

Enclosure Module Design Thesis for Endoblend:
A Novel Surgical Device for Laparoscopic Hysterectomy

By

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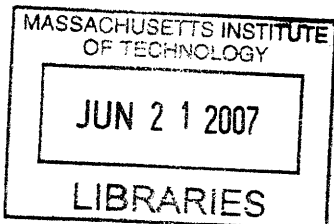
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ABSTRACT

The Endoblend device concept was developed by a 2.75 design team, of which I was a member; the purpose of the device is to remove tissue laparoscopically. The detailed design of one of its modules, the enclosure module, is the subject of this paper. The Endoblend has the potential to reduce morcellation surgery time from upwards of half an hour to minutes, with reduced risk of the most common complications of nicking the abdomen wall and leaving tissue behind. There are three primary functional requirements of the enclosure module. First, for ease of use, simplicity, and safety the bag and guard in combination must passively feed the tissue into the blades. This was accomplished using a cone shape to make the bottom of the bag act as an equilibrium state through a gravity feed. Second, the bag must remain intact to prevent tissue from being left behind. To accomplish this it will be shaped with a flat region near the blades so that inflating the bag keeps it away from the blades, and the Ziploc type seal through which the tissue enters will be a double seal with micro beads of cyanoacrylate to make a strong permanent seal. Third, since the main benefit of the Endoblend is shorter surgery time, it is vital that the extra steps incurred from use of the enclosure module do not take up a significant portion of the time saved by its rapid tissue processing capabilities. The prototype bag met these functional requirements, and was used to successfully process tissue in a bench-top experiment. The successful design and integration of the enclosure module will allow this project to continue moving forward. This thesis along with the thesis on the guard answered the remaining critical questions that preceded putting together a next iteration prototype to use in order to perform animal tests.

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Enclosure Module Design Thesis for Endoblend: A Novel Surgical Device for Laparoscopic Hysterectomy

Daniel Hernandez-Stewart

1 Introduction

The Endoblend device was developed by a 2.75 design team of which I was a member.* The detailed design of one of its modules, the enclosure module, is the subject of this paper. The Endoblend concept will allow for faster and safer laparoscopic removal of tissue. For example, the time spent processing the uterus in current laparoscopic hysterectomies is anywhere from thirty minutes to hours, whereas this portion of the procedure utilizing the Endoblend will be on the order of minutes. The first level prototype from 2.75 can be seen below in figure 1.1.

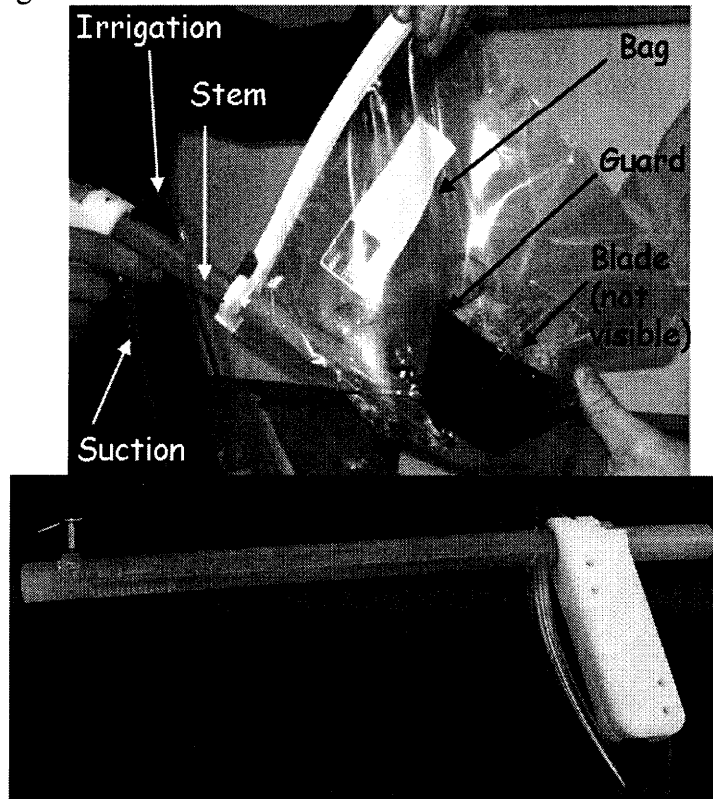


Figure 1.1: The top image shows the various modules of the Endoblend Device. The bottom image shows the blade and stem in more detail. [1]

The first difference between the new and old procedures will be that the uterus will be enclosed in a protective bag after the separation from the cervix and fallopian tubes. This will allow the tissue to be rapidly and safely processed by a spinning blade into small

* Developed for 2006 2.75 team 1 taught by Professor Alex Slocum. Team doctor was Zev Williams. Team members were Chris Brown, Darragh Buckley, Daniel Hernandez-Stewart, Aparna Jonnalagadda, and Samuel Kesner. Patent Pending

pieces that are aspirated through the device stem. The enclosure model improves safety by preventing the abdominal wall from being nicked and by preventing tissue from being left behind in the abdominal cavity, both of which would be serious complications and require open surgery to fix. The concept of enclosing tissue in a bag during surgery is not new - Endocatch bags are used in a number of procedures, including the retrieval of ovarian teratomas[4], nephrectomy[5] and splenectomy[6] [1]. However, these bags were only used for much smaller amounts of tissue removal, and in these cases there was no processing of the tissue in the bag.

2 Background [1]

The background section is taken from the original paper [1] on the device.

2.1 Hysterectomies

A hysterectomy is the surgical removal of part or the entire uterus. Hysterectomies are the second most common gynecological surgeries performed in the United States, with 600,000 procedures every year[1]. Abdominal hysterectomies involve the removal of the uterus through a large incision in the abdomen and vaginal hysterectomies remove the uterus vaginally. Abdominal hysterectomies are more common than vaginal (65% vs. 35%), and 28% of the vaginal hysterectomies include laparoscopic assistance to some degree.

2.2 Laparoscopy

A laparoscope is a tubular endoscope inserted through an incision in the abdominal wall. Laparoscopy is the general term encompassing surgeries and examinations done with a laparoscope. Laparoscopic hysterectomy is the removal of the uterus through a small incision (15mm) after surgically separating of the uterus from the cervix and fallopian tubes and cutting the uterus into small pieces. Laparoscopic hysterectomy currently takes longer to perform than abdominal hysterectomy (median time 72 to 84 minutes vs. 50) but results in less postoperative pain, shorter length of hospitalization, quicker recovery, and better quality of life six weeks post operation[2].

2.3 Current Procedure

Current laparoscopic hysterectomy procedures use a device called a morcellator to cut the uterus into small pieces. Morcellators use a spinning blade at the end of a shaft to cut through tissue that is grasped by forceps and pulled through its hollow core. The process is slow and fatigue-inducing as the surgeon must make precise and repetitive cuts. In addition, the exposed blade of the morcellator runs the risk of causing accidental nicks, resulting in damage that requires open surgery to repair. The coring action can produce small tissue fragments that must be painstakingly removed from the abdominal cavity. Accidental retention of tissue can lead to severe complications [3].

3 Functional Requirements

3.1 Feeds Tissue into Blades

For ease of use, simplicity, and safety the bag and guard in combination must passively feed the tissue into the blades. A passive system that does not require the surgeon to move the Endoblend once the blades are spinning will require much less skill on the surgeon's behalf and be much easier for surgeons new to the procedure. In many of our preliminary experiments the immersion blender and bag were moved relative to each other. The spatial motion of a rotating blade inside the abdomen increases the risk of causing damage to the bag or the abdomen, and led to several bags being cut during preliminary experiments.

3.2 Maintain Bag Integrity

Two key improvements of the Endoblend are that it reduces procedure time and that it prevents the surgeon from accidentally leaving fragments of tissue behind. A breach of the bag would do negate or both of those improvements. If a leak allows tissue to escape the tissue fragments will need to be cleaned up, and it's likely that conventional surgery will be required. Additionally, the bag's integrity also serves to show that the abdomen has not been cut and is not in danger.

3.3 Quick, Easy, Safe Deployment and Retrieval

Since the main benefit of the Endoblend is shorter surgery time, it is vital that the extra steps incurred from use of the enclosure module do not take up a significant portion of the time saved by its rapid tissue processing capabilities. Also, since the rest of the Endoblend is designed to not require much surgical dexterity, the deployment and retrieval steps should not add complexity or risk to the procedure.

3.4 Transparent

For surgeons' piece of mind, and so that they will know when the tissue has been processed, surgeons must be able to see into the bag. A spinning blade that can be seen is much less scary than one in an opaque bag.

4 Satisfying the Functional Requirements

4.1 Feeds Tissue into Blades

Several options were identified for feeding the tissue into the blades after active surgeon manipulation was ruled out in the original 2.75 project. During preliminary work for 2.75 the following experiments took place [1]. In the first experiments a cube of steak (simulating tissue) was exposed to an immersion blender. This left a "puree" of tissue, but was quite slow. When water was added, the process was sped up tremendously. The water acted as a cutting fluid aiding the blade and taking away processed tissue allowing untouched tissue access to the blade. The effect of water can be seen in figure 4.11.



Figure 4.1.1: This is a picture from a bench level experiment in which a cube of steak was quickly processed (10 seconds) with an immersion blender.[1]

The orientation of the blender in this experiment is shown in the above figure. The blender blades were pointed downward and the tissue was trapped between the blender guard and the bag. The two biggest disadvantages of this setup were that it required the surgeon to move the tool relative to the bag and that the blades were in close proximity to the bag. Also, this setup only worked when a large guard to hold the tissue in place was present, and as such placed restrictions on the guard. Additionally, when the guard was removed the tissue was kicked around the bag and cut unacceptably slowly. In 2.75 a gravity feed was tried, but only worked with a hard guard in place. This setup would couple the bag and blender module and would prevent the use of a “soft guard” like Kevlar as opposed to a rigid guard structure.

To get past this roadblock at which 2.75 work left off different feed systems were considered and re-evaluated as shown below in Table 4.1.1

Functional Requirements	Design Parameters	Risks	Counter Measures
Bag Feed	Guard Pins to Bag	Need to move guard and or blades/relative to bag	Varying Size Guard
	Liquid Mechanical Gravity	Fluid could overflow/over-pressurize bag Complicated, hard to pack into small space Not strong enough	Release Valve Expanding Sharper Blades

Table 4.1.1: This table summarizes the risks and countermeasures of various feed systems.

The simplest feed available was a gravity feed as shown in figure 4.1.2



Figure 4.1.2: This is a picture from a bench level experiment in which a cube of steak was quickly processed (order of 10 seconds) with an immersion blender with a gravity feed , which decoupled bag and guard modules. [7]

This issue of the tissue being kicked away from the blades was resolved by using an immersion blender with sharper blades and by making contact with the blades an equilibrium. In this experiment gravity feed angles were used from 30, 45, and 90 degrees with little variation in processing time, thereby decoupling the blender and guard modules. It was found that all that was necessary was a stable equilibrium in which the tissue would be in contact with the blades when the blades were not turned on.

Using a jet of water or a mechanical feed was considered a possible countermeasure if a gravity feed proved weak or not robust. However, a water feed would introduce the possibility of quickly over pressurizing the bag, and a mechanical feed would introduce extra complexity hard to fit through a 15 mm incision. A gravity feed proved to be simple and robust, and will be used to feed the tissue into the blades.

4.2 Maintain Bag Integrity

Two key improvements of the Endoblend are that it is faster and that it prevents the surgeon from accidentally leaving fragments of tissue behind. A breach of the bag would do anything from to reverse either or both of those improvements. Some of the key design parameters and their associated risks and countermeasures are summarized in the following table.

Functional Requirements	Design Parameters	Risks	Counter Measures
Maintain Bag Integrity	Shape	Bag sucked into blade	Pressurized bag with flat area of bag next to blades
	Ziploc Seal	Opens/Leaks	Double Ziploc, and/or Micro beads of cyanocrolate create permanent seal

Table 4.2.1: This table summarizes the risks and countermeasures associated with maintaining the bag's integrity.

The least likely place for an integrity failure is the seal through which the stem passes. The stem port seal will be stronger if it does not have to be made within the abdomen environment by the surgeon. Given that the seal is made before operation, the seal must not take up much space on the 15mm diameter budget for the device. A pre-operation O-ring type seal should be more than sufficient for this low pressure small diameter seal. For folding purposes this seal may need to be made on a retractable sheath so that the bag and guard can lead the stem. For prototyping sake this seal will be made with rubber sealant.

To explore the strength of Ziploc style seals with and without cyanocrolate a bench level experiment was performed. Weights were balanced on 3 different types of inflated, sealed bags, Ziploc sandwich bags, Glad Double Lock Freezer bags, and Glad Double Lock Freezer bags with cyanocrolate. A 2.5 lb weight of annulus shape with an outer diameter of 6.25 in and an inner diameter of 2.125 in was used as the bottom weight to apply pressure to the bag. The experimental setup is shown below in figure 4.2.1.

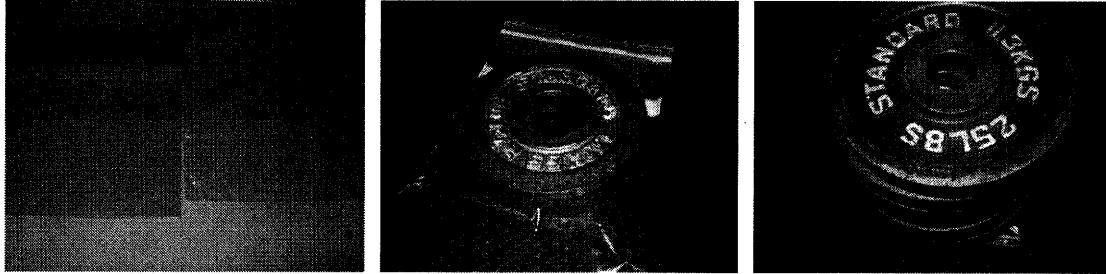


Figure 4.2.1: This is a picture from a bench level experiment to get an idea of the pressures different types of Ziploc seals could handle. The two types of bags used are shown on the left. And the method is shown by the two images on the right.

Five, ten, and twenty five pound weights were then stacked on top of the 2.5 lb weight to increment the pressure felt by the bag. The weights were added relatively fast, since a blowout rather than a slow air leak is the failure mode of concern. The summary of the experimental results is shown below in table 4.2.2.

	Sustained Weight (lb's)	Pressure (psi)
Ziploc Sandwich Bag	30, 30, 35, 45, 100*	1.1, 1.1, 1.3, 1.7, 3.7*
Glad Double Lock Freezer Bag	75, 100, 125, 150, 150, 240*	2.8, 3.7, 4.6, 5.3, 8.8*
Glad + Cyanocrolate	150, 200, 225*, 225*, 295*	5.5, 7.4, 8.3*, 8.3*, 10.9*

Table 4.2.2: This table summarizes the results of the Ziploc seal bench level experiments.

*Means that the bag failed before the seal.

The results show that a double seal adds a considerable amount of strength as does cyanocrolate, and that it should not be hard using those two features to make a seal that can handle the same amount of pressure as the bag itself. Also, the seal will be oriented such that it is in contact with air rather than water, so that any slight leak will be made up of air and any large leak should be predominantly air.

Other problems could be associated with the slider that the surgeon would manipulate to close the bag. The slider itself creates a small leak so the Ziploc portion of the bag must be in a region in which only gas can leak out. The possibility of a one way or locking slider was considered. It might be preferable that the bag cannot open again. The surgeon could accidentally open it during surgery or during removal. Again a simple way to accomplish permanent sealing would be to place small micro beads of cyanocrolate along the seal. If that seal did not prove strong enough, though it seems it would, it might be possible to make an ultrasonic weld within the abdomen to create a perfect seal.

The most important and difficult aspect of this functional requirement is making sure the blades do not come in contact with the bag. In many of our bench level experiments the bag would get accidentally cut leading to a result similar to that shown in figure 4.2.1.

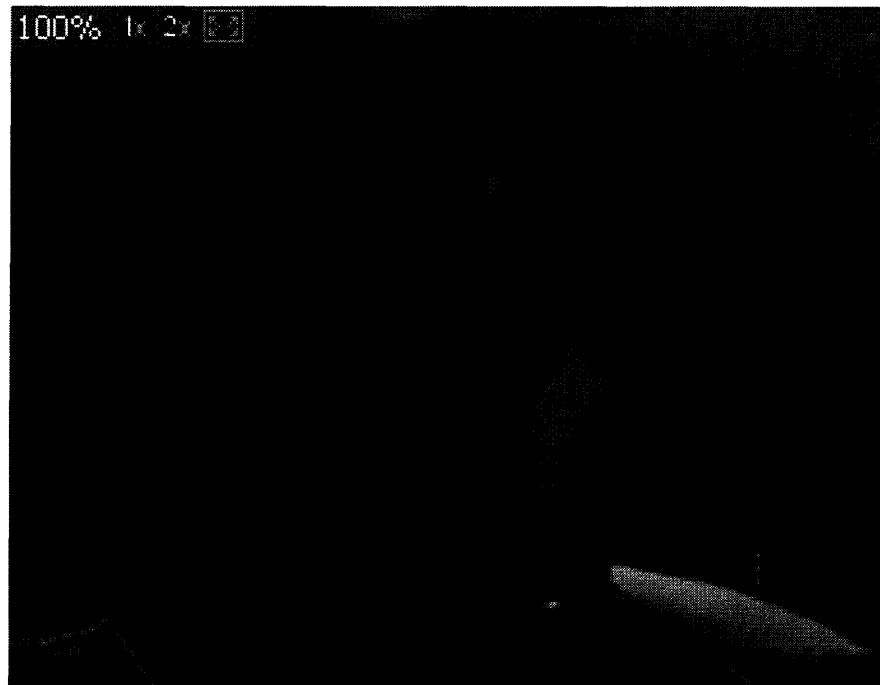


Figure 4.2.2: This is a picture from a bench level experiment illustrating a failure mode in which the rotating blender blades come into contact with the bag module.[7]

The guard is obviously the first line of defense preventing this type of failure. But additional measures can further prevent this type of failure. Inflation of the bag combined with bag shape can keep the guard from touching the blades as well as making sure the bag is not sucked into the blades and breached. The way to accomplish this is by making a portion of the bag that will remain relatively flat when inflated, and make this the region that is near the blades. This doesn't limit overall bag shape significantly, and will be the main feature of the bag whose effectiveness will be tested with the prototype.

4.3 Quick, Easy, Safe Deployment and Retrieval

To make sure we could minimize the time and dexterity requirements that the enclosure module would require, the following steps were taken.

To initially test the feasibility of manipulating the Ziploc feature of the bag and the uterus, Dr Zev Williams, the ob/gyn assisting us with our project made a video in which he uses laparoscopic tools to place a grapefruit in a Ziploc bag in less than one minute. He first had unrolled and opened the bag with the same tools, as shown in figure 4.3.1.

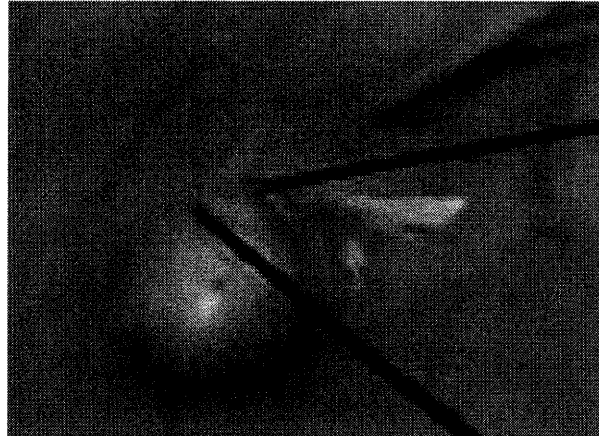


Figure 4.3.1: This is a picture from a bench level experiment by Zev Williams in which he manipulates a grapefruit into a Ziploc bag with only laparoscopic tools.

To make insertion of the bag easy it will be pre-attached and sealed to the Endoblend stem and inserted at the same time. The wrapping up or folding of the bag around the stem for insertion will depend on the final bag shape, but given the thickness of the plastic should not be a major issue. The bag will be rolled up and lead the stem, and only add two bag thicknesses to the diameter of the device. To make it so that almost all the bag and guard can lead the stem, it will be attached to a retractable sheath that pulls the bag into the correct position when appropriate. Fitting through a small hole will be more of an issue for the guard module that Darragh is working on as shown in figure 4.3.2 below.

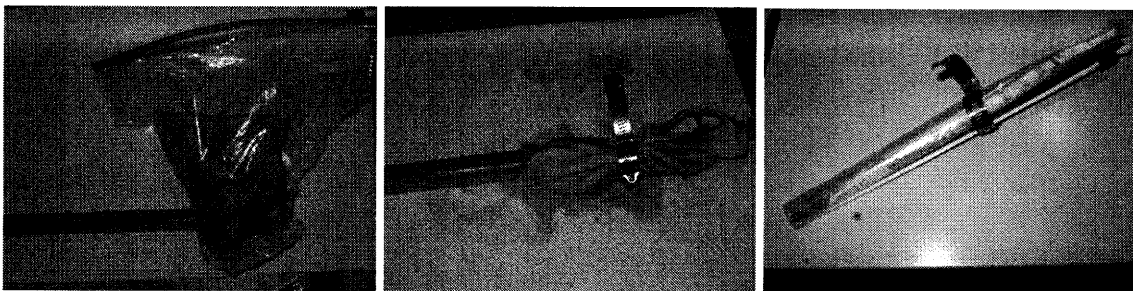


Figure 4.3.2: This picture shows the guard going through a 15mm hole. The bag takes up much less space than the guard folded up, and as such it's folding/wrapping is not as much of an issue. [7]

In order to save time and reduce variation, the bags will be pre-folded/wrapped and kept that way either by a piece of tape or plastic tabs of the bag to be cut. To mitigate the possibility of leaving anything behind a biodegradable tape is preferable. Bench level tests show that the easiest way to make sure not to cut the bag while cutting the tape is to pinch the bag with forceps. Once inside the body with the tape cut, the bag will unfold as it is inflated. The tissue to be processed is manipulated into the bag through the open

Ziploc portion of the bag. The opening is then sealed shut permanently by closing the Ziploc slider breaking the micro beads of glue.

4.4 Transparent

This requirement is met through material selection. Since the bag will only be under low pressure and other forces a thin see through plastic such as what constitutes a Ziploc bag can be used. For the piece of mind of the surgeons, and so that they will know when the tissue has been processed, the surgeons must be able to see into the bag. The only materials that might need to be opaque will be those needed by the guard, but since the guard will not block the blades from a top view, repositioning the optical device will allow the surgeon to keep a visual on the blades and tissue.

5 Prototype and Testing

The prototype will mainly be testing the functional requirement with the most doubt remaining after the initial bench level experiments, which is maintaining the bag's integrity, specifically by having the blades be kept away from the bag by inflating the bag and having the blades be next to a relatively flat spot. At the same time the already tested gravity feed will also be utilized. The bag will also be tested with and without the guard module in place. Construction of the bag is somewhat limited by the ultrasonic welding equipment available, and as such a relatively simple bag shape will be used. A Ziploc bag will be modified in the following way to create a cone with a flat spot on the bottom and a pinched Ziploc top when inflated and sealed as shown in figure 5.1.

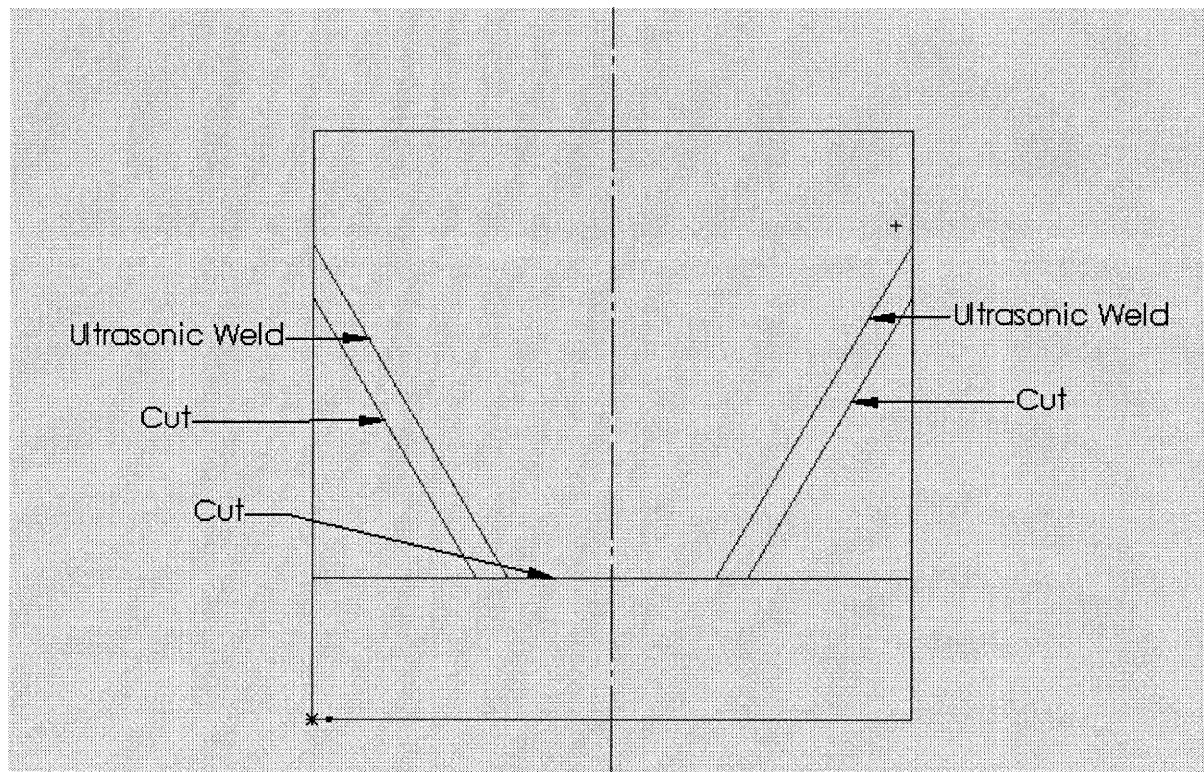


Figure 5.1: This is a drawing of the cuts and welds needed to modify a normal Ziploc bag to attain a flat bottom surface of the correct diameter.

First all the cuts will be made, then another piece will be welded to the bottom in an ellipse pattern, and finally the sides will be re-welded together. A sample of such modification is shown in figure 5.2 below.

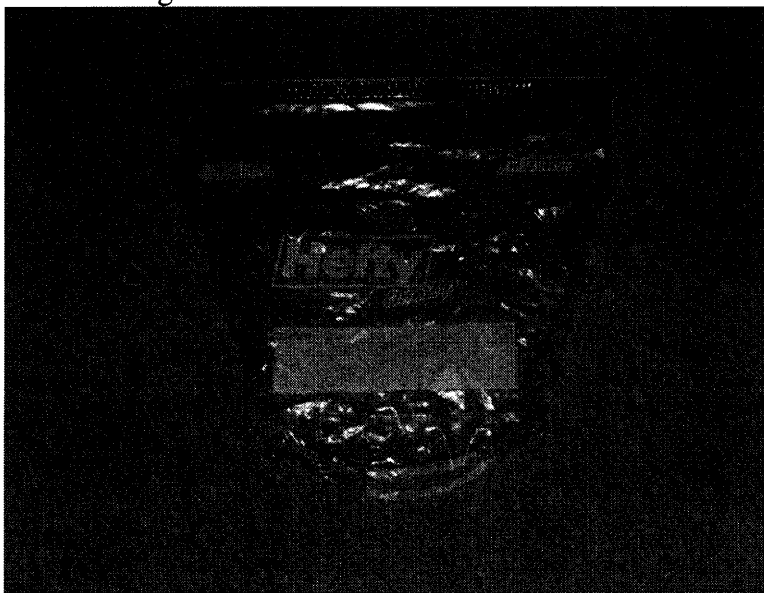


Figure 5.2: Ziploc bag modified to have a flat spot on bottom.

The bag was modified to have a flat bottom and a cone like feed for our final testing. It was integrated with the guard module and an immersion blender as shown in figure 5.3.



Figure 5.3: Ziploc bag modified to have a flat spot on bottom integrated with guard module. [7]

In this integrated device, the guard was raised up from the bag by the immersion blender body. In the final design, the guard itself might provide this raised feature, as it helps to keep the blades even further from the bag. This bag, guard, immersion blender device was used to successfully and safely process a uterus sized piece of beef as shown in figure. The guard module here was almost like a second open bag [7]. It was raised away from the plastic and used itself to create the gravity feed.

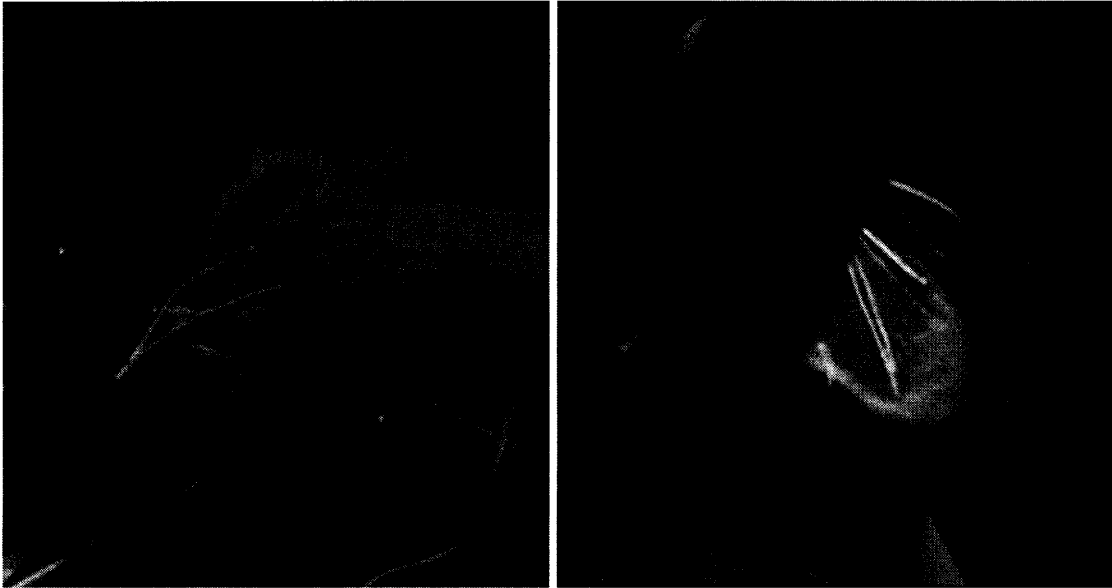


Figure 5.4: Ziploc bag modified to have a flat spot on bottom integrated with guard in joint final experiment [7].

The tests were successful in that the piece of beef was processed in approximately 10 seconds and the bag remained in tact even though during processing the blender was moved around to try and force the blades to come in contact with the guard.[7] The implications of the successful tests are discussed in the conclusions.

6 Conclusions

The successful design and integration of the enclosure module that fulfills its functional requirements will allow this project to continue moving forward. This paper along with the paper on the guard answered the remaining critical questions that preceded putting together a next iteration prototype to use in order to perform animal tests. The main questions answered were what features the bag would need to feed the blades while remaining a safe distance away, and whether or not a Ziploc style seal would be enough to maintain the integrity of the bag.

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