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Wilson-Cook sewing device: the device, technique, and preclinical studies

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Gastroesophageal reflux disease (GERD) occurs in 5% of the population of Western countries [1]. Medical therapy is associated with a lifetime commitment to expensive medications [2]. While some patients are noncompliant with medical therapy, others remain refractory and progress to surgical intervention. Surgical therapy has evolved from open laparotomy to a minimally invasive approach using laparoscopic techniques. The perceived morbidity of general anesthesia and a surgical procedure, along with postoperative complications including gas bloat and dysphagia, have limited widespread acceptance of this procedure for the treatment of GERD. An endoscopic approach to GERD is very appealing. It can offer a potentially cost-effective therapy for GERD without the associated morbidity of surgery and the necessity for long-term compliance with medical therapy.

The ideal anti-reflux treatment would mimic surgical therapy with a mechanical effect on the lower esophageal sphincter without the associated risks of invasive surgery. Endoluminal methods for the treatment of GERD fall into three categories: (1) injection of implants into the lower esophageal sphincter (LES) and gastric cardia; (2) thermal energy induced fibrosis and resultant contraction of the GE junction; and (3) suturing/stapling methods to alter the angle of His or elongate the intra-abdominal esophageal segment, thereby decreasing GERD.

The ability to place sutures at flexible endoscopy has dramatically changed the treatment options for GERD. With the development of flexible endoscopic suturing methods, a reliable antireflux barrier can be created without the risks for injections and thermal injury. Antireflux procedures performed with flexible endoscopic suturing have the potential to alter the angle of His, lengthen or tighten the sphincter mechanism, or refashion the valvular mechanism at the cardioesophageal junction [3]. This article reviews the Wilson-Cook Endoscopic Suturing Device (Wilson-Cook Medical, Winston-Salem, NC) with particular attention to techniques and early clinical results.

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Recently Wilson-Cook Medical introduced a unique flexible endoscopic sewing device. This suturing system is passed alongside a standard gastroscope. The side channel is made of a specialized bilayered extrusion plastic tube incorporating a wire mesh. This accessory channel is thin walled (ID 6.0 mm), small sized, flexible, and kink resistant. It is attached to the gastroscope in four places allowing the accessory channel to move in relation to the endoscope, to minimize inhibition of instrument steering. The distal end of the side channel has an adapter to fit over the distal end of the endoscope and fits flexible endoscopes of 8.6 to 10.1 mm diameters. The linear arrangement avoids visual impairment. Proximally, the side channel consists of a diaphragm that seals the channel against pressurized air leakage, while permitting instrument insertions and luminal flushing. With the endoscope positioned in the gastric lumen, the side channel allows multiple sutures to be placed without esophageal reintubation or the need for an esophageal overtube.

The flexible Sew-Right device (Wilson-Cook Medical, Winston-Salem NC) uses a dual needle system with a single suture loop. The device consists of an 80-cm shaft of which the distal 50-cm is flexible. It has a diameter of 5.2 mm and is placed through the side channel. Suction is applied to the handle of the device and tissue is entrapped in the chamber where the sutures are deployed (Fig. 1).

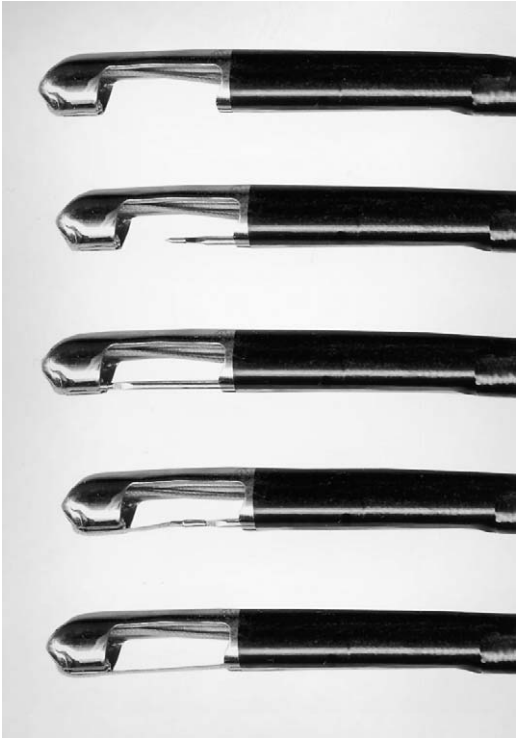

Fig. 1. Distal tip of suturing device with two needles and two ferrules on distal end of suture loops.

This device has two ferrules on the distal end of the suture loops. PTFE 2-0 coated, braided polyester suture is used. When the device is fired, one needle passes through the tissue within the chamber and engages the first ferrule (Fig. 2). With the needle engaged in the ferrule the distal end of one of the suture loops is brought through the tissue. Next the other needle is fired through the tissue and engages the second ferrule and brings it through the tissue. Thus, both ends of the suture loops are brought through the tissue and the suturing device is brought out through the side channel allowing the suture loop to approximate the tissue. When the instrument is removed from the side channel the suture loop apposes the two areas of tissue. Next, the two suture tails are cut from the suturing device.

The Flexible Ti Knot Device (Wilson-Cook Medical, Winston-Salem NC) crimps a titanium sleeve forming a mechanical knot without the need for tying or suture trimming. The Ti Knot Device consists of an 80-cm shaft of which the distal 50 cm is flexible. It has a diameter of 5.2 mm. In order to place a knot, the suture tails are brought through a titanium clip at the distal end of the Ti Knot Device. This device is then introduced down the side channel over the suture tails. Once the device is positioned under direct vision approximating the two suture tails the titanium clip is crimped over the suture mechanically fastening the suture while simultaneously cutting excess suture. This titanium clip has been tested and shown not to disrupt with up to 4 kg of tensile stress.

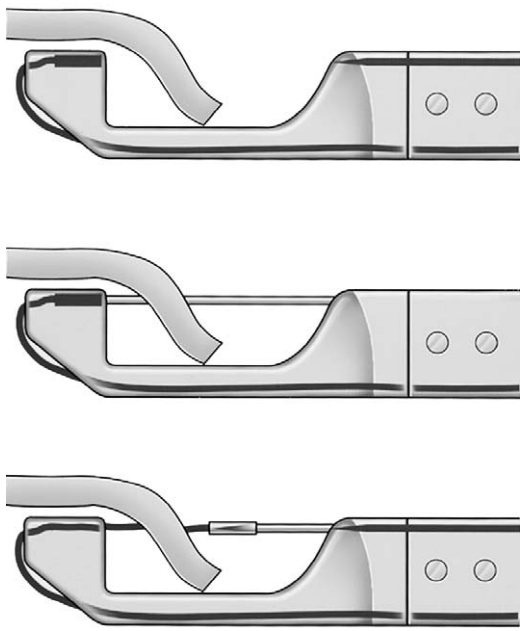

Fig. 2. Artist depiction of suturing mechanism with needle deployed through tissue chamber and engaging distal ferrule and pulling suture loop through tissue.

The authors have used this device in two patients with reflux disease. The first patient had a Nissen fundoplication one year prior. She became symptomatic and refused another surgical intervention. The patient underwent an endoscopic cardioplication while under conscious sedation. This cardioplication was performed by placing two sutures in a linear fashion approximating proximal cardia to the gastroesophageal junction (Fig. 3). Sutures were placed at the 12 o'clock and 3 o'clock position. The patient has remained asymptomatic requiring no medical therapy since the procedure and is currently at 6 months of follow up. No objective studies have been obtained. The second patient with symptomatic reflux, who was not a surgical candidate, has undergone endoscopic cardioplication. This patient underwent a similar procedure and has remained asymptomatic for 6 months of follow up. While only long-term clinical follow up can demonstrate the true value of this technology the first two patients treated with this device have had excellent resolution of their symptoms during this short follow up period.

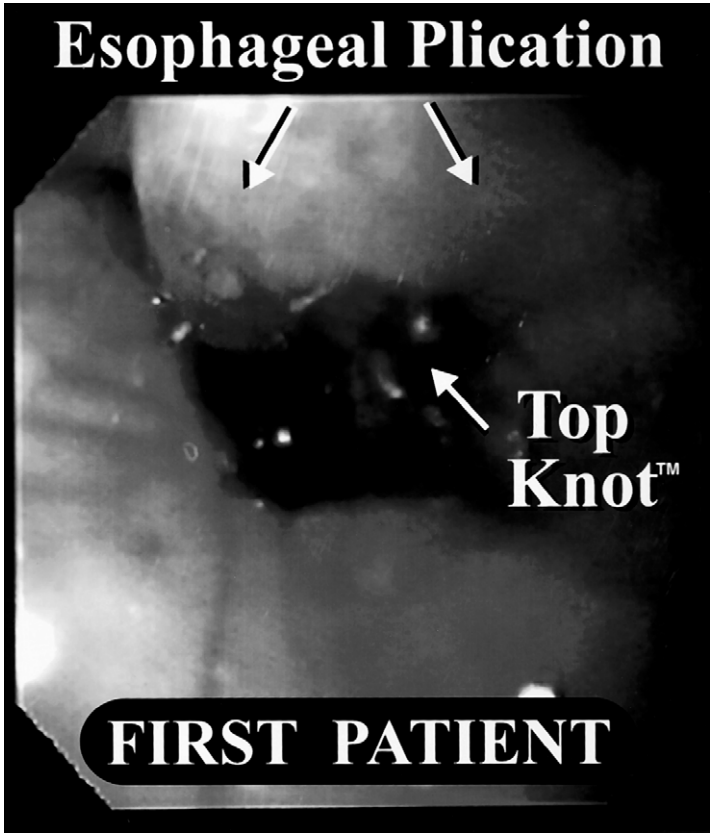

Fig. 3. Intraoperative picture of cardioplication with proximal suture visible and the plication apparent. (See also Color Plate 1.)

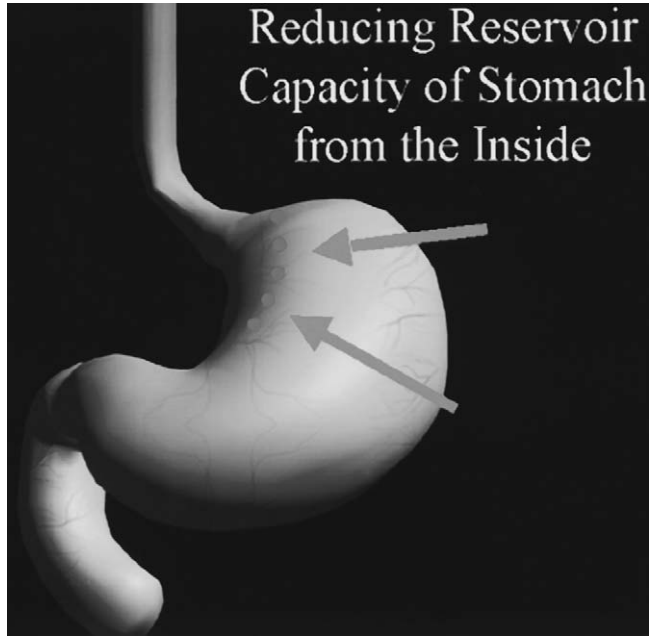

Fig. 4. Proposed artist depiction of endoscopically performed gastric restrictive procedure.

Another potential application of an endoscopic suturing device is in the treatment of morbid obesity. In 1991, in the United States, 12% of the population was considered obese; by 1998, it had reached 20%. People considered to be at least over weight, climbed from 44% to 54% in that period. Severe obesity causes a multitude of health risks and reduces quality of life. A surgical procedure called gastric partitioning has been used in open surgery to successfully reduce the volume of the stomach, making a person feel satiated after eating smaller amounts of food [4,5]. An effective, minimally invasive endoscopic mediated outpatient procedure for weight reduction could become an excellent, inexpensive alternative to help elective weight control for millions of overweight Americans (Fig. 4). Other populations who may benefit from this approach, include patients requiring endoscopic mucosal resection (EMR), tracheal esophageal fistula closure, and suture mediated hemostatic procedures. With the development of longer ESD kits this technology can be used for treatment of colonic diverticular disease, over sewing arterial venous malformations, or even colonoscopic appendectomy.

Summary

Endoscopic treatment of GERD is still in its infancy, however the potential benefits of an endoscopic treatment for GERD are great. These procedures can be

performed on an outpatient basis, without the risks of general anesthesia. The absence of abdominal incisions eliminates the morbidity of wound infections and hernia formation. The procedures are certainly less painful than laparoscopic or open surgery for reflux disease. These procedures might even be more cost effective than long-term acid suppression. These benefits make endoscopic treatment for reflux disease an appealing alternative. While the ideal endoscopic therapy has not been developed, all of these approaches have promise for the future and with further study the role of endoscopic therapy for GERD will continue to be defined.

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