Hand-Assisted Laparoscopic Radical Nephrectomy Specimen Retrieval Bag

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December 8th, 2010

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I. Abstract

Specimen retrieval bags are necessary during a hand-assisted laparoscopic radical nephrectomy for the safe removal of a cancerous kidney from the abdominal cavity. The central purpose of this project is to design and manufacture a more efficient specimen retrieval bag to decrease total operative time of the nephrectomy by decreasing the time it takes to get the cancerous kidney into the specimen retrieval bag. The final two designs selected were a finger port design and an accordion design. Tests were conducted using a model of the human abdominal cavity, which suggested that the final designs are more time efficient than the current specimen bags. In the future, the client will have medical students practice the nephrectomy in a pig lab to test the total time and efficiency of the procedure for each the final designs and compare those results to the current specimen bags.

II. Background

A. Procedure – Hand-Assisted Laparoscopic Radical Nephrectomy

A hand-assisted laparoscopic radical nephrectomy is a procedure used to remove a cancerous kidney from the abdominal cavity of a patient. This procedure uses a small camera called a laparoscope to view the inside of the abdomen or pelvis during surgery. Its use reduces the size of the incisions made on the patient, thereby shortening the post-operative recovery time (Patel, 2010). A laparoscope, a machine for the inflation of the abdomen, and a pair of graspers (Figure 26 Appendix G) are inserted into the abdomen through 3 incisions of 0.5 cm (0.20 in) to 1.5 cm (0.59 in) in length (Dhobada, Patankar, and Gorde, 2006). An extra incision, dependent on the size of the surgeon's hand, is made to allow the surgeon to use his/her hand to assist in the removal of the kidney. A hand-port with gel foam is placed in this incision to ensure easy insertion of the hand. Once the kidney is severed from the ureter and blood vessels, a specimen retrieval bag is used to remove the kidney from the body (Patel, 2010). Images from the procedure can be seen in Figures 1 to 3 in Appendix B.

B. Bags on the Market

The client currently uses the LapSac® Surgical Tissue Pouches, which are manufactured by Cook® Medical. It is a simple plastic bag with a drawstring closure (Figure 4 of Appendix C). There is no widely accepted design on the market. Some surgeons choose to make their own specimen bags, such as the Nadiad bag seen in Figure 5 of Appendix C (Ganpule, and Gotov et al., 2010). Other products with a similar function are the EndoCatch bags, which is pictured in Figure 6 of Appendix C. The most common features among the specimen retrieval bags on the market are the drawstring closure and their flat shape with no fixed structure.

C. Motivation

Although the abdomen is inflated with CO_2, it is usually difficult to retrieve the kidney due to the limited maneuvering space within the abdominal cavity. The fluids present in the cavity and the enlarged size of the cancerous organ make it difficult to remove the kidney. The bag is primarily used in the procedure to prevent metastasis, the spread of cancerous cells from one area and/or organ to another, while the kidney is being removed from the abdominal cavity (Patel, 2010). The abdominal cavity and the incision sites are the main areas of concern for metastasis in this procedure (Dhobada, Patankar, and Gorde, 2006). The bag also helps minimize the size of the incision for the hand port by providing the surgeon with a better grasp on the kidney.

The problem with the current specimen bag is that it is difficult to maneuver the kidney into the bag. Once inside the abdomen, the bag conforms back to its original, flat shape. Because the surgeon only has one hand to work with and a small pair of graspers, he/she cannot hold the bag open to insert the kidney into it. This is further complicated by the size, weight, and slippery texture of the organ. These complications can increase the surgery time by up to 10 minutes. It is critical to reduce the total surgery time as much as possible in order to reduce post-operative recovery time and any risk of complications (Patel, 2010). The main focus of this project is to design and construct a specimen retrieval bag that will minimize the amount of time spent maneuvering the kidney into the bag that also prevents metastasis.

III. Design Criteria

The design must decrease the time required to place the kidney in the bag while protecting the abdominal cavity from metastasis. The bag should be non-permeable and water-tight to prevent tumor spillage. It must also be sterile before use. The bag should support a weight of 4.54 kg (10 lbs) while held from the closure apparatus. The bag must fit through the hand port while containing the kidney. With all of the above features, the surgeon must be able to properly handle the bag with one hand and graspers. For more detailed specifications of the final product, see the Product Design Specifications in Appendix A.

IV. Design

Due to the nature of this project, multiple designs for specific aspects of the current bag were developed. These different aspects can be interchanged to create unique specimen bags that will improve the ease of inserting the kidney into the bag and therefore the total operative time.

A. Enclosing the Kidney

The purpose of the bag in this procedure is to enclose the entire kidney with a secure closure. The bag is maneuvered over the kidney with the help of a single hand and a pair of graspers.

i. Bag Form

1. Accordion

The bag would be shaped as a cylinder in its inflated form and would be able to stack down like an accordion into a thin disk, allowing it to be inserted into the abdomen (Figure 8 Appendix D). The bag would be made from a low-density polyethylene.

2. Finger Ports

For this design, the surgeon has the option to remove his hand from the abdomen and reenter with the bag, or insert the bag through the hand port prior to disconnecting the kidney from the abdomen. This bag would have three finger ports on each side, allowing the surgeon to properly insert his/her hand in the ports from either side (Figure 9 Appendix D). This bag would also be constructed from low-density polyethylene.

3. Rigid Bottom Plate

Regardless of the form or material of the bag, a rigid piece of curved plastic would be adhered to the bottom of the bag (Figure 7 Appendix D). This material would allow the bag to keep its structure. The bag would be made from low-density polyethylene and the ridged bottom from moldable silicone.

ii. Closure Features

1. Drawstring

A simple drawstring could be affixed to the opening of the bag to allow proper closure of the bag, as well as to provide a material that can be easily grasped and pulled on (Figure 10 Appendix D).

2. Concentric Rings

A flexible set of plastic rings would be added to the opening of the bag to create a concentric rings closure. This set of plastic rings would overlap, allowing the mouth of the bag to be opened or closed. The surgeon only needs to exert a minimal amount of pressure to open or close the set of rings, which would remain in position until acted on by the surgeon (Figure 11 Appendix D).

3. Tabs

The addition of a 2.54 cm by 2.54cm (1 in x 1 in) tab on both sides of the bag's opening (Figure 12 Appendix D) would be helpful when using the graspers to get an adequate hold on the bag.

B. Lining the Abdomen

Based on the current designs on the market and information provided by the client, the design of the bags used in this procedure focuses on enclosing the kidney within a fitted bag large enough to hold the cancerous organ. This method encloses the kidney, which thereby protects the abdominal cavity by minimizing contact with the kidney and reducing the risk of metastasis. However, an alternative way of using the bag is to line the abdomen instead of the kidney. The bag would be inserted into the abdomen at the beginning of the procedure and rest on the floor of the cavity. Once the organ has been detached from the body and placed in the bag, the edge of the bag would be lifted over the kidney and through the hand port. This action would be simple due to the relatively large size of the bag, which should line the entire abdomen. To remove the organ, the edges of the bag, exposed from the incision, would be pulled (Figure 13 Appendix D).

The bag would be shaped as a cylinder in its inflated form with a 20 cm (7.87 in) diameter and 40 cm (15.75 in) height. The bag would be made from a low-density polyethylene. To keep its shape two flexible plastic rings would be used. A ring with a 20cm (7.87in) diameter would be attached to the bottom of the bag and a 10cm (3.94in) diameter ring would be attached to the top of the bag.

C. Materials and Sterilization

The material of the specimen bag must be flexible, smooth, strong, and also be able to withstand a weight of 4.54 kg (10 lbs) while being held by its closing device. It must not corrode when briefly subjected to the internal human environment, such as blood and bodily fluids within the abdomen. Based on these factors, low density polyethylene was selected as the primary material to form the body of the bag. According to Dynalab Corporation, a manufacturer of low density polyethylene, their product can withstand temperatures between -50°C (-58°F) to 80°C (176 °F) and can be exposed to temperatures as high as 95°C (203 °F) for a short period of time. It can be translucent to opaque in color, has a tensile strength of 1172 kPa (1700 psi), and is not reactive at room temperature (Dynalab Corporation, 2010). The drawstring will be made of nylon string because it is cheap and has been proven to work on other designs.

The threat of contamination continues to be a concern during the manufacturing process; however, many steps can be taken to reduce the amount of contamination and ensure a sterile product. The specimen retrieval bag will be manufactured and packaged in a sterile environment, and will be removed from its packaging in the sterile operating room. The polyethylene material cannot be autoclaved and cannot undergo chemical sterilization. To further ensure a sterile product, gamma radiation can be used. This is the most accepted method currently used to sterilize polyethylene; however, exposing polyethylene to radiation has shown to slightly decrease the wear of the material *in vivo* (Crowninshield, and Muratoglu, 2010). This process has deep penetration power, which allows for the sterilization of densely packed and pre-packed products (Sharma, 2010). There are no toxic residues and no quarantine periods required (Sharma, 2010). Gamma radiation appears to be an effective additional form of sterilization for the retrieval bag.

V. Design Matrix

In order to compare all of the different aspects of the above designs, a design matrix (Table 1) was constructed. First, the different designs were grouped based on whether they focused on protecting the abdominal cavity or the organ. For the designs that involved protecting the organ, they were further subdivided based on their overall form, the types of closures they could have, and whether tabs could be added to the openings. Each category was weighted based on its importance to the overall design, with all of the categories adding to 100 points. From these comparisons, it was decided that the "finger ports" design and the "accordion" design are the final designs for this project.

Table 1. In order to determine the final design, the features were evaluated with a design matrix.

Protection	Sub	Options	Client Preference (40)	Practicality (40)	Ease of Construction (20)	Total (100)
Kidney	Form	Accordion	23	37	10	70
		Finger Ports	35	20	15	70
		Rigid Bottom	25	25	10	60
	Lid	Drawstring	30	20	15	65
		Concentric	35	20	10	65
		Tabs	20	35	10	65
Abdomen	Cylinder		20	10	10	50

A. Client Preference

Given the professional stance of the client and his intimate knowledge on the procedure, his suggestions were taken into consideration when comparing designs.

B. Practicality

Practicality is important because it considers the possibility of each design being successful while taking into account how it will reduce the time it takes to get the kidney into the bag.

C. Ease of Construction

Ease of construction was considered because it is important for the bag to be easily constructed in order to maintain a low manufacturing cost.

VI. Final Designs

Keeping in mind that each hand-assisted laparoscopic radical nephrectomy procedure is unique due to various factors, such as the size of the kidney, the degree of cancerous growth, and the preferences of the surgeon, two final designs were selected. The finger ports design and the accordion design were selected for the body of the bag with both designs featuring a drawstring closure.

A. Finger Ports Design

One of the main issues urologists have with the current specimen bags on the market is it is extremely difficult to transfer the kidney into the specimen bag since the mouth of the bag tends to conform back to its flat shape. This main area of concern is what is primarily addressed in the finger ports design. The six finger ports around the bag, three on each side, allow the surgeon to essentially hold the mouth of the bag open, making it much easier to guide the kidney through the mouth and into the bag. With any three fingers in the ports and the bag resting in the palm of the hand, the mouth of the bag is brought around the kidney, and once the kidney is entirely through the mouth of the bag, the finger ports are used to bring the rest of the bag over the remaining portion of the kidney. The surgical graspers used in the operation can also be used to pull the mouth around the kidney. Above the finger ports is a drawstring, which will be pulled after the kidney is entirely closed within the bag to help prevent metastasis. The drawstring not only ensures the complete enclosure of the kidney in the bag but also makes for a simple, easy removal of the bag and kidney through the hand port.

B. Accordion Design

The second final design incorporates the accordion bag design and the drawstring closure into one concept. The accordion bag will be able to collapse into a flat position and also expand into a full size bag; much like an accordion expands and contracts. The bag will be made from polyethylene in such a way that gives the side of the bag the general accordion shape and function. The bag will be inserted into the abdominal cavity in its flat formation and placed at the bottom of the cavity. The polyethylene material combined with a large number of seals on the edges of the plastic will provide enough structure for the bag to maintain its shape. When the kidney is ready for extraction, it is maneuvered on top of the bag and the sides of the bag are pulled upward. Once the drawstring is tightened, the bag can be removed through the hand port.

VII. Construction

A. Finger Ports Design

The body of the finger ports design is 20.32 cm x 25.40 cm (8 in x 10 in). The mouth of the finger ports is semicircular in shape with a diameter of 4 cm (1.57 in) and an outer perimeter of 6.35 cm (2.5 in). The finger ports have a length of 7.62 cm (3.0 in). First, the finger ports are sealed onto a 30.48 cm x 22.86 cm (12 in x 9 in) piece of plastic using a straight impulse heat sealer (Figure 14 Appendix E). 3.81 cm (1.5 in) was folded over at the top of the bag to create a lip. The sheet was then trimmed down to 20.32 cm x 25.40 cm (8 in x 10 in). This procedure was done for another sheet of plastic and the two bags were sealed together with the finger ports facing the inside of the bag. The bag was then turned inside out to create a smooth edge on the outside of the bag. Finally, a nylon string was pulled through the lip at the top of the bag to create the drawstring closure (Figure 19 & 20 Appendix F).

An alternative method of construction was attempted using moldable silicone (EcoFlex). A clay mold was sculpted from earthenware clay in the form of the body of the finger ports bag (Figure 16 Appendix E). It was originally planned to coat the mold with a thin layer of EcoFlex and allow it to dry. Placeholders for the finger ports were to be molded out of clay and positioned onto the initial layer of EcoFlex once it had cured. An additional layer of EcoFlex was to be applied on top of the placeholders to form the finger ports. However, when trying to remove the first layer of EcoFlex from the clay mold, the material turned out to be extremely stretchy, which is not ideal for a specimen retrieval bag design (Figure 17 & 18 Appendix E). Upon this discovery, this method of construction was discontinued.

B. Accordion Design

Two approaches were considered when making the accordion bag. The impulse heat sealer has a straight edge of 30.48 cm (12 in). The edge is inflexible and the length cannot be changed. This is a problem due to the fact that the accordion design has a circular shape; hence, sealing the layers with a straight-edged impulse heat sealer was difficult. The bag was constructed by cutting out polyethylene rings and sealing them to form the shape of an accordion. The plastic rings have an inner diameter of 15.88 cm (6.25 in) and an outer diameter of 20.32 cm (8 in). The impulse heat sealer was used on the edges of the rings to seal together the individual layers. The bottom-most ring was attached to the second ring by the outer radius, and the second ring was attached to the third ring by the inner radius. This process was continued for the remainder of the structure. There are a total of six layers with an additional length of polyethylene that contains the drawstring. The bag stands up to a maximum height of 20.32 cm (8 in). A single circular layer of polyethylene with a diameter of 20.32 cm (8 in) was attached to the outer diameter of the first ring to form the bottom of the bag (Figure 21 & 22 Appendix F).

C. Limitations

During the procedure of making the prototypes, several problems surfaced. There were difficulties in terms of the material purchased for manufacturing the finger ports design using a mold. The material turned out to be too elastic, so the product could not maintain the general shape of a bag after it was removed from the mold and would not have been able to withstand the weight of a cancerous kidney.

The impulse heat sealer also presented difficulties while making the accordion design. The sealer has a straight edge of 30.48 cm (12 in). The edge is inflexible and the length cannot be changed. Since the impulse heat sealer contains a straight, inflexible shape and the design requires a curved seal, it was difficult to properly seal the rings along the inner circumference of the rings. In order to compensate for this setback, hundreds of individual vertical seals were made using the edge of the heat sealer around the entire perimeter of each inner seal (Figure 15 Appendix E). Unfortunately, this method of construction cannot guarantee a watertight seal.

VIII. Testing

Upon successful construction of the prototypes of the two different specimen bag designs, the prototypes were tested to determine the effectiveness of each design in collecting the kidney from the abdomen. In an ideal testing situation, both prototypes would be used in a hand-assisted laparoscopic radical nephrectomy performed on a living pig. Such “pig labs” are typically performed in medical schools and hospitals to provide medical students and interns with the opportunity to practice surgeries in a realistic setting before performing the procedure on a human being. However, as previously learned from the client, no pig labs were scheduled during the construction of the two prototypes; therefore, testing in a pig lab was impossible this semester.

A testing environment was generated that accurately replicates the conditions encountered during an actual hand-assisted laparoscopic radical nephrectomy. An abdomen, a cancerous kidney, a laparoscope, a pair of graspers, and a specimen retrieval bag were all needed in order to properly simulate the removal of the kidney. A cardboard box with dimensions of 39.37cm x 29.21 cm x 16.51 cm (15.5 in x 11.5 in x 6.5 in) was used for the abdomen. The box was stuffed with slippery, dense packing material to simulate the internal organs encountered by the surgeon during the procedure. Three holes, which correspond to the hand port, grasper incision and laparoscope incision, were cut on the top of the box. The hand port hole had a diameter of 10.80 cm (4.25 in) and small holes were made for the graspers and the cord of the webcam laparoscope. A model cancerous kidney with dimensions of 17.78 cm x 11.43 cm x 8.89 cm (7 in x 4.5 in x 3.5 in) and a weight of 3.31 kg (7.3 lbs) was constructed from clay and metal bolts (Figures 23-25 Appendix G). The kidney was wrapped in plastic wrap and covered in aloe vera in order to properly replicate the texture of a real kidney. The laparoscope was simulated using a webcam, and a pair of graspers was used (Figure 26 Appendix G).

The kidney was placed into the shoebox along with one of the prototypes. The timer was started when one of the tester’s hands entered the hand port, and the timer was stopped when the bag, along with the kidney, was removed from the box. Times were recorded for a normal flat bag which replicated the LapSac® specimen bag, the finger ports prototype, and the accordion prototype. Two separate trials were performed for the finger port specimen bag: one where the tester places the bag inside of the box and then inserts his/her fingers into the finger ports and another where the tester inserts his/her fingers into the finger ports prior to putting the bag in the box. These two methods represent the surgeon’s preference as to whether or not he/she would place the specimen bag inside the abdominal cavity at the beginning of the surgery; or remove his/her hand from the abdomen, retrieve the specimen bag and reinsert his/her hand into the abdominal cavity. The results of the time trials for each bag and technique are found in Table 2.

Table 2. Individual test times for each bag.

Specimen Bag	Time (s) – Kevin	Time (s) – Sarah	Time (s) – Vivian	Time (s) – Claire	Time (s) – Josh
Flat bag (control)	75	44	30	45	81
Finger port (inserted with fingers not in ports)	120	32	43	94	58
Finger port (inserted with fingers in ports)	34	22	50	38	30
Accordion	19	20	21	23	21

In general, when the finger ports prototype was initially inside the box, it took longer for the tester to retrieve the kidney. In all cases, except for one, the testers were able to extract the kidney from the box in much less time when the bag was inserted into the box with their fingers already placed in the finger ports. In most cases, the flat bag took the longest for the testers to retrieve the kidney, except for two people. In both of these cases, having the finger ports prototype initially inside the box took the longest amount of time. This is probably due to the specific technique used rather than the actual design of the prototype. However, it is undeniable that the accordion bag prototype is the design that allowed for the quickest and most efficient removal of the kidney considering this was the fastest time for all five testers.

In order to test the strength of the seals, individual weights were added into a flat bag. After 75 seconds of holding a weight of 6.94 kg (15.3 lbs), the plastic, not the seals, started to tear (Figure 27 Appendix G). Another test was conducted to test the watertight capabilities of the seal by inserting water into the flat bag. Upon inspection of the bag, the seals proved to be watertight (Figure 28 Appendix G).

IX. Future Work

Given the difficulty encounter during construction, a heat sealer that could create rounded seals would be ideal for the construction of both bags. This type of sealer could create watertight seals along the inside perimeter of the accordion bag, which was not possible with the straight impulse heat sealer. This would make the accordion bag completely watertight which could not be done with the current strait impulse sealer. Also, a heat sealer that could create rounded seals would provide the finger ports of the finger ports design more 3D shape. This would make it easier for the surgeon to locate the finger ports once the bag is inside the abdominal cavity and most likely decrease the time it takes to get the kidney into the bag even more.

The next step in determining if the designs facilitate the removal of the kidney is to have medial students and surgeons use the prototypes. Because time taken to remove the kidney is largely dependent on surgeon performance and ability, whether the design decreases operative time can only be assessed once surgeons have tested each bag. For more accurate assessment of the prototypes ability to reduce the time it takes to get the kidney into the specimen retrieval bag, interns and surgeons will perform a nephrectomy using each of the prototypes and the current bag in a pig lab conducted by the UW-Madison hospital. These results will show both user preference and more accurate removal times compared to the testing performed out of the model abdomen.

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