NTNU
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Implementing 3D Printing in the Production Process of Individual Insoles

Nikors Sivarajah

Master of Science in Mechanical Engineering
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Problem Statement

Title: *Implementing 3D Printing in the Production Process of Individual Insoles*

Candidate: *Nikors Sivarajah*

Objective: The overall objective is to replace time consuming and labour-intensive processes in the production of prostheses, orthoses and other orthopaedic aids with simpler and faster solutions based on new production technology. This concerns products that are custom-made for the user and not products that are produced by batches.

The short dated and specific objective of this thesis is to find solutions for footbeds and insoles based on 3D printing. This includes the application of 3D-printing for final products, but it can be also interesting for models/moulds. It is most relevant and interesting for the highly complex and advanced footbeds. This implies challenges in several areas.

The overall problem to be addressed:

Can 3D printing be used in an effective way to make footbeds or parts of it with satisfactory properties?

Materials:

It is important to find suitable materials, but it should not get the main attention in this thesis. However, it is important to include the requirements for the materials, and it should be clarified if the materials can withstand the exposed load.

Structure:

When it comes to the structure of the product, 3D printing gives new possibilities. We have been presented for Materialize Magics, a software specifically made for 3D printing. In this software it is possible to build inner structures in printed components (for instance honeycomb). These are not structures on an atom level, but a millimetre level. The first impression is that this is a function which could bring new possibilities to vary softness/hardness on the different areas of the footbed.

This should be examined. It is uncertain if there will be granted access to this software. In this case, the student should by any chance simulate it in an ordinary 3D system (or if the student finds other available softwares). Other possibilities are to choose different materials for different layers of a footbed, and perhaps also vary the properties of materials inside a layer.

Production process:

An obvious objective is to increase the efficiency of the production process to achieve cost and time savings. This is not the main topic of this thesis, but the biggest interest is the usefulness of the technology.

The thesis is carried out in close collaboration with Trøndelags Ortopediske Verksted AS (The Orthopaedic Workshop of Trøndelag). Contact person at TOV is Tobias Goihl.

Problemformulering

Tittel: *Bruk av 3D-printing i produksjonsprosessen for fotsenger*

Kandidat: *Nikors Sivarajah*

Målsetning:

Den overordnede målsettingen er å kunne erstatte langsomme og arbeidskrevende prosesser i framstillingen av proteser, ortoser og andre ortopediske hjelpemidler med enklere og raskere løsninger basert på ny produksjonsteknologi. Dette gjelder produkter som spesialtilpasses bruker, ikke produkter som serieproduseres.

Den konkrete og kortsiktige målsettingen er å finne fram til løsninger for fotsenger og innleggssåler basert på 3D-printing. Dette omfatter både bruk av 3D-printing til endelige produkter, men kan også være interessant for modeller/former. Det er mest interessant for de vanskeligste, mest avanserte fotsengene. Dette innebærer utfordringer på flere områder.

Overordnet problemstilling

Kan 3D-printing brukes til å lage fotsenger eller deler av fotsenger på en effektiv måte med gode egenskaper?

Materialer:

Å finne fram til materialer som egner seg er selvsagt veldig viktig, men skal ikke være hovedfokus i denne oppgaven. At krav til materialene tas med er dog viktig, og problemstillingen med om materialer tåler den belastningen de utsettes for må belyses.

Oppbygning:

Når det gjelder oppbygning av produktet, gir 3D-printing nye muligheter. Vi har blitt presentert for Materialize Magics, en programvare spesielt laget for 3D-printing. Der er det mulig å lage indre strukturer i printede komponenter (for eksempel honeycomb) – og da snakker vi om strukturer på millimeternivå, ikke på atomnivå. Førsteinntrykket er at dette er en funksjon som kan gi helt nye muligheter for å variere mykhet/hardhet på de ulike stedene av en fotseng.

Dette må undersøkes. Vi vet ikke om vi vil ha tilgang på denne programvaren – studenten må muligens simulere det i et vanlig 3D-system (eventuelt om han finner annen tilgjengelig programvare for det). Andre muligheter er å velge ulikt materiale i ulike lag av en fotseng, og kanskje også å variere materialegenskapene innenfor et lag.

Arbeidsprosesser:

En opplagt målsetting er å effektivisere arbeidsprosessene for å oppnå besparelser både med hensyn på tid og penger. Vi legger ikke spesielt vekt på det i denne oppgaven, her er det mest brukbarheten av teknikken vi er interessert i.

Oppgaven utføres i nært samarbeid med Trøndelag Ortopediske Verksted. Kontaktperson der er Tobias Goihl.

Preface

This thesis was written to fulfill the final requirement for graduation at the Norwegian University og Science and Technology (NTNU). The five year master's degree programme in Mechanical Engineering, with a specialization in Product Development and Materials Engineering, was ended by handing in this thesis in the spring of 2018. With a background in developing products for the elderly and the disabled, and with an interest in applied engineering in the health sector, choosing this topic for my thesis was an easy decision. It was written for Trøndelags Orthopedic Workshop (TOV) in the Departement of Mechanical and Industrial Engineering (MTP) at the Faculty of Engineering. This thesis was written under the supervision of Knut Einar Aasland and Jan Torgersen from NTNU, and Tobias Goihl from TOV.

Acknowledgement

First of all, I would like to thank my main supervisor, Associate Professor Knut Einar Aasland at NTNU, Department of Mechanical and Industrial Engineering. Thank you very much for helping me find an interesting topic and for guidance through the project. I appreciate the collaboration we have had the past years and you always being available when your help is needed.

Secondly, I would like to thank my co-supervisor, Associate Professor Jan Torgersen at NTNU, Department of Mechanical and Industrial Engineering. My knowledge in 3D printing would not have been the same without your inputs, passion, and you challenging my work and the way of thinking. Thank you for helping me finding important insights in the product development process. Your knowledge in additive manufacturing is truly inspirational.

A special thanks to Tobias Goihl, Development Manager at TOV. I highly appreciate the useful feedback you gave and you taking the time in your busy schedule. Thank you for providing me the opportunity to present my work at the Nordic Prosthetist Conference. Your inputs from an orthopedic perspective and devotion lead up to the results of this thesis.

I would also like to thank Mirco Peron, PhD Candidate at NTNU, Department of Mechanical and Industrial Engineering. The material tests would not have been fulfilled without your help.

Finally, I would like to thank my family and friends for always motivating me and supporting me morally and emotionally. I am grateful for having you in my life. I would like to dedicate this thesis to my dear dad, Sivarajah Rasaiah, mom, Ranjithamalar Sivarajah, sister, Nirujah Sivarajah and brother-in-law, Thusyanthan Balasingam who have been there for me since the very beginning.

June 2018, Trondheim

Nikors Sivarajah

Abstract

The short dated and specific objective of this project is to find solutions for insoles based on 3D printing. This includes the application of 3D-printing for final products. Off-the-shelf insoles, also called generic insoles, are often manufactured in large batches. Therefore, it is most relevant and interesting to focus on 3D-printing on highly complex and advanced insoles, also known as individual insoles.

The overall problem to be addressed:

Can 3D printing be used in an effective way to make individual insoles or parts of it with satisfactory properties?

The problem was approached by first observing the current process at TOV, an orthopedic workshop in Trondheim. It was found that the insoles can be classified into three categories which are off-the-shelf, milled and vacuum produced. Vacuum production is the process which is most time consuming one. It is therefore the main area of focus since it has the greatest potential concerning 3D-printing. 3D scanning applications were tested and a 3D printer was built to get a clear understanding of the true objective. A thorough research on existing solutions was conducted to learn from other company's experiences. Technicians and orthotists were also interviewed to obtain knowledge about how an insole should behave. This increased focus on material types and the requirements to find a suitable material for an individual insole.

Different product development methodologies such as Design Thinking and IPM-model was used in the development process to solve several issues concerning the production of 3D-printed insoles. Scrum was used as a framework to push the project in the right direction. CAD software was used to design a model of the insole to make it 3D-printable, and different flexible filaments were tested to find a suitable material for printing the insoles. Compressive tests and hardness tests of the polymer-material, which is used for making the

current insoles, were performed to acquire relevant material properties. This would help designing a resembling structure with comparable properties of the current insoles. The solution was a general method which could be used and adapted into the diverse types of currently existing 3D-printers. Finding an expression for a material property depending on 3D printing parameters could help obtaining new values for the material properties when the aforementioned parameters changes.

This thesis was written to fulfill the final requirement from a 5 year master‘s degree programme in Mechanical Engineering at NTNU in Trondheim and was carried out in close collaboration with Trøndelags Ortopediske Verksted AS (The Orthopaedic Workshop of Trøndelag) in Norway.

Abstrakt

Den konkrete og kortsiktige målsettingen er å finne fram til løsninger for fotsenger og innleggssåler basert på 3D-printing. Dette omfatter bruk av 3D-printing til endelige produkter. Det er mest interessant for de vanskeligste, mest avanserte fotsengene.

Overordnet problemstilling:

Kan 3D-printing brukes til å lage fotsenger eller deler av fotsenger på en effektiv måte med gode egenskaper?

Det ble først observert hvordan en såle lages i dag på TOV, et ortopedisk verksted i Trondheim. Sålene kan deles inn i tre kategorier som er prefabrikerte hyllevarer, freste og vakuum produserte såler. Vakuum produksjon er den prosessen som er mest tidskrevende. Derfor bør denne prosessen bli fokusområdet siden den har størst potensiale når det kommer til 3D printing. 3D skanning applikasjoner ble testet og en 3D printer ble bygget fra bunnen av for å konkretisere målet med prosjektet. En grundig markedsundersøkelse ble gjennomført for å lære om erfaringer til andre selskaper. Ortopedi-ingeniører og -teknikere ble også intervjuet for å få kunnskap om hvordan en såle bør oppføre seg. Dette økte fokuset på 3D printematerialer og krav til materiale for fotsenger, for å finne et egnet 3D printemateriale for fotsenger.

Ulike produktutviklingsmetodologier som Design Thinking og IPM-modellen ble brukt i utviklingsprosessen for å finne løsninger angående produksjon av 3D printet fotsenger. Scrum ble brukt som et rammeverk for å føre prosjektet i riktig retning. CAD programvare ble brukt til å designe en modell av fotsengen for å gjøre det mulig å 3D printe og forskjellige fleksible 3D printematerialer ble testet for å finne egnet materiale til fotsengene. Kompresjonstester og shore hardhetstester ble utført på et av materialene som brukes for å lage de nåværende fotsengene til å finne dens materialegenskaper. Dette vil hjelpe å designe en lignende struktur med sammenlignbare egenskaper av den ek-

sisterende sålen. Løsningen er en generell metode for som kan bli brukt og tilpasset ulike eksisterende 3D printere. Et matematisk uttrykk for en materialegenskap som er avhengig av 3D printeparametere kan bidra til å finne tallverdier for de nye materialegenskapene hvis disse parameterne endres på.

Denne masteroppgaven er et avsluttende krav fra et 5-årig masterprogram i Produktutvikling og Produksjon på NTNU i Trondheim og ble utført i tett samarbeid med Trøndelags Ortopediske Verksted AS (TOV) i Norge.

Contents

1 Introduction

1.1 Background

3D printing have become more and more sought after in the industry the last decade and is often considered the ultimate technology for digital production. By a press of a button, the products will be ready in a few hours. The 3D printing market have grown about 30 percent each year. In the last decade, the 3D printers have developed from slow machines and low resolution products to rapid machines and highly detailed products. The vision is that these machines will take over current production processes. It is possible to print in different materials like metals, plastic, and different colours, shapes and sizes. The increase in the market have lowered the prizes for 3D printers and have become more available for the people. 3D printers have great potential in front end development as well. The 3D printers are still in the development phase, but could become a big competitor for other production processes. Valmot (2018).

From a marketing perspective, 3D printed footwear is the next big thing. The reason for this is that 3D printed insoles and midsoles is a simpled way to introduce 3D printing and customization to the marketplace. 3D printing an entire shoe and still maintain a good appearance may be difficult, but insoles and midsoles have great potential. It is possible to introduce weight savings, unique designs such as lattice structures, provide better cushioning and increase performance. Due to these possibilities, several companies have started showing their interest in the market, and are exploring the technology and possibilities for mass production. Molitch-Hou (2017*b*).

The advantage of 3D printing insoles is that it is feasible to manufacture products which are customized to customers feet. It goes beyond the prefabricated insoles, which are made to fit all customers. Futurists and 3D-printing aficionados are expecting a day in which every product will be tailored to the consumer and produced in mass, a concept referred to as “mass customization.”

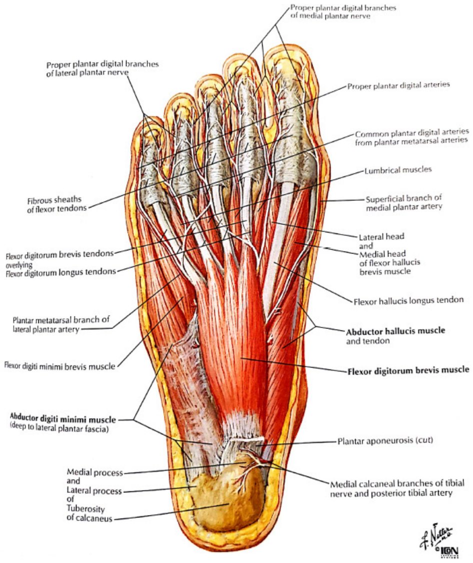
Molitch-Hou (2017*b*).

Before proceeding to the next chapter it is important to understand the difference between prefabricated insoles, individual insoles and generic insoles. Prefabricated insoles, are soles produced to fit customers with no customization. Generic insoles, are soles that are semi-finished with some degree of customization which patients at a orthopedic workshop needs to pay full price. Individual insoles is an orthopedic aid that are fully customized which are supported financially by the Norwegian Labour and Welfare Administration (NAV). This thesis will mainly focus on developing individual insoles for the most demanding patient group. (Aga 2012, p. 65).

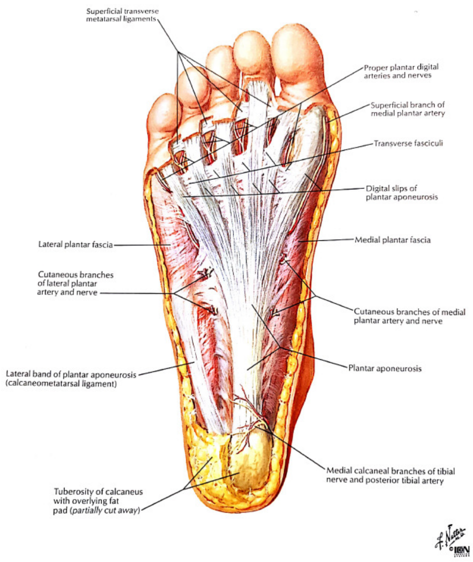
2 Theory

2.1 The Anatomy and Illnesses of the Foot

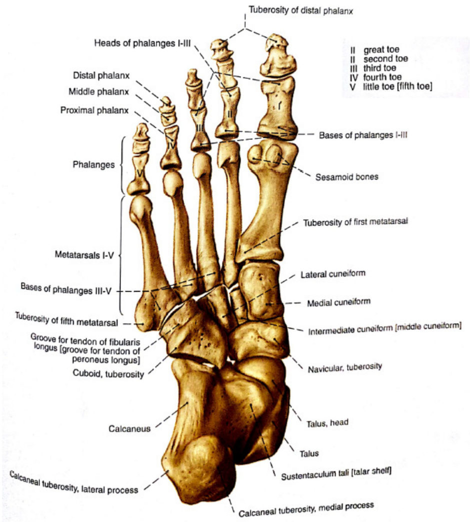
Orthopedic engineers often meet people with pain and suffering in their feet, calves, or knees. This is often due to wrong positioning or repetitive strain injuries. Some sufferings could be removed by being less active, others develop it in a chronic way. For this type of pain-development, it takes orthopedic and physiotherapeutic measures to remove and prevent pain. This project will mainly focus on the orthopedic standpoints based on biomechanical principles. The illustrative figures below are included to get an overview of the anatomy of the foot and will be helpful for explaining the disorders below. (Aga 2012, p. 12).



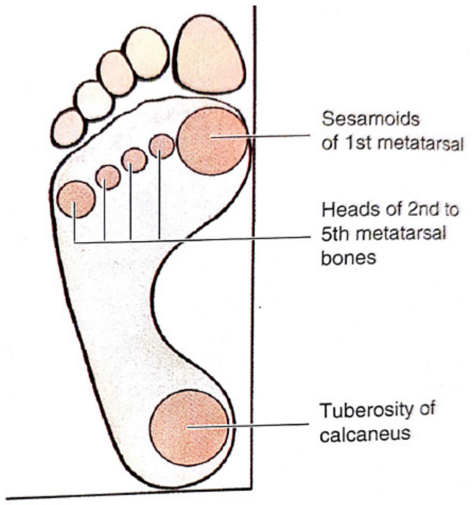
(a) Muscles of the sole of the foot: first layer.



(b) Superficial dissection of the sole of the foot.

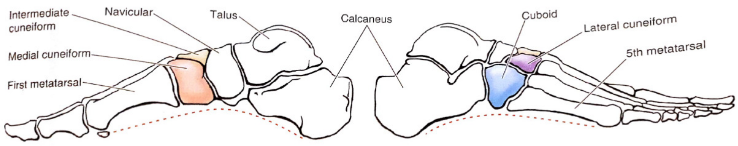


(c) The skeletal system of the foot.

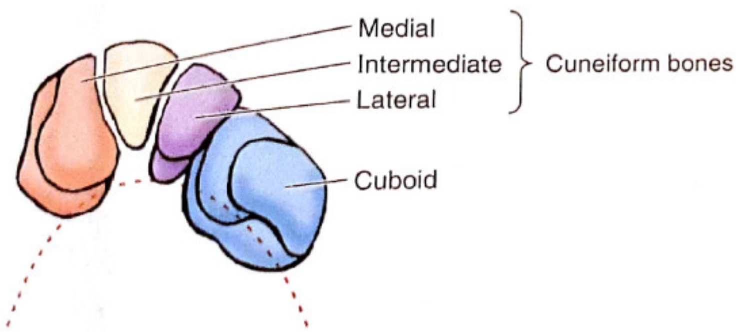


(d) Weightbearing areas of the foot. The bodyweight is approximataley equally divided between the calcaneus and the heads of the metatarsals.

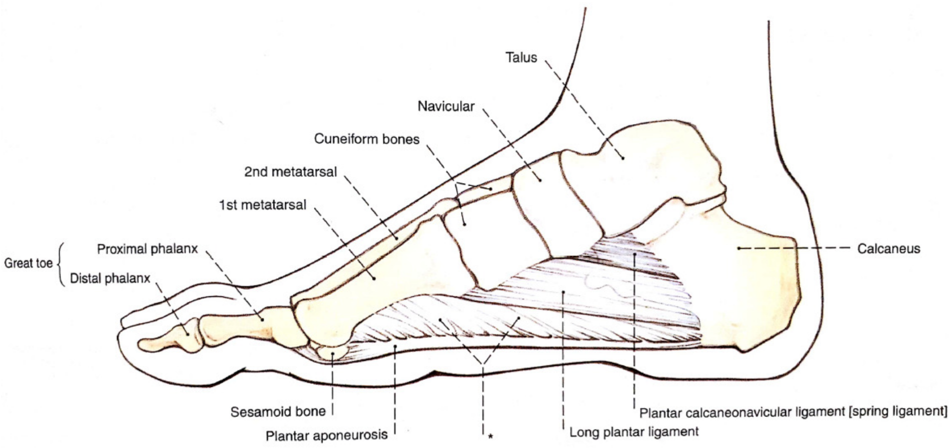
Figure 2.1: Anatomy of foot. Reproduced from (Netter 2003, p. 514-515), (Putz & Pabst 2001, p. 297) and (Moore & Dalley 1999, p. 640).



(a) Medial longitudinal arch on the left and lateral longitudinal arch on the right.



(b) Transverse arch.



(c) Tendons in the longitudinal arch.

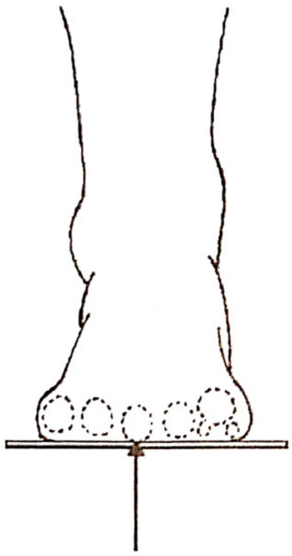
Figure 2.2: Arches and tendons in the foot. Reproduced from (Moore & Dalley 1999, p. 641) and (Putz & Pabst 2001, p. 301).

2.1.1 Forefoot Diseases

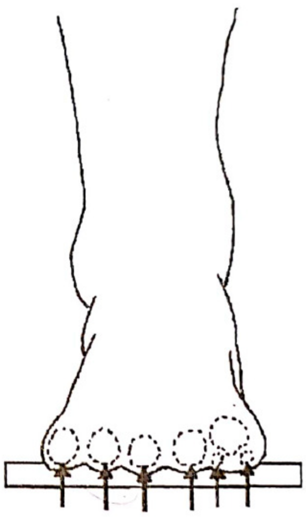
Pain in the forefoot often occurs in an adult foot. Repetitive- and large amount of strains in the forefoot, and the metatarsal results in a loosening in the elastic structure of the aforementioned areas. The forefoot's transversal arch gets weakened, see figure 2.2b. The disorder is called transversal flat feet with most of the pain located in the MTP-joints. The MTP (Metatarsophalangeal)

- joint is a joint between the foot and toe, which also are weightbearing areas of the foot as shown in figure 2.1d. (Aga 2012, p. 12).

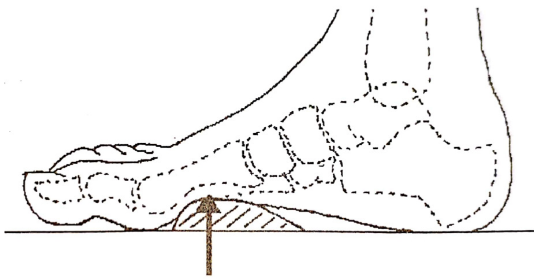
To relieve pain, the orthopedic engineer have two possibilities. One is to reduce pain in each MTP joint by supporting the joints with a shock-absorbent material. This means that the pressure around each joint gets distributed to the surrounding surfaces as shown in figure 2.3a and 2.3b. The other possibility is to move the pressure to a point in the musculoskeletal system which can tolerate the loading as illustrated in figure 2.3c. The engineer often uses a combination of both principles. (Aga 2012, p. 12-13).



(a) Transversal flat feet concentrate the pressure force to the middle of the MTP-joints.



(b) An insole will distribute the force to all MTP-joints.



(c) Moving the pressure point.

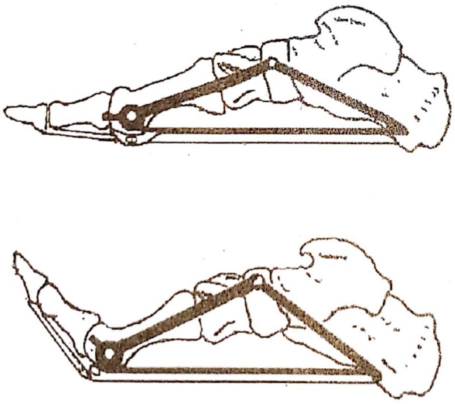
Figure 2.3: Forefoot diseases. Reproduced from (Aga 2012, p. 12-13).

2.1.2 Medial Instability

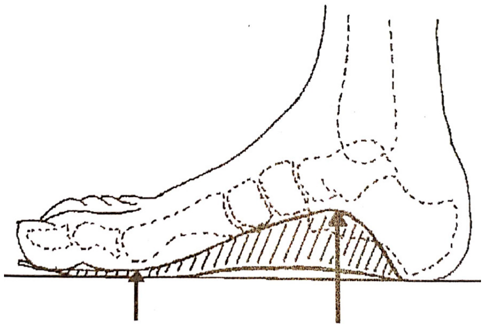
The foot's main function is to dampen the pressure forces. When the foot is in contact with the ground, it shows outstanding dynamic and elastic capabilities to adapt to different types of bases. As the heel leaves the ground and the forces are relocated to the forefoot, the foot is transformed to a more stable construction. The medial foot forms a clear longitudinal arch, which is illustrated in figure 2.4a and 2.2a. Failure in the medial longitudinal arch can cause overpronation (inwards rotation of the ankle) and underpronation, also called suppination (outwards rotation of the ankle). If this is the situations, the orthopedic engineer will put a medial support under the foot's longitudinal arch and under the forefoot as shown in figure 2.4c and 2.4b. (Aga 2012, p. 14).

Research has been carried out to check if there exists a correlation between the behavior of the foot, when the person stands, and the behavior of the foot, when the person walks or run. It resulted in no correlation. This means that the foot needs to be considered in both situations for the engineer to give a proper assessment. (Aga 2012, p. 15).

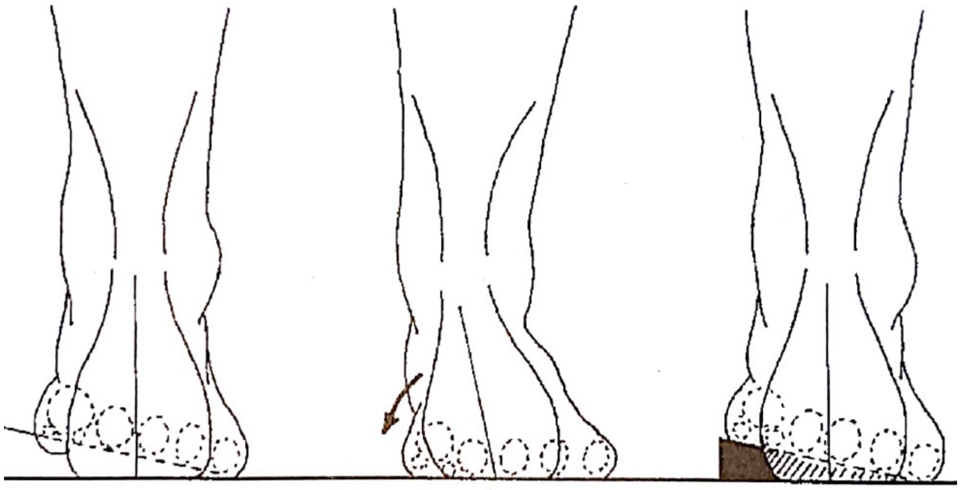
Flat foot is caused by the aforementioned longitudinal arch not existing in the feet as shown in figure 2.4d. Persons with flat feet notice pain and fatigue due to repetitive strain. It can cause secondary suffering in calves and lead to overpronation. Therefore, insoles with increased stability is made for persons with this type of disorder. (Aga 2012, p. 15).



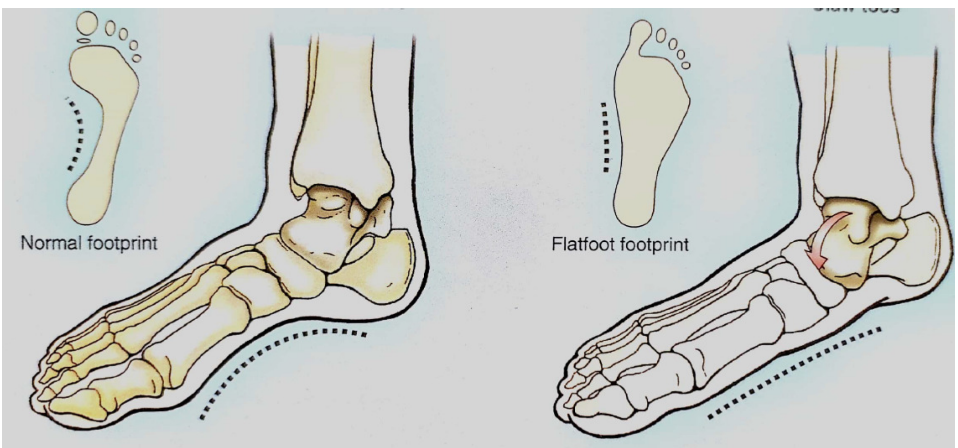
(a) The longitudinal arch bend. The foot gets more stable as the heel leaves the ground.



(b) Medial support to impede overpronation.



(c) Correcting the suppination of the foot.



(d) Flat foot.

Figure 2.4: Medial instability. Reproduced from (Aga 2012, p. 14-15) and (Moore & Dalley 1999, p. 642).

2.1.3 Lateral Instability

Instability in lateral direction occurs when the ankle gets sprained. This is due to the foot loosing its grip around the ankle region. This is a disorder which has its origin in an impairment in the foot's inner structure. 85-95 % of ligament injuries in Norway are lateral. (Aga 2012, p. 16).

The orthopedic measure for this type of injury is a lateral wedge as shown in figure 2.5. It can either be implemented in the insole or added outside the sole of the shoe. 70-80 % of the patients with critical ligament injuries in the ankle have no symptoms within 6 months. (Aga 2012, p. 17).

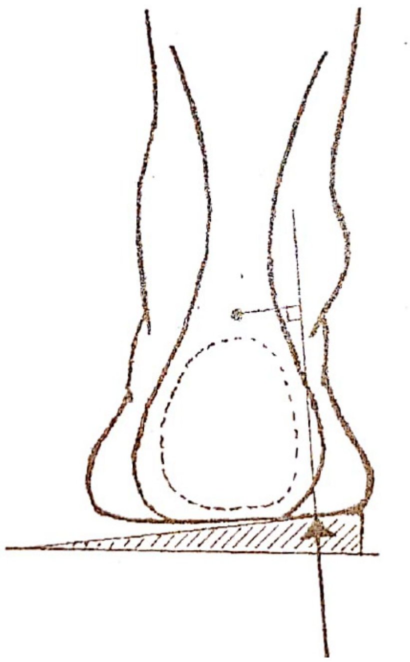


Figure 2.5: Lateral instability measure. Reproduced from (Aga 2012, p. 17).

2.1.4 Suffering in the Heel

Most of the suffering in the heel region have occurred repeatedly in recent decades. One can ask if there has been a change in daily human activities which strains the heel more often. A common disorder is plantar fasciitis which results in pain close to the heel region. This is due to longterm and large amount of loading, which can lead to impairment in the foot's muscles and ligaments, often combined with overweight or too much activity. (Aga 2012, p. 17).

The orthopedic measure for this disorder is an insole with tight-fitting, high and thick lateral edges. This solution will stabilize and lift the heel. It will also obstruct the fat pads in the heel to flow in medial and lateral direction as shown in figure 2.6. This will increase the foot's shock absorbing capability in the heel by 50 %. (Aga 2012, p. 18).

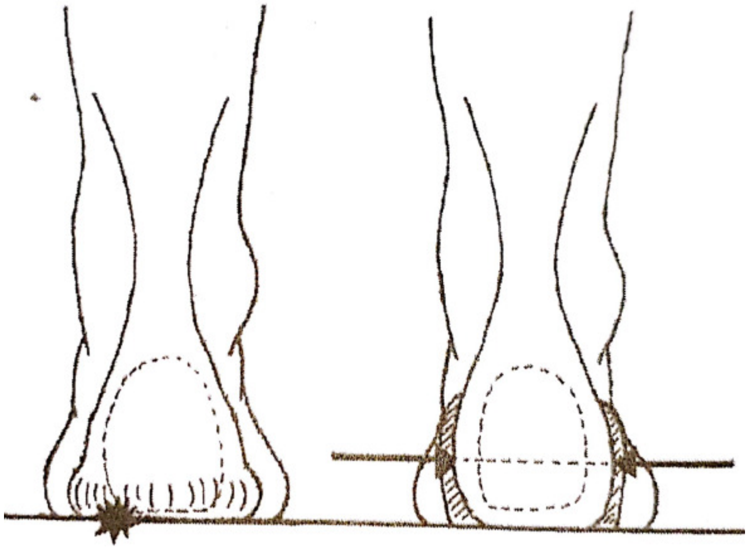


Figure 2.6: Solution to remove suffering in the heel. Reproduced from (Aga 2012, p. 18).

2.2 Foot Orthoses

What is the definition of orthopedic and foot orthoses? To get a proper understanding of the project, these terms are important to get grasp of. They are defined below.

> "*Orthopedic* is pertaining to the correction of deformities of the musculoskeletal system, defined by Dictionary of Medicine, Nursing, and Allied Health" Miller-Keane (2003).

> By definition, *foot orthoses* is a functional foot orthotic is a device that is contoured to the entire foot and used to reduce abnormal motion or abnormal position of the foot. A functional foot orthoses is also used to control the abnormal motion or abnormal position of the lower extremity that is affected by the position and/or motion of the foot. FootcareExpress (2011).

Plantar surface, also called sole of foot, is an important medical terminology for this project. Farlex Partner Medical Dictionary defines it as:

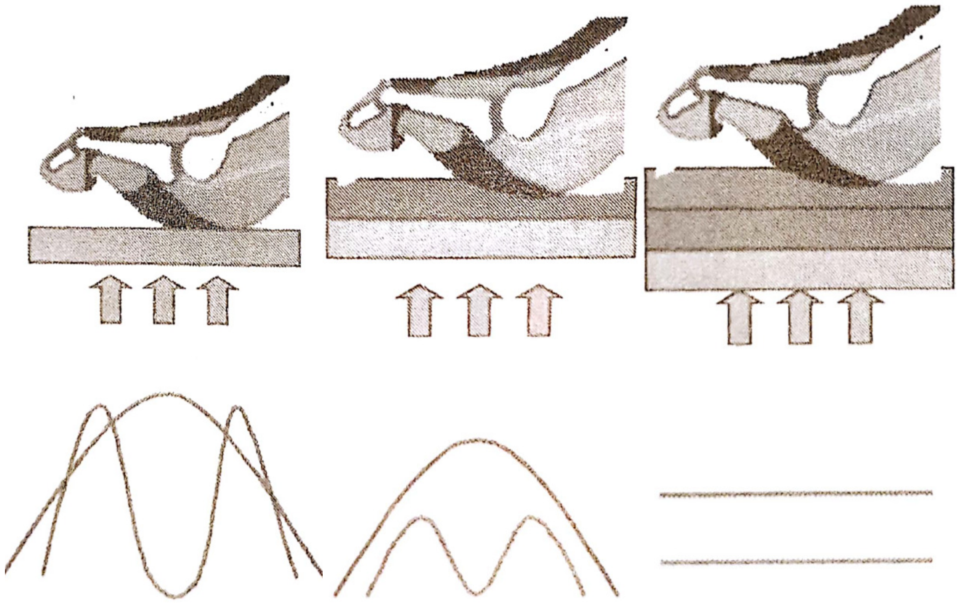
> The inferior aspect or bottom of the foot, much of which is in contact with the ground when standing; it is covered with hairless, usually nonpigmented skin that is especially thickened and provided with epidermal ridges over the weight-bearing areas. *Farlex Partner Medical Dictionary* (2012).

To design proper foot orthoses, five important factors needs to be considered:

- **Function**: foot orthoses can be corrective, give support, relieving, shock absorbing, pressure distributive and prophylactic for deformities and suffering. The technical aid can also help adjusting and correcting differences in bone lengths.
- **Material**: the orthoses can be produced in soft and rigid materials. It depends on if the aim of the technical aid is to correct or relieve. Traditional materials like leather, rubber and metal or up to date materials like thermoplastic soft foam with different hardness (Shore) or hard thermoplastic materials like polypropylene, polyethylene, pre-ipregnated composite fibers and acrylic laminate are normally used.
- **Production**: the most simple orthoses are made by adjusting the semi-manufactured insoles. The more complex insoles, are made by vacuum forming and milling. The last step in the production is usually grinding the insoles to fit the shoes.
- **Shape**: the soles can be distinguished between half soles and full soles. Half soles do not correct the forefoot and do not fill the whole shoe.
- **Aesthetics**: different type of shoes needs different type of support. Formal shoes often have little space to have an optimal insole. Sports shoes often need more stiff insoles than soft. One of the biggest challenges when making the insoles, is finding a balance between aesthetics and function.

2.2.1 The Effect of Foot Orthoses

Foot orthoses help reducing stresses that arise on the plantar surface. The maximum compression stress and some shear stresses gets reduced. The compression stresses are redistributed and the shear stresses are almost removed. The goal is to find a solution that follows the hydrostatic principle. This principle concerns matter that gets placed in water or fluid, which is affected by equal compressions stresses on the whole contact surface. Shear stresses do not exist and cannot arise. (Aga 2012, p. 23).



(a) Pressure- and shear-tresses when setting foot on a hard surface.

(b) Effect of the foot orthoses.

(c) The hydrostatic principle.

Figure 2.7: How stresses act in different states. Reproduced from (Aga 2012, p. 22-23).

2.3 Additive Manufacturing

Additive manufacturing (AM) is also commonly known as 3D printing, rapid prototyping, layer-by-layer fabrication, solid freeform fabrication or layer manufacturing. It is one of the most rapidly developing fields in industrial engineering. AM has a great potential, especially in medical technology. Current applications in health care are prostheses, orthoses, implants, dental aids and medical instruments. AM is a method of manufacture where solid objects are built layer by layer. The process can be divided into five steps (Redwood (2018*b*), Torgersen et al. (2017)):

1. **CAD:** computer aided design is used to make a digital model.
2. **STL conversion and file manipulation:** the STL files from the 3D model is converted into G-code which makes the paths for where the material feeder is moved.

3. **Printing:** the G-code is implemented to the 3D printer and the model is printed
4. **Removal of prints:** separating the print from the build platform
5. **Post processing:** some prints need removal of printed support structures. Some parts also need to cure under UV and metal parts needs to be stress relieved.

2.3.1 Advantages

Understanding the advantages help designers to make better decisions when selecting manufacturing process to give an optimal product. For AM, the advantages are(Redwood (2018*c*)):

- **Speed:** short production time from CAD to final product
- **Single step manufacture:** from CAD to part versus milling, welding, surface finish etc.
- **Cost:** 3D printing eliminates material waste, labor and tooling costs
- **Risk mitigation:** able to verify a design by printing a production-ready prototype before investing in expensive manufacturing equipment
- **Complexity and design freedom:** complex geometries can be made and compared to other machines which can have limited degrees of freedom
- **Customization:** builds single parts one at a time and are therefore perfectly suited for one-off production
- **Ease of access:** as there has been an exponential growth in the 3D printing industry
- **Sustainability:** environment friendly if the filament/material used is recyclable. The use of resources is limited to the actually needed amount of material with only minimal waste as it is additive and not subtractive.
- **Low inventory:** as the parts are continuously printed

2.3.2 Disadvantages

Most of the disadvantages for 3D printing is similar to the disadvantages of implementing automation. It is therefore important to understand, since the disadvantages of automation are becoming null due to developed technology. For AM, the disadvantages are(Shaleen (2016), Techspirited (2018)):

- **Expensive:** implementing 3D systems are expensive

- **Size limitations:** the size of the objects are limited to the build platform
- **Post processing:** some 3d printers can give low quality in surface finish which would need polishing
- **Qualified operators:** it can be time consuming to give operator proper training and get approvals
- **Supervision:** often, the prints needs to be supervised and controlled during printing.
- **Mass production:** need for several machines working at the same time, and printing time needs to be reduced which again makes it expensive and time consuming.
- **Material:** some material limitations since different type of 3D printers will require different types of materials.

2.4 3D Printing Techniques

3D printing comes in various types. It can be distinguished between fabricating parts from the liquid phase or solid phase. Figure 2.8 is included to get an overview and the under-categories are described below.

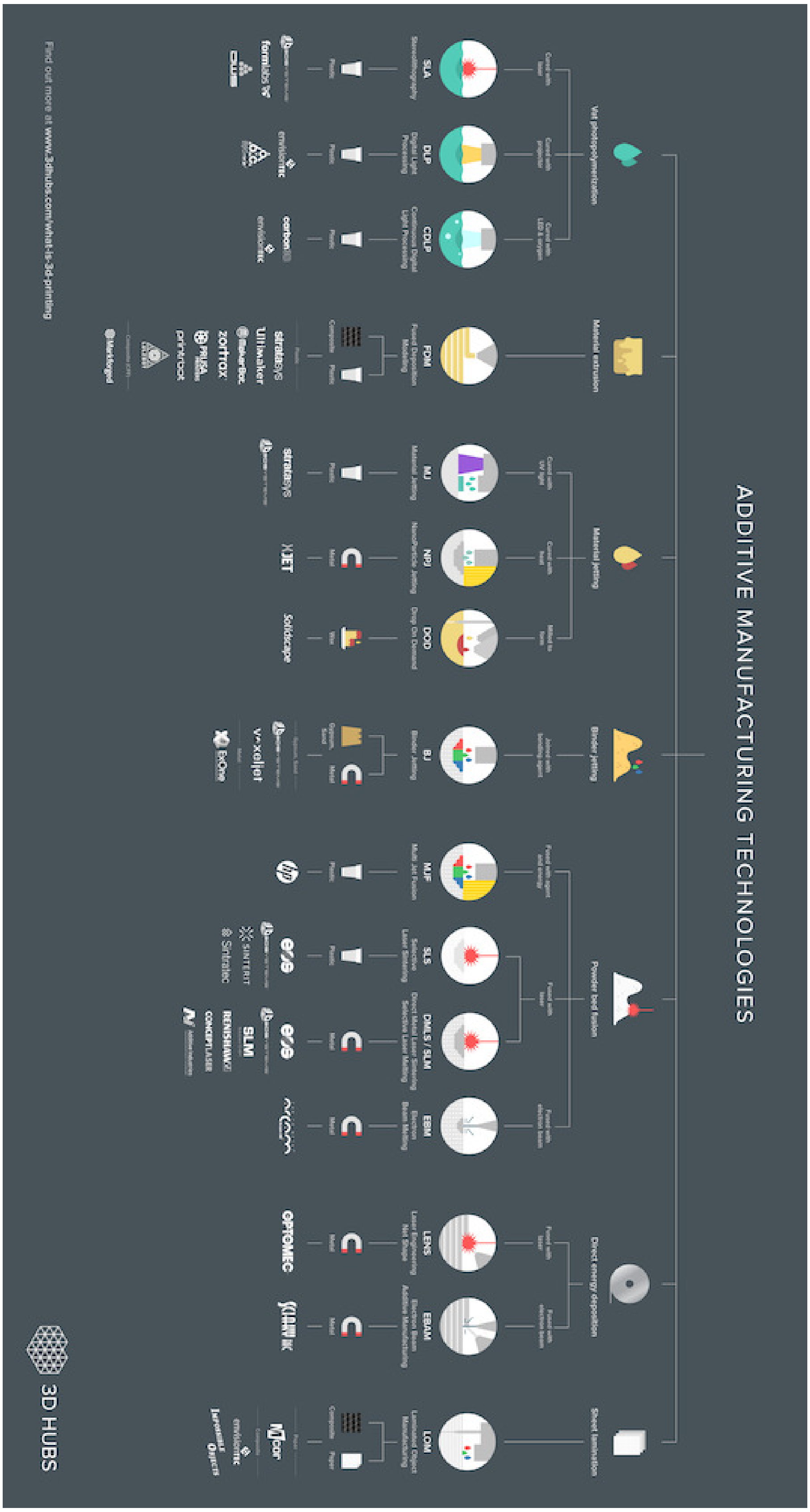


Figure 2.8: Overview of 3D printing techniques. Reproduced from Redwood (2018a).

2.4.1 From the Liquid Phase

Material Extrusion

Fused Deposition Modeling (FDM) is the most common 3D printing technology. Solid thermoplastic material is pushed through a heated nozzle with constant pressure and gets melted. The nozzle traces the part's geometry layer by layer as the extruded material solidifies continuously. Redwood (2018*a*), CustomPartNet (n.d.*c*).

Advantages: accuracy up to 0.025 mm, a broad range of materials, cheap

Disadvantages: needs support structure, long printing time, anisotropic

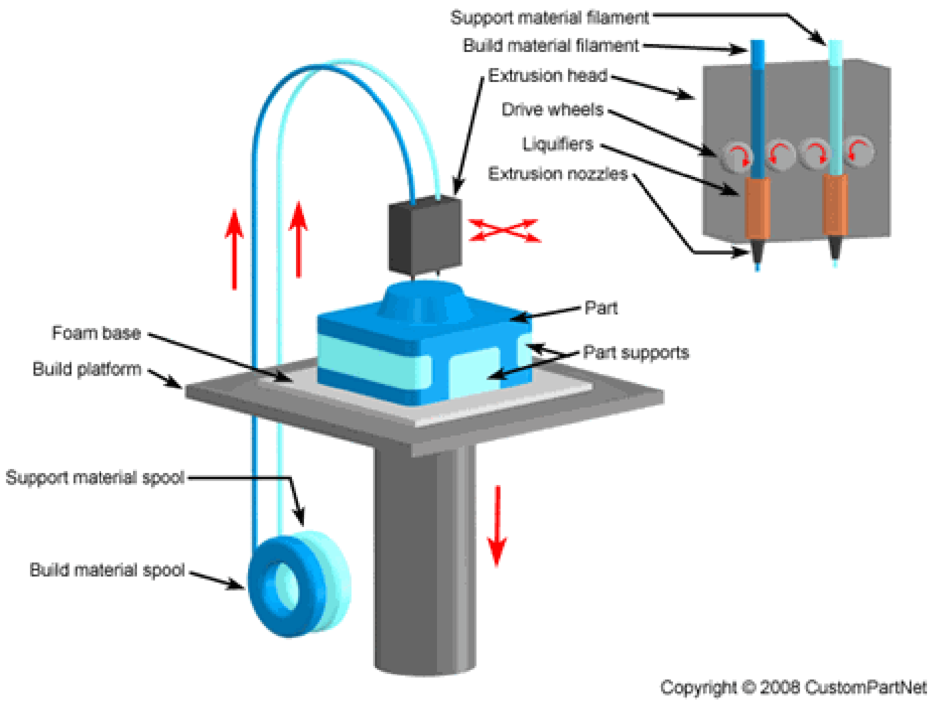


Figure 2.9: Fused Deposition Modeling. Reproduced from CustomPartNet (n.d.c).

Material Jetting

Material jetting is often compared to the 2D ink jetting process. First, droplets are deposited on the build platform. These droplets are then cured and solidified using UV-light. There also exists other types of material jetting like Nano Particle Jetting (NPJ) and Drop-On-Demand (DOD), which mainly follows the same principle. Redwood (2018*a*), CustomPartNet (n.d.*d*).

Advantages: fast printing speed, high accuracy, smooth surface

Disadvantages: needs large spaces, require support, expensive, brittle printed parts

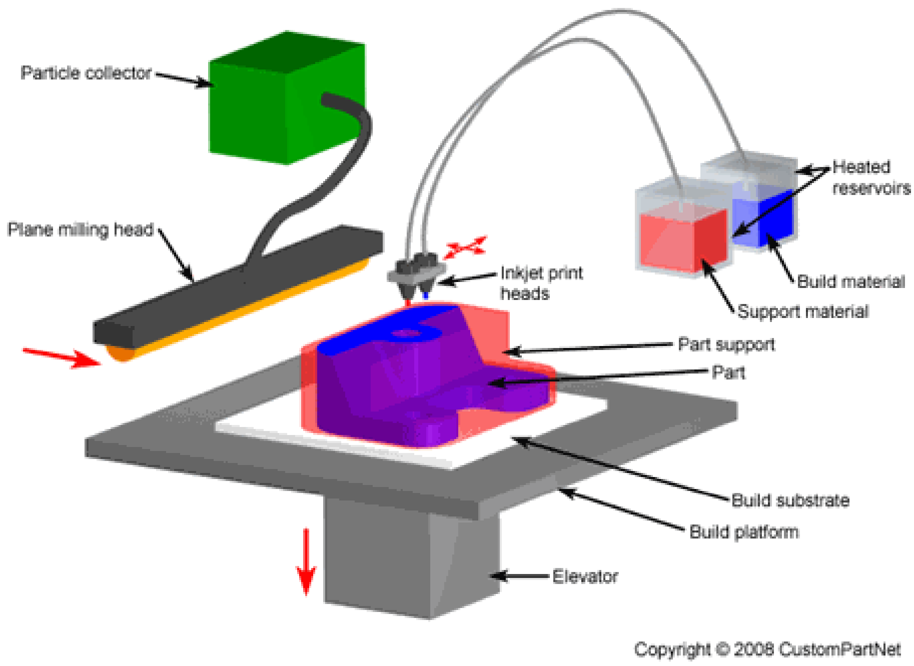


*Figure 2.10: Material jetting. Reproduced from CustomPartNet (n.d.*d*).*

VAT Photopolymerization

Photopolymerization occurs when a photopolymer resin is exposed to light of a specific wavelength and undergoes a chemical reaction to become solid. (Redwood (2018*a*), CustomPartNet (n.d.*g*)).

- **SLA:** stands for Stereolithography. The build platform is submerged into a tank filled with photopolymer resin. A laser is beamed along the path of the cross sectional area to make a solidified layer. The platform is lifted to make the next layer. Most parts are post cured by UV light to improve mechanical properties.
- **DLP:** Direct Light Processing has the same process as SLA. The difference is a digital light projector that is used to flash to solidify a layer, all at once. Also known as Digital Light Synthesis (DLS).

- **CDLP:** Continuous Direct Light Processing or also known as Continuous Liquid Interface Production (CLIP) has the same process as DLP. The only difference is that the build plate move continuously during prints.

Advantages: smooth surface, fine details, fast printing speed

Disadvantages: brittle printed parts

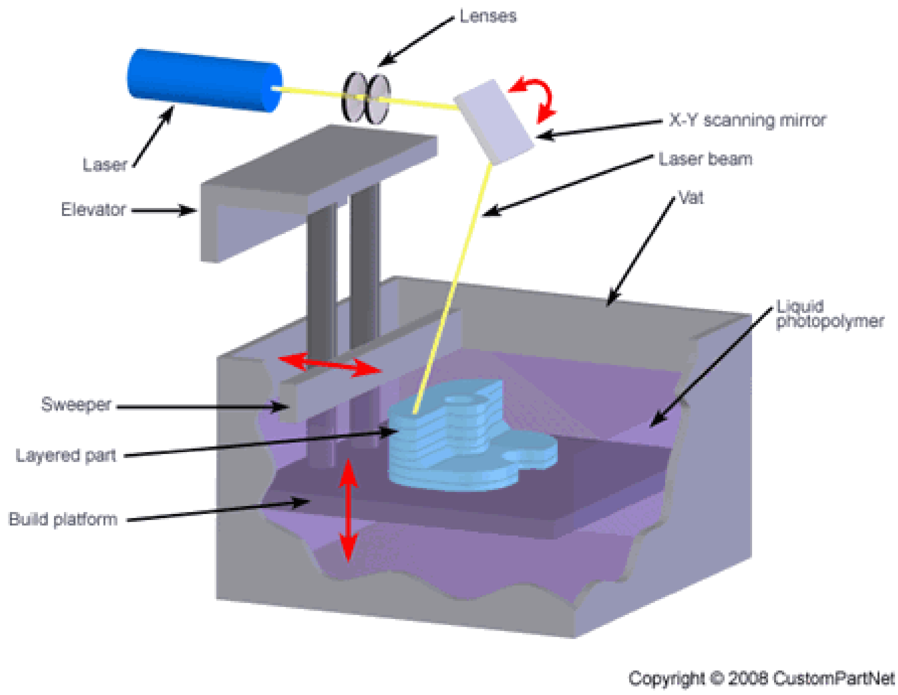


Figure 2.11: Stereolithography. Reproduced from CustomPartNet (n.d.g).

2.4.2 From the Solid Phase

Binder Jetting

A binding adhesive agent is deposited on thin layers of powder material which can be ceramic-based or metal. The print head moves over the printing area and deposits binder, like 2D printing. When the layer is complete, the build plate is moved downwards and fresh material is supplied, covering the previously fabricated layer. Redwood (2018*a*), CustomPartNet (n.d.*a*).

Advantages: no support needed, can be used to create molds for sand casting

Disadvantages: low surface finish, low strength, removal of residual powder, very brittle

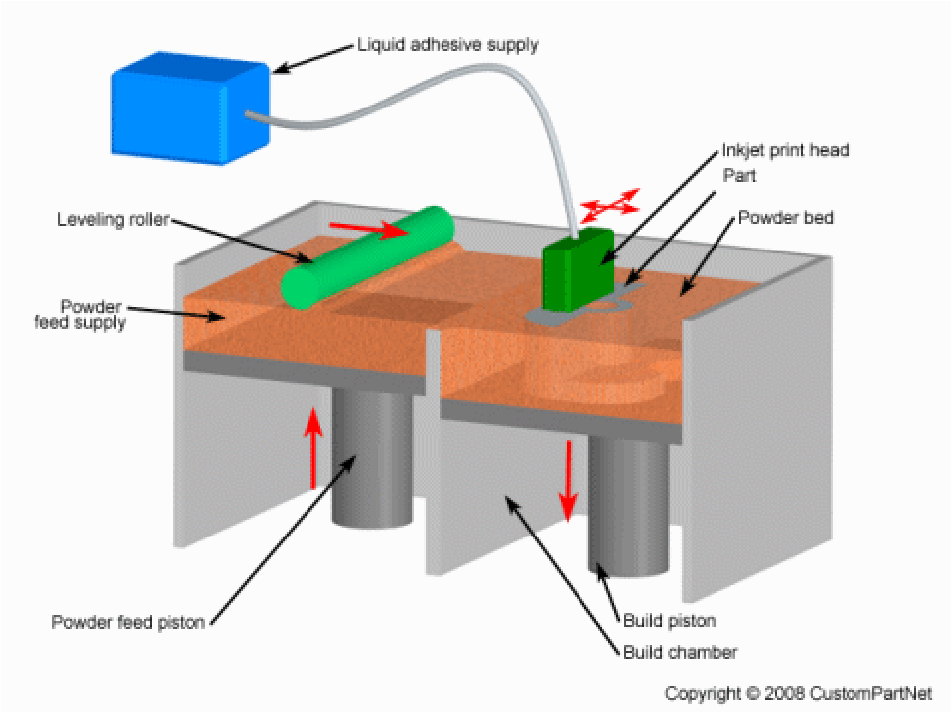


Figure 2.12: Binder Jetting. Reproduced from CustomPartNet (n.d.a).

Laminated Object Manufacturing - LOM

Two spools advances an adhesive-coated sheet over a build platform and a heated roller applies pressure to bond the sheet to the layer below. At last, a laser cuts the outline of the part in each sheet layer. CustomPartNet (n.d.*e*).

Advantages: easily controllable, inexpensive, little shrinkage, low residual stresses, recyclable material

Disadvantages: hard to achieve high accuracy in cutting, inhomogeneous material properties, a lot of material wasted compared to used material

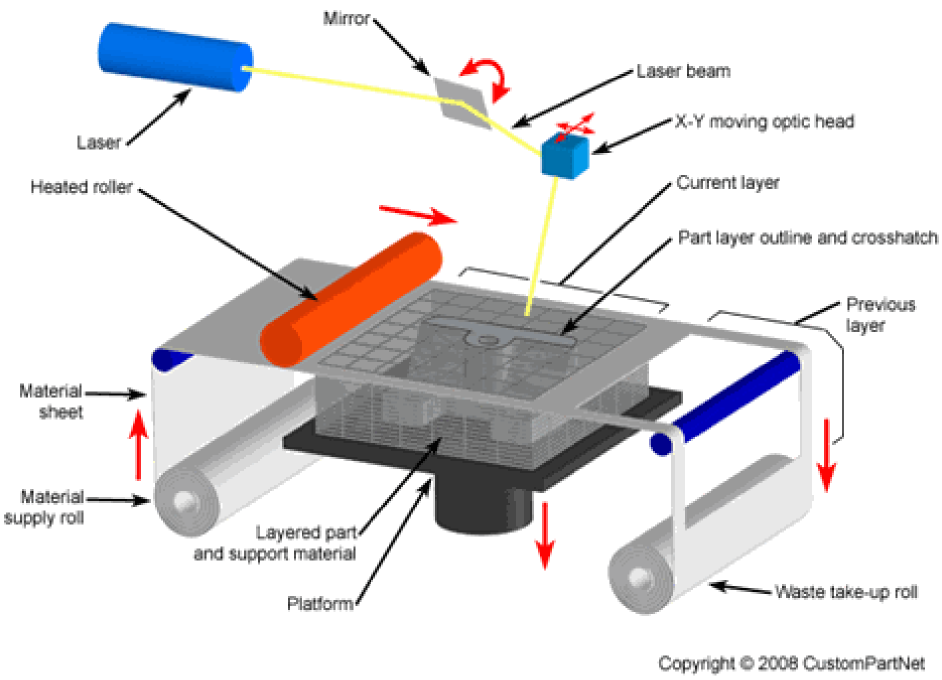


Figure 2.13: Laminated Object Manufacturing. Reproduced from CustomPartNet (n.d.e).

Powder Bed Fusion

Powder Bed Fusion (PBF) technologies produce a solid part using a thermal source that induces fusion (sintering or melting) between the particles of a plastic or metal powder. Sintering is the fusion of a solid mass by heat or pressure below the melting point. (Redwood (2018*a*), CustomPartNet (n.d.*f*)).

- **SLS:** Selective Laser Sintering production starts with spreading powder over the build platform. The cross section of the part is scanned and sintered by a laser. The build plate is lowered and then new powder is spread again.
- **SLM and DMLS:** Selective Laser Melting or Direct Metal Laser Sintering produce parts similar to SLS. The difference is that this process is used to melt metal powder. SLM fully melts the powder, but DMLS heats the powder near melting temperature until fusion occurs.
- **EBM:** Electron Beam Melting uses high energy beam rather than a laser. The cross sectional area gets beamed, causing localized melting and solidification
- **MJF:** Multi Jet Fusion is a combination of SLS and Material Jetting.

> An inkjet deposits fusing agent on the plastic powder. At the same time, a detailing agent which inhibits sintering, is deposited near the edge of the part. A high power IR energy source passes over the build plate and sinters the area with the fusing agent and leaves the rest of the powder untouched.

Advantages: can print metal, SLS/EBM do not need support, high strength, smooth finish if post processed

Disadvantages: powder needs to be removed, SLM/DMLS needs support structure, EBM require conductive materials and can only be produced in vacuum, internal porosity, rough surface

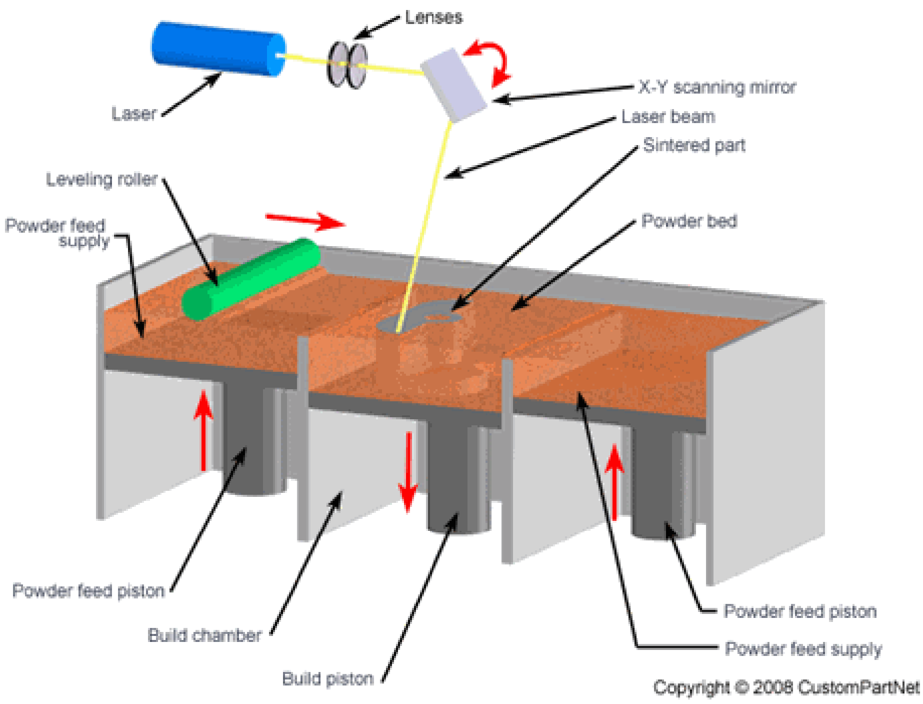


Figure 2.14: Selective Laser Sintering. Reproduced from CustomPartNet (n.d.f).

Direct Energy Deposition

Also known as Direct Metal Laser Sintering (DMLS). The parts are created by melting powder material as it is deposited or by having a powder bed such as binder jetting as shown in figure 2.12. The main difference is that a laser is used instead of a binder. (Redwood (2018*a*), CustomPartNet (n.d.*b*))

- **LENS:** Laser Engineered Net Shape uses a deposition-head which consists of three elements, a powder dispenser, laser and inert gas tubing. This may remind of the Metal Powder Welding technique.
- **EBAM:** Electron Beam Additive Manufacture uses metal powder or wire and gets welded together using electron beam as a heat source.

Advantages: suited for repairing other components, can print with metal

Disadvantages: low surface finish, not suited for producing parts from scratch

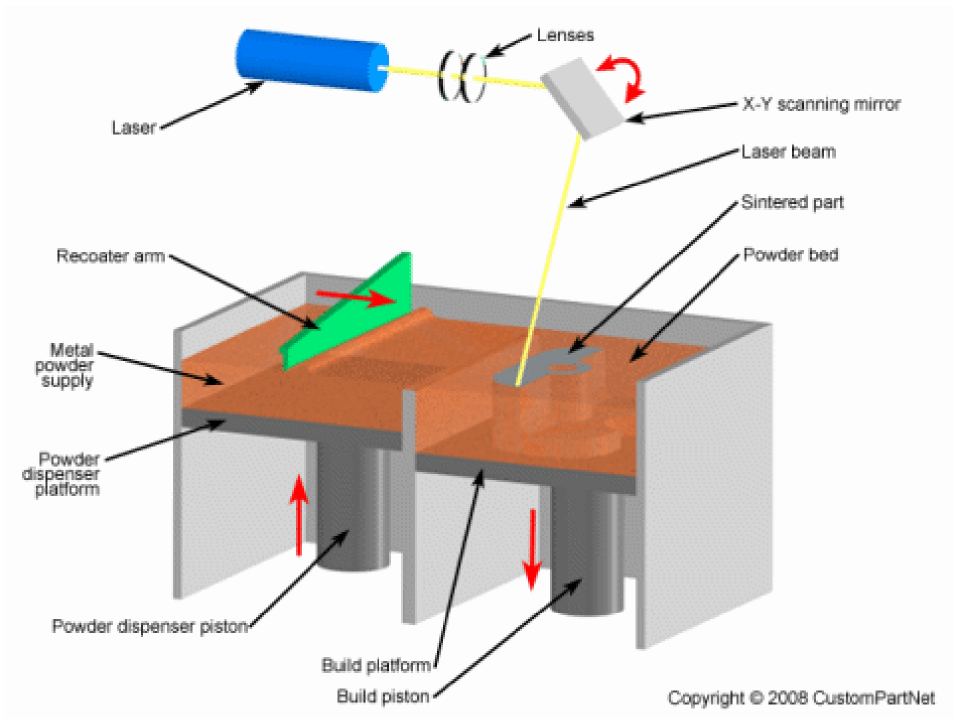


Figure 2.15: Selective Laser Sintering. Reproduced from CustomPartNet (n.d.b).

2.5 Product Development Methodology

2.5.1 Design Thinking Methodology - Main

The main product development (PD) methodology used in this project is the DT methodology. It is a design methodology that provides a solution-based approach to solving problems. It is useful for finding solutions for problems that are ill-defined, by understanding the human-needs involved. It is also known as a hands-on approach using prototyping and testing. There are various versions of the DT model in use, but in this project the five-stage model proposed by the Hasso-Plattner, Institute of Design at Stanford (d.school) is chosen. The five stages consists of (Dam & Siang (2018), Platner (n.d.)):

1. Empathize
2. Define
3. Ideate
4. Prototype
5. Test

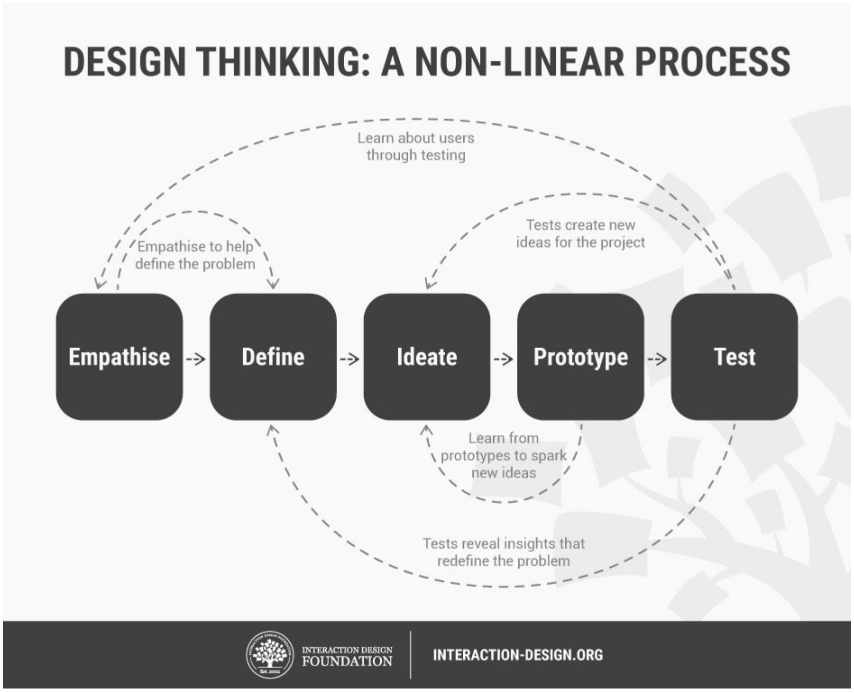


Figure 2.16: Design Thinking: A Non-Linear Process. The illustration is reproduced from Dam & Siang (2018).

2.5.2 IPM - Methodology

The second product development methodology, which partially used in this project, is called the IPM -model (Institute of Product development and Materials), which is a methodology taught at the Department of Mechanical and Industrial Engineering in NTNU. The IPM-model is a milestone oriented process which is divided into five phases:

1. Vision

2. Need finding - and Technology Analysis
3. Concept Development
4. Structure and design
5. Production Preparation

The details of the product is gradually increased from demands by the market. Each phase is closed with a milestone where final decisions for the phase are decided. It is important to use sufficient time and effort in the second phase to avoid complications in further development. In this project, it is mainly focused on the first three phases. The last phase consists of establishing tolerances, type of fits, surface finish, cost calculations and documentation acquisition. This will be something to consider if the company is satisfied with the final solution. (Grave 2013, p. 113).

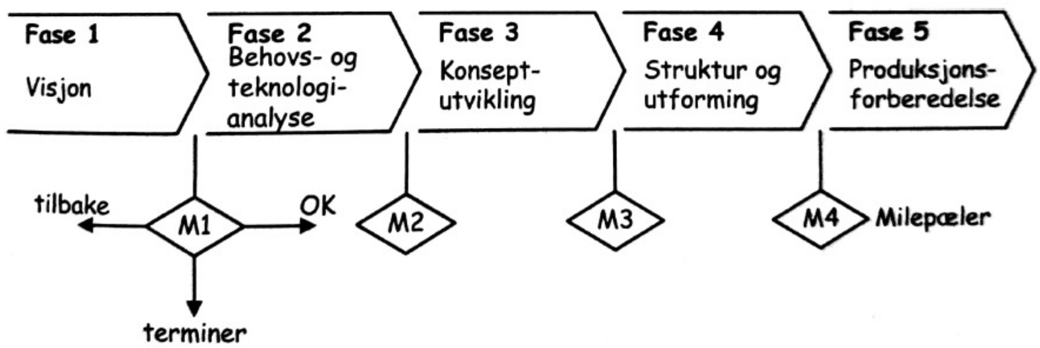


Figure 2.17: The IPM-model. The illustration is reproduced from (Grave 2013, p. 113).

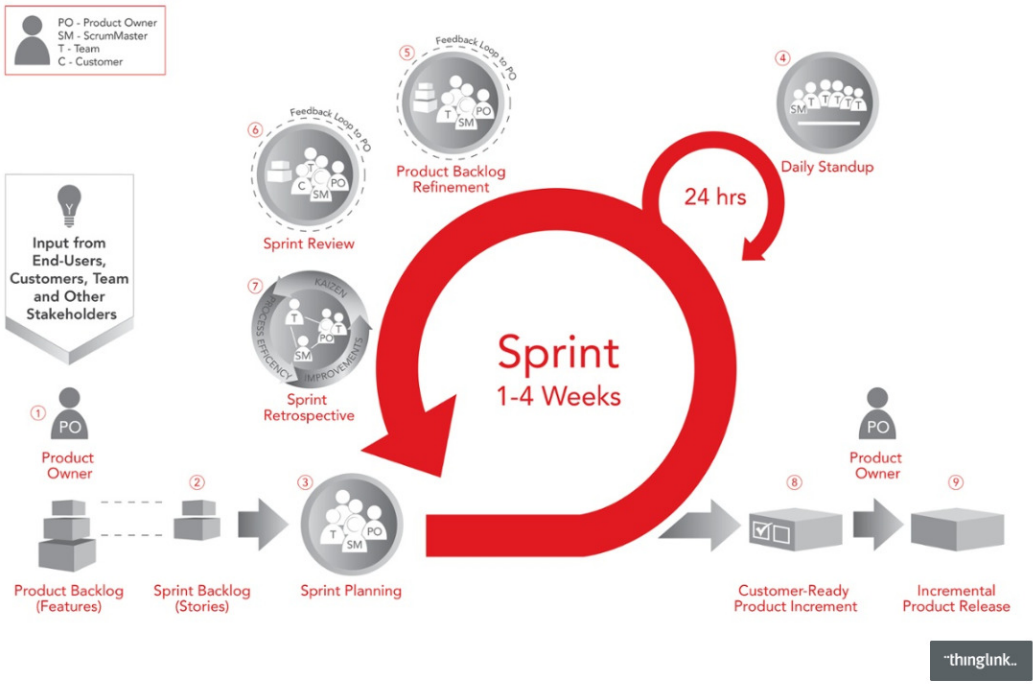
2.5.3 Scrum

Scrum is not a PD methodology, but a framework. This framework focuses on decision making from real-world results rather than speculations. It was used to regularly push the project in the correct direction. The development time is divided into time intervals, called sprints. For this project, each sprint was approximately two weeks long, where at the end of each sprint, a counseling-meeting took place with the supervisor. During this meeting, the current status of the project was presented and the next steps of the process was planned. Scrum consists of a simple set of roles, responsibilities, and meetings that never change. This helps removing unnecessary unpredictability that can occur in continuous discovery and learning. Scrum consists of three roles(Scrum Methodology (2018)):

- **Product Owner**: The product owner is a person with authority and availability. It is important that the vision and priorities are continuously communicated with the team. In this project, the supervisor from TOV is considered as the product owner
- **Scrum Master:** The scrum master acts as a facilitator for the product owner and the team. The scrum master should also remove obstacles that are limiting the team from reaching the sprint goals. The supervisors from NTNU is considered to be the scrum master in this project.
- **Team:** The team is responsible for developing the product. The team should be self managing and self organizing to complete work. In this case, the student is considered as the team.

Scrum Board

A Scrum Board is a tool to help the team to get an overview of the tasks that needs to be completed for the sprint. The board is traditionally divided into three categories, such as To Do, Work in Progress and Done. The board, in this case, is a physical one as shown in figure 2.18b, but it can also be a virtual one. During a sprint planning, the team writes tasks on post-it notes and decide which items they would like to complete and then move it into the Work in Progress column. When the task is finished, it is moved to Done. Scrum Inc. (2018).



(a) Scrum Framework.

(b) The Scrum Board used for this certain project.

Figure 2.18: The Scrum Process. Illustration 2.18a is reproduced from Scrum Inc. (2018).

2.5.4 A New Tailor-Made Methodology

DT methodology is all about making the process one's own. Some parts of the Scrum framework and IPM methodology are included. Experience has shown which parts of the framework and the methodologies works and which parts does not. For example, the milestones from the IPM-model are removed and the structure phase comes very late in the development phase. Only the sprints and the Scrum board are included from the Scrum framework. Not all typical DT techniques are used during the process either. The following chapters shows how the methodologies are fused into a new-tailor made methodology in this project which works for the designer.

3 | Product Development

3.1 Empathize

The Emapthize mode is one the most important stages in the design process. It is the work where one tries to understand people and the problem. It is important to engage and try to find out the way things are done and why. This is important because the insights are hard to recognize and the best insights will help create the best solutions. By observing and interacting in the environment of the problem, people share their thoughts and values that can reveal unanticipated insights. Building on the comprehension of these insights, can result in good designs. To empathize one can do observations, interview in form of a conversation, watch and listen. The Vision and Need Finding phases from the IPM model is included in the empathize phase. (Platner n.d., p. 2).

3.1.1 Vision

The vision is known the initial and fundamental idea for the project. The fundamental idea of this project was to develop a satisfying and functioning individual insole which is 3D printed. The mission was to make a product with the same behavior as the existing insole and make it applicable for the user.

3.1.2 End user

Idealistically, it would have been beneficial to get a patient perspective, but in practice it would have been a time consuming, hard and comprehensive task. The reason for this, is that patients who come to the orthopedic workshop have different diagnoses, challenges, functional loss and their own demands for the function of the insoles. For example, diabetes patients with peripheral neuropathy often have weakness, numbness and pain in their feet. It can get ulcerated and it would therefore be a high priority to pressure discharge this area. On the other hand, a patient with neuropathy would not be able to say anything about how the insole actually feels because of the numbness. Mayo

Clinic (n.d.).

Some patients focus on the function of the sole, others focus on the insole not occupying too much space. Some insoles need to be soft to discharge pressure and other insoles need to be stiff to correct. Insoles differ in shape and size, depending on if they shall be used in sandals, formal shoes, jogging shoes or bicycle/ski shoes. It is also a difference in the insoles depending on children, active adults (playing fotball, ski, bicycle, running, dancing), elderly who uses rollator, persons with poor vision or dementia. At TOV, there mostly are patients that have been satisfied in many years, but there also are some patients that are still looking for a good product. Since it is a broad specter of the patient-population, it would be more beneficial to talk to a specialist in the beginning of the development. Patient tests can be executed later in the development as solutions start to take shape.

3.1.3 Observe, Engage, Watch and Listen - Current Process

There are two types of processes when making individual insoles. One is executed manually by vacuum production and the other one is by automated milling. Bjørn Isaksen, a technician at TOV, walked trough the process and explained while making an insole.

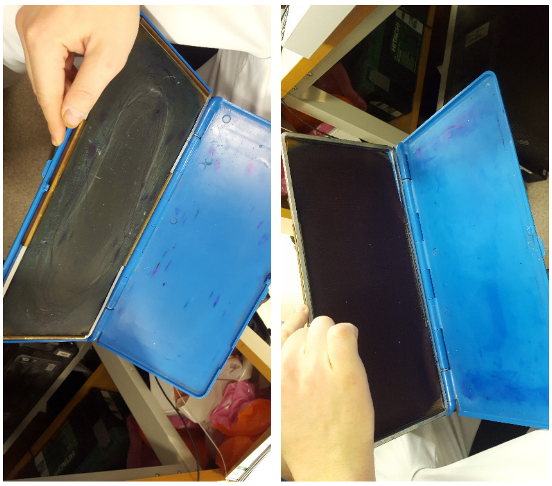
Production by Vacuum Forming

Vacuum forming production is only ten percent of the total production of individual insoles.The process starts when the patient is called in for an appointment. It is made an imprint of the patient's foot in copyfoam as shown in figure 3.1. Imprint can also be taken by using a carbon copy imprint as shown in figure 3.2, where the foot is pressed against a paper sheet with an ink-plate between, or a 3D scanner can be used to scan the foot directly. This is to duplicate the shape of the foot in order to make a 3D-model, see fig. 3.6. The next step is to smoothen the edges of the foam with e.g. a spoon as shown in figure 3.1c.

Further, the foam with the imprint is used as a mold. It is filled with plaster and left to dry. The dried plaster is taken out of the mold and is carefully grinded to smoothen the edges as shown in figure 3.3. This process is the most time consuming one. At last, the materials are chosen according to the patient's needs. It is placed layer by layer on the dried plaster, heated to attach the materials together and vacuum formed with the vacuum forming machine shown in figure 3.4. This process takes approximately one hour of labor. The vacuum forming process is used to make more complex insoles for patients with special needs.

(a) (b) (c)

Figure 3.1: A foot-imprint made in copyfoam.



(a) (b)

Figure 3.2: Carbon copy imprint.

Figure 3.3: Plaster grinding.

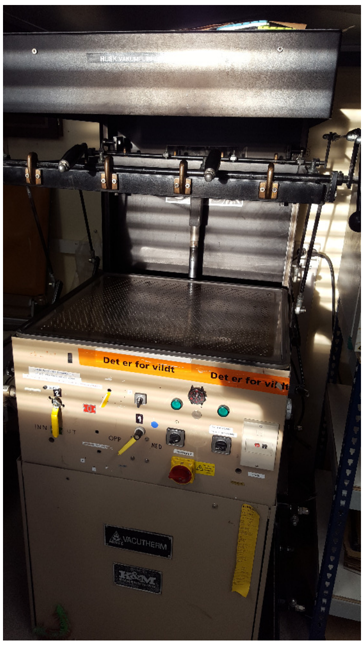
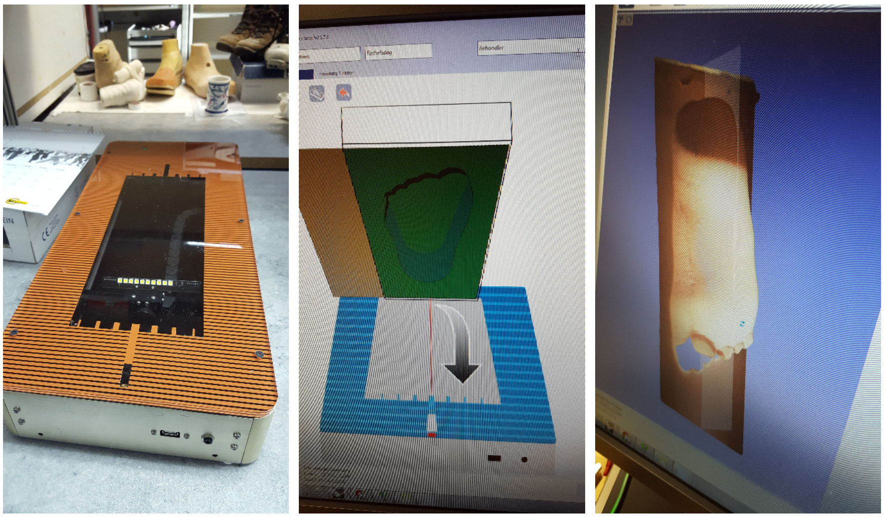


Figure 3.4: The vacuum forming machine used at TOV.

Production by Milling

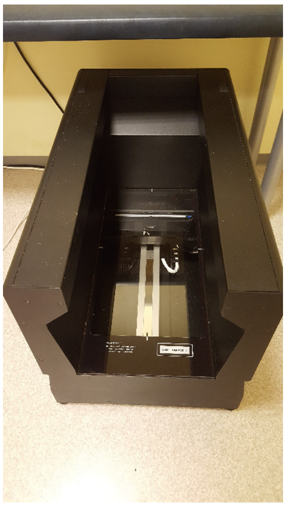
The milling process is ninety percent of the total production of individual insoles. The start of the process is the same as for vacuum forming except the use of plaster. The foam is 3D-scanned with the *LSR 3D Laser Foot Scanner* as shown in figure 3.5. After the imprint is 3D-scanned, the model is uploaded to the computer. The orthopedic workshop also have a more detailed 3D-scanner called *Foot-in-3D* as shown in figure 3.6, which scans the whole foot, including the ankle. This scanner is used for production of fitted footwear like shoes, sandals and for production of shoe molds, see figure 3.7.

The uploaded 3D-scan is opened in the *Ortowear* software, see figure 3.5c and then transferred to a software called *FootMILL*, see figure 3.8. This is a helpful tool to model the individual insoles in accordance to the 3D-scan. It is also possible to insert relieve points as shown in figure 3.8c and add support to make corrections for the foot. These corrections are decided by the orthopedic engineer. The new modeled insole is sent to the milling machine which holds its own software called *Paromed*. The engineer chooses a block of material with the most suitable hardness (A30, A40 or A50), see figure 3.9a and starts the automated milling process, as shown in figure 3.9b. One insole can also consist of different hardnesses, see figure 3.11. At last, the insoles are cut out of the block and grinded by a sander, see figure 3.9d, to fit the patient's shoes. The whole process takes approximately one hour, where the modeling takes 10 minutes, the milling takes 20 minutes and 30 minutes for residual work by engineer. It is made approximately 14 pairs of insoles per day.

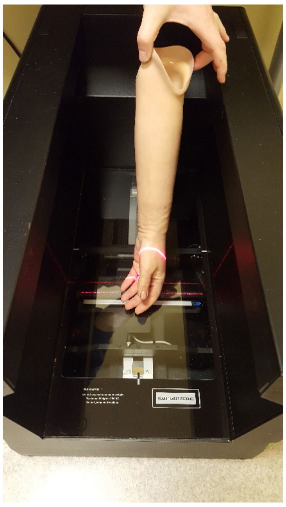


(a) (b) (c)

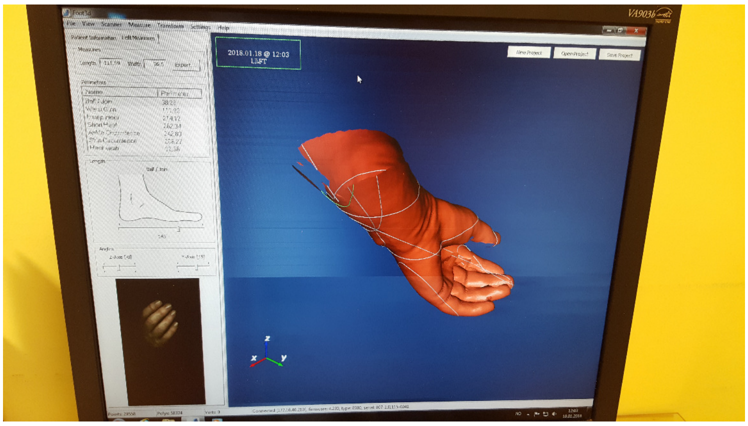
Figure 3.5: LSR 3D Laser Foot Scanning process.



(a)



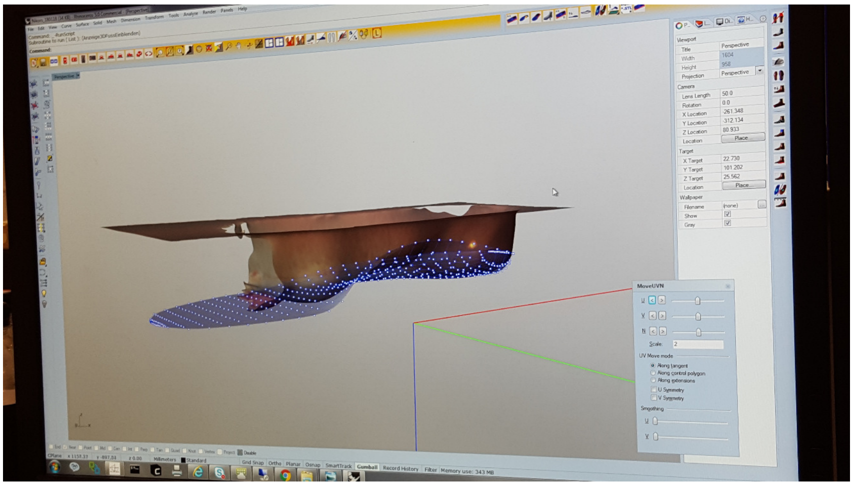
(b)



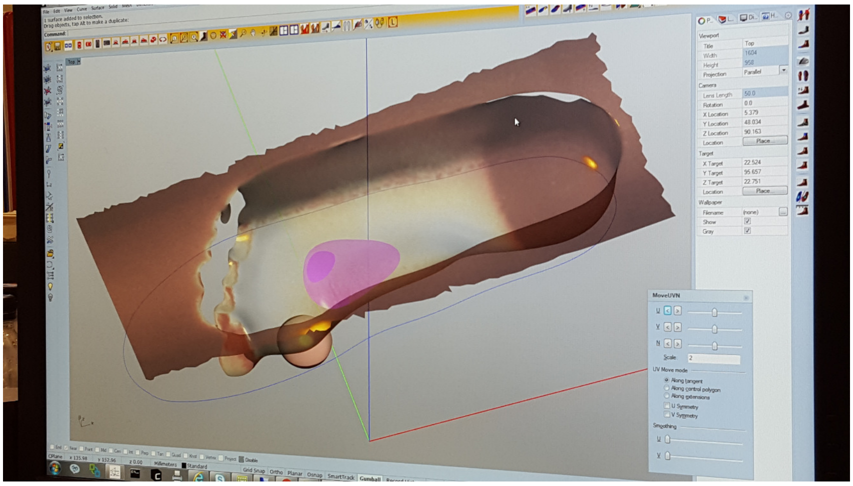
(c)

Figure 3.6: Foot-in-3D scanning process. A plastic hand was used to illustrate the process.

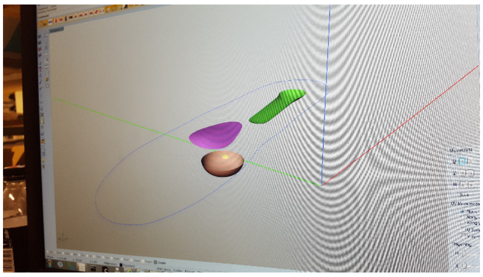
Figure 3.7: Shoe mold.



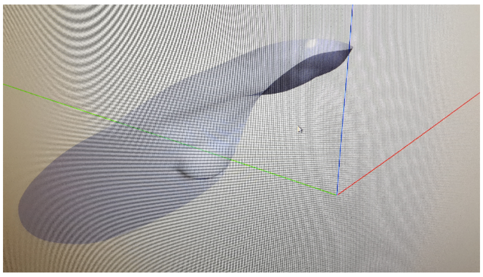
(a) Noumerous data points on the scanned imprint used to make a model of the insole.



(b)



(c) Relieve points.



(d) Relieve points in modeled insole.

Figure 3.8: FootMILL.

(a) Blocks of material with different hardness (A30, A40 or A50).

(b) Milling of insoles.

(c) Result after milling is finished.

(d) Grinding.

Figure 3.9: The milling process.

Figure 3.10: Material waste.

Figure 3.11: An insole with different hardnesses.

Advantages of the Current Process

The advantages of the current production is that the process is relatively quick when patient is present. After the 3D-scanning is completed, the computer-modeling of the insoles are not that time consuming as one would consider. This is due to the repetition of work which makes the experienced engineer work even faster for each insoles that is modeled. Another advantage is that the insoles are customizable according to the patient's needs. There also are a lot of varieties in materials with different hardness, colors, shapes and brands.

Disadvantages of the Current Process

One of the disadvantages in production of individual insoles is that there is time wasted on waiting in each step of the process. Since there are multiple steps, added up, it can result in many hours. The employees also need to adapt to several softwares for each step. This can increase chances of making errors along the process.

The most important disadvantage, when it concerns 3D-printing, are the huge amount of material that goes to waste. Almost 30-40 percent of the material is considered as waste. There is also need for some post processing and grinding after milling, and the accuracy of the grinding gets as good as the skills of the engineer. The patient also have to come back to get the insoles fitted to the shoes. If the shoe's dimensions are known, the insoles can be sent by mail directly to the patient's house. Another important aspect is that even though there are a lot of varieties in the materials, it also makes it difficult for the engineer to choose the correct material. As the number of varieties increases, so does the complexity.

3.2 Define

The Define mode is about bringing clarity and focus to the design space. It is about making sense of all the information learned from the Empathize mode. The goal is to define a meaningful and actionable problem statement based on insights and needs. Narrowing down the problem yield greater quantity and higher quality solutions when generating ideas. The scrum board was also used to synthesize the scatter information and select which tasks that were important to proceed with. The problem statement results in a point-of-view (POV) which should be the guidelines for Ideation mode. A POV can be articulated by focusing on the three elements: user, needs and insights. (Platner n.d., p. 3).

A good POV is one that:

- Provides focus and frames the problem
- Inspires the team

- Informs criteria for evaluating competing ideas
- Empowers the team to make decisions independently in parallel
- Captures the hearts and minds of people one meets
- Saves oneself from the impossible task of developing concepts that are all things to all people (i.e. the problem statement should be discrete, not broad.)

3.2.1 Main Take Aways

From the empathize phase, it was learned that vacuum produced individual insoles are more customized. It requires different materials and most importantly is time consuming to produce. It is therefore the main area of focus since it has greatest potential concerning 3D-printing. 3D printing makes it easier to produce insoles for specific shoes and makes it easier and cheaper to produce two mirrored insoles. The existing model for the insoles can also be adapted easily for other types of shoes by making changes in a software.

3.2.2 User-Need-Insight

Table 3.1: Defining point-of-view

User	Need	Insight
Technician who works at an orthopedic workshop	To make customized individual insoles in shorter time	The user wants to produce customized insoles faster and easier as it takes too much of the user's time to make one insole. On the same amount of time, the user could have made more insoles with the milling process. The main reason for faster production, is so more insoles can be made per day so the end user can start using the insoles earlier and perhaps prevent more damage

POV: The TOV technician *needs* insoles faster *because* it is important that the end user starts using the insoles as fast as possible.

3.3 Ideate

The main goal in the Ideate mode is idea generation. It can be compared to the Concept development phase in the IPM model. It is about pushing for a widest possible range of ideas that can be selected and not about finding the best solution. This will be found in the Testing mode. Ideation techniques can be brainstorming, adding constraints, prototyping, bodystorming, mindmapping and sketching. Ideation is about separating idea generation and evaluation of the ideas. (Platner n.d., p. 4).

3.3.1 Idea Generation

With the information from the Empathize mode and by having a brainstorming session, it was concluded that time and work can be saved in two areas. One is the scanning process, the other is replacing the vacuum process.

Scanning

It is time consuming to make an imprint of the foot, fill it with plaster, waiting for it to dry and then grinding the plaster to shape it. It would be less time consuming and less work to 3D scan the foot and milling a shoe mold. Another suggestion can be to test 3D scanning applications for phones so the patient does not have to come all the way to the workshop. The patient can scan the foot at home and send the 3D model by email to the workshop.

3D printing

Time and work can also be saved by replacing the whole vacuum process with 3D printing.

3.4 Prototyping

The Prototype mode is the iterative generation of artifacts intended to answer questions that help getting closer to the final solution. A prototype can be anything that a user can interact with for example a wall of post-it notes, a gadget put together, a role-playing activity or a storyboard. Prototypes can help to ideate and problem-solve, to communicate, to start a conversation, to fail quickly and cheaply, to test possibilities, to manage the solution-building process. (Platner n.d., p. 5).

3.4.1 3D Printed Insoles

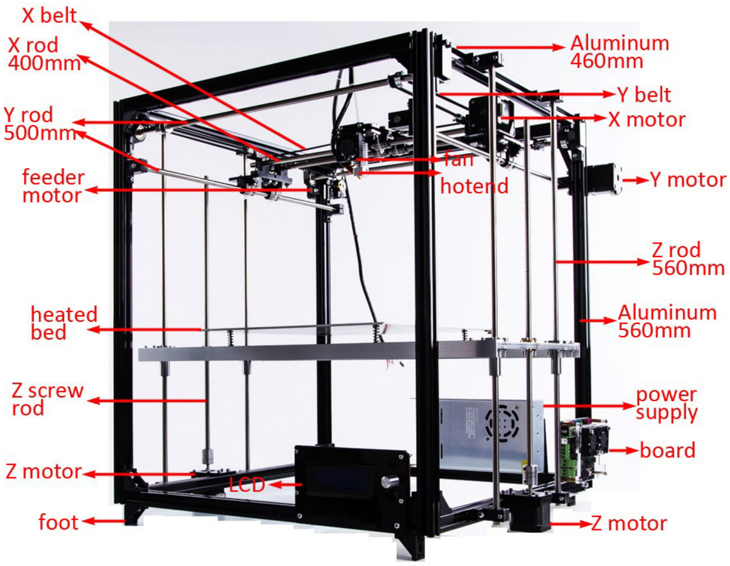
From the theory chapter it was learned that FDM-printers are the most inexpensive printers on the market. It was therefore decided to build this type of 3D printer from scratch. This was to get a proper understating of how 3D printers work and their structure. It will also give estimation of the time it takes to build and calibrate a printer. When it was ready for use, the 3D printer was applied for prototyping individual insoles.

Building a 3D Printer

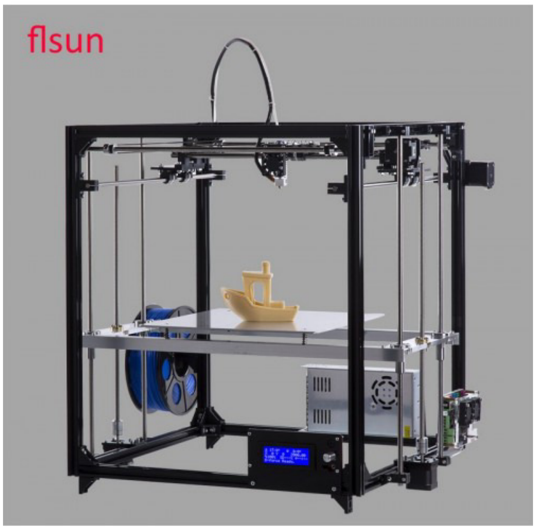
Parts for the 3D printer was ordered through FLSUN 3D. Building the 3D printer from scratch, gave an understanding of the structure and how a 3D printer consists of different modules like a frame, feeder, heated building platform etc., see fig. 3.12b. The printing area was 260x260x530 millimeters, which was larger than most FDM printers. The 3D printer was built following these steps:

1. Assembly of the frame
2. Assembly of X- and Y-axis
3. Assembly of the Z axis
4. Assembly of switches to let the printer know if feeder has reached the edges
5. Assembly of the feeder-motor
6. Mounting circuit board, LCD-screen and power supply on the frame
7. Connect the cables
8. Connect the printer to a computer and install the required softwares
9. Leveling the printer
10. Execute a test-print

(a) Parts for a 3D printer.



(b) Different modules in a 3D printer.

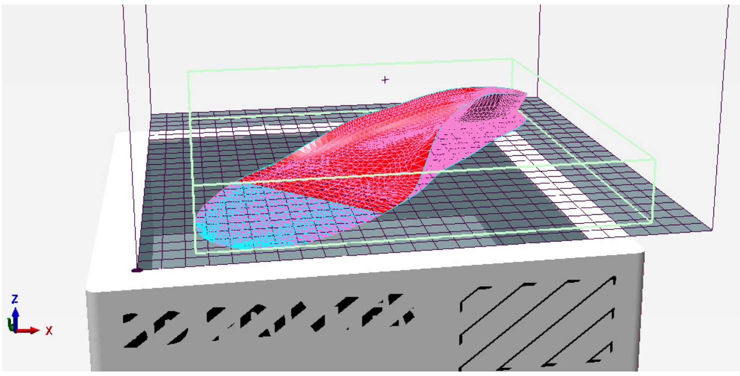


(c) 3D printer.

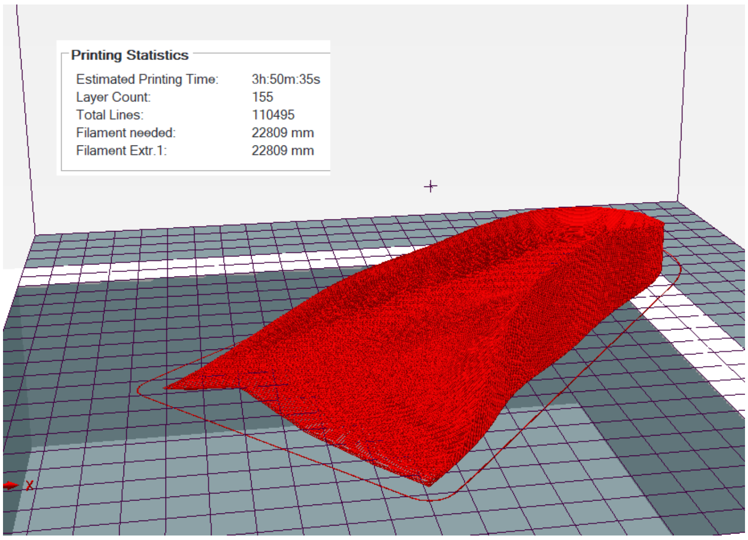
Figure 3.12: The FLSUN 3D Printer. Images are reproduced from FLSUN.

3D Printing an insole

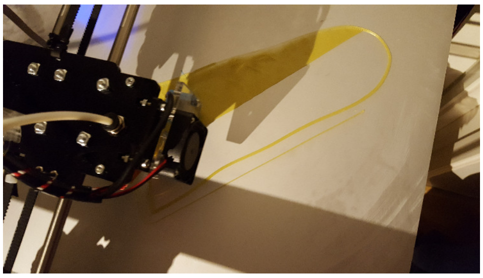
An STL-file from TOV of the insole was implemented in the Repetier-Host software to make a GCODE. This GCODE was then interpreted by the machine and printed into a sole, see figure 3.13b. PLA-filament, which came with the parts, was used as printing material. The insole was printed with a 0.4 mm nozzle diameter and 20 % infill. The front part of the sole was removed to fit the printer, but it was also insignificant for functional purposes as it was only 2 mm thick.



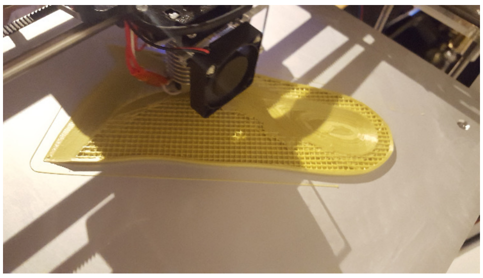
(a) STL-file implemented into the Repetier-Host software.



(b) The 3D model is sliced into a gcode which makes a path or the print head to move. Notice the printing time.

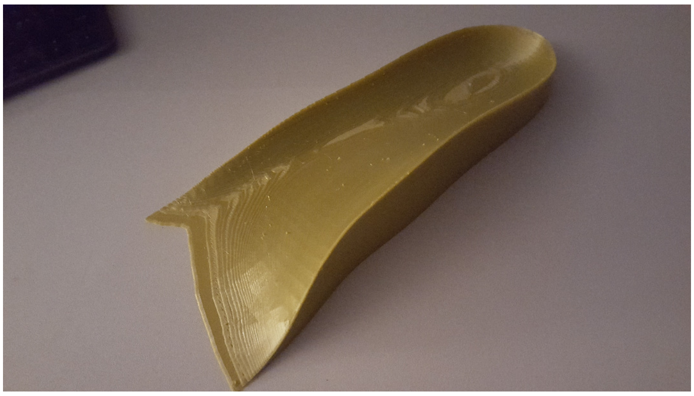


(c) First print of the insole.

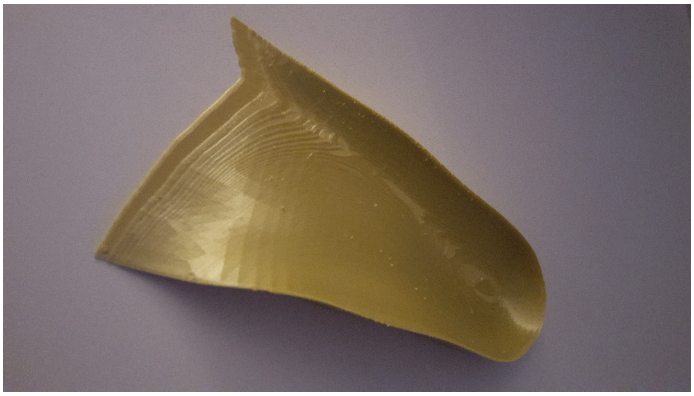


(d) Printing with 20 % infill and rectilinear infill structure.

Figure 3.13: 3D printing the PLA-insole.



(a)



(b)

Figure 3.14: The PLA-insole

3.5 Test

The Test mode is about soliciting feedback of created prototypes and gaining empathy for the user. It is important to not only focus on whether the prototypes are good or bad, but also asking why. By testing the prototypes in situ or by trying to make a realistic situation one can get proper feedback. Tests can help refining prototypes and solutions, learning more about the user and refining the POV. In this project, the prototypes were mostly tested by the supervisor, a technician at TOV and the designer. This is because the prototypes could be compared to the existing solution. (Platner n.d., p. 6).

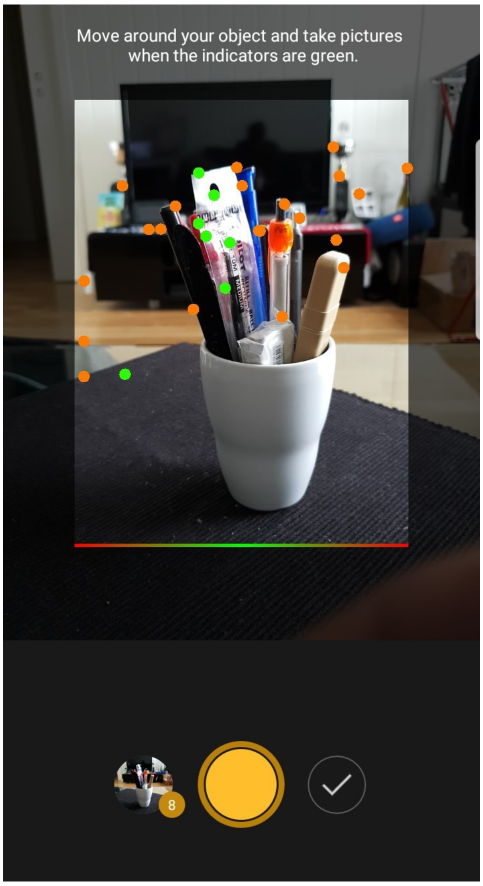
3.5.1 3D Scanning

Several 3D scanning applications like SCANN3D and Qlone were tested. Some 3D scanning applications did not even respond at all. The applications with the most potential were SCANN3D and Qlone. SCANN3D required minimum 20 images of the object, taken at different angles. After the images were taken, processing them to an object-file was time consuming. When testing, it took almost an hour. The result was not adequate to get a proper 3D model. It missed important edges and was hollow in specific areas. Qlone required a mat to place the object on. It took images automatically by moving the phone around the object. This was also time consuming and the result was not detailed enough. It also required payment to export the object. SCANN3D mentions some requirements which also Qlone required for making a proper 3D scan.

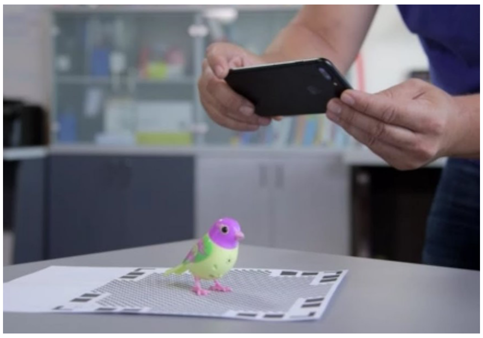
Requirements:

- Encircle the target
- Glue regions: make sure the each segment of the object is on at least two pictures
- Do not take pictures too far from the object
- Lighting: spotlights, hard shadows and uneven lighting give poor results
- Be mobile: the person needs to move around the object and not rotate the object itself
- The object should not move. The target must not be transparent, reflective, untextured or homogeneous as well.

As the requirements shows, there is a lot that needs to be taken into consideration when making a scan. It would therefore be more beneficial and time saving to perform a proper scan at the orthopedic workshop. A scan from an application also does not show the contours of the plantar surface and how the pressure distributes itself when foot is set on the ground.



(a) A screen shot of SCANN3D which focuses on specific data points when making a scan.



(b) A mat needs to be placed under object when using Qlone.

Figure 3.15: 3D scanning applications.

3.5.2 3D printed insoles

The PLA-insole was tested by comparing it to a milled individual insole. It was tested by feeling the texture with the hands. Testing was also executed with the foot by trying to step on the insoles, both with and without a shoe, as shown in figure 3.16e. It was concluded that the shape was good when comparing it to the individual insole, but the material was too stiff and may give blisters in long term use. The insoles also had no cushioning as well.

(a) Testing the insole.

(b)

(c)

(d) Comparing the printed insole with the current insole.

(e) The insole was also tested in a shoe.

Figure 3.16: The PLA-insole.

4 Iteration

Design thinking is a non-linear process, as shown in figure 2.16 on page 23. The methodology was practiced in a more flexible and nonlinear fashion. The five stages in DT are not always sequential and do not follow a specific order. Making the process one's own and adapting it to one's own style and work is important when it comes to the Design Thinking methodology. Dam & Siang (2018), (Platner n.d., p. 6).

4.1 Empathize

From the Testing mode it was found that additional time needs to be used in empathizing. Knowledge needs to be increased in areas concerning individual insoles and 3D printing as well.

4.1.1 Engage

An interview with Tobias Goihl, a development manager at TOV, was conducted to establish knowledge on the properties of a 3D printed insole. It was commented that sport shoes have limited amount of space and that an insole would need to be rigid. An insole that is grinded thin, would have little effect on the foot. Increasing knowledge about the diseases and anatomy of the foot could be beneficial. It was also found that 3D printing could be advantageous when it comes to the grinding process, since the 3D printer makes a ready to use product. It was also commented that an insole consists of both cushioning and stiffening parts. The main task, was to conduct a research on existing solutions to see what already exists on the market and what can be learned from these solutions.

4.1.2 State of the Art

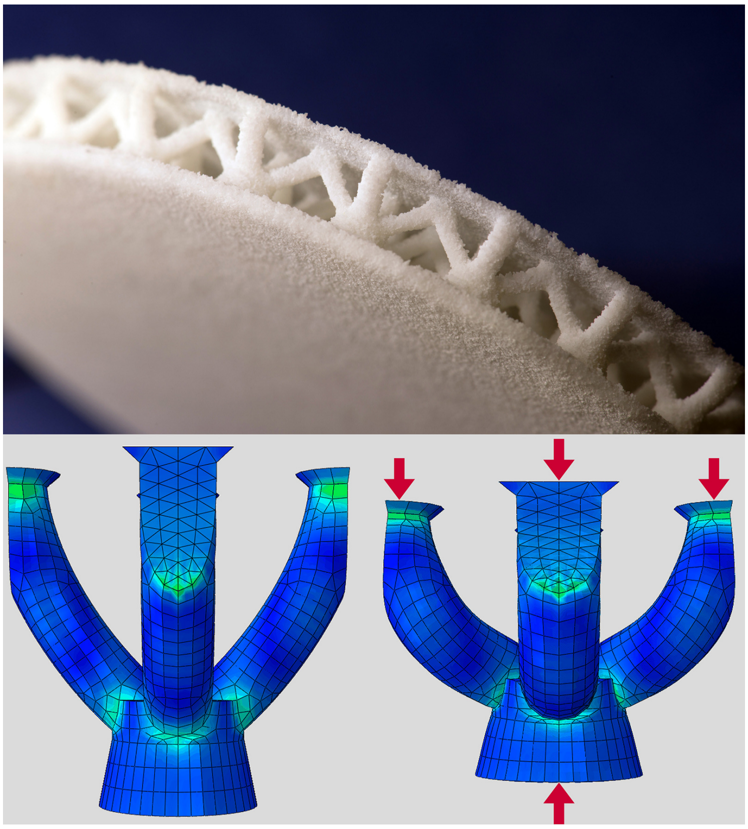
There already exists several solutions for 3D printed generic and individual insoles on the market. To find a sufficient and a good solution, it is important to make a thorough research of the existing solutions which was learned from the interview. This will help save time for further development and expand knowledge about the topic. Below are some solutions that has already been developed.

Fraunhofer-Gesellschaft

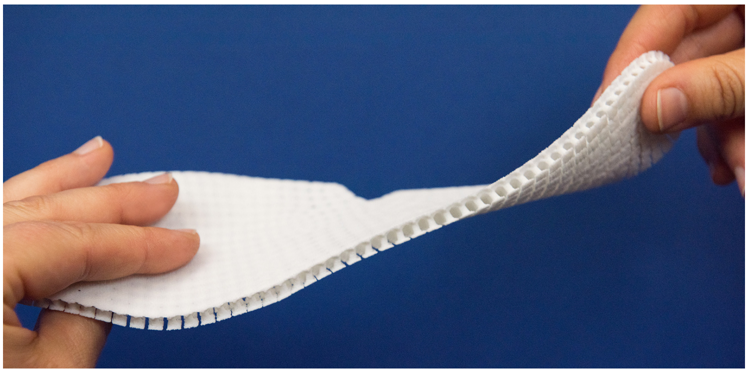
A research company from Munich has developed customized insoles for diabetes patients. LAUF is a funded project and is a German acronym which stands for laser-assisted construction of customized footwear. The production process begins with deciding the structure i.e. straight rods, crooked arms or triangles as shown in figure 4.1a. From these structures and the data for a particular material, a computer model is made. The materials' load-bearing strength and expected lifespan is tested in a simulation software in order to select the final structures. At last, the 3D printers print the insoles by selective laser sintering, as mentioned earlier in chapter 2. Fraunhofer Institute for Mechanics of Materials IWM (2016).

RSprint

A joint venture between Materialise and RSscan International in Belgium have started making 3D printed insoles through a set of processes. First, a dynamic gait scan is made by a specialist using footscan system from RSscan. The next step is to analyze the footprint and further, the specialist will decide where support is needed. A design is generated based on the specialist's feedback, which is then sent to RSprint. The design is 3D printed in powder form into a thin, lightweight and dynamic insole. The last step is a cushioning layer, glued on top of the insole to increase comfort.The 3D printed insoles from RSprint are called Phits. Takahara (2014), WSA (2014).



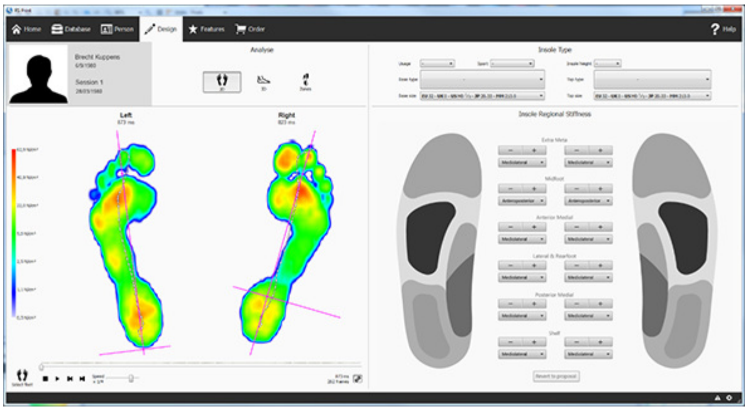
(a) 3D structures designed using CAD.



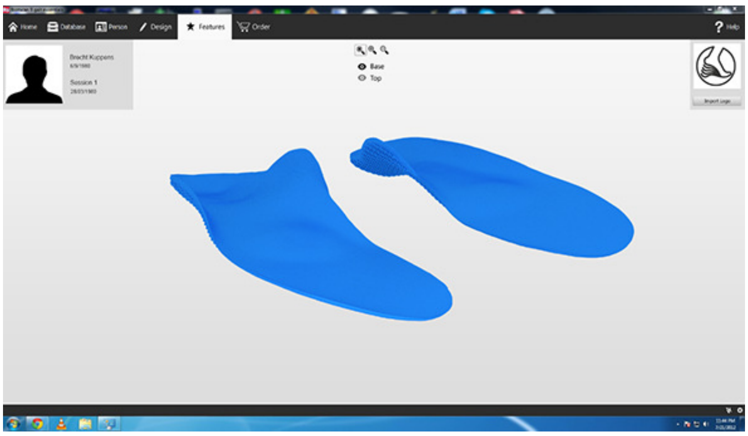
(b) Combination of different structures can give adjustable rigidity and flexibility.

Figure 4.1: 3D printed individual insoles from Fraunhofer. Reproduced from Fraunhofer Institute for Mechanics of Materials IWM (2016).

(a) RSscan's footscan system.



(b) Dynamic gait scan analysis.



(c) 3D model of insoles.

(d) 3D printed bottom layer and cushioning top layer.

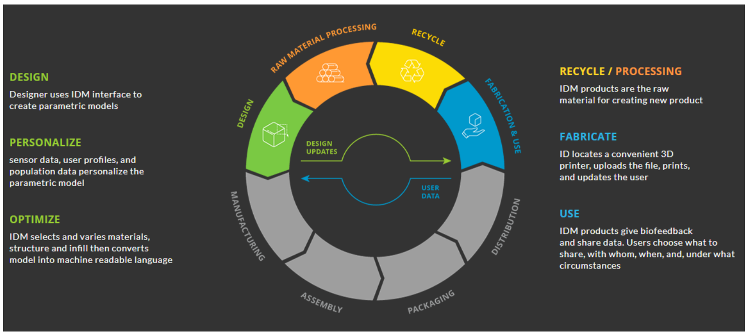
Figure 4.2: 3D printed insoles from RSprint. Reproduced from Takahara (2014) and WSA (2014).

Jumpstartcsr

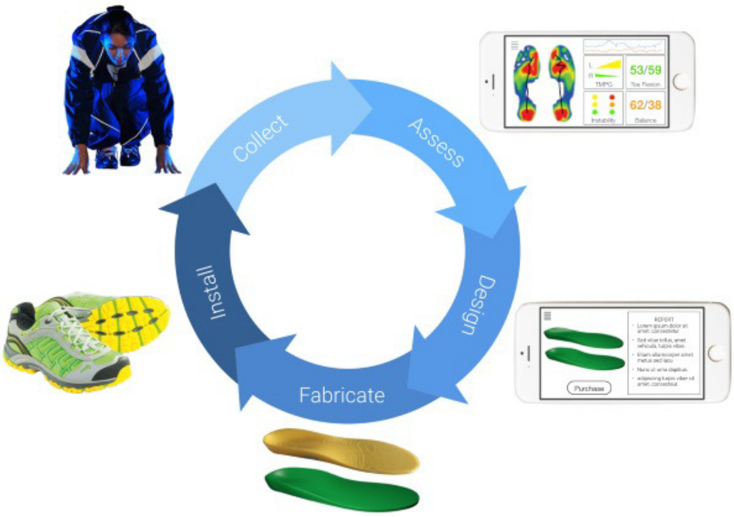
A startup in Seattle, US works with offering innovative solutions to treat and prevent musculoskeletal disorders (MSDs). The company is developing a cognitive expert system called IDM Perform, showed in figure 4.3a. This system collects and interprets data from several sources such as sensors, user and clinician input, electronic medical records, population health data, and radiological data to provide alerts, biofeedback, and actionable insights (JumpStartCSR (2018)). The data will help predict risks of musculoskeletal injuries such as falls and help people regain, maintain and improve their performance. These insights are then used to design and fabricate 3D printed personalized orthopedic devices. The development process is illustrated in figure 4.3b and 4.3c. JumpStartCSR (2018), Helsel (2016).

Shapecrunch

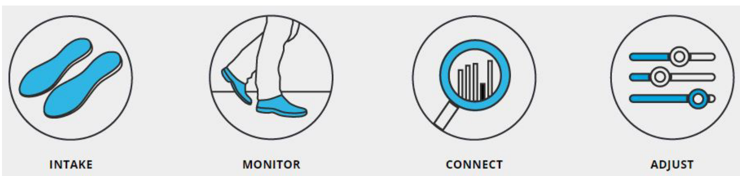
A Delhi-headquartered company is 3D printing orthotic insoles for patients suffering from diabetes, flat feet and plantar fasciitis. The process begins with downloading the Shapecrunch application which requires three pictures of each foot taken from three different angles as shown in figure 4.4a. The next step would be to select pain areas and pain intensity under and over the foot. Personal details such as weight, age and height are also filled in the application. At last, foot bio details such as activity level, purpose of the insole, shoe type and size are filled in. These details are evaluated and a 3D model with corrected properties is made. Shapecrunch uses FDM 3D-printing process and flexible material for making the insoles. The flexible material is a compound plastic, PLA, and rubber material which provides support and relief. The upper layer is made from Poron shown in image 4.4c, a breathable, shock-absorbing material which cushions the foot and has anti-microbial properties to keep feet feeling fresh and healthy. Shapecrunch (2018*a*), Shapecrunch (2018*b*), O'Neal (2018).



(a) The IDM (Intelligent Digital Materialization) Perform system.

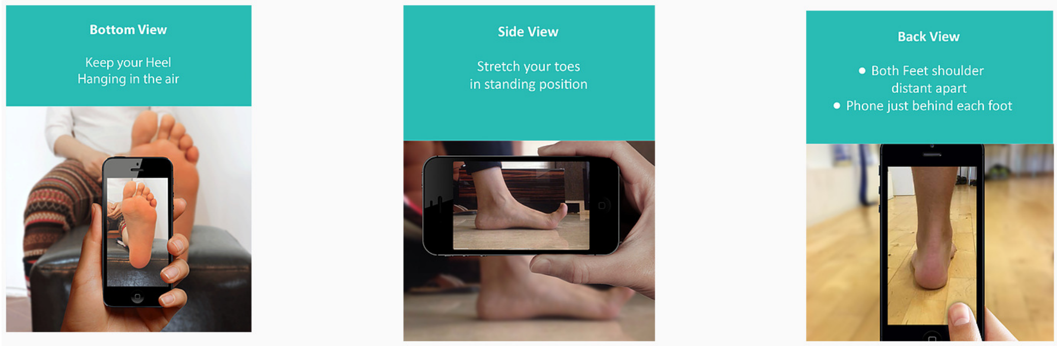


(b) The process starts with assessing the patient and intelligent insoles are designed and fabricated with sensors to collect data. Tess (2016*a*)



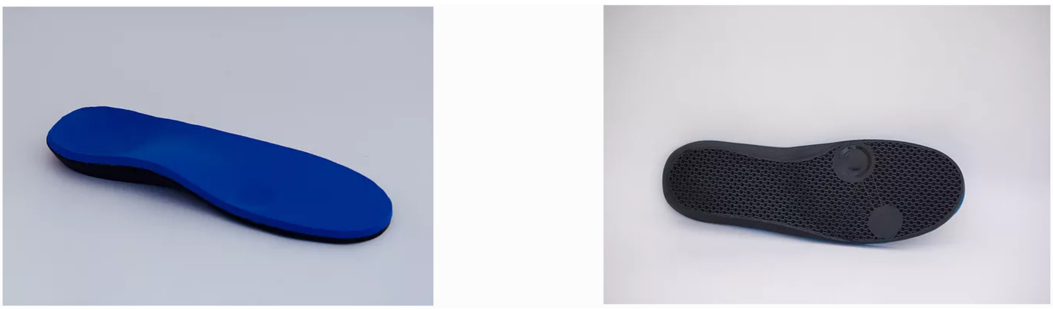
(c) After data is collected the patient's use is daily monitored. The patients stay updated by getting feedback from the insoles' sensors with an app. The collected data is then used to adjust and fabricate improved insoles. JumpStartCSR (2015*a*)

*Figure 4.3: The process of making Jumpstartcsr-insoles. The illustrations are reproduced from JumpStartCSR (2015*b*), Tess (2016*a*) and JumpStartCSR (2015*a*).*

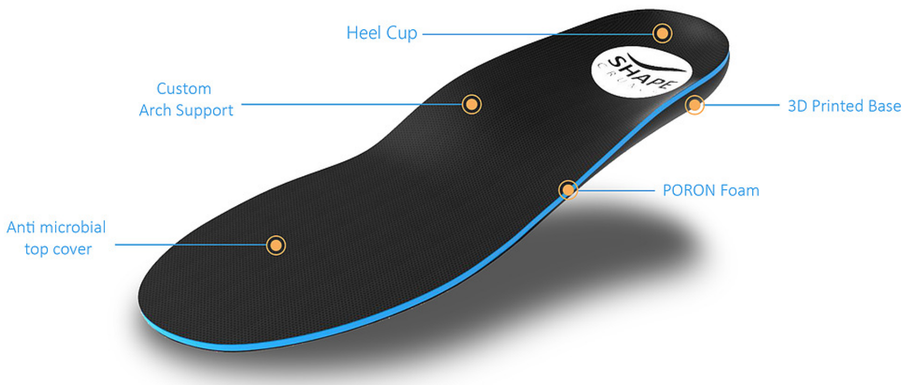


(a) Foot scanning in the Shapecrunch app.

(b) A custom insole is 3D modelled based on the foot bio info.



(c) Images of the 3D printed insole. The blue material, Poron, is visible on the image to the left.



(d) Structure of the insole.

Figure 4.4: 3D printed insoles from Shapecrunch. The illustrations are reproduced from Shapecrunch (2018a) and Shapecrunch (2018b).

Superfeet - ME3D

Brooks Running Company, from Seattle, is teaming up with HP and Superfeet to produce 3D printed insoles. A HP powered company, named Fitstation, is responsible for making 3D scan and pressure scan of the feet which is showed in figure 4.5b. In-depth analysis is used to detect a runner's motion path and create a unique digital profile that combines the user's biomechanics, experience and fit. The analysis is used to create a 3D model of the insole. Superfeet then manufactures the ME3D insoles using Multi Jet Fusion (MJF) 3D Printing technology from HP. Saunders (2017*b*), Goehrke (2017), Superfeet (2017).

Podfo

Peacocks Medical Group and Stratasys Direct Manufacturing joined together and founded Podfo with its headquarter in UK. Podfo introduced world's first 3D printed foot orthotics for more than three years ago. The company's process are quite similar to other the companies mentioned earlier. The process starts with a 3D scan taken directly of the patient's foot or scans of cast or impressions as seen on figure 4.6a. The plantar surface of the foot is 3D modeled. At last, the insoles are 3D printed by laser sintering technique. The material used is Nylon 11, which helps to keep the insoles thin, lightweight, flexible and highly durable. Saunders (2017*a*), Molitch-Hou (2014), Griffiths (2018), Benedict (2017).

(a) The process of making the ME3D insoles.

(b) Gait analysis for Fitstation.

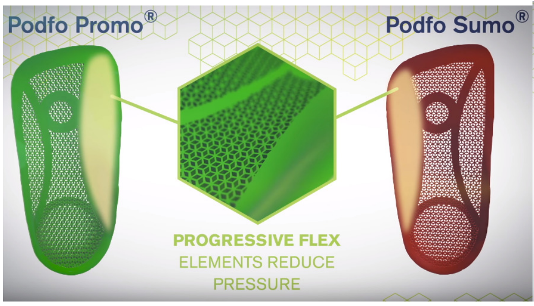
(c) Multi Jet Fusion 3D Printed insole.

(d) Foam is glued on the 3D printed insoles.

Figure 4.5: 3D printed insoles from Superfeet. The illustrations are reproduced from Goehrke (2017), Saunders (2017b) and Superfeet (2018).

(a) 3D scanning of foot.

(b) Analysis scan for finding patients' requirements.



(c) Flex elements to reduce pressure and resistance.

(d) Precise control and comfort for heel.

(e) Podfo - The 3D printed insole.

Figure 4.6: 3D printed insoles from Podfo. The illustrations are reproduced from Peacocks Medical Group (2016).

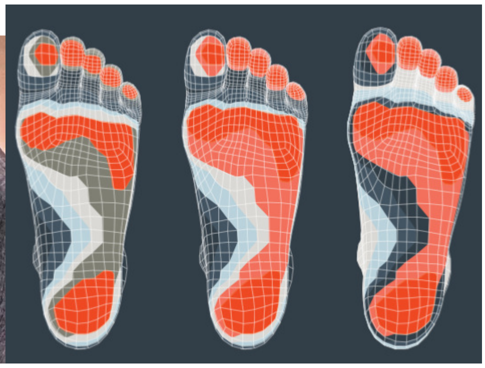
RESA

RESA, an Arizona based company, is cooperating with Shenzhen eSUN, a filament manufacturing company, to bring 3D printing of insoles in high street kiosks across China. The potential kiosk can be seen in figure 4.7c The idea is that a technician will help the customer to scan the feet with the RESA 3D gel scanner and capture accurate 360 degrees contours of the feet, showed in figure 4.7a and 4.7b. The next step is to design the shoes with the certified technician according to the customers' needs. Once the design is ready, the insoles will be 3D printed using FDM printing technique as mentioned earlier. Due to this type of printing, there are several print-specifications that can be changed to give the desired properties. For example, fine tuning layers, changing infill densities and machine settings to create the thickness and overall durability of the soles. The total printing time is estimated to be between 50 to 75 minutes. The last steps are gluing top covers and laser cut to ensure an even cut around the insoles. Scott (2017), Jackson (2017), RESA (2017).

Wiivv

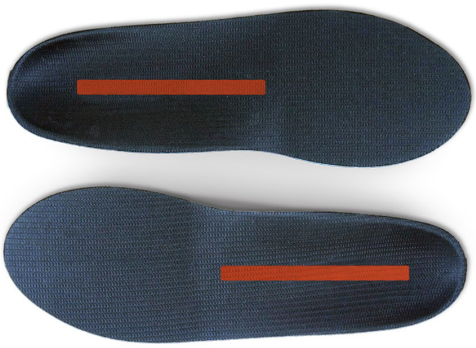
Wiivv is a startup company from Vancouver. This company also uses an app, like Shapecrunch, were the customer has to take pictures of the top of the feet, and the sides to see the arches as illustrated in figure 4.8a. Once the images have been taken, deep learning technologies is used to map each of the unique feet to over 200 points. Biomechanic enhancements are made after identifying foot pathologies like flat feet with the biomechanic filters. Figure 4.8c shows that the next step is to convert the foot data into a 3D printable file. At last, the model is 3D printed using selective laser sintering technique with Nylon 12 material. Kingma (2016), 3D Systems (2018), Wheeler (2015), Wiivv (2018).

(a) Foot-hugging module which will be used to 3D scan.



(b) Analysis of the 3D scan to find pain points.

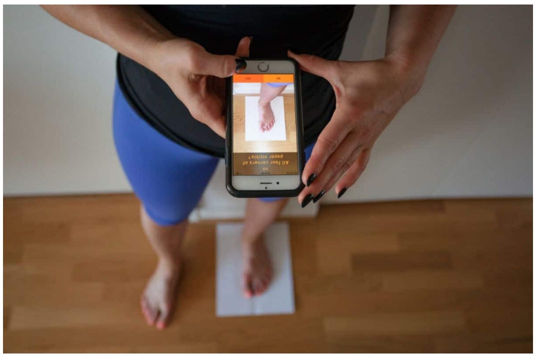
(c) RESA kiosk.



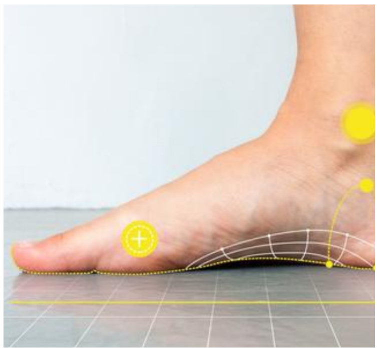
(d) The 3D printed insole with top cover.

(e) The insole displayed sideways.

Figure 4.7: 3D printed insoles from RESA. The illustrations are reproduced from Jackson (2017) and RESA (2017).

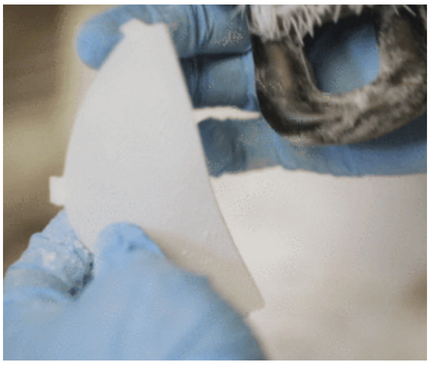


(a) 3D scanning of foot with the Wiivv App.

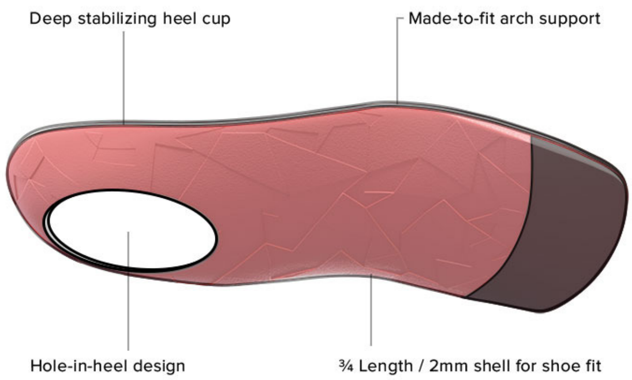


(b) Map each of the feet to over 200 data points.

(c) Converting foot data into a 3D file.



(d) SLS printing technique with Nylon 12 material.



(e) The features of the Wiivv's insole.

(f) Sideways image of the insole.

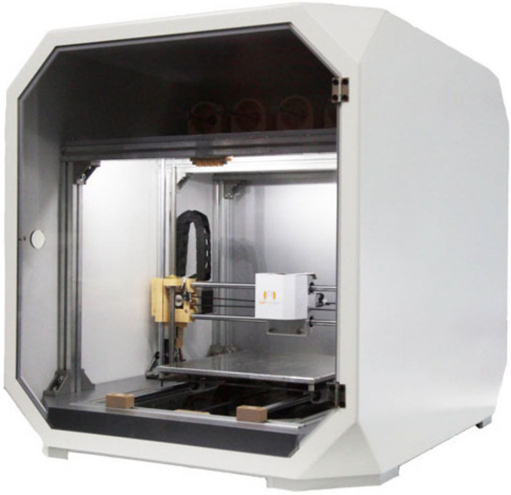
Figure 4.8: 3D printed insoles from Wiivv. The illustrations are reproduced from Kingma (2016), Wiivv (2018), Relentless Pursuit Partners (2018) and Wheeler (2015).

San Draw

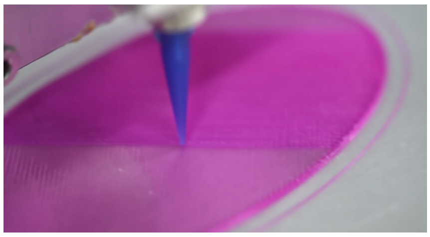
A group from Stanford University alumni have developed a Full-color, Adjustable hardness, and Multi-material (FAM) 3D printing technology. The printer is shown in figure 4.9a. What makes this product distinct, is that it is the first insole to be made of silicone and to offer adjustable hardnesses. The FAM 3D printing system works in such way that it draws from CMYK inkjet printing technologies for its multi-material capabilities. Silicone is solidified from a liquid to a solid and not melted, therefore the type of silicone can be adjusted during a single print which means different hardness can be achieved for the same print. The insole from San Draw are under development and are not commercially available yet. San Draw (2016), Tess (2016*b*).

Carbon

Addidas is currently developing midsoles using Carbon's Speedcell 3D printers which is illustrated in figure 4.10a and figure 4.10b. What is interesting to look at is the 3D printing method. Carbon uses Digital Light Synthesis (DLS) technique which was explained earlier. The advantage of this process is the printing speed, which is 25-100 times quicker than many other processes. The continuous printing procedure also gives isometric strength properties in the parts. It also make it possible to make complex components and due to this, it is possible to get high end components directly from the print as shown in figure 4.10c. The structure is different in the heel zone and forefoot zone to give changeable cushioning as needed for the different parts of the feet as shown in figure 4.10c and figure 4.10e. The material used is called EPU - Elastomeric Polyurethane which is highly elastic, tear resistant and resilient. This makes it perfect for achieving effects like cushioning, impact absorption and vibration isolation as shown in figure 4.10e. One downside is that the part needs cleaning after printing is finished. Carbon provides a machine named Smart Part Washer which cleans the components quickly. Molitch-Hou (2017*a*), Carbon (2018*b*), Carbon (2018*a*).



(a) The FAM 3D Printer.

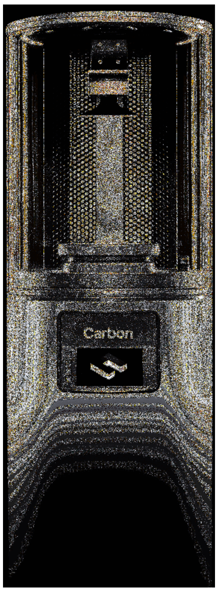


(b) 3D printing the insole.

(c) The silicone made insole from San Draw.

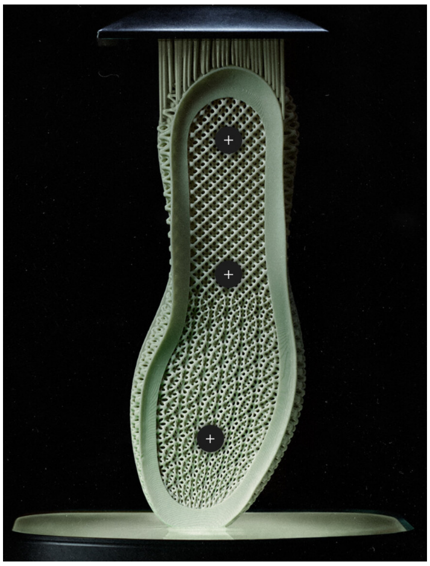
(d) The flexibility of the insole.

*Figure 4.9: 3D printed insoles from San Draw. The illustrations are reproduced from San Draw (2016) and Tess (2016*b*).*



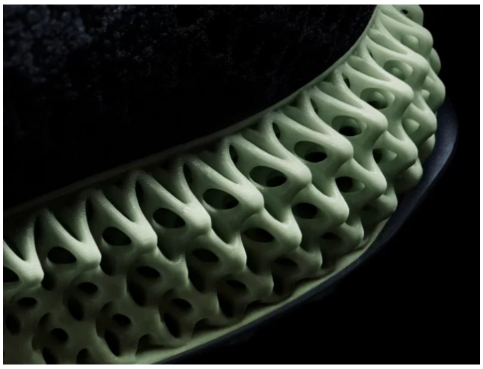
(a) The M2 SpeedCell 3D printer.

(b) The Smart Part Washer.



(c) The midsole printed using DLS, carved by light and oxygen.

(d) The Futurecraft 4D shoe.



(e) Close-up image of the structure.

*Figure 4.10: 3D printed midsoles from Carbon. The illustrations are reproduced from Molitch-Hou (2017*a*) and Carbon (2018*b*).*

4.2 Define

It was concluded that flexible materials, which give a cushioning effect in addition to the stiffening effect, needs to be tested.

4.2.1 User-Need-Insight

Table 4.1: Defining point-of-view

User	Need	Insight
Technician who works at an orthopedic workshop	To 3D print the insoles more similar to the existing insoles	The user wants to produce customized insoles that behave more like the existing ones.

The POV needs to be concretized:

POV: The TOV technician *needs* to 3D print insoles that behave like the existing ones *because* the insoles needs a cushioning and stiffening effect.

4.3 Ideate

There are numerous material types used for making insoles. Below, there are some examples of which type of materials that are used nowadays. (Aga 2012, p. 68-70).

- **Leather:** is often used as cover, a top layer. The material is environment friendly and not injurious to health.
- **Cork:** can be distinguished between nature-cork, press-cork and rubber/thermo-cork, which is a lightweight material. One has to find a balance between durability and weight when finding a suitable cork-material.
- **Thermoplastic plastic materials:** have different hardnesses, weights, porosities and shape abilities.
- **Soft insoles:** can be made by semi finished products. Must be used with supporting shoes. They are also shock-absorbent.
- **Hardened plastic:** rigid material used to correct.
- **Braced materials in plate-shape:** same purpose as hardened plastic.
- **Adhesive:** insoles are often made by several types of materials that need proper adhesive to hold the materials together for a long time.

These materials not are suited for 3D printing. The goal was to find a 3D printing material which holds most of the aforementioned properties.

Figure 4.11: Numerous materials at TOV just for the vacuum production section.

Even though it is almost impossible to make an insole that follows the hydrostatic principle, see page 12, orthopedic engineers have created some requirements for the material used for an insole ((Aga 2012, p. 23)):

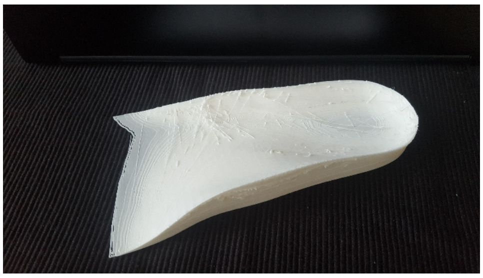
- Adapt to a prominent skeletal part without resistance.
- A fast recover to the original shape after compression.
- Have contact with as much surface as possible.
- Not give a "bottom out". Insoles that loose their elasticity, get thin and compressed. This means they have lost their characteristic properties.
- Relieve/inhibit shear stresses which arise during movement.
- Hygienic.
- Lightweight.
- Durable.
- Corrective.
- Shock absorbent.

There are several flexible materials for 3D printers which can cover most of the requirements. It was conducted a research of types of flexible material that exists for 3D printers which use FDM-technique. Cheetah, NinjaFlex, Armadillo and PrimaSELECT Flex are some of the most used 3D printing filaments on the market. The materials are Thermoplastic polyurethane (TPU) which holds properties like elasticity, transparency and resistance to oil, grease and abrasion. It was focused on testing materials with different shore hardness, which is a unit that expresses hardness in rubber-like materials. It can be distinguished between Shore A and Shore D. Shore A is used for soft rubber and Shore D is used for hard rubber. Before testing, the insoles needed to be printed. The material properties can be found in the Appendix .1. Store norske leksikon (2017).

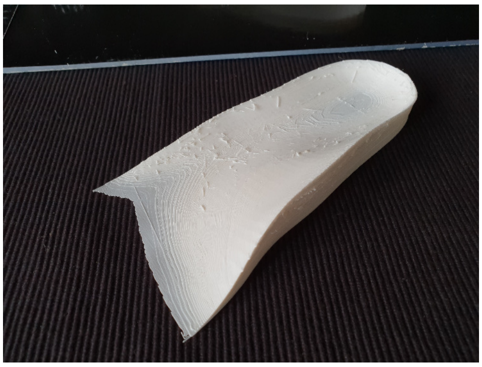
4.4 Prototype

The insoles were printed with the aforementioned material types. See figures below.

(a) Cheetah, Shore hardness: 95A.



(b) NinjaFlex, Shore hardness: 85A.



(c) Armadillo, Shore hardness: 75D.

(d) PrimaSELECT Flex, Shore hardness: 45D.

Figure 4.12: 3D printed flexible insoles.

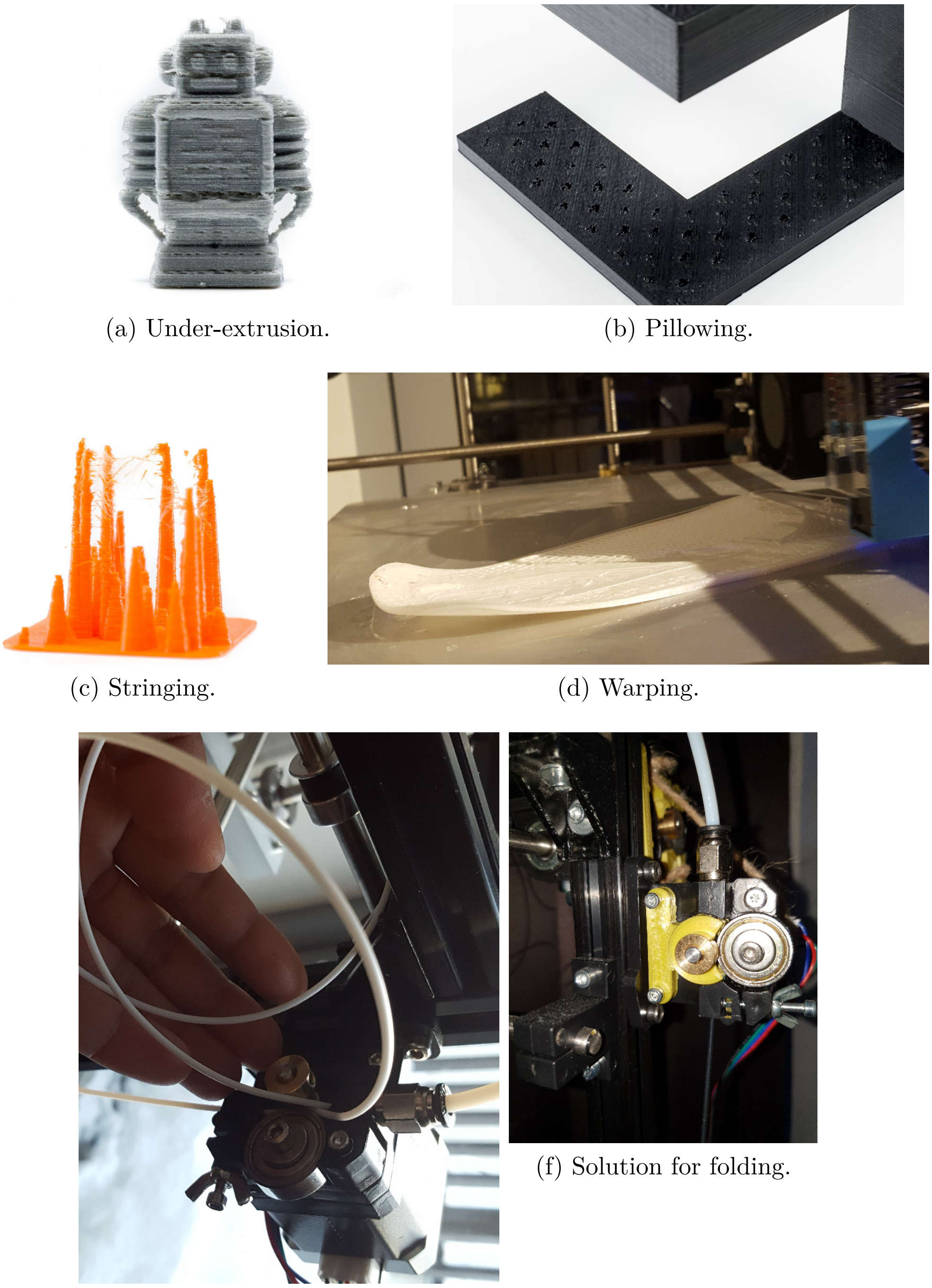
4.4.1 3D Printing Errors

3D printing the insoles made some complications. Some recurring 3D printing errors to be alert of are (Ultimaker (n.d.*c*), Ultimaker (n.d.*a*), Ultimaker (n.d.*b*), Ultimaker (n.d.*d*)):

- **Under-extrusion:** occurs when the printer is unable to supply the right amount of material. It happens when there are missing layers, very thin layers or layers that have random dots or hole in them.

- **Pillowing:** occurs when the top surface is not properly covered. The surface e.g. can have dots or bumps.
- **Stringing:** occurs when material is fed in areas the print head is only supposed to move but not feed.
- **Warping:** occurs due to material shrinkage while 3D printing. This makes the corners of the print to lift and detach themselves from the build plate. This particular incident occurred when printing with the Cheetah and PrimaSELECT Flex material. The solution was to put a brim, a large ring around the part, to keep the print attached to the build plate.

Another important error occurred on the extruder when printing with the Ninjaflex material. Since the material was so flexible compared to the others, it managed to fold itself in the extruder during the printing process. The solution was to place a printed artifact as shown in figure 4.13f. This part had connecting holes so the material could continuously be pushed through these holes, preventing the material to fold itself.



(a) Under-extrusion.

(b) Pillowing.

(c) Stringing.

(d) Warping.

(e) Folding.

(f) Solution for folding.

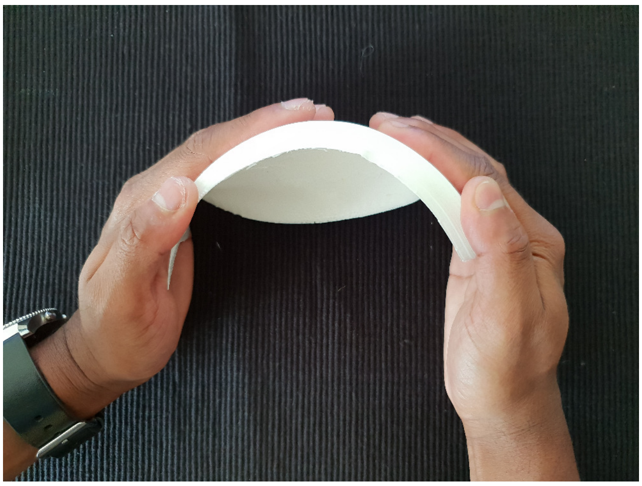
Figure 4.13: 3D printing errors. Some of the illustrations are reproduced from Ultimaker (n.d.c), Ultimaker (n.d.a), Ultimaker (n.d.b) and Ultimaker (n.d.d).

4.5 Test

The printed flexible insoles were tested in the same way the PLA-insole was tested. The insoles should have the ability to be stiff and soft in different areas of the sole. The insoles were also tested by a technician at TOV. It was mentioned that the insoles feel and behave the same way as a regular individual insole, but the surface finish was not good enough to sell the insole. This can be due to stringing. When the insoles were tested by the supervisor, it was commented that the insoles feelt similar to an existing insole, but may behave different in the long term. How the insole can achieve almost identical properties with the current one, was also discussed. The tests resulted in that the Ninjaflex material was the material which gave the most similar feeling to the existing one. It should be noted that this was the insole with the lowest shore hardness value. Cheetah had higher shore hardness value, Armadillo and PrimaSELECT Flex had shore D hardnesses which were even harder.

(a) Ninjaflex insole tested in shoe.

(b) Flexibility of current insole.



(c) Flexibility of ninjaflex insole.

Figure 4.14: Testing the 3D printed insoles.

5 Iteration 2.0

5.1 Define

It was concluded that FDM-printers print to slow and there were also room for a lot of errors. Research on existing solutions showed that 3D printed soles on the market are seldom printed with the FDM technique. There are also many types of 3D printers on the market and it is uncertain which type of 3D printer the orthopedic workshop will end up with. Therefore the problem needs to be redefined.

5.1.1 User-Need-Insight

Table 5.1: Defining point-of-view

User	Need	Insight
Technician who works at an orthopedic workshop	To 3D print the insoles which can be adaptable to any 3D printer the company buys	Find a generic method which makes 3D printed insoles that have similar properties to the current produced insole

POV: The TOV technician *needs* to print an insole with similar material properties as the existing one, and that can easily adapt to any 3D printer *because* he/she does not know what type of 3D printer the company will invest in.

5.2 Ideate

How can the POV be satisfied? It was essential to understand the POV properly. The solution could not be a tangible product. The product had to be a method, a method with guidelines which could adapt to any 3D printers. If the material specifications for the current insole did not exist or were hard to find, the action for this type of problem needed to be included in the method.

Proposed method:

1. Find out what type of 3D printer the insoles will be produced in and understand how it works.
2. Choose a suitable 3D-printing material for an insole. Flexible material is recommended.
3. Perform compression and hardness tests on the existing sole's material to find material properties.
4. Find Young's modulus and shore hardness values for the current material.
5. Draw a test-element in a CAD-software e.g.. Fusion 360 by Autodesk and assign the chosen 3D printing material, by implementing the material properties for the test-element in the software.
6. Test the element by varying infill structure, surface thickness and amount of infill in a simulation software, e.g. Ansys.
7. Perform tests until similar values for Young's modulus and shore hardness are achieved.
8. Find a mathematical expression for the material properties like Young's modulus and shore-hardness, as shown in 5.1.
9. 3D print test-element with the obtained values for the total structure with parameters such as infill structure, surface thickness and amount of infill.
10. Perform the same tests as in step 3 and control if the obtained values are similar to the ones obtained from the simulation software.
11. If the values are similar, 3D print the insoles with the obtained values for the total structure. If not, try to change the structure or printing material.
12. Test if the insoles feel the same as the current ones. Test the insoles with shoes over a long period to get proper feedback.
13. If changes need to be executed, change softness and hardness in the required areas and use the expression from step 8 to obtain values for the material properties.

5.2.1 Why Young's Modulus and Shore Hardness?

Properties, such as Young's modulus and shore hardness, were chosen as relevant parameters to explore. Shore hardness gives information about the material's indentation resistance and about flexibility. High values for shore hardness indicate harder and less flexible material. Young's modulus describes the material's ability to withstand elastic deformation. High values for modulus represent stiffer material. Both properties are relevant for a product that needs cushioning and stiffening at the same time.

5.2.2 Ratio

Finding the values for the parameters of the total structure, can give a ratio between the total structure and the material properties. It can be possible to find an expression for e.g. the Young's modulus, were the parameters mentioned above are the variables. The mathematical expression would look something like the equation below, see equation 5.1:

$$E = f(T, S, AI, IS) \tag{5.1}$$

where E is the Young's modulus, T is the top and bottom wall thickness, S is the side wall thickness, AI the is amount of infill and IS is the infill structure .

The mathematical expression could be used to make the demanded stiffness in the required areas of the insole with less material. This could provide faster production time and lower material costs. One can for instance achieve higher stiffness by increasing the infill percentage, but the degree of stiffness is still decided by the material properties. The expression can therefore provide the value of the new material property which occurs when tweaking the parameters to change the behavior of the insole. Even though it takes a bit of work in the start, it would be beneficial in the end by saving time to find the new material properties.

5.3 Prototype and Test

The Prototype and Test phase are combined together in one sub-chapter since the prototyping and testing were conducted almost simultaneously. Testing the proposed method was the next step in the development process.

5.3.1 Material-Tests

Compression Test

Equipment: Test specimens, a vernier caliper, EPLEXOR 150 N (an instrument for testing materials), a computer with EPLEXOR 8 (Software).

Scope: Compressive properties describe the behavior of a material when it is subjected to a compressive load. Loading is at a relatively low and uniform rate. Compressive strength and modulus are the two most common values produced. Intertek Plastics Technology Laboratories (n.d.*a*).

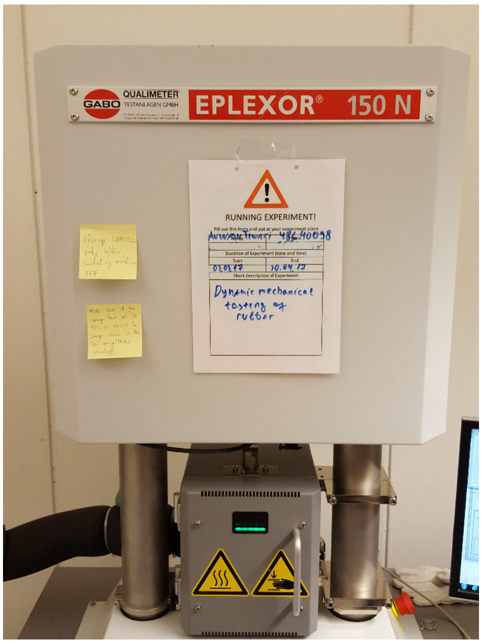
Test procedure: Three test specimens are cut into 40x40x40 mm cubes as shown in figure 5.1a. Before the first specimen was placed between compressive plates, they are measured with a vernier caliper to get accurate dimensions of the specimens. The specimen was then compressed, as seen in figure 5.2a, to a specific strain value. Then the load was removed and the specimen was further compressed to a larger strain. For each time the compression was increased, the force in newton for the correlating strain was registered. After the compression-test was completed, the cross section was calculated and a stress/strain-curve is made. The same process was performed for the remaining specimens. All the tests were conducted in room-temperature, 30°Celsius.

Results and interpretation: An overview of the results can be seen in the appendix on page 111. The Young's modulus was obtained by making a regression line of the data from beginning of the stress-strain graph, were the material exhibits elastic behavior. The expression used for finding Young's modulus, was stress divided by the corresponding strain, as shown in equation 5.2. The slope of the regression line which intercepts the origin could also be considered as the modulus. The average of the moduli was assumed to be the Young's modulus of the polymer material used in the existing insole. The obtained value for the Young's modulus was *0,0058369 GPa*, which seemed acceptable when comparing to values for foam-materials that have 0.005-0.0065 GPa, obtained from Styrodur (2016). The specimens were compressed to approximately 64 % strain to observe the behavior of the material and to find when the material reached the plastic region. These values were irrelevant for this part of the project, but could be interesting for future purposes.

$$E = \frac{\sigma}{\epsilon} \tag{5.2}$$

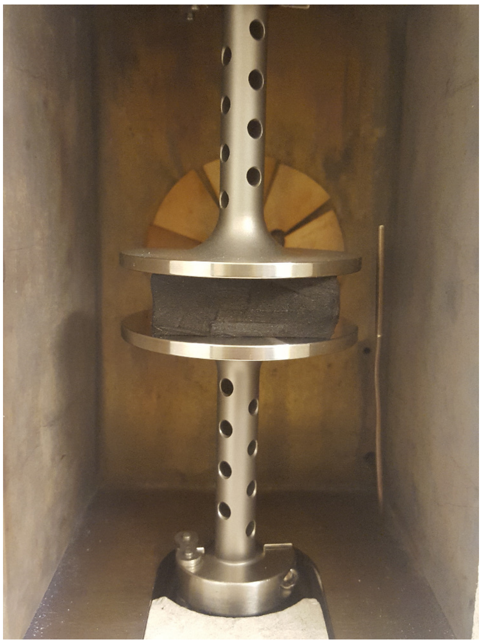
Sources of errors and uncertainties: can be reading errors when registering the forces from the data and from the vernier caliper. The specimen was not compressed at a uniform rate, which makes it differ from an ISO 604 Compressive test. The specimens could also have been cut inaccurately which could have affected the test results when measuring the cross section by giving inaccurate strain values. To get more accurate result, more specimens could have been tested.

(a) Testspecimens.

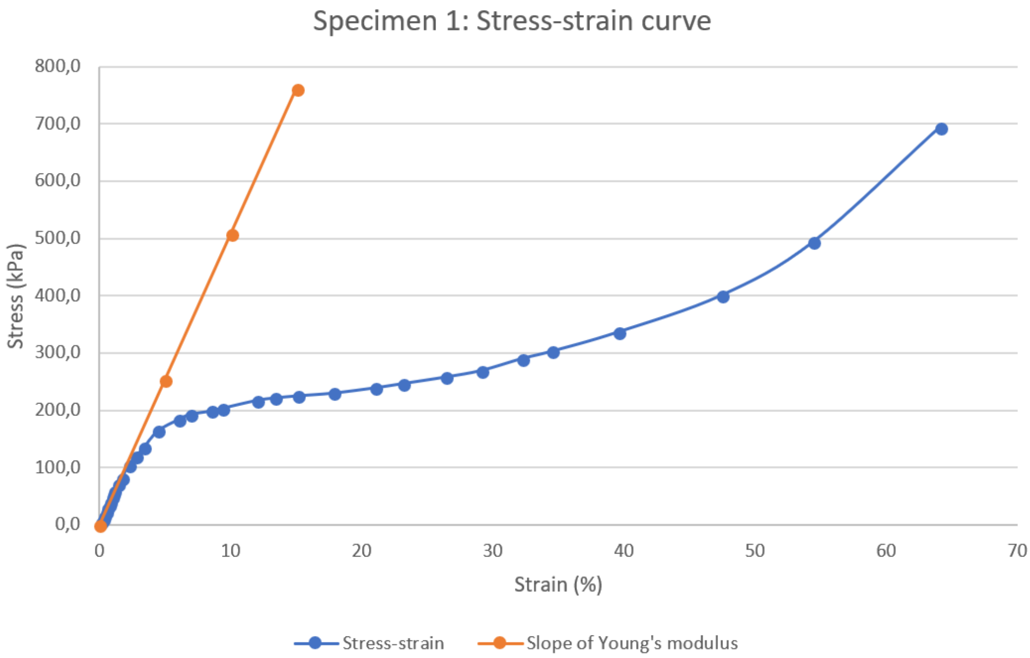


(b) Eplexor test instrument.

Figure 5.1: Compression test equipment.



(a) Compressed test specimen.



(b) Stress-strain curve.

Figure 5.2: Compression test.

Shore A Hardness Test

Equipment: a durometer, test specimens with an even surface and minimum 6,4 mm thickness (ISO 868).

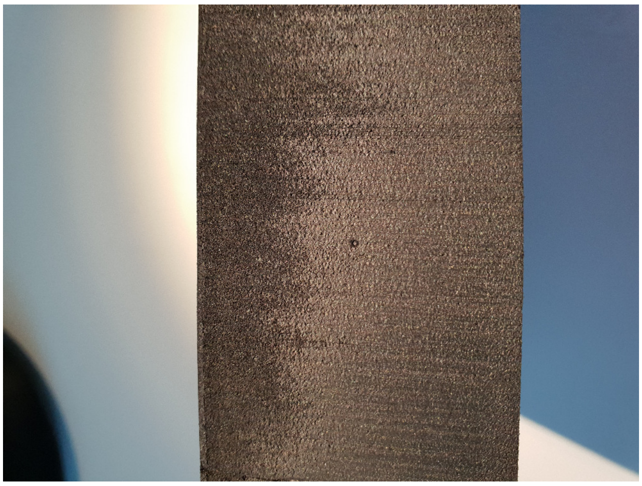
Scope: Durometer Hardness is used to determine the relative hardness of soft materials, usually plastic or rubber. The test measures the penetration of a specified indenter into the material under specified conditions of force and time. The hardness value is often used to identify or specify a particular hardness of elastomer or as a quality control measure on lots of materials. Intertek Plastics Technology Laboratories (n.d.*b*).

Test procedure: The test specimen was placed on a hard surface. The indenter on the durometer was then pressed, parallel to the surface, into the specimen. The shore hardness value was marked instantly on the durometer, as shown in figure 5.3a. Minimum 4 tests were conducted on each plane of the test specimen.

Results and interpretation: An overview of the results can be seen in the appendix on page 119. The shore hardness was found by calculating the average of the results from the plane with parallel direction of compression. The obtained value for the Shore hardness was *45A*. It was also made some shore hardness test in the XZ- and YZ-planes. These value could be interesting to look at for finding Poisson's ratio, but since there were little expansion in the perpendicular direction of compression, see figure 5.2a, it seemed irrelevant to find this value. There were also some irregularities in these surfaces as it seemed machined, see figure 5.4, which could have affected the values. To compare, Ninjaflex had a shore hardness of 85A which was the 3D printing material with the lowest shore hardness value of all the tested materials. This means that if a 3D printing filament with a lower shore hardness is produced in the future, it may be more suitable for an insole printed by a FDM-printer.

Sources of error and uncertainties: There could have been some unevenness in the surface which was difficult to detect with the naked eye. There could also have been some reading errors when registering values from the durometer.

(a) Shore A Durometer.



(b) Indentation made by the duromenter.

Figure 5.3: Shore hardness test.

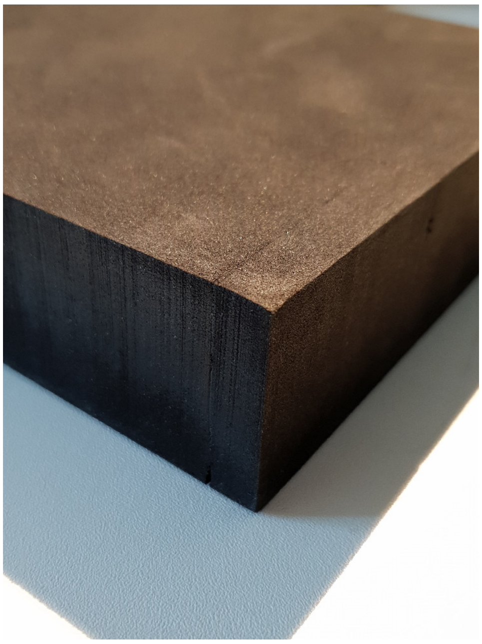
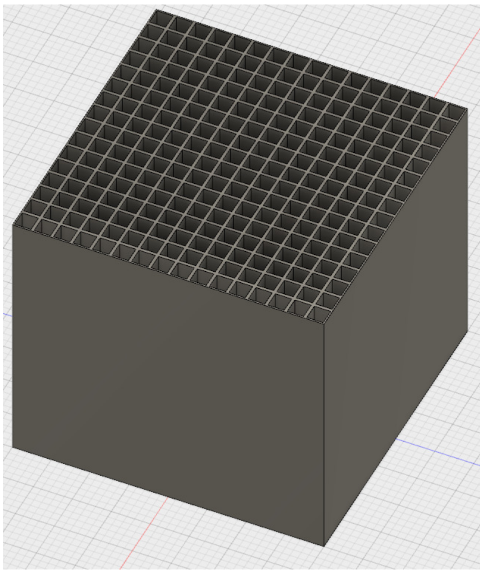


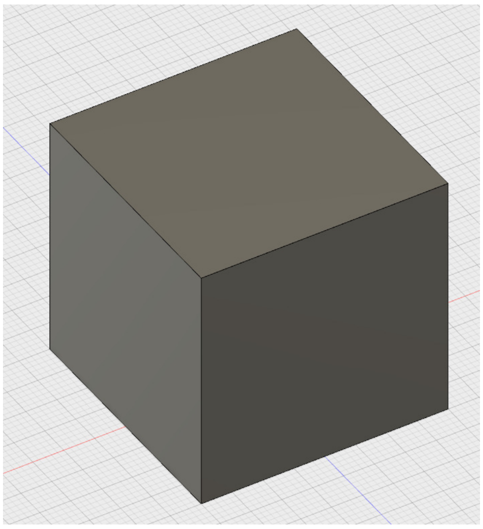
Figure 5.4: Machined irregularities in the surface on the sides.

5.3.2 CAD

A test specimen with 2 mm top and bottom layers, 40 % infill and rectilinear structure was modeled in CAD (Fusion 360 - Autodesk), see figure 5.5a. Since the structure also decides the rigidness and softness of the insoles and not only the material, different structures can also be tested by changing infill structures, see figure 5.6b.

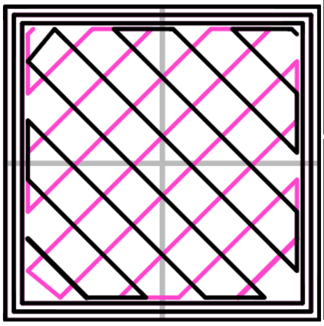


(a) CAD model of testspecimen with rectilinear infill structure.

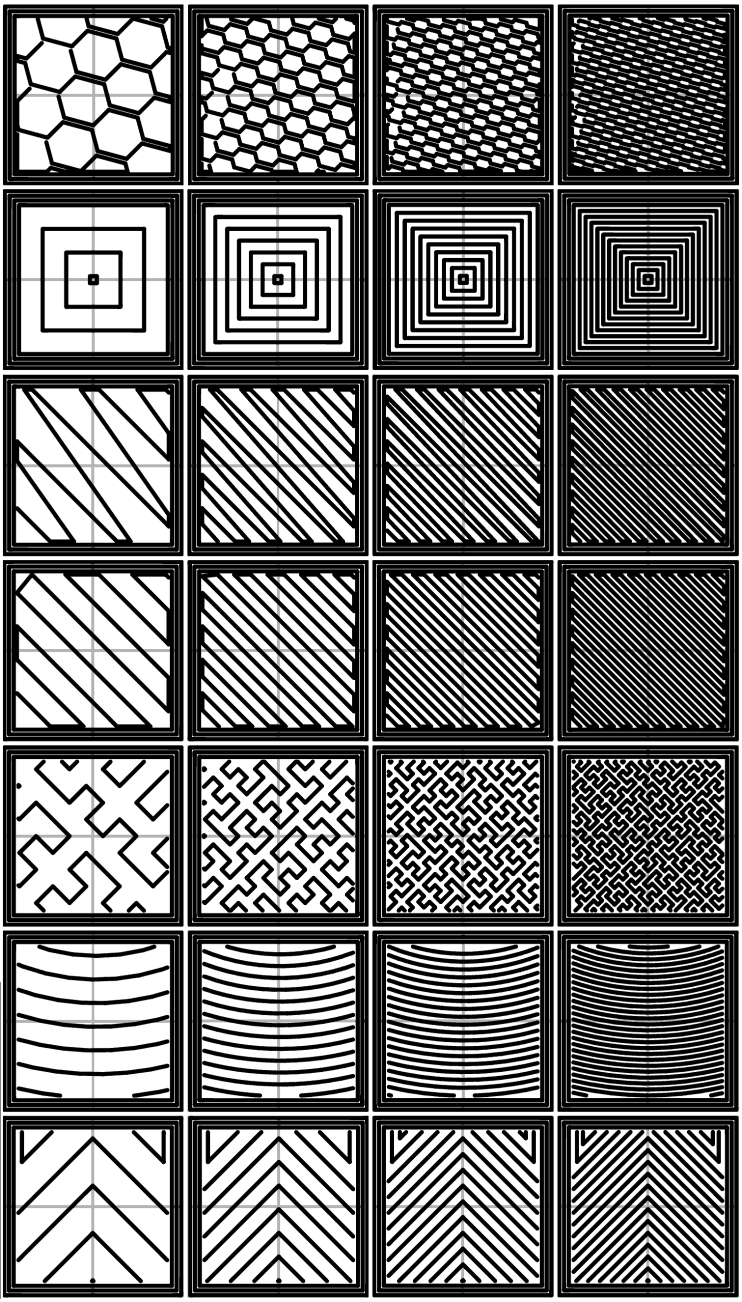


(b) CAD model of enclosed test specimen.

Figure 5.5: CAD model.



(a) The rectilinear pattern used for the CAD model.



(b) Infill patterns at varying densities. Left to Right: 20%,40%,60%,80%. Top to Bottom: Honeycomb, Concentric, Line, Rectilinear, Hilbert Curve, Archimedean Chords, Octagram Spiral. Reproduced from Slic3er Manual.

Figure 5.6: Infill patterns.

5.3.3 ANSYS

The 3D model made in Fusion 360 was implemented in Ansys, version 17.2. The modeled got meshed and constrained. Pressure of 900 Mpa was applied for the analysis. The Ninjaflex material was also assigned for the model. As seen in fig. XXX, the the strain is too low. Either, parameters need to be changed or the model needs to be expected in CAD and Ansys to control if everything is as it should be.

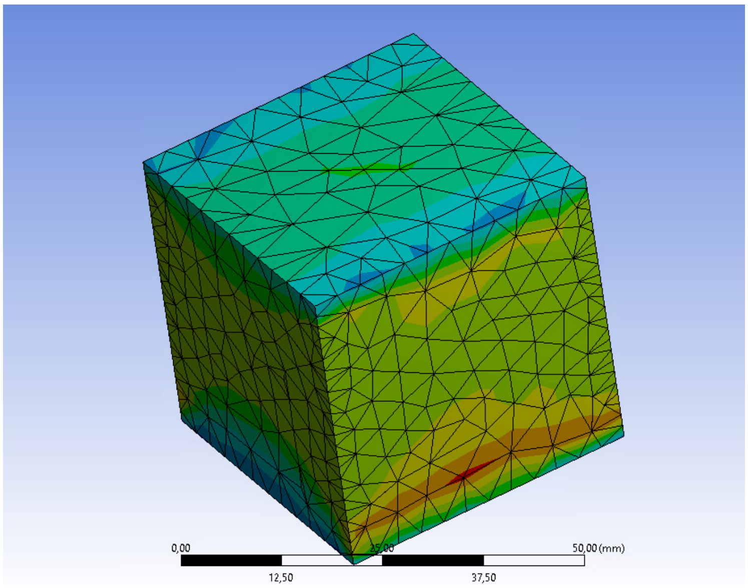


Figure 5.7: Simulated model in Ansys.

From the proposed method, these steps be tested:

5.3.4 Proposed method - Tested

1. Name of the 3D printer: FLSUN.
2. Suitable material: Ninjaflex.
3. The compression test and shore hardness test is explained in details in the subsections below.
4. Young's modulus = 0,0058369 GPa, Shore hardness = 45A.
5. CAD-drawing of test-element with the Ninjaflex material.
6. Simulation in Ansys of test specimen drawn in CAD.

6 | Discussion and Conclusion

The process of material testing started very late in the process and were time consuming. Due to this, there was shortage of time to finalize testing the proposed method in the Test mode. If the project gets continued, it is advised to proceed testing the method were the next step is step nr. 7. It is about performing tests in a simulation software until similar values as the material properties are obtained. The method has proven to have potential. It has the possibility to be a good solution if followed properly.

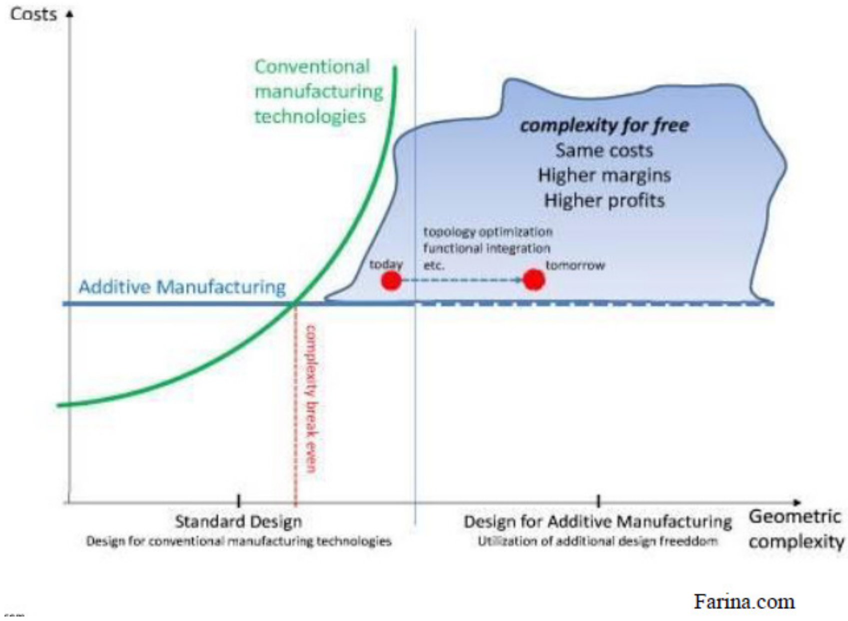
It can also be discussed how much the the behavior of the 3D printed insole will resemble the current insole by only testing two material properties. It could be beneficial to conduct other types of material tests as well. This will be discussed further in chapter 7.

The FDM-printed insoles are clearly not products that are ready to be sold in the market. If the proposed method proves to be a solution the orthopedic workshop wants to implement, it should be focused on investing in a proper 3D printer. This will lead to insoles that are ready to be sold. The company can also start to conduct end-user-test and obtain useful feedback. This is the main motive behind the final solution. The proposed method is adaptable to any 3D printer. If the printer does not have the optimal performance as wished, the method can still be used with another printer. As the 3D printing technology is developing rapidly, the 3D printers will have the possibility to be upgraded, but the method for making the insole will remain the same.

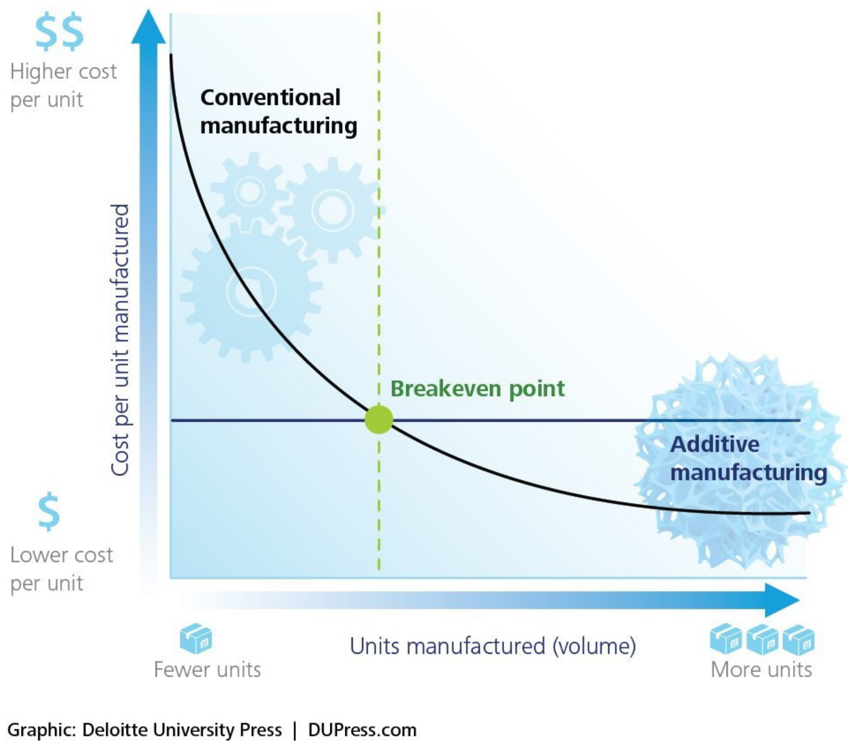
Research on existing solutions showed that there are mostly SLS printers that are used for mass customization. SLS has a high throughput and the materials used are engineering-grade materials such as nylon and thermoplastic polyurethane. This is why it is the most preferable technology for batch production and therefore recommended to use for production of insoles. However, there are also other new technologies entering the market. E.g. Adidas uses CDLP technique for the rapid printing speed and the quality material. MJF technique, used by Superfeet, has also become more appealing for mass customization which is marketed to be 10 times faster than SLS. Molitch-Hou (2017*b*).

From an economical perspective, additive manufacturing or 3D printing in this case, reduces costs for higher complex products as shown in the graph on figure 6.1a This means that developing complex structures inside the insole is free, but for conventional production the cost of producing a more complex insole would increase exponentially. The cost curves in figure 6.1b illustrate the change in average cost for each incremental unit of production. For 3D printing or additive manufacturing, the cost per unit is the same for any volume manufactured. For conventional manufacturing, the cost per unit is low if the manufacturing volume is high. The break even between these production methods approaches where the curves intersect. This means that 3D printing is efficient for low-to-medium production runs, which fits TOV perfectly. Cotteleer & Joyce (2014).

It can be concluded that it would be beneficial for the orhopedic workshop to implement 3D printing, replacing the vacuum production process. There are still some work needed in figuring out how implementation should be executed and how the 3D printing structure correlate to the existing cushioning mechanism. The method is a guidance tool which will help implementing 3D printing by following each step. It is about finding a suitable 3D printing material, obtaining material properties, finding infill structures, finding an expression, adapting it to any 3D printer and 3D printing. The solution is not about printing tangible insoles, but about finding a method for making an insole with similar material properties like the existing sole.



(a) Complexity is free



(b) Breakeven analysis comparing conventional and additive manufacturing processes

Figure 6.1: Economical perspective of 3D printing. The illustrations are reproduced from (Torgersen et al. 2017, p. 12) and Cotteleer & Joyce (2014).

7 | Further work

Based on the work carried out in this thesis, the following suggestions for further work are presented.

- Continue testing the proposed method.
- Carry out more material tests such as abrasion and wear tests, dynamic stress tests and bending/flexural tests. The material properties found from these test can help finding a more suitable 3D printing structure.
- Conduct end-user (patient) tests.
- Try other types of 3D printers, like SLS, which prints better end-products.
- There is a difference between material properties and geometrical properties. It could be beneficial to conduct more research on the effect of 3D printing structures like honeycomb, rectilinear etc. for insoles. It can be recommended to perform a topology optimization which can help find efficient structures.
- How material properties can be obtained if the existing insole consists of more than one type of material. It should be conducted research in e.g. how the Young's modulus a total block that consists of the three different materials can be obtained when each material holds its own modulus.
- 3D printing is advantageous to make insoles for high heels which would require a huge block of material for the milling machine. Research can be made on how one can decrease material waste and support structure when 3D printing these high heels.
- It should be focused on the exterior part of the insole as well. As figure 7.1a and 7.1b shows, the insoles need to be grinded to fit the shoes. It should be focused on how the insoles should be designed to fit shoes when they are 3D printed.

(a) Grinded insoles to fot shoe. Bottom view.

(b) Grinded insoles to fot shoe. Back view.

Figure 7.1: Grinded exterior part of the insoles to fit shoe

7.1 Ideas for TOV

- Use dynamic gait scan analysis, like Fitstation and RSscan, in addition to 3D scanning to get a better image of how the foot gets used in the daily life.
- Make an application for mobile phones. If e.g. pressure-sensors are implemented in the soles, the information from these sensors can be sent to the patient through the application. Information of the patient's activities can be given to the technician as well to help improving the insoles. 3D scanning can also be implemented in the application when the technology of depth sensing is improved and implemented in phones.
- Implement a pawn-solution for used 3D printing filament so less material is wasted and the production becomes more environment friendly.

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Appendix

.1 Material properties for 3D printing filament

.1.1 Cheetah

NinjaTek *Technical Specifications*

Cheetah™ 3D Printing Filament

Flexible Polyurethane Material for FDM Printers

Cheetah™ flexible filament is the fastest and easiest to print flexible filament on the market. The focus in development of this material was on optimizing the user experience. The result is a filament that is printable across all types of desktop 3D printers at ABS and PLA speeds, many times twice the speed of other flexible materials on the market.

General Properties	Test Method	Imperial	Metric
Specific Gravity	ASTM D792	1.22 g/cc	1.22 g/cc
Moisture Absorption - 24 hours	ASTM D570	0.18 %	0.18 %

Mechanical Properties			
Tensile Strength, Yield	ASTM D638	1,250 psi	9 Mpa
Tensile Strength, Ultimate	ASTM D638	5,650 psi	39 Mpa
Tensile Modulus	ASTM D638	3,800 psi	26 Mpa
Elongation at Yield	ASTM D638	55%	55%
Elongation at Break	ASTM D638	580%	580%
Toughness (integrated stress-strain curve; calculated stress x strain)	ASTM D638	17,000 in·lbF/in^3	117.2 m*N/m^3 x10^6
Hardness	ASTM D2240	95 Shore A	95 Shore A
Impact Strength (notched Izod, 23C)	ASTM D256	9.1 ft.lbf/in^2	19.1 kJ/m^2
Abrasion Resistance (mass loss, 10,000 cycles)	ASTM D4060	0.06 g	0.06 g

Thermal Properties			
Melting Point (via Differential Scanning Calorimeter)	DSC	428° F	220° C
Glass Transition (Tg)	DSC	-11° F	-24° C
Heat Deflection Temperature (HDT) @ 10.75psi/ 0.07 MPa	ASTM D648	165° F	74° C
Heat Deflection Temperature (HDT) @ 66psi/ 0.45 MPa	ASTM D648	120° F	49° C

NinjaTek filament is capable of being printed by a variety of printers in a variety of configurations. This specification sheet gives results as they pertain to the defined test standard and specimen details. Different slicing and/or printing configurations, test conditions, ambient environments, etc. may result in different results.

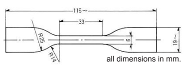
Impact Strength and Heat Deflection Temperature results were both provided by an accredited university testing laboratory. Specific Gravity and Hardness are innate characteristics of the material. Moisture Absorption, values associated with the Tensile Strength tests, Melting Point and Glass Transition data were prepared by Fenner Drives, Inc.

Test Specimen Details (by ASTM Test Number)
All printed specimens were created using the TAZ5 printer 0.75mm nozzle. For ASTM D638 tests, the extrusion multiplier is 1.05.

Specific Gravity (D792): Results determined by nature of material.

Moisture (D570): 30g of filament tested in moisture analyzer evaluated at 125°C until the mass change is < 0.005% over 1 minute.

Tensile (D638): Dogbone Style IV, 100% fill, diagonal line fill. Dimensions: 5mm thick. See drawing for other dimensions.



Hardness (D2240): Solid testing block.

Dimensions:
2"L x 2" H x 0.75" W

Impact (D256): Un-notched test specimen, notch added post print by testing facility.

Dimensions:
2.5 " L x 0.25" H x 0.5" W

Abrasion (D4060): Rectanglar block sized to fit tabor abrader.

Dimensions:
5" L x 0.5" H x 0.5" W

HDT (D648): Bar shape.

Dimensions:
7.5" L x 0.125" H x 0.5" W

.1.2 Ninjaflex

Technical Specifications

NinjaFlex® 3D Printing Filament

Flexible Polyurethane Material for FDM Printers

NinjaFlex flexible filament leads the industry with superior flexibility and longevity compared to non-polyurethane materials. Its consistency in diameter and ovality (roundness) outpaces other polyurethane materials. Made from a specially formulated thermoplastic polyurethane (TPU) material, this patented technology contains a low-tack, easy-to-feed texture. The result is uniquely flexible, strong prints ideal for direct-drive extruders.

General Properties	Test Method	Imperial	Metric
Specific Gravity	ASTM D792	1.19 g/cc	1.19 g/cc
Moisture Absorption - 24 hours	ASTM D570	0.22 %	0.22 %

Mechanical Properties			
Tensile Strength, Yield	ASTM D638	580 psi	4 Mpa
Tensile Strength, Ultimate	ASTM D638	3,700 psi	26 Mpa
Tensile Modulus	ASTM D638	1,800 psi	12 Mpa
Elongation at Yield	ASTM D638	65%	65%
Elongation at Break	ASTM D638	660%	660%
Toughness (integrated stress-strain curve; calculated stress x strain)	ASTM D638	12,000 $in\cdot lbF/in^3$	82.7 $m*N/m^3$ x10^6
Hardness	ASTM D2240	85 Shore A	85 Shore A
Impact Strength (notched Izod, 23C)	ASTM D256	2.0 $ft.lbf/in^2$	4.2 kJ/m^2
Abrasion Resistance (mass loss, 10,000 cycles)	ASTM D4060	0.08 g	0.08 g

Thermal Properties			
Melting Point (via Differential Scanning Calorimeter)	DSC	420° F	216° C
Glass Transition (Tg)	DSC	-31° F	-35° C
Heat Deflection Temperature (HDT) @ 10.75psi/ 0.07 MPa	ASTM D648	140° F	60° C
Heat Deflection Temperature (HDT) @ 66psi/ 0.45 MPa	ASTM D648	111° F	44° C

NinjaTek filament is capable of being printed by a variety of printers in a variety of configurations. This specification sheet gives results as they pertain to the defined test standard and specimen details. Different slicing and/or printing configurations, test conditions, ambient environments, etc. may result in different results.

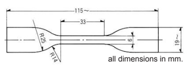
Impact Strength and Heat Deflection Temperature results were both provided by an accredited university testing laboratory. Specific Gravity and Hardness are innate characteristics of the material. Moisture Absorption, values associated with the Tensile Strength tests, Melting Point and Glass Transition data were prepared by Fenner Drives, Inc.

Test Specimen Details (by ASTM Test Number)
All printed specimens were created using the TAZ5 printer 0.75mm nozzle. For ASTM D638 tests, the extrusion multiplier is 1.05.

Specific Gravity (D792): Results determined by nature of material.

Moisture (D570): 30g of filament tested in moisture analyzer evaluated at 125°C until the mass change is < 0.005% over 1 minute.

Tensile (D638): Dogbone Style IV, 100% fill, diagonal line fill. Dimensions: 5mm thick. See drawing for other dimensions.



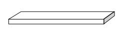
Hardness (D2240): Solid testing block.


Dimensions:
2"L x 2" H x 0.75" W

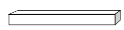
Impact (D256): Un-notched test specimen, notch added post print by testing facility.

Dimensions:
2.5 " L x 0.25" H x 0.5" W

Abrasion (D4060): Rectanglar block sized to fit tabor abrader.


Dimensions:
5" L x 0.5" H x 0.5" W

HDT (D648): Bar shape.


Dimensions:
7.5" L x 0.125" H x 0.5" W

.1.3 Armadillo

NinjaTek *Technical Specifications*

Armadillo™ 3D Printing Filament

Semi-Rigid Polyurethane Material for FDM Printers

Armadillo™ 3D printing filament is a perfect alternative to some of the most common rigid materials on the market. Made from a specially formulated thermoplastic polyurethane (TPU), its advantages against PLA and ABS lie in its printability and toughness.

General Properties	Test Method	Imperial	Metric
Specific Gravity	ASTM D792	1.18 g/cc	1.18 g/cc
Moisture Absorption - 24 hours	ASTM D570		

Mechanical Properties			
Tensile Strength, Yield	ASTM D638	3,900 psi	27 Mpa
Tensile Strength, Ultimate	ASTM D638	6,900 psi	48 Mpa
Tensile Modulus	ASTM D638	57,500 psi	396 Mpa
Elongation at Yield	ASTM D638	18%	18%
Elongation at Break	ASTM D638	295%	295%
Toughness (integrated stress-strain curve; calculated stress x strain)	ASTM D638	14,000 in·lbF/in^3	96.5 m*N/m^3 x10^6
Hardness	ASTM D2240	75 Shore D	75 Shore D
Impact Strength (notched Izod, 23C)	ASTM D256	1.41 ft.lbf/in^2	3.0 kJ/m^2
Abrasion Resistance (mass loss, 10,000 cycles)	ASTM D4060	0.03 g	0.03 g

Thermal Properties			
Melting Point (via Differential Scanning Calorimeter)	DSC	413° F	212° C
Glass Transition (Tg)	DSC	14° F	-10° C
Heat Deflection Temperature (HDT) @ 10.75psi/ 0.07 MPa	ASTM D648	115° F	46° C
Heat Deflection Temperature (HDT) @ 66psi/ 0.45 MPa	ASTM D648	106° F	41° C

NinjaTek filament is capable of being printed by a variety of printers in a variety of configurations. This specification sheet gives results as they pertain to the defined test standard and specimen details. Different slicing and/or printing configurations, test conditions, ambient environments, etc. may result in different results.

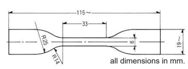
Impact Strength and Heat Deflection Temperature results were both provided by an accredited university testing laboratory. Specific Gravity and Hardness are innate characteristics of the material. Moisture Absorption, values associated with the Tensile Strength tests, Melting Point and Glass Transition data were prepared by Fenner Drives, Inc.

Test Specimen Details (by ASTM Test Number)
All printed specimens were created using the TAZ5 printer 0.75mm nozzle. For ASTM D638 tests, the extrusion multiplier is 1.05.

Specific Gravity (D792): Results determined by nature of material.

Moisture (D570): 30g of filament tested in moisture analyzer evaluated at 125°C until the mass change is < 0.005% over 1 minute.

Tensile (D638): Dogbone Style IV, 100% fill, diagonal line fill. Dimensions: 5mm thick. See drawing for other dimensions.



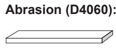
Hardness (D2240): Solid testing block.


Dimensions:
2”L x 2” H x 0.75” W

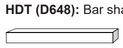
Impact (D256): Un-notched test specimen, notch added post print by testing facility.

Dimensions:
2.5 “ L x 0.125” H x 0.5” W

Abrasion (D4060): Rectanglar block sized to fit tabor abrader.


Dimensions:
5” L x 0.5” H x 0.5” W

HDT (D648): Bar shape.


Dimensions:
7.5” L x 0.125” H x 0.5” W

.1.4 PRIMASELECT Flex

From http://www.primafilaments.com/product/primaselect-flex/ : Online; accessed 11/06/18

PrimaSELECT™ Flex

PrimaSELECT™Flex is a new type of Thermoplastic Co-Polyester (TPC) with very rubber – like characteristics. This material is perfect when you need a strong, but still flexible filament. Our filament has a shore hardness of 45, which means that it´s rigid but still pliable.

WHY SHOULD I USE PRIMASELECT™ FLEX?

- High flexibility with a shore hardness of 45D
- Good resistance to chemicals
- High UV resistance
- Good heat resistance

Dimensions

Size:	Ø tolerance	Roundness
1,75 mm	±0,05 mm	95 %
2,85 mm	±0,10 mm	95 %

Physical properties

Description:	Testmethod	Typical value
Specific gravity	ISO 1183	1,14 g/cc
Melt volume flow rate	ISO 1133	39 cm³/10 min

Description:	Testmethod	Typical value
Stress at break	ISO 527	24
Strain at break	ISO 527	530,00 %
Tensile modulus	ISO 527	95 MPa
Impact strength Charpy method 23 °C	ISO 179	Notched No break
Shore D	ISO 868	45

Thermal properties

Description:	Testmethod	Typical value
Printing temp.	–	220-260 °C
Melting temp.	ISO 11357	180 °C

.2 Testing of mechanical properties

.2.1 Compression test

Compression test

Specimen	Length	Width	Height	Temp.		
1	41,6	41,3	40,41	25	**Cross section**	1718,08
strain (%)	**Initial length(mm)**	**final length(mm)**	**true strain(%)**	**Load(N)**	**(mm^2)**	**Compression stress (kpa)**
			0	0		0
	40,41	40,37	0,099	7,59		4,4
		40,31	0,247	16,83		9,8
		40,26	0,371	27,71		16,1
		40,22	0,470	38,66		22,5
		40,17	0,594	51,01		29,7
		40,13	0,693	60,71		35,3
		40,08	0,817	69,57		40,5
		40,04	0,916	81,82		47,6
		40,00	1,015	90,84		52,9
		39,95	1,138	100,50		58,5
		39,84	1,411	123,10		71,6
		39,72	1,707	140,40		81,7
		39,51	2,227	179,90		104,7
		39,28	2,796	206,20		120,0
		39,05	3,366	231,30		134,6
		38,61	4,454	281,60		163,9
		37,98	6,013	315,50		183,6
		37,62	6,904	331,00		192,7
		36,98	8,488	341,30		198,7
		36,63	9,357	349,44		203,4
		35,57	11,977	373,10		217,2
		35,01	13,363	380,50		221,5
		34,30	15,120	386,90		225,2
		33,20	17,842	395,10		230,0
		31,93	20,985	410,80		239,1
		31,06	23,138	423,60		246,6
		29,74	26,404	443,40		258,1
		28,64	29,126	463,00		269,5
		27,40	32,195	498,40		290,1
		26,46	34,521	521,00		303,2
		24,43	39,545	578,20		336,5
	37,28	21,24	47,439	688,50		400,7
	36,85	18,42	54,417	848,60		493,9
	36,25	14,52	64,068	1192,00		693,8

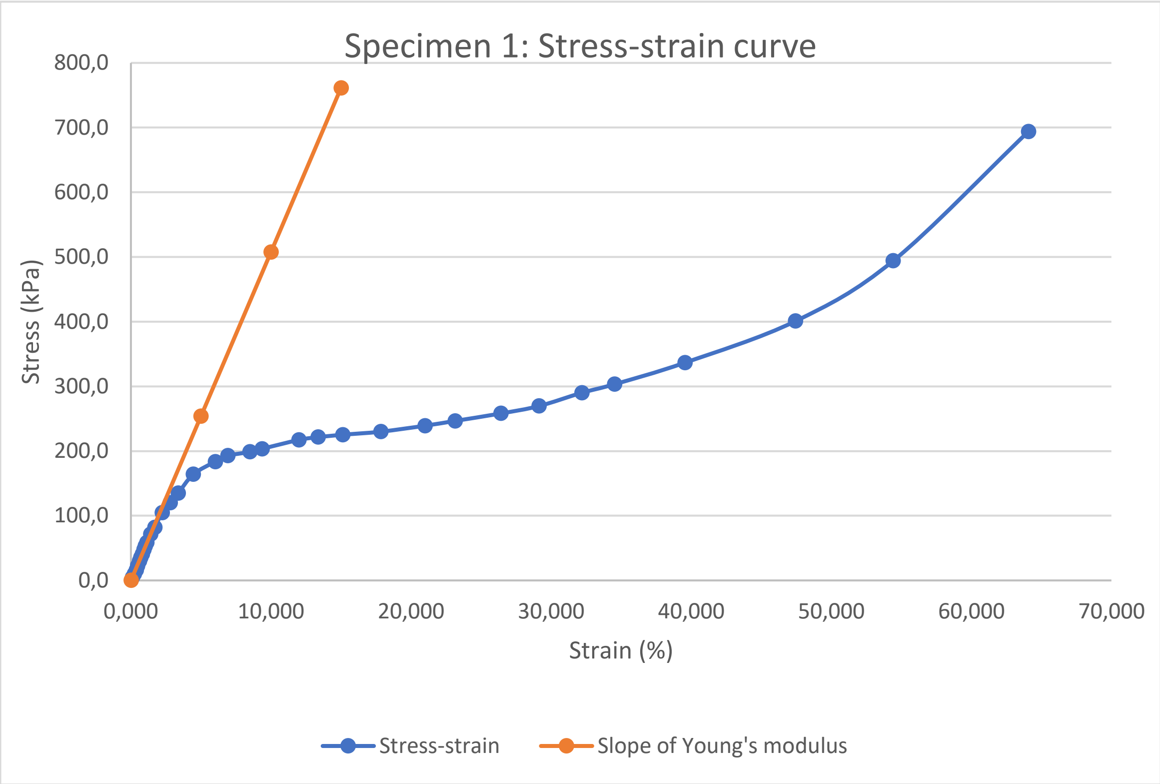
Compression test

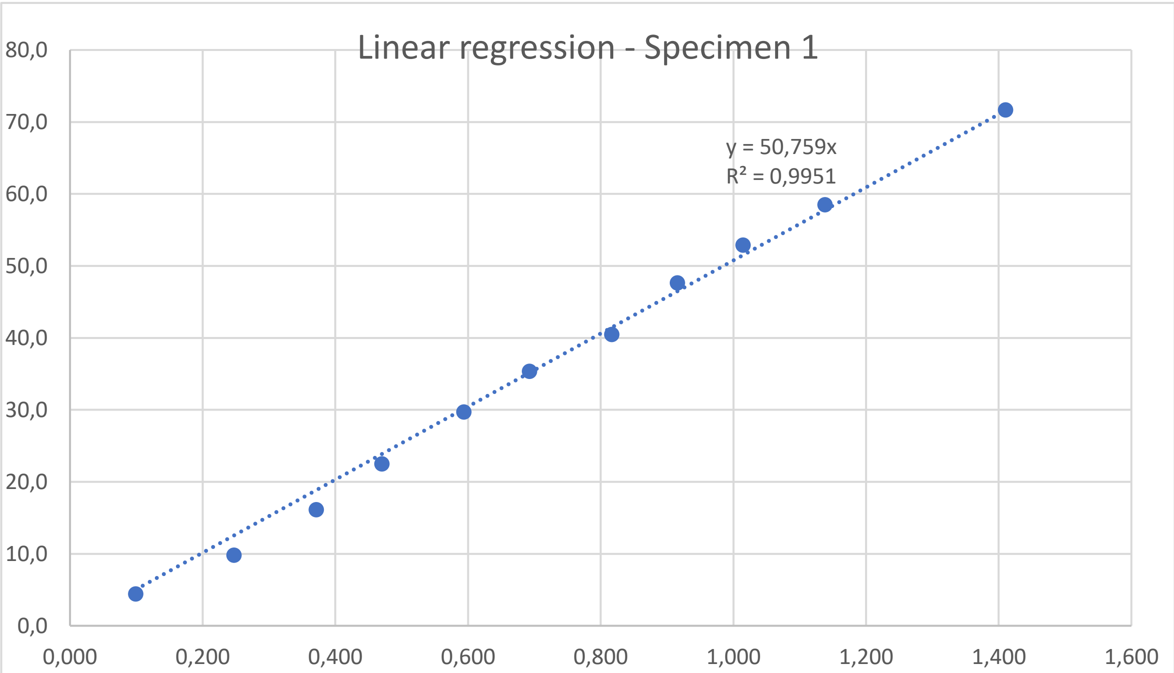
Specimen	Length	Width	Height			
2	37,80	36,30	40,24		Cross section	1372,14
strain (%)	Initial length(mm)	final length(mm)	true strain(%)	Load(N)	(mm^2)	Compression stress (kpa)
0,1	40,24	40,20	0,099	9,17		6,68
0,2	40,23	40,15	0,224	19,88		14,49
0,3	40,22	40,10	0,348	29,20		21,28
0,4	40,22	40,06	0,447	39,06		28,47
0,5	40,21	40,01	0,572	48,33		35,22
0,6	40,22	39,97	0,671	56,65		41,29
0,7	40,21	39,92	0,795	66,03		48,12
0,8	40,20	39,87	0,919	74,92		54,60
1	40,20	39,79	1,118	90,51		65,96
1,25	40,18	39,68	1,392	113,30		82,57
1,5	40,15	39,55	1,715	132,80		96,78
2	40,14	39,34	2,237	163,10		118,87
2,5	40,11	39,11	2,808	189,80		138,32
3	40,12	38,92	3,280	211,80		154,36
4	40,12	38,51	4,299	246,70		179,79
6	39,97	37,57	6,635	296,30		215,94
8,5	39,97	36,58	9,095	321,40		234,23
10	39,93	35,94	10,686	329,40		240,06
12,5	39,47	34,54	14,165	337,90		246,26
15	39,03	33,17	17,570	355,90		259,38
17,5	38,79	32,00	20,477	368,60		268,63
20	39,03	31,22	22,416	377,90		275,41
25	38,35	28,76	28,529	412,90		300,92
30	37,93	26,54	34,046	449,50		327,59
35	37,24	24,20	39,861	490,70		357,62
40	37,03	22,21	44,806	559,00		407,39
50	36,58	18,29	54,548	738,40		538,14
60	36,03	14,41	64,190	1082,00		788,55

Compression test

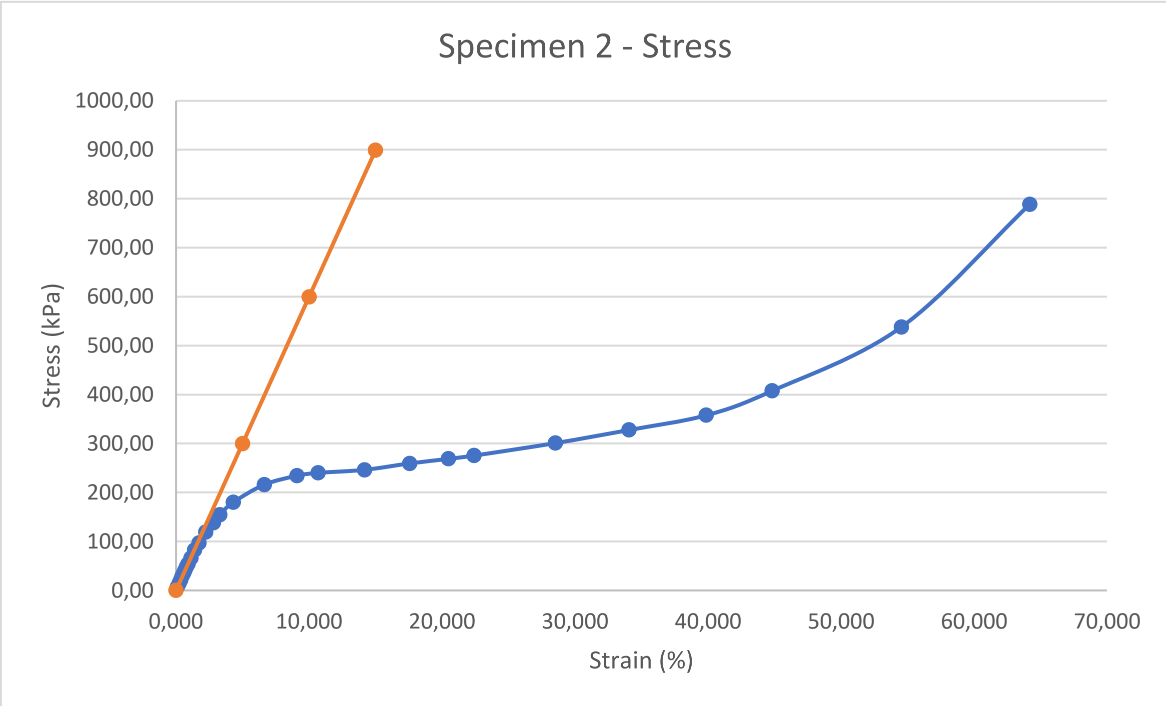
Specimen	Length	Width	Height			
3	35,50	36,00	40,26		Cross section	1278
strain (%)	Initial length(mm)	final length(mm)	true strain(%)	Load(N)	(mm^2)	Compression stress (kpa)
0,1	40,26	40,22	0,099	9,30		7,28
0,2	40,24	40,16	0,248	19,90		15,57
0,3	40,24	40,12	0,348	29,73		23,26
0,4	40,24	40,08	0,447	38,60		30,20
0,5	40,24	40,03	0,571	47,32		37,03
0,6	40,23	39,99	0,671	56,54		44,24
0,7	40,23	39,95	0,770	64,88		50,77
0,8	40,22	39,89	0,919	74,20		58,06
1	40,21	39,81	1,118	90,17		70,56
1,25	40,21	39,71	1,366	110,00		86,07
1,5	40,20	39,59	1,664	128,00		100,16
2	40,17	39,36	2,235	159,40		124,73
2,5	40,07	39,07	2,956	192,80		150,86
3	40,10	38,90	3,378	210,20		164,48
4	40,09	38,49	4,396	244,80		191,55
6	40,01	37,61	6,582	290,10		227,00
8,5	39,62	36,25	9,960	318,70		249,37
12,5	39,34	34,43	14,481	341,80		267,45
15	38,97	33,12	17,735	347,00		271,52
20	38,71	30,96	23,100	373,70		292,41
25	38,36	28,77	28,539	404,70		316,67
30	38,03	26,62	33,880	441,90		345,77
35	37,67	24,48	39,195	488,20		382,00
40	37,29	22,37	44,436	548,00		428,79
50	36,87	18,44	54,198	724,90		567,21
60	36,16	14,47	64,059	1076,00		841,94

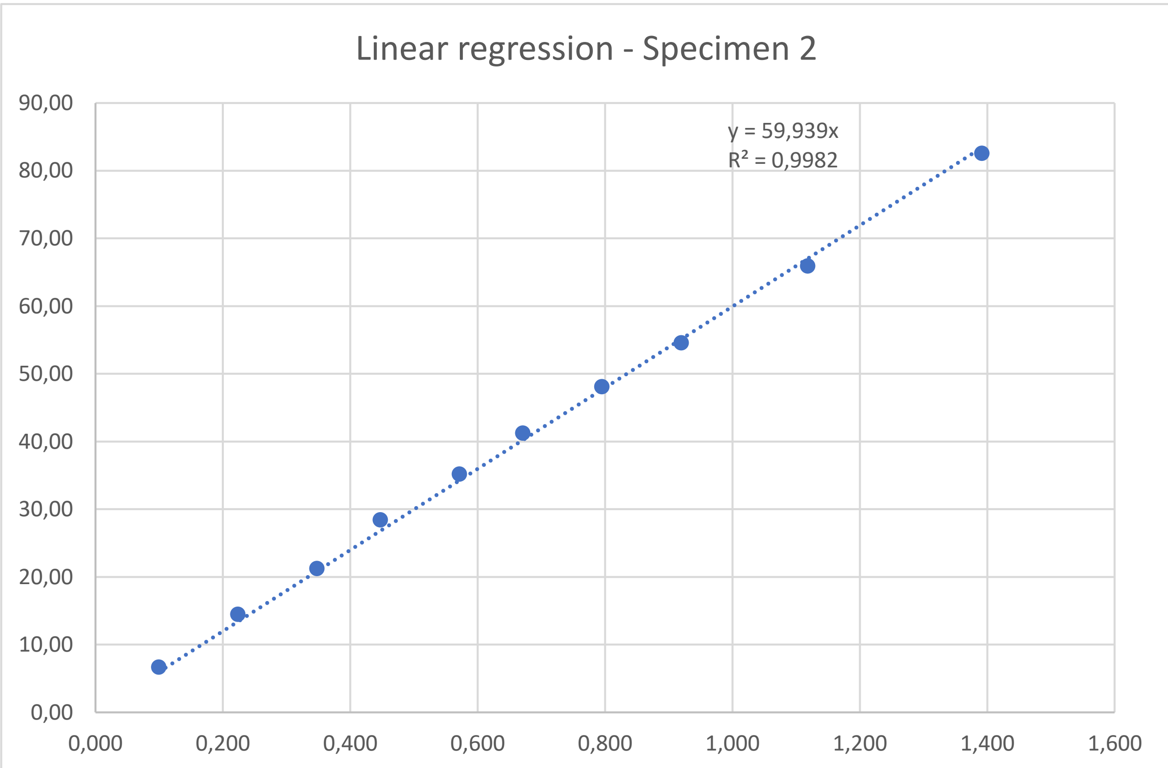
Compression test



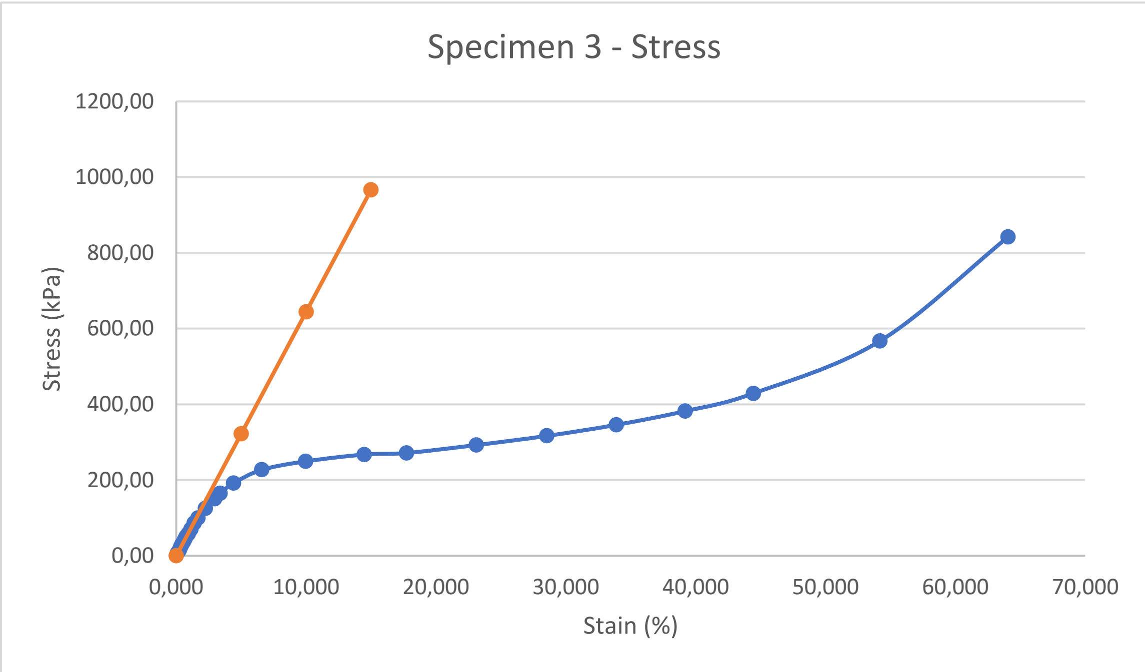


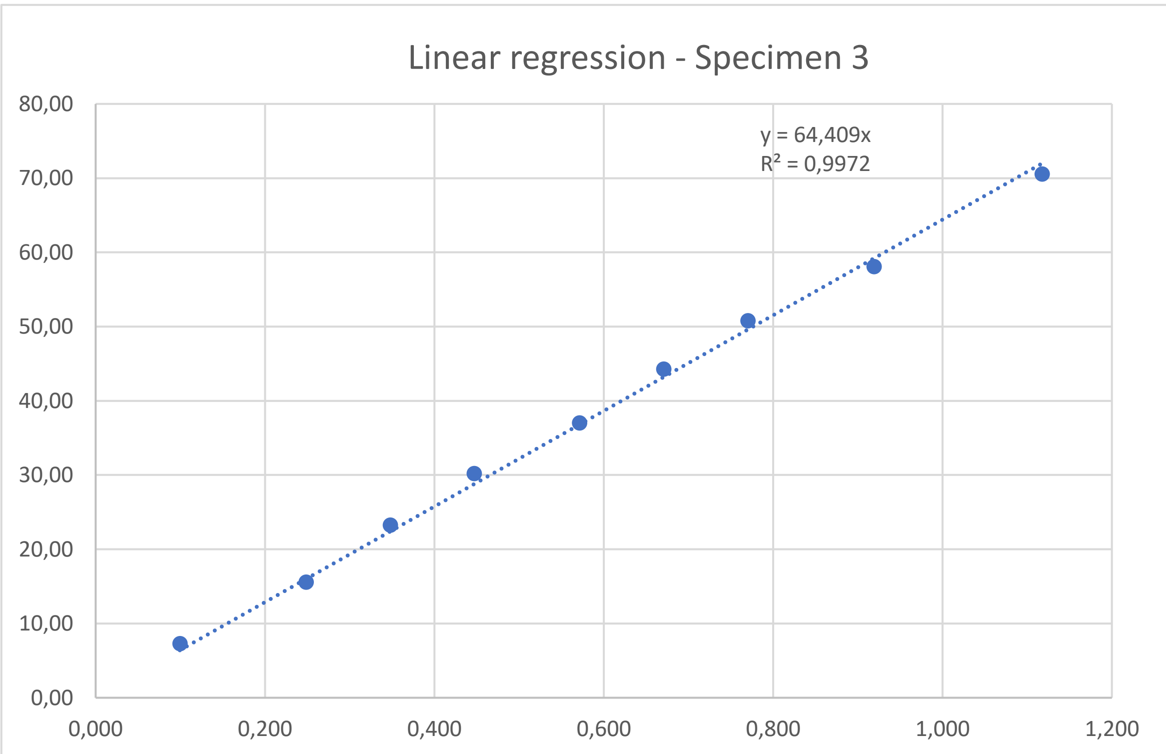
Compression test





Compression test





Elastic region

Specimen 1

x	y
0	0
5	253,795
10	507,59
15	761,385

E-modulus 1

5075,9 kPa
0,0050759 GPa

Specimen 2

x	y
0	0
5	299,695
10	599,39
15	899,085

E-modulus 2

5993,9 kPa
0,0059939 GPa

Specimen 3

x	y
0	0
5	322,045
10	644,09
15	966,135

E-modulus 3

6440,9 kPa
0,0064409 GPa

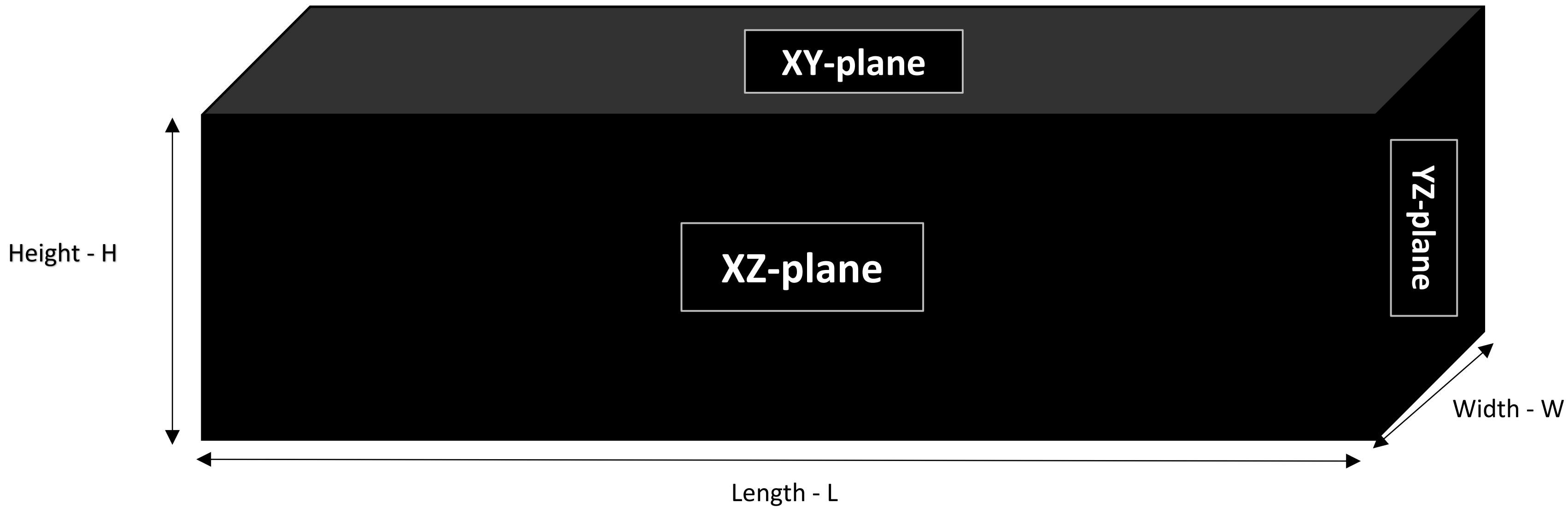
Avg. E-modulus

5836,9 kPa
0,0058369 Gpa
5,8369 Mpa

.2.2 Shore A hardness test

Shore hardness test (A)

test nr.	hardness			
1	44	Measure on XY plane	take average of each side and maybe then take average of the averages	
2	45			
3	45		one can see that the flipped short and longside are machined contrary	
4	44		to the biggest surfaces	
5	43		Ha med bilde av identation, maskinert side, store overflaten og hjørnet	
6	45			
7	46	Turn the specimen upside down	anoaloge instrumenter har nøyakighet på 0,5 av den minste målingen.	
8	46		hvis minste målingen til en linjal er 1 mm, er nøyaktigheten på ±0,5 mm	
9	47			
10	47			
11	46			
12	46			
13	41	Measure on XZ plane	<--------	disse verdiene er ikke relevant å se på i forhold til mitt prosjekt,
14	43			men kan være interessant for poisson ratio
15	43			
16	42			**Average Shore Hardness**
17	44	Turn the specimen upside down		45,3333333 A
18	43			
19	43			
20	41			
21	41	Measure on YZ plane		
22	42			
23	42			


XY-plane
XZ-plane
YZ-plane
Height - H
Length - L
Width - W

.3 Risk Assessment

ID	23809	**Status**	**Date**
Risk Area	Risikovurdering: Helse, miljø og sikkerhet (HMS)	Created	08.11.2017
Created by	Nikors Sivarajah	Assessment started	08.11.2017
Responsible	Nikors Sivarajah	Actions decided	08.11.2017
		Closed	08.11.2017

Risk Assessment:

RIsk Assessement: Master Thesis

Valid from-to date:
10/23/2017 - 18/06/2018

Location:
Trondheim

Goal / purpose
Reduce risks associated with the project

Background
Standard procedure for master thesis

Description and limitations
NTNU, Trøndelags Ortopediske Verksted AS, supervisors and the author of the thesis is affected by the subject of the risk assessment

Unit: Department of Mechanical and Industrial Engineering (MTP) **Date:** 08.11.17

Line manager: Torgeir Welo (Head of Departement)

Participants in the identification process (including their function): Knut Aasland (Supervisor), Nikors Sivarajah (Student)

Short description of the main activity/main process: Master project for Nikors Sivarajah
- **Project title:** Implementing 3D Printing in the Production Process for Footbeds

Is the project work purely theoretical: NO

Signature:

Responsible supervisor: Knut Einar Aasland

Student: Nikors Sivarajah

Summary, result and final evaluation

The summary presents an overview of hazards and incidents, in addtition to risk result for each consequence area.

Hazard: **Danger of using machines at workshop**

Incident: **Cuts, crushing and burning**

Consequence area: Helse (Health) — Risk before actions: Risiko after actions:

Planned action	Responsible	Registered	Deadline	Status
Practical course for students	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted
HSE- and fire- course	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted

Incident: **Fire**

Consequence area: Ytre miljø (Environment) — Risk before actions: Risiko after actions:

Planned action	Responsible	Registered	Deadline	Status
HSE- and fire- course	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted

Incident: **Poor functionality in machines**

Consequence area: Materielle verdier (Material assets) — Risk before actions: Risiko after actions:

Planned action	Responsible	Registered	Deadline	Status
Practical course for students	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted
HSE- and fire- course	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted

Hazard: **Danger of using machines and 3D printers**

Incident: **Poor functionality**

Consequence area: Materielle verdier — Risk before actions: Risiko after actions:

Planned action	Responsible	Registered	Deadline	Status
3D course	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted

Incident: **Crushing and burning**

Consequence area: Helse — Risk before actions: Risiko after actions:

Planned action	Responsible	Registered	Deadline	Status
3D course	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted

Hazard:	**Danger of using machines and 3D printers**
Incident:	**Fire**

Consequence area: Ytre miljø   Risk before actions: Risiko after actions:

Planned action	Responsible	Registered	Deadline	Status
3D course	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted
HSE- and fire- course	Nikors Sivarajah	08.11.2017	18/06/2018	Submitted

Final evaluation

The risk assessement conclude that all risks are acceptable for the master thesis. A proper caution is taken by having relevant courses to reduce all the critical risks to acceptable risks.

Organizational units and people involved

A risk assessment may apply to one or more organizational units, and involve several people. These are lsited below.

Organizational units which this risk assessment applies to

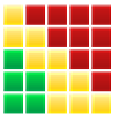
- Department of Mechanical and Industrial Engineering (MTP)

Others involved/stakeholders

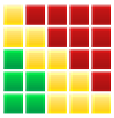
Knut Einar Aasland
Tobia Goihl (Trøndelags Ortopediske Verksted AS)

The following accept criteria have been decided for the risk area Risikovurdering: Helse, miljø og sikkerhet (HMS):

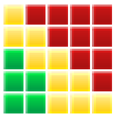
Helse



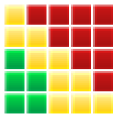
Materielle verdier



Omdømme



Ytre miljø



Overview of existing relevant measures which have been taken into account

The table below presents existing measures which have been take into account when assessing the likelihood and consequence of relevant incidents.

Hazard	Incident	Measures taken into account
Danger of using machines at workshop	Cuts, crushing and burning	Personal protective equipment
	Cuts, crushing and burning	Ventilation
	Fire	
	Poor functionality in machines	Personal protective equipment
Danger of using machines and 3D printers	Poor functionality	
	Crushing and burning	
	Fire	

Existing relevant measures with descriptions:

Personal protective equipment

Personal protective equipment must be used when using the workshop

Ventilation

Ventilation must be used when f.ex. soldering

Risk analysis with evaluation of likelihood and consequence

This part of the report presents detailed documentation of hazards, incidents and causes which have been evaluated. A summary of hazards and associated incidents is listed at the beginning.

The following hazards and incidents has been evaluated in this risk assessment:

- **Danger of using machines at workshop**
  - Cuts, crushing and burning
  - Fire
  - Poor functionality in machines
- **Danger of using machines and 3D printers**
  - Poor functionality
  - Crushing and burning
  - Fire

Detailed view of hazards and incidents:

Hazard: Danger of using machines at workshop

Danger of crushing, burning, and cuts using machines at workshop for prototyping

Incident: Cuts, crushing and burning

Likelihood of the incident (common to all consequence areas): **Likely (3)**

Kommentar:

Uncarefulness or uncertainty of knowing how to use the machines properly and correctly can increase the chance of incidents

Consequence area: Helse

Risk:

Assessed consequence: **Large (3)**

Comment: Can cause injuries on bodyparts

Incident: Fire

Likelihood of the incident (common to all consequence areas): **Less likely (2)**

Kommentar:

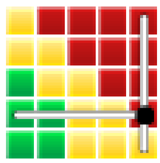
More likely to spot fire and easy to prevent spreading of fire

Consequence area: Ytre miljø

Risk:

Assessed consequence: **Catastrophical (5)**

Comment: A fire, depending on the size, can give huge economical loss and loss of lives is also a probability.



Incident: Poor functionality in machines

wear and tear of machine components and tools

Likelihood of the incident (common to all consequence areas): **Quite likely (4)**

Kommentar:

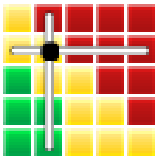
Wear and tear of machines will occur in the end if not properly maintained or used

Consequence area: Materielle verdier

Assessed consequence: **Medium (2)**

Comment: Machines get broken if not given proper maintenance

Risk:



Hazard: Danger of using machines and 3D printers

Danger of crushing and burning using 3D printers for prototyping

Incident: Poor functionality

Wear and tear of machine

Likelihood of the incident (common to all consequence areas): **Likely (3)**

Kommentar:

Wear and tear of printers will occur in the end if not properly maintained or used

Consequence area: Materielle verdier

Assessed consequence: **Medium (2)**

Comment: Economical loss from broken machines

Risk:

Incident: Crushing and burning

Hot components in the 3D printer can f.ex. lead burning of fingers

Likelihood of the incident (common to all consequence areas): **Quite likely (4)**

Kommentar:

One must clean hot nozzle when heated to 200 degrees celsius

Consequence area: Helse

Assessed consequence: **Large (3)**

Comment: Can cause hand injuries

Risk:

Incident: Fire

Unsupervised machines and misprinting can lead to fire

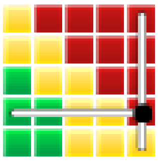
Likelihood of the incident (common to all consequence areas): **Less likely (2)**

Kommentar:

More likely to spot fire and easy to prevent spreading of fire

Consequence area: Ytre miljø

Risk:



Assessed consequence: **Catastrophical (5)**

Comment: A fire, depending on the size, can give huge economical loss and loss of lives is also a probability.

Overview of risk mitiating actions which have been decided:

Below is an overview of risk mitigating actions, which are intended to contribute towards minimizing the likelihood and/or consequence of incidents:

- 3D course
- Practical course for students
- HSE- and fire- course

Overview of risk mitigating actions which have been decided, with description:

3D course

Mandatory 3D course has been taken at the lab to prevent these type of dangers.

Action decided by: Nikors Sivarajah

Responsible for execution: Nikors Sivarajah

Deadline for execution: 18/06/2018

Practical course for students

A practical course inlcudes how to execute operations like milling, turning and welding on various machines

Action decided by: Nikors Sivarajah

Responsible for execution: Nikors Sivarajah

Deadline for execution: 18/06/2018

HSE- and fire- course

Mandatory HSE- and fire-course needs to be taken to prevent these type of dangers

Action decided by: Nikors Sivarajah

Responsible for execution: Nikors Sivarajah

Deadline for execution: 18/06/2018

Detailed view of assessed risk for each hazard/incident before and after mitigating actions

Hazard: Danger of using machines at workshop

Incident: Cuts, crushing and burning

Likelihood assessment (common to all consequence areas)

Initial likelihood: Likely (3)

Reason: Uncarefulness or uncertainty of knowing how to use the machines properly and correctly can increase the chance of incidents

Likelihood after actions: Unlikely (1)

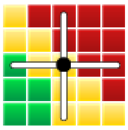
Reason: The practical course for students informs how to use the machines correctly which again reduce the risk of incidents

Consequence assessments:

Consequence area: Helse ***Risk:***

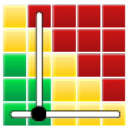
Initial consequence: Large (3)

Reason: Can cause injuries on bodyparts



Consequence after actions: Medium (2)

Reason: HSE course and proper information about how to use the machines (practical course) reduce the consequence of the incident



Incident: Fire

Likelihood assessment (common to all consequence areas)

Initial likelihood: Less likely (2)

Reason: More likely to spot fire and easy to prevent spreading of fire

Likelihood after actions: Unlikely (1)

Reason: The HSE and fire course informs how to prevent fire

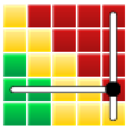
Consequence assessments:

Consequence area: Ytre miljø

Risk:

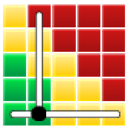
Initial consequence: Catastrophical (5)

Reason: A fire, depending on the size, can give huge economical loss and loss of lives is also a probability.



Consequence after actions: Medium (2)

Reason: The consequence can be reduced as the course informs how to prevent and reduce damage from fire.



Incident: Poor functionality in machines

Likelihood assessment (common to all consequence areas)

Initial likelihood: Quite likely (4)

Reason: Wear and tear of machines will occur in the end if not properly maintained or used

Likelihood after actions: Unlikely (1)

Reason: The courses reduce the likelihood of incidents when given proper maintenance and used correctly

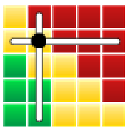
Consequence assessments:

Consequence area: Materielle verdier

Risk:

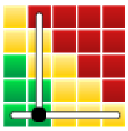
Initial consequence: Medium (2)

Reason: Machines get broken if not given proper maintenance



Consequence after actions: Medium (2)

Reason: The consequence remains the same even though the risk is reduced



Hazard: Danger of using machines and 3D printers

Incident: Poor functionality

Likelihood assessment (common to all consequence areas)

Initial likelihood: Likely (3)

Reason: Wear and tear of printers will occur in the end if not properly maintained or used

Likelihood after actions: Less likely (2)

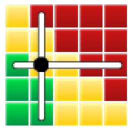
Reason: Proper maintenance and use of machines decrease the likelihood of incidents

Consequence assessments:

Consequence area: Materielle verdier ***Risk:***

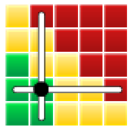
Initial consequence: Medium (2)

Reason: Economical loss from broken machines



Consequence after actions: Medium (2)

Reason: The consequence remains the same



Incident: Crushing and burning

Likelihood assessment (common to all consequence areas)

Initial likelihood: Quite likely (4)

Reason: One must clean hot nozzle when heated to 200 degrees celsius

Likelihood after actions: Unlikely (1)

Reason: The 3D course informs how to use and give the printers the proper maintenance

Consequence assessments:

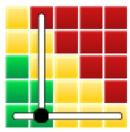
Consequence area: Helse ***Risk:***

Initial consequence: Large (3)

Reason: Can cause hand injuries

Consequence after actions: Medium (2)

Reason: The consequence is reduced as the course informs how to properly use and clean the printers



Incident: Fire

Likelihood assessment (common to all consequence areas)

Initial likelihood: Less likely (2)

Reason: More likely to spot fire and easy to prevent spreading of fire

Likelihood after actions: Unlikely (1)

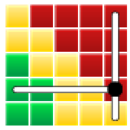
Reason: The 3D, HSE and fire course informs how to prevent fire

Consequence assessments:

Consequence area: Ytre miljø ***Risk:***

Initial consequence: Catastrophical (5)

Reason: A fire, depending on the size, can give huge economical loss and loss of lives is also a probability.



Consequence after actions: Medium (2)

Reason: The consequence can be reduced as the course informs how to prevent and reduce damage from fire.