Laparoscopic tool with adjustable sponge at distal tip for direct/indirect suction modulation

David Orozco, Kamyar Davoudi, Christopher Ding, Rachel Field, Rashid Yasin, Ellen Roche, Donal Holland, Conor Walsh
School of Engineering and Applied Sciences
Harvard University

Abraham Frech
Beth Israel Deaconess Medical Center

1 Background

In current surgical practice, physicians use suction and irrigation to clear the field of view during procedures. Devices designed for this purpose often employ strong negative forces, which can cause tissue damage and occlusion of the device lumen. When this occurs, the surgeon is forced to stop the procedure while the problem is fixed, creating inefficiencies and delays in the surgical procedure. To prevent this problem, some surgeons will place a gauze or sponge to the target area before applying suction, thereby reducing the pressure to which tissue is exposed. In laparoscopic surgery, however, sponge insertion is time consuming and requires careful tracking of sponges to ensure proper removal at the end of the procedure. This paper describes the design and development of a laparoscopic suction device that combines sponge and suction techniques to address these clinical problems, while also incorporating irrigation to create a novel medical device that will improve safety and efficiency of these surgeries.

2 Device Design

A number of interviews with surgeons were conducted to identify unmet needs and design requirements within laparoscopic blood suction and irrigation. Physicians desired a device that allowed for timely switching between strong suction for removal of large blood volumes and indirect suction through a sponge for removing blood near tissue. For laparoscopic surgery, such a device is limited to 1cm in diameter. The final concept is an adjustable sponge that may be moved to cover or expose bypass channels through which suction is applied (Figure 1).

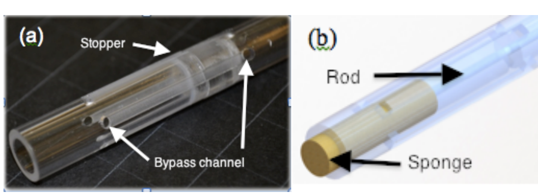

Figure 1- a) Distal end bypass channels b) CAD model with sponge

Four channels etched into the outer surface of the cylinder traverse the stopper section of the cylinder and have holes extending into the lumen on either end. When a heat-shrink coating is applied on top, they form a four-channel bypass system. The sponge is attached to the end of the rod and inserted from this location up to the control handle. When the sponge is full deployed, the distal tip of the sponge is approximately 3mm outside of the tube. Suction is still applied as the main method of liquid removal, but the sponge acts as a buffer, protecting vulnerable tissue from strong negative pressures. However, when needed the sponge can be retracted to expose the channel openings and quicken the rate of liquid removal, through direct suction.

There is a central stopper within the tube that the bypass channels pass over, allowing liquid suctioned to be carried up to a tube in the control handle. This central disk also has a central hole, through which the rod with sponge attached connects to the control handle, from where it is controlled. The lumen is a total length of 10” and made of clear material to give the surgeon increased visibility. Within the control handle, the lumen inserts into a screw cap, into which is also inserted tubing for the liquid to be suctioned away. A centrally located Y-valve is connected to this screw cap, as well as a water source and a disposal source. Under one setting, liquid coming up from the tube will flow through the Y-valve and towards the disposal source, and under the other setting, water will flow down through the lumen into the surgical area. This Y-valve is controlled by the user via an external valve (see Figure 2). This external valve switch on the control handle is arrow-shaped and controls the current setting. It points at whichever setting it is currently on, Irrigation or Suction. The control handle also features an ergonomic trigger along the bottom of the design, which allows the user to control the extension of the sponge at the distal end of the lumen. The control handle itself is also ergonomically shaped, with finger rests and a small handle, allowing easy and comfortable use.

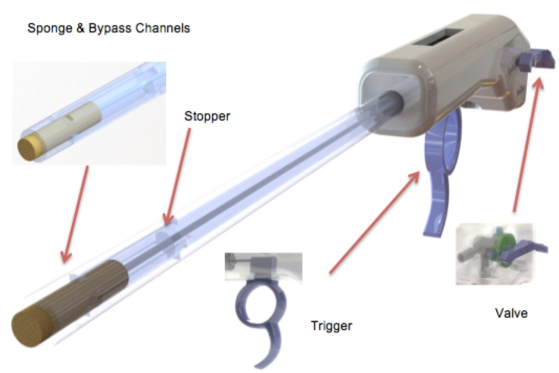

Figure 2- Prototype illustration. The trigger on the handle can be used to toggle between direct and indirect suction by moving the distal sponge distal or proximal to the by-pass vanes.

The device was designed to be user-friendly. All the surgeons interviewed said that the current devices are easy to use, and are “point-and-suck”. There is little conscious thought put into the handling of the device, unless it gets stuck on tissue or is otherwise clogged and so it was important to maintain this feature in the new design. The handle and trigger mechanism emulate current surgical products for natural gripping and easy sliding of the sponge.

Movement of the sponge is constrained to 5mm (0.75 in) to prevent overextension and potential damage to tissue.

3 Material selection

The absorbent material used for the sponge must not only block tissue from occluding the device but must also allow liquid to flow through it at a comparable rate to current suction devices. Darcy's (discharge) velocity dictates that a material with high permeability will increase the speed of fluid flow through the material, as will a small distance of material for the fluid to pass through. Following this, the design would optimally use a very thin segment of highly permeable material. To determine the best absorbent material, flow rate over time was tested using yellow sponges, diaper sponge, and packed medical-grade gauze. Figure 3 shows the change of volume of the fluid against time.

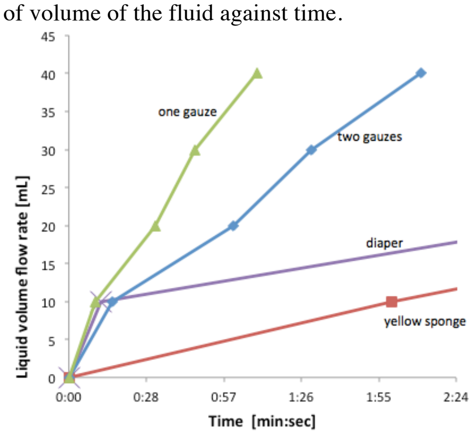

Figure 3- Comparison of absorbent material flow rate

While diapers and yellow sponges are very absorbent, they cannot transfer fluid well, and the curves plateau, so a single surgical sponge was selected for the final prototype.

4 Testing

Several tests were conducted to measure the device's performance against a number of metrics. Fluid flow rate tests (**Figure 4**) showed that the final prototype was able to suction effectively using indirect suction as well as direct suction. As was expected, the rate of flow was lower for the case of indirect suction. Modification of the sponge length and type as well as channel size and location would be able to vary the ratio of direct/indirect suction achievable.

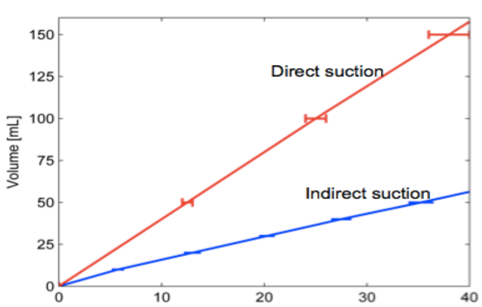

Figure 4- Flow rate using direct and indirect suction

A number of tests were also performed to evaluate the level of damage to delicate surfaces using direct and indirect suction methods. Gelatinous material was used as an analog of human tissue and a layer of fluid was placed over the surface. As can be seen from Figure 5, indirect suction maintained a smooth gel surface, while direct suction tore the surface of the gel. This experiment highlighted the benefit of the indirect suction for removing fluid from delicate tissues.

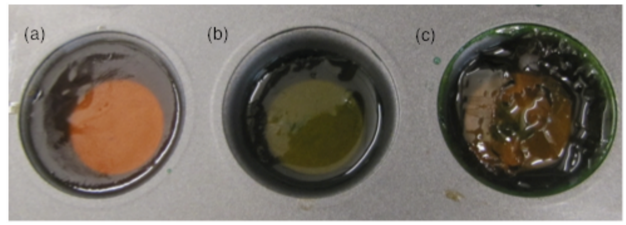

Figure 5- a) control b) indirect suction c) direct suction

A key limitation of existing devices was that they can get clogged with tissue and so an experiment was conducted on chicken tissue bought from a store that had fluid with green dye place on its surface. Figure 6 illustrates an experiment where the fluid was removed with a commercially available laparoscopic fluid removal device (A) as well as with the current device design in indirect suction mode (B).

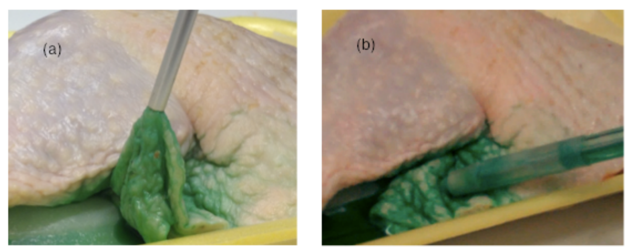

Figure 6- (a) direct (b) indirect applied to chicken tissue

5 Conclusions and future work

The present design combines direct suction, indirect suction and irrigation for improved efficiency during laparoscopic surgery. It allows the surgeons to easily switch between direct and indirect suction, as well as to irrigation. Testing conducted to date demonstrates low lumen occlusion rate, even with coagulated liquid, and fast removal of blood analogues. Upon further testing, the device may ultimately prove safe for soft tissue and time-saving during surgery.

In the future, this device could be made more multi-functional with the addition of a cautery tool associated with the sponge rod. This would reduce operation time and further prevent the need to remove and re-insert the device through ports. In addition, the device can also be improved by adding a check mechanism, to ensure that irrigation cannot be used while the sponge is in the out position

References

[1] R. J. Charbeneau, Grownwater Hydraulics and Pollutant Transport, Wavelanf Press Inc., Long Grove, Illinois, 2000.