A DESIGN FOR A NEW CLUBFOOT TREATMENT

THE PARENTS VIEW

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Title

A design for a new clubfoot treatment, the parents view

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SUMMARY

1 in 1000 babies is born with clubfoot (Ponseti, 2008). Nowadays this handicap is treated with the Ponseti method; in 6 to 8 weeks the deformity is corrected. Each week the foot is manipulated and a cast to secure the new position is applied. This cast goes up to the groin of the baby.

With a survey, held among the parents of children with clubfoot, the main problems were mapped. Clothing does not fit, the care of the child is difficult, parents get bad reactions from other people, the cast is heavy and hard which makes hugging less tempting and when the cast is just applied, it is wet and cold which makes the body temperature drop. From these problems scenarios were created which were used to determine requirements for a more user-friendly treatment method.

Eight concepts were made to solve the problems and they were presented to the parents. The parents are the focus group and therefore their opinion weighed highly in the concept choice. The chosen concept consisted of a cast applied to just over the knee and a plastic shell which protects the cast from getting dirty. This concept was detailed in cooperation with Orthin, an orthopaedic instruments manufacturer who is specialised in making prostheses and ortheses. A few changes were made to make it even better; the cast was lowered to under to knee to give the parents more room when changing diapers and cleaning their children and the shell was secured to the cast to make sure the parents put it back on when they are finished with changing the diapers.
The concept which was created after this first meeting with Orthin was improved in a second meeting. The first concept had a lot of metal sticking out which does not have an appealing look, is dangerous and clothing will get stuck behind it. The final concept consist of an under the knee cast, an anchor which is placed in the cast and connects the shell with use of a hinge, and the plastic shell which is secured to the upper leg to make sure the foot can still be fully corrected. The anchor and the arm are made of PET with use of a 3D printer and the shell is made of LD-PE. The final product solves the problems of the negative reactions because it looks less like cast, the cast is reduced by half and therefore it will be less have and stay less long cold and wet and the care has become easier because there is more room for cleaning and changing diapers.

The parents were asked again for their opinion and they were quite satisfied. There are still some problems which are not resolved, like the fact that cloths will still not fit and it is still hard to the touch. The parents are sceptical about the usage of the product and if the child is not able to kick the cast off. This will have to be examined with a usability test in further research.

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ACKNOWLEDGEMENTS

During this project several people helped me by sharing their knowledge and views with me. I would like to thank them.

First of all I would like to thank Bob Giesberts for tutoring me during this project, his opinions en views helped me to create the final product.

Next I would like to thank Dr. Schuppers and Dr. Kempink for sharing their knowledge and views on the Ponseti method. Special thanks to Dr. Kempink for letting me watch a treatment session.

I would also like to thank Orthin for letting me use their workshop and materials and for the brainstorm sessions with Karel Wilbrink, which made it possible to create a realistic prototype.

Last but not least I would like to thank the Dutch Clubfoot Organization for their collaboration in this project. Special thanks to all the parents who answered the survey and gave their thoughts about the concepts.

INTRODUCTION

One in 1000 babies is born with congenital clubfoot (Ponseti, 2008). A clubfoot is a severe deformity of the foot of which the cause is unknown. The ankle joint is flexed in a certain direction and cannot be used in its normal range of motion. Clubfeet are currently treated with the Ponseti method which is currently the most effective, non-invasive treatment. The Ponseti method requires manipulation of the foot and serial casting. The joint is stretched to its end range and fixated with a plaster cast for a week. Over time the contracted tissue will adapt itself to the new position. After repeating this process a number of times the joint is fully corrected, but the child will have to sleep with a brace for four years to prevent a relapse.

According to Nogueira (2013) 80% of the questioned families considered the casting phase as the most difficult phase of the Ponseti treatment. The casting treatment can cause difficulties in the nurturing of the child. With the Ponseti treatment the legs are casted from toe to the groin which makes daily tasks like changing diapers very difficult and bathing the child almost impossible. Besides the difficulties in the nurturing, the treatment is also time-consuming for the physician who performs the Ponseti treatment.

The Ponseti method is an effective solution but might not be very efficient. As the joint adapts, it is assumed that the momentum of the cast on the joint decreases and correction slows down. The current solution only controls the position, not the force on the foot. Therefore it might be possible to improve this treatment. Bob Giesberts researches this possibility by developing a forced controlled treatment for clubfoot. As the Ponseti method is an effective treatment, the basic principles should be kept in mind.

In this assignment a replacement for the current treatment is designed. The focus lies not on the technical aspects, but on the user experience. The main research question is therefore: how can the Ponseti method be adjusted to make it a more pleasant experience for the parents and the child?

To get a better understanding of the pathology of a clubfoot and its treatment, an overview of the relevant anatomy is given in Chapter 1 and the most relevant treatments are discussed in Chapter 2. The needs and wishes of the parents are determined with a survey which is described in Chapter 4. In this chapter the outcomes of an interview held among physicians to analyse their wishes and needs can also be found. The main problems, needs and wishes are transformed into a list of requirements in Chapter 5. With use of all the previous gathered information some concepts are made which can be found in Chapter 6. This chapter also shows the concept choice which is made with use of the earlier drafted list of requirements and the feedback of the parents. In Chapter 7 the chosen concept is detailed and translated into a functional prototype. The whole process is discussed in Chapter 8 after which some recommendations are made.

THEORETICAL BACKGROUND

To get a better understanding of the clubfoot its anatomy is compared to the anatomy of a healthy foot. A few treatment methods are analysed to understand what is necessary to correct a clubfoot and to see where there is room for improvement.

ANATOMY

Leonardo da Vinci once described the human foot as a biomechanical masterpiece of art and technique (Schreurs, et al., 2007, pp. 12-16). A foot exists out of 26 bones, 33 joints and over 100 muscles, tendons and ligaments. All these structures combined give support, balance and mobility. If there is only one error the foot will lose parts of its function, which leads to problems with the mobility and balance of the body. Disturbances in the anatomy of the foot during the embryological development or the growth of a child's foot can lead to deformations in an adult's foot.

BONES AND JOINTS

The foot can be divided in three parts; the tarsus, metatarsus and the phalanges [Figure 1.2] (Teach Me Anatomy, 2016). The tarsus or hindfoot is the rear part of the foot. The human body is mainly supported by two of the seven bones in the hind foot; the talus and the calcaneus [Figure 1.1] (Remedy Health Media, 2015). These two bones also form the subtalar joint which allows inversion [Figure 1.7] and eversion [Figure 1.8] of the foot. Together with the lower leg bones, the talus forms the ankle joint which allows dorsiflexion [Figure 1.5] and plantarflexion [Figure 1.6]. The two joints together make that the foot is able to pronate [Figure 1.9] and supinate [Figure 1.10]. The other five tarsal bones give the foot its typical arches which provide balance and shock absorption.

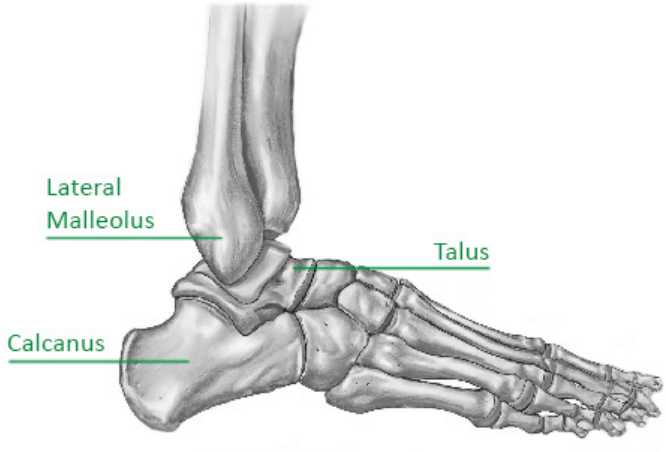


Figure 1.1 *Most important bones in the tarsus [1]*

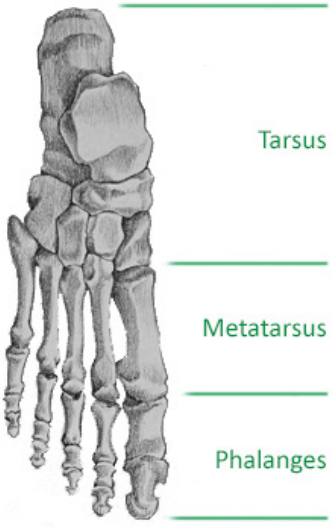


Figure 1.2 *Divisions of the foot [1]*

Figure 1.3 *Abduction [2]*

Figure 1.4 *Adduction [2]*

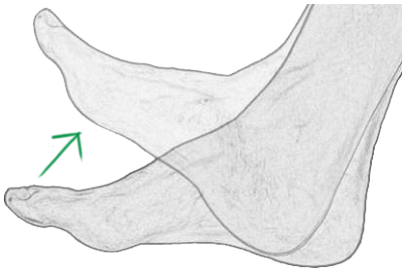


Figure 1.5 *Dorsiflexion [2]*

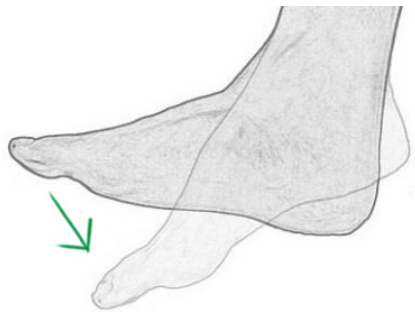


Figure 1.6 *Plantarflexion [2]*

Figure 1.7 *Inversion [2]*

Figure 1.8 *Eversion [2]*

MOTIONS OF THE FOOT AND ANKLE

The foot is with its 33 joints very flexible. The motions of the foot and ankle are discussed below. Supination and pronation are a combination of the other movements. Supination is a combination of inversion, plantar flexion and adduction, whilst pronation is a combination of eversion, dorsiflexion and abduction (Nothcoast Footcare, 2015).

Figure 1.9 *Pronation [2]*

Figure 1.10 *Supination [2]*

THEORETICAL BACKGROUND

MUSCLES AND LIGAMENTS

Most of the movements in the foot are controlled by the muscles in the lower leg, also called the extrinsic muscles. The main groups are:

- The anterior muscles, which provide dorsiflexion and inversion [Figure 1.11]
- The posterior muscles, which provide plantar flexion and supination [Figure 1.12]
- The lateral muscles, which provide eversion and plantar flexion [Figure 1.13]

Tendons of muscles in these groups end in the foot. The muscles in the foot, also called the intrinsic muscles, are mostly responsible for the fine motor actions and for the assistance of the extrinsic muscles. But they also support the natural arches of the foot (Teach Me Anatomy, 2016). These arches are important to maintain the balance of the human body and to absorb the shock produced during walking. If these arches do not have their proper form, walking can cause injuries and pain (Learning Support BV, 2016).

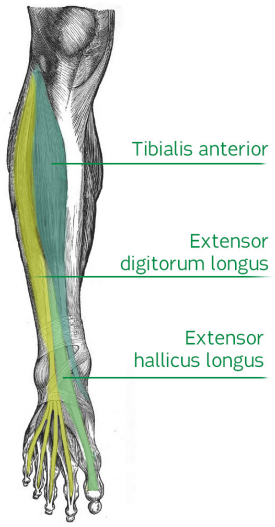


Figure 1.11 *Anterior muscles [3]*

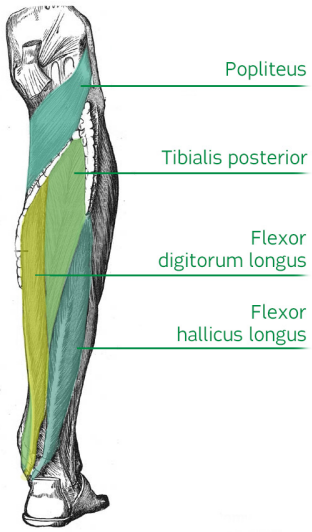


Figure 1.12 *Posterior muscles [3]*

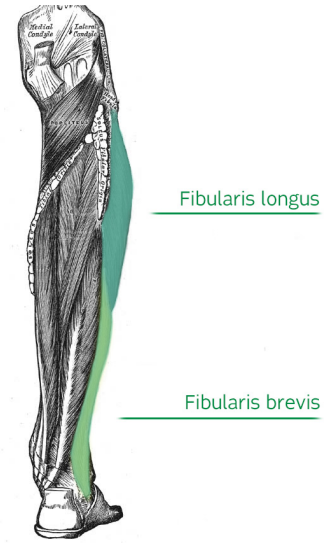


Figure 1.13 *Lateral muscles [3]*

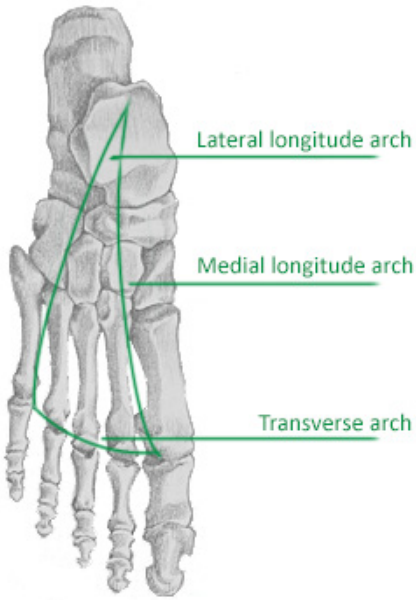


Figure 1.14 *Foot arches [1]*

Ligaments hold the tendons in place, stabilize the joints and they provide stability. The largest ligament in the foot is the plantar fascia. This ligament is important for forming the plantar arch. Contracting or stretching it allows the arch to curve or flatten, providing balance and giving the foot strength to initiate walking. The ligaments on the inside and outside of the foot provide stability and enable the foot to move up and down (Remedy Health Media, 2015).

THE CLUBFOOT

A congenital clubfoot is a deformation of the foot. Depending on the race of the parents, it appears every 0,4 to 6,8 per 1000 births (Schreurs, et al., 2007). Boys are twice as much diagnosed with clubfoot than girls. Whilst the cause of the clubfoot is still unknown, it seems to have a genetic origin.

Figure 1.15 *Clubfoot VS normal foot [4]*

THEORETICAL BACKGROUND

CLUBFOOT VERSUS NORMAL FOOT

The symptoms of a clubfoot start under the knee; the muscles, tendons and ligaments are shorter and stiffer than those of a normal leg. The lower leg is thinner and the foot is shorter and thicker (Ponseti, et al., 2006). There are large skinfolds around the ankle and the midfoot. Besides these symptoms the hindfoot is supinated whilst the forefoot is pronated. This is the result of four major deformities (Ponseti, 2008), namely:

- Cavus, the medial longitude arch is higher than normal. The foot is shaped like a banana.

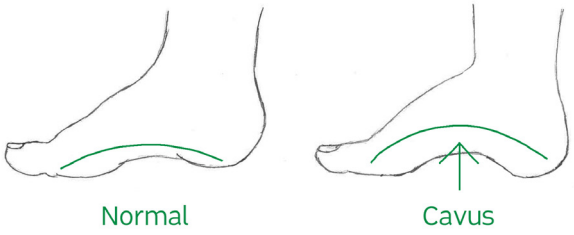


Figure 1.16 *Normal foot vs cavus*

- Adductus, adduction of the foot. The forefoot and midfoot are rotated inwards. Usually the lower leg is also slightly rotated inward.

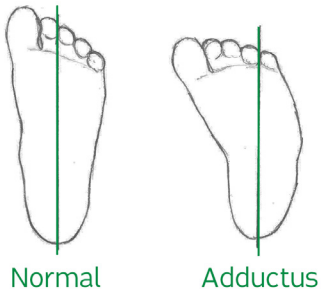


Figure 1.17 *Normal foot vs adductus*

- Varus, inversion of the foot. The hindfoot is rotated inwards.

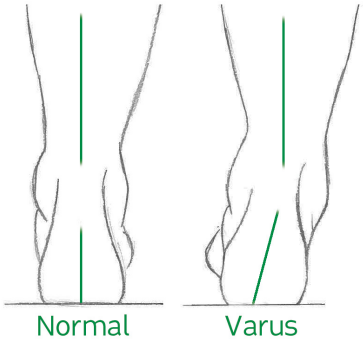


Figure 1.18 *Normal foot vs varus*

- Equinus: plantar flexion of the foot. The foot is pointed downwards.

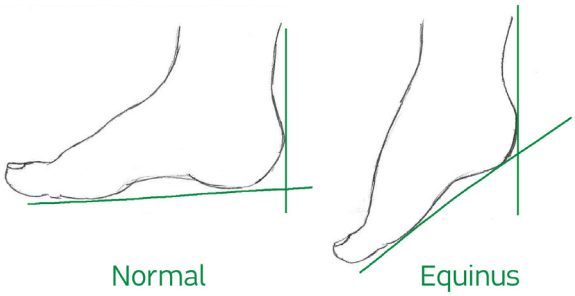


Figure 1.19 *Normal foot vs equinus*

The stiff muscles, ligaments and tendons determine the severity of the clubfoot. The stiffer these are, the harder it is to correct the foot (Ponseti, et al., 2006).

DIAGNOSE

The clubfoot can be first diagnosed at the 20 week ultrasound (Schreurs, et al., 2007, p. 35). If a clubfoot is seen on this ultrasound it does not necessarily mean the child will have clubfoot, the feet can also look deformed due to entrapment. The real diagnose cannot be done until the child is born.

TREATMENT

Over the years, many treatments have been developed, from surgery to casting and physiotherapy. Each physician has his own preference of treatment. The main goal of each treatment is to correct the foot to the normal position and create a natural range of motion so the child will be able to walk normally (Ponseti, 2008).

SURGERY

Surgical treatment can involve the adjustment of tendons, ligaments and joints. Surgery often results in a stiffer foot; therefore it is not used as much anymore. Major reconstructive surgery for clubfoot involves extensive release of multiple soft tissue structures of the foot (AAOS, 2014). The foot of a baby is very small. The structures are very difficult to see even using magnifying glasses. Blood vessels and nerves may be damaged or cut during the operation.

The bones of the baby foot are mainly made of cartilage which is easily damaged, resulting in deformities of these bones (Orthopod, 2005).

Once the correction is achieved the joints of the foot are usually stabilized with pins and a cast. The most common complications of extensive soft tissue release are overcorrection, stiffness, pain and muscles and tendons are often numbed and have become immobile because of all the internal scar tissue (Ponseti, 2008). Up to half of all patients undergoing clubfoot surgery will require at least one additional surgical procedure later in life (Faulks & Richards, 2009).

PONSETI METHOD

The Ponseti method is based on the natural flexibility and adaptability of the human foot (Ponseti, 2008). The method consists of series of manipulation and casting, in some cases a small operation, followed by a brace period. After four years the clubfoot should be fully corrected and function as a normal foot.

The method follows the CAVE order. First of all the Cavus should be corrected, the forefoot should stand in a correct line with the hindfoot. This is done by supinating the forefoot. After the correction of the cavus, the Adduction and Varus are corrected at the same time, for which the foot is abducted around the talus head. A thump is placed on the talus head and with the other hand the foot is abducted. To correct the equinus a small surgery is performed, the Achilles tendon is cut under a local anaesthesia. The foot is then positioned in dorsal flexion and casted for another three weeks. After this last cast the foot looks over-corrected, this is done to prevent relapses.

The manipulation should be within the limits of the child's comfort. When the physician gives too much pressure this can result in complications and the talus might deform because of the softness of the bones. Too little pressure and the treatment might not

work or may take much longer than necessary. On average a physician applies 12 N on the talus and 4 N on the first metatarsal to manipulate the foot [Figure 1.21] (Giesberts, 2016).

The foot is casted in the new position. The cast runs from the toes all the way up to the groins with the knee bend at least 90˚ (Ponseti, 2008). The 90˚ angle of the knee is necessary to prevent the cast from slipping of the leg and to make sure the rotations are made in the ankle and not in the hip joint. The cast should be moulded around the foot to avoid sores.

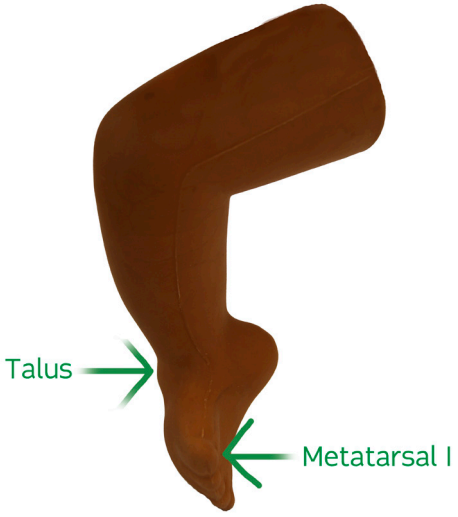


Figure 1.21 *Pressure points*

For four years the child has to wear a brace [Figure 1.22], the first three months for 23 hours a day, after that only when he or she is sleeping. Without the brace, relapses can be seen in 80% of the cases (Ponseti, et al., 2006). After this treatment the child is able to walk, run and sport like a normal child. Only from the slightly smaller calf and foot one could see the child once had clubfoot.

Figure 1.23 *The Ponseti brace [5]*

FRENCH METHOD

The French Functional Method [FFM] originated in the 1970's (Faulks & Richards, 2009). The method is a combination of physiotherapy, splinting and minimal-invasive surgery and is performed by specialized physical therapists. FFM involves daily gently mobilization and stretching of the contracted tissue, stimulation and strengthening of immobilized muscles and taping and splinting to maintain the corrections. The goal is to reduce the deformity quickly but without over haste, the baby must be relaxed during the treatment (Dimeglio & Canavese, 2012). The correction should never be forced.

Figure 1.25 *Fixation of manipulated foot [6]*

Full correction is obtained, depending on the severity, in three to five months (Dimeglio & Canavese, 2012). The parents will then learn the FFM so they can continue it at home until the child starts to walk. The FFM aims to avoid surgery as much as possible. If the conservative treatment is no longer effective, surgery should be considered. The mini-invasive surgery preserves ligaments, tendons and tries to avoid fibrosis. The regular manipulations and splinting make surgery easier and less extensive.

Studies show that the Ponseti method is only slightly more successful in the treatment of clubfoot (Faulks & Richards, 2009) (Dimeglio & Canavese, 2012). The FFM is a lot more intensive as the child needs to be treated every day. On the other hand the Ponseti method has a long follow-up period where the child needs to wear a brace. Both methods have their advantages and flaws, therefore, as Dimeglio and Canavese (2012) said; combining the advantages of both methods is the future.

A clubfoot consists of four mayor deformities; the Cavus, Adduction, Varus and Equinus. To fully correct the clubfoot these four deformities need to be corrected. This can be done with several treatment methods of which surgery is the least appealing since it causes lots of complications. The Ponseti method has the best overall results, followed by the FFM which has a close second place. Both methods consist of manipulation of the foot and fixating the new position. Combining the advantages of both methods might be the future.

USER ANALYSIS

This analysis is done to map the needs and wishes of the parents of children with clubfoot. Not only the needs and wishes of the parents were taken into account, but also those of the physicians.

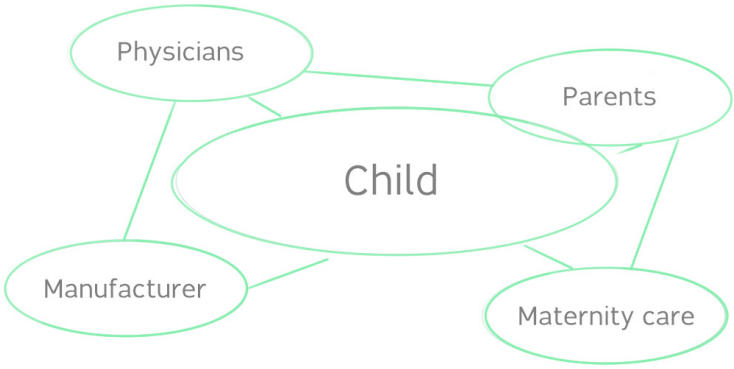


Figure 2.1 *The stakeholders*

PHYSICIANS

Interviews are held with two orthopaedic physicians who are certified to treat clubfoot in the Netherlands. The goal of this interview was to map the needs and wishes of the professionals. The most important outcomes are presented.

Both physicians are very supportive of the Ponseti method, although there are some things which can be improved. It is a difficult method to learn and even if the physician is very skilled he or she will still make errors. The cast is easily too tight, which will result in pressure sores and bad blood flow, or too loose, in which case the cast will fall off.

The cast needs to be modelled around the leg to avoid sores, one cannot simply push on the talus head to manipulate the foot into the right position. The bones of a baby are very soft, when pushed too hard the bones might deform permanently.

The cast easily gets dirty with stool. Functionally, this is not a problem but it can give discomfort to the parents. The cast will turn green-yellow and it cannot be cleaned. This gives an unpleasant look.

Every week the cast needs to be replaced. To remove the cast a saw or a blunt knife is used or the cast is soaked in water. Especially the saw can be very scaring for both the parents and the child, it gives a lot of noise and the skin of the child may be cut. It is however the fastest way to remove the cast.

Both physicians say the Ponseti method is not aggravating for the parents. A cast master stated the opposite. He said the method is very demanding on the parents and the children. The parents are not likely to come to the physician with their problems because they are thankful to the physicians for helping them. The cast master however spends relatively more time with the parents and hears more of their troubles.

The Ponseti method is very time consuming for both the physicians and the parents, therefore it would be nice if a new way to treat the clubfoot can be found.

PARENTS

To get a better understanding of the needs and wishes of the users a survey was conducted. The survey questions can be found in appendix [A]. 49 parents responded on the survey and shared their experience with the current treatment for clubfoot. The survey consisted of quantitative as well as qualitative questions. Qualitative questions give the parents the opportunity to share their experiences.

The survey was published on the Facebook page 'Nederlandse vereniging klompvoetjes – voor ouders' by one of the owners. This is the official Dutch clubfoot page, for parents who have a child with clubfoot. The page has over 600 members who place 10 to 20 messages a day. The parents ask questions and share pictures and experiences with each other. Normally a question will get 10 responses within an hour.

The survey was based on the research question: How do the parents of children with clubfoot experience the treatment. This question was divided into several categories:

- Basic information; to gain some knowledge about the treatment
- Products; if there were any products which had to be bought or adjusted
- Care of the child; how did the parents and the child experience the cast
- Complications; did any complications occur during the treatment
- Reactions of other people; how did people react when they saw the cast
- Future treatment; to see if the parents have ideas for a new treatment

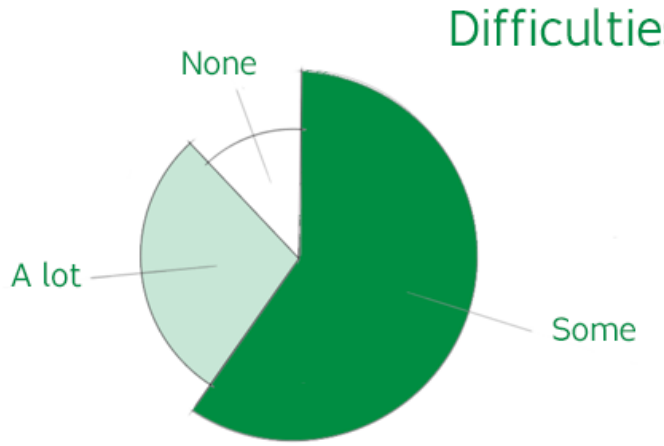
QUANTITATIVE DATA

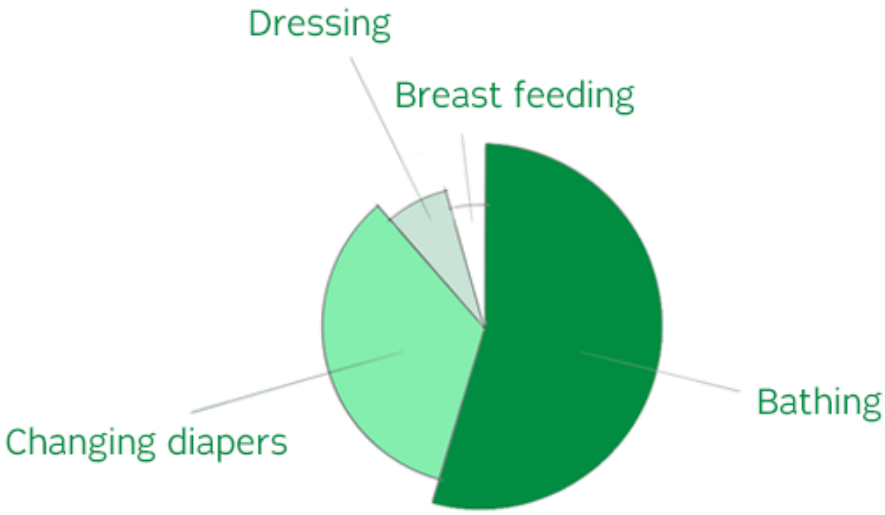
The quantitative data is converted into diagrams. The most important can be found in the infographic on the next page, the others are shown in appendix [B].

Quantitative data gives a nice overview of the problems, but it does not give a sense of the severity of the problems. Therefore not many statements can be made with just this information. The qualitative data can give more clarity.

The experiences of par

In clubfoot treatment





64% Never had skin irritations

13% Never encountered the cast dirty with stool

80% Did not special pr

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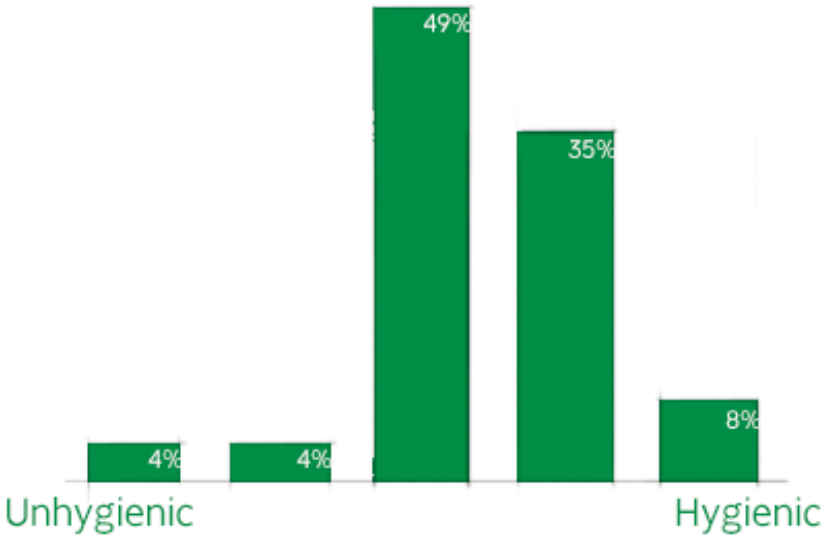
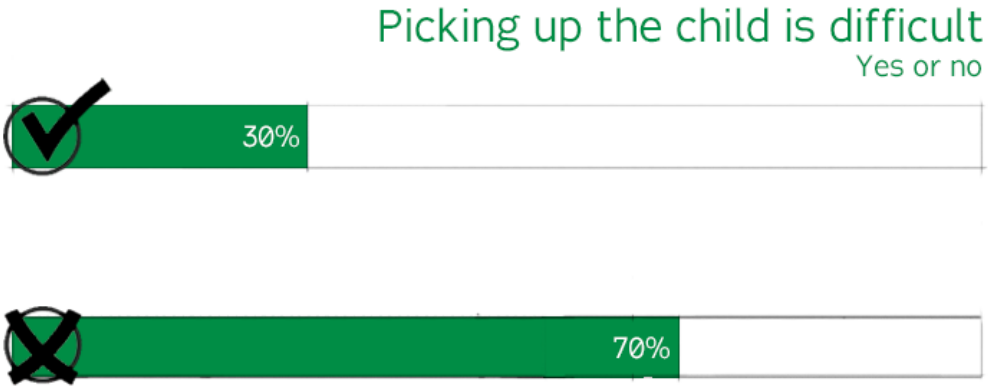




t buy any
roducts

65% Of the children did not fit their clothes

75% Of the maternity care had no knowledge about clubfoot

USER ANALYSIS

QUALITATIVE DATA

All the other data gathered with the survey which was held among parents of children with clubfeet was analyzed using the Qualitative Data Analysis. This analysis consists of giving the data a code which is basically a descriptive label, the grouping of the codes which creates an analytical framework, applying this framework to the data, charting the data into a framework matrix and interpreting the data (Gale et al., 2013).

The coding was partly done with use of the survey questions. Only the few open questions in the end of the survey had to be coded. Eventually the following list of codes was formed.

- Specially bought products
- Adapted products
- Clothing
- Care of the child
- Tracking growth of the child
- Experiences parents
- Picking up the child
- Holding the child
- Experiences child
- Reactions direct surroundings
- Reactions surroundings
- Maternity care & birth clinic
- Physicians & cast masters
- Hospitals
- Complications
- Current treatment
- Information
- Improvements current treatment
- Requirements new treatment
- New treatment

These codes were then categorized in a framework:

- Products
- Experiences
- Reactions
- Current treatment
- Caretakers
- Future treatment
- Care

All the data was grouped and placed in a matrix, which can be found in appendix [C].

OUTCOMES

Both the quantitative as the qualitative data from the survey are discussed per framework.

PRODUCTS

Parents did not buy special products or adjusted products that often. One parent had to buy an extra layer for the crib to avoid damage to the crib and the cast.

Clothing was an issue for more of the parents. 38 out of the 49 parents who responded said to have problems with some clothing. Especially playsuits, jeans and other non-stretch trousers, leggings, maillots, socks and slippers were not practical. Also a lot of the parents mention they had to buy larger sizes of clothes. Trousers and suits with snap buttons had the preference of the parents during the cast period.
When the parents are given poor advice in advance they will run into some problems with

the clothes. All the clothes should be bought a few sizes bigger and also not everything will fit over the cast.

EXPERIENCES

The most occurring answers to the question about the experience of the parents are “it was part of the deal” or “it had to be done”. Parents accept the troubles because the result is what counts; they want the best for their child.

Hugging is not experienced very different for most parents, in the beginning it is difficult but they all say they got used to it. But some parents mention they missed the soft, naked legs of their child, one parent even said they did not pick up their daughter if it was not necessary. Another parent said the hugging of their son with clubfoot was very different from his twin without clubfoot. When picking up the child it is important to support the legs because of the heavy cast.

The children seem to have less problems with the cast, only during the cast changes and the first day after they tend to be a little upset and restless and therefore they will cry more. Some children will be a bit feverish.

Overall the parents seem to have more problems with the cast than their children. The parents accept the treatment but would probably like some changes.

REACTIONS

The direct surroundings (family and good friends) find it sad and feel sorry for the children. It is hard to see a small child with such heavy cast. But this feeling is quickly gone when the parents assure them it is going to be alright. A few parents tell that their families did not visit or did not want to hold their child.

Parents mention that they have the feeling that people on the street are often startled; they stare and whisper behind their back. Cast is seen as a stigma for broken bones. People think the parents have dropped or abused their child. They are scared to ask the parents what is really going on. Some parents mention they do not want to take their child to the supermarket because of all the looks and whispers.

A lot of people think of broken bones when they see cast. When a small child has two casted legs, this will call for questions. Not all the parents will be affected by the reactions of other people; this will depend on how sensitive the parents are for such things. As a parent, when you are secure you will be able to just ignore these looks and whispers, but if you are insecure this can have great influence on your life.

CARE

A lot of the parents found it difficult they could not bath their child, especially after a really dirty diaper. The cast does not give much room to clean the buttocks of the baby. The cast itself is not cleanable, which means the parents have to wait until the next cast change to get it ‘cleaned’.

USER ANALYSIS

CARETAKERS

Parents have to instruct the maternity care how to take care of their child. Parents would like to see more knowledge about the clubfoot at the maternity care and the birth clinic. Parents often experience a lot of incomprehension from the latter.

CURRENT TREATMENT

Overall, parents are satisfied with the current treatment; the Ponseti method gives very good results in a relatively short period. But there are some aspects which could be improved.

Especially the cold and wet cast is seen as a problem of the current treatment. A large part of the body of the baby is covered in cast. When the cast is wet it drops the body temperature of the child drastically. Many parents say they had trouble keeping their child warm.

The cast is also very heavy compared to the weight of a new born, which makes it difficult for some children to lift their legs or turn around in their cribs. The cast is also hard and sharp at the edges which can damage the buttocks of the baby.

The cast is not cleanable: when is gets wet it becomes soft again. When a child has diarrhoea it tends to seep out of the diaper and it ends up on and even inside the cast. Normally this is not a problem; the dirty clothes are washed and the child is given in a nice bath. With the casted legs the parents have to settle with a washing cloth.

FUTURE TREATMENT

The most important requirement of the parents is that the new treatment should have at least as satisfying results as the Ponseti method. The Ponseti method gives good results without the need for big operations.

Other suggested requirements for the future treatment are listed below.

The future treatment should be:

- Water-resistant or removable so the parents can bath their child
- More easy to clean
- More easy to change diapers
- Less cold and wet
- Less heavy
- Soft to the touch
- Have better information to give the parents
- The future treatment should not go up all the way to the groin

SCENARIOS

From the survey data several scenarios were conducted. By placing experiences of the parents into a scenario the reader gets a better feeling of what parents go through. The scenarios are set up per framework. The final concept is placed in these scenarios to see how it solves the problems. The scenarios can also help to detail the final product.

SCENARIO CARE

Anne and Mike are both 32, they have two sons. The oldest is Tom (4 years) and the youngest is Ted. Ted is born with clubfoot and therefore both of his feet are casted. Because they already have a son they have some experience with the care.

The first time changing Ted's diaper Anne sees he has diarrhoea. The poo is spread everywhere, not only on his buttocks and groins, but also on the cast. Anne starts to clean her son with washcloths which is time consuming and actually doesn't work that well. Every time when Tom used to have diarrhoea Anne would just give him a quick bath. After three dirty washcloths Ted is finally clean, but the edges of the cast turned yellowish and it isn't possible to clean. The next cast change isn't until next week, Ted will have a dirty cast until then. Just when Anne is putting on the new diaper Ted starts pooping again…

SCENARIO REACTIONS

Sarah is a single mother of 23 years, she just got her first child Emily. A few days ago Emily got her first cast. Sarah is quite insecure because of her first child having a handicap.

Sarah needs to go grocery shopping and by lack of a babysitter she decides to take Emily along. It's a nice warm summer day so Sarah dresses Emily in a dress which shows her cast. Sarah decides to put a blanket over Emily's legs. In the line for the checkout Emily manages to kick off her blanket, showing her cast. People in the line immediately start to whisper. Sarah's insecure feeling starts to grow. When she is almost at the check-out she hears two women talk behind her. One of the women says "look at that poor baby! She must have dropped her." The other woman then states "I think she is abusing her daughter…" Sarah feels tears boiling up, she quickly pays her groceries and runs to her car where she start crying. She will never ever take Emily with her again…

SCENARIO CURRENT TREATMENT

Marc and Sasha are in their thirties and already have two daughters. They got their son Daniel a week ago. Daniel has clubfeet and today he gets his first cast.

The casting went quite quick and Daniel was really good during the treatment. In the car he starts crying though. His parents aren't sure what is wrong and they assume he is just tired of the long and intensive day. Once they get home Marc takes Daniel out of the car. He immediately notices that Daniel feels cold. Once inside, Sasha takes Daniels temperature and it's below average. The cast is wet and cold and therefore it has cooled down Daniels body temperature. Whenever their daughters would feel cold Marc and Sasha would give them a warm bath or put a hot water bottle in their cribs. Both these solutions won't work with Daniel. The cast is full of water and this will conduct the heat of the hot water bottle which can result in skin burns. Marc puts Daniel in his crib and adds a lot of blankets. Every hour he changes the blankets because they get wet from the fresh cast.

SCENARIO EXPERIENCES

Jill gave birth to twins, Linda and Stacy. Linda is born with clubfoot and is treated with the Ponseti method. Both her legs are casted. Sandra soon finds differences in her care for both the girls.

It is 5 am and Sandra wakes up, Linda is crying again. Sandra separated her twins because Linda would wake up her sister all the time. Sandra takes Linda out of her crib, making sure she is supporting the head as well as the legs. She holds Linda against her chest and feels the cold, hard cast scratching in her tummy. As soon as Linda stops crying she puts her back in the crib. A few hours later Stacy starts crying. Sandra takes Stacy out of her crib and puts her in her own bed. While hugging her child tightly against her chest Stacy falls back asleep. Sandra feels sorry for Linda because she isn't able to hold her like her twin sister.

The physicians are very supportive of the Ponseti method, though there are some disadvantages of the method. It is very time-consuming for both the physician as the parents. It is difficult to learn and complications can easily occur. Parents seem to accept the Ponseti method but would probably like some changes. Overall, it looks like the parents have more problems with the cast than their children. One of these problems is the fact that some clothing does not fit any longer. Clothing has to be bought a few sizes bigger to fit over the cast. Cast is seen as a stigma for broken bones and this may cause some whispering and strange looks, parents can feel insecure by this. The cold and wet cast is the source for another problem because it drops the body temperature of the child in some cases. The Ponseti method gives good results with minor surgical operations and therefore the most important suggested requirement is that the new treatment has to work as least as good as the Ponseti method.

REQUIREMENTS

From the information which is collected in the previous chapters, the following requirements were conducted.

GENERAL REQUIREMENTS; the product should...

1 Correct the clubfoot following the Ponseti method (Ponseti, 2008)
2 Have a pressure point on the talus head
3 Have a pressure point on the metatarsal I bone
4 Apply a force on the pressure points to correct the clubfoot deformity
5 Prevent slippage
6 Maintain the applied moment
7 Cost no more than € 150,-

REQUIREMENTS OF THE PARENTS; the product should...

8 Allow easy donning and doffing by an inexperienced person
9 Ease the changing of diapers
10 Allow easy cleaning
11 Be more comfortable for the child than the Ponseti method
12 Be more comfortable for the parents than the Ponseti method
13 Weigh no more than 200 g per leg
14 Allow fitting of clothing, without damaging the clothes
15 Allow to hold the child, without being an obstacle
16 Not cause any allergic reactions
17 Not damage the skin of the baby
18 Not irritate the skin of the child or parent
19 Not give the impression of broken bones/ communicate that it serves the purpose of treating a clubfoot
20 Not decrease the body temperature of the child below 36˚ (Bibiana, 2013)

REQUIREMENTS OF THE PHYSICIAN; the product should...

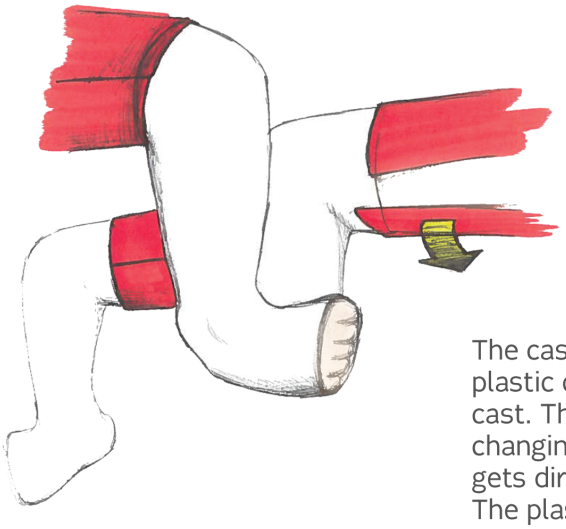
21 Be easily set and adjusted by the physician
22 Not damage the soft tissue inside the foot and leg by adding too much pressure (Giesberts, 2016)
    - o No more than 12 N on the talus head
    - o No more than 4 N on the first metatarsal bone
23 Not cause pressure points; the pressure needs to be equally distributed
24 Fit patients from 0 to 12 months
25 Keep the knee bend in an angle smaller than 120 degrees (Ponseti, 2008)
26 Reduce the treatment time for the physician compared with the Ponseti method

WISHES; the product should...

- Persuade parents to adhere to a strict wearing regime / reduce noncompliance
- Allow bathing of the child
- Allow movement of the knee
- Be available in several colours
- Be reusable
- Cost no more than € 100,-
- Be dynamic
- Invite hugging
- Allow injections in the heel

CONCEPTS

From the requirements and the input of the parents several concepts were designed with use of an iterative process. The concepts are focussed on the needs and wishes of the parents, not as much on those of the physicians, because the parents are the main users.

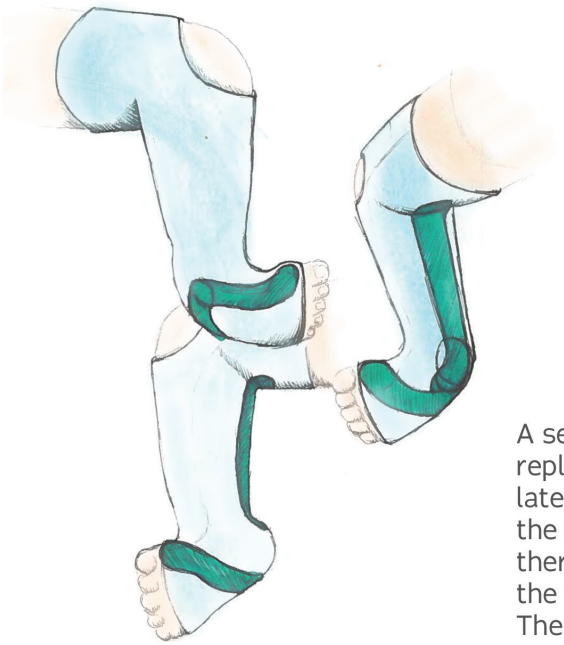


Concept 1

The cast is applied to just over the knee. A plastic cover shall be placed above the cast. This part can be removed to make changing diapers easier. When the cover gets dirty it can easily be cleaned.
The plastic cover will be connected to the cast with Velcro.

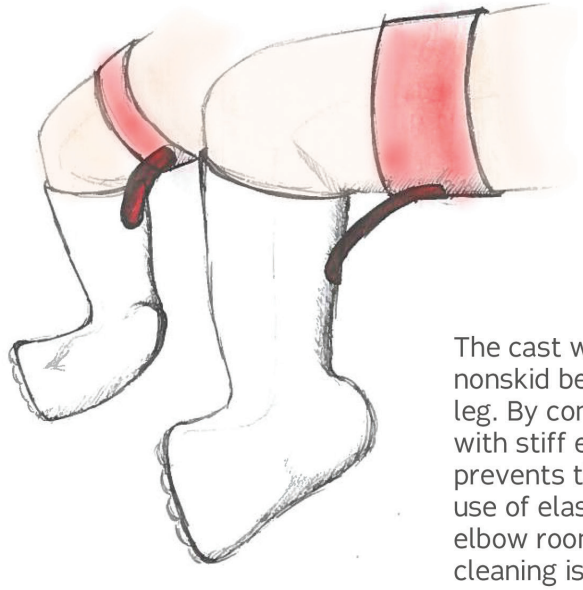
Concept 2

A semi-flexible sock with a nonskid inside replaces the cast. The foot will be manipulated in the same way as the Ponseti method, but instead of cast to hold the foot in the corrected position Velcro will be used. The sock can get wet, which makes it possible to wash the child.



Concept 3

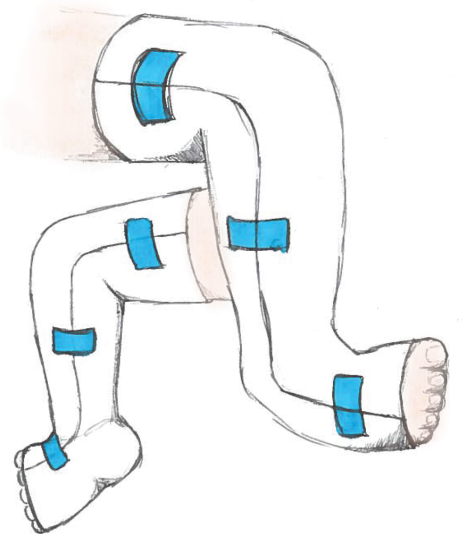
A semi-flexible sock with a nonskid inside replaces the cast. The foot will be manipulated by means of elastic and stiff parts in the sock. The brace will be dynamic and therefore you will see results earlier and the family has to have less hospital visits. The sock can get wet which makes bathing at home possible.



Concept 4

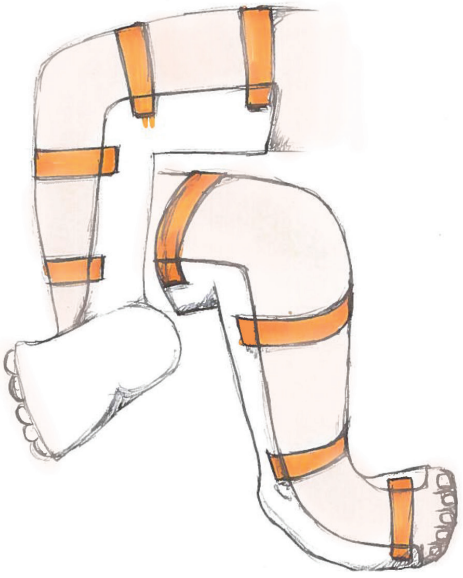
The cast will be applied up to the knee. A nonskid belt will be placed on the upper leg. By connecting these two elements with stiff elastic the knee will bend. This prevents the cast from slipping off. With use of elastic the child will have some elbow room. The belt can be removed if cleaning is necessary.

CONCEPTS



Concept 5

The cast will be cut open on both sides. The two shells will be hold together with Velcro. The parents are now able to remove the cast at home and bath their child. After bathing the cast should be put back on.



Concept 6

The top part of the cast will be removed. The cast will now never be too tight. By removing half of the cast the weight will also be reduced and it will be less long wet and cold. The cast will be attached to the leg with use of Velcro. The parents can remove the cast if they want to bath their child.

Concept 7

In this concept only the bottom half of the cast will be used, this is after all the part where most of the treatment takes place. The weight will decrease greatly. This peace will be attached with Velcro and it will have a nonskid inside to prevent it from sliding off. The cast can be removed by the parents if they want to bath their child.

Concept 8

The foot is manipulated according to the Ponseti method. But instead of the cast to secure the new position, tape is used. With this tape the parents will still be able to bath their child. There are no hard parts, the skin is visible and this solution will never be too tight.

CONCEPT CHOICE

The concepts are compared with the requirements and presented to the parents. With these two inputs a final concept is chosen. The outcomes of the comparence with the requirements can be found in aooendix [D].

REQUIREMENTS

When looking at the requirements concept 7 scores the best, however studies show that below-knee cast has a higher failure rate (Maripuri, et al., 2013). This research was stopped because of the bad results. Below-knee cast can easily slip off and it does not give the support to maintain the applied moment. With this knowledge, concepts 4 and 7 were discharged. Concept 8 is basically the French method but instead of daily manipulation, weekly manipulation will be used. It is proven that the Ponseti method has slightly better results and therefore scores concept 7 less high on the general requirements (Faulks & Richards, 2009). Out of the four remaining concepts concept 2 and 3 score best.

CONCEPT CHOICE PARENTS

The parents are the main users and therefore their opinion is of great influence. From the parents who responded on the survey 38 left their contact information. These parents were asked to take a look at the concepts and give their opinion on a few questions:

- Does the concept solve the problems you have encountered with the Ponseti method?
- Does the concept have added value?
- Would you like to use this concept?
- Do you have tips or adjustments to the current concepts?
- What is your favourite concept?

10 of the 38 parents responded. The majority chose concept 1. This concept solves the problem of the cast getting dirty and the chance of the cast sliding of is limited. By being able to clean the top part of the cast the hygienic of the treatment improves. The only concern with the first concept is the plastic shell, this may cause skin irritations due to the sweat which will probably built up underneath it.

A small group was interested in concept 3 but they were sceptical. They are not sure if the socks will be strong enough to correct and fixate the foot. Also there is a possibility for parents to take it off and after bathing the child the socks will probably be wet and cold.

With last three concepts the parents were afraid of the cast sliding off. Also when the parents are given the opportunity to take the cast off it is doubtable if they will put it back on and if it is put on in the correct way. Opinions were divided on this subject; some parents really like the idea of being able to remove the cast, others fiercely opposed this freedom.

FINAL CHOICE

Concept 3 has potential, but there will have to be some scientific evidence to support this idea. Based on the requirements concept 3 scores better, mainly on the requirements of the users. But when asking the parents their preference lies with concept 1. Therefore concept 1 has been chosen.

PROTOTYPE

Concept 1 is not ready to be realized into a prototype and therefore it is further specified in cooperation with Orthin; an orthopaedic instruments manufacturer specialized in designing and making prostheses, ortheses and braces. Orthin has the potential to become the main manufacturer of the new treatment solution.

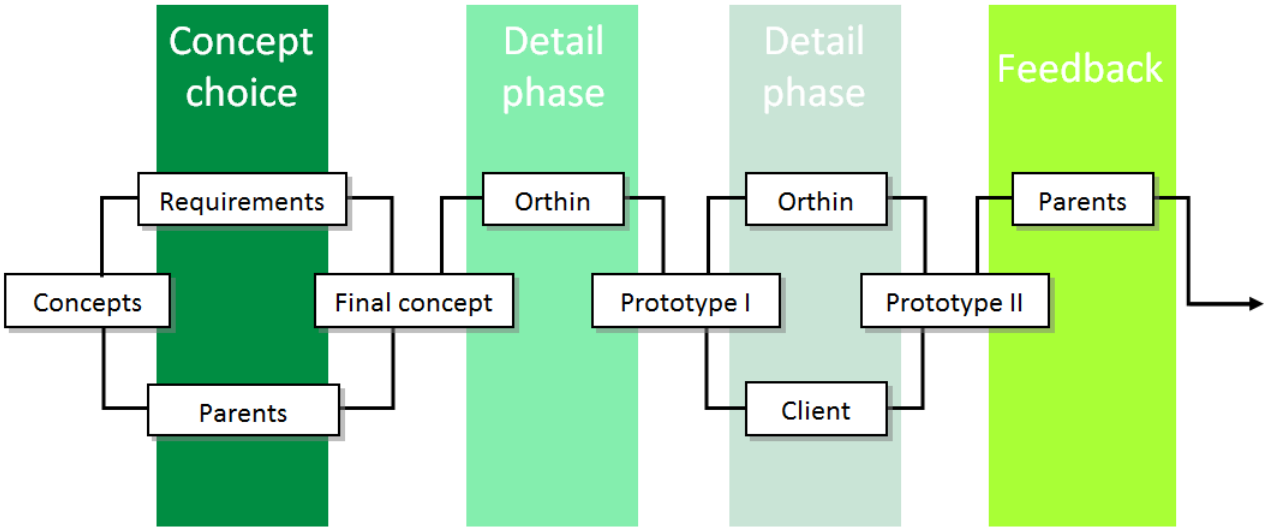


Figure 8.1 *Diagram of the course of this chapter*

FIRST PROTOTYPE

The chosen concept needs to be detailed; this is done with a brainstorm meeting with Orthin. In cooperation with Karel Wilbrink, the main designer at Orthin, a few problems with the concept are tackled.

The first point of focus is the cast, in the concept it goes over the knee. This is necessary to prevent the knee from stretching but it leaves not much room for the plastic shell. It is decided to let the cast end just under the knee. The shell on the upper leg is secured with Velcro. A stiff piece between the cast and the shell makes sure the knee stays fixated and prevents the cast from slipping off. The upper-leg cast also gives the abduction to the foot. The stiff arm is placed on the outside of the leg to make sure it still has this function.

The parents will still want to remove the shell to clean it and to have more space when changing diapers. But if the shell is completely removable the parents might not put it back on. By adding a swivel hinge between the stiff arm and the connection to the cast, the shell can be removed but forms a clumsy obstacle, forcing the parents to put it back on when they are done changing diapers.

Several options to keep the stiff arm locked in place are considered. When the arm is not locked in place the child will still have some room to bend his knees. A reversed push-button was chosen. By pulling the button the arm can move, by releasing it the button will fall back into the lock because of the little spring.

The arm needs to be connected to the cast, by placing a piece underneath the cast it creates a lot of strength. This piece (the L-piece) is made quite long and it has holes in it to make sure it will not shift. The places where the L-piece is connected to the arm are slightly raised to make sure the connections are still free after applying the cast.

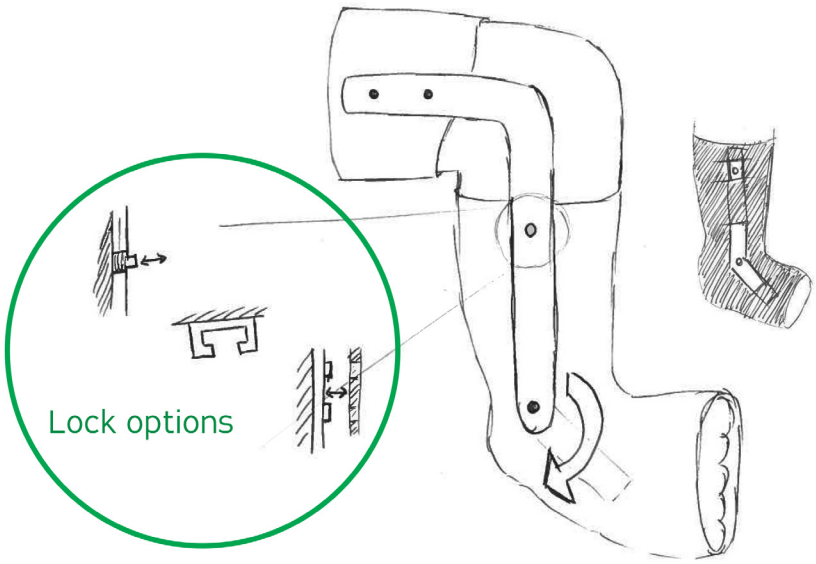


Figure 8.2 *Sketch for first prototy & lock options*

PROTOTYPE

Both the arm and the L-piece are made with a 3D printer using PET. This material is inexpensive. But when looking at other materials which are often used for 3D-printing, PLA has favourable properties. It is only a little bit more expensive, lighter and stronger. It also has the highest shape factor, which means it will less quickly buckle when shaped into small, long beams. If the parts are made of PLA, the price for one brace will be around € 0,20 and the parts together will weigh about 10 gram.

	PET	ABS	PLA
Price (EUR/kg)	1,59 - 1,75	1,93 – 2,03	1,65 – 1,98
Density (kg/m³)	$1{,}29 \cdot 10^3$ - $1{,}39 \cdot 10^3$	$1{,}02 \cdot 10^3$ – $1{,}08 \cdot 10^3$	$1{,}24 \cdot 10^3$ – $1{,}27 \cdot 10^3$
Yield Strength (MPa)	50 – 55	29,6 – 44,1	55 - 72
Shape factor	5,7	6,3	7,2

Table 1 *Material properties for the 3D printed parts*

The shell is made out of 2mm Thermolyn Trolene, a material manufactured by Otto Bock (Otto Bock HeathCare, 2015). This material is made of PE-LD. The material has high flexibility and a low weight. It is easily moulded when heated to 125˚C. It has a density of 0.92 g/cm3, the shell ways approximately 10 g. The costs for this material are 1.61 EUR/kg, which makes the total costs about €0,016.

Figure 8.3 *Photograph of the first prototype*

Figure 8.4 *Photograph of the first prototype with the top part detached*

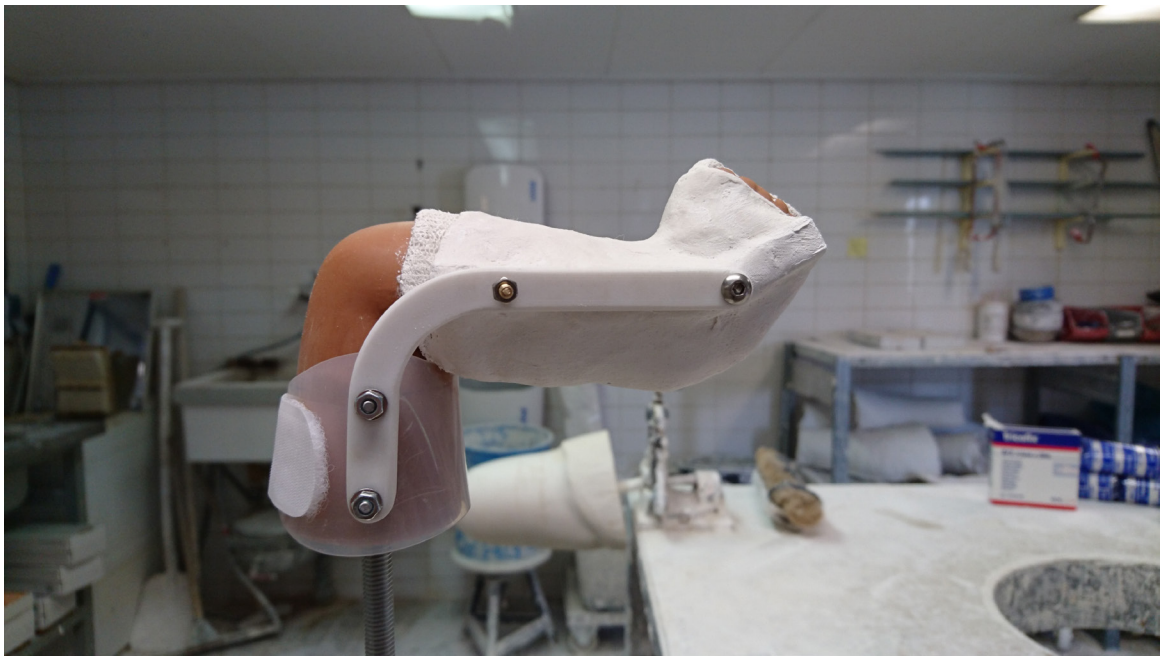


Figure 8.5 *Photograph of the first prototype*

PROTOTYPE

DISADVANTAGES FIRST PROTOTYPE

When making the first prototype a few problems occurred. The first problem was the alignment of the L-piece in the cast. When this piece is placed too much to the front of the leg if will not give the abduction the foot needs and if it is placed too far to the back of the leg it will over correct the foot and probably give a lot of discomfort for the child.

The second problem which occurred was the weakness of the hinge. When the shell is taken off it will stick out quite a lot. When the baby moves or kicks the connection can break easily.

The shell was fastened with Velcro on top of the leg. This can give problems with clothes and it gives a less neat look to the brace.

The last big problem was all the metal sticking out, as can be seen in Figure 8.3 - 8.5. This may frighten the parents, it is impractical with clothes, blankets, etcetera and the parents or the child may hurt themselves on it.

FINAL PROTOTYPE

To solve these problems a second brainstorm session was held. This time Bob Giesberts also participated. Together we found solutions for the problems.

To solve the first problem the shell should be placed on the upper leg when applying the cast. This way the pieces align themselves. By placing the hinge a bit higher the lower part of the L-piece can be connected to the cast. After this part is secure the shell can be taken off and the upper part is secured into the cast.

By creating a butt hinge the weak spot is dissolved; in the x- and z-direction is a lot more material which gives more strength and in the y-direction the arm can move freely. With this new hinge a new lock system had to be made. A simple snap connection was the easiest solution. The hinge also makes sure the child cannot stretch its leg with the shell on. The Velcro closure of the shell was moved to the bottom of the leg.

With the new hinge and the snap connection two of the metal projections were removed. The two remaining were to connect the shell to the arm. By making a blind insertion in the arm this problem was also solved.

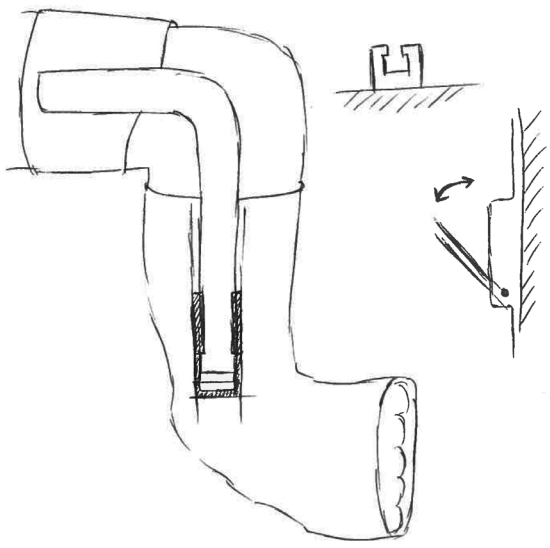


Figure 8.6 *Sketch of second prototype*

Figure 8.7 *Final prototype*

Figure 8.7 *Final prototype with the top part detached*

PROTOTYPE

ADVANTAGES - DISADVANTAGES

The advantages and disadvantages of the final prototype are determined with use of the requirements and can be found below.

- Changing diapers becomes easier
- When there has been an accident it is easy
to clean
- Looks less like a broken leg
- Option to add a bit more colour
- Less cast, less heavy, less cold and wet

- Not dynamic, parents need to go back to the hospital every week, treatment time is not reduced
- The cast will still cool down the body temperature of the child
- Parents may not put the shell back on
- A bit more time consuming for physicians
- 3D printed materials might cost more, production time increases
- The Velcro may give skin rash
- Children may be able to open the Velcro themselves

PARENTS OPINION

The parents were asked once again to give their opinion on the final concept. From the 39 people who received the mail 13 responded. The parents responded positive to this concept. The removable upper-leg shell is a great advantage, also the fact the knee is no longer covered is seen as a major pro. The foot is still corrected according to the Ponseti method and the cast will stay in place.

Parents are still a bit sceptical about handling the new brace. Questions like 'how easy is it to take off' are quite common amongst the responses. A usability test would be a nice next step. The parents also wonder if the construction is strong enough to overcome the kicking out of the cast. The connection of the shell to the cast raises a few questions, when the cast is still wet it can deform under the pressure of the plastic parts. These points will have to be researched.

SCENARIOS

In the beginning the problems were translated into scenarios. To see if the final concept solves these problems the scenarios are re-written.

SCENARIO CARE

Anne and Mike are both 32, they have two sons. The oldest is Tom (4 years) and the youngest is Ted. Ted is born with clubfoot, therefore both of his feet are casted. Because they already have a son they have some experience with the care.

The first time changing Ted's diaper Anne sees he has diarrhoea. The poo is spread everywhere, not only on his buttocks and groins, but also on the plastic shell. Anne takes off the shell and starts cleaning her son. She can use some water without worrying about the cast getting wet. Ted has some more freedom and can stretch his legs, which makes the cleaning a lot easier. It is still a lot more work than giving Ted a bath, but it is doable.

SCENARIO REACTIONS

Sarah is a single mother of 23 years, she just got her first child Emily. A few days ago Emily got her first cast. Sarah is quite insecure because of her first child having a handicap.

Sarah needs to go grocery shopping and by lack of a babysitter she decides to take Emily along. It's a nice warm summer day so Sarah dresses Emily in a dress which shows her cast. Sarah decides to put a blanket over Emily's legs. In the line for the checkout Emily manages to kick off her blanket, showing her cast. People behind Sarah show interest in the strange looking brace on Emily's legs. They ask Sarah why Emily has to wear this, if it is hard on her and if everything is going to be okay. Once in the car Sarah sighs of relief, this was not as bad as she had anticipated, though she felt a bit uncomfortable with all the people looking and asking questions.

SCENARIO CURRENT TREATMENT

Marc and Sasha are in their thirties and already have two daughters. They got their son Daniel a week ago. Daniel has clubfeet and today he gets his first cast.

The casting went quite quick and Daniel was really good during the treatment. In the car he starts crying though. His parents aren't sure what is wrong and they assume he is just tired of the long and intensive day. Once they get home Marc takes Daniel out of the car. He immediately notices that Daniel feels cold. Once inside Sasha takes Daniels temperature and it is a bit low. The cast is wet and cold and therefore it has cooled Daniels body temperature slightly. Whenever their daughters would feel cold Marc and Sasha would give them a warm bath or put a hot water bottle in their cribs. Both these solutions won't work with Daniel. The cast is full of water and this will conduct the heat of the hot water bottle which can result in skin burns. Marc puts a lot of blankets with Daniel in his crib and checks every hour. After a few hours the cast starts to dry and Daniels body temperature starts to rise again.

SCENARIO EXPERIENCES

Jill gave birth to twins, Linda and Stacy. Linda is born with clubfoot and is treated with the new method. Both her legs are casted. Sandra soon finds differences in her care for both the girls.

It is 5 am and Sandra wakes up, Linda is crying again. Sandra separated her twins because Linda would wake up her sister all the time. Sandra takes Linda out of her crib, making sure she is supporting the head as well as the legs. She holds Linda against her chest and feels the cold, hard cast scratching in her tummy. As soon as Linda stops crying she puts her back in the crib. A few hours later Stacy starts crying. Sandra takes Stacy out of her crib and puts her in her own bed. While hugging her child tightly against her chest Stacy falls back asleep. Sandra feels sorry for Linda because she isn't able to hold her like her twin sister.

Not all the scenarios have been changed. The scenario of experiences is quite the same. The cast is still hard and cold, even though it has been decreased. The scenario of the current treatment is changed slightly, the cast is reduced by half and therefore it will cool

PROTOTYPE

down the body temperature less and it will hold less water which means it will dry quicker. Both the scenarios of reaction and care are changed. The new method still looks like cast, but a ‘strange’, brace-looking part has been added. This will give a lot of people the sense it is not simply a broken leg. The care has become easier with the removable top part, this gives the parents a little bit more room to change the diapers and clean the buttocks of the baby.

Step 1 Prepare the leg by stretching it to its limits, just like with the Ponseti method

Step 2 Cover the leg with a sock and/or some cotton wool

Step 3 Cover the lower leg with cast just like with the Ponseti method

Step 4 Trim the sock and turn it over the cast

Step 5 Place the brace on the upper-leg and secure it

Step 6 Secure the lower part of the anchor with cast, make sure you give the leg the correct abduction in this step

Step 7 Detach the shell and fold it down

Step 8 Apply cast to the upper part of the anchor and place the shell back on the upper leg

DISCUSSION

A few methods have been used to come to the final concept. These methods are discussed in this chapter to see how reliable they have been.

LIMITATIONS

The theoretical background was analysed with use of many different articles and websites. Most of the used articles have more than 10 citations, which means they are quite reliable. The websites which are used may have been less reliable. The reliability of the information extracted from the sites was tried to increase by using different websites on the same subject.

The user analysis was done with a survey. The parents were contacted via a Facebook page, therefore it is not sure how reliable the responses are. Nothing is known about their lifestyle or how much they normally exaggerate things; there is a bias in this group. Only 49 out of the 600 members responded on the survey, which is a relatively small group. Preferably the survey was done face to face, this way explanations to certain answers can be asked. It would also have helped to see how the parents handle their child treated with the Ponseti method at home. Unfortunately no reaction came to the question if families were open to help with this. The responses to the survey were the only input for the parents' experiences with the Ponseti method.

The responses on the survey were analysed using the Qualitative Data Analysis method. This method is well known with researchers who collect a lot of qualitative data. Normally two co-workers also label the data and make a frame work, all the frameworks are compared and one final framework is made. This is however very time consuming and it was decided to neglect this part. It will not have major impact on the further study because it is mainly used to make all the collected data more accessible.

40 parents were asked to give their opinion on the created concepts, 10 parents replied. For the final concept these 40 parents were asked again to give their opinion, this time 13 replied. These are relatively small groups and it is not sure if their opinion is the main opinion of all the other parents. No more responses came after reminders were sent and therefore it was assumed their opinion was the opinion of the majority of the parents.

PRODUCT

The goal of this assignment was to create a dynamic brace, which could replace the Ponseti method, with use of the wishes and requirements of the parents. The final concept is not dynamic but does comply with the wishes of the parents. The final product has been compared with the requirements and the results are discussed below.

Because the brace still uses the lower part of the cast as used in the Ponseti method, it satisfies the general requirements. Slippage is prevented with use of the shell and the arm connected to the lower-leg cast. The design also meets the requirement of maximal costs; the material costs are no more than € 5,-.

The upper part of the brace can be removed which makes cleaning and changing diapers easier. The design is more comfortable for the child because it is less heavy and will dry quicker. For the parents it is also more comfortable because changing diapers and cleaning the buttocks has become a lot easier. It looks less like cast, and thus less like broken bones, because of the colourful 3D-printed parts. It is however still an obstacle when holding the child.

The design satisfies most of the requirements of the physicians, the only one it does not satisfy is the requirement of the new method being less time consuming. Now the physician can apply the cast up to the knee and directly apply a second roll up to the groin. The process has gotten more complex.

Because the shell is quite clumsy when removed, we hope to persuade the parents to adhere to the strict wearing regime. The parts can be reusable if someone has the patients to remove it from the cast.

CONCLUSION

The product does not meet all the requirements, but it is a good beginning. Usability tests will have to be performed to solve some small errors, but a physician is already enthusiastic and wants to test the prototype.

RECOMMENDATIONS

Further research has to be done on the functionality of the new design. It is assumed it will work, but this is based on the prototype on a silicon foot. This situation is not very realistic. The most important thing is to discover if this method really works or if it is necessary that the cast comes all the way to the groin for full correction. Also the possibility of the children kicking the cast off has to be taken into account, babies are a lot stronger then they seem.

Some tests on the material have to be done to see which is most suited for 3D printing. We're ready for usability tests will have to be performed to see how easy in use the brace is. Research has to be done to see how willing the parents are to put the shell back on or if they are too tempted to leave it off. When applying the cast the plastic parts can deform the cast underneath due to the given pressure, how much this will affect the cast has to be measured. The last point which needs to be taken into account is the fact that the shell can have a muggy effect, especially on warm summer days. The severity and the problematically of this issue have to be explored.

For the future the possibilities of the dynamic brace of concept 3 should be examined. This concept has a lot of potential but also a lot of uncertainties. If there is scientific evidence this solution works it will have the preference of a lot of the parents.

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APPENDICES

APPENDIX A

SURVEY QUESTIONS

Is uw zoon/dochter met klompvoetjes uw eerste kind?

Ja – Nee

Heeft uw zoon/dochter één of twee klompvoetjes?

Een – Twee

Met welke methode is uw zoon/dochter behandeld?

Op welke leeftijd is uw zoon/dochter behandeld?

Hoelang heeft uw zoon/dochter in totaal in het gips gezeten?

Hoeveel gips wissels zijn er geweest?

Heeft u speciale producten moeten aanschaffen vanwege het gips?

Ja – Nee

Zo ja, welke producten?

Heeft u producten moeten aanpassen vanwege het gips?

Ja – Nee

Zo ja, wat voor producten?

Kon uw zoon/dochter alle kleding aan?

Ja – Nee

Zo nee, welke kledingstukken konden niet worden gedragen?

Hoe heeft u het gips van uw zoon/dochter ervaren?

Werd de verzorging van uw zoon/dochter bemoeilijkt door het gips?

Ja – Nee – Een beetje

Zo ja, welke handelingen en hoe werden deze bemoeilijkt?

Werden zaken als meten en wegen bemoeilijkt door het gips?

Ja – Nee

Zo ja, hoe heeft u dit opgelost?

Hoe hygiënisch heeft u het gips ervaren?

Onhygiënisch: 1 – 2 – 3 – 4 – 5 : Hygiënisch

Heeft er wel eens ontlasting aan of in het gips gezeten?

Werd het oppakken van uw zoon/dochter bemoeilijkt door het gips?

Zo ja, kunt u hier toelichting op geven?

Hoe heeft u het knuffelen met uw zoon/dochter ervaren?

Hoe reageerde uw zoon/dochter op het gips?

Heeft uw zoon/dochter huidirritaties gehad door het gips?

Heeft uw zoon/dochter drukplekken gehad door het gips?

Zijn er complicaties opgetreden tijdens de gips periode?

Zo ja, kunt u uitleggen welke complicaties?

Wist de kraamzorg en/of het consultatiebureau hoe om te gaan met klompvoetjes?

Kunt u hier toelichting op geven?

Hoe reageerde de directe omgeving op het gips van uw zoon/dochter?

Heeft u ooit negatieve vragen of opmerkingen gehad van mensen in uw directe omgeving over het gips?

Hoe reageerde de omgevind op het gips van uw zoon/dochter?

Heeft u ooit negatieve vragen of opmerkingen gehad van mensen in uw omgeving over het gips?

Heeft u verder nog punten waar u tegen aanliep tijden de gips periode?

Zijn er dingen die u graag verbeterd zou willen zien aan de gipsperiode?

Heeft u tips of ideeën over wat een goede vervanging of aanvulling zou zijn voor het gips?

Stel dat er in de toekomst een vervanging voor het gips mogelijk is, wat zou u dan als eis willen stellen?

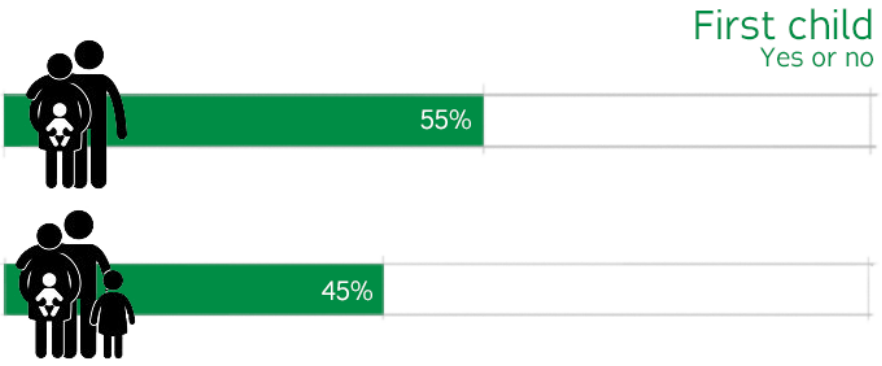
Mag ik naar aanleiding van deze vragenlijst contact met u opnemen?

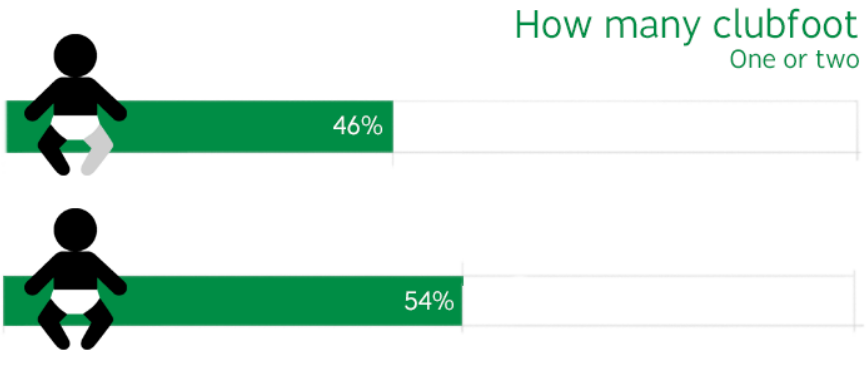
Mag ik in de toekomst contact met u opnemen voor verdere vragen en uw mening?

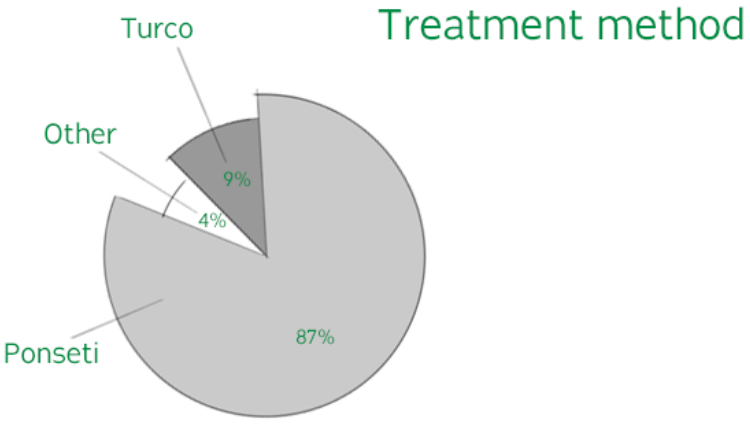
Wilt u op de hoogte worden gehouden van de uitkomsten van dit onderzoek?

APPENDIX B

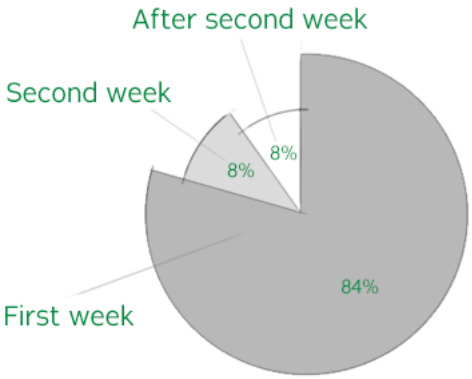
QUANTITATIVE DATA





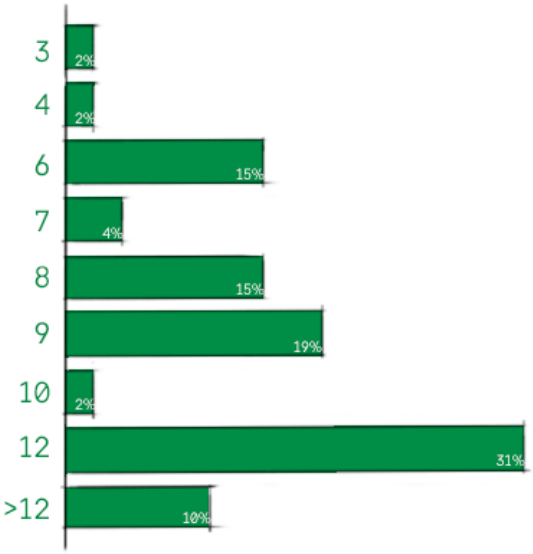


Start treatment



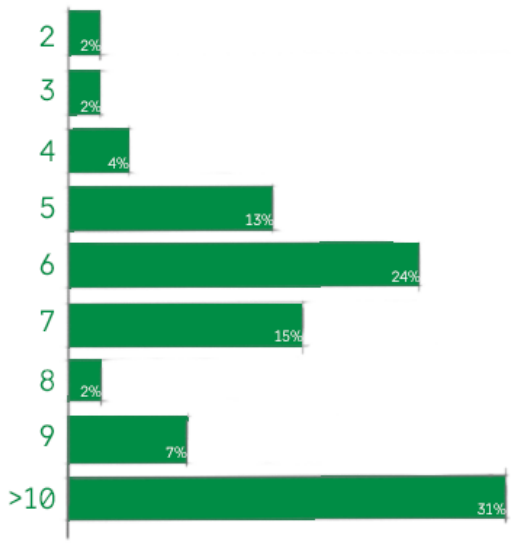
Duration of cast treatment

In weeks

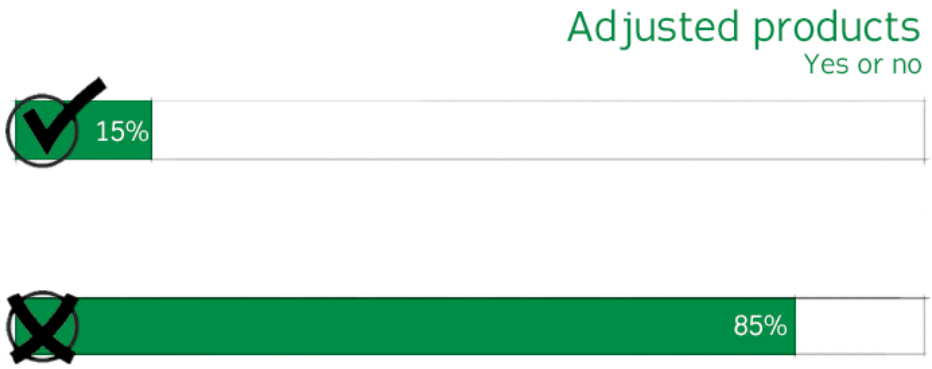


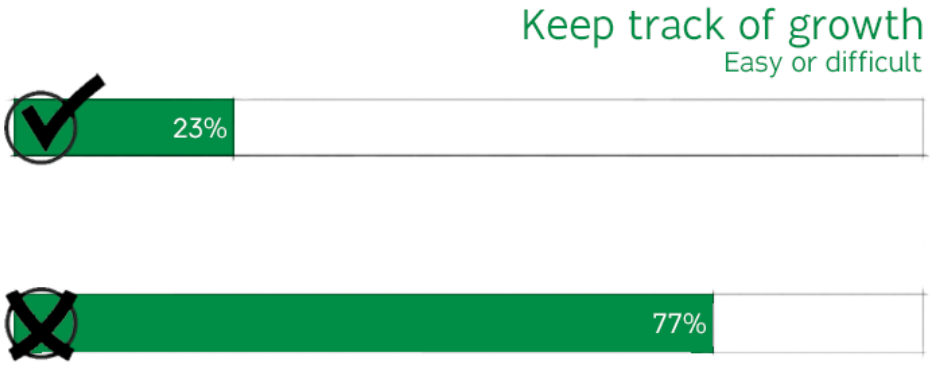
How many cast changes

Number of changes



APPENDIX B


Adjusted products
Yes or no
15%
85%

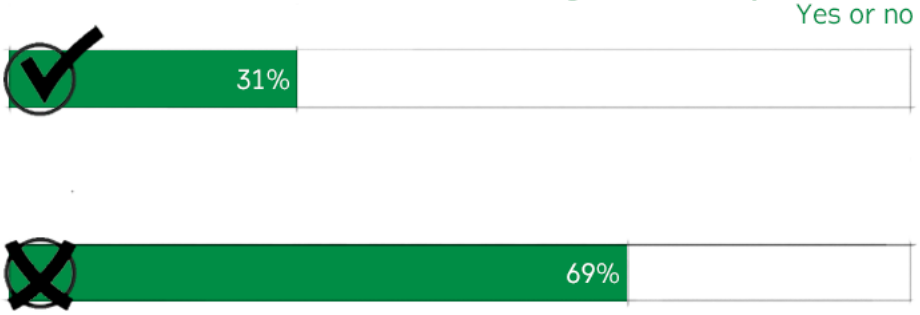

Keep track of growth
Easy or difficult
23%
77%

Complications during treatment

Yes or no

Damage due to pressure

Yes or no



APPENDIX C

	Products	Current treatment	Future treatment
#38056	Tight trousers are not practical.	Our daughter had difficulties keeping herself warm in the first 48 hours after a cast change.	
#38244	Bought different clothing which she could not wear. Jeans and playsuits were not practical.	The cast was too thick.	Develop something to allow the child to bath at home. Bath at home, lightweight, it should not be removable because parents will take it off every time the child cries.
#38248	Jeans, playsuits, socks and tight trousers could not be used.	The cast stuck to the skin because of eczema, really bad itch when the cast was removed he scratched his skin until it bled. The sharp edges of the cast damaged his groins. It was heavy and hot and it was a pity we could not bath him.	It should be less of a burden for the children.
#38251	Tight trousers or trousers without stretch could not be used.	You can't use a hot-water bottle because the cast is heat conducting.	
#38252	Jeans and tight trousers did not fit.		
#38254	He mostly wore rompers because they were easy with changing diapers. All the clothing was a size bigger.	Because our son had only one clubfoot he always slept on his side. We got comments about it and we had to force him to sleep in other positions.	
#38261		The new wet cast cooled down the body temperature of our son very quick. We had to put a pillow under his leg, else his toes would start turning blue.	It should be less long wet and therefore less cold for the child.
#38262		The cast was 2 times too tight. The body temperature of our son dropped because of the wet cast.	It should be just as effective and efficient as the current treatment.
#38275	Playsuits and non-stretch trousers like jeans or cottons, socks.	Because of leaking diapers the cast became dirty.	It should have at least just as good results as the current treatment.
#38279	Leggings and maillot did not fit.	The cast was once too tight and once it was too lose and fell off.	
#38292	Playsuits with socks and jeans did not fit.		
#38294	Jeans and tight clothing did not fit.	We didn't get any information during the casting. Some personal information about the treatment would have been nice.	It should have a nice color and it should be less heavy. More personal information about the treatment.

#38499	Trousers and playsuits did not fit.		
#38509	Not every trouser could be worn, socks did not fit.	The injections in the heel went wrong and this resulted in a wound. The cast was put over it.	
#38651	He mostly wore rompers.		
#38656			A rim to protect the cast from stool and moisture, which can be changed when it is dirty.
#38658	Playsuits and trousers with tight legs did not fit.	The cast rips your fingers, you can't enter every mother-child class and the cast cools down really fast. It would be nice if there was more awareness so you don't have to defend yourself all the time.	A 3D printed model which can be removed for bathing. The result should be the same or better, the ease of use should increase.
#38669	Tight trousers did not fit.		It should not be wet and cold. It should have the same result. It should not be easily removed or shifted.
#38672	Trousers and socks did not fit.		It should be lightweight.
#38689	I made clothing out of water-resistant material for the first days after the cast changes.	The toes were dirty because of the moisture.	The result should be at least as good.
#38690	/	/	/
#38692	We used wide trousers, preferably with snaps.	The wet and cold cast was unpleasant.	A less ponderous way should be nice. It should be less thick, from other material, less heavy, soft to the touch and it shouldn't be over the knee.
#38695	Cotton trousers were difficult. We preferred jogging pants.		
#38696	We put an extra layer in the box to avoid damage to the box and the cast. Playsuits and everything with sown-on socks did not fit. Also tight clothing like maillots.	Once the cast was too tight which made here inconsolable. It became difficult to put her in the buggy and maxi cosi. We had the option to choose colors to brighten it up.	It would be nice if it could be taken off to bath. It should be cleanable.
#38703	Playsuits and trousers with small legs did not fit.		It should be water-resistant. The result should be as least as good as the current treatment.
#38719	Maillots did not fit.	The cast was difficult with sleeping, especially in the beginning when it was cold.	A 3D brace which is changed each week. It should be light weight.
#38724		The cast got easily dirty after diarrhea.	It should not get easily dirty, maybe not up to the groin.
#38752	Shoes and tight trousers did not fit.	We had uncertainties about her growth. It is difficult to measure it with the cast.	A separable top would be nice so you can clean it after changing the diapers. It should be easy to clean and it should not give

			allergic reactions.
#38759	Socks and playsuit did not fit.	He got a blemish spot in his popliteal. He got a growth spurt with the final cast which had to stay on for three weeks which had as a result that the cast was very tight at the end.	It should be easy to clean.
#38764	Tight trousers did not fit.	Once the cast was too tight.	The result should be as least as good as the current treatment.
#38819	Cotton trousers did not fit. We mostly used jogging pants.		It should be removable so you can bath your child at home.
#38861	Jeans did not fit, the legs were too tight.		It should be water-resistant.
#38885			It should have good quality and it should be equivalent to the current treatment.
#38906	/	/	/
#38908	/	/	/
#38927	Playsuits, socks and shoes could not be worn.		It should be lightweight.
#38951	/	/	/
#38952	Trousers and socks were always one to two sizes bigger.		
#38963	Jeans did not fit, therefore we bought jogging pants.	Our son was crawling; this caused the edge of the cast around the toes to damage fast.	It should be flexible.
#39251	He wore a lot of jogging pants.	He managed to get the cast off.	
#39253		The hygiene was disappointing.	It would be nice if it didn't have to go all the way up to the groin. It should be removable and washable.
#39296	/	/	/
#39432	Trousers did not fit.	The cast was really heavy. Because my son was premature he could not move his own legs.	It should be lightweight and less thick. Maybe some kind of brace.
#40101	We bought a *delta baby sleep* related to the lateral sleeping position. Playsuits, anything with sowed on socks and tights legs did not fit.	Last cast was too tight; he had a growth spurt during this time. It would have been nice to have more information about the care of your child.	It should be more comfortable and work just as well as the current treatment. Maybe a brace with can be taken off for bathing or cleaning.
#40435	Wider trousers		It should be removable so you can bath.
#40569			It should work according to the Ponseti rules. It should be lightweight.
#41041	We bought trousers with wide legs.		It would be nice if it could be removed every now and then so you could wash him.
#42741	Playsuits didn't fit.	Once she had friction wounds on her	Some sort of sock which can protect the buttocks from

		groins/buttocks because the padding wasn't high enough.	friction wounds. It would be nice if the cast is removable so you can bath your child. I think this is very important for the connection with your child.

	Experiences	**Reactions**	**Care**	**Caretakers**
#38056	It was part of the deal. It was really nice to feel the legs of our daughter once they were out of the cast, but I never experienced it as absent during the treatment, it was part of the deal.	The surroundings were concerned, just like us. Strangers often concluded my daughter had two broken legs.	In case of a really dirty diaper you can't give your child a bath. Weighing was done in the hospital during the cast change. Measuring was never done.	Maternity care and the birth clinic had no experience, but were open for suggestions.
#38244	Our son accepted the cast pretty good, only on the day of the cast change he was a bit out of sorts. You adapt quite quick.	Some people found it piteous.	We missed the bathing; because we could not do it often our son really hated it for the first few months after the cast was removed. Weighing was done in the hospital during cast changes.	
#38248	We experienced it as bothersome, but you know it is for a good cause. When the cast was removed he had to adjust, touch on his skin was new for him.		Bathing and changing diapers was difficult. In between cast changes we weighted our son.	The birth clinic had no idea, vaccinating was difficult and the heel injections did not work. Our first hospital was really bad; as a result we had to do the whole process over at 9 months.
#38251	You get used to it. Holding our son was difficult for us in the beginning and for visitors.	Many people felt sorry for our son because the cast is heavy. Some people were startled.	We weighted our son with the cast.	
#38252	It was just the way it was. When picking up you had to pay attention to supporting the legs.	They felt sorry for her and us. They were wondering if she was going to be okay. Some were a bit frightened.	We could not bath her, which was difficult. Weighting was done during the cast change.	
#38354	The first night after the cast change was hell. Every day it went a bit better until the next change. We found a way to hug and feed him quite quick.	Much pity for our son. People were startled, looked at the cast but did not dear to ask anything.	We could not let him enjoy a bath. Therefore we used a washcloth and a plastic bag to protect the cast. We weighted the cast and subtracted this from the total weight.	Nobody told us we could bath our son during the cast changes, so the total duration of the treatment we haven't washed our son.

#38261	The first day after the cast change he cried more. We got used to the right way of hugging quite quickly.		Changing dirty diapers was difficult; you had to keep the cast clean. During the cast period we did not weigh or measure our son.	The wait time in the hospital was very long.
#38262	We felt really sorry for our son. We were very frightened because the cast was to tight the first time and had to be removed really fast. It was a real burden for us. Our son learned to cry during this period.	We got a lot of questions about it.	Changing diapers was difficult. We weighed our son during the cast changes.	The journey to the hospital was very long and exhausting.
#38275	Our son adapted quickly. Hugging him was no different from our youngest son.	Many people thought he was treated for hip dysplasia. They felt sorry.	Changing diapers, bathing was only possible during cast changes. We weighted the cast and subtracted this from the total weight.	They had to find another way to vaccinate.
#38279	Because of wrong treatment it was hell. We had a secluded life because of the bad treatment, our daughter became extremely irritable.	Some people reacted shocked, others just looked.		
#38292	We had a hard time figuring out practical things like picking her up and holding her. She had no troubles with the treatment.	People had a lot of sympathy and were curious.	Bathing was difficult. We weighted her with the cast.	The birth clinic had to find another way to vaccinate. We had to instruct the maternity care about clubfeet.
#38294	We needed some time to get used to it.	People looked weird at our daughter, but did not dear to ask anything. People felt sorry.	Changing diapers was difficult and we could only bath her during cast changes. Weighing was also done during the cast changes.	
#38499	We did not experience it as difficult.	Pity and interest. Strangers asked weird questions and pointed at us.	Bathing was difficult.	
#38509	We did not pick her up if it was not necessary; we just let her lie in her bed. She could not lie against you. During the cast changes she was crying a lot.		Bathing, changing diapers and dressing was difficult.	Heel injections were given in her finger.
#38651	He was restless after the cast changes.	Strangers just stared at us.	Changing diapers and bathing was difficult. Weighing was done during the cast changes.	
#38656	We got used to it very	People felt sorry.	The cast became dirty	

	quick.		really quick. Weighing was done during cast changes.	
#38658	The first day after the cast change he cried a lot.	Some people didn't visit and some didn't want to hold him. Once someone thought I had hurt my son. Nieces and nephews thought all babies were born with cast.	Bathing was difficult. Weighing was done during cast changes.	
#38669	People were afraid of hurting her. We needed some time to get used to the hugging. She struggled with the cast changes and the wet and cold cast.	People felt sorry and were startled when they first saw her. Strangers looked strange at us. We got lots of judgments from strangers.	Bathing and dressing her was difficult. Weighing was done during the cast changes.	I had to fill the birth clinic in about the treatment.
#38672	She didn't know better.	People felt sorry for her.	Weighing and measuring was done during the cast changes.	The wait time in the hospital was very long.
#38689	With every change we had to adjust. It was a pity he could not lie naked against me like his twin brother.	Some were concerned.	When he had diarrhea it would end up inside the cast. Weighing was done with the cast on.	The birth clinic did not understand the different cast could be different in weight. They were unsecure; I think this could be frightening of insecure parents.
#38690	He didn't notice it.	Many people felt sorry. We coffered his legs with blankets as much as possible.	We could not bath him and when he had diarrhea it would end up inside the cast. Weighing was done with the cast changes.	We had to inform them.
#38692	It was okay, but difficult. Such a small body with hard and cold legs. The cast on your own baby was a very unpleasant feeling. I think it was for me as a mother harder than for my child. The cast changes were difficult for her, but otherwise she accepted it.	Interested, concerned and loving.	Bathing and dressing were difficult. We weighted the cast and subtracted this from the total weight.	I had to teach them on this subject.
#38695	It was necessary. When holding him we had to support the legs. I didn't like handing him to other people during the cast period. He didn't make a fuss about it.	Once somebody asked if he had broken both his legs. Interested and amazed.	Bathing was difficult. We did not weigh him.	The birth clinic was very consistent in their usual ways, whilst this was not always possible in this situation. The handicap and treatment are unknown; if we weren't prepared they couldn't have

				helped us.
#38696	It was difficult for us because you can't bath her every day. Looks from people in your surroundings are very hard. Hugging was, if she was in the right position, no problem. She did not know better, on the day of the cast change she was feverish.	When the family heard they were a bit upset. We got often negative comments from strangers. People would stare at us. Often people gossip behind your back that you must abuse your child. This was really hard.	Bathing and changing diapers was difficult. Breastfeeding was also difficult. Weighing was done during the cast changes.	
#38703	It was doable.	Some people felt sorry. People who did not know the situation reacted strange.	Bathing was difficult. Weighing was done with the cast on, we did not measure.	I had to inform the maternity care and birth clinic. The wait time in the hospital was very long.
#38719	Not extremely difficult. Our daughter had trouble with sleeping.	Strangers thought she fell and had broken both of her legs		The ignorance of the physician.
#38724	It was doable. Sometimes we had doubts if the cast wasn't too tight. Only when it was hot he would have some troubles with the cast.	Quite shocked. A small baby with cast up to the groins looks sad.	Changing very dirty diapers was difficult, and we couldn't bath as often as we wanted. The weight was estimated.	Birth clinic didn't know anything about clubfeet. Both the midwife and the general practitioner did not see the clubfoot. We were referred to a physiotherapist who was the first to notice it.
#38752	It was intensive. I missed the skin to skin contact with my child. After each cast change her body temperature would drop. She was upset the first two days after the cast change.	Strangers asked how such a small child got two broken legs. Some people thought I did drop tests with my child.	Bathing and showering was not possible, we washed her with a washcloth. Weighing was done during the cast change.	The birth clinic insisted on a hip echo. I told them it would not work because she already had the cast. They did it anyway, with no results. All the pulling on the legs of my daughter caused her to be upset and cry for three days.
#38759	I was not looking forward to it, but it was okay in the end. You had to support the legs at all times, when picking him up you had to watch his legs; they could easily get stuck behind the blanket. Hugging was difficult in the beginning. Only the day of the cast change he was a bit restless.	We mostly had his legs covered, but when people saw it you would hear whispers behind you. People felt sorry. Nobody dears to ask what is wrong.	Bathing was not possible, so we washed him with a washcloth. Changing diapers was sometimes quite a challenge. Weighing was done during the cast changes.	
#38764	His leg had to be up	Some felt sorry.	Bathing and	They had to learn

	all the time, this was difficult in the beginning but over time you will get the hang of it. I was glad it wasn't our first child otherwise it would have been really difficult.		breastfeeding was difficult. Weighing was done with the cast or not at all.	everything from us. Physicians were always busy, it would have been nice if they had more time to inform us.
#38819	It was necessary. We knew quite early so we had time to prepare. You always had to support the legs. Because he was so small he had no troubles.	People were interested. Some just stared and once someone asked if he had broken both his legs.	With everything you did you had to support the legs. Bathing at home was not possible. Weighing was done with the cast.	The birth clinic was very persistent; they had to have a weight. The handicap and the treatment are unknown, we had to explain it to everyone.
#38861	You are not happy with it, but our son did not have any troubles with the cast so it was okay for us. You always have to support the legs. He could not lie real close to you.	Some felt sorry, especially when they saw the cast was all the way up to the groin. It was winter so his legs were covered.	His legs were less flexible which was difficult with changing diapers. Weighing was done during the cast changes.	Every physician has a different story, some say put the leg up and others say this is not necessary. It would be nice to have a directive for this.
#38885	Our son had some troubles with the treatment.	Friends stayed away because they couldn't handle it. Father had also much trouble with the handicap and its treatment. People talk behind your back.		Birth clinic was acting difficult; they were convinced children like this should not be at home. There was a big difference between hospitals.
#38906	Afterwards it was okay. Our son had no troubles with the cast, which made us more relaxed. Hugging and picking him up were a bit difficult in the beginning.	People were not scared by the cast.	We couldn't bath him and therefore we could not was his toes. Weighing was done during cast changes	
#38908	We experienced no problems.	People reacted okay, because of our positive energy.	Changing diapers and bathing were difficult. Weighing was done during cast changes.	We had to instruct them.
#38927	We experienced a lot of insecurity. He could be quite upset after the changes. It was a pity he could not take a relaxing bath. We had to support his legs.	People were scared to hold him; they did not know how to handle it. Once someone sad it was sad to see him in cast, like something had happened to him.	It was difficult with real dirty diapers. Cleaning was difficult. Weighing was done during cast changes.	
#38951	He didn't know better.	We got a lot of questions.	When changing diapers we put a sock around the cast so it would not get dirty when he would	

			accidently pie. Bathing was only possible in the hospital.	
#38952	It was a heavy period for us. Our son was crying a lot. We got used to the hugging and holding. I think it was hot for our son (it was summer).	Many people felt sorry and didn't dare to pick him up. Also changing diapers was something they didn't want to do, scared they would hurt him. Loads of people would stare. It was hard for me to go shopping with my son because of all the looks. People would ask if I had dropped my son, if I shouldn't keep him at home. This made me feel very uncomfortable.	I missed the bathing. Especially whit leaking diapers. Weighing was done in the hospital.	We had to inform everyone.
#38963	Our son only had difficulties with removing the cast.	People felt sorry.	Weighing was done with the cast.	
#39251	We had to support the legs all the time. Hugging was less nice with the cast.	People didn't notice it because of the long trousers. When they did see it they felt sorry.	Properly bathing, changing diapers and dressing was difficult. Weighing was done during the cast changes.	Birth clinic made a problem of the fact they couldn't weigh him.
#39353	The cast limited the hugging. I felt sorry for her, she was premature and therefore the cast was even heavier (in comparison with her body weight). The hugging was different from the hugging with her twin sister.	They felt sorry.	Changing diapers and bathing was difficult.	
#39296	She had no problems with the cast.	Once someone asked if I wasn't very disappointed. Once someone accused me of abusing my child.		They kept asking if she had broken her leg.
#39432	It was doable. The first day after the cast change he would be really tired.	They knew it was necessary.	The whole care of our child was difficult. The weight was estimated.	
#40101	The cast was okay, we had more troubles with the procedure. Our son was restless and frightened after the cast changes. Holding him you will get used to.	People would whisper. They thought I had dropped my child and that he had a broken leg.	Changing diapers and bathing was difficult. It would have been nice to have more information about the care of your child.	
#40435	It wasn't a pleasant	You often get	Changing diapers and	The information is

	time. Hugging wasn't always as nice because of the cast. The first 24 hours he was really upset.	negative reactions. You just have to take it, which was really heavy on us.	bathing were difficult. We did not weigh him.	unclear.
#40569	It was okay. With every new cast he was a bit upset.	They felt sorry. People were restrained and didn't dare ask questions.	Subtracting the weight of the cast from the total weight.	
#41041	I could not carry my son in a blacked. It was necessary, but very intensive. He was frustrated about the fact that he could not move his legs. We needed to support his hips. It was heavy to pick him up. Hugging was different, he could not lie against you in fetus position.	They were scared to hold him, be we were relaxed so this passed fast.	Changing diapers was difficult. Weighing was done with the cast.	I had to inform them. The physician once told me that I shouldn't feel sorry for my son. This made quite some impact on me. I felt misunderstood in the hospital.
#42741	It was difficult to lay her on your chest.	Some felt sorry.	Bathing was not possible so we washed her with a washcloth. Changing diapers was also difficult. Weighing was done with the cast.	

APPENDIX D

Requirement	Concept							
	1	2	3	4	5	6	7	8
General								
Correct foot	+	?	?	-	+	+	-	+
Pressure talus	+	?	?	+	+	+	+	-
Pressure metatarsal I	+	?	?	+	+	+	+	-
Apply force	+	+	±	+	+	+	+	-
Slippage	+	+	+	+	+	+	-	+
Moment	+	-	-	-	+	+	-	-
Costs €150,-	+	±	±	+	+	+	+	+
Users								
Donning & Doffing	+	Does not apply	Does not apply	+	-	-	-	Does not apply
Changing diapers	+	+	+	+	+	+	+	+
Cleaning	+	-	-	+	-	-	+	+
Comfortable child	+	+	+	+	-	+	+	+
Comfortable parents	+	+	+	+	-	+	+	+
Weight	+	+	+	+	-	+	+	+
Fitting cloths	-	+	+	-	-	-	+	+
Holding child	-	+	+	±	-	±	+	+
Allergic reactions	+	+	+	+	+	+	+	+
Damage skin	+	±	±	+	-	+	+	-
Irritate skin	-	-	-	-	+	+	+	-
Broken bones	-	+	+	-	-	+	+	+
Body temperature	-	+	+	-	-	+	+	+
Physicians								
Set & adjusted	+	+	-	+	+	+	+	+
Damage soft tissue	±	+	+	±	±	±	±	±
Pressure points	±	+	+	±	±	±	±	+
Fitting	+	-	-	+	+	+	+	+
Knee bend	+	±	±	+	+	+	-	-
Treatment time	-	+	+	-	-	-	-	-
Wishes								
Wearing regime	-	-	+	+	-	-	-	+
Bathing	-	+	+	-	+	+	+	+
Knee movement	-	+	+	+	+	+	+	+

Colours	+	+	+	+	+	+	+	+
Reusable	+	±	±	-	-	-	-	-
Costs €100,-	+	-	-	+	+	+	+	+
Dynamic	-	+	+	-	-	-	-	-
Hugging	-	+	+	-	-	-	+	+
Heel injection	-	-	+	-	+	+	+	+

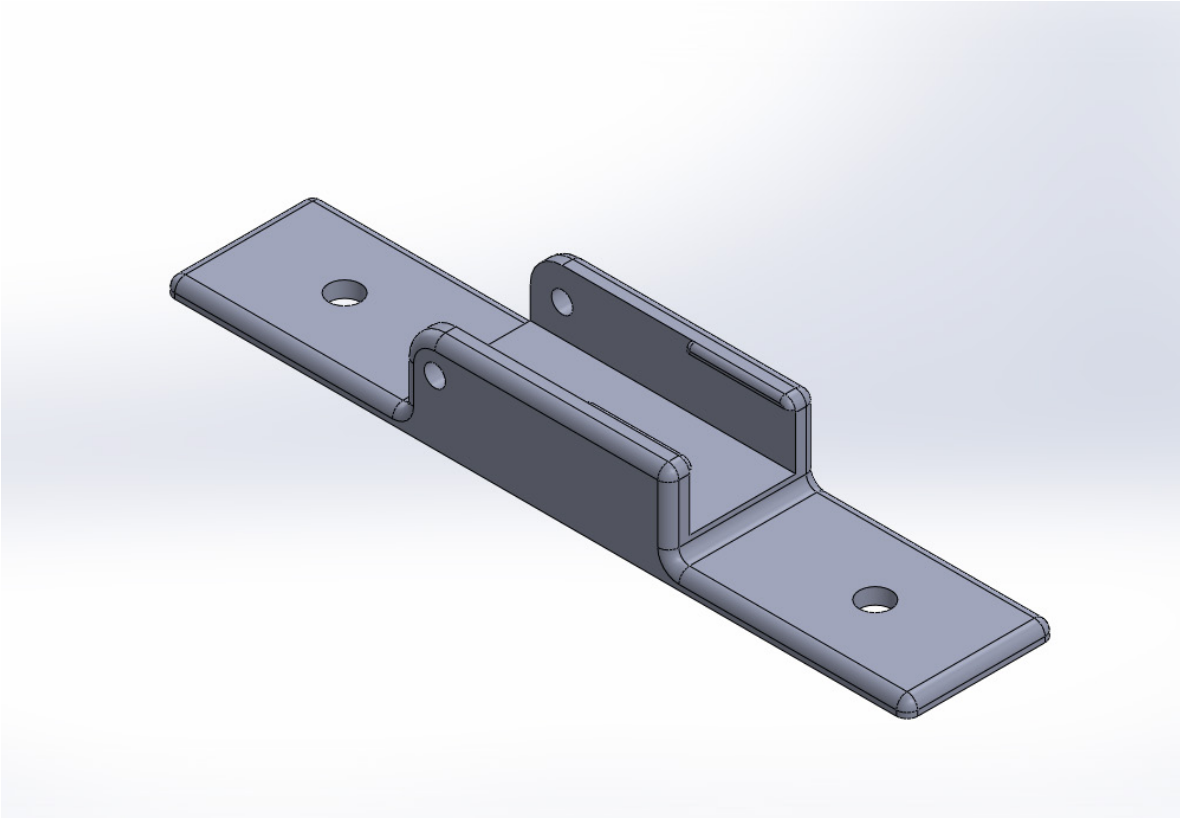
Argumentation

Req. 1 - 4; For concept 2 and 3 this is not sure, this will require some research. Concept 8 is basically the French method, it follows the cave principle but does not have the pressure points. For the other concepts it is proven, these concepts all consist of cast following the Ponseti principles. Only concept 4 and 7 may not work. According to a research (Maripuri, et al., 2013) the failure rate with below-knee cast is a lot higher. This research was stopped because of the bad results.

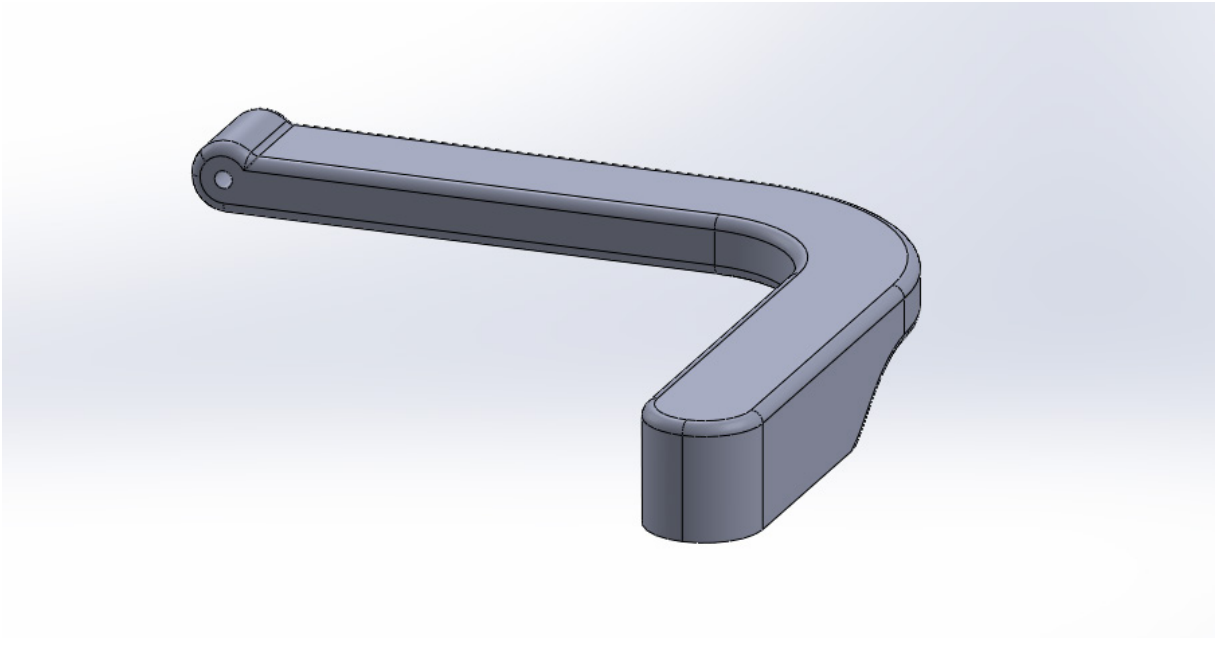
Req. 8; Concepts 5-7 may not be easily put back on, the foot needs to lie perfectly in the cast to avoid sores.

Req. 22 - 23; With the cast concepts this depends on the skills of the physician.

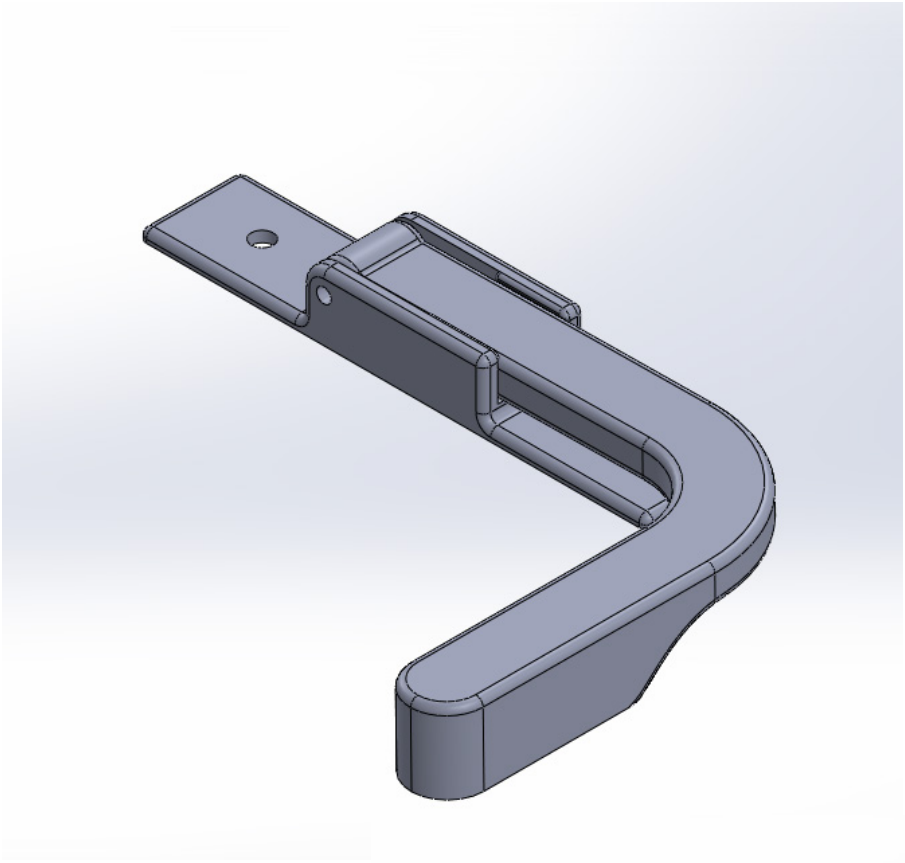
APPENDIX D



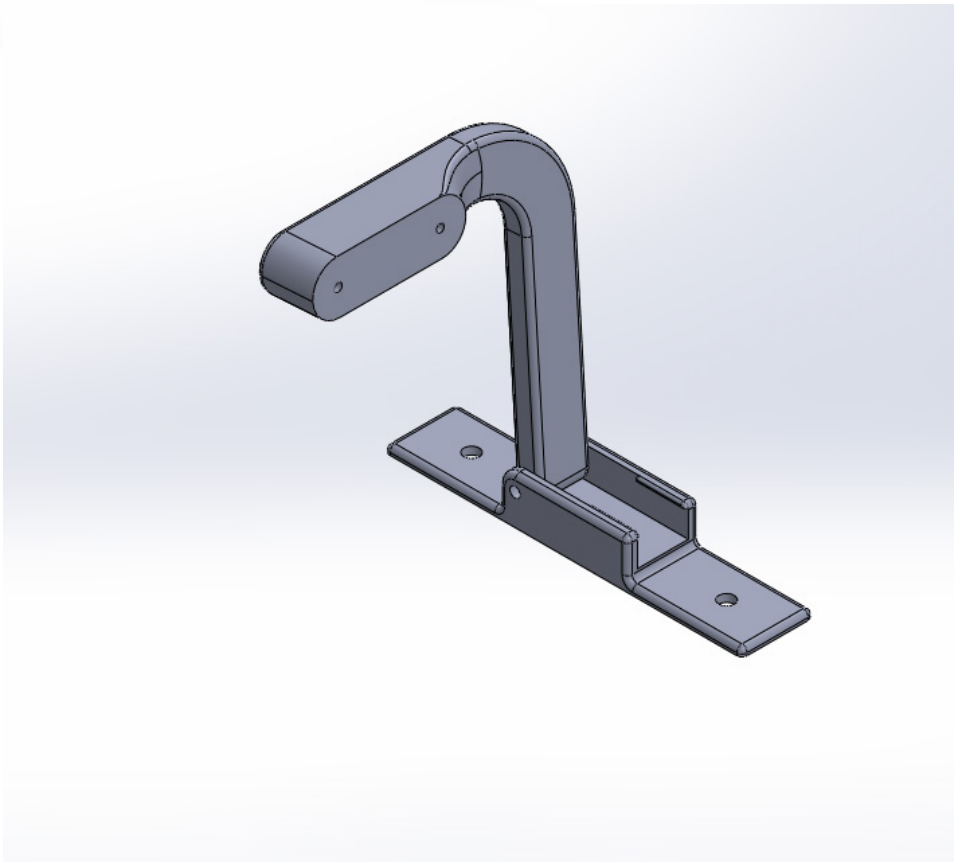
The anchor of the final prototype



The arm of the final prototype



Assembly of arm and anchor



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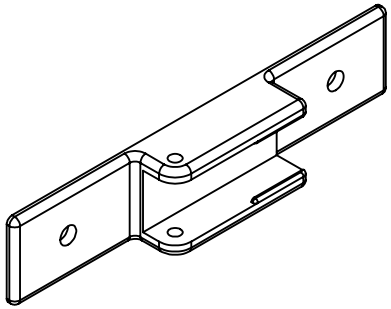
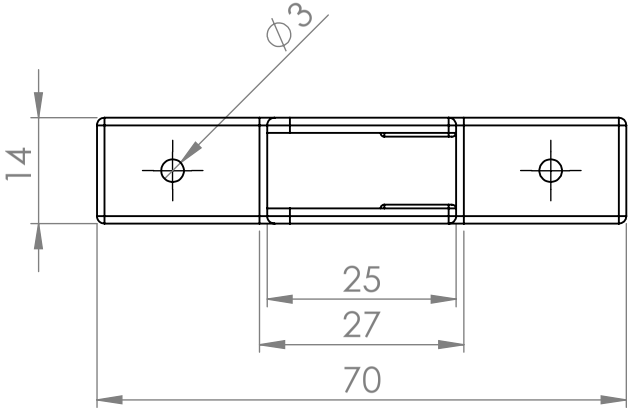
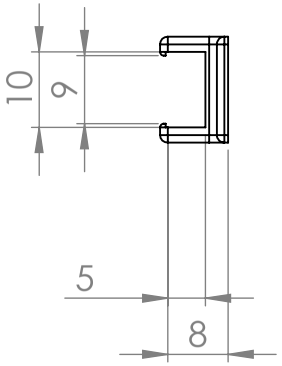
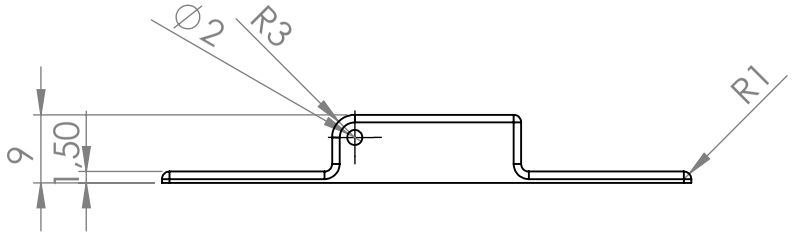
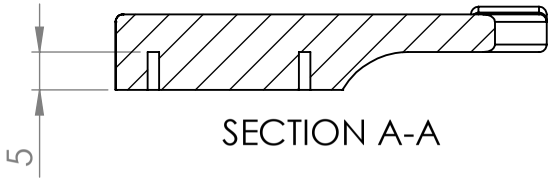


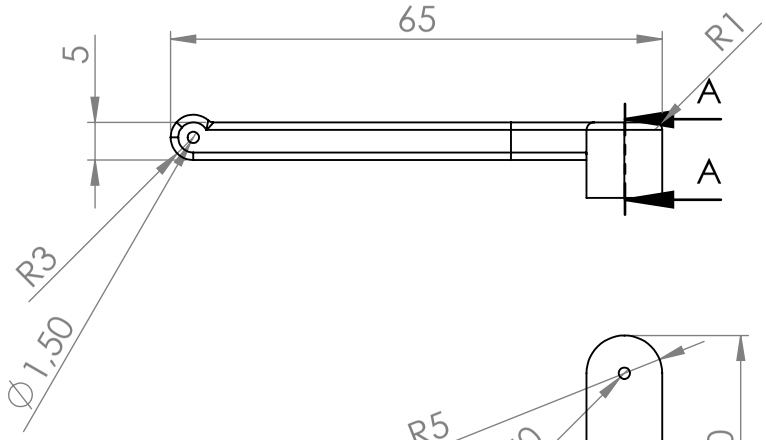


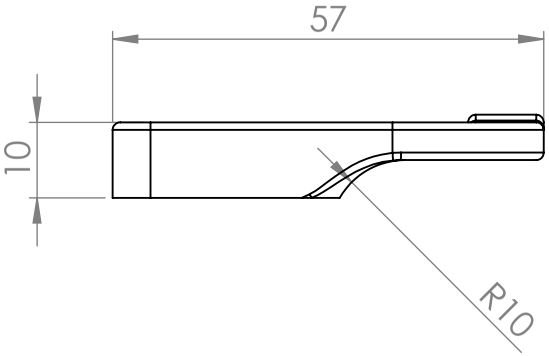


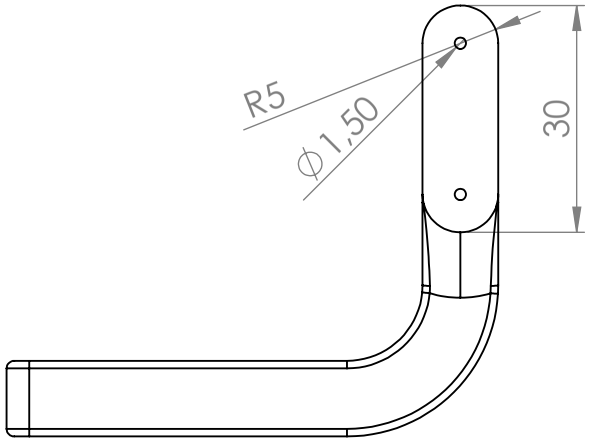


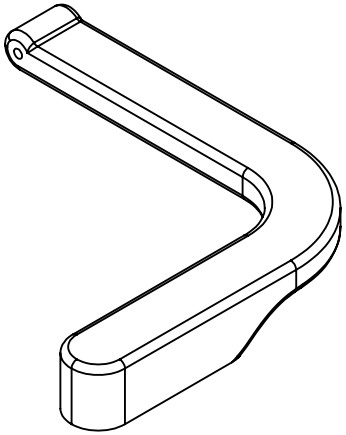
PROJECTION METHOD	UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM	DRAWN	Elleke van Doorn	DATE	27-6-2016
		CHECKED	Jari Kamphuis	SCALE	1:1
MATERIAL: PET --	SURFACE FINISH: --	TITLE: Anchor			REV.: 01
		DRAWING NO.: 2.1			
UNIVERSITY OF TWENTE.		FILE / PART NAME: Ingips - anker			A4
FACULTY OF ENGINEERING		DIMENSIONS IN MILLIMETERS			SHEET 1 OF 1











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		CHECKED	Jari Kamphuis	SCALE	1:1
MATERIAL: PLA --	SURFACE FINISH: --	TITLE: Arm			REV.: 01
		DRAWING NO.: 1.1			A4
UNIVERSITY OF TWENTE.		FILE / PART NAME: arm			
FACULTY OF ENGINEERING		DIMENSIONS IN MILLIMETERS		SHEET 1 OF 1	