Self-Suturing Laparoscopic Port

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Motivation

Students in the SBME Clinical Immersion Program conducted field research on medical instruments at the Medical Center of the Rockies (MCR), a Level II Trauma Center. Several hundred hours were collectively spent in the operating room (OR) studying clinician-device-patient interactions, when the need for a novel laparoscopic device was identified.

Laparoscopic Surgery
- Minimally Invasive
- Faster Healing Time
- Lower Risk of Infection
- Longer Operating Times

Figure 1: Laparoscopic instrumentation and abdominal access[1]

Goal: Create a time-saving, laparoscopic suturing instrument that provides the patient with a proper abdominal closure

Goals and Design Process

Device Needs
- Safe
- Easy to Use
- Time saving

Process:
- Observe laparoscopic procedure w/ Dr. Dunn
- CAD with Creo & Solidworks
- 3D print with PLA
- Test & refine with advisors

Validation
- Failure Mode & Effect Analysis (FMEA)
- Finite Element Analysis (FEA)
- Discussions w/ advisors & surgeons

Self-Suturing Laparoscopic Device

Verification

Clinical Constraints

- Device diameter needs to be 6-12 mm
- Peritoneum and fascial layers of the skin are closed
- Suture needs to "grab" at least 1 cm of tissue on each side of the device
- Device needs to be simple for clinical use

Figure 2: Abdominal wall [2]

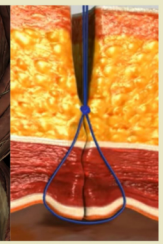


Figure 3: Example of a quality closure[3]

Instrument Design

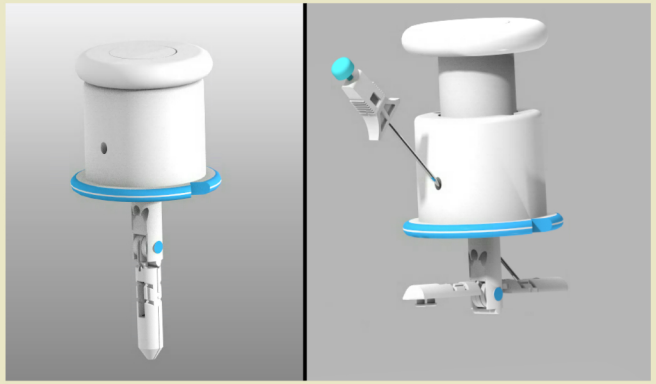


Figure 4: Final laparoscopic instrument design

Operational Procedure:
1. Insert the device into the incision with the wings in the vertical position until the bottom lid is flush with the skin.
2. Twist the plunger into the second lock (moves wings to the horizontal position) and insert the suture passer into one of the channels on the side and retrieve the suture from the wing.
3. Pull through the device and repeat for the other side.
4. Remove the device from the incision and tie the suture to close.

Results

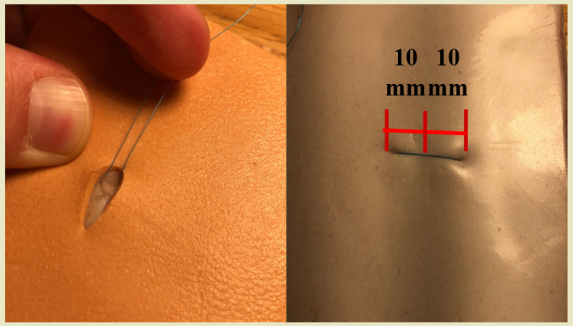


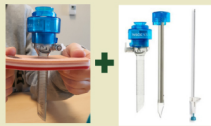
Figure 5: Device securing fascial and peritoneal layers while anchoring 10mm of tissue

The team successfully completed an interrupted stitch using the device. The stitch secured the fascial and peritoneal layers of the suture pad while maintaining a 10mm anchoring of tissue. The device dimensions remained within the clinical constraints and allowed for quick retrieval of the suture from the wings.

DISCLAIMER: Due to COVID-19 restrictions on physical work on senior design, further results were not obtained.

Verification & Validation

Testing Approach



High fidelity tissue model, suture passer, and trocar [4]

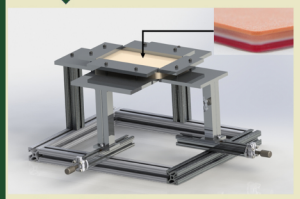


Figure 6: Biaxial stress test to simulate abdominal insufflation

Figure 7: Lead screw to impart stress

Finite Element Analysis

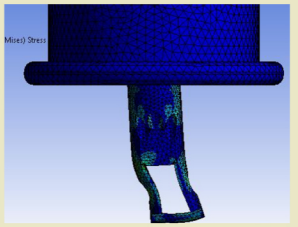


Figure 8: Stress contour plot for PLA part with 0.5N pin insertion force

Table 1: Von Mises stress and deformation

Force [N]	σ min [MPa]	σ max [MPa]	σ average [MPa]	Total deformation max [m]
1.00	2.095E-10	0.0014	2.368E-5	3.407E-7
1.50	3.143E-10	0.0021	3.553E-5	5.111E-7
2.00	4.190E-10	0.0027	4.747E-5	6.814E-7
2.50	5.238E-10	0.0034	5.922E-5	8.518E-7
3.00	6.286E-10	0.0041	7.106E-5	1.022E-6

Human Factors Engineering

User-device-environment interaction analyses were performed through interviews and ethnographic studies to ensure the project would be of desirable, functional use to its end users, the clinicians.

Conclusion & Future Work

The Capstone group was successful in bringing a student-lead, original design concept to fruition. The novel laparoscopic instrument was directly designed around the needs of clinicians, and has the potential to offer safe, timely abdominal closure. In the future, this design may further developed using ethnographic studies to confirm OR reliability and ensure cost competitiveness.

References

[1] "What Is Minimally Invasive Surgery?" *Colorectal Cancer Alliance*,www.ccalliance.org/blog/patient-support/what-is-minimally-invasive-surgery.
[2] Guan, X., and R. K. Zurawin. "Comparison of Neat Stitch and Carter Thomason Trocar Port Closure Techniques." *Journal of Minimally Invasive Gynecology* 18.6 (2011): S175.
[3] Ackerman, Michael J. "The visible human project." *Proceedings of the IEEE* 86.3 (1998): 504-511.
[4] Vista, Weck. "Access Ports/Trocars.",*Teleflex*,teleflex.com/usa/en/product-areas/ surgical /access-ports-trocars/weck-vista/

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