Proceedings of the 2010 Design of Medical Devices Conference
DMD2010
April 13-15, 2010, Minneapolis, MN, USA

DMD2010-3849

DESIGN OF AN ENDOSCOPE LENS SHIELDING DEVICE FOR USE IN LAPAROSCOPIC PROCEDURES

Sterling J Anderson
Dept. of Mechanical Engineering
Massachusetts Institute of Technology
Cambridge, MA, USA

Julia C. Zimmerman
Dept. of Mechanical Engineering
Massachusetts Institute of Technology
Cambridge, MA, USA

Emily F. Houston
Dept. of Mechanical Engineering
Massachusetts Institute of Technology
Cambridge, MA, USA

Kevin M. Farino
Dept. of Mechanical Engineering
Massachusetts Institute of Technology
Cambridge, MA, USA

Nikolai D. Begg
Dept. of Mechanical Engineering
Massachusetts Institute of Technology
Cambridge, MA, USA

ABSTRACT

In recent years, laparoscopic surgical procedures have revolutionized many gynecological and abdominal procedures, leading to dramatic reductions in recovery time and scarring for the patient. While techniques and instruments for performing laparoscopic surgery have improved over the years, loss of vision through the endoscopic lens caused by fog, liquid, and solid debris common to laparoscopic procedures remains a significant problem. In this paper, a shielding mechanism that maintains visibility through the laparoscope by removing debris from the distal end of the lens is presented. This device provides an inexpensive and convenient alternative to the current practice of removing, cleaning, and re-inserting the laparoscope during surgical procedures. This device is shown in multiple trials to repeatably remove debris from the distal tip of the lens, thereby restoring vision for the surgeon without requiring removal or reinsertion of the endoscope.

INTRODUCTION

Laparoscopic surgery provides a minimally invasive alternative to often-risky open procedures. Increasingly popular in recent years, laparoscopic surgery is currently used in many medical specialties, including urology, gynecology, and gastroenterology [1, 2]. Its benefits include decreased operative trauma, decreased wound complications, shortened hospital stay, and shorter-term disability after surgery. Laparoscopic surgery is facilitated by a laparoscope, which provides a view of the anatomical structures in the abdomen and pelvis during the procedure [3].

In many laparoscopic procedures, a (5-10mm diameter) cannula sleeve is inserted into the incision to serve as an entry port for the endoscope and allow the endoscope to move with respect to the abdominal wall. A typical laparoscope consists of a lens and light source on the distal (inserted) end, an elongated lens shaft (passing through the cannula), and a camera or viewfinder on the proximal end (outside the body). One of the limitations of conventional laparoscopes is that during surgical procedures, the distal lens frequently contacts and/or is obscured by fog, blood, saline, and other particulate. This reduces or obscures the surgeon's view of the worksite and often requires an interruption of the procedure to clear the debris. Currently, surgeons often attempt to restore vision through the endoscopic lens by wiping it on nearby organs, or removing it from the body to wipe it by hand. In a procedure where the surgeon's vision of the working area is entirely dependent on the scope image, obfuscation of the lens can waste precious time and reduce visibility at times when it is needed most (such as those in which bleeding or other fluid loss occurs) [4].

To address the problem of lens obfuscation and its attendant procedural interruption, the current system is presented and described. This system uses a transparent film to shield the endoscopic lens from debris and thereby avoid the loss of vision common to current practice. This design consists of a single, disposable lens shielding tool that when used in conjunction with existing laparoscopes increases visibility and

decrease the procedural interruptions during minimally invasive surgery.

Prior Art

While many solutions for cleaning the laparoscopic lens have been proposed, none has been effectively implemented nor widely adopted. Ranging from lens flushing devices to mechanical wipers to continuously-flowing air jets, these solutions seek to clean the lens once it has been fogged or soiled by debris [5,6]. Shielding, or the use of a cover over the lens to prevent the lens from actually getting dirty, provides a mechanical, repeatable solution to the problem of lens dirtying in laparoscopic surgery.

U.S. Patent No. 6,193,731 discloses a method for inserting a thin sheet or film of surgical material into the abdomen via a cannula. This patent describes inserting and leaving behind this thin sheet or film of surgical material, and is thus not a lens cleaning method. The disadvantage of leaving a film behind is that it increases risk to the patient during recovery. Another use of shielding is disclosed in U.S. Patent No. 4,976,254 and No. 5,123,402 though these patents disclose a shield to prevent the surgeon or close observers from experiencing splashback of bodily fluids outside of the body. U.S. Patent No. 6,607,606 discloses a method and apparatus for shielding a lens, as in a camera, from dry particle contaminants through a rotating cleaning mechanism. The invention described in this paper serves as an add-on to current laparoscopes. It shields the lens from both solid and liquid debris and prevents contaminants from obscuring the image seen through the camera. This device is self-contained, leaving no film or residue behind in the body.

DESIGN DEVELOPMENT

The concept development and evaluation that lead to the selected design is presented and discussed below.

Functional Requirements and Strategies

In order for this device to provide a useful replacement for the current methods and devices available, it needs to meet several important criteria. Because this is a medical device, it is absolutely imperative that it pose no increased risk to the patient as a result of the device. The device must also provide adequate visibility through the scope and improve visibility in the case of partial or full lens obfuscation for at least 60 cycles per procedures. It is also absolutely necessary that the device meets FDA standards and conforms to industry standards. This requires that the device integrate with 5mm laparoscopes and 5mm cannulas as to ensure no increase in incision size. Other non-critical, though beneficial requirements include keeping device actuation time under 5 seconds and its cost under $100. An exhaustive list of all functional requirements is outlined in Table 1, in addition to metrics for evaluating the success of this device in fulfilling the functional requirements.

Table 1. Functional requirements and design parameters

Rank	Functional Parameter	Metric
1	Does not increase risk to patient	Incidence of scope related complications
2	Provides adequate visibility through lens and improves visibility in the case of partial or full lens obfuscation	Lens clarity
3	Meets FDA standards	Obtain FDA classification and certification
4	Meets industry standards	Works with 5mm trocar and does not require an incision of >10mm
5	Risk to patient in event of complications minimized	
6	Procedure modification or disruption minimized	Doctor training time
7	Works with existing technology	Money spent by hospital to integrate the product less the cost of the product
8	Minimize time of obscured visibility	Frequency of cleaning and duration of cleaning cycle
9	Minimize cost	Money spent by hospital to use the product
10	Versatility of cleaning	Types of obstructions the system can remove
11	Minimal interference with surgical environment	Change in available workspace

Strategies developed to address these requirements were assessed using the Pugh chart shown in Table 2 A product known as the EndoScrub was chosen as the control in Pugh chart evaluation. Developed by Medtronic, this device uses a combination of fluid rinse and suction to clean the lens of debris. Some of the strategies evaluated are similar to those found in prior art, such as using fluids to wash debris off the lens or using a mechanical device to wipe debris off the lens, entitled "fluid-gas" and "passive wiper" respectively in Table 2. Several novel strategies were also considered. The "sliding shield" strategy involves covering the lens with a piece of clear plastic that can be removed and replaced when dirtied by sliding the tape across the lens, similar to the paper on a doctor's examination table. Another strategy, entitled "onion," uses a stack of false lenses that are successively removed as they are dirtied. The strategy entitled "weeping lens" uses a

hydrophilic lens material that is kept constantly covered by a thin layer of saline kept clear by continually dripping new saline across the lens. The final strategy evaluated uses vibration to shake debris of the lens. The Pugh chart evaluation found that the sliding shield strategy best addresses the functional requirements.

Table 2. Pugh chart evaluation of selected concepts

	Endo Scrub	Fluid-gas	Sliding Shield	Onion	Weeping Lens	Passive Wiper	Vibration
sterilizable	0	0	0	0	0	0	-1
workspace clutter	0	-1	1	-1	-1	1	1
visibility	0	0	-1	-1	-1	0	0
compatibility	0	0	1	1	0	1	0
risk of failure	0	0	-1	-1	0	-1	0
no procedure disruption	0	1	1	0	1	-1	0
cleaning versatility	0	0	1	1	0	-1	?
cleaning cycle time	0	0	1	1	1	0	-1
cost	0	0	-1	1	0	0	-1
ease of use	0	0	0	0	1	-1	0
visibility during cleaning	0	0	1	0	1	0	0
implications of failure	0	0	0	-1	0	-1	-1
TOTAL	0	0	3	0	2	-3	-3

Concept Selection

Given the parameters of a shielding strategy, the goal of the concept selection stage was to create the simplest machine that would achieve the goal of restoring clear vision to the surgeon. Many solutions were considered, including a fluidic weeping lens, layered shields, and a spooling shield. Each was evaluated in terms of its feasibility and performance through bench level experiments.

The bench level test on the ability to spool polyethylene proved that it was capable. Different thicknesses, including 0.0005 in, 0.001 in, and 0.005 in of polyethylene were tested. The material was run through a sheath containing a phantom scope and translated through the mechanism without sheering, binding, or crazing. Further tests were performed on the materials in relation to this concept. Each shielding material was tested for its ability to be drawn across the face of a ~5-12mm endoscope. In these tests, thicker materials performed much better than thinner materials, exhibiting less crazing and stretch-deformities while maintaining sufficient flatness across the surface of the lens (so as to avoid optical distortion). Taken together with the results of transparency testing, this suggests that a single layer of thicker, stiffer, and non-self-adhesive material is best-suited for a spooling shield embodiment of this strategy.

The layered shielding concept did not fare well. The visibility through multiple layers was tested using the vision chart seen through a 4mm-thick acrylic lens (Figure 1).

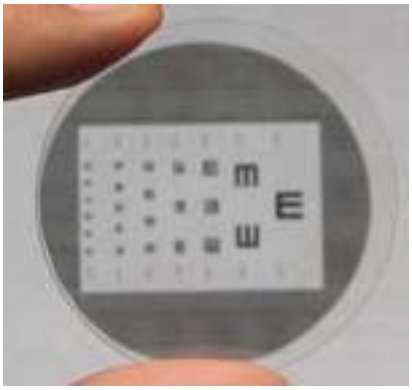


Figure 1. Vision test through 4mm acrylic lens

Figure 2. Vision test through 4mm acrylic lens and four .05mm layers of polyethylene

Although clear vision was obtained through eight layers of the .01 thickness, the polyethylene was self-adhering and did not clean very well. Opacity was aggravated with additional layering. The vision was obscured after only four layers, proving this concept inefficient. Figure 2 shows vision through four .05mm layers. Second, the thicker materials used in this study did not self-adhere and were therefore more difficult to layer tightly. Without a tight seal between shielding layers, air pockets form, reducing vision and potentially trapping debris. These results suggest that thicker materials should be used for spooling and re-circulating embodiments of the shielding strategy rather than for discard-type approaches.

The spooling mechanism faired best in these large scale tests, proving the most effective means of restoring vision. The spooling mechanism eliminates many of the risks associated with the other concepts. The unknowns and increased complexity surrounding the fluidic weeping lens and the layered lens did not outweigh the potential benefits the concepts offered and lead the development team to pursue the spooling mechanism as the concept of choice.

DESIGN DETAILS

The design has several principal components, which are described below. The mechanisms chosen to perform each of these functional requirements are included.

Tape Guidance and Sealing

A continuous strand of shielding tape was chosen to protect the lens tip from various sources of obfuscation. The tape enters the cannula alongside the laparoscope, travels linearly down the length of the scope, over the tip of the scope, back up the other side of the scope and out the top of the cannula. The annulus formed by the inner diameter of the cannula and the outer diameter of the scope, representing the working space in which the tape travels down to the tip of the scope and back, has a thickness of 0.017 inches. Therefore, this clearance is fully occupied by a mechanism to guide the tape, and the actuation mechanism for the tape is located above the cannula. The shielding tape is protected from friction against the cannula by a thin-walled stainless steel sheath. At the distal end of the sheath, where the scope passes beyond the tip of the cannula, the sheath holds the tape flat against the sides of the scope and protects it from getting dirty before reaching the tip of the scope.

At the tip of the scope, the tip guide piece guides the tape over the lens and back into the other side of the sheath. The guide is a molded plastic part that is glued to the end of the sheath. The tip guide also clamps down on the tape when the lens is not being cleaned, in order to prevent creasing or buckling in the tape surface and to preserve the clarity of the surgeon's view. Activation of the tip guide is described in section 3.2. Figure 3 shows the tip guide assembled to the distal end of the sheath.

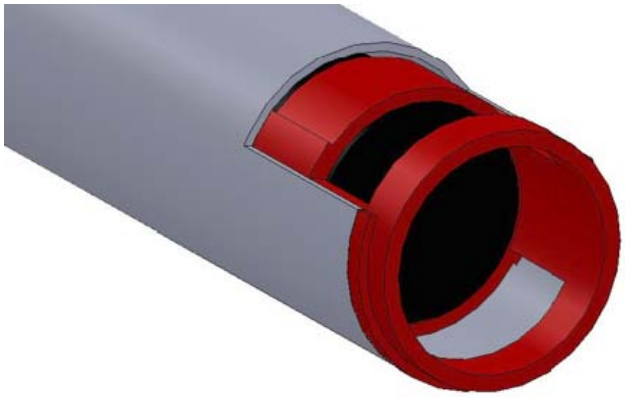


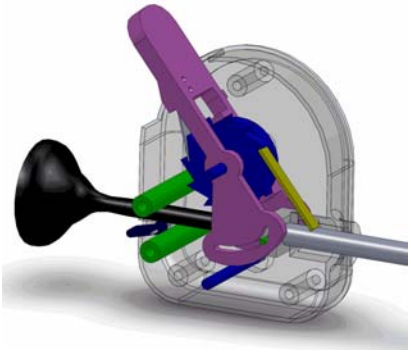
Figure 3. Tape guide mechanism showing tip guide and protective sheath at distal end of scope

The shielding tape is 4.6mm wide (for 5mm diameter scopes) to ensure that the entire lens is protected. Biaxially-oriented polyethylene terephthalate (boPET) was chosen for as the shielding tape material because of its high yield strength and commercial availability. Since the tape travels a distance over 100 times its width and is subjected to a variety of shear and normal stresses, boPET is an appropriate material for the tape.

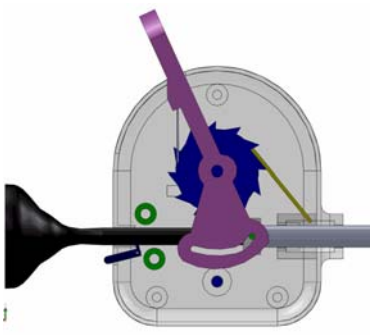
Tape and Shield Actuation

Multiple methods for actuating the tape were considered. These methods included both discrete and continuous actuation modes and recirculating vs. spooling tape feeds. Discrete actuation modes move the tape across the lens in discrete increments. Continuous actuation, in contrast, feeds the tape around the end of the scope to maintain a clear viewing surface without requiring an external trigger. Two methods for feeding the tape (either discretely or continuously) across the surface of the lens, were also considered. In the recirculating approach, a continuous belt of tape is rotated along the sheath and around the end of the scope. This approach might require a method for cleaning used portions of the belt before they are again fed onto the surface of the lens. The spooling approach, on the other hand, moves a strand of tape from the supply reel, across the surface of the lens, to a take-up reel, where dirty tape is stored for the remainder of the procedure. This approach eliminates the requirement for cleaning used tape.

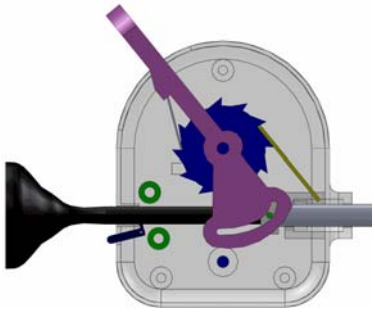
In order to accommodate a discretely-clamping tip guide and avoid the need to clean used tape, a discrete, spooling actuation scheme was chosen. This scheme utilizes a ratcheting spool to incrementally advance a continuous strand of shielding tape across the surface of the lens. This advancement is made on demand using a single, thumb-actuated handle. For ease of use, this handle is positioned at 65 degrees from the horizontal and travels 45 degrees downward when actuated. During the first 15 degrees of this travel, a cam on the base of the handle advances the sheath by 0.15 inches while the handle-fixed pall does not contact the indexing ratchet. This moves the tip guide (which is rigidly attached to the sheath) off the surface of the tape to allow translation. For the remaining 30 degrees of handle rotation, the handle-fixed pawl advances the ratchet, which is rigidly attached to the 0.95 in (24.13 mm) diameter take-up spool. Thirty degrees of rotation in this spool advances the tape by 0.248 in (6.3 mm), thereby covering the lens with a clean section of shielding tape. A torsional spring provides the 2 in-lb. (0.226 N-m) of torque necessary to return the handle to its upright position once the tape has been advanced. A stationary pawl anchored to the casing fixes the ratcheting wheel and take-up spool as the handle returns to its rest position. During the final 15 degrees of this return, the handle-fixed cam retracts the sheath, thereby clamping the tip retaining ring onto the end of the scope. Figure 4 illustrates this assembly. In Figure 4 b, the handle is shown in its upright (rest) position. Figure 4 c shows the position of the handle, sheath, and ratchet pawls when, after 15 degrees of handle rotation, the sheath reaches the end of its travel and the pawl makes contact with the ratchet tooth. By d, the ratchet has advanced one full turn (45 deg.), and the stationary pawl fixes it in place.



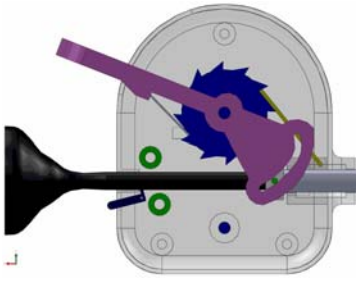
a. Isometric view of ratchet mechanism compartment



b. Rest position



c. After 15 degrees handle rotation



d. After 45 degrees handle rotation

Figure 4. Ratchet mechanism illustration.

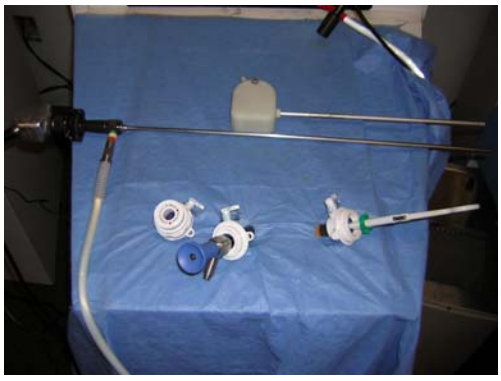
Dimensions for the steel pawls were chosen to accommodate the 0.12 in (3 mm) maximum deflection required by the ratchet teeth without exceeding (in pawl-tooth friction) the 2 in-lb. (0.226 N-m) restoring torque exerted by the torsional spring for returning the handle to its rest position. Buckling calculations for this pawl design gave a safety margin of 1.5.

RESULTS AND DISCUSSION

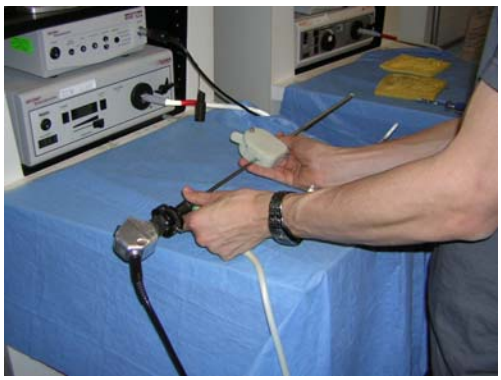
The first order prototype of the design was assembled and tested to ensure that the design fulfills the functional requirements. The tests performed include compatibility with existing equipment, ease of use, failure, time to clean the lens, and removal of debris from the lens. Tests to determine full sterilization as well as risk to the patient are planned.

Compatibility and Ease of Use

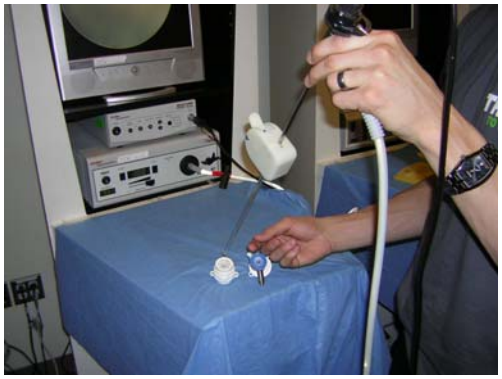
Taken together, the ratchet mechanism casing and tape shield form a single, self-contained, and disposable unit. In contrast to alternative solutions that require external air or saline hookups, this design may be installed and used without adding additional tethers or clutter to the operating space. Its non-intrusive, self-contained packaging allows operating room personnel to quickly slide the scope into the casing ports, lock the shielding mechanism in place, and proceed with known procedures. An intuitive lever placement provides the surgeon with a quick means of advancing the shielding tape when necessary to restore vision through the scope. Figure 5 illustrates the assembly and insertion process, all of which took less than 5 seconds to perform.



a. Endoscope and shielding device before assembly



b. Endoscope and shielding device upon assembly



c. Endoscope and shielding device during insertion

Figure 5. Illustration of shielding device before assembly (a), after assembly (b), and upon insertion into cannula (c)

During a laparoscopic procedure, operating room staff frequently manipulates the scope both along its axis and about the cannula pivot to see areas of interest in the insufflated abdomen. This scope placement is conducted through a single port, and may be completely described by an axial translation (r), an inclination angle (α), an azimuthal angle (ψ), and a roll angle (φ). This coordinate system is illustrated in Figure 6. Directions most sensitive to motion and most utilized when manipulating the field of view include the axial direction (r), the inclination angle (α), and the azimuthal angle (ψ). Roll angle about the scope axis (φ), in contrast, is less utilized and therefore less sensitive to interference.

Coupling the shielding device to the scope limits the achievable range of motion along each of these coordinate dimensions. The degree of this limitation in angular dimensions varies with scope insertion -- when the scope is inserted little, the shielding mechanism disturbs the range of motion less; for large insertion, this impedance becomes more significant. For the tests illustrated below, impedance was calculated for an 11.8 in (30 cm) scope inserted 5 inches (12.7 cm) into the abdomen.

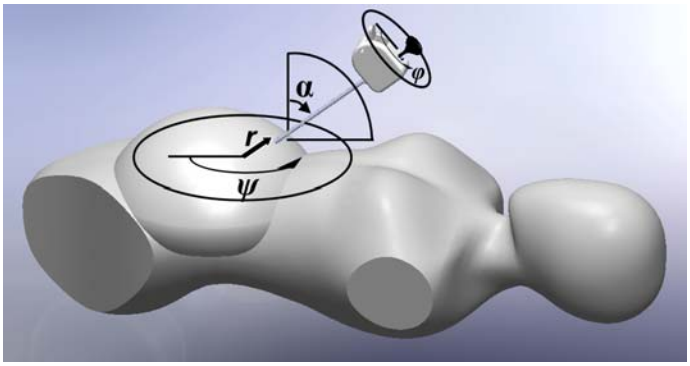


Figure 6. Model of scope placement in a virtual, life-sized model of an insufflated female abdomen

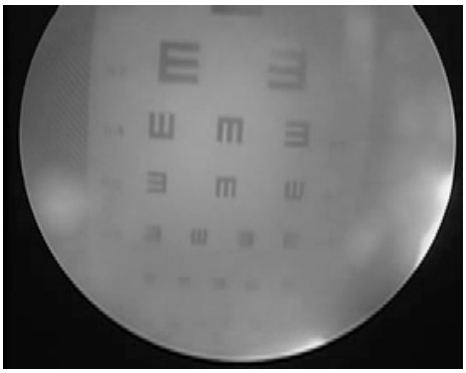
Table 3 contrasts the scope's maximum range of motion with and without the lens shielding mechanism. Note that any motion lost is lost only at extreme deflections. For instance, the scope must be inserted deeply into the abdomen (r large) or angled upward nearly as far as possible (α large) before the shielding mechanism begins to impede motion. Also note that with the exception of the axial direction, scope motion is inhibited very little by the presence of the shielding mechanism.

Table 3. Range of motion for a 30 cm scope with and without the shielding mechanism

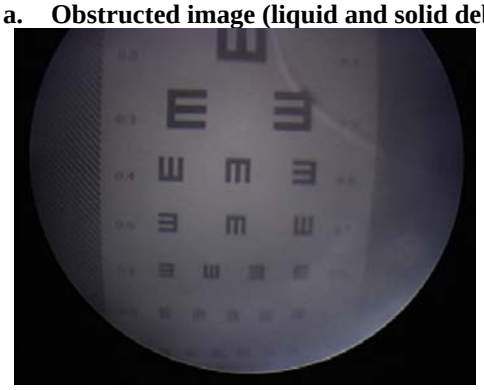
Dimension	Description	Maximum Range	Range at 12.7 cm Insertion	% Change
r	Translation along scope axis	30 cm	23.4 cm	23 %
α	Elevation angle from vertical	90 deg.	79 deg.	12 %
ψ	Azimuthal angle (about vertical axis)	360 deg.	343 deg.	4.6 %
φ	Roll angle (about scope axis)	360 deg.	317 deg.	12 %

Cleaning Efficiency

The functionality of the tape advancement mechanism and the device's ability to restore vision were tested at the Carl J. Shapiro Simulation and Skills Center at Beth Israel Deaconess Hospital. A standard 5mm laparoscope was connected to an output monitor to simulate an operating room setup. The scope was fixed in a vertical orientation above a flat surface and its distal end shielded with the tip guide and tape from the device. A visual test pattern similar to an "e-game" distance visual acuity test was placed directly below the distal end of the scope so that it was clearly visible on the output monitor. The image on the monitor was digitally captured and recorded. In order to simulate a typical endoscopic image interruption, a mixture of organic fluids and particulate was applied to the end of the lens, obscuring vision of the test pattern. The tape was advanced by one full device actuation sequence, and the image on the monitor was again digitally captured. The clarity of the two images was then compared to determine the effectiveness of the device to restore visibility. In all cases, the clarity of the image on the output monitor was unchanged from before obstruction of the image to after the image had been restored. Figure 7 shows the image through a dirtied endoscope before and after one actuation cycle.



a. Obstructed image (liquid and solid debris)



b. Image after one advancement of shielding tape

Figure 7. Endoscopic test image before (a) and after (b) one tape advancement

First order tests of removal of a variety of debris were conducted. Sterile saline was placed on the tape, obscuring the view of through the scope. Four tape advancements were required to advance the tape enough to obtain a clear image through the lens. Moist air at approximately 98 degrees (Fahrenheit) was blown over the tip of the scope to cause fogging. This fog required one advancement of the tape to clear the lens. While further testing of a variety of debris, including bodily fluids and solids, is required before validation of this functional requirement is complete, it is anticipated that similar results will be achieved for various debris due to the fundamental physics surrounding the shielding mechanism's operation.

Robustness and Cleaning Time

In order to ensure that this device is both safe for the patient and functional for the operator, the apparatus was designed to function the same way the control, non-shielded laparoscope would. In the case of failure of this device to advance the tape across the lens and thus provide a clear image through the laparoscope, the operator will simply continue the procedure as if he or she had a laparoscope with no cleaning ability. In designing the device this way, the design team strove to ensure that use of the product would enhance or maintain the surgeon's ability to perform the given procedure. In a test of 90 clicks of the handle, the tape advanced 100% of the time. The mechanical system that causes the tape to advance did not fail over 90 repetitions, which would allow a surgeon to remove obfuscations from his or her workspace view 90 times without ever having to remove the laparoscope from the body cavity during surgery.

The time needed to clean a dirtied lens during a surgical procedure becomes of critical importance in particularly "messy" surgeries that require the laparoscope lens to be cleaned several times. Over a period of ten timed trials of this device, the mean time to remove the dirtied tape from the lens was 0.61 ± 0.18 seconds. In videos of four gynecological surgeries that were witnessed, the lens fogged for as little as 30 seconds and as long as 2 minutes when the scope was removed and reinserted into the body. In a hysteroscopy which lasted only 24 minutes, the camera was dirtied sixteen times for a total time of 178 seconds, or nearly three minutes. In total, the time the lens was obscured accounted for 14.5% of the time of the surgery. If this device were in use, it could in the best case reduce the time the lens is obscured to approximately 10 seconds, or 0.6% of the total surgical time.

Sterilization

In order for the device to be practical for use in the operating room, an appropriate sterilization method had to be chosen. Since a large portion of the device is made of polymer materials that can be damaged by high temperatures, traditional autoclave steam sterilization was found to be an impractical sterilization method. Other available sterilization methods include ethylene oxide (EtO) gas, Sterad® or hydrogen peroxide gas, and gamma irradiation. EtO and hydrogen peroxide gas sterilization processes require that the surfaces of all components of a device be exposed to the gas. The internal geometry of this device is relatively complex, especially when considering the tightly-wound tape spools. Therefore, exposing the full surface area of the device would be very difficult, making gas sterilization methods impractical for this device. Gamma irradiation was chosen as the most probable sterilization method for this device for its ability to penetrate complex devices and sterilize a variety of polymers without degrading mechanical or visible properties.

To confirm that the device can be sterilized using gamma irradiation, each component in the design had to be considered individually. Since gamma irradiation is widely accepted as safe for sterilizing metals used for mechanical applications, the metal components of the device were considered appropriate for the chosen sterilization method. Many opaque thermoplastics, such as polyether ether ketone, have been validated for use in medical devices that are sterilized using gamma irradiation. Therefore, it was determined that the purely structural polymer components of the device, including the handle, coupler piece, and casing, are appropriate for gamma sterilization. Finally, the shielding tape was evaluated. A manufacturer of boPET and a large gamma sterilization contractor independently verified that boPET film has been

sterilized using gamma irradiation at high radiation dosages with no significant detriment to mechanical or visible properties. Therefore, it was determined that the shielding tape would likely withstand gamma sterilization. Further testing is needed to fully validate the device for gamma sterilization. A sterilization study including many copies of the finished device will be able to determine the correct radiation dosage to fully and safely sterilize the device.

Cost

Production costs for this device are estimated at 20.45 USD/unit. This estimate assumes high-volume (>10K parts/year) production of plastic components from injection-molded ABS, commercial off-the-shelf springs, dowels, and tape, and custom-extruded sheaths. Assembly time is estimated to total 0.6 hours/device while gamma sterilization is expected to cost 4 USD/unit. Finally, for a given scope size (5mm and 10mm are the most commonly-used), only the sheath length and/or tip guide mechanism will require differentiation to accommodate various scope lengths and tip angles.

CONCLUSIONS AND FUTURE WORK

While further testing is required to refine its design, the current embodiment of the device fulfills the majority of functional requirements that were established at the beginning of the design process. The device fits well within the spatial limits of the operating workspace. Future development will further reduce the size and improve the ergonomic appeal of the product casing. Functioning as a self-contained add-on to existing scopes, this device requires no insufflation or power hook-ups, and thereby eliminates the need for additional operating room infrastructure. The current embodiment has been shown to quickly and effectively remove 100% of liquid, solid, and gaseous debris from the lens, though further testing with other debris is planned. Finally, future work will focus on improving visual robustness to surface defects in the tape as the current design has shown some tendency for scratches and/or flaws in the tape to reflect light from the scope source.

More exhaustive and quantitative tests are planned to gauge the feasibility of full-scale device sterilization, the amount of vision obstruction through the tape, and the versatility of cleaning various debris from the end of the lens. Ergonomic tests will be conducted to gauge surgeon preference as to the size and position of the product casing. Other steps for improving cost and marketability include designing various sheaths and tape guide mechanisms for compatibility with scopes of various lengths, diameters, and tip angles. Finally, manufacturing considerations will be incorporated into the design, to improve its part cost, part count, and assembly time.

The current embodiment of the device requires roughly twenty minutes to assemble. Most of this assembly time is related to inserting the tape into the tip guide, threading it through the sheath, and wrapping it securely around the spools inside the casing. The feeding of the tape into the device may need to be reworked to reduce assembly time. To avoid the possibility of the tape becoming dirty or binding upon insertion of the scope into the sheath, a barrier will need to be designed to fit between the scope and the sheath to protect the tape. This will be a challenging aspect of the redesign, since the clearance between the scope and the standard 5 mm cannula is only a few thousandths of an inch. A possible countermeasure to this problem is to require the use of a slightly larger cannula, of inner diameter of 6 to 7 mm. This size cannula should still be small enough to avoid the use of sutures on the cut made for the camera port. Currently, the device is designed for a scope with a particular length, diameter, and tip angle. In the future, a product or line of products that can be adapted to fit all scope lengths, diameters, and tip angles will be developed.

ACKNOWLEDGMENTS

This product was developed as a part of the MIT course 2.75: Precision Machine Design. The authors would like to thank Professor Alex Slocum, Dr. Julio Guerrero, Dr. Keith Isaacson, Dr. David Custer, Conor Walsh, Nevan Hanumara, Dr. Joan Spiegel, and Dr. Hiep Nguyen. We are also grateful to Boston Children's Hospital, Newton-Wellesley Hospital, and Beth Israel Deaconess Medical Center for the use of their facilities. Finally, we would like to thank Lynn Osborn and Dr. Tom Brady of the Center for Integration of Medicine and Innovative Technology (www.cimit.org) for financially supporting this course and project. CIMIT support comes from DOD funds with the FAR 52.227-11.

REFERENCES

[1] Champault, G; Cazacu, F; Taffinder, N. "Serious Trocar Accidents in Laparoscopic Surgery: A French Survey of 103,852 Operations." Surgical Laparoscopy, Endoscopy, and Percutaneous Techniques. Vol. 6, Num. 5. October 1996.

[2] Reich, H; DeCaprio, J; McGlynn, F. "Laparoscopic Hystorectomy." Journal of Gynecologic Surgery. Vol. 5, Num. 2. Summer 1989. pp. 213-216.

[3] Cadière, G; Himpens, J; Germay, O; Izizaw, R; Degueldre, M; Vandromme, J; Capelluto, E; Bruyns, J. "Feasibility of Robotic Laparoscopic Surgery: 146 Cases." World Journal of Surgery. Vol. 25, Num. 11, Nov. 2001.

[4] Zheng, B; Martinec, DV; Cassera, MA; Swanstrom, LL. “A quantitative study of disruption in the operating room during laparoscopic antireflux surgery.” Journal of Surgical Endoscopy. Vol. 22, Num. 10. October 2008.

[5] H. Akiba, “Observation window washing device of endoscope” , October 28, 2003.

[6] G.D.I. Grice and J.C. Miles, “Disposable scope cleaner and method of using same” , December 28, 2006.

[7] D.T. Kato, “Automated laparoscopic lens cleaner”, March 12, 2002.