Design of a prototype for the inner shoe casting for an orthopaedic modular shoe to be used in developing countries

A Masters Project

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1. Background

1.1. Clubfoot

1.1.1. Introduction

Clubfoot, also known as congenital talipes equinovarus (CTEV), is one of the most common congenital anomalies in the musculoskeletal system (1). Clubfoot occurs in nearly 1 in every 1,000 live births worldwide.

The cause of CTEV is not entirely clear; however, it is widely considered to be multifactorial and polygenic. This means that there is more than one gene responsible for increased susceptibility to the development of this anomaly and that this anomaly is associated to environmental factors. In an example cited by Gibbons and Gray to exemplify this statement, the following facts are presented: If there is a history of clubfoot within a family, the odds ratio of a baby having clubfoot is 6.52. If the mother smoked during early pregnancy, the odds come to 1.34. In the case of both factors, a combination of family history and the smoking mother, the odds ratio of the baby having clubfoot escalate to 20.3 (2).

According to Gourineni and Carroll (3), CTEV is classified into 4 different categories based on its origin and response to treatment:

- Postural; benign, it resolves completely with stretching and casts.
- Idiopathic; true congenital clubfoot of variable severity.
- Neurogenic; as seen in spina bifida.
- Syndromic; associated with other anomalies. These feet are often quite rigid.

1.1.2. Anatomy

The mnemonic “CAVE” is used to remember the four main anatomical abnormalities in clubfoot: Cavus, Adduction, Varus and Equinus. The anatomy of CTEV is presented in Figure 1.

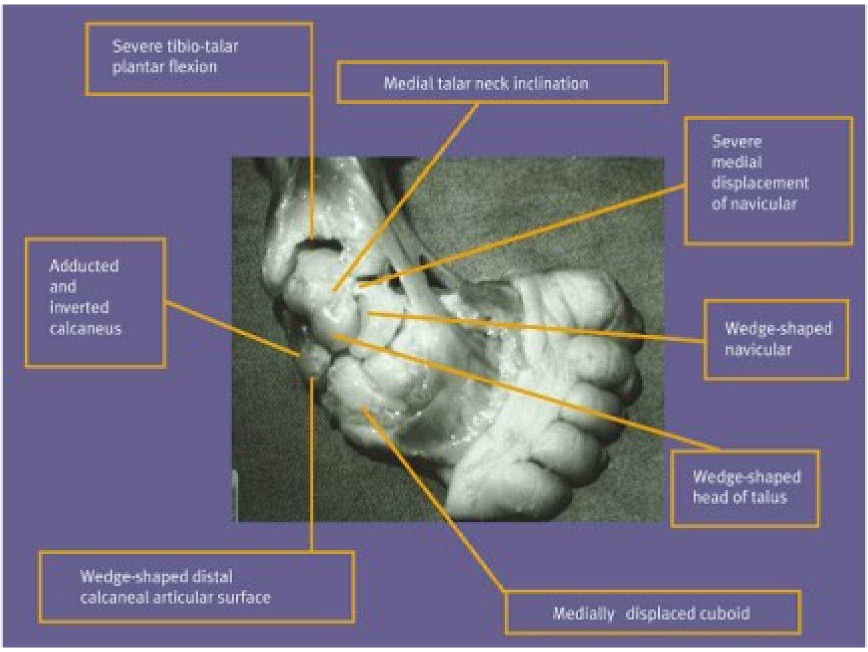


Figure 1 Anatomy of deformity on clubfoot (4)

Cavus refers to an increased height of the vault of the foot, which in clubfoot is present due to pronation of the forefoot in relation to the hindfoot, with plantar flexion of the first ray. The midfoot is adducted, primarily at the talo-navicular joint. The talus and navicular are wedge shaped and the talus' neck is facing medially and plantar flexed. The navicular is displaced medially and articulates with the medial surface of the head of the talus. The calcaneus is severely plantarflexed, medially displaced and inverted below the talus such that it lies below and almost in line with the talus. This accounts for the equinus and varus deformities and for the reduced AP (anteroposterior) and lateral talo-calcaneal angles seen on x-ray (4) (Figure 2). The ankle, although in a plantarflexed position, is relatively normal (5).

Figure 2 A clubfoot model (MD Orthopaedics, Iowa, USA) showing the deformities from the front (A), lateral (B) and medial (C) sides. TH - talar head. NO - calcaneocuboid joint. (5)

1.1.3. Assessment

In order to assess an infant with clubfoot, the patient undergoes four different stages: antenatal diagnosis, examination, assessment of severity and investigations (5).

Antenatal diagnosis

Although clubfoot diagnosis is also conducted post-natally, there is an increasing tendency towards antenatal diagnosis by means of a 20-week anomaly scan. The positive predictive value of clubfoot by an antenatal ultrasound is over 80%, with almost no false negatives, which allows counselling and discussions regarding the treatment of the child as well as the outcome (4) .

Examination

A child with clubfoot must undergo a thorough examination from head to toe. This examination should include the spine and a full neurological assessment, as well as an examination for stiffness and deformity on the rest of the joints.

Assessment of severity

The severity of the disease is an indicator of the treatment to follow as well as its outcome. It is also important to be able to distinguish a fully correctable positional clubfoot from a fixed deformity. In order to achieve this, there are different systems in place such as the Harold-Walker, the Dimeglio and the Pirani (4). Even though no single classification is ideal, the preferred one found in literature is the Pirani score.

The Pirani score is divided into the examination of hindfoot and the examination of midfoot. For each part there are 3 different aspects to grade: Look, feel and move. After the examination, a grading of 0, 0.5 or 1 must be chosen, depending on which describes best the examination. When added up, the resulting number ranges from 0 to 6; the higher the score, the more severe the clubfoot. Table 1a and 1b contain the different aspects to be examined (5).

Table 1a Pirani score, hindfoot

'LOOK' Posterior crease	0	No heel crease
	0.5	Mild heel crease
	1	Deep heel crease
'FEEL' Empty heel sign	0	Hard heel (calcaneum in normal position)
	0.5	Mild softness
	1	Very soft heel (calcaneum not palpable)
'MOVE' Rigidity of equinus	0	Normal dorsiflexion
	0.5	Foot reaches plantigrade with knee extended
	1	Fixed equinus

Table 1b Pirani score, midfoot

'LOOK' Lateral border of foot	0	No deviation from straight line
	0.5	Medial deviation distally
	1	Severe deviation proximally
'FEEL' Talar head	0	Reduced talo-navicular joint
	0.5	Subluxed but reducible talo-navicular joint
	1	Irreducible talo-navicular joint
'MOVE' Medial crease[a]	0	No medial crease
	0.5	Mild medial crease
	1	Deep crease altering contour of foot

[a] The foot should be moved to the position of maximum correction when assessing the medial crease.

Investigations

Different types of imaging are used on the initial diagnosis of clubfoot. For new-borns, radiographs are limited (since there is very little ossification in the bones at that age).

However, in older children, there are different techniques used to determine the timing of surgery, such as Turco's view. Investigations also include the Talocalcaneal (Kite's) angle, in both anteroposterior and lateral view. In the former, the measurements for the normal foot range between 20 – 40°, while for the clubfoot it is <20°. On the lateral view this angle ranges from 25-50° for the normal foot and is <25° in the clubfoot (Figure 3) (4).

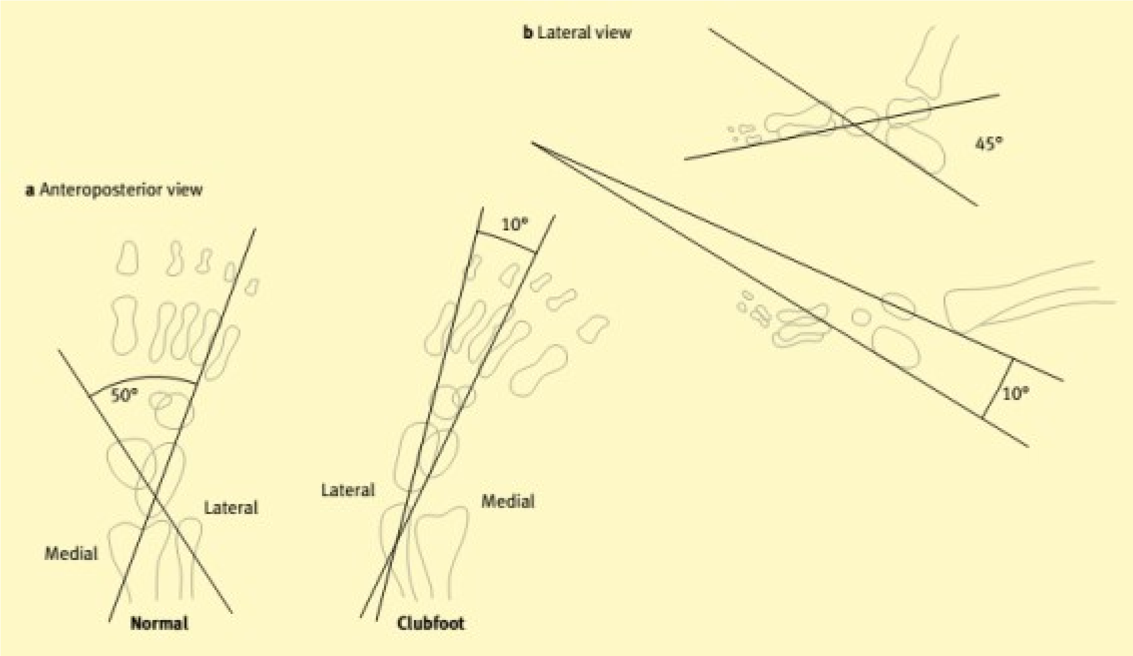


Figure 3 Talocalcaneal (Kite's) angle

1.1.4. Management trends

The main goal of treatment for clubfoot patients is to correct the deformity early and fully and maintain this correction achieving a flexible, pain free and plantigrade foot (4). In the literature there are 3 main methods described: the Ponseti method, the French technique and the surgical management, with the Ponseti method being the most widely practiced according to the 2013 review by Gibbons and Gray (2).

The Ponseti Method

In the 1950s, Ignacio Ponseti (Iowa, USA) developed a method consisting of different castings and manipulations in order to correct clubfoot; this consisted of two main stages. In the first stage, the patient undergoes different manipulations each week after which a cast is applied to maintain the position achieved. The average number of casts in this phase is six. When successful, this part of the procedure corrects all the deformities apart from equinus, which is present in about 90% of the feet at this stage. An Achilles tenotomy is then performed which should achieve full dorsiflexion at the ankle. This is followed by a cast which should be in place for 3 weeks. Figure 4 shows the development of a patient before and after 3 and 5 weeks on the Ponseti method. Once the final cast is removed, the position of the foot is fully corrected (4).

On the second stage of this method, the patient wears a device called "boots and bars" until the patient is 4 years old. This final stage aims to maintain foot abduction and its compliance is key to achieving successful results in the long term.

As mentioned before, the Ponseti method is the method most commonly used, having a documented success rate of 95% (2).

Figure 4 Pictures of patient before the implementation of the Ponseti method (A, B); pictures of the patient after 3 and 5 weeks on the Ponseti method respectively (C, D).

Figure 5 "Boots and bars" device

The French technique

As described by Bensahel, the French technique approach is similar to the Ponseti method. In this technique, the patient undergoes 30-minute treatments daily for 2 weeks and then twice a week until achieving foot correction. A flexible splint is used between sessions. The average time of this method ranges between 6 to 8 weeks, with all the deformities being corrected apart from equinus. This method reports a 93% success rate (6).

Surgical treatment

Surgery in patients with clubfoot is mainly performed in two different scenarios:

- Primary surgical release is reserved for patients who have undergone conservative techniques, but failed to achieve the full correction of the foot.
- Surgery for residual deformity or recurrence. This category comprehends the surgical procedures for under correction or residual deformities such as dynamic supination and adduction, residual hindfoot equinus, fixed varus hindfoot deformity in the older child, residual internal rotation, among others.

1.1.5. Clubfoot Care in Low-Income and Middle-Income Countries

80% of the 200,000 children born with clubfeet annually live in low- and middle-income countries (LMICs) (7). Regrettably, treatment is not always available for the majority of them, which increases preventable disability in these countries. The methods previously discussed have shown very good results in high income countries; however, the methods and results used in LMICs vary significantly.

There are many barriers to be considered in LMICs countries, when aiming for effective clubfoot care. For example, Kazibwe and Struthers found that the barriers to attending clubfoot clinics in Uganda included several factors such as the parents having to care for other children at home, the lack of financial support, the expenses of transport and the distance from home to the clinics (8).

Harmer and Rhatigan (1) applied a public health analysis model known as the Care Delivery Value Chain (CDVC) after conducting a systematic literature review using the keywords “developing countries” and “clubfoot”. CDVC is a result of adapting a value chain analysis for health care. A value chain maps all the steps required in the production of a manufactured good as well as the resources required in each step. One of the biggest advantages of this tool is that it allows assessing each step individually, instead of assessing them as part of a single process.

After the literature research, Harmer and Rhatigan came up with a care delivery value chain for clubfeet, based on methods and techniques used for high-, middle- and low-income countries (Table 2).

Six best practices resulted from the analysis of clubfoot care in LMCIS:

- Diagnosing clubfoot early.
- Organizing high-volume Ponseti casting centres.
- Using non-physician health workers.
- Engaging families in care.
- Addressing barriers to access.
- Providing follow-up in the patient’s community.

Table 2 Clubfoot care in LMICs: care delivery value chain

	Case Surveillance	Accurate Diagnosis	Sequential Cast Treatment	Achilles Tenotomy	Bracing	Recurrence Monitoring	Complex Surgery
Primary Activities	- Midwife or Trained Birth Attendant screening - Immunization Clinic screening - Clubfoot screening in all health worker training programs	- Deformity recognition - Objective deformity grading (Pirani score) - Exclusion of secondary etiology - Family education - Creation of a management plan - Acknowledge and address barriers to care	- Ponseti casting - Home or temporary accommodation near regional hospital for duration of treatment - Decentralize clinics to optimize tradeoff between clinic volume and patient convenience - Education of family about importance of eventual bracing - Practical education health care workers	- Tenotomy by expert non-physician providers - Final cast in place for three weeks - Practical education of health care workers	- Fulltime dynamic bracing for three months - Nighttime only dynamic bracing until age four - Practical education of health care workers	- Monitoring for recurrence as increasing intervals - Brace maintenance and replacement as needed - Brace sizing and adjustment with growth - Monitoring for other limb anomalies - Repeat Ponseti casting when needed (return to "Sequential Cast Treatment")	- Open tendon transfer or posterior medial release - Postoperative bracing and / or casting - Education of local physicians and surgeons
Location	- Community Clinics - Maternity Clinics	- Regional Clinic	- Regional Clinic - Mobile Clinic	- Regional Clinic	- Patients homes - Community Clinics	- Regional Clinic	- Tertiary Hospital
Personnel	- Midwifes - Trained Birth Attendants - Community Health Workers - Immunization Providers	- Orthopedic technicians - Orthopedic Surgeons - Interested Primary Care Physicians	- Orthopedic technicians	- Orthopedic technicians - Orthopedic Surgeons - Interested Primary Care Physicians	- Families - Orthopedic technicians - Orthopedic Surgeons - Interested Primary Care Physicians	- Community Health Workers - Families	- Orthopedic Surgeons - Anesthetists - OR personnel - Inpatient nurses
Supplies			- Cast padding - Cast material	- Local anesthetic - No. 11 scalpel - Skin prep - Cast padding - Cast material	- Locally manufactured "Boots and Bars" type brace		- General anesthetic equipment - Operating room and all related supplies - Inpatient bed
Patient and Family Engagement							

Patient Value Created

1.2.Orthopaedic shoes as a tool for clubfoot patients

1.2.1. Beter ter Been Foundation

Clubfoot, as many other foot problems, can restrict movement and limit the patients in their daily activities. Patients who suffer of foot problems are often prescribed orthopaedic shoes in order to reduce the impact of the disease in their daily routines. However, some of these shoes are not affordable in developing countries, where patients can only access these types of shoe through foundations, such as the Beter ter Been foundation.

Founded in 1992, the foundation Beter ter Been has the goal of supplying orthopaedic footwear to the less privileged, particularly on rural areas. As consequence, this organization hopes to increase the mobility of patients and therefore improving their lives. The main activities of this foundation consist on contributing to the training of orthopaedic shoemakers, the joint organization of orthopaedic shoe makers and providing production materials for shoes as well as other mobility equipment, such as wheelchairs (9).

The foundation Beter ter Been has started with the development of a modular orthopaedic shoe for clubfeet patients. The aim for this shoe is to be produced locally using local resources. Also it should have a production time not greater than a day, maintaining the production costs low is of course a main goal as well. Producing an orthopaedic shoe on rural areas presents an additional challenge: the manufacturing materials and techniques used in these countries may not be the same as those found in more developed countries, for example the Netherlands.

1.2.2. Previous and ongoing projects

Hans van Dalen and Toos Rook, on behalf of the Beter ter Been foundation, reached the University of Groningen (RUG) in order to tackle different engineering concerns regarding the design of their orthopaedic shoe, after the own foundation tried different prototypes (Figure 6 a, 6b).

In a previous thesis project at RUG, M.A.T. (Merlijn) de Wolf developed a prototype to build an orthopaedic shoe to be produced in developing countries in collaboration with Beter ter Been (10). The scope of this project included the development of a prototype for the filling between the inner shoe and the outer shoe. The filling is used in order to provide a better fit according to the foot morphology of each patient. A drawing of the prototype is shown in Figure 6c.

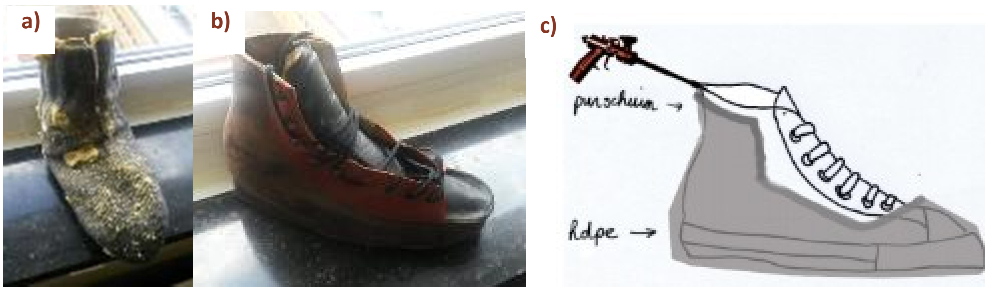


Figure 6. Evolution in the design of Beter ter Been's orthopaedic shoe, from the first designs in a) and b), to the diagram of the prototype proposed by de Wolf in c) (Purschuim: polyurethane foam Hdpe: High-density polyethylene)

The thesis hereby presented is part of the follow-up efforts of the work done by Merlijn for the foundation Beter ter Been.

1.1.1. Reduction of foot pain and Pressure

The challenge of this project is not only providing patients with an orthopaedic shoe, but also making sure that the patients will use them. Regrettably, diverse sources report that there is an important non-use of orthopaedic shoes rate that varies from 8% to 75% (11).

As a consequence of the deformation of the foot, there is a change in the plantar pressure distribution which often translates in pain while standing or walking. This also results on normally unloaded regions becoming overloaded or more sensitive to pressure.

In 2006, Jannink *et al.* (12) evaluated the effectiveness of custom-made orthopaedic shoes, in terms of pressure and pain, in patients with degenerative disorders of the foot. They also did a study on the relation between planar pressure parameters and foot pain. Seventy-seven patients participated in the study where the Questionnaire for Usability Evaluation for Orthopaedic Shoes was used to assess perceived foot pain, and the Pedar in-shoe pressure measurement system (Novel GmbH, Munich) to measure plantar pressures. The results proved that custom-made orthopaedic shoes decreased foot pain by at least 23% (Table 3a). These type of shoes also reduced plantar pressure under the foot regions by at least 9% (Table 3b). It was concluded that custom-made orthopaedic shoes are effective in reducing foot pain and foot pressure.

Table 3a Comparison of foot pain during standing, walking, climbing stairs, activities of daily life, and work activities between ordinary shoes and orthopaedic shoes

Activities	Ordinary shoes	Orthopaedic shoes	Pain decrease (%)	*p*
Pain during standing	6.3 (2.7)	3.5 (3.2)	44	0.000
Pain during walking	7.1 (2.6)	5.5 (2.5)	23	0.001
Pain during climbing stairs	3.4 (3.8)	2.2 (3.2)	35	0.007
Pain during activities of daily life	5.2 (3.2)	3.1 (3.5)	40	0.000
Pain during work activities	3.9 (3.9)	2.1 (3.2)	46	0.000

$\alpha = 0.05$.

Table 3b Peak pressure (P_{max}; N/cm^2), pressure time integral (PTI; N/cm^2), and average pressure (P*average*; N/cm^2) data (SD) for all regions per shoe type

Foot region	Ordinary shoes; mean (SD)			Orthopaedic shoes; mean (SD)			Pressure decrease (%)		
	Pmax	PTI	*Paverage*	*Pmax*	PTI	*Paverage*	*Pmax*	PTI	*Paverage*
LH	19.8 (4.9)	6.7 (2.2)	10.9 (2.5)	17.5 (5.1)	5.8 (2.3)	9.9 (3.4)	11.7**	13.4**	9*
MH	19.8 (5.2)	6.7 (2.1)	11.1 (3.0)	16.9 (3.8)	5.6 (1.6)	9.2 (2.1)	14.6**	16.4**	17**
LM	15.9 (5.0)	6.7 (2.2)	9.7 (2.6)	14.2 (3.4)	6.1 (2.7)	8.7 (1.7)	10.7**	9.0*	10**
MM	15.9 (5.2)	6.5 (2.2)	9.7 (3.12)	14.1 (3.7)	5.9 (2.5)	8.6 (2.0)	11.3**	9.2*	11**
MTH1	26.0 (13.4)	7.9 (4.0)	12.1 (5.6)	20.6 (8.5)	6.0 (2.6)	9.6 (3.4)	20.8**	20.7**	12**
MTH2-3	25.9 (10.7)	8.3 (3.1)	11.9 (3.9)	20.5 (8.0)	6.5 (3.2)	9.6 (2.9)	20.8**	19.3**	19**
MTH4-5	18.9 (9.5)	6.7 (2.8)	9.5 (3.7)	16.1 (7.4)	5.8 (2.5)	8.4 (2.8)	14.8**	11.6**	12**
Hallux	28.2 (12.9)	8.2 (4.2)	12.1 (5.5)	23.5 (9.1)	6.3 (4.0)	9.6 (3.0)	16.7**	20.7**	21**
T2-5	23.6 (9.7)	7.3 (3.1)	10.5 (4.0)	19.6 (7.6)	5.9 (3.1)	8.9 (2.6)	16.9**	15.2**	15**

*$p < 0.05$; **$p < 0.001$; lateral hindfoot (LH), medial hindfoot (MH), lateral midfoot (LM), medial midfoot (MM), first metatarsal head (MTH1), second and third metatarsal heads (MTH2-3), fourth and fifth metatarsal heads (MTH4-5), hallux (H), and second through fifth toes (T2-5).

2. Analysis phase

The start point of the project is the analysis phase. The aim of this phase is to define and delimit the problem and in this way set the goals and scope, as well as the design requirements.

2.1. Problem definition

During this step, all issues related to the given problem are analysed. The root problem is the need of special shoes from patients with clubfoot. The design of these shoes should avoid harm in pressure points on the foot at all times. If the shoes produced some kind of pain, patients might not be willing to wear them. Three students from RUG will be working during the spring semester in this project. After a group meeting with the problem owners and the supervisor, the assignations for each student are:

1. Bender Ziegerink will be taking on the subject of "Improvement of the process of filling the shoe with the foam"
2. Aline Hoeve will be taking the subject of "Improvement of ways to contain the expansion of the foam on the outer sides of the shoe"
3. Ana Gonzalez will be taking the subject of "A study on the pressure points on the foot by the shoe and a way to protect the feet in these points."

During a meeting with the stakeholders, different diagrams were drawn in order to show which were the areas of the foot where they needed the less pressure to be applied, as well as the areas where the pressure could be applied instead (Figure 7)

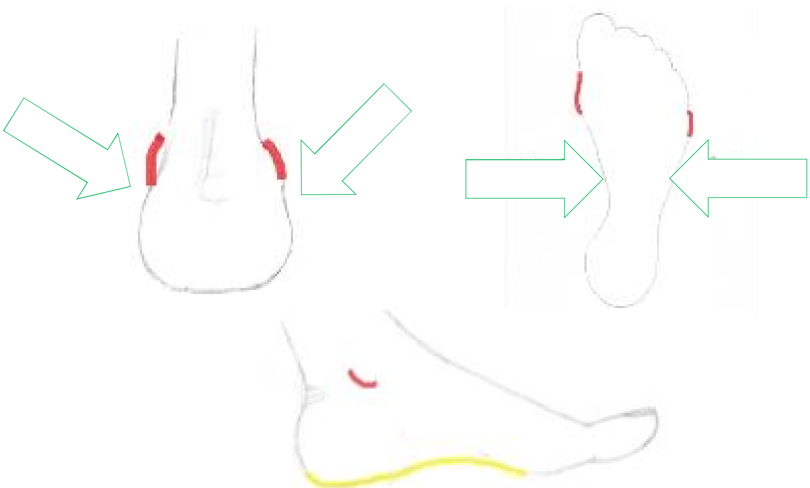


Figure 7 Foot views (clockwise top left: posterior, plantar and lateral view) and pressure areas. In green: points to exert pressure to hold the shoe; red: outstanding bones where high pressure needs to be avoided; yellow: pressure to be added for support and to prevent shoe from slipping

It is of great importance then, to take into consideration these areas during the development any of the pre-concepts in the future.

2.1.1. Stakeholders

Stakeholders are defined as all the persons that are involved in the given problem. These people must be considered, in order to have a complete overview of the issues related to the given problem. Table 4 serves as an inventory of said issues, related to each stakeholder.

Table 4 Stakeholders scheme

Who	What	When	Where	Why
Patients with clubfoot	Need of special shoes without harm in the pressure points of the foot	While walking	Everywhere	If there is pain, the patient might not be willing to wear the shoe
Medical Specialists	Find a way to help clubfoot patients	At all times	Everywhere	Share knowledge and give expertise point of view on the topic
Beter ter Been Foundation Hans van Dalen and Toos Rook	Manufacturing a modular orthopaedic shoe in developing countries	In a few hours	To be manufactured in developing countries	Because people from rural areas have limited access and resources to obtain orthopaedic shoe
Students	Develop a solution to implement on the current shoe design	Deadline in July	RUG	Present as Bachelor's/ Master's Thesis
Community	Include patients into work and social activities	At all times	Rural areas	Avoid the neglect or discrimination of patients

2.1.2. Cause-effect diagram

Translating what is found on Table 4 into a cause-effect diagram, results on the information shown on Figure 8.

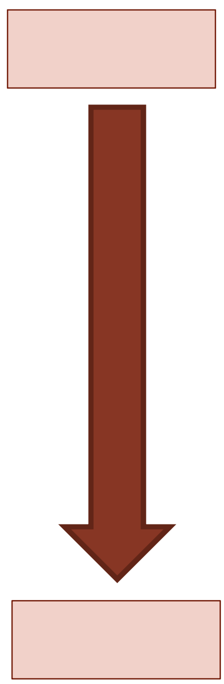


Figure 8 Cause-effect diagram of problems

It is easier here to visualize that the most fundamental problem to solve is the design flaws on pressure points caused by the shoe.

2.2. Goal

After having a close look to the secondary issues derived from the fundamental problem, a goal cause-effect diagram is created in order to set a goal for each of the problems listed on the cause-effect diagram of the problems. Figure 9 shows the findings of this stage.

Therefore, the fundamental goal of this project is to develop a product or method of fabrication for the shoe (including the inner shoe casting between the foot and the filling, and the sole), taking into consideration the filling casting method proposed in Merlijn's thesis and avoiding or removing harmful pressure points. Changes to the original filling casting may be made if needed for the overall improvement of the prototype. This design must avoid harmful and painful pressure points in the foot and guarantee support on the foot during casting and while using the shoe.

The boundaries of this project are reflected on the cause and effect diagram of the goals, particularly on the steps from the cause to the effect. The design of the shoe must remain comfortable to wear so the patient is keen on wearing it. If the patient does wear it, the walking of the patient is less limited, allowing him/her to perform his/her daily activities.

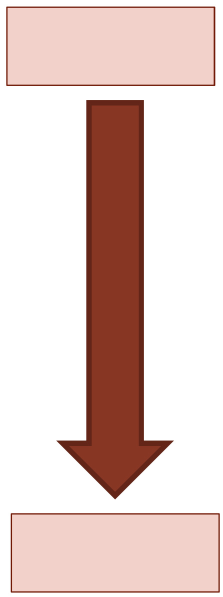


Figure 9 Cause-effect diagram of goals

2.3.Design assignment

The result of this design project is thought to be used in the current prototype of orthopaedic shoe by the foundation Beter ter Been. This shoe is thought to be used in feet whose position deviates so much from the standard that they become unstable, reason why they need support, mainly focused on patients with club feet.

Although there are different types of clubfoot, this project does not aim for a specific type. The main considerations it is important to consider low resistance from the ankle joint, as well as the outstanding bones on the foot, which are the areas where pressure is an issue in terms of comfort.

There main strategy that will be used to achieve the goal of this project is the redesign of the shoe mainly on the plantar side, in order to redistribute the weight in a better way and/or relieve the pressure on the pressure points.

This redesign will be done inspired on methods and techniques applied to other foot problems.

2.4. Requirements and wishes

After speaking with the problem owners, the requirements of the final product are listed as follows:

- The product should help to reduce or remove pressure points in the orthopaedic shoe of any club foot patient provided by the Beter ter Been foundation's orthopaedic shoes. These pressure points will be located and measured in further tests.
- The product should be able to adapt to the morphology of each patient that wears these shoes.
- After the customization process, the product should be removable without any extra tools needed (i.e. cutting off the product to release the shoe)
- The product should use materials that are attainable within rural India.
- The product's cost should not exceed 25 euro.
- The product should not increase the weight to the current shoe prototype for more than 10% of the current weight of the shoe before the implementation of the product.
- The product should be able to be fitted inside the current shoe prototype.
- The customization of this product must be within a time frame of 4 hours.

As for wishes of this product, the problem owners would like for it to be possible to produce this product without any prior knowledge, just as the rest of the shoe. It should also be delivered if possible a product that does not interfere with transpiration of the patient's feet.

2.5.Function analysis

One of the function of the product to develop in this project is to relieve the pressure on the pressure points; Figure 10a illustrates this function as energy transform, since the goal of the product is to distribute the pressure of the maximum pressure points in such a way that it translates into a decrease or even full suppression of foot pain for the patient.

Another function is the material storage. This can be discussed from two different points of view. First, if we consider the foot as the "material" to be stored, it is important for the shoe to have a proper storage of the foot, which in this case would refer to a proper grip and collocation of the shoe (Figure 10b).

Finally, since the foam with the shape of the patient should maintain its shape and provide the needed support for the foot, even after any modifications done to the original concept (Figure 10c).

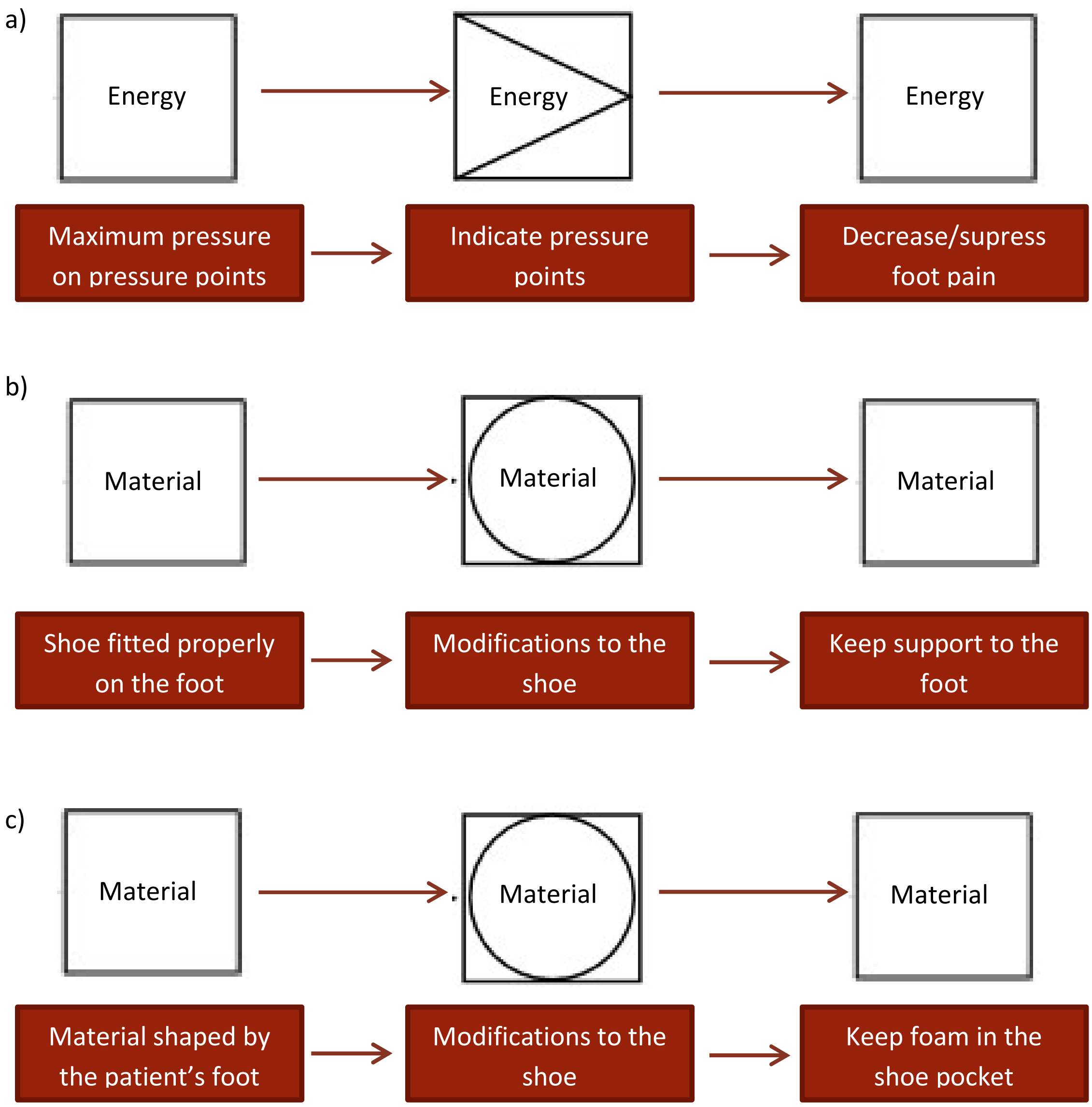


Figure 10 Function analysis diagrams

3. Synthesis I

According to the Design Reader (document used as reference for the structure of this master's project) (13), there are two different types of approach in order to solve a problem: the holistic and the reductionist approach. The former sees the solution of the problem as a whole, while the latter divides the problem into smaller sub-problems that are easier to solve; because there is one main function involved on the goal of this project, the holistic approach is chosen.

3.1. Brainstorming

This phase is started with brainstorming, where all ideas are accepted as long as they are feasible, although they might not be reasonable. This is done in order to open the creativity of the designer by removing limitations and exploring different scenarios to solve the problem.

As stated before, the goal of this project would be the redistribution of pressure in order to achieve a more comfortable design for the patients who wear the Beter ter Been orthopaedic shoes. Among the brainstorming techniques we find "reformulating the problem into short questions"; rephrasing the problem of this project into a short question would result in: How to redistribute pressure in a given area?

Another technique is to formulate analogies using the given problem, for example:

- What else redistributes pressure?
- Who/what else has a problem similar to this one?

After a new literature research using the words "pressure" "distribution" and "change", several articles were found. Even though the solutions suggested by these studies are not intended for clubfeet patients, the foot problems they treat share the necessity of finding a better distribution of forces and pressure, particularly on the heel and bottom of the foot.

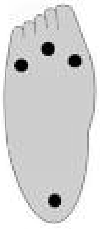
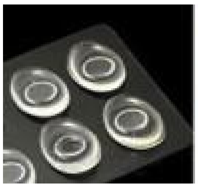
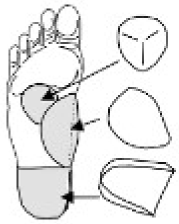
The ideas which came as an output to the brainstorming activity are listed below:

- Individual small pads to be placed in the specific points of the foot where the pressure is higher, in order to reduce the friction between the shoe and the sock
- A set of pressure sensors that sends data to a set of actuators in order to change the position of the insides of the shoe
- An insert that helps the whole shoe to adopt the shape of the foot, not only on the sole, but all around the foot.
- Taping, as used with other foot conditions such as plantar fasciitis.
- The use of proprioceptive foot orthoses.
- Modifying the heel of the shoe, so there is a change in the pressure distribution.
- Modifying the sole of the shoe into a rocker shoe style.
- Removing parts of the shoe in the points of peak pressure.

3.2. Morphological map

In the following morphological map, the different ideas are presented in order to better visualize the different possible combinations in relation to the function analysis. This will later lead to the building of pre-concepts for the solution of this project's problem.

Table 5 Morphological Map

Group	
Energy transformation	Proprioceptive orthoses, pressure sensors, pads, inserts, modifications to the heel modifications to the sole, material removal from the shoe, taping         
Matterial storage	Safeguarding and maintaining the design for tighting or losing shoelaces only 
Material storage	PUR foam filling between the inner lining and the sole of the shoe 

3.3.Pre-concepts and Sketches

By the ideas presented in the morphological map, it can be deducted that there are 8 different possibilities. The ideas and their sketches are detailed below.

1. Pads:

Adding pads to the different areas where the patient experiences discomfort or pain. The advantages of this method are: these pads can be made out of cheap and easy to procure materials such as cotton or foam; pads are highly configurable and adaptable for each patient.

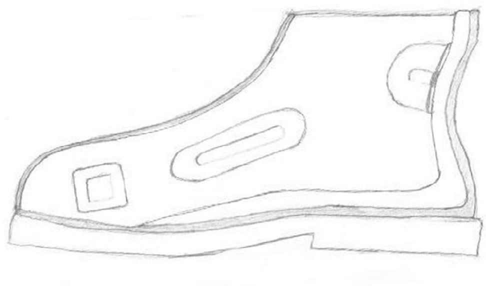


Figure 11 Lateral cross-section view of the shoe with pads in place

2. Pressure Sensors:

Sensors have proved to be very good tools in different applications, not only within the biomedical field, but in several other areas. However, given the location of where the sensors would need to be placed, they could easily lose their calibration. This represents a problem in remote areas such as rural India, as well as the increased cost of the product in general.

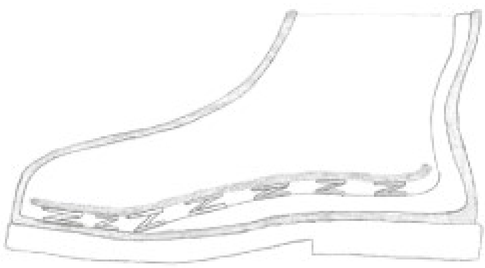


Figure 12 Lateral cross-section view of the shoe showing a suggested location for pressure sensors

3. Inserts:

The advantage of inserts in relieving pain caused by foot problems has been proved in different studies. For this particular project, the arch support and the heel cup are advised, as previously discussed, those are the regions where this type of foot needs more support. These inserts help also in correcting the position of the foot in order to put the shoes on them.

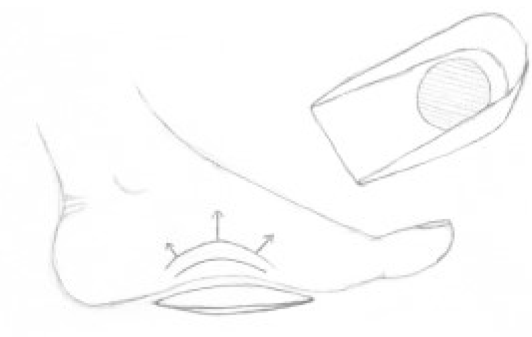


Figure 13 Heel cup (above) and arch support (below)

4. Taping:

Low Dye taping is a technique used by physiotherapists in order to treat altered or excessive pronation (14). For the users of this modular shoe, taping the feet would help to get a better position of the foot which would be beneficial not only for the proper location of the shoe, but also with the possibility of reducing abnormal peaks of pressure during the gait cycle.

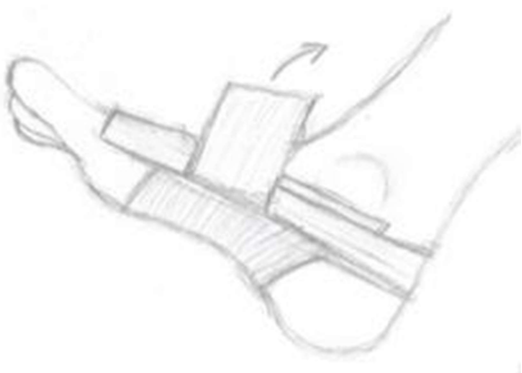


Figure 14 Taping technique

5. Proprioceptive orthosis

Some of the studies found in the literature research propose effectiveness of orthotic intervention when using insoles with textured surfaces. This may be as a result of the proprioceptive mechanism. Nurse and Nigg (15) stated that peak pressure and muscle patterns were changed when sensory feedback was altered. They concluded that sensory feedback is important in modification of gait pattern and it can be considered as an approach in orthotic treatment.

Figure 15 Proprioceptive Orthosis

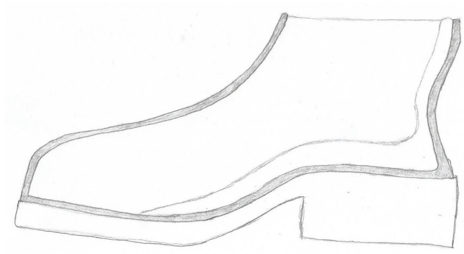


Figure 16 Modifications to the heel

6. Modifications to the heel

Studies show that modifying the height of the heel has an impact on the distribution of the pressure in the bottom of the foot (16). By analysing these results, it might be possible to apply the findings on this project and change the distribution of pressures on the clubfoot.

7. Modifications to the sole

Rocker shoes have showed to offer pressure relief on the plantar surface of the foot. (17). This modification should be done directly to the patterns of the current prototype. The use of this modification would need to be evaluated, given the different morphology of each patient, which might limit its application to special cases.

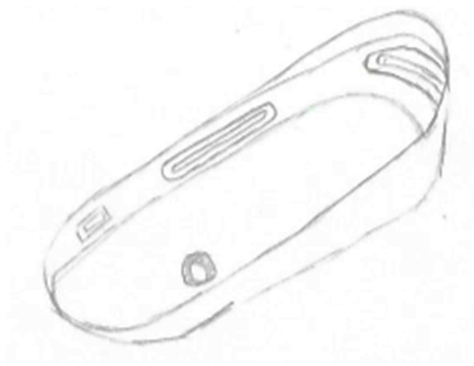
Figure 17 Modifications to the sole of the shoe into a rocking shoe sole

Figure 18 Sketch displays a hole cut in the sole of the shoe

8. Removing material from the sole.

Consider a given peak pressure point on the foot. By removing material of the shoe that is in direct contact with this pressure point, the distribution of the pressure changes to the area surrounding this cut.

Using these main ideas, there are different pre-concepts that could be built by combining different ideas. Figures 19-22 show examples of these possible combinations.



3.4.Pre-concept selection

From the pre-concepts shown in the previous section, some of them are discarded given the complexity of fabrication, especially when thinking of the materials and expertise available in rural areas. Table 5 shows the evaluation of the most feasible pre-concepts, in terms of the most important requirements and wishes. Each requirement and wish has been given a weighting which corresponds to their contribution and importance to the overall solution. Each requirement and wish is given a grade from 0 to 5, 0 signifying “not applicable”, 1 for “poor”, and 5 for “excellent”.

Table 5 Pre-concept grading

	Pressure relieving	Adaptable to morphology of foot	Availability of materials in rural area	Cost	Customization time	Total
Weighting	**5**	**4**	**4**	**4**	**3**	
Pads	4	4	5	5	4	**88**
Pressure Sensors	4	4	1	2	5	63
Inserts	5	4	4	4	5	**88**
Taping	4	5	5	4	3	**85**
Proprioceptive orthoses	3	3	1	2	4	51
Modifications on the heel	3	4	5	3	3	72
Modifications on the sole	5	5	5	4	5	**96**
Material removal from shoe	5	5	5	5	4	**97**

From the results from this grading we select the five best pre-concepts are:

1. Pads
2. Inserts
3. Taping
4. Modifications on the sole
5. Material removal from shoe

4. Synthesis II

In this phase, the five pre-concepts resulting from the Synthesis I Phase turn into concepts and are applied in the fabrication of three pairs of shoes, in collaboration with the team from Beter ter Been. These prototypes are to be used in tests in the near future, which would be very useful to determine and to evaluate the effectiveness of the solution offered by each of the concepts.

4.1. Concept implementation

The foundation Beter ter Been provided 3 pairs of shoes to be customized and to implement the modifications proposed by the concepts. These shoes are designated by different colours: brown, blue and black. One healthy patient (Male, 29) was used for the customization of the three pairs. It was agreed to customize each pair as shown in Table 6 in order to test each concept individually.

With this distribution, Inserts, pads and material removal on the shoe can be implemented in one of the pairs, since the first two methods can be easily added, tested and removed. After this is done, the material of the shoes can be removed in the same first pair of shoes. The modifications to the sole and taping are techniques which affect in a more permanent way the customization of the shoes; therefore we require one pair of shoes for each of these concepts.

Table 6 Customization of shoes

Pair	Sole	Inner	Pre-concept
Brown	Original	Original	Inserts, pads and material removal from shoe
Blue	Rocker	Original	Modifications on the sole
Black	Original	Taping	Taping

4.1.1. Inserts and Pads

The inserts and pads to be used in the tests are thought to be off-the-shelf and commonly available on the Indian market. There is a range of prices and product presentations. The brand proposed to be used in the tests is Dr. Scholl's (Figure23), since it is a brand available in many countries around the world, including India.

Figure 23 Dr Scholl's inserts and pads

4.1.2. Taping

The idea of implementing taping came of a literature research of other foot problems which also had peaks of pressure as a common issue. Dr. Ralph Dye developed a taping method to offer extra support of the foot and ankle. This method is known as low-Dye taping, and is used to control pronation and act as a temporary orthoses. The description of the method can be found below (18).

While the patient is sitting with the leg extended and the foot at right angle to the leg. The first of three strips of on 1 or 1-1/2 inch tape is applied, starting proximal to the fifth metatarsal joint. After the tape is secured on the outside of the foot, one must grasp the end in one hand and wrap it around the heel while simultaneously inverting the heel slightly. After this, the other end of the tape is attached just behind the big toe joint on the inside of the foot. This is repeated two times (as illustrated in Figures 24-a, 24-b and 24-c) overlapping the first piece of tape by about two-thirds of the tape thickness, both above and below.

For taping the bottom of the foot (as shown in Figures 23-d, 23-e, 23-f and 23-g), two-inch adhesive tape is cut in pieces approximately five inches long. Either end of the two-inch rest straps is grasped firmly and forcefully pressed against the bottom of the foot, making contact with the bottom-outside first. The pressing is continued even more firmly so the bottom inside is applied with more force. The application of these strips is not done in a pulling fashion; pulling the tape from the bottom outside to inside would cause wrinkling of the skin and subsequent discomfort. The bottom of the foot is covered, extending out to within two inches of the ball of the foot.

Figures 23-h and 23-g show a side view of the foot and the application of one last side strip in the same manner as Figure 23-a to cover the ends of the rest straps. A strip of two-inch tape over the top of the foot is applied so the adhesive side is away from the skin. Finally, another two-inch strip is directly applied over the first (Figure 23-j) to anchor the previously applied tape, and prevent irritation to the hair and skin (18).

On the article "A biomechanical analysis of the effects of low-Dye taping on arch deformation during gait", Yoho *et al.* calculate the medial longitudinal angle (MLA) following low-Dye taping in order to assess the changes during gait following dye-taping. The subjects were evaluated prior to and immediately after applying low-Dye tape, as well as at 48 hours from application.

For our project, the taping is intended to be used only once, during the fitting of the shoe on the process of customization. In the case of patients with clubfoot, the previously described technique for low-dye taping should be modified for each patient, by considering each foot's shape and condition. The two main goals for the taping should remain the same: to correct the pronation of the forefoot in relation to the hindfoot and to correct the adduction of the forefoot. By doing so, the print that we obtain in the foam will be made from the patient's foot in a corrected position to some extent. This could help to relieve the points of peak pressure by distributing the forces in a more evenly way, therefore increasing the comfort of the patient.

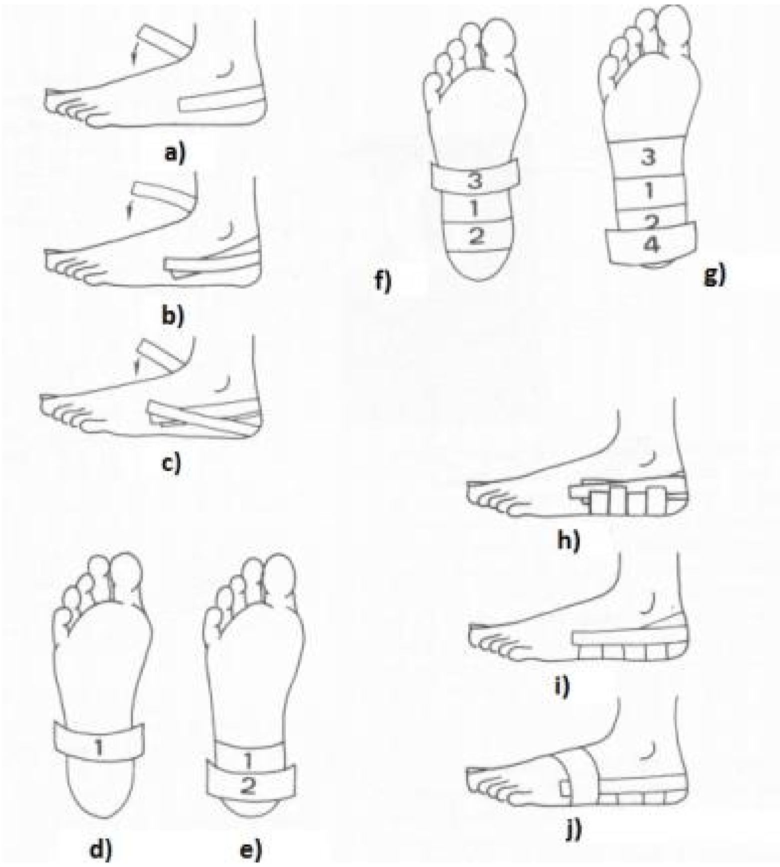


Figure 24 Low-Dye taping process

The results from Yoho *et al.* showed 19.3% reduction in MLA immediately after the application of the tape; however after 48 hrs the reduction was only of 4.01% (19). This time constraint does not conflict with the proposal for this project, since the patient's feet will be taped only during the customization process.

4.1.3. Modifications on the sole

As mentioned before, the modification suggested for this project is called a rocker profile. The basic function of a rocker profile is rocking the foot during the gait cycle, from the heel strike phase to toe-off (20). This type of shoe profile is frequently prescribed to relief plantar pressure of the foot (17) by restricting sagittal plane motion in the targeted joints on the foot.

This adaptation has shown a reduction on forefoot plantar pressures. For example, in a study from Sobhani *et al* (21), a standard running shoe and a rocker shoe were compared by measuring the in-shoe plantar pressure among other parameters. As a result, running with a rocker shoe showed a significant reduction in all pressure parameters in the central and lateral forefoot.

There are different conditions reported as benefiting from reduction or elimination of motion via the addition of rocker profiles such as midtarsal joint osteoarthritis, rheumatoid metatarsal head pain and dysfunction, plantar fasciitis and pathologies or injuries affecting ankle ROM, among others (17).

4.1.4. Material removal from shoe

As previously mentioned, this concept consists in the removal of material from the shoe in and around the peak pressure points. As the problem owners advised, one way to detect the pressure points on the shoe is by an assessment of the inner lining of the shoe after a couple of weeks, where these points tend to change colour (from a clear to a darker one) given the constant friction. Once these points are found, the removing of material works by avoiding concentrated loads and instead, distributing the load on a bigger area. Since the pressure is calculated by dividing the load over the area where this load is applied, increasing this area will decrease the pressure exerted on the foot.

4.2.Prototype modelling

In order to start the customization procedure, each foot of the patient is covered with a plastic bag, followed by a pair of tights as shown in Figure 25. The plastic protects the skin from any damage caused by a leak of foam from the inside layer of the shoe, while the tights keep the shape of the foot.

Figure 25 Feet protected first with plastic bag (a), and then with a pair of tights (b); c) Feet ready to be inserted in the

Afterwards, the shoes are filled with polyurethane foam that is inserted into the shoe from one of four holes placed in the sole. At the same time, some of the product is also applied to a nearby surface, which serves as an indicator throughout the customization procedure of how far the foam has solidified.

Once this is done, it is important to manually distribute the foam in the shoe wall cavity, between the inner and outer linings of the shoe, by manipulating the inner lining of the shoe. After the shoemaker feels that the foam has been evenly distributed, a flexible insole is placed in each shoe before putting the shoes in the patient and doing the shoelaces as tight as it is still comfortable by the patient (Figure 26).

In order to prevent over expansion, as in previous prototypes, a new mechanism is implement. It consists of a c shaped shell made out of rubber and leather, which is placed around the ankle. A quick release clamp is then positioned around the shell and then tightened (Figure 27), as much as the patient is still comfortable to start with. This clamp is loosened slightly after around 45 minutes, since by then the foam has expanded and the pressure on the patient’s feet increases.

After an hour and a half the patient can stand up on the place where he’s seated. This is done in order for him to apply some weight, and therefore some extra pressure on the bottom of the shoes, in order to compress the foam even further, and get some feedback from the patient on how the shoes feel in terms of solidification of the foam and comfort.

Figure 26 a) Shoes being filled; b) Evenly distributing the foam inside the pocket of the shoe; c) Placing the insole; d) Tying the shoelaces

Figure 27 Quick clamps positioned to prevent over expansion of the foam that used to lead to bulky shoes

After around 2.5 hours, the foam has solidified and the patient is instructed to walk around with the shoes on to once more get feedback on the solidification of the foam and comfort. This is the last step of the customization with this procedure, which took an average of 3 hours from beginning to end. After the shoes are customized, the shoemakers glue the sole on the shoe.

The brown and blue pairs were customized with the method previously described. For the third pair of shoes (black), a different method was implemented in order to make this prototype suitable to test the taping concept.

For the third pair, the idea proposed was to implement a taping of the foot in a similar way as with low-dye taping. After being taped (Figure 28), the feet were protected with a plastic bag and a tight and the same procedure as the first two pairs was under taken.

Figure 28 Patient's feet with taping

The final product of his project is the 3 pairs of orthopaedic shoes (shown in Figure 29), where the 5 concepts have been implemented in the following way:

- Brown pair: This pair of shoes will be used to implement the inserts and the pads. After the measurements of these 2 techniques, some material will be removed around the areas of high pressure points, in order to test these third technique
- Blue pair: This par has been adapted with a rocker sole (modifications on the sole method).
- Black pair: This pair was customized by previously taping the feet of the patient (Taping technique)

Figure 29 Final products. From left to right: Brown, blue and black pair

4.3.Failure Mode and Effect Analysis (FMEA)

In this section we analyse the risks of the developed product. For this project, a risk is defined as any event which is likely to adversely affect the ability of the modification on the shoe to achieve the goal of this project. We start by defining the categories of risks which are: requirements, benefits, schedule, scope, suppliers and communication. Within these categories, the risks that might affect the project are listed and graded according to their likeliness to happen, as well as their possible impact. The grading is given based on the following scale:

Grading	Rating
0 – 20	Very low
21 – 40	Low
41 – 60	Medium
61 – 80	High
81 – 100	Very High

After the corresponding grade, a grading is given and actions are recommended as part of a risk plan, which gives either preventive or contingent actions to be taken to avoid, transfer or mitigate each risk.

Table 7 Risks with likelihood and impact grading

Category	Id	Description	Likelihood	Impact
Requirements	1.1	The requirements have not been clearly specified	60	80
	1.2	The requirements specified do not match the customer's needs	60	100
Benefits	2.2	The final solution delivered does not achieve the required benefits	40	60
Schedule	3.1	The schedule doesn't provide enough time to complete project	80	60
Scope	4.1	The scope of the project is not clearly outlined	40	100
Suppliers	5.1	Suppliers do not meet the expectations defined	40	80
Communication	6.1	Key project stakeholders are 'left in the dark' about progress	80	40

Table 8 Risks with priority score and actions planned

Id	Description	Priority Score	Rating	Action
1.1	The requirements have not been clearly specified	70	High	Have an initial meeting with all the stakeholders in order to outline the requirements
1.2	The requirements specified do not match the customer's needs	80	High	Have an initial meeting with all the stakeholders in order to outline the requirements
2.2	The final solution delivered does not achieve the required benefits	50	High	Look for concepts which already showed good results when implemented to solve similar problems
3.1	The schedule doesn't provide enough time to complete project	70	High	Elaborate a time planner with supervisor's help, given his high expertise in this type of projects
4.1	The scope of the project is not clearly outlined	70	High	Have an initial meeting with all the stakeholders in order to outline the project's scope
5.1	Suppliers do not meet the expectations defined	60	Medium	Look for the proposed materials on shopping websites based and operating in India
6.1	Key project stakeholders are 'left in the dark' about progress	60	Medium	Keep the stakeholders updated via mail at least once a month.

5. Synthesis III

5.1. Detailed concepts

Once the shoes have been customized to the patient, we define the shoes materials, tools and estimated costs for each concept.

5.1.1. Inserts

The choice of inserts proposed is the Dr. Scholl's® DreamWalk™ Hidden Arch® Supports. On their website (22), this insert is described as "helping prevent arch pain" and "removable without damage to the shoes" which complies with the product requirements. The cost of this product in websites from India is around 12 euro.

5.1.2. Pads

As for the pads, the Dr. Scholl's® Molefoam® Padding (23) with an approximate cost of 13 euro for a 24" x 4 5/8" roll (based on the price displayed in Indian shopping websites). Bearing in mind that a roll could be used for at least 3 pairs of shoes, this product is still cost-effective for this project's goal, with an approximate cost of 4.3 euro per pair of shoes.

5.1.3. Taping

The tape used in the making of the shoes was a climbing tape. A similar one was found online available in India from the brand Nasara (24). The 5 cm width tape has a length of 5 m and costs around 8.10 euro per roll. For each foot we used around 1 m of the tape, therefore the cost per patient would be around 3.24 euro.

5.1.4. Modifications on the sole

For this concept, the modification is done after the customization of the shoe. This change represents adding material to the normal shoe sole and would increase the cost of the whole product by 2 euro.

5.1.5. Material removal from shoe

The material removal on the shoe does not add any cost to the shoe in terms of materials. Since the removal is done with any sharp tool available, the only possible cost could be if there were no tools available on site. In this case, a simple cutter would be enough. A simple cutter found on an online shop in India costs around 2 euro (25).

5.2.Testing

Developing the five concepts made it possible to continue to the next stage: a test that made it possible to obtain and compare the difference in pressure between the concepts.

5.2.1. Goal

The goal of the test is the collection of pressure data of the 3 pairs of shoes, by applying each of the five concepts on them. Once this information is gathered, a comparative study can performed in order to find the advantages and disadvantages of each design. This can lead to choose the best concept or to a new and optimized design.

5.2.2. Test group

Since we are looking to prove a concept, only one healthy patient is needed. This also reduces the cost of the test, since each pair of shoes is customized and more patients would involve the manufacturing of more pairs of shoes.

5.2.3. Method

In order to test the difference in pressure between each design, I would like to measure the in-shoe plantar pressure for each of these concepts in one healthy participant. If we can determine the difference in plantar pressure, this may later translate on the pressure on the walls of the shoe.

The Pedar system (Figure 30) by novel will be used to measure and record the in-shoe pressure while the participant walks 20 meters per test. The technical data for the Pedar insoles is shown in Table 9. The Pedar system is available in the motion laboratory of the UMCG and frequently used for similar measurements.

Figure 30 Pedar insoles

Table 9 Technical Data for Pedar insoles (30)

shoe size	22 to 49 (European), 3 widths
thickness (mm)	1.9 (min. 1)
number of sensors	85 - 99
pressure range (kPa)	15 - 600 or 30 - 1,200
hysteresis (%)	< 7
resolution (kPa)	2.5 or 5
offset temperature drift (kPa/K)	< 0.5
minimal bending radius (mm)	20

There will be 3 stages of these tests:

1. Measure the plantar pressure without any modifications to the shoe in order to find high pressure points.
2. Measure the plantar pressure with each of the five modifications to the shoe.
3. Compare the difference in pressure and analyse the redistribution of pressure on the plantar area.

5.2.4. Regulation

In order to perform tests in the University Hospital at Groningen, permission from the UMCG Medical Ethics Committee is needed by law. However, in our particular case we requested of an exemption, since the tests incur in no medical implications; the tests rather consist on the measurement of plantar pressure using different techniques already used in shoes on the market. This letter must include background information of the project, as well as detailed information about the tests to be performed. The letter sent to the committee can be found on Annex A of this document.

6. Conclusion

The aim of this project was the design and fabrication of a testing prototype to be used in plantar pressure measurements, in order to find the better way to handle high pressure points on the orthopaedic shoe from the foundation Beter ter been. A fundamental consideration of the design is the fact that this shoe is intended to be used in rural areas in India, which constrains the materials and tools to use.

A literature research on clubfoot, as well as the treatment and the management of other foot pathologies, lead to having a better understanding of the condition. Based on all the information read from different sources, a brainstorming process took place and several new ideas came to light. Some of these ideas however, where not fully feasible, given the restrictions of material availability in rural areas in India. After an evaluation of the pre-concepts, five ideas were chosen to be further developed: pads, inserts, taping, modifications on the sole and material removal from shoe.

The foundation Beter ter been provided three pairs of shoes on which we could implement the different concepts for the tests. Since the use of pads and inserts do not require a permanent modification on the shoes, these concepts will be tested first and the three remaining concepts can be tested last (each concept on one different pair of shoes).

Just as the prototypes are essential in the technical aspect of this project, so is the paperwork in order to perform the tests of these prototypes. A letter was sent to the Medical Ethics Committee at UMCG, requesting clearance and guidance in the documentation needed to proceed with the tests. At the moment of delivery of this document, we are still waiting for their response.

Only after these tests could we have enough data to judge which concepts fulfils better the requirements of this project.

7. Recommendations

In the beginning of the project, a time planner was proposed in order to manage the work load towards an on-time delivery (Figure 31)

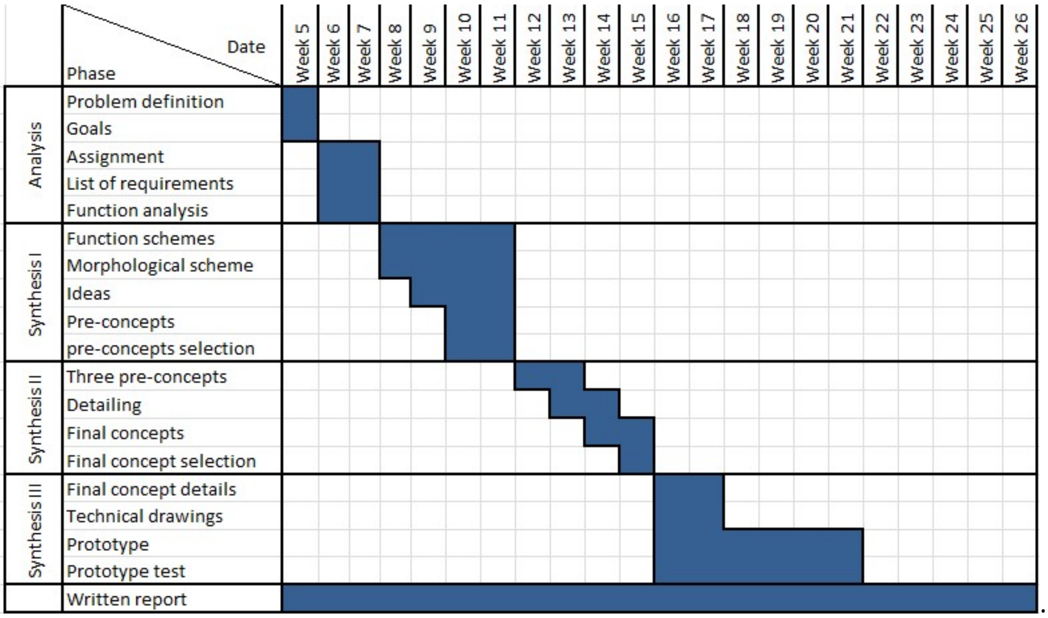


Figure 31 Time planner proposed before the start of the project

As the diagram proposes, a constant activity during the development of this project is the report writing. I highly recommend taking notes and writing the project as it develops, since it is easier to remember the details of what has been done, and it leads to a less complicated way of wrapping up of the project.

There were of course deviations from this initial planning. Due to other academic commitments, the start date of the project was postponed for Week 11. Because the initial planning aimed to finish a month before the submission deadline, it did not represent a big issue.

It was proposed to develop a Finite Element Model of the shoe for this project. However, there were different setbacks around this idea, mainly technical issues during the modelling by using COMSOL Multiphysics. The idea had to be quit, because of this and a different approach was taken: an actual measurement of the plantar pressure on prototype shoes instead. Anyway, this took around of 3 weeks of the project as well, moving the schedule forward again.

Finally, one more thing that was not taken into consideration was the waiting time for the approval of the tests by the Medical Ethics Committee of the UMCG. This process takes around 6 weeks, which made impossible for the tests to be performed in July as planned. The tests were moved to august and will be posteriorly annexed to this report.

After working on this project I realized the challenge to translate the techniques and facilities that we have access to in countries such as the Netherlands into materials and tools that can help people in middle and low income countries. I recommend for anyone who follows up this project to read the stories online and realize how the project might change people's lives, I personally found it really inspiring.

In terms of the tests it is important to analyse the outcome of the change in plantar pressure, but it would also be important to make a further test on the best concepts, but this time with a larger group of people. In our case, we wanted a proof of concept, and one patient was enough, however it would be interesting to see if the change in plantar pressure remains constant from one patient to another.

Questionnaires to assess the concepts in terms of the patient's comfort are also highly recommended, such as the "Questionnaire for usability evaluation of orthopaedic shoes" developed by Jannink *et al* (26).

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Annex A. Letter to the UMCG Medical Ethics Committee

UMCG Research Register Number: 201600594

To:
UMCG Medical Ethics Committee
drs. J. Davids, mr. S. Chakor, drs. J. Ummels and P. Vos.

Date: July 22nd, 2016

Subject: Review needed for informed consent for plantar pressure tests

Dear members of the Medical Ethics Committee,

I am writing to ask for clearance from METc, in order to perform the related tests for my Masters project:

"The effect on plantar pressure of five conventional modifications to orthopaedic shoes to be used in developing countries"

A.E. (Ana) Gonzalez Salinas[1], ing. H.M. (Herman) Kuis[1] and prof. dr. ir. G.J. (Bart) Verkerke[1]

[1]Department of Biomedical Engineering, University of Groningen.

Introduction

Hans van Dalen and Toos Rook, on behalf of the Beter ter Been foundation, reached the University of Groningen (RUG) in order to tackle different engineering concerns regarding the design of their orthopaedic shoe. In a previous thesis project at RUG, M.A.T. (Merlijn) de Wolf developed a prototype to build an orthopaedic shoe to be produced in developing countries in collaboration with Beter ter Been (1). The scope of this project included the development of a prototype for the filling between the inner shoe and the outer shoe. The filling is used in order to provide a better fit according to the foot morphology of each patient. A drawing of the prototype is shown in Figure 1.

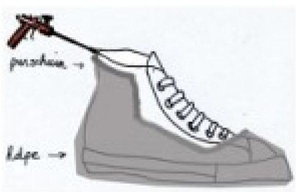

Figure 1. Diagram of the prototype proposed by de Wolf
(Purschuim: polyurethane foam; Hdpe: High-density polyethylene)

The goal of this Master's project is to develop a tested prototype for the inner shoe casting (between the foot and the filling), avoiding harmful and painful pressure points in the foot, which still guarantee support on the foot during casting and while using the shoe. After following the design methodology of the Biomedical Engineering Department at RUG (2), five different pre-concepts are proposed as shown in Figure 2.

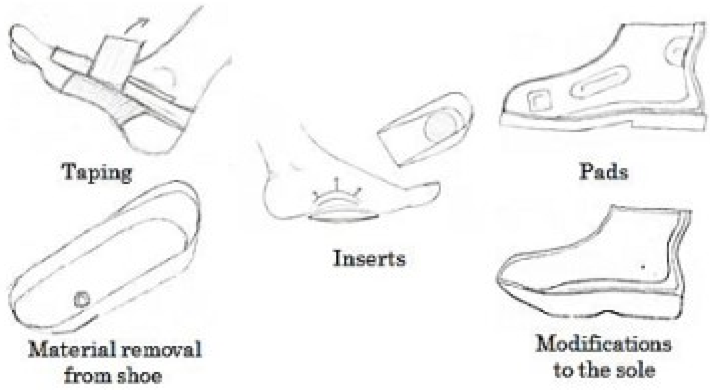

Figure 2. Pre-concepts

By removing material from the shoe, we increase the area on which the person's weight is applied and therefore we could decrease the pressure on this area.
The inserts and pads are currently available in the market. As for taping it is widely used to treat other foot problems, such as plantar fasciitis. The modifications proposed to the shoes (aka rocker shoes) are widely used in commercial orthopaedic and sports shoes.

Information regarding the research methodology

Target audience

The study population consists of 1 healthy participant.

Method

In order to test the difference in pressure between each design, I would like to measure the in-shoe plantar pressure for each of these concepts in one healthy participant. If we can determine the difference in pressure, this may help us to make a better decision of which pre-concepts to implement in the final design of the orthopaedic shoe.

The Pedar system by novel will be used to measure and record the in-shoe pressure while the participant walks 20 meters per test. The Pedar system is available in the motion laboratory of the UMCG and frequently used for similar measurements. There will be 3 stages of these tests:

1. Measure the plantar pressure without any modifications to the shoe in order to find high pressure points (1 test)
2. Measure the plantar pressure with the five modifications to the shoe.
3. Compare the difference in pressure and analyse the redistribution of pressure on the plantar area.

In our opinion, these tests have no medical implications but rather will try to solve a technical question. We therefore expect that no permission from the METc for the above study is required, as described in the law. However, we would like to hear your opinion on this.

With this letter, we hope to have provided with sufficient information to make a judgment. For any more information, please contact me.

Sincerely,

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