Alternative closure method for laparoscopic gastrointestinal anastomosis

Development of a surgical tool to facilitate hand suturing in minimally invasive surgery

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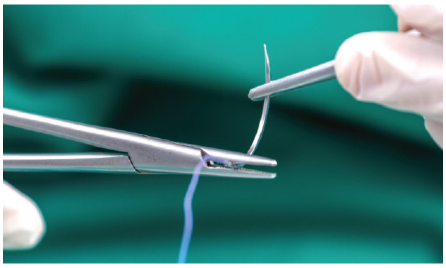
Summary

Hand suturing is one of the most challenging tasks in laparoscopic surgery and requires high cognitive effort from the performing surgeon. Nevertheless, it is also one of the basic skills of minimally invasive surgery and it is a critical skill due to its high requirements and broad application.



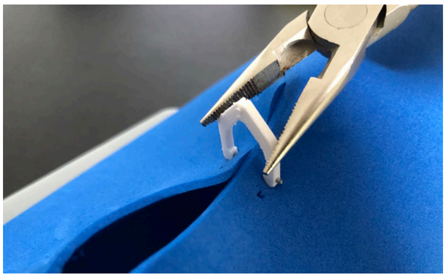
Hand suturing

During gastric bypass surgery, there are multiple moments of hand suturing which makes the procedure physically and cognitively challenging. This research focuses on possible alternatives for internal tissue closure to reduce the frequency of hand suturing. The main objective of the research was to develop a method which reduces cognitive effort and procedure time while enhancing comfort for the surgeon.

Hand suturing in laparoscopic setting

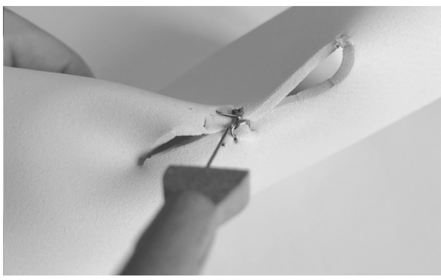
To get insights into the current procedure of hand suturing, it was analysed on the example of anastomosis closure. Observations of gastric bypass surgeries gave the required information to generate a detailed workflow which identified hand suturing as a key difficulty during the process. The analysis results gave a starting point for the ideation of a new closure method. Additionally, requirements for the closure method were formulated and taken into account during the development.

Multiple concepts like differently shaped clips, hooks and staples were created and prototypes were built. Materials like metal wire staples and 3D printed prototypes were used and tested on foam, silicon and rubber. Through tests and interviews with healthcare professionals, one concept could be chosen and further detailed.



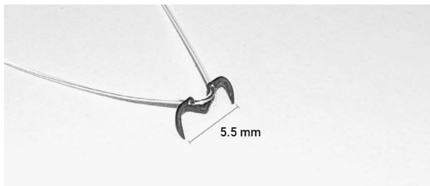
Prototype of one of the first concepts

The newly developed method combines the advantages of both hand suturing and the commonly used stapling technique. The staples are attached in an alternating way on the edge of the tissues, while a suture is pre-threaded through the staples. When pulling the suture, the two sides approximate each other. The advantage of this method is that the tissue does not need to be positioned before the application which makes the procedure less challenging for surgeons.



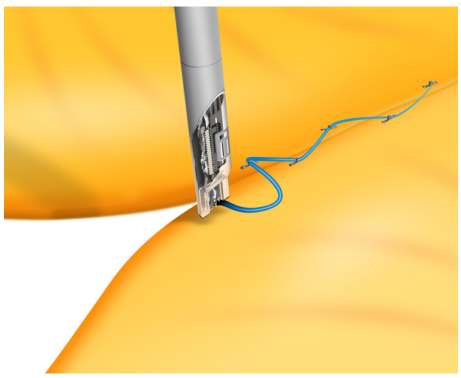
Prototype of newly developed method

A real scale prototype of the method was build to test manufacturability and proof of principle. Further optimization was done with Finite Element analysis and co-creation sessions with medical doctors. The evaluation of the concept was done in close collaboration with multiple bariatric surgeons, by conducting interviews and hosting discussion sessions.



1:1 model of the staple

The result of the evaluation showed that some of the safety requirements on anastomosis closure cannot be met with the newly developed concept. More suitable alternatives like the closure of mesenteric windows was investigated. Mesentery defects occur e.g. due to anatomic changes during gastric bypass surgery. If left untreated they may lead to internal hernia and small bowel obstruction. The newly developed method has the potential to close mesenteric windows time efficiently while enhancing the surgeon's comfort. Risk assessment and further interviews showed that this application is safer and more accepted by surgeons which makes it a promising solution for hernia repair.



New application: mesentery closure

Reading guide

This project is the result of an interdisciplinary research approach which combines the expertise of healthcare professionals, designers and engineers. The knowledge of the partners involved in the project was combined into a report which bridges this expertise and creates a common understanding. To make it comprehensible for all professions, additional explanations and visuals were added on the side of the text in blue[1].

[1]**Explanations**
Additional explanaitions and visuals are shown next to the text in blue.

There are chapters which focus more on the medical, design & engineering and strategy parts. Figure 1 shows which chapters have more emphasis on which field.

Each chapter begins with the approach and ends with the main insights that were gathered. These insights lead to the final design and can be found in blue boxes.

Insights

- Insights are summarized at the end of each chapter
- They lead to the final design

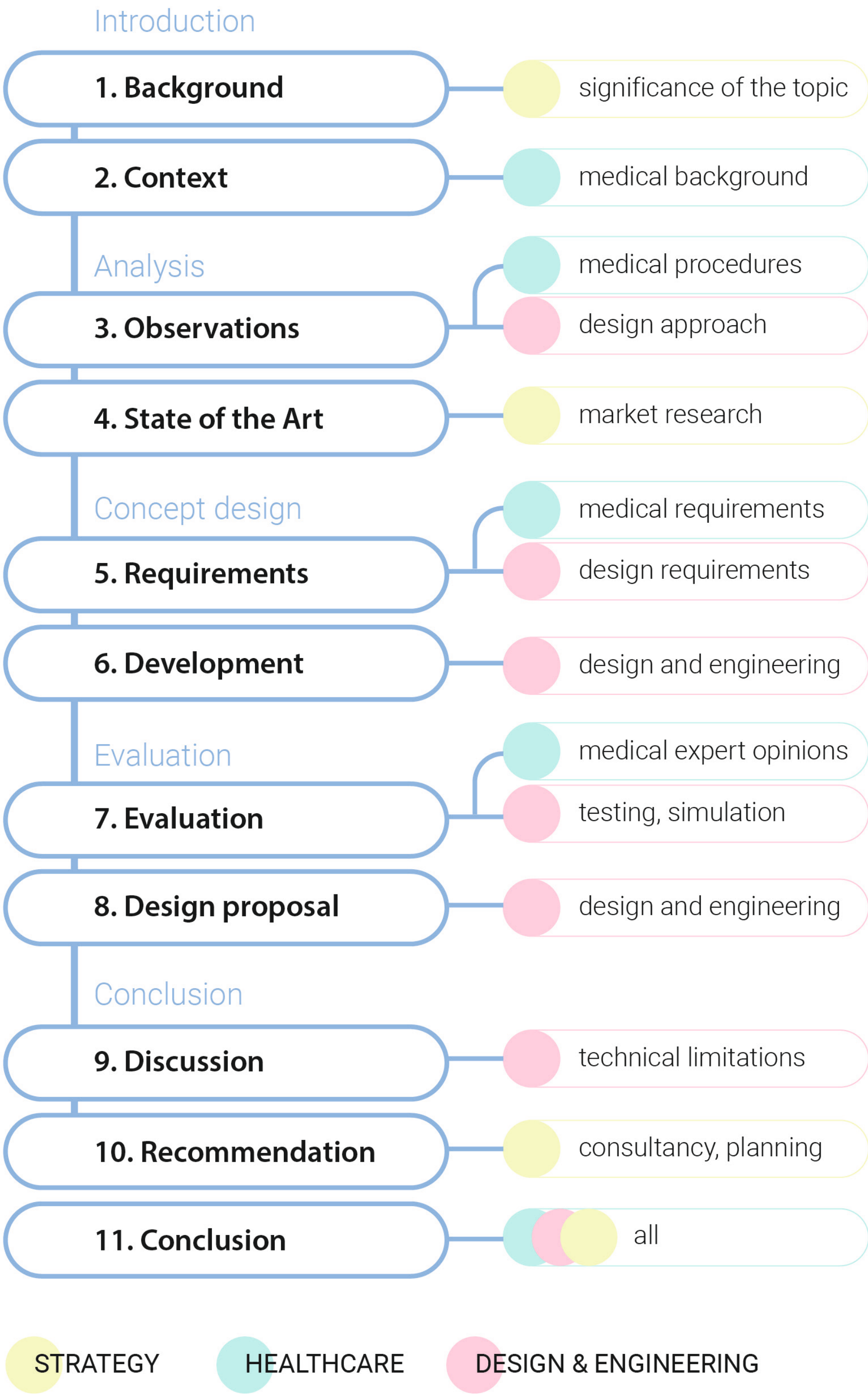


Figure 1: Reading guide: overview of different fields presented in the report

Content

1. BACKGROUND

This master's thesis was done in collaboration with the bariatric department of Spaarne Hospital in Hoofddorp, where more than a thousand patients per year undergo bariatric surgery, most of them performed laparoscopically. Dr Maurits de Brauw is one of the bariatric surgeons and the main initiator of the project. He approached TU Delft with the master's thesis tender about an alternative closure method for gastrointestinal anastomosis. Besides his profession as a bariatric surgeon, he is involved in several research projects related to obesity and engages in obesity[1] prevention.

Obesity is the main cause of diseases after smoking and the number of people suffering from it is increasing worldwide (Ritchie, 2017). In the Netherlands, many children and more than half of all adults are overweight[2], with 18.8% being obese[3] (Government of the Netherlands, n.d.) (WHO, 2013). Non-operative treatments like dietary changes, physical activity, or pharmacotherapies (Mitchell, 2021) are not as efficient with less average long-term weight loss compared to bariatric surgery (Gloy, 2013). To be eligible for this type of surgery, patients need to meet the criteria set by the state's authorities (Mitchell, 2021). In the Netherlands this is the Dutch Morbid Obesity Directive[4] ("Richtlijn Morbide Obesitas", 2011) (Poelemeijer, 2018).

Gastric bypass surgery is one of the most effective weight-loss surgeries.

The Roux-en-Y gastric bypass shows good outcomes and fewer risks than similar procedures, e.g., the gastric band (Personal communication, February 2022), with some literature suggesting that it is the only effective long-term treatment for morbid obesity (de Blasi, 2013). The first gastric bypass procedures were performed in open surgery, but in 1994 there were primary attempts to perform the surgery laparoscopically[5] (Wittgrove, 1994). Some years later, authors reported laparoscopic surgery (Figure 2) for the gastric bypass as being a safe alternative to the open approach (Nguyen, 2001). Now, the performance of laparoscopic gastric bypass is the standard procedure in Dutch hospitals with an estimate of less than 10% being performed with open surgery (personal communication, December 2021).

[1] **Obesity**
Obesity is defined based on the BMI (body mass index) which is the weight (kg) divided by the height squared (m2).

[2]**overweight**:	BMI over 25
[3]**obese**:	BMI over 30
extremely obese:	BMI over 40

(WHO, 2022) (Mitchell, 2021)

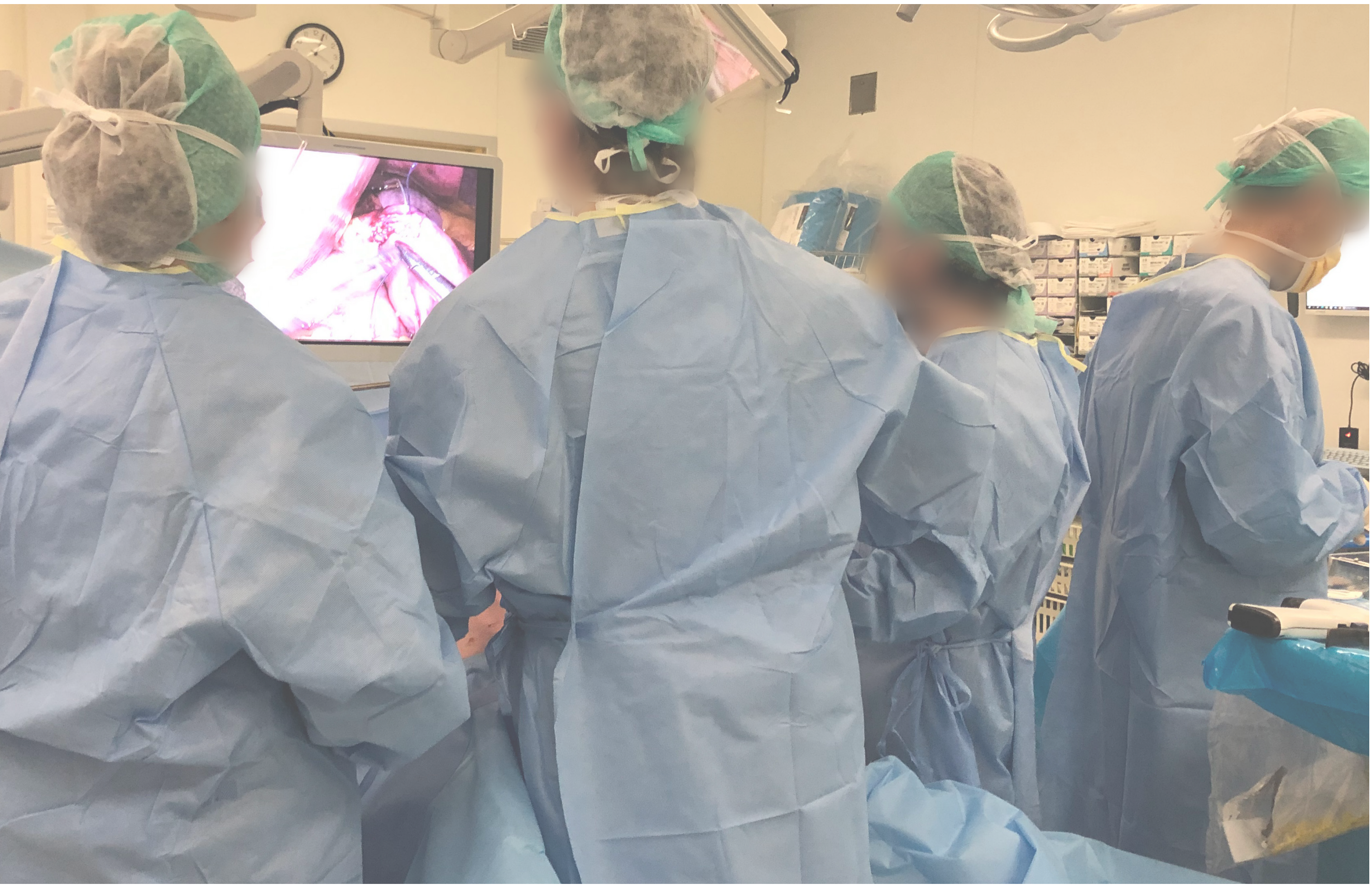
[4] **Requirements for bariatric surgery**
To be eligible for gastric bypass surgery, patients need to fulfil certain requirements, e.g.:
BMI >40 or > 35 with co-morbidities
all nonoperative measures have failed to maintain weight loss for >6 months
participation in specialist obesity service
commitment to long term follow up

(Mitchell, 2021)
("Richtlijn Morbide Obesitas", 2011)

[5]**Laparoscopic surgery**
Alternative to open surgery where only small incisions are being made to gain access to the abdominal cavity. The surgeon is using a laparoscope with a light and camera and the image is projected on an external screen.

Figure 2: Gastric bypass performed laparoscopically

2. CONTEXT



2.1 Laparoscopic surgery

The number of laparoscopic surgical procedures has been increasing since the method has been introduced (Philipose, 1994) (Siddaiah-Subramanya, 2017). Laparoscopic surgery proves to be advantageous for the patient due to less adhesion formation (Molinas, 2010), less blood loss, fewer complications (especially infectious), smaller scars and better cosmetic outcomes (Agha, 2003). The patient generally recovers faster which leads to a shorter hospital stay (Mandrioli, 2016) (Buia, 2015). However, next to all the advantages the laparoscopic approach brought, it also introduced several challenges, especially for the performing surgeons.

2.1.1 Challenges

There are ergonomic, visual, and technical difficulties, which cause a simple task in traditional surgery to become a challenging and time-consuming procedure in laparoscopy (Leonard, 2014). It requires greater concentration and puts more cognitive stress on the surgeons compared to open surgery (Berguer, 2001).

This is mainly caused by the general setup of laparoscopic procedures. The surgeons are watching the three-dimensional procedure on a two-dimensional screen which reduces depth perception and can cause perceptual errors (Chung, 1998) (Sinha, 2017). Another visual challenge is the magnification of the objects closest to the laparoscope which gives a degraded visual image of the anatomy (Gallagher & Smith, 2003).

Technical issues include hand-eye coordination. The perspective is slightly displaced since the tools are not at the same angle as the camera axis. The so-called azimuth angle[2] is about 30° away from the point of interest (Figure 3). This can cause misinterpretations of angular relationships (Gallagher and Smith, 2003). Surgeons do not have direct control over the position and orientation of the endoscope so an unintended camera movement or rotation can lead to disorientation and/or misinterpretation (personal communication, February 2022). Due to the Fulcrum effect[4] (Figure 4), the movements performed are shown in opposite directions on the screen (Harrington, 2018).

The tactile feedback when manipulating organs is reduced and the force transmission ratio is worse with 4-6 times more force needed due to the long instruments that are used (Berguer, 1999). This also causes ergonomic discomfort because the surgeons are holding their arms higher than usual while pulling the shoulders and elbow up (personal conversations, 2022).

All the mentioned problems complicate surgical tasks, especially the ones which require precision, repetition, and flexibility such as reconstructing or suturing (Leonard, 2014). Surgeons are required to have a large set of skills and knowledge, including hand-eye coordination, technical proficiency, highly developed motor skills and visuospatial abilities, to carry out these tasks (Harrington, 2018).

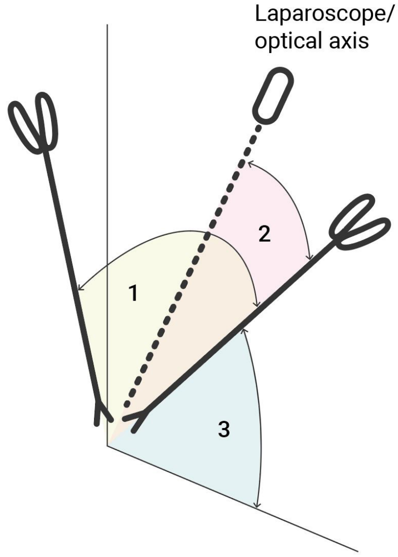


Figure 3: Manipulation angle[1], azimuth angle[2] and elevation angle[3]

[1] **Manipulation angle**
The manipulation angle is the angle between two laparoscopic tools. For optimal experience, it should be 60 degrees.

[2] **Azimuth angle**
The azimuth angle is the angle between the laparoscope (camera axis) and the surgical tool. For an optimal laparoscopic procedure, the azimuth angle should be 30 degrees.

[3] **Elevation angle**
Angle between horizontal plane and tool.

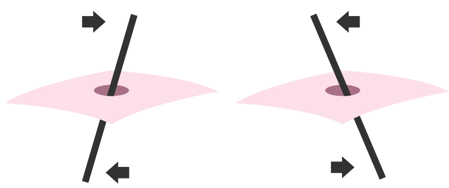


Figure 4: Fulcrum effect[4]

[4] **Fulcrum effect**
When the pivot point makes the actuators of the tool move in the opposite direction of the tool's handle.

2.2 Laparoscopic suturing

Laparoscopic suturing is one of the basic skills for surgeons who want to perform advanced laparoscopic surgery because it is needed for a number of procedures including reconstruction and internal wound closure (personal conversations, 2022). Nevertheless, hand suturing is a challenging task in minimally invasive surgery. Experienced surgeons are mastering hand suturing and can work around challenges in the procedure. However, it still remains a cognitively stressful task for them, especially under time pressure (personal conversation, 2022). A detailed workflow of laparoscopic suturing is described in chapter 3. Observations.

2.1.1 Suturing in the gastric bypass procedure

Gastric bypass surgery is a weight loss surgery in which the stomach is divided into a stomach pouch of 30ml and a larger remaining stomach. The intestines are arranged in a Y-shape to connect them both, so stomach fluids can mix with the food and digest them (Figure 5). Laparoscopic suturing is hereby used for the creation of two anastomoses[1], the gastrojejunostomy and the jejunojejunostomy.

Anastomosis suturing is a critical procedure with complications related to a flawed anastomosis (e.g., leakage) causing morbidity and mortality (Facy, 2013). Laparoscopy has been widely used for anastomosis suturing since it has been introduced (Chung, 1998). Researchers showed that the quality and safety can be compared to open surgery, with similar risks for major complications (Buia, 2015). The main difference is that the closure of a laparoscopic anastomosis is technically more challenging and time-consuming than the open approach. This is mainly related to the difficulties described in chapter 2.1.1 Challenges.

[1] **Anastomosis**
An anastomosis is a natural or surgical connection of two nearby blood vessels, intestines or other tubular structures in the human body. It usually follows a resection and is traditionally either stapled or hand sutured.

[1.1] **Bowel anastomosis**
When two intestines are connected, it can also be called bowel or intestinal anastomosis. This includes hemicolectomy, jejunojejunostomy, gastrojejunostomy, ileocolic anastomosis, colorectal anastomosis, esophagogastric anastomosis and more.

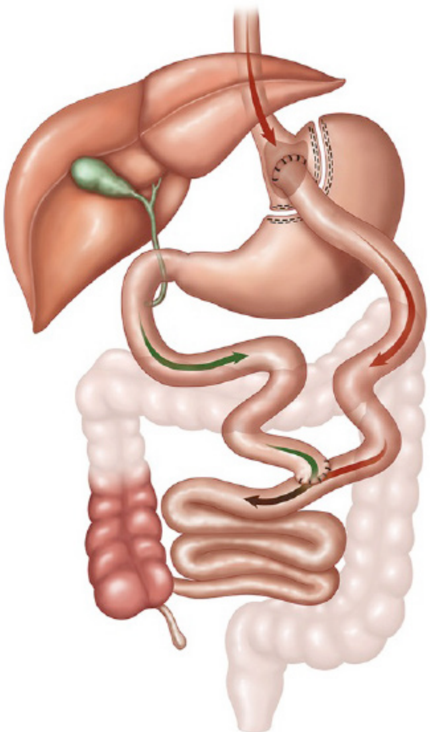
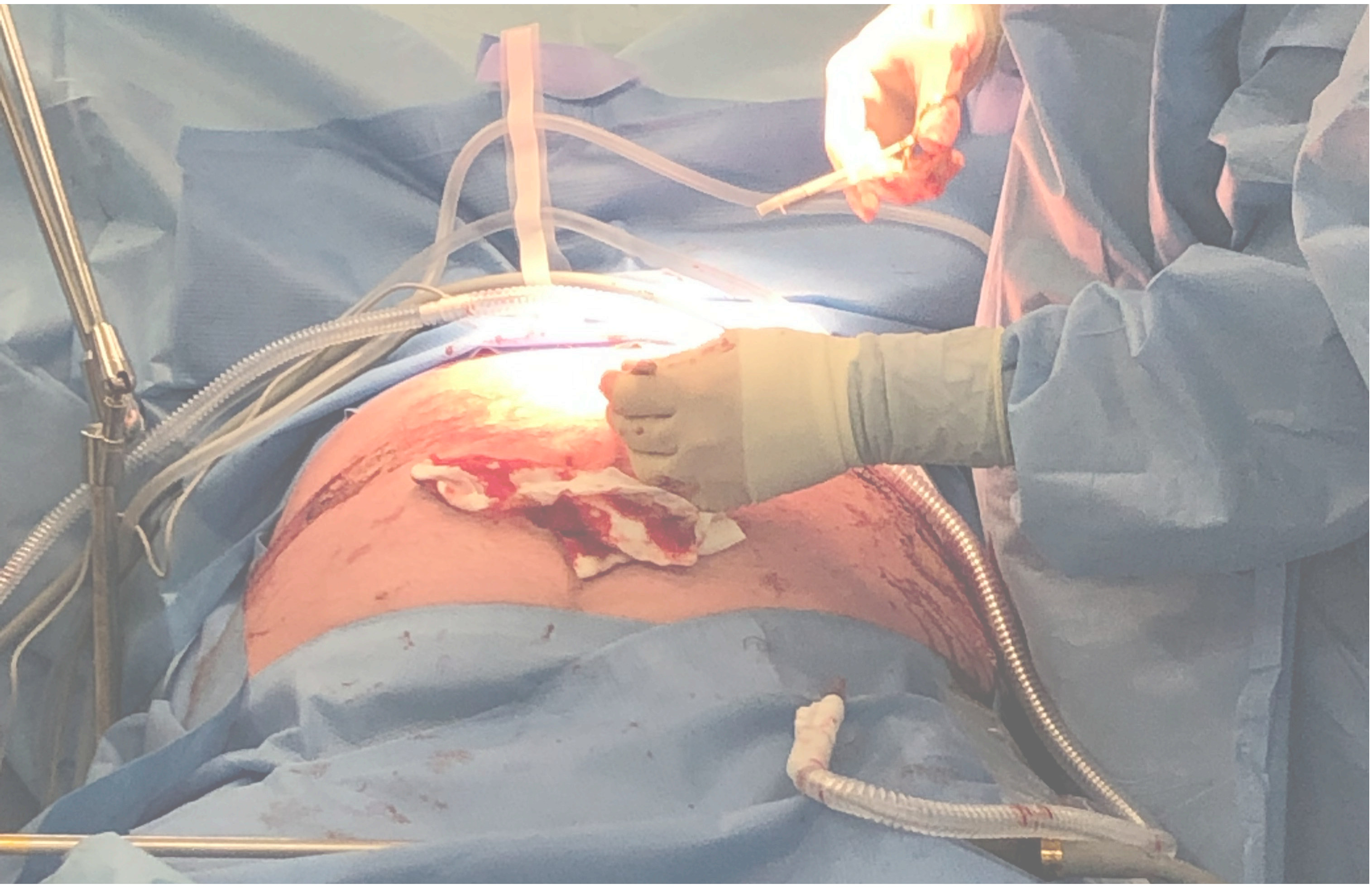


Figure 5: Roux-en-Y Gastric Bypass (source: Lake Health, 2019)

Insights

- Laparoscopy introduced a lot of benefits for patients
- It also introduced new challenges for surgeons due to the general setup of minimally invasive surgery.
- Surgeons who perform advanced laparoscopic surgery need to be highly skilled
- The performance of hand suturing is essential, however, it is one of the more challenging tasks in laparoscopic surgery
- During gastric bypass surgery, the two performed anastomoses require hand suturing with high requirements on the closure strength

3. OBSERVATIONS



Since this project requires high medical expertise, a contextual design approach was used to get first-hand insights and experiences from the users, which are the surgeons and the medical team. For contextual research, it is important that the user's environment is as natural as possible and they perform their activities as usual. The observer is hereby looking over their shoulder and gathering insights about the workflow, possible issues and needs of the user. The advantage of this method is that the observer can identify low-level details of the user's behaviours that are not always recognized by them in the routine of their daily practice. The 'Design for Emotion' method[1] (Desmet, 2007) was used to identify underlying emotions, motives and hidden intents. The moments of the individual's activities and experiences were determined and documented in a workflow which clarified relations between team members and issues while performing specific tasks. Impressions from the contextual research are shown in Figure 6-14.

[1]Theory of emotions
An emotion occurs whenever there is a stimulus (event) and a motive (need, goal, value) (Desmet, 2007). A stimulus is an event so e.g., the needle slips out of the needle holder. Surgeons might experience frustration because their need for competence is not met, and they must take action to pick up the needle again.

Figure 6: Patient table with option for splitting the legs

Figure 7: Tools prepared for gastric bypass surgery

Figure 8: Tools from the storage prepared and packed for different types of surgery

Figure 9: During the gastric bypass procedure

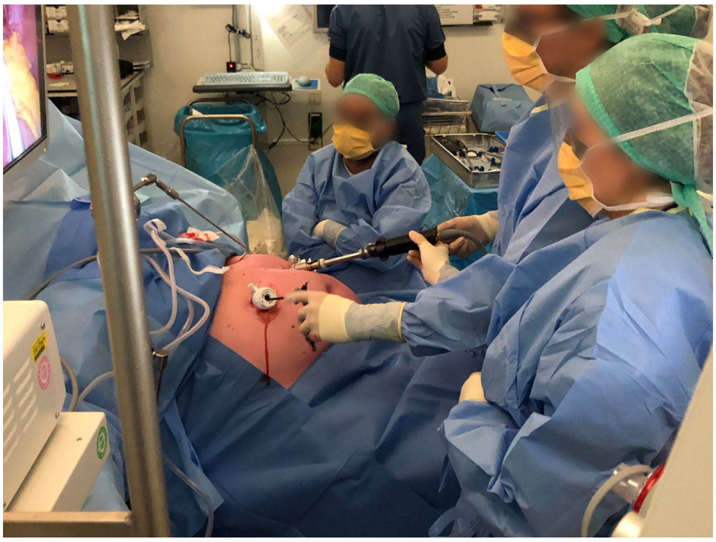


Figure 10: During the gastric bypass procedure

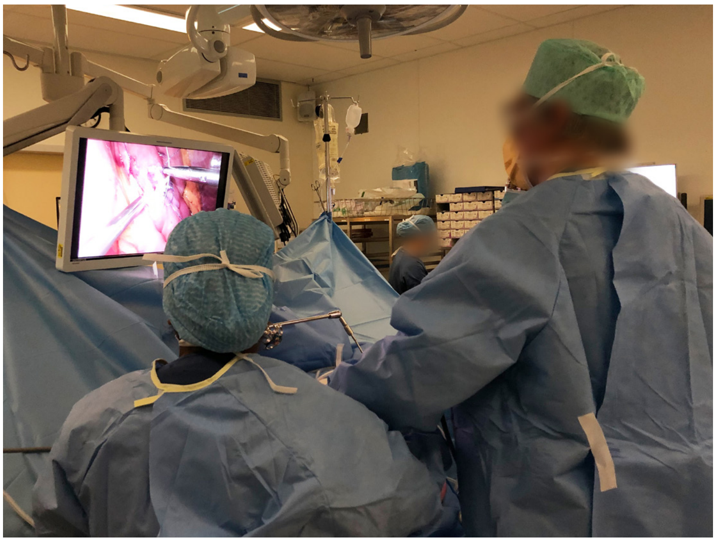


Figure 11: Surgeon hand suturing the anastomosis

Figure 12: Scrub nurse preparing tools

Figure 13: Used linear stapler cartridges

Figure 14: Storage of used sharped objects, including needles

3.1 Roux-en-Y gastric bypass (RYGB)

The research objective of the observations was to find out how surgeons perform anastomosis during a gastric bypass procedure and what problems occur. Hereby, the way of working of three surgeons was observed during a total of 12 RYGB surgeries. Information was gathered by watching the procedures and interviewing the surgeons during and after the surgeries. Protocols of the hospital visits can be found in Appendix A. The insights were compared with the "gold standard"[1] procedure and literature online. The protocols of personal communications can be found in Appendix B. All insights were visualised in a user experience workflow which represents the responsibilities of each member of the surgical team (see Appendix C). This chapter presents a summarized version of how the surgical team works.

3.1.1 Surgical team

The surgical team consists of sterile and non-sterile people. During gastric bypass surgery, there are three people, who can be in the sterile area (Figure 15), the lead and assistant surgeon and the scrub nurse.

The lead operator stands between the legs of the patient and performs all interventions. His assistant stands on the right or left side, holding the laparoscope and sucking tube. If the assistant is a resident, the surgeon lets them do the suturing part for practice. Often, the assistant is a medical student doing an internship.

The scrub nurse stands behind the surgeon and prepares the tools for handing over to the surgeon.

Depending on the team there are one or two theatre assistants. They prepare the tools and open the packages so the scrub nurse can take them out. They also take care of writing the protocols, scanning the packages, and handling the instruments outside of the sterile area (e.g., screens, pumps or light).

The anaesthesia[2] team is located on the other side of the room, where the head of the patient is. They are non-sterile and responsible for patient monitoring. They prepare the patient, give anaesthesia, and wake them up after the procedure. The anaesthesia team also handles the gastric tube (for measuring the pouch and adding methylene blue[3]) during the procedure.

Visitors can stay within the non-sterile area, remaining outside the pathways of the surgical team.

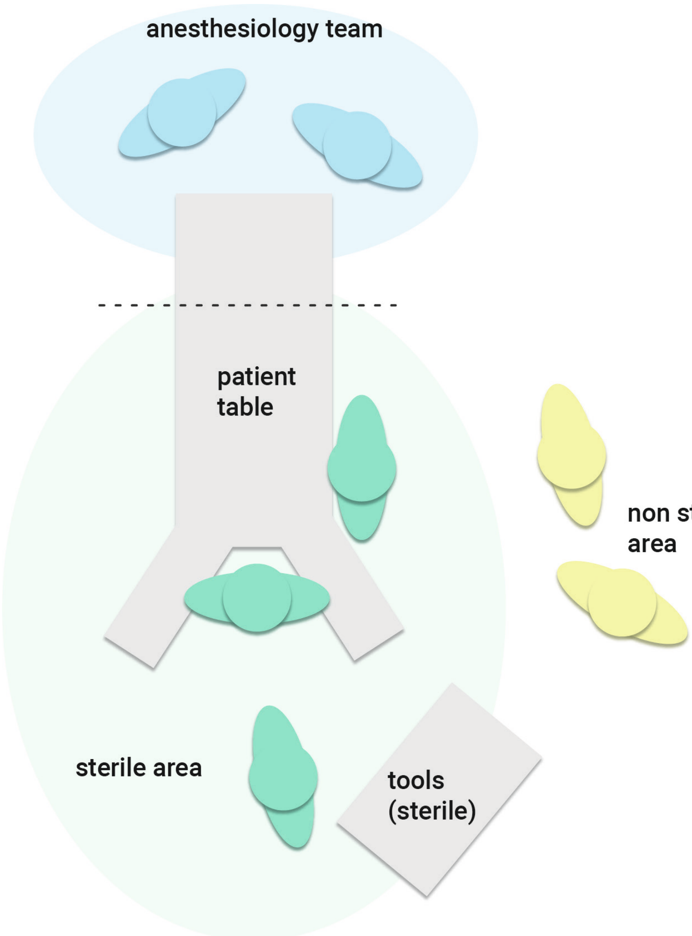


Figure 15: Sterile and non-sterile are in the OR

[1]Gold standard
"For a surgical procedure to be not only approved but also considered "gold standard," scientific evidence gathered over time must show that it's the most successful surgery delivering the best outcomes compared to surgical alternatives" (Santos, 2016)

[2]Anaesthesia
Consists of three things: analgesia (pain relief), hypnosis (sleep, unconsciousness), muscular relaxation

[3]Methylene blue
A dye used for controlling the water tightness of the anastomosis. It is introduced through the mouth and the surgeon checks if there is any leakage around the performed anastomosis.

3.1.2 RYGB Workflow

The steps of the gastric bypass procedure are mapped on the workflow chronologically (Appendix C). A summary of it is outlined in this chapter. Additional explanations about the bowel anatomy can be found in Appendix E.

Preparation

In preparation for the surgery, the patient is brought into the OR by the anaesthesia team. The patient is asked to move over to the surgery table and receives a short education talk. When the team is ready, the anaesthesia is given, and the patient is placed in the French position (Figure 16), with the table tilted by 30 degrees. Then, the surgeon starts inflating the abdomen with a Veress needle and makes incisions for the trocars (Figure 17). As soon as all four trocars are placed, the liver retractor is placed to lift the liver which is covering the stomach.

Creation of the gastric pouch

The surgeon makes a hole in the gastrohepatic ligament with an ultrasonic dissector to gain access to the lesser sac. This is necessary for the stapler to reach behind the stomach and create the stomach pouch (Figure 18). The pouch is made with one 30mm stapler, released horizontally and two more 30mm staplers in the direction of the corner of His. To be sure that the stomach pouch has the right size, the anaesthesia team inserts a gastric tube with 30 ml through the mouth.

Gastrojejunostomy (first anastomosis)

Then, the just-created gastric pouch needs a connection to the small bowel again. Therefore, the part of the jejunum where the Ligament of Treitz ends is brought up towards the stomach. The surgeon makes a hole with the dissector in both the pouch and the jejunum for the stapler jaws to enter. As soon as the stapler is in the right position, the surgeon fires the stapler and so creates an anastomosis between the stomach and jejunum. The remaining hole after removing the stapler needs to be hand sutured. Therefore, the surgeon uses a V-loc 3-0 suture of 23 cm and a perpendicular stitch technique. The Roux limb is created.

Jejunojejunostomy (second anastomosis)

To enable the stomach fluids from the old stomach to enter the small bowel and mix with the food, the Bilio-Pancreatic Limb needs to be measured to about 120-150 cm and connected to the jejunum in a Y shape. The surgeon makes two holes, into the just measured

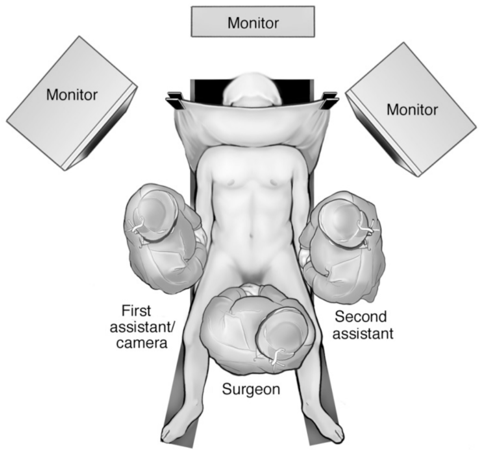


Figure 16: French position (Trelles, 2008)

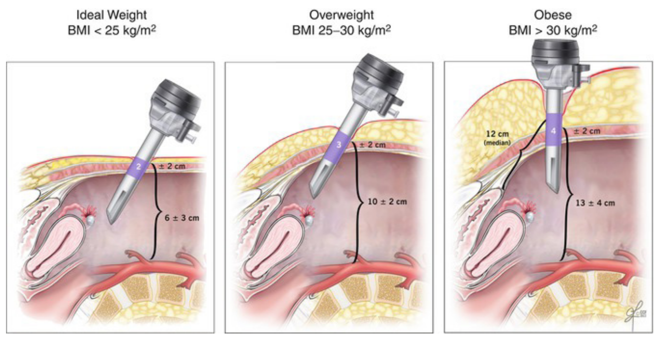


Figure 17: Access with trocars

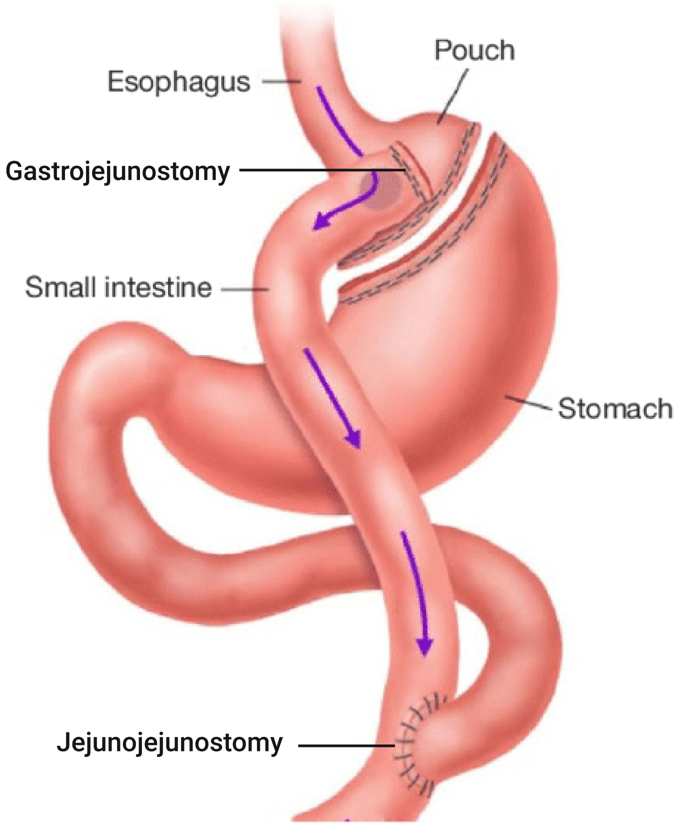


Figure 18: Stomach pouch, Gastrojejunostomy and Jejunojejunostomy (Levine, 2017)

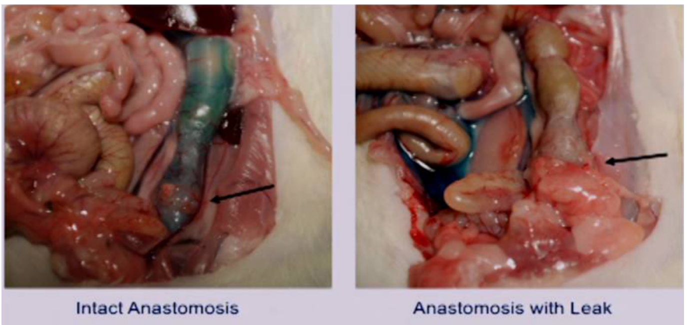


Figure 19: Leakage test with methylene blue

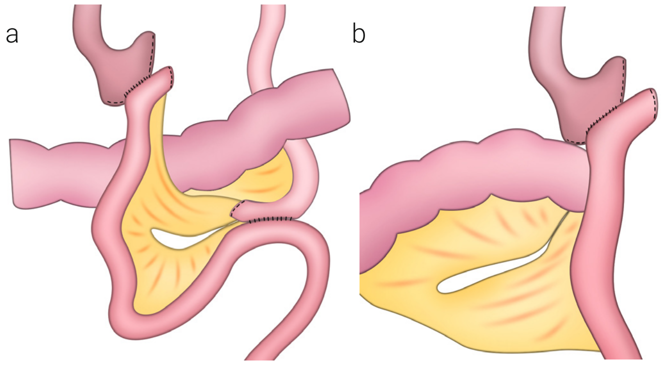


Figure 20: Closure of mesocolon defects (a: Petersen's space, b: mesojejunal space)

spot in the jejunum and right next to the first anastomosis, the gastrojejunostomy. Then the stapler is inserted again to create the Jejunojejunostomy. The remaining opening is closed by parallel suturing with a V-loc 3-0 of 16 cm. Right in between the two anastomoses, the jejunum is being stapled apart to finalize the gastric bypass.

Leakage test
A leakage test on the gastrojejunostomy is being performed with methylene blue via the gastric tube (Figure 19). The jejunojejunostomy is not tested, because it is not well accessible. In case of leakage, additional clips (e.g., endo clip II) or extra suturing is done.

Closing
To prevent the intestines to slip through and strangulate, the mesocolon defects (Figure 20) are closed with a hernia stapler which is refilled 2-3 times.

Finishing
All the tools are removed, needles and tissues counted, and the light is turned on. The surgeon and assistant close the incisions with a needle and suture. As soon as the patients wake up, they are asked to transfer back to the patient bed.

Insights
The learnings gained during the observations are later being used to formulate requirements (see chapter 5. Requirements) for the new closure device.

- Surgeons do up to six GB surgeries a day, with no long breaks. This makes them extensively more mentally and physically exhausted (requirements on comfort).
- During the surgery, the creation of an anastomosis is the part where surgeons are most tense and focused.
- One surgery takes about 45-60 min. Based on my measurements of six surgeries, the gastrojejunostomy takes on average 7:55 min and the jejunojejunostomy 5:35 min. If complications occur, the anastomosis suturing could take up to 20 min (requirements on time).
- Bleedings and leakages happen. If they are found during the surgery they can usually be stopped or closed (requirements on safety).
- If a spot within the cavity cannot be reached, different trocars are used to gain access (requirements on flexibility).
- The heavier the patient the more difficult the process (bigger liver, more fat, sick tissue etc) (requirements for adaptability).
- The hands of the sterile team are often interfering due to limited space (requirements for one-handed operation).

3.2 Hand suturing

As described earlier, two anastomoses are performed during the gastric bypass, the gastrojejunostomy and the jejunojejunostomy. Both are performed by creating access to the intestines with the dissector and using the stapler to connect them. The remaining opening needs to be hand sutured (Figure 21). This chapter provides a summarized version of the step-by-step hand suturing, whereas Appendix D shows the detailed workflow.

For gastrointestinal anastomosis, the inverted continuous seromuscular parallel stitch is used most commonly (see Figure 22), whereas seromuscular means that the stitch depth is until the seromuscular tissue layer. There are other suture techniques, like the interrupted and the parallel stitch, which are shown in Figure 22. Depending on the technique used, the tissue aligns differently (apposition, inverted or everted). The tissue alignment options are described in chapter 5. Requirements. More stitching techniques can be found in Appendix F.

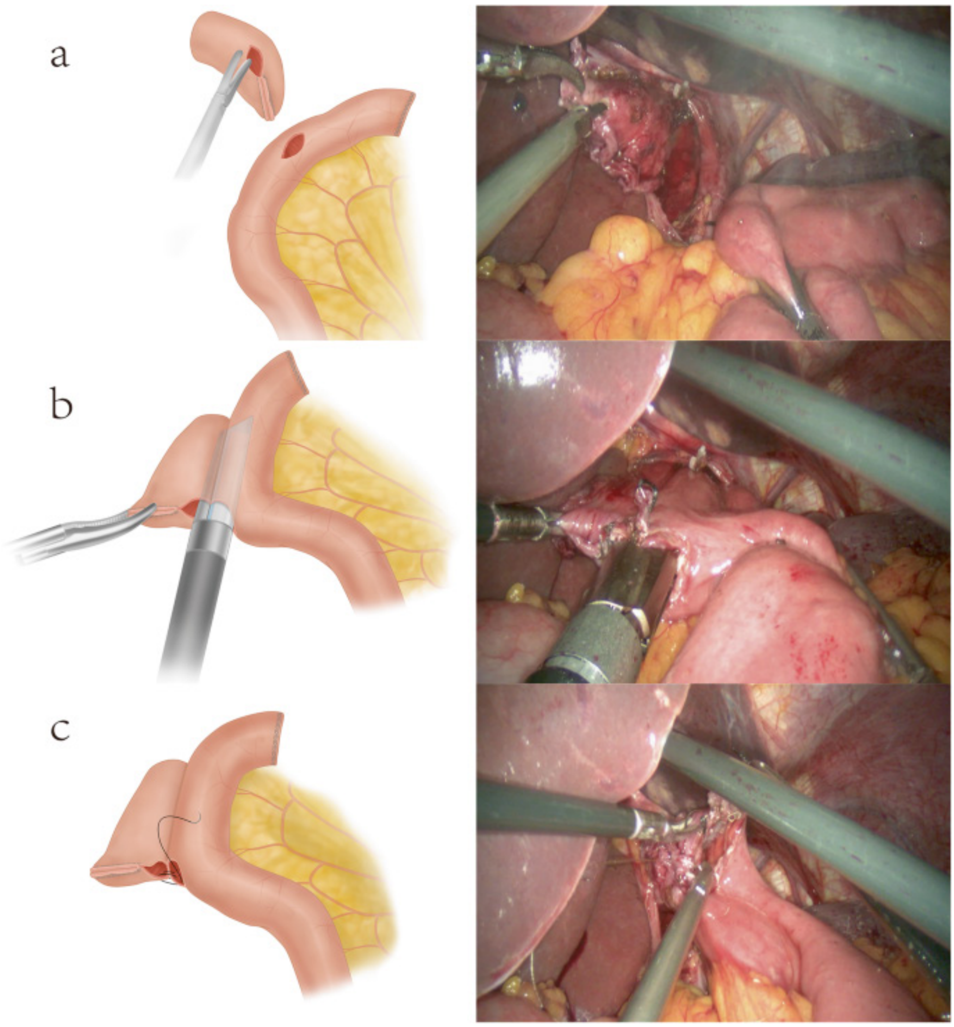


Figure 21: Stapled and hand sutured anastomosis (Wang, 2021)

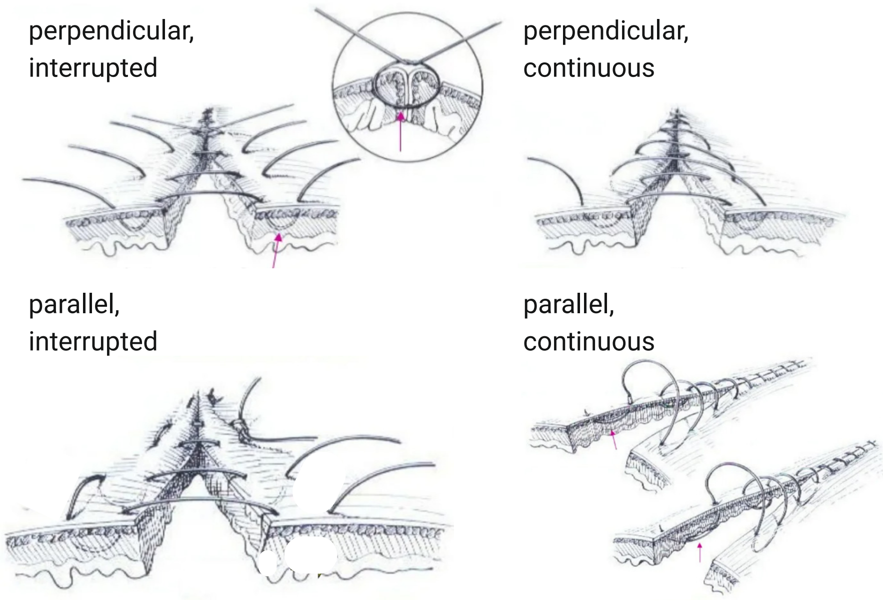


Figure 22: Examples of inverted stitching techniques (Singh, 3013)

3.2.1 Workflow

Assuming the surgeon is right-handed, they hold the tissue grasper in the left and the needle holder in the right hand. The needle holder is handed over by the scrub nurse with the needle and V-loc 3-0 suture[1] clamped to it.

1. While holding the tissue of the jejunum with the left, the surgeon pierces the needle, perpendicular to the anastomosis (Figure 23).

2./3. Depending on the space, the surgeon can pick up the tissue from the stomach immediately or pull the needle fully through first before piercing the stomach tissue. The second option takes longer because the needle needs to be handed over twice between the instruments.

3. Once the needle is pierced through both tissues, the grasper grabs the tip of the needle and pulls it through.

4. While holding the needle with the tissue grasper, the surgeon grabs the suture close to the incision and pulls it until the loop at the end of the suture comes close to the hole.

5. The surgeon hands over the needle to the needle holder and pushes it through the loop. Again, the needle needs to be handed over to the grasper and back to have the needle looped through completely.

6./7. The surgeon tightens the suture by pulling it with the grasper.

8. The next stitch is done like the first one. The tissue from the jejunum is collected, then the one from the stomach pouch. The suture is pulled tight. When all stitches are done and the anastomosis is closed, the end of the suture is cut with a dissector.

[1] **V-loc™ 3-0 suture**
Barbed sutures from Medtronic are named V-loc. 3-0 indicates the thickness of the thread.

[1.1] **Laparoscopic sutures**
Originally, sutures were made from catgut, but nowadays they are made from synthetic materials.

[1.2] **Absorbable:** polyglycolic acid, polylactic acid, Monocryl and polydioxanone , polydioxanone, and caprolactone

[1.3] **Nonabsorbable:** polypropylene, polyester, PVDF or nylon

[1.4] **Suture thickness**
Originally, there were the sizes #1 (smallest in diameter) until 6# (largest in diameter) but as manufacturing improved, there are way thinner threads possible, so the scale got extended until #000000 (written #6-0 or #6/0)
See overview in Appendix G
(United States Pharmacopeia (U.S.P.))

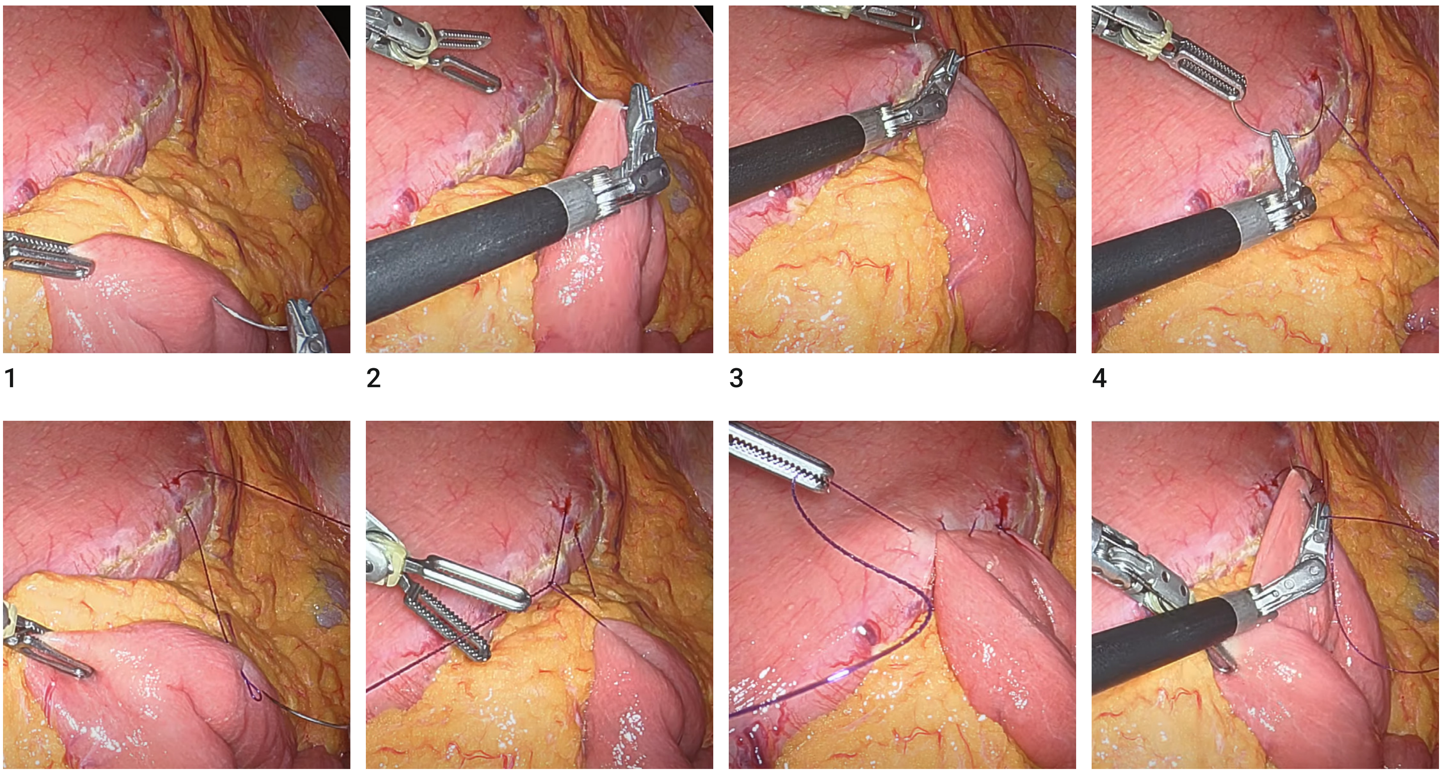


Figure 23: Suturing steps

Need for suturing skill

Laparoscopic suturing is a fundamental skill for a laparoscopic surgeon, but it takes significantly more time to learn than suturing in open surgery (Leonard, 2014). Hereby, practical training is essential to improve suturing and knot-tying skills (Mori, 1998) (Chung, 1996). Students get a better experience when practising on laparoscopic simulators (Figure 24), which decreases suturing and knot tying time significantly (Ninh, 2000) (Croce, 2000). Standardized training programs have been developed and shown to be successful in teaching reconstructive laparoscopy (Teber, 2005).

Despite the efforts of learning and performing laparoscopic suturing, it is a valuable technique and a required skill for all complex laparoscopic procedures (Ninh, 2000). Even with the availability of supporting instruments, it is beneficial if surgeons have the skill to perform conventional laparoscopic suturing. Reasons for this include the availability of the devices, wide application, and low cost (Croce, 2000) (Kollár, 2016). Surgeons should know hand suture techniques also to act if complications or technical problems with stapling occur (Toure, 2021).

Figure 24: Examples of laparoscopic training devices (Laparoscopyboxx, 2022)

Insights

The performance of an anastomosis is one of the challenging parts of gastric bypass surgery because of the high risks related to it. This causes the surgeons stress & emotional reactions (requirements on comfort and safety). The most common slips were identified and used to identify requirements which are formulated in the next chapter:

- The needle might fall because the transfer from one tool to another is challenging.
- The tissue slips because it is very elastic.
- The suture entangles itself if it is kept too long.
- If the needle is positioned wrong repositioning is needed.
- 3D movements are challenging, especially for inexperienced surgeons.
- The field of view is small, so all objects need to be brought into the operating field.
- The tip of the needle might slip back through the tissue while pushing it through. Fewer transfers from one tool to another are beneficial.
- Pushing the needle through the tissue takes some force due to the tissue´s elasticity.

4. STATE OF THE ART

4.1 Mechanical vs manual closure techniques

Despite many attempts from science and industry of developing new methods and devices for anastomosis closure, the most commonly used techniques are still the stapling[1] (Figure 25) and hand-suturing (Figure 26).
In the following chapter, mechanical and manual closure techniques are compared.

[1] **Staplers**
There are three types of staplers: linear cutting staplers, linear non-cutting staplers, and circular staplers. Previously, staples were made of stainless steel, now they are made of biocompatible titanium alloy. (Toure, 2021)

Figure 25: Linear stapler

Figure 26: Needle and suture

Laparoscopic intestinal anastomosis is commonly closed with mechanical staplers or manual suturing. The mechanic closure, however, still requires hand suturing of the remaining opening (Facy, 2013) (de Blasi, 2013) (personal communication, February 2022). Studies that have been comparing different techniques with each other found various advantages and disadvantages (Schineis, 2021). These are important to analyse because they reveal what characteristics the new closure method should have.

Time
Hand suturing and knot tying are the most time-consuming tasks while increasing the operative time significantly (Croce, 2000) (Facy, 2013 (Naito, 2017). There are not many experienced surgeons who fully hand suture a jejunojejunostomy with a barbed suture in less than 30 min (personal conversation). Most surgeons use the mechanical technique using a linear stapler and a barbed suture. This procedure takes about 10 minutes (personal communication, February 2022). On average, performing stapled anastomosis can save about 22 min operating time (Schineis, 2021)

Costs
The purchase costs of stapling devices are higher, compared to needles and sutures, with one disposable linear stapler being about 600€ and each load about 200€. For one RYGB about six loads are being used (Kollár, 2016) (personal communication, February 2022). A suture from the brand Ethicon can be purchased online for about 3.50€ (Medicali store, 2022), whereas the barbed version cost about 18€ (personal conversation, 2022). However, taking all operation costs into account, surgeries with stapled anastomoses saved 183€ in operation costs and 496€ in overall hospital costs. This is due to the shorter operation time (Schineis, 2021).

Safety
Research on the safety of mechanical or manual closure techniques did not show a clear advantage of either, regarding anastomotic leakage, hospital stay and 30-day-readmission rate (Schineis, 2021) (Toure, 2021). It is important to have in mind, that there are a lot of factors that play a role in creating a safe anastomosis, including the type of anastomosis, the technique used, the experience of the surgical team and varying stapling and suture material (Toure, 2021).

Usage
Conventional suturing and knot tying are more challenging tasks in laparoscopic surgery (Croce, 2000) (Facy, 2013). Reasons for that are the restricted spaces, the difficulty in handling the tissue and positioning the needle and performing a knot (de Blasi, 2013) (Ninh, 2000) (personal conversation, 2022). Staplers are easier to use and quicker than needles and sutures (Toure, 2021).

Decision making
Surgeons should make their decisions individually and based on the type of surgery, personal convenience, costs, availability, personal experience and environmental factors, like the patient's physical characteristics (Toure, 2021) (Goulder, 2012).

4.2 Market analysis

For both, stapling and suturing, there have been developments in the past decades. Parallely research was done on alternative methods. A summary of the current state of art is presented in the following paragraphs.

4.2.1 Stapling technology

The linear staplers which are commonly in use have three shifted staple lines on each side and a blade to dissect the tissue in between. They have been further developed to allow for better closure and better healing. Staplers come in different sizes, meeting the requirements for different tissue thicknesses and lengths, e.g. the Endo GIA Black Reload from Medtronic which is developed especially for thick tissues. The stapler reloads commonly fit onto the same handle which makes the usage simple and intuitive (personal communication, 2022). Medtronic developed the Tri-Staple technology (Figure 27), where the three staple lines have different lengths. This should allow for better perfusion of the tissue which leads to better healing. Another invention Medtronic introduced is the Reinforced line, which has an additional polyglycolic acid pad (Figure 28). They claim that this is improving the tightness of the closure, which should lead to less leakage. The studies performed on the Tri-staple and polyglycolic acid pad technologies are performed internally and are not proven to be beneficial (personal communication, 2022).

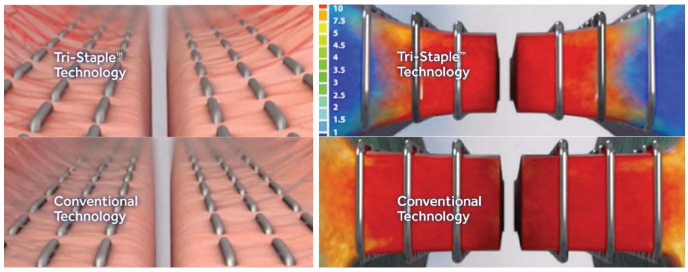


Figure 27: Tri staple technology (Medtronic, n.d.)


Figure 28: Endo GIA Reinforced (Medtronic, n.d.)

4.2.2 Barbed suture

In terms of usability, the barbed sutures (Figure 29) have been a real improvement of hand suturing. Because of the hooks that are standing out of the thread, the suture secures itself in the tissue and knot tying is not necessary anymore (Li, 2021) (personal communication, 2022). The handling is easier and causes less effort, however, the thread still needs to be tightened which involves a lot of transfers of the needle (Li, 2021) (Greenberg, 2013) (Facy, 2013).

Time

The usage of barbed sutures saves time because knot tying is not necessary anymore. (Greenberg, 2013) (Facy, 2013). For inexperienced surgeons, there is a reduction in time to learn the skill of suturing using barbed sutures, compared to using conventional threads (Blasi, 2013).

Costs

Barbed suture is more expensive compared to conventional sutures (18€ vs 3,50€). However, comparing the total cost of the surgery, using barbed sutures is more cost-effective because it saves time (de Blasi, 2013) (Greenberg, 2013).

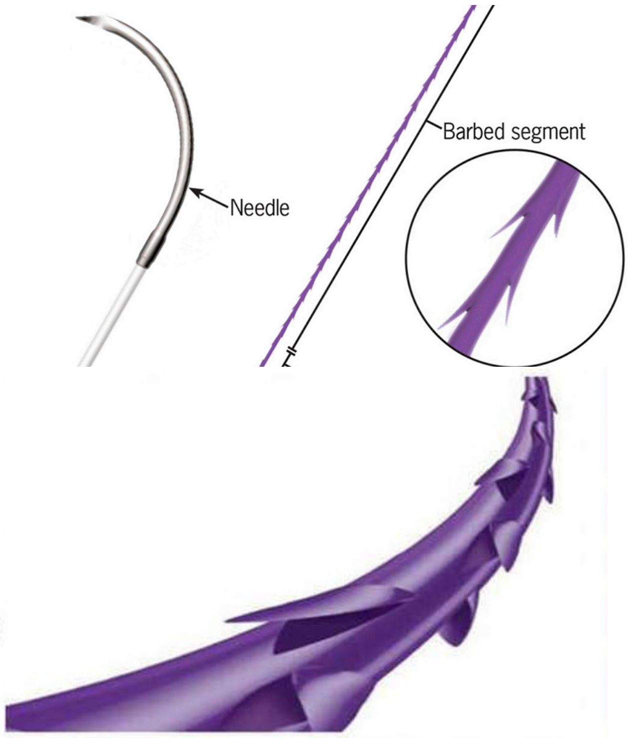


Figure 29: Barbed suture

Safety
Since the introduction of barbed sutures, there has not been an official recommendation for the use of bowel anastomosis, with Food and Drug Administration warnings written on their instructions of use (Greenberg, 2013) (personal communication, 2022). Many researchers, however, proved that the use of barbed sutures for this application is safe. First studies have been done in 2013, showing the feasibility, reproducibility, and safety of using unidirectional barbed sutures in intestinal anastomoses, with no increased risk for anastomotic leakage or complications (Facy, 2013) (de Blasi, 2013). Other studies confirmed that there is no significant difference and barbed sutures are at least as good in performance as smooth sutures (Einarsson, 2012) (Greenberg, 2013). They even showed better results in tensile strength properties and better outcomes in leakage tests (Greenberg, 2013).

When it comes to the usage of barbed sutures in bariatric surgery, the opinions of surgeons contradict. While some surgeons use barbed sutures daily, other surgeons are not using barbed sutures for intestinal anastomosis at all. Reasons for this are lacking trust and personal preferences (personal communication, 2022).

4.2.3 Endo Stitch and SILS Stitch
The Endo Stitch (Medtronic) is a single-use device designed to facilitate suturing in laparoscopic surgery (Figure 30). It allows the placement of different suture types including barbed sutures (Omotosho, 2011). The needle of the Endo Stitch is attached to the device and can be handed between the jaws which facilitates the handling and reduces execution time significantly (Ninh, 2000). In a study by Ninh (2000) residents preferred the Endo Stitch in all four categories, suturing, knot tying, handling and overall preference.

Critics of the Endo Stitch complain about the complications and the trauma it causes to the tissue. Surgeons also say that the handling is cumbersome and it is not intuitive to use. The performance of an anastomosis, e.g., jejunojejunostomy, is more complicated because the manipulation angles are not convenient (personal communication, 2022). In 2010, Medtronic released an improvement of the Endo Stitch, the SILS Stitch. It is based on the same technology but has more degrees of freedom, which allows surgeons to manoeuvre in tight spaces. However, the surgeons involved in this research do not see the advantages so they do not use either of them in their daily practice (personal communication, 2022).

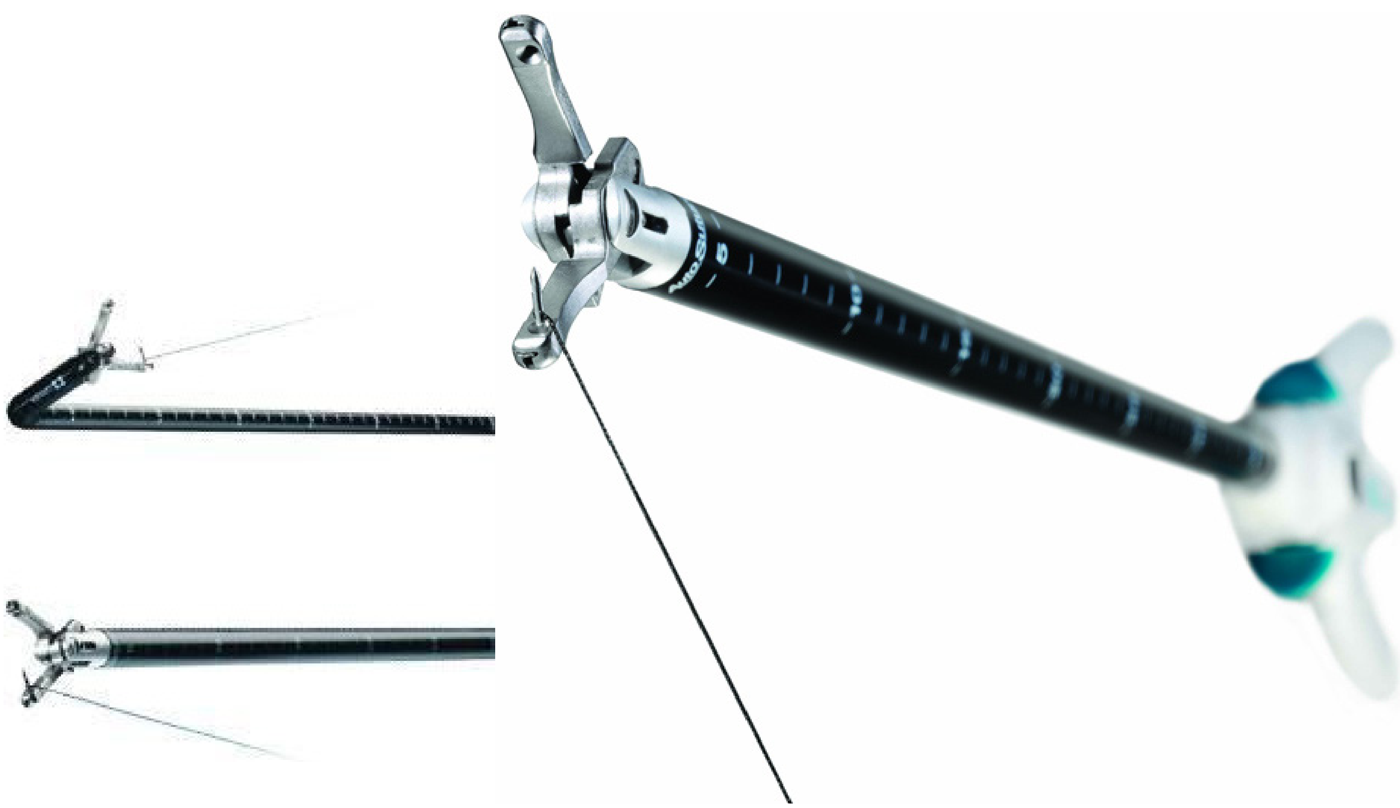


Figure 30: Endo Stitch and SILS Stitch (Medtronic, n.d.)

4.2.4 Needle holder

To improve the conventional suturing process, the industry has been focussing on the development of different shaped needle holders. Each of them has its pros and cons with surgeons having their personal preferences for different applications. A selection of needle holder shapes can be found in Figure 31.

Figure 31: Examples of different shaped needle holders

Another approach to improve the experience of hand suturing is the development of multi-degree of freedom needle holders. They have shown to be useful to reach specific angles so the surgeons do not have to manipulate the tissue so much.

One attempt to develop a multi-degree of freedom tool was the Radius Surgical System by Tuebingen Scientific (Figure 32). The idea was to develop something between conventionally used techniques and robotic devices. The Radius is cheaper than a robotic system (35.000$), but it did not fulfil what it was claiming (Ishikawa, 2012). With its seven degrees of freedom, surgeons need a significant amount of time to be able to handle the Radius needle holder. Transitioning from a stiff needle holder to a multi-degree of freedom tool can lead to confusion and complicate the process. The feedback of surgeons was that the device caused tremors, and it was not intuitive to use with them not being able to perform delicate manoeuvres (personal communication, 2022). They felt limited in articulation due to the fixed jaws and the wrist is not as flexible (Ishikawa, 2012). Research has been done on the efficiency of the Radius needle holder, as well as on other multi-degree of freedom needle drivers, e.g. from Takazawa (2016) or Deam (2022) but they are all not used in common practice (Figure 33). Culmone (2021) even developed a steerable needle holder which is fully 3D printed (Figure 33) but as well as the others, it is still in an experimental stage.

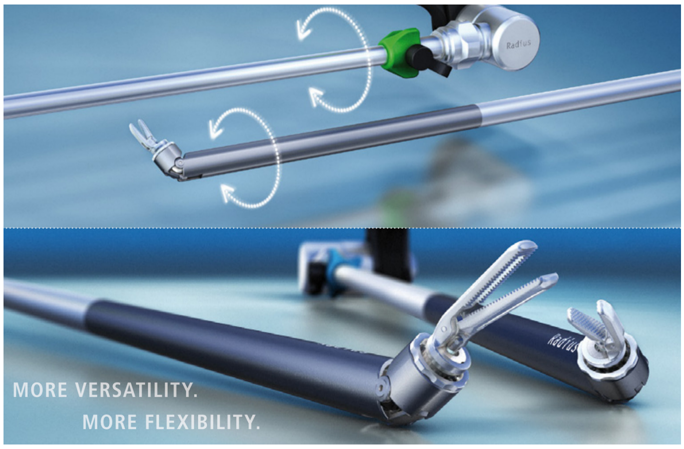


Figure 32: Radius System (Tuebingen Scientific)

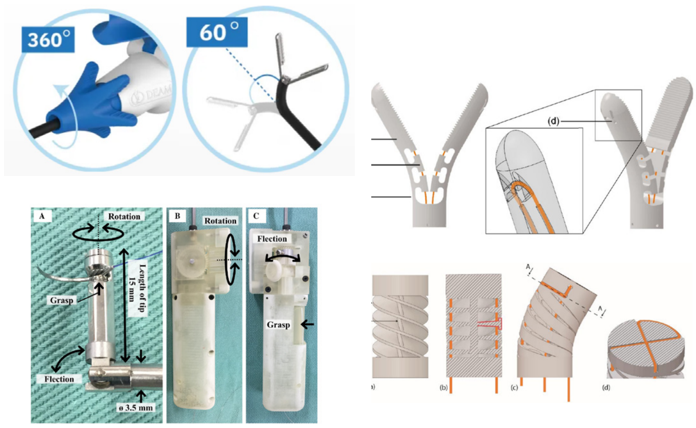


Figure 33: Multi-degree-of-freedom needle driver - left bottom (Takazawa, 2016), Laproflex - left top (Deam, 2022) and steerable 3D printed needle holder - right (Culmone, 2021)

Needles

Depending on the type of closure, there are various needles available. For laparoscopy, the half-curved (or ski) needle and the half-curve needle are suitable because they are slim enough to fit through the trocars (Figure 34). More needle shapes can be found in Appendix H.

Figure 34: Needle shapes which are suitable for laparoscopic surgery

4.2.5 Robotic surgery

Robotic assisted surgery
The da Vinci is the most mentioned robotic-assisted system (Figure 35). Like the Radius surgery system, it has seven degrees of freedom (Ishikawa, 2012). It translates the surgeons' hand, wrist, and finger movements into device movement and is thereby filtering out unintended movements like tremors. Surgeons say it is intuitive to use, and the learning curve is shorter than using the Radius needle holder. The downside is that it does not give any tactile feedback, which is a disadvantage most indirect instruments have compared to stiff ones (Ishikawa, 2012) (personal communication, 2022). The da Vinci can be used for most surgeries, but the initial and maintenance costs are significantly higher, with the initial investment being about 3.750.000$. The bulky system is time-consuming to set up because the trocars need to be placed in a way the arms do not collide (Ishikawa, 2012).

Autonomous robotic surgery
In 2014, Leonard developed the robotic setup STAR with Saeidi publishing research on an improved version of it (Figure 36). The researchers showed that autonomous robotic solutions have the potential to improve efficacy, safety and consistency, with less dependency on surgeons' experience and daily performance. In surgeries on rigid bony tissues, hair restoration or removal of brain or spine tumours, autonomous robotic systems showed to be successful. Autonomous soft tissue surgery is still a challenge due to the lack of pre-planning of surgery, reliability of the imaging system, detection and tracking of tissue, tissue deformation, precision and disturbances from patient movement, like respiration. Another downside is the lack of availability and lack of applicability in complex, non-commercial surgeries (Saeidi, 2022).

Figure 35: Robotic assisted device: Da Vinci (Intuitive, n.d.)

Figure 36: Autonomous robotic system: STAR (Saeidi, 2022)

4.2.6 Alternative methods

Shape memory alloys

A type of material which is gaining popularity throughout many applications, including healthcare, is the shape memory alloy. Alloys made of nickel-titanium (NiTi) or, and zinc, lithium and manganese (Zn-Li-Mn) are biocompatible and return to pre-defined shape based on thermal conditions (Kusnierz, 2013) (Zbar 2012). Next to their usage in stents, there have been experiments trying to use them for the closure of wounds. Ng (2006) tested a shape memory alloy fixator for skin wounds on rats (Figure 37). The results confirm the efficacy and safety of the method. Lui (2008) tested a clip for compression anastomosis in sixty-six patients with none of them experiencing complications. Their results suggest that using CAC (compression anastomosis clips) is safe in various circumstances, including gastrointestinal anastomosis. Kusnierz (2013) performed a study of 20 patients of which two experienced complications (Figure 38). The latest research using shape memory alloys for gastrointestinal anastomosis showed promising potential (Guo, 2021) (Figure 39).

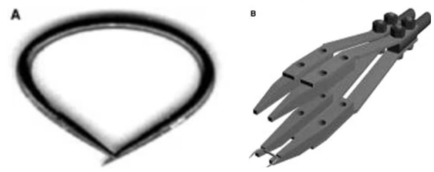


Figure 37: Shape memory stapler (Ng, 2006)

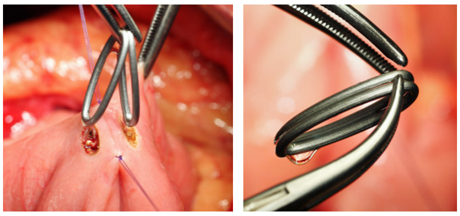


Figure 38: Compression anastomosis clips (Kusnierz, 2013)

Magnetic compression

Both Fan (2011) and Jamshidi (2009), respectively, developed a magnetic tool for sutureless anastomosis. They are designed in different ways (Figure 40) but both consist of two parts, the mother and the daughter part, which hold to each other by use of magnets. Fan's design shows advantages compared to the hand-sutured method and can be used for side-to-side or end-to-side anastomoses. However, the prototype is just in an experimental stage and is not suitable for laparoscopy (Fan, 2011). Jamshidi's magnetic compression device is safe and effective in animal models and compatible with endoscopy (Jamshidi, 2019).

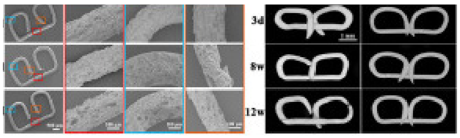


Figure 39: Shape memory stapler (Guo, 2021)

Other methods

Newer techniques to strengthen the suture line are being studied. The approach is to shield it from the influence of the microbiome to improve the healing. Techniques include glueing, seaming the staple line, attachment of laminar biomaterials, and temporary intraluminal tubes (Reischl, 2021). Other methods include self-gripping mesh or laser-YAG to connect tissues. They are not further described because they are out of the scope of this project.

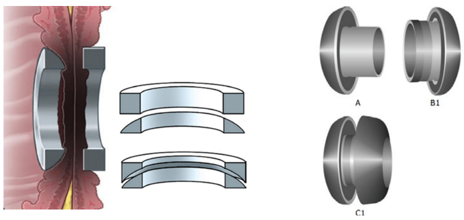


Figure 40: Magnetic compression (Jamshidi, 2009 and Fan, 2011)

Insights

- The most commonly used devices for anastomosis closure are the linear stapler and the needle and suture.
- Some surgeons perform an anastomosis fully hand sutured, but this requires exceptional skills.
- The barbed suture is a great development which cleared out the need for knot tying.
- Suturing devices like the Endostitch facilitate suturing but are not widely used by experienced surgeons due to tissue damage and little control over the closure.
- Robotic-assisted surgery is considered the future of surgery. It is well received by surgeons who experienced it. Disadvantages are the high price and the large setup time. The new closure method should aim to bridge the gap between traditional methods and robotic-assisted surgery.

5. REQUIREMENTS

The previous chapter showed that research on improving techniques and new medical devices has been remarkable in the past decades (Vrakopoulou, 2020). However, there have been devices launched which were never fully accepted by practising surgeons. This chapter aims to determine the requirements needed to create a successful method. Requirements were formulated and updated in an iterative approach. From the literature review, insights on possible risks to the patient criteria could be generated. Those are summarised into “themes” which can be found in Appendix I. In the following months, the requirements were shaped and prioritised based on learnings from suturing courses (Appendix J) and discussions with surgeons (Appendix K). The most relevant requirements are explained in this chapter.

5.1 Safety

Most complications[1] that are occurring during or after gastric bypass surgery are related to the performed anastomosis (Mitchell, 2021) (de Blasi, 2013). These complications include leakage (3% of the cases) and haemorrhage[2] (bleeding) due to the piercing of the needle and staples. Later complications can include internal herniation[3] (7% of the cases) and stricture[4] at the performed anastomosis (5% of the cases) (Mitchell, 2021). The quality of the closure is determined by the successful healing of the tissue and its watertightness. Achieving that consistently remains a significant challenge even for experienced surgeons (Vrakopoulou, 2020).

5.1.1 Tightness

A watertight closure can only be achieved if the stitch positioning and spacing are correct. Stitches should be regular and at an appropriate distance, both, to each other and the edge of the anastomosis. Research suggests that the optimal distance to the edge of the anastomosis, in terms of mechanical strength, is 7 mm with a spacing of 6 mm for 3-0 silk and 3-0 polydioxanone sutures (Khoorjestan, 2017). However, the correct positioning has to be defined by the performing surgeon, based on the individual situation.

Additionally to the spacing, the tension of the stitch also plays a crucial role in the tightness of the anastomosis. If there is too much spacing, granulation tissue cannot form successfully and the risk for leakage is increased. If there is too much force on the anastomosis, there is not enough blood supply and the tissue cannot heal.

5.1.2 Perfusion (blood supply)

Perfusion is essential for tissue healing. Looking at the healing mechanism, it is important that blood vessels can extend in order to allow proinflammatory substances and immune cells (neutrophils, monocytes, and macrophages) to reach the wound. This enables the new connective tissue to build (Vrakopoulou, 2020) (Toure, 2021). If blood vessels are blocked, e.g. by pinching them or applying too much tension, tissue is not supplied with necessary substances which might lead to tissue damage.

5.1.3 Hemostasis (blood stop)

Haemorrhage (bleeding) might happen during any procedures and needs to be stopped. (Toure, 2021). Reasons for bleeding are e.g. staples rupturing blood vessels or blood vessels being hurt when dissecting tissue. If hemostasis (stopping of the blood flow) cannot be achieved, tissue healing is hindered. Without tissue healing, watertight sealing cannot be guaranteed. In rare cases, when there is strong bleeding which cannot be stopped, open surgery is needed.

[1] **Complications**
Early complications include leakage (3% of the cases) and haemorrhage[2] (bleeding) due to the piercing of the needle and stapler. Later complications can include internal herniation[3] (7% of the cases) and stricture[4] at the performed anastomosis (5% of the cases) (Mitchell, 2021).

[2] **Haemorrhage**
Blood escaping a ruptured blood vessel.

[3] **Internal herniation**
Occurs if defects in the mesentery are not closed and can cause strangulation of the intestines.

[4] **Stricture**
When there is a narrowing of the tubular structure after performing an anastomosis.

5.1.4 Tissue alignment

There are three main techniques for aligning the tissue of the dissected intestine[1]: the inverted[2] (serosa-to-serosa), everted[3] (mucosa -to-mucosa), and end-to-end ('buttjoint')[4] method (Figure 43). Benjamin Travers was the first one who described the healing processes of intestinal anastomosis in 1812. They suggested that the healing of the anastomosis needs to be end-to-end, with the entire circumference of the intestine being in contact. Since then, the safety of various suturing techniques has been tested, including inverted, everted and end-to-end methods, suggesting that all of them are suitable and provide a safe and leak-free anastomosis (Nagaya, 1971) with a tendency that the inverted, serosa-to-serosa method is the most desirable procedure (Rusca, 1969). Research by Yauw (2014) suggests that healing may improve by abrading the surface of the serosa when performing an inverted anastomosis. This is based on the concept that serosal damage induces inflammatory adherent processes. An in vivo study showed, however, that the abrasion does not have a positive impact on anastomotic strength or leakage (Yauw, 2014). Another approach causing the minimal mechanical injury of the serosa proved that there is a positive impact on the healing process. In this study, researchers removed the serosa at the place of the anastomosis (deserosalization) and so could increase the mechanical strength of a jejunojejunostomy (Vrakopoulou, 2020).

In common practice, the serosa-to-serosa alignment is preferred by most surgeons, because it shows the best healing and least leakage probability. The reasons for that are the accessibility of the serosa and the tissue properties. Whereas the mucosa is highly vascularized and does not have much strength to hold sutures, the serosa provides an immobile strength layer which is more beneficial for maintaining sutures (Clatterbuck, 2022). Deserosalization is not practised because it is too time-consuming with too few benefits. (personal communication, February 2022).

[1] Tissue of the small bowel (Figure 42)
The intestinal wall of the small bowel consists of three main layers: mucosa, muscularis and serosa. Other layers are not distinguishable without magnification, so they are not important for the creation of an anastomosis.

Mucosa (outer layer)
Facing the lumen (hollow part of the intestine) and is highly vascularized.

Muscularis
Consisting of longitudinal and circular muscles, is responsible for the bowel movements.

Serosa (inner layer)
Consists of multiple connective tissue layers and creates a clear boundary between the gut and surrounding tissues.

(Clatterbuck, 2022)

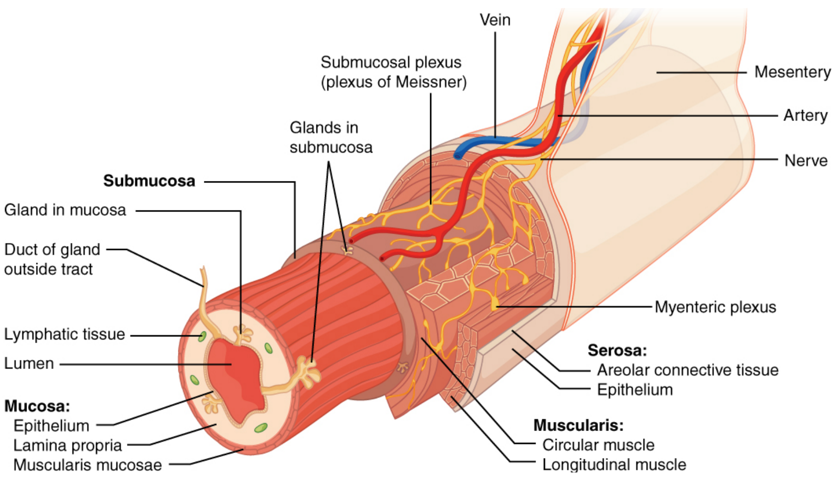
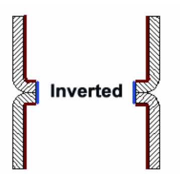
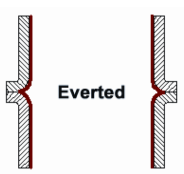


Figure 42: Tissue layers of the small bowel (Oregon State University, n.d.)

[2] Inverted anastomosis



[3] Everted anastomosis



[4] 'Buttjoint' anastomosis

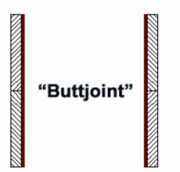


Figure 43: Tissue alignment options Suyker, 2022)

5.1.5 Safety risks

While performing an inverted anastomosis, not only the tightness and healing are important, but also the maintenance of primary functions of the bowel, meaning that the lumen (inner diameter) of the intestine is large enough to pass food to be digested. Therefore, stricture (narrowing) (Figure 44) and obstruction (blockage) should be avoided. These can occur e.g. due to swelling of the wound or a too large inverted cuff. This happens when the stitches are placed too far away from the anastomosis opening and too much tissue is inverted into the bowel.

5.1.6 Materials

There are multiple biomaterials available which are suitable for usage inside the body (Figure 45). Especially the parts which stay inside the body need to fulfil requirements on corrosion resistance, chemical biocompatibility, strength and ductility. Suitable materials include stainless steel (e.g. F139 316LVM), titanium or several alloys (e.g. Nitinol). Biodegradable metals are in research with Amano (2019) showing that a magnesium alloy can be suitable for surgical staples (Figure 46). Regardless of the type of material used, the amount of it needs to be kept low. The total surface of the parts needs to be as small as possible to reduce the risk of infection and rejection.

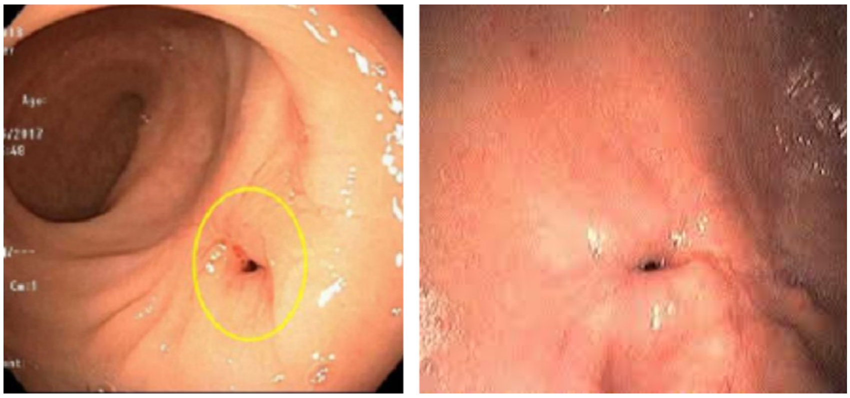


Figure 44: Example of a stricture (Kawak, 2019)

Figure 45: Hip implant made of biomaterials (atriainnovation, 2021)

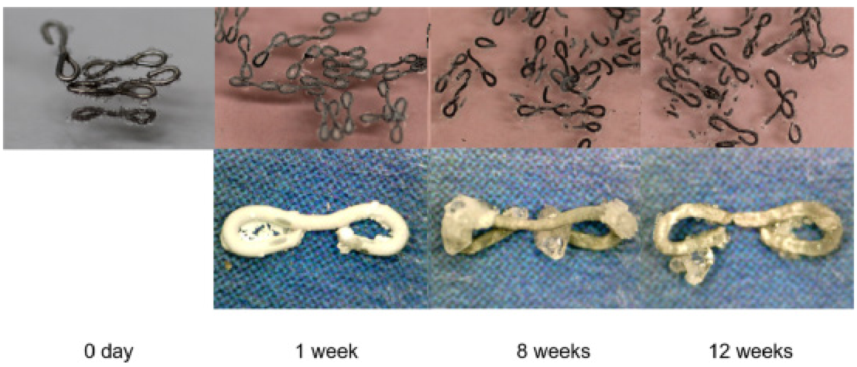


Figure 46: Degradable staples (Amano, 2019)

5.2 Comfort

5.2.1 Workflow

In the analysis of the hand-suturing (chapter 3. Observations), slips were identified. Even though experienced surgeons can work around these slips, they can lead to delays in the procedure and discomfort for the performing surgeon. From the learnings of the analysis, requirements can be formulated in order to avoid slips in the new closure method.

Time
In some surgeries, time is essential for the safety of the patient. In a carotid artery surgery, for example, every second counts to supply the brain with blood. In gastric bypass surgery, time is only a risk factor for the patient if the delay is larger. For the surgeon, however, a delay can cause discomfort due to cognitive effort and physical strain.
In the traditional method, multiple steps needed to be taken in order to do one stitch. The new method should reduce steps to make the application easier. This can be achieved by having fewer transfers from one tool to another. Another step that prolonged the procedure time previously, was the threading of the needle through a loop at the end of the barbed suture. Fine manoeuvres like this should be avoided. Additionally, there should be no loose parts which can fall and need to be picked up again, like the needle.

Flexibility
With the tool operated by one hand only, the other hand is free to position the tissue. This gives the surgeon more freedom to handle the tissue and decide on the optimal position of the next stitch. Additionally, the shape of the remaining opening has to be considered. The anastomosis opening is not symmetric after the application of the linear stapling. Surgeons have to adapt to that to create a watertight closure. Since the tissue is very elastic and parts of the opening are out of view, it is impossible to plan the placement of all stitches from the beginning. A one-action closure therefore not desirable. During interviews with surgeons, I discovered that they prefer to position the needle on each side first and then approximate the tissue. Positioning the tissue first is technically difficult and requires two hands. Therefore, the new method should be placed without positioning the tissue first.

5.2.2 Surgeon's needs

Accomplishment
The closure method should require technical skill to a certain amount for the operator to feel they accomplished something. The basic needs for challenge and achievement were identified during the observations in the operating room. For the surgeons to get the feeling of success, they should have control over the closure instead of the device doing everything automatically. The new method should empower surgeons rather than question their skills.

Acceptance
During surgery, there is not much room for the surgeon to make mistakes because that might lead to critical outcomes for the patient. For surgeons to change their current workflow and devices they are used to, is a big step. It is risky and requires a lot of trust. One of the most important things surgeons base their trust on is their own skills. Many surgeons would rather neglect their personal comfort instead of relying on an unknown device. For the development of a new closure method, it is therefore essential to keep surgeons involved in the process from the beginning and listen to their concerns. Acceptance can be achieved by engaging users in the development and testing.

5.2.3 Device requirements

Cardridge
Taking the device out of the body and putting it back requires time and is cumbersome. The device needs to be pulled out and handed over to the scrub nurse. The scrub nurse is doing the refill while the surgeon is waiting. Then it needs to be handed back and put inside the abdomen and stirred into the field of view again. The new device should have a cartridge included or the possibility to reload inside the body for reduction of workflow steps and time.

Suitable for laparoscopy
During field research, I observed that the suture can entangle itself when it is kept too long. Additionally, a too-long suture cannot be tightened in one go due to little space in the abdomen. Conventional sutures also have a shape memory effect, which often leads to difficulties when performing a knot. The new device should be suitable for small spaces and work without requiring large movements. It should work in a laparoscopic setting and therefore fit inside a 12mm trocar.

5.3 Prioritisation

Figure 47 shows an overview of the above-formulated requirements. The priority for this project is patient safety which is mainly concentrating on leakage prevention. The surgeon's comfort is also prioritised high because the surgeon's performance ultimately affects patient safety.

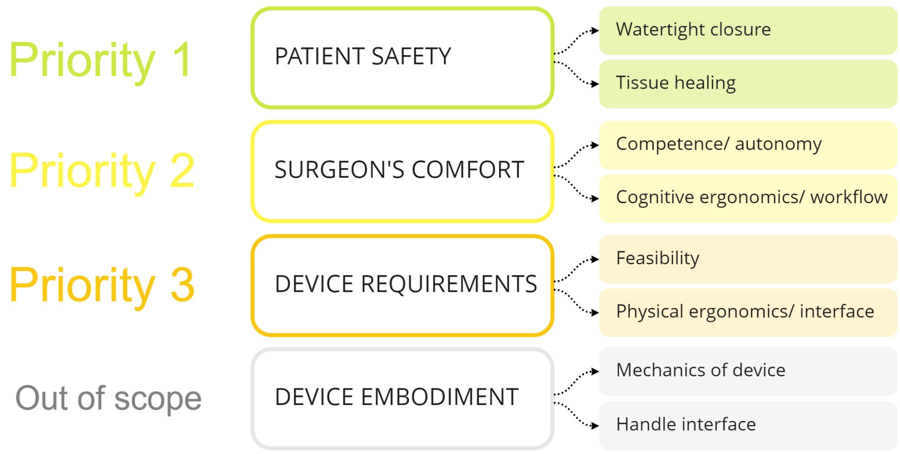


Figure 47: Overview and prioritisation of the formulated requirements

Insights

The requirements described in this chapter were taken as a guide for the development of the new closure method. Thereby requirements for the safety of patients and surgeons had the highest priority. Requirements for the comfort of the surgeon are also important because the surgeon's performance ultimately influences the quality of the surgery.

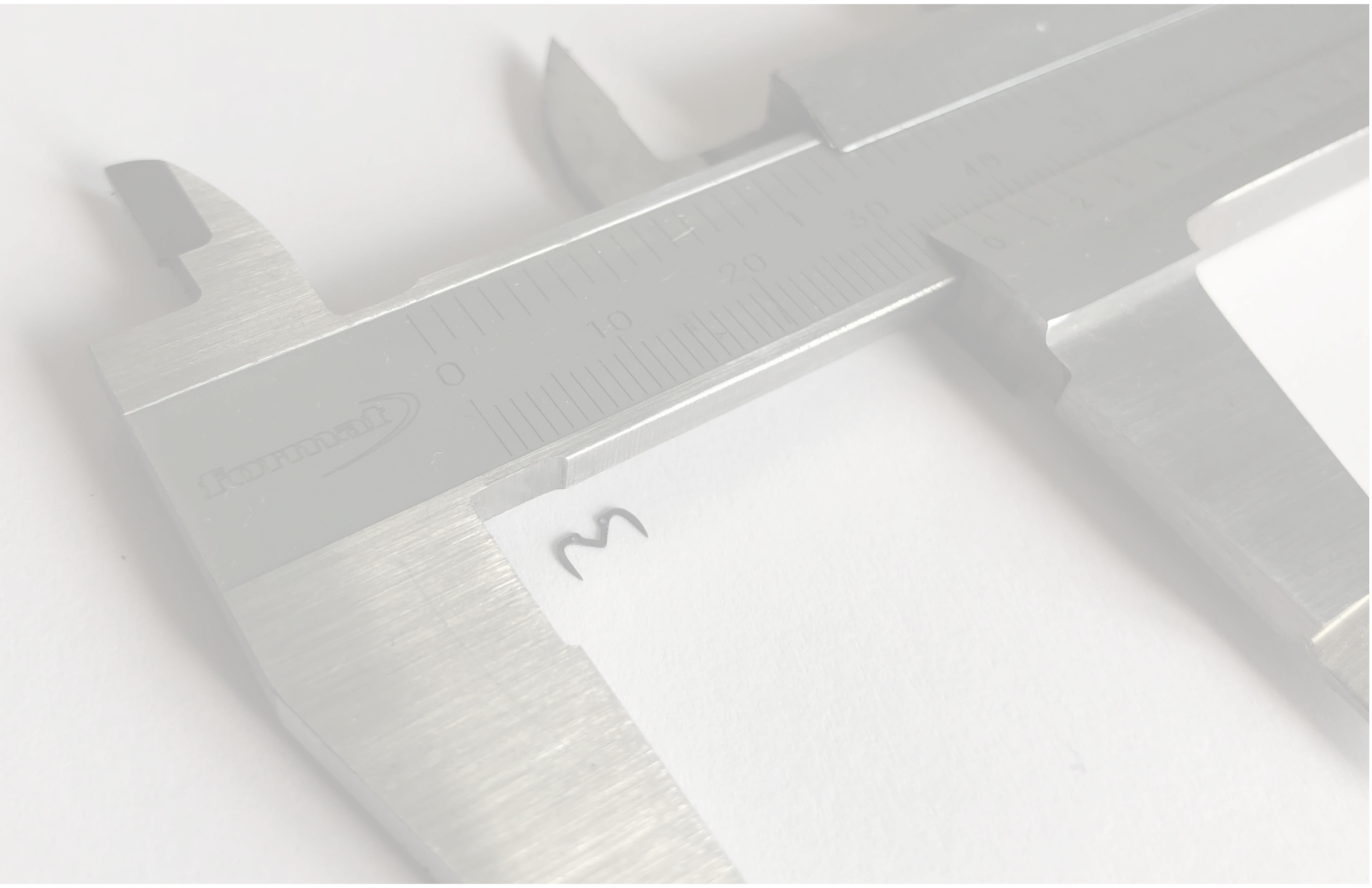
Safety requirements (most important ones)

- The water tightness and healing of the anastomosis are the most critical requirements for the performance of an anastomosis. In order to achieve that, tissue perfusion and hemostasis need to be warranted and the tissue should be aligned correctly.

Comfort requirements

- For the surgeons, it is important that the closure method fits into their current workflow. Thereby, the time should be reduced while having a more intuitive procedure. Since the surgeon needs control over the closure, flexibility in positioning stitches should be offered.
- By having full control of the closure, surgeons gain a feeling of accomplishment and mastery.
- Surgeons should be included in the design process in order to achieve acceptance.

6. DEVELOPMENT



6.1 Ideation

This project is an intersection between medical expertise, engineering and design. Since I am seeing the problem from a design perspective, I used Design Thinking as an approach to explore possible solutions. With iterations of converging and diverging phases, I engaged in problem-solving with the participation of the user from the very beginning (Design Council, 2005). Hands-on prototyping and testing were done to evaluate ideas and concepts quickly. The Loughborough Design School iD cards (Evans, n.d.) helped to find the right visualisation method for each step of the process.

After defining the requirements I diverged widely to explore different closure methods. The ideas were driven by fulfilling one or more requirements and helped to build a base for discussion with the users. Together with the surgeons, I could identify which requirements are more and less important. An overview of the first ideas can be found in Figure 48.

One-action closure: Supposed to close the remaining opening in one action, with as little time as possible. The disadvantage is that there is not much adaptability which compromises patient safety in terms of leakage.

Clip: Multiple clips are added to locations where it is needed. Fulfils the requirement of adaptability and the surgeon's freedom of closure but takes more time and introduces new steps in the procedure.

Stapler: Known concept for surgeons which enhances acceptance. The angle is not optimal which might require a mechanical solution for tilting the head.

Suture device: Using the traditional suturing technique and improving suturing devices which are on the market, like the Endostitch. Rounding the needle, for example, might improve the suturing workflow, however, the stitching device already has a bad reputation which will make acceptance difficult.

Compression: The advantage of compression closure is that the tissue is not pierced. The pressure, however, might cause similar or worse damage to the tissue.

Tacks: The tack solution is based on the reduction of time and easy workflow. It compromises the requirements on safety regarding water tightness because the tacks might be ripped out.

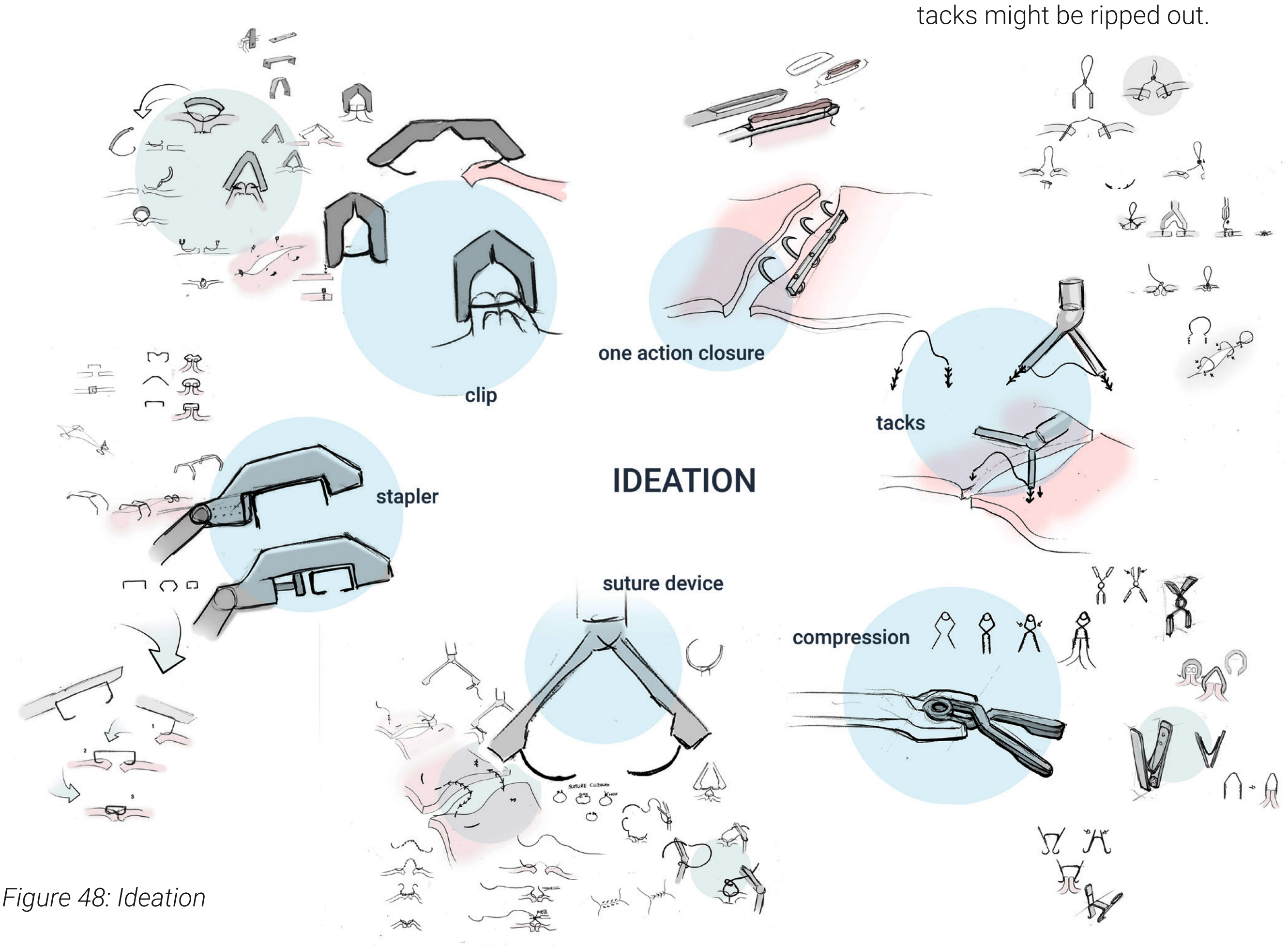


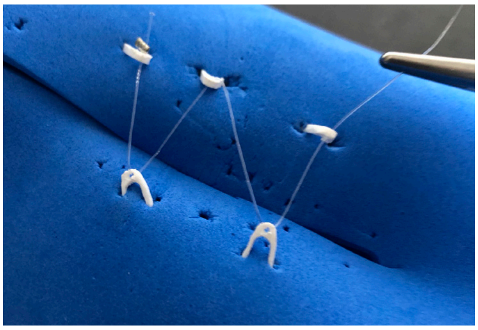
Figure 48: Ideation

6.2 Conceptualization

From the ideas that were generated, four concepts were chosen to be the most promising. In order to evaluate them, first scaled-up prototypes were made to test feasibility and ergonomics. Participants in the evaluation were surgeons and medical students.

6.2.1 Concept tacks

The idea of this concept is to puncture tacks into the tissue which have small hooks on them that do not allow them to slide back. The tacks are connected by a suture which can be tightened after positioning the tacks correctly. The suture also acts as a cartridge and it prevents the tacks to get lost within the abdominal cavity.



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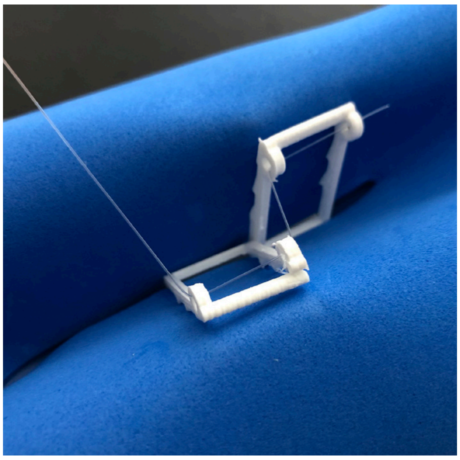
- Tissue grasper (or another tool) is needed to press tissue against
- Risk of tissue damage
- No possibility to remove
- Tacks might be ripped out
- Material might prevent tissue to touch

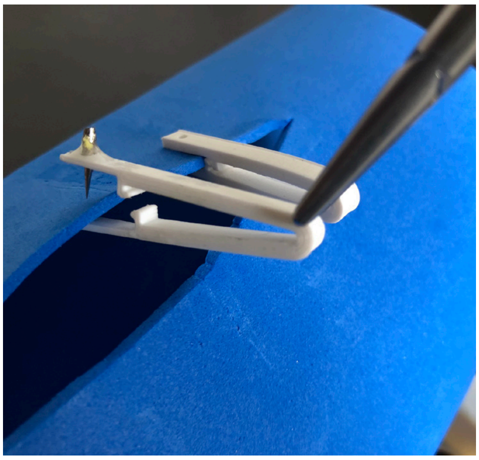
+

+ Tacks hold very strong
+ Tissue inverts if tacks have distance to the edge

6.2.2 Concept clamps

The clamps were an idea inspired by compression anastomosis since they do not puncture the tissue. However, there were clear signs of tissue damage, especially with thicker tissue. During user testing, it turned out that the attachment is cumbersome and the method is not suitable for different tissue thicknesses.





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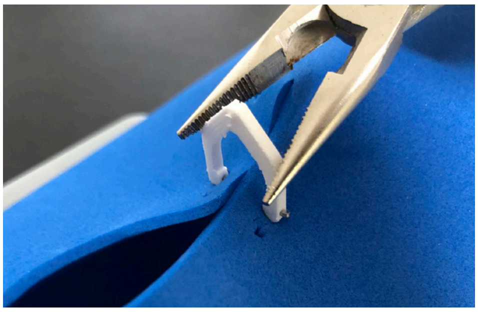
- The pre-stretched clamp is difficult to position
- Clamp strength can not be adapted to the tissue thickness
- Tissue trauma from pinching
- Needle might damage tissue when positioning
- Too much material use
- No strong holding (without a needle)
- Not suitable for different tissue thicknesses
- No inverting of the tissue

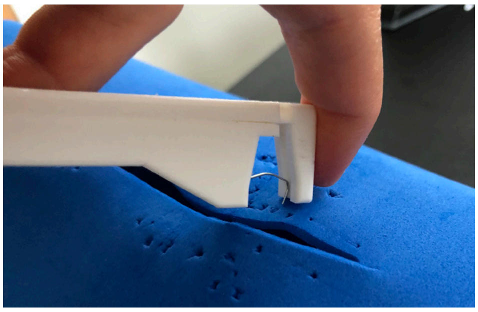
+

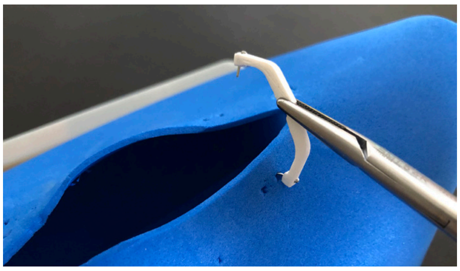
+ Simulation of the parallel stitch
+ Strong holding (with a needle)

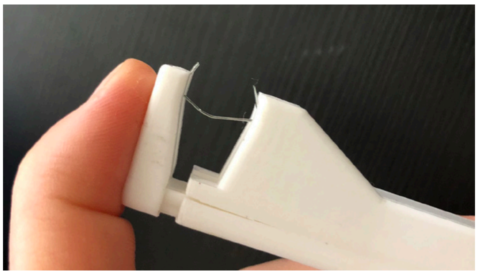
6.2.3 Concept perpendicular (a) clip and (b) staple

This concept has two variations, a clip and a staple. Both are attached to the tissue and closed in a similar way. Both clip and staple have two symmetric legs which have a hook. The hook is supposed to grab the intestinal tissue when positioning the tissue. The idea is that one side of the tissue is picked up and brought to the other side, where the second part of the tissue is attached. Finally, the clip or staple is pushed together to approximate both sides of the tissue to each other.









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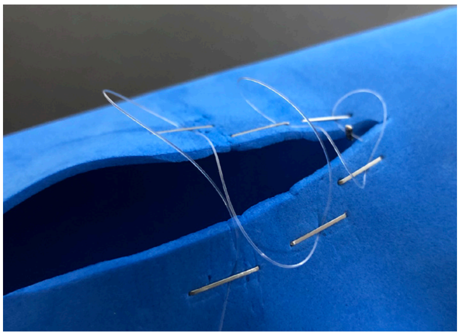
- Hook slips out when picking up the tissue
- Everted closure, not easy to control tissue alignment
- The handling is cumbersome
- The closing needs a lot of force
- Too much material use
- Accessibility is an issue

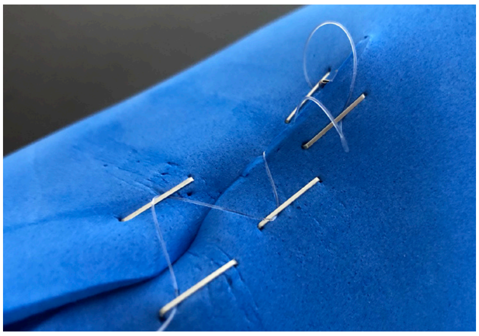
\+

\+ Possibility to have adaptable closure force (in steps)
\+ Flexible positioning

6.2.4 Parallel stapler - WINNING CONCEPT

The parallel stapler combines the advantages of stapling and suturing. Whereas stapling is quick and easy to attach with one hand, the suture has the ability to bring the two sides of the tissue together in a precise and controllable manner. In this concept, the thread is already attached to the staples and can be pulled as soon as the staple is attached to the tissue. This facilitates attachment and closure of the opening.





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- If too much pull, staples come out
- Access on the edges is difficult if attached from the side
- Staple is squishing the tissue (can be solved with a round design)

\+

\+ Quick and easy workflow, with one hand
\+ Does not require tissue placement first
\+ Inverted stitch, if staples have a distance to the opening
\+ Flexible attachment of staples

The decision for this concept was made because it had fewer risks compared to other concepts. Since patient safety is the highest priority, bad patient outcomes are not acceptable. In terms of comfort, the parallel stapler is more intuitive to use and contains less material surface. These insights were taken from testing with medical students. The decision-making was based on the testing, requirements and evaluations of the researchers which can be found in Appendix L.

6.3 Design considerations

Several design considerations had to be taken into account when further developing the parallel stapler, including staple shape, attachment of the suture, the closing mechanism and the cartridge design. In this chapter, the most impactful design choices and the outcomes are presented.

The staple design is one of the factors that influence the validity of the concept in terms of safety and producibility. For the staple design, shape, behaviour when penetrating the tissue and behaviour when closing need to be considered.

6.3.1 Staple mechanism

There are a number of possible variations of how a staple could look like. A selection of the shapes I experimented with can be found in Figure 49. The closure principles which had the most potential are shown in Figures 50-52. Whereas principles 1 and 3 are applied without from the top of the tissue, principle 2 needs a counter force from underneath the tissue. In principle 1 the forces are applied from the side and in principle 3 two forces apply downwards and the counter force applies from the middle towards the opposite direction.

To evaluate which principle is the most beneficial, an experiment on a pig intestine was made. Since there was no bowel with all tissue layers available at the local butcher, the experiment was made only with the serosa layer. To hold the tissue in place, it was pulled over a construction made of plastic (Figure 53).

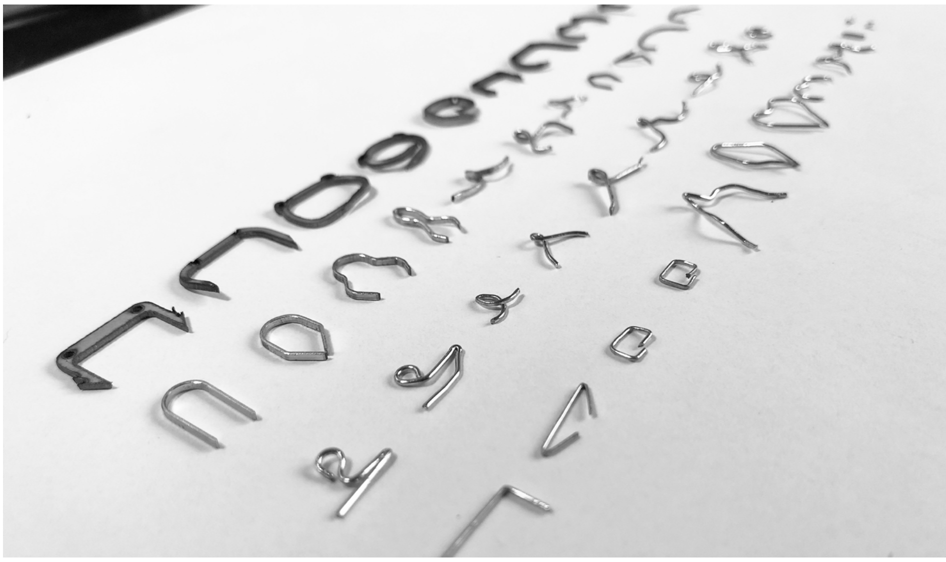


Figure 49: Selection of staple shapes

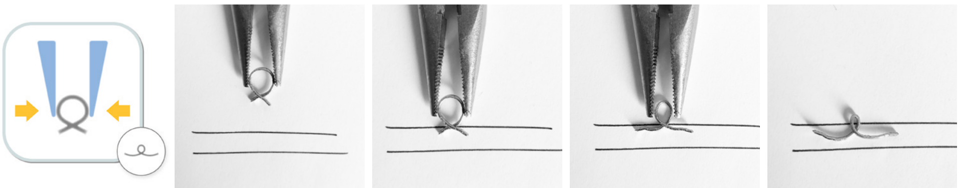


Figure 50: Principle 1: Pressing-from-the-side principle

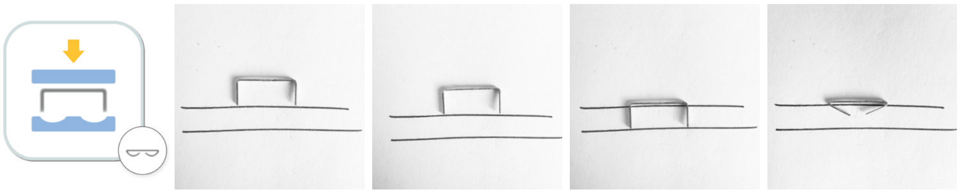


Figure 51: Principle 2: Office stapler principle

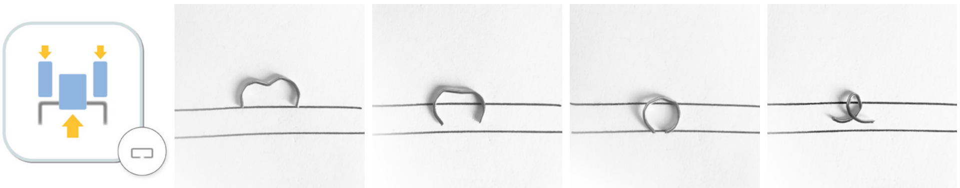


Figure 52: Principle 3: Skin stapler principle

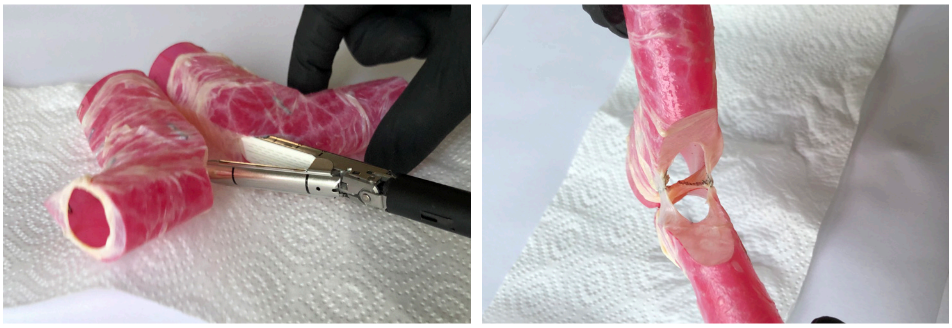


Figure 53: Preparation of the test setup, creation of the connection with the linear stapler

Even though only one tissue layer was used, the test results are still valid. The serosa is the layer where the suture traditionally holds on because it is the strongest layer.

The goal of the experiments was to compare the behaviour of the staples when piercing the tissue, the easiness of the staple closure and the strength they hold into the tissue. Impressions can be seen in Figure 54-56.

The main findings were that the staple legs had to be as straight as possible to penetrate the tissue easily, but still direct towards the closing direction to not rip the tissue. Regarding grip strength in a closed position, horizontal legs were the most beneficial. Hooks in the staple did not improve the strength and damaged the tissue.

The 'skin stapler principle' had the best outcomes in terms of feasibility and performance. However, the staple shape had to be optimized. This was done in Solidworks. A simple rotation shows how the legs are supposed to bend together. In Figure 57 the first design can be seen, which explains why the tissue was ripped. After the optimization, the legs are supposed to slide into the tissue without squishing (Figure 58).

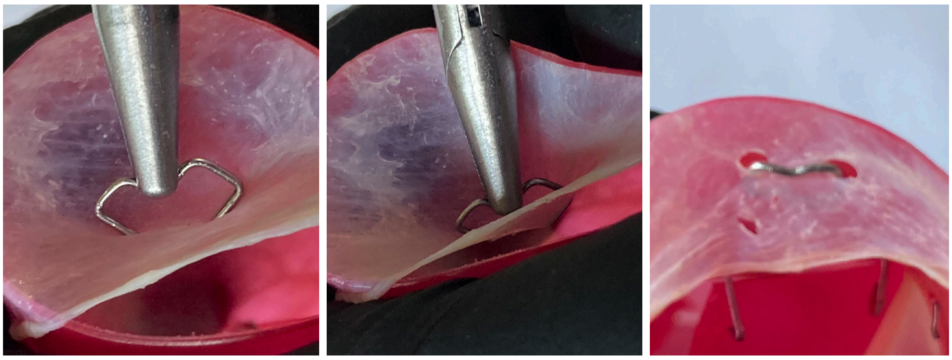


Figure 54: Behaviour of staples and tissue when piercing

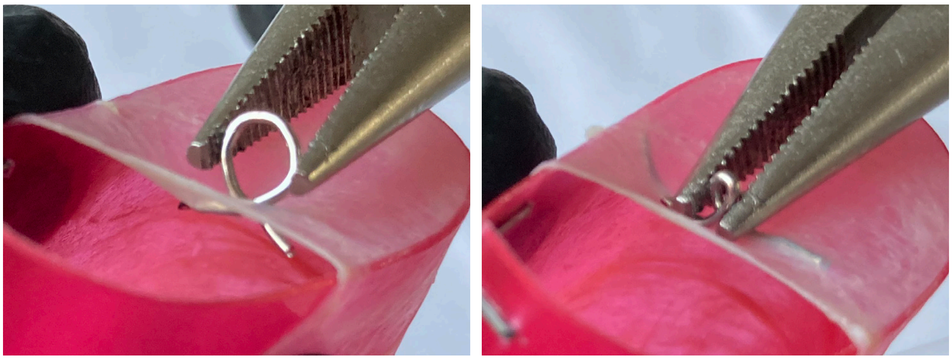


Figure 55: Behaviour of staples when closing

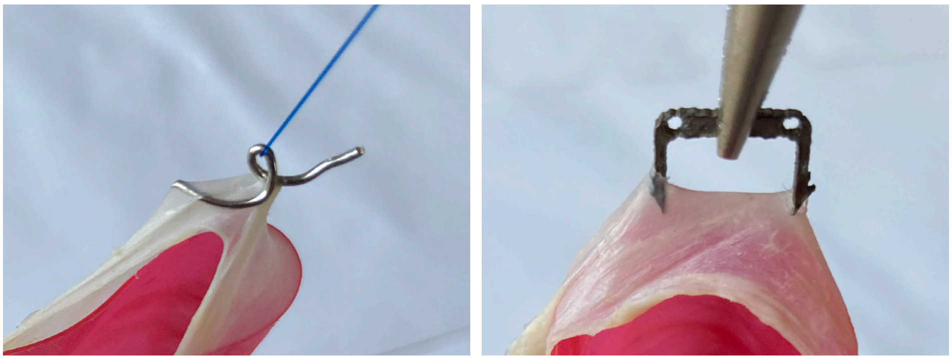


Figure 56: Behaviour of tissue when pulling the staple out

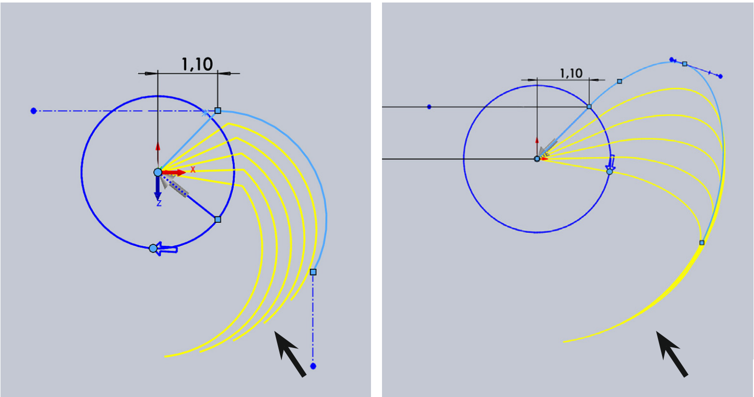


Figure 57: Staple shape before and after optimization

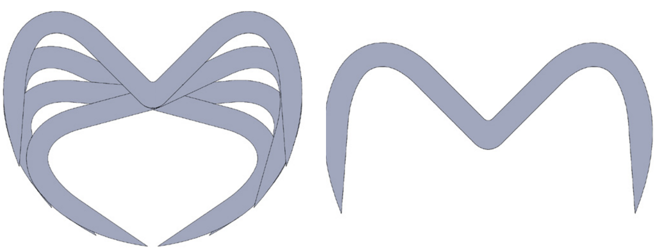


Figure 58: Staple shape after optimization, closure (left), open staple (right)

6.3.2 Attachment of the suture

The concept requires a suture to be attached to the staple. Thereby, the suture is only supposed to slide through the staple in one direction. In the other direction, it should be locked so the surgeon can pull the stitch tight.

The first option being explored was to have two holes in the staple where the suture runs through (Figure 60). This idea was inspired by the parallel stitch where the needle is positioned parallel to the opening and so creates the suture to go in and out of the tissue. A prototype of this idea was built and the suture sliding was tested (Figure 61). The results showed that two holes which are cut perpendicular to the front plane would create too much resistance which would not allow the suture to move. This problem might be solvable by changing the orientation of the holes by 45 or 90 degrees (Figure 62). This, however, might cause an increase in costs because traditional laser cutting manufacturing will not be possible. Another disadvantage is that the pulling force might not be distributed equally on both sides which might cause the staple to tilt and fall out (Figure 59).

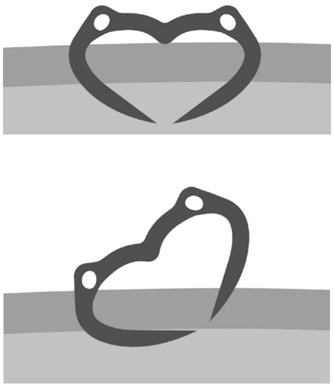


Figure 59: *Risk of falling out when staple is pulled more on one side*

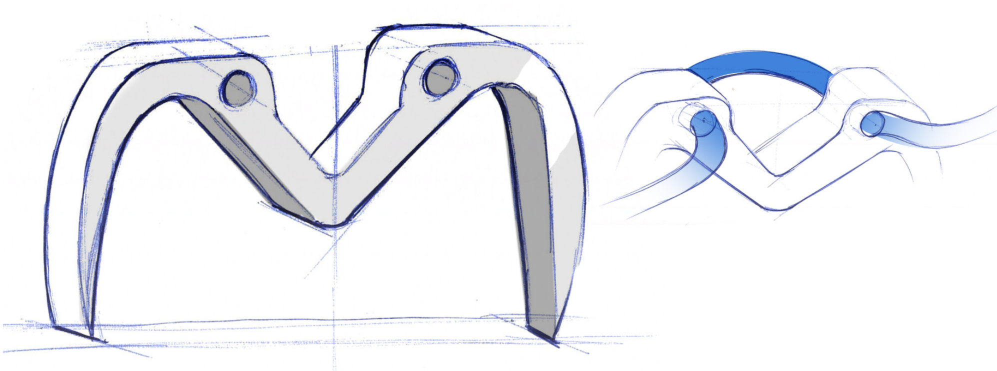


Figure 60: Staple with two holes

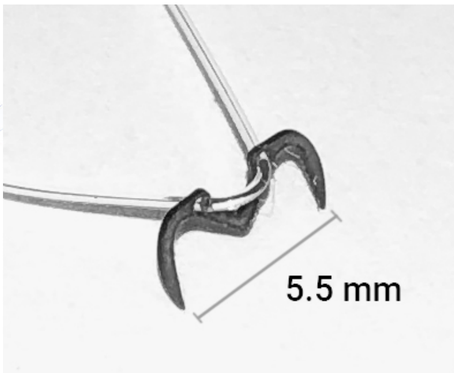


Figure 61: Prototype made of stainless steel

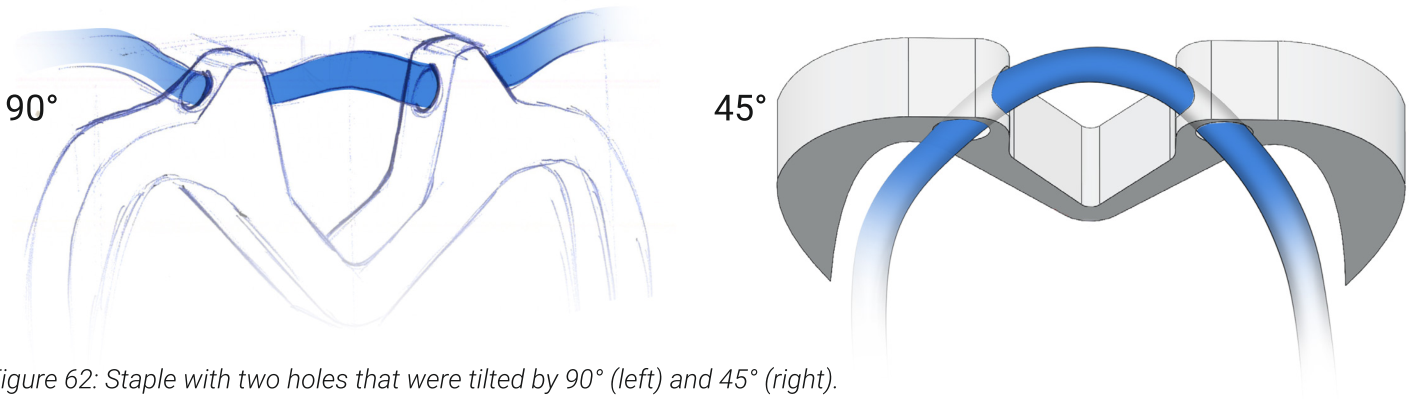


Figure 62: Staple with two holes that were tilted by 90° (left) and 45° (right).

Another shape which was thought of was the tube on top of the staple (Figure 63). Due to the limitations of producing such a shape during the project, there was no prototype built. However, assumptions can be made about the performance. Since the previously chosen staple shape requires force on the top part of the staple to close it, a tube is not recommended in that location because it will lead to deformation. The length of the tube and the openings for the suture being perpendicular to its further course might lead to similar outcomes than with the two holes, that the suture will not run smoothly. Finally, the estimated production costs in this version are higher than for other variations so it is not recommended to continue with it.

In order for the suture to run smoothly, the number of holes was reduced to one (Figure 65). This gives the advantage of having less resistance when pulling the suture in direction of the hole but creating a locking mechanism when pulling the suture in the opposite direction (Figure 66). Another advantage of having only one hole is that the force is always distributed equally on both legs so the staple does not tilt. This prevents it from sliding out from one side (Figure 59). Regarding storage, having one hole is also beneficial because the suture can simply run straight (Figure 64) (also see chapter 6.3.4 Cartridge).

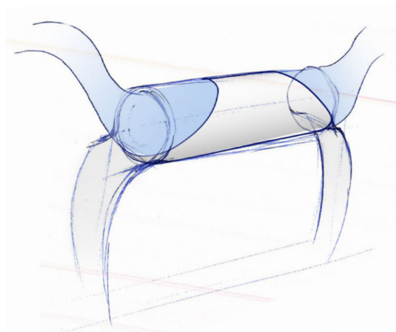


Figure 63: Staple with tube for suture

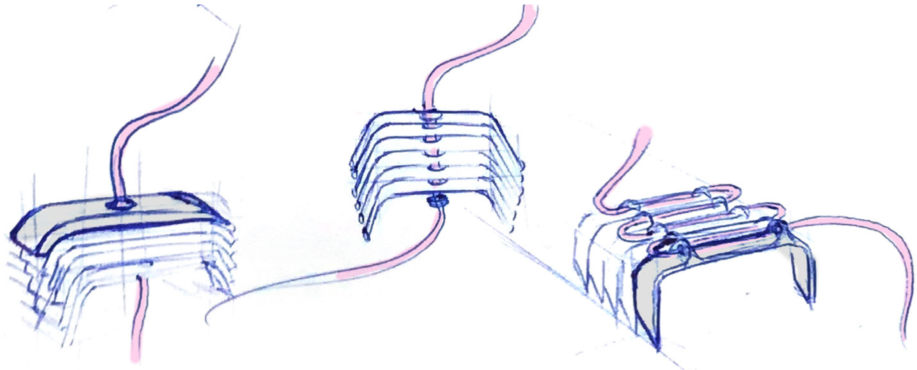


Figure 64: Variations of suture attachments in cartridge

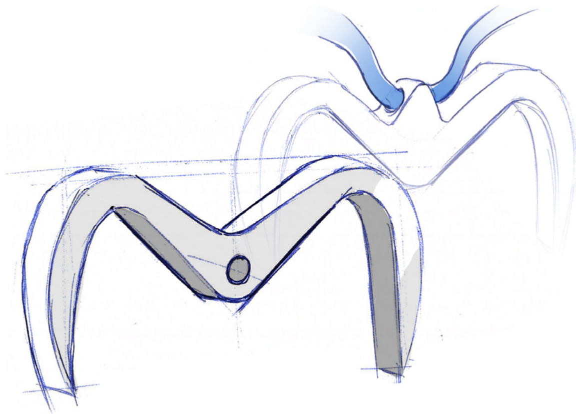


Figure 65: Staple with one hole, variations

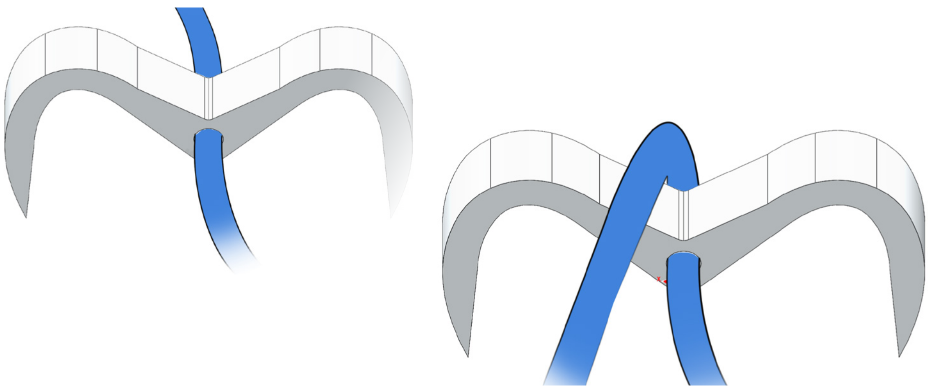


Figure 66: Change of resistance when pulling the suture in direction of the hole or in opposite direction

6.3.3 Locking mechanism

The method requires the suture not to slide back in order to guarantee a tight closure. Therefore, a locking mechanism should be integrated into the design. Different options were explored, including a closing hinge in the staple, similar to a valve or a barbed suture which locks itself in the opening. Considering the size of the hole (0.35 mm), a precise valve of this size will be very difficult and very costly to manufacture. The option with the barbed suture is both cost-effective and already known by surgeons which enhances the acceptance. For the barbed suture to run smoother, one side of the hole will be rounded off. For it not to slide back easily the other side will stay edgy (see Figure 67).

Further optimization of the shape led to a final design which can be seen in Figure 70. The process of how this shape developed is described in chapter 7.1 Finite Element Analysis.

6.3.4 Cartridge

During the talks with surgeons, it came apparent that a cartridge needs to be included in the design because reloading outside of the body takes too much time and effort. The hernia stapler[1] was taken as a reference for the cartridge. Here, up to 10 staples are included in the device (Figure 68). Those are arranged on top of each other, parallel to the staple application. For the new method, another storing is considered because more staples are needed. Placing the staples next to each other allows to place as many staples as needed because the length of the device is not as restricted as the diameter (Figure 69). The only disadvantage here is that the staples need to flip before they can be applied. Tilting them by 45° takes some more space but the flipping angle is reduced significantly which makes the mechanism more feasible (Figure 71).

The embodiment of the device, including the mechanics of the cartridge, is not in the scope of this project. One option is proposed, however, there are a more possibilities on how the device can be designed. The suture could, for example, only be attached to the staple when it is applied. For this, the staple shape should be open and enclose the suture as soon as fired. More variations should be explored in further research and tested.

[1] **Hernia stapler**
The hernia stapler is used to close the mesentery defect after gastric bypass surgery.

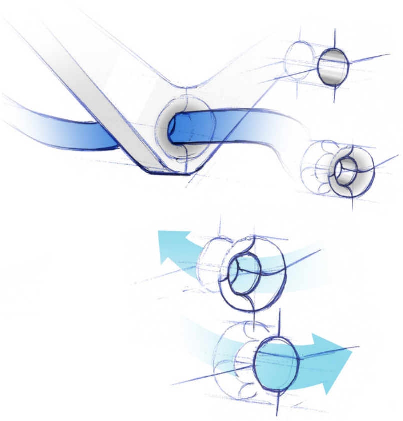


Figure 67: Detailing of the staple hole, to make barbed suture run only in one direction

Figure 68: Original hernia stapler cartridge

Figure 69: Cartridge with different orientation

Figure 70: Final staple shape (open and closed)

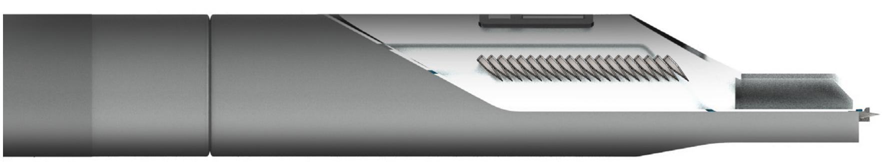


Figure 71: Staples in 45° for easier flipping

6.3.5 Workflow

During interviews and testing with surgeons, I also addressed the current and desired workflow. This gives hints about which functions the device should include and how it should work.

Tissue positioning
During the observations, I discovered that the positioning of the tissue is not an easy task, especially if the tissue needs to be dragged a lot. Therefore it is desired to apply fixators on the tissue first and then approximate these (Figure 72). For the fixation of staples in the tissue, some force is needed. To create a counterforce, the tissue needs to be pressed against the device. The surgeons were asked if an application from the top or from the side was desired, whereas the side version includes a counterforce (Figure 73). Surgeons expressed that an application from the top is better even if the tissue grasper is needed to hold the tissue in place. Since the surgeons need a free hand for the grasper in this case, the new method was developed to operate with one hand.

Suture handling
One of the issues that were identified in the analysis was the entangling of the suture. Surgeons mentioned that the longer the suture the more difficult it is to handle it. For most flexibility, surgeons should have control over the suture length during the procedure.

Finalizing the stitch
There should be the possibility to end the stitch at any time, also when there are still staples left. Due to the locking mechanism, the surgeon has the option to cut the suture at any position without it sliding back. It is recommended though to first pull the stitch tight.

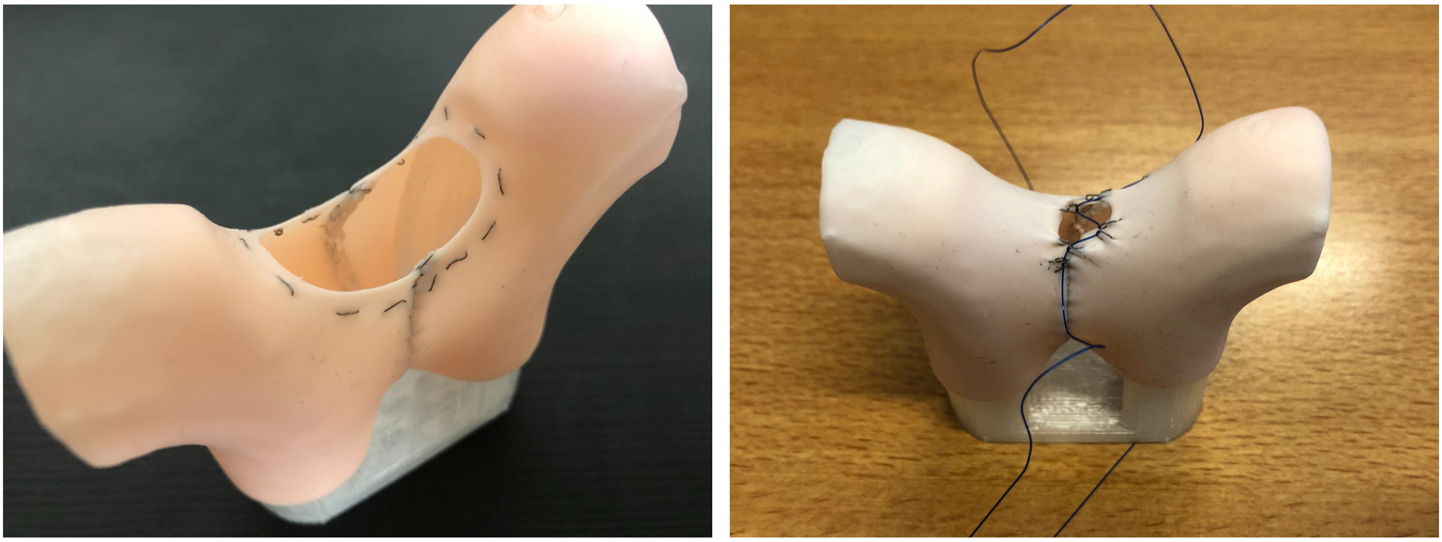


Figure 72: Jejunojejunostomy model with staples being placed first (left) and the two sides approximated after (right)

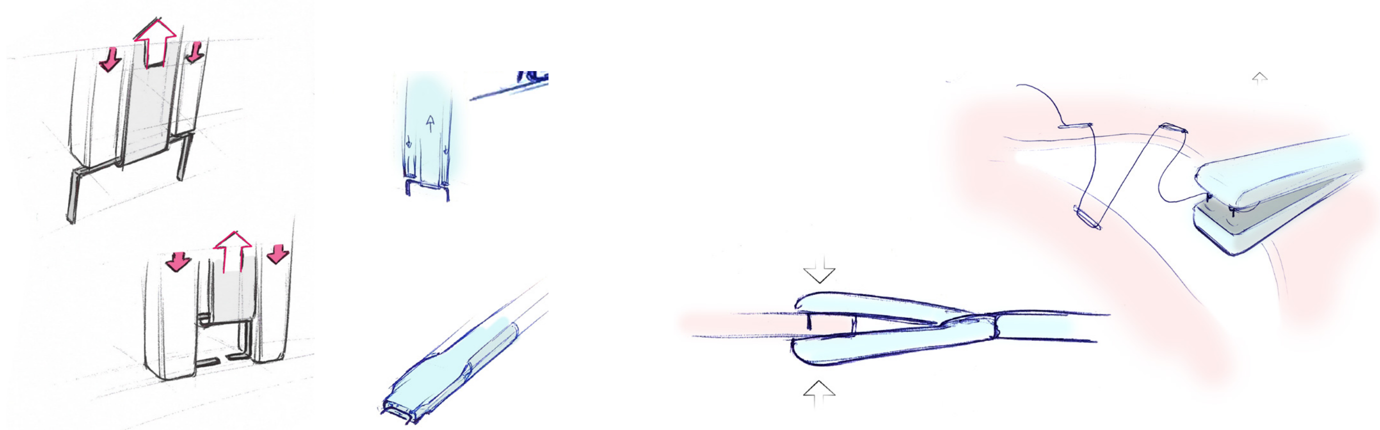


Figure 73: Two verstions of staple application: from the top (left), from the side (right)

6.3.6 Prototyping

The first staples were manufactured with a metal laser cutter[1], however, it could not provide the needed accuracy so those parts were made on a 1:10 scale (Figure 74). Different shaped staples were tested on foam paper. The damage to the material was observed to make decisions about the staple shape. Straight legs, for instance, led to significant tissue squishing (Figure 76) whereas rounded legs prevented the tissue from squishing. The tests also proved that the tissue approximates in an inverted manner if the staples have a certain distance to the edge (Figure 75). Later in the process, a batch of 1:1 scale staples was produced with a UV laser cutter[2] from TU Delft. The staples could be produced with dimensions of 5.5x2.5x0.2 mm and a hole of 0.35 mm. This proved the feasibility of producing staples of that size. However, the initially planned thickness was 0.6 mm. Due to production limitations, this thickness could not be manufactured on the available resources so stainless steel with 0.2 mm was used for the staples (Figure 77).

[1] **Laser cutting**
Laser cutting is a method which uses a laser to melt or vaporize a material. Hereby a high-power laser beam is directed onto a sheet material by an optical setup.

[2] **UV Laser cutting**
The short wavelength of ultraviolet light translates to smaller spot sizes. Also, no extra heat stress is generated on the material which leads to more accurate cuts in the manufacturing.

Figure 74: Staples produced on a CO2 laser cutter, 1:10 scale

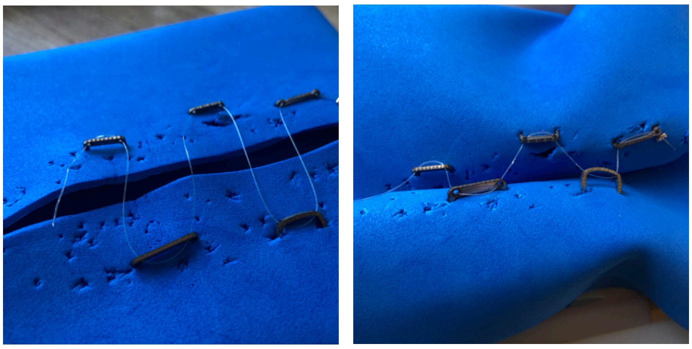


Figure 75: Proof of principle: Foam paper inverts when pulling the suture

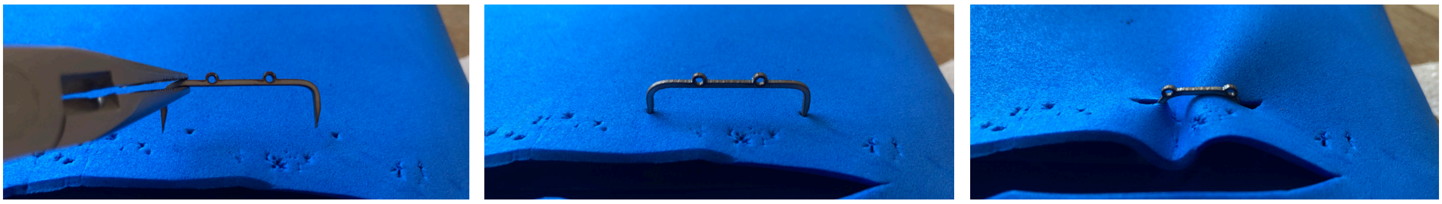


Figure 76: Staple with straight legs squishing the material

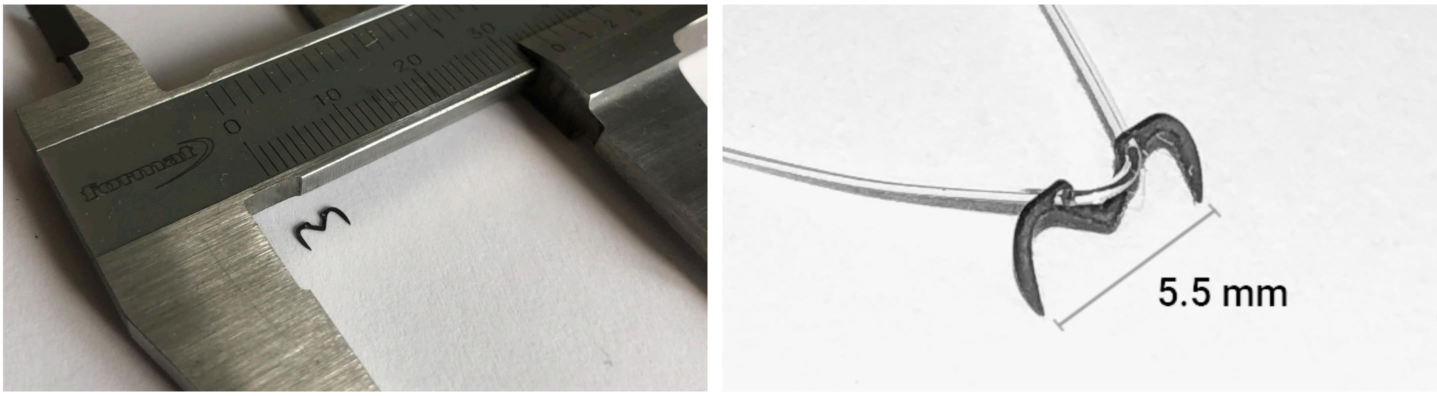


Figure 77: Staples produced on a UV laser (1:1 scale). The suture is 0.3 mm thick and fits through the 0.35 mm holes (right)

Since the dimensions of the device are very small, most of the first prototypes were built on a bigger scale. This is because a casual FDM 3D printer[1] has tolerances of at least 0.1 mm. Most of the parts require smaller tolerances, so quick prototyping on a real scale was not ideal. For the feasibility tests, however, a 1:1 scale "proof of principle" prototype was manufactured.

Existing laparoscopic training devices (Figure 78) were considered for reusing the mechanisms. The dissector turned out to be most useful so it was manipulated for prototyping (Figure 79). Hereby, the top of the dissector was carefully removed with a hand saw and the bolts of the mechanism were taken out. What remained was the handle, tube and pole which moves up and down when triggering the handle (Figure 80).
Then, the new top parts were produced by external manufacturers. SLS printing[2] was chosen to be suitable because it is more accurate than FDM printing. Nylon was chosen as the material because it is not as costly as metal printing whilst providing enough strength for a prototype (Figure 81).

To make manufacturing easier, the design was simplified in the way that it only shows the closure mechanism, without a cartridge. The staples had to be inserted manually into the device to test them. When inserting, pressure could be applied to the hook to fixate the staple (Figure 82). When applying more force, the hook pulls the middle part of the staple which makes it close. The function of the prototype can be seen in Figure 83.

[1] **FDM printing**
Fused Deposition Modeling (FDM) printing works by extruding thermoplastics through a nozzle which heats up the material and makes it deformable. When touching the building plate, the material cools down and goes back to the solid state. In this way 3-dimensional structures can be built layer by layer.

[2] **SLS printing**
Selective laser sintering works with a laser which selectively melts powdered plastic material. This allows for higher precision and more complex shapes compared to FDM printing.

Figure 78: Laparoscopic training devices that were considered for prototyping

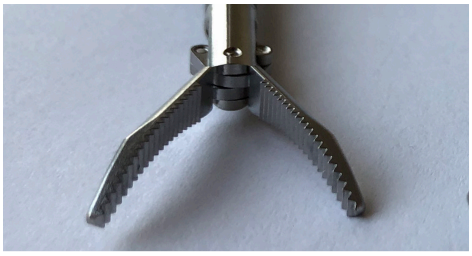


Figure 79: Laparoscopic dissector which was used for prototyping

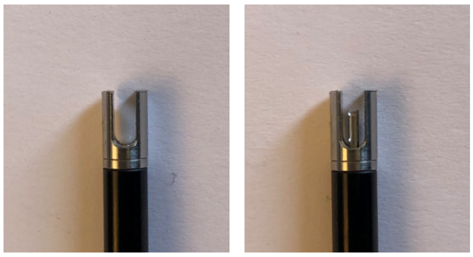


Figure 80: Laparoscopic dissector after manipulation

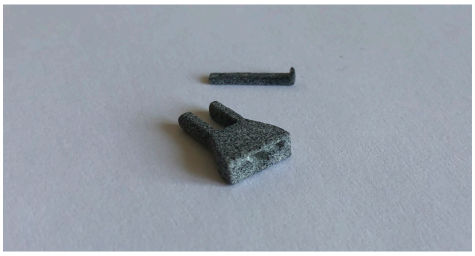


Figure 81: SLS printed parts

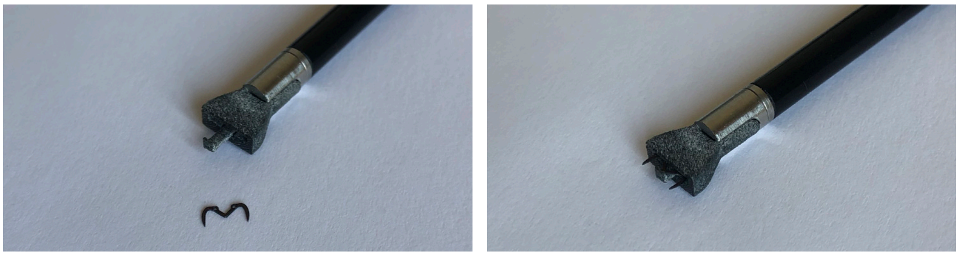


Figure 82: Device with hook, manual insertion of the staple

Figure 83: Device with staple inserted (left), positioned (middle) and placed (right)

7. EVALUATION

7.1 Finite Element Analysis

To predict the bending behaviour of the staples, a small batch was produced with a UV laser cutter (see chapter 6.3.6 Prototyping). However, due to limitations in the manufacturing, the staples were produced at 0.2 mm thickness instead of 0.6 mm which made the proportions of the cross-section inadequate for bending. When applying force on the handle, the staple was supposed to bend but not enough force could be created for it to perform this action. Since the test could not show the behaviour of the staples when bending, a Finite Element Analysis (FEA) was done. Hereby, a staple version presented in chapter 6.3.6 Prototyping was used. The simulations helped to understand the staple movement and led to further optimization of staple shapes and suture attachment. The most important results of the FEA are presented in this chapter.

A nonlinear simulation with 2D simplification was used to reduce the computing power. As a material, titanium alloy and stainless steel which are classified as biomaterials were tested. Both showed similar results with varying values in yield strength. Before running the simulations a mesh was created. Hand force should not exceed 45 Newton (MEADinfo, 2009) so considering the handle displacement being 5cm and the hook displacement being 2mm, the force applied to the staple was estimated to be 1125 Newton.

FEA 1: Roller fixation on the top edges
An important factor to consider when performing FEA is the fixation of the part. For example, the top edge of the staple was fixed on the first try, whereas the force was applied to the outer fillet (see Figure 84). This led to a deformation of the middle part, but the staple was not able to close the way it was anticipated (Figure 84).

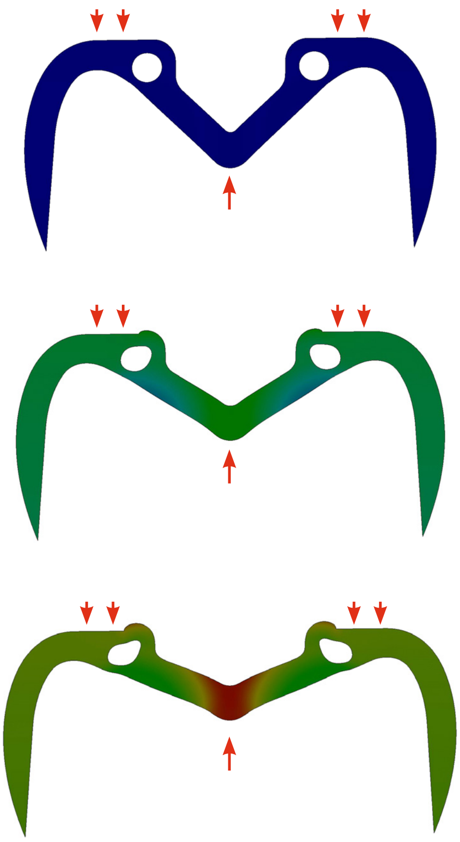


Figure 84: First Finite Element Analysis (stress)

FEA 2: Simplification, without holes
Going one step back and simplifying the shape helped to simulate the closing of the staple. In this version, the holes were left out. Forces were applied to the outer diameter and the top edges. Since a fixation was mandatory, the inner fillet was fixated. Results showed that the staple legs bent together but the inner fillet did not straighten because of the fixation (Figure 85)

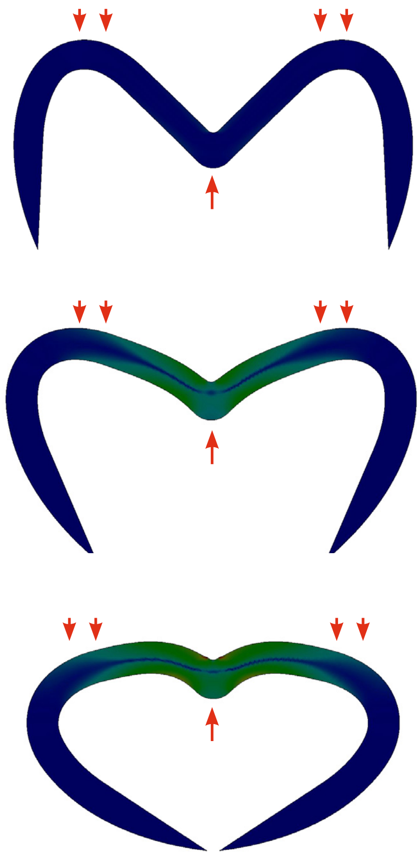


Figure 85: Second Finite Element Analysis (stress)

FEA 3: FEA 2 with holes

To see the impact of the deformation of the holes, the fixators and forces of FEA 2 were repeated with the first staple version. The deformation showed the same results with slight deformation of the holes (Figure 86).

FEA 4: Different fixation

Since the top edge of the staple should be straight in a bent position, the fixation of the inner fillet is not optimal because it does not allow it to straighten. A different approach was to fixate one hole fully and allow another to move only in the x-direction while restricting it in the y-direction. The results show similar bending behaviour, however, the colour coding is not symmetric in this version since the whole part itself moves as well (Figure 87). Because the different approach did not add much to the straightening of the top, the symmetric version (fixation of FEA 2) was considered more informative.

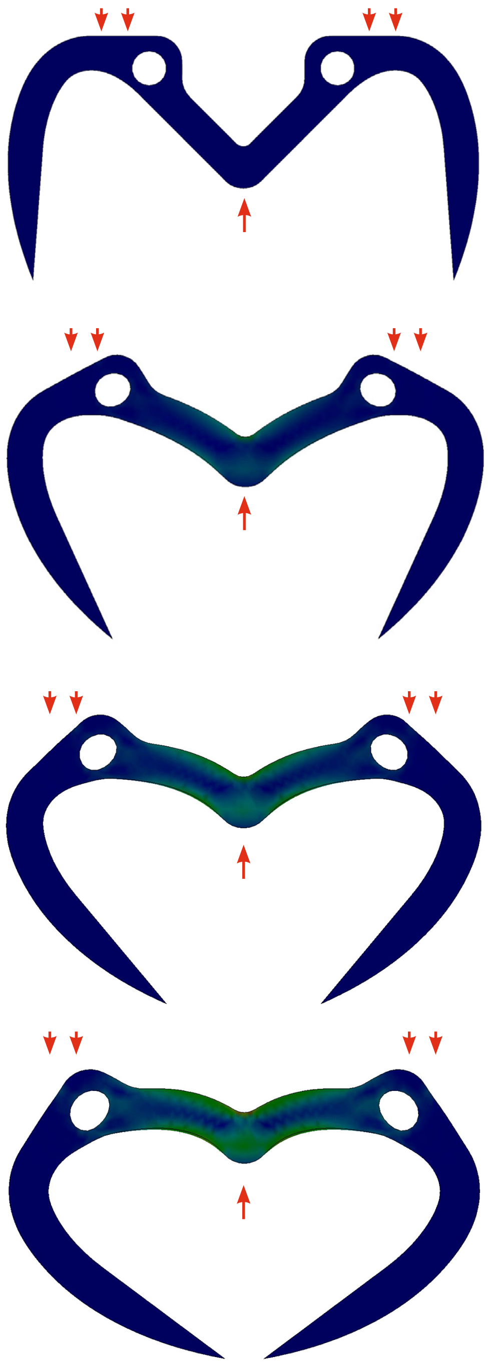


Figure 86: Third Finite Element Analysis (stress)

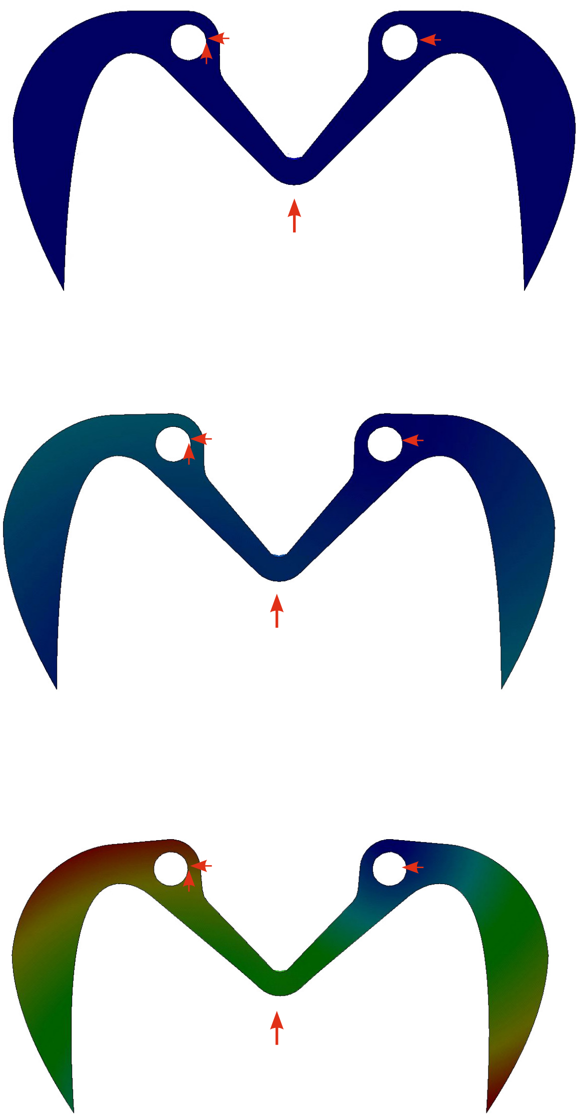


Figure 87: Fourth Finite Element Analysis (displacement)

FEA 5: One hole

Because of the remaining V-shape of the inner fillet and the cartridge design, a reduction of holes to one was considered. In the first model, the staple thickness was simply enlarged and the hole was placed in the middle. This led to significant deformation of the hole which would lead to too much resistance during suture sliding. The deformation of the middle part also did not allow the legs to bend together as desired (Figure 88).

FEA 6: One hole optimised

Through multiple optimizations in material distribution, a staple design was created which would not lead to deformation of the hole (Figure 89). In this version, however, a gap was created between tissue and staple in the closed position (Figure 90). Further optimizations reduced this gap and led to the final staple shape (Figure 91). Here it is to consider that the deformation exceeds the yield strength which leads to the desired permanent deformation. In Figure 91 this permanent deformation can be seen in green.

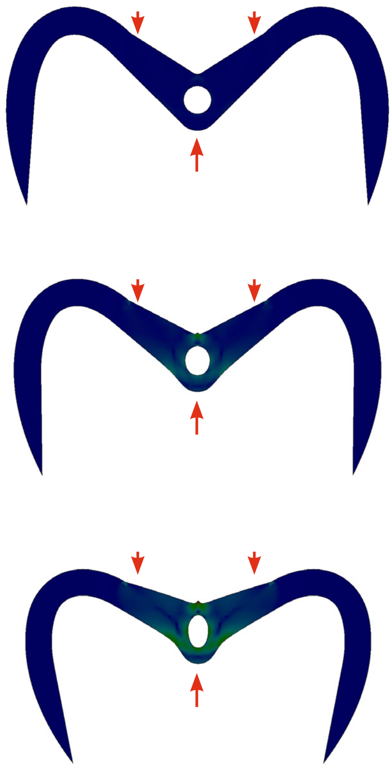


Figure 88: Fifth Finite Element Analysis

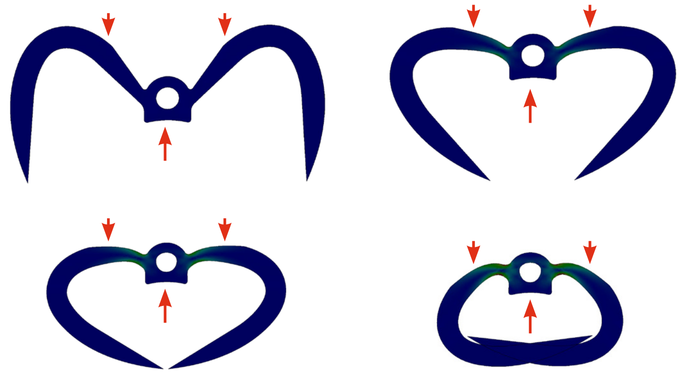


Figure 89: Sixth Finite Element Analysis

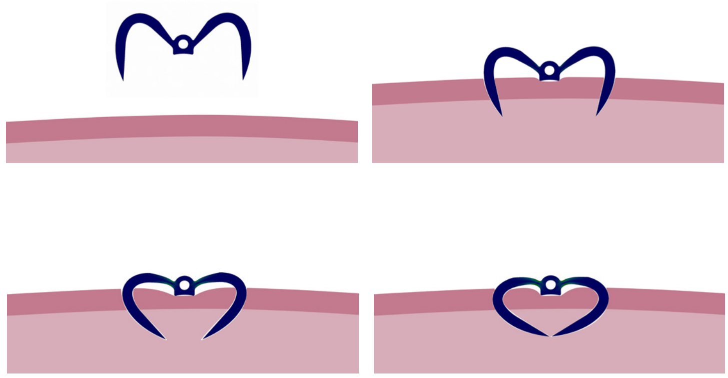


Figure 90: Staple behavior in the skin

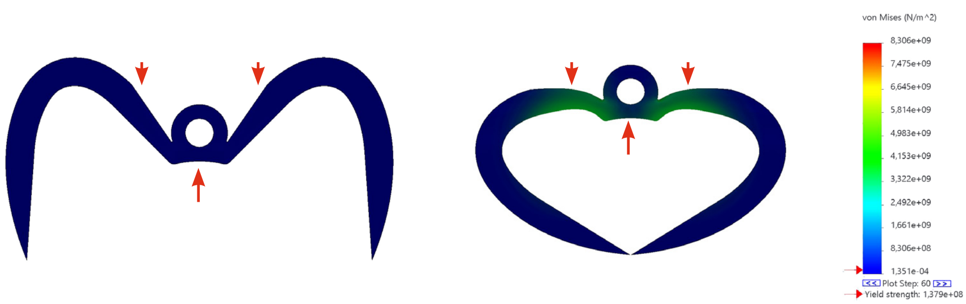


Figure 91: Finite Element Analysis after optimization

7.2 Expert opinions

At the beginning of the project, four surgeons were introduced to the project and interviewed about their experiences with the current workflow and the necessity of a new closure method. Throughout the project, three of them were following the process closely. Additional 6 surgeons were introduced to the developed solution and interviewed individually about their opinion on the feasibility, necessity, and safety. The project results were presented to about 20 more surgeons, leading to a discussion with interesting insights. The opinions of both experienced and inexperienced surgeons who contributed to the project are summarised in this chapter.

7.2.1 Current procedure

In the analysis, possible issues during the procedure were identified. These were presented to the surgeons, and they were asked if they recognized the situation. The responses were varying with some surgeons not recognizing issues at all and others struggling with them in their practice.

"I have no problems with hand suturing. It is an essencial skill in advanced laparoscopic surgery."

However, most surgeons acknowledged that slips could happen to everyone but that the challenge is that one can work around it to solve the issue. Hereby, every surgeon has their own methods of solving challenges. The way surgeons perceived that challenge was differing with some surgeons finding it joyful and empowering and others experiencing it as stressful. In general, slips happen more to inexperienced surgeons which also leads to more time and higher stress levels for anastomosis closure. The more experienced and skilled surgeons get, the less time hand suturing takes. However, even experienced surgeons feel higher stress levels during hand suturing compared to other parts of the surgery.

After talking about possible issues with the current procedure, the newly developed method was introduced to the surgeons. Different aspects, related to the requirements defined in chapter 5, were addressed.

7.2.2 Safety

Tightness
In theory, the concept seems to create a leakproof closure. However, surgeons had doubts about the closure tightness. Leaks might be caused by small gaps which can occur due to multiple reasons. Risks include one or more of the staples not being fully fixated on the tissue or falling out. The linear stapler, for instance, has three rows of staples to avoid this risk. Furthermore, in the new method, the suture is attached to the top of the suture which might cause a small gap when two staples approach each other. Another concern was that a staple could not be removed and placed new, if once wrongly placed.

"The remaining opening is not symmetric. We must compensate for that with differently sized bites."

A solution to that is, however, to place another one next to it or use a new suture. A new insight which was discovered during the interviews is that the opening of the remaining hole after applying the linear stapler is not symmetric. Some of the interviewed surgeons mentioned that closure with the same number of staples on each side is not possible. Others, however, believed that this can easily be compensated with varying gaps between the staples. This method can be compared with leaving more space between stitches when hand suturing.

Perfusion
Due to the risk of tissue damage from necrosis, staple pressure should not be too high. Most surgeons agree that rounded staple legs are better to avoid tissue squishing. What is also important for the perfusion of tissue is not to have too many staples on one spot. Since the staples are small, the risk for tissue damage was estimated to be small.

Hemostasis
Bleeding is high risk because it can happen hours later which can lead to complications for the patient. For haemostasis to happen, there must be pressure on the edge of the tissue and on the mucosa. Many of the interviewed surgeons expressed doubts that haemostasis can be achieved. Due to a lot of small blood vessels, there is often bleeding from the edges of the opening. With the suturing technique, pressure can be applied to the tissue and bleeding can be stopped. A staple cannot create the same ligation as the suture, so surgeons do not see them as a safe alternative. A few surgeons believe that haemostasis and healing might work if there is a tight connection, however, the majority would not take the risks it brings.

Tissue alignment
If staples are attached at a distance to the edge, the tissue will be inverted, just as in the suturing.

Materials

Surgeons did not have concerns regarding the materials. Nowadays, a lot of variations of staples and sutures are suitable for surgical applications. It is critical to reducing the amount of material to the minimum, meaning having as least surface as possible. Complications due to allergies or the body rejecting the material, however, are rare.

All safety concerns of the surgeons were added to the risk analysis to estimate possible outcomes for the patient and can be found in chapter 7.3 Risk analysis.

7.2.3 Comfort

Workflow

Regarding the new closure method, there were varying reactions between experienced and inexperienced surgeons. Experienced surgeons had more doubts about comfort improvement because of additional training which would be needed. Inexperienced surgeons accepted training time more easily because they are still learning. Most experienced and inexperienced surgeons think that new slips might be introduced with the new method, e.g., tissue might slide away from the grasper when pressing the stapler against it.

“There should be as little steps as possible to make the procedure economic. The flow of movements should not be interrupted.”

During the development period, multiple options for the application of the method were discussed with surgeons. I asked for example if pulling the suture at the end or tightening the suture after every staple is better. The surgeons clearly preferred to have control over the closure after every stitch. Pulling the suture at the end is not recommended because there is no guarantee for the same pressure at each spot. The resistance of the suture is also higher and might cause tissue damage. Even though there are surgeons who pull the suture at the end of all the stitching, others recommend not to do that because it might cause leakage. Surgeons liked that in the new method they can decide for themselves, based on their preference and environment, when it is better to tighten the suture.

Surgeons also played a role in deciding how to apply the staple to the tissue. There was the option to apply them from the top or from the side, encompassing the tissue. Surgeons liked the version where the staple is applied from the top because they can access it straight from the trocar. In the current workflow, the needle holder needs to be tilted for the needle to pierce the tissue perpendicularly, and it needs to be rotated 180° to leave the tissue. Applying the staple from the top is an improvement because not as many fine manoeuvres are needed.

For better ergonomic handling of the device, surgeons wished to have the function to rotate the head of the stapler. Articulation to the sides, however, is not necessary because it might not add much and lead to confusion. Surgeons liked that the holes in the staples were reduced to one because it allows for application in any direction.

“Integrating a cartridge is necessary, because refilling the device is time consuming.“

Cartridge

Some surgeons did not mind refilling the cartridge outside of the body, but most of them wished to have a cartridge included because changing instruments is time-consuming. With every removal, organs need to be repositioned and when adding a new device, it needs to be navigated into the view again. Therefore, having a cartridge included in the device was received positively.

Easiness

Estimating the comfort without having a working prototype was difficult for the participants. Therefore, the two user experience workflows of both the old method and the new method were compared (Figure 92).

Figure 92: Workflow of tissue closure using hand suturing and using the new method

As it can be seen in the overview, the new method is expected to have significantly fewer steps compared to hand suturing. It can also be seen that fine manoeuvres and transfers of tools could be fully abolished. There are still moments where two hands are necessary, especially when applying the staple. Here, the second hand is responsible to create a sufficient force for the staple to grab fully into the tissue. However, this is an improvement compared to hand suturing because here, both hands are required to deal with the needle, which means that there is not always a free hand to handle the tissue. In the new method, one hand can focus fully on handling the tissue. This might facilitate tissue positioning and reduce tissue slipping.

Surgeons needs

Some surgeons experienced hand suturing as a frustrating task, while others see it as a satisfactory challenge. In the requirements, it is formulated that surgeons should perceive the task as an accomplishment. If the new method allows for that depends on the level of difficulty and chance of success. Based on the results of the workflow comparison, the new closure method has advantages in its usage, compared to the old one. If that leads to a successful closure depends on if the method proofs to be leakproof and if it supports tissue healing. Since there were no tests done on real bowel material, no evaluation can be done about that yet.

“Hand suturing is challenging. This can be frustrating but also empowering“

Trust

Some surgeons’ reactions to the project were sceptical at first. The reason for that was the misconception that an alternative closure method should replace the hand suturing fully. As it is mentioned in chapter 3. Observations, hand suturing is a basic skill and needs to be performed by every surgeon. It had to be communicated very clearly that the project does not aim to replace hand suturing fully but just to reduce the moments of it, in applications where it makes sense. In case of the anastomosis, however, the trust in the new method was very low. Surgeons did not trust in the tightness and healing of the tissue. Since there is a high risk related to the closure, they rely solely on methods which have proven to work in practice. At this stage, no fully functioning prototype of the concept was built so in vitro/ in vivo tests were not possible. Further development and embodiment of the device will make testing possible, and a re-assessment of trust should be done.

“I would not use this method for the jejunojejunostomy. For mesenteric repair, however, I imagine it could work“

Costs

Mechanical solutions usually increase material costs. A more expensive device however can be financially beneficial if it is significantly faster than the current method. The barbed suture, for example, costs currently about 18€ whereas the traditional suture costs 3€. One minute in the OR is estimated to be 16€, so the barbed suture still saves costs because it reduces the operation time by more than a minute. The costs for the new device cannot be estimated exactly yet. A hernia stapler, which is closest to its functionality, is about 100€, so if one parallel stapler is about 150€, it would have to save at least 8.25 minutes to be worth (calculation: (150-18)/16).

7.2.4 Additional fields of application

Due to the high requirements for anastomosis closure, surgeons advised investigating other fields of application. Surgeons were very positive about the idea itself and brainstormed about other closure procedures where it could be implemented. The discussions led to promising ideas which could lead to new applications.

Joint surgery

Compared to other types of surgery, there is a lot more space in abdominal surgery. In joint surgery, which includes shoulder, knee and wrist procedures, there are a lot of treatments which need the repair of ligaments in a very limited space. This includes e.g., treatments of the meniscus (knee), labrum and articular cartilage (shoulder), repair of the Bankart lesion (shoulder), arthroscopy of the wrist, like treatments of the triangular fibrocartilage complex (tfcc ligament) and more. In the scope of this project, there was no additional research done on these applications because they were too far away from the initial application.

Mesenteric defect[1]

Another application which multiple surgeons suggested, and which was related to the gastric bypass was the closure of the mesenteric defect[1] (Figure 93). As described in chapter 3. Observations, the gastric bypass procedure causes a change in the anatomy which leads to windows in the mesentery[2]. To close them, surgeons use a hernia stapler or hand suturing. In both methods, they experience some difficulties. The closure with the hernia stapler was observed during visits to the hospital. Hereby it could be seen that the surgeons struggled with the positioning of the tissue and the correct positioning of staples. Since each leg of a staple is supposed to grab one side of the opening, the tissue already needs to be held in the final position when the staple is fired. While triggering, the device must be pressed against the tissue to ensure proper fixation of the staple. If there is not enough force applied, it will fall out. In practice, it is a challenge to do all of this with two hands only. As result, a large portion of staples are not positioned properly or even fall into the abdominal cavity. To compensate for that, surgeons used more staples close to each other. For closure with hand suturing the purse string technique is used. Hereby, stitches are placed along the opening and then pulled together. For anastomosis, this technique is not safe enough because of gaps, but for mesenteric closure it is sufficient. However, hand suturing brings the same difficulties as identified for anastomosis suturing, including visuospatial, ergonomic and cognitive challenges.

[1]Mesenteric defect
Gastric bypass surgery causes a change in anatomy which forms mesenteric defect of which one is the Petersen hernia.

[2]Mesentery
The mesentery is a tissue which is connects the intestine to the abdominal wall. The function is to keep it in place.

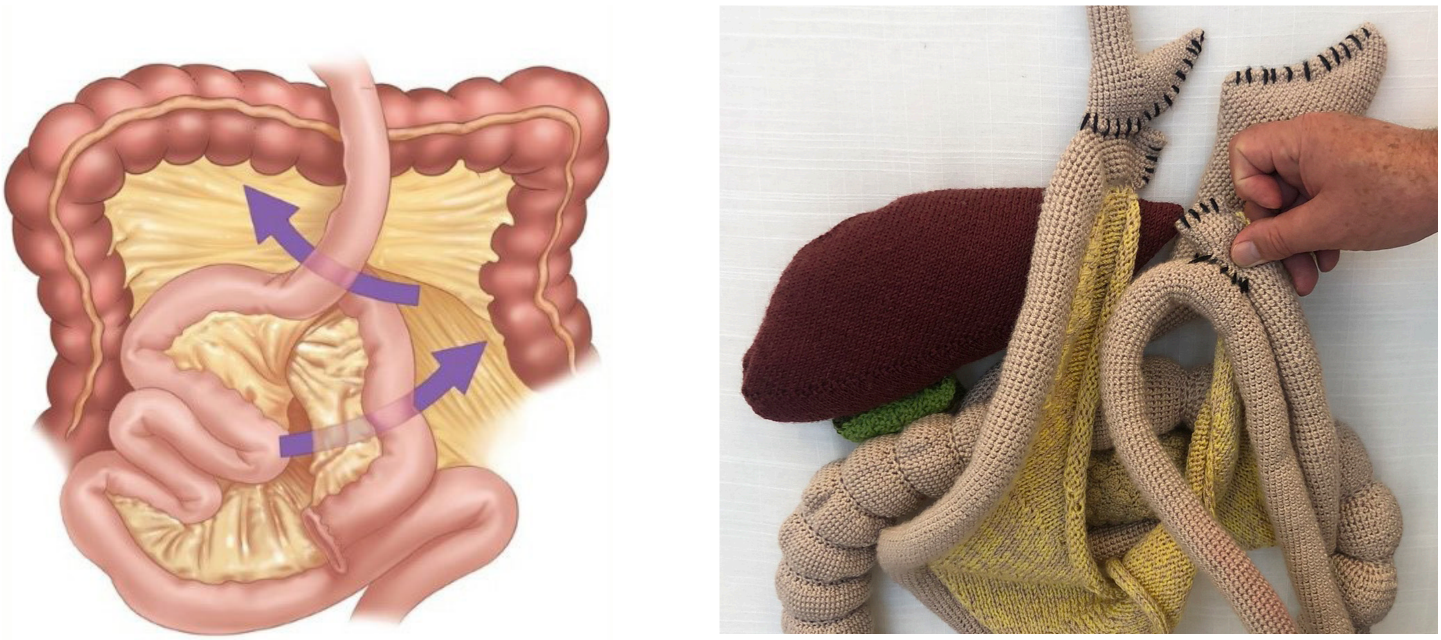


Figure 93: Mesenteric defenct after gastric bypass procedure, illustration (left), model (right)

A new method for hernia repair was therefore identified as a potential new field of application. When presenting the parallel stapler as a solution for mesentery repair instead of anastomosis closure, all interviewed surgeons could imagine the method to work. More than half of the surgeons were convinced that they would use it. One said that the idea combines "the best of both worlds", meaning the combination of hand suturing and stapling.

Compared to the anastomosis closure, where only a few surgeons saw potential in the concept, this is a big increase. The reason for this is that the requirements for the closure of the mesenteric defect are not as critical. It does not need to be watertight, and it can have small gaps, as long as the bowel does not fit through. The requirements on leakage can therefore be neglected. Bleeding can still occur if a blood vessel is hit. However, the same risk occurs when using a suturing needle. Table 1 compares which requirements are fulfilled for anastomosis closure and hernia repair.

Table 1: Comparison of fulfilled requirements for anastomosis closure and hernia repair

Requirements	Anastomosis closure	Mesentery closure
Necessity for new method	✗ mostly no	✓ yes
Watertight closure	✗ mostly no	✓ not necessary
Tissue healing	? maybe	✓ likely
Hemostasis	✗ no	✗ no
Perfusion	? maybe	? maybe
Tissue alignment	✓ yes	✓ yes
Avoid stricture	? maybe	✓ not necessary
Avoid obstruction	? maybe	✓ not necessary
Easy application: one hand, reduce steps	✓ yes	✓ yes
Flexibility in application	✓ yes	✓ yes
Time reduction	✓ yes	✓ yes
Accomplishment	? maybe	? maybe
Acceptance	✗ no	✓ yes
Cartridge	✓ yes	✓ yes
Laparoscopic use	✓ yes	✓ yes

7.3 Risk analysis

7.3.1 Medical device standards

ISO 9001 is the most commonly used quality standard for quality management systems. ISO 13485 is used in addition to ISO 9001 for quality management of medical devices. Both describe requirements for consistent quality and build a framework for the implementation of good manufacturing practices. ISO 14971 focuses especially on medical device risk management, with ISO 24971 providing further guidance on how to apply ISO 14971 in practice. Risk analysis is a component of risk management, so ISO 14971 is used for the implementation in this example.

7.3.2 Risk management

Both ISO 9001 and ISO 14971 suggest that risk-based thinking should be applied from the start of the project (conceptualization) throughout the whole process until the end of life (e.g. disposal). The aim is to reduce risks for the intended use for safe and effective use of medical devices. Risk management enables organisations to identify, analyse and evaluate possible hazards in order to plan actions to diminish or prevent the risks. An overview of a risk management process can be found in Figure 94.

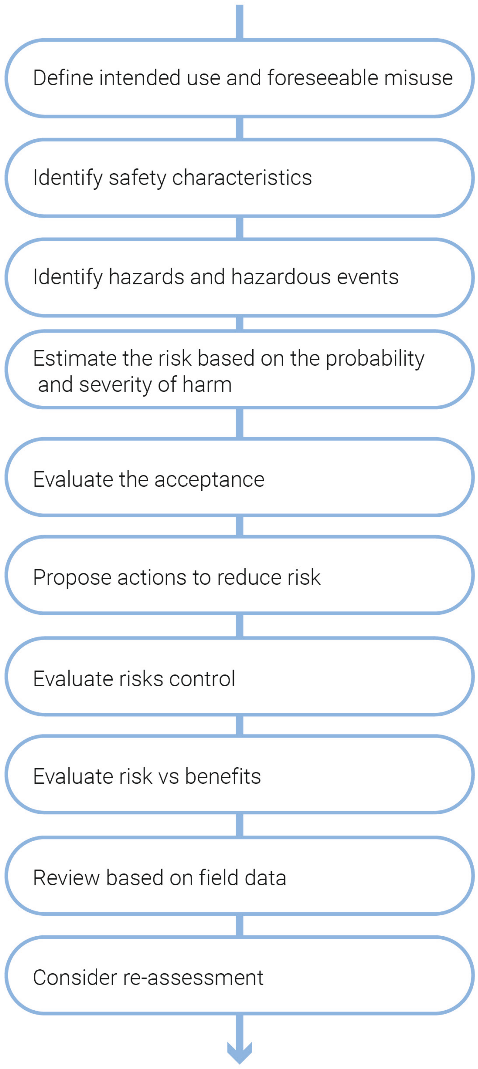


Figure 94: Overview of the steps needed for risk management

7.3.3 Risk analysis

Risk analysis is the first part of risk management and should be done from the first concept until the end of life, e.g. disposal of the product. First, a manual of intended use and foreseeable misuse should be made. An overview of the intended use can be found in Figure 95.

	Application 1: anastomosis closure	**Application 2: hernia repair**
intended medical indication	Device to close the remaining openings after generating a side-to-side gastrojejunostomy or jejunojejunostomy with a linear stapler.	Closure device to repair hernia defects. Can be used for the Petersen's space and mesentery defect.
patient population	Patients who have to undergo gastrointestinal, especially bariatric surgery.	Patients who have to undergo gastrointestinal, especially bariatric surgery or patients who suffer from hernia defects.
part of the body interacted with	Stomach tissue, jejunum tissue	Mesenteric tissue
user profile	The device is designed for gastrointestinal surgeons with different levels of experience but especially surgeons who struggle with hand suturing.	
use environment	Operating room, laparoscopic surgery. Sterile area.	
operating principle	The staple is applied by pushing the handle grip. By pulling the device, the suture is released. The suture can be locked with a button to pull the suture tight which approximates the staples to each other. The suture locks itself. Then, the next staple is applied.	
possible misuse	The suture should not be tightened too much, but also not too loose. Incorrect application of staples, e.g. not enough pressure or too early release of the staple. Incorrect stapling spacing. Too much space leads to leakage and too little space leads to excessive material.	

Figure 95: Intended use manual for different applications

Fault tree analysis

Since the project is in a very early development stage, a failure modes and effects analysis (FMEA) was not applicable. Therefore a preliminary hazard analysis (PHA) was done to identify safety characteristics and possible hazards. I used a top-down approach by using the fault tree method (FTA). Hereby I started with identifying undesirable harms based on the prior defined requirements. Then I worked back to determine possible scenarios which result in that undesirable consequence. Two FTA was made for the two possible applications, anastomosis closure and mesenteric repair. The results of the analysis can be found in Figure 96 and 97.

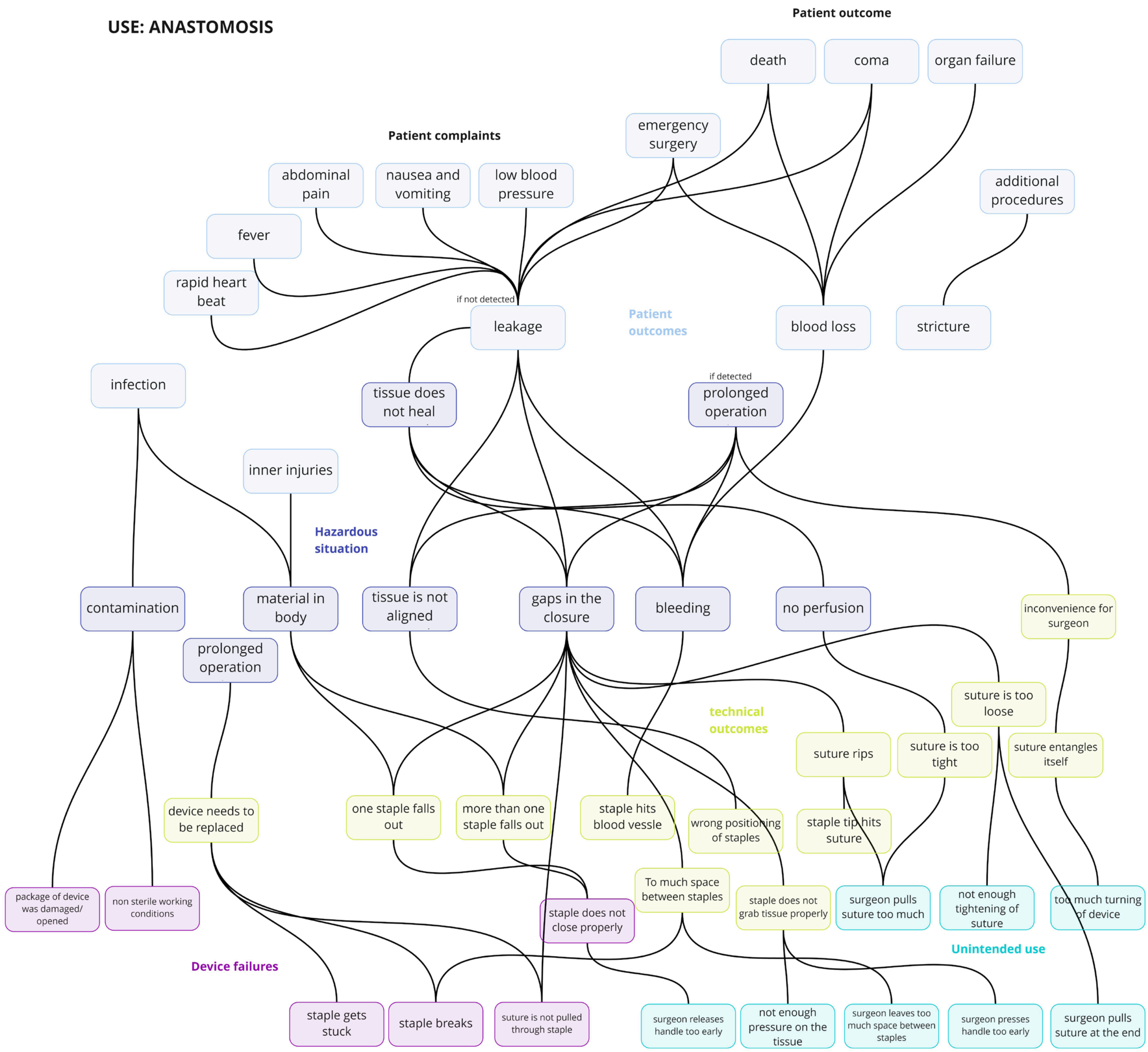


Figure 96: Fault tree analysis for anastomosis closure

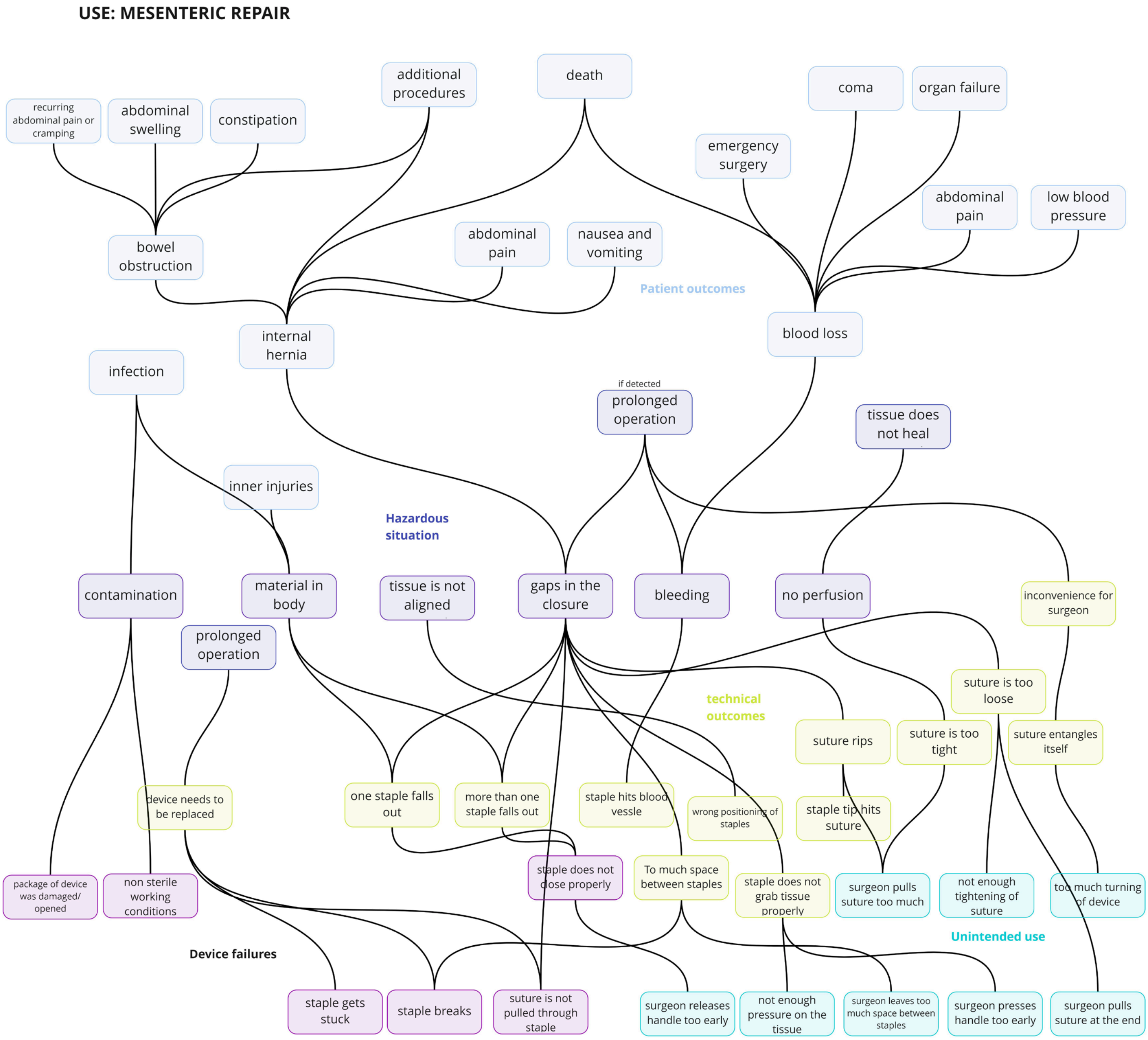


Figure 97: Fault tree analysis for mesentery repair

7.3.4 Risk assessment

To estimate the risk of the parallel stapler, possible hazards were identified and evaluated. The evaluation was based on the probability of occurrence and severity. In case of unacceptable risk, further actions for reducing the risks were formulated. Unacceptable is hereby harming the safety of the patient or the user in a way that they have long-term consequences. In the following chapter, the severity scale, probability scale and risk chart are presented.

Severity scale

The severity scale determines categories of harms which have more or less impact on the patient or operator. Hereby temporary discomfort is the lowest possible harm and long-term damage or death is the biggest harm. The definition of severity scales 1-4 can be found in Figure 98.

Ranking		Definition	Example
1	Minor	No impact on patient safety. No injuries to the operator. Temporary discomfort/ inconvenience. Delay up to 10min.	Nausea, discomfort
2	Moderate	Surgery delayed up to 30min. Product failure without impact on the patient or operator. Slight effect but no significant harm , self-healing injuries.	broken instrument outside the body, instrument failure before use
3	Serious	Reversible, temporary injury. Delay in surgery more than 30min. Broken fragments in body. Additional procedures, e.g. surgical interventions are needed.	Foreign material inside the body, broken components, revision surgery
4	Critical	Hazard could lead to death or serious physical injury and/or long-term damage to health to patient or operator.	coma, organ failure, death

Figure 98: Severity scale

Probability scale

The probability (P) is calculated by adding the probability of the sequence of events (P1) and the probability of the hazardous situation (P2): P=P1+P2. The probability scale gives the resulting P-value a scale from 1 to 4 (improbable to frequent) (Figure 99).

Ranking		Definition	Frequency
1	Improbable	The hazard never occurred during the life of the product. The occur-rence of hazard is not reproducible.	P < 0,001%
2	Remote	The occurrence of the hazard is infrequently during the life of the product. The hazard could occur further to unusual actions.	0,001% ≤ P < 0,1%
3	Occasional	The occurrence of the hazard is occasional during the life of the product.	0,1% ≤ P < 2%
4	Frequent	The hazard could occur regularly or many times during the life of the product. The hazard could repeat during normal use of the device.	P ≥ 2%

Figure 99: Probability scale

Risk assessment

To assess possible risks, a list of most probable hazards and foreseeable hazardous situations with an assessment of severity and probability was made (Figure 100). For simplification reasons the probability for the event to happen is the same for both applications hernia repair and anastomosis closure. The severity, however, is different because it results in different patient outcomes. Since there is no field data available yet for the newly developed method, the numbers are based on a personal estimation, considering the stakeholder concerns, expert opinions and comparison to existing devices. The aim was not to get precise numbers but to give an estimation of which risks are worse in order to formulate possible actions/ recommendations.

List of scenarios	Probability	Severity (anastomosis)	Severity (hernia repair)	Risk (anastomosis)	Risk (hernia repair)
Staple only grabs tissue half... ...because surgeon presses too early ...because surgeon does not put enough pressure ...because the tissue slips away ...because of device fault ...because the surgeon does not press the handle fully ...because the device fails to close the staple properly	0.028 -> 2 0.01 0.005 0.001 0.001 0.01 0.0001	3 (if it stays undetected, leads to leakage) 2 (if it is detected and fixed immediately, delay) 1 (if it does not lead to leakage)	2 (multiple staples do not grab and hernia might occur) 1 (it is detected and fixed immediately) 1 (other staples make up for it)	6 (it stays undetected, leads to leakage) 4 (it is detected and fixed immediately, delay) 2 (if it does not lead to leakage)	4 (multiple staples have to fail for hernia to occur) 2 (it is detected and fixed immediately) 2 (other staples make up for it)
Staple breaks and falls into the body ...detected ...undetected	0.0001 -> 1 0.00009 0.00001	3 (undetected, 1 (detected,)	3 (undetected, 1 (detected,)	3 (undetected, 1 (detected,)	3 (undetected, 1 (detected,)
Staple falls out of tissue ...because too much pulling of suture ... because the tissue rips	0.0015 -> 2 0.001 0.0005	1 (detected) 3 (undetected)	1 (detected) 2 (undetected)	2 (detected) 6 (undetected)	2 (detected) 4 (undetected)
Staple is not released from the device ...because of device failure	0.0005 -> 1 0.0005	1 (no damage to patient)	1 (no damage to patient)	1 (unlikely, no harm)	1 (unlikely, no harm)
Too much spacing between staples ...because of wrong positioning	0.001 -> 2 0.001	4 (leakage)	1 (most likely no hernia)	6 (might lead to leakage)	2 (most likely no harm)
Staple hits blood vessel ...bleeding stops itself ...bleeding does not stop but is detected ...bleeding does not stop and stays undetected	0.01 -> 3 0.001 -> 2 0.005 -> 2 0.004 -> 2	2 (no significant harm) 2 (temporary injury) 4 (leakage)	2 (no significant harm) 2 (temporary injury) 3 (blood loss)	4 (self fix) 4 (can be fixed) 8 (leakage	4 (self fix) 4 (can be fixed) 6 (bleeding)
Suture rips ...because of too much pulling ...because of a production error	0.0011 -> 2 0.001 0.0001	1 (no significant harm, change of device)	1 (no significant harm, change of device)	2 (no significant risk	2 (no significant risk)
Suture entangles itself ...because surgeon keeps it too long ...because of too much turning of the device ...because of the wrong positioning of the staples	0.0021 -> 2 0.001 0.001 0.0001	2 (no harm, delay)	2 (no harm, delay)	4 (no significant risk, inconvenience for the surgeon)	4 (no significant risk, inconvenience for the surgeon)
Suture is too tight ...because surgeon pulls too much	0.001 -> 2 0.001	3 (no perfusion, leakage)	2 (perhaps no perfusion)	6 (risk of leakage)	2 (no perfusion)
Suture is too loose ...because the surgeon does not pull enough ...because the surgeon pulls at the end	0.011 -> 2 0.01 0.001	4 (gaps in anastomosis, leakage)	1 (no harm)	8 (gaps in anastomosis, leakage)	1 (no harm)

Figure 100: Risk assessment

Probability / Severity	Minor: 1	Moderate: 2	Serious: 3	Critical: 4
Frequent: 4	4	8	12	16
Occasional: 3	3	6	9	12
Remote: 2	2	4	6	8
Improbable: 1	1	2	3	4

Figure 101: Risk chart

Risk chart
Figure 101 shows the risk chart which was used to assess the risks in the list of scenarios (Figure 100). Hereby, more risks are identified for application scenario 1 (anastomosis closure) than for application scenario 2 (hernia repair). This reflects the strict requirements for anastomosis closure. The table also shows that the risk can be reduced significantly when it is detected during the surgery. Most complications can be avoided when fixed immediately. However, each fix takes time so the goal is to improve the device and instructions in a way that harm does not occur in the first place. The biggest risk for anastomosis is leakage which can occur by staples not grabbing the tissue properly or falling out. Also, wrong positioning of staples like too much or too little spacing of the staples as well as too much or too little tightening of the suture might lead to leakage. The second big risk, which also applies to hernia repair, is bleeding which can occur by staples rupturing a blood vessel. The hernia closure does not have to be watertight. Even if there is an opening in the closure, it most likely does not lead to bowel obstruction. So the only risk for hernia repair is that it might lead to bleeding which might cause complications if it stays undetected.

Risk control
Figure 100 (risk assessment) uses the colour code of the risk chart which is a matrix made of the severity and probability scale. Risks up to scale 2 are acceptable. For risks between scales 2 and 4, it has to be decided per case if actions are recommended or if the risk is acceptable. For risks higher than score 6 actions are recommended and for risks bigger than score 9 immediate actions have to be taken to mitigate them. Figure 102 shows the unacceptable risks with possible actions that can be taken.

Unacceptable risks (anastomosis closure)	**Possible actions**
Staple only grabs half and it leads to leakage	• Make sure the surgeon applies enough pressure, e.g. integrate a pressure sensor • Make the device “smart” so it only releases when fully pressed against the tissue • Design tissue holder to make application easier, e.g. an extra tool or perhaps integrated into the parallel stapler, which approximates the tissue and the device. • Let the handle only release when fully pressed
Staple falls out of the tissue and it leads to leakage	• Choose material which does not break easily • Extra checks in the manufacturing for possible cracks in staple • Do not allow to pull too much -> automatic brake release in the device when too much pulling
The surgeon leaves too much/ too little spacing between the staples	• Training, experience • For inexperienced surgeons: machine learning which shows the quality of the staple positioning via the operating screen
The staple ruptures a blood vessel which leads to undetected bleeding	• Recommend to always perform a leakage test
The suture is too tight or too loose which leads to leakage	• Training, experience • Do not allow to pull too much -> automatic brake release in the device when too much pulling • Recommendation not to pull suture at the end
Entangling of suture	• Too long sutures can be pulled back manually
Unacceptable risks (hernia repair)	**Possible actions**
The staple ruptures a blood vessel which leads to undetected bleeding	• Train surgeons to detect bleeding • Treatment with a dissector or vessel embolization can be used to stop bleeding

Figure 102: Possible actions for unacceptable risks

Insights

Feasibility
- The anticipated staple shape is technically feasible.
- Staples bend in the way they were designed, with no tissue squishing.
- The head can fit enough staples to have a cartridge included in the device.

Expert opinions
- The workflow comparison shows that the new method has significantly fewer procedure steps.
- Surgeons have doubts about the tightness of the anastomosis closure.
- Surgeons doubt that hemostasis can be achieved with the staples.
- There is not enough trust for surgeons to try out the new method at this stage.
- A new application was found to be more suitable for the new method.
- The parallel stapler could be used for mesentery repair.
- For this application, surgeons have more trust because there are fewer requirements.

Risk analysis
- Most risks are related to the surgeon’s performance. Excessive instructions for the new device and training should be provided in addition to the control actions.
- The risk analysis confirmed the doubts surgeons had about the new closure method.
- If used for anastomosis closure, high risks for the patient could be identified.
- For the usage of mesentery closure, the risks were significantly lower, which makes it a more suitable application.

8. DESIGN PROPOSAL

8.1 Design proposal

This thesis proposes a method to approximate tissues in laparoscopic gastrointestinal surgery. While the initial research focussed on anastomosis closure, the closure of mesenteric defects was found to be more promising. Previous chapters show the research, development, and evaluation. This chapter describes how the method works and what advantages it has compared to previous techniques.

How it works

The newly developed closure method combines the advantages of hand suturing and stapling. It was developed together with bariatric surgeons to ensure the best possible user experience. To apply the staples, the surgeons must hold one side of the tissue with a grasper and press the device against it. When enough force is applied, the trigger can be pushed, and the staple is released into the tissue. Then, the second staple is applied in the same way on another side of the opening. A suture is pre-attached to both staples so by locking and pulling the device, the staples come together, and the tissue is closed. The remaining staples are added in an alternating way along the open tissue, whilst pulling the suture tight after every stitch. The surgeons have the option to release and pull the thread based on the available space. This avoids too long or too short sutures which might lead to entangling or discomfort. Figure 103 shows the step-by-step workflow of the closure.

Step-by-step workflow (Figure 103):

1. Opening of the anastomosis after using a linear stapler.
2. The first staple is attached to the tissue. The beginning of the stitch should have enough distance to the opening and form a v shape, like in the stitching pattern.
3. The second staple is placed.
4. The suture is locked with a button and the stitch is pulled tight.
5. A third staple is placed and the suture is pulled.
6. Half of the opening is closed with another half still being open.
7. The staples are applied in an alternating way on the edge of the opening.
8. The last staples are applied and the suture is pulled to approximate them.
9. After pulling the stitch tight, the end of the suture is cut with scissors.
10. The tissue opening is closed.

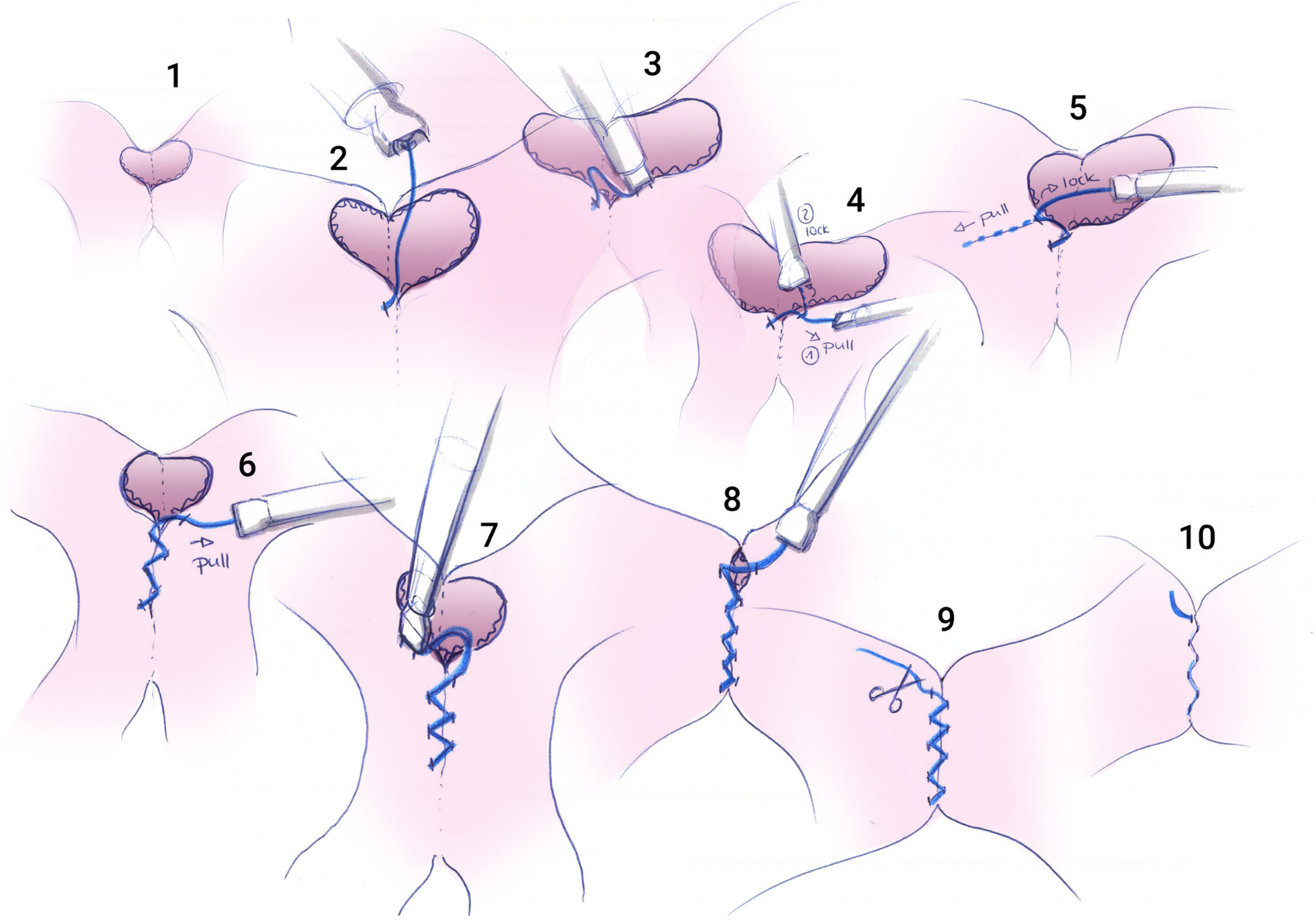


Figure 103: Workflow of anastomosis closure with new method

Details

Figure 104 shows how the first staple is already hooked into the tissue and how the second staple is positioned. The suture is fixed to the first one and runs through the rest of the cartridge. In case the surgeon needs more length of suture, they can release it by simply pulling the device while having the suture free running (Figure 106). To avoid entangling the suture the surgeon has the possibility to also pull back extensive suture with a wheel close to the handle.

When a surgeon wants to tighten the stitch, the suture should be fixed in the device so the staples approximate each other (Figure 107). A simple locking button close to the handle should switch from one mode to another.

As mentioned earlier, a counterforce has to be created for the staple to grasp the tissue properly. Since the new method is developed for usage with one hand, the tissue grasper can be used to position and press the tissue against it (Figure 105).

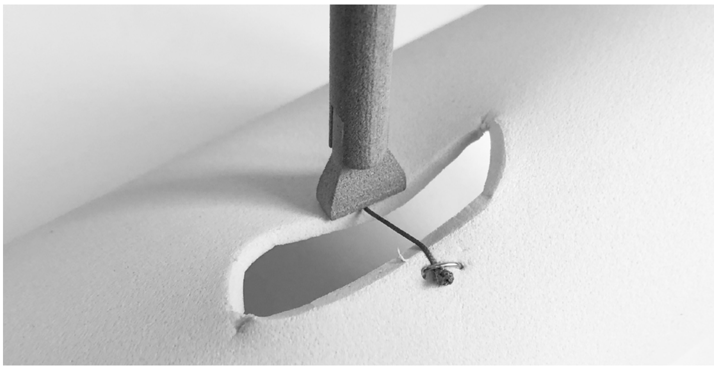


Figure 104: Fixating the second staple

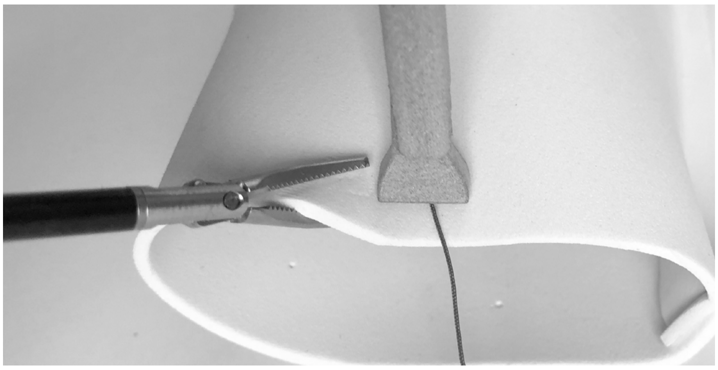


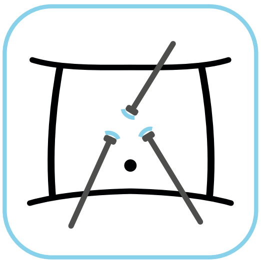
Figure 105: Creating a counter force with tissue grasper

Figure 106: Releasing suture

Figure 107: Closing stitch with locked suture

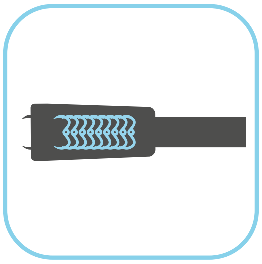
Function

A suture is pre-threaded through the staples that are stored in a cartridge in the head of the device. The thread is barbed which causes it to lock itself in any position as soon as it is pulled tight. This gives the surgeon enough freedom to control the closure of the opening, whilst ensuring tissue healing and cease of bleeding. The thread is stored in a reel which gives the surgeons the option to increase or decrease the amount of suture they have available.



Suitable for laparoscopy

The device is suitable for laparoscopic surgery and fits through a 12mm access trocar.

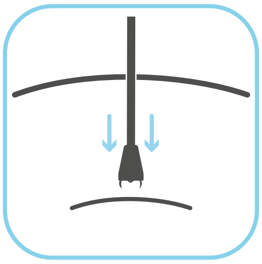


Cartridge

It has a cartridge in the head that fits up to 30 staples. This is enough for multiple procedures, including anastomosis closure and mesentery repair.

Pre-threaded suture

The suture is threaded through the staples . This facilitates application for the surgeon because it reduces fine manoeuvres.



Application from the top

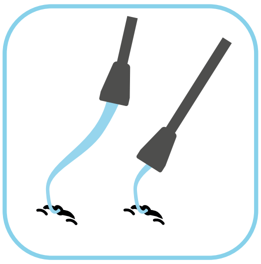
Staples are applied from the top of the tissue which makes it easier to reach from the trocar.

Rotatable head

The head of the device is rotatable, giving access to hardly reachable spaces.

Locking mechanism

The suture is barbed which causes it to lock itself in any position as soon as it is pulled tight. This gives the surgeon enough freedom to control the closure of the opening.



Suture length control

The surgeons have the option to release and pull the thread based on their needs.

Application

Closure of the mesenteric windows (Figure 108 and 109) is necessary because they can lead to hernia and obstruction of the small bowel. There are surgeons perform the closure with a hernia stapler. However, the application is not always accurate with a significant number of staples not attaching properly to the tissue. Other surgeons therefore chose to close mesenteric windows with needle and suture which is a cognitively and physically challenging task.

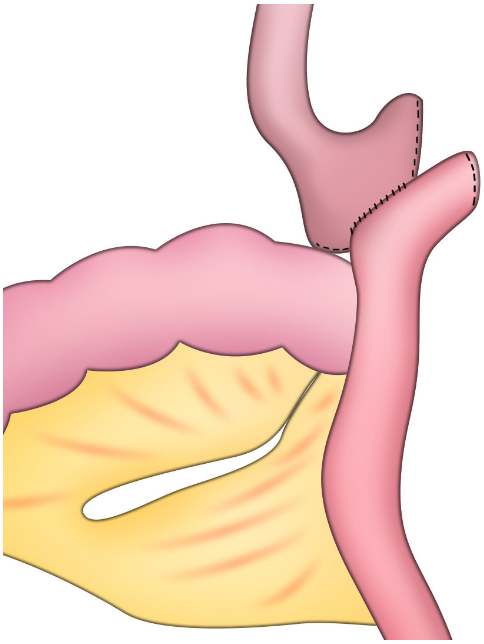


Figure 108: Petersen's defect after GB

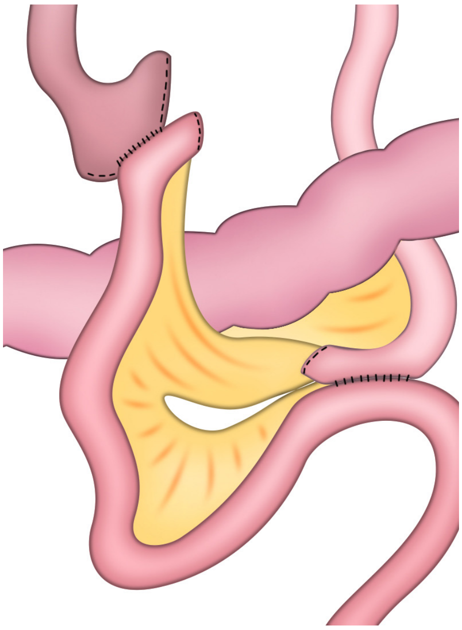


Figure 109: Mesenteric window after GB

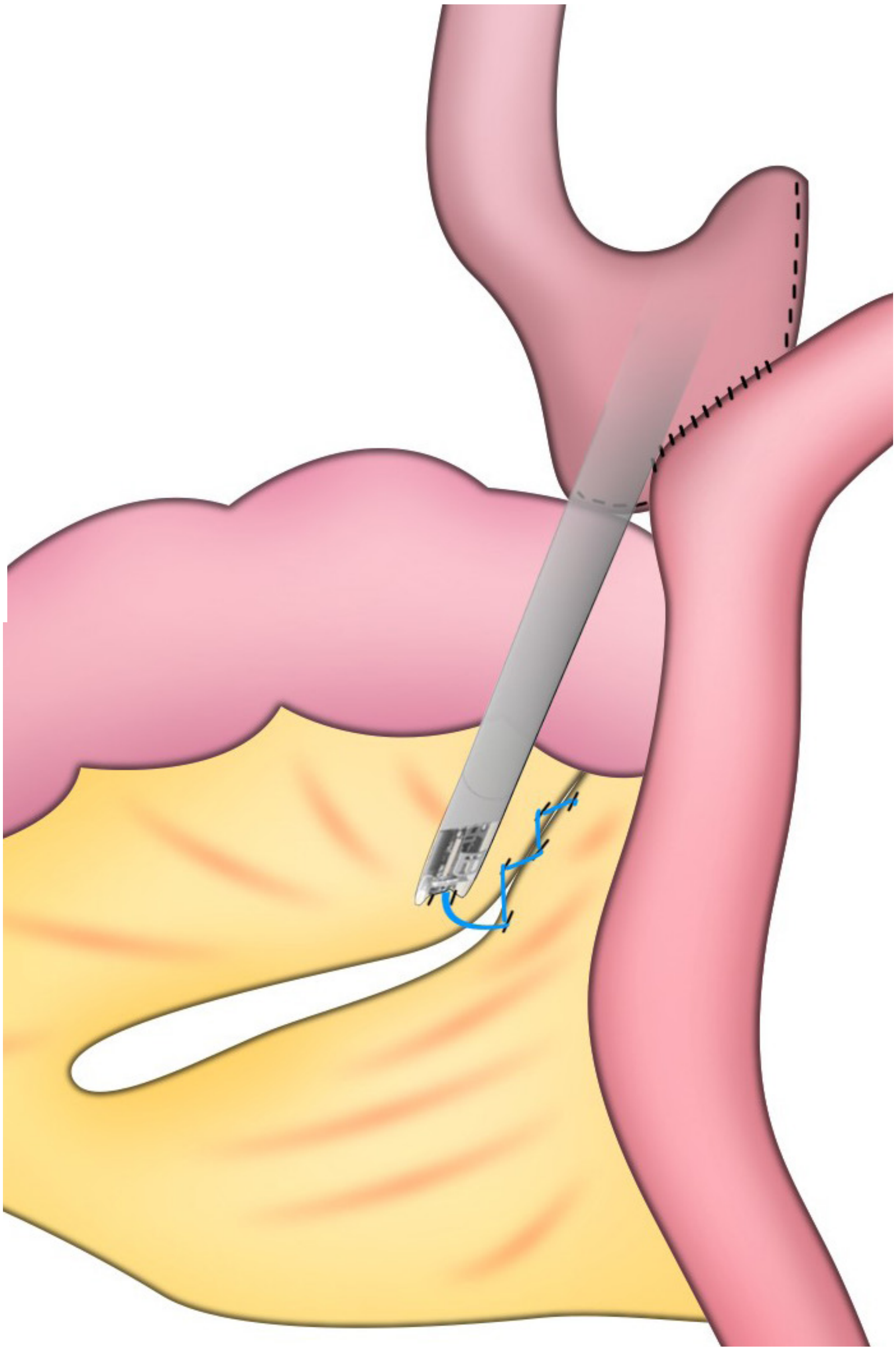


Figure 110: Petersen's repair with newly developed method

The newly developed method combines the characteristics of both suturing and stapling while decreasing the identified issues (Figure 110). It ensures an easy and safe application with one hand, and it gives the surgeon the necessary flexibility to adjust the closure based on environmental conditions. Thereby, the goal is to enhance ergonomic comfort for the surgeon and safe costs while reducing OR time (Figure 111 and 112).

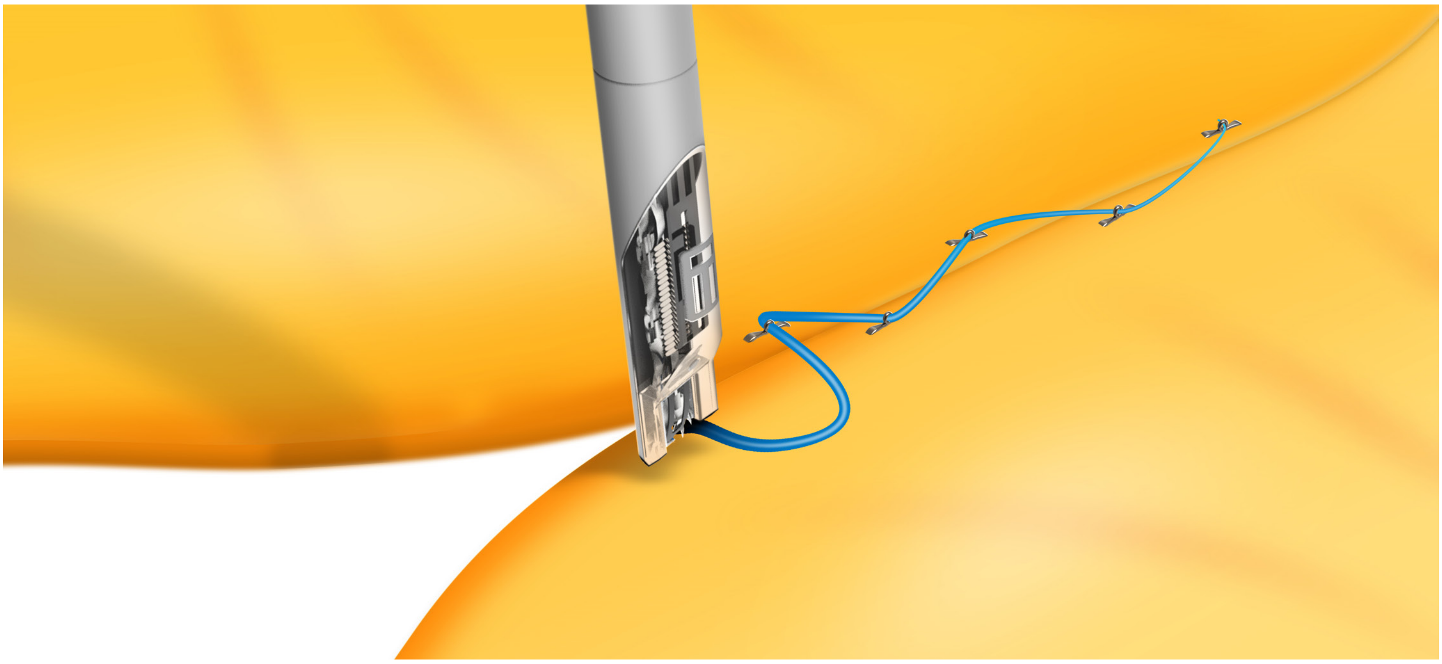
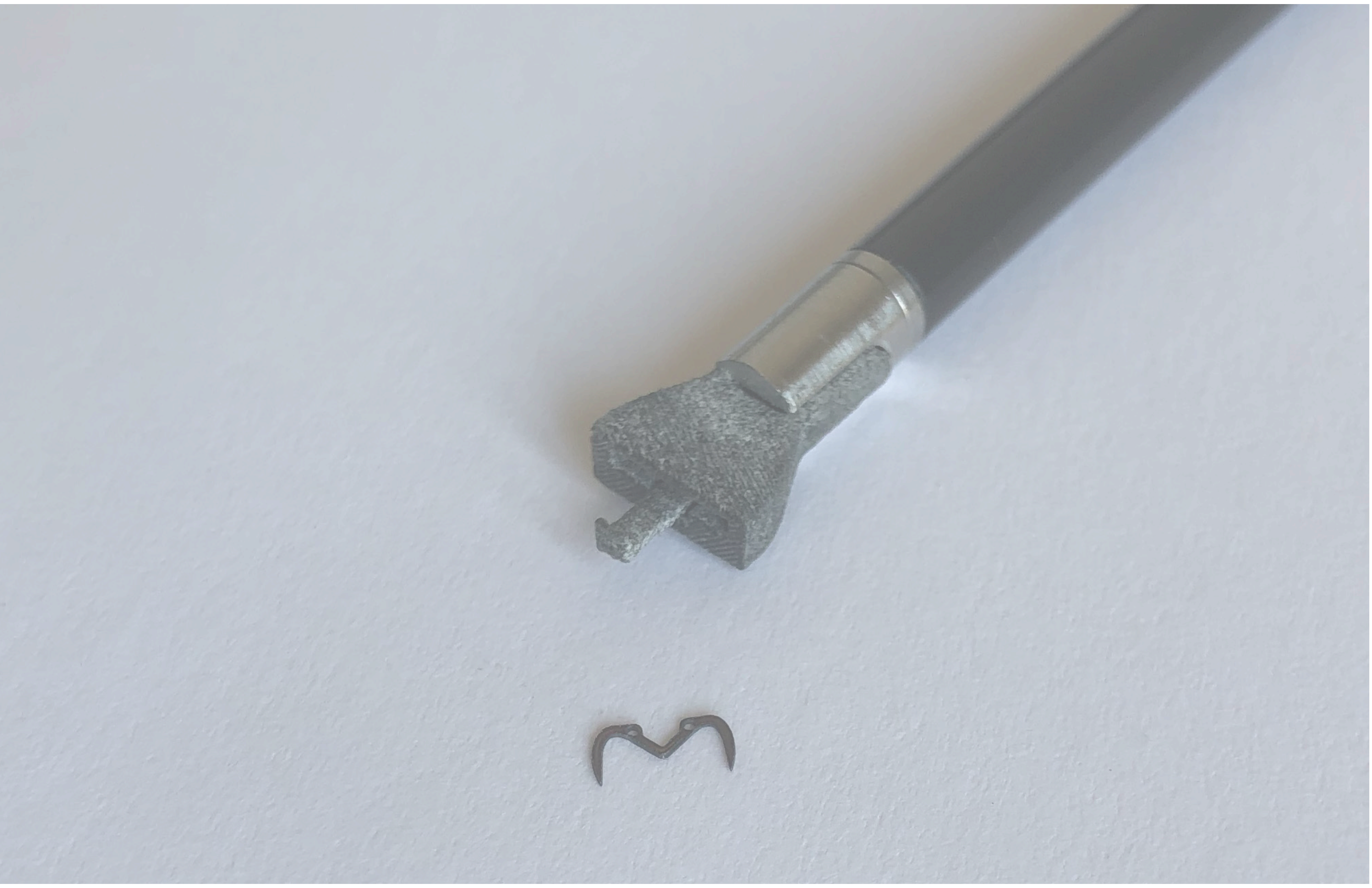


Figure 111: Mesentery closure with new method

Figure 112: Rendering of possible appearance of the device

9. DISCUSSION



9. Discussion

In this chapter, the findings of the project and an interpretation of the results are described. A comparison to prior studies is given with limitations of this research being shown. It also provides a reflection of the project structure and outcomes.

Need for a new method

In the literature review hand suturing was recognized as one of the most challenging tasks in laparoscopic surgery. It needs extensive training and multiple supervised procedures for beginner surgeons to master anastomosis suturing. In papers from the early invention of laparoscopy until today researchers try to find a solution for the technical difficulty of hand suturing. Controversially, more than half of the surgeons I talked to during the research, did not see laparoscopic suturing as a challenging task. When addressing the slips identified in the observations, they associate inexperienced surgeons with having those issues. Experienced surgeons acknowledge slips but they do not see them as a problem because they found their way to work around them. When experienced surgeons refer to the time they need to suture the remaining hole of an anastomosis, they guess a number around 2-3 min. Because this number is very objective, measurements have been taken during gastric bypass surgeries. The observations showed that the corrections of slips take time and the more slips happen, the more OR time is influenced. In 12 observed gastric bypass surgeries, performed by two surgeons, it was measured that an anastomosis closure takes about 6:30 minutes. It also showed that even though an anastomosis could be hand sutured by an experienced surgeon in a short time, the same surgeon might need three times as long for the same anastomosis in another patient. To reach enough statistical power, more surgeries of different surgeons must be observed and time should be measured.

Surgeon's responsibility

Many surgeons I talked to during the research had the opinion that slips during hand suturing can be overcome by training. There was little trust in new devices on the market or in research, including the newly developed method of this project. It is interesting to have a closer look at this trust because it describes a common character trade of healthcare professionals with high responsibility. Due to this responsibility, they need to be fully convinced before changing their current workflow and implementing new equipment. Even if a device offers more comfort for the operator, it won't be used if there is an increased risk to the patient.

Innovation in healthcare

A long-term investment is needed for medical devices and costs increase exponentially throughout the project. With this curve also the risks of failing increase which makes most medical innovations stop at an early stage. This makes innovation in healthcare additionally difficult.

Ergonomics

For a surgeon, a good skill set and dexterity are one of the most important to fulfil a task successfully. They believe that training and experience are what improves these skills and makes them better surgeons. Relying on devices which take away part of that skill is not always wanted because surgeons do not want to lose the skill in case the tool is not available.
However, another important factor for successful surgery was discovered during observations and interviews. It was found that being at ease and not feeling overwhelmed in stressful situations is beneficial for the patient outcome. Even though surgeons seem very calm during the procedure, it can be seen that the tension drops as soon as the surgery is finished satisfactorily. This observation underlines the importance of physical and cognitive ergonomics for surgeons, even if they are not always aware of the discomfort.

Desirability

During the first research, the need for a new closure method was analysed by making extensive workflows of the procedure. These showed that anastomosis suturing is not only time-consuming but also the most stressful part of the gastric bypass procedure. This could be seen, for example, because the radio in the OR was turned off, especially in this situation. However, when talking to surgeons some did not see the need for a new method for hand suturing. Critical participants were not convinced that the newly developed method was safe enough for anastomosis closure. Others, however, were interested in the topic from the beginning and helped with their assessment until the end. When broadening to other fields of application, surgeons were more convinced and saw possible benefits from the concept. Throughout the process, even the surgeons with critical opinions showed engagement and discussed possible solutions and alternatives. After all, interviews with surgeons about the research turned out to be positive with some asking when the device will be on the market.

Validity of the concept

When comparing traditional hand suturing with the new closure method, there are multiple advantages the new concept brings. It needs significantly fewer steps compared to hand suturing to finish the same task. The new closure method also reduces fine manoeuvres and no transfers of tools are needed. Finally, only one hand is needed to apply staples which facilitates tissue positioning and reduces tissue slipping. Nevertheless, the new concept also introduced new risks. Whereas hand suturing is a commonly used and widely available method all over the world, the new method is more costly to purchase and it will not beavailable in a large area of hospitals at first. This made surgeons sceptical of using it because it makes them more dependent on a device and they were concerned that beginner surgeons would not learn hand suturing properly. The interviews and risk analysis showed that the new concept is not as suitable for anastomosis closure because it brings too many safety risks for the patient. However, surgeons believe that the method is suitable and better than current methods for mesenteric repair.

Feasibility of the concept

A Finite Element Analysis of the staple and its behaviour was made. The aim was to analyse if the staple would bend in the way it was designed when applying a force. FEA helped to optimise the staple shape and proved that it would bend without tissue squishing. The manufacturability of the staples could be proved by producing a small batch of staples in 1:1 size. Additionally, there are many medical staples on the market already which are similar in size and can be produced in large amounts.

The method is suitable for laparoscopy which was a main requirement for the project. The closing mechanism which is used for the staple was designed in a way that suits a laparoscopic setup and a 1:1 simplified prototype was manufactured by SLS printing.

The idea for having a cartridge was taken from an existing hernia stapler where staples are stored in the head of the device. For the new concept, staples were arranged differently, so more staples could fit, and the suture could walk through them more easily.

Limitations

For the prototyping, facilities of TU Delft were available, however, there were some limitations. Due to the small scale of the product, it was not possible to do rapid prototyping with commonly used FDM printers or laser cutters. Also, manufacturing methods like milling machines or lathes were not suitable. Therefore, large-scale prototypes were manufactured to test the concepts. Later, a 1:1 scale prototype of the staples was produced on a UV laser cutter of the 3ME facilities. The maximum thickness this machine could cut was 0.2 mm whereas a thickness of 0.6 mm would have been needed for the staples to bend. Another laser cutter which was capable of cutting thicker materials was in maintenance and therefore not available for usage. For presentation purposes, the final staple shape was supposed to be produced on the UV laser cutter but as a student from another faculty, the service was limited so a second batch could not be produced. Possibilities for UV laser services around Europe were explored, however, the only service which was found was in the United States. A quote was requested butdue to high costs and too long shipping time it was not possible to manufacture the latest version of staples there.

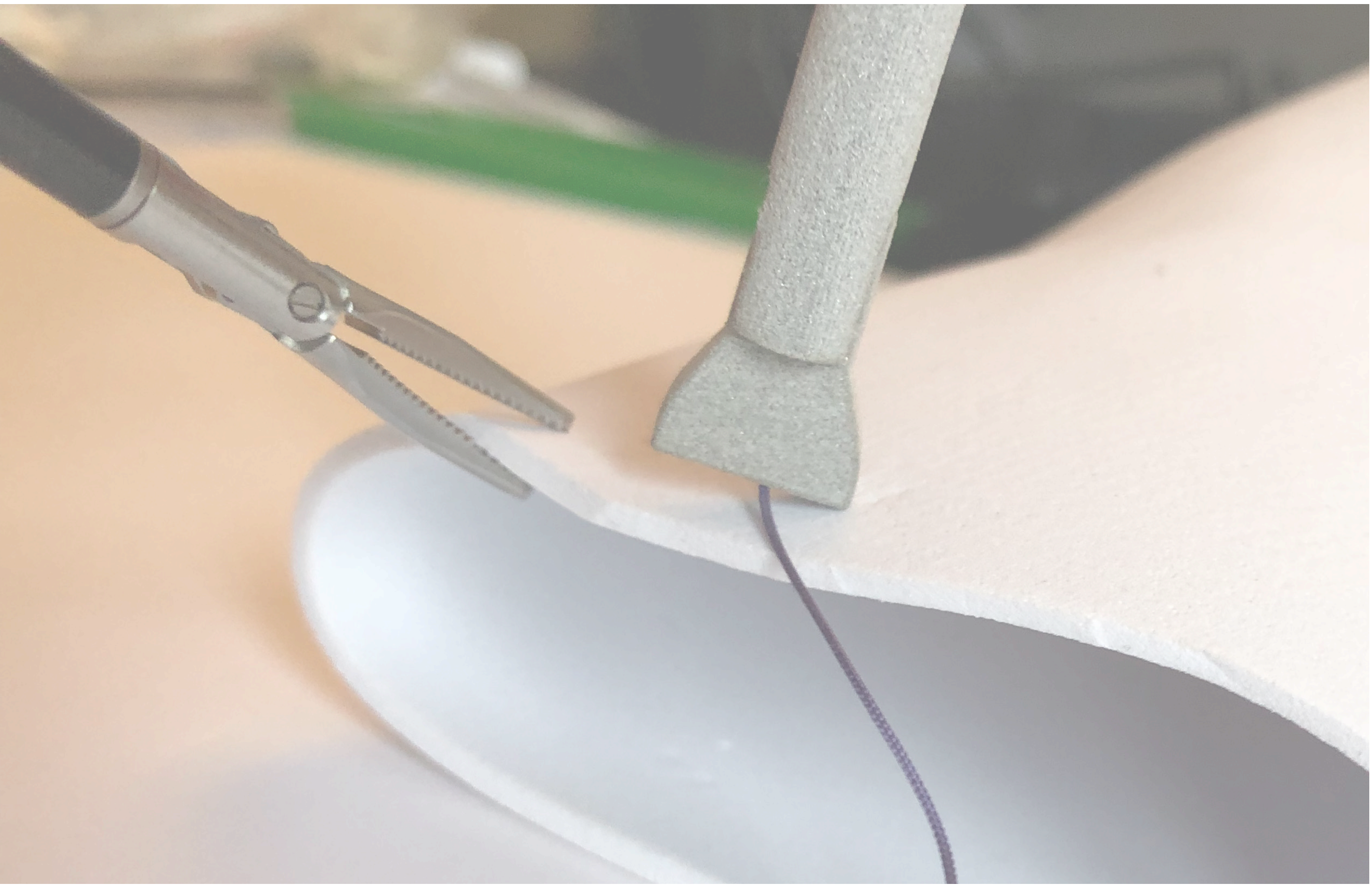
Testing was done on silicon and foam. Later, an animal bowel was purchased from a local butcher for testing. However, the tissue consisted only of the outer mucosa layer which did not give realistic indications of the tissue behaviour.

For more statistical significance, a larger set of surgeons must be observed during surgery and the time they need for anastomosis closure must be measured. In the scope of this master thesis, it was difficult to access hospital infrastructure, especially getting in contact with surgeons who are tight on schedule. A bigger research study which included an analysis of video material was explored. Unfortunately, this was not possible in this study, because the researcher did not get access to video material of surgeries due to confidentiality reasons. Also, the purchase of more commonly used surgical devices for the analysis was not possible due to limited financial resources.

Project structure

The project was the first collaboration of TU Delft and Spaarne Gasthuis on the topic of tissue closure. Prior to this master's thesis, there was no research team working on the topic yet so all experts and resources around the project were gathered in the context of the master's thesis. The topic was explored with an industrial design approach, using contextual design research and co-creation as the main methods. Hereby the designer moderated the sessions with stakeholders, including medical experts, surgeons, and other industrial design engineers. The design methodology made it possible to bring together different fields of expertise and gain clarity on the complex topic. In further meetings, it needs to be discussed if project partners are still available for the continuation of the project.

10. RECOMMENDATION



10. Recommendation

Further testing
Since medical device approval is a cost-intensive process, the project needs to be tested and risk analysis needs to be done at every stage. The project is in the very first development phase and a proof of principle has been done. The next step is to do a proof of concept. Therefore, a working prototype needs to be manufactured and tested. For testing, a setup with an animal bowel consisting of all tissue layers is recommended to analyse tissue behaviour.

Prototype
To improve the existing prototype, the head, especially the hook, should be built from metal to make it more stable. The staples should be made from thicker material to make the deformation possible. It is recommended to do additional research on the material of the staples. The metal should have an optimal yield strength and a late breaking point to avoid broken particles in the body. Implementing a cartridge is not recommended at this stage. Instead, staples should be refilled by hand.
It needs to be tested, if the existing barbed suture is suitable for the locking mechanism or if other types of barbs are more suitable. When using the barbed suture in tissue, all the barbs share the strength of the pulling. In the new method, only the barbs which are in contact with the staple hold all the strength.

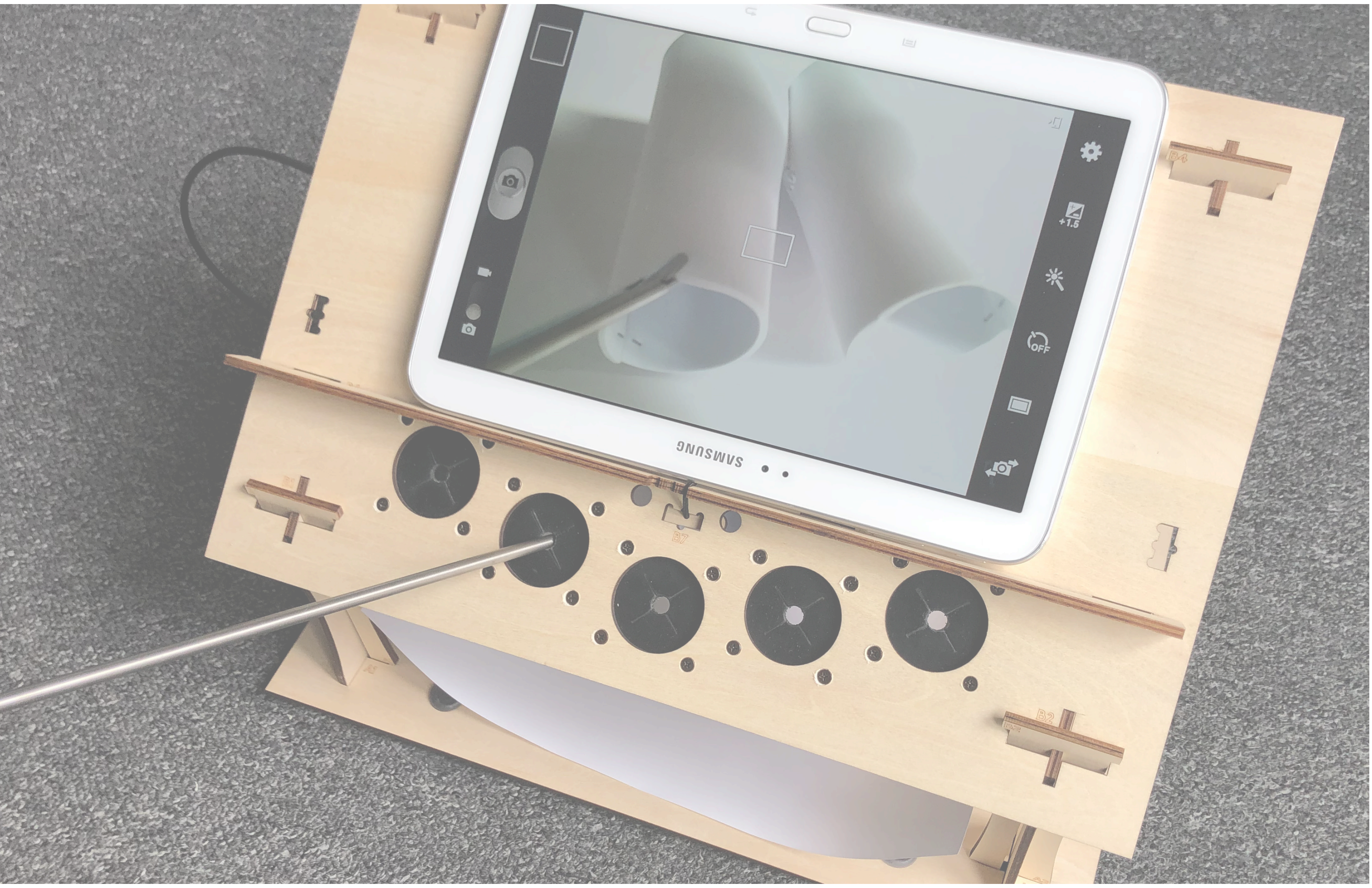
Additional functions
The risk analysis showed that most hazards are related to the surgeon's performance. If the surgeon e.g., does not apply enough pressure when releasing the staple, staples might have small gaps or fall out. It is recommended to build a more elaborated prototype with an integrated pressure sensor. This can give the surgeon feedback about the amount of pressure which needs to be applied. Additionally, there could be a function that staples are only released when enough pressure is applied.
Another risk is the slipping of tissue when applying pressure to it. This can be avoided by implementing a small hook which can act as a tissue holder. The idea is that it retracts tissue and presses it against the staple. It needs to be tested if this is technically feasible and if it is intuitive to implement this function.
To avoid too much stress on the tissue, an automated break release should be implemented in the device. If the surgeon pulls the device too much, there is a risk of tissue ripping. This could be avoided by releasing the suture when there is too much force. The function that the suture can be pulled back into the device manually should be implemented in case the suture gets too long. Surgeons are also advised to pull the suture after every stitch instead of at the end to avoid tissue ripping and small gaps.

Further development
In the next step, ergonomics and user interface need to be designed and iterated. This includes the handle shape and the design of use cues, including the suture release/ lock button, staple trigger, and interface to rotate the head. Research into the necessity to tilt the head including assessment (cost-benefit analysis) is recommended.
As mentioned, most risks are related to the surgeon's performance. Extensive instructions for the new device and training should be provided. For beginner surgeons, this training can be implemented in their common training environment, for experienced surgeons, this should be an additional workshop.
Since the initial application changed, additional research needs to be done into the requirements of hernia repair. Research with more surgeons from multiple hospitals into the necessity of a new closure device is recommended.
From a business point of view, the device should first be approved for hernia repair only. This application has fewer risks which makes market entry easier. Additionally, this is a way to gain the acceptance of surgeons. When this is successful and implemented into the hospital environment, other applications can be tested.

Project planning
For the project to continue, one or more project briefs need to be formulated for upcoming master students to get involved and continue with the project. Possible thesis topics could be:

- Embodiment of a newly developed closure method for mesenteric defect after gastric bypass surgery. (proof of concept, Integrated Product Design)
- Research into the need for hand suturing and testing of a new surgical tool for closure of mesenteric defects (research project, Product/ Strategic Product Design)
- Development of ergonomic interface for a newly developed mesenteric closure method. (Design for Interaction)
- Development of a market entry strategy of the parallel stapler. (Strategic Product Design)
- The continuation of the project by students is advised to bring it to a higher Technology Readiness Level before presenting it to the industry. (Strategic Product Design)

11. CONCLUSION



11. Conclusion

Hand suturing is one of the most challenging tasks in laparoscopic surgery. Nevertheless, it is also one of the basic skills and it must be done by all residents in the first year of training. It is a necessary skill due to its high requirements and broad application. This project does not aim to fully replace hand suturing, but to make its use less frequent. The newly developed method reduces cognitive effort and time, while enhancing comfort for the surgeon. Literature suggests that the patient's outcome improves with more surgeon's comfort.

Requirements on anastomosis closure are high. The tissue must be closed watertight while enabling perfusion, hemostasis and tissue healing. A new closure method was developed to fulfil these requirements. It combines the advantages of stapling and suturing by having staples which attach to the sides of the opening and a suture which connects these. To close the opening the suture is pulled tight and the sides of the tissue approximate each other. However, an evaluation showed that there are risks when using the method for anastomosis closure. Other applications were explored, and it was found that requirements for mesenteric repair during Gastric Bypass are lower. The tissue needs to be closed tight to enable healing, but it does not need to be closed watertight. Later it was investigated if the developed solution is also suitable for mesenteric repair. Due to fewer requirements, this application showed to be a more suitable alternative.

For a proof of concept, a functioning prototype needs to be built and tested on an animal bowel. Further user testing and interviews with a larger number of surgeons should be done to evaluate the concept. It is advised to continue with the project in the context of university research, in collaboration with the project partners.

An abstract of the project will be given to Spaarne Gasthuis science committee for review. After approval, the project will be presented on the science day at the hospital.

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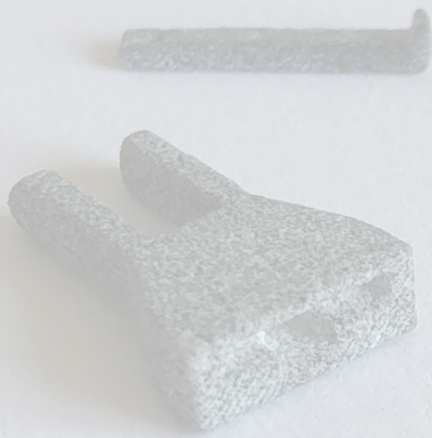
13. APPENDICES

A: Protocols of hospital visits (confidential*)
B: Personal communications (confidential*)
C: User experience workflow: Gastric Bypass
D: User experience workflow: Hand suturing
E: Additional information about bowel anatomy
F: Suturing and knot tying techniques
G: Suture thicknesses
H: Needle shapes
I: Themes
J: Suturing course
K: Surgeon's opinions (confidential*)
L: Concept evaluation (confidential*)
M: Project brief



*appendices which are marked as confidential are not uploaded to the TU Delft repository