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New Suturing System for Flexible Endoscopy in The Gastrointestinal Tract

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1. Abstract

1.1. Background: We have assessed an approach, enabling an endoscopist together with surgical assistance to perform endoscopic sutures based on minimally-invasive principles.

1.2. Aim: Assessment of a new suturing-system in the gastrointestinal tract.

1.3. Methods: An endoscopist and a surgical assistant used a standard flexible scope and an external 5mm needle-holder with a flexible shaft and articulating end-effectors to perform sutures within the esophagus. For knot-tying, a 5mm flexible knot-pusher was used. The procedures were performed by 4 surgeons with different levels of experience. Assessment of this system consisted of initial box-testing in explants and subsequently in a porcine model to explore different prototypes of needle-holder, suture-materials and time-consumption with suturing. In the final series duration of closure of an esophageal incision was measured.

1.4. Results: Results show a good feasibility with a mean duration for single bite suturing of 10 min (8-35) and extracorporeal knot-tying median duration 5 min (2-8). The closure of an esophageal incision required a double bite procedure, followed by 3 knots in a median time of 20 min (14-45), performed by 4 endoscopists/surgeons of different level of experience.

1.5. Conclusion: In animal studies we established the feasibility of a new flexible articulating instruments with flexible endoscopy and surgical assistance to perform reliable intraluminal sutures.

Key words: endoscopy, Interventional endoscopy, endoscopic suturing, endoscopic closure, esophageal perforation, esophageal fistula

2. Introduction

Suturing in interventional flexible endoscopy is a challenging problem considering the level of complexity. Early endoscopic technology lacked the deep bite necessary to reach the muscular is of the gut wall [1-7]. Very complex endoscopic platforms had been developed, but have not reached the market for a number of reasons such as expensive technology, cumbersome technique with long learning curves and lack of corporate interest [5-8]. Currently only one of these platforms has achieved widespread use in clinical practice (Overstitch™-system; Apollo Endosurgery, USA) [5-11].

We have focused on the development of a simple approach by combining flexible endoscopic with laparoscopic elements of technology as well as surgeon`s know-how, enabling a team of endoscopist and surgeon to perform sutures in the GI-tract based on minimally invasive technological principles [1-7]. Our aim was to develop a flexible needle-holder, which can be introduced into the gut alongside any flexible endoscope, permitting suturing under direct endoscopic visualization.

The purpose of the study is to experimentally assess a new suturing system for application in the esophagus based on flexible endoscopy, using flexible suturing instruments following a laparoscopic paradigm for the closure of an esophageal incision.

3. Methods

Our group focused on developing an endoscopic suturing-technique using a standard flexible endoscope and the newly designed, flexible, articulating instrument (EndoSuture, Fortimedix-Surgical BV, Geleen, Netherlands) allowing for complex end-effector movements [12, 13]. Initially we set up prerequisites. We sought a suturing system that 1) would not require large monetary investments, 2) would require only standard commercially available endoscopes, 3) would permit easy flexible endoscopic application without a prerequisite for complex set-up, 4) would be applicable with a reasonable learning curve for experienced endoscopists and minimally invasive surgeons, 5) would permit delicacy of tissue handling at the gut wall; 6) would consist of adequate end-effector movement to perform effective suturing and provide sufficient maneuverability for knot tying; 7) would allow for use of commercially available suture material.

4. Initial Testing and Set-up of Material, Instruments and Operators

A standard pediatric endoscope and a standard gastroscope were utilized to develop this technique. Details of this development are summarized earlier [14]. It must be emphasized that this system needs a team of an endoscopist and a surgical assistant. The 5mm needle-holder (EndoSuture Fortimedix Surgical™ Geleen, Netherlands) was designed following laparoscopic principles. The shaft of the needle-holder (length 80cm) is flexible and allows for smooth passage of bends such as the human mouth and pharynx (Figure 1). The end-effectors are capable of articulation and can be steered in all directions via movement of the external handle. The needle-holder is anchored externally to a Strong Arm™ Surgical Holder (Mediflex, USA), attached to the operating table (Figure 2). Since the needle-holder is independent from the scope, it can be maneuvered in and out of the esophagus without limitation. In order to facilitate repetitive passage through the oropharynx, an overtube (Guardus®-overtube, US-Endoscopy, USA; outer diameter: 18,5 mm) was routinely used.

By manipulating the handle of the needle-holder in different directions, the tip of the needle holder with the end-effectors was steered as needed for the suturing process (Figure 3). The direct force-transmission within the stable steel-instrument diminished a delay in movement and allowed for a "good bite" at the tissue level. Stabilization of the needle-holder-shaft in the Strong Arm™ was critical. For knot-tying, the well-established, extracorporeal technique from laparoscopy was used. A 5mm EndoSuture-knot-pusher with a similar, flexible shaft was used to advance the knots to the suture-site.

In the initial phase of testing we used several sizes of endoscopes, different suture-materials, different needle-holder prototypes with varying shapes of the mouth. We choose for this series, the closure of a esophageal incision in a porcine model, 3/0 Prolene™ suture material (Ethicon, Johnson & Johnson, Cincinnati, USA) for optimal handling within the esophagus (needle size 11mm) (Figure3). Surgeons from various levels of training (1st and 3rd year surgical resident, certified colorectal surgeon and certified GI-surgeon, all with flexible endoscopic experience) participated in this study. Each participant went at least 4 times through both functions as endoscopist and as surgical assistant in the box training and in the initial porcine model training.

Figure 1: The 5mm EndoSuture needle holder (Fortimedix Surgical BV, Geleen, The Netherlands) has a flexible shaft (length 80cm) following established laparoscopic principles. The tip with the actual needle holder is capable of articulation in all directions via movement of the handle outside the body.

Figure 2: Overview on the set up in the operating room. The team consists of an endoscopist and a surgical assistant, manipulating the needle-holder. The needle-holder is fixed on a Strong-arm™ on the operating table to provide stable maneuvering using the technology to move the needle-holder tip in different directions.

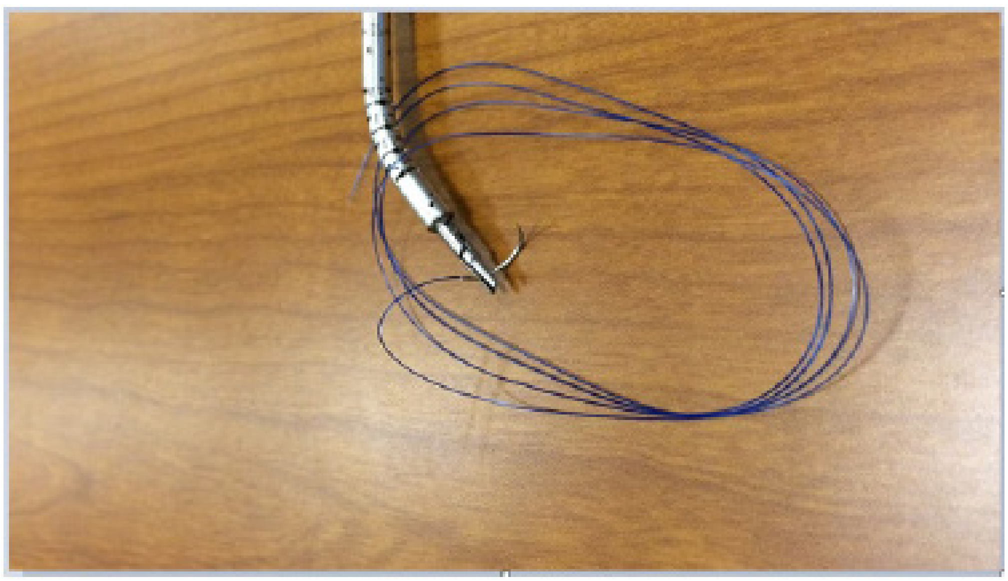

Figure 3: By manipulating the handle of the needle-holder in different angles in relation to the shaft, the tip of the needle-holder is directed in different directions.

5. Closure of an Esophageal Perforation

Prior to the experiments all necessary requirements for animal testing were granted by the University of California San Diego (UCSD), Institutional Animal Care and Use Committee (IACUC). All training was performed at UCSD, the Center for the Future of Surgery, animal care facility in La Jolla, CA, USA. Care was taken to adhere to the rules for good laboratory practice and use of laboratory animals. The animals were placed under general anesthesia in the supine position on the operating table. They remained under continuous monitoring by trained personnel for the duration of the procedure.

For the assessment of esophageal closure, the test was started with an incision in the esophageal wall through the muscle using a TT-knife. With the mounted needle, flatly fixed in the jaws of the needle-holder, the latter was advanced under direct endoscopic visualization to the incision site (Figure 4). The edges of the incision were inspected, and the closure commenced by driving the needle through one side of the wound opening (Figure 5). The needle tip was re-grasped and pulled through the tissue. The needle was again re-grasped with the needle holder, and the next bite performed on the corresponding side of the wound. Care was taken to include as much of the muscular layer in the bite as possible to simulate closure of a perforation. Since the esophageal mucosa exhibits a degree of laxity, it was often necessary to perform repeated needle driving with the instrument, as stepwise penetration of the needle was required to drive the tip of the needle through the mucosa and muscle. Once the tip of the needle was visualized, it was then re-grasped and pulled out. After pulling both needle and thread out through the oropharynx, three extracorporeal knots were tied and placed with the flexible knot pusher, thus completing closure of the esophageal incision (Figure6). Each participant performed at least 2 closures of the esophageal incision in the final series. Feasibility and duration of procedures were documented.

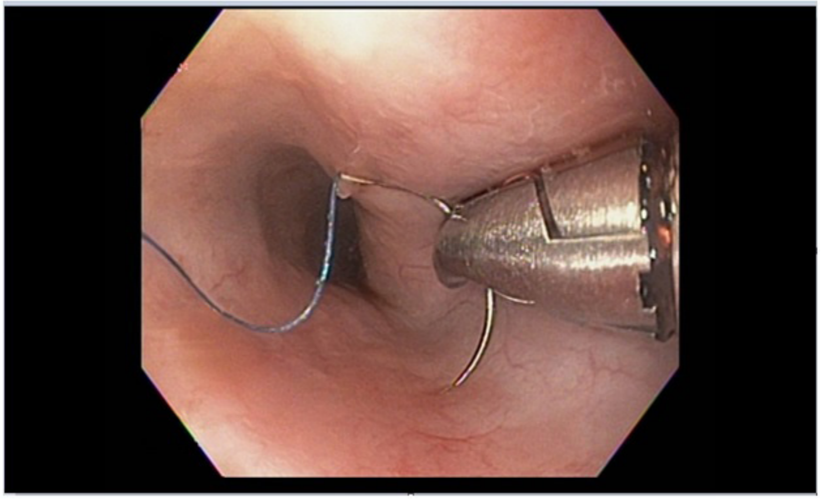

Figure 4: Inside the esophageal lumen traditional surgical suture material can be used for a suture, performed by the flexible needle holder under endoscopic vision.

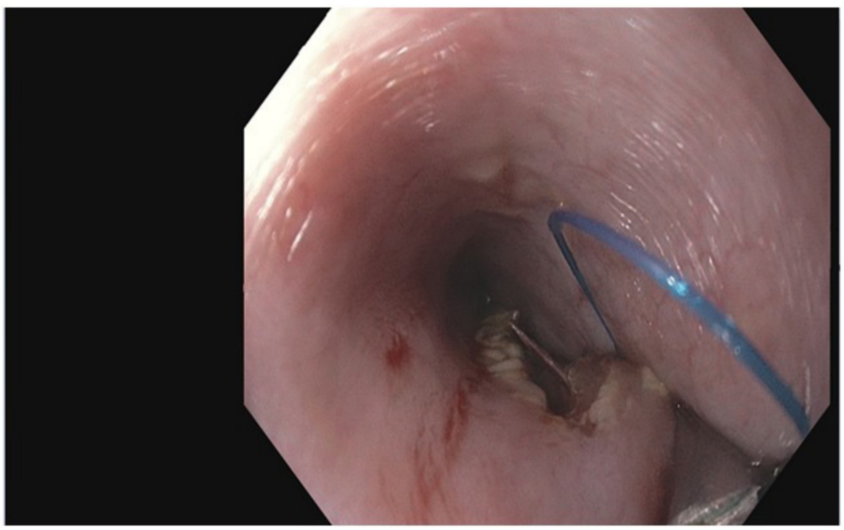

Figure 5: After a deep incision of the esophageal wall was made, closure can be performed with the EndoSuture system. With the mounted needle in place, the needle holder can be advanced under direct endoscopic visualization to the level of the incision site Closure can be commenced by driving the needle through the wound edges under endoscopic control by turning the needle holder outside the body.

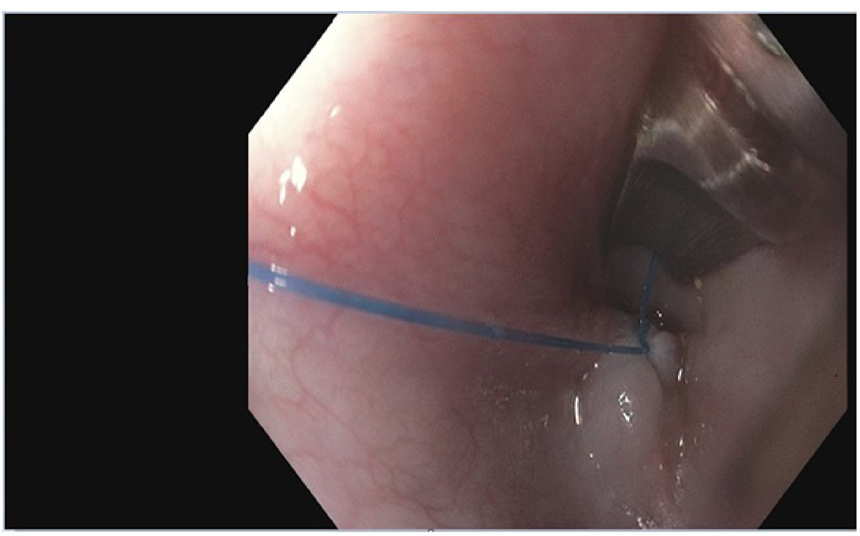

Figure 6: After performing an extracorporeal knot in the laparoscopic technique, the knot is pushed by the flexible knot pusher inside the esophageal lumen down to the incision site.

6. Results

The results of the box training on esophago-gastric explant showed good feasibility. Median duration for single bite suturing and knot tying was 10min (8-35). The process of extracorporeal knot-tying was easy with the flexible knot-pusher, and the median duration was 5min (2-8). A problem was the insufficient stability of the needle in the mouth of the needle holder during the process of driving it through the tissue. The needle was frequently displaced and the optimal position was lost to drive it through the tissue. These problems were improved in the final prototype. No issues were encountered with respect to either friction or sizing using a pediatric endoscope in conjunction with the EndoSuture needle-holder.

The results of the training with the final prototype show the duration of double bite suturing and approximation of the incision and 3 knots tying (Figure7). The median duration was 20min (14-45). Suturing was completed with the needle holder in all attempts.

In summary, suturing and closure of incisions with this EndoSuture endoscopic system was feasible and rather easy to apply in the esophagus. The learning curve was fairly steep.

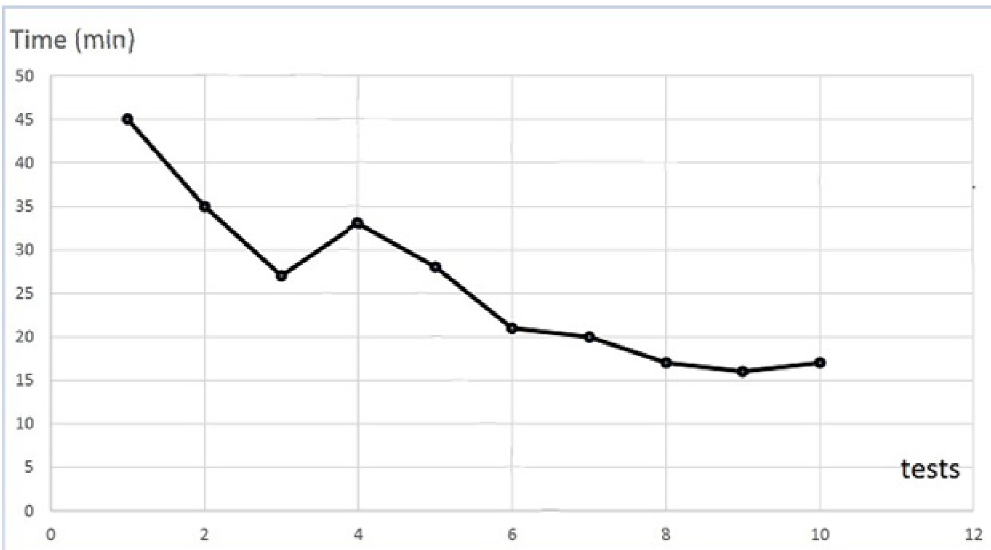

Figure 7: The results of the series (training in porcine model) with the final prototype are demonstrated. The Figure shows the duration (in Minutes) of the double bite suturing and approximation of the incision after 3 knots tying. The median duration was 20 min (14-45). The decrease in duration of the procedures, performed by all participants underlines the reasonable short learning curve.

7. Discussion

Intraluminal suturing in the esophagus faces a number of severe challenges. One is the limited space to manipulate a needle-holder for precise movements. A second issue may be the limited degrees of freedom with some instruments [5-11]. The latter is even increased by the tangential approach of any instrument, which is maneuvered down the esophageal tube. On the other hand, endoscopic closure techniques of esophageal perforations and leaks are important and can be considered an unmet need.

Currently, this field is covered by the application of the Ovesco™ Clips and endoscopic suturing by Apollo Overstitch™ [8-13, 15]. These techniques are quite successful in cases of perforation and closure of the gut after endoscopic resections [8-13, 15]. Clinical experience with robotic endoscopic systems has been published showing a successful application [16]. The Overstitch™ average closure duration was approximately 9 minutes after POEM-mucosotomy in the hands of experts [8]. Additional literature examining the Overstitch system documents procedure times of with a mean of 10-15 min [9-11]. Duration of Ovesco clip placement in an experienced center averaged 5-10 min (44-47) [8, 14]. Clinical experience with a new "through-the-scope" suturing system has been published showing a successful application [17, 18]. Some limitation may be possible, since the narrow diameter of the shaft may limit the applicable force transferred to the end-effectors.

Despite the success of the available techniques, it seems desirable to rely on a reusable suturing system, which can be applied together with any commercially available endoscope and regular suture material. This system would not require any substantial investment for the hospital and could be available anywhere. Thus, the advantages of the tested endoscopic suturing-system permit the use of standard 10 mm endoscopes, as well as 5 mm endoscopes. Another advantage of the system is the use of standard suture-material, which is readily available in any operating room. The prerequisite is a team of an endoscopist and a surgical assistant. The results of our study demonstrated an acceptable learning curve for this technique, therefore lack of familiarity with suturing should not be a deterrent to use of the system.

7. Conclusions

In animal studies we established the feasibility of new flexible articulating instruments with flexible endoscopy and surgical assistance to perform reliable intraluminal sutures.

8. Funding

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