

Backstory

Water, a powerful tool in surgery

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Inflammation of the gallbladder, also known as acute cholecystitis, may be caused by infection and inflammation of the gallbladder wall due to bile stasis, with or without gallstones. It is one of the most common surgical procedures that are performed laparoscopically. Gangrenous gallbladders are one of the most difficult conditions to treat clinically and surgically, being the cause of many medical malpractice litigations. Gangrenous gallbladders constitute 15% of all laparoscopic surgeries, with the cost of these surgeries being approximately \$48,000, compared to other laparoscopic gallbladder surgeries being around \$7,000. Dr. Dinesh Vyas and his team have worked together to develop the novel Hydro-Lap, which is a tool that utilizes hydrodissection technology during laparoscopic cholecystectomies to remove the delicate, dead tissue while preserving the healthy tissue of surrounding structures. This decade-long journey began in the operating room and resulted in an innovation that is awaiting Food and Drug Administration (FDA) approval for use in 2023.

Acute cholecystitis is inflammation of the gallbladder. This may occur when a gallstone becomes lodged at the entrance of the gallbladder or within the duct that drains the contents of the gallbladder. This blockage

Illustration of hydrodissection being utilized to remove a gangrenous gallbladder



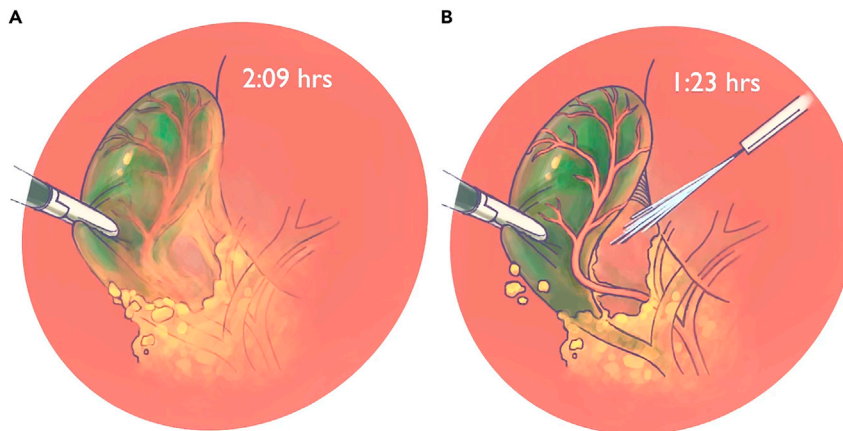


Illustration demonstrating the difference in clarity of anatomy during surgery for Gangrenous gall bladder with the standard and novel hydrodissector technology

A more clarity in visualization leads to shorter operating time with less bleeding as well as more completion of surgery. (A) Blunt dissection does not provide sufficient visualization of the important structures in a laparoscopic cholecystectomy, resulting in an average operating time of 2:09 hours (172.1 ± 28.1 min). This includes converting to open and/or incomplete surgeries.

(B) Jet-streams of normal saline with hydrodissection results in dissection of the necrotic tissue without damaging healthy tissue in addition to improving visualization of the important structures in a laparoscopic cholecystectomy, resulting in an average operating time of 1:23 hours (83.6 ± 4.9 min).

prevents the proper drainage of the gallbladder contents, thus creating a buildup of pressure and causing inflammation. When this occurs, a patient experiences intense stomach pain and may require medical or even surgical treatment.

The surgical treatment of acute cholecystitis is the removal of the gallbladder, termed cholecystectomy. The current gold standard procedure for cholecystectomies is to perform it laparoscopically or using a camera to visualize the abdominal contents, thus avoiding the need for a large incision. One rare, but serious, complication of acute cholecystitis is a gangrenous gallbladder, which occurs when the gallbladder loses oxygen supply, resulting in tissue death, the tissue becoming delicate and thus difficult to surgically handle. Among cholecystectomies, gangrenous gallbladders are the most challenging to treat due to damage of the delicate tissue. This results in a high incidence of complications during the procedure including many procedures being either partially or completely abandoned. In the last 35 years, laparoscopic cholecystectomies treating gangrenous gallbladders have not seen improvements in outcome. It continues to be the most litigious procedure.

Dr. Vyas and his team are introducing the HydroLap, a tool that utilizes hydrodissection during laparoscopic cholecystectomies for gangrenous gallbladders. This technology is a modification of a Food and Drug Administration (FDA)-approved laparoscopic irrigation tool. “HydroLap harnesses the energy from water pressure to act as a dissector and knife,” removing the delicate dead and inflamed tissue of the gangrenous gallbladder while preserving the live tissue of the important surrounding structures.

This backstory discusses the serendipity of this team’s journey to create the HydroLap which can aid surgeons in performing laparoscopic cholecystectomies in patients with gangrenous gallbladders. This journey began in the operating room when the team’s surgeon noticed that there may be a better way to perform this procedure and resulted in building a team of researchers, engineers, and financial advisors to bring this innovation to fruition.

Proximity

What inspired/motivated your research?

One commonly known fact among healthcare professionals, even learned early in one’s medical education, is that a laparoscopic cholecystectomy is one of the most common surgeries performed in the United

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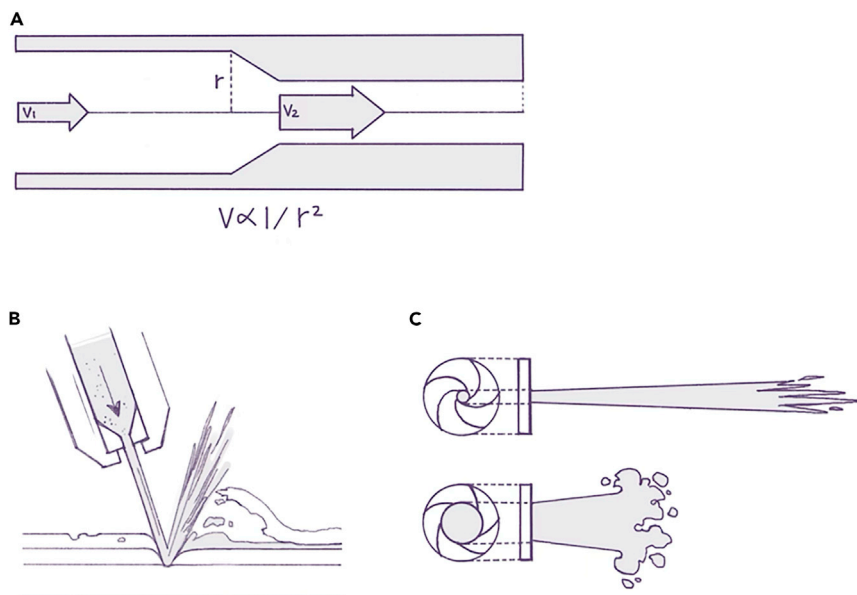
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Innovative application of water jet in abdominal and thoracic tissue surgeries improve outcomes

(A) Change in vessel radius results in an inverse change in velocity of the fluid moving through the vessel.

(B) With the appropriate change in aperture, the jet stream pressure can cut into necrotic tissue without harming healthy tissue.

(C) Change in the diameter of the aperture results in a change in jet stream pressure and velocity, enabling the jet stream to function as a knife.

States. Dr. Dinesh Vyas (Adventist Health Dameron Hospital) is a general surgeon who practices in the busy city of Stockton, CA. Every year he encounters roughly 200 cases of acute cholecystitis requiring removal of the gallbladder. When he was the Surgical Residency Program Director at the local community hospital, San Joaquin General Hospital, he noticed that “the high volume of laparoscopic cholecystectomies treating gangrenous gallbladders resulted in a high volume of resources utilized due to the operation and its associated complications, which is financially unviable for the healthcare system.” Realizing this huge impact on the healthcare system, he decided to explore techniques used by other surgical fields to improve the outcome of this common procedure.

Why did you feel the need to pursue this research?

This research is important because acute cholecystitis is very common, requiring 750,000 laparoscopic cholecystectomies each year in the United States.¹ Though gangrenous gallbladders are rare among this patient population, they still constitute roughly 15% of laparoscopic cholecystectomy cases and are associated with high patient morbidity and mortality, greatly impacting the healthcare system in terms of time and finances.² To give a sense of the scale of financial impact, management of these surgical complications ranges from \$100,000 to \$1.5 million per patient for health insurance companies, and the malpractice financial burdens for surgeons range from \$250,000 to \$1.2 million per lawsuit.³

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Research methods

How did you approach developing the methodology for your research?

To develop the methodology for this research, different ways to utilize water were analyzed. Using the basic physics equation, $A_1 \cdot v_1 = A_2 \cdot v_2$, where A is the cross-sectional area of the tube and v is the velocity, a jet stream of water can generate pressure powerful enough to act like a knife. The aperture of the tube was then adjusted to enhance the force of water to create a pressure which enabled the disruption of the



Members of the team include (Left) Kayla Umemoto, (Middle) Wenjia Wang, and (Right) Dr. Dinesh Vyas

delicate gangrenous gallbladder tissue without perforating the surrounding, healthy organs (Figure 3). This resulted in the creation of the surgical tool called the HydroLap.

Governance

Where did you get help from or seek advice to execute your project?

First, a retrospective study on the use of hydrodissection was conducted, determining its efficacy. Then a team was created to convert this idea into a reality. This team was composed of biomedical, mechanical, and human factor engineers in addition to a product development company to aid in the tool design of the HydroLap. Additionally, a finance team was assembled to raise \$3 million which funded designing a fully disposable kit that could be used in the operating room.

Challenges

What challenges have you faced so far or project for the future?

As with any research, it is important to create a complete and cohesive team with every role filled. Many surgical instruments are designed very specifically to complete a task in the operating room. For this specific technology, the correct motor system must be created. Since surgical technology belongs in such a niche part of the workforce, the greatest challenge entailed finding the right engineers with both knowledge of surgery and expertise in miniaturizing the tool for laparoscopic application.

Publication/final thoughts

What breakthroughs do you imagine or hope to see in upcoming years?

The research team conducted a retrospective study analyzing the efficacy of hydrodissection relative to the current standard of care, blunt dissection. This study demonstrated statistically significant ($p < 0.05$) decreases in the rate of conversion from a laparoscopic to open procedure, the time the surgeon was operating and the patient was under anesthesia, and the number of days the patient had to stay in the hospital after the operation.² There was a 35% reduction in operating time.² These results indicate that, if this technology becomes global, it has the potential to save much of the \$100,000 to \$1.5 million per patient managing the complications from the laparoscopic cholecystectomies and the \$250 to \$1.2 million in malpractice costs.³

The hope is that, in the upcoming years, the patented HydroLap will be fully tested and ready for production. If the utility of hydrodissection is realized by the surgical community, as a whole, "HydroLap can improve patient care for the 750,000 patients requiring cholecystectomies each year" and lessen the financial burden on the healthcare system. Additionally, the HydroLap is designed to be used in five other major, difficult surgical fields, and will hopefully be utilized in the future. These include thoracic trauma, chest empyema, complicated gastrointestinal surgeries, gynecology (i.e., hard-to-treat endometriosis), and urology (i.e., nephrectomy and adrenalectomy).

"HydroLap can improve patient care for the 750,000 patients requiring cholecystectomies each year"

What questions does your research open now?

As with any research, more and larger-scale studies must be conducted to further explore the values and limitations of hydrodissection use during laparoscopic cholecystectomies treating gangrenous gallbladders. For example, is it a feasible task to train surgeons who have already performed thousands of laparoscopic cholecystectomies during their practice? How about surgical residents during their five years of general surgery training? How feasible will it be to disseminate the technology into operating rooms?

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