Development of a Collapsible Guard Component for a Novel Surgical Instrument

by

Darragh Buckley

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ABSTRACT

The Endoblend is a novel surgical device for use in laparoscopic hysterectomy surgery. Laparoscopic hysterectomy surgery requires that the uterus be removed through a laparoscopic port. To achieve this, the Endoblend liquefies the uterus through the use of cutting blades. The Endoblend has a stem containing aspiration tubes, irrigation tubes and power transmission elements. A spinning blade is attached at the end of this stem for the purpose of liquefying previously separated tissues such that they can be removed from the abdominal cavity through the aspiration tubes. In order to effectively process the tissues, they must be placed with a sealed enclosure. This enclosure is at risk of being compromised by the spinning blades and therefore the need arises for a guard module to prevent this. The guard module must function to direct the tissue towards the blades and prevent any tearing of the enclosure. It must also be capable of fitting through a 15 mm laparoscopic port.

A guard has been developed comprising of three Nitinol rings and an ultra-high molecular weight polyethylene fiber. The guard's functionality has been tested and the guard is capable of meeting all the functional requirements.

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1. Background

1.1 Laparoscopic Hysterectomies

Hysterectomy is the second most frequently performed gynecological surgical procedure, after cesarean section, for women of reproductive age within the United States. Approximately 600,000 hysterectomies are performed annually in the United States, and approximately 20 million U.S. women have had a hysterectomy [1]. Hysterectomies may be performed abdominally, vaginally or laparoscopically. There are many surgical advantages to laparoscopy, particularly magnification of anatomy and pathology. Patient advantages are multiple and are related to avoidance of a painful abdominal incision. They include reduced duration of hospitalization and recuperation and an extremely low rate of infection [2].

Laparoscopic hysterectomy denotes ligation of the uterine arteries either by electrosurgery desiccation, suture ligature or staples [2]. Laparoscopic dissection continues until the uterus lies free of all attachments in the peritoneal cavity. Uterine removal by morcellation can then be performed [2]. A similar technique can be used for the removal of fibroids. Hysterectomy tissue morcellation is performed using a morcellator.

1.2 Morcellator

A commonly used tissue morcellator used in laparoscopic procedures includes a rotationally fixed, axially movable inner tube disposed within a rotating cutting member. The cutting member is located between the inner tube and an outer tube. A laparoscopic grasping instrument is inserted through the lumen and draws the tissue proximally through the morcellator. As the cutting member severs tissue, the tissue is drawn into the fixed lumen of the inner tube with forceps [3].

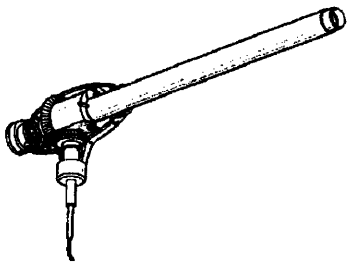


Fig. 1: A popular morcellator design: US Patent 6,039,748, 2000 [3].

Although laparoscopic procedures decrease patient recovery time they can increase surgical time. A typical morcellation process alone was observed to require up to forty minutes. This leads to the primary complaint levied against the current tool; the

morcellation process is too slow. Prolonged surgical procedures lead to surgeon fatigue. Some surgeons have also voiced fears of having an exposed spinning blade within the abdominal cavity. There exists a risk that processed tissue might be accidentally released back into the cavity and cause necrosis. The morcellator has also been criticized for overheating during operation.

1.3 Endoblend

The Endoblend is a novel surgical device designed to decrease the time requirement for laparoscopic hysterectomy procedures and address some of the other concerns surgeons have with the current morcellator. The Endoblend was designed, prototyped and tested by a team of MIT students for course 2.75; Precision Machine Design[1]. The guard and enclosure modules were not designed as part of this class. The enclosure module is the subject of Danny Hernandez-Stewart's thesis [4] and many of the experiments testing the guard module were also used to test the enclosure module.

The Endoblend has been developed to allow for faster and safer laparoscopic aspiration of tissue. This new tool requires that the uterus be enclosed in a protective bag after separation from the cervix and fallopian tubes. The tissue is then rapidly processed by a spinning blade while the processed tissue is simultaneously aspirated throw the stem. The bag is necessary to ensure that no tissue is accidentally left behind in the abdominal cavity; furthermore, the bag/guard will be resistant to cutting by the blades. An image of the earliest prototype of the Endoblend is shown below.

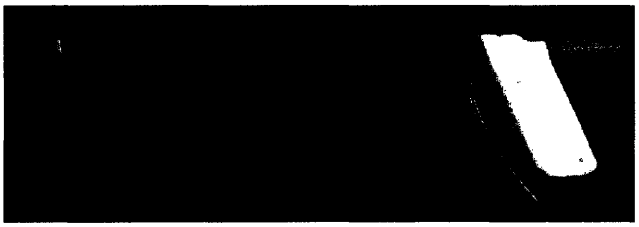


Fig. 2: Prototype of Endoblend shown without bag and guard modules

1.4 Guard

The Endoblend design requires the use of a guard to protect the bag from being compromised by the spinning blade. The guard also serves to direct the tissue towards the blades and prevent the tissue from being thrown. The design, prototyping and testing of this guard is the focus of this paper. A rendering of the Endoblend including the desired final configuration of the guard and bag modules is shown in figure 3.

[1] The Endoblend was designed as a class project for 2.75: Precision Machine Design in the fall 2006 semester by Samuel Kresner, Christopher Brown, Daniel Hernandez-Stewart, Aparna Jonnalagadda, Darragh Buckley, Dr. Samuel Williams and Prof. Alexander Slocum. A provisional patent was filed in March 2007.

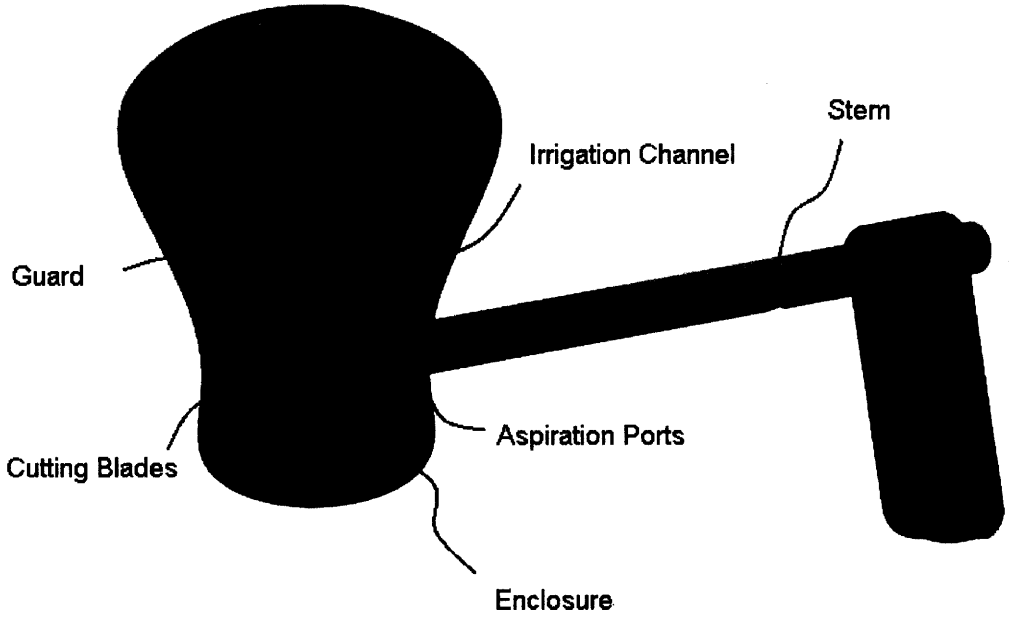


Fig. 3: A rendering of the Endoblend showing the desired final configuration of the bag and guard module

The guard module is required to fit through a 15 mm laparoscopic port. Any guard setup procedure should not significantly increase the time requirements for the surgery or the complexity of the operation. The guard must be capable of withstanding the tearing forces resulting from the cutting action of the spinning blade so as to prevent bag failure which would lead to leakage of processed and unprocessed tissue to the abdominal cavity requiring emergency surgery or worse, causing necrosis and possibly death.

2. Strategies

The goal of this project is to design, prototype and test a guard for the Endoblend that functions to prevent the bag module from being compromised by the spinning blade and to effectively direct tissue towards the blade while not noticeably increasing surgical time or complication. Two different strategies were considered while attempting to meet these goals.

2.1 Separate Port

During a typical laparoscopic hysterectomy, three ports are maintained. The first of these ports is reserved for use by optical instruments to allow the surgeon view what she is doing. The second and third ports are available for insertion of surgical instruments and removal of tissue. These ports are typically 15 mm in diameter. There is no fundamental requirement that the guard be attached to the Endoblend upon insertion. The guard could be introduced independently of the tool and expand to a suitable size and shape. This could be done either through the same port the Endoblend is to be placed through or through the remaining usable port. The advantage of such a strategy is that it is less restricted than that of the in-line strategy. A major drawback however is the necessity to dock with the Endoblend and effectively seal. The possibility exists that the bag could be attached to the device upon insertion and a separately inserted guard

could then be fixed to the bag when both modules are within the abdominal cavity. This has the disadvantage of adding another step to the surgical procedure.

2.2 Same Port as Endoblend

An alternative strategy is to have the guard and bag module permanently attached to the stem of the Endoblend. The guard and bag modules are inserted at the same time as the rest of the device. This has the major advantage of not requiring a docking mechanism to create a seal. Although more design restrictions apply to this strategy, the set-up time and complexity demands of the independent bag and guard justify the pursuit of the in-line strategy. It was therefore chosen to focus on this strategy.

3. Concept Development and Testing

In order to meet the functional requirements, a number of concepts were developed and tested. Bench level experiments were conducted to examine the efficacy of each concept and identify those with the most promise. Table 1 summarizes the concepts and their related risks and countermeasures. Although the final blade configuration of the Endoblend is subject to change it is believed that all of these concepts can be adapted to a new configuration.

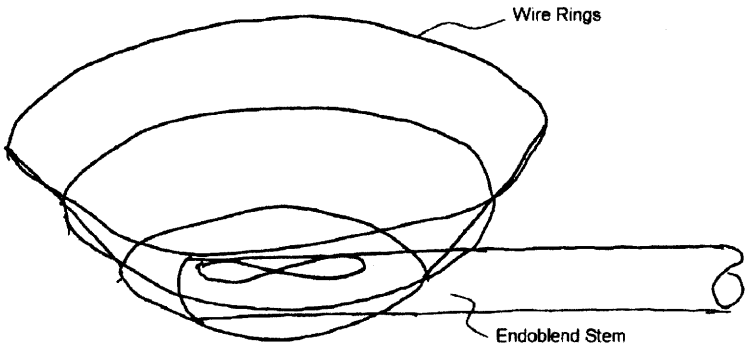
Functional Req.	Design Parameters	Analysis	Ref.	Risks	Countermeasures
Maintain Shape	Nitinol Wire	Deformation upon applied force	[8]	Entanglement	Position within bag lining
	Nitinol Sheet			Folding difficulties	Move towards wires
	Rib Inflation		[6]	Puncture	More ribs, segregation of ribs
	Honeycomb Inflation		[6]	Puncture	Segregated sections
Tear Resistant	Kevlar	Tear Resistance		Lack of pliability	Thinner sheet
	Steel Mesh			Lack of pliability	Coarser mesh
	Dyneema			Piercing	Maintain distance from blade

Table 1: The functional requirements and the concepts that were investigated to meet these requirements.

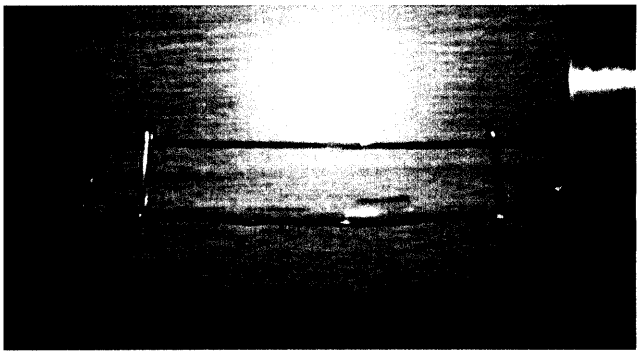
3.1 Nitinol Wire

Super-elastic wire [5] can serve to provide the desired shape of the bag in order to direct the tissue towards the blade. This shape can also maintain the enclosure walls away from the turning blade and so prevent damage to the bag. Super-elasticity is necessary to allow the guard to be reduced in volume such that the guard can pass through the diameter of a standard port and then expand. Figure 4 displays a sketch of the concept.

(a) Bench level mock-up



(b) Fully expanded rings



(c) A 3.5" Nitinol ring reduced to fit within a 15 mm port. The plastic deformation was observed

Fig. 4: The Nitinol rings lie flat upon insertion and retraction to allow the guard to be passed through a standard 15 mm port. Retraction requires drawing the Endoblend back through the port while the port walls force the guard to a suitable diameter. The testing of this is discussed later.

This concept maintains the bag module distant from the cutting surface of the blades and so prevents the bag from being compromised. It does not allow for the possibility of an accident such as unintended outside contact against the enclosure wall bringing the blade within range of the wall material.

In order to test this concept, rings were fabricated from Nitinol wire and attached to a mock up of the bag module. The wire frame served to give the bag the desired shape yet still allow the bag to be rolled to a sufficiently small size such that the module could fit through the required diameter. This embodiment does not negate the problem of contact causing the blade to penetrate the bag wall.

3.2 Nitinol Sheet

Following from the concept of using super-elastic wire is the concept of using super-elastic sheets to negate the problem of external contact causing the blade to tear the bag. This causes the blade's cutting surface to contact sheet metal rather than fabric. This extension does however bring about a new difficulty of how to fold the guard.

It was assessed that although this obstacle is surmountable, far simpler solutions exist that have similar benefits.

3.3 Rib Inflation

In order to form the guard's necessary shape an inflatable guard was considered. An inflatable guard consists of ligated ribs of hollow fabric. This concept requires that part of the stem's current insufflation channel be diverted so as to pressurize the ribs. An alternative is that a new channel be constructed within the stem and for this channel to be pressurized when the device is in use. Figure 5 displays a potential embodiment of such a guard.

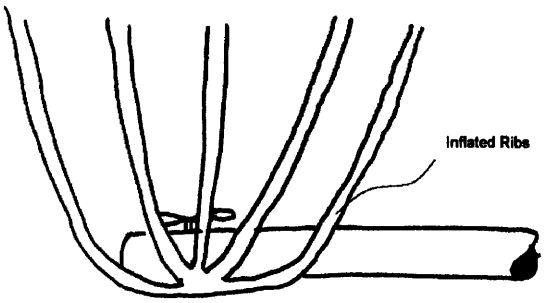


Fig. 5: Bag shape can be maintained through the use of inflatable ribs.

The rib structure adds rigidity and shape to the bag. But once again, the drawback exists of the design being unable to properly allow for an external contact forcing the enclosure to collapse against the blade. Should the blades contact the enclosure wall, a new risk now exists of the ribs being punctured and unable to serve their purpose. One collapsed rib could compromise the functions of the others and exacerbate the difficulty.

3.4 Honeycomb Inflation

Further rigidity can be added to the concept of using inflatable ribs by utilizing an inflatable honeycomb matrix. An example of the use of such a matrix can be seen in [6].

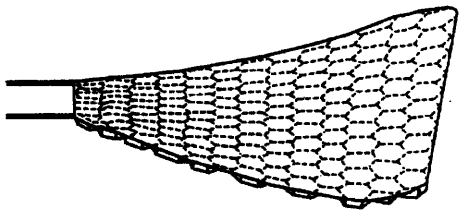


Fig. 6: An inflatable honeycomb matrix can supplement the rigidity of the inflatable rib concept.

This concept still retains a major challenge present with any use of inflatable structures for the purposes desired: the risk of the structure being punctured by the blade. The main defense against such an event is the shape of the inflatable structure but it is believed that surgeons will need more reassurance than this and so it is necessary to continue in the search of a viable concept.

3.5 Flexible Guard

If the bag is inflated to a pressure greater than that of the peritoneal cavity the necessary shape can be maintained. It is therefore viable that a tear resistant fabric might be sufficient to act as a guard. Because of this and given that all concepts described so far have the ability to maintain shape but not withstand blade contact; it is worthwhile investigating the materials that might be employed to prevent the enclosure from being compromised.

3.5.1 Kevlar/Nomex/Fiberglass Blend

In order to assess the viability of this blend, a sample was subjected to tear testing with a blender blade. The blender blade serves as a close approximation of the final blade embodiment. The test sample is shown in figure 7.

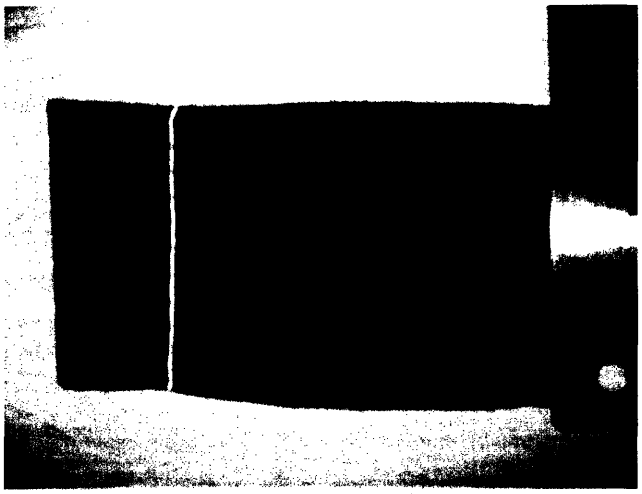


Fig. 7: The Kevlar fabric blend subjected to tear and puncture testing.

The weave is effective at preventing tearing but piercing can still occur. Tearing is defined as applying pressure to the blade and running it over the fabric and assessing whether or not the blade passes through the material. Piercing is defined as applying pressure to a stationary blade and observing if the blade tip penetrates the test sample. This weave allowed the blade tip to be observed passing through the fabric by piercing. This in and of itself is not reason to disqualify the material as a suitable candidate as a thicker sample would prevent such penetration. A challenge with the Kevlar blend however is its rigidity. The material does not fold or roll well and if a thicker sample is necessary this problem is exacerbated.

3.5.2 Steel Mesh

A steel mesh can prevent puncture of the enclosure. It is also possible that such a mesh can have sufficient rigidity to maintain guard shape and structure. Figure 8 shows a sample that was tested in order to assess the viability of a mesh to meet the guard requirements.

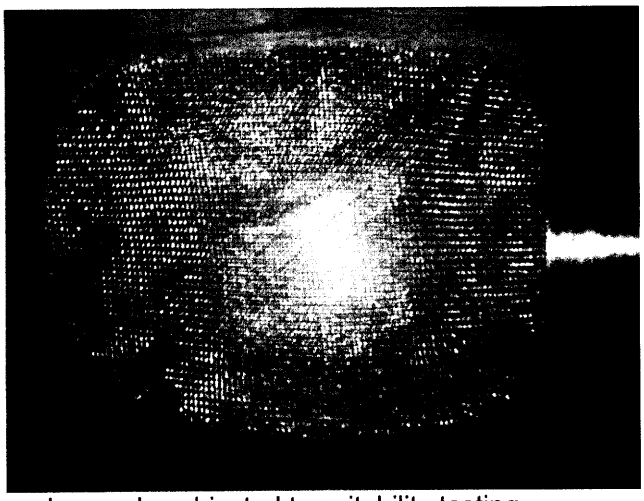


Fig. 8: The steel mesh sample subjected to suitability testing

The steel mesh proved to be effective in preventing both tearing and puncturing of the enclosure however; similar to the Kevlar blend, its flexibility is a major concern. It is extremely difficult to force the mesh into a cylindrical volume capable of passing through the surgical port.

3.5.3 Dyneema

The need for a more flexible, yet tear resistant material led to Dyneema. This fiber is made from ultra-high-molecular-weight polyethylene (UHMWPE) and is exceptionally tear resistant. The samples tested are shown in figure 9.

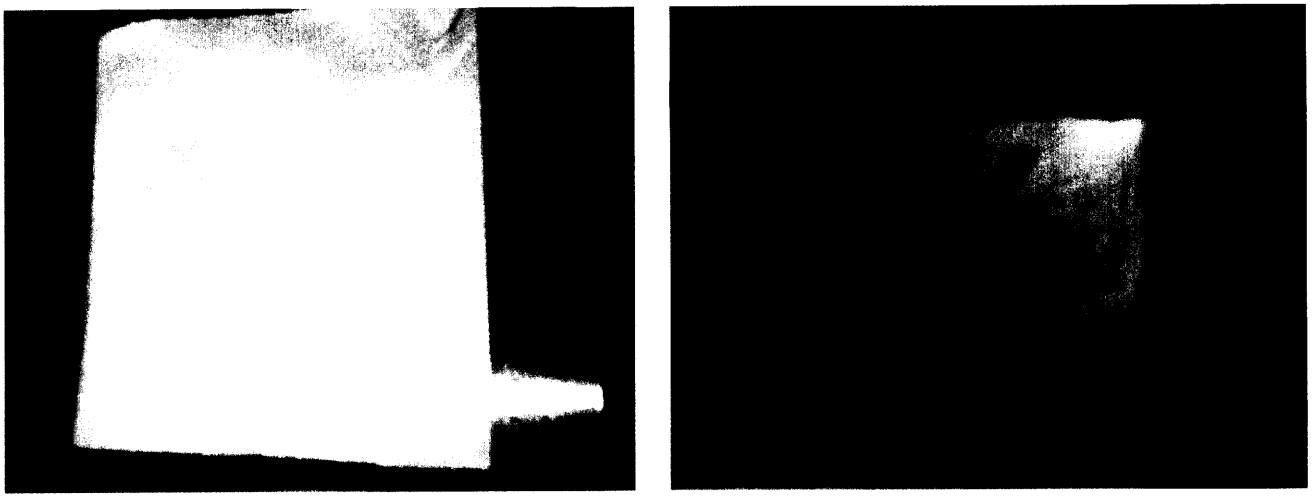


Fig. 9: The Dyneema samples subjected to testing. The material sample is show here with a trim that is removable.

The samples proved to have the tear resistance necessary to serve as a guard while maintaining the flexibility required such that the guard can pass through a standard port diameter. The damage to the material shown in figure 9 resulted from 5 second exposure to an immersion blender while the material was held in tension and the blade was maintained within the plane of the material. This is believed to be the worst-case

scenario for the guard during operation as ordinarily the guard material would be thrown from the blade almost instantaneously.

On completion of concept development and testing it was decided that a Nitinol-wire support Dyneema guard held the most potential to meet the functional requirements.

4. Design

4.1 Shape

The Endoblend design calls for a guard shape that mimics that used in an immersion blender shield. An immersion blender has a bell-shaped shield with an open top. The shield wall has a conical shape. This configuration serves primarily for the diversion, comminution and enhanced processing of the material to be processed while the clearance spaces are used for receiving and discharging the material. This configuration allows for a more intensive and thorough mixing in a minimum of time [7]. Figure 10 shows how this shape is incorporated into the Endoblend's guard design.

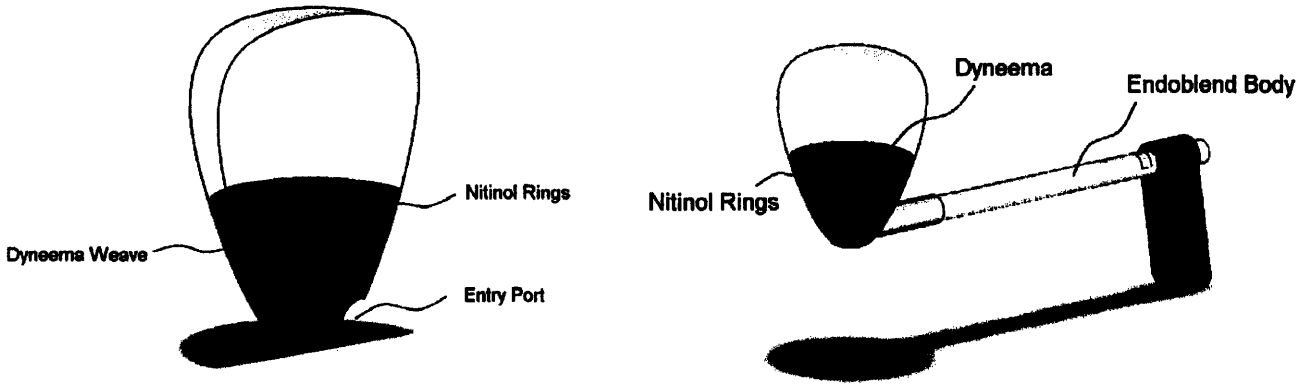


Fig. 10: The guard requires a conical shape to aid in tissue processing. A sectional-view of the guard is shown.

The shape is maintained through the use of the Nitinol rings. Three rings are formed, each with increasing diameter and mounted to the Dyneema which is cut such that it tends towards the required conical configuration when the enclosure module is pressurized. An entry port is also formed in the guard to allow for the insertion of the Endoblend's stem. This entry port is then permanently sealed off as the bag and guard modules are fixed to the stem.

4.2 Nitinol Rings

As stated, rings are employed to give the guard its required shape. Nitinol was chosen because of its super-elasticity. Nitinol allows for elongation of 8% before the onset of plastic deformation. This is necessary as the rings must be arranged such that they can fit through the 15 mm port upon insertion to and withdrawal from the abdominal cavity. Figure 11 shows a bench-level experiment using three rings (D 5", 3", 2") inside a sealable plastic bag.

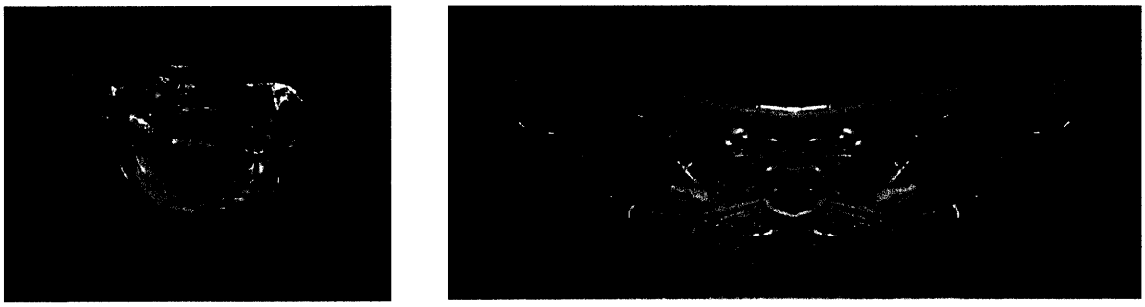


Fig. 11: An experiment was performed to ensure that the rings could pass through a 15 mm port without losing shape. The rings began in the configuration on the left. A force was applied and the rings took on the configuration on the right. When this force was removed the rings returned to the original configuration.

4.3 Dyneema

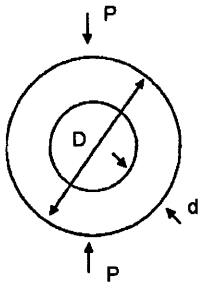
Dyneema was fashioned into a conical shape with an open top and a flat base. Dyneema is already used in medical applications ranging from surgical cables to orthopedic sutures.

Fig. 12: A bench-level experiment to test the tear resistance of Dyneema. The fabric was fashioned into an appropriate shape and tested using an immersion blender and a Ziploc bag. Details of this test are given in the prototype testing section.

5. Analysis

It is necessary to assess the force required to cause the Nitinol rings to have a vertical diameter of no greater than 15 mm. The decrease in the vertical diameter of a thin ring due to an applied vertical load is given in [8].

$$\Delta = \frac{kPD^3}{EI}[\text{inches}] \tag{1}$$



The cross-sectional moment of inertia of the wire about its center is given by:

$$I = \frac{\pi d^4}{64} \tag{2}$$

The force necessary to reduce the vertical diameter is therefore given by:

$$P = \frac{\Delta E d^2}{8kD^3} \tag{3}$$

D	Ring diameter
d	Wire diameter
E	Modulus of elasticity
I	Moment of inertia
K	Equation constant: 28.82
P	Applied force
Δ	Change in vertical diameter

Table 2: Nomenclature

Equation (1) and therefore (3) represents only a first approximation as flattening and buckling related shape change of the ring at large deformations as well as nonlinearity due to transformation from the austenitic phase to the austenitic martensitic phase. The omission of the latter is justified in [9]; showing that only 3% of the thin ring material undergoes the stress-induced phase transformation to the martensitic phase.

For a 51 mm (2") diameter ring constructed of 0.381 mm (0.015" - chosen because it is the largest, easily available diameter) diameter wire, the force required to reduce the vertical diameter to 15 mm is 1.52 N. Six identical rings are bundled together to form one ring which requires 9.12 N to deform. This is a reasonable force requirement

for the initial packing of the guard and for repacking after use. The total force required for compressing all three rings (D 5", 3", 2") is 15.55N.

This force is large enough to maintain the guard in its open position but not too large to make it overly difficult to draw the rings back through the port open completion of using the device. The primary method of keeping the guard and bag module in their open configurations is the pressure difference due to inflation of the bag. The rings are necessary as the movement of the tissue or the fluid during operation of the device can cause the guard to tend towards the blades. The rings negate this. Also the rings serve to protect the guard and bag in the case of a sudden pressure loss. This is a stated fear of the surgeons and therefore it is necessary to address this concern.

6. Prototype Performance

In order to test module design and performance, a prototype was constructed. Dyneema was cut and sewn into an appropriately conical shape. Two Nitinol rings (D 2.5", 3") were constructed from Nitinol wire. The wire was soldered into rings and sewn into the interior of the guard module. Figure 13 shows the configuration.

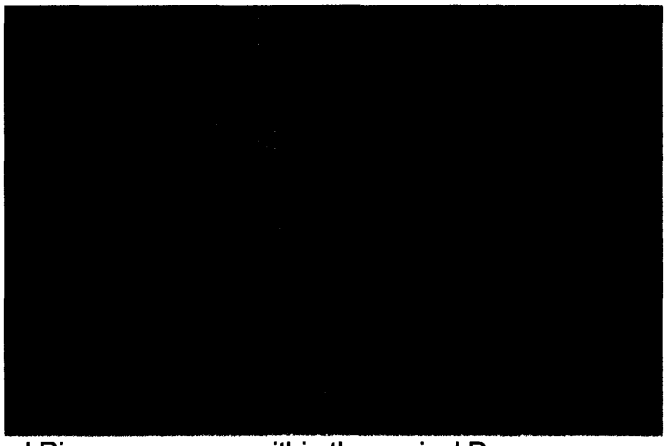


Fig. 13: The Nitinol Rings were sewn within the conical Dyneema.

In order to appropriately test the guard prototype a modified immersion blender was used. Ordinarily an immersion blender has a shield surrounding the blade. There is also usually a surface beneath the blade such that the footprint of the blade never passes outside the surface. For the purpose of testing the guard module both of these features were removed. It was desirable to have the bag held from the spinning blade solely by the Nitinol rings and not by the platform that usually lies beneath the blade. It was also necessary to allow the cutting blades to contact the Dyneema fabric in order to judge the fabric's performance within its operating environment. This was done by removing the shield that normally protects from unintentional cutting. The modified blender is shown alone in figure 14a and with the guard and bag modules attached in figure 14b.

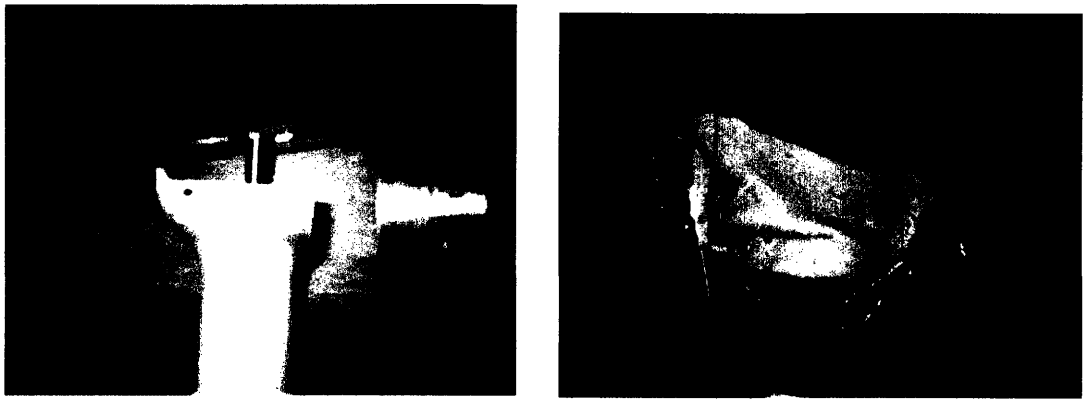


Fig. 14: Safety features were removed from an immersion blender and the guard and bag module were attached and sealed. The guard was attached such that the remainder of the platform under the blades of the immersion blender did not help maintain the guard away from the blades.

The Endoblend calls for liquid to be added to the bag before tissue processing as this is found to decrease processing time. Water was therefore added to the prototype until the tissue to be processed is completely immersed. Previous testing revealed that when insufficient liquid is added tissue processing cannot occur. Round steak was used as uterus mimicking material and was placed inside the bag. Approximately 50 g of round steak was used. Air was allowed to remain in the rest of the bag. The bag was then sealed. The immersion blender was activated and allowed to operate until the tissue had been processed. This took on the order of 10 seconds. During this time the immersion blender was moved around to try to force the blades against the guard. Due to the opacity of the guard and the reddening of the fluid as the tissue was processed it was difficult to observe whether or not the blade contacted the fabric or rings. However, if the blades had come in contact with the bag, leaking would have been noted. The bag remained uncompromised while the guard maintained its desired shape.

The test also revealed the difficulties that exist if an attempt is made to re-sterilize the guard module and it is therefore believed that the guard should not be reused. This is in line with the rest of the Endoblend which is also designed to be disposable.

In addition to preventing the bag module from becoming compromised by the spinning blades, the guard module is required to pass through a 15 mm port. An assessment of this functional requirement was performed by employing a port simulator. The guard module was attached to the Endoblend prototype, passed through the port and allowed to expand as shown in figure 15.

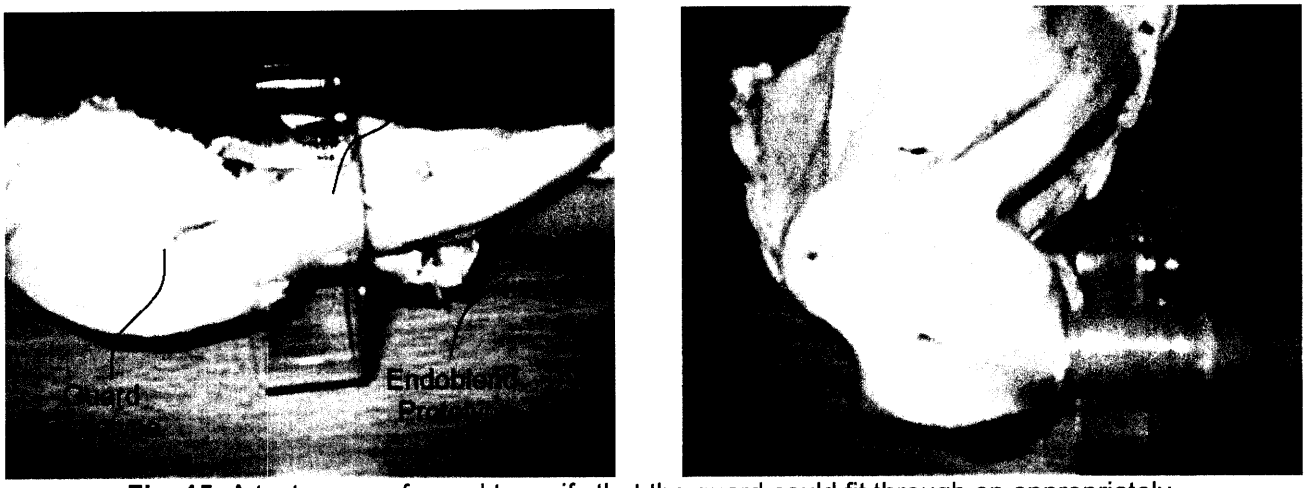


Fig. 15: A test was performed to verify that the guard could fit through an appropriately sized opening using an adjustable collar.

The test proved successful as the guard prototype was capable of passing through the test collar. These two tests show the viability of using a guard module comprising of Dyneema supported by Nitinol rings.

7. Conclusion

After choosing the strategy of an attached in-line guard module, various concepts were explored and tested. The most promising concept was determined to be an ultra-high molecular weight polyethylene fabric supported with Nitinol rings. This concept was prototyped and tested to assess whether or not it met functional requirements. The first test comprised of modifying an immersion blender so as to (4)removing expose the blade as much as possible. The prototype guard module along with a bag was attached to the blender. The blender was then used to process tissue much in the same way the Endoblend does. The guard was able to keep the bag from being compromised.

The second test involved passing the guard through a port mock-up to demonstrate that the guard could be folded to allow it pass through a standard laparoscopic port. Again, the guard prototype verified that the design could meet the functional requirements.

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