

Design of an Endoscopic Stitching Device for Surgical Obesity Treatment Using a N.O.T.E.S Approach

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Abstract—This paper proposed a design of an endoscopic stitching device for surgical obesity treatment using a N.O.T.E.S (Natural Orifice Transluminal Endoscopic Surgery) approach. This proposed N.O.T.E.S gastroplasty approach performs stitching and resizing of a stomach from inside, aiming at further reducing postoperative complications by avoiding the use of skin incisions. The presented design can be inserted into the stomach in a folded configuration and be unfolded into a working configuration to perform stitching. It uses pre-curved super-elastic NiTi (Nickel-Titanium) alloy needle to facilitate the stitching motion. Role of the NiTi needle is demonstrated in in-vitro tissue penetrating experiments, while deployment and stitching motions of this device are verified using simulations.

I. INTRODUCTION

OBESITY has become a public health concern in the United states and Europe because of its fast prevalence in the past decades [1, 2]. It is widely accepted that morbid obesity is often associated with diabetes, dyslipidemia, cardiovascular diseases, etc. Although various methods could be used for obesity control (e.g., behavior therapy and pharmacologic intervention), surgery remains the most effective treatment of morbid obesity [3]. Current surgical interventions mainly include i) gastric restrictive methods (e.g. Vertical Banded Gastroplasty, VBG [4], Laparoscopic Adjustable Gastric Banding, LAGB [5], Laparoscopic Sleeve Gastrectomy, LSG [6]), ii) malabsorptive procedures (e.g. jejunoileal bypass [7], Laparoscopic Roux-en-Y Gastric Bypass, LRGB [8]), and iii) combination of the two methods (e.g. VBG-RGB procedures [9]).

Although the surgical treatment is quite effective, it is only considered for patients with morbid obesity (Body Mass

Index, BMI over 40 kg/m²), because of high postoperative complication rates and many premature deaths even when most procedures were performed laparoscopically [3]. If the postoperative complications and premature deaths could be further reduced, surgical treatment for obesity might be applied to a greater population with obesity.

N.O.T.E.S (Natural Orifice Transluminal Endoscopic Surgery) might be a way to further reduce postoperative complications. N.O.T.E.S is a recent development after the minimally invasive laparoscopic procedures. It uses patient's natural orifices (e.g. vagina, esophagus and stomach, etc.) for surgical interventions [10, 11]. Recent clinical studies [12] and many animal studies [13] have shown N.O.T.E.S effective in further diminishing postoperative complications. Encouraged by these results, a N.O.T.E.S gastroplasty, which performs stitching and resizing of a stomach inside the stomach, could possibly further reduce the postoperative risks. Hence surgical treatment could be extended to more patients with obesity.

In order to accomplish a N.O.T.E.S gastroplasty, an endoscopic device which could effectively perform suturing and knot tying in confined spaces will be needed. This device could also be useful in other N.O.T.E.S procedures to close incisions in walls of stomach or vagina. Previous studies showed that, if a traditional rigid circular suture is used, suturing (and knot tying) in confined spaces is cumbered even if the task was assisted by robots [14-16] or it was manually performed by a specially designed endoscope [17]. This paper presents an alternative design of an endoscopic stitching device using pre-curved super-elastic needle made from NiTi (Nickel-Titanium) alloy, shown in Fig. 1.

This design is inspired by the work done by Xu *et al* [18] where a robotic system is designed for SPA (Single Port Access) laparoscopic surgery. In the folded configuration, this device would be easily swallowed by patients; after deployed into the stomach, the device can perform operational procedures in an unfolded configuration. The use of pre-curved NiTi needle is inspired by the work done by Webster *et al* [19, 20] and Dupont *et al* [21] where continuum robots made from pre-curved concentric NiTi tubes were studied for navigation and drug delivery.

Major contribution of this paper is the proposal of fabricating suture using pre-curved super-elastic NiTi alloy. While released from a straight housing, the NiTi needle bends back to its preset shape and generates a circular penetrating

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path in tissues to facilitate a stitching motion. Complicated motion planning for robotic suturing could be simplified. **Minor contribution of this paper** is the presentation of one possible design to realize this proposed concept.

The paper is organized as the following. Section II presents design requirements and a new surgical concept on how a N.O.T.E.S gastroplasty could be performed. System overview and detailed design descriptions are presented in Section III. Simulation and in-vitro experiments are presented in Section IV with conclusion and future work followed in Section V.

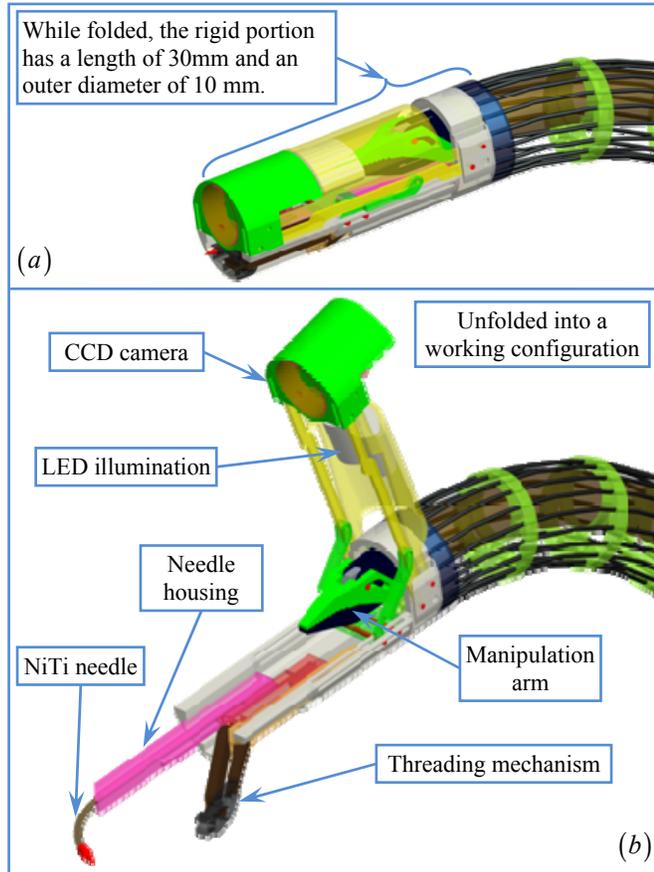


Fig. 1. Design of an endoscopic stitching device using needles made from pre-curved super-elastic NiTi alloy: (a) the folded configuration and (b) the unfolded working configuration.

II. DESIGN REQUIREMENTS AND SURGICAL CONCEPTS

A N.O.T.E.S gastroplasty demands a device with the following capabilities:

- 1) The device should be foldable to facilitate its insertion into stomach through pharynx and esophagus. Gastrosopes from Olympus® have outer diameters from 11.3mm (GIF-1TQ160) to 12.6mm (GIF-XTQ160), while existing endoscopes for N.O.T.E.S [17] usually have outer diameters from 14.3mm (Olympus “R” scope) to 18mm (USGI Transport scope). The design proposed in this paper shall have a smaller diameter (currently 10mm).
- 2) The device can deploy itself into a working configuration for stitching, knot tying, ablation, etc.
- 3) Additional channels should be available for insufflation,

manipulation tools for knot-tying, ablation, etc.

- 4) The device can be positioned and oriented to achieve stitching motion within the entire stomach. This can be achieved by placing the device at the distal tip of an endoscope such as the ShapeLock® [22].
- 5) The device has a vision unit with integrated illumination.
- 6) The device is actuated by its actuation unit. The actuation unit will always remain outside patient’s mouth.

Using such an endoscopic stitching device with these aforementioned capabilities, a N.O.T.E.S gastroplasty can be achieved in many ways. One possibility is shown in Fig. 2. This endoscopic stitching device will be inserted into the stomach and insufflation (pneumoperitoneum alike) will be generated. After enough space is created, the device deploys itself into the working configuration to perform stitching. A lockable band could be attached to the inner wall of the stomach by multiple stitches. After the stitching device is retracted, the band can then be tightened and locked to create a small pouch to achieve the stomach resizing.

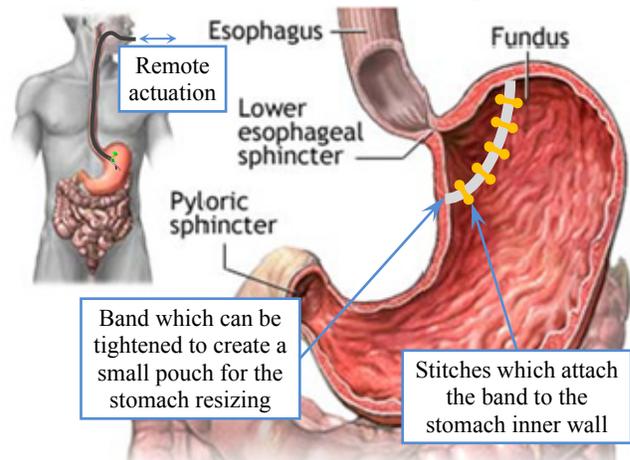


Fig. 2. Schematic drawing of a proposed new surgical concept for stomach resizing. The stomach diagram is from the University of Maryland Medical Center Encyclopedia.

III. SYSTEM OVERVIEW AND DESIGN DESCRIPTION

The endoscopic stitching device in Fig. 1 was conceived to meet the requirements mentioned in Section II. In the folded configuration, the device can be inserted into stomach through the esophagus. Its forward-looking vision unit could guide the surgeons through the insertion phase. In the stomach, the device first creates insufflation (pneumoperitoneum alike) to generate enough space for its unfolded working configuration. Suturing and knot-tying can then be performed. An accompanying video (snapshots in section IV) animates this deployment and stitching motions.

As shown in Fig. 1, the device consists of a CCD camera (CSH14V4R1 from NET Inc. with an outer diameter of 6.5mm), the integrated LED illumination, a rigid needle housing with a pre-curved super-elastic NiTi needle, a threading mechanism and an exchangeable snake-like continuum manipulator arm. This snake-like continuum manipulator arm can be replaced by sensor modules (e.g. an ultrasound probe) or energy sources (e.g. a cautery).

All the controlled joints will be actuated by NiTi tubes or rods in push-pull mode. The actuation unit will remain outside patient's month, as indicated in the inset of Fig. 2. Motion discrepancy caused by backlash or friction might be compensated as in [23]. Design considerations and solutions for critical components will be discussed as follows.

A. NiTi needle

If a traditional rigid circular suture is used, suturing motion involves a distal rotation along an axis normal to the suture plane, passing through the suture's center. Using a pre-curved super-elastic NiTi needle might greatly simplify this suturing motion. When the needle is housed in a rigid housing as shown in Fig. 3, the pre-curved super-elastic NiTi needle will be forced straight; when the needle is pushed outwards, it will bend back to its original circular shape, penetrating tissues in a circular path to facilitate the suturing motion.

The NiTi needle will be housed in rigid needle housing during insertion of the device. Since the length of this rigid housing is limited, the size of the suture can then be determined. According to literatures (e.g. [24]), super-elastic NiTi alloy usually has an elastic strain ranging from 4% to 6%. If a 4% strain is allowed,

$$\epsilon_{strain} = r_{needle} / R_{suture} \leq 4\% \Rightarrow r_{needle} \leq 0.04 R_{suture} \quad (1)$$

Where r_{needle} is the radius of the needle's round cross section and R_{suture} is the radius of the suture.

If a $3\pi/4$ suture with a length of 20mm will be used,

$$3\pi R_{suture} / 4 = 20mm \quad (2)$$

$$R_{suture} = 8.49mm \xrightarrow{r_{needle} \leq 0.04 R_{suture}} r_{needle} \leq 0.34mm \quad (3)$$

In the design and in the in-vitro tissue penetrating experiments presented in Section IV, a NiTi rod with an outer diameter of 0.69mm is used. Although this selection does not comply with Eq. (3) strictly, strain slightly over 4% usually still falls in the elastic region for super-elastic NiTi alloy.



Fig. 3. A $\emptyset 0.69mm$ needle made from pre-curved NiTi alloy: it bends back to its original circular shape after released from a straight rigid housing. The needle's radius is about 9mm. Thinnest grids in the background are 1mm x 1mm.

B. Needle tip

Using a pre-curved super-elastic NiTi needle only simplifies the suture penetration. To achieve a complete stitch, a suture thread should be guided through the tissue as well. The thread shall be attached to the NiTi needle so that it penetrates the stomach wall together with the needle.

Using a traditional suture, thread is attached to one end of the suture and will be pulled through after the suture penetrates the tissue. If only a short piece of NiTi needle will be used to apply the same technique, it will be difficult to pick

up the needle and straighten it by pulling it into another (or the original) rigid housing to carry out the next stitching motion. Hence, the design converged to the use of one single long NiTi thin rod as the needle. After penetration, the pre-curved portion can be pulled back into the original rigid housing. The needle is actuated in a push-pull mode remotely, as shown in the inset of Fig. 2.

Since the needle shall be pulled back into the original rigid housing without bringing the thread back, a detachable needle tip has to be used. The thread can then be attached to the needle tip. After tissue penetration, the needle tip is detached from the needle and the NiTi needle is pulled back for the next stitching motion. An animation explaining these motions is attached as a multimedia extension with snapshots in Fig. 7.

Using a separate needle tip brings additional benefits. NiTi alloy is a hard and brittle material. It will be difficult to directly drill an eyelet in the thin body of a $\emptyset 0.69mm$ NiTi needle. It is also relatively easy to grind cutting edges on the needle tip made from stainless steel. A grinded needle tip will facilitate the penetration in a circular path.

C. Threading mechanism

If a separate needle tip is used, a threading mechanism shall be used to complete one stitching cycle. As shown in Fig. 4.(a), the threading mechanism needs to grasp and detach the needle tip from the needle after tissue penetration. After the needle is retracted back to the rigid needle housing, the threading mechanism also needs to assemble the needle tip back to the needle for the next stitch, as shown in Fig. 4.(b).

After penetration, shape of the NiTi needle might change due to the disturbance from tissues. The threading mechanism shall accommodate the shape discrepancy by including a few DoFs. One prismatic DoF and one revolute DoF are currently integrated. Further positioning and orienting can be achieved by rotating the device along the axis of the needle housing.

The threading mechanism should be able to pick up and release the needle tip as desired. Integrating one more active DoF is difficult due to the limited space in the device. A passive needle tip grasper is designed. The needle tip grasper holding a needle and its cross section are shown in Fig. 4.(c).

After the needle penetrates the tissue, the needle tip grasper will be positioned and oriented so that the needle tip can be wedged into the grasper by prying open the grasper, as shown in Fig. 4.(a) and Fig. 4.(c). Due to the geometry of the needle tip and the grasper, the tip can only wedge through the grasper in one direction. Hence when the needle is retracted, the needle tip will be kept in the grasper. Then the needle tip grasper can place the needle tip back at the outlet of the needle housing, as shown in Fig. 4.(b); when the needle is pushed out again, it will wedge the needle tip out for the next penetration. An animated process of this motion cycle is presented in the attached multimedia file and in Section IV.

A simple linkage system is designed to position and orient the needle tip grasper. Since the NiTi bends into a $3\pi/4$ circular arc, the linkage should be able to open the needle tip grasper for 135° . The closed and open configurations of this

linkage are shown in Fig. 4.(a) and Fig. 4.(b) respectively. It can also translate along the needle housing as well.

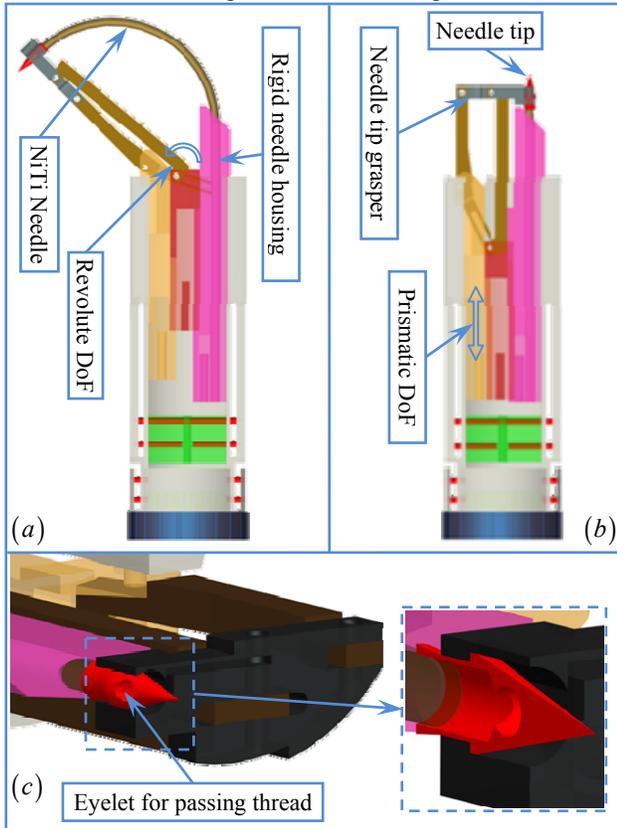


Fig. 4. The threading mechanism: (a) it shall grasp and detach the needle tip from the needle after penetration, and (b) assemble the tip back after the NiTi needle is retracted into the rigid needle housing; (c) the needle tip can only wedge through the tip grasper in one direction.

IV. SIMULATION AND IN-VITRO EXPERIMENTS

A. In-vitro tissue penetrating experiments

In order to demonstrate the effectiveness of the proposed idea, in-vitro tissue penetrating experiments are conducted.

Using a mockup setup as shown in Fig. 5, an $\text{\O}0.69\text{mm}$ pre-curved NiTi needle penetrated a silicone tissue, creating a circular penetrating path.

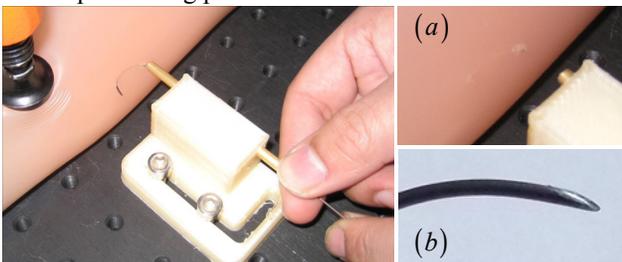


Fig. 5. In vitro tissue penetrating experiments in a silicone tissue mockup for an $\text{\O}0.69\text{mm}$ pre-curved NiTi needle: (a) when the needle is removed, there is a curved path cut in the tissue; (b) the needle is manually grinded at one end to facilitate the penetration.

Fig. 6 shows the same needle penetrated wall of a porcine stomach: (a) the needle housing approached the tissue and (b) then pushed against the tissue; (c) the NiTi needle was pushed out to start the penetration; (d) and the needle generated a circular cutting path; (e) it was shown this penetration could

grasp enough tissue; (f) the needle could be retracted back to the housing to carry out a second penetration.

These tissue penetrating experiments are also attached in the multimedia extension.

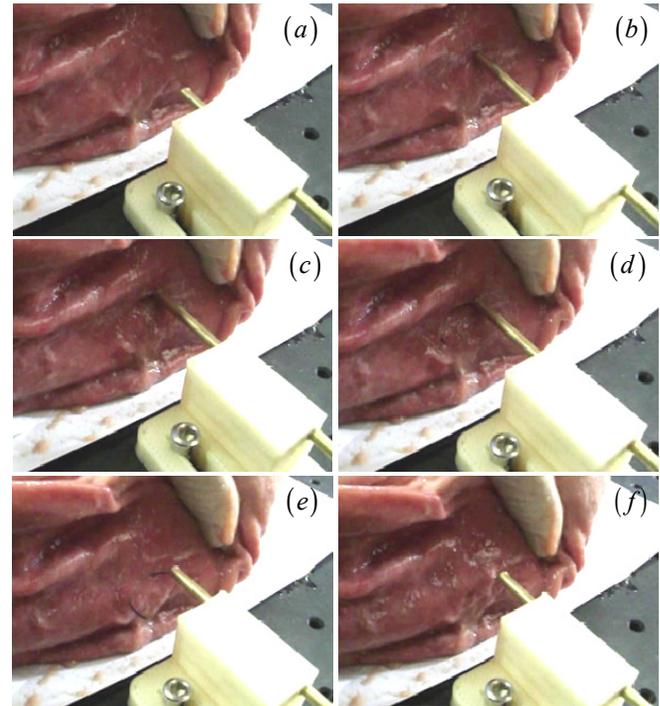


Fig. 6. In vitro tissue penetrating experiments: the same needle shown in Fig. 5 penetrates a porcine stomach wall.

B. Simulated stitching motion

Motivation of this presented work is to facilitate the stitching motion, which used to be hard to perform endoscopically. It is important that the stitching motion can be carried out in a continuous manner.

Fig. 7 and the attached multimedia file show a cycle of the stitching motion: (a) after the device is positioned and oriented, (b) the threading mechanism is opened and the needle housing is extended to press against the surface of the stomach wall; (c) the pre-curved NiTi needle is pushed out to create a circular penetrating path in the tissue; (d) then the threading mechanism will position and orient the needle tip grasper and pick up the needle tip; (e) when the needle tip is wedged into the grasper, the needle will be retracted; (f) the needle housing will also be retracted to generate space so that the threading mechanism can close; (g) the threading mechanism brings the needle tip back to the outlet of the needle housing and (h) pushing the needle out places the tip back to the needle and wedges the tip through the tip grasper; then the threading mechanism opens and it returns to the pose of (a) for the next stitch.

A two-segment continuum snake-like manipulation arm can be inserted through the available channel in the device to assist suturing and knot tying, as shown in Fig. 8. Workspace analysis and instantaneous kinematics of such a continuum manipulation arm are available in [15, 18], while knot-tying using such manipulation arms was achieved in [15]. This exchangeable tool can be replaced by sensor modules (e.g. an

ultrasound probe) or energy sources (e.g. a cautery).

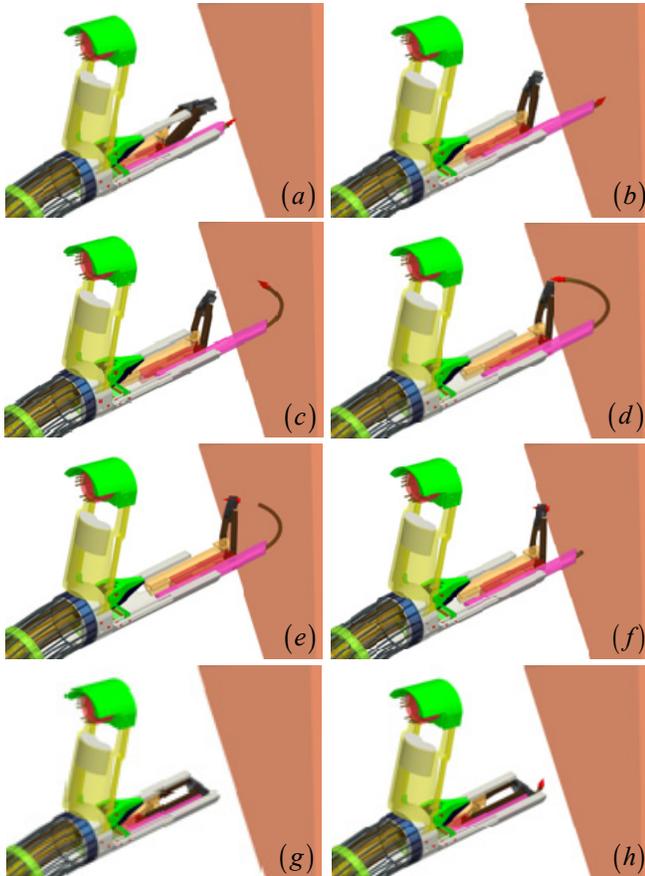


Fig. 7. Simulated stitching cycle. An animation is attached in the multimedia extension.

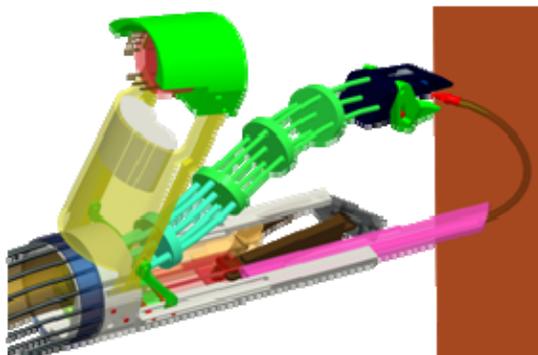


Fig. 8. A two-segment continuum snake-like manipulation arm can be inserted to assist suturing and knot tying.

V. CONCLUSION AND FUTURE WORK

This paper proposed a design of an endoscopic stitching device for surgical obesity treatment using a N.O.T.E.S approach. This proposed N.O.T.E.S gastroplasty approach performs stitching and resizing of a stomach from inside, aiming at further reducing postoperative complications hence making surgical obesity treatments available for a bigger obese population.

An endoscopic stitching device is designed to realize the proposed idea. The presented design can be inserted into the stomach in a folded configuration and can be unfolded into a

working configuration to perform stitching. It uses pre-curved super-elastic NiTi alloy needle to facilitate the stitching motion. Role of the NiTi needle is demonstrated in in-vitro tissue penetrating experiments. Deployment and stitching motions of this device are verified using simulations.

Future work regarding this design includes i) fabricating and assembling the components (some fabricated parts are shown in Fig. 9), and ii) designing and building actuation and control units so that tissue stitching and knot-tying can be achieved in a more realistic experimental setting.

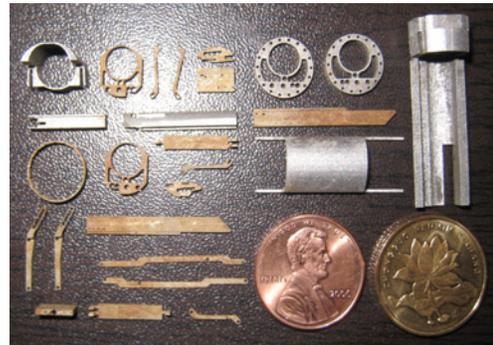


Fig. 9. Some parts of the endoscopic stitching device are fabricated and placed aside to a US penny and Chinese 50-cent coin

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