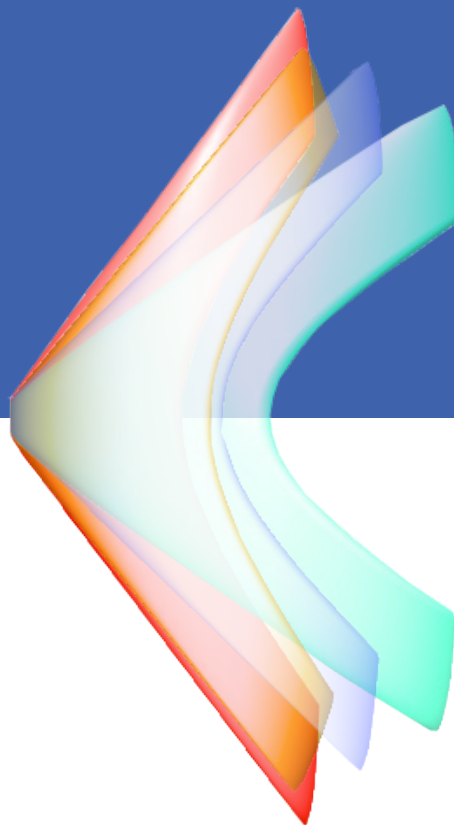


# LOCAL FABRICATION OF A CUSTOM-FIT FINGER SPLINT

Using parametric design and additive manufacturing

A design research to address guidance in the quality and safety of medical device manufacturing in the context of digital fabrication and the Maker Movement



Master thesis Biomedical Engineering

I. Poortinga



waag society



university of  
 groningen

# Local fabrication of a custom-fit finger splint

Using parametric design and additive manufacturing

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# Preface

In front of you lies the thesis “Local fabrication of a custom-fit finger splint, using parametric design and additive manufacturing”, a design research to address guidance in the quality and safety of medical device manufacturing in the context of digital fabrication and the Maker Movement. It has been written to fulfil the graduation requirements of the master degree Biomedical Engineering at the University of Groningen. I was engaged in researching and writing this thesis from March until September 2016.

The project was undertaken at the Creative Care Lab at Waag Society. The Waag Society explores emerging technologies, and provides art and culture a central role in the designing of new applications for novel advances in science and technology. The Creative Care Lab concentrates on the design issues found in the field of healthcare. In the context of MakeHealth - a programme that explores a crossover between Healthcare and the ‘Do It Yourself’ makers culture of Fab Lab – Software developer Taco van Dijk and Designer Mickael Boulay developed a working demo of an app on a tablet to generate a ready-to-be-3D-printed finger splint. This concept seemed like a potential breakthrough, but it was still unclear where such a product has to meet for a potential market introduction.

I was challenged to identify the quality and safety requirements for such a ‘customized’ orthosis. During the project, I got fascinated by approaching it as a design case to see what happens when such a novel technology meets the traditional pathways of medical device development. Due to the simplicity of a finger splint, I was able to approach this design case from the many different aspects of medical device development. I learned the skill of parametric modelling and 3D-printing; immersed myself in regulatory rules and guidelines; discussed the ethical issues; analysed the biomechanics and materials science; looked into strategies for market introduction; acquired knowledge of digital fabrication and got inspired by the Maker spirit. With this study I hope to provide an example of how additive manufacturing can be guided to find their way to patient’s and healthcare professionals in a responsible manner, and I hope more will follow soon.

I am very grateful to my supervisor at the Waag, Jurre Ongering, and my supervisor at the University of Groningen prof. dr. ir. G.J. Verkerke. Thank you sincerely for your help, guidance, and support during the project. I also like to thank my colleagues at the Creative Care Lab for making me feel part of the team: Sabine Wildevuur, Pauline Melis, Janine Huizinga and Hester van Zuthem, it was inspiring to work with you. And to my colleagues at Fab Lab, Nicolo Merendino and Nina Papakonstantinou, thank you for teaching me the ‘maker’ skills. Furthermore, I would like to thank all external contacts for their help and advice during the project: Ing. H.M kuis (RUG), R. Groeneveld (Oceanz), T. Heitman (Zaans Medical Centre), Mattie Dapper (VUMC), prof. dr. C.K. van der Sluis (UMCG), N. Liberton (3D-innovatie Lab VUMC), P. van Ooijen (3D-innovatie Lab UMCG).

I hope you enjoy reading,

Ida Poortinga

Amsterdam, September 14, 2016.

## Abstract

The rise of digital fabrication and the Maker Movement has enabled people to start playing an active role in devising and developing their own medical devices. The benefit of digital fabrication for healthcare is its ability to rapidly alter size and shape of orthoses to meet specific patient sizes and needs. In addition, digital fabrication offers an on-demand supply chain that potentially increases sustainability of the medical device industry. However, more clarification is needed to point out whether it is feasible to locally 3D-print a customized orthosis that can be considered safe and effective.

This study aims to revisit medical product development in the context of the aforementioned rise of additive manufacturing and the maker movement. Therefore, the following research question is addressed: *“Can digital fabrication enable patient access to local fabrication of customized orthoses with the quality and safety of professionally-graded medical devices?”* Quality and safety is hereby approached with reference to the regulatory rules and guidelines for medical devices. This research question is addressed by means of the design specific case study of the customizable finger splint.

The first part of this study explores the effects of digital fabrication on the quality, safety and access customized orthoses. This reveals that still many challenges need to be overcome for a successful clinical application. First, the current regulatory system does not seem suitable for local fabrication of personalized medical devices. Second, it reveals that the underlying technique of additive manufacturing limits material options and negatively affects the quality and mechanical safety of the printed object. Third, it demonstrated that the access to digital fabrication is still restricted to people with 3D-modelling skills and knowledge of additive manufacturing. The second part of this study, the development of the finger splint, made clear that these challenges can be tackled. The provided solution is an application that enables the hand therapist or patient to 3D-print a customized finger splint, without need the for 3D-modelling skills or knowledge of digital fabrication. This is enabled by parametric design software and a ISO-certified 3D-printing service. From this it can be concluded that digital fabrication can be guided to enable patient access to local fabrication of customized orthoses with the quality and safety of professionally-graded medical devices.

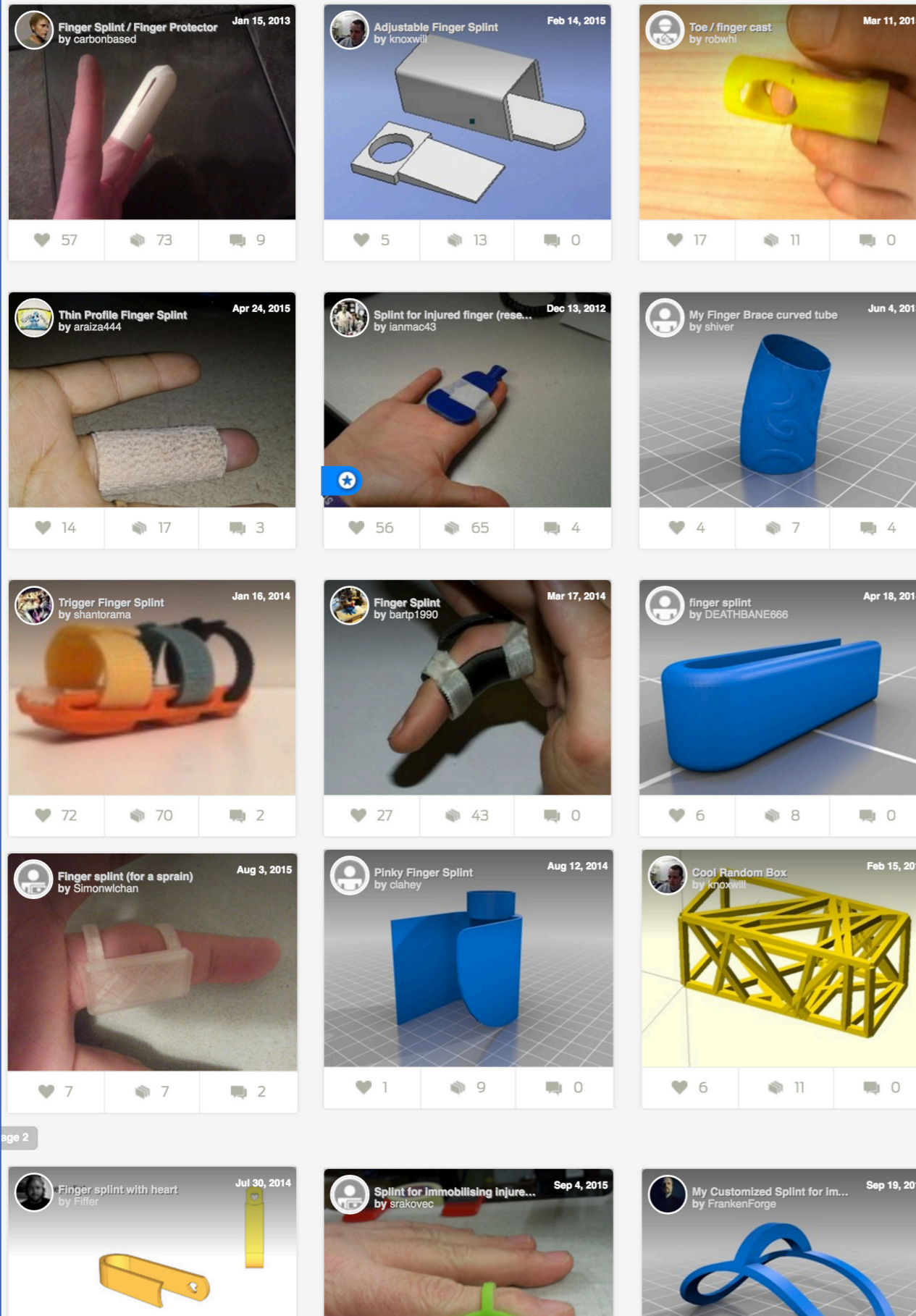
Drawbacks of the provided solution are fabrication- and delivery time resulting from the selected manufacturing process. In order to enable fabrication closer to the patient, future research should be focussed on the development of 3D-printers suitable for implementation within the clinic of the hand therapist. A second drawback of the provided solution is that the design freedom is limited design by the parametric input. In order to allow automated modelling of more complex orthoses, parametric software should be further developed with the aim of orthoses design. Now that the possibilities of parametric design and additive manufacturing are approved to be successful for local fabrication of orthoses, it is recommended to further develop the final solution for introduction to the market. This would be an important step in the accomplishment of on-demand production and mass-customization in the context of healthcare.

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35 results for **finger splint**: [Things](#) (35) | [Users](#) (0) | [Collections](#) (0)

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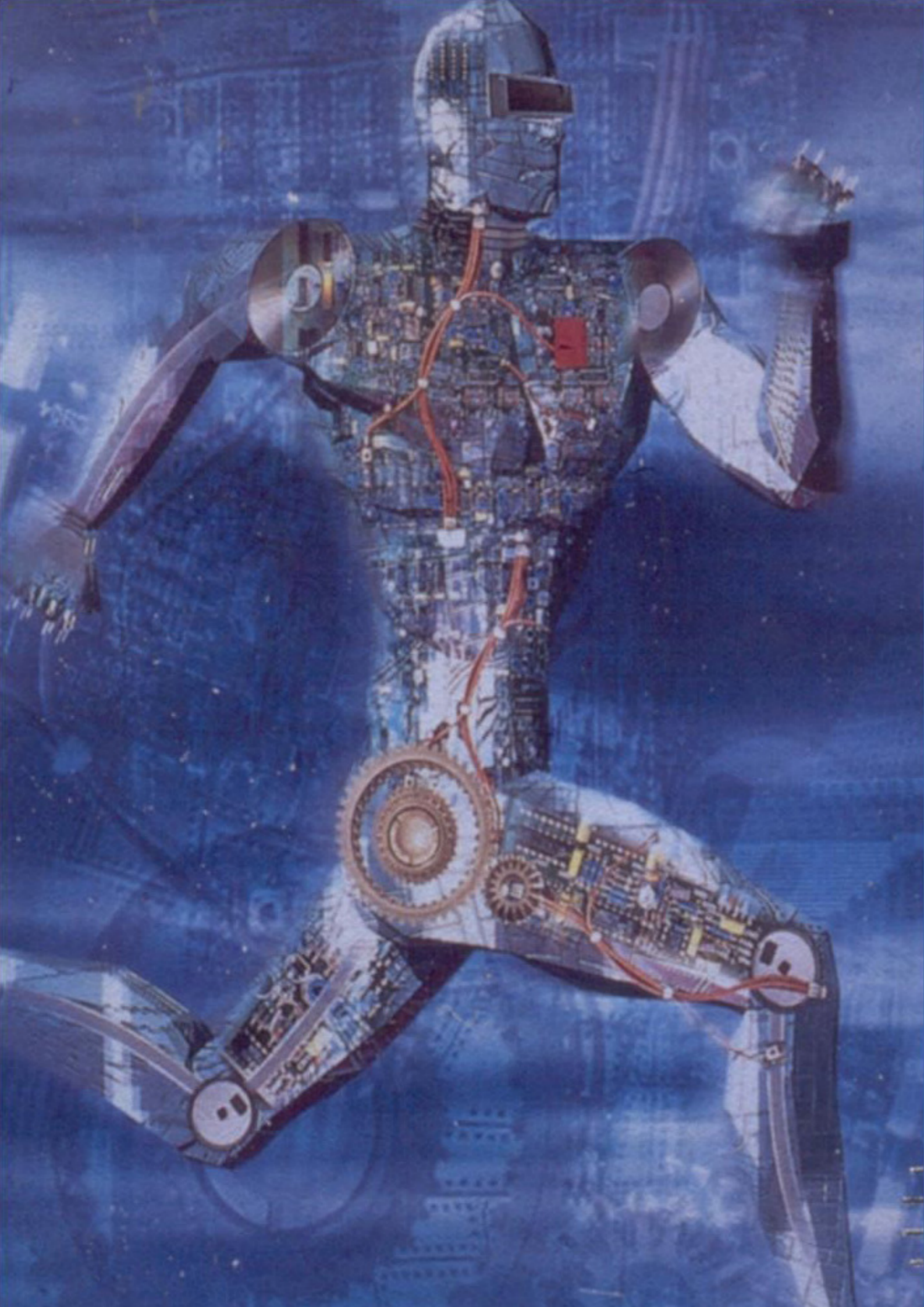
## Introduction

*Searching different combination of the search terms 'Do It Yourself (DIY) Finger splint' on Google, reveals many examples of how to create a finger splint oneself. Adding '3D' to the search terms, even reveals a variety of design files that is freely shared over the Internet. It seems like one could easily make a finger splint from the comfort of his or her own home, just by clicking the bottom 'print now'. With some 3D-modelling skills, a healthcare practitioner, rheumatic patient, or other person could even start creating a personal design. One could imagine orthoses design breaking free from the traditional healthcare institutions and production processes that it was constricted to for many years.*

The scenarios described above are enabled by the emergence of additive manufacturing, also referred to as 3D-printing, and unlimited access to knowledge through the Internet. which has made it possible for individuals to develop and locally fabricate their own products. This has led to a so-called Maker Movement. It is of interest to explore the developments arising from this Maker Movement and the emergence of digital fabrication in the context of healthcare, as it potentially opens up possibilities for local fabrication of custom-made orthoses.

This thesis is focussed on revisiting medical product development in the context of the aforementioned rise of additive manufacturing and the maker movement. The following research question is addressed: "Can digital fabrication enable patient access to local fabrication of customized orthoses with the quality and safety of professionally-graded medical devices?" This research question will be discussed by means of the design specific case study of the customizable finger splint.

The traditional medical device industry is strictly regulated to enable patient access to high quality, safe and effective medical devices, and restricting access to those products that are unsafe or have limited clinical use. While in the in the context of open design and DIY- culture, official approval is not required. The popularity of digital fabrication in orthoses design is clearly present, yet little can be found to actually be used in a clinical setting. Clarification is therefore needed to point out whether it is feasible to locally 3D-print a customized orthosis that can be considered safe and effective. The first part of this study aims to reveal the challenges that might limit a successful introduction in a clinical setting. The second part of the study, the design case, aims to provide one specific solution that confirms the feasibility of locally 3D-printing a customized finger splint.



# 1 Methodology

This chapter describes the *research approach* and the *design methodology* for the case study of the finger splint, that is used to address the research question.

- 1.1 Research approach
- 1.2 Design methodology

### 1.1 Research approach

The research question will be discussed by developing a customizable finger splint for local fabrication using digital fabrication. The first part of the study includes a background study to explore how the rise of digital fabrication and the Maker Movement affects the quality, safety and access of customized orthoses. Therewith the following sub-question will be answered: *“What are the expected challenges of the aforementioned changing manufacturing landscape in which medical devices could possibly be introduced?”* During this study, the European guideline for medical devices will be used to provide guidance in the validation of quality and safety. These findings form the foundation for revisiting biomedical products design and manufacturing. In the second part of the study, the development of the finger splint will be completed to address how the expected problems can be tackled. This will be done following the design method as described below.

### 1.2 Design methodology

Many methods are available for designing consumer products. However, for designing biomedical products these methods cannot be used directly, since the circumstances are quite different from designing consumer products. The development of biomedical products is a multidisciplinary specialism covering several knowledge areas, like biomechanics, biomaterials, transport phenomena, tissue engineering, medical physics, physiological modelling and interaction, medical informatics, artificial intelligence and biotechnology (10).

The design method for designing biomedical products by Verkerke, G.J and van der Houwen, E.B is, is developed to account for such issues. Because of this multidisciplinary approach, this method is used for the design study of the finger splint.

The design methodology is depicted on the next page in Figure 1.1. It distinguishes five phases, the analysis phase, three synthesis phases and the use-phase. Each phase contains several activities. In the analysis phase the given problem is analysed extensively; the fundamental problem is defined; the goal and required functions of the solution are defined and a list of requirements is made. In Synthesis I various solutions for the formulated fundamental problem are generated, with plenty of creativity and design freedom, a few ideas are combined into what are called pre-concepts. The best solution for the problem is selected by evaluating the solutions on meeting the requirements. The three best concepts are further detailed into concepts in Synthesis II. Then the best concept is selected. In synthesis III the final selected concept is worked out in detail; prototyped; tests are performed to make a proof-of-principle; and the product manufacturing process is developed.

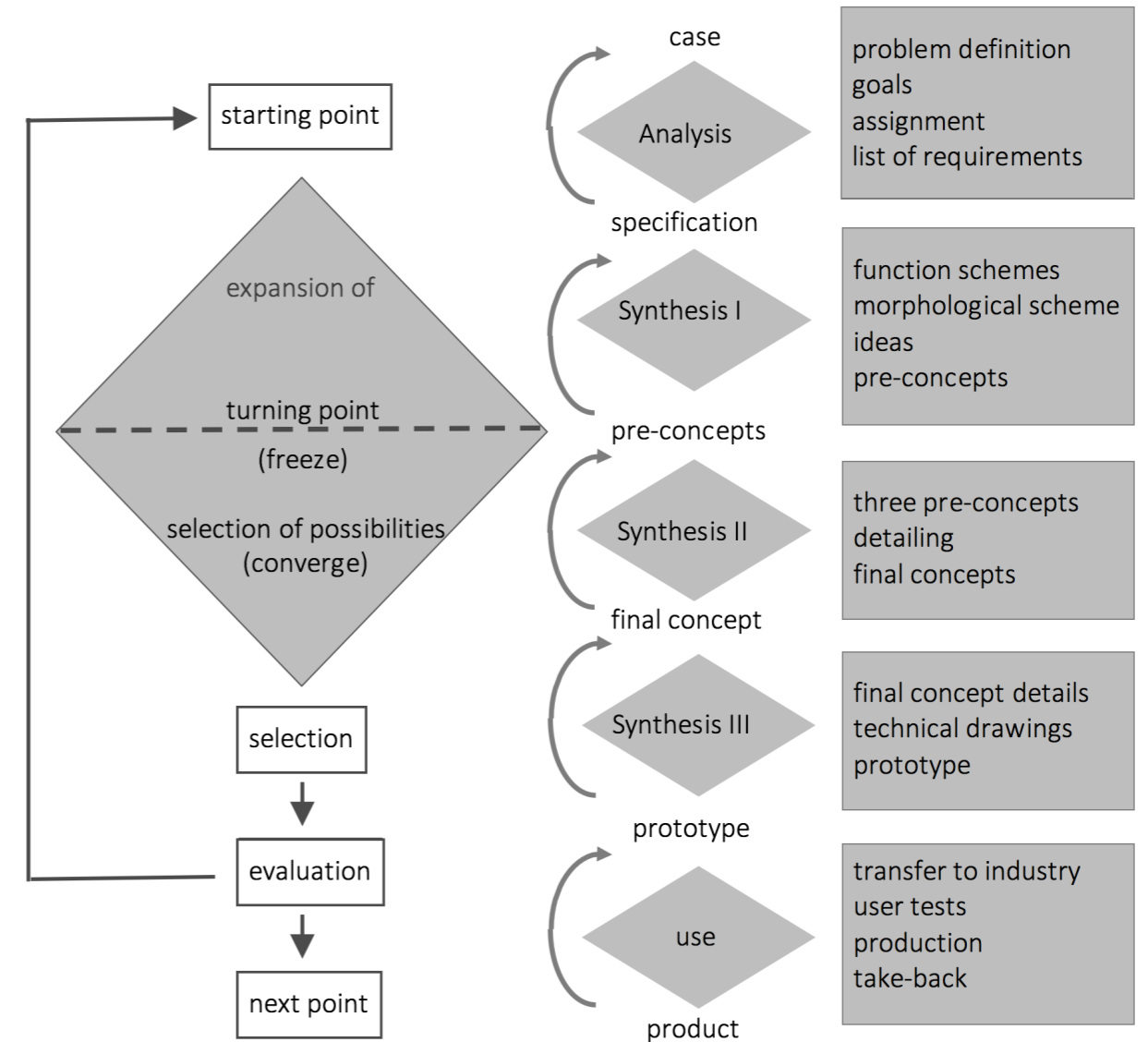


Figure 1.1: Methodical process for designing biomedical products.



For the purpose of this study, the structure of the synthesis phases is altered from the original structure suggested by Verkerke, G.J and van der Houwen, E.B. Since this design study aims to focus on rethinking an existing solution (a finger splint) with reference to the application of new and more innovative technologies (digital manufacturing). Inherent to designing the configuration of the product, is selecting the proper material and manufacturing technique. The material dictates the production method, the

production method dictates the configuration of the design, and the configuration dictates its function. It is also possible to follow a totally reverse process. Both approaches have their own rationale for doing so: it's a circle of function, design, manufacturing and material. In the context of this study the following approach is most suitable: The manufacturing method dictates the material, and both the manufacturing method and material dictate the design (figure 1.2)

Therefore, Instead of creating new ideas for the medical problem, Synthesis I will focus on the creation and selection of material and manufacturing concepts. Synthesis II continues with the generation of three new designs adapted to the previously selected material and manufacturing process. Now that the basic structure of the method has been introduced in this chapter, the following chapters will address these phases in more detail. By doing so, describing the design process of the finger splint will go hand in hand with a further elaboration of the methodical model.

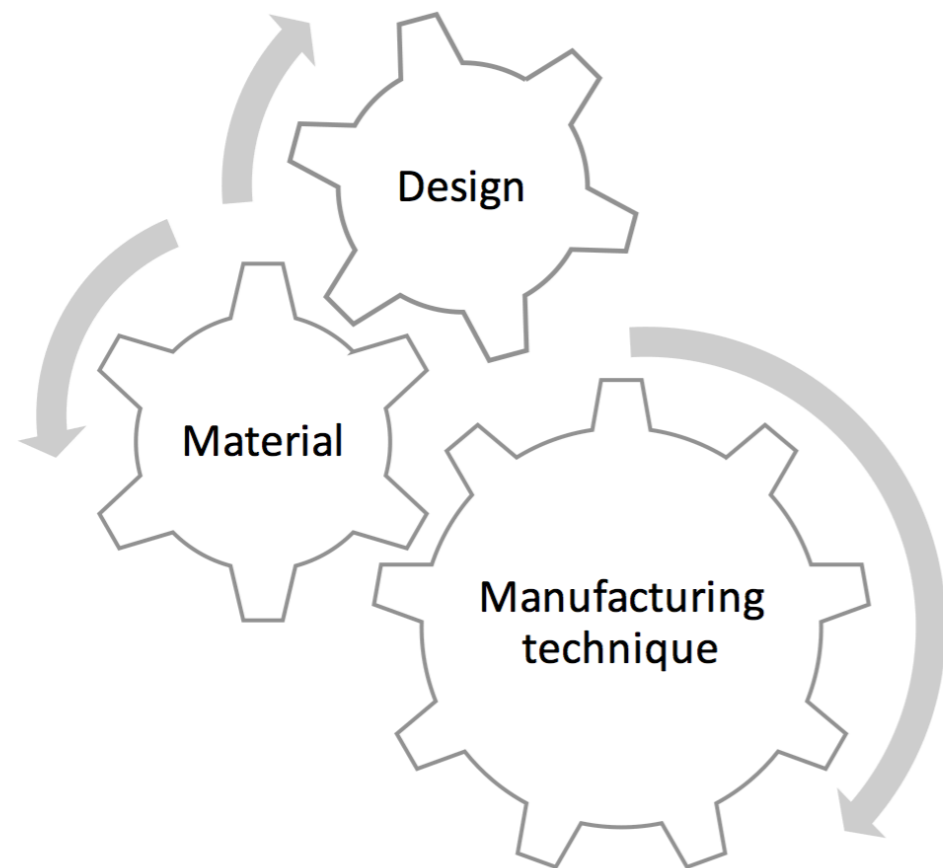
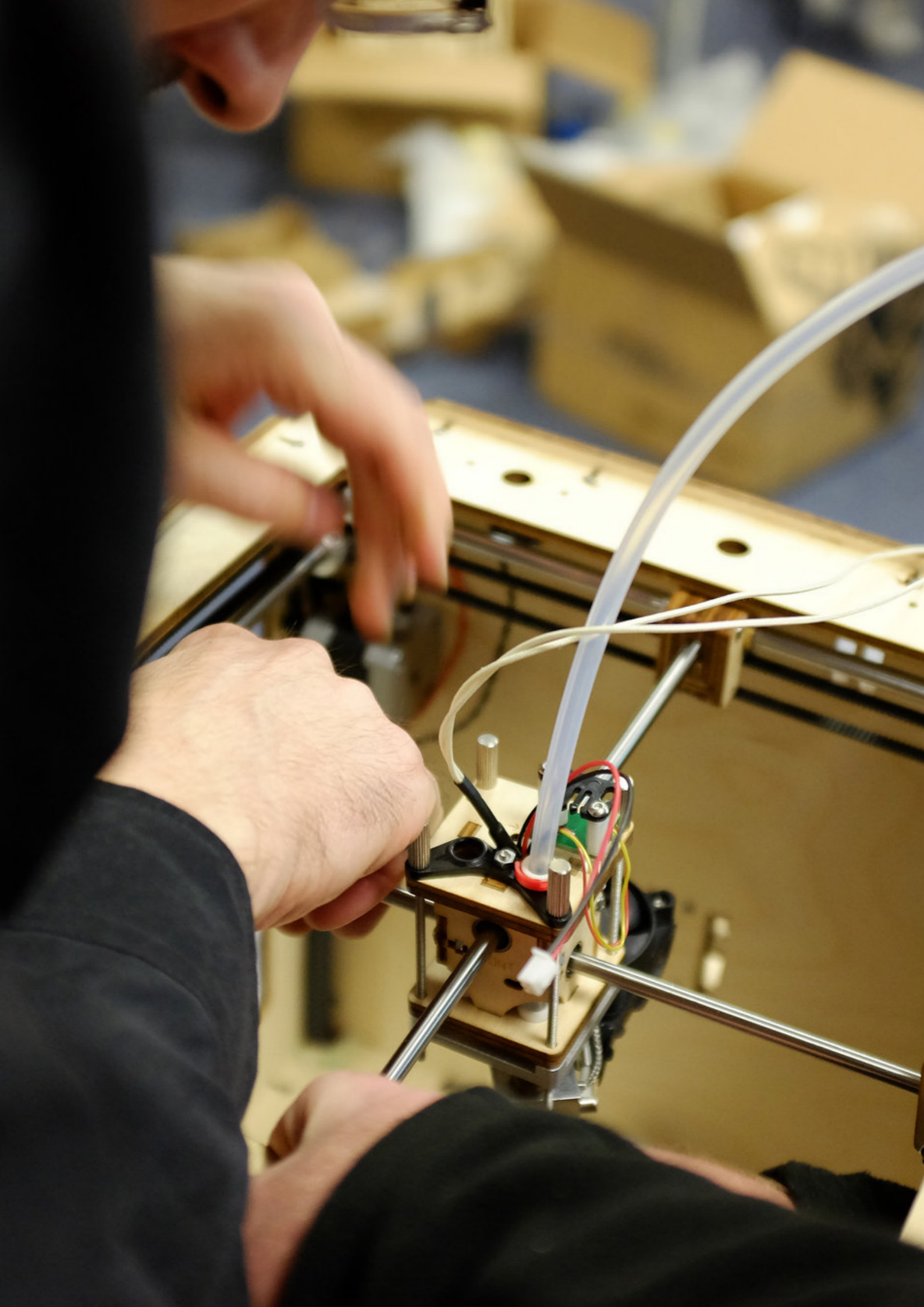


Figure 1.2: The relations between design, material and manufacturing technique



## 2 Context

In this Chapter the *Maker Movement* and the concept of *digital fabrication* is introduced. The opportunities of the cross-over between the Maker Movement, digital fabrication and healthcare will be described, and addresses to the relevance of this study. The *current developments* in these fields are explained at the end of this chapter.

- 2.1 The Maker Movement
- 2.2 Digital fabrication
- 2.3 Current developments

### 2.1 The Maker Movement

*The emergence of additive manufacturing and unlimited access to knowledge via the Internet enabled individuals to develop their own products. This has led to a so-called Maker movement. This paragraph introduces the Maker Movement and addresses how this movement creates possibilities for both patient and professional.*

#### 2.1.1 The Maker Movement

The Maker Movement is as a community of people determined to create their own products using digital fabrication tools like CAD-programs, laser cutters and 3D printers (1). The Maker Movement is spreading worldwide over different disciplines. Online maker communities, physical makerspaces, and maker fairs arise and continually grow in size and participation (2). This online and offline community brings together a wide range of people including scientists, engineers, entrepreneurs, designers and citizen inventors, to share ideas and build products. The technology and the community both represent the basic principles for the current modification and building of tangible things.

The movement is unified by a commitment of open exploration by sharing knowledge, open-source soft- and hardware tools and open design files, and is supported by the Internet in different ways: From the sharing of design files and code libraries to social support, and online knowledge exchange. Open innovation The difference that Internet and open exploration creates in the make-process is defined as: "Make-it stands for making tangible objects specified and designed as virtual 'bits' which can be shared globally but then reproduces as things which manifest themselves locally – blurring the interface between the virtual and the physical "(3).

This digitalized make-culture offers new opportunities to individuals, communities and organizations to innovate, design and make physical products based on manipulation and sharing of virtual bits (3). This also creates the need and will to open up more devices, to understand their inner workings and their outside impact, in order to redesign and personalize them.

#### 2.1.2 Impact on healthcare

This quickly growing maker movement empowers people to become more self-reliant and connects communities to be collaborative in creating the tangible things they use. One can imagine this spreading towards the field of healthcare as well. Enabling people to become active makers of their own medical devices, will significantly contribute to the empowerment of patients (4). Therefore, the make-philosophy in the context of healthcare complies with the new positive definition of health defined by Huber et al. (2011) whereby health is approached as "the ability to adapt and self-manage, in the face of physical, emotional and social challenges" (5). This definition approaches health as a personal challenge instead of it being something that one simply is or isn't. The approach of Huber opens possibilities for a paradigm

shift that enables people to start playing an active role in devising and developing their own medical devices that will positively impact their health.

### 2.2 Digital fabrication

*The following paragraphs will describe the tools and technology of digital fabrication and how this changes the manufacturing landscape. The last paragraph address how digital fabrication can contribute to sustainability technical innovations in a healthcare context.*

#### 2.2.1 Digital fabrication

The power of the Maker Movement is catalysed by the rise of digital manufacturing. Digital fabrication tools like Computer Aided Design (CAD) – software, additive manufacturing, laser cutters or a CNC-milling machine enable personal, flexible and local fabrication. For the purpose of study we only focus on the CAD-software and additive manufacturing. Using computer aided design a virtual 3D-model (CAD-file) can be created. Additive manufacturing is a more technical term for 3D-printing, and covers a range of technologies that translate the virtual data into a physical model. During this process the virtual 3D-data is sliced into 2D-cross section of a specified thickness, from which the physical 3D-model is build up by the machine in a layer-by-layer sequence. Compared to traditional fabrication methods, this technique enables rapid production of unique, personalized products.

Makerspaces and professional online 3D-print services provide public access to digital fabrication tools and expertise. Makerspaces support makers by providing workshops into digital fabrication skills, the necessary soft- and hardware and the space where members are free to work on whatever they want under supervision and mentoring (4). Fab Lab is a global community of qualified Makerspaces all sharing common tools and processes forming a distributed laboratory for research, invention and entrepreneurship (7). The democratizing access to these professional-grade tools for personal fabrication is enabling makers to make almost anything (6). While professional 3D printer companies provide the service have your product delivered at home, just by uploading the file.

#### 2.2.2 Impact on industry and healthcare

The accessibility of additive manufacturing rapidly changes the way everything around can be designed, made and distributed. The emergence of affordable and flexible manufacturing methods has created an alternative supply chain. Products are no longer physically distributed, but as digital files that can be printed everywhere. Customized products make up an increasing portion of the market consequently eroding the mass-produced portion of the market (8). This on-demand production close to the patient increases sustainability of the medical device industry, as it substantially reduces the carbon footprint of manufacturing and transport (8).

In multiple studies additive manufacturing is embraced as a promising technique for orthoses (9-12). Compared to prefabricated orthotic devices, custom-fit orthoses provide individualized comfort and function. Currently, laborious and time-intensive methods need to be performed by skilled therapist to provide a custom-fit. The added value of additive manufacturing lies in the fact that this method makes it possible to locally create personalized devices, both in terms of fit and functionality (12). And the ability to rapidly alter size and shape of these devices to meet specific patient needs decreases fabrication time and cost especially in case of a replacement (9). In addition, imagine when the assembly function moves closer to the end user, the designer can integrate aesthetical preferences of the end-users like, colour, texture or material. The local aspect enables patients to play an active role in devising and developing medical devices.

### 2.3 Current developments

Additive manufacturing has rapidly penetrated the medical device industry over the past several years, and innovative groups and individuals have harnessed it to create devices with unique composition, structure, and customizability (13).

A search on Thingiverse or Instructables, websites for sharing and distributing designs for 3-D printing, uncovers various design files for orthotic and prosthetic devices like finger splint, braces, and even a “DIY hip replacement,” all available to download (14). In addition to these individual projects developments also occur in a more organized context. By means of peer-peer manufacturing co-creation takes place between designers and patients. An organisation that embraces peer-to-peer manufacturing is E-nablethefuture. This organisation brings together children and designers together to enables children with prosthetics that printed in Makerspaces (15). Health making communities, like MakerNurse, arise that support and motivate individuals working in healthcare to create their own solutions (16). And by means of peer-peer manufacturing co-creation takes place between designers and patients. Furthermore, in hospitals 3D innovation labs pop up where surgeon’s work in close collaboration with engineers to create innovative solutions to optimize care involving digitally modelling an additive manufacturing. In these kind of ways the Maker Movement and digital fabrication accelerates innovation of prosthetics and orthotics by prototyping new and exciting designs.

The popularity of digital fabrication in orthoses design is clearly present, but yet little was found to be used in a clinical setting. Next chapter will explore the challenges that might withhold these innovative new products from a market introduction. As more clarification is needed to point out whether it is feasible to locally 3D-print a customized orthosis that can be considered safe and effective. Regarding the relatively new field of digital fabrication and healthcare, no studies were found that specifically address the guidance or analyzation of quality and safety in the context of local and personal fabrication of medical devices.

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## 3 Background study

This chapter explores digital fabrication and the Maker Movement affects the quality, safety and accessibility of customized orthoses. Therewith the following sub-question will be answered: *“What are the expected challenges of the aforementioned changing manufacturing landscape in which medical devices could possibly be introduced”?* These challenges will be categorized under regulatory, technological and clinical challenges. This chapter is composed of the following items:

- 3.1 Regulatory challenges
- 3.2 Technological challenges
- 3.3 Clinical challenges
- 3.4 Conclusions and implications for the design project

### 3.1 Regulatory challenges

Compared to most consumer products, safety and reliability is paramount for medical devices. The medical device industry is highly regulated by the National Regulatory Authority (NRA), to protect public health. According to the World Health Organization (WHO) “The overall objective of a NRA for medical products is to ensure that all medical devices are of assured quality, safety and efficacy and are accompanied by appropriate information to promote their rational use” (1). Article 2 of the European guideline for medical devices states that a medical device can only be put on the market when the requirements stated in the guideline are met (2). In Europe the CE (“European Conformity”) mark is used to declare that the product complies with the essential requirements stated in the Medical Device Directive (3). In order for a medical device to get the certification, a pre-market notification (PMA), also known as a 510k approval, is required(4). A 510(k) is a pre-marketing submission to demonstrate that the device to be marketed is as safe and effective. The applicant must receive approval of its PMA application prior to marketing the device by a regulatory authority, the Notified Body.

According to the medical device definition and classification rules of the European Medical Device Directive (MDD), a finger splint is a limb orthoses, which is classified as a low risk medical device (5). A class I medical device does not require the involvement of a Notified Body. But the manufacturer is responsible for ensuring that his product complies with all the relevant Essential Requirements of the Directive and must draw up a written statement to this effect (self-certification). They will be audited regularly to see if they have this quality control system in order. Furthermore, a custom-made medical devices can be exempted from official regulations (6). In this case the medical practitioner is held responsible instead of the manufacturer. A more detailed description, including the MDD’s essential principles checklist, of the European rules and guidelines for marketing a finger splint can be found in Annex 3.1.

However, these rules and guidelines were designed for mass production in industry and seem less suitable for local fabrication of personalized devices. Since in the context of local, digital fabrication and the open exploration of the Maker Movement, the fundamental definitions of a ‘medical device’, ‘manufacturer’ and ‘custom-made’ get blurred, as explained below.

#### Medical device

In the new manufacturing landscape, a medical device not only relates to a tangible product, but also to a digital file that can be freely shared over the Internet and locally manipulated and manufactured. Could the regulatory authorities evaluate the designs themselves in addition to the devices? Subsequently, the regulatory process could be divided in two: regulation of the digital files and regulation of the on-site manufacturing process. The print process technically falls under manufacturing regulation (Quality System Regulations). While the device itself falls under other regulations like the premarket approval (PMA). However, separate approval of the design file imposes quite a challenge, since quality and safety is not solely inherent to the design file but also to the manufacturing process.

#### The manufacturer

In addition, the manufacturing regulation also becomes a considerable challenge. In the current system the manufacturer is defined as “any person who designs, manufactures, fabricates, assembles, or processes a finished device”(7). With the rise of additive manufacturing anyone with access to a 3D printer can become a “manufacturer”, and can personalize a design to make the product according to his personal needs and want. In this situation the final product is distributed, created and manufactured by various parties. For instance, the designer of the originally shared file; the end-user modifying the file; the manufacturer of the raw materials; the manufacturer of the printer; the facility where the printer is accessed; the final maker and possibly the people instructing him. In this context several supply-chains are optional: business to consumer when an individual makes use of a professional 3D-printing services; business to business when a company uses a professional 3D-printing service; consumer to business when an individual makes products for a company; or consumer to consumer when one makes a product for another individual, which is called peer-to-peer manufacturing. Due to the disappearance of a standardized supply-chain and manufacturer, the final device can vary considerable as different printers and settings can be used. While reproducibility is paramount for manufacturing regulation to ensure quality and safety (4).

The blurred line between manufacturers and end-users also creates challenges in apportioning liabilities and poses traceability issues (7). Traceability is part of the Quality Management System of the manufacturer, with the purpose to facilitate notifications and recalls in the case of serious risks to health presented by the devices. It provides the ability to trace the history, application, or location of an item or activity by means of recorded identification. For insurers it will be difficult to identify the liable party for injuries caused by a defect product, when this is creation and manufacturing process is attributed by various parties. Therefore, it is necessary to mitigate risks at each stage from creation and modification of the design file, to the printing process and the quality of raw materials.

#### Custom-made

Since Custom-made devices are exempted from the CE certification, it is of interest to consider if a digitally customizable finger splint can be covered by this term. In general language ‘custom-made’ is defined as “Made according to the specifications of an individual purchaser”(8). Starting with this definition, a finger splint that adapts to the patients sizes and preferences should indeed be called ‘custom-made’. The Medical Device Directive describes a ‘custom-made device’ as “any device specifically made in accordance with a qualified medical practitioner’s written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient”(6). With a side-note that “Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices” (6). This division into custom-made or mass-produced devices does not seem sufficient anymore regarding the evolution of digital fabrication. In this context a ‘customizable’ finger splint could only be covered by this term when made in accordance with a qualified medical practitioner’s personally written prescription.

Furthermore, if patients and healthcare professionals become inventors of their own medical solution, consumers could avoid obtaining their devices through the regulated medical device industry or healthcare

practitioners. This raises questions about responsibility and the future of medical device regulation. To what extent is regulation necessary and when does the concept personal responsibility come into play?

### 3.2 Technological challenges

Although the possibilities of digital manufacturing might sound very promising, the quality and controllability of additive manufacturing differs from traditional mass-production methods like injection moulding. The layer-by-layer building technique of additive manufacturing is the reason for its success, but also its weakness. These paragraphs will address the challenges related to on-site additive manufacturing orthoses.

#### Rethinking mechanical design

Parts manufactured using additive manufacturing technology, are not as strong as traditional manufactured parts (9-11). Fracture happens at a much lower load than traditionally manufactured parts. Traditional manufacturing methods like injection moulding create solid parts, while the printed structure is porous and non-consistent. In addition, additive manufacturing deals with laminate weaknesses as the layer bonding is to some extent direction depend. This has to be considered when designing the part and defining the build orientation. This so-called anisotropic behaviour, the decreased mechanical strength and the porosity are risk factors in the functionality of prostheses and orthoses, where mechanical performance is of great importance. Traditional design concepts cannot simply be copied, orthoses-designers are challenge to rethink their designs with reference to mechanical performance.

#### Prediction and verification of mechanical performance

Finite Element Analysis (FEA) is a method used in the development of orthoses and prostheses design to verify mechanical behaviour (12). FEA is a computational method applied on CAD-files. As an alternative to practical mechanical testing, it avoids sacrifice of manufactured devices and can be easily applied to a wide variety of design variations for design optimisation. In the case of the finger splint it would be required to know whether a design can withstand certain forces, and under what forces it would break or bend.

Additive manufacturing complicates the verification of material strength testing and characterization, because FEA computational models are based on traditional engineering isotropic materials. Notwithstanding the fact that the FEA discipline there are always simplifications and assumptions made. The porosity, anisotropic and in-consistent behaviour of parts created with additive manufacturing, requires more assumptions increasing the challenge to predict mechanical behaviour.

#### Achieve a controlled and consistent output

Adding to this problem, the degree of impact on mechanical performance highly depends on the build parameters (9, 13, 14). These parameters are controlled by the user, and limited by the specifications and proper maintenance of the machinery. There are many different types of additive manufacturing technologies available, not only with a variation in underlying techniques and material but also in brands and system capabilities. As a result, the design space is constantly changing when different printers are

used. Sharing a file that is approved to be safe, does not necessarily result in a safe product. This way of manufacturing possesses a significant challenge to achieve a controlled and consistent output.

#### Limited material options

The variety of materials suitable for each additive manufacturing technology that are approved for the application in medical devices is still limited (7). Due to all of the above limitations, in current medical applications it is often seen that not the final product itself is printed. Instead, additive manufacturing is widely used as a method for prototyping or for the creation of moulds. In this way the traditional, approved materials can still be used in the final product. It could be a challenge to select the material that suits the purpose of the respective medical device. Adding to this problem that each individual manufacturer should apply the right material and technique that suits the purpose of the design file.

#### Time and expertise

Many people without any experience in additive manufacturing live with the illusion that one could have a product in hands in no-time. Despite the fact that additive manufacturing enables 'rapid prototyping', that printing an object of only a few square centimetres still takes up to an hour (15). Furthermore, additive manufacturing technologies do not create a fully finished part. Cleaning of additive manufactured parts to remove support material is necessary regardless of the technique used. Some techniques require additional post-processing steps, like polishing, coating are dying, to achieve a high quality finish. This could possess an extra challenge for medical devices when post-processing threatens biocompatible of the material. This amount of post-processing required to finish the printed part even further increases time. Furthermore, creation of the CAD-file also requires necessary time and modelling expertise. Therefore, the entire process from the creation of a CAD-file to a finished product is a challenging, time-intensive procedure.

### 3.3 Clinical challenges

If patients and healthcare professionals become inventors and/or producers of their own medical solution, consumers could not only avoid obtaining their medical devices through medical device industry, but also avoid the involvement of a doctor. Involvement of a medical expert in the design process and rehabilitation process, may not be underestimated. Fess advocates:

*"Too often illustrations of books, journals, and advertisements serve as the foundation of making splint design decisions. Without sound understanding of biomechanical concepts, selection of critical splint configuration or splint material may be founded on the prevailing fad rather than on science. First and foremost, a splint must work. It must do the job for which it was applied. If it does not, then why use it? Splints are not fashion statements, nor are they edifices to their creators. They are serious engineering devices that, when used appropriately, can accomplish functions that other traditional modalities cannot achieve (16)."*

Furthermore, the safety and reliability of a medical device is not solely inherent to its functionality, but also

determined by proper use conforming to the patients diagnose. In the case of the finger splint, improper rehabilitation could result in a permanently crooked finger: the hand has a complex mechanism and a seemingly minor injury can have considerable consequences if not properly treated. Acknowledging the fact that the make-culture is spreading in the field of healthcare, the healthcare system is challenged to develop tools that bring together DIY healthcare and traditional medical consulting.

#### 3.4 Conclusions and implications for the design project

It could be concluded that for a successful implementation of the make-culture and digital fabrication still many challenges need to be overcome. At first, the current regulation system of medical devices does not seem sufficient for this new manufacturing landscape. Revision in the guidance of quality and safety of locally fabricated, customized medical devices, seems required. Otherwise it results in complex regulatory issues and raises many questions about responsibility. Secondly, this quality and safety of local fabrication is challenged by the technological limitations of additive manufacturing regarding mechanical performance; predictable results; a controlled and consistent output; material options and time and expertise. Furthermore, the safety and reliability of a medical device is also determined by proper use, which requires clinical guidance of a medical professional.

Looking back on these findings, it can be concluded that tools are needed to guide how the overall process - from creating the digital 3D-model until the use of the finished device - can be designed in such a way that it guarantees quality and safety in areas that have been introduced in this chapter. In addition, this process should be made more time-efficient and accessible for a wider audience than the Maker Movement, so that all stakeholders can benefit from it. Therefore, the purpose of the design project should be to provide a DIY finger splint solution with the accessibility, quality and safety of professionally-graded medical devices. The challenges that have been described in this chapter will be considered during the design process.

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## 4 Analysis phase

In the analysis phase the clinical problems related to finger splinting are inventoried, all clinical goals formulated and the design assignment, requirements and functions of the solution defined. The analysis phase is composed of the following items:

- 4.1 Clinical background
- 4.2 Current solutions
- 4.3 Problem definition
- 4.4 Goals
- 4.5 Design assignment
- 4.6 List of requirements
- 4.7 Function analysis

The *clinical background* describes the anatomy, kinesiology, pathologies and treatments which are of importance in the context of finger splint design. In *current solutions* the strengths and weaknesses of current splinting methods will be analysed. From this, the most fundamental problems of the currently available splints could be introduced at the *problem definition*. Subsequently, the *goals* of the solution to this problem will be defined. All of the above will lead to the *design assignment*, which is the strategy applied to create a suitable solution to the problem, and reach the mentioned goals. Subsequently, the *list of requirements* and wishes is composed. This list will be used in the synthesis phases of next chapters to test whether the product is actually a well-designed solution. Finally, the *function analysis* will describe the functions of the product in detail.

## 4.1 Clinical background

Normal finger position and movement occur from the balanced actions of many important structures. Ligaments support the finger joints; muscles hold and move the fingers; tendons help control the fine motion of each finger joint. Finger trauma and diseases are common and usually heal without significant problems. Some injuries are more serious and may develop problems if not treated carefully. This chapter describes the anatomy, kinesiology, pathologies and treatments, which are of importance in the context of finger splint design.

### 4.1.1 Anatomy

This section describes important anatomical structures related to injuries that require finger splinting. After visually introducing the anatomy of the finger, different anatomical characteristics will be further described.

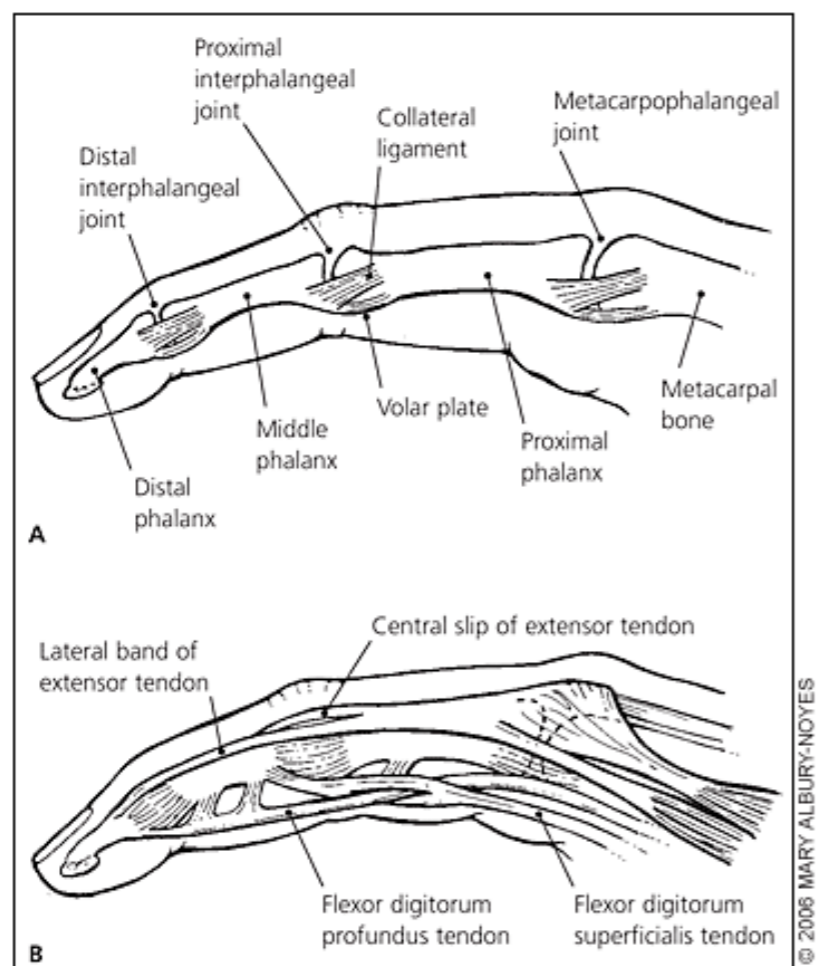


Figure 4.1 Anatomy of the finger (A) joints and ligaments (B) tendons

### Bones and joints

The hand consists out of nineteen bones that make up the palm and fingers. The palm is formed by five metacarpal bones radiating from the wrist. Each finger consists out of three bones: the proximal, middle, and distal phalanges. The bones in each finger articulate with one another through joints, called interphalangeal joints (IP joints). The joint near the end of the finger is called the distal IP joint (DIP joint). The one closest to the knuckle is called the proximal IP joint (PIP joint). The thumb only has a proximal and distal phalanges and one IP joint. The knuckle joints are formed by the connections of the phalanges to the metacarpals. These joints are called the metacarpophalangeal joints (MCP joints).

### Ligaments

Ligaments provide support and stability for controlling finger movement. Two collateral ligaments on either side of the joint connect the bones together. The collateral ligaments prevent abnormal sideways bending of the joint. In the PIP joint, the strongest ligament is the volar plate. The volar plate connects the proximal phalanx to the middle phalanx on the palm side of the joint. The ligament tightens as the joint is straightened and keeps the PIP joint from bending back too far (hyperextending). Finger deformities can occur when the volar plate loosens from disease or injury.

### Muscles and tendons

There are two categories of muscles that function within the hand: extrinsic and intrinsic muscles. The extrinsic muscles originate in the forearm, while the intrinsic muscles are contained within the hand. The intrinsic muscles guide the fine motions of the fingers by getting the fingers positioned and holding them steady during hand activities.

Tendons help to control the fine motion of the finger joint. The tendons that allow each finger joint to straighten are called the extensor tendons. The extensor tendons of the fingers begin as muscles that arise from the backside of the forearm bones. These muscles travel towards the hand, where they eventually connect to the extensor tendons before crossing over the back of the wrist joint. As they travel into the fingers, the extensor tendons become the extensor hood. The extensor hood flattens out to cover the top of the finger and sends out branches on each side that connect to the bones in the middle and end of the finger. The place where the extensor tendon attaches to the middle phalanx is called the central slip. When the extensor muscles contract, they pull the extensor tendon and straighten the finger. Problems occur when the central slip is damaged, as can happen with a tear.

### Nerves

The hand is innervated by three nerves: the radial, medial and ulnar nerves. The radial nerve innervated the long wrist extensors and the medial nerve the long flexors. The ulnar nerve innervated the ulnar hand flexors, the majority of the intrinsic muscles, and the muscles responsible for finger flexion and extension.

## 4. Analysis phase

### 4.1.2 Kinesiology

The finger and thumb joints have two degrees of freedom: flexion, extension, abduction and adduction. The IP joints only have one degree of freedom: contribution to flexion and extension motion. Hand movements can be categorized into a five basic prehensile and grasp patterns including fingertip prehension; palmer prehension; lateral prehension, cylindrical grasp, spherical grasp, hook grasp, and intrinsic plus grasp (figure 4.2). Prehensive movements require less strength than grasp movements. The grasp and prehensive patterns are determined by the muscles that are functioning, potential and present deformities, and how the hand is used (1). The fine motor skills of the hands are very complex and balanced system, only a small injury can bring the whole system out of balance.

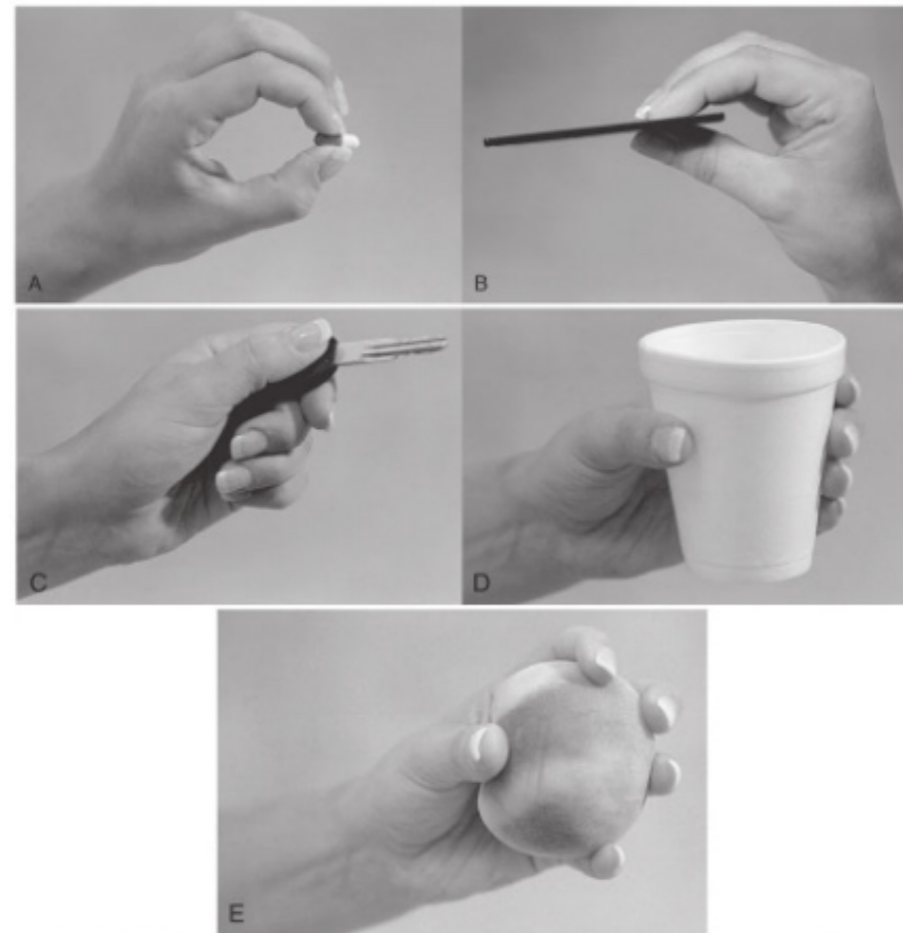


Figure 4.2 Prehensile and grip patterns of the hand (a) fingertip prehension (b) Palmer prehension (c) lateral prehension (d) cylindrical grasp (e) spherical grasp (10)

### 4.1.3 Pathologies

Finger trauma or diseases can disturb the balance in these structures, altering normal finger alignment and function. Injuries involve fractures or inflammation of the bones, ligaments, tendons or muscles. Commonly seen diagnoses that require finger splints are mallet finger; swan-neck deformities; boutonniere deformities; lateral deviated fingers and trigger finger. All these DIP and PIP joint pathologies are described in table 1 on the next page, in terms of the affected parts; causes; symptoms; mechanism and symptoms; splinting treatment and consequences.

In the design assignment later in this chapter, the most common pathology will be selected to create a solution for. After a proven success, this design could simply be adjusted to the remaining pathologies without the need to go through the whole design methodology from start. With this in mind, the components of the analysis phase are applicable for all DIP and PIP joint pathologies.

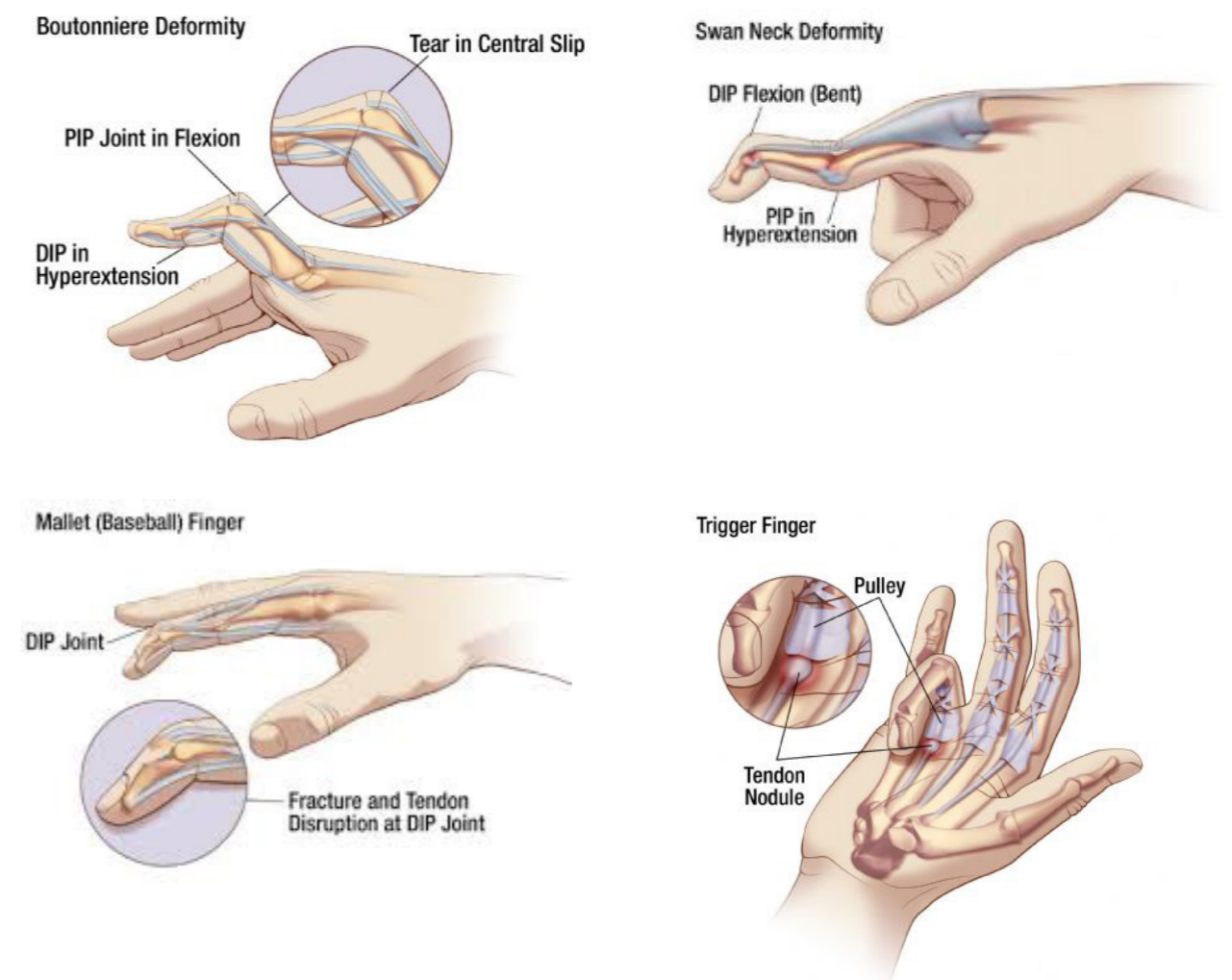


Figure 4.3 Finger pathologies requiring splinting (from <http://www.blog.ohmyarthritis.com>)

| Pathology   | Affected parts  | Cause  | Mechanism and symptoms  | Splinting treatment   | Consequences of incorrect treatment  |
|---|---|--|---|---|--|
| Mallet finger, also known as baseball finger or drop finger | Loss of the extensor mechanism at the distal interphalangeal (DIP) joint.   | Results from an extensor tendon rupture or an avulsion fracture of the distal phalanx  | Mallet finger leads to an imbalance in the distribution of the extensor force between the proximal interphalangeal (PIP) and DIP joints. Resulting in a drooped fingertip.  | Six weeks of continuous splinting to maintain full extension or slight hyperextension at the DIP joint, followed by 2-6 weeks of splinting at night. Scar formation repairs the tendon. If the splint is removed and the finger is allowed to bend, the process is disrupted and must start all over again. Therefore patients should be instructed on how to change the splint for periodic cleaning and examination of the skin without allowing the DIP joint to flex. | Neglecting a mallet injury or incorrect treatment can lead to DIP joint dysfunction. 1 mm lengthening of the terminal extensor tendon results in 25 degrees of extension lag, and a shortening of 1 mm will seriously restrict DIP joint flexion. Surgery is contraindicated if there is a fixed deformity of the DIP joint. |
| Swan-neck deformity or hyperextension injury                | Hyperextended PIP joint and possibly a flexed DIP joint, due to a loosened PIP joint ligaments. As the PIP joint flexes, the extensor tendon gets out of balance and the PIP joint hyperextends.  | Inflammation or injury of the volar plate ligament or extensor tendon loosens the PIP joint. Caused by Rheumatoid arthritis (RA), hand trauma, or various nerve disorders, such as cerebral palsy, Parkinson's disease, or stroke. A hyperextension injury could also be result of a dorsal fracture dislocation of the PIP joint. | Inflammation may cause pain and swelling of the PIP joint. The PIP joint eventually is free to bend back too far into hyperextension. As a consequence the DIP joint can be bent downward into flexion (the typical swan-neck deformity). | Dorsal blocking splint that positions the PIP joint in slight flexion while limiting full PIP joint extension, but also allowing for full PIP flexion and full DIP range of motion.<br><br>The degree of extension blocking depends on the severeness of the hyperextension injury. In some cases, the splint should be modified weekly to progressively decrease the degree of extension blocking.   | If not treated in an early stage, surgical reconstruction is required.   |
| Boutonniere Deformity/ Jammed finger                        | Finger stuck in a bend position at the PIP or DIP joint and hyper extended at the DIP joint. Because the middle phalanx no longer is pulled by the central slip, the flexor tendon on the other side begins to bend the PIP joint without resistance. The lateral bands begin to slide down along the side of the finger where they continue to straighten the DIP joint. | Caused by a crushing trauma or an inflammation likely due to rheumatoid arthritis (RA).<br>Tear or rupture the attachment of the extensor tendon to the central slip. Imbalance in the extensor hood resulting from the torn tendon causes deformity.  | Finger is painful and swollen around the PIP joint. The PIP joint may not straighten out completely under its own power. The finger can usually be straightened easily with help from the other hand.                                     | Splinting of the PIP joint for 12 weeks to prevent hyperextension of the DIP joint, and align the PIP joint, while allowing the DIP joint to bend. Exercise prevents stiffening of the DIP joint. Rehabilitation requires an occupational therapist. Special splints use a spring to apply pressure to slowly straighten the PIP joint.   | Imbalance can lead to contractures (tightening of the tendons) and other changes that result in a permanently crooked finger.  |
| Lateral deviated finger                                     | Fingers are lateral deviated due to sideways pushed joints.   | Cushing injury or build-up of arthritic nodules  | Lateral deviated fingers  | Splint to straighten the joint by reducing DIP and PIP joint deviation, pressure needs to be applied ulnar or radially to reduce deviation.   | Lateral deviation of a finger may result in a painful joint, disrupted normal movement, and an unstable finger.  |
| Trigger finger  | Restricted movement at finger flexion. As the tendon thickens a nodule is formed.   | Inflammation of the tendon due to rheumatoid arthritis, partial tendon lacerations or repeated trauma from gripping tools.   | Pain during movement and a funny clicking sensation when the finger is in bent  | Splint to rest the finger (block it from triggering) by limited MCP or DIP/PIP joint flexion. Wear full-time 2-4 weeks until triggering stopped   | When rest is neglected, the nodule increases. If the nodule becomes too large, the finger can be locked in a bend or flexed position. Eventually imbalance could lead to a swan-neck deformity.  |

Table 1 Description of DIP and PIP joint pathologies treated with splinting (1-4)

## 4.2 Current solutions

This paragraph first addresses the pros and cons of the different types of splint methods. This will be supported through quotations of professionals that have been interviewed. This was done to get a clear understanding of the needs that are still not met by the current splinting methods. The problem definition will follow from the limitations found. Second, this paragraphs addresses the principles of successful splinting treatment. These findings will be included in the list of requirements and wishes.

### 4.2.1 Splinting methods

The matter of hand splinting is the task and responsibility of hand therapists. Hand therapist are experienced in making the right decisions for the splint design and function. For instance about the angle of immobilization, which is patient and treatment specific. Clear instructions on the use and maintenance need to be provided to the patient, and follow up is needed to check compliance.

Finger splints come in a varied assortment of configurations and sizes to accomplish many different functions for support and immobilization. Splints can be categorized as static and dynamic splints: static splints are used to rest tissue, provide external support and gain or maintain motion; dynamic splints provide a constant force to the joints, by a rubber band or wire spring coil, to actively improve motion. Figure 5 to 9 provide an overview of different splint designs for each of the earlier described pathologies. The hand therapist has the option to use a prefabricated splint, make a thermoplastic custom splint or order a professionally developed personalized splint for a more permanent purpose. These three option will be described below.

#### Prefabricated splints

Prefabricated splints are commercially available, and offer some advantages over custom-made thermoplastic splints: they are more durable, less bulky and often more aesthetically pleasing. Prefabricated splints are available in standard convection sizes.

**“The standard convection-splints, usually do not fit. In that case, we make ourselves a custom one”**

- Hand therapist 1, Zaans Medical Center

**“We have a huge box of this type of mallet splints but never use them, because they never fit properly. Alternatively, we use custom made splints”**

- Hand therapist 2, Zaans Medical Center

An example of a novel commercial splint design is the oval8 splint, which is low-profile multifunction and relatively low cost (€18,95 for a set of three sizes). It is promoted that the oval8 can be worn for all

## 4. Analysis phase

5 pathologies described in table 1. The oval 8 is available in 14 different sizes, and can be adjusted by moulding. However, they do not always fit; moulding doesn't work well; they are not really strong or durable and only available in 1 colour.

**“Changing the shape of the oval8 splint by heating does not work well, fiddling with a patch to create a better fit does not work properly either”**

*- Hand therapist 1, Zaans Medical Center*

**“Sometimes we placed a little extra fabric inside the mallet splint, to put the finger slightly in hyper extension. But after a few weeks people came back and then the added fabric was dirty and not in the right place anymore. So at some point we said: that no longer works”**

*-Hand therapist 2, Zaans Medical Center*

### Custom made splints

Custom splints are made using low temperature thermoplastic material and, if necessary, fabric straps for fixation. The material is cut to size and moulded to fit by heating with water or a fohn. Advantages of custom made splints is that they are patient specific and low-cost. But as a disadvantage they are time-consuming; not really durable; have a bad quality finish (i.e. sharp edges) ; are bulky and often non-aesthetically pleasing.

**“I am half an hour to one hour busy to make one splint, and find it difficult to make a good quality finish”**

*-Hand therapist 1, Zaans Medical Center*

**“Properly finishing the thermoplastic requires considerable effort”**

*-Hand therapist 2, Zaans Medical Center*

### Permanent splints

In the case of rheumatoid arthritis one could need a permanent splint. If the temporarily thermoplastic splint design complies an orthopaedic instrument maker can order a professionally developed personalized splint, like a silverring-splint. Permanent splints are made at request of a rehabilitation doctor to make sure the expensive solution is functional. The advantages of these silverring splints are: aesthetically pleasing for most patients; low-profile; long-lasting; custom fit and has possibilities for personal adaptations. But they happen to be very expensive (€80 - €160); the material is really soft; and it is a fiddly procedure to find the right measure.

**“There are patients who say about the silverring-splint: that is nothing for me”**

*-Hand therapist 1, Zaans Medical Center*

**“The silver is such a soft material that the forced position is undone again”**

*-Hand therapist 2, Zaans Medical Center*

**“A silverring-splint on the DIP joint easily falls off”**

*- Professor in rehabilitation medicine, University of Groningen*



Figure 4.4 Fixation splints for mallet finger: a variation in design but all with the same principle to maintain full extension or slight hyperextension at the DIP joint. (a) oval8 (b) custom ordered silverring-splint (c,d,e) prefabricated splints (f) custom

## 4. Analysis phase

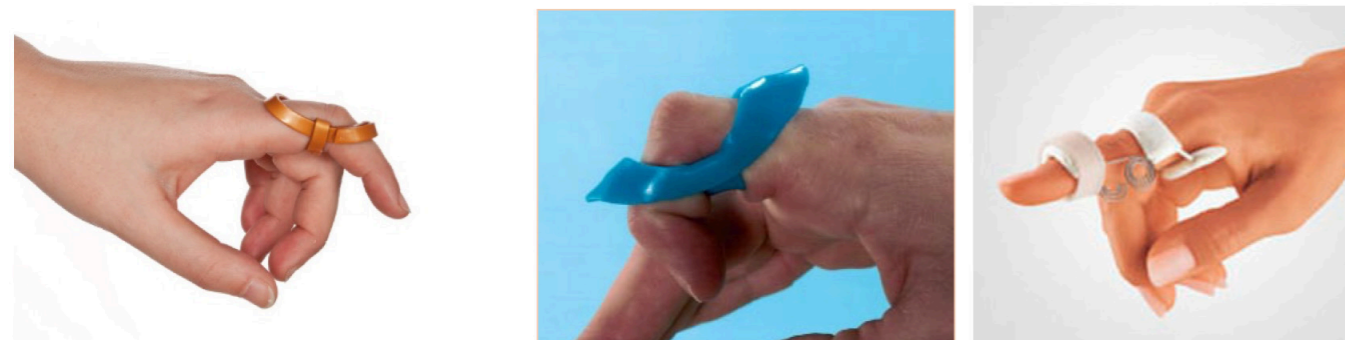


Figure 4.5 Dorsal blocking splints for Swan-neck or hyperextension injury: a variation in design but all with the same principle to position the PIP joint in slight flexion while limiting full PIP joint extension, but also allowing for full PIP flexion. (a) oval 8 (b) prefabricated splint (c) silvering model (d) custom-made (e) prefabricated dynamic splint

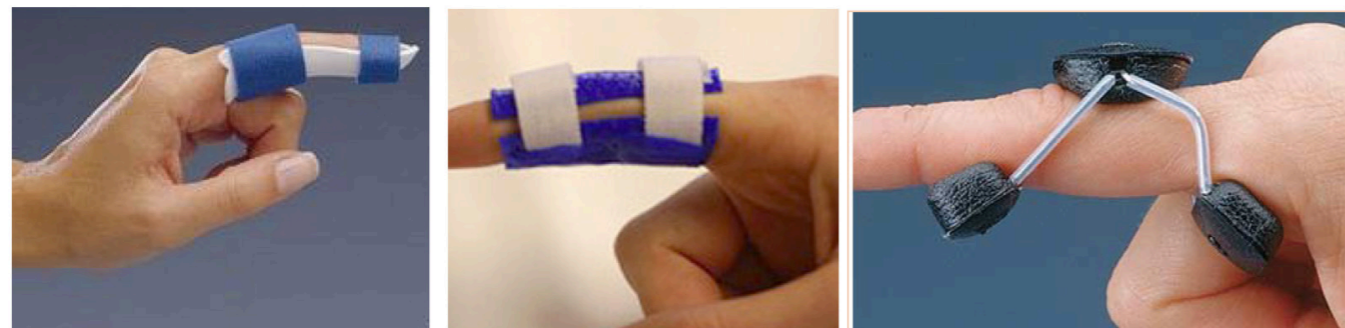


Figure 4.6 Finger splints for Boutonniere Deformity/ Jammed finger: a variation in design but all with the same principle to prevent contraction of the PIP joint (a) oval8 (b) silvering-splint (c) silvering-splint to prevent flexion greater than 25 degrees (d) prefabricated splint (e) custom made (f) dynamic model



Figure 4.7 Finger splints for lateral deviated fingers: a variation in design but all with the same principle to straighten the joint by reducing DIP and PIP joint deviation. (a) oval 8 (b,c) silvering-splint

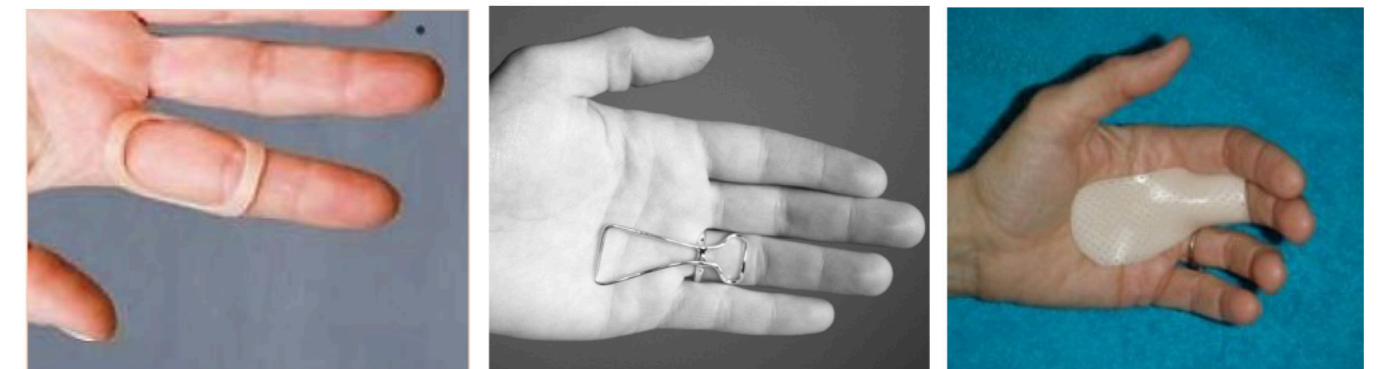


Figure 4.8 Finger splints for trigger finger a variation in design but all with the same principle to rest the finger (block it from triggering) by limited MCP or DIP/PIP joint flexion. (a) oval8 (b) silvering-splint (c, d) custom-made thermoplastic

### 4.2.2 Principles of successful splinting treatment

Understanding the biomechanical engineering principles are of great importance for successful splinting techniques. If misused, for instance due to a lack of understanding, splints can be inefficient or create additional problems (6). Manipulation of Biomechanics increases splint efficiency and improves splint durability while decreasing costs and frustration (6). An accurate fit is not only accomplished by dimensional properties but also by well distributed pressure. Correct biomechanics of a splint design results in an optimal fit and reduces risks of skin irritation and pressure areas, which ultimately lead to client comfort, compliance, and function (4). An extensive analysis of the biomechanics of splinting is provided in Annex 4.1a

Furthermore, successful splinting is dependent upon the patient wearing the splint. Consideration of factors unique to the patient like their attitudes lifestyle and living and working environment, will increase the potential for an optimal outcome (5). All these factors should be considered in the design process of the finger splint. A more detailed description can be found in Annex 4.1b

### 4.3 Problem definition

During the problem definition, the most fundamental problem of the currently available splints will be introduced. In order to get an improved understanding of the problem, all persons related to the given problem were first inventoried through a stakeholder analysis. Subsequently the most fundamental problem will be formulated by means of a cause-effect order.

#### 4.3.1 Stakeholder analysis

Before defining the most problems, all persons that are involved were considered. These people are called stakeholders. Not only the patient with an injured finger is involved, but also his boss, his co-workers, his family and the society in general. Another viewpoint is to realise that a medical product will be selected by the physician, financed by the health insurance, bought by the healthcare provider, used by the patient, and approved by the notified body. All those people were considered, because they all will face related problems. To have a complete overview these problems were inventoried as well. The scheme of the stakeholders, their characteristics; expectations; and potentials and deficiencies are given in table 2. From the stakeholder analysis implications and conclusions for the solution will follow, as a contribution to the design assignment and list of requirements and wishes later in this chapter.

| Stakeholder               | Characteristics  | Expectations   | Potentials and deficiencies   | Implications and conclusions for the solution   |
|---------------------------|--|--|---|---|
| Patient                   | Pain in the finger, reduced freedom of movement, discomfort, social and emotional problems | Relief of pain; restoration finger function; acceptable and comfortable and quick solution | Simple solution; All fingers and personal needs and wishes' are different   | Aesthetic acceptance and comfort is important for treatment compliance (14).                          |
| Family                    | Lives together with patient, cares for patient   | Healthy, happy and independent patient   | Needs to care for patient when needed   | Maintain patient independency in daily activities   |
| Boss                      | Aims productive and successful employees   | Sick employee asap back to work  | Properly working hands and fingers are important in most jobs (physical and administrative)                               | Fast and effective solution; non-time-consuming; no interference with working activities              |
| Therapist                 | Strives for the best treatment of his patient; Focused on ad-hoc and fast solutions        | Easy treatment with optimal functional result  | Expert in treatment, lacks knowledge and expertise in digital manufacturing; Could be conservative towards new techniques | The implementation of digital manufacturing should be accessible                                      |
| Healthcare facility       | Provide optimal care at low costs; governmental coordinated organization; strict policy    | Cost-effective products and treatment  | Could be conservative towards the implementation of new techniques  | Implementation of a new technique should be cost-effective and accessible                             |
| Society                   | Demands low costs of health care, but high quality   | Social and environmental interests   | Huge market, big impact   | The solution should increase the sustainability of medical devices, and have a positive social impact |
| Health insurance          | Aims cost-effective care   | Lower costs of treatment   | Only interested when cost-effective and low complications   | Cost-effectiveness is essential for success of the product  |
| Industry                  | Interested in successful products at low development costs                                 | Profit   | Commercialising the product   | Knowledge of market potential and manufacturing   |
| Notified Body             | Regulates quality and safety   | Documentation of technical files and process quality control system                        | Essential requirements and standardization manifest quality and safety  | Comply with essential requirements and standardization rules  |
| Waag Society (contractor) | Develops technical, social innovations   | Wants to accelerate innovation of DIY healthcare solutions                                 | Expert in bringing DIY solutions to a professional level  | Patient must be able to use the solution independently, without the need of a medical expert          |

Table 2 Stakeholder analysis for a finger splinting

## 4. Analysis phase

### 4.3.2 Fundamental problem

All problems related to the limitations of the currently available splinting methods, were linked by placing them in a cause-effect order. In this way the most fundamental problems were found. When these most fundamental problems are solved, all related problems are solved. From figure 4.9 it can be seen that the most fundamental problem is that current methods to heal finger deformities cannot provide a good quality, aesthetic and cost-effective custom-fit solution.

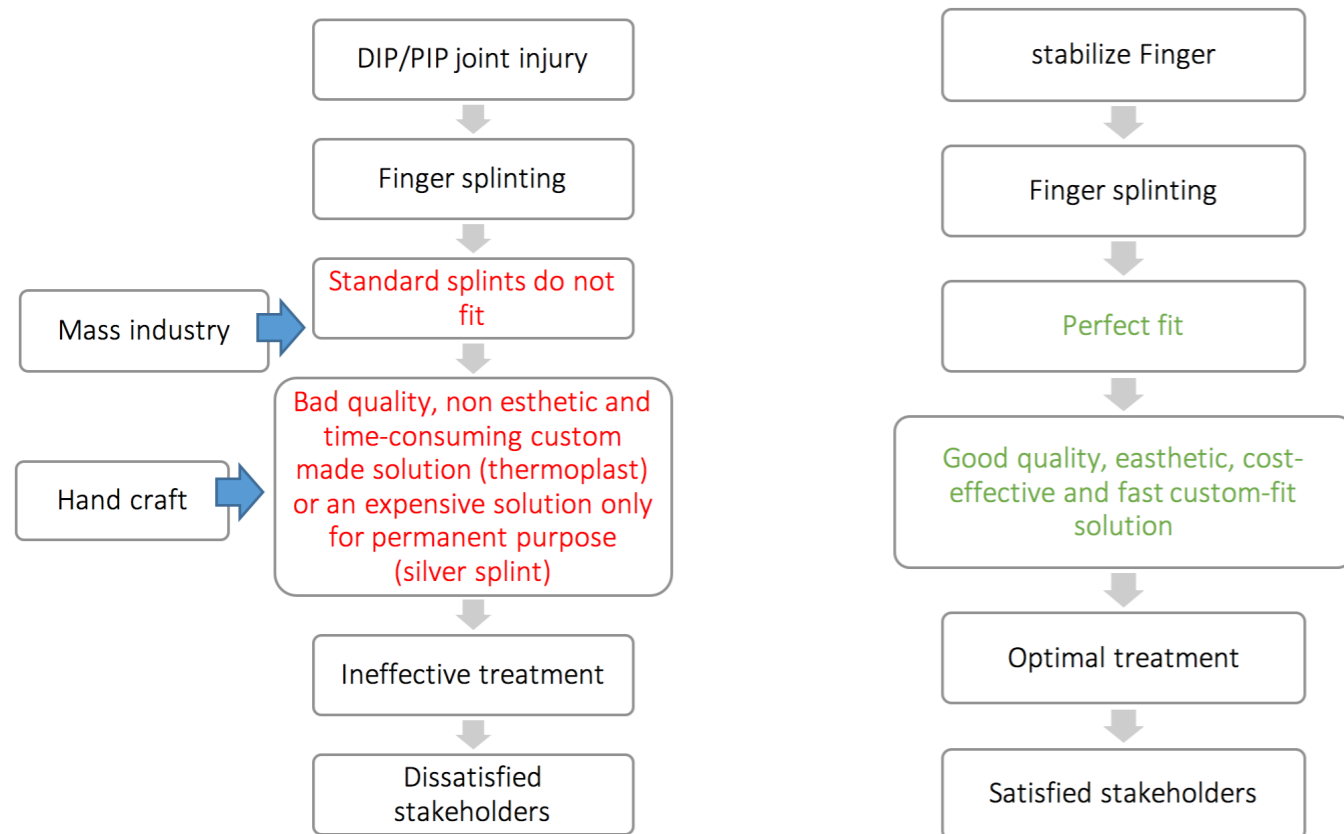


Figure 4.9 (a) cause-effect diagram of all problems (b) Cause-effect diagram of all goals

### 4.4 Goals

First, there is the primary goal of the project: increase the patient's quality of life and improve efficiency and innovation of the healthcare system. If this bottom line is not reached – the product cannot be regarded as successful. Then, we have the fundamental goal of the product solution itself.

Subsequently, for each of the stated problems in the cause-effect order a goal could be formulated. Then the most fundamental goal has been selected. If the most fundamental goal can be realised, all other goals will be realised automatically as well. In figure 4.9 can be seen that the most fundamental goal of the product is to stabilize finger deformities with a good quality, aesthetic, cost-effective and fast custom-fit solution.

### 4.5 Design assignment

*This section describes the design assignment, which is the strategy that will be applied to realize the above mentioned goals.*

The design assignment is to realize a mechanical device that cures minimally one of the earlier described PIP and DIP joint deformities, that allows customization for a perfect ergonomic fit. The device should be better than current solutions in providing an ergonomic fit considering aesthetics; quality; time-efficiency and cost-effectiveness. The hereby imposed design and manufacturing method of the device is 3D-modelling and additive manufacturing (3D-printing). The selection of the most suitable manufacturing method, which covers the material and printer selection, will be extensively researched. The design process concerns redesigning an existing solution, adapted to the alternative design and manufacturing technique. A final prototype will be printed and tested to prove quality and safety of the design and manufacturing method.

Through the following paragraph, the design assignment will be further demarcated. This will be done by looking at different elements relevant for focus and limitation.

#### 4.5.1 Focus and limitation

The elements relevant for focus and limited are the pathology to solve; the strategy to obtain the 3D model; the measurement method to obtain the finger dimensions; the definition of the maker and the print locations that may be considered for 'local' manufacturing. The different strategies that could be selected, are depicted in the table below.



## 4. Analysis phase

| Pathology               | Trigger finger                         | Mallet finger   | Swan-neck deformity  | Boutonniere deformity   | Lateral deviation            |
|-------------------------|--|---|--|---|------------------------------|
| <b>3D modelling</b>     | Educate hand therapist in 3D modelling | Exclude the need for 3D modelling skills using a parametric modelling | Patients with modelling skills can design their own splint | Co-creation between a designer with 3D modelling skills, hand therapist and patient |                              |
| <b>Measuring method</b> | Digitalized calibre                    | 3D scan   | Photo capture  | Measure drawn outline of the finger   |                              |
| <b>Maker</b>            | Patient                                | Hand therapist  |  |   |                              |
| <b>Print location</b>   | Patient's home                         | Makerspace  | Hand therapist's clinic                                    | Joined print facility in healthcare centre  | External 3D-printing service |

Table 3 : Strategies for the design assignment

### Pathology

Since the design assignment functions as a proof of concept, the solution must solve at least one of the relevant pathologies that were described in the clinical background. Because splinting for swan-neck deformity is the most common, this is the first to be developed. After a possible proven success in this project, a database can be developed with splints for the other relevant pathologies.

### 3D modelling

Most hand therapists and patients lack in 3D modelling expertise and technical knowledge of 3D printing. In addition, they could be conservative towards learning new techniques as they simply don't have the time. Using parametric modelling, both problems can be tackled. Since a parametric 3D-model can be customized without the need for 3D-modeling skills. The potential of parametric modelling will be further discussed in chapter X. The software used for parametric modelling is the Grasshopper Plug-in for Rhinoceros (CAD software). Other software possibilities will not be further explored.

### Measurement method

The method to obtain the finger dimensions will be an automated calliper. Compared to a 3D scan or photo capture, the output of an (automated) calliper can be used as a direct input for the parametric model. The obtained data is less detailed, but the few data points seem to be sufficient to realize a perfect ergonomic fit of a finger splint. Moreover, the method is inexpensive and very accessible. If this method does not happen to be sufficient, alternative methods should be explored.

### The maker

The maker is defined as the person measuring and implementing the input parameters to create the 'custom-made' splint design. The patient and/or the hand therapist should both be considered as the maker. However, the role of the importance of the hand therapist in this process requires further research.

### Location of manufacturing

The location considered as most local, is preferred. But the location of manufacturing is inherent to the manufacturing technique that will be selected. Therefore, the location possibilities need to be looked into when researching the manufacturing technique.

## 4.6 List of requirements and wishes

To test whether at the end of a design phase or at the end of the entire process the product is actually a good solution to the problem, a checklist is used: the list of requirements and wishes. This list of requirements is based upon the literature findings as described in the previous chapters, and the medical background of this chapter; the stakeholder analysis **(S)**; interviews with experts in the field of hand splinting **(I)**; and the essential requirements for Class I Medical Devices as described in the European Medical Device Directive 93/42/EEC **(R)**. The letter at the end of the requirements indicates wherefrom the requirement is derived, S for stakeholders. The list is used to accept or reject a solution, failing one of the requirements means the product fails. The concepts that pass the list of requirements can be ranked by the wishes. The more wishes it fulfils and the better it fulfils them, the better the product is. The complete list is presented below.

### 1. User requirements

1. The user should be able to wear the device during daily activities without any negative interference (i.e. showering, sleeping, cooking, clothing) (S)
2. The device can be put on and off with one hand and without pain or causing harm (R)
3. The device enables normal hand movements (prehensile and grasp patterns including fingertip prehension; palmar prehension; lateral prehension, cylindrical grasp, spherical grasp, hook grasp, and intrinsic plus grasp) (A)

### 2. Ergonomic requirements

The device should..

1. align the finger in a natural, relaxed angle (I)
2. immobilize the particular joint, while involving other joints as few as possible (A)
3. not restrict movement of other fingers (S)
4. not slip off or rotate around the finger (I)
5. provide a personalized ergonomic fit for each individual user (I)
6. be comfortable to wear (S)
7. enable a patient specific angle of immobilization (I)
8. enable a patient specific length and volume (I)

## 4. Analysis phase

9. keep the knuckle, which is very sensitive for pressure point, free as far as possible (I)
10. be thin enough so that several splints can be worn at the same hand, without causing pressure points (I)

### 3. Safety requirements

The device should..

1. well serve the purpose of the particular trauma (I)
2. prevent soft tissue stress by implementing (A):
  - Round edges
  - The MA principle: maximize splinting arm length segment
  - Increase area of skin contact at pressure points
3. tolerate temperatures of at least 50 degrees Celsius (R)
4. not break when falling or hitting (S)
5. be well ventilating to the skin (I)
6. not initiate sweating of the skin (I)
7. allow air circulation to the injured part (A)
8. not restrict blood flow in the finger (R)
9. minimize risk on window oedema (A)
10. not cause joint stiffness or permanent deformation (due to incorrect force application) (A)
11. The device should withstand the system of forces resulting from the biomechanical analysis (Annex 4.2) (A)

### 4. Maintenance requirements

The device should..

1. be cleaned with water and soap within 5 minutes (S)
2. have a lifetime of minimally 3 months (A)
3. not allow penetration of contaminants or water (S)
4. be easy to replace by the patient himself in case of failure (within a few days for less than €20,- manufacturing costs) (A)

### 5. Material and manufacturing requirements (materialisation)

The material and manufacturing requirements are divided into 5 criteria: Material safety; quality and appearance; safety and reliability; mechanical performance; and ease of implementation. These criteria will be used for the materialisation selection in chapter 5.

#### Material safety requirement

1. The material should be non-irritating to the skin (biocompatible approved according to the ISO 10993-1)(R)
2. Approved for food contact in compliance with the EU Plastics Directive 2002/72/EC. (R)

#### Quality and appearance requirements

3. Complexity: The product should be printed as one part and the manufacturing method should allow for a complex shape with large overhangs and thin sections that may not have a stable standing position to be printed on. (B)
4. Surface finish: The product should have a smooth finish and may not contain any sharp corners. (B)
5. Resolution: The resolution should be high enough to enable display of tiny details for a more aesthetic design or personalisation details like a text or figure. (B)
6. Water tightness and contamination: The product should be resistant to water and contaminations (S)
7. Post-processing: Post-processing steps should compensate the above mentioned requirement if not reached (requirement), but should be minimized as much as possible(B)
8. Colour: It should be possible to change colours to one's individual wishes (S)

#### Mechanical requirements

9. Strength and rigidity: The mechanical properties must provide sufficient strength and rigidity to resist the applied forces (as defined in Chapter X) under all conditions, without rupture or deformation. (B)
10. Isotropy: The manufacturing method should maximize strength in all directions as much as possible. (B)
11. Failure risk: Possible mistakes made in the manufacturing process may not lead to mechanical failure, or should be detected in time. (R)

#### Implementation requirements

12. Accessibility: an autonomous patient and hand therapist both should have easy access to the material and manufacturing method.(B)
13. Location: It is preferred that the manufacturing method allows manufacturing at location, if not then a 3D printing service also complies. (B)
14. Time-effectiveness: the fabrication process should cost the maker not more than 10 minutes. And printing and/or delivery time of the splint should be as low as possible. (S)
15. Costs-effectiveness: materialisation costs should be as low as possible, preferable below €20,- per splint (€30,- including development costs) (A)

#### Safety and reliability requirements

16. Accuracy: the printer should be properly calibrated to achieve dimensions equal to the input dimensions. (R)
17. Reproducibility: The device manufacturing process should give equal results when repeated at different locations by different makers. (R)
18. Traceability: In case the product results in complications inherent to a manufacturing failure, the cause of the failure should be traceable. (R)

## 4. Analysis phase

### 6. Whishes

1. It should be possible to change colours, material and design to one's individual wishes (A)
2. The product should be as lightweight as possible (S)
3. The product should be aesthetically pleasing the user's personal taste (S)
4. The materials should be biodegradable (B)
5. The device should be as cheap as possible (A)

## 4.7 Function analysis

The function analysis will describe the function of the product in more detail. As mentioned in the clinical background, the general function of finger splints is to improve joint kinematics by immobilize the joint in a certain position. More specifically, the motion around the PIP and/or DIP joint must be restricted in one or two direction. First, all sub-function will be set out for each of the relevant pathologies. Secondly a function analysis will be performed, to be used later on during the design phase as method to stimulate creativity.

### 4.7.1 Sub-functions

For each relevant pathology, the following sub-functions can be considered:

Swan neck deformity:

- Prevent hyperextension PIP joint
- Allow flexion PIP joint

Mallet Finger:

- Hold DIP joint in full extension
- Prevent DIP joint flexion

Trigger Finger:

- Rest finger (block from triggering)
- Limit DIP/PIP joint flexion

Boutonniere/Jammed Finger:

- Prevent DIP joint hyperextension
- Allow DIP joint flexion

Lateral deviated Fingers:

- Align PIP/DIP joint
- Prevent deviation PIP/DIP joint

### 4.7.2 The function analysis approach

In order to distract from reality and allow the creation of many solutions without being limited by thoughts on existing ideas, this paragraph focusses on describing the design assignment in very abstract words. This approach enables the designer to come up with richer solutions when used during the design phase (Verkerke & van der Houwe).

To describe the function, only two words could be used. The first word was selected out of: *Material, Energy, Information*. The second word was selected out of: *transportation, transformation, storage, separation/connection, combination*.


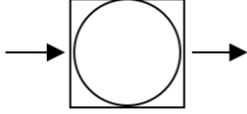
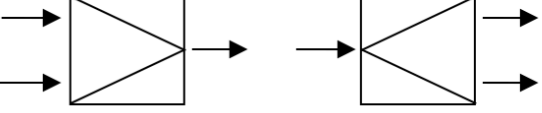
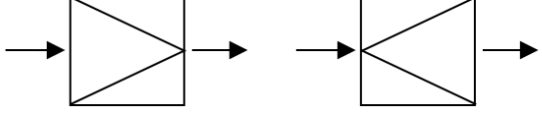
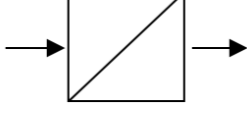
| Function               | Verbal meaning  | Symbol  |
|------------------------|---|---|
| Transport              | Transport, conduct, move, pump, relay                                       |    |
| Store                  | Store, keep, hold, memorise   |   |
| Connect (and separate) | Add, print, mix, connect, stir (cut, distil, scrape, read, saw, distribute) |  |
| Transform              | Flatten, grind, parse, translate, step-down, adapt                          |  |
| Convert                | Drive, power, time, use, control, generate, convert, burn                   |  |

Table 4: Fundamental functions of the function analysis approach

## 4. Analysis phase

The general function of the finger splint, to restrict movement around the PIP/DIP joint in one or two directions, can then be described as Material Connection. Then the sub-functions can be described as following:

1. Fixation to the finger: Material transport
2. Align joint: Material transport
3. Prevent hyperextension PIP/DIP joint: Energy storage
4. Prevent flexion PIP/DIP joint: Energy storage
5. Allow flexion DIP/PIP joint: Material transport
6. Prevent deviation DIP/PIP joint: Energy storage
7. Positioning the splint: Information transport

All possible sub-functions are ordered in the scheme in figure 4.10. From this analytical standpoint, boxes could be moved around to mix functions.

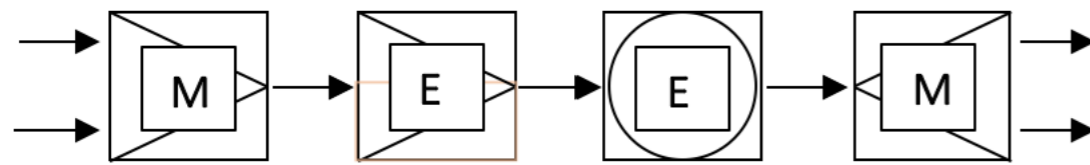
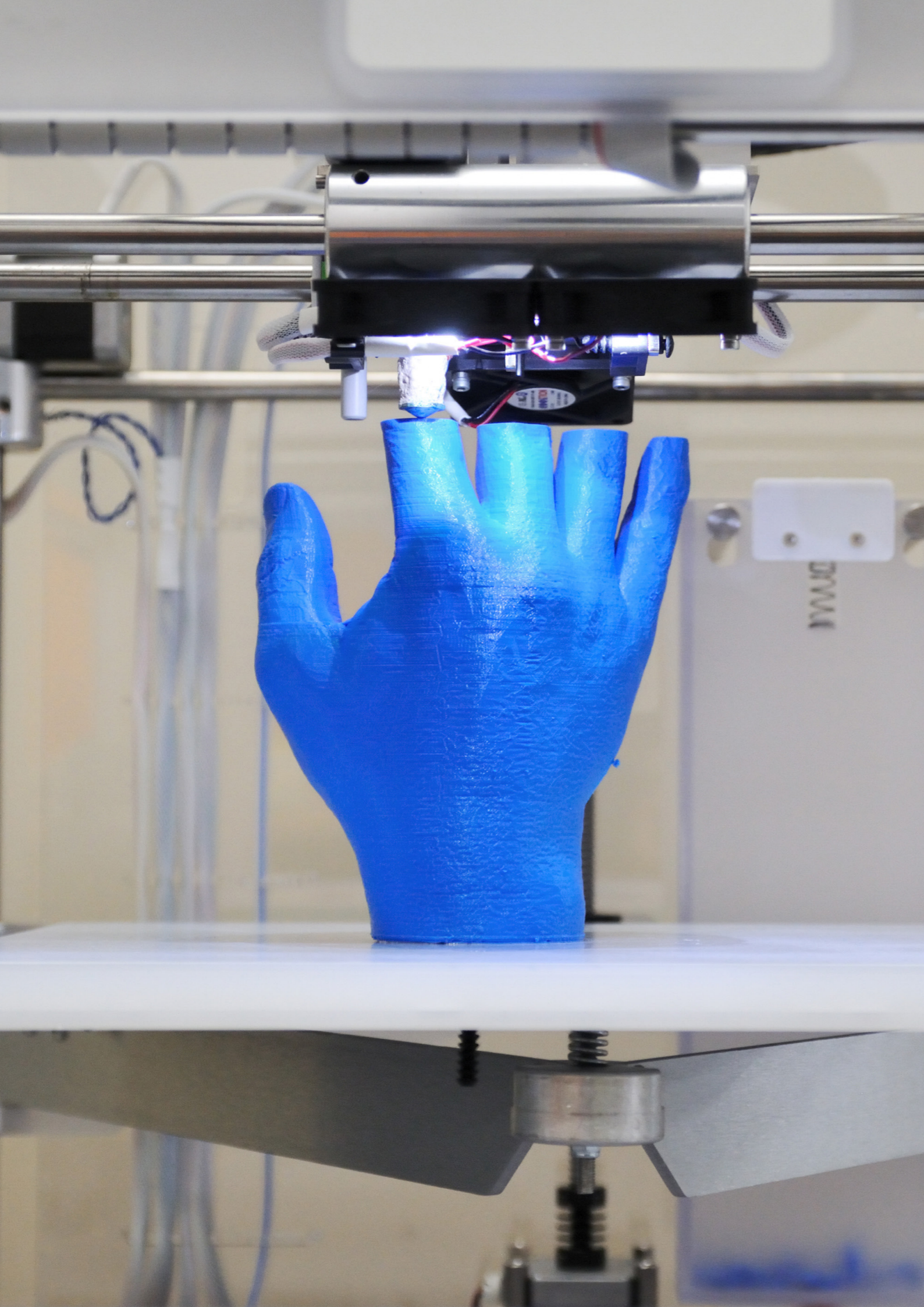


Figure 4.10 Function scheme of the finger splint functions

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## 5 Synthesis phase I Materialisation

In this chapter five materialisation concepts are created, extensively analysed, and finally the best is selected. The material and manufacturing method are grouped under the single term; materialisation. The chapter is composed of the following items:

- 5.1 Materialisation concepts
- 5.2 Quality and appearance
- 5.3 Mechanical performance
- 5.4 Ease of implementation
- 5.5 Safety and reliability
- 5.6 Concept selection

First the *materialisation concepts* will be created and explained regarding the underlying technique of each manufacturing method. All materialisation concepts are analysed concerning the following criteria: the *quality of the printed object*; *mechanical performance*; *the ease of implementation*; *safety and reliability*. These criteria refer to specific materialisation requirements, defined in the Analysis phase. The requirements are used as a checklist to see in what extend each concept would be a good solution to the problem. Paragraphs 2-5 provide the results of this checklist and a ranking of all concepts per criteria. In the *concept selection* the best overall performer will be selected. This material and manufacturing method will be embraced for further product development.

5.1 Materialisation concepts

Many types of 3D print technologies exist. Each type is characterised by different strengths and weaknesses. It depends on the product requirements which option is best suitable for the job. Not every material on each printer's list is suitable for medical purpose. Starting from the materials that comply with the material requirement be skin and food safe (requirement 5.1), five materialisation concepts were created. The materialisation concepts are shown in table 5.1. It should be noted that concept number five does not involve a 3D printing technology as implied in the design assignment. The argument to create this alternative concept was to double check if 3D printing truly would be the best solution to the problem. How this 2D technique can be of use for creating a 3D object, will be explained later.

Table 5.2 provides an overview of the material properties that are of importance to describe the mechanical behaviour of the material options. Tensile strength is the stress required to initiate deformation. The Young's modulus is a mechanical property that defines the relation between stress (force per unit area) and strain (proportional deformation). Values are obtained from the material data sheet by the manufacturer (1-4), who all tend to provide the properties based on printed test samples. Next, the underlying technique of each manufacturing method will be described.

| Nr. | Manufacturing technique          | Material options                  |
|-----|----------------------------------|-----------------------------------|
| 1   | Fused Deposition Modelling (FDM) | ULTEM1010                         |
| 2   | Selective Laser Sintering (SLS)  | Nylon (PA2200)                    |
| 3   | <u>PolyJet (PJ)</u>              | MED610                            |
| 4   | Stereo lithography (SLA)         | DSM <u>Somos WaterShed® 11122</u> |
| 5   | 2D Laser cutter (LC)             | Medical thermoplastic             |

Table 5.1 Overview of materialisation concepts

| Print method | Material                          | Tensile strength (MPa)            | Young's modulus, E (MPa)                       |
|--------------|-----------------------------------|-----------------------------------|--|
| FDM          | ULTEM1010                         | 64 (XZ axis)<br>42 (ZX axis)      | 2770 (XZ axis)<br>2200 (ZX axis)               |
| SLS          | Nylon (PA2200)                    | 48 (Y-direction, 47 (X-direction) | 1700 (X and Y-direction,<br>1650 (Z-direction) |
| SLA          | DSM <u>Somos WaterShed® 11122</u> | 47 - 53 (no direction mentioned)  | 2650 - 2880 (no direction mentioned)           |
| PJ           | MED610                            | 50-65                             | 7250-9450                                      |

Table 5.2: Tensile strength and Young's modulus of the material options (1-4).

1. Fused Deposition Modelling (FDM)

Fused Deposition Modelling (FDM) works by material being melted and extruded through a nozzle to 3D print a cross section of an object each layer at a time. The bed lowers for each new layer and repeats until the objects is completed. Layer height determines the quality of the print. For object with overhanging areas, support structures need to be printed and manually removed afterwards. Higher range FDM 3D printers have multiple nozzles that can print different colours and print support structures for overhanging areas of a complex 3D print.

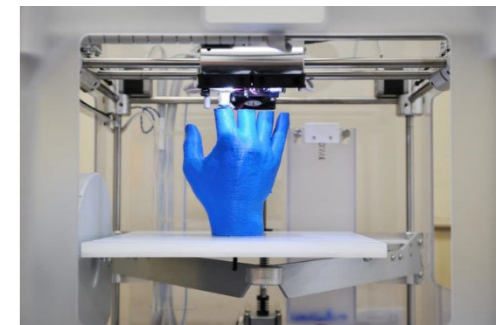


Figure 5.1 Fused Deposition Modelling

2. Selective Laser Sintering (SLS)

Selective Laser Sintering is a 3D printing technology that uses a powder bed fusion process to build 3D parts. Sintering is the process of compacting and forming a solid mass of material by heat without melting it to the point of liquefaction. A thin layer of polymer powder is selectively sintered in the shape of the 2D cross-section using a powerful laser beam. After each layer, the build platform descends one layer depth and is recoated with a fresh layer of powder. The laser scanner process simultaneously generates the current layer and joints it to the previous layer, creating a solid part. Iterating this process for each cross-section of the object results in the complete object. As the finished object is buried in a container of the un-sintered powder, no support structures are required. This allows the construction of complex structures and interlocking parts.



Figure 5.2 Selective Laser Sintering

3. Stereo Lithography (SLA)

The process of the SLA technology is similar to SLS but uses a near-UV laser beam focussed on a thin layer of liquid photopolymer resin. The photosensitive resin reacts solidifying forming the 2D cross-section of the object. In contrast to SLS support structures are required, and the in liquid resin soaked object needs to be cleaned. The removal of support structures often leads to scars on the object's surface.



Figure 5.3 Stereo Lithography

4. PolyJet (PJ)

Similar to SLA, a PolyJet printer uses a UV light to crosslink a photopolymer. But instead of scanning laser to cure layers, a printer head jets tiny droplets of the photopolymer in the shape of the cross-section layer. After which a UV lamp, attached to the printer head,

## 5. Synthesis phase 1 - Materialisation

Crosslinks the polymer. The build platform lowers before each new layer is deposited directly onto the new layer. These steps are iterated until the 3D part is completely finished.

### 5. 2D Laser cutter

The laser cutter is a machine that uses a laser to cut materials such as chip board, matte board, felt, wood, and acrylic up to 3/8" (1 cm) thickness. The laser cutter is often bundled with a driver software which interprets vector drawings produced by any number of CAD software platforms. The laser cutter is able to modulate the speed of the laser head, as well as the intensity and resolution of the laser beam, and as such is able both cut and score material, as well as approximate raster graphics. Objects cut out of materials can be used in the fabrication of physical models, which will only require the assembly of the flat parts.

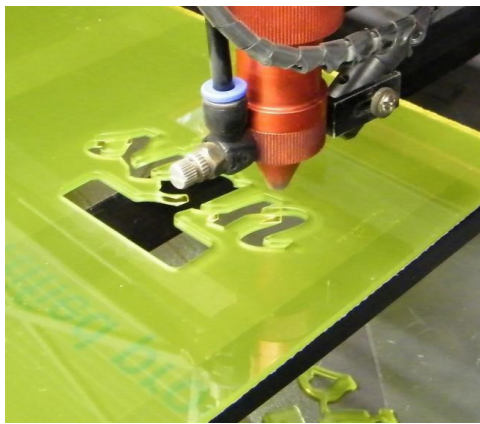


Figure 5.4 2D Laser cutting

Using a 2D laser cutter is precise method of cutting a pattern from a sheet of material using a CAD file to guide it. A laser beam cuts the material by melting, burning and vaporizing the material. A fine level of detail on a wide variety of materials can be achieved including the common used medical thermoplastic, are the biodegradable Woodcast®, used for splinting.

This method can be used to cut out a parametric 2D splint model, instead of manual drawing and cutting, after which the traditional process of fitting by moulding and heating is followed using a laser cutter reduces time and overcomes the difficulties of the current manual method to make a custom splint. Instead of using pre-perforated sheets, more aesthetically pleasing patterns can be made with a more detail and a more comfortable and clean finish.

### 5.2 Quality and appearance

In this section the materialisation concepts are ranked with reference to the quality and appearance requirements for materialisation. These are requirement 5.2 – 5.7 of the list of requirements and wishes, defined in the Analysis phase (chapter 4). To each requirement a weight is assigned, saying that it is very, or less, important, than another. Secondly, each concept is given a score per requirement from 0 to 10 for bad to good. The total concept score of all quality and appearance requirements is calculated as seen on the left.

$$\text{Total concept score} = \frac{(\text{weight} \times \text{score per requirement})}{\text{total of weights}}$$

### Results

An overview of the results is shown in the figure and table below. The descriptions of the requirement fulfilment as an argument for the given score, can be found in Annex 5.1.

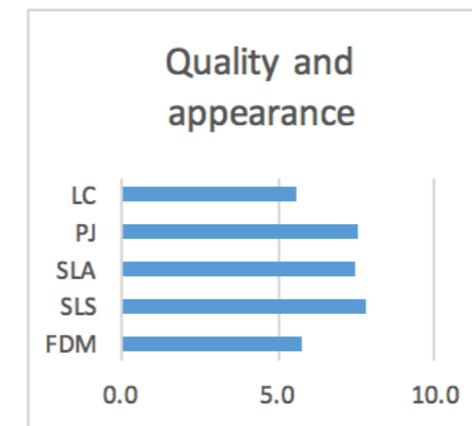


Figure 5.5 Quality and appearance results

### Conclusion

It can be concluded that Selective Sintered Nylon is the best option to create a finger splint with a good quality and appearance. It is excellent in printing complex objects with overhangs and small details, it's surface has a good look and feel and there are many colour options. As a disadvantage the porous surface is not water-tight and easily becomes dirty and contaminated, but this can be overcome with some additional post-processing steps. A more smooth and shiny surface can be achieved by polishing, and different coatings could be applied to realize a water-tight and clean final product. The surface of the printed object is a SLA or PJ both would be more suitable if superior quality surface finish is required or parts need to be transparent, unfortunately the medical resins for these printers are not as limited in colour as their commercial options.

### 5.3 Mechanical performance

In this section the materialisation concepts are ranked with reference to the mechanical requirements for materialisation. These are requirement 5.8 – 5.10 of the list of requirements and wishes, defined in the Analysis phase (chapter 4). The same ranking method as described in paragraph 5.2 is applied.

### Results

An overview of the results is shown in the figure 5.6 (on the next page) The descriptions of the requirement fulfilment as an argument for the given score, can be found in Annex 5.2.

## 5. Synthesis phase 1 - Materialisation

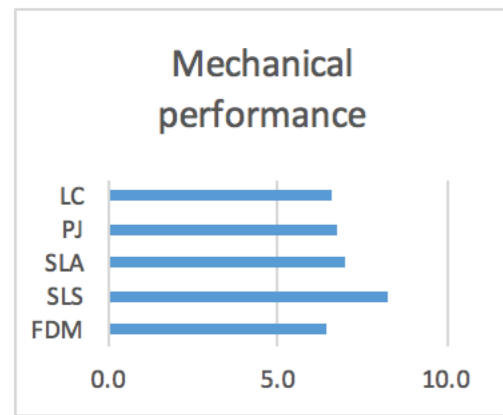


Figure 5.6 Mechanical performance results

| Requirement             | Weight      | FDM        | SLS        | SLA        | PJ         | LC         |
|-------------------------|-------------|------------|------------|------------|------------|------------|
| 5.8 Strength & rigidity | 5,0         | 9,0        | 8,0        | 7,0        | 7,0        | 8,0        |
| 5.9 Isotropy            | 3,0         | 4,0        | 9,0        | 7,0        | 6,0        | 9,0        |
| 5.10 Failure risk       | 4,0         | 5,0        | 8,0        | 7,0        | 7,0        | 3,0        |
| <b>Total score</b>      | <b>12,0</b> | <b>6,4</b> | <b>8,3</b> | <b>7,0</b> | <b>6,8</b> | <b>6,6</b> |

### Conclusion

Due to its isotropy and relative elasticity Selective Sintered Nylon is the best all-rounder that offers durability, strength and wear resistance. Second, SLS printers are highly professional machines controlled by experts, limiting the risk on mechanical failure due to manufacturing mistakes. With its high strength FDM would be a good option, but due to a low isotropy only when strength in one direction is required. However, the mechanical strength of FDM printed parts highly depend on the build parameters controlled by the user and limited by the specifications and proper maintenance of the printer. This increases the risk on mechanical failure. SLA and PJ both are less suitable than SLS, because photo polymeric resins tend to be very rigid and thus brittle. Under load rigid resins almost do not deform until they suddenly fracture into multiple pieces.

### 5.4 Ease of implementation

In this section the materialisation concepts are ranked with reference to the implementation requirements for materialisation. These are requirements 5.11 – 5.14 of the list of requirements and wishes, defined in the Analysis phase (chapter 4). The same ranking method as described in paragraph 5.2 is applied.

#### Results

An overview of the results is shown in figure 5.7. The descriptions of the requirement fulfilment as an argument for the given score, can be found in Annex 5.3.

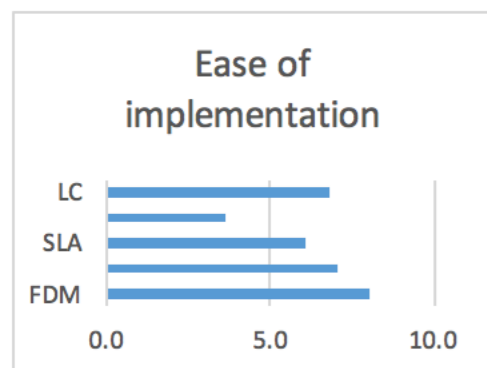


Figure 5.7 Ease of implementation results

| Ease of implementation requirements | Weight      | FDM        | SLS        | SLA        | PJ         | LC         |
|-------------------------------------|-------------|------------|------------|------------|------------|------------|
| 5.11 Accessibility                  | 4,0         | 9,0        | 8,0        | 6,0        | 2,0        | 5,0        |
| 5.12 Cost-effectiveness             | 5,0         | 9,0        | 8,0        | 6,0        | 2,0        | 7,0        |
| 5.13 Time-efficiency                | 3,0         | 4,0        | 7,0        | 5,0        | 6,0        | 8,0        |
| 5.14 Location                       | 1,0         | 9,0        | 5,0        | 7,0        | 5,0        | 7,0        |
| <b>Total score</b>                  | <b>15,0</b> | <b>8,0</b> | <b>7,0</b> | <b>6,1</b> | <b>3,6</b> | <b>6,8</b> |

### Conclusion

With FDM being the most popular, affordable and simple technique it is the most easy to implement. An independent patient could easily purchase an FDM printer at home or in a makerspace, and for a healthcare facility it would be an affordable investment. In addition, an FDM printer could be used at remote locations. The use of both SLS and PJ depend on a 3D printing service, since these machines are too expensive and inefficient to have in a makerspace or healthcare facility.

Despite all these advantages, the DIY spirit accompanied with FDM is not time-efficient, it can take up to a few hours to finish the product. Although it requires a few days delivery time, it would be more time-efficient to order the splint at a company with a 3D-print service. Probably also delivering a better quality result.

### 5.5 Safety and reliability

In this section the materialisation concepts are ranked with reference to the safety and reliability requirements for materialisation. These are requirements 5.11 – 5.14 of the list of requirements and wishes, defined in the Analysis phase (chapter 4). The same ranking method as described in paragraph 5.2 is applied.

#### Results

An overview of the results is shown in figure 5.8. The descriptions of the requirement fulfilment as an argument for the given score, can be found in Annex 5.4.

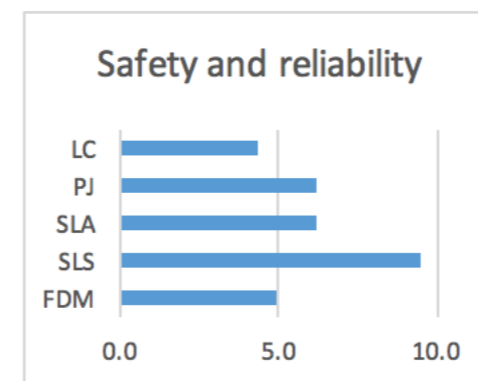


Figure 5.8 Safety and reliability results

| Safety and reliability requirements | Weight      | FDM        | SLS        | SLA        | PJ         | LC         |
|-------------------------------------|-------------|------------|------------|------------|------------|------------|
| 5.15 Dimensional accuracy           | 5,0         | 6,0        | 9,0        | 7,0        | 7,0        | 6,0        |
| 5.16 Reproducibility                | 3,0         | 5,0        | 10,0       | 7,0        | 7,0        | 3,0        |
| 5.17 Traceability                   | 2,0         | 2,0        | 10,0       | 3,0        | 3,0        | 2,0        |
| <b>Total score</b>                  | <b>10,0</b> | <b>4,9</b> | <b>9,5</b> | <b>6,2</b> | <b>6,2</b> | <b>4,3</b> |

### Conclusion

Selective Laser Sintering is currently far-out the most safe and reliable technique to use for the fabrication of medical devices. It is the only technique offered by specialized medical printing services that manufacturing according to the medical printing standard (ISO 13485). In this way very accurate dimensions and reproducible results can be achieved, and in case of failure every product is traceable. Considering regulatory issues, SLS would therefore be a very good option. In the case of FDM or LC the



## 5. Synthesis phase 1 - Materialisation

manufacturing process is the responsibility of independent makers at dispersed locations and quality results highly vary with this, traceability and reproducibility then become uncontrollable.

### 5.6 Materialisation concept selection

In this section all materialisation concepts are ranked according to their overall performance, and the best selected. To each criteria a weight is assigned, saying that it is very, or less, important, than another. The score per criteria are the aforementioned results. The score for the overall performance can then be calculated as following:

$$\text{Total score} = \frac{(\text{weight} \times \text{score per criteria})}{\text{total of weights}}$$

#### Results

An overview of the results is shown in figure 5.9.

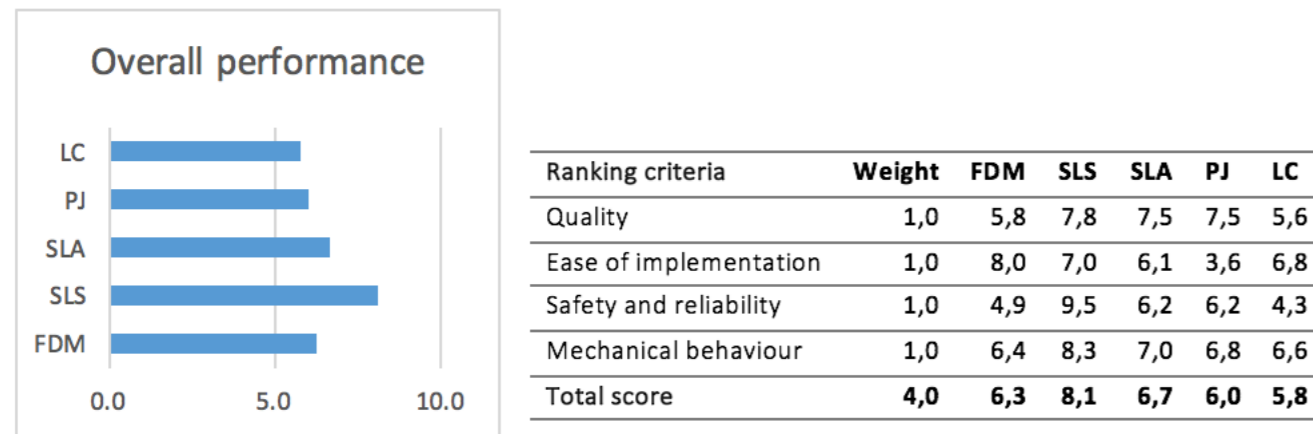


Figure 5.9 Overall performance results

#### Materialisation conclusion

It may be clear that Selective Laser Sintered Nylon is the best overall performer in providing an high quality; low cost; mechanically functioning; safe and reliable finger splint. The only drawback is that use of this technology depends on a 3D printing service requiring a few days waiting time to have the product in hands. Purchasing an SLS printer at location is not (yet) realistic due to the high investment and the fact that the technique is not suitable to print one single product. Since one can purchase a finger splint from the comfort of his own home when using a 3D-printing service, this may still be considered as 'local' fabrication. For this project, the SLS option will be embraced for further product development.

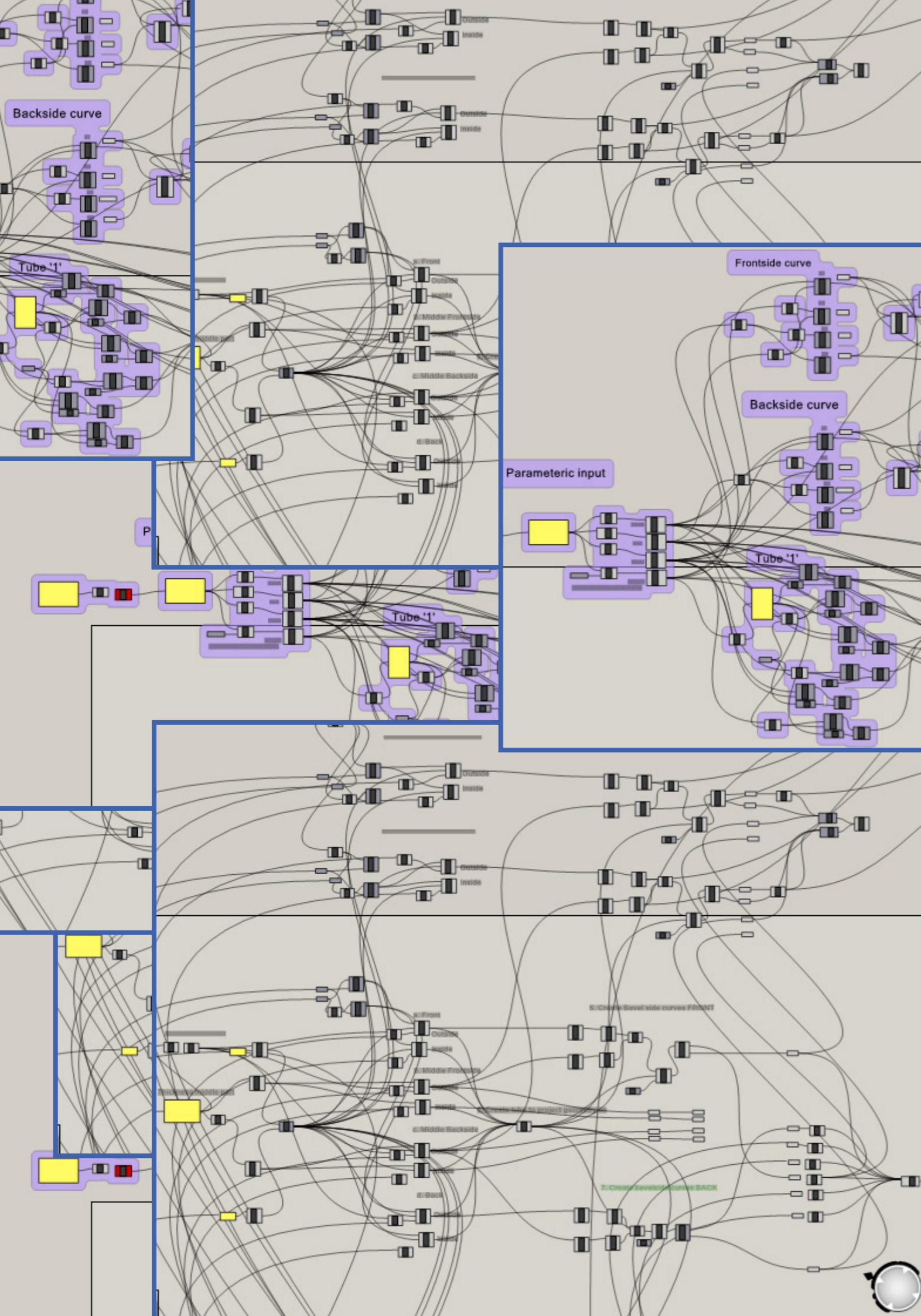
#### Materialisation discussion

Given that the parametric finger splint design application is a standalone concept, the materialisation selection could be seen as an advice rather than an obligation. SLS is the best overall performer considering the requirements and their importance set for this project, but situations may occur where these requirements and their importance differ.

If a more DIY approach, FDM is the best option to enable a patient or hand therapist to really make the finger splint himself at a desired or remote location. However, this option should only be considered if this requirement is of such great importance that it compensates for the drastically decreased quality, safety and reliability. When a superior quality surface finish is required or parts need to be transparent, then an SLA print will be the way to go while taking into consideration the high costs.

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# 6 Synthesis phase II

## Parametric Design

In this phase three design concepts are created, extensively analysed, and finally the best selected. This chapter is composed of the following items:

- 6.1 Method
- 6.2 Results
- 6.3 Concept selection

The *method* describes the design approach to address the following technological challenges revealed in the background research: allow for quick and easy customization; rethink mechanical design; and verify mechanical performance. In *results* the three parametric design concepts are provided including an analysis of their mechanical performance. Finally, the concepts are prototyped and the design that best fulfils the product requirements will be *selected* for further development in Synthesis III.

## 6. Synthesis phase 2 - Parametric Design

### 6.1 Method

The finger splint design creation, verification and validation includes the following steps (Fig. 6.1). 1) Parametric design model development in Grasshopper, 2) FEM analysis of the splint designs using related loading conditions resulting from the biomechanical analysis, 3) qualification of the printed prototypes, and 5) an experimental validation of the mechanical performance. This last step will be further addressed in Synthesis III, step 1-3 will be performed in this phase as described in the following.

#### 6.1.1 Parametric design

Unlike most CAD-software, parametric design software allows one to change the virtual 3D-model after the design is completed, so that it can be adjusted dimensions, volume or for instance surface patterns. The software used for parametric modelling is the Grasshopper Plug-in for Rhinoceros. Grasshopper is a graphical algorithm editor tightly integrated with Rhinoceros' 3D-modeling tools. It enables manipulation of the relationship between elements to change the design of complex geometries and structures. The final design is a formula, based on a set of data. Some data is fixed (the design choices made by the designer for functionality reasons for example), some data is open (the parameters that can still be changed).

Parametric design will be used to provide a basic design for the finger splint that can easily be adjusted to patient ergonomic dimensions. In this study the following parameters will be open for the user's input: finger length; front- ;middle- ; back-diameter; and the angle of immobilization. Grasshopper receives this data from an external text file, which is updated in real-time. Each script of the parametric concepts visualisation in the Results section, start with the grasshopper script in the figure 6.2.

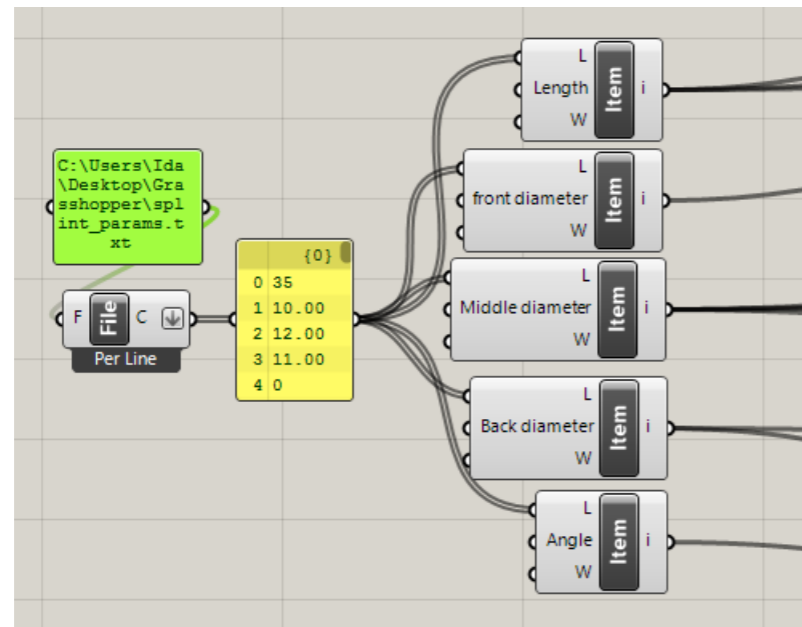


Figure 6.2 Parametric input in the design script (Grasshopper)

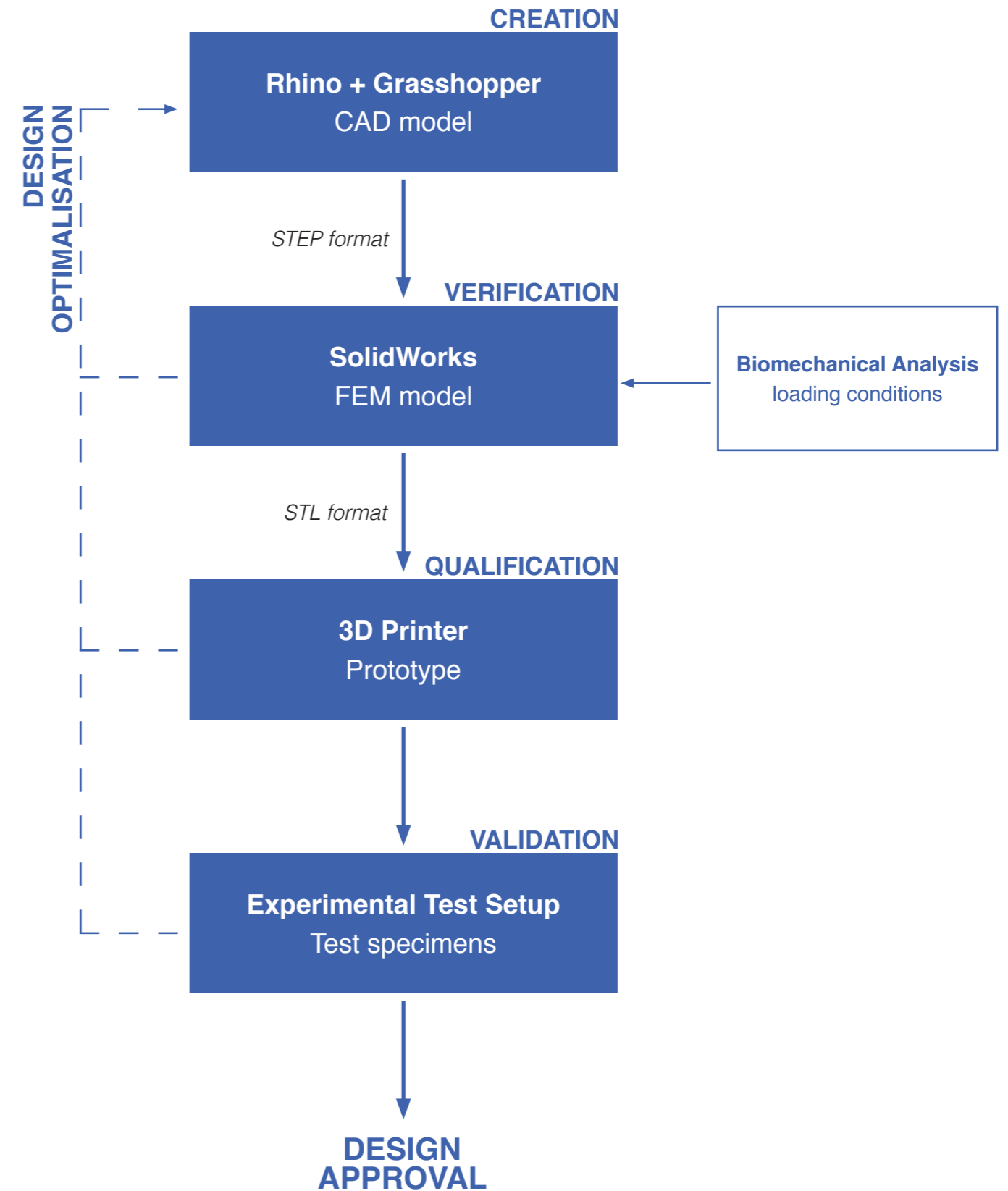


Fig. 6.1 Design development process

### 6.1.2 Design verification (FEM)

The Finite Element Method (FEM) is a computational method used to predict the mechanical response of the engineered component under the predicted loading conditions, prior to manufacturing. Prediction of mechanical performance is necessary because it must be proven that the splint will not break or bend under the specified force requirement. Traditionally, FEM analysis is based on the assumption that materials are uniform homogeneous solids. While 3D-printed objects are not homogeneous but anisotropic, as mentioned in chapter 2. However, selective laser sintered parts could nearly be considered isotropic. Therefore, the sufficiency of this method will first be further explained.

In different studies the Finite Element Method was successfully applied in the framework of orthotic design using Selective Sintered Nylon (1,2). In these studies the Selective Laser Sintered Nylon was implemented in the finite element models as an isotropic material using the published mechanical properties provided by the data-sheet. While more recent studies revealed a discrepancy between measured mechanical properties and the data provided by the manufacturer, that mostly refer to isotropic materials (1). To account for such issues, the data-sheet for SLS nylon refers to the anisotropic mechanical properties of printed test samples instead of the raw material (3).

From this it was concluded that the Finite Element Method can be used as a tool to predict and optimize the parametric finger splint design. The CAD-files created in Rhinoceros are exported as step.-files to perform the studies in the Solid Works Simulation module. The predictions rely on the geometry, the implementation of loading conditions and the material characteristics. These subjects will be further addressed below.

#### Design geometry

Rethinking the mechanical design started with analysing the two traditional three-point finger splint configurations: the ring-based and oval-8 design (figure 6.3). The FE-analysis of these basic models, were used to predict the sufficiency of these design to be manufactured using SLS nylon. Based on the revealed strengths and/or weaknesses of , three new designs were created and analysed to achieve a sufficient geometry (change width/thickness).

#### Loading and restraints

First an extensive biomechanical analysis of the finger splint was performed to predict the system of forces acting on the finger splint. This biomechanical analysis is attached in Annex4.2. In SolidWorks Simulation a static study was performed for a variation of models by implementing the predicted loading conditions. A uniform, directional applied force of 15.6 N (purple arrows) was applied at the proximal and distal components of the splint, while the middle part was fixed to restrict it from moving (Fig. 6.4). Calculations were performed using the solid, standard mesh type (Fig. 6.5).

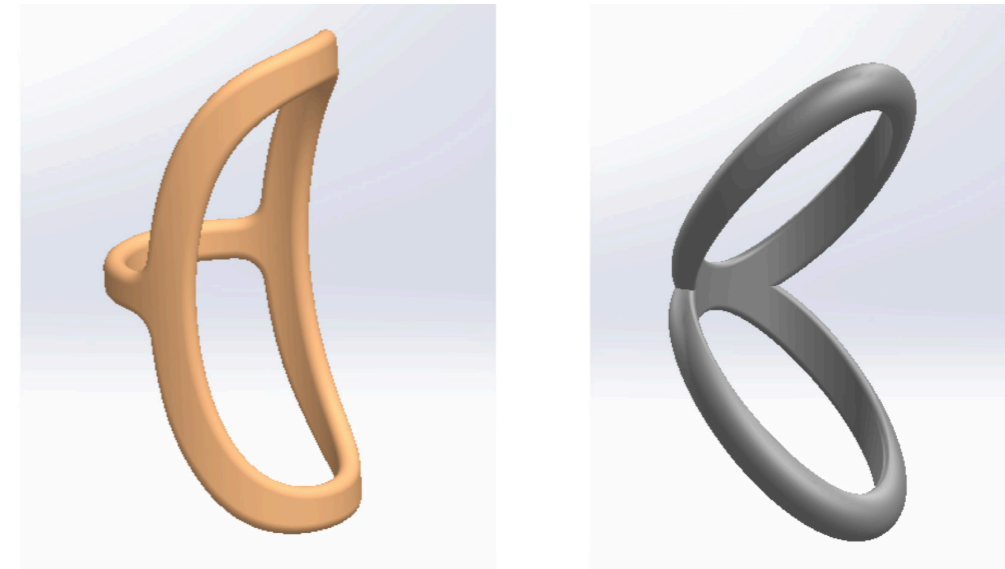


Figure 6.3 The basic 3-point-splint configurations a) oval-8 design b) ring-model

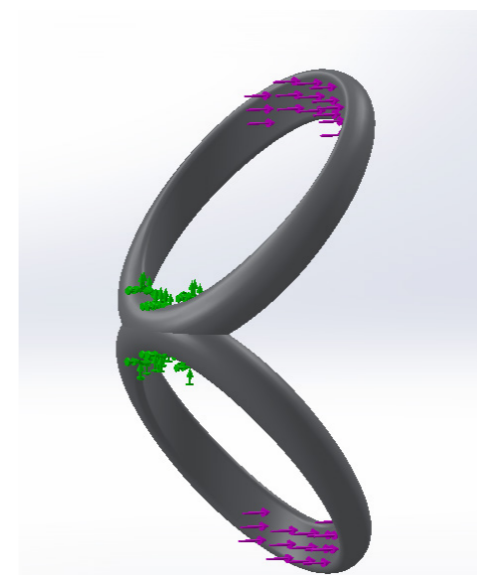


Figure 6. 4 Loading conditions



Figure 6.5 Mesh generation

## 6. Synthesis phase 2 - Parametric Design

### Material characteristics

The Selective Sintered Nylon was implemented in the Finite Element models as a Linear Elastic Isotropic material with the necessary material properties shown in the table below. These values refer to mechanical properties in the Z-direction of the printed object, which is the weakest direction. This isotropic approach was considered to be sure that the positioning of the model during the build process has no negative influence on the mechanical performance.

| Material properties of Selective Sintered Nylon (1, 2) |                       |
|--|-----------------------|
| Tensile modulus (Z-direction)                          | 1650 MPa              |
| Tensile strength (Z-direction)                         | 47 MPa                |
| Yield strength   | 40 MPa                |
| Poisson ratio  | 0,35                  |
| Density  | 930 kg/m <sup>3</sup> |

Table 6.1 Material properties of Selective Sintered Nylon (1, 2)

For a proper interpretation of the result the stress/strain behaviour of SLS nylon (Fig. 6.7) was considered in comparison to general elastic behaviour (Fig. 6.6). The stress/strain curve displays the amount of deformation (strain) at intervals of tensile loading (stress). In the linear region elastic deformation occurs, allowing an object to recover its original shape and size when unloaded. In the non-linear, so-called plastic region (beyond yield strength) permanent deformation occurs. While the ultimate strength is the maximal stress a material can withstand before fracture. The stress/strain curve of SLS Nylon test samples provided by the manufacturer, reveals a linear elastic region while in the nonlinear region the material behaves more like a brittle material. A typical stress-strain curve for a brittle material is linear: brittle materials do not have a yield point and at the ultimate strength fracture occurs without a noticeable prior change in the rate of elongation. The stress/strain curve of SLS nylon shows some non-linear plastic deformation, but fracture suddenly occurs without the typical strain-hardening and necking. For the functionality of the finger splint permanent deformation (non-linear plastic deformation) is unacceptable, and is used as the design limitation. It can be concluded that that SLS nylon can be modelled as linear elastic material using a yield strength of 40 MPa. If the von Mises stress reaches the critical value of the yield strength, material failure will be considered due to permanent deformation (while fracture occurs at an Ultimate strength of 50 MPa).

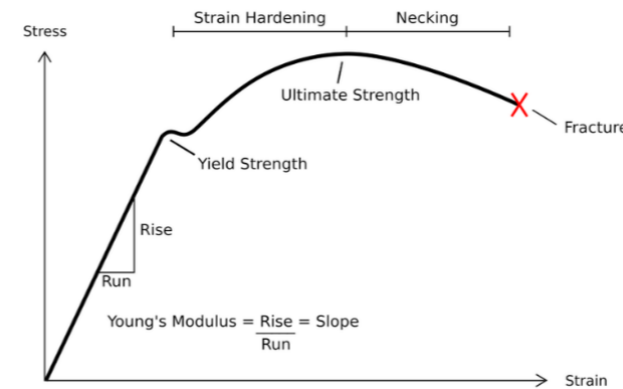


Figure 6.6 General stress/strain curve

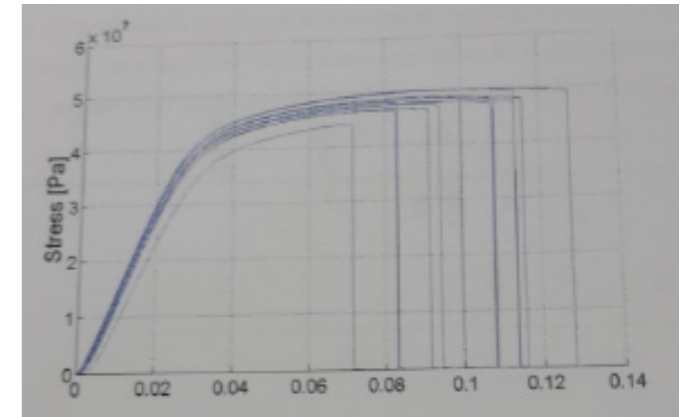


Figure 6.7 Stress/strain behaviour of SLS nylon test samples

## 6.2 Results

The results of the design process are provided as following 1) FEM analysis of the two basic models, 2) three improved parametric design concepts, 3) Final FEM results of the three design concepts. The FEM results include visualisation of the Von Mises stresses and total displacement under the applied loading conditions. The von Mises Stress addresses if and where material failure would occur under the applied load, while the displacement provides insight in the rigidity of the designs to maintain finger immobilization.

### 6.2.1 FEM analysis basic design models

The FEM analysis of the stresses within the ring based splint design under loading that would be experienced during finger extension (Fig. 6.8) predicted that the maximum stress occurred at the connection of the proximal and distal ring (95 MPa) and exceeds the material tolerance of SLS nylon (40 MPa) and the Ultimate strength (50MPa) resulting in a fracture. When the same study was performed with the implementation of pure silver (Source: Solid Works model library), the ring design does appear to be suitable with 0,13 mm displacement and a maximal von Mises stress of 115 MPa (with reference to a tensile strength of 125 MPa).

The oval-8 based splint design (Fig. 6.9) revealed a lower stress level (41 MPa), but this stress still exceeds the material tolerance of SLS nylon (40 MPa) within the plastic region. This would result in permanent deformation of 4,5 mm displacement (Fig. 6.8b) at the distal and proximal end of the splint. This means that the design would fail in keeping the finger in the right immobilization angle, in order to prevent hyperextension. When the same study was performed with the implementation of injection moulded nylon (Solid Works model library: nylon 101) the design appears to be more sufficient with 1,4 mm displacement and a von Mises stress of 41 MPa (with reference to a yield strength of 60 MPa).

## 6. Synthesis phase 2 - Parametric Design

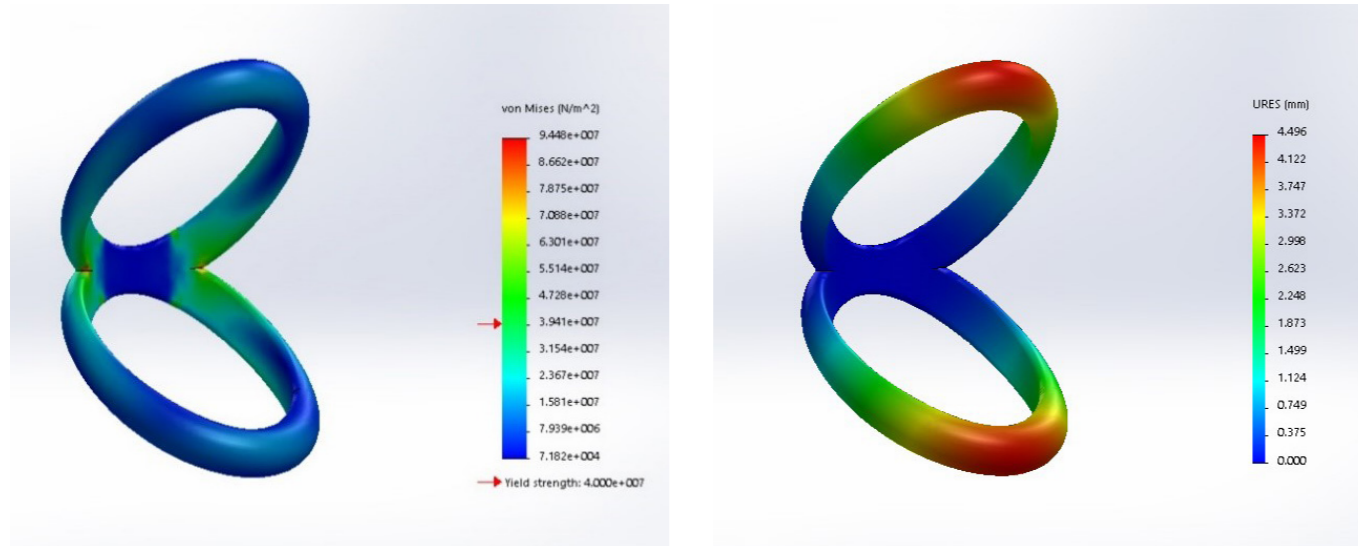


Figure 6.8 a) Stress plot ring based splint design in SLS nylon b) displacement plot

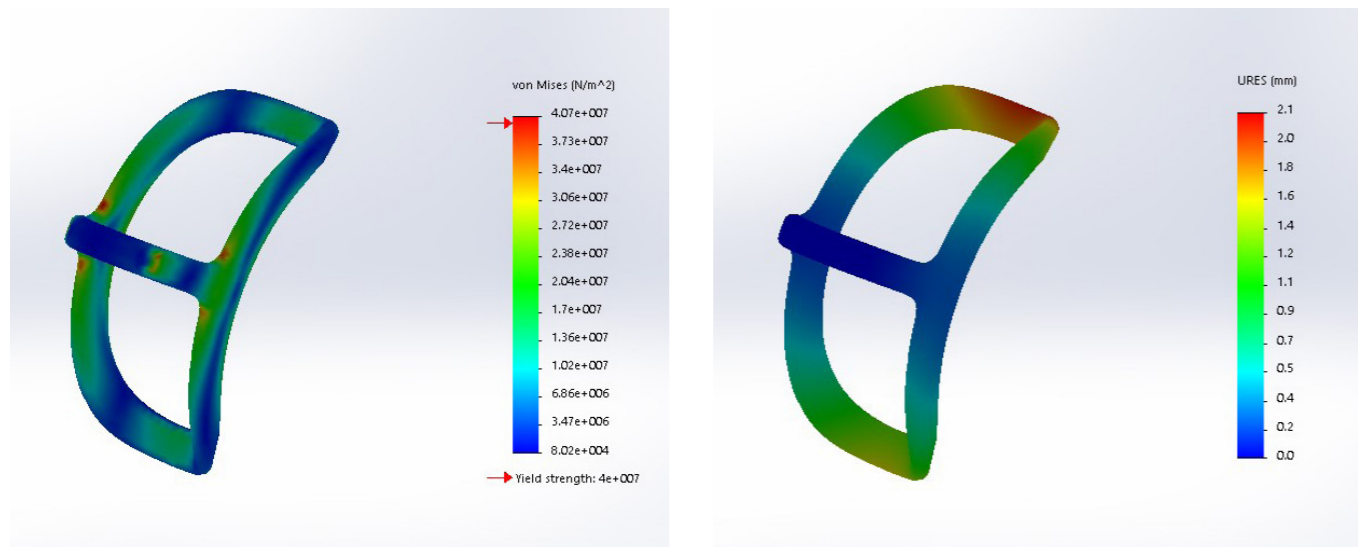


Figure 6.9 a) Stress plot oval-8 based splint design in SLS nylon b) displacement plot

### 6.2.2 Parametric design concepts

According to the FEM-analysis of the basic design it was concluded that reinforcement was required to make the designs stronger and more rigid, in order to decrease the risk of permanent deformation or material fracture. To integrate this reinforcement in the design, a brainstorm session was conducted in which various design strategies were explored through sketching. Three designs were then chosen to create a parametric model using Grasshopper. Each design is constructed from a different approach, as visualized in figures 6.10-6.13.

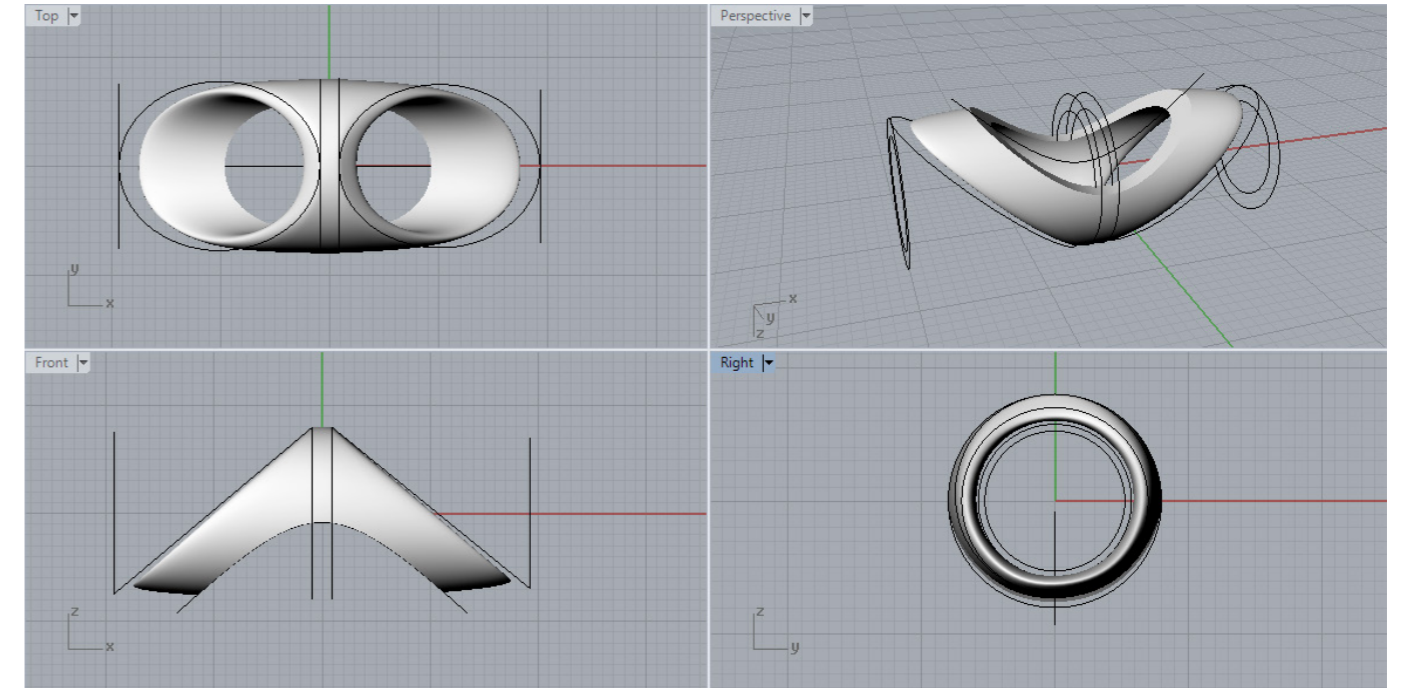


Figure 6.10 Parametric design I

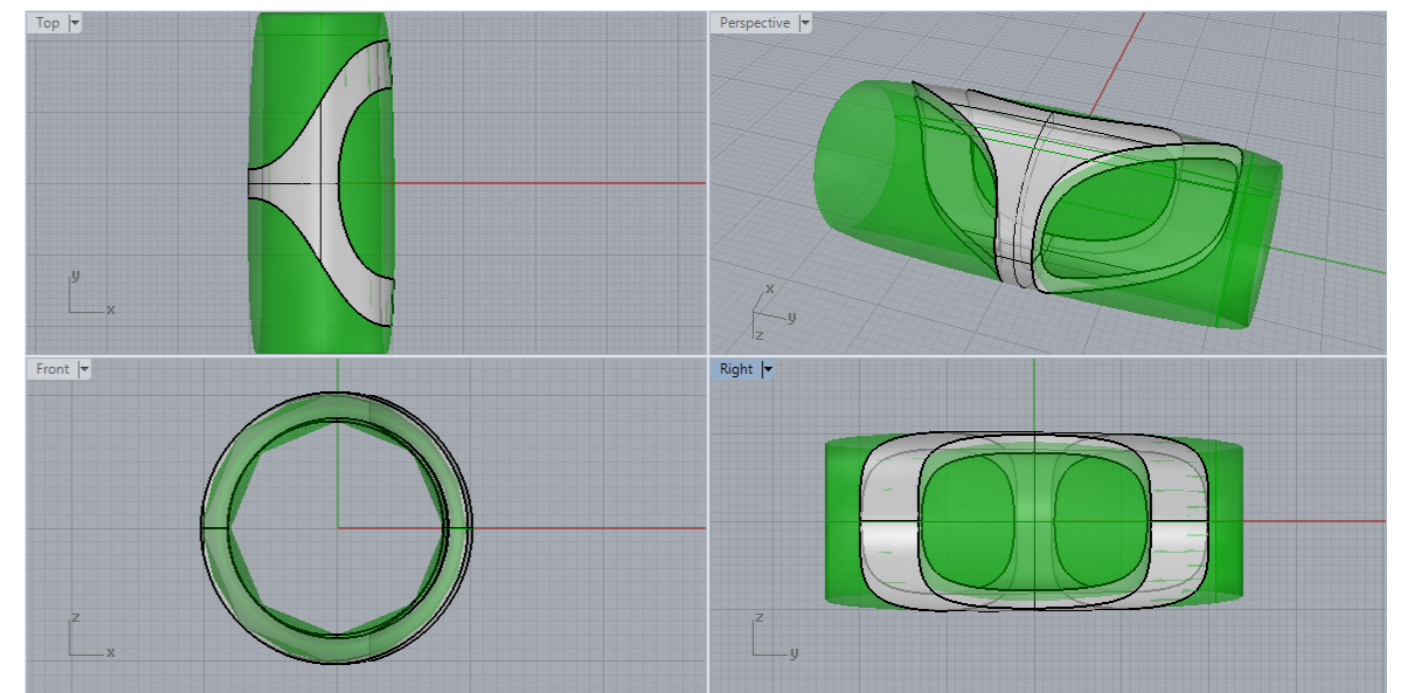


Figure 6.11 Parametric design II

## 6. Synthesis phase 2 - Parametric Design

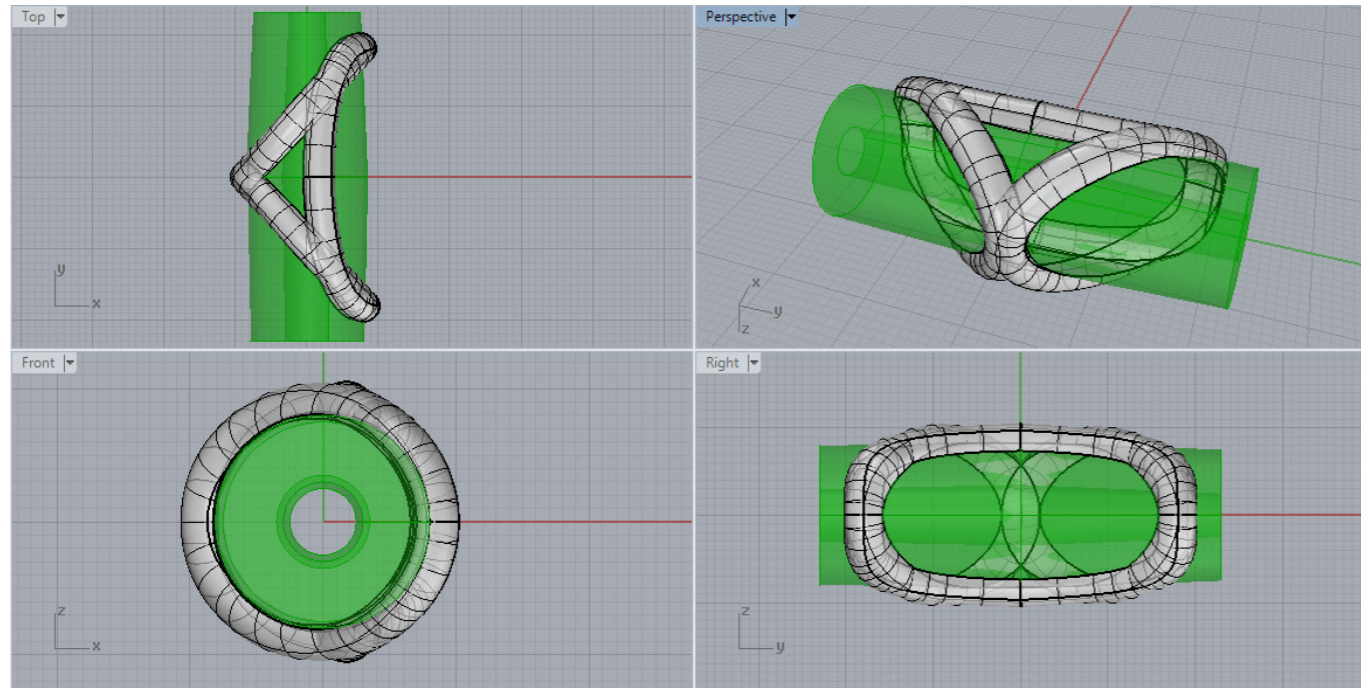


Figure 6.12 Parametric design III

### 6.2.3 FEM analysis design concepts

All three design concepts were created and optimized using a FEM-analysis to study the influence of width and thickness on mechanical performance. The FEM results of the 3 final concepts are provided in figures 6.12-6.14. Design I and II both are expected to be sufficient with a similar prediction of the mechanical performance: a von Mises stress of 20 MPa and 1,0 mm (Design I) and 0,85mm (Design II) displacement. Design III performed worse: it was expected to fracture under the predicted loading conditions. The design is stiff enough with 0.88mm displacement but the maximal stress level (54 MPa) exceeds the ultimate strength (50 MPa).

However, this interpretation is debatable. A closer look at the areas with the maximal stress revealed that in design II and III, the maximal stress (red spots) was initiated at the boundary between the free and fixated part of the splint model (clear blue area). The back part of the splint should indeed be restricted from moving as it is fixed around the finger. However, in the FEM model this boundary condition was implemented by fixating a demarcated part of back of the splint in all directions. In reality, it is expected, that this boundary conditions would distribute the stress much more gradually. But the computational model was restricted to four axis and straight boundary lines. Therefore, it is expected that the stress in this area will be better distributed in reality, and thus the risk on fracture in model II and III would be less than predicted. For the two basic designs and design concept I this was not the case, and for design concept II it did not result in an incorrect assumption. Therefore, revision of the FEM-analysis was only required for design III. Moving the boundary of the fixated part (Fig. 6.15), indeed revealed a gradual stress build up towards the boundary condition. From this point of view, it is expected that in reality crack initiation would not take place since the stress would not build up towards one specific point.

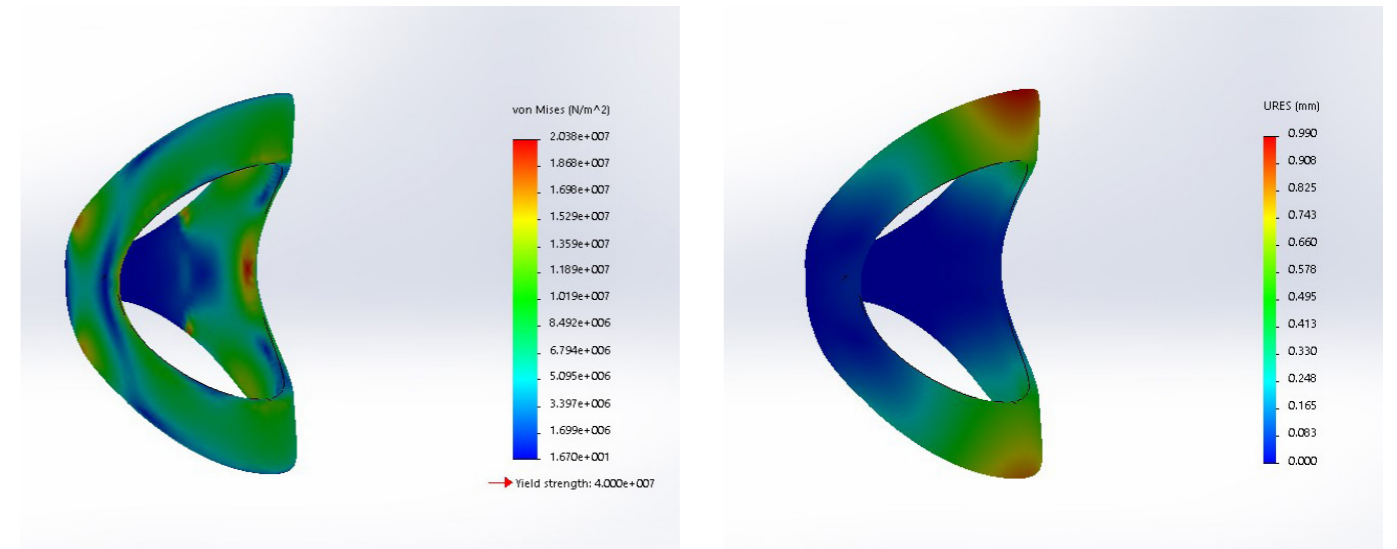


Figure 6.13 a) Stress plot design I in SLS nylon b) displacement plot

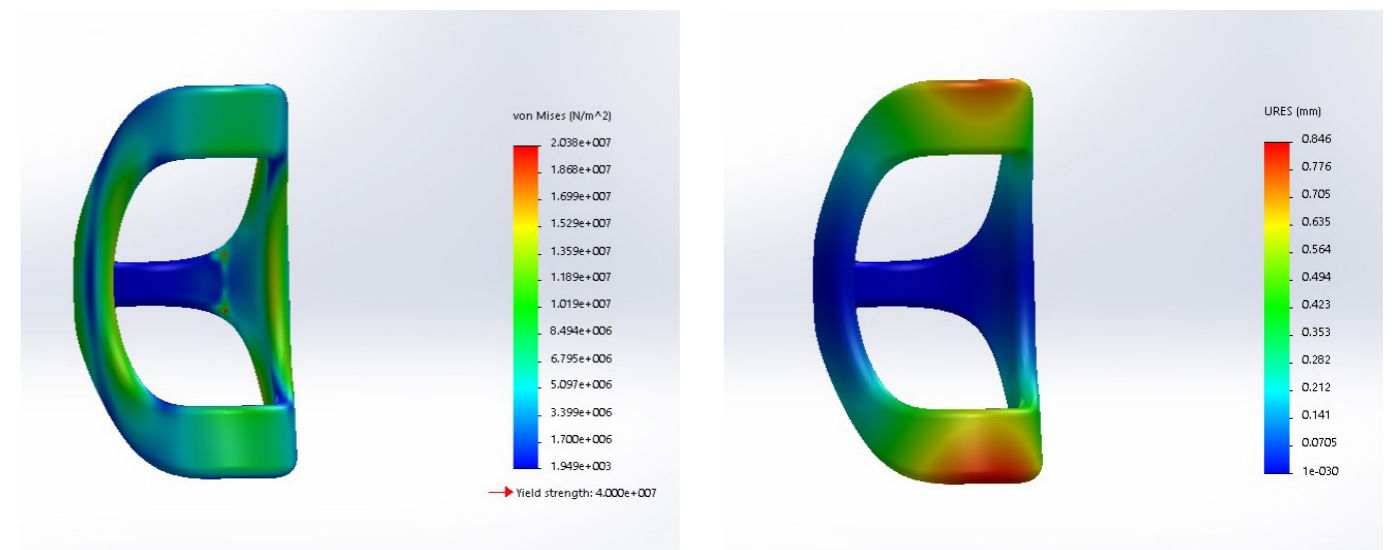


Figure 6.14 a) Stress plot design II in SLS nylon b) displacement plot

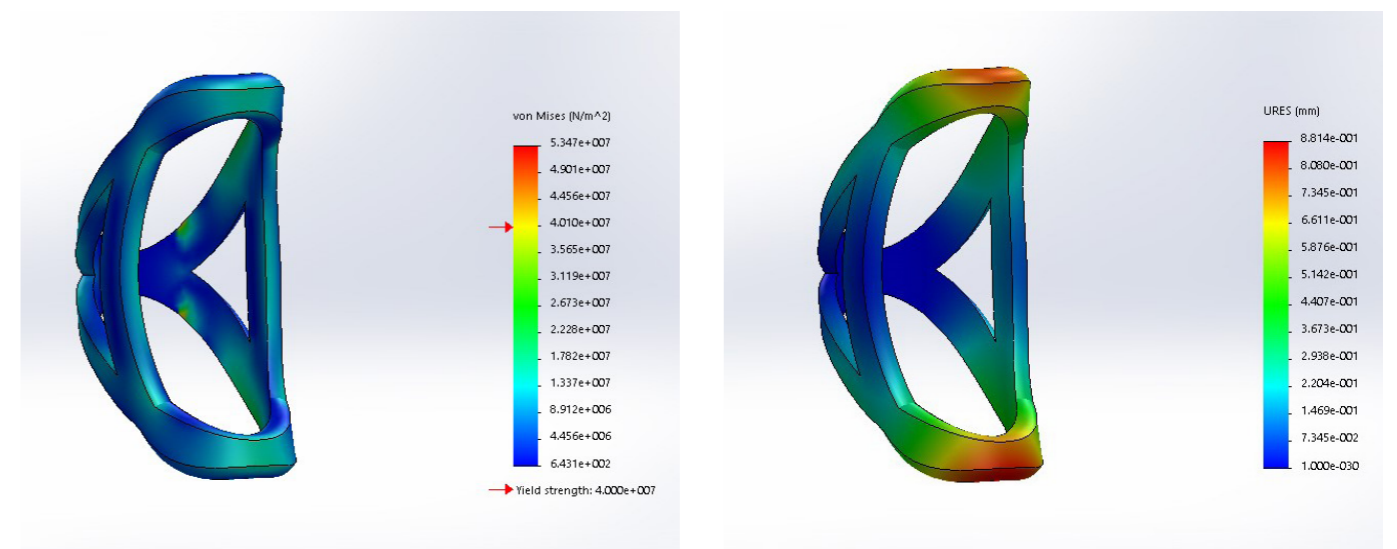


Figure 6.15 a) Stress plot design III in SLS nylon b) displacement plot



## 6. Synthesis phase 2 - Parametric Design

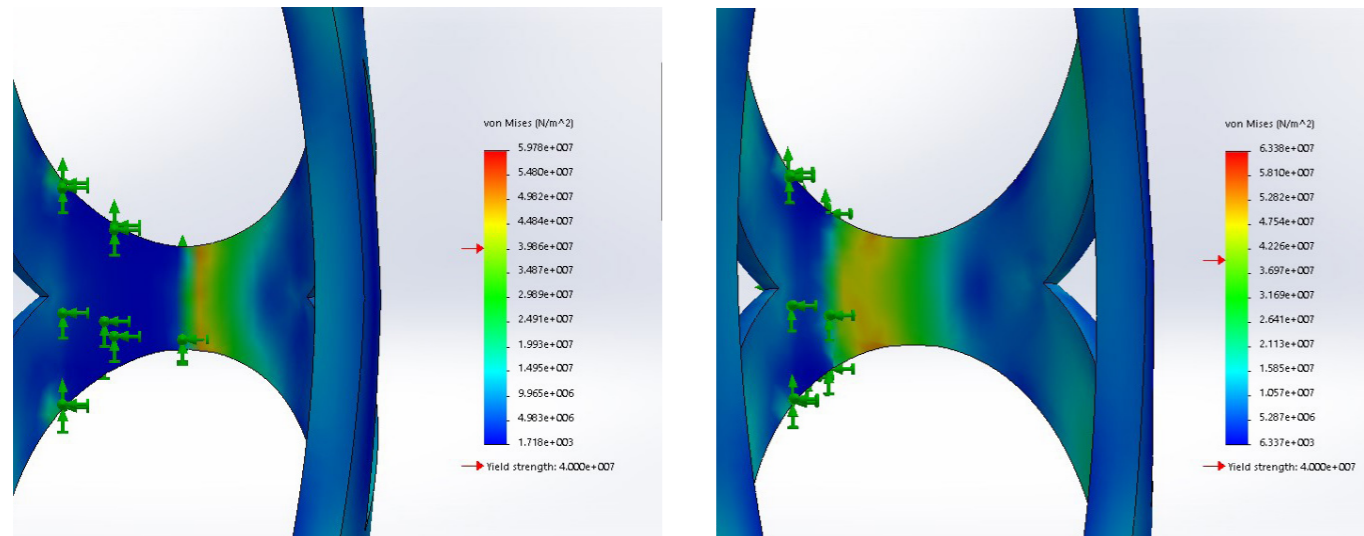


Figure 6.16 a) Stress plot with a displacement of the fixated boundary condition (clear blue area)

### 6.3 Concept selection

Prototypes were manufactured using SLS (Fig. 6.17 & Fig. 6.18) to test whether the product is actually a good solution to the problem. The list of product requirements was used as a checklist to analyse if all product requirements were fulfilled, this qualification process was conducted in collaboration with hand therapists as provided in Annex 6.1. An overview of the results per requirement category are provided in the table below, and the remarkable results are discussed to select the best option for further development.

| Requirements category       | Design I | Design II | Design III |
|-----------------------------|----------|-----------|------------|
| 1. User requirements        | ✓        | ✓         | ✓          |
| 2. Ergonomic requirements   | ✓        | ✓         | ✓          |
| 3. Safety requirements      | ✓        | ✓*        | ✓*         |
| 4. Maintenance requirements | ✓        | ✓         | ✓          |

Table 6.2 – Design qualification

The three design concepts all were approved, but design I was preferred with respect to requirement 3.1. \*To create soft splint edges (requirement 3.1) necessary to prevent soft tissue stress, design II and III both require a modification outside the grasshopper script (The Rhinoceros function 'fillet edges' is not available in Grasshopper). This modification adds an extra step in the development process that still requires 3D-modelling skills, which is not preferred. This problem could (possibly) be overcome by writing an additional GH-script for the therefore required function. But for this project, design I will be embraced for further product development.

It should be noted that Requirements 1.2 ; 2.4 ;2.6 ; 2.10 ; 3,1 ;3,6 ;3,7 ;3,8 ;3.11 ;4.2 also require further investigation in a long-term clinical test. Due to time-constraints this will not be addressed in this project.



Figure 6.17 – Prototypes. From left to right: design 1; design 2; design 3.



Figure 6.17 – Prototypes. From front to back: design 1; design 2; design 3.

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## 7 Synthesis phase III

### Final Solution

This phase starts with the selected concept and ends with a prototype that is successfully fabricated and tested. This chapter is composed of the following items:

- 7.1 Detailing
- 7.2 Technical drawings
- 7.3 Cost analysis
- 7.4 Mechanical testing
- 7.5 Failure Mode and Effective Analysis (FMEA)

First, all steps of the overall 'make' process will be described in *detail*. Then, the *technical drawings* will be explained in order to provide the necessary knowledge to replicate the parametric design models. The *cost-analysis* gives an overview of the cost of the 3D-printed splint compared to alternative solutions. Hereafter, the experimental test method and results for the validation of the mechanical performance are described under *mechanical testing*. Finally, through a *FMEA*, all possible risks related to the product will be verified and concluded into a risk plan.

7.1 Detailing

As a final solution, the overall process for local fabrication of a custom-fit finger splint includes the four steps as visualised in figure 7.1. To ensure quality and safety of the final device, this process of health service provision should be provided within this closed system. In this paragraph, each step will be further described in detail.

7.1.1 Measurement & Fabrication process

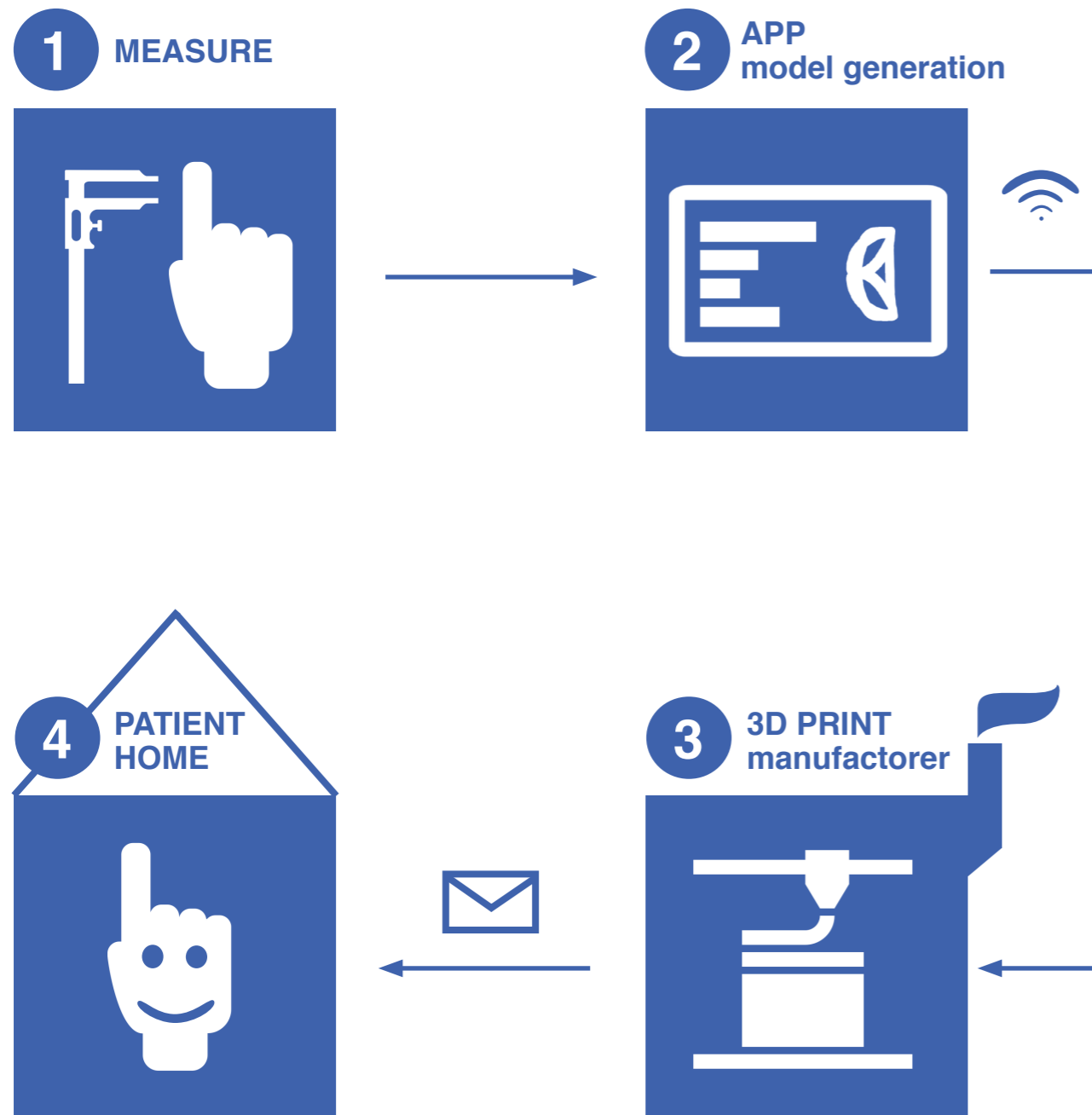


Figure 7.1 Measurement & fabrication process scheme

1. Measure

Through an app on a tablet the user will be guided through the steps of measurement needed to generate the finger splint. The required measurements include the following parameters, and are visualized in figure 7.2:

- $\varnothing F$  (mm) = front diameter
- $\varnothing M$  (mm) = middle diameter
- $\varnothing B$  (mm) = back diameter
- $\theta$  (°) = angle of immobilization

The measurement input is automated through a digital calliper and hand goniometer communicating with the tablet. When using an analogy measurement instrument, the measurement input can also be entered manually.

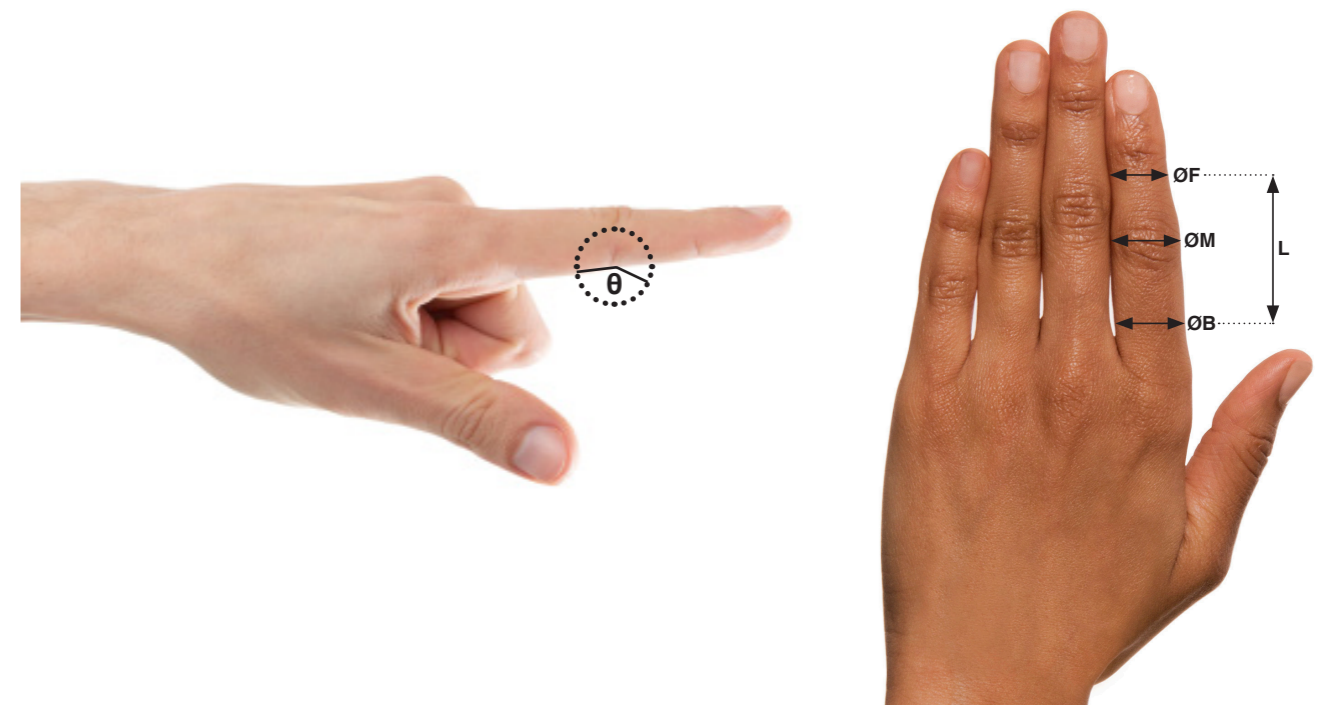


Figure 7.2 Measuring the finger

## 7. Synthesis phase 3 - Final Solution

### 2. Model generation

The app enables the user to make a customized 3D-printed finger splint without any 3D-modelling skills or knowledge of digital fabrication. A working demo of the app, was successfully developed by Waag Society as shown in figure 7.3.



Figure 7.3 App 3D-print inger splint generation, Waag Society

In the working demo a tablet was connected to a local server (laptop), with 3D-modelling software (Rhinoceros & Grasshopper) running. Once the few measurements are taken, the server updates the tablet with a ready-to-be-3D-printed STL-file. This concept can be improved by creating a stand-alone tablet, excluding the need of a local server. In this way the user does not need to purchase the 3D-modelling software. However, this standalone operating procedure requires the generation of a database with all possible outcomes of the parametric model.

### 3. Fabrication & 4. Delivery

Fabrication is performed by a professional 3D-printing services that prints according to the ISO standard for 3D-printing of medical devices. The app generates a standard order mail order including the STL file of the splint, and the following information to inform the manufacturer about the standardized manufacturing steps:

- Material: Nylon, PA2200 (ISO 9001)
- Print technology: Selective Laser (ISO-1348)
- Print orientation: according to figure 7.4
- Post processing:
  - Tumbling (for a fine and smooth finish)
  - Dyeing (colour option still limited to 13 colours)
  - Waterproof poly-urethane coating (stable, biocompatible polymer)

According to the current order-to-delivery time of 3D-prints, the splint will be delivered at the patient's home within 5 workdays.

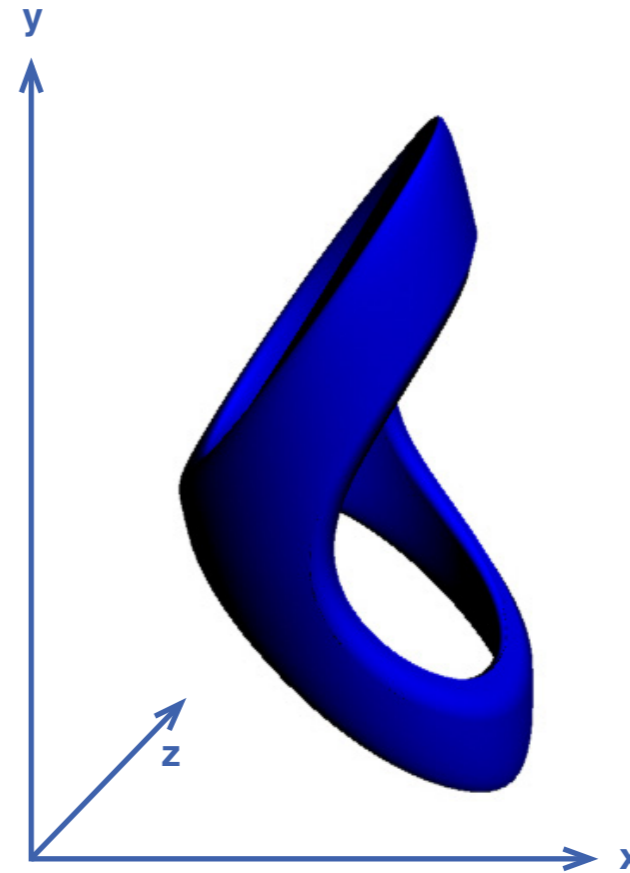


Figure 7.4 Print orientation, the Z-direction has the weakest tensile strength

### 7.1.2 Boundaries of the parametric model

The outcome of the parametric model is bounded by four input parameters, still the number of possible outcomes is infinite. For the generation of a size database the iteration process will therefore be limited as following:

- Length (L):
  - Min: 27 mm
  - Max: 47,5 mm
  - Step size: 1,0 mm
- Middle diameter ( $\varnothing M$ ): 26 mm
  - Step size: 1,0 mm

## 7. Synthesis phase 3 - Final Solution

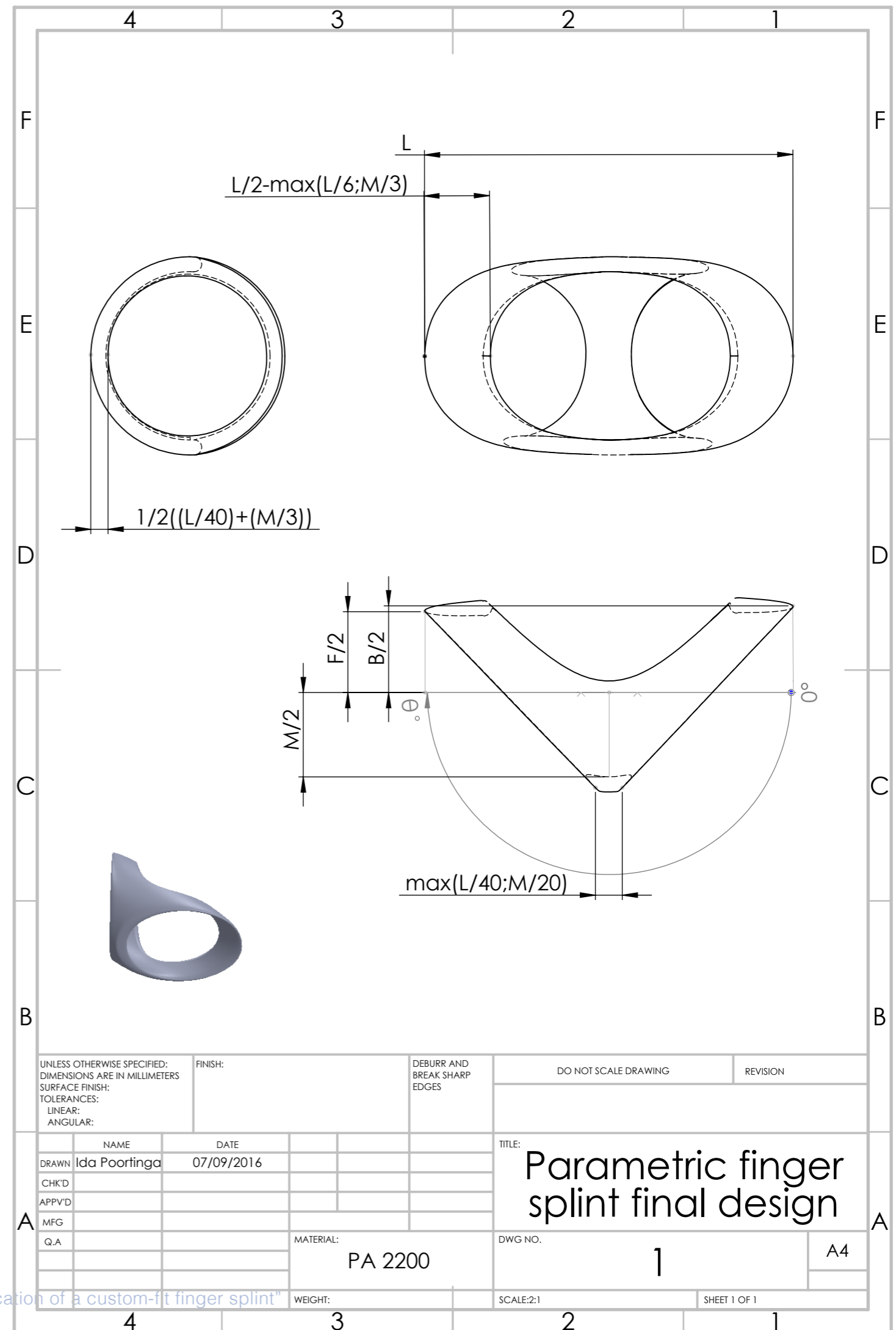
- Difference between diameters:  
 $\varnothing M - \varnothing F$  and  $\varnothing M - \varnothing B < 3,0$  mm
- Angle ( $\theta$ ):  
 Min:  $150^\circ$   
 Max:  $180^\circ$

This demarcation of the size range resulted from an evaluation of maximal and minimal finger dimensions: A maximal finger length of 95 mm was found and a maximal diameter at the joint of 26 mm, referring to the index finger of male participants (1). While the minimal finger length was found to be 54 mm with a width of 16 mm, which referred to the pinkie finger of female participants (1). The maximal and minimal splint length was approximated as half of the finger length.

Now that the boundaries of the parametric models are known, all possible outcomes could be tested. However, testing procedures can be limited by verifying the most extreme output dimensions, as these exhibit the most extreme mechanical behaviour. Using the FEM analysis, it was predicted that an increased length result in a less rigid splint, and a wider splint is more prone to break. Therefore, this influence of the input parameters on mechanical performance is compensated through a change in splint width and thickness. The formulas implemented in the script of the parametric model are provided in the technical drawings in next paragraph.

### 7.2 Technical drawings

The final parametric finger splint dimensions are provided in the technical drawing on the right. The Grasshopper script of the parametric finger splint model is provided in Annex 7.1.



### 7.3 Cost analysis

Table 7.1 present the costs of the parametric 3D-finger splint, in comparison with the 2 alternative solution that could be purchased by a patient him- or herself. The costs are based on the prices offered by Oceanz, the first professional 3D printing company in the Netherlands with ISO 9001 and ISO 13485 certification. This final price includes:

- Raw materials (PA2200, processed in accordance with ISO-9001)
- Printing process in accordance with ISO-13485
- Service costs
- Post-processing: tumbling, dying and coating
- Labour costs
- 21% BTW

| SPLINT SOLUTION              | PRICE          | COMMENTS                                |
|------------------------------|----------------|---|
| PARAMETRIC 3D- FINGER SPLINT | €10,00 – 15,00 | Price is size dependent                 |
| OVAL-8 (1)                   | €18,95 (2)     | Can only be ordered as a set of 3 sizes |
| SILVER RING SPLINT (2)       | €96 (3)        | Tailor made upon request                |

Table 7.1 Cost analysis

### 7.4 Mechanical testing

An experimental test was developed to validate the mechanical performance of the fabricated splints. The purpose of the practical experiment is to determine if the test samples meet requirement 3.11. According to this loading requirement, all possible dimensional outcomes of the parametric finger splint model may not break under an applied load of 15,6 N, and the deformation under loading may not exceed an angular displacement of 10 degrees. This paragraphs described the method used to assess the structural response during loading, and provides the results and conclusion drawn from the experiment.

#### 7.4.1 Materials and method

In order to cover all possible dimensional outcomes of the parametric model, the test samples included the aforementioned most extreme dimensions. Each test sample was fabricated twice, giving a total of 8 samples, as shown provided in the table and figure on the right.

| Test sample    | Quantity | Material | Manufacturing technique | L(mm) | ØF (mm) | ØM (mm) | ØB (mm) |
|----------------|----------|----------|-------------------------|-------|---------|---------|---------|
| 1) Max.L;max.W | 2        | PA2200   | SLS                     | 47,5  | 25      | 26      | 25      |
| 2) Max.L;min.W | 2        | PA2200   | SLS                     | 47,5  | 15      | 16      | 15      |
| 3) Min.L;min.W | 2        | PA2200   | SLS                     | 27    | 15      | 16      | 15      |
| 4) Min.L;max.W | 2        | PA2200   | SLS                     | 27    | 25      | 26      | 25      |



Figure 7.5 Test samples

The loading condition of the finger splint during hyperextension, as described in Annex 3.1, was simulated in an experimental test-setup according to the following steps:

- The middle part of the splint was fixated as shown in figure 7.6.
- A camera on a tripod was located at a fixed position at 20 cm from the test sample, as shown in figure 7.6.
- A vertical force was applied at the distal ends of the splint by means of a physical weight. To limit the effect of horizontal forces compared to the setup in figure 7.6, the weight on each side of the splint was distributed through a separate rope, as shown in figure 7.7.

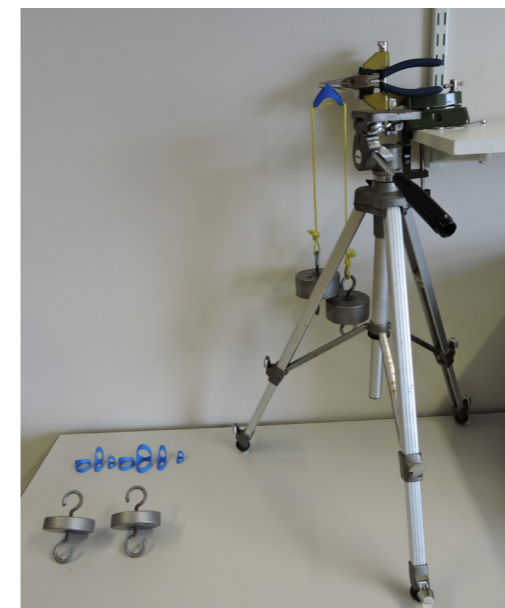


Figure 7.6 Experimental setup

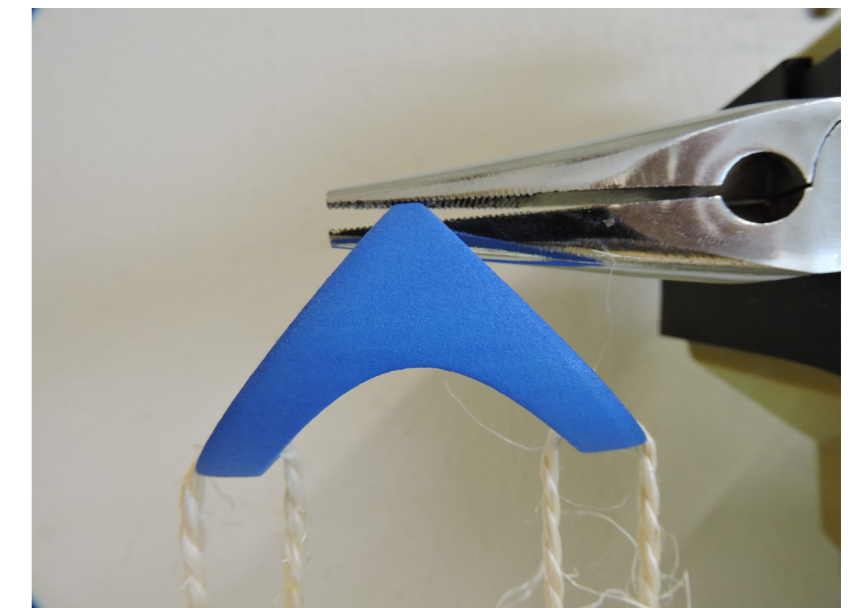


Figure 7.7 Experimental setup

## 7. Synthesis phase 3 - Final Solution

The purpose of the practical experiment was to determine the failure and deformation behaviour under increased loading. The experiment was performed for all 8 samples according to the following steps:

- The splint was fixated in the test-setup as described above.
- A photo was taken to capture the state of the splint before loading.
- The applied load was increased from 0 to 30 Kg (29,43 N), with steps of 5 Kg.
- A photo was taken each time a new load was applied, as shown in figure 7.7.
- After removal of the load, the sample was examined fractures and plastic deformation.
- The angle of deformation under the applied load was subtracted from the photos, using a protractor.
- The experiment was performed twice at separate days, including the preparation of the test-set up.

### 7.4.2 Results

The raw data provided in Annex 7.2 includes all photos and measurement of the loaded sample. Figure 7.8 provides an overview of the measured deformation under the increased load. The slope of the graph represents the rigidity of the splint: the splint with minimal length and width was the least rigid and thus the most prone to deform, while the splint with minimal length and maximal width was the most rigid. It should be noted that all other possible dimensions as an outcome from the parametric model, could be covered by the area bounded by these slopes. Since these slopes refer to the behaviour of the most extreme dimensions, exhibiting the most extreme behaviour.

From figure 7.8 it can be seen that under an applied load of 15,6 Newton, none of the samples exceeds the angular displacement limit of 10 degrees. In addition, no fractures or permanent deformations were reported until an applied load of 30 N.

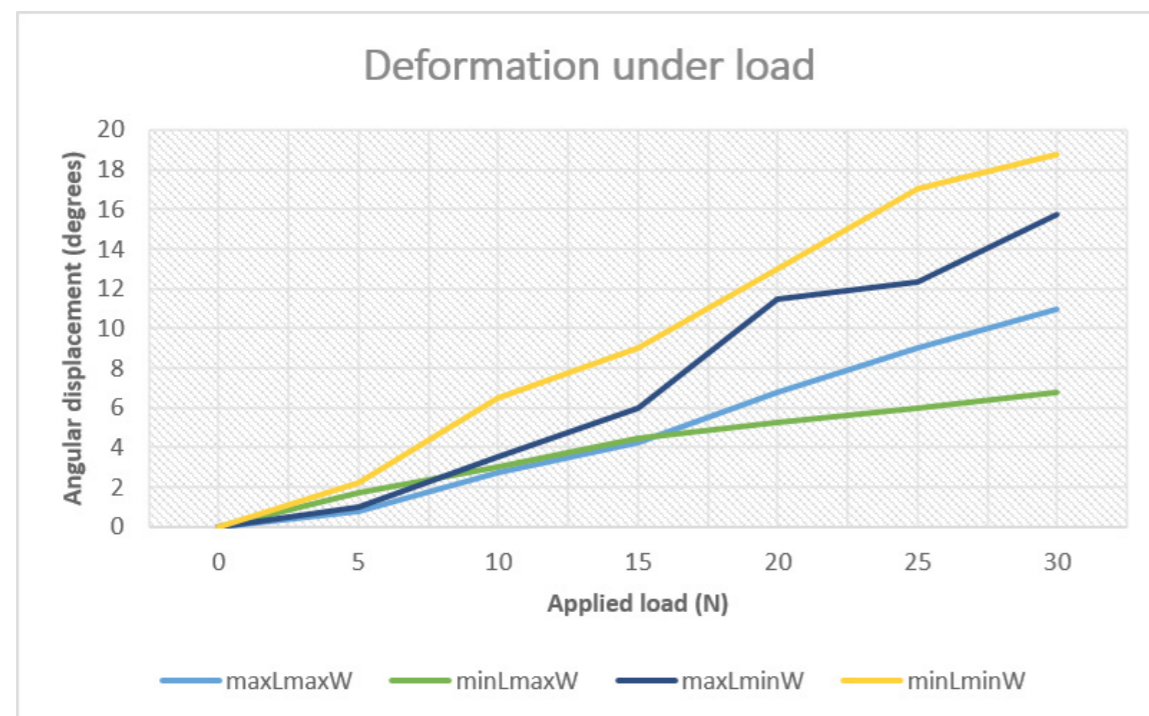


Figure 7.8 Test results

### 7.4.3 Conclusion

In order to meet the loading requirement, all possible dimensional outcomes of the parametric finger splint may not break under an applied load of 15,6 N, and the angular displacement under loading may not exceed 10 degrees. According to the result of this experiment, this requirement is met. From this it can be concluded that the design and material concept can be approved, regarding mechanical performance.

## 7.5 Failure Mode and Effective Analysis (FMEA)

A Failure Mode and Effective Analysis (FMEA) was used to analyse the mechanical risks of the developed product. Through identification of the major risks, the product can be improved in such a way that the risks are acceptable.

The first step in creating a Risk Plan is to *identify the likely risks* which may affect the product. A risk is defined as “any event which is likely to adversely affect the ability of the product to achieve the defined objectives”. First, a series of *risk categories* are identified and for each category a list of *potential risks*. Second, *risk quantification* will be performed to quantify the likelihood of each risk’s eventuating, its impact on the product and surrounding business and the chance that the risk is not detected in time. The unacceptable risks are documented within the *Risk Plan*.

### 7.5.1 Risk identification and quantification

The identified risk are provided in the table starting at the next page according to the following risk categories:

1. Ergonomic fit
2. Manufacturing and delivery
3. Functionality
4. Maintenance
5. Acceptance

The risks are quantify regarding the likelihood of each risk’s eventuating, its impact on the product and surrounding business and the chance that the risk is not detected in time. Each risk was prioritized according to the overall score, which is found by multiplying the score of the likelihood (F), impact (S) and chance (P) of not detecting in time. Risks with a score (R) higher than 20 are not acceptable.



## 7. Synthesis phase 3 - Final Solution

| ID   | Failure  | Possible cause(s)   | Effect  | P | S | D | R  | Status |
|--|--|---|---|---|---|---|----|--------|
| <i>Risk category 1: Ergonomic fit</i>              |  |   |   |   |   |   |    |        |
| 1.1  | The device does not fit properly   | a.) Inaccurate measurement<br>b.) scaling problem in file export<br>c.) Dimensions changed due to oedema  | Non-functioning device, replacement required                              | 7 | 3 | 4 | 84 | Not OK |
| 1.2  | The device initiates damaging forces at possible pressure points                   | a.) Sharp edges<br>b.) MA-principle not optimal applied (short splint length)<br>c.) Skin contact area too small (bad stress distribution)                            | Soft tissue damage (i.e. oedema, necrosis, ischemia)                      | 2 | 5 | 5 | 50 | Not OK |
| 1.3  | The device is not comfortable to wear  | a.) Parameters are a wrong estimate for a comfortable fit<br>b.) Material initiates sweating  | A dissatisfied patient can result in incompliance to splinting treatment. | 2 | 2 | 4 | 16 | OK     |
| <i>Risk category 2: Manufacturing and delivery</i> |  |   |   |   |   |   |    |        |
| 2.1  | Delivery takes too much time   | a.) Printer only runs for a sufficient amount of orders<br>b.) Print speed too low<br>c.) Time-consuming pre- and post-processing operations<br>d.) Remote area       | Patient cannot be helped within a sufficient time frame                   | 8 | 3 | 1 | 24 | Not OK |
| 2.2  | Bad quality print (i.e. insufficient strength, sharp edges, poor dying or coating) | a.) Insufficient design<br>b.) Machine failure during manufacturing operations<br>c.) Post-processing failure<br>d.) Lack of expertise<br>e.) Damage during transport | Possibly anaesthetic, uncomfortable or non-functional splint              | 1 | 4 | 4 | 16 | OK     |
| 2.3  | The user cannot access the manufacturing facilities                                | a.) Too expensive<br>b.) The user does not have the right expertise<br>c.) Too time-consuming   | User should purchase an alternative solution                              | 1 | 1 | 2 | 2  | OK     |

|                                       |  |  |  |   |   |   |    |        |
|---------------------------------------|--|--|--|---|---|---|----|--------|
| <i>Risk category 3: Functionality</i> |  |  |  |   |   |   |    |        |
| 3.1                                   | The user is not satisfied with the offered functions   | a.) The product range is too small<br>b.) It is not possible to change the functional design to personal needs                             | User should purchase an alternative solution                                     | 8 | 2 | 2 | 32 | Not OK |
| 3.2                                   | The device in use does not serve the purpose of the particular trauma                        | a.) Lack of knowledge or medical expertise   | Treatment failure  | 1 | 6 | 5 | 30 | Not OK |
| 3.3                                   | The device breaks or deforms, in the short- or long-term                                     | a.) Material failure<br>b.) Design failure<br>c.) Manufacturing failure  | Device replacement/ pain or permanent finger deformity                           | 2 | 2 | 5 | 20 | OK     |
| <i>Risk category 4: Maintenance</i>   |  |  |  |   |   |   |    |        |
| 4.1                                   | The device wear's too quick  | Material failure   | New device required  | 5 | 2 | 2 | 20 | OK     |
| 4.2                                   | The device becomes dirty   | a.) Material failure<br>b.) Personal activities  | Cleaning required  | 5 | 1 | 3 | 15 | OK     |
| 4.3                                   | The device is not easy to replace  | a.) Expensive<br>b.) Time-consuming<br>c.) Insufficient access   | Non-functional solution  | 3 | 2 | 2 | 12 | OK     |
| <i>Risk category 5: Acceptance</i>    |  |  |  |   |   |   |    |        |
| 5.1                                   | The product is not chosen over existing alternatives through patients and/or medical experts | a.) Less cost-efficient<br>b.) Less time-efficient<br>c.) Less aesthetically pleasing<br>d.) Worse fit/function<br>e.) Lack of reliability | Use alternative solution   | 3 | 1 | 5 | 15 | OK     |
| 5.2                                   | The patient does not like the appearance of the device                                       | a.) Material options<br>b.) Colour options<br>c.) Design   | Dissatisfied patient, possibly resulting in incompliance to splinting treatment. | 5 | 2 | 2 | 20 | OK     |
| 5.3                                   | The product is not acknowledged through regulatory authorities and/or insurance              | a.) Too expensive<br>b.) Does not meet the regulatory rules and guidelines<br>c.) unreliable or unsafe product                             | Personal responsibility in risk and costs  | 4 | 2 | 3 | 18 | OK     |

Table 7.2 Identified risks and qualification

7.5.2 Risk plan

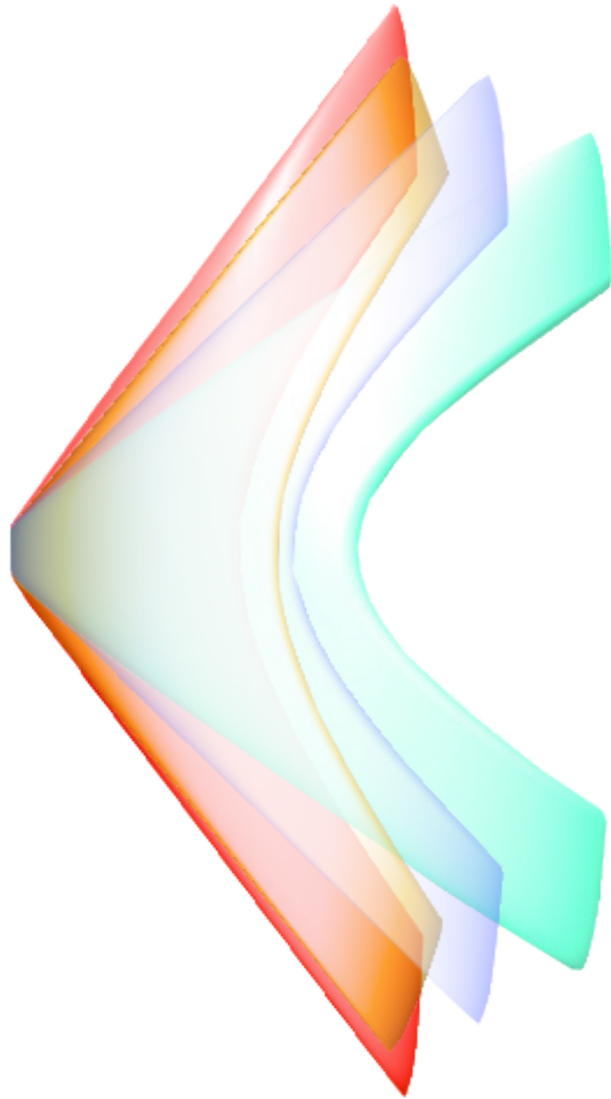
All unacceptable risk are documented within the Risk Plan in the table below. The Risk plan includes a set of actions to be taken to avoid, transfer or mitigate each risk. For each risk action identified, a resource is assigned to be responsible for undertaking the action.

| Risk score | ID  | Preventative Actions  | Action Resource   |
|------------|-----|---|---|
| 84         | 1.1 | 1.) Perform clinical trial to identify mistakes causing an improper fit<br>2.) Provide clear instructions on the finger measurements, including a check of the measured values.<br>3.) When risk remains too high: replace measuring tool (automated calibre) with an alternative method (i.e. scanning)<br>4.) Order different sizes in the presence of oedema | 1.) Research investigator<br>2.) Developer<br>3.) Developer<br>4.) User |
| 50         | 1.2 | 1.) Provide clear instructions on the finger measurements, including a check of the measured values.<br>2.) Perform clinical trial to verify product safety<br>3.) If necessary, improve design   | 1.) Developer<br>2.) Research investigator<br>3.) Designer              |
| 32         | 3.1 | 1.) Create a database with a wide product range<br>2.) Provide an open design file for additional modifications outside of the parametric input   | 1.) Designer<br>2.) Designer  |
|            | 3.2 | 1.) Provide the patient with the right knowledge needed to purchase the device suitable for the specific trauma<br>2.) If unsure, ask advice of a medical expert  | 1.) Developer + medical expert<br>2.) User                              |
| 24         | 2.1 | 1.) Increase process efficiency<br>2.) Use a temporary solution<br>3.) Investigate the possibilities to bring the manufacturing process closer to the patient   | 1.) Printer company<br>2.) User<br>3.) Project lead                     |

Table 7.3 Risk Plan

References

- Hsiao H, Whitestone J, Kau TY, Hildreth B. Firefighter Hand Anthropometry and Structural Glove Sizing: A New Perspective. Hum Factors. 2015 Dec;57(8):1359-77.
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- Silver Ring Splint Company (2016, September) Price List Effective 1/1/2016 [Price list]. Retrieved from: <http://www.silverringsplint.com/wp-content/uploads/Pricelist.pdf>



## 8 Conclusion, Discussion, and Recommendations

This chapter summarizes the main findings of this study, provides conclusions, discusses results and indicates where further research should focus on. This chapter is composed of the following items:

- 8.1 Conclusion
- 8.2 Discussion
- 8.3 Recommendations

In the conclusion the research question will be answered. The discussion debates the disadvantages of the solution and the limitation of this study. Finally, recommendations will be provided for further research and development of the final solution.

### 8.1 Conclusion

The answer on the research question “Can digital fabrication enable patient access to local fabrication of customized orthoses with the quality and safety of professionally-graded medical devices?” will be provided in two parts. First, the expected challenges resulting from the background study will be concluded. Second, the final solution resulting from the design case study of the finger splint will be summarized.

The background study revealed how digital fabrication effects the quality, safety and access to local fabrication of orthoses. This was concluded based on the following findings: First, the current regulatory guideline is designed for mass production and less suitable for local fabrication of personalized medical devices. Due to the distributed manufacturing landscape enable by the rise of 3D-printing and Internet, the fundamental definitions of a ‘medical device’, ‘manufacturer’ and ‘custom-made’ get blurred. This was expected to results in complex regulatory issues and raises many question about safety and responsibility. Second, the background study revealed that underlying technique of additive manufacturing limits material options and negatively affects the quality and mechanical safety of the printed object. Adding to this problem that a controlled and consistent output is difficult to achieve with the currently available desktop 3D-printers. Therefore, it wat expected that orthoses designers and biomedical engineers are challenged to rethink mechanical design, verification and validation methods. Third, the background study demonstrated that the access to digital fabrication is still restricted to people with 3D-modelling skills and knowledge of additive manufacturing. This challenges software developers to develop tools to provide digital fabrication to a wider audience.

The second part of the research, the design case of the finger splint, made clear how these limitations can be overcome. The provided solution is an application that enables the hand therapist or patient to 3D-print a customized finger splint, without the need for 3D-modelling skills or knowledge of digital fabrication. This is made possible by parametric design software and a ISO-certified 3D-printing service. Parametric design allows for easy adjustment to the patient’s personal anatomical characteristics of the finger. In this production process the print company could guarantee quality and safety of the manufacturing process. While parametric design guarantees quality and safety of the design file. The development process demonstrated that mechanical verification and validation methods could still be applied due to the parametric design boundaries. This leads to the conclusion that digital fabrication potentially enables patient access to local fabrication of customized orthoses with the quality, safety of professionally-graded medical devices.

### 8.2 Discussion

A considerable drawback of the provided solution is the fabrication- and delivery time resulting from the selected manufacturing process. Contrary to expectations, the technology and healthcare system is not yet ready for time-efficient and high-quality fabrication closer to the patient. It is questionable to what extend this is vital in the future. However, if the technology and the healthcare system evolves, the provided application would be still viable in a different manufacturing setting.

This study did not address the guidance of quality and safety when fabrication of orthoses happens in a more Do-It-Yourself context, for instance within the settings of a Fablab. The study focussed on a solution that meets the quality and safety standards of the regulatory authorities. For a low-risk medical device, like a finger splint, this approach is quite overdone as it increases complexity and limits possibilities. However, this approach makes the study results relevant for higher risk devices. On the other hand, it would be of interest to explore what makers themselves can do to minimize risks.

A second drawback of the provide solution is that the design freedom is limited design by the parametric input. This makes it difficult to develop more complex orthoses. However, this limited customizability also appeared to be an advantage. Compared to traditional ‘custom-made’ devices, this way of customizing has a finite number of outcomes making all results predictable. In addition, the closed manufacturing process was designed is such a way that all results could be traceable and reproducible just like professionally-graded medical devices. Contrary to expectations, the provided solution enables custom-made orthoses that can meet the regulatory guidelines of mass-production. Therewith, this study proved that this way of mass-customization could be the future of the medical device industry.

It should be noted that the provided proof-of-concept was approached from an engineering perspective. Although the product was presented and positively received by medical experts, the clinical application still requires further research. Moreover, the verification and validate method of the mechanical performance was arguable as it included many assumptions. Revision of the loading assumptions and design optimization after experimental testing, was not performed due to time constraints. In addition, the export steps into solid works was an inefficient, time-consuming process requiring a lot of trial and error. In future research, more efficient methods should be explored. However, a proper foundation is provided to continue the developed with focus on the user and the clinical setting. Finally, to come to a more generalised answer to the research questions, other orthoses should also be studied.

### 8.3 Recommendations for further research

In order to enable fabrication closer to the patient, future research should be focussed on the development of 3D-printers suitable for implementation within the clinic of the hand therapist. that enable a fast, controlled and consistent output that meets the requirement for orthoses. Furthermore, the 3D-technology should be improved regarding the quality of the printed object, to decrease the required amount of post-processing.

To improve the possibilities of parametric design in the context of healthcare, the software should be further developed to meet the desired functions for the creation of orthoses. For instance, integration 3D-scan data into the model would be interesting to allow automated modelling of more complex orthoses . Furthermore, integration of the FEM analysis into the parametric modelling software would be a significant improvement to allow real-time mechanical feedback and automated design optimization.

Now that the possibilities of parametric design and additive manufacturing are approved to be successful for local fabrication of orthoses, it is recommended to further develop the final solution for a market introduction. First steps would be a usability research of the overall make-and manufacturing process, and a clinical research to approve the effectiveness of the final product. Subsequently, the database can be expanded with different functional splints and different design options. In addition, a business model should be developed to investigate how the system can be implemented. Market introduction would be an important step in the accomplishment of on-demand production and mass-customization in a healthcare context.