A Novel Suction-Irrigation Catheter for Use in Minimally-Invasive Fluid Evacuation

Rachel L. Davis, MD[1], Fernando Mier, MD[1], Jason S. Lees, MD[1]

[1]University of Oklahoma Health Sciences Center, Department of Surgery

ABSTRACT

Current minimally invasive suction-irrigation catheters are inefficient at removing viscous fluid from surgical sites. Available options clog easily, especially when tasked with the removal of inflammatory tissues or clotted material such as with empyemas or hemothoraces. This leads to longer operative times, need for additional access ports and often conversion to an open approach to allow adequate removal. This new suction-irrigation catheter looks to mitigate these difficulties through a novel approach to the removal of viscous fluid & material in minimally-invasive surgery.

This is accomplished through a single-unit surgical evacuation apparatus compatible with suction and irrigation systems currently used in the operating room. The apparatus features a flexible scoop at the distal end for mobilization of the material at the surgical site for evacuation. Once gathered in the scoop, this material is injected with irrigation fluid, breaking the mobilized tissues into small pieces, and facilitating its evacuation from the surgical field under suction.

Initial technology development has resulted in small-scale prototyping. Early testing has shown the device's ability to effectively dilute & evacuate viscous fluids. In addition, partnership with internal consulting programs has revealed potential partnership and commercialization opportunities through initial market assessment, segmentation, and sizing.

Future directions for this technology will focus on prototype development and testing in both in vitro and animal models. Continued prototyping will assess for ideal materials, dimensions, and configurations of the device. Once refined, the device should be assessed in a surgical environment, to determine compatibility with current suction systems and investigate potential development of proprietary irrigation technology.

BACKGROUND

Suction-irrigation catheters are widely used in minimally invasive abdominal and thoracic surgery to rinse the surgical field with sterile saline and remove fluid & other material for the surgical site for improved visibility. However, many current models are inadequate at effectively removing high viscosity fluid during minimally invasive procedure.

Current options utilize a smaller 5mm internal diameter, and have no mechanism to directly dissolve viscous material, which increases the instance of clogs and loss of suction. This is most apparent during Video-Assisted Thoracoscopic Surgery (VATS) procedures for evacuating highly viscous empyema or retained hemothorax. Inability to evacuate materials using a minimally-invasive suction-irrigation catheter can lead to extended incisions, additional incisions, or conversion to thoracotomy. These work-arounds lead to longer recovery time, increased post-operative pain, and increased risk of complication. In addition, this leads to increased operative time for instrument exchange, resulting in increased procedure cost.

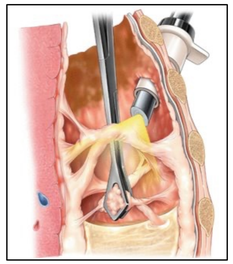


Figure 1: Illustration of current invasive methods of piecemeal removal of viscous material such as retained hemothorax or empyema

OBJECTIVES

- Design a novel suction-irrigation device for use in minimally invasive surgery
- Improve upon current options for removal of highly viscous material, particularly retained empyema and hemothorax
- Use strategic partnerships to promote technology development & future device implementation in practice

PRODUCT CHARACTERISTICS

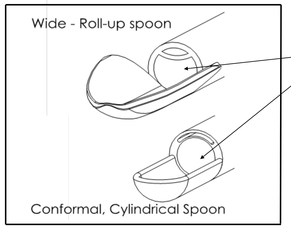


Figure 2: Proposed configurations for flexible scoop apparatus used to collect material for evacuation

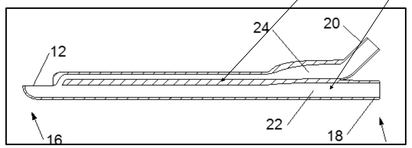


Figure 3: Irrigation is injected into distal end of suction catheter to aid in dissolving and evacuating viscous material from the surgical field

- Mechanism to increase fluidity: soft tipped scoop
- Larger internal diameter of 8 mm
- Compatible with currently used 10mm ports
- Minimally Invasive Incisions
- Decreased OR Time
- Cost savings
- Decreased Post-Op Pain and Recovery Time

- Flexible scoop allows for targeted collection of material for removal
- Irrigant is injected into collected material to actively decrease viscosity & facilitate removal
- Increased internal diameter allows for decreased resistance & increased removal of target tissue
- Decreased cost through decreased OR time and fewer instrument exchanges
- Current prototype tested in in vitro models with initial proof of concept and acceptable preliminary results

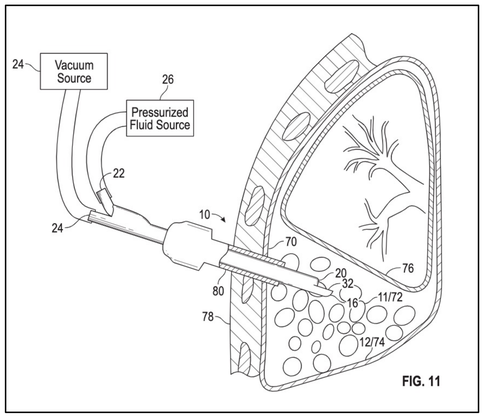


Figure 4: Schematic of potential use of the technology during VATS procedure to collect, dissolve, and evacuate empyema or retained hemothorax from the pleural space

FUTURE WORK

Further research, development, and testing is required to better optimize technology performance and design, as well as determine substantial equivalence to currently-existing devices on the market. These steps are essential for expedited FDA approval through the 510(k) pathway, allowing this product to be introduced into the market and used by surgeons at an accelerated rate.

	Year 0	Years 1-2	Years 3-5
Research & Development	In vitro and In vivo prototype testing & characterization	Non-clinical product testing Product and design revisions	Post approval evaluation and feedback
Regulatory Affairs	Substantial equivalence testing	Submit 510(k) application	FDA approval and device marketing

Figure 5: Timeline for future research and development required to further characterize and optimize the technology

Specific testing should include:

- In vitro characterization of irrigation and suction properties, including optimal flowrates for irrigation injection
- In vivo performance optimization using large mammal animal models
- Performance tests showing substantial equivalence to current suction-irrigation catheters with special regards to appearance, measurements, tensile strength, and leak tests
- Biocompatibility testing of all materials used, including assessments to ensure low cytotoxicity systemic toxicity
- Stability and shelf-life testing to ensure retained sterility during transport and storage

SUMMARY

- This novel technology provides solutions to challenges with currently available suction-irrigation catheters, including intra-operative clogging of catheters and inadequate removal of viscous material from the surgical field.
- It does this through a targeted irrigation mechanism and novel, flexible scoop attachment to target & remove viscous fluids and materials in the surgical field.
- Initial prototyping and testing have shown promise and proof of concept, with future testing needed to further develop the technology
- Future research focuses on technology characterization and optimization in both in vitro and in vivo models to determine substantial equivalence to current options on the market

ACKNOWLEDGEMENTS

- Special thanks to Dr. Lees and Dr. Mier for their guidance and support of this project.
- Thank you to the OU Ronnie K. Irani Creation for the Center of Economic Wealth for their help in developing market analysis and long-term financial planning for this project.

Contact: Dr. Jason S. Lees, Email: Jason-lees@ouhsc.edu

REFERENCES

Brooks T. "The complex and indispensable requirements for instrument reprocessing." http://www.infectioncontroltoday.com/. Accessed March 31, 2015.

Macario A. "What does one minute of operating room time cost?" [editorial] J Clin Anesthesia. 2010;233-236.

Semenkovich, T. "Current State of Empyema Management." *The Annals of thoracic surgery* vol. 105,6 (2018): 1589-1596. doi:10.1016/j.athoracsur.2018.02.027

Welker D. The Clinical and Economic Case for Sterile, Disposable Instruments and Implants. https://www.infectioncontroltoday.com/. Accessed February 27, 2022.