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A New Laparoscopic Morcellator Using an Actuated Wire Mesh and Bag

Laparoscopic morcellation is a technique used in gynecological surgeries such as hysterectomy and myomectomy to remove uteri and uterine fibroids (leiomyomas) through a small abdominal incision. Current morcellators use blades or bipolar energy to cut tissue into small pieces that are then removed through laparoscopic ports in a piecewise manner. These existing approaches have several limitations; (1) they are time consuming as the tissue must be manually moved over the devices during the cutting step and removal is piecewise, (2) they can lead to accidental damage to surrounding healthy tissue inside the body and (3) they do not provide safe containment of tissue during the morcellation process which can lead to seeding (spreading and regrowth) of benign or potentially cancerous tissue. This paper describes a laparoscopic morcellator that overcomes these limitations through a new design that is based on an enclosed, motor-actuated mesh that applies only an inward-directed cutting force to the tissue after it has been loaded into the protective mesh and bag. The deterministic design approach that led to this concept is presented along with the detailed electromechanical design. The prototype is tested on soft vegetables and an animal model to demonstrate successful morcellation and how the device would be compatible with current clinical practice. Results show that the time required to morcellate with the new device for a set of tests on animal tissue is relatively uniform across samples with widely varying parameters. Including tissue manipulation and extraction time, the new device is shown to have an improvement in terms of speed over current morcellators. The mean time for cutting animal tissue ranging from 100 g to 360 g was 30 s with small variations due to initial conditions. The time for cutting is expected to remain approximately constant as tissue size increases. There is also minimal risk of the protective bag ripping due to the inward-cutting action of the mesh, thereby potentially significantly reducing the risk of seeding during clinical procedures; thus, further increasing patient safety. Finally, this design may be applicable to other procedures involving removal of tissue in nongynecologic surgeries, such as full or partial kidney or spleen removal. [DOI: 10.1115/1.4026294]

Keywords: laparoscopic devices, minimally invasive surgery, morcellation, wire mesh

1 Introduction

Over 600,000 hysterectomies are performed each year in the United States, making it the second most common surgical procedure for women [1]. Often, hysterectomies and other gynecologic surgeries such as the removal of uterine leiomyomas (fibroids) can be performed laparoscopically. The current standard laparoscopic procedure for the removal of tissue through a small abdominal incision is as follows: a morcellator (Fig. 1(a)) is inserted into the abdomen (Fig. 1(b)), either directly or through a trocar. A tenaculum is extended through the main shaft of the morcellator, grasping the tissue and pulling it towards the rotating blades inside the sheath (Fig. 1(c), inset). The tissue is peeled away (Fig. 1(d)) or cored and pulled through the shaft. If parts of the tissue are cut completely from the central mass (i.e., the central tissue is dropped) or fragments fall around the abdominal activity, these pieces are picked up and brought towards the morcellator and the grasping-cutting-pulling cycle continues until the tissue has been removed.

An immediate procedural risk is posed by the proximity of the morcellator blade to critical structures in the abdomen, which can result in major injury to a loop of bowel or colon [2]. Since "it is likely that surgeon experience confers some protection from these injuries," [2] some surgeons report being apprehensive about allowing their senior residents or even surgical fellows [3] to perform morcellation. The largest postoperative risk occurs from fragments scattering from the main tissue due to the forces being directed outwards from the center of the tissue. Small pieces of tissue which are inadvertently left inside the body increase the probability of seeding (spreading and regrowth) [4–6]. Seeding is especially dangerous when a tumor is malignant, since it may result in further spread of the cancer. In addition to safety risks, current morcellators are inefficient because they operate in a piecewise or serial manner. Studies of the operating time required have suggested that tissue size and surgeon training may prolong the length of the morcellation step [7,8], and in the case of enlarged uteri the average morcellation time can be over half an hour [9].

The laparoscopic morcellator presented in this paper has the potential to be safer and more efficient than current gynecologic morcellators. The enclosed, bladeless design could decrease the

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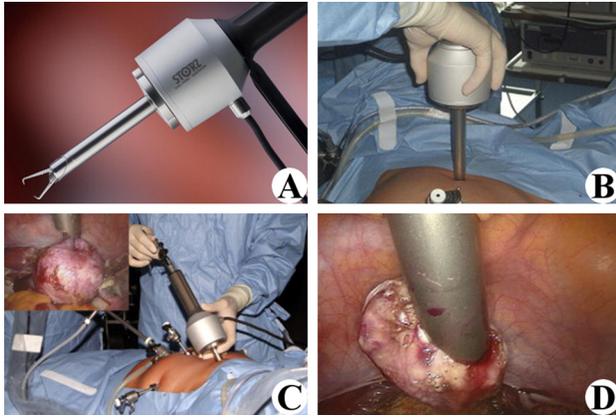


Fig. 1 Overview of the most common way morcellation is currently performed. Figure modified from Ref. [18]. (a) Rotocut G1 morcellator (Karl Storz GMBH, Tuttlingen, Germany). This morcellator is designed for laparoscopic hysterectomies and myomectomies. (b) Insertion directly into abdominal cavity. (c) Surgeon holds the tenaculum, grasping the tissue (shown on inset). (d) Cutting the tissue once it is pulled inside the sleeve.

probability of accidental damage to healthy tissue and the probability of seeding. The parallel cutting mechanism of the new morcellator may also decrease operating time, especially in procedures involving larger tissue.

2 Design Process

At the start of the design process, input was obtained from both the active users of current morcellation devices (surgeons) and those who analyze the morcellated tissue (pathologists). A total of five surgeons from two hospitals with primary expertise in gynecology and one pathologist familiar with morcellated samples were interviewed. A thorough review of the medical literature was also conducted to complement the end-user perspectives.

It was determined that the time taken to morcellate tissue varies primarily according to surgeon skill and tissue size. In the majority of cases, single pieces of tissue are less than 10 cm in diameter [5] and can have a consistency similar to a raw potato, bovine kidney, boiled squid [3], or bovine tongue (for uteri) [10]. However, fibroid sizes can range from the order of 1 cm to over 15 cm in diameter with consistency ranging from almost-liquid to calcified. This variation in tissue consistency can present a challenge to current morcellators. A limitation of the current grasping-and-peeling designs of current morcellators is that soft tissue cannot be efficiently manipulated with the tenaculum while hard tissue can dull or break the morcellator blades [11], thus, making this approach suboptimal for many tissue types. Furthermore, larger sized tumors quickly become difficult and costly to be morcellated with the current devices [12] due to the piecewise nature of the morcellation process with these devices.

Coupled with the safety risks and inefficiencies of the current designs, these constraints not only represent difficulties in current surgeries requiring laparoscopic morcellation, but may prevent wider-spread use of laparoscopy. An improved device would need to eliminate the major safety issues present in current devices and decrease morcellation time for currently difficult cases, making it more uniform across procedures. This research led to a set of functional requirements for an improved morcellator that were used to guide the concept generation and selection as part of a deterministic design process [13]:

- (1) remove tissue up to 12 cm in diameter
- (2) cut through tissue with a consistency similar to that of: raw potato, squid, kidney, and cow tongue
- (3) fit through a standard 1.5 cm trocar or a similar size incision
- (4) prevent seeding and accidental damage to nearby healthy tissue

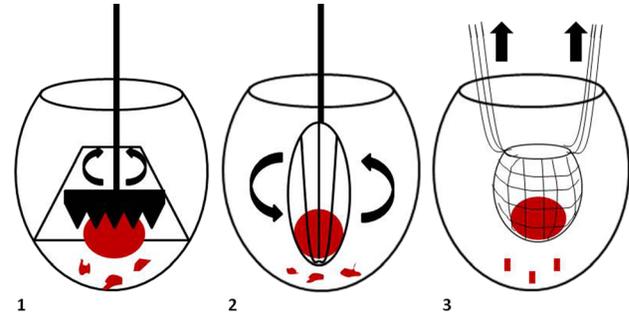


Fig. 2 Initial schematic rendering of three concepts in the mechanical debulking strategy. The first concept is the addition of a modified blade cover and a bag surrounding current morcellators. The second concept is rotary cutting along the edge of the tissue, with pieces falling into a bag. The third concept is linear radial cutting with a mesh, such that pieces fall into the surrounding bag.

- (5) be more efficient for procedures currently requiring over 15 mins of morcellation time
- (6) maintain tissue structure required for pathologic analysis by producing intact pieces of tissue [14]
- (7) have comparable cost to current disposable devices (~\$700) [15]

Based on these functional requirements, the strategy of enclosing the tissue in a bag and using a cutting mechanism to safely morcellate the tissue in a manner that protected the bag was selected. The three most promising concepts which emerged from this strategy selection (Fig. 2) were

- (1) altering the current morcellator by attaching a protective blade cover along with a bag to its distal end
- (2) using a “whisk” in a bag for rotary cutting
- (3) using a mesh in a bag for linear radial cutting

These three concepts were evaluated against the current standard morcellator using a Pugh Chart (Table 1). For the scoring, +1 corresponds to having a noticeable advantage over the current technology in a specific category, 0 corresponds to having a similar capability, and -1 corresponds to a marked disadvantage. The category selection was driven by the identified functional requirements.

The linear radial cutting idea emerged as the most promising, primarily due to the fact that the containment mechanism prevents spillage and is protected from outward directed forces and that a single pass is required for the entire process, with cutting speed and maximum tissue size fixed by external parameters. The cost of the device was estimated to be similar to other commercially available laparoscopic morcellators. Maneuverability was marked down over the current standard since the proposed device requires tissue to be manipulated into a bag prior to cutting.

While the time required for manipulation of tissue into the bag and cutting speed were deemed to be weakly dependent on size,

Table 1 Comparison of concepts with current market leader (bladed morcellator)

Attributes	Current bladed morcellator	Bladed morcellator with cover and bag	Rotary cutting	Linear radial cutting
Safety	0	1	1	1
Cost	0	0	1	0
Maneuverability	0	0	0	-1
Tissue size range	0	0	-1	1
Tissue density range	0	0	-1	1
Cutting speed	0	1	1	1
Ease of pathology	0	0	0	0
Total	0	2	1	3

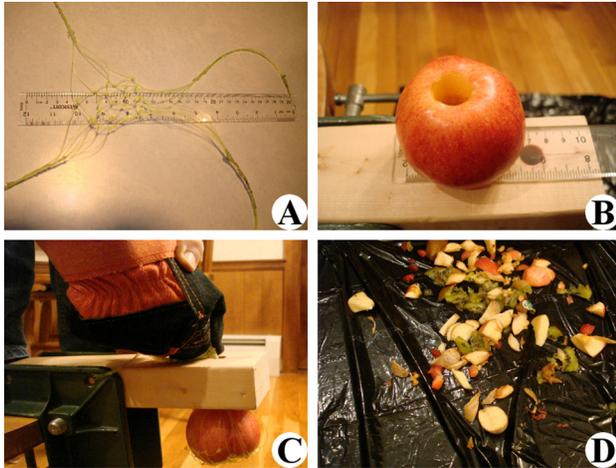


Fig. 3 First bench-level experiment for concept validation. (a) Hand-woven mesh made out of nylon fishing line, approximately 5 cm in width. Wires are connected outside of the cutting area for ease of pulling. **(b)** A cored apple with diameter much larger than a hole drilled in the wooden board; the board is the surface against which the cutting happens. **(c)** The apple is held in the mesh and force is applied upwards. **(d)** Fruit samples are reduced in size as the mesh is successfully pulled through.

the time for extraction of tissue was expected to scale with tissue size. However, three features of the extraction process were expected to lessen the effect of this scaling. First, part of the tissue would be compressed and extracted automatically along with the mesh. Second, not all tissue would have to be extracted from the bag to be able to retract the bag through the trocar (especially if the tissue were in small pieces). Finally, operating rooms tend to have access to reasonably powerful wall suction pumps and the pieces are trapped in the well-defined area of the bag. Thus, it was estimated that large tissue could be cut and extracted significantly faster than with the current method. Small pieces of tissue were expected to take comparable time to current morcellators.

3 Cutting Mechanism Validation and Characterization

Before beginning the detailed design of the device, a number of bench-level experiments were performed in order to validate the feasibility of the selected concept, after which a more quantitative characterization of the cutting mechanism was performed. The first experiment for concept validation was done with a rough 5 cm by 5 cm grid mesh made out of 18.1 kg tensile strength monofilament nylon fishing line (Fig. 3(a)). The mesh pattern was created by hand with double knots. Using a board with a 1.5 cm hole drilled through it to simulate a typical laparoscopic incision diameter, food samples of varying consistency (a strawberry, an unpeeled kiwi, a cored apple, and an unpeeled potato), all initially larger than the hole diameter (Fig. 3(b)), were placed into the mesh beneath the board. The ends of the mesh were secured by hand over the board (Fig. 3(c)) and the mesh was successfully pulled through the samples, resulting in pieces of material reduced in size to fit through the hole (Fig. 3(d)).

While these early experiments demonstrated that the radial cutting approach could be used to successfully morcellate various samples with properties equivalent to tissue, the effort required to pull the mesh through the hole was significant. This information was used to select an initial mesh size that would be used for a more detailed set of experiments which were then performed with an Instron Model 5566 tensile testing machine so that the force required for pulling on the mesh could be quantified.

For the experimental setup, a 64 mm thick black acrylic sheet with a 1.5 cm hole through the center (to simulate a standard tro-

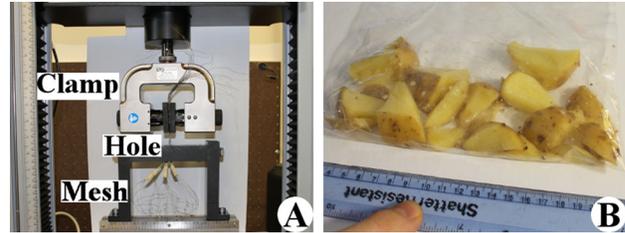


Fig. 4 (a) The mesh wires extend through the 1.5 cm hole in the plastic and attach to the clamp. The Instron pulls up while the plastic provides the normal force required for cutting the specimen. **(b)** The specimen is cut and the pieces are captured in a bag. The pieces are commensurate with the mesh spacing along at least one side.

car diameter) was attached to one side of the Instron and after the target sample was placed in the mesh. The ends of the wire were gathered through the hole in the cutting surface and secured to the Instron clamp (Fig. 4(a)). The Instron exerted an upward force on the wires as the clamp moved upward and caused the specimens to be sliced into pieces commensurate with the dimensions of the mesh spacing (Fig. 4(b)). A bag was placed around the specimen during testing to prevent leakage onto the equipment and to collect the specimen in a manner similar to the clinical workflow. Force was plotted against extension, and representative maximum force values were noted for each case. Video footage of experiments was taken for more detailed visual analysis.

Meshes with dimensions $n \times n$ (where n represents the number of wires per side) were used to cut a variety of materials of similar consistency to some uterine fibroids: potato, squid, kidney, and cow tongue. The nonbiological tissue (potato) was also chosen for ease of experimentation in the early validation stage. Tissue sample sizes for potato, kidney, and tongue were chosen such that they filled the mesh and would not pass easily through the 1.5 cm hole. Each wire had a diameter of 0.3 mm and was made from steel. Data were examined to determine the functional form of the change in maximum force exerted as a function of the number of

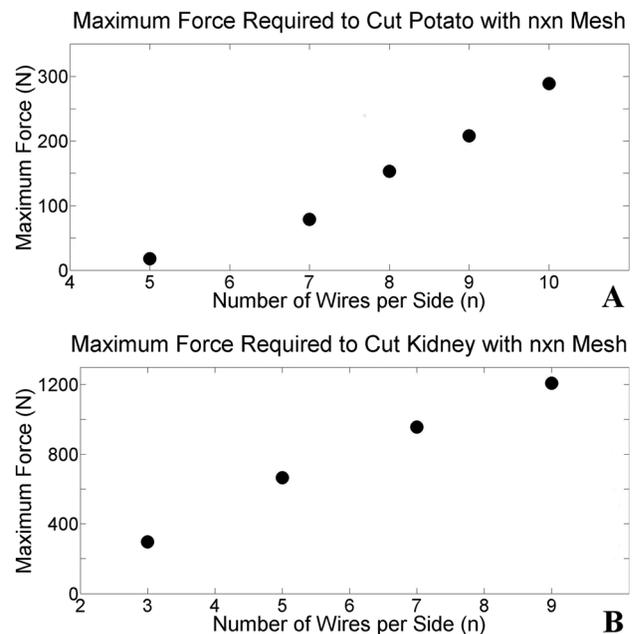


Fig. 5 Meshes with dimensions $n \times n$ (where n represents the number of wires per side) were used to cut potato (a) and kidney (b) samples. The meshes were made of 0.3 mm diameter steel wire. Data points represent the maximum force attained in pulling the mesh through the sample. The maximum cutting force increases approximately linearly in n .

wires per side during cutting potato (Fig. 5(a)) and kidney (Fig. 5(b)) as these samples were found to be the most representative since appropriately-sized homogenous pieces could be easily created from the same kidney and consistently-sized potatoes could be chosen. As expected, the maximum force required to cut both types of tissue increased roughly linearly as the number of wires n increased. Compression sometimes occurred prior to or concurrently with cutting and helped to pull samples through the hole. For example with squid, the samples were not large enough to fill even the 6×6 mesh and only light compression was needed before they began to slip through the hole. Here, the maximum force required remained essentially steady (standard deviation 9.4 N about a mean of 117 N), as expected.

Since it is difficult to preoperatively predict the density of tissue to be removed in a standard clinical setting, the actuation force was specified as the maximum force found from the experimental testing. This value was approximately 1200 N from cutting a kidney with a 9×9 mesh (~8 cm diameter). To satisfy the functional requirement of morcellating tissue up to 12 cm in diameter, the 1200 N force was multiplied by a 1.5 safety factor to account for tissue inhomogeneity, different mesh weaves, and to provide an acceptable safety factor for the end user, for a total device rating of approximately 2000 N. The data from these experiments suggested that the cutting force cannot be easily and safely achieved by pulling on the mesh by hand, so it was determined that the cutting action of the mesh should be motor-actuated.

4 Detailed Design and Assembly

The data collected on the mesh cutting was used along with first-order calculations to provide specifications for the motor, bearings, and structural components for a hand-held actuation system. Given the large force required for morcellation, the approach taken was to provide an external motor coupled via a flexible shaft to a handheld device that could be lightweight enough to facilitate the manipulation of the tissue into the bag. However, a lightweight design is not as critical for this approach as it is for current morcellators because there is no need for repeated fine manipulation of the tool after the tissue is placed inside the bag. A rendering of the design concept identifies the main active components (Fig. 6).

4.1 Cutting Mechanism. The wire-mesh cutting mechanism was deemed the most critical module and was divided into the following submodules: wire mesh and support rod. Having demonstrated successful cutting of tissue with the steel wire, a number of equivalent strength materials that were more conducive to weaving were chosen for prototyping. A small hand-made batch of prototype meshes was woven by a professional weaver out of SpiderWire Spectra™ braid 22.7 kg tensile strength fishing line with 0.3 mm diameter. These meshes (Fig. 7(a)) had a cutting surface of 30 cm by 30 cm and were made in an open, knotless weave. The wire threads extended 1.1 m on each side beyond the cutting surface of the mesh to allow for travel between a separate deployment mechanism and a motor-driven spool to which the ends are attached. A commercially available rip-stop nylon bag (TRS200™, Anchor Products) was chosen to encase the mesh (an almost identical bag with commercial deployer, TRS190SB2™ [16], is shown in Fig. 7(b)). The bag had an opening diameter of



Fig. 6 A CAD rendering of a prototype with main system components identified



Fig. 7 A professionally woven mesh (a) made of 22.7 kg tensile strength SpiderWire™ line. The diagonals of the squares are 1.5 cm in length. The threads extend 1.1 m away from the edges. A commercially available surgical bag shown with the deployer (TRS190SB2™, Anchor Products) (b) was used to encase the mesh and prevent tissue spillage. Fig. 7(b) modified from Ref. [16].

14.2 cm, a length of 28.2 cm, and a volume of 3000 mL [17]. The bag does not experience forces of a magnitude that would cause tearing using the proposed device; thus preventing tissue or fluid leakage during surgery.

The support rod was critical to the operation of the mechanism as it would need to withstand large reaction forces acting on it when the wire mesh with tissue was pulled towards it, causing the tissue to be cut by the wire mesh. The design goal was to have as thin a wall as possible so that the maximum amount of tissue could be pulled through it. A steel tube with an outer diameter of 1.43 cm and a wall thickness of 0.89 mm was found to possess the required yield strength.

4.2 Actuation. The actuation of the mesh was accomplished with an electric motor that transmits torque to a spool, causing it to rotate and wind the wires around it; thus, pulling the mesh into the stainless steel support rod (Fig. 8). Based on feedback from end-users, the linear speed of the wire retraction was set to approximately 1.2 cm/s. Using a 2.54 cm diameter spool ensures that a large (12 cm diameter) tumor can be cut in approximately 10 s, while giving the surgeon time to turn off the motor before the mesh comes completely out of the proximal end of the tube and contaminates the spool.

Since pulling the wires is a fixed rotation frequency operation and the motor is off-board, an AC motor was chosen for the prototype. Given a 2.54 cm diameter spool, the torque required at the spool was approximately 25 Nm to meet the force requirement. For simplicity, the prototype features a Bison 482 series split phase parallel shaft gearmotor (115 VAC, 3.97 A, 8 RPM, and 110 Nm), which satisfies the torque and speed requirements without additional external gear reductions. Alternatively, a smaller motor could be used in conjunction with a worm-gear reduction directly on the main body of the device. Torque transmission from the motor to the worm gear is achieved by a heavy-duty flexible drive shaft connected between the motor and the spool.

4.3 Prototype Manufacturing and Assembly. To prepare the bag and mesh combination, the ends of the threads on the mesh were gathered into four bunches, one on each side of the square, and held together with an adhesive. The bag was initially inside a commercial deployer (Anchor Tissue Retrieval System™). The deployer consists of a plastic deployment tube encasing a rod

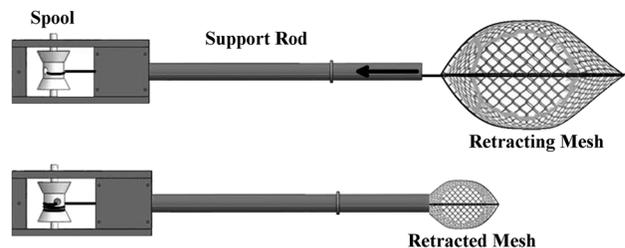


Fig. 8 A motor attachment turns the spool, winding the wires and retracting the mesh through the support rod

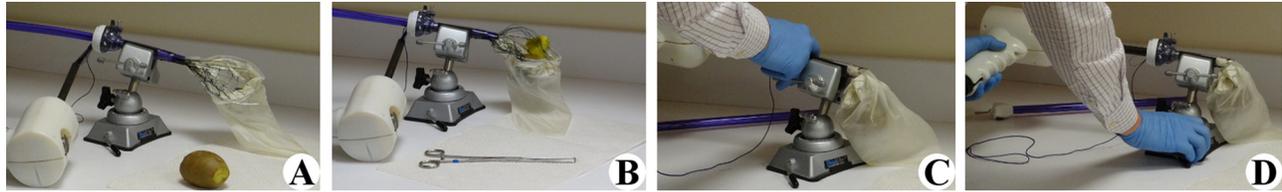


Fig. 9 Jon Einarsson simulating the surgical procedure in a laboratory setting. (a) The bag-mesh combination is deployed. (b) Tissue (a kiwi) is inserted with the tenaculum. (c) The morcellator is inserted and the bag is closed. (d) Morcellated tissue falls into the bag.

with a handle on one end and a metal bag expander attached to the bag on the other end. The expander springs open when it pushed out of the enclosing tube, opening the bag (Fig. 7(b)). The bag was deployed and the cutting surface of the mesh was attached to the interior of the bag with a light adhesive tape. Then, the bag-mesh combination was re-inserted inside the deployment tube and the ends of the wires were wrapped around the spool located in the morcellator handle casing.

The mechanical part of the device was assembled from a combination of off-the-shelf and custom made components. The motor, flexible shaft, bearings, an electrical switch, and standard hardware were purchased from outside vendors. The spool, main body, and motor-to-flexible shaft coupler were machined. The spool was snug fit into the side bearings and further held in place with e-clips. The end of the spool acts as a coupler to allow for fast connection to the flexible shaft. The support rod was secured with a light interference fit into the body and rests against a mechanical stop. Three-dimensional printing was leveraged for the esthetic/ergonomic parts of the device such as the handle, which was printed in two halves and connected with screws.

5 Preliminary Testing in Preclinical and Clinical Setting

First, the step-by-step procedure was tested in a laboratory setting on fruit. The deployment mechanism was inserted into the trocar and the bag-mesh combination was deployed (Fig. 9(a)). Tissue was placed into the bag-mesh combination (Fig. 9(b)). The deployer was withdrawn and the morcellator support rod was inserted into the trocar. The lip of the bag was positioned around the rod. The bag was closed using the drawstring (Fig. 9(c)), preventing any morcellated tissue from escaping in subsequent steps. Closing the bag around the end of the morcellator support rod prevents the retracting mesh from potentially pulling the bag through the metal rod and cutting it. The morcellator was turned on, retracting the mesh into the support rod and cutting the tissue. As the wires cut the tissue, which was also pressed against the distal end of the tube, the morcellated tissue fragments fell into the bag (Fig. 9(d)). Finally, the morcellator was removed, leaving the bag with small pieces of tissue inside which could then be removed through aspiration before the bag was pulled out of the body.

Finally, in vivo and ex vivo prototype validation with animal tissue was conducted at the animal testing facility at Harvard Medical School, Boston, MA. A sedated pig was used for in vivo testing of the feasibility of inserting organs into the bag/mesh. Figure 10(a) shows the initial surgical setup, while Fig. 10(b) is the view of a kidney inside the mesh, as seen on the endoscope display. Due to carbon dioxide leakage from an accidentally expanded incision in the abdomen, visualization was subsequently lost and the morcellation procedure could not continue inside the pig. Further, in vivo testing of the prototype will be done in future work.

To evaluate the tissue cutting capabilities of the device, the morcellator was removed and tested ex vivo on bovine kidneys. Quantitative data on tissue size, mass, and cutting time were recorded (Table 2).

The time to cut tissue varied over the order of seconds (mean = median = 30 s, population standard deviation = 7 s) while tissue

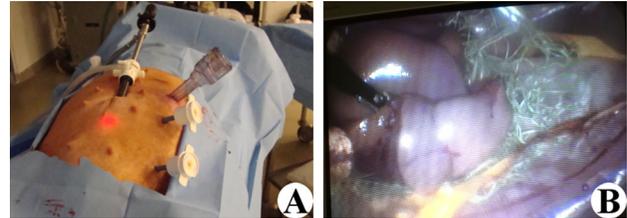


Fig. 10 The initial surgical setup with the porcine subject at the moment of insertion of the deployment mechanism (a). An endoscope is connected to the screen, and two trocars are placed for inserting other laparoscopic instruments. (b) A screen-capture of the endoscope, where the kidney is placed inside the mesh.

Table 2 Summary of ex vivo prototype testing on bovine kidney

Tissue	Shortest side of tissue (cm)	Tissue mass (g)	Time to cut tissue (s)	Cutting speed (g/min)
Kidney 1	12.7	260	30	520
Kidney 2	5.1	100	38	160
Kidney 3	7.1	180	36	300
Kidney 4	6.4	120	17	420
Kidney 5	5.1	100	32	190
Kidney 6	6.4	160	24	400
Kidney 7	18.5	360	30	720

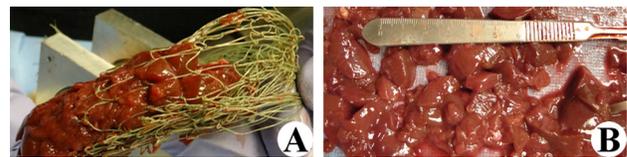


Fig. 11 A large piece of tissue is left intact as it is compressed and pulled into the support rod directly (a). The remaining small pieces of kidney would fall into the bag (b). The variability in sizing is due to using professional meshes and hand-woven meshes on different runs. Pieces over 1 cm in greatest dimension are from hand-woven meshes.

mass varied on the order of hundreds of grams. The time variation was largely due to nonuniform starting extensions of the wires, as seen on video recording. The lack of a correlation between the cutting time and tissue mass and size confirms that the design performs as expected, so cutting times can be treated as approximately constant.

During the cutting step, the retracting mesh cuts cubes of tissue from the main bulk. Once the bulk has been reduced to the diameter of the morcellator support rod, some tissue is pulled inside the morcellator support rod and can be directly extracted from the body (Fig. 11(a)). For more deformable tissue, compressive forces

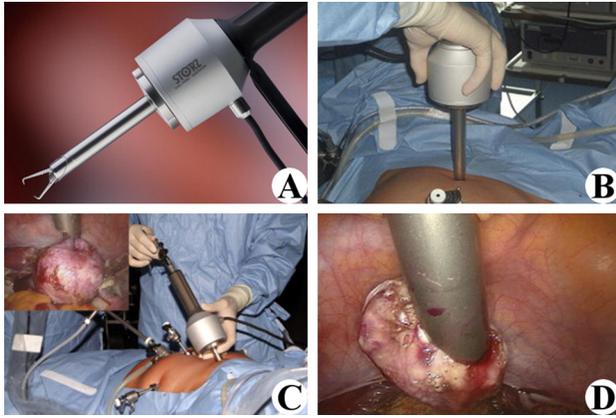


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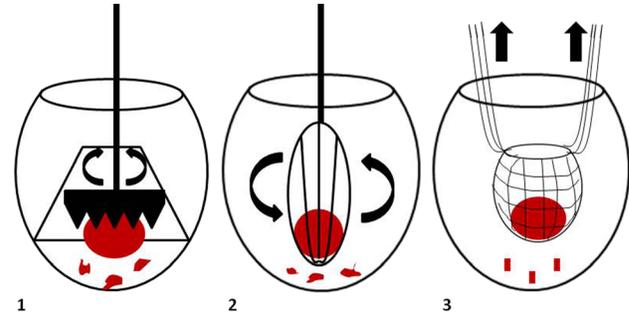


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- (2) using a “whisk” in a bag for rotary cutting
- (3) using a mesh in a bag for linear radial cutting

These three concepts were evaluated against the current standard morcellator using a Pugh Chart (Table 1). For the scoring, +1 corresponds to having a noticeable advantage over the current technology in a specific category, 0 corresponds to having a similar capability, and -1 corresponds to a marked disadvantage. The category selection was driven by the identified functional requirements.

The linear radial cutting idea emerged as the most promising, primarily due to the fact that the containment mechanism prevents spillage and is protected from outward directed forces and that a single pass is required for the entire process, with cutting speed and maximum tissue size fixed by external parameters. The cost of the device was estimated to be similar to other commercially available laparoscopic morcellators. Maneuverability was marked down over the current standard since the proposed device requires tissue to be manipulated into a bag prior to cutting.

While the time required for manipulation of tissue into the bag and cutting speed were deemed to be weakly dependent on size,

Table 1 Comparison of concepts with current market leader (bladed morcellator)

Attributes	Current bladed morcellator	Bladed morcellator with cover and bag	Rotary cutting	Linear radial cutting
Safety	0	1	1	1
Cost	0	0	1	0
Maneuverability	0	0	0	-1
Tissue size range	0	0	-1	1
Tissue density range	0	0	-1	1
Cutting speed	0	1	1	1
Ease of pathology	0	0	0	0
Total	0	2	1	3

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