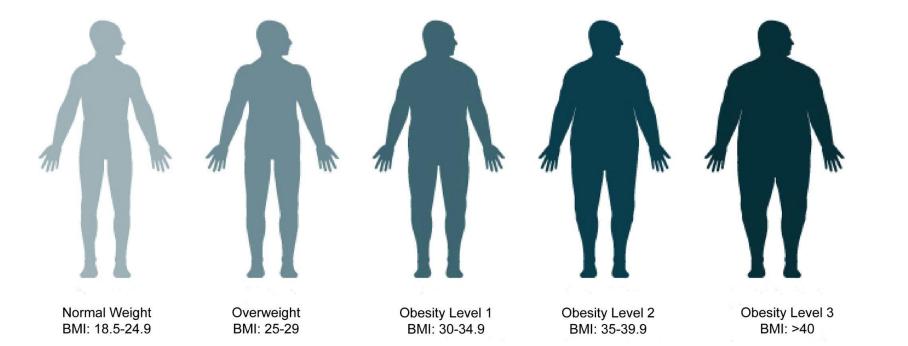
Master's thesis presentation

StapleStitcher







(Higuera-Hernández et al., 2018)

Excessive fat accumulation, leading to serious health risks

50%

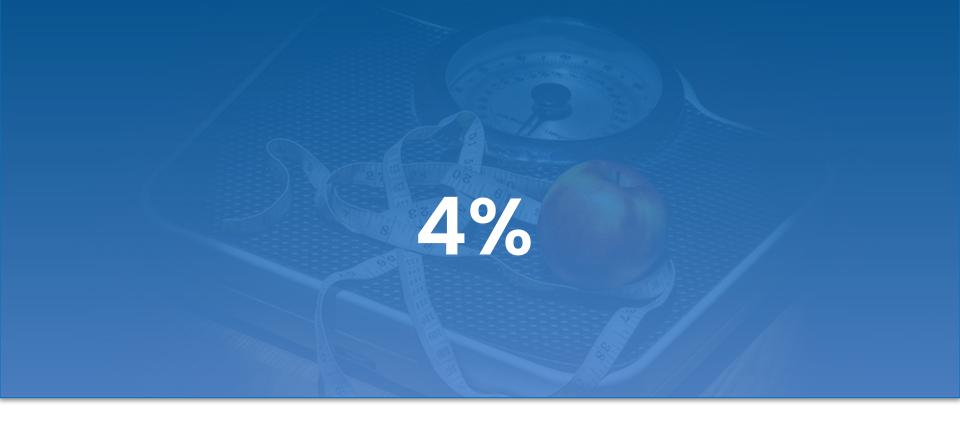
of Dutch population was overweight (CBS, 2022)

14%

severely overweight (obese) (CBS, 2022)

4 mill

deaths, annually (WHO, 2020)



Only 4% achieves long-term weight loss with non-operative treatments (Mitchell & Gupta, 2022)



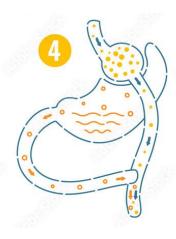
The term "Bariatric" originates from the Greek "baros" (weight) and "iatros" (healer)

Bariatric surgery





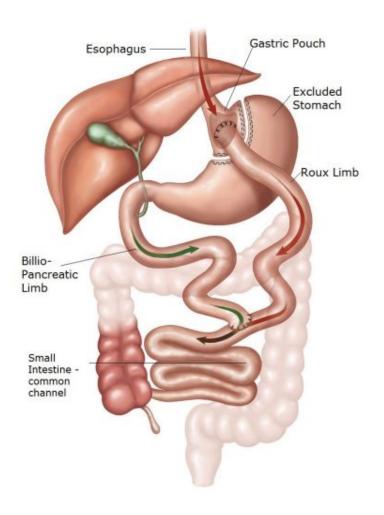




- 1 ADJUSTABLE GASTRIC BAND
- MINI-GASTRIC BYPASS

- 2 GASTRIC SLEEVE
- 4 ROUX-EN-Y GASTRIC BYPASS

(Adobe stock, n.d.)



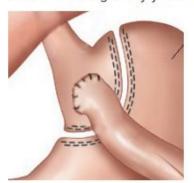
1. Creation of the gastric pouch

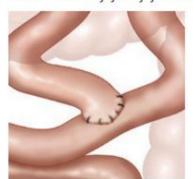


2. Dissection of small bowel

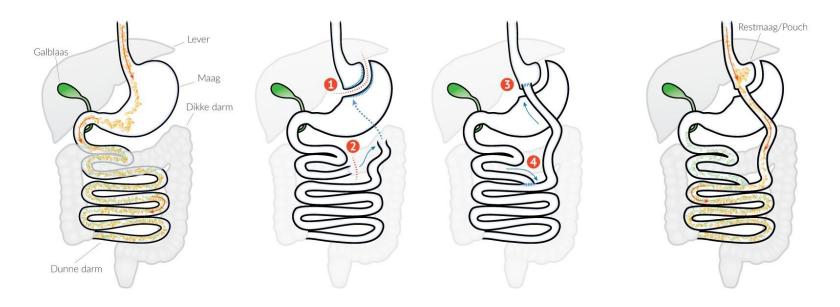


3. Creation of gastrojejunostomy 4. Creation of jejunojejunostomy

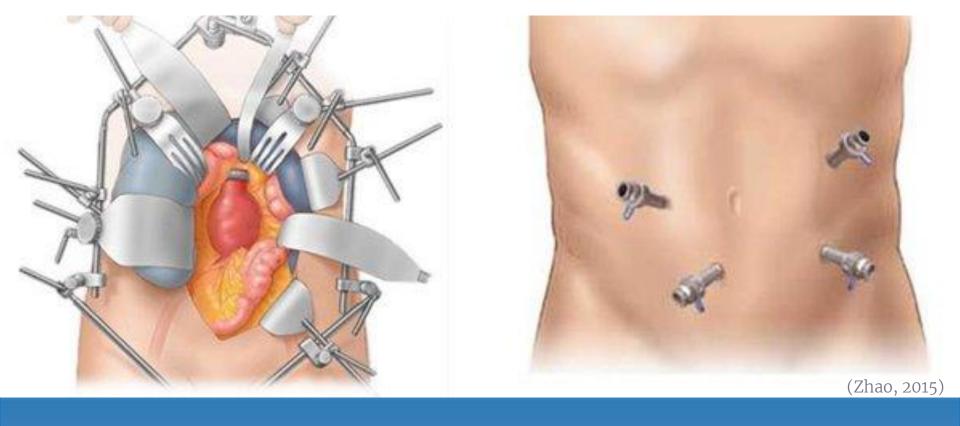




(Wochner, 2022)



(Nederlandse obesitas kliniek, 2020)

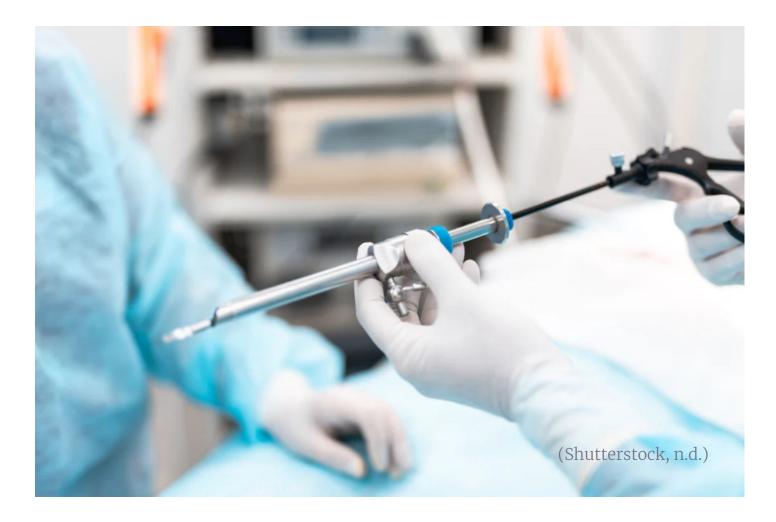


Open surgery (left) Minimally invasive surgery, laparoscopy (right)









Abdomen filled with CO2

Laparoscope projects video on screen

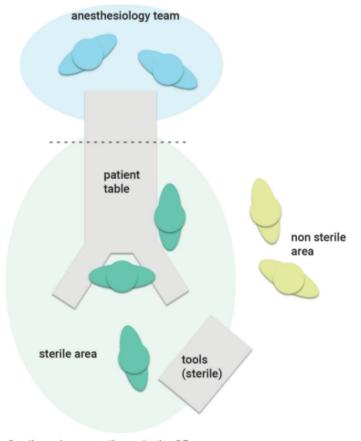




Hydraulic surgical table

Patient is inclined with head downward and legs upward, for better access for the surgeons (Shoves the organs away)





Sterile and non-sterile are in the OR

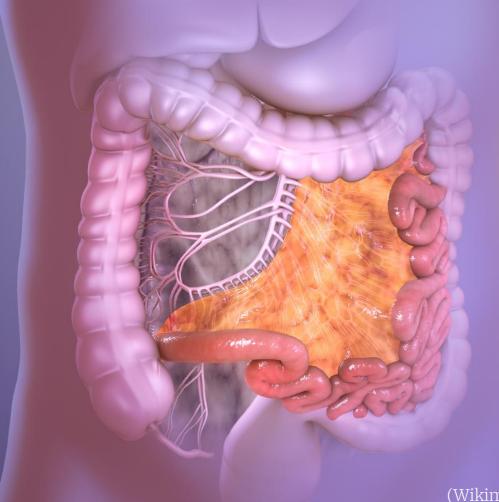


This is what robotic surgery looks like

Da vinci robot

Mesentery

attaches the intestines to the abdominal wall, and also helps storing the fat and allows the blood and lymph vessels, as well as the nerves, to supply the intestines.



(Wikimedia commons, 2018)

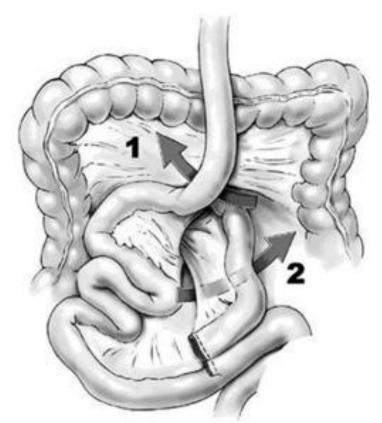
WARNING Graphic content



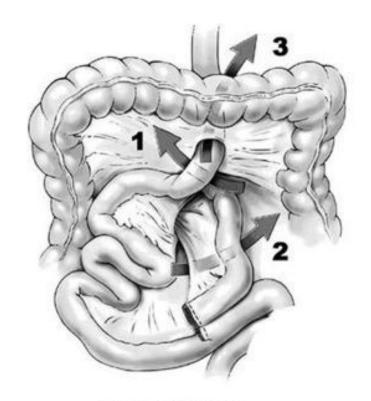
Open spaces called Mesenteric defects

- Petersen's space Mesojejunal space

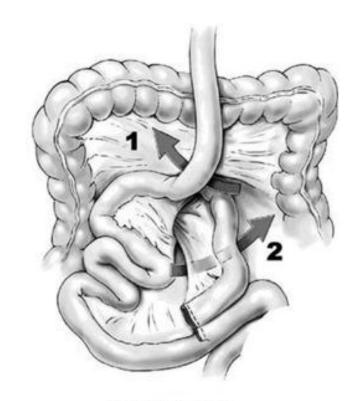
About 2 - 5 cm long (Xu & Zhou, 2023)



(Pokala et al., 2022)



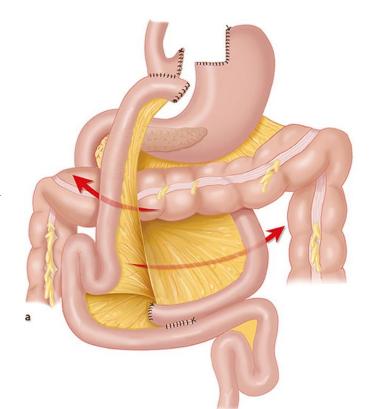
RETROCOLIC

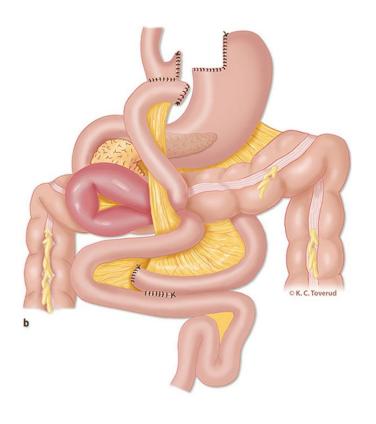


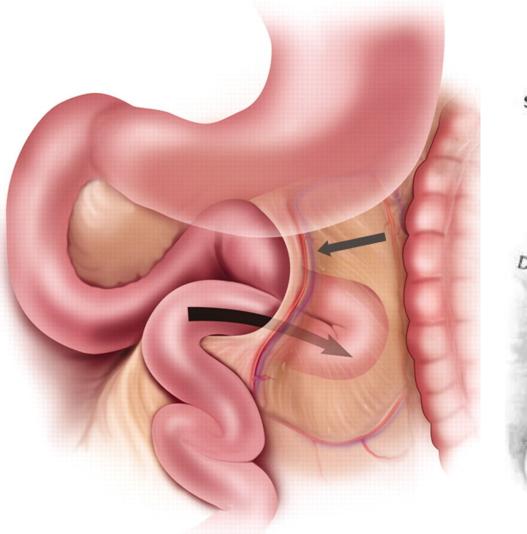
ANTECOLIC

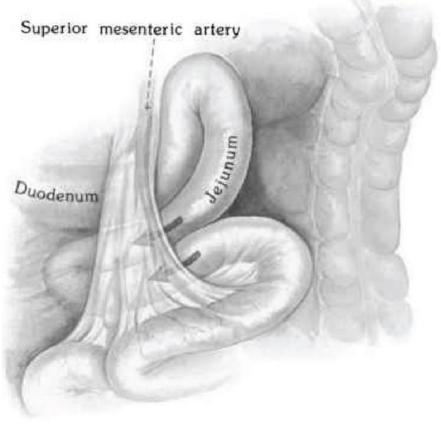
intestinal loops
bowel obstruction
internal herniation

Thus defects must be closed









WARNING Graphic content

Healthy intestines and mesentery (left)

and a necrotic (dying) bowel segment



Two most used ways to close defects

Suturing

Manual suturing offers great freedom

Stapling

Stapling offers faster closure

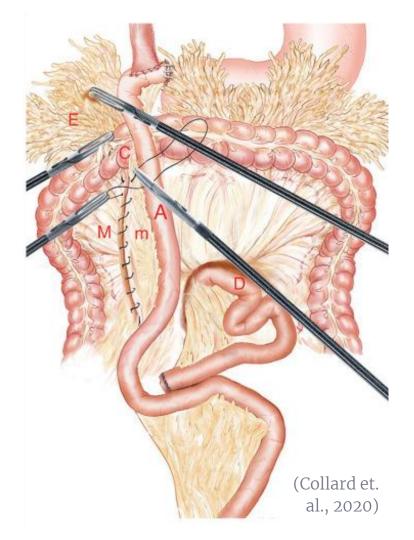
CLOSURE PROCEDURE

Assistant's grasper maintains transverse colon (C) to expose the bottom of the Petersen's defect.

Alimentary limb is pushed to patient's left to optimize exposure of the space.

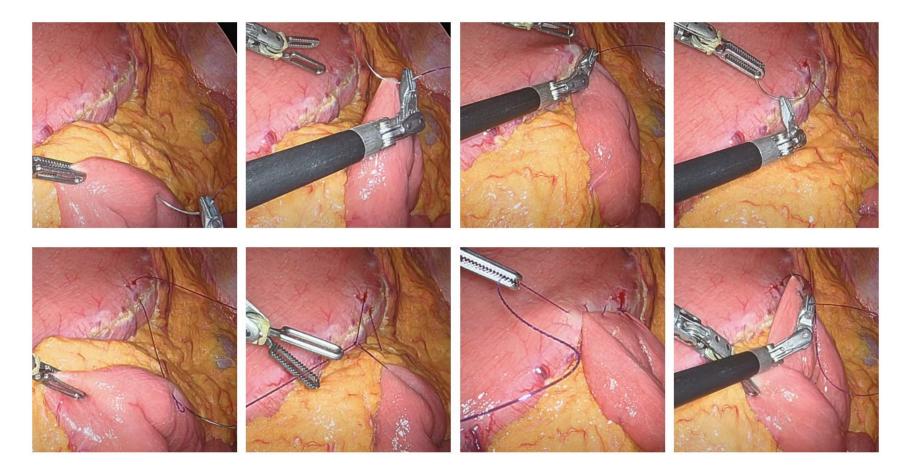
Defect is closed with non-absorbable suture (as the tissue will not grow together by itself).

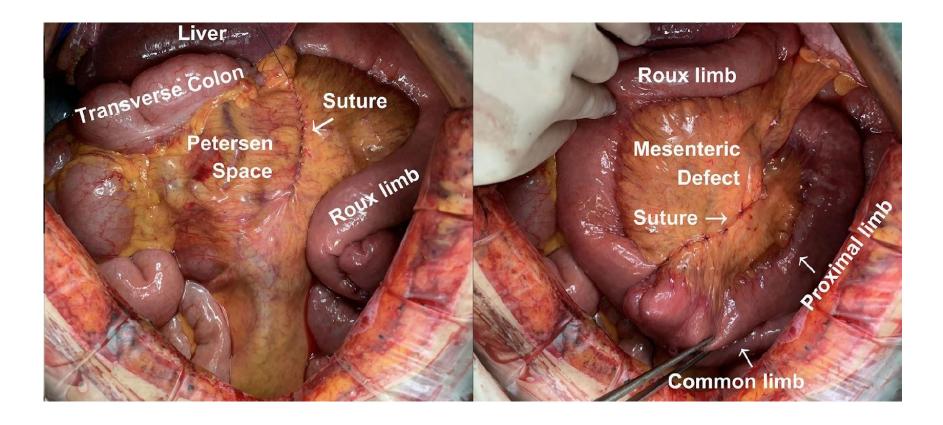
Taking care not to include omental fringes or the greater omentum (E) in the suture.



WARNING Graphic content

CLOSURE PROCEDURE (Wochner, 2022)





CLOSURE PROCEDURE

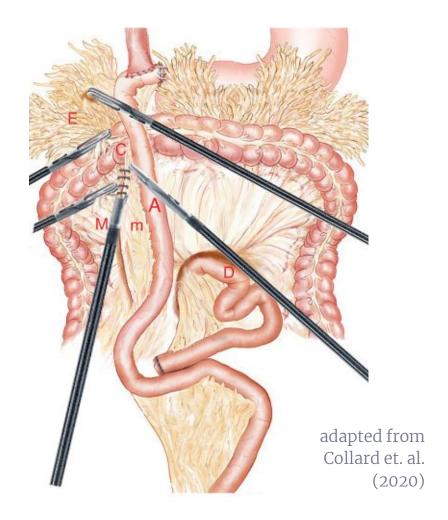
Assistant's grasper maintains transverse colon (C) to expose the bottom of the Petersen's defect

Alimentary limb is pushed to patient's left to optimize exposure of the space

Two graspers maintain each a side of the tissue and align it for stapling (and another one to provide counterpressure for stapler)

Defect is closed with non-absorbable staples

Take care not to include omental fringes or the greater omentum (E) in the stapling



WARNING Graphic content

CLOSURE PROCEDURE











(Acherman, 2023)

PROBLEM

When stapling:

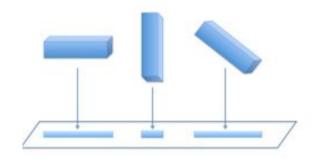
- 50% of staples fall out over time
- Catching both sides of the tissue is difficult
- Reloading is cumbersome, must be done 4x

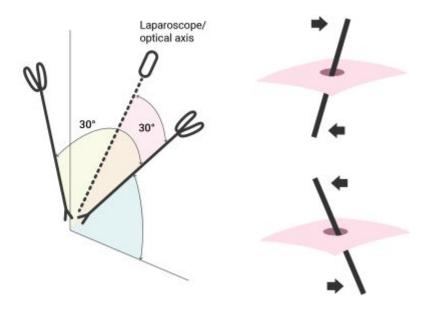


PROBLEM

Additional challenges:

- Cognitively demanding
- Ergonomic discomfort
- Hand-eye coordination
- Reduced depth perception and degraded visual image
- Fulcrum effect
- No direct control on laparoscope position and orientation
- Reduced tactile feedback
- Narrow workspace







PROBLEM







PROBLEM

Tools used upside down, due to lack of space

Reduce time and cognitive effort required for MDs closure

Offer an alternative approach without the need for precise tissue alignment





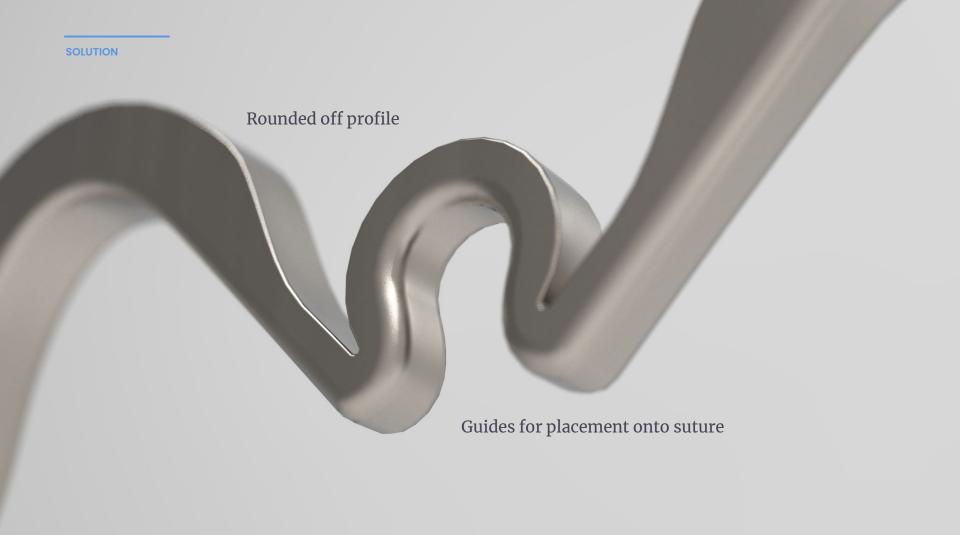
Application from the top Direct haptic feedback 360°+ rotation Left- right handed and upside-down usage

35cm effective length Diameter of 9 mm 200 grams



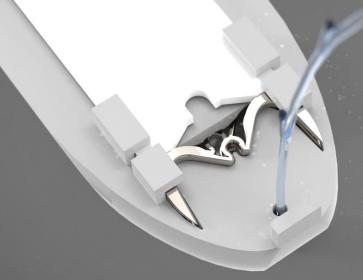
Special staples





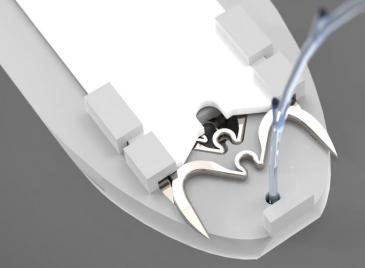


Punch picks up a staple



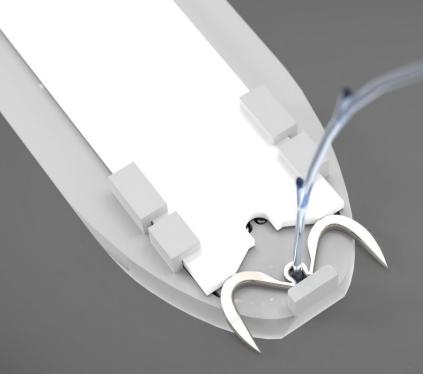


Punch picks up a staple

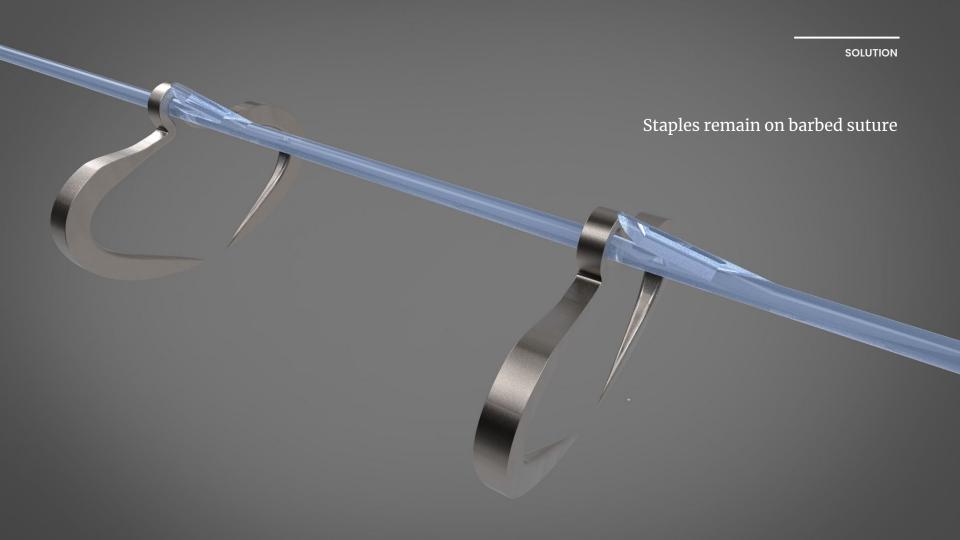


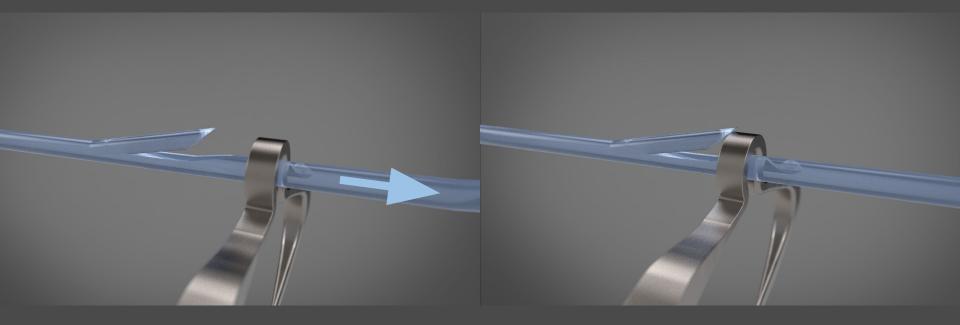


Places staple onto barbed suture

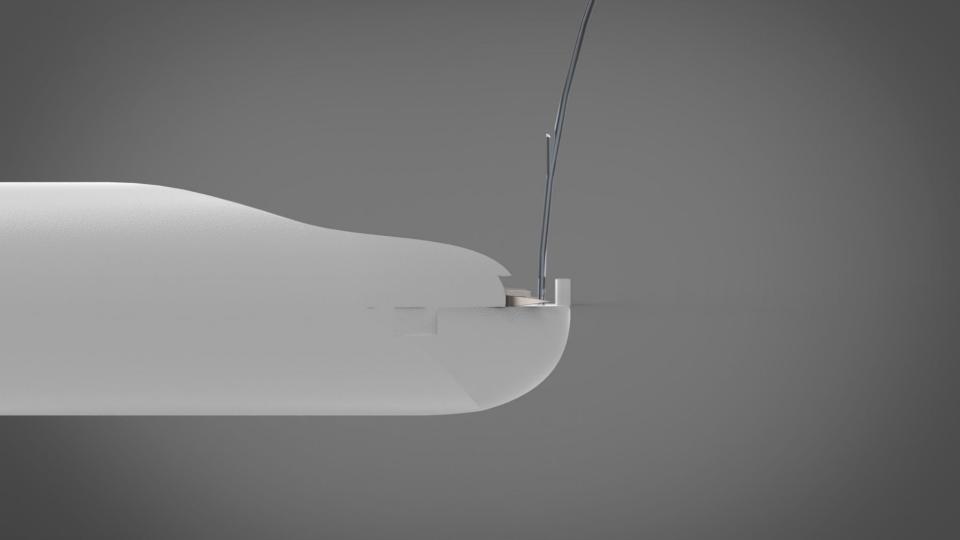


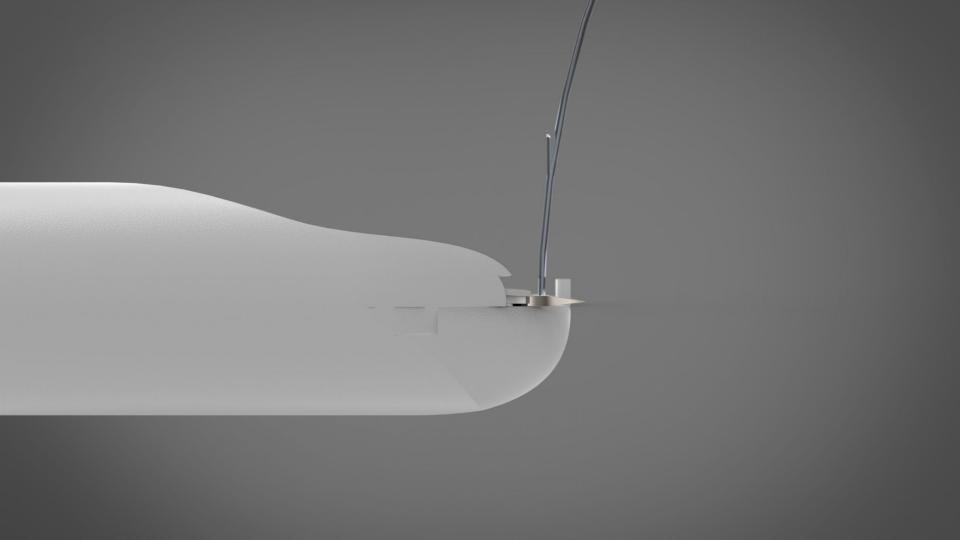
and pushes it into the right shape

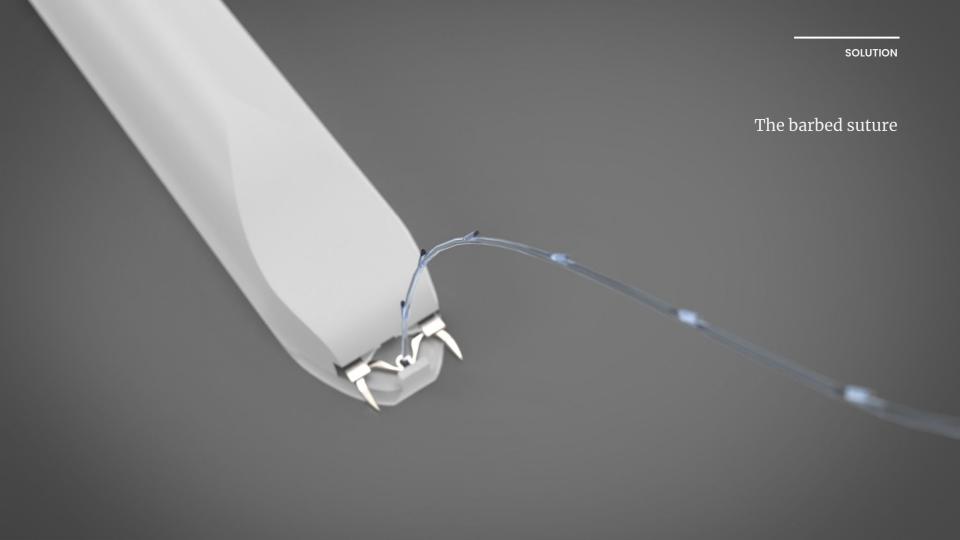




Barbed suture can slide through to tighten, and will not open after tightening

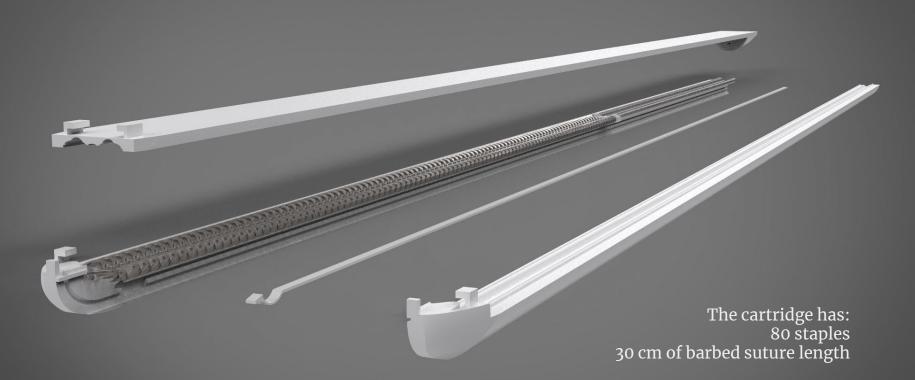






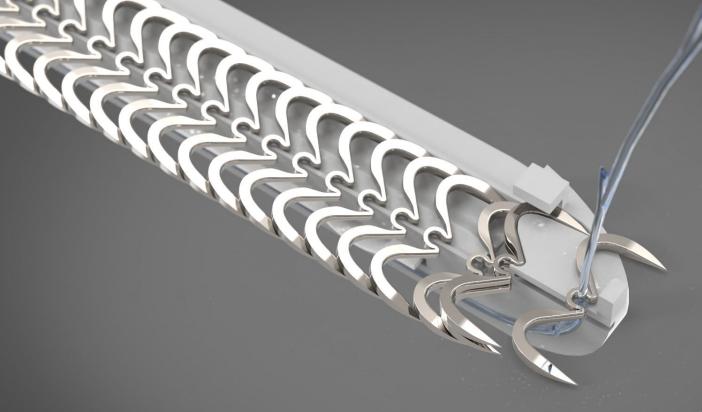
The beginning of the barbed suture to act as a blockade

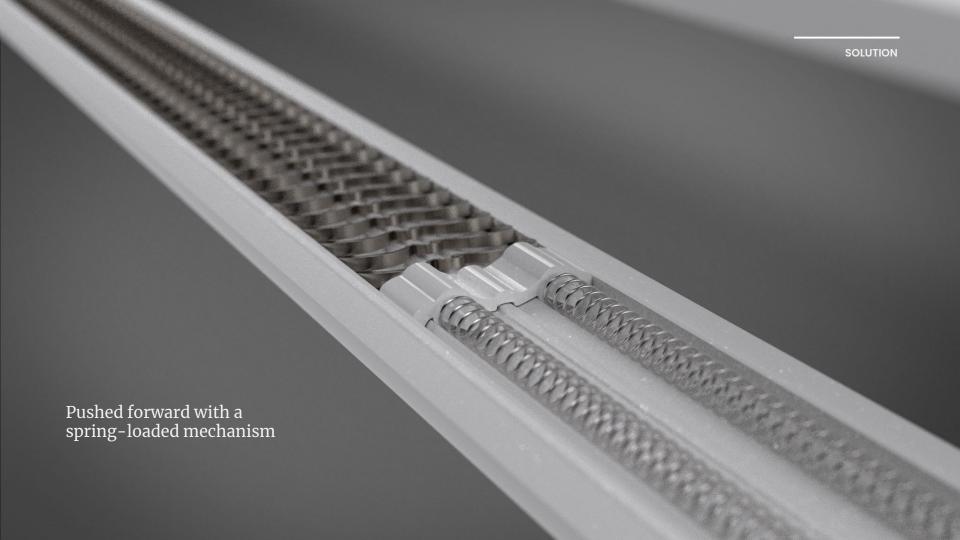
No need to make a knot

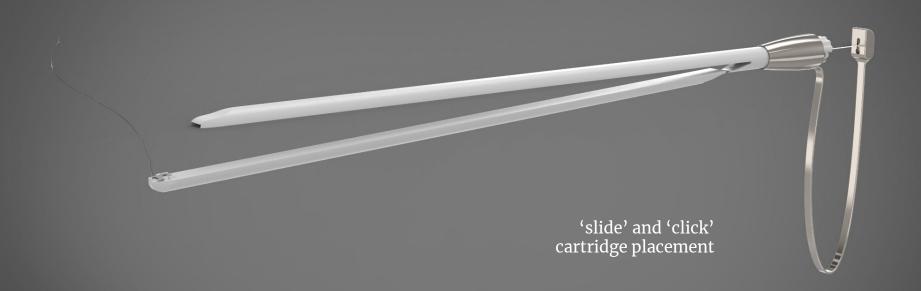




Staples slide underneath each other, creating a 'lift'

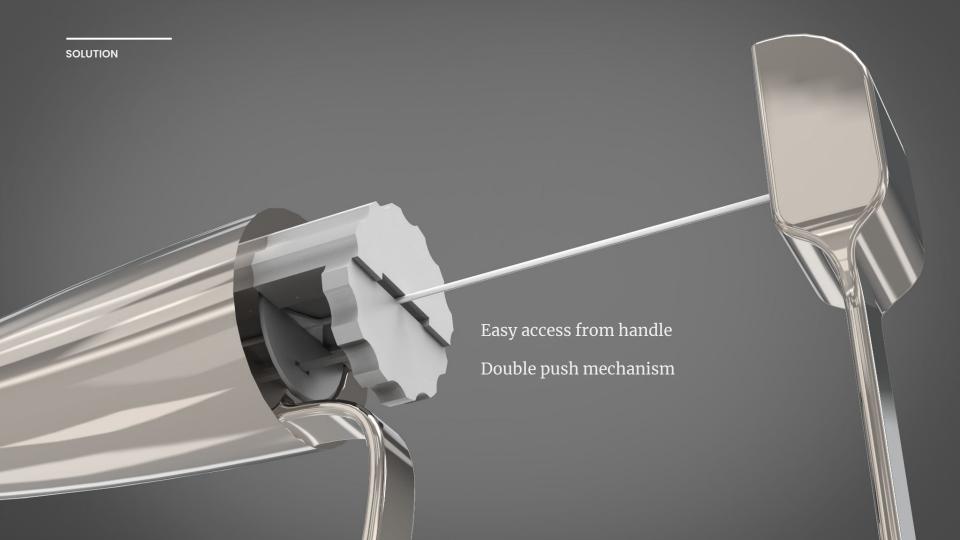


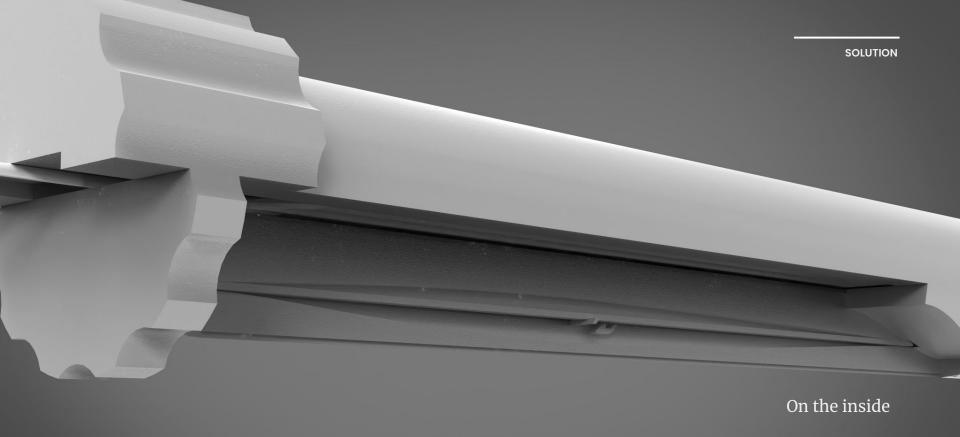








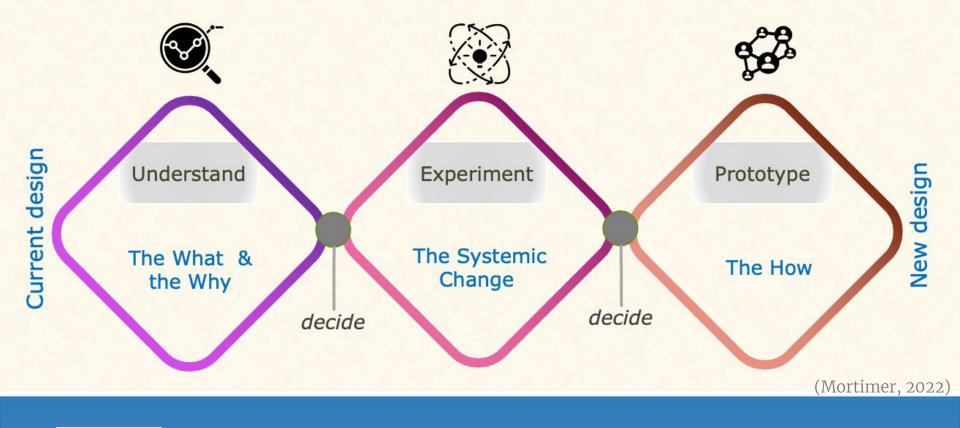






SOLUTION Compliant mechanism to lock the suture, when tightening

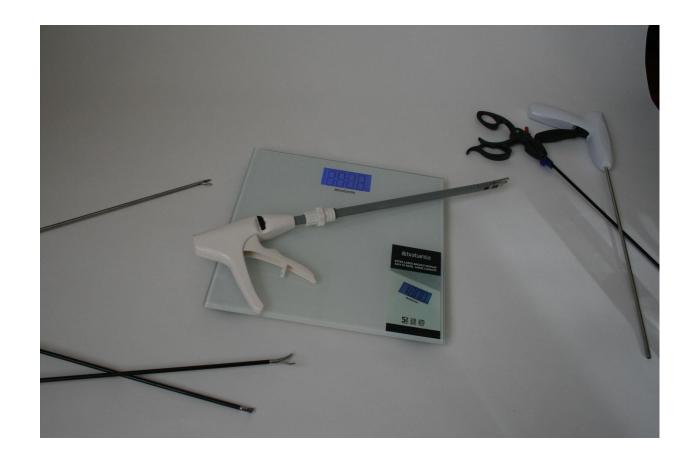
Compression of suture



Open surgery (left) Minimally invasive surgery, laparoscopy (right)

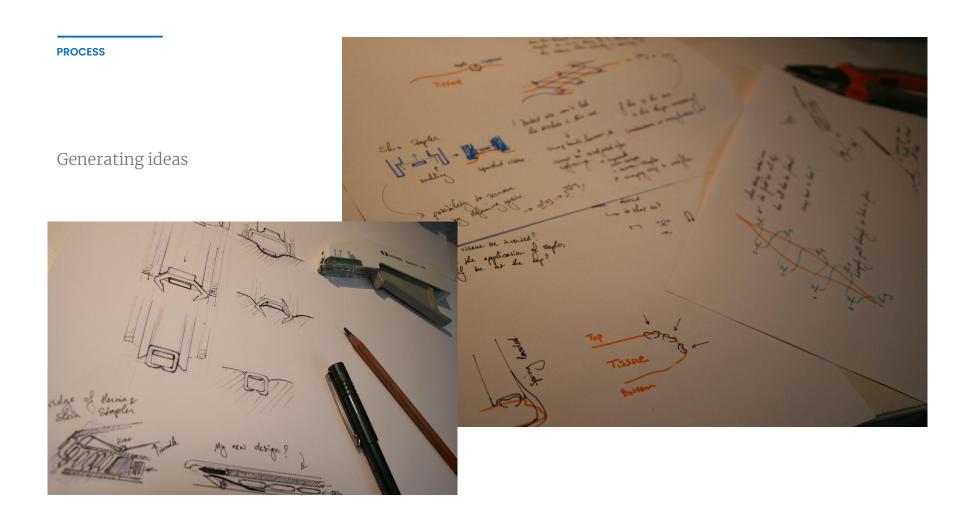
PROCESS

Weighing existing tools



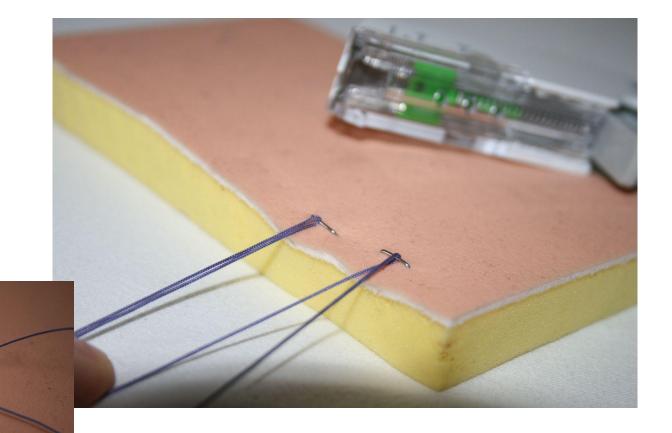
PROCESS



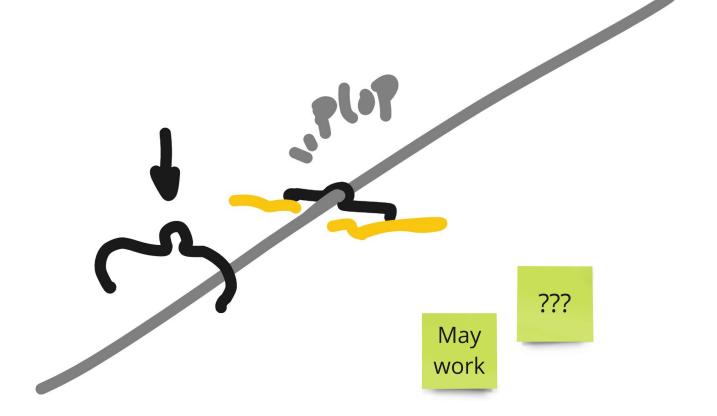


PROCESS

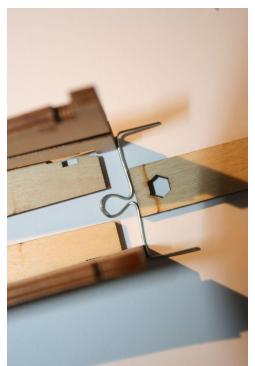
Selecting some ideas through simple tests

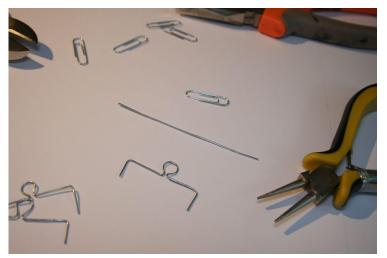


A new idea, based on previous attempts



Low-fidelity testing





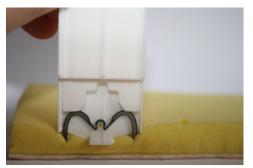


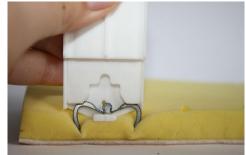






More low-fidelity testing

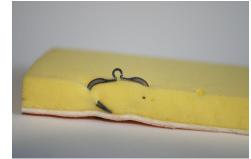




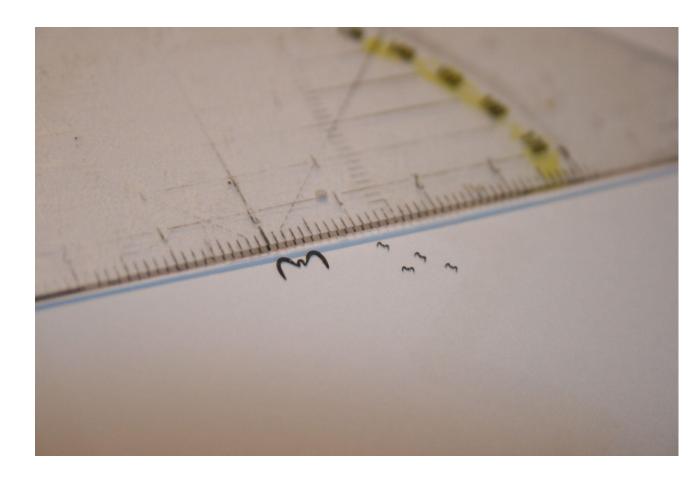






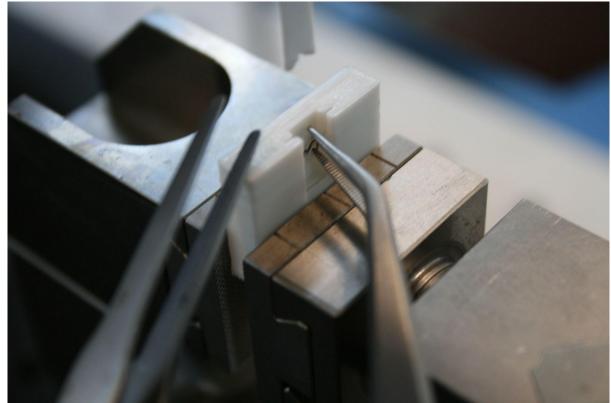


Making them too small was also possible..



PROCESS More testing









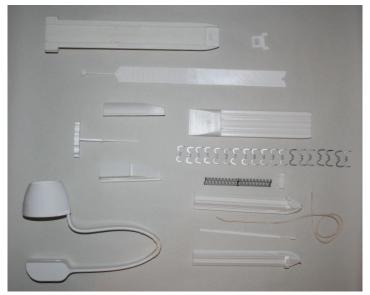






The same process applies to the cartridge

.. and to the rest of the product





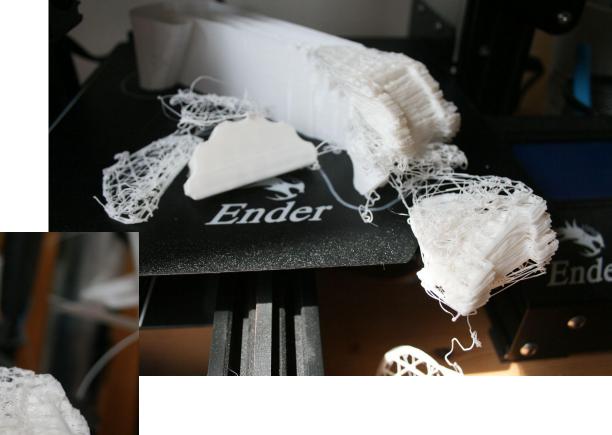








Not without problems of course



Questionnaire

The Dutch Society for Metabolic and Bariatric Surgery, and linkedin

10 participants



Surgeons from:

- > Spaarne Gasthuis
- Nederlandse Obesitas Kliniek Den Haag en Gouda
- WeightWorks Amersfoort
- ➤ Maxima MC Veldhoven
- ➤ Catharina Ziekenhuis Eindhoven
- Obesitas center Weert
- Albert Schweitzer ziekenhuis
 Dordrecht, Zwijndrecht en Sliedrecht
- Horacio Oduber hospitaal Oranjestad

- Three main parts
 - Defined the factors for successful MD closure
 - Product proposal
 - Using multimedia approach: CAD models, textual concepts, animation.
 - Then evaluate product according to those factors

| of the device? | | | | | | | | | |
|---|---------|------------|-----------|-----------|---------|------------------|--|--|--|
| Consider comparing it to manual suturing or regular staplers. | | | | | | | | | |
| 1 2 3 4 5 | | | | | | | | | |
| Very ineffective | 0 | 0 | 0 | 0 | 0 | Very effective | | | |
| Based on the available information, how would you rate the comfort of using the device? | | | | | | | | | |
| Consider comparing it | to manu | al suturii | ng or reg | gular sta | aplers. | | | | |
| | 1 | 2 | 3 | 4 | 5 | | | | |
| Very uncomfortable | 0 | 0 | 0 | 0 | 0 | Very comfortable | | | |
| What aspect of the device should be altered to improve your comfort? Jouw antwoord | | | | | | | | | |
| Do you foresee any complications or limitations with this device? Please substantiate. | | | | | | | | | |
| | | | | | | | | | |

The difficulties mentioned in literature and observed during observations were reaffirmed

"To invest enough time during the operation to visualize and close both defects."

"When using staples, catching the tissue before staple formation. When suturing, it takes more time."

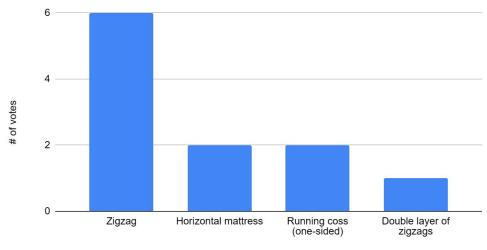
"technique, technique, technique and patient factors."

"Quick, persistent, stable closure. At least 50% will open up."

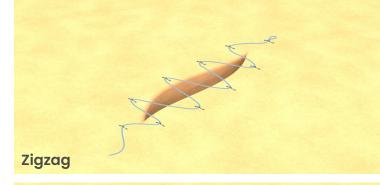
"Hernia staplers are insufficient in grasping enough tissue and give inadequate closure."

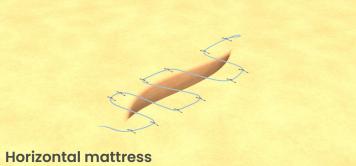
"You are short of a hand to get proper exposure, hence the EHS stapler is used which can work single-handedly, but it does not suffice either. So suturing is better, but that took a lot of time, cave bleeding."

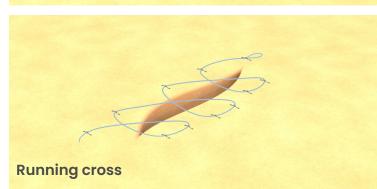
What technique surgeons would use



Preferred technique

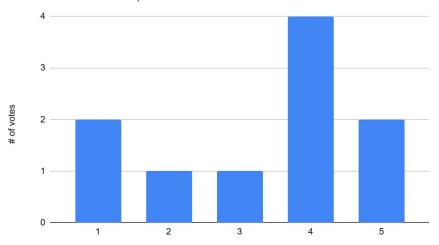






Fulfillment of critical factors

Does it fulfill the requirements of successful MD closure?



1 - Does not align with my requirements at all, 5 - Aligns perfectly with my requirements

Negative ratings:

"Most limitations are tissue-related."

"staples are too atraumatic".
"The mesenteric sides of the defect have to grow together. With this system, the tw

to grow together. With this system, the two sides remain intact and therefore the tissue will have less tendency to grow together."

Positive ratings:

"It appears easier in use seeing that there's no need to align directly and that the suture can be tightened later".

9 out of 10 found the StapleStitcher to be innovative.

Some reactions include:

"YES"

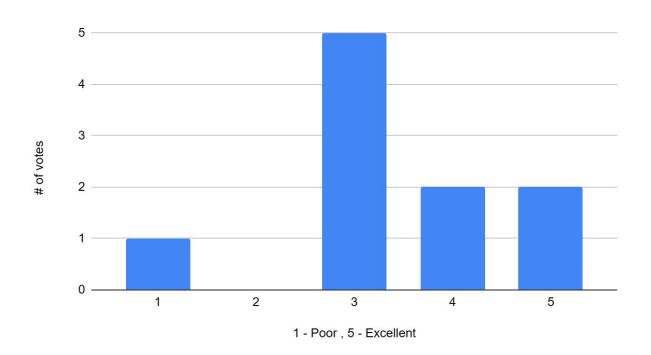
"Yes, but the success depends mainly on the success of the staples holding the tissue."

"Yes, but I still have a lot of questions about its long-term effects, cost, etc."

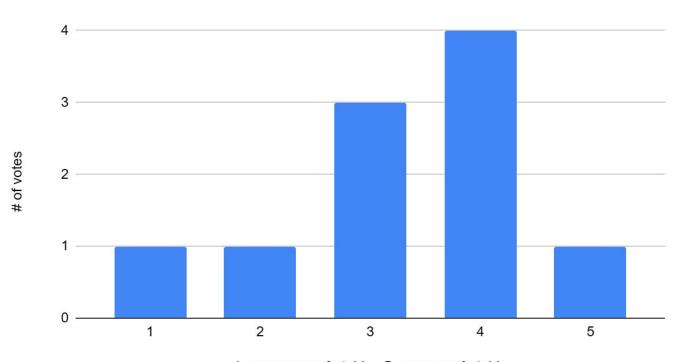
"Absolutely, unprecedented"

"Amazing!"

Perceived quality of the device

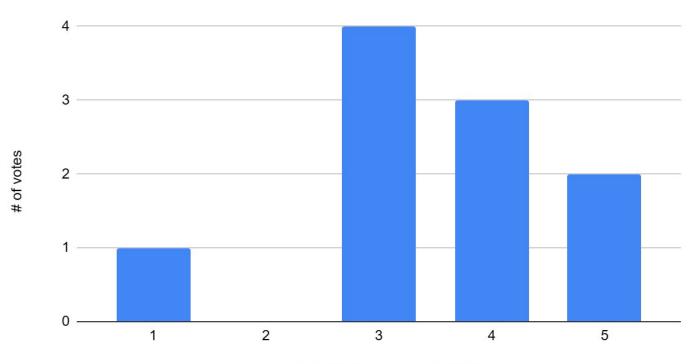


Perceived comfort of using the device



1 - very uncomfortable , 5 - very comfortable

Perceived effectiveness of the device



1 - very ineffective , 5 - very effective

Perceived quality, comfort and effectiveness

"Can't evaluate it, as I would have to have it in my hands."

"It depends on handling the device."

"It remains to be seen how good the staples will grab the tissue."

"Depends on cost, effectiveness, time, and eco-friendliness."

"I have to see and feel it in real life first."

"Have to see it at work first"

"I don't know the device good enough to have an opinion about it"

"The handling is still unknown to me."

Improvements, additional features

"Automatic stabilizing / tightening the thread per staple."

"Feedback system after placing a staple confirming that the staple is placed."

"An indication for how much suture length is remaining."

Additional fields of use

"Inguinal surgery" Liesbreuk

Anastomose van darmen "Intestinal anastomosis"

Rectopexie "Lap rectopexy"

(which stands for transabdominal "TAPP"

preperitoneal repair)

"Closing of ventral hernia defects as a part of IPOM"

(which stands for intraperitoneal

onlay mesh technique)



Closing remarks

"Keep me posted!"

"I am curious to see the end result"

"Nice approach to a common problem in bariatrics. I would like to hold the instrument sometime. I am always ready for consultation."

"proof is the eating of the pudding".

RECOMMENDATIONS

- Handle design and ergonomics
- More iterative design
 - o Improve components
 - o Material usage
 - ISO tolerances
- Manufacturing
- Sustainability
 - o LCA
- Risk management
- Medical safety research





| | D | Discovery phase | | Development ph | ase | | Demonstratio | on phase | | Deployment phase | |
|----------------------------------|---|---|----------------------------------|---|----------------------------|------------------------|-------------------------------------|--|-------------------|------------------------------|--|
| Milestones | Mockups and models | | POC POC | Prototypes | | MVP | | Production | Produc | t Release | |
| Legal affaris | Develop Intellectual Property stra | | Provi | sional patent application | | | | File & defend patent application Product CE registration process (ISO 13485:2016) | CE review | w and approval certification | |
| Risk Management | User risk identification | CE risks identi | | gy risk identification al issues in late-stage integrated solutions) funding and revenue risk mitigation | User risk mitigation | (| Technology risk mitigation | | | | |
| Ergonomics & Human factors | Handle design research (physical | ergonomics, haptics) Ons (cognitive ergonomics, propriocepti | bservational studies | | | | | | | | |
| Medical safety | Research into biocompatibility of | staples User test in | lab setting Sterilisation | Biocompatibility | Clinical trials | | | | Post m | narket surveillance | |
| Product design | Handle design Define TRL | User tests with product models | Iterations | Minimal viable product (MV | (P) Invention refine | ement and optimisat | Production-read | dy design Product | tion improvements | | |
| Sustainabi lity | LCA Research possibility of using recy | Optimisation | on of material use in product | | Optimisation of production | n process (e.g. reduce | e waste, CO2 emissions, use of reso | purces) | | | |
| Manufactur ing | Research into staple production method for staples, new alterna | | ation of parts for manufacturing | | | | | Pilot production | Volume n | nanufacturing | |
| Strategic | Develop revenue model | Product pron | notion | Find investors, apply for funds, share | Follow | w discussions and re | sults of Medical Device Coordinatio | n groups (MDCG) | | | |
| | | | | | | | | | | | |

CONCLUSION

- Underlying problems identified
- * Addressed through systematic design process
- Innovative design proposal
- Overall positive evaluation
- Still early design stage
- ❖ More research needed
- Promising outlook



Thank you

For your attention

Any questions?

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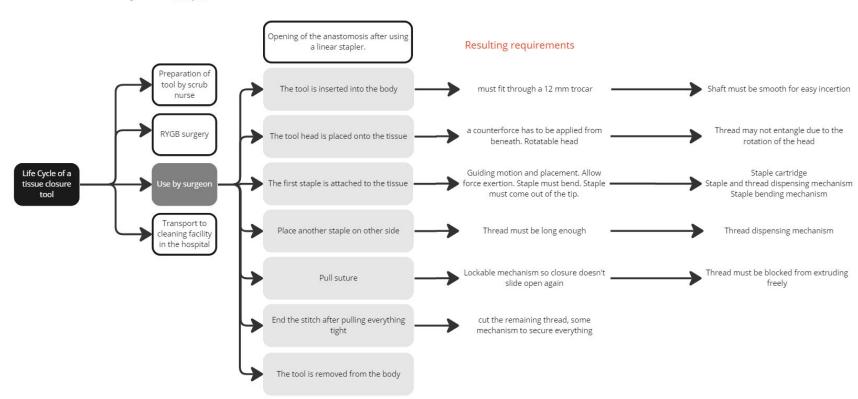
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Function analysis

Function Analysis

Delft Design Guide p. 61



Risk analysis

Severity scale

| Rank | | Definition | Example | | |
|------|---------------|---|---|--|--|
| 1 | Insignificant | No impact on patient safety. No impact on the surgeon. Minor nuisance of <10 minutes for the surgeon. of <10 minutes for the surgeon. | The surgeon briefly maintains an uncomfortable position, has to briefly exert force to place a stapk tissue slips out of the grasper. Temporarily reduced product performance. | | |
| 2 | Minor | No impact on patient safety. No injuries to the surgeon. Discomfort of and/or inconvenience up to 10 minutes for the surgeon. | Nausea, muscle stiffness after operating in an unusual position/posture. Degraded product performance. | | |
| 3 | Moderate | Slight impact on patient safety, no significant harm. Slight impact on the surgeon, no significant harm. Surgery delayed up to 30 minutes. Product failure. | Broken instrument outside the patient's body, instrument failure before use. Loss of product function. | | |
| 4 | Major | Temporary injury to patient, reversible. Broken fragment(s) in patient's body. Surgery delayed > 30 minutes and/or Additional surgical interventions needed. | Foreign material incide the patient's body, broken component, revision surgery needed. Safety related product failure. | | |
| 5 | Catastrophic | Significant impact on patient safety, hazard could lead to long-term damage, serious physical injury or even death. Significant impact on the surgeon, hazard could lead to long term damage, serious physical injury or even death. | Organ failure, coma, death. Catastrophic safety related product failure. | | |

These are indicated with a letter S + rank

Occurrence scale

| Rank | | Definition | Occurrence probability Legarithmic scale | | |
|------|---------------|---|---|--|--|
| 1 | Very unlikely | Extremely rare event. The occurrence of the event is not reproductible. Never occurs during the product lifetime. | P < 0,01% | | |
| 2 | Improbable | Event rarely occurs. There is indirect evidence of the event. Could occur due to unusual situations. | 0,01% > P < 0,1% | | |
| 3 | Moderate | Occasional event. There is direct evidence of the event. Occasional occurrence during the product lifetime. | 0,1% > P < 1% | | |
| 4 | Probable | Likely-event. There is strong direct evidence of the event. Event could occur regularly during the product. Ifetime. | 1% > P < 10% | | |
| 5 | Very probable | Near certain occurrence. There is irrefutable direct evidence of the event. The event could repeatedly occur in a single product if lettime. | ρ > 10% | | |

These are indicated with a letter O + rank

Risk priority rating

Occurrence

| | | 1 | 2 | 3 | 4 | 5 |
|----------|---|---|----|----|----|----|
| Severity | 1 | 1 | 2 | 3 | 4 | 5 |
| Sev | 2 | 2 | 4 | 6 | 8 | 10 |
| | 3 | 3 | 6 | 9 | 12 | 15 |
| | 4 | 4 | 8 | 12 | 16 | 20 |
| | 5 | 5 | 10 | 15 | 20 | 25 |
| | | | | | | |

These are indicated with a background colour

Stakeholders







Patient



Scrub nurse



Anesthesiology team



Other hospital personnel

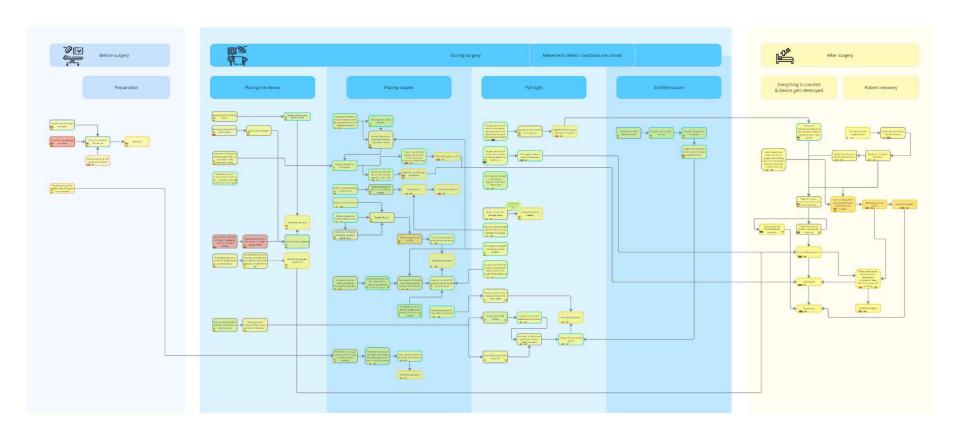


Manufacturer



These are indicated with a coloured border

Risk analysis



Staple requirements

PHYSICAL PROPERTIES CHEMICAL PROPERTIES

- Should have sufficient mechanical and tensile strength to penetrate the tissue,
 No
 - high strength to diameter ratio,

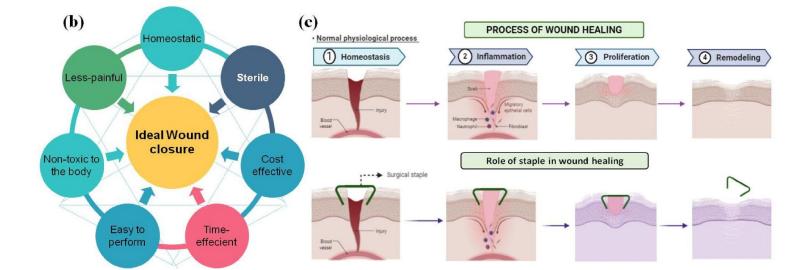
(a)

- It should has a consistent diameter throughout the body
- Pliable, and it should be resistant to shrinkage,
- Easy removal procedure or can be biodegradable
- Easy to sterilize without alterations to its properties
 - Predictability of performance
 - · Economical to use

- Non-electrolytic, non-ferromagnetic, noncapillary
- Should not leach any chemicals under physiological condition
- Does not interfere normal biochemical process of human body
- Should not show any cross-reactivity in physiological environment
 Stable in body pH as well as wound pH

BIOLOGICALRESPONSES

- would not provide a medium for bacterial growth.
- Should not elicit any hypersensitivity and allergenic reaction
 - Non-carcinogenic
 - · Has optimal tissue acceptancy
- · Absorbed with minimal tissue reaction
- · Should not undergoes in-vivo corrosion
- Should not generate any toxic chemicals in-vivo
- Does not shows any secondary surgical site infection



Staple requirements



Acceptable Condition: Ideal "B-shape" (Both points even with crown)



Acceptable Condition: Ideal "B-shape" (Both points below crown)



Condition:

Ideal "B-shape"

Acceptable Condition: Ideal "B-shape"

Illustration 4



Condition: Jnbalanced "B-shape" (Different size loops)



Condition: Unbalanced "B-shape" (Different size loops and right point above crown)



Condition: Unbalanced "B-shape" (Different size loops)



Condition: Unbalances "B-shape" (Different size loops)



Acceptable Condition: Unbalanced "B-shape" (Left leg approaching parallel to crown)



Acceptable Acceptable Condition: Condition: Distorted "B-shape" Bowed crown (Both legs pointing towards (Loops formed crown crown)



Acceptable Condition: Distorted crown (Loops formed crown bent or distorted)





(Pointing away from crown)





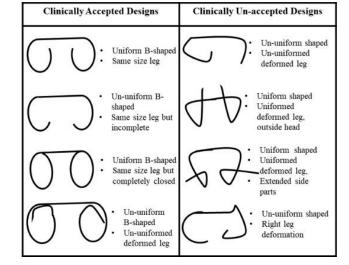
(Pointing away from crown)

Illustration 7

(Pointing away from crown)

bowed)



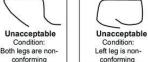




Condition: Both legs are nonconforming (Legs partially formed crown folded)



(Misdirected forming)





Disposed instruments

- Mostly single-use and disposable
 - Cheap materialisation and production
 - Some

 instruments
 leaked blood at
 handle
 - o Get incinerated





Hand positions



Suture Staple strength

Intraoperative <u>photograph</u> showing skin staples placed outside the skin markings at the level of the hash marks on the right thigh (medial view) in a female <u>patient</u>. b. The same patient shown with the staples brought together as a bootlace using silk sutures (medial view).

Intraoperative <u>photograph</u> of the same <u>patient</u> shown in Figure 1 demonstrating the operative technique on the left thigh. As the dissection is continued proximally paired staples immediately below the level of resection are reapproximated using silk sutures (anteromedial view). b. The same patient shown with the bootlace closure applied to the whole thigh prior to final closure (anteromedial view).









We have found that the bootlace thighplasty technique using a staple and suture system ensures that the correct amount of skin is excised with even tissue tension, and is therefore superior to skin pinch or simple tailor tacking with staples.4 Our refinement of planning and closure in thighplasty ensures simple, safer resection of tissues, reduced intraoperative oedema, and facilitated closure. This technique is easily reproducible, produces a more predictable result, with potentially fewer scars, and optimised soft tissue contouring. This diminishes the risk of excessive tension resulting in skin necrosis and dehiscence and may reduce the requirement for revision surgery. The new technique does not add surgical time to thighplasty as it is more precise, reducing the need for adjustments, and staples are not replaced during closure.

#0A6EBD #5A96E3 #A1C2F1

Poppins and Merriweather