Endoscopic Suturing Devices

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Introduction

Suturing is a necessary step in any surgical operation. In flexible endoscopic surgery within and beyond the gastrointestinal tract, the task of suturing is more difficult due to limited working space and the non-rigidity of the endoscope’s shaft making it impossible to provide a stable base for surgical manoeuvres. Besides, tactile feel is lost in the flexible endoscopic approach. Unlike in laparoscopic procedures, performing suturing and tying of knots endoscopically is a very tedious process requiring high manual dexterity and excellent hand-eye coordination. Endoscopic suturing devices currently available for use in gastrointestinal surgery are too complex for the average endoscopist to handle, requiring much training with long learning curves. While most of the earlier endoscopic suturing devices developed for upper gastrointestinal tract uses were aimed for procedures such as fundoplication, recent developments in natural orifice translumenal endoscopic surgery (NOTES) have prompted designs suitable for transluminal surgical applications. In the absence of better visceral closure devices, most early trials in NOTES have resorted to the use of endoscopic clips or tissue anchors to reinforce closures of visceral perforations. Better, more dextrous and yet easy to handle endoscopic suturing devices are awaited.

Development of endoscopic suturing devices to date

In contrast to earlier suturing/stapling devices designed for the treatment of gastroesophageal reflux disease and obesity, innovations of endoscopic suturing devices specifically for use in flexible endoscopic surgery had only been in progress for at most a decade. In fact, clinical trials of some of these endoscopic suturing devices debuted only in the mid 2000s, which was followed by commercialisation of the OverStitch™ developed by Apollo Endosurgery, Inc., Austin, TX, USA, and the InScope™ Tissue Apposition System developed by Ethicon Endo-surgery, Cincinnati, OH, USA, for use in various types of flexible endoscopic surgery. Over the recent years, a few other newer suturing devices/systems have emerged, with most being in pre-clinical evaluation stage.

1. Commercially available endoscopic suturing devices - functions and applications

A limited number of flexible endoscopic surgery suturing systems have been cleared by the US Food and Drug Administration (FDA) agency for clinical applications. Amongst the better known ones are the OverStitch™ su-
turing device, the InScope™ Tissue Apposition System, and the g-Prox™ Tissue Approximation Device (USGI Medical, Inc., United States), which will be described in the following paragraphs.

The OverStitch™ suturing device is a disposable, single-use suturing device designed to be front-loaded onto a double-channel endoscope for deployment. It employs a lateral needle-passing mechanism and allows continuous or interrupted stitches to be made. Cinching capability is incorporated into the system to provide fast, secure closure of perforation without the need to tie complex surgical knots. The OverStitch™ can deliver multiple stitches in one single endoscopic insertion to provide secure approximation of tissue. Its curved needle design allows operator to better control the depth of suture placement. Cinching and reloading of needle can be done without the need to remove the endoscope from the stomach. Designed for single-handed system control, it requires only one operator to handle the system and is suitable for use in a wide range of endoscopic application, including endoluminal tissue apposition and endoscopic closure of submucosal or full-thickness mural defects. The OverStitch™ has been successfully applied to perform gastric full-thickness suture during endoscopic mucosal resection,1 suturing of gastric full-thickness resection,2 suturing of defects in treat-and-resect colonic procedures,3 suturing of large defects in the stomach and colon left after endoscopic mucosal dissection,4 suturing of gastric fistulas,5 and suturing of the mucosal entry site in full novel submucosal tunnelling procedures.6 The OverStitch™ has an edge over other existing suturing devices in that it is also effective for closure of larger defects. The downside is that orientation of the curved needle requires much skill and the assistance of an endoscopic grasper is required during operation. It is however generally considered complex to use and more appropriately apply for use in bigger lumens such as in the stomach rather than smaller lumens, although recent trials conducted in human have demonstrated the feasibility of its use in some colonic procedures.3,4

The InScope™ Tissue Apposition System is designed for endoscopic placement of sutures and approximation of soft tissue. The system uses an endoscopic hollow bore needle and non-absorbable, synthetic, polypropylene suture, and works by sequentially deploying threaded T-tag through the soft tissue on each side of the gastrointestinal defect to be sewn. Suture position is maintained by means of a metal tissue anchor attached to the distal end of each suture strand. Threaded T-tags placed on either side of the defect are then cinched using a component called the Knotting Element. The InScope™ Tissue Apposition System can be used for endoscopic treatment of a variety of defects, including ulcers and perforations. One shortcoming in the design of the system is that the operator cannot visualize the deployment of T-tag from the extra-luminal side of the defect, thus posing a risk of inadvertent injury to surrounding tissue or blood vessels during deployment of the tags. Preclinical studies showed the feasibility of making leak-proof endoluminal closure of a 4-cm-long colon perforation in 3 of 4 cases tried.7 Subsequently, trials conducted in human demonstrated safe closure of defects by the InScope™ Tissue Apposition System during endoscopic polypectomy of polyps which were otherwise deemed unresectable.8 The system is now being further developed by Ethicon Endo-Surgery as part of a NOTES Toolbox specifically for use in flexible endoscopic transluminal surgery applications.

The flexible g-Prox® Tissue Approximation Device is a multi-function instrument that works on the TransPort® multitasking endoscopic platform, both manufactured by USGI Medical, Inc., United States. The g-Prox® Tissue Approximation Device, designed to suit single-operator handling, is equipped with independent torqueing capacity. To do suturing, the device is first deployed through the lumen of the TransPort® endoscopy platform. Once the device is deployed at the endoscope’s tip, it acts as a needle driver that delivers its propriety
Snowshoe Suture Anchors™ which are preloaded into the g-Cath™ EZ Delivery Catheter inserted into the g-Prox® device. Once anchors are used up, reloading of the anchors can be performed without the need to withdraw the instrument. In contrast to the InScope™ Tissue Apposition System, anchor placement here is made via an off-axis needle. The suture passage is thus off-tangential, permitting thus full visualization of the anchor placement. This is an advantage as it mitigates the risk of inadvertent injury to adjacent tissue as may happen in blinded placement. The system is so designed that the operator can singularly control the tension of the tissue anchors and adjusts it to tighten the closure. Knot strength is quite easily achieved. The g-Prox® Tissue Approximation Device also has the additional functionality of acting as a tissue grasper, providing a robust grasping function and tissue manipulation capability. Pre-clinical trials in animals have demonstrated excellent full-thickness suturing using the system. The system which is already CE marked for marketing in Europe, is now being developed as part of USGI Medical’s Incisionless Operating Platform™, a complete multitasking endosurgical platform designed to support the performance of intricate endoscopic endoluminal, as well as transluminal surgical procedures such as those in NOTES.

2. Emerging endoscopic suturing devices

Despite the availability of various endoscopic suturing devices that can do suturing tasks as described above, there is still no perfect technological solution for consistent and reliable closures of larger mural defects such as those deliberately made in NOTES. Current commercially available systems have been found by many users to be technically complex, with some reporting finding it difficult to mount the devices correctly on the endoscope. The complexity of the applications, long learning curve, lack of equipment dexterity, and inadequate tissue closure strength are persistent issues that continue to spur innovations for better solution. Recent development of NOTES has prompted renewed interest in the development of easily deployable endoscopic suturing devices that can make sutures that are as strong, secured and reliable as hand-sewn ones. Several new and promising innovations are now in proof-of-concept or pre-clinical evaluation stage. Amongst them are: (i) a novel Korean designed prototype device featuring the capability of making successive sutures, and aptly named the successive suturing device, and (ii) two prototypes of an interesting Japanese designed suturing system, the double-arm-bar suturing system and the triple-arm-bar suturing system.

Pre-clinical evaluations of the novel successive suturing device were recently reported by Song et al (2013). The successive suturing device appears to be quite simple by construct, with three major components - a needle, teel plastic tubing that holds major parts of the system, a handle - plus a suction cap. The protective tubing has an external diameter of 3.2 mm, making it small enough to pass through the accessory channel of a standard therapeutic endoscope. The tubing encases the main components of the device, including the transfer tube for the needle, suturing thread and accompanying biodegradable trapezoidal shaped bead which is used as anchor. The handle drives the movement between the components. To perform the suturing of a deliberate or iatrogenic defect in the wall of the stomach or gastrointestinal tract, the entire system is deployed through the accessory channel of the endoscope, and the needle is pushed through the gastric or intestinal wall. A stitch bead is deployed from the needle and it anchors a stitch on the outer surface of the wall while the needle is pulled back from inside the lumen. As beads are anchored on both sides of the incision, pulling the stitch tightens and securely closes the incision. Recently, Song et al (2013) reported their validation of the suturing efficacy of the prototypic device on Erlangen porcine stomach models, in which they compared the strength and reproduc-
bility of incisions sutured by the device to that of incision sutured by hand or closed by endoclips. Deliberate incisions of 2–3 mm length were made on the anterior lower body of 30 porcine stomachs. These 30 incisions were then closed using the novel suturing device, by hand suturing or by endoclips, 10 incisions for each method of suturing. The experimental results showed that the stomachs sutured by the successive suturing device exhibited significantly higher air leakage pressure than those closed by Endoclips ($P<0.05$), but lower than those closed by hand suturing ($P<0.05$). Although the bursting pressure of device sutured stomachs was significantly smaller than that of hand-sutured stomachs, it was similar to that of Endoclip closed stomachs. The suturing device took about 1 minute to complete a stitch.

The experimental trials of two prototypes of a novel Japanese designed endoscopic suturing system were recently reported by Mori et al, (2013; 2014). The prototypes were named the double-arm-bar suturing system and triple-arm-bar suturing system. Although experiments are still preliminary at this stage, results indicate good potential for the novel innovations to make it to clinical applications. The triple-arm-bar suturing system consists of three main arms: (i) a guide needle arm, (ii) a stopper arm at the tip of the device for receiving the puncture needle arm, and (iii) a puncture needle arm. In contrast, the double-arm-bar suturing system has only two arms, one arm holding the puncture needle and a small hook, and the other holding the suture. In 2013, Mori et al reported the use of the triple-arm-bar suturing system to close twenty 5-cm incisions in resected swine stomachs. Comparing it to hand-sewn stitches, they found similar maximum pulling force durability between full-thickness stitches made by triple-arm-bar suturing system and stitches made by hand ($P = 0.335$). In another study, Mori et al (2014) tested the reliability of the double-arm-bar suturing system, and the feasibility of using it to perform endoscopic full-thickness resection. Full-thickness resections of 40 mm diameter were carried out on 30 swine stomachs. Based on resistance to air-leak tests, they found no significant difference between hand-sewn sutures and sutures made by the double-arm-bar suturing system ($P = 0.542$), indicating that the strength of sutures made by the double-arm-bar suturing system was as good as hand-sewn ones. Whether it is single-stitch and multiple-stitch sutures, the sutures produced by the above prototypic suturing devices were as strong as simple, interrupted handmade sutures.

3. The Future - robotic enhancement of endoscopic suturing systems

Currently available endoscopic suturing devices enables suturing to be performed endoscopically but they still have functional limitations, especially when performing in confines of smaller working space, and when dealing with bigger perforations. Primarily, all these systems are mechanically driven and thus lack the motion range and functional dexterity for fast, efficient and safe operation in complex procedures such as those in NOTES. Although emerging innovations are increasingly aimed at providing better articulation in instrumental mobility, with all mechanical systems, there is limitation to the range of surgical movement of tools. Moreover, poor perception of depth with current 2D endoscopic video imaging and the lack of tactile sensation pose hurdles in the management of the orientation of tools and judgement of appropriate amount of force to apply, risking injury to tissue. To mitigate these technical challenges, the incorporation of robotics into the control of suturing and knotting function is an attractive option. Recently, the developer of the MASTER (Master And Slave Transluminal Endoscopic Robot) in Singapore demonstrated the practicality of this idea in their first ex-vivo trial on robotics-enabled suturing and knot-tying. They demonstrated the feasibility of performing endoscopic suturing and knot-tying using commercial suturing kit with robotics enablement through the MASTER, a sta-
Incision closure is one of the most challenging tasks in endoscopic surgery such as NOTES. Current mechanical endoscopic suturing devices lack dexterity and suffer numerous functional limitations. While ongoing innovations of better mechanical endoscopic suturing devices are anticipated to fill in some of the unmet demands of reliable, reproducible, and secured suturing in endoscopic surgical applications, the ultimate solution for adequately dextrous, safe and efficient endoscopic suturing could lie in the incorporation of robotics into future suturing systems.
References


