42	202
99	0.97119	64	322
148	1.45188	84	410
182	1.78542	110	537
230	2.2563	337	1642
502	4.92462	375	1832
513	5.03253	400	1955
1000	9.81	510	2492
1111	10.89891	456	2228
1495	14.66595	555	2712
1508	14.79348	469	2292

D Risk Factors

Table 12 and 13 show the meaning of each score regarding the risk factors.

Table 12: Failure Probability (P) and Severity (S) Scoring

Score	Failure probability	Severeness of failure
1	Very low (1 per 20 yr)	Possibly not detected (no costs)
2	Low (1 per 10 yr)	Low (repair costs < €50)
3	Less low (1 per 5 yr)	Less severe (repair + consequences costs < €100)
4	Below average	Below average (overall costs < €1000)
5	Average	Average (overall costs > €1000)
6	Above average	Above average (costs > €1000 and/or slightly wounded)
7	Rather high	Rather serious (costs > €10,000 and/or slightly to severely wounded)
8	High	High (costs > €10,000 and/or 1 dead person)
9	Very high	Very high (costs €100,000 and several dead)
10	Sure	Catastrophic (costs > €1M and/or more than 10 dead)

Table 13: Probability of Not Detecting (D) Failure in Time

Score	Probability of *not* detected in time
1	Failure is immediately detected
2	Failure is detected within an hour
3	Failure is detected within a day
4	Failure is detected within a week
5	Failure is detected within a month
6	Failure is detected within a year
7	Failure is detected at routine inspection
8	Failure is detected at intensive inspection
9	Failure is detected only with specialized equipment
10	Failure is not detected in time

Note: Total risk score $R = P \cdot S \cdot D$. Scores > 20 are not acceptable.

E AI Declaration Form

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Appendix: Declaration on the use of generative AI systems during BME projects

Title of the project:	Design of a Clubfoot Orthosis: A Valid Alternative for the Ponseti Method?
Your full name:	Sigrid Jacobje Algera
Student number:	S5220440

In the project I have used systems based on generative artificial intelligence (AI)[1, 2]
(please check one of the boxes with X).

[X] Yes [ ] No

If you have selected "Yes", complete the rest of the form. If you have selected "No", simply fill in the place, date and signature below.

I have used the following generative AI based systems in the creation of this thesis: [1, 2]
(please list all systems used below)

1.	ChatGPT
2.	
3.	
Other:	

I further declare that I
(please check one of the boxes with X).)

[X] have actively informed myself about the capabilities and limitations of the above-mentioned AI systems to the extent that I can use them responsibly,
[X] have labelled the content taken from the AI systems listed above with my details in the table below,
[X] have verified that the content generated by the above-mentioned AI systems and adopted by me is factually correct,
[X] am aware that, as the author of this work, I am responsible for the information and statements made in it,
[X] am aware that the violation of the disclosure of the use of generative AI in my work is a deception and leads to an evaluation with an insufficient grade.

- Indicate in the table on the next page when the above-mentioned AI systems have been used during your project.
- When you have completed and signed the form, please add it to the beginning of your thesis/report, straight after the standard title page).

[1] This declaration does not apply to the use of basic widely used tools for checking spelling and grammar, translating texts and improving software quality for data analysis and software prototypes.
[2] If you are unsure whether an IT system used is a generative AI system and/or whether you need to declare it, declare it.

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I have applied the above-mentioned AI systems as indicated below.

Areas of contribution	Number AI system(s) used	Description of the manner of use and compliance with good scientific practice, if necessary separately by chapter of the work
Development and conception of the research project	None	
Collection and evaluation of literature sources	None	
Elaboration, collection and/or procurement of data	None	
Processing of data	None	
Selection of methodology	None	

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Programming	None	
Analysis/evaluation of the data/sources	None	
Interpretation of the analysis /evaluation and derivation of conclusions	None	
Writing of the manuscript: Creation of visualizations	None	
Writing of the manuscript: Structuring the text	None	
Writing of the manuscript: Formulation of text	1	Spelling checks of short sentences were performed by ChatGPT. ChatGPT was asked for synonyms of often reoccuring, or better fitting words.

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Writing of the manuscript: Revision of text	None	

Further contributions / additional information:

Place	Date	Signature
Haren Gn	30-06-2025	

F Design Map

All SolidWorks files can be found in the Design Map separately attached to this report.