Design of an Endoscopic Full-Thickness Lesion Removal Device

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Gastroenterologists would like to remove, through endoscopy, full-thickness lesions in the stomach, but currently there are no surgical devices capable of sealing the wound left after the lesion is removed. This paper describes the design, analysis, and prototyping of a device meant to address this problem. The device is intended to be used in conjunction with currently available endoscopes and comprises five key components including spikes, a beam, a hinge, a latch, and a positioning mechanism. Trials of positioning and placing a clamp on an in vitro pig stomach tissue were successfully completed. [DOI: 10.1115/1.2884269]

1 Introduction

Endoscopic surgeries are less invasive than traditional and laparoscopic surgeries. There is less induced trauma to the patient; thus, recovery times and hospital stays are significantly shorter, resulting in lower cost. Furthermore, there is a lower risk of infection because the surgery is performed from one side of the gastrointestinal tract, while the sterile side of the tract is not penetrated.

At present, endoscopic surgery can only treat a limited number of stomach diseases and ailments. For example, full-thickness stomach lesions cannot be treated because removing such a lesion would require breaching the wall of the gastrointestinal tract. Currently, there are no endoscopic tools capable of sealing this breach, and a tear of the tract requires an immediate transfer of the patient into conventional surgery.

It would be possible, with the proper tools, to treat diseases extending through the depth of the gastrointestinal tract wall. Essentially, the diseased tissue could be tented, the healthy tissue beneath the tent sealed to itself, and the diseased tissue cut away. Figure 1 is an illustration of this process. It is imperative that the tissue be clamped before the lesion is excised; currently, no tools that are reliably capable of placing a clamp below a tented lesion exist.

Some tools have been produced to address this problem, with limited success. An endoscopic stapling tool, essentially the stapler cartridge from a laparoscopic stapler attached to an endoscope, has been developed [1]. This tool is large and lacks maneuverability and must be used in parallel with another endoscope. In addition, it is capable of operating on only a small portion of the stomach. Hence, it becomes necessary to develop a tool that is capable of sealing a wound and accessing all parts of the stomach. Presented here is the design, analysis, prototyping, and preliminary trails of a clamp and positioning mechanism used to seal full-thickness stomach lesions through endoscopy. Figure 2 displays the final clamp and positioning prototype constructed and used in the preliminary trials.

2 Functional Requirements and Design Development

A tool designed to treat full-thickness stomach lesions endoscopically must meet a number of functional requirements. Ideally, such a tool would be small enough to pass through the biopsy channel of an endoscope, so that it could be quickly changed as the circumstance required. In addition, the tool would need to be independently articulated from the endoscope itself. It must also be capable of permanently sealing the base of the tented tissue to itself. Anything left behind in the stomach must not cause any damage or irritation and must be magnetic resonance imaging (MRI) compatible. Finally, the tool must also be inexpensive and disposable.

From these requirements, two major strategies for wound closure were initially developed and explored. The "encirclement" strategy involved applying radial pressure to the base of the tent, using a loop of cord, string, or cable. The "piercing" strategy focused on sealing the two sections of tissue together using a device to penetrate the tissue and mechanically fasten both sides. Figure 3 illustrates these two strategies.

Neither of these strategies is without risk. Encirclement, while simple in concept and relatively easy to apply, comes with the danger of tissue necrosis. Pinching the tissue tightly enough such that the cord would not slip off the excised lesion might result in blockage of blood flow and subsequent tissue death. Should the tissue die, the band would fall off and the stomach wound would reopen, with potentially catastrophic consequences. Piercing, on the other hand, is much more mechanically complex. Inserting fasteners requires a tool capable of automatically reloading itself and would probably require access to both sides of the tent to properly deform or connect any pierced fastener.

Nevertheless, a series of bench level experiments was performed to evaluate these two strategies. The experiments consisted of using various types of encirclement devices and piercing fasteners on a tissuelike neoprene rubber and on a bovine stomach. The results of the experiments were mixed; encirclement devices generally sealed tissue well but tended to slip off. Piercing devices did not slip but tended not to provide adequate sealing force.

As a result, a third hybrid strategy was developed, which incorporated the best elements of both the encirclement and piercing strategies. It was hypothesized that a device incorporating piercing elements while applying a radial pressure through a rigid element would have the best overall chance for success. This rigid element would be large enough to avoid pinching the tissue and therefore avoid the tissue necrosis danger but would not slip off the wound because the piercing elements would hold it in place.

This hybrid strategy led to the development of a device consisting of a pair of rigid beams with integral spikes, held at the ends with a flexible hinge and an adjustable latch. The device is called the "spiky clamp." An early spiky clamp prototype concept is shown in Fig. 4.

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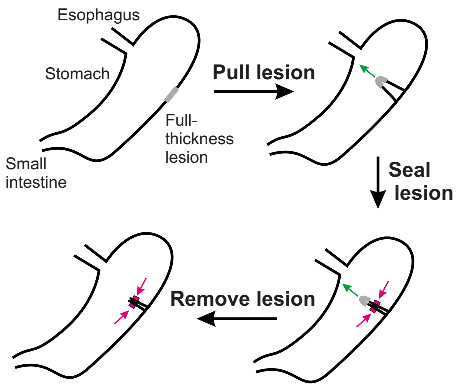

Fig. 1 Illustration of the proposed method for removing full-thickness stomach lesions. The tissue is tented, clamped, and excised.

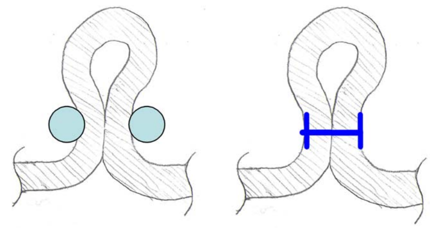

Fig. 3 The drawing on the left is an illustration of the encirclement strategy; the lesion is clamped with radial pressure provided by a ring or a band. The drawing on the right illustrates the piercing strategy; the lesion is clamped by forcing opposing sides of the tent together with mechanical fasteners that penetrate both walls of the tissue.

3 Structural Analysis

During the operation of the spiky clamp, various loads are applied to the spiky clamp by the stomach walls, the clamping mechanism, and the spiky clamp positioning mechanism. A first estimation of these loads is necessary for the proper design of the spiky clamp itself and also for the design of the spiky clamp positioning mechanism.

The geometry of interest is shown in Fig. 5. The z axis is normal to the stomach surface, the y axis is normal to the sealing surface, and the x axis is the longitudinal axis of the seal surface and the axis of the spiky clamp beams. The most sensitive direction of operation is the z axis. The spikes help prevent slip in the z direction, and pressure in the y direction seals the wound. Possible errors can result in not sealing the whole lesion properly.

Figure 6 shows the forces applied to the spiky clamp by the stomach walls, the flexible hinge, and the positioning mechanism. However, it is difficult to estimate the size and locations of these forces without experimentation. Fortunately, the properties of several gastrointestinal tract tissues have been previously characterized. For example, Yamada, through extensive testing, has mea-

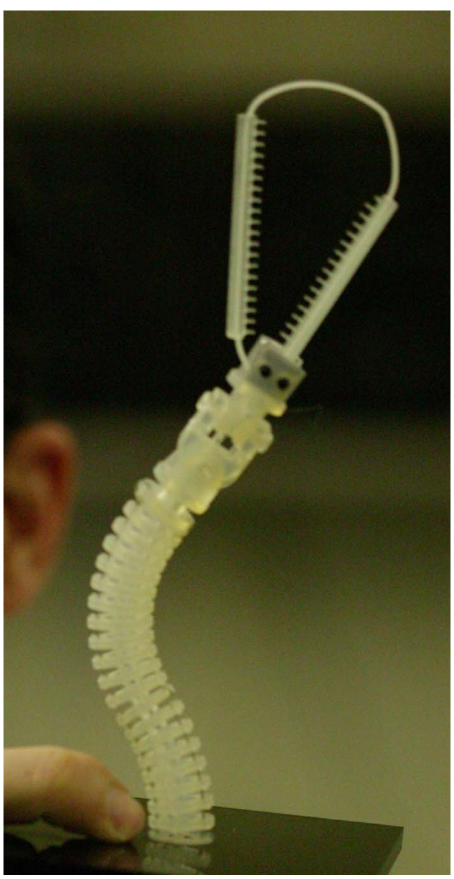

Fig. 2 Picture of the final prototype system including the spiky clamp and positioning mechanism

Fig. 4 An early prototype spiky clamp concept, consisting of a pair of beams, hinged at one end and with a snap-fit latch at the opposite end. A row of spikes is set in one beam to provide a piercing element.

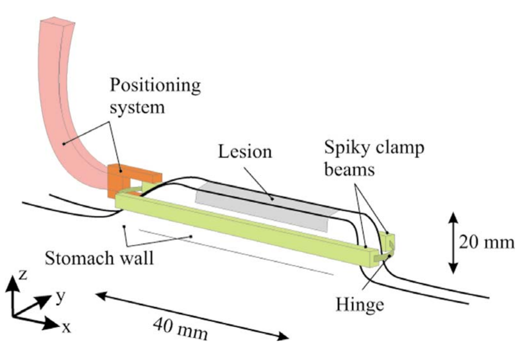

Fig. 5 The spiky clamp concept, its positioning system, stomach walls, and the geometry of the lesion during the operation

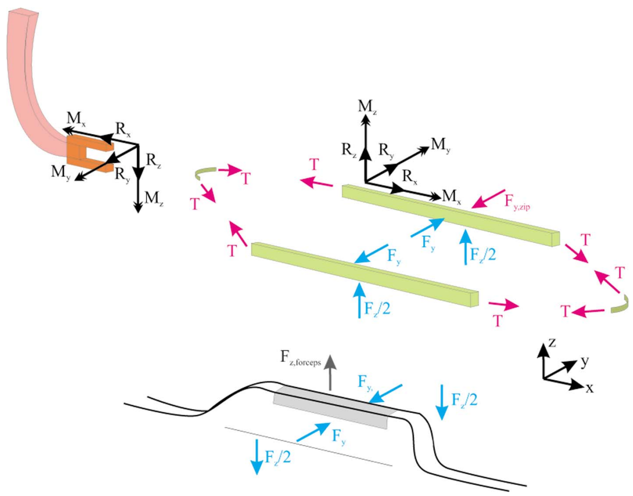

Fig. 6 A free body diagram of the forces applied to the spiky clamp beams by the stomach walls

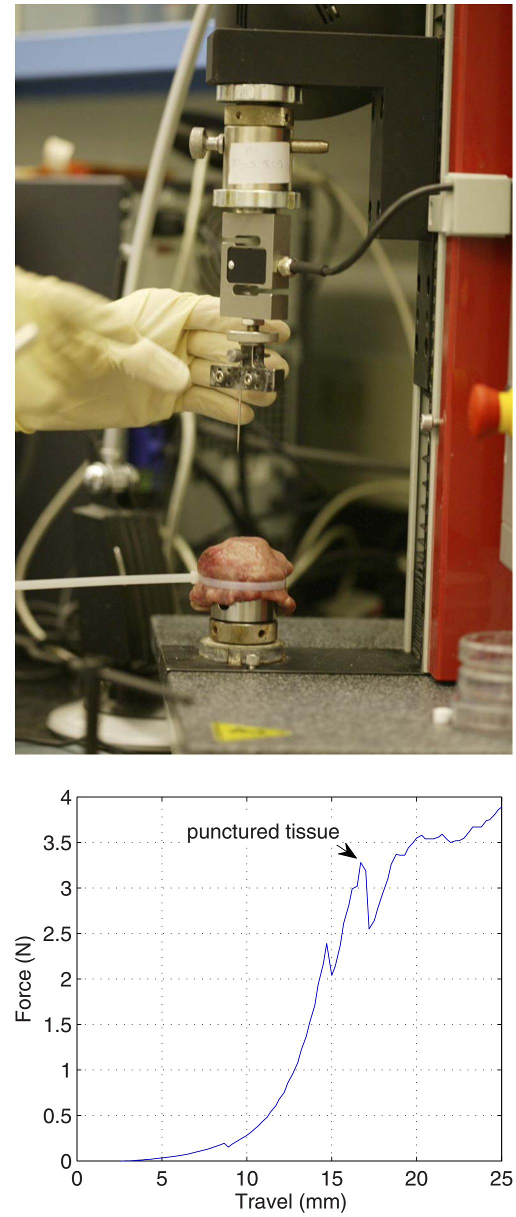

Fig. 7 Experimental setup and results used to determine the force needed to pierce the pig stomach tissue

sured several of the key mechanical properties of the stomach [2]. From this knowledge of the stomach, initial estimations of the forces were performed.

It is assumed that the spiky clamp positioning mechanism firmly grasps one of the spiky clamp beams at one of its ends and applies reaction forces $\mathbf{R}=[R_x\ R_y\ R_z]$ and reaction moments $\mathbf{M}=[M_x\ M_y\ M_z]$. In order to estimate the magnitude of these reaction forces, it would be necessary to know where the forces F_y, F_z, and T are applied. However, the exact location of these forces is not known. Therefore, the values of $\mathbf{R}$ and $\mathbf{M}$ were calculated for various possible locations of force application around the nominal position and the largest values were picked as design specifications. The results for the reaction forces and moments are $\mathbf{R}$ (N) $=[50\ 25\ 20]$ and $\mathbf{M}$ (N mm) $=[150\ 400\ 500]$. Also, in addition to these initial force estimations, experiments were conducted to gain a better understanding of the magnitude of the forces involved. These experiments are discussed in the following section.

4 Detailed Design

The design of a spiky clamp to be used in endoscopic stomach surgery can be broken down into five major components: the spikes, the beam, the hinge, the latch, and the positioning mechanism.

4.1 Spike Design. Of critical importance in the design of a spiky clamp is the design of the piercing elements (spikes). Much of the rest of the design of the clamp is dependent on the spike dimensions. For example, the beams must resist the spike reaction forces, the hinge must account for the spike length, the latch must hold against the spikes, the closure mechanism must be capable of providing the requisite force to close the device, and the entire device must lay open flat for insertion through the endoscope.

A series of experiments was run to determine the approximate force necessary to pierce a stomach tissue with a spike. Sewing needles of ~1 mm diameter were affixed to the moving element of a dynamic mechanical analyzer and driven through a section of pig stomach tissue stretched over a cup. The insertion force was recorded and was found to be in the range of 1.5–4 N. A photograph of the experimental setup and a plot of the insertion force is shown in Fig. 7.

In addition to puncturing the tissue, the spikes need to provide adequate resistance to the lateral (y direction) motion of the clamp to prevent it from sliding off the stomach tissue. A second set of experiments was run to investigate the load required to initiate transverse ripping. Sewing needles of ~1 mm diameter were inserted into pig stomach tissue normal to the plane of the tissue. The needles were loaded in a direction perpendicular to the axis of the needle. The force required to initiate ripping was recorded and was found to be in the range of 4–8 N/needle.

A conservative assumption is that the maximum transverse load the clamp will have to carry is similar in magnitude to the failure strength of stomach tissue, which is on the order of 600 kPa [2]. This load will be distributed across all of the spikes. The force on an individual spike must not exceed the ripping force and the maximum bending load the spike can support. A large number of spikes would reduce the load on each spike and avoid ripping. Restrictions on the overall size of the clamp, as a result of the geometry of the endoscope's biopsy channel, tend to require the spike diameter to decrease as the number of spikes increases. A set of 20 conical spikes per beam, 3 mm in length and 1 mm diameter at the base that taper to a sharp tip, provides a good balance between the need to spread the load to avoid ripping and the desire to reduce the overall size of the clamp.

If the sharp points of the spikes cause irritation of the tissue,

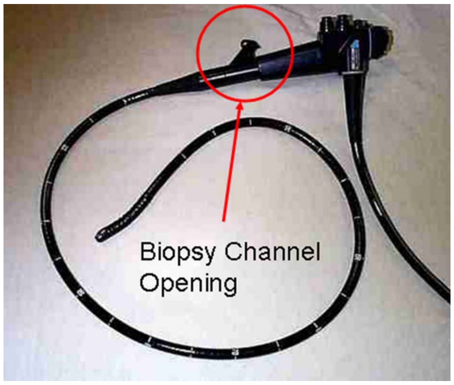

Fig. 8 A photograph of an endoscope highlighting the biopsy channel opening

they could be tipped with a bioabsorbable polymer. As the polymer dissolves, the tip would become blunt over a period of hours or days, and the tips would no longer irritate the stomach tissue.

4.2 Beam Design. There are two main components of the spiky clamp beam design: beam geometry and beam material selection. Ideally, this device will fit down an endoscope's biopsy channel (see Fig. 8). Depending on the endoscope, the biopsy channel internal diameter ranges between 3.7 mm and 6 mm. In addition to passing through the biopsy channel, the spiky clamp must pass through a bend near the biopsy channel opening. The obtuse angle of this bend is roughly 135 deg. These are the two key geometric constraints that drive not only the entire spiky clamp design but more specifically the beam design. However, if the device is not passed down a biopsy channel because the channel is being used by another tool, it is still critical to minimize the cross-sectional area of the beams to allow clearance in the gastrointestinal tract for the endoscope and an externally attached spiky clamp and positioning mechanism.

Similar to the hard geometric constraints of the biopsy channel internal diameter and the biopsy channel bend, the beams must not deflect more than a small fraction ($1/3-1/2$ as per Saint Venant's principle applied to design) of the length of the spikes. Otherwise, the spikes might become fully disengaged from the tissue, leading to a poorly sealed wound. Hence, it becomes critical to calculate the maximum deflection of the beam. However, minor beam deflection is advantageous because it applies a preload to the tissue that is being sealed. This preload will enhance the integrity of the seal in the wound.

In addition to the beam geometry, the material selection for the beams is critical not only because of the inherent mechanical properties of a given material, but also for biocompatibility reasons. Fortunately, there are several materials including plastics, stainless steels, and titanium that are biocompatible. Therefore, there is a great deal of flexibility left to the designer to choose the material not only for biocompatibility but for mechanical properties.

A simple back-of-envelope calculation was performed to determine the deflection of a plastic beam. Equation (1) calculates the maximum deflection for a simply supported beam with a uniformly distributed load,

$$\delta = \frac{5WL^4}{384EI} = 2.4 \text{ mm} \tag{1}$$

This equation assumes a rectangular beam with a 5 mm width and a 4 mm height, which is roughly the size necessary to fit down the biopsy channel. Furthermore, the equation uses a Young's modulus value of 2.5×10^3 N/mm^2, which is the modulus for the stereolithography (SLA) plastic used to rapid prototype the beams. This initial result suggests that soft plastic may not be the best material selection because the calculated deflection is near the spike height of 3 mm. Table 1 shows additional deflection values for other common medical-grade materials that can survive the acidic environment of the stomach.

Table 1 A comparison of deflection calculations for different materials

Material	Deflection (mm)
Stainless steel	0.031
Titanium	0.055
HDPE	5.2

Next, a spreadsheet was created to perform similar calculations while facilitating changes in the Young's modulus and moment of inertia. As a result, we were quickly able to determine the maximum deflection for a range of beam geometries and beam materials. From this spreadsheet, a final beam geometry that would maximize beam stiffness was chosen.

Finally, a finite element model was created to check the maximum deflection of the final beam prototype. Once again, the model was created using the mechanical properties of the SLA plastic used for the rapid prototyping. This was done to compare the computer model with actual experiments. In NASTRAN, the beam was modeled as a simply supported cantilevered beam with a pressure distribution of 0.319 N/mm^2 to simulate the force transmitted to the beam through the spikes. The maximum deflection calculated by NASTRAN was 2.75 mm. Figure 9 shows a picture of the finite element analysis of the beam, and Fig. 10 shows a picture of a prototyped beam clamping on pig stomach tissue.

Figure 10 shows the final beam prototype deflecting a few millimeters, which corresponds well with the initial calculations, the spread sheet calculations, and the finite element model. This result confirms that our computer models accurately capture the physics that govern the beam design. However, this result disagrees with the previously stated functional requirement that the beam should not deflect more than $1/3-1/2$ of the 3 mm spike length. After experimentation, it was observed that a few millimeters of deflection actually helped seal the wound by applying a preload to the tissue. As a result, this functional requirement was abandoned.

The final beam prototype was nearly small enough to fit down a 6 mm biopsy channel opening. In order to shrink the beam sufficiently to fit it down the biopsy channel, the beams could be constructed from stainless steel or titanium.

4.3 Latch Design. The latching mechanism must withstand the spike reaction forces and provide the clamping force necessary to prevent the wound from opening. A number of different latch

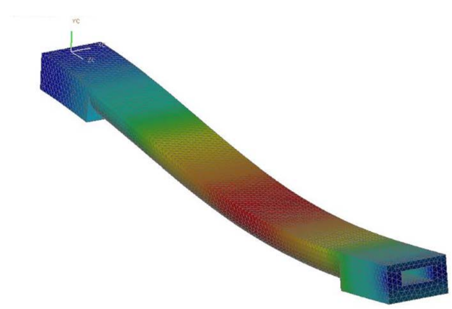

Fig. 9 NASTRAN finite-element analysis of the final prototype beam. The maximum deflection is 2.75 mm. To obtain these results the left end was fixed, the right end simply supported, and a pressure distribution of 0.319 N/mm^2 was applied to the top face of the beam.

Fig. 10 Photograph of the final prototype beam deflection while clamping pig stomach tissue

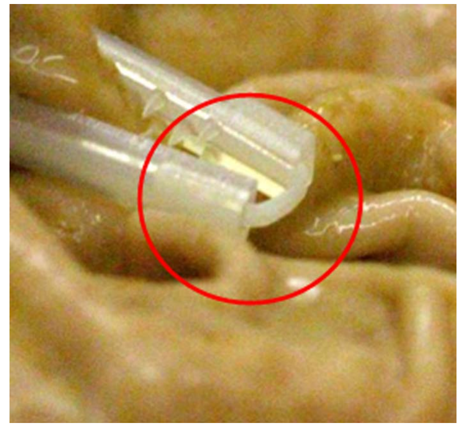

Fig. 11 Zip tie acting as both the latch and hinge in final prototypes

geometries were explored.

Geometries that could incorporate a variable-force or a variable-length latch were preferable, as the aim is to produce a clamp capable of treating any size stomach lesion. Adjustability in the field would save time and frustration during a lesion removal procedure.

Ultimately, it was decided that the type of flexural latching mechanism used in commercial "zip ties" would be most appropriate, and the prototype design used a zip tie latch.

Due to the relative motion of the zip tie with respect to the main body of the mechanism, the capstan effect on the tension of the zip tie needs to be considered. Since the application of large forces and moments inside the stomach cavity make the design of the positioning mechanism challenging, it is desired to minimize this effect, probably by using proper lubrication between the zip tie and the mechanism main body. In the case of lubricated plastic-metal surface contact, the coefficient of friction is assumed to be around $\mu=0.1$. Equation (2) shows the increase in tension due to the capstan effect. For $\theta=\pi$ radians (i.e., the total arc angle, which can be assumed for simplicity to take place around the hinge part of the design), then $e^{\mu\theta}=1.4$, and since the tension T_1 is estimated to be roughly 25 N, the amount of force required to tighten the zip tie is around 35 N,

$$T_2 = T_1 e^{\mu\theta} = 35 \text{ N} \tag{2}$$

4.4 Hinge Design. In order to fit the spiky clamp down the biopsy channel, some type of kinematic assembly must be designed to integrate all of the different components. The simplest kinematic joint is a hinge. There are two basic classes of hinges: pin joints and compliant hinges. Pin joints are common and very functional, but they add additional parts and complexity to the assembly. Passive pin joints require an external force to keep the two separate pieces in contact. Compliant hinges tend not to be as strong as pin joints, but they can be an integral piece of the device, which would provide the possibly of a monolithic device.

There are several different types of compliant hinges, including flexural pivots, living hinges, cross-axis flexural pivots, and torsional hinges [3]. We investigated the use of a 2D small length flexural pivot as an integral piece connecting the two beams.

Although the initial experiments that were conducted with these hinges failed (mainly due to the brittle SLA material from which the hinges were made), flexural hinges show promise for future implementation. Because of these failures and time constraints, all of the spiky clamp prototypes used a simple zip tie as both the latch and hinge (see Fig. 11). Zip ties, as well as having a mature variable-length latching mechanism, also have an excellent tensile strength and the ability to withstand large strains, and thus make excellent flexural hinges. Ultimately, zip ties were used for prototype testing, and they may prove a viable option for a production device.

4.5 Positioning Mechanism Design. An important functional requirement for the spiky clamp is related to its ability to operate successfully on lesions located at various locations inside the stomach. The spiky clamp needs to be positioned parallel to the stomach wall in line with the lesion, be in contact with the stomach wall, and remain in this position during the operation. These requirements drive the design of the positioning mechanism.

The proposed positioning system is shown in Fig. 12. It consists of two parts: a coarse manipulator and a wrist. The coarse manipulator positions the spiky clamp in the proximity of the lesion. The wrist positions the spiky clamp finely with respect to the lesion. At least one of the wrist joints (pitch) must have a large range of motion (around ± 90 deg) in order to reduce the required length of the coarse manipulator to reach most parts of the stomach. This results in a stiffer positioning system and simplifies the operation of the spiky clamp during the surgery.

Since the spiky clamp needs to operate in collaboration with other tools (e.g., forceps) that manipulate the lesion, both the positioning system and the forceps need to work simultaneously with the endoscope. There are two alternative solutions for this to happen: (1) design the positioning system to fit inside one of the biopsy channels (3.7 mm outer diameter) and pass the forceps through the other biopsy channel; (2) design the positioning system as an external attachment to the endoscope and let the endoscope head clear so that forceps pass through one of the biopsy channels. In this study, the second alternative was considered as it was easier to design and manufacture in our limited time, but also appearing as if it might be the best solution.

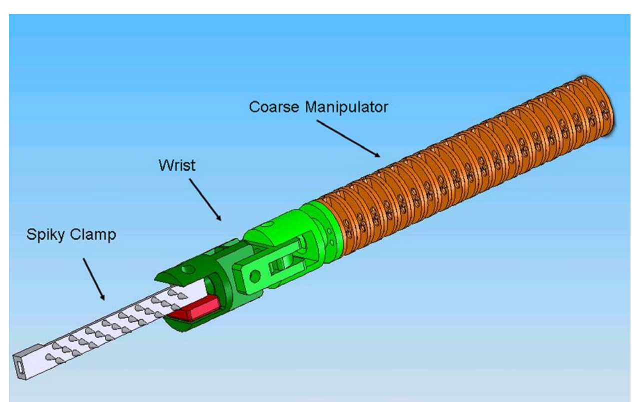

Fig. 12 Schematic of the spiky clamp positioning system

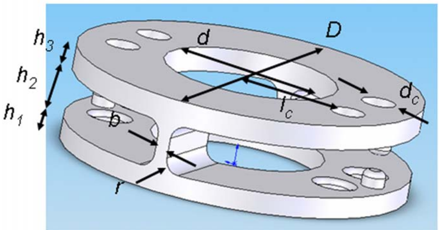

Fig. 13 Drawing of a single sector of the flexible snake

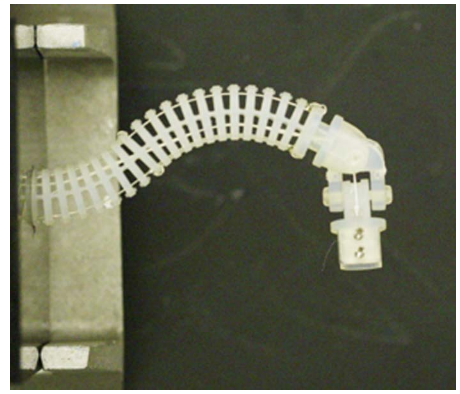

Fig. 14 Using four cables makes it possible to induce *s*-shaped displacements in the flexible snake and enhance its ability to access locations inside the stomach

4.5.1 Coarse Manipulator Design. The functional requirements for the coarse manipulator include the ability to position the spiky clamp to reach the majority of the stomach, adequate stiffness to handle the forces required to close the spiky clamp, and a size restriction to fit alongside the endoscope (or through a biopsy channel). The first functional requirement is that the coarse manipulator should be long and maneuverable enough to access at least half the stomach surface.

Three concepts were considered for the design of the coarse manipulator. The first concept consists of a flexible tube actuated by cables. The second concept is a planar two-link manipulator system. The third concept is a vertebratelike structure comprising of disks connected by flexures, actuated by cables.

The third concept, the flexible snake, was chosen because it provides a balance between manufacturing simplicity and performance in terms of workspace and stiffness. A similar design was implemented in an industrial robot, known as the spine robot, for the automotive industry in Sweden in the early 1980s [4]. The potential risk of material failure in the flexures can be avoided by proper design (minimize stress concentration while providing enough load capacity) and by avoiding large motions using mechanical stops.

The flexible snake consists of disks connected by flexures in a monolithic design. Two adjacent disks connected by two thin beamlike flexures form the elementary part of the flexible snake, called a "sector." The application of a normal force to the disk surface results in a bending deflection of the flexures and relative angular displacement of the adjacent disks. Assuming rigid disks and small angular displacement between adjacent disks, the kinematics of such a mechanism can be reasonably approximated by modeling each sector as a simple pin joint and a torsion spring [5].

Figure 13 shows a single sector of the flexible snake along with its dimensions: the outer D and inner d diameter of the disks, the disk height h_1, the gap size h_2 (the sector length then is $l=h_1+h_2$), the flexure thickness b, and the flexure-disk fillet radius r. The dimensions of the prototype are $D=15$ mm, $d=7.5$ mm, $h_1=h_2=2.1$ mm, $b=0.6$ mm, and $r=0.63$ mm. Also, hard stops prevent angular deformations larger than 5.5 deg to prevent material failure.

The flexible snake can provide angular displacement along one or two axes by using a pair of cables for each axis [6,7]. Based on the maximum estimated angular deflection per sector (5 deg), it was chosen to make the flexible snake planar (the axes of angular displacement of all sectors are parallel) in order to maximize the total angular displacement of the coarse manipulator.

Another way to enhance the flexible snake maneuverability is to use two pairs of cables to control its motion. The first pair applies force to all N sectors, whereas the second actuates the $N/2$ sectors closer to the snake axis. This feature makes it possible for the flexible snake to reach all points of the stomach walls (having constant N) by inducing an s-shaped deformation. An example of the resulting dexterity of the spiky clamp positioning system is shown in Fig. 14. Such strategies have been used for several years in commercially available endoscopes.

4.5.2 Wrist Joint Design. The wrist joint is designed to place the spiky clamp against the stomach lining in a direction perpendicular to the axis of the coarse manipulator. For maximum effectiveness, the wrist should be able to place the clamp irrespective of the relative locations of the endoscope head and the contortions of the coarse manipulator. Thus, the wrist joint must be able to bend a full 90 deg in any of four directions. The wrist joint must be capable of resisting the reaction forces of the spiky clamp and closing the mechanism without failure. Additionally, the length of the wrist joint should be minimized because additional joint length is detrimental to overall positioning mechanism strength; the longer the positioning mechanism, the larger the forces the actuating cables must resist.

The wrist joint could be designed in a number of different ways. A ball joint provides the most freedom in the shortest length. However, a detailed analysis of the forces involved indicates that a ball joint with the strength to resist the clamp's reaction forces would require that the cup half of the joint be so large that a true 90 deg motion could not be achieved. Thus, a pinned universal-type joint was designed. Pin joints offer a large range of motion in a small length, and although the overall wrist joint is longer for two degrees of freedom than a ball joint, the extra strength provided by pin joints makes it necessary to use them.

Thus, a Hookes (pin) joint was designed and constructed. The joint is designed to be integrated with the coarse manipulator section. The outer diameter of the wrist joint was 15 mm. The individual pin joints were 3 mm in diameter. A computer aided design (CAD) diagram of the wrist joint is shown in Fig. 15.

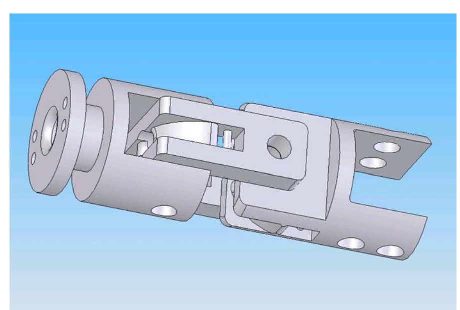

Fig. 15 CAD drawing of the wrist joint

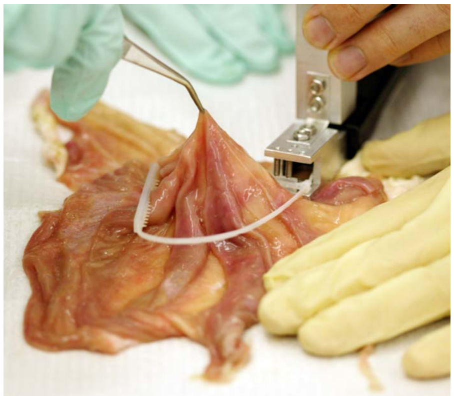

Fig. 16 A photograph of a first generation spiky clamp being closed onto sheep stomach tissue

5 Design, Testing, and Verification

The first prototype, designed with the original design specifications, was tested on sheep stomach tissue, as pig tissue was not immediately available. The prototype enabled a spiky clamp to be installed on a sheep stomach and closed. Figure 16 shows the first prototype spiky clamp being applied to sheep stomach tissue. Under tension, some tearing of the tissue was observed, but it was further noted that the sheep stomach tissue was significantly thinner than the pig stomach tissue for which the clamp was designed. It was hypothesized that the lower strength of the sheep stomach tissue contributed to its failure.

A second prototype was tested in conjunction with the positioning mechanism. A spiky clamp was remotely installed on pig stomach tissue using only the positioning mechanism and a pair of forceps to simulate the forceps that would be available as an endoscopic tool. The prototype performed well; it sealed the stomach wound against liquid and held well without tearing when put under tension. A sequence of photographs of the remote installation of the spiky clamp on pig stomach tissue is shown in Fig. 17.

6 Conclusions and Recommendations

The overall spiky clamp and positioning mechanism design performed very well. The clamp was capable of being placed in an environment similar to that in which an endoscope would be used. The clamp held the wound closed, even in tension, and prevented liquid from leaking through the wound.

This tool is a proof of concept and needs to evolve in several respects before it could be used, and several improvements need to be made before the spiky clamp system would be ready for in vivo testing in clinical trials. Of primary importance is the material selection: The rapid prototype material used does not scale well to the size needed to produce a useable endoscopic tool. A production device would be made of medical-grade stainless steel or titanium, and initial calculations suggest that it could be feasible to construct a system that fits down a 6 mm biopsy channel.

Secondly, the commercial zip ties used as the hinge flexure and latching mechanism need to be replaced with an improved design. The rectangular cross section of the commercial tie tends to resist the bending of the wrist joint. This problem could be solved by switching to a tie design with a circular cross section. The addition of a weak point in the tie could provide an adequate clamp release mechanism; the clamp would be held and positioned by the tie and would be released when the tie broke under the proper clamp tension. Also, the zip tie would need to be fabricated from a biocompatible polymer in order to survive in the stomach environment.

Finally, as addressed earlier in the spiky clamp design section, it may be important that the spikes do not continuously irritate the stomach tissue after installation. The spikes' sharp tips should be of a biodegradable polymer; so over time, the polymer would dissolve, leaving blunt spikes that would not further damage the tissue.

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Fig. 17 A sequence of photographs showing the application of a second generation prototype to pig stomach tissue using a remote positioning mechanism

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