Minimally Invasive Flexible Needle Deployment for Laparoscopic Surgery

MCEN 5065/5075 Graduate Design

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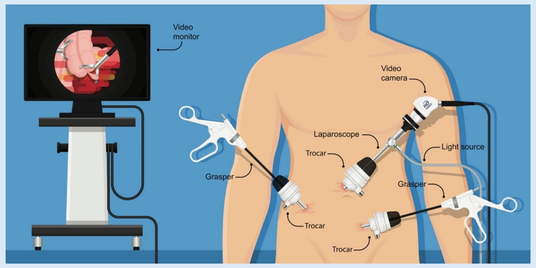
DESIGN CENTER COLORADO

Background

Laparoscopic surgery is a minimally invasive surgical technique where small incisions are made, and a camera is inserted to guide the procedure. It allows for quicker recovery, less pain, and reduced scarring.

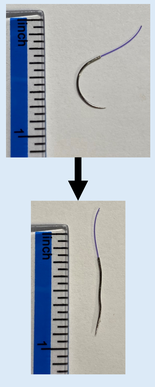


While performing laparoscopic surgery, surgeons routinely must place internal sutures to close incisions, lacerations, or wounds inside the operating body cavity. These needles are half-circle-shaped, and larger than a normal working port, making it difficult for the needle and suture to be placed inside the body for use.

Surgeons often face a unique challenge when introducing and extracting a suture and needle into the surgical area. Therefore, an opportunity exists to develop an efficient solution of introducing and extracting a suture and needle laparoscopically.

Existing Solutions

1. Manually straighten curved suture needle to fit inside of laparoscopic port.



Disadvantages:
- *Complexity*: this approach requires the surgeon to physically bend the needle material which is imprecise in a surgical environment.
- *Time*: modifying the needle takes time, which prolongs the duration of surgery.
- *Risky*: there is a chance the modified needle may become lodged in a port, which would then require the port to be replaced, adding additional time to the surgery.

2. "Needle-Through" – Remove laparoscopic port and insert needle through port site in abdomen.

Top: *Typical Laparoscopic Port 5.0 mm ID, 8.5 mm OD*
vs.
Bottom: *12 ga. Angiocath (2.3 mm ID, 2.8 mm OD)*

Disadvantages:
- *Deflation:* loss of insufflation pressure in working cavity, which triggers alarms, and leads to other complications.
- *Time:* 15+ minutes wasted if port has robotic arms in it, which increases chances of acidosis from CO_2
- *Restricted:* only one suture can be inserted at a time, hindering multi-suture surgeries.
- *Contamination:* Sterile barrier must be broken temporarily for this method, leading to heightened risk of infection.

Need Statement

Surgeons need a safe, reliable, and minimally invasive method of introducing a suture and suture needle into pediatric patients during laparoscopic surgery.

Proposed Solution Workflow

Surgeon selects introducer/extractor preloaded with suture and needle of desired size. → Surgeon places microport (12 ga. angiocath) into abdominal wall above the site to be sutured. → Surgeon removes trocar and inserts introducer/extractor into microport. → Surgeon depresses plunger and introduces flexible suture needle and suture into surgical area. → Surgeon performs suturing laparoscopically. → After suturing is complete, surgeon removes needle and suture using introducer/extractor, via microport.

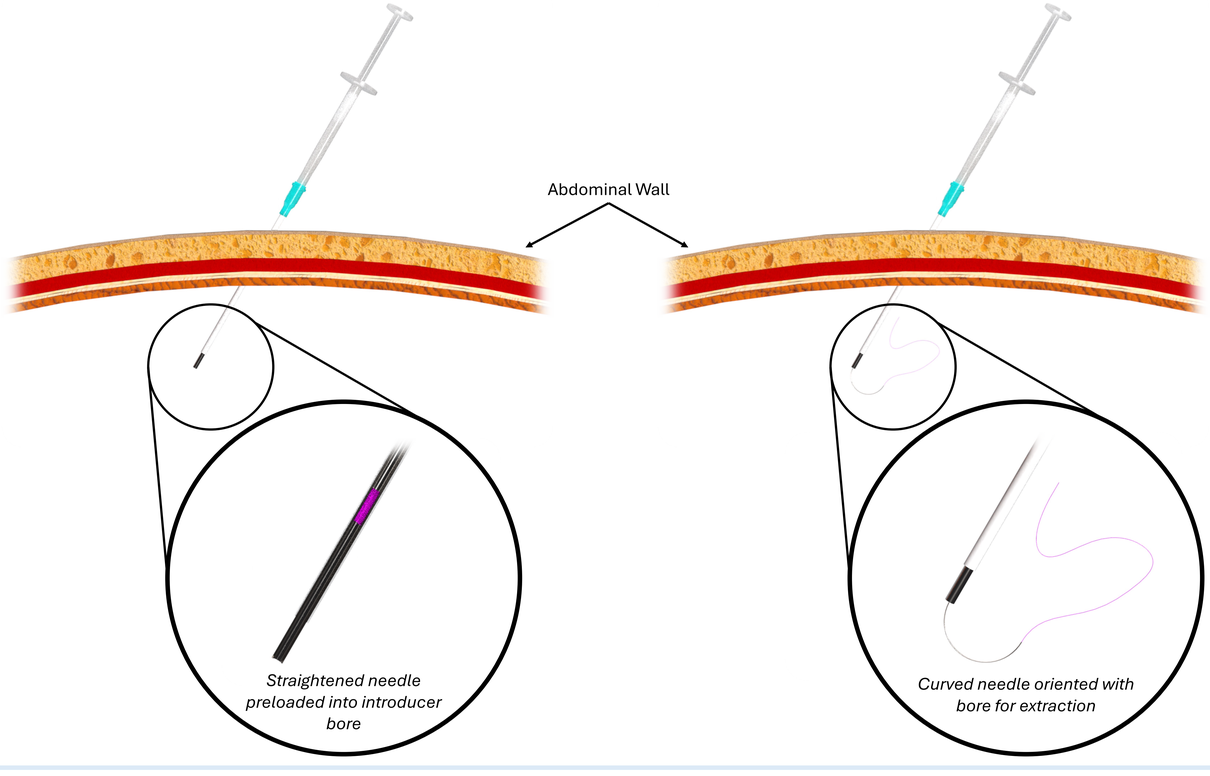
Device Overview

Microport (12 ga. Angiocath) and Trochar

Introducer/Extractor with Flexible Nitinol Needle

Suture and Needle Introduction

Suture and Needle Extraction

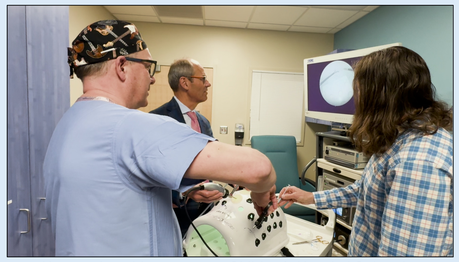


Key Requirements and Clinical Needs

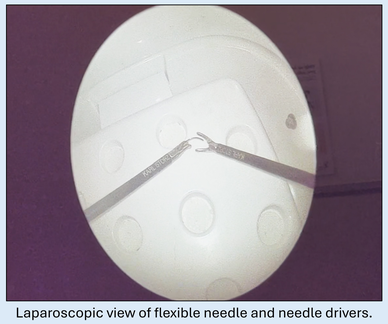
1. Must introduce and extract a flexible Nitinol needle into and out of the surgical field in the most minimally invasive manner.
2. Must be compatible with laparoscopic ports of diameter 3 mm or less.
3. Must be ergonomically friendly and easy to use by all surgeons.
4. Must be constructed of biocompatible materials that are safe for the patient.
5. Design must be adaptable to a wide variety of needle shapes and sizes.
6. Should be simple, non-complex, and low cost.

Testing and Validation

The design team conducted user testing with surgeons at Children's Hospital Colorado. The testing involved using a laparoscopic trainer to simulate placing the microport, then introducing and extracting the flexible needle into and out of an abdominal cavity. The results from this testing will lead to further refinements in the overall system design, specifically around the method for extracting needles.



User testing with surgeons at Children's Hospital Colorado.



Laparoscopic view of flexible needle and needle drivers.

Future Work

1. Development of Nitinol needle
   - $165k required for additional research and development
   - Need for materials and FDA experts
2. FDA validation
3. Steps towards mass production
   - Mold-making
   - Sterilization processes
   - Sterile assembly procedure
4. Further extraction method user testing
5. File for patent (provisional already filed)

Acknowledgements

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