I. ABSTRACT

Laparoscopic surgery is a form of minimally invasive surgery, in which procedures are performed via multiple small incisions. The advantages of laparoscopic surgery are that the smaller incisions result in reduced hemorrhaging, minimal scaring, reduced pain, shorter recovery times, and reduced infection and contamination risks. However, surgeons often face visibility loss during the procedure as a result of fogging, bleeding, or tissue smearing, and therefore laparoscopic cameras must be removed and cleaned several times over the course of a surgery. This is particularly dangerous because cleaning can take upwards of five minutes, in which surgery is being conducted without any visual of the operating area.

To address these challenges, we have developed a self-cleaning laparoscope, which will circumvent to need to remove the instrument from the patient mid-surgery. In vivo cleaning will not only reduce operation times but also reduce risk of complications and interruptions from removing and reinserting the instrument. In addition, visibility will remain high throughout the procedure because this self-cleaning laparoscope will maintain a clear optical pathway. In addition, large debris will not be introduced into either the patient or the device, while small debris will be removed using integrated saline and vacuum channels. The self-cleaning laparoscope has a simple mode of operation, where it is controlled by an external switch on the handle area, and has the potential to eventually replace conventional laparoscopes.

II. DESCRIPTION OF CLINICAL NEED

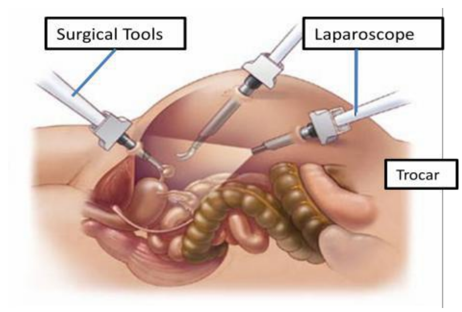

Figure 1: Laparoscopic surgery.

Laparoscopic surgery is a minimally invasive surgical technique performed in the abdomen through multiple, small incisions around 5 -11mm wide. One of the main surgical tools is the laparoscope, which is an imaging device inserted into the abdomen that provides visualization throughout the procedure (**Figure 1**).[1] There are several advantages to laparoscopic surgery, including reduced hemorrhaging, alleviated post-operation pain, shorter recovery times, and reduced infection and contamination risks. This procedure has a few disadvantages such as limited range of motion, poor depth perception, limited tactile response, and longer operation times.[1,2,4]

One of the main problems that surgeons face is the issue with visibility, which includes fogging, spraying, abdominal bleeding, and contact with patient tissue during passage through the trocar.[24] Fogging of the laparoscope occurs because there is a difference in room temperature and abdominal temperature, causing condensation on the distal lens. Abdominal bleeding can also occur as a result of the surgical procedure and can obscure vision when it covers the lens. Finally, tissue inside of the trocar can smear the lens upon laparoscope insertion, requiring subsequent removal and cleaning.[25]

Traditionally, whenever vision of the surgical area becomes obscured, the physician removes the laparoscope and cleans it by wiping the tip with Dr. Fog Cleaning Solution.[6] This interrupts the flow of surgery and is time consuming, sometimes taking up to 30 minutes during a 4 hour surgery.[6] In order to generate user needs relevant to laparoscopic surgery, we conducted some preliminary online research and met with our client, Dr. Forrester, MD, MSc, a 2nd year resident at Stanford University School of Medicine, Department of Surgery. Dr. Forrester placed a strong emphasis on the need for continual cleanup of the device during surgery due to fog, volatile blood or bodily fluids, and stray tissue, making it impossible for the surgeon to see clearly. He noted that it would be ideal for surgeons to single-handedly operate the instruments and to cut down cleaning times both for surgery efficiency and reducing expenses.

Current solutions to this problem utilize external cleaning devices, such as D-HELP. D-HELP is a plastic unit that sits on the surgical table next to the patient that simultaneously cleans the imaging lens and applies anti-fog solution. This ideally reduces cleaning time by automating a procedure that the physician traditionally does manually. However, this solution still requires the removal and reinsertion of the laparoscope from the patient, which significantly increases the time needed to continue the procedure. Another solution that has been developed is called EndoClear, which is a microfiber device that gets placed inside the patient and adheres to patient tissue. Once visibility becomes obscured on the laparoscope, the physician can rub the camera tip on the microfiber hatch, which is also placed in the operating area. After the procedure is completed, the device can be removed through one of the small incisions on the abdomen. The advantage with this solution is that cleaning can occur inside the patient, without the need to physically remove the laparoscope. However, this solution utilizes many small mechanical parts, which can easily get lost inside the patient if broken. It also has a limited number of uses before the fiber becomes saturated with debris.

Another solution modifies the laparoscope itself to address this unmet need. The FloShield laparoscope utilizes carbon dioxide to create an air curtain near the tip of lens, which will prevent any debris from entering it. Any debris that manages to pass this air vortex can be cleaned either manually or through a built-in saline wash. However, the downside to this solution is that increases the bulk of the instrument and requires the use of larger unconventional incisions.

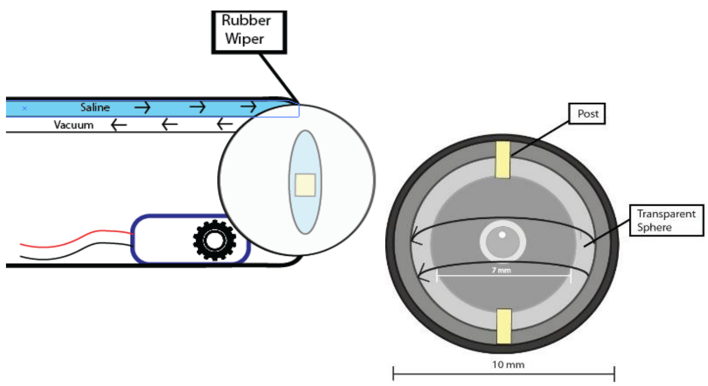

Figure 2: Conceptual sketch of ballpoint laparoscope.

III. SOLUTION DESIGN

The Ballpoint Laparoscope (**Figure 2**) derives its mechanism from the traditional ballpoint pen. Similar to the rolling ball that moves ink to paper, the glass ball rotates to maintain clear vision. As seen in the above left, the lens is mounted and stationary within a glass sphere. The glass sphere is held in an O-ring and allowed to spin on its axis. A gear mechanism is used to rotate the sphere, while saline-vacuum combination on the other side removes all liquid and obstructions to the vision. Along the edges of the sphere, there is a rubber wiper that removes solid debris from sphere as it rotates. Essentially, the dirty side is rotated into the laparoscope by the motor where is it cleaned by the system of saline and vacuum channels, and dried by rubber wipers. This is a novel cleaning mechanism that has not been reported in existing art to date.

The ballpoint laparoscope was selected as our top concept, primarily for the following reasons:

1) The solution addresses the selection criteria from **Table 1** relevant to the top concept with several advantages.
2) The client, Dr. Forrester, is also interested in the solution. He thought that it was a novel solution that elegantly addresses the need for continual clean up, while only requiring the use of one hand. Our client is a representative of professionals and experts who would be interested in our product, giving it marketability and practicability approval.
3) The SolidWorks rendering demonstrated feasibility of product design. This idea was further validated by the 3D-printed prototype that was scaled by 3-fold.

Selection Criteria	Weight	Rating	Reason
Ease of Cleaning	25%	5	Continuously cleaning throughout surgery
Clarity of Image	20%	5	Lens protected by encasing glass sphere
Ease of Use	15%	4	Occurs in situ (no need to remove from patient)
Portability	15%	4	Cleaning mechanism housed inside
Ergonomic	15%	4	Allows for single-hand operation
Functionality	10%	4	Cleaning done with the touch of a button

Table 1: Justification of ballpoint laparoscope in the context of selection criteria.

Part 1: Solid Works Rendering/3D Printed Prototype

After selecting the ballpoint laparoscope design concept, the next step was to prototype the design. A rendering on SolidWorks was created which would show the design and the dimensions to demonstrate the feasibility of the product. The SolidWorks assembly consisted of two main parts – the glass sphere and the laparoscope body. This, along with the complete setup, is shown in **Figure 3.**

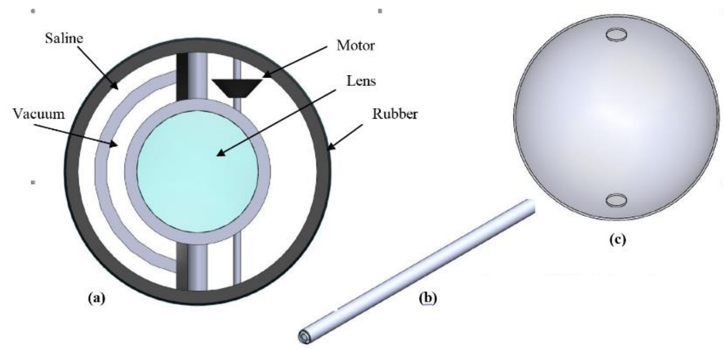

Figure 3: Solid Works rendering showing **(a)** the front view of laparoscope body **(b)** the isometric view of the complete set up and **(c)** the isometric view of glass sphere

The glass sphere has an outer radius of 5 mm and an inner diameter of 4.9 mm, giving the sphere a thickness of 0.05 mm. There are openings on the top and bottom of the sphere for the posts from the laparoscope body. The laparoscope lens will be located within the glass sphere and will be held in place by the posts.

The laparoscope body (**Figure 3b**), which is 450 mm long (the normal length of a laparoscope), has an outer diameter of 11 mm to fit within the largest common trocar size (11 mm). The outer wall has a thickness of 0.5 mm. In the front view of the laparoscope, there are two channels with 1 mm thickness and with 0.5 mm walls separating them from each other. The outer channel is the saline channel and the inner channel is the vacuum channel (**Figure 3a**). The channels are shaped such that their walls will be directly touching the glass sphere with the exception of the middle wall, which is pushed back to allow flow between the two channels. The walls that are touching the glass sphere have rubber ends. The rubber ends contact the glass sphere (**Figure 3c**) to make sure no residue will leave the cleaning areas. Located 2 mm away from the central axis, on the opposite side of the two channels, is a motor charged rubber gear that is shaped to fit with a snug contact with the glass sphere to move it. The lens is held in place by a 1 mm thick ring that has a 5 mm inner diameter (which corresponds to the diameter of the lens). The ring stays in place by the posts that are mentioned above.

(a) **(b)**

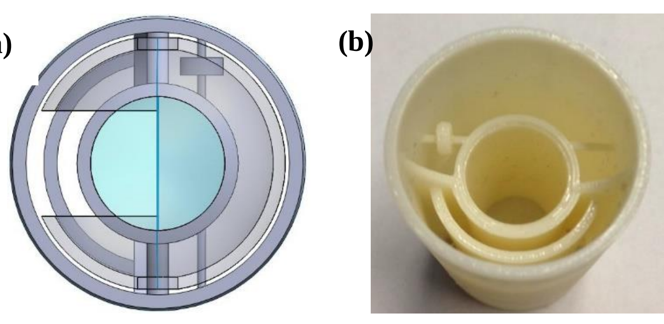

Figure 4: 3D printed prototype showing **(a)** the Solid Works design and **(b)** the 3D printing of the revised Solid Works rendering.

A 3D printed model was used for a form prototype (**Figure 4**). In this version, the channels and the gear came out properly but the glass sphere and the lens did not print. This model, shown in **Figure 4b**, is useful to demonstrate the relative dimensions of the channel design.

Figure 5: Inside view of ballpoint laparoscope with rotating motor mechanism.

While the 3D printed prototype mimicked the actual dimensions of the laparoscope, a functional prototype was created to demonstrate the cleaning mechanism. Aluminum sheet metal was bent into a cylinder and immobilized by metal cable ties and rivets. A 0.59 inch through-hole was made on a 2.7 inch diameter plastic sphere using a diamond-crusted drill bit on a mill. The plastic sphere was then mounted on a pipe replacement O -ring, which was then fit inside the cylinder. A plastic gear that was lined with rubber was mounted on a 3V DC motor, and then secured inside of the cylinder so that the rotating gear would cause the sphere to rotate.[57] This can be seen in **Figure 5.** The motor was powered by an external voltage generator. Additional aluminum sheet metal was cut and molded to form the vacuum and saline channels. The completed functional prototype is show in **Figure 6.** This prototype was then decomposed and modularized to test the cleaning mechanism and optical properties of the sphere.

IV. WORKING PROTOTYPE

Figure 6: Outside view of ballpoint laparoscope.

Several parameters were tested using our prototype and the resources available at the Light Microscopy laboratory, including 1) resolution and contrast, and 2) cleaning time. The first metric was tested using the optical rigs that are available in the laboratory, and the second metric was tested in a fume hood using a saline and vacuum channel.

1. Resolution and Contrast[56]

Resolution and contrast were calculated using the microscopy optical rigs where a glass sphere covered the objective lens and images of USAF targets were used to test these parameters. **Figure 7** shows the set-up and process of testing resolution and contrast. Images were collected with and without a glass sphere (**Figure 8**). The calculated values are illustrated in

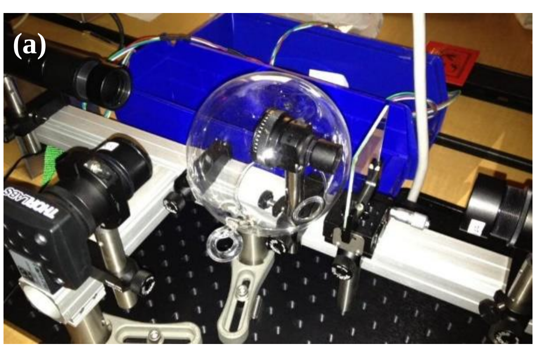

Figure 7: Optical rig set-up for testing resolution, light intensity, and contrast, using the glass sphere

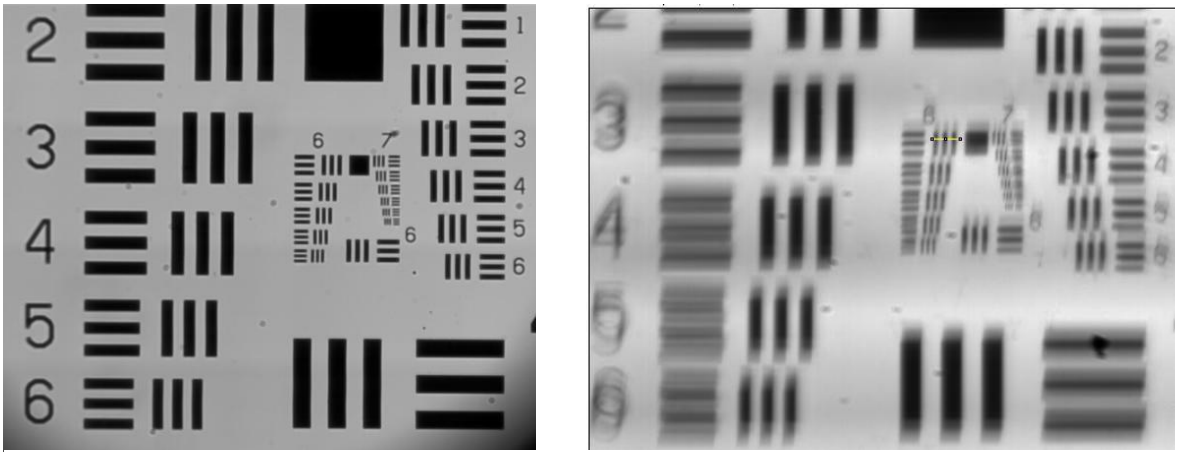

Figure 8: USAF target images with **(a)** no glass sphere and **(b)** with a clean glass sphere placed over the objective lens.

Table 2.

As seen in **Figure 8**, the no sphere image and the clean glass sphere are very similar. There is a slight distortion and a bit of aberration, but overall quality is retained. The glass sphere only results in a resolution change from 4.93 μm to 6.21 μm, which is barely noticeable to the human eye, and the contrast remains constant despite the two additional imaging surfaces.

Optical Condition	Res.	Contrast
No sphere	4.93μm	1
With clean glass sphere	6.21μm	1

Table 2: Resolution and contrast values as a result of optical condition.

2. Cleaning Time

Figure 9: Dirtied sphere prior to cleaning (left). Sphere after cleaning (right).

Due to the potential hazards associated with incorporating electronics and a saline pump, the clean time was tested by decomposing the prototype. The O-ring plastic ball system was removed from the cylinder and placed in a fume hood equipped with a vacuum. A torque was manually applied on the sphere, while saline was provided from a water jet and dried by a vacuum tube. Images from the test are shown in **Figure 9.**

After several tests, the average clean time was approximately 7-10 seconds. This is significantly faster than the conventional cleaning procedures, which requires removal of the laparoscope, cleaning, reinsertion, and finding the correct location. While the physical act of cleaning takes a matter of seconds, finding the correct position to be able to resume surgery can take up to 1.5 minutes.[6] By having a system that can continuously clean in vivo, the limiting factor is the amount it takes to clean the sphere, not the time associated with repositioning.

Figure 10: Set-up of automated cleaning

As a way to further test the cleaning mechanism, we automated by the process by incorporating the motor to rotate the sphere instead of doing it manually. Since our prototype lacked proper internal machining of the channels to protect the motor and run the cleaning mechanism, we mimicked the cleaning on the outside by having the water jet and vacuum tube on the outside as shown in **Figure 10**. This cut down cleaning times to 3-5 seconds and verified that the sphere could be cleaned while the ball is mechanically rotating.

In conclusion, we have created a novel imaging device that can significantly reduce the amount of time needed for cleaning. Traditional laparoscopic procedures can take upwards of 5 minutes to clean, whereas our ballpoint laparoscope can clean within a matter of seconds. The slight tradeoff to this is the image resolution, since the light has to pass through two glass surfaces instead of one. However, as demonstrated during the prototype testing, there is no significant loss in resolution as a result of the glass sphere. This device has the potential to transform the way laparoscopic procedures are conducted by making them safer and more efficient for both the physician as well as the patient.

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