TU Delft

MINIMALLY INVASIVE TENSIOMETRY

MINT

E.F.VAN KOTEN
MASTER THESIS
BIOMEDICAL ENGINEERING

MINT

Minimally invasive tensiometry: a novel method to quantify tension during laparoscopic herniorrhaphy

by

E.F. van Koten

to obtain the degree of Master of Science
at the Delft University of Technology,
to be defended publicly on Tuesday July 6th, 2021 at 9:30 AM.

Student number:	4373391	
Project duration:	Nov 2, 2020 – July 6, 2021	
Thesis committee:	Dr. J. van den Dobbelsteen,	TU Delft, supervisor
	Dr. B. Bloemendaal,	RDGG (Reinier de Graaf Groep)
	Dr. M. van Der Elst,	TU Delft/ RDGG

This thesis is confidential and cannot be made public until July 6th, 2023.

TU Delft

Preface

This Master's thesis marks the ending of a journey that we like to call student life. After finishing my Bachelor's degree in Industrial Design Engineering, I decided to pursue my childhood dream of working in healthcare. What goes on inside a hospital and how the human body works has always intrigued me, thus I chose to continue my studies in BioMedical Engineering. This program gave me the opportunity to explore the medical sector and feed my growing interest in healthcare innovation.

In the spring of 2020 I started looking for a thesis subject. I wanted to engage in a project in collaboration with a hospital, as this was something I had not experienced before during my master's Biomedical Engineering. I have always been interested in what goes on behind the scenes in a hospital, thus being able to witness this first hand was very exciting to me. Prof. dr. M. van der Elst connected me to dr. B. Bloemendaal. Soon, this project was initiated, as he expressed a clinical problem that had been on his mind for quite some time. I owe him a big thanks for being an excellent mentor in the Reinier de Graaf hospital. From the start he has made time for me to witness procedures, exchange ideas and guide me when needed, in the midst of a pandemic. His enthusiasm and passion for this project inspired me to strive for the best possible outcome. A special thank you also goes out to the REPAIR research group for supporting me in my current and future research.

Furthermore, I would like to thank my supervisor dr. J. van den Dobbelsteen for being my supervisor and always taking time to discuss obstacles with me. He pushed me to step out of my comfort zone and connected me to the right people in the field. His knowledge and experience in medical device development were very helpful and motivated me throughout this project. I would also like to praise Ing. J. van Frankenhuyzen, without whom this project would not have been possible. His guidance during the development of MINT has been outstanding.

Last but not least I would like to thank my family and friends for their support in the last nine months. Their interest in my project and encouraging words have helped me tremendously.

I am excited to see what the future holds for MINT. I hope that further research will substantiate what has been done throughout this project, and minimally invasive tensiometry will be implemented during ventral hernia repair. Enjoy reading!

Eveline van Koten
Delft, July 2021

Abstract

In up to 30% of hernia patients revision surgery is needed due to infection, pain and defect recurrence. The role that abdominal wall tension plays in this is incontrovertible: most repair techniques in herniorrhaphy aim to reduce tension at the aponeurotic edge, as excess tension is directly related with local ischemia and recurrence of the hernia. Currently, fascial tension is subjectively observed by the surgeon and rarely quantified intra-operatively. The choice of procedure is based on pre-operative characteristics of the defect, surgeon experience and preference, which can be highly variable. Research shows that an objective assessment of fascial tension can be a feasible adjunct to surgical decision making. Therefore, this thesis provides a proof of principle for MINT: minimally invasive tensiometry. MINT is an add-on tool for existing laparoscopic instruments, which enables an objective assessment of abdominal wall tension by the use of a linear spring. Universal applicability has been evaluated and confirmed in this research. MINT is fabricated using carbon fibre reinforced PA-12 (”Onyx”) at the TU Delft. The device’s safety and effectivity have been validated using several experiments and sterilisation test runs. MINT provides accurate and consistent results in Newton without further calibration. Forces up to 60N can be quantified, with an accuracy of 5.5+/-2%, expressed in Mean Absolute Percentage Error (MAPE). Results show that ”Onyx” and the silicon used can be sterilised using an autoclave at least five times. Moreover, its ease of use and functionality have been assessed in a clinical setting using an embalmed cadaver. Further testing will have to be done to substantiate the results from this research through a larger study. In addition, redesign will have to take place to decrease part count and further improve assembly of the device. The findings of this thesis provide a first step in the implementation of fascial tension measurements for intra-operative decision making during laparoscopic surgery.

Contents

Glossary **1**

List of Figures **2**

List of Tables **4**

1 Introduction **7**
1.1 Abdominal wall hernia . . . 7
1.2 Ventral hernia repair . . . 8
1.3 Problem statement . . . 8
1.4 Objectives . . . 9

2 Background **11**
2.1 Anatomy of the abdominal wall . . . 11
2.2 Risk factors . . . 12
2.3 Ventral hernia repair techniques . . . 12
2.4 Literature review . . . 14
2.5 Clinical need . . . 16

3 Methods **17**
3.1 Development process . . . 17
3.2 Thesis structure . . . 17

4 Problem Analysis **19**
4.1 Translation clinical problem to technical problem . . . 19
4.2 Technical problem to design direction . . . 21

5 Requirements **23**
5.1 Design requirements . . . 23

6 Conceptualisation **27**
6.1 Clamping mechanism . . . 27
6.2 Mechanical force gauge . . . 29
6.3 Handle and housing . . . 31
6.4 Prototyping . . . 31

7 Material & Manufacturing **33**
7.1 Material analysis . . . 33
7.2 Manufacturing procedure . . . 36

8 MINT - Final Design **37**
8.1 Design . . . 37
8.2 Procedure . . . 40

9 Validation **41**
9.1 Technical validation . . . 41
9.2 Clinical Validation . . . 43
9.3 Improvements . . . 44

10 Discussion **47**
10.1 Limitations 49
10.2 Recommendations. 50

11 Conclusion **51**

Appendices **53**

A Literature Review **55**

B Measuring Techniques **59**

C Design Solutions **61**

D Spring Selection **63**

E Material review and printer settings **65**

F Validation Data **69**

G Parts and Tools **73**

H General dimensions MINT **75**

Glossary

Tensiometry	The study of the measurement of tension.
Herniorrhaphy or hernioplasty	Refers to the surgical repair of a hernia.
Ventral or anterior	Nearer the front, especially in the front of the body, or nearer to the head.
Prevalence	Prevalence is the proportion of a population who have a specific characteristic in a given time period.
Fascia	Sheet of connective tissue, primarily collagen, beneath the skin that attaches, stabilizes, encloses, and separates muscles and other internal organs.
Xiphoid process	The cartilaginous section at the lower end of the sternum.
Obliques	The outermost abdominal muscles.
Wound ischemia	Inadequate wound healing due to ischemia (blocked blood supply).
Posterior	Further back in position.
Compliance	The property of a material of undergoing elastic deformation when subjected to an applied force.
Laparoscope	A laparoscope is a slender, lighted telescope, which allows the surgeon to see inside the body.
Iterative	A series of steps that you repeat, tweaking and improving your product with each cycle.
Sterilisation	The process of making something free from bacteria or other living microorganisms.
Harris profile	Used to evaluate design concepts and facilitate decisions on which concepts to continue with in a design process.
Compliant mechanism	A flexible mechanism that achieves force and motion transmission through elastic body deformation.

Rapid prototyping	The construction of a three-dimensional object from a computer aided design (CAD) model or a digital 3D model.
Autoclave	A heated container used for chemical reactions and other processes using high pressures and temperatures, e.g. steam sterilization.
Artificial pneumoperitoneum	Achieved by insufflating the abdomen with carbon dioxide. Technique is currently used in the operating room to perform laparoscopic surgery.

Acronyms

MINT	Minimally INvasive Tensiometry
AW	Abdominal Wall
MIS	Minimally Invasive Surgery
EHS	European Hernia Society
OR	Operation Room
ACS	Anterior Component Separation
PCS	Posterior Component Separation
DOF	Degrees Of Freedom
EMC	Erasmus Medical Center
PLA	Polylactic Acid
PA-12	Poly-Amide 12
COF	Coefficient Of Friction
FDM	Fused Deposition Modelling
FFF	Fused Filament Fabrication
CFR	Continuous Fibre Reinforcement
MAPE	Mean Absolute Percentage Error
APE	Absolute Percentage Error

List of Figures

1.1 Various types of abdominal wall hernia 7
1.2 Schematic drawing ventral hernia. 7
1.3 EHS Classification of ventral hernia. 8

2.1 Layers of the abdominal wall. 11
2.2 Anatomy of the abdominal wall. 11
2.3 Schematic representation of pulling force. 13
2.4 Drawing of a traditional open hernia repair. 13
2.5 Component separation techniques 13
2.6 Laparoscopic procedure. 14
2.7 Robot-assisted surgery set-up. 14
2.8 Principle for assessment of tension. 15

3.1 Flowchart displaying the design process. 17

4.1 Schematic representation of forces acting on the aponeurotic edge. 19
4.2 Trocar placement during herniorrhaphy. 20
4.3 Laparoscopic instruments Aesculap. 20

5.1 Requirements for the design of the force sensor. 24
5.2 Different handle designs. 24

6.1 Three parts to achieve functionality of the device. 27
6.2 Laparoscopic handle characteristics. 28
6.3 Compliant mechanism prototype with varying hole diameter. 29
6.4 Compliant mechanism prototype with varying hole diameter. 29
6.5 First C-clamp prototype with adjustable block. 29
6.6 Holes to attach the spring using a pin. 29
6.7 Prototype with spring attached using a pin. 29
6.8 Schematic drawing of displacement of the AW. 30
6.9 Prototype of device housing. 30
6.10 All prototypes. 31

7.1 Schematic drawing of the forces acting on the clamp housing. 34
7.2 Prototype failure PLA. 34
7.3 Schematic drawing of the inlay. 35
7.4 Schematic drawing FDM process. 36

8.1 Side view of the final design for MINT. 37
8.2 Final design clamp with nut and bulges. 38
8.3 Final design clamp with spring, nut and bolt. 38
8.4 Final design clamp with block and silicone pad. 38
8.5 Adjustable block with cut-out, top view. 38
8.6 Adjustable block with cut-out, bottom view. 38

8.7 Turning knob with bolt and silicone sealant. 38
8.8 Connecting the spring to the handle. 39
8.9 Assembly of the handle and the spring to the housing of the device. 39
8.10 Spring connected to the housing. 39
8.11 Slide block onto housing. 40
8.12 Slide clamp on handle. 40
8.13 Turn turning knob to ensure tight clamping. 40
8.14 Assembled device attached to clamp. 40
8.15 Assembled device attached to clamp. 40
8.16 Assembled device attached to clamp. 40

9.1 Before and after sterilisation. 43
9.2 Experimental set-up with ruler to measure displacement relative to the trocar. . 44
9.3 Experimental set-up with MINT attached to laparoscopic handle. 44
9.4 Side view of ruler clamp in use. 45
9.5 Back view of ruler clamp. 45

C.1 Harris profile assessing the two attachment styles. 61

E.1 Dragon Skin ™silicon pads in use 66
E.2 Eco-Flex ™silicon pads in use 66
E.3 Technical data on three materials from Smooth-on. 66
E.4 Image displaying both concentric and isotropic fiber fill. 67
E.5 Image displaying concentric fiber fill. 67
E.6 Image displaying concentric fiber fill. 68
E.7 Image displaying isotropic fiber fill. 68
E.8 Image displaying isotropic fiber fill. 68

F.1 Calibration force sensor voltage to Newton. 69
F.2 Assessment of accuracy using force gauge. 70
F.3 Accuracy and precision expressed in APE. 71

G.1 All separate parts of MINT. 73

List of Tables

2.1 Risk factors abdmonal wall hernia. 12

6.1 Search criteria used in Tevema shop. 30

9.1 Maximum resisted pulling force with regard to clamping force. 42

B.1 Drawbacks per method to assess feasibility. 60

E.1 maximum pulling force per inlay material. 65

1 Introduction

Herniorrhaphy is one of the most common general surgery procedures: annually more than one million Americans suffer from abdominal wall hernias [46]. An increased prevalence of ventral hernia has been observed worldwide as a result of an increasing number of intra-abdominal operations and obesity [33]. Unfortunately, up to 30% of patients needs revision surgery. This thesis aims to improve success rates and decrease hernia recurrence rates by developing a method that quantifies abdominal wall tension to aid in surgical decision making.

1.1. Abdominal wall hernia

A defect in the fascia of the abdominal wall is mostly referred to as a ventral hernia (Figures 1.1 and 1.2). Preperitoneal fat, or even abdominal contents such as bowel, can protrude through the defect and cause complications. A visible bulge can be noticed in the anterior abdominal wall. Most frequently defects occur in the linea alba between the rectus abdominis muscles and between the umbilicus and the xiphoid process, or in the inguinal canal, but they can exist at any weakened spot of the abdominal wall [25].

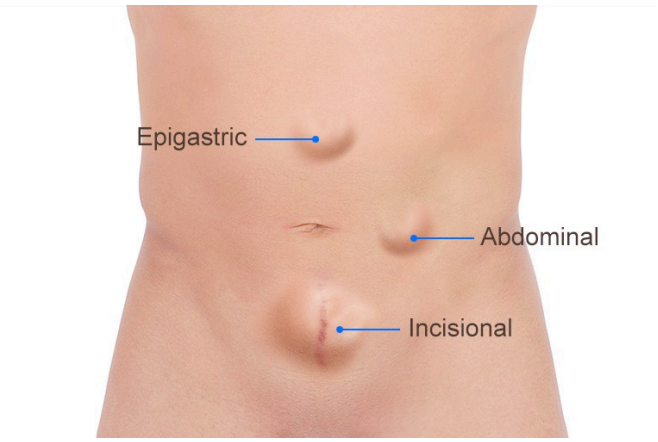


Figure 1.1: Various types of abdominal wall hernia [12].

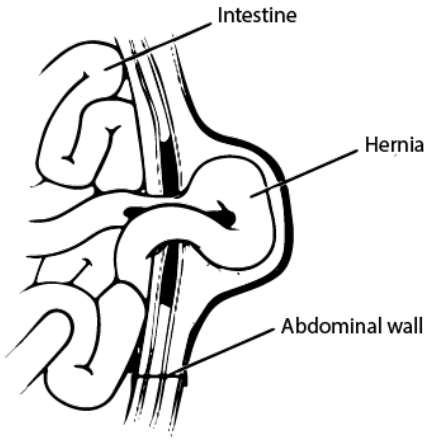


Figure 1.2: Schematic drawing ventral hernia.

There are two main types of hernias: primary and secondary hernias. Primary hernias occur at natural weak spots of the abdominal wall such as the umbilicus or the groin, or where weakness exists due to different muscles coming together. Secondary hernias occur at weak spots generally caused by surgery or trauma. In the case of a hernia through a surgical scar we refer to an incisional hernia (Figure 1.1). Hernia terminology describes their anatomic

location (Figure 1.3).

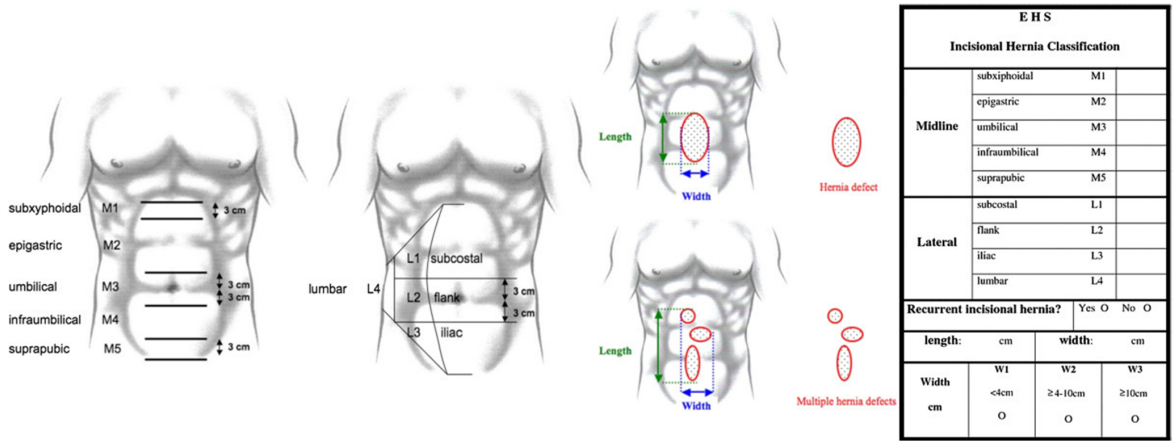


Figure 1.3: EHS Classification of ventral hernia [35].

1.2. Ventral hernia repair

Several well-known methods exist to repair abdominal wall hernias. Surgical treatment options include the standard open hernia repair or the more recent laparoscopic repair. Unfortunately, in up to 30% of patients, revision surgery is needed due to infection, pain and hernia-recurrence [47]. Attempts to reinforce the abdominal wall using mesh prosthetics have gained popularity and improved surgical outcomes, nevertheless, recurrence rates remain high [25]. A lot is still unknown about factors involved in unsuccessful outcomes of herniorrhaphy and literature is inconclusive. Which repair is the best remains unknown, but several guidelines have been presented by the European Hernia Society (EHS) [20], [42]. Unwanted reactions between the host tissue and bio-materials, the used closure technique, wound ischemia, infection, excessive straining and factors such as older age, obesity, malnutrition or diabetes are known to cause problems such as wound failure. In addition, excess tension in the abdominal wall can have a negative effect on the repair of the wound [21].

Recurrence rates worsen with each subsequent repair of the abdominal wall, therefore, choosing the right procedure is of high priority [8]. Improved understanding of bio-mechanical behavior and properties of the abdominal wall and the negative effects of surgical intrusions are of great importance to improve surgical outcomes [25].

1.3. Problem statement

It is well known that excess tension at the aponeurotic edge can cause wound failure and hernia recurrence [37]. EHS guidelines recommend to close the mid-line during hernia repair, yet some defects are more difficult to close than others [20], [23]. The forces necessary to close a defect cannot directly be related to its size [22], [27], [32]. Instead, literature shows the magnitudes of these forces are patient specific and related to the compliance of the patient's abdominal wall [22]. Currently, the course of the procedure is based on pre-operative characteristics and surgical expertise. Fascial stiffness is subjectively observed by the surgeon during the procedure [27]. If the fascia can be approximated with little tension, direct closure can be utilised. If the abdominal wall is rather

rigid, components separation will be used.
Even though the importance of tension is incontrovertible during hernia surgery, it remains a rarely objectively quantified value. Utilizing surgeon ”experience” can be highly variable and may be subjective [27]. Objective knowledge on the magnitude of fascial tension can be a feasible adjunct to surgical decision making [45]. By collecting enough data on these forces, and correlating them to surgery outcomes, threshold values could be found at which elevated risk of recurrence exists. Some methods have been found in literature that enable assessment of fascial tension during open hernia repair [47]. Not much data is available and none have provided a solution that can be applied during minimally invasive hernia repair.

1.4. Objectives

The ultimate goal is to develop a device that can be used during laparoscopic hernia repair and indicates which procedure is to be proceeded with for the best possible outcome. Fascial tension needs to be quantified before it can be used to aid in surgical decision making. Knowledge on the magnitude of these forces can help objectively assess patient specific hernia characteristics. For now, it is relevant to develop an accurate, reliable and safe measurement of abdominal wall tension as the first step in this research. Therefore, the goal of this thesis is the development of a method to quantify closing forces during laparoscopic ventral herniorrhaphy. This thesis work includes the following:

- Identifying how abdominal wall tension can quantitatively be assessed during laparocopic herniorrhaphy.
- Providing solutions based on the design requirements.
- Evaluation of the solution with regard to mechanical forces and clinical setting.
- Presenting a safe and reliable solution with a working prototype.

2

Background

It is believed that the objective assessment of tension in the abdominal wall can be a feasible adjunct to decision making in the OR [22]. This thesis describes the development of a method to do so. In the following chapter some key concepts related to ventral hernia and its repair will be elaborated.

2.1. Anatomy of the abdominal wall

The abdominal wall consists of several layers: skin, subcutis, anterior fascia, muscle & aponeurosis, posterior fascia, fascia transversalis, peritoneum (Figure 2.1). All layers are made up of connective tissue, some containing more dense connective tissue than others. The layers carrying most of the tension in the abdominal wall are the layers made up of dense connective tissue: the anterior fascia, the posterior fascia and the aponeuroses, on which the linea alba is located.

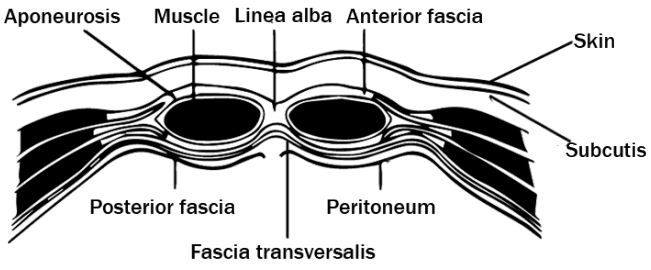


Figure 2.1: Layers of the abdominal wall.

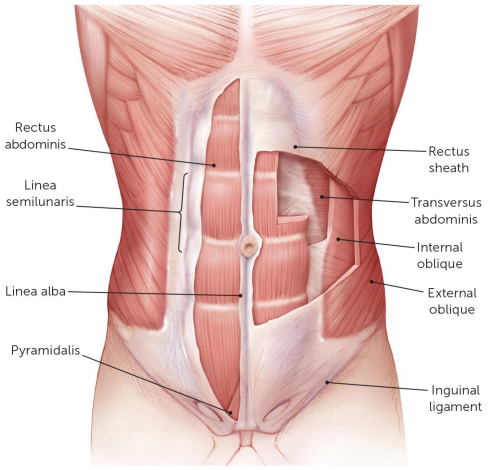


Figure 2.2: Anatomy of the abdominal wall.

The fascia attaches, stabilises, encompasses and separates muscles and other organs in the abdominal cavity (Figure 2.2) [24]. Sites of the body subject to frequent, or even constant, strain are at risk for hernia formation. Repeated stretching of the connective tissue can lead to tearing of the fibers that make up the fascia. Unhealthy fascia has less tensile strength than healthy fascia, and thus defects can occur more easily [24]. Risk factors for hernia formation are age, obesity, diabetes mellitus, malnutrition, smoking, and steroid use [25].

2.2. Risk factors

The fibrous connective tissue that makes up the layers of the abdominal wall is primarily made of closely packed collagen fibres. In healthy human fascia the mature and stable collagen type I and the immature and mechanically unstable collagen type III are in balance. In unhealthy fascia less type I collagen is found, which leads to thinner collagen fibers that have less tensile strength [24]. Areas of the body with a decreased collagen type I\III ratio, and that are subject to frequent or constant strain, are at risk of stretching and causing a defect.
Risk factors associated with decreased abdominal wall quality, and thus (incisional) hernia formation, can be classified into three categories: pre-, per-, and postoperative factors [25]. These factors interact and influence each other, an overview can be seen in the table below. Pre-operative factors influence the quality of the tissue and can sometimes be prevented by maintaining a healthy lifestyle. Per-operative factors are factors such as quality of closure, type of procedure and complexity of a procedure, which can, in some cases, be influenced by surgeon skill and expertise.

Table 2.1: Risk factors abdmonal wall hernia.

Pre-operative	Per-operative	Post-operative
Age	Quality of closure	Wound infection
Weight	Complexity of Surgery	Wound ischemia
Malnutritrion	Emergency Surgery	Seroma
Diabetes Mellitus	Complications in Surgery	Wound dehiscence
Smoking		
Steroid use		

2.3. Ventral hernia repair techniques

To repair a hernia the edges of the defect need to be brought together [20], [42]. Therefore, tension created by the pulling of the shortened oblique muscles must be overcome (Figure 2.3). Reducing or relieving tension is the objective in most hernia repair techniques [47].
Ventral hernias are repaired via traditional open surgery or by minimally invasive techniques [11]. Currently, the majority of hernias are repaired using open techniques, despite the many benefits offered by a minimally invasive approach. Laparoscopic repairs have a higher degree of technical difficulty, which contributes to the lower number of minimally invasive repairs.
During this research several surgeries were witnessed, making sure an understanding was created for the different procedures and the clinical environment.

Open repair

During open repair an incision is made in the abdominal wall to access the abdomen. The surgeon repairs the defect using sutures, mesh or a tissue flap. The placement of mesh is used to reinforce the abdominal wall (Figure 2.4). The alloplastic mesh can be seen as a platform for new tissue to grow in and on as a result of the body's inflammatory response. This creates a strong barrier that bridges the defect, distributes tension and hence supports the abdominal wall [10]. In addition, myofascial release techniques, such as component separation are used to [37]. If the tension is considered to be too great during hernia repair, these techniques can be utilised to decrease tension to physiological values (Figure 2.5). This way the defect can be closed more easily with less undue tension at the site of the suture. Several variations of component separation exist and can be seen in the figure below. The most frequently used are Rives-Stoppa, ACS and PCS [10], [37]. Techniques

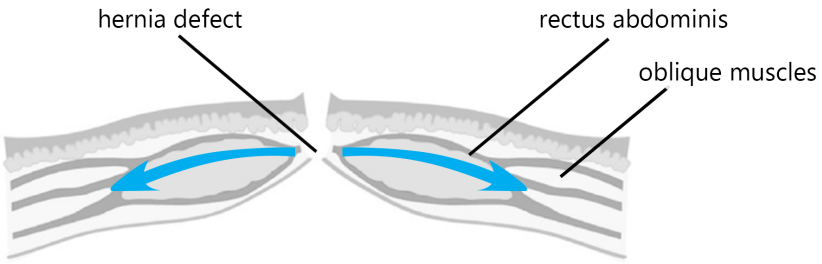


Figure 2.3: Schematic representation of pulling force (blue arrows) created by contraction and/or shortening of oblique muscles.

have several variations, which one to use is based on the nature of the defect and surgeon preference.
Component separation is very invasive and many complications can occur. Accordingly, careful examination needs to take place to assess if this is the right procedure for the patient and if it is absolutely necessary [27]. Large defects are often repaired this way as medialisation cannot be realised without it. Even though open repair is used most frequently, it has a significant complication rate and hernia recurrence occurs in up to 30% of hernia cases.

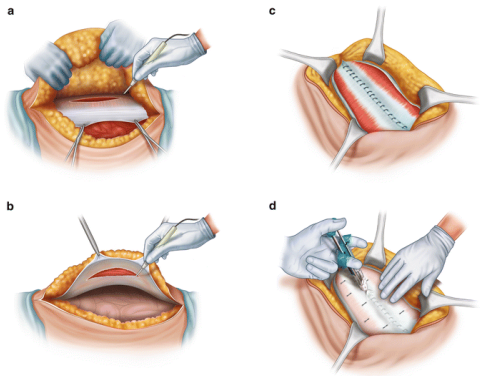
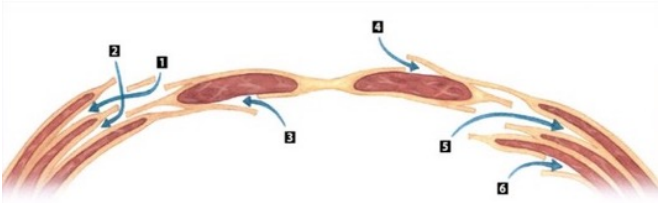


Figure 2.4: Traditional open hernia repair and placement of mesh (onlay technique) [43].



Technique	Author (Year)	Steps Involved
Components Separation Release	Ramirez (1990)	1 3
External Oblique Release	Shestak (2000)	1
External & Internal Oblique Release	Levine (2001)	1 2
"Sliding Door" Release	Kuzbari (1998)	1 3 4
External Oblique/Transversus Abdominis Release	Thomas (1993)	1 6
External Oblique/Anterior Rectus Release	Lucas (1998)	1 4
Anterior Rectus Fascia Release	Yeh (1996)	4
"Lateral" Release	Mathes (2000)	5
Modified Components Separation Release	Fabian (1994)	1 2 3

Figure 2.5: Component separation techniques with steps involved [40].

Minimally invasive repair

During laparoscopic repair small incisions are created in which trocars are placed, creating an opening into the abdomen. The tissue is manipulated using long, slender instruments that are inserted through the ports and a laparoscope is used to guide the procedure (Figure 2.6). Laparoscopic hernioplasty offers many benefits such as less post-operative pain, shortened hospital stay, quicker return to normal activity and less wound infections [14], [46]. Nevertheless, laparoscopic repairs have a higher degree of technical difficulty, due to a reduction in space and DOF when compared to traditional open repair.
Robotic or robot assisted surgery uses the same principle as laparoscopic surgery. In most cases the robotic surgical system uses a camera arm and mechanical arms with surgical instruments attached to them. The surgeon controls the robot through a computer console

near the operating table, the set-up can be seen in Figure 2.7. The mechanical arms replicate movements the surgeon makes using the console. This way more complex surgeries can be performed with high precision, as the arms have an increased number of DOF that mimic motions created by wrists.
Minimally invasive and robot assisted hernia repair have shown improved results, such as lower infection rates and shorter hospital stays without significant increases in cost when compared to open repair [11]. With the rise of the robotic option of hernia repair, minimally invasive repair has gained popularity in the past 10 years, as more difficult surgeries can be performed this way. More surgeons are gaining training and the robotic platform is becoming more and more available, resulting in an increasing number of minimally invasive hernia repair operations [47].

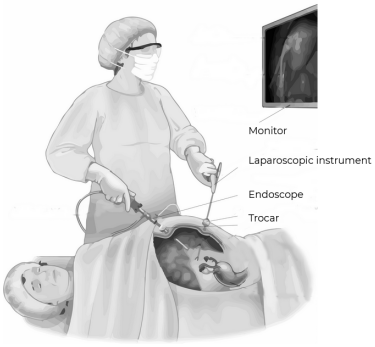


Figure 2.6: Laparoscopic procedure with laparoscope, instruments and video monitor.

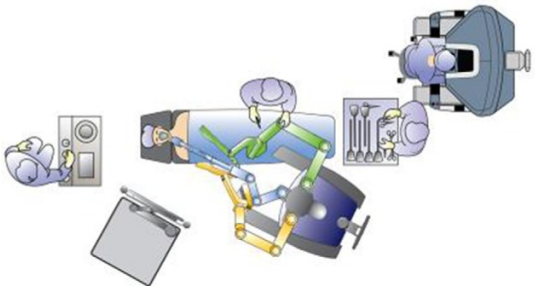


Figure 2.7: Robot-assisted surgery set-up with mechanical arms and computer console [11].

Not all defects can be repaired using minimally invasive techniques. After thorough examination and characterisation of the defect, a choice will be made if the patient is suited for a certain type of repair. Often, more complex repairs are preferred to be done using the traditional open approach due to the limited DOF offered by regular laparoscopic surgery. However, robotic assisted surgery offers many opportunities with regard to complex repairs. Technically difficult surgeries can be performed minimally invasively due to better visualisation and the ability to make articulated movements [11]. Nevertheless, not many surgeons have the skills to perform these difficult surgeries using a robotic platform. Robot-assisted surgery has a long learning curve and access to the robotic platform is limited.

2.4. Literature review

From September to December 2020 a literature study was performed to identify what has been done so far regarding the assessment of fascial tension. Researchers have used tension measurements in the past to define bio-mechanical behavior and properties of the abdominal wall, even as a decision tool in herniorrhaphy. This review assesses how tension in the fascia can be measured, how usable measuring modalities are and how knowledge of the tension in the fascia of the abdominal wall can improve surgical outcomes in abdominal wall hernia repair. An overview of all methods found can be found in Appendix A. In this section a concise summary of the discussion on the relevant methods found and recommendations for further research will be given. For more information the literature review may be consulted [49].
The importance of tension with regard to herniorrhaphy is incontrovertible. Improved understanding of the anatomy, bio-mechanical properties and behavior of the abdominal wall

have lead to the development of improved surgical procedures to reduce or relieve tension during hernia repair. However, physiologic abdominal wall tension as it relates to herniorrhaphy is not completely understood [47]. To date there is no universally accepted method to quantify abdominal wall tension and use it for intra-operative decision-making. Although some research has been done with regard to the tension in the fascia during abdominal wall hernia repair, the literature is difficult to compare due to variability in methods, results and conclusions.

Tensiometry for bio-mechanical properties & behavior

Several studies have used tensiometry to better understand the bio-mechanical behavior and properties of the fascia. This has been done using fairly standard uniaxial and biaxial tensile tests, with specimens from (human) cadavers and in animal studies A. Research has lead to better prediction of recurrent incisional hernia formation, wound healing and evaluation of closing modalities. Results have also been used to develop artificial human tissue or even models of the abdominal wall to mimic the in vivo physiology, such as the AbdoMAN [24], [50]. Further research needs to be done to optimise the AbdoMAN and other artificial models. This way more accurate tests can be done to evaluate the body's reaction to surgical intrusions. It needs to be kept in mind that these models are currently an approximation of the actual human body. Phenomena such as wound healing or material property changes driven by contraction cannot yet be imitated. Digital models, simulations and other testing modalities besides are a feasible addition to modelling the abdominal wall with regard to forces acting on it.

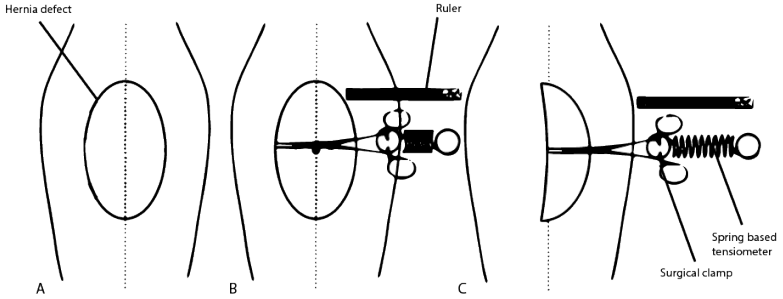


Figure 2.8: Used principle for the assessment of tension using a ruler, surgical clamps and in this case spring-based tensiometer.

Tensiometry to assess abdominal wall tension

Literature shows that fascial tension has often been quantified during open surgery using a dynamometer, tensiometer or linear spring scale in combination with surgical clamps as can be seen in Figure 2.8. One or more points of attachment are used and the force needed to mobilise the fascia a given distance is measured. The instruments used are affordable and widely available. Several studies use a "traction-index" or "-coefficient" to compute a value that is independent of the travelled distance [3], [5]. Other studies document 'maximum tension' during mobilisation of the abdominal wall to the mid-line. Some studies have collected enough data to identify threshold values that can be used during surgery [22], [38]. Hope et al. and Reingruber et al. use these values to decide if direct closure or components separation should be performed.

Several methods have been found that do not rely on the use of a spring scale as described before. These methods can be found in Appendix A, and are still in the developing stages and not yet implemented intra-operatively [26], [39], [51], [52].

Knowledge gaps & further research

Measuring abdominal wall tension has not propagated in the hernia community, even though its importance has been recognised for quite some time [47]. Several studies have been published about the measurement of physiological tension in the fascia, but none have been implemented yet. In addition, outcomes and data on tension measurements are often not reported [13], [23]. Many of these studies used cadavers as their subject and thus results cannot be translated directly to humans due to the difference in anatomy and physiology [5], [39], [41]. Studies done intra-operatively are believed to be clinically useful even when done under general anaesthesia. Other studies have several drawbacks which result in subjective data such as a small population or low patient enrollment and a low variability in surgeon technique. Even though the described techniques are fairly similar and simple, no standardised method has yet been defined [46]. Questions remain unanswered with regard to amount of points of attachment, measurement location and threshold values.
Tension has not been objectively assessed during laparoscopic or robotic procedures. Only Bradley et al. used a calibrated tension gauge which can be placed into the abdomen via a trocar during hiatal hernia repair [7]. This shows that it might be possible to develop a device that can be used laparoscopically or even robotically. Taking the improved results into account, the development of a laparoscopic tension gauge to assess closing forces necessary to repair the defect seems promising [11], [47].

Literature review conclusion

Further testing needs to be done to accurately model the formation and recurrence of abdominal wall hernias to better understand the underlying mechanisms, using tensiometry and other testing modalities. The assessment of fascial tension is shown to be a feasible adjunct to surgical decision-making and needs to be evaluated further. A normalised procedure should be developed and proven useful that can be used and adopted by surgeons in the field. The technique needs to be sterile, reproducible, quick and safe without hindering the surgeon during the surgery. The possibility to implement this technique during minimally invasive and robotic surgery would make it applicable across many different procedures. This way the assessment of fascial tension during herniorrhaphy could decrease the recurrence of ventral and incisional hernias.

2.5. Clinical need

Currently, fascial tension is rarely quantified intra-operatively, with the previously mentioned exceptions. No method has been standardised, especially not in MIS. Fascia compliance is observed subjectively by the surgeon and techniques to close the defect and which closing procedure to proceed witch are based on experience and preferred approach [27]. A standard to measure tension in the fascia of the abdominal wall could guide surgical procedures and decision making during hernia repair, aiming to increase surgical success rates [22]. Tension can be used as an additional characterisation of hernia defects during their operations and as a result choose the path of the procedure more objectively. The clinical need to effectively quantify abdominal wall tension with regard to herniorrhaphy is clear [47].
In this thesis knowledge gaps in literature will be addressed by developing a solution for minimally invasive hernia repair. Dedicating this research to minimally invasive repair leaves the opportunity for incorporation during both robot assisted surgery, without interfering with the robotic platform, and laparoscopic techniques.

3

Methods

The development process applied in this thesis is based on the generic product development process as described by Ulrich and Eppinger [48]. The development process has been adapted accordingly to match the scope of this project.

3.1. Development process

The project revolves around the development of a method to quantify abdominal wall tension during MIS. Throughout the entire process, opinions of clinical experts have been taken into consideration and the design process has been adapted accordingly. This process can be characterised by the saying ”learning by doing” as a result of the iterative nature of the development, causing constant re-visiting of the decisions that were made.

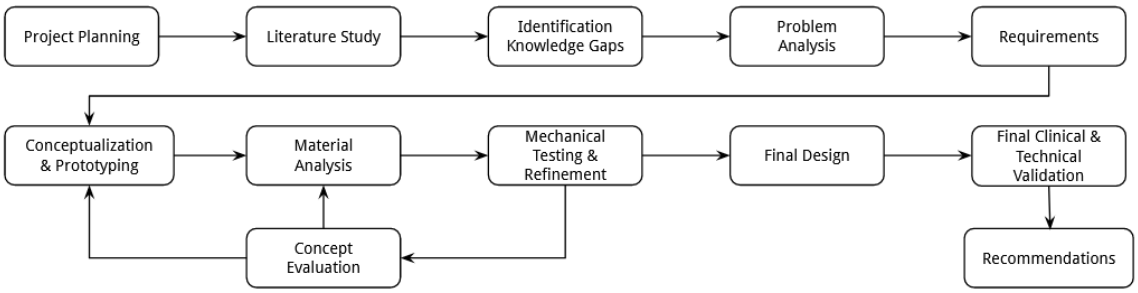


Figure 3.1: Flowchart displaying the design process.

3.2. Thesis structure

This thesis is structured around the previously described development process. In the following sections each step will be described briefly. Project planning, literature study and the identification of knowledge gaps have been elaborated in the previous chapters (Chapter 1 and Chapter 2).

Problem analysis
After having explored what can be found in literature and having identified knowledge gaps, the clinical problem was formulated. This was analysed and translated into a technical problem using sub-problems. Extensive research was done to answer these questions and several surgeries were witnessed to get a feel of the procedures. Many options were explored to exploit all possible solutions. In this chapter methods were chosen to quantify the closing forces on the abdominal wall during hernia repair. Collaboration with clinical and technical experts took place at this stage to make sure the design direction was in line with their expectations. Finally, the most feasible design directions were formulated.

Requirements
As possible design directions were formulated, the general requirements were identified and set-up, in close collaboration with the surgeons. A pilot-test during a hernia repair procedure took place to assess the forces and principles used during hernia-repair. In this chapter the two design directions were evaluated using a Harris Profile and surgeon feedback. Accordingly, one design direction was chosen and based on this more specific design requirements were set up. These requirements served as a basis for the next steps.

Conceptualisation
Through careful translation of the clinical problem into a technical problem, both clinical and functional insights have been transformed into concepts. The solution was divided into three parts, which were considered separately in this phase of the project. The design requirements were constantly revisited to guide decision making at this step. In addition, clinical and technical experts were consulted to assess feasibility of several design solutions. Prototypes were made, using the 3D-printers at the Delft University of Technology, to quickly assess feasibility of the concepts. Accordingly, alterations were made to the concepts to achieve an iterative process.

Material analysis & manufacturing
Throughout the previous phase concepts were evaluated using mechanical experiments to validate concept functionality. In addition, material choices were considered, as these played a large part in the functionality of the device. Thus, refinement of the concepts took place simultaneously with the material analysis, creating a feedback loop that can be seen in the flow chart above. In addition, the material choices heavily influenced the manufacturing procedure, which are elaborated on in this chapter too.

Final Design
After five witnessed hernia surgeries, 16 different SolidWorks models, 13 prototypes and mechanical tests a final design was drawn up. All iterations were considered during the final design. The final prototype was created and ready for the clinical and technical validation.

Validation
In this chapter both clinical and technical validation are elaborated. The devices' strength and accuracy were assessed using several mechanical tests. In addition, a sterilisation test followed by manual inspection took place to make sure the device is suited for steam sterilisation. Lastly, the devices' functionality was tested in a clinical setting at the Erasmus Medical Center facilitated by R.E.P.A.I.R. research group. This resulted in some changes to the design and some recommendations for further research.

4

Problem Analysis

Several methods to assess tension in the abdominal wall during ventral hernia repair have been found in literature, nevertheless some knowledge gaps remain. Applications during MIS are limited and no standardised method is implemented. In the following chapter the clinical problem will be analysed and translated into a technical problem. Lastly a design direction will be formulated.

4.1. Translation clinical problem to technical problem

A method needs to be developed to quantify the tension in the abdominal wall during abdominal hernia repair. To answer the clinical question, some sub-problems need to be considered: what is abdominal wall tension, how can we measure this tension and how do we access the tissue laparoscopically?

Measuring abdominal wall tension

For the scope of this project it is important to narrow down which values can be measured, that are directly related to the tension in the abdominal wall. The measurement should easily be replicated to enable objective comparison of results.

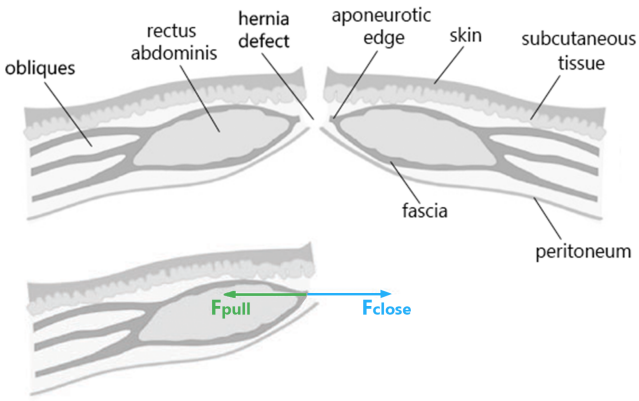


Figure 4.1: Schematic representation of forces acting on the aponeurotic edge.

Tension refers to the state of being stretched tight. The abdominal wall is stretched as a result of the pulling force exerted by the oblique muscles. This creates a pulling force on the

aponeurotic edge (F_{pull}). This force will have to be overcome (F_{close}), when bringing the defect edges back together, and will exist in the abdominal wall when the defect is closed. The magnitude of these forces depends on patient specific characteristics such as connective tissue quality and compliance. To quantify the tension in the abdominal wall the force necessary to bring the edges together in the defect mid-line will have to be measured.

Several techniques were identified and explored to measure tension in tissue, they can be found in Appendix B. It was decided to go for a mechanical measurement of tension using a spring with a known spring constant. This is based on Hooke's law, in which F is the force exerted on the spring, k is the spring constant and u is the spring elongation:

$$F = k * u$$

Other methods were deemed less reliable, safe or realistic due to the time restriction of this research. Not having to use sensors and include electronics makes implementation of the device easier with regard to sterilisation and calibration. The simplicity that this method offers is preferred. This approach has been used previously during open hernia repair to quantify forces necessary to close defects in the abdominal wall (Chapter 2). To collect relevant data, both force and elongation or displacement of the abdominal wall need to be measured. Researchers used linear spring scales attached to surgical clamps to measure force and calipers to measure displacement. The application during laparoscopic surgery brings restrictions with regard to size and working space, therefore the previously described set-up is not possible and a different approach needs to be found.

Tissue manipulation

The test-setup described in literature cannot be used during laparoscopic repair due to the restriction in working space. To measure abdominal wall tension during and maintain benefits from laparoscopic repair, trocars have to be used to access the abdomen (Figure 4.2). Long slender instruments are used during MIS to reach the abdominal wall. Several instrument tips exist and can be used with the same handle, as can be seen in Figure 4.3. A way to grasp the abdominal wall through a trocar must be conceived in order to measure the closing forces.

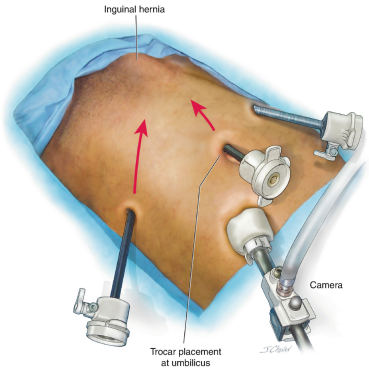


Figure 4.2: Trocar placement during herniorrhaphy [9].

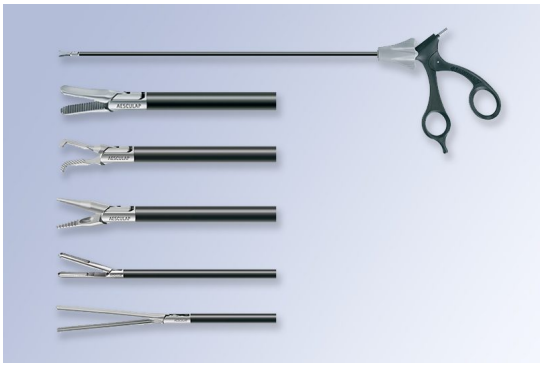


Figure 4.3: Laparoscopic instruments by Aesculap [1].

To keep the design solution applicable for multiple types of surgeries, it was chosen to focus on the minimally invasive application instead of solely on robot assisted procedures. This way

the design solution can be used during both laparoscopic and robotic surgeries with the help of an assistant.

4.2. Technical problem to design direction

Taking these sub-problems into consideration, two design solutions were considered within this specific clinical setting:

1. Developing a new laparoscopic instrument to grasp the tissue and measure forces necessary to pull the fascial edge to the mid-line.
2. Developing an add-on for an already existing laparoscopic instrument (grasper), that can be used to measure forces necessary to pull the fascial edge to the mid-line.

5

Requirements

Through attending numerous hernia repair surgeries at the Reinier de Graaf hospital in Delft, an image of the clinical environment during operations was drawn. This was used as a basis during the formulation of the list of requirements.

To further define the measuring technique a Harris Profile was used to assess which of the two design directions is more feasible within the scope of the project: the development of a new laparoscopic device or the development of an add-on for an existing, already implemented instrument (Appendix C). Using existing laparoscopic instruments has several advantages such as their proven safety and functionality. In addition, the surgeon is familiar with the instrument, hence comfortable using it during the procedure, which makes incorporation of the device accessible. When developing a novel instrument these aspects are not yet fulfilled and within the scope of this project safety and ease of use are of high priority. In addition, a lot of research has been done to develop the right laparoscopic gripper jaws, ensuring their functionality is achieved and the tissue can be manipulated effectively. Therefore, trying to develop a new laparoscopic instrument within the given time-frame seems futile. Experts in hernia surgery (R.E.P.A.I.R., EMC) vouch for the option to use already existing instruments instead of re-inventing a new one. Accordingly it was chosen to utilise what was at hand to grasp the tissue in question.

5.1. Design requirements

The list of requirements can be found below in Figure 5.1. They can be sectioned into four basic requirements effectivity, safety, ease of use and manufacturability.

Requirements where quantified where possible. Most importantly is the pulling force it needs to resist while using the device. Clamping needs to withstand a pulling force of up to 50N, based on the literature found on forces during laparoscopic herniorrhaphy [5], [27]. In these studies measurements do not exceed 50N. In addition, a pilot measurement was done during ventral hernia repair, under supervision of clinical experts, confirming the force range.

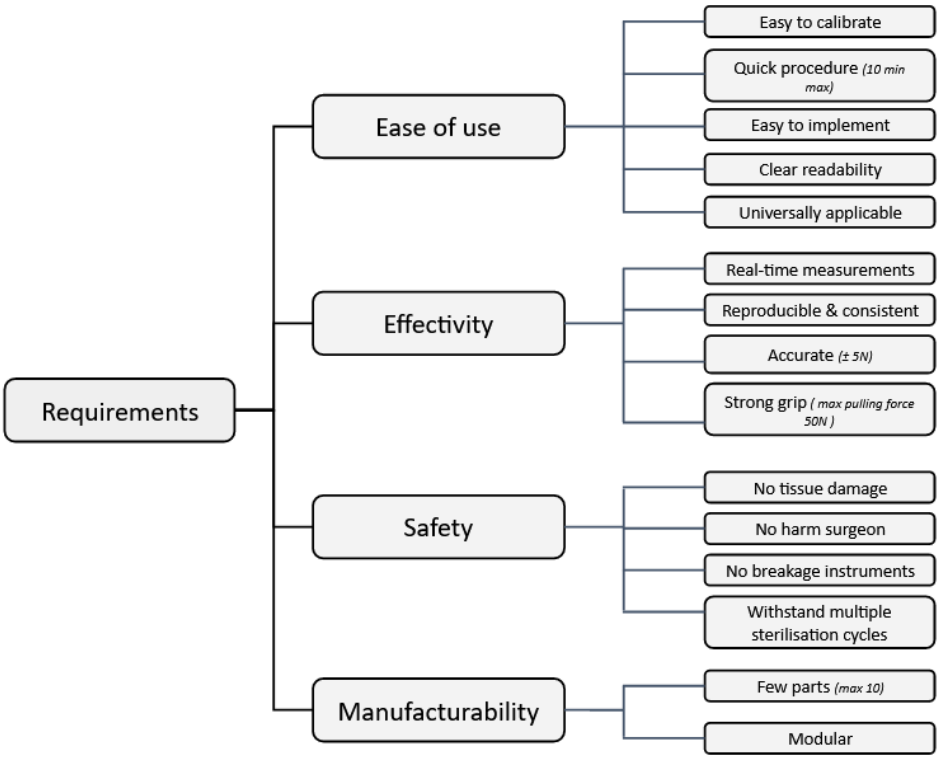


Figure 5.1: Requirements for the design of the force sensor.

Measuring the tension should be performed within 10 minutes. This is based on an estimation on how much time surgeons would want to spend on an extra step in the procedure. The shorter, the better. The measurements need to be accurate and reliable: they cannot differ more than 5N from the actual applied force. In order for the device to be sterilised, the design needs to be modular so it can be easily disassembled and all parts can be sterilised separately. This will also increase the durability of the design as parts can be replaced independently. Part count should not exceed 10.

Figure 5.2: Differences in handle design between different manufacturers, most left contains a ”rack”.

Various manufacturers offer laparoscopic instruments, this causes variation in shape and size of the handle, as can be seen in Figure 5.2. For easy implementation, the device needs

to be compatible with a diversity of handle shapes and sizes, so that it can be utilised in any hospital. In addition, the device must attach to the instrument in a sturdy manner so that it can be used without harming the patient or the surgeon. When the device is attached too loosely, it might influence the accuracy of the gripper. Likewise, the rigid attachment ensures the device will be pulled in the same direction each subsequent measurement, making it reproducible and consistent. This is necessary for acquisition of reliable results. Furthermore, the device cannot obstruct using the ”rack”, as this is necessary to ensure tight grip of the tissue.

These requirements will be kept in mind and reconsidered in the following chapters to develop and design the device. Lastly, they will be used to validate the design.

6

Conceptualisation

To achieve the functionality of the device it needs to consist of three parts. Each part has been considered separately during the ideation phase. The parts are the following:

1. A clamping mechanism that attaches to the laparoscopic instrument.
2. A mechanical force gauge that measures the closing force and displacement of the abdominal wall.
3. A handle to exert pulling force on and operate the device with.

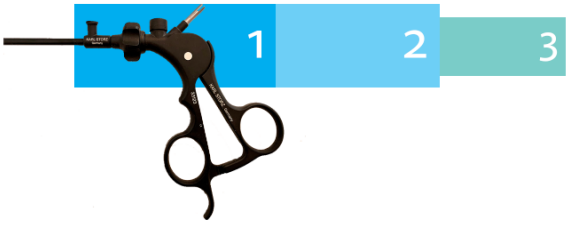


Figure 6.1: Three parts to achieve functionality of the device.

6.1. Clamping mechanism

The force gauge needs to be connected to the laparoscopic instrument in order to yield a reliable measurement. Accordingly, a mechanism needs to be developed that attaches to the laparoscopic instrument in a sturdy manner, so that it resists the pulling force necessary to close the defect (max. $50N$ [27], [5]). To tackle this design challenge, similarities in laparoscopic device design were sought. These were identified, the most important characteristics can be seen in Figure 6.2. As most laparoscopic devices have these features, they can be used to guide the design of a solution to the problem.

Looking at the characteristics, design solutions to clamp the laparoscopic device were set out. A design tree was made to explore several solutions and can be found in the appendix

(Appendix C). Solutions can be classified into two types of attachment: attachment to the shaft and attachment to the handle. When attaching the force gauge, it is important to keep the pulling direction in line with the shaft, in order to prevent creating a torque on the handle. Accordingly, when attaching to the handle, the pinch or ring grip cannot be used. Instead, the device needs to attach at the position indicated in Figure 6.1. Several options were explored and presented to experts. A Harris Profile was created and can be found in the Appendix (C). It was chosen to go for attachment to the handle, with regard to safety. Clamping the shaft brings safety risks, such as the possibility of breaking the insulating layer on the shaft and influencing the diathermy, which could harm the patient or surgeon. Consequently, design solutions were sought in effectively clamping the handle of the used laparoscopic instrument.

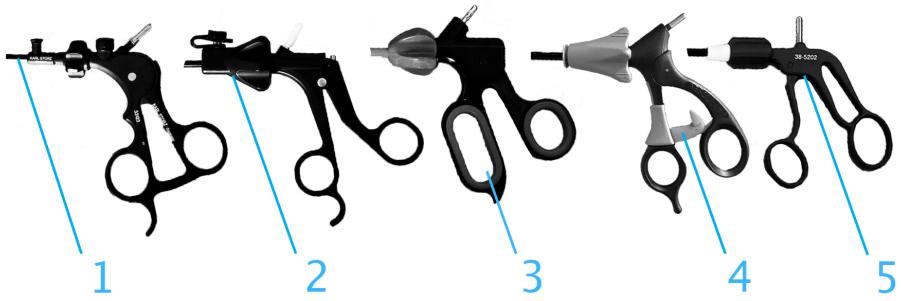


Figure 6.2: Laparoscopic handle characteristics 1= shaft, 2= rotation knob, 3= pinch\ring grip, 4= ratchet, 5= flat sides.

Initially, keeping the manufacturing requirements in mind, it was preferred to design a compliant mechanism, to keep part count as low as possible, in which the elasticity of the material created a clamping force. Several designs were drawn out to explore this solution. A first prototype was printed to quickly evaluate the functionality of this mechanism. This first print was needed to get a picture of the dimensions and basic principles of rapid prototyping. As a result, the first prototype was very large and rigid. Next, the design was altered to see if sufficient clamping could be achieved using a round cutout at the end of the clamp, as can be seen in Figures 6.3 and 6.4. This, again, did not create sufficient clamping to resist the pulling force of 50N, due to the low friction coefficient of the polymer of the handle and the printed prototype. Furthermore, the difference in thickness between various laparoscopic handles was too large to account for with a compliant mechanism: some handles had a thickness of 5mm and others 20mm. Therefore, it was decided to proceed with a design that uses mechanical fastening to create a sufficient clamping force. In addition, the friction between the two components needed to be increased in order to resist a pulling force up to 50N.

Re-visiting the design tree, several design solutions were evaluated (Appendix C). To keep the complexity and part count as low as possible and clamping force as high as possible, it was chosen to use a linear clamping mechanism based on the mechanism used in a C- or G-clamp (Figures 6.3, 6.4). This way a simple design can be used while making it possible to clamp different shapes and sizes, making sure it is compatible with various different handles. Several prototypes of the clamping mechanism were drawn in SolidWorks, 3D-printed and evaluated with regard to the design requirements. In this stage prototypes were printed using PLA. Mechanical tests were done to see if the prototype met the needs and the design was adapted accordingly, creating and iterative design process (Chapter 9).

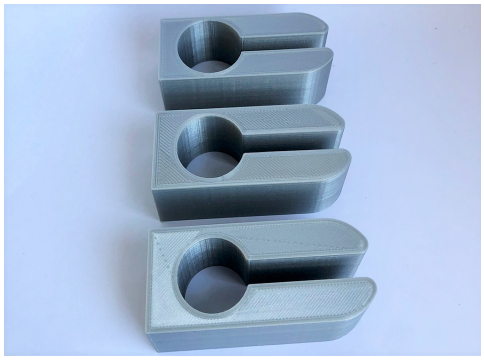


Figure 6.3: Compliant mechanism prototype with varying hole diameter.

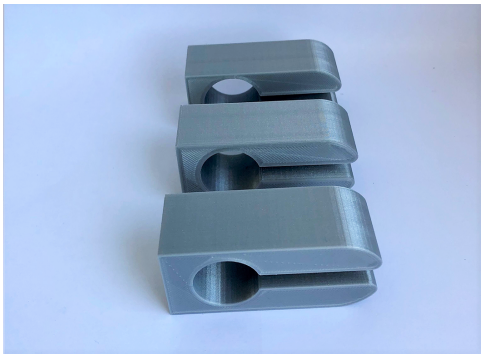


Figure 6.4: Compliant mechanism prototype with varying hole diameter.

One of the challenges in this phase of the project was the influence of the material choices on the design. Knowing that PLA is not suited for sterilisation, other materials needed to be considered. In addition, a method needed to be sought to increase friction in the clamping contact surfaces, and thus decrease the needed clamping force, in order to withstand the pulling forces. The material choices will be elaborated in the next chapter (Chapter 7).

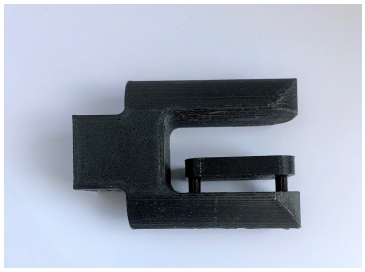


Figure 6.5: First C-clamp prototype with adjustable block.

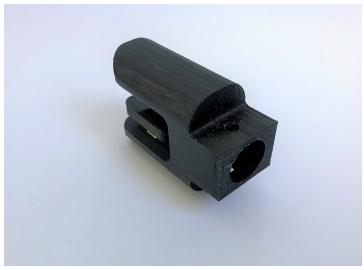


Figure 6.6: Holes to attach the spring using a pin.

Figure 6.7: Prototype with spring attached using a pin.

Another challenge is the device's compatibility with various ring or pinch grips. These differ not only in shape, but also in thickness. As the device will be clamped on the flat surface of the handle, thickness plays the biggest role here. In order to enable a variable clamping thickness, a moving part needed to be integrated. The first prototype of this part can be seen in Figure 6.5. In addition, some handles have a slightly curved cross section, creating a shape that is more difficult to clamp, due to a decreased contact surface. Several methods to tackle these challenges were drawn up and evaluated, resulting in the final design which can be seen in Chapter 8.

6.2. Mechanical force gauge

Tension in the abdominal wall

The star of the show is the force gauge. Keeping requirements regarding safety, simplicity and sterility in mind, it was decided to go for a purely mechanical force sensor using a linear spring scale, inspired by methods found in the literature review (Chapter 2). Force is measured by assessing the elongation of the spring as a result of the pulling force. The force sensor needs to attach to the laparoscopic instrument through the clamping mechanism described previously. To use the force gauge the spring will be stretched through pulling of the handle,

this part will be elaborated in the next section.
The most important part of this design aspect is the stiffness of the spring. On one hand it needs to be stiff enough to give an accurate representation of the force exerted on it, on the other hand its elongation needs to be large enough so the surgeon can quickly and clearly read the results during the procedure. This trade-off between ease of use and functionality of the device needs to be made and the right balance between the two needs to be found. Several springs were selected using the criteria and threshold values found in the table below, keeping this trade-off in mind. Values were selected based on the required dimensions of the device. The search yielded 10 springs offered by Tevema (Appendix D).

Table 6.1: Search criteria used in Tevema shop.

Variable	Value
Material	Stainless steel
F	50-70 N
L_0	11-50 mm
S_n	30-70 mm

Now, looking at initial length (L_0) and maximum suspension (S_n), a balance is sought. Ideally L_0 is kept as low as possible, to keep the size of the device to a minimum, and S_n as high as possible to make sure the surgeon can read the measured value without making mistakes. Keeping this in mind, a spring was chosen to use in the design. This spring has a an elongation of 53.2mm when using a force of 50N, which is expected to be enough to yield a clear reading.

Displacement of the abdominal wall

When collecting data from different measurements, it is important to know what the displacement of the abdominal wall is. The amount of force necessary to close the defect depends on how easily the abdominal wall is stretched. Consequently, assessing its strain will add to the entirety of the measurement and without it it would be incomplete [16]. Therefore, a method needs to be presented that simultaneously tracks the displacement of the fascia.

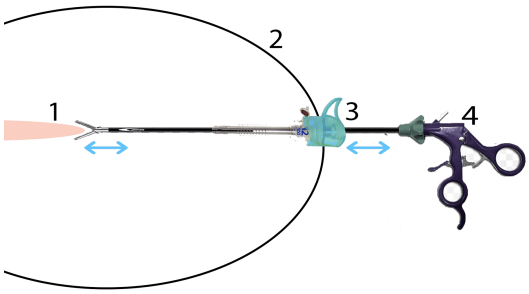


Figure 6.8: Schematic drawing of displacement of the abdominal wall (1= abdominal wall, 2= abdomen, 3= trocar, 4= laparoscopic instrument).

Figure 6.9: Prototype of device housing with handle and cutouts to attach the spring, made of PLA.

For the sake of this project it is assumed that the abdominal wall is linearly elastic, as the tissue is loaded in its ultimate states of loading [16]. As a result the abdominal wall

displacement is proportional to the displacement of the handle relative to the trocar, as is illustrated in Figure 6.8.
The endoscope could be used to observe the stretching of the fascia. With regard to accuracy, it is preferred to use a caliper or ruler on the outside of the abdomen, to measure displacement relative to the trocar. Several methods were explored to simultaneously measure tissue displacement, keeping in mind that it is not favorable to alter or attach anything to the shaft of the laparoscopic instrument or the trocar, due to the safety requirements. In consultation with laparoscopic surgeons it was chosen to use a stainless steel ruler, keeping simplicity and safety of highest priority. The ruler can be held along the trocar during the closing tension measurement to assess how much the abdominal wall has displaced. This procedure will be tested experimentally to make sure it is in line with the requirements with regard to ease of use.

6.3. Handle and housing

The surgeon uses the handle to operate the device (Figure 6.9). The handle is attached to the spring, hence displacement of the handle causes elongation of the spring. A scale on the hand grip indicates how much force (in Newton) is exerted on the spring and consequently on the fascia of the abdominal wall. The scale is created by first calibrating the spring and later using Hooke's Law to convert spring elongation into measured force. The housing connects all parts together: the clamping mechanism, the linear spring scale and the handle and makes it into one device.

6.4. Prototyping

Several 3D-printed prototypes were created using PLA. First, only the clamping mechanism was printed as this was where the most design steps were needed. The designs were evaluated, this will be elaborated in Chapter 9. Next, the housing was added to the design to house the spring for the linear spring scale. In the next chapter the material analysis will be described and the final design will be elaborated in Chapter 9: Final Design. An overview of the most important steps in the prototyping stage can be seen in the figure below.

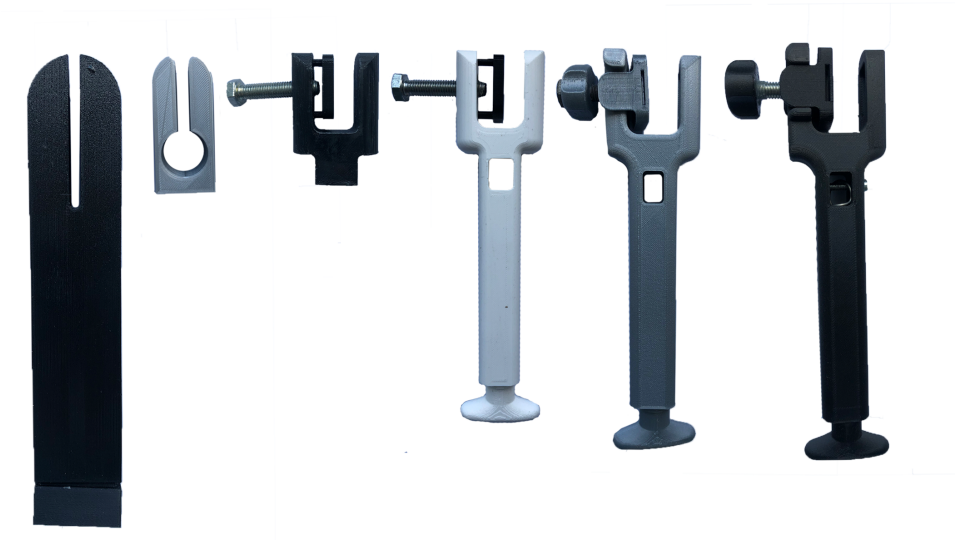


Figure 6.10: Most important steps and changes during the prototyping stage of this thesis.

7

Material & Manufacturing

During the conceptualisation phase several prototypes were made to assess functionality and design of the device. Part of the design process is making choices with regard to the material and manufacturing processes, which will be covered in this chapter.

7.1. Material analysis

The part consists of two materials: one used for the housing of the device and the other used to increase friction on the contact surfaces of the device. Keeping in mind that the prototype is solely used for initial research, thus only few devices are needed, it was chosen to focus on 3D-printing in this thesis. If sufficient clamping force can be achieved depends on the choice of material for the inlay. The inlay material determines how much friction is created in the contact surfaces between the housing of the laparoscopic handle and the device. This in turn determines how much clamping force is needed to withstand a pulling force of $50N$. The housing needs to withstand this clamping force.

Housing

Not all materials are suited for 3D-printing. It was decided to solely focus on polymers, as 3D-printing metals seemed undue. Rapid prototyping experts were consulted and several material options were selected based on the ease of printing, strength, stiffness and its ability to be sterilised. The device will be loaded in tension, as a result of the direction of the pulling force needed to close the hernia. In addition, forces will come into play as a result of the clamping forces acting on the device. These forces are created by the fastening of the bolt and are assessed in Chapter 9. The material of choice will have to withstand these forces during use (Figure 7.1). During the design of the shape this has been taken into consideration and the design has been adapted accordingly (Chapter 8).
During the refinement phase the prototype was printed in both PLA, tough PLA and carbon fibre reinforced PA-12 (”Onyx”, Markforged). PLA cannot be used in this clinical setting, as sterilisation is difficult considering its sensitivity to heat. In addition, its material properties are not sufficient with regard to the forces created by the tightening of the bolt: during regular use PLA failed to withstand the clamping forces and fractured, as can be seen in the figure below. This cannot only be accounted for by the material properties, but also the printing direction, printing settings and design of the device come into play here. Tough PLA and PA-12 did not fail under the same circumstances. PA-12 is not only known for its tensile strength, impact strength and toughness, it is also easier to sterilise. PA-12 is recommended for making parts of surgical instruments that need to be sterilisable by autoclaving [55]. Literature indicates

Figure 7.1: Schematic drawing of the forces acting on the clamp housing.

that no drastic decrease of material properties exists after several cycles, making it a suitable material in this application [19]. This claim will be tested in Chapter 9 and recommendations will be made with regard to sterilisation of the material. The carbon reinforced nylon guarantees that the device will not break during use, due to its increased material properties as a result of the carbon fibres placed throughout the material. Therefore, it was chosen to go further with this material.

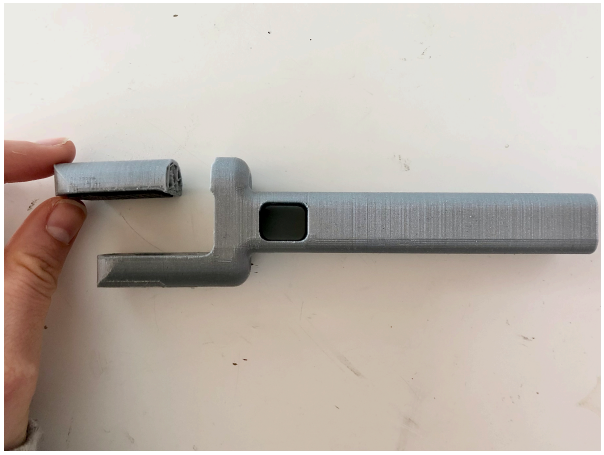


Figure 7.2: Image displaying prototype failure (PLA).

Inlay

Friction between the housing of the handle of the laparoscopic device and the clamp is very low. As a result, a lot of clamping force needs to be applied to ensure a strong grip. This could, in return, cause failure of both the laparoscopic device as the force gauge. To decrease this force, friction between the two surfaces needs to be increased. This way less clamping force is necessary to ensure rigid clamping. Increasing surface roughness was assumed to be insufficient, hence in the early prototyping stages anti-slip dashboard pads made of unknown latex were used and placed on the location indicated in the figure below. Keeping sterilisation requirements in mind, an alternative needed to be found.

The friction between the inlay and the handle of the laparoscopic instrument needs to be sufficient to keep the handle from slipping away while being used. The friction force is

Figure 7.3: Schematic drawing of the inlay, indicated in blue, to increase the friction.

dependent on the normal force and the coefficient of friction (COF) between the two materials [29]. The normal force is a reaction to (and equal to) the clamping force. Consequently, if the device needs to withstand a pulling force of 50N, the friction force needs to be at least 50N. This means that if the clamping force is 50N, the COF needs to be at least 1 in order to keep the device from slipping away. The COF between rubber and other surfaces can yield from 1 to 2. Between silicone rubber and other surfaces the COF is substantially larger than 1 [29]. Therefore, these two types of material seem like a suitable option for the inlay of the clamp.
Natural rubber, silicone and polyurethane rubbers are used quite frequently in medical applications such as for prostheses, artificial skin, catheters, tubes and seals etc. [36]. Several rubber and silicone suppliers were consulted to assist in choosing the right materials with the right properties. The material has to create enough friction between the housing of the clamp and that of the handle, it needs to be sterilised and it should act as a cushion for the handle to aid in ensuring the clamp does not damage the handle and ensure applicability to several shapes. Several samples of EPDM rubber pads and silicone pads were ordered from Rubbermagazijn. In addition, liquid silicon was ordered from FormX (Ecoflex™GEL, SORTA-Clear ™37 and DragonSkin™10) and molded using 3D printed molds out of PLA. Differences between the material properties can be found in the Appendix (Appendix E). These different materials were evaluated and tested using a pressure sensor and tensiometer. A pressure sensor (Singletact 100N) was placed between the silicone rubber and the clamp. Next, the clamp was closed until a certain pressure was reached. This pressure was converted to a clamping force in Newton (Appendix F) and kept constant between the different samples. A force gauge was used to assess which material enabled the tightest grip.

DragonSkin ™silicon can resist temperatures up to 232°C, whereas SORTA-Clear ™can resist up to 204°C. In addition, SORTA-Clear ™is certified ”Food Safe” [17]. EcoFlex did not meet the requirements with regard to temperature, and was accordingly left out of the selection. SORTA-Clear ™37 was able to easily withstand a pulling force of 50N (Chapter 5). With a clamping force of around 123N, the device only started slipping with a pulling force of more than 180N, which is many times more than what the requirement calls for. Both other silicon pads were too soft for this application. Due to the clamping force the materials deform and do not create sufficient grip to resist a pulling force of 50N. Based on these experiments it was chosen to go further with SORTA-Clear ™37 in this prototype. In Chapter 9 claims

with regard to sterilisation will be evaluated.

7.2. Manufacturing procedure

Prototypes were created using the 3D printers available at the Delft University of Technology. The used printers (Ultimaker 3) rely on Fused Deposition Modeling (FDM) or Fused Filament Fabrication (FFF), during which material is melted and extruded through a heated extrusion head. The filament is fed through the nozzle and deposited on the table. A schematic figure of the process can be seen below (Figure 7.4).

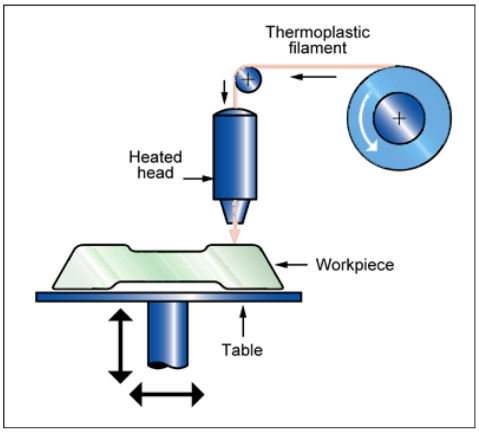


Figure 7.4: Schematic drawing FDM process [18].

It was decided to proceed with FDM 3D printing as the manufacturing method of choice for this thesis due to the many benefits this technique offers. Benefits are its low cost, short lead times and availability of material choices. Drawbacks are low dimensional accuracy and resolution, visibility of layer lines and anisotropy of the parts [6]. As the parts in question do not contain many small details required for its function and the anisotropy can easily be taken into account during the design, the positives outweigh the negatives. In addition, printing with ”Onyx” enables impeccable surface finish [30]. The device is used for research purposes, thus only few devices are needed. As a result, producing a costly mold for injection molding or similar manufacturing methods seems undue. Rapid prototyping is an ideal option for such small runs and costs can be kept low this way. Furthermore, new copies of the device can easily be made when needed, possibly even on site due to the wide availability of desktop FDM printers.

Continuous fiber reinforcement

To increase the strength of the device even further, consequently ensuring safety during use, continuous fibres can be deposited throughout the device using Markforged 3D Printers at the TU Delft. This printer uses Onyx, a thermoplastic (Nylon) filled with chopped carbon fibers. The fibres improve mechanical properties and print quality significantly of thermoplastics printed using FDM/ FFF. Continuous fibers can increase part strength by an order of magnitude [30]. First, the outer shell and infill is printed with Onyx using FDM. A secondary nozzle extrudes long-strand fibers, which can be placed using the software. Fibers can selectively reinforce the perimeter, select features, or entire layers of the part [30]. The resulting parts are stronger, stiffer and more durable than both filled and regular plastic. It maintains the heat resistance, chemical resistance and print quality of the thermoplastic matrix they are printed with. Print settings are found in Appendix E.

8

MINT - Final Design

After several iteration steps and technical evaluation of the prototype, the design was finalised to meet the requirements. The device goes by MINT, which stands for ”Minimally INvasive Tensiometry”. The different aspects will be elaborated in the following sections.

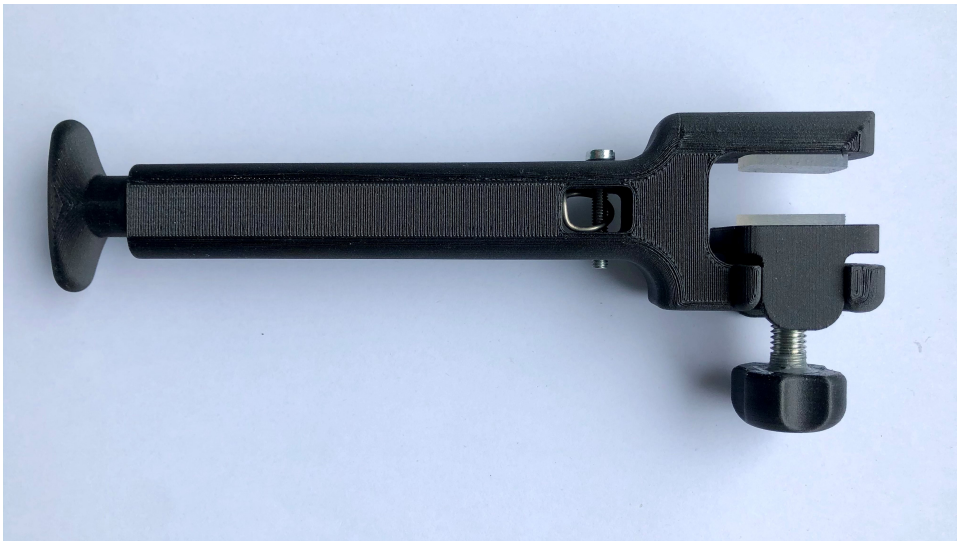


Figure 8.1: Side view of the final design for MINT.

8.1. Design

The clamp design is inspired by the well-known C-clamp (Figure 8.1). It consists of a frame, shaped like a C, which forms into a slender, hollow rod shaped segment that houses the spring and handle of the device. The bottom of the C-shaped frame contains a hole in which a bolt and nut are placed (Figure 8.2). The bolt protrudes through the hole and simultaneously pushes against the block that creates the second contact surface between the handle of the clamped device and the frame. This way, the device can be adjusted to clamp handles with varying thicknesses (Figure 8.4). This block is designed so that it can only move up and down without moving forward, backward or sideways. The bulges on the lower beam of the frame create slots for the walls of the block to slide through whilst the device is being used (Figure 8.3). The two contact surfaces contain cutouts that house silicon pads. These do not only account for different handle shapes by cushioning the

handle, but they also protect the handle from breaking during clamping and increase friction between the handle and the clamp (Figure 8.4). The cushions are fabricated at the TU Delft using Smooth-on silicon kits (SORTA-Clear ™37) and a 3D printed mold. At the bottom of the block a cutout is created in which a stainless steel plate is placed (Figure 8.6). This plate fits into the cutout perfectly and does not need any adhesive. The sheet makes sure that the bolt does not damage the block while adjusting the device and fastening the clamp. The slender rod shaped part of the housing contains a hole throughout its entire length. The handle, connected to the spring, is inserted here and connected to the housing using a pin (Figures 8.8, 8.9 and 8.10). Holes on the side of the housing enable easy assembly of the device. MINT is designed in such a way that the pre-tension of the spring is taken into account whilst using the device.

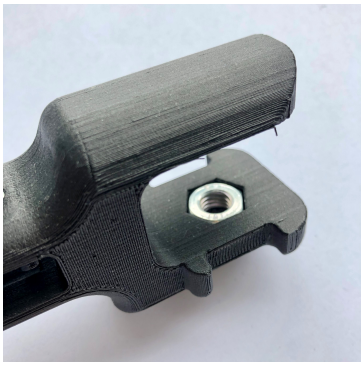


Figure 8.2: Final design clamp with nut and bulges.

Figure 8.3: Final design clamp with spring, nut and bolt.

Figure 8.4: Final design clamp with block and silicone pad.

MINT is completely modular so that it can easily be assembled and disassembled for sterilisation. It consists of four printed parts: the housing, the clamping block, the handle and the turning knob. Additional parts that need to be fabricated are the silicon pads and the stainless steel sheet. All other parts are used for mechanical fastening such as the nut and bolt and the pins that fasten the spring. The turning knob is glued onto a bolt using silicone sealant, creating a permanent fixation. All together the device contains 11 parts.

Figure 8.5: Adjustable block with cut-out, top view.

Figure 8.6: Adjustable block with cut-out, bottom view.

Figure 8.7: Turning knob with bolt and silicone sealant.

The handle of the device will be pulled out of the housing, displaying the measured force necessary to do so. The scaling was created after the spring constant was validated using weights. After repeated calibration, the scaling on the handle is set to $1,1$mm per 1N. The

spring has a working range between 10N and 60N, the upper limit was based on the found literature (Chapter 2). It is assumed that most force measurements will be within this working range, as lower forces point to direct closure and higher forces will most likely indicate component separation (Chapter 2).

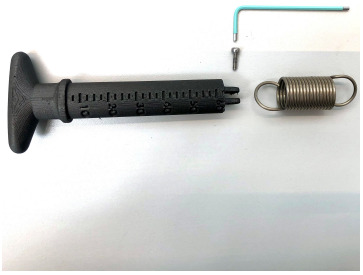


Figure 8.8: Connecting the spring to the handle using a pin (2mm) and hex key.

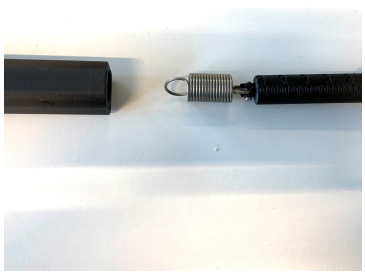


Figure 8.9: Assembly of the handle and the spring to the housing of the device.

Figure 8.10: Other side of spring connected to the housing using pin and nut (4mm).

The materials used for the housing are carbon fibre reinforced Nylon with continuous carbon fibres placed throughout the length of the device to further increase part strength. ”Onyx” creates a smooth surface finish when compared to other FDM printed materials. The handle, the turning knob and the block are made out of the same material. All parts are fabricated at the Delft University of Technology at the department Mechanical, Maritime and Materials Engineering (3mE) using ”Mark Two” (Markforged). The stainless steel plate located at the bottom of the block is made using laser cutting. After 3D printing the part, the cut-out was measured precisely to ensure a perfect fit. As a result, no adhesive is needed. The spring used is manufactured by Tevema (T42010) and the silicon pads are made using a premium water white translucent silicone rubber (SORTA-Clear ™37 from Smooth-on).

8.2. Procedure

MINT will be used between measuring the size of the hernia and closing the defect. During the procedure the surgeon will be working with a laparoscopic gripper to manipulate the tissue. To perform the measurement, the surgeon will grasp the tissue and fasten the rack to ensure a strong grip. The assistants will make sure the device is assembled correctly and that the ruler is in place. Next, MINT will be attached to the handle of the laparoscopic instrument in use by turning the rotation knob until sturdy clamping is achieved (Figures 8.11-8.16). The surgeon will apply tension to the grip in order to pull the edge of the defect to the mid-line of the abdomen. This way, the spring is stretched and the applied force can be read out. The measurements will be repeated several times at different levels in the abdominal wall, making sure results are accurate and reliable. Simultaneously the user will read out the displacement of the device relative to the trocar using the ruler. Results will be logged for further research. After having acquired enough results, MINT will be detached. Now the surgeon can proceed with the surgery according to his judgement, taking the measurement into account when guidelines have been formulated. Instructions for assembly can be found in the Instruction Manual.

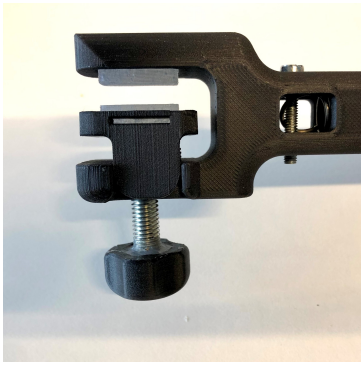


Figure 8.11: Slide block onto housing.

Figure 8.12: Slide clamp on handle.

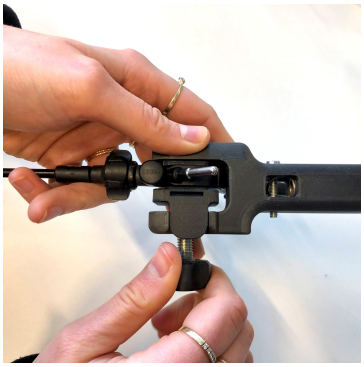


Figure 8.13: Turn turning knob to ensure tight clamping.

Figure 8.14: Assembled device attached to clamp.

Figure 8.15: Assembled device attached to clamp.

Figure 8.16: Assembled device attached to clamp.

9

Validation

As MINT was finalised, the prototype was manufactured at the Delft University of Technology. This was used during experiments to assess the prototype's functionality both clinically and technically. The experiments are set up to assess ease of use, effectivity, safety and manufacturability.

9.1. Technical validation

Technical validation took place throughout the prototyping phase. Several experiments were repeated to assess MINT's functionality. Results were used to optimise the design until requirements were met. After refinement of the design similar methods were used to assess accuracy and reproducibility. Lastly, a sterilisation test was done to substantiate the literature found on the selected materials.

Testing for strength & safety

Firstly, the applied forces during use needed to be quantified. For this a force sensor (SingleTact, 8mm diameter, 100N/22lb) was used. The sensor was calibrated before measurements were executed (Appendix F). The sensor was placed between the silicon pad and the block enabling the variation in thickness of the laparoscopic device handle. A slit was modelled into the block to facilitate sensor placement. Next, the device was clamped and the measured value was read out and converted into a force. The set-up was used to assess how much clamping force, as a result of fastening the clamp using the bolt, the device can handle. Results show that the device can withstand clamping forces up to 130N, without breaking, which equals the tightest possible fastening of the device. The clamping force with regular use will lie between 50N and 120N, this is based on tightening of the clamp by a grown up man.
Next, an analog spring scale was used to assess how much pulling force the device resists before letting go, with a known clamping force, using the same set-up as described previously. A higher clamping force results in an increased allowance of pulling force. The magnitude of the pulling force applied will be no more than 50N. Results of the experiment can be seen in the table below. With a clamping force of around 60N the device let go with a pulling force of around 85N. This is a lot higher than the maximum pulling force in this application.

Table 9.1: Maximum resisted pulling force with regard to clamping force.

Clamping Force (N)	Pulling Force (N)
57 N	84,4 N
123 N	176,6 N
173 N	>190 N

Testing for accuracy & reproducibility

A force gauge (0-50N) was used to validate the scaling on MINT. The device was clamped on a workbench and measurements were repeated three times. In between each measurement the spring was relaxed completely before repeating the measurement and/or increasing force. All data can be found in Appendix F. The error, absolute error, Absolute Percentage Error (APE) and Mean Absolute Percentage Error (MAPE) were calculated using Excel. The calculated accuracy of the device is accuracy is 5.5+/-2 %, expressed in MAPE. Measurements using the device consistently overestimate measurements using the force gauge by 1.7N on average.

Testing for sterilisation

MINT needs to be sterilised before it can be used in the OR. As the device is in contact with a sterile laparoscopic instrument, it needs to be free from micro-organisms and all forms of life. This requirement was taken into account during selection of the materials, as not all materials can be sterilised. In addition, it was made sure that the device's separate parts can be disassembled, so that all parts can be sterilised separately.
Some evidence is found that PA-12 is suited for sterilisation by autoclave [19], [55]. The carbon fibers used should not have an effect on the thermal properties [30]. The silicone, used for the cushions, was chosen based on its ability to be processed at high temperatures (204 degrees Celsius [17]). Lastly, a silicone sealant (Bison) was used to fixate the turning knob onto the bolt. This sealant can be treated in temperatures up to 120 degrees Celsius. All other accessories used in this design are made of stainless steel, which are known to be easily sterilised using steam sterilisation in an autoclave.
Not only is the literature on the matter limited, 3D printing can also cause difficulties with regard to sterilisation. As FDM creates porous parts micro-organisms might get stuck here. To substantiate the literature on the matter, and validate that the used materials are suited for this application, a sterilisation test was done. Sterilisation experts at Combi-ster (central sterilisation department of Reinier de Graaf hospital) were consulted. It was decided to let the prototype go through five sterilisation runs from start to finish. The sterilisation cycle consists of the following steps: transport, cleaning, assembly, check, packaging and sterilisation. During the sterilisation steam is heated to 134 degrees Celsius for four minutes. Afterwards drying and cool-down take place before the instruments can be used.

Sterilisation experts quickly evaluated the design before the tests were done. It was emphasised that the part count is rather high. This makes assembly, sterilisation and use more tedious. After having gone through the whole sterilisation process 5 times, no major changes were observed in the device. The device showed some minor deformation (Figure 9.1). In addition, some dents were found on both sides of the device. This could be due to contact with the heated sterilisation basket and indicates that the shape can be slightly affected by the heat. The silicon sealant did not withstand the heat: discoloration and displacement was observed. Concerns with this material had been voiced already, consequently this was to be expected. As a solution another sealant will have to be found.

Lastly the silicon pads came out with some slight discoloration, but no other changes were observed.

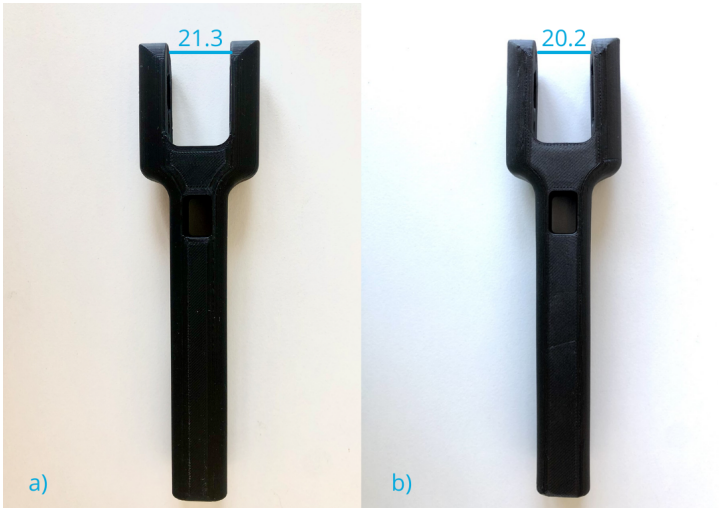


Figure 9.1: a) Before sterilisation vs. b) after sterilisation.

Technical tests were repeated with the sterilised parts to assess its mechanical function. No changes were observed with regard to clamping force. The requirements were still easily met as a pulling force more than 100N was resisted with a clamping force of around 120N.

9.2. Clinical Validation

For a complete proof of principle, MINT was to be tested in a more realistic setting. A laparoscopic procedure was mimicked using a human cadaver to assess requirements with regard to ease of use and safety in a clinical setting. These experiments were carried out at the Erasmus Medical Center.

Embalmed human bodies offer normal anatomical relations, which is preferred during surgical training. However, traditional embalmed human bodies do not offer the possibility to create a functional pneumoperitoneum, which is necessary to accurately mimic minimally invasive procedures. The department of Anatomy of the University Medical Centre of the Erasmus University Rotterdam invented and developed an embalming method (pre-rinsing), which enables insufflation with normal pressures (12-14mmHg) on human bodies. AnubiFIX®makes it possible to embalm human bodies donated for science and preserve them for years while offering the natural flexibility and tissue handling [15]. This offers a realistic training environment for laparoscopic surgery.

During the clinical validation, or proof of principle of the device, an AnubiFix ®embalmed torso was facilitated. Three trocars were used: one for the laparoscope and two for the laparoscopic grippers used to manipulate the tissue with inside the abdomen. It was decided to use cloth to perform the experiment on instead of the fascia. This way it was ensured no undue damage was done to the cadaver.
After having placed the trocars, the laparoscope was inserted. One laparoscopic gripper was used to insert the cloth through the more distant trocar, the other was used to grasp the cloth through the closest trocar. The device was attached to the closest instrument, while holding a stainless steel ruler against the trocar (Figure 9.2). Simultaneous to the measurement

being taken, the ruler was used to measure the travelled distance relative to the trocar. The measuring angle was kept as constant as possible during use. Images displaying the procedure can be seen in the figures below.

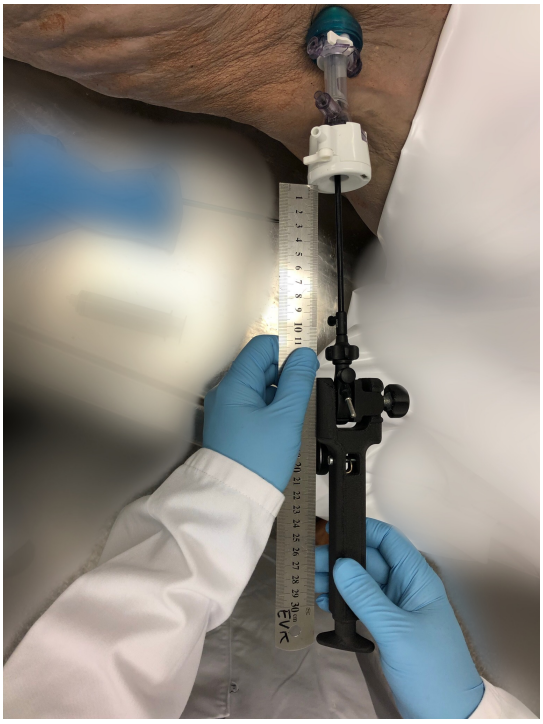


Figure 9.2: Experimental set-up with ruler to measure displacement relative to the trocar.

Figure 9.3: Experimental set-up with MINT attached to laparoscopic handle.

The measurements took less than one minute to execute, from the moment of attachment to detachment. The surgeons perceived MINT as easy and straight forward to use due to its resemblance with the well-known C-clamp. The device felt nice and sturdy while using it due to the weight of the material and the sleek and simple design. The turning knob was comfortable to operate, and sufficient clamping was easily achieved. Results were clear to read and measuring distance with the ruler was satisfactory. Although the design works adequately, it was chosen to make some finishing touches to ensure optimal use during further research. These will be elaborated below.

9.3. Improvements

As a result of the validation, some alterations were made to the design. Technical validation took place throughout the whole design process. As a result, several iterations were made during refinement of the design and have been described in Chapter 8. The clinical validation was executed with the final prototype. During this validation the usability of MINT was tested with clinical experts. The findings of this validation have lead to the last finishing touches of the device.

The main drawback of the prototype was having to use a separate ruler to measure the displacement of the fascia. The displacement of the device relative to the trocar was used to assess this value, as can be seen in the figures above. During the prior design phase, having to hold a ruler against the trocar seemed satisfactory to the clinical experts. Throughout the experiments they experienced this as awkward to use and rather impractical. As a result it was decided to seek a method that improves this aspect of using the device.

The solution was sought in designing a clamp for a thin (13mm) stainless steel ruler. This clip-on part will hold the ruler parallel to the device. At the start of the measurement the ruler will be placed against the trocar to measure the starting position. During use the ruler can slide through the holder and the new distance can be measured. This addition combines the two separate parts, making it easier to use without a set of extra hands. The figures below display the holder.

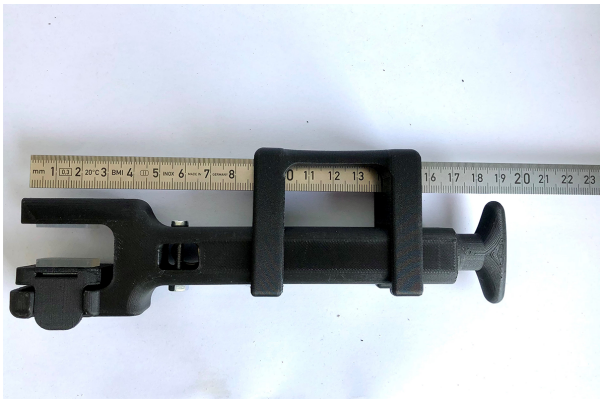


Figure 9.4: Side view of ruler clamp in use.

Figure 9.5: Back view of ruler clamp.

10

Discussion

The aim of this work was to develop a method that quantifies the closing forces during ventral hernia repair. A need for an objective assessment of the tension existing in the abdominal wall during hernia closure has been identified. It is believed that quantifying abdominal wall tension can act as a feasible adjunct to surgical decision making during herniorrhaphy [22]. MINT successfully enables objective assessment of fascial tension during MIS. Further research and development can lead to implementation in the OR. As a result, surgical outcomes and hernia recurrence rates could be improved, as excess tension is directly related to hernia recurrence [5].

The device's performance and functionality have been validated. A "proof of principle" in the OR was done to verify its feasibility and user-friendliness. Experiments have shown auspicious results, nevertheless some points of improvement have been found that can further enhance the performance and use of the device. For now, it can be stated that MINT serves as a promising prototype that can be used for further research on the assessment of abdominal wall tension during hernia repair.

In the following chapter the effectivity, safety, ease of use and manufacturability & assembly will be discussed. In addition, the limitations of this research will be defined and recommendations will be given for further research and improvement of the technique.

Effectivity

To fulfil the objective of this thesis, a real-time, accurate and reproducible measurement technique needed to be developed that can be used in the OR. By using elongation of the spring, real-time measurement is enabled during surgery, as no further calibration is needed. Technical validation showed that the device ensures sufficient clamping to withstand pulling forces of more than 170N, due to the silicon pads and the used mechanism. The magnitude of the applied forces during herniorrhaphy lies between 0N and 50N, thus the requirement is met with a safety margin [5], [27]. Measurements show an overestimation bias of the device. On average, the device measures a higher force than what is actually applied (1.7N on average, Appendix F). This difference is fairly consistent, and can be accounted for by the friction inside the shaft. A possible solution would be to lubricate the lumen to ensure smooth displacement of the spring when stretched. The MAPE is increased due to an outlier. Accuracy of the device is satisfactory, +/- 2%, indicating that the device generates reproducible measurements. The spring has a working range up to 65.26N, with a pretension

of 5.52N. Pretension is the tension that needs to be applied before elongation is initiated. During design pretension was taken into account. However, this is a difficult measure to implement, and it could have an effect on the scaling on the device. For this research, the accuracy and precision achieved was deemed sufficient.

In this research the focus was on finding a quantitative measure that provides information on the tension in the abdominal wall during hernia repair. Literature found on the subject shows that there is no standardised method that is being implemented in the OR [47]. In addition, no technique has been found that can be used during minimally invasive hernia repair. This thesis describes the first steps for implementation of MINT during MIS. Effectivity has been demonstrated in a human cadaver, yet a broader study will have to substantiate these conclusions. In addition, questions regarding the amount and location of points of attachment to the tissue remain unanswered and will have to be looked into. Approaches on this matter diversify [13], [46]. For now, this prototype serves as an effective starting point to measure abdominal wall tension during surgery.

Safety

Safety of both the user and the patient is a must. In addition, the device cannot cause any damage to the surgical instruments used. As a result of the cushioning effect of the silicon pads, it is ensured that the device will not damage the laparoscopic instrument. The silicon forms around the housing perfectly, ensuring rigid clamping without breakage. It was not possible to load the device to failure by hand. All sharp edges are obviated and loose parts are secured to ensure safe use.
During use, the rack of the handle will be secured, locking the jaws of the gripper in position. When the device is operated, the gripper will extend the tissue to the mid-line. As the surgeon will not exert forces larger than during regular minimally invasive repair (0-50N), the assumption can be made that no damage will be done to the tissue. In addition, it is believed that the gripper will slip off the tissue when high forces are applied, due to a lack of grip created by the jaws. Accordingly, the gripper will slip before it can damage the tissue. Further research will have to be done with real human tissue to substantiate this claim.

As part of the validation, the device went through the complete sterilisation cycle five times. Repeated technical validation proved that the performance of the sterilised device was not changed: sufficient clamping was still achieved and the device did not break during use. In addition, official reporting of the re-validation of the equipment showed that the materials reached sufficient temperatures during the cycle. Sensors were placed on the material in the thermal disinfection and steam sterilisation steps. This confirms disinfection processes achieve sufficient death rate of micro-organisms. The appearances of the sterilised housing and silicon pads were not altered to an alarming extent. Some dents are observed as a result of clamping inside the stainless steel sterilisation basket. The silicon sealant did not withstand the heat and deterioration was evident. An alternative turning knob out of SS will be used to enable sterilisation and improve assembly. It was not possible to assess structural changes of the materials used. Further research needs to be done to study if this material is safe to use for other medical applications, especially in vivo.

Ease of use

Through consistent collaboration with clinicians, user-friendliness was optimised. This collaboration resulted in a proof of principle that can be fixated around already existing instruments. Implementation of the measuring technique will be stimulated if surgeons can work with what they are used to. Clinical validation took place to assess its usability in the OR. This experiment showed promising results. The measurement could be executed within minutes, which enables smooth and quick implementation. Calibration is not needed, as this is already implemented in the design. Tevema claims that extension spring lifespan is almost unlimited, thus it is assumed that calibration will last. One of the main requirements is universal applicability. Due to the adjustable block with silicon cushions, several device thicknesses and shapes can be accommodated. Prior field research shows that laparoscopic handles used in hospitals will not exceed a thickness of $20mm$. If this is the case, the design can easily be adapted to accommodate thicker handles.
During the proof of principle, some points of improvement were identified. It was perceived as tedious to hold a separate ruler during measurement. This calls for an extra pair of hands, yet seems like an easy problem to solve. An addition to MINT was developed that holds the ruler up along the device. This addition seems promising, but has yet to be validated in the OR.

Manufacturability and assembly

It was chosen to focus mainly on rapid prototyping in this thesis. This makes manufacturing of the housing affordable and quick. Requirements regarding part count were not met: the device consists of more than 10 parts, including pins, nuts and bolts. This is rather high after consultation with sterilisation and clinical experts. Especially small parts such as the pins and bolts are easily lost and tedious to assemble. In addition, assembly is not possible without a hex key. Redesign needs to take place to reduce the part count and enable assembly solely by hand. This should be of high priority in the next steps of this research, as this will also increase ease of use and consequently ease of implementation. Quick fixes are permanently fixing several parts in place, such as the nut in the bottom of the C-clamp and the silicon pads, using sterilisation safe adhesives. When doing so, it needs to be kept in mind that small cracks and internal thread are difficult to clean. Considering that MINT will not enter the body, this might easily be overcome.

10.1. Limitations

Some limitations should be noted about the study. Firstly, only few materials for the housing were explored in this research. Other materials might be more suitable for this application, but have not been explored due to what was available and the given time frame. Secondly, MINT was not loaded until failure. Accordingly, no data is available on when the device will break. It is assumed that the device will not be loaded in these extreme conditions during regular use, hence this was left out of consideration in this thesis. Nevertheless, this may be a useful variable to explore in the future, especially when evaluating the effects sterilisation has on the materials used. Resources to assess if the material's properties have changed, as a result of sterilisation, were not available. Therefore, it was only possible to validate that "Onyx" resists high temperatures and chemicals during five sterilisation cycles without alarming effects. This validation was done manually, but more extensive testing, with regard to material properties such as yield strength and porosity, could give more insights. Furthermore, MIS was not replicated accurately during clinical validation. The cadaver used for clinical validation had been used many times before. This caused air to leak through the incisions, impeding the functional pneumoperitoneum. Lastly, a cloth was used to grasp, rather than actual human

tissue. Using human tissue could enable testing how much pulling force can be applied before slippage of the gripper jaws occurs. Consequently, these limitations might be reflected in the results of this study.

10.2. Recommendations

Results indicate a promising future for MINT. For further research, some changes are recommended based on the instrument design and the testing method. Firstly, improvements should be made to the design with regard to part count and assembly. Also, more research will be done to further assess its applicability in minimally invasive hernia surgery. To do so, a follow-up study of larger scale is being set-up to prove functionality of the device. Remaining questions with regard to number and location of attachment points should be answered to further improve this measuring technique. Implementation during robot assisted surgery and open surgery could be explored, to assess applicability to all types of hernia repair. Most importantly, enough data will have to be collected from real patients over the years, to assess if these measurements can act as a feasible adjunct to intra-operative decision making.

11

Conclusion

Tension has been at the forefront of hernia surgery research for a long time and most techniques aim to decrease tension in the abdominal wall. Even though tension is rarely measured intra-operatively, it remains an important, yet non-quantified variable during defect closure. Reproducible measurements of fascial forces during hernia repair could be valuable in risk stratification of hernia recurrence and intra-operative decision making. In order to implement tension measurements in the repair of abdominal wall hernia defects, the development of MINT is a first step in its realisation. This method is presented to accurately and safely quantify closing forces during laparoscopic herniorrhaphy. This thesis presents a proof of principle for minimally invasive tensiometry. Functionality is substantiated through several technical experiments. Implementation during laparoscopic procedure has been assessed during clinical validation in a human cadaver. Although results are promising, further research has yet to prove functionality and ease of use during real procedures. Results indicate that the prototype withstands at least five cycles of steam sterilisation. Further studies have to be done to prove safety of ”Onyx” for medical devices, as this was not possible within the scope of this project. MINT serves as a promising method that can be utilised for further research on the assessment of abdominal wall tension during herniorrhaphy and further research is being initiated.

Appendices

A

Literature Review

From September to November 2020 a literature review was done to explore what literature was available on the assessment of tension during ventral hernia repair. Here, an overview of the measurement techniques can be found. For more background information the literature review may be consulted [49].

Study	Measurement Used	Measured Value	Subject	Attachment	Type of specimen
Dubay et al. (2005)	Instron tensiometer	Yield strength, yield energy, yield extension and stiffness	Rat	Mounted into load frame using pneumatic graspers	Fascial strips
Dubay et al. (2006)	Instron tensiometer	Breaking strength, tensile strength, toughness, elongation, stiffness	Rat	Mounted into load frame using pneumatic graspers	Fascial strips (I-shaped)
Van Os et al.(2006)	Dynamometer	Stress-strain behavior established with stress-strain curves	Based on human	\	50x50 mm fascial square linea alba located in the midline of the specimen
Ishida et al. (2011)	Dynamometer	Breaking strength	Cadaver (human)	vertical and horizontal 0-nylon sutures connected to dynamometer	\
Förstemann et al. (2011)	Instron tensiometer	Stress-strain behavior established with stress-strain curves	Cadaver (human)	wider ends of samples were wrapped with paper	10x35 mm fascia taken from linea alba
Lyons et al. (2014)	Uniaxial: tensile testing machine Biaxial: custom equi-force biaxial testing rig and pulley system connected to a testing machine. DIC strain analysis	Stress-strain behavior established with stress-strain curves	Cadaver (porcine)	Uniaxial: jigs covered in P60 sandpaper. Biaxial: jig used to ensure equal placement of each edge	Uniaxial: Rectangular specimens (16–66x 12–20mm) Biaxial: square samples (39.5x39.5mm)
Culbertson et al. (2016)	Instron tensiometer	Breaking strength, tensile strength, yield strength, yield energy, stiffness	Rat	Mounted into load frame using pneumatic graspers	10 × 30-mm transverse strips left internal oblique muscle sheet
Kroese et al. (2017)	Tensile testing machine	Stress-strain behavior established with stress-strain curves	Human	\	
Van Wingerden et al. (2020)	Microstrain® displacement sensor	Elongation	Human	Surgical forceps used to apply force	4x4 cm sample from anterior and posterior rectus sheath
Le Ruyet et al. (2020)	DIC	Strain fields	Cadaver (Human)	White paint on anterior rectus sheath and on external surface of external oblique muscle, random black pattern	

Table 1: Techniques to assess biomechanical behavior and properties

Study	Measurement Used	Unit	Subject	Population	Attachment	Levels or Points
Reingruber et al. (2001)	Tensiometer	kp	Intraoperative	533 patients	Kocher clamps	1 point at midline
Peiper et al. (2001)	Wound retractor w. strain gauges & potentiometric distance sensor	N	Intraoperative	20 patients	Branches fixed to rectus sheath	1 point
Amorim et al. (2007)	Analog dynamometer and pachymeter	kgf to traction index (kgf/cm)	Cadaver (Human)	20 cadavers	Traction loops (Nylon 00), mobilized 10 mm in medial direction	16 points
Van Ramhorst et al. (2008)	New device measuring force needed to indent distance	N/mm	Cadaver (Human)	2 cadavers	Directly on the skin	6 points
Dragu et al. (2009)	Analog dynamometer	kp	Intraoperative	23 patients	Kocher clamps	1 point at midline
Silveira et al. (2010)	Analog dynamometer and pachymeter	kg to traction index kg/cm	Cadaver (Human)	24 male	Traction loops (Nylon 2-0), mobilized 10 mm in medial direction	14 points at 7 levels
Van Ramhorst et al. (2011)	Device measuring force needed to indent distance	N/mm	Cadaver (Human) and healthy volunteers	14 cadavers, 42 volunteers	Directly on the skin	6 points
Barbosa et al. (2014)	Analog dynamometer	N to traction index N/cm	Cadaver (Human)	20 cadavers	Traction loops (Nylon 2-0), mobilized to midline	8 points
Bradley et al. (2015)	Calibrated tension gage (11 mm port)	dag	Intraoperative	64 patients	Suture on left crus and hooks of tension gage opposite on right crus	1 point
Afifi et al. (2017)	Analog dynamometer	gf	Intraoperative	26 patients	Allis clamp	3 points
Hope et al. (2018)	Digital fish scale and analog linear spring scale	lb	Intraoperative	59 patients	Kocher clamps	1 point of maximum width on two sides
Majumder et al. (2020)	Pulley aparatus	gf	Cadaver (Human)	15 fresh torsos	Kocher or towel clamp	3 points along midline
Roca et al. (2018)	Dynamometer to measure force and distance	N, mm	Cadaver (Porcine)	/	Tines introduced to holes	Multiple points along incision
Tenzel et al. (2019)	Tensiometer	lb	Intraoperative	11 patients	Kocher clamp	1 point at midline
Tenzel et al. (2019)	Analog linear springscale	lb	Intraoperative	45 patients	Kocher clamp	1 point at max. width on two sides
Parikh et al. (2020)	Tensiometer	lb	Intraoperative	30 patients	Kocher clamp	1 point at max. width on two sides
Levy et al. (2020)	Analog linear springscale	N	Cadaver (Human)	4 torsos	Kocher clamp	3 points

Table 2: Techniques used to assess abdominal wall tension

B

Measuring Techniques

How can tension be measured?

The first step in this design process was figuring out *what* it is we want to measure and how this can be assessed. Research was done on methods to quantify tension. A basic understanding was created on how these methods assess tension. Afterwards the drawbacks of each were listed and a decision was made based on their feasibility in this clinical setting.

Strain Gauge

Microstrain sensor Tension can be measured relating to strain. Van Wingerden et al. used microstrain sensor attached to specimens of the abdominal wall to assess resistance changes due to deformation [54]. Specimens are loaded in tension. This was used to assess the elastic behavior of the anterior and posterior rectus sheaths.

Skin tensiometer Paul et al. use a strain element force sensor with a sensing range of 0–10 newton's to assess the reaction force to force applied to the skin [34]. Simplified, two pins are used to push two points on the skin away from eachother and the reaction force is measured using a strain gauge.

Electrical Impedance

Tendon and ligaments as a strain gauge West et al. found that the electrical properties of tendons change as a result of stretching. Tendon has the potential to act as it's own strain gauge [53]. Suguma et al. found a strong correlation between the tension of the ligament and the force applied to the ligament. Electrical impedance was used to measure tendon tension [44]. The assumption can be made that fascia are composed of similar material as tendons and ligament. Research can be done to assess if this principle can be used in fascia too.

Intra abdominal pressure

Indentation van Ramhorst et al. have developed a device that relates IAP to abdominal wall tension. The device measures abdominal wall tension by measuring force and distance. The abdominal wall is indented using the device and the force needed to do so is assessed. Hardness of the abdomen which can be related to the tension in the abdominal wall (linear relationship between hardness and tensile strength) [51], [52].

Strain Gauge	Force gauge	Image based	Electrical Impedence
Tissue attachment	Tissue attachment laparoscopically	Tissue Access: pattern or marker on or in tissue	Tissue sample
Accuracy	Monitoring elongation	Accuracy	Assumption needs to be researched: fascia equal to tendon/ligament
Sterilisation		Monitoring several variables (pressure, elongation etc)	Sterilisation
Wires		Wires and equipment	Wires and equipment
Calibration		No real time measurements	No real time measurements
		Difficult clinical setting	Difficulty clinical setting
		Calibration	Calibration
		Tissue properties need to be homogeneous and equal per person	Small cross sectional area
			Tissue properties need to be homogeneous and equal per person
			First validation before it can be used

Table B.1: Drawbacks per method to assess feasibility.

Visual based assessment

Digital Image based Correlation (DIC) Le Ruyet et al. and Lyons et al. have used DIC based methods to assess strain fields of the abdominal wall. A pattern is created on the surface and cameras are used to investigate the displacement as a result of increasing the pressure in the abdomen or stretching the abdominal wall [26], [28].

Speckle tracking Ultrasound can be used to measure displacement in heart Speckle tracking echocardiography. The necessary images are acquired on the echocardiography machine and stored and transferred to a workstation. Software is then used to analyze the images and to generate the strain data [4].

Force Gauge

Analog force gauge Several methods have been found in literature that used linear spring based scales to assess tension during open hernia repair. Bradley et al. even used a custom made tension gauge to assess tension during hiatal hernia laparoscopically [7]. Navaratne et al. used a similar approach to assess tension of crural closure during hiatal hernia repair [31].

Digital force gauge Digital spring scales can be used the same way as described before.

Drawbacks per method were assessed and set out, these can be seen in table B.1. Based on this feasibility assessment, it was chosen to go with the force gauge method. This method seems the most promising within the given time-frame and resources.

C

Design Solutions

As it was chosen to develop an add-on for a laparoscopic instrument a design tree was created to guide the brainstorming phase. Two attachment-styles were identified: to the handle and to the shaft. Several methods were sought within these two styles and quick conceptual sketches were made.

The two forms of attachment were assessed using the relevant set-up requirements. Some requirements were left out as they depend on more specialised design, which is not relevant yet (such as sterility, assembly and requirements with regard to the force sensing). The criteria were listed and each “concept” was assessed using a Harris Profile in consultation with clinical experts (Figure C.1).

Attachment to the shaft is favored when looking at easy implementation, attachment, detachment, universal applicability and reproducibility, as the shape of the shaft is the exact same for every laparoscopic instrument. This enables easy use that will be the same for every surgeon. The handle shape and size depends on the type of instrument supplier the hospital uses, thus the design will have to adapt to these shapes and will thus be used slightly differently depending on the type of handle.
Attachment to the handle is favored when looking at safety. Safety is inhibited when the shaft is damaged. If the shaft is damaged, the diathermy can be obstructed, which can cause negative outcomes for both the patient and the surgeon. In addition, it is believed that the shaft is more fragile than the handle, and thus more susceptible to breakage.

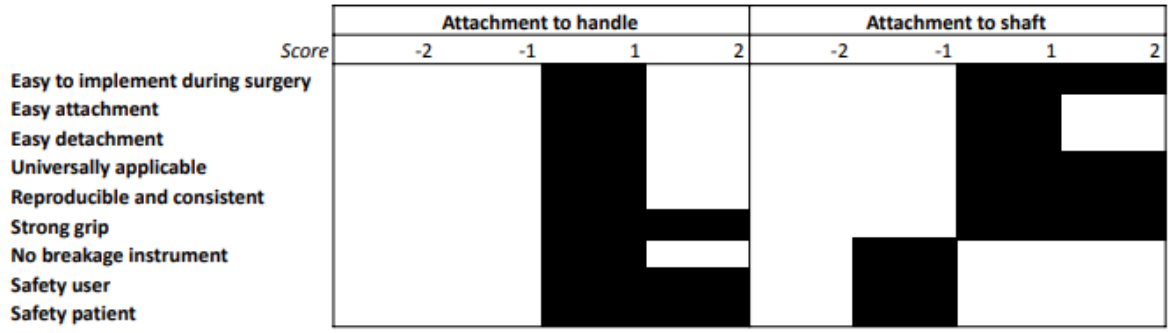
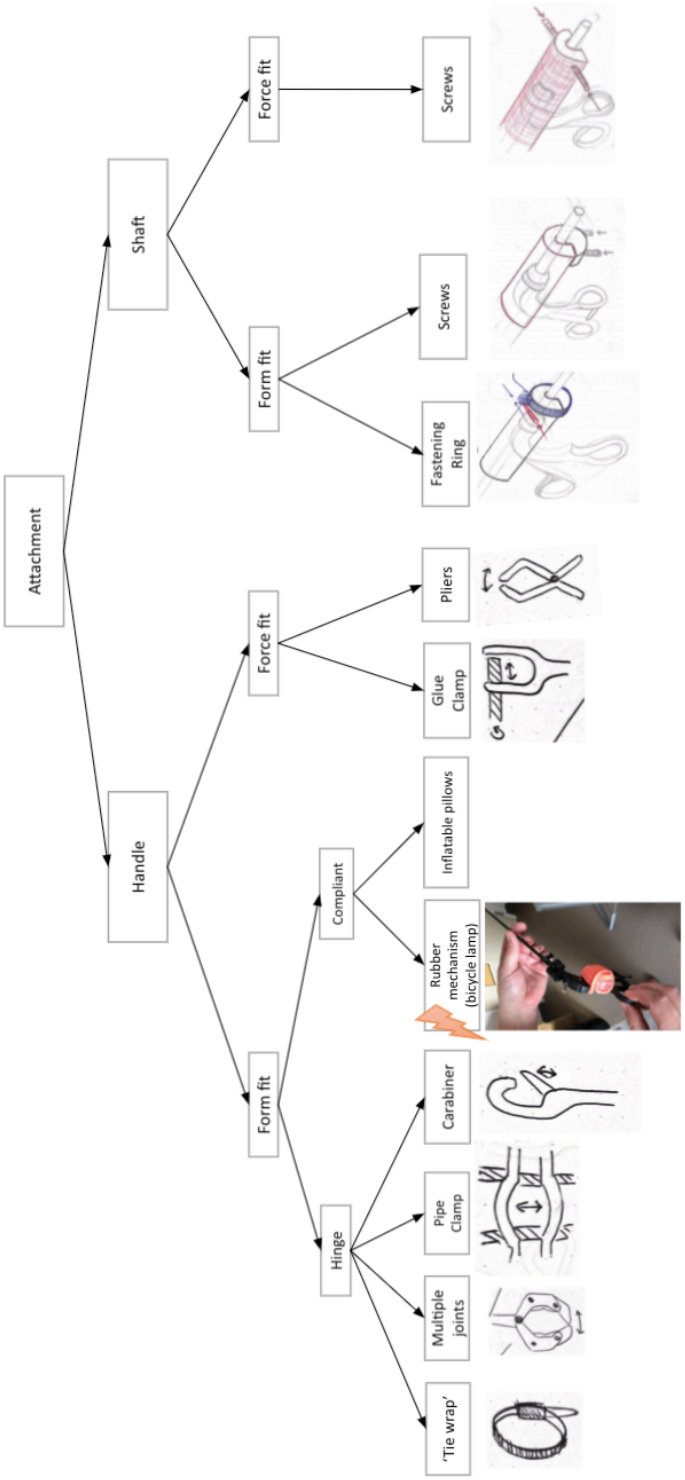


Figure C.1: Harris profile assessing the two attachment styles.

In this application, safety is more important than ease of use. As attachment to the handle still

scores rather positively on ease of use, this approach is preferred.



D

Spring Selection

Search

- ☒ F (N): 50 - 70
- ☒ Lo (mm): 11 - 50
- ☒ Sn (mm): 30 - 70
- ☒ VST of RVS: RVS

Alles wissen

C (N/mm)

d

Di (mm)

d (mm)

Dm (mm)

Du (mm)

10 artikel(en) volgorde 25

Artikelnummer	Prijsgroep	d (mm)	Dm (mm)	Du (mm)	Lo (mm)	Lk (mm)	Fo (N)	C (N/mm)	Sn (mm)	F (N)	VST of RVS	Verwachte levertijd
T42000	H	1.40	13.60	15.00	34.90	12.90	5.52		36.85	65.26	RVS	1-3 dagen
T41600	F	1.00	6.00	7.00	49.00	40.00	6.53		47.77	56.15	RVS	1-3 dagen
T42010	H	1.40	13.60	15.00	43.30	21.30	5.52		63.67	65.26	RVS	1-3 dagen
T41720	G	1.10	6.40	7.50	37.10	27.60	8.14		30.12	69.32	RVS	1-3 dagen
T41565C	F	1.00	5.00	6.00	47.40	40.20	8.39	1.79	33.04	67.40	RVS	1-3 dagen
T41565D	F	1.00	5.00	6.00	48.40	41.20	8.39	1.74	33.89	67.40	RVS	1-3 dagen
T41611A	F	1.00	6.30	7.30	34.40	24.90	6.08	1.47	32.31	53.47	RVS	1-3 dagen
T41611B	F	1.00	6.30	7.30	49.40	39.90	6.08	0.90	52.62	53.47	RVS	1-3 dagen
T41916A	H	1.25	9.95	11.20	46.50	30.80	6.39	0.92	63.33	64.41	RVS	1-3 dagen
T41918	H	1.25	12.45	13.70	34.20	14.00	4.26	1.08	43.62	51.45	RVS	1-3 dagen

Search

- ☒ F (N): 50 - 70
- ☒ Lo (mm): 11 - 50
- ☒ Sn (mm): 30 - 70
- ☒ VST of RVS: RVS

Alles wissen

C (N/mm)

d

Di (mm)

d (mm)

Dm (mm)

Du (mm)

10 artikel(en) volgorde 25

Artikelnummer	Prijsgroep	d (mm)	Dm (mm)	Du (mm)	Lo (mm)	Lk (mm)	Fo (N)	C (N/mm)	Sn (mm)	F (N)	VST of RVS	Verwachte levertijd
T42000	H	1.40	13.60	15.00	34.90	12.90	5.52		36.85	65.26	RVS	1-3 dagen
T41600	F	1.00	6.00	7.00	49.00	40.00	6.53		47.77	56.15	RVS	1-3 dagen
T42010	H	1.40	13.60	15.00	43.30	21.30	5.52		63.67	65.26	RVS	1-3 dagen
T41720	G	1.10	6.40	7.50	37.10	27.60	8.14		30.12	69.32	RVS	1-3 dagen
T41565C	F	1.00	5.00	6.00	47.40	40.20	8.39	1.79	33.04	67.40	RVS	1-3 dagen
T41565D	F	1.00	5.00	6.00	48.40	41.20	8.39	1.74	33.89	67.40	RVS	1-3 dagen
T41611A	F	1.00	6.30	7.30	34.40	24.90	6.08	1.47	32.31	53.47	RVS	1-3 dagen
T41611B	F	1.00	6.30	7.30	49.40	39.90	6.08	0.90	52.62	53.47	RVS	1-3 dagen
T41916A	H	1.25	9.95	11.20	46.50	30.80	6.39	0.92	63.33	64.41	RVS	1-3 dagen
T41918	H	1.25	12.45	13.70	34.20	14.00	4.26	1.08	43.62	51.45	RVS	1-3 dagen

E

Material review and printer settings

Housing

The housing was 3D printed using PLA, tough PLA and Onyx. PLA and tough PLA were deemed not suited due to their insufficient thermal properties. Onyx was selected based on it's high heat resistance (heat deflection temperature $145°C$), suited for medical applications [2], [19]. In addition, due to the carbon fibre placement throughout the material, the mechanical properties are outstanding.

Inlay

Several types of rubber and silicon were ordered to assess which created the best grip. Materials were selected based on their thermal properties. The selection criterion used was that they need to be able to withstand high temperatures used during sterilisation (120-140 degrees Celsius). A list of the selected materials can be seen below with the pulling force they allowed.

Table E.1: maximum pulling force per inlay material.

	Max Pulling force with 1V clamping(N)
EPDM (Rubbermagazijn)	slipped before measurement could be taken
Silicone plaatrubber (Rubbermagazijn)	slipped before measurement could be taken
EcoFlex (Smooth-on)	slipped before measurement could be taken
SORTA-Clear 37 (Smooth-on)	100+ N
Dragon-Skin 10 (Smooth-on)	34N

For the test set-up we used a SingeTact force sensor (8mm diameter, 100N \22lb force), which was placed between the inlay and the device. Clamping was kept constant (1V) to assess how much pulling force can be achieved with the same magnitude of clamping force. This way we could see how much friction was created. The material that created the tightest grip was chosen.
Both EPDM and Silicone rubber from Rubbermagazijn slipped before the force gauge could measure a pulling force. Both materials were quite smooth and thus did not create enough friction. In addition, they were quite thin and hard and did not create a cushioning effect. EcoFlex and Dragon skin created friction with the handle, but were too soft. As a result they were pulled out of the sockets due to the pulling force, as can be seen in figure E.2, which caused the clamp to slide and loose grip. SORTA-Clear performed the best during the experiments: it stayed in place and enabled tight clamping. More than $100N$ could be

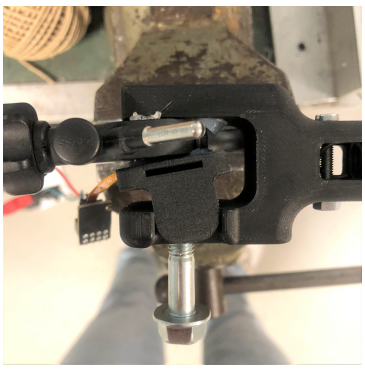


Figure E.1: Dragon Skin ™(shore 10) silicon pads slip and create crooked clamping as a result of the soft material.

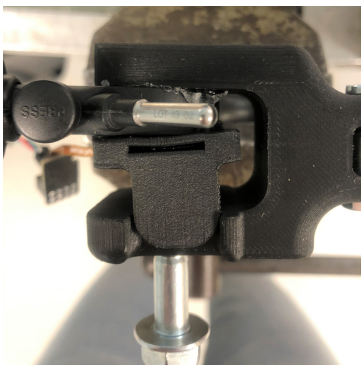


Figure E.2: Eco-Flex ™silicon pads are squashed due to clamping and create insufficient clamping.

applied without slipping. Accordingly this material was chosen for the design. SORTA-Clear ™is certified food safe and can be treated at temperatures up to 204 degrees Celsius.

All Technical Data

	Ecoflex™ GEL	*Dragon Skin™ 10 MEDIUM*	*SORTA-Clear™ 37*
Product Type	Silicone Rubber - Platinum Cure Skin Safe FX Materials	Silicone Rubber - Platinum Cure Flame Rated Materials	Silicone Rubber - Platinum Cure
Mixed Viscosity	9,300 cps	23,000 cps	35,000 cps
Mix Ratio By Volume	1A:1B	1A:1B	1A:1B
Mix Ratio By Weight	1A:1B	1A:1B	1A:1B
Pot Life	15 minutes	20 minutes	25 minutes
Cure Time	2 hours	5 hours	4 hours
Shore A Hardness	000-35	10	37
Specific Gravity	0.98 g/cc	1.07 g/cc	1.08 g/cc
Specific Volume	28 cu. in./lb.	25.8 cu. in./lb.	25.6 cu. in./lb.
Color	Translucent	Translucent	Water White Translucent
Die B Tear Strength	—	102 pli	105 pli
Tensile Strength	—	475 psi	600 psi
Elongation @ Break	>1000 %	1,000 %	400 %
100% Modulus	—	22 psi	90 psi
Shrinkage	<.001 in. / in.	<.001 in. / in.	<.001 in. / in.
Useful Temperature (min)	—	-65 °F	—
Useful Temperature (max)	—	450 °F	—
Refractive Index	1.40451 nm	—	—

Figure E.3: Technical data on three materials from Smooth-on.

Printer settings

MINT is printed using MarkTwo by Markforged. This printer is able to place continuous fibers throughout the part using CFR (continuous fiber reinforcement). Onyx is used, which is nylon (PA-12) reinforced with carbon fibers. Not only are chopped fibers distributed throughout the material, continuous fibers are also placed along the outer shells of the device to even further strengthen the part. The images below illustrate fiber placement.

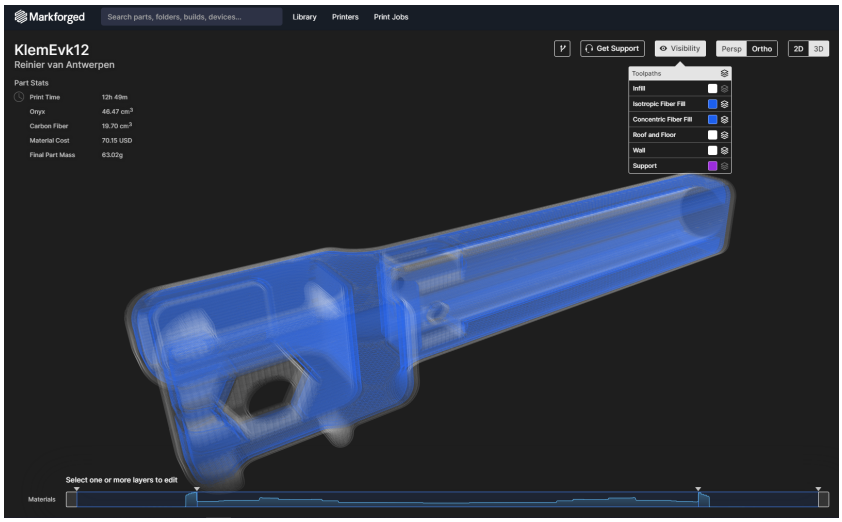


Figure E.4: Image displaying both concentric and isotropic fiber fill.

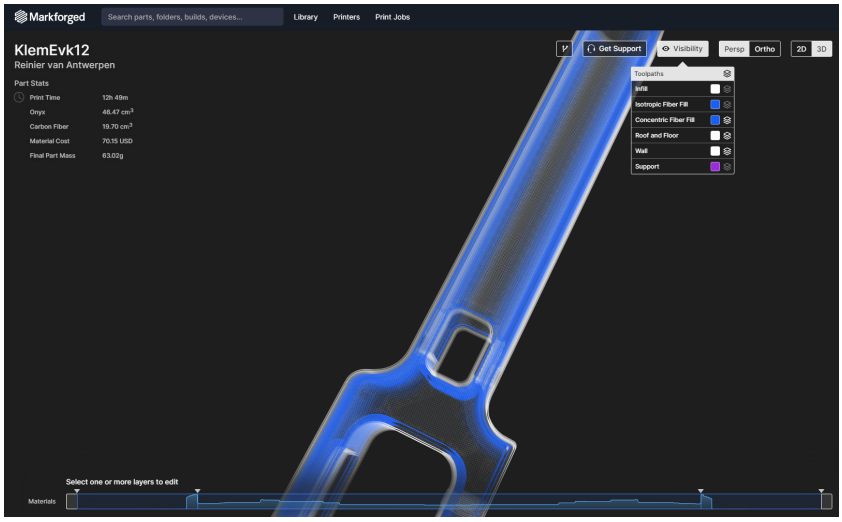


Figure E.5: Image displaying concentric fiber fill.

The default settings are used when printing with Onyx. A layer thickness of 0.125mm is used throughout the entire part. Two concentric fiber layers are placed along the perimeter of the part, as can be seen in Figure E.5 and Figure E.6. In addition, the outermost layers contain isotropic fiber fill, to make sure all sides are filled with carbon fiber. This can be seen in Figures E.7 and E.8. Figure E.4 illustrated all fiber placement. The other parts (moving block and ruler clamp) only contain chopped fiber and concentric fiber fill.

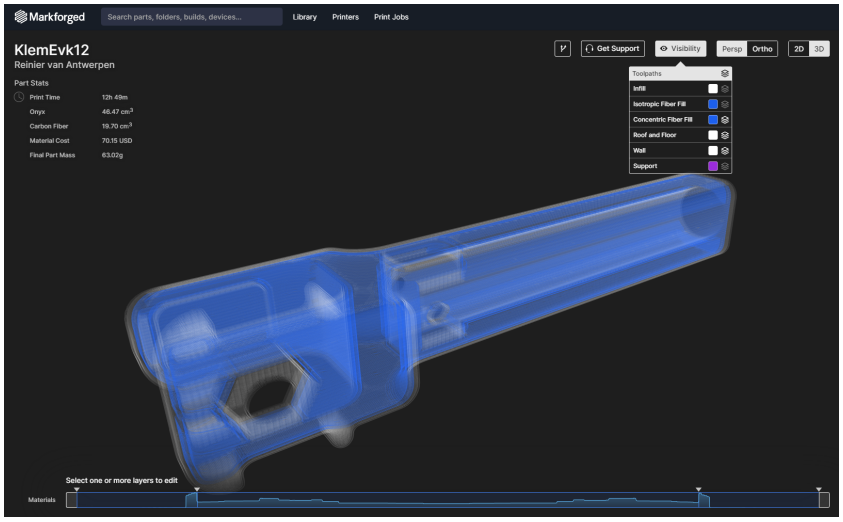


Figure E.6: Image displaying concentric fiber fill.

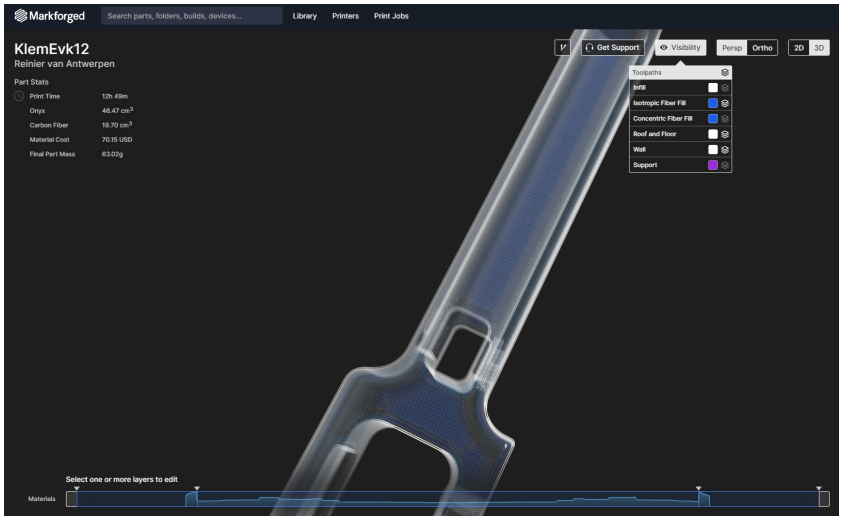


Figure E.7: Image displaying isotropic fiber fill.

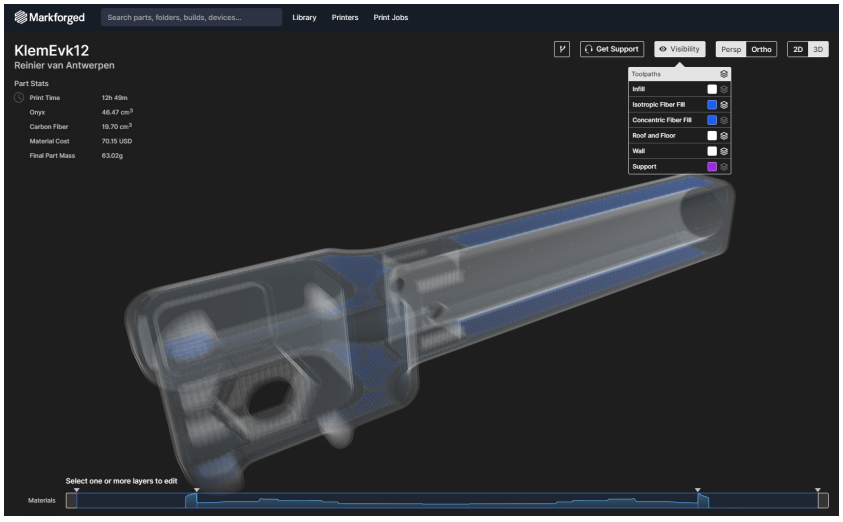


Figure E.8: Image displaying isotropic fiber fill.

F

Validation Data

Calibration force sensor

In order for the sensor to be used it had to be calibrated. During the experiments a SingleTact sensor (8mm diameter, 100N/22lb force) was used. The table below displays the outcomes and formula used to convert voltage (V) to force (N).

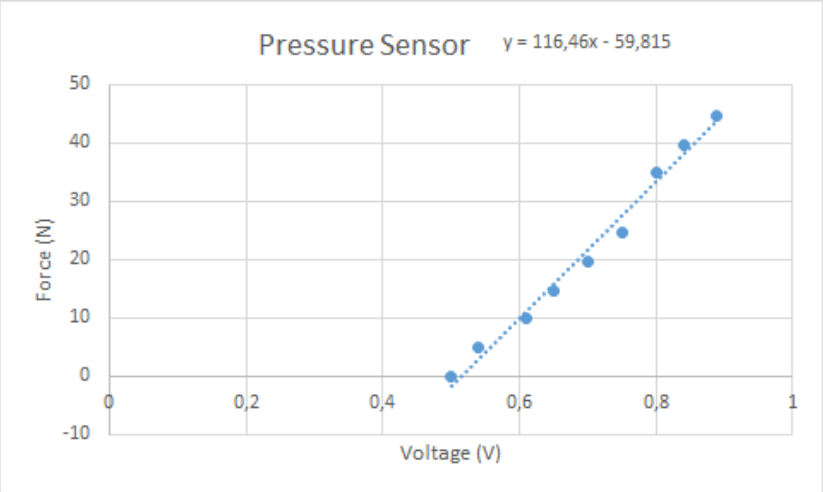


Figure F.1: Calibration force sensor voltage to Newton.

Accuracy and precision

To assess the device's performance it's accuracy and precision needed to be validated. The device was clamped and a force gauge (0-50N) was used to measure it's accuracy. Measurements were repeated three times, the set-up is pictured in the figure. To assess the accuracy of the device the handle was attached to a force gauge. Tension was applied to the device and the corresponding measured value on the force gauge was documented. Each measurement was repeated three times, after which the force was increased with 5N on the handle. Results can be seen in the table below. The error, absolute error, absolute percentage error (APE) and mean absolute percentage error (MAPE) were calculated in Excel. Lastly, the precision is expressed in absolute percentage error as well.

Figure F.2: Assessment of accuracy using force gauge.

Figure F.3: Accuracy and precision expressed in APE.

Force Device (N)	Force Gauge (N)	Error (N)	Abs Error (N)	APE (%)
20	18,8	-1,2	1,2	6,38297872
20	18,8	-1,2	1,2	6,38297872
20	18	-2	2	11,1111111
25	23	-2	2	8,69565217
25	23,4	-1,6	1,6	6,83760684
25	24	-1	1	4,16666667
30	28	-2	2	7,14285714
30	28,4	-1,6	1,6	5,63380282
30	28,5	-1,5	1,5	5,26315789
35	34	-1	1	2,94117647
35	33,8	-1,2	1,2	3,55029586
35	33	-2	2	6,06060606
40	37,8	-2,2	2,2	5,82010582
40	37,9	-2,1	2,1	5,5408971
40	38	-2	2	5,26315789
45	43	-2	2	4,65116279
45	43,2	-1,8	1,8	4,16666667
45	43	-2	2	4,65116279
50	48	-2	2	4,16666667
50	49	-1	1	2,04081633
50	48	-2	2	4,16666667

Accuracy in MAPE (APE)	5,45886634
Precision (SD of APE)	1,98902301

G

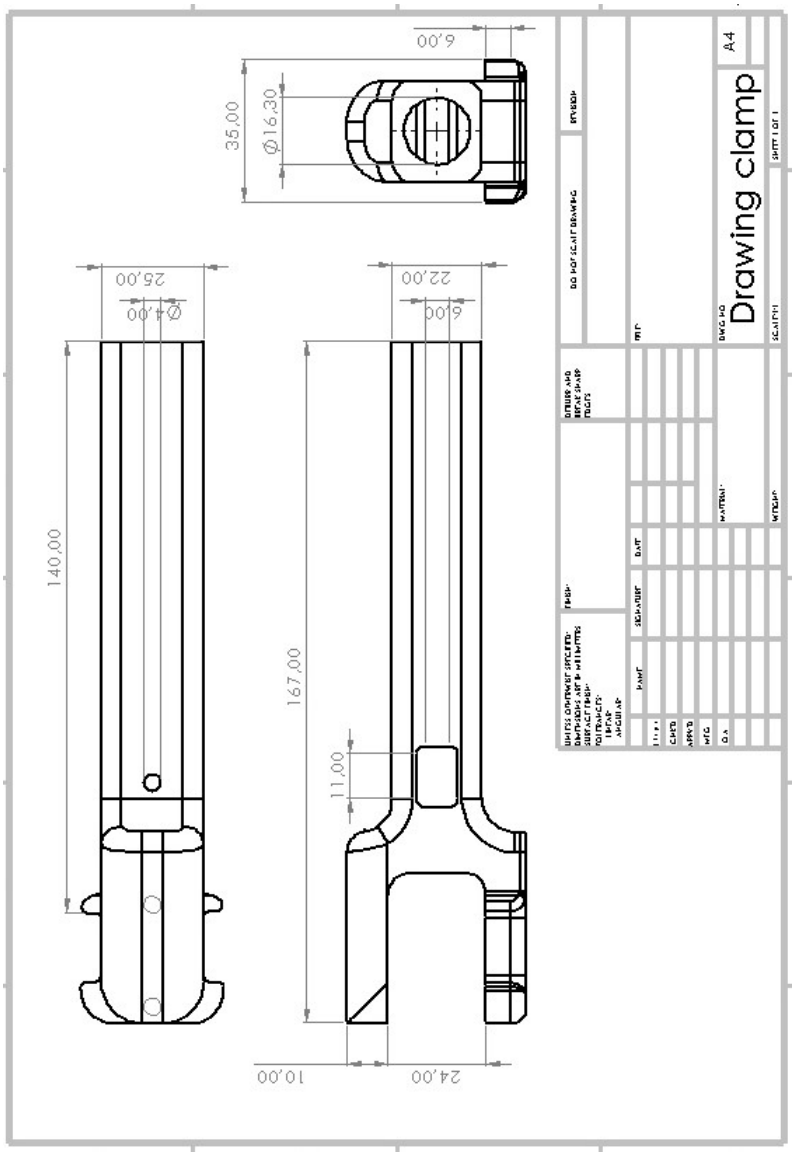
Parts and Tools

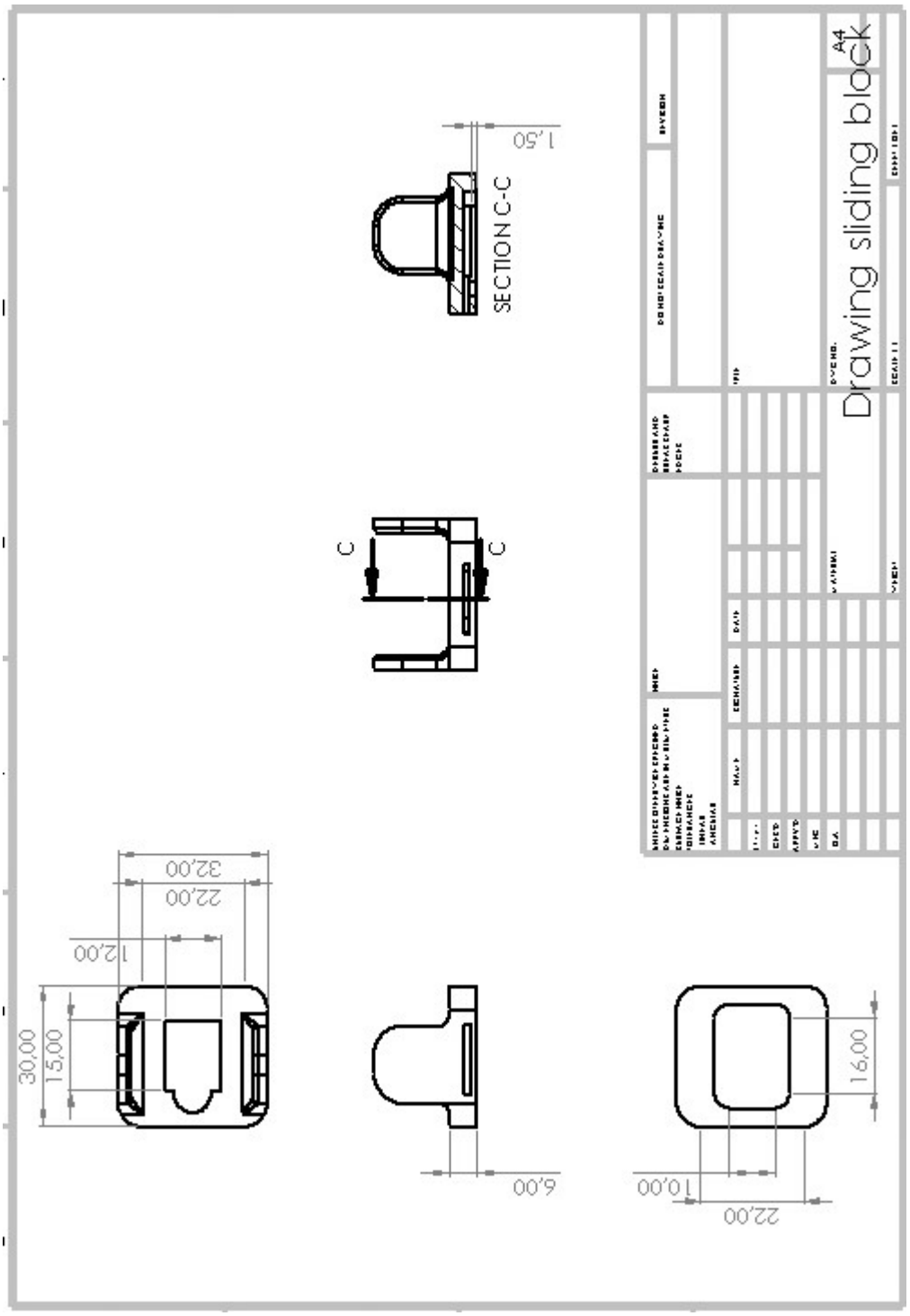
Instructions can be found in the ”Instruction manual”. The figure below illustrates the separate parts.

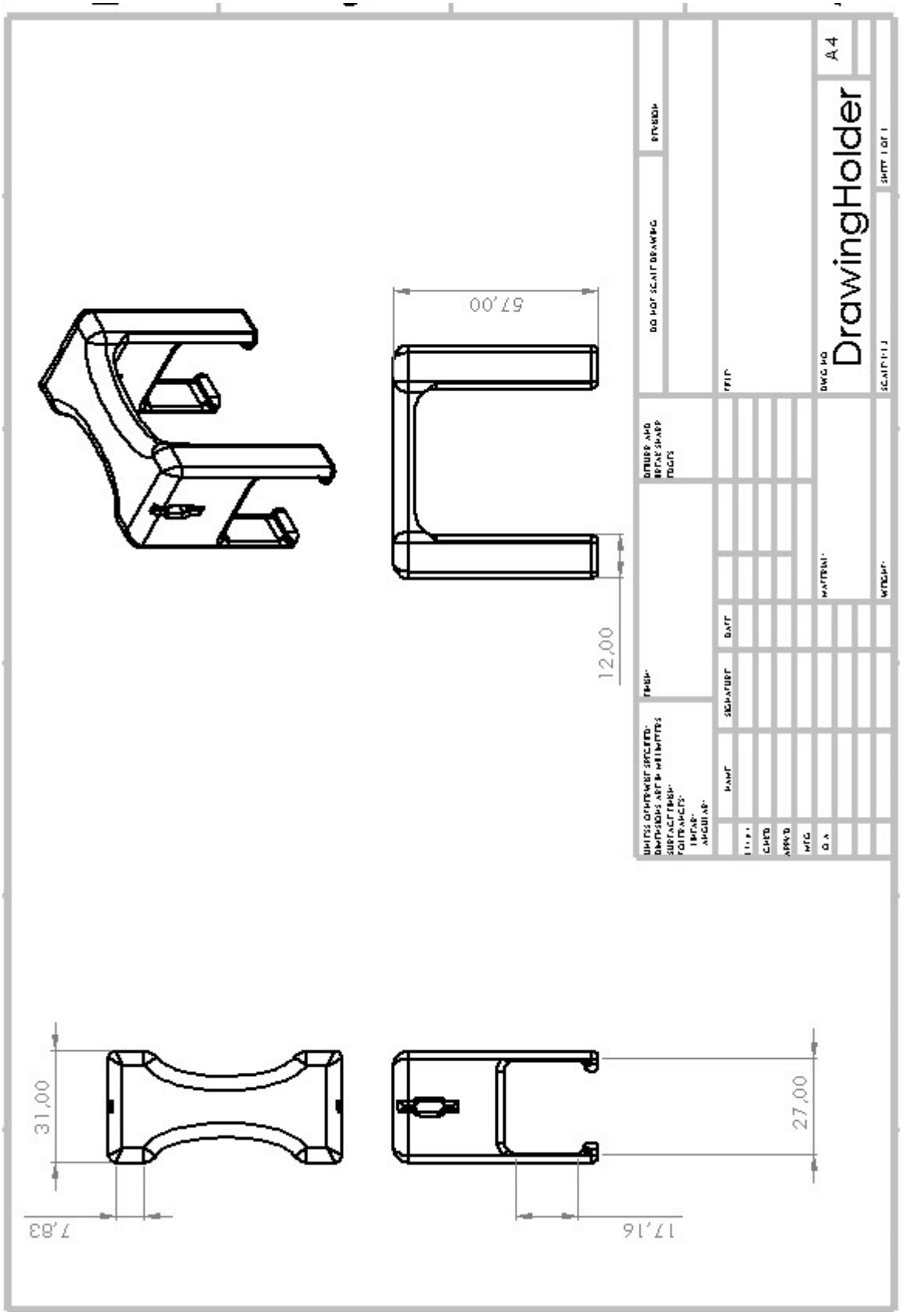
Figure G.1: All separate parts of MINT.

H

General dimensions MINT




SECTION C-C
1,50
C
C
32,00
22,00
12,00
30,00
15,00
6,00
22,00
10,00
16,00
Drawing sliding block
A4


57,00
12,00
31,00
7,83
27,00
17,16
DrawingHolder
A4

Bibliography

[1] *A Complete Laparoscopic Portfolio*. URL: https://www.aesculapusa.com/.

[2] ACT Team. *HP Internal Effect of different sterilization methods on MJF parts*. Tech. rep. 2018.

[3] Carlos Roberto Amorim et al. “Tensile strength of the posterior and anterior layer of the rectus abdominis muscle sheath in cadavers.” In: *Acta Cirúrgica Brasileira* 22.4 (2007), pp. 255–259. DOI: 10.1590/s0102-86502007000400005.

[4] Manish Bansal and Ravi R. Kasliwal. “How do I do it? Speckle-tracking echocardiography”. In: *Indian Heart Journal* 65.1 (Jan. 2013), pp. 117–123. DOI: 10.1016/J.IHJ.2012.12.004.

[5] M. V.J. Barbosa et al. “Improving tension decrease in components separation technique”. In: *Hernia* 18.1 (2014), pp. 123–129. ISSN: 12654906. DOI: 10.1007/s10029-013-1094-7.

[6] A. Bournias Varotsis. *Introduction to FDM 3D printing | 3D Hubs*. URL: https://www.3dhubs.com/.

[7] Daniel Davila Bradley et al. “Assessment and reduction of diaphragmatic tension during hiatal hernia repair”. In: *Surgical Endoscopy* 29.4 (2015), pp. 796–804. ISSN: 14322218. DOI: 10.1007/s00464-014-3744-y.

[8] E.J. Culbertson et al. “Reversibility of abdominal wall atrophy and fibrosis after primary or mesh herniorrhaphy”. In: *Physiology & behavior* 176.1 (2016), pp. 139–148. DOI: 10.1016/j.physbeh.2017.03.040.

[9] Jorge Daes. “Minimally Invasive Surgical Techniques for Inguinal Hernia Repair: The Extended-View Totally Extraperitoneal Approach (eTEP)”. In: *The SAGES Manual of Hernia Surgery*. Springer International Publishing, 2019, pp. 449–460. DOI: 10.1007/978-3-319-78411-3{_}33.

[10] Tammo S. De Vries Reilingh et al. “”Components separation technique” for the repair of large abdominal wall hernias”. In: *Journal of the American College of Surgeons* 196.1 (Jan. 2003), pp. 32–37. ISSN: 10727515. DOI: 10.1016/S1072-7515(02)01478-3.

[11] Charan Donkor et al. “Current perspectives in robotic hernia repair”. In: *Robotic Surgery: Research and Reviews* Volume 4 (May 2017), pp. 57–67. ISSN: 2324-5344. DOI: 10.2147/rsrr.s101809. URL: https://pubmed-ncbi-nlm-nih-gov.tudelft.idm.oclc.org/30697564/.

[12] Dr. Marc Zaré. *Ventral Or Incisional Hernia Repair San Jose*. URL: https://www.marczaremd.com/.

[13] Adrian Dragu et al. “Tensiometry as a decision tool for abdominal wall reconstruction with component separation”. In: *World Journal of Surgery* 33.6 (2009), pp. 1174–1180. ISSN: 03642313. DOI: 10.1007/s00268-009-9991-8.

[14] David Earle et al. *Laparoscopic Ventral Hernia Repair Information - SAGES*. URL: https://www.sages.org/publications/patient-information/patient-information-for-laparoscopic-ventral-hernia-repair-from-sages/.

[15] Erasmus University Medical Center Rotterdam. *Over AnubiFIX | AnubiFIX*. URL: http://www.anubifix.com/.

[16] T. Foerstemann et al. “Forces and deformations of the abdominal wall-A mechanical and geometrical approach to the linea alba”. In: *Journal of Biomechanics* 44.4 (2011), pp. 600–606. ISSN: 00219290. DOI: 10.1016/j.jbiomech.2010.11.021.

[17] FormX. *Dragon Skin™ 10 MEDIUM vs. Ecoflex™ GEL vs. SORTA-Clear™ 37*. URL: https://www.smooth-on.com/compare/.

[18] Granta Design. *CES EduPack*. 2019. URL: https://grantadesign.com/education/ces-edupack/.

[19] M Haerst et al. “Ageing processes in laser sintered and injection moulded PA12 following hygienic reprocessing”. In: *Rapid Prototyping Journal* 21 (2015), pp. 279–286. DOI: 10.1108/RPJ-06-2013-0061.

[20] N A Henriksen et al. “Guidelines for treatment of umbilical and epigastric hernias from the European Hernia Society and Americas Hernia Society on behalf of the European and Americas Hernia Societies”. In: *British Journal of Surgery* 107 (2020), pp. 171–190. DOI: 10.1002/bjs.11489.

[21] Joerg Hoeer and Oliver Wetter. “Miniaturized sensors registering the long-term course of suture tension in vivo under varying intra-abdominal pressure”. In: *Sensors (Switzerland)* 18.6 (2018). ISSN: 14248220. DOI: 10.3390/s18061729.

[22] William W. Hope et al. “Rationale and technique for measuring abdominal wall tension in hernia repair”. In: *American Surgeon* 84.9 (2018), pp. 1446–1449. ISSN: 00031348. DOI: 10.1177/000313481808400947.

[23] P. Klein et al. “Die Rekonstruktion von Narbenhernien – Intraoperative Tensiometrie zur Objektivierung der Verfahrenswahl”. In: *Der Chirurg* (1996). ISSN: 0009-4722. DOI: 10.1007/s001040050098.

[24] L. F. Kroese et al. “The ‘AbdoMAN’: an artificial abdominal wall simulator for biomechanical studies on laparotomy closure techniques”. In: *Hernia* 21.5 (2017), pp. 783–791. ISSN: 12489204. DOI: 10.1007/s10029-017-1615-x.

[25] Leonard Frederik Kroese. “Closing gaps - risk factors , occurrence , and treatment of abdominal wall hernias”. PhD thesis. 2018, p. 242. ISBN: 9789463750042.

[26] A. Le Ruyet et al. “Differences in biomechanics of abdominal wall closure with and without mesh reinforcement: A study in post mortem human specimens”. In: *Journal of the Mechanical Behavior of Biomedical Materials* 105.January (2020). ISSN: 18780180. DOI: 10.1016/j.jmbbm.2020.103683.

[27] A. S. Levy et al. “Quantifying fascial tension in ventral hernia repair and component separation”. In: *Hernia* 0123456789 (2020). ISSN: 12489204. DOI: 10.1007/s10029-020-02268-6.

[28] Mathew Lyons, Des C. Winter, and Ciaran K. Simms. “Mechanical characterisation of porcine rectus sheath under uniaxial and biaxial tension”. In: *Journal of Biomechanics* 47.8 (2014), pp. 1876–1884. ISSN: 18732380. DOI: 10.1016/j.jbiomech.2014.03.009.

[29] Vladimir N. Malyshev. “Tribological aspects in friction stir welding and processing”. In: *Advances in Friction-Stir Welding and Processing*. Elsevier Ltd, Oct. 2014, pp. 329–386. ISBN: 9780857094551. DOI: 10.1533/9780857094551.329.

[30] Markforged. *Print the world's strongest parts with Markforged*. URL: https://markforged.com/.

[31] Lalin Navaratne, Hutan Ashrafian, and Alberto Martínez-Isla. "Quantifying tension in tension-free hiatal hernia repair: a new intra-operative technique". In: *Surgical Endoscopy* 33 (1234), pp. 3040–3049. DOI: 10.1007/s00464-019-06843-6. URL: https://doi.org/10.1007/s00464-019-06843-6.

[32] Rajavi S Parikh et al. "An Evaluation of Tension Measurements During Myofascial Release for Hernia Repair". In: *The American Surgeon* (2020). DOI: 10.1177/0003134820945243.

[33] S. G. Parker and A. C. J. Windsor. "Ventral Hernia Surgery in Europe: Trends and Actual Situation". In: *The Art of Hernia Surgery*. Springer International Publishing, 2018, pp. 103–113. DOI: 10.1007/978-3-319-72626-7{_}10.

[34] Sharad P Paul, Justin Matulich, and Nick Charlton. "A New Skin Tensiometer Device: Computational Analyses To Understand Biodynamic Excisional Skin Tension Lines OPEN". In: *Scientific Reports* (2016). DOI: 10.1038/srep30117.

[35] Marijn Poelman et al. "The INCH-Trial: A multicentre randomized controlled trial comparing the efficacy of conventional open surgery and laparoscopic surgery for incisional hernia repair". In: *BMC Surgery* 13.1 (2013). ISSN: 14712482. DOI: 10.1186/1471-2482-13-18.

[36] A. Rahimi and A. Mashak. *Review on rubbers in medicine: Natural, silicone and polyurethane rubbers*. 2013. DOI: 10.1179/1743289811Y.0000000063.

[37] Oscar M. Ramirez, Ernesto Ruas, and A. Lee Dellon. ""Components separation" method for closure of abdominal-wall defects: An anatomic and clinical study". In: *Plastic and Reconstructive Surgery* 86.3 (1990), pp. 519–526. ISSN: 00321052. DOI: 10.1097/00006534-199009000-00023.

[38] Bertram Reingruber et al. "Incisional hernia repair: Tensiometry for the selection of the appropriate procedure". In: *European Journal of Surgery* 167.12 (2001), pp. 903–908. ISSN: 11024151. DOI: 10.1080/110241501753361587.

[39] Joan Roca et al. "Surgical dynamometer to simultaneously measure the tension forces and the distance between wound edges during the closure of a laparotomy". In: *Sensors (Switzerland)* 18.1 (2018). ISSN: 14248220. DOI: 10.3390/s18010189.

[40] M.D. Rosen Michael. *Abdominal Wall Reconstruction: Patch the tire or rebuild the car? Comprehensive Hernia Center Case Medical Center Cleveland OH*.

[41] Romar Ângelo Barbato Silveira et al. "Mapping traction strength of the anterior rectus sheath in cadaver". In: *Acta Cirurgica Brasileira* 25.4 (2010), pp. 347–350. ISSN: 01028650. DOI: 10.1590/S0102-86502010000400009.

[42] M P Simons et al. "European Hernia Society guidelines on the treatment of inguinal hernia in adult patients". In: *Hernia* 13 (2009), pp. 343–403. DOI: 10.1007/s10029-009-0529-7.

[43] Nathaniel Stoikes, David Webb, and Guy Voeller. "Onlay ventral hernia repair". In: *Hernia Surgery: Current Principles*. Springer International Publishing, June 2016, pp. 99–105. ISBN: 9783319274706. DOI: 10.1007/978-3-319-27470-6{_}11.

[44] Jun Suganuma and Shigenori Nakamura. "Measurement of tension of tendon tissue based on electrical impedance". In: *Journal of Orthopaedic Science* 9.3 (2004), pp. 302–309. DOI: 10.1007/s00776-004-0782-7.

[45] Paul L. Tenzel et al. “A Preliminary Assessment of Abdominal Wall Tension in Patients Undergoing Retromuscular Hernia Repair”. In: *Surgical technology international* (2019). ISSN: 10903941.

[46] Paul L. Tenzel et al. “Physiologic tension: Technique for measuring and baseline values”. In: *American Surgeon* 85.9 (2019), pp. 998–1000. ISSN: 00031348. DOI: 10.1177/000313481908500942.

[47] Tenzel P et al. “Tension measurements in abdominal wall hernia repair: Concept and clinical applications”. In: *International Journal of Abdominal Wall and Hernia Surgery* 1.1 (2018), pp. 1–8. DOI: 10.4103/ijawhs.ijawhs.

[48] Karl T Ulrich and Steven D Eppinger. *Product Design and Development; Sixth Edition.* 2016. ISBN: 9780078029066.

[49] Eveline Van Koten. *The Assessment of Tension with regard to Abdominal Wall Hernia: Modalities and Applications*. Tech. rep. 2020.

[50] J. M. Van Os et al. “Artificial midline-fascia of the human abdominal wall for testing suture strength”. In: *Journal of Materials Science: Materials in Medicine* 17.8 (2006), pp. 759–765. ISSN: 09574530. DOI: 10.1007/s10856-006-9687-7.

[51] G. H. Van Ramshorst et al. “Non-invasive measurement of intra-abdominal pressure: A preliminary study”. In: *Physiological Measurement* 29.8 (2008). ISSN: 09673334. DOI: 10.1088/0967-3334/29/8/N01.

[52] Gabriëlle H. Van Ramshorst et al. “Noninvasive assessment of intra-abdominal pressure by measurement of abdominal wall tension”. In: *Journal of Surgical Research* 171.1 (2011), pp. 240–244. ISSN: 00224804. DOI: 10.1016/j.jss.2010.02.007.

[53] Christopher R. West and Anton E. Bowden. “Using tendon inherent electric properties to consistently track induced mechanical strain”. In: *Annals of Biomedical Engineering* 40.7 (2012), pp. 1568–1574. ISSN: 00906964. DOI: 10.1007/s10439-011-0504-1.

[54] Jan Paul van Wingerden et al. “Anterior and posterior rectus abdominis sheath stiffness in relation to diastasis recti: Abdominal wall training or not?” In: *Journal of Bodywork and Movement Therapies* 24.1 (2020), pp. 147–153. ISSN: 15329283. DOI: 10.1016/j.jbmt.2019.10.015.

[55] I M Zaikina et al. *Polymers for reusable medical components*. Tech. rep. 1975.