

# NOTES<sup>®</sup> transgastric abdominal wall hernia repair in a porcine model

D. B. Earle · D. J. Desilets · J. R. Romanelli

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## Abstract

**Introduction** With approximately 1 million ventral and inguinal hernia repairs performed in the United States each year, even small rates of complications translate into large numbers of patients. Less invasive approaches that potentially lower morbidity deserve consideration, recognizing there are many technical considerations that currently limit their use. We describe a reproducible technique and lessons learned in our laboratory that answer some existing questions with regards to the use of NOTES<sup>®</sup> for hernia repair. **Methods** A non-survival porcine model with general anesthesia was utilized in all cases. Each animal underwent transgastric peritoneal access with a percutaneous endoscopic gastrostomy (PEG) technique, and the gastrostomy was dilated with a wire-guided balloon dilatation catheter. An Esophageal Z-stent delivery device (Cook Medical, Winston-Salem, NC) was modified ex-vivo to allow us to introduce and protect a 10 × 15 cm lightweight polypropylene hernia prosthetic with pre-placed sutures. Once deployed, the sutures were pulled through the abdominal wall using a looped spinal needle technique in combination with the flexible endoscope. After the four anchoring sutures were tied, proprietary endoscopically placed tacks

(Cook Medical) were placed at regular intervals between the sutures to secure the edges of the prosthetic.

**Results** Hernia repairs were performed on five animals. In each case, we successfully completed prosthetic delivery and deployment into the peritoneal cavity, anchoring to the abdominal wall with full-thickness abdominal wall sutures, and endoscopically placed nitinol tacks. All prosthetics were deployed flat against the anterior abdominal wall. Operative times ranged from 65 to 120 min.

**Conclusion** Transgastric abdominal wall hernia repair is feasible, consistent, and reproducible. In particular, the delivery system can successfully deliver the prosthetic across the gastric wall via a transoral route. Survival animal experiments investigating outcomes related to quality of repair, microbiology, adhesions, and visceral closure need to be done. Human studies are not recommended until these issues are formally investigated.

**Keywords** Polypropylene hernia prosthetic · NOTES<sup>®</sup> · Ventral hernia · Inguinal hernia · Percutaneous endoscopic gastrostomy

## Introduction

There are approximately 1 million hernia repairs performed in the United States annually [1]. Because of the high case volume, even low complication rates translate into large numbers of patients. As wound complications are a major part of the morbidity, eliminating abdominal wall incisions may ameliorate these complications, thus improving overall outcomes. With regards to NOTES<sup>®</sup>, many barriers exist to the successful repair of abdominal wall hernia. These include transluminal access and closure, sterile prosthetic delivery, prosthetic deployment and

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D. B. Earle · J. R. Romanelli (✉)  
Department of Surgery, Baystate Medical Center,  
Tufts University School of Medicine, 759 Chestnut Street,  
Springfield, MA 01199, USA  
e-mail: john.romanelli@bhs.org

D. J. Desilets  
Division of Gastroenterology, Department of Medicine,  
Baystate Medical Center, Tufts University School of Medicine,  
759 Chestnut Street, Springfield, MA 01199, USA

fixation. Naturally, clinical outcomes should be the primary metric regarding the ultimate fate of a given procedure or technique.

## Methods

Five Yorkshire female pigs, 35–44 kg in weight, were used for this experiment. The animals were anesthetized and cared for according to our IACUC (Institutional Animal Care and Use Committee)-approved protocol.

Utilizing a GIF-140 diagnostic gastroscope (Olympus America, Center Valley, PA), we utilized a standard percutaneous endoscopic gastrostomy (PEG) technique to place a 0.035 inch (0.1 cm) guidewire through the abdominal wall, into the stomach, and out through the mouth. Once the wire was in place, we insufflated the peritoneal cavity to 12 mmHg with CO<sub>2</sub> utilizing a Veress needle. We then fed extra wire into the peritoneal cavity through the abdominal wall.

A loop-anchor purse-string gastrotomy closure technique was employed prior to creation of the gastrotomy to facilitate eventual gastric closure with some animals with our previously described a technique [2]. Briefly, a single monofilament, non-absorbable suture was placed in a purse-string fashion using four full-thickness looped T-anchors (Cook Medical). A needle-knife gastrotomy was then performed in the center of the purse string, and dilated with an 18 mm, wire-guided balloon dilatation catheter (Cook Medical).

Once the gastrotomy was dilated and the endoscope was introduced into the peritoneal cavity, the 0.035 inch guidewire was then removed, and a Savary wire was placed into the peritoneal cavity through the endoscope. The animal was now considered properly prepared for prosthetic implantation.

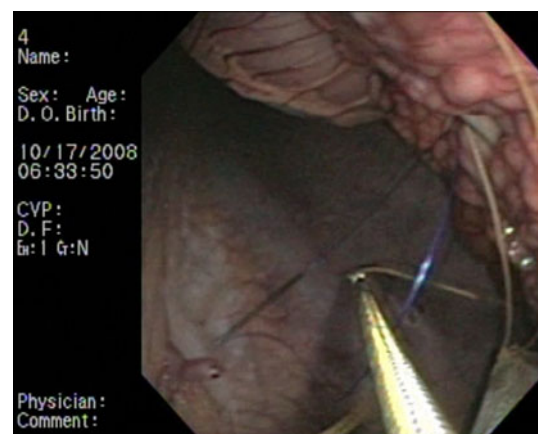
A 10 × 15-cm lightweight polypropylene prosthetic (ProLite™ Ultra; Atrium Medical; Hudson, NH) was used. Four 2–0 silk sutures were placed at the 12, 3, 6, and 9 o'clock positions. The prosthetic was marked at one of these sutures to allow for proper orientation. The mesh was then back-loaded into a modified esophageal stent introducer (Fig. 1; Cook Medical). The stent introducer's wire channel is separate from the lumen of the introducer that houses the prosthetic, thus keeping the prosthetic in a sterile environment during placement into the peritoneal cavity. The stent introducer was then passed over the Savary wire alongside an endoscope until the introducer tip was completely through the gastrotomy, and in the peritoneal cavity. The prosthetic was then deployed with the stent introducer under direct endoscopic (and for the first two cases, laparoscopic) vision, and the introducer was removed.



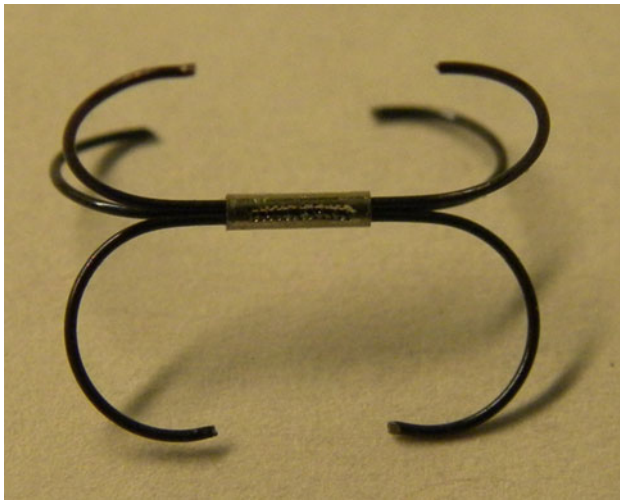
**Fig. 1** Esophageal stent introducer, modified to introduce mesh into abdomen; intraabdominal view of mesh deployment

Four stab incisions were made in the abdominal wall corresponding to the locations of the sutures on the prosthetic. The prosthetic was partially unfurled and manipulated into position by using a grasping forceps via the endoscope. Once the marked suture was located, we pulled this through the abdominal wall using a looped spinal needle (Fig. 2), and repeated the process for each of the four sutures, in a technique previously described by us [3]. This was performed such that each suture tail was pulled through two separate locations of the abdominal wall via a single skin incision, as would be done for a typical laparoscopic or open ventral hernia repair. Once the sutures were tied, the mesh lay taught against the anterior abdominal wall.

Proprietary endoscopic Nitinol tacks (Fig. 3; Cook Medical), as described by Bhat et al. [4], were then passed through the working channel of the endoscope, and



**Fig. 2** Intraabdominal view of endoscopic suture (*right of center, almost horizontal*) manipulation via looped spinal needle with Prolene suture (*right of center, vertical-diagonal*)



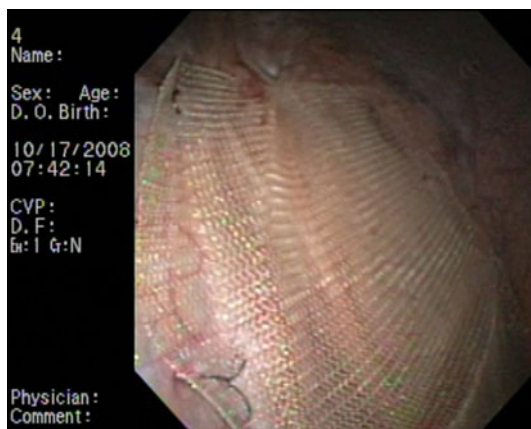
**Fig. 3** Endoscopic tack

deployed into the abdominal wall through the periphery of the prosthetic, including the corners, at 2–3 cm intervals. The repair was completed when the mesh was tacked circumferentially (Fig. 4).

The endoscope was then withdrawn into the stomach, and the purse-string was tightened, thus closing the gastrotomy, and crimped with a friction fit collar. The excess suture was then cut with endoscopic scissors. The animal was then euthanized per our standard animal protocol.

## Results

Transgastric access to the peritoneal cavity and prosthetic deployment was successful in all five cases. Additionally, in each case, the prosthetic was successfully anchored to the anterior abdominal wall with a combination of full thickness anchoring sutures and tacks solely with the



**Fig. 4** Mesh secured to the abdominal wall with transabdominal fixation sutures and endoscopically deployed tacks

transgastric flexible endoscope. The first two cases were performed with the assistance of laparoscopic visualization, primarily to obtain external video of the endoscopic maneuvering and to hasten the learning curve. The third case was performed with the endoscopist blinded to the laparoscopic view, and the final two cases were performed without the use of a laparoscope. Two of the five gastrotomy sites were not closed due to logistical constraints, and the fact that it was a non-survival model. Operative time was defined as time of endoscope insertion to gastrotomy closure or full mesh fixation, and ranged from 65 to 120 min.

## Discussion

Early excitement regarding the implementation of NOTES<sup>®</sup> techniques has led to successful early human case reports [5–15], including an early human case report of a NOTES<sup>®</sup> transvaginal umbilical hernia [16]. Despite this, much scientific investigation is required prior to widespread adoption of this new surgical approach. The promise of little to no recovery coupled with a commonly performed operation has prompted us to investigate techniques to improve the current performance of hernia repair. In order to focus our efforts on a systematic pathway to developing the technique, we have broken the procedure down into the components (Table 1): abdominal access, prosthetic handling (preparation, delivery, manipulation and fixation), and visceral closure. In this non-survival porcine model, our efforts were concentrated primarily on the technical aspects of

**Table 1** Components of NOTES<sup>™</sup> hernia repair

Access to abdominal wall
Transgastric
Transrectal
Transvaginal
Transvesical
Prosthetic delivery
Prosthetic type
Sterility
Transport through natural orifice and across viscera
Prosthetic fixation
Manipulation of prosthetic
Suture anchoring
Tacks
Other
Visceral closure
Loop anchor purse string
Mucosal clips
Other

prosthetic delivery, manipulation, and fixation. Certainly, peritoneal access and secure visceral closure are critical for safety, and remain the focus of other ongoing experiments.

Other investigators have also explored NOTES<sup>®</sup> techniques for hernia repair. Hu et al. [17] made a muscular defect using a needle knife and pull-type sphincterotome; they were able to close it endoscopically using a prototype suturing device. Miedema et al. [18] simulated transgastric incisional hernia repair in a porcine model, similar to our experiment, except that they utilized only four tacking sutures, and biologic mesh (Surgisis<sup>®</sup> Gold<sup>™</sup>, Cook Medical). Sherwinter and Eckstein [19] simulated transgastric inguinal herniorrhaphy in a nonsurvival canine model employing human acellular dermal matrix (AlloDerm, Lifecell, Branchburg, NJ). Interestingly, their choice of mesh fixation was with BioGlue<sup>®</sup> (CryoLife, Kennesaw, GA) delivered through the endoscope. Another study by Lomanto et al. [20] describes NOTES<sup>®</sup> transvaginal hernia repair in a survival porcine model, using Parietex<sup>™</sup> mesh (Covidien, Mansfield, MA), covering a created defect in the abdominal wall. The mesh was secured to the abdominal wall again employing preplaced sutures, and laparoscopic tacks or fibrin glue. They reported no infections and adhesions in two of the five cases. Lastly, there is a recent case report [21] of a transrectal umbilical hernia repair in a human cadaver; obviously, troubling questions regarding infection are not assessed in this feasibility study.

Regarding the prosthetic choice, we chose a lightweight polypropylene prosthetic because this is the most common and well studied hernia prosthetic on the market. It represents a group of prosthetics that tolerates clinical infection relatively well, and effects a long lasting repair of abdominal wall defects compared to other types of prosthetics [22–25]. This study does not aim to compare prosthetics, or suggest which prosthetic is best for this type of repair. It is certainly possible that the prosthetic for a NOTES<sup>®</sup> hernia repair has yet to be developed. Future studies comparing prosthetic types for clinically relevant parameters such as infection rates, ease of deployment, and adhesion formation are necessary.

Delivery of the prosthetic to the posterior part of the anterior abdominal wall without injuring tissue, damaging the prosthetic or introducing infection is an obvious obstacle to performing a NOTES<sup>®</sup> hernia repair. One study examined delivery of a very small prosthetic via a transanal approach in a porcine model with both survival and non-survival techniques. Without necessarily protecting the prosthetic from the colonic flora, they found no problems associated with infection [26]. Although the small prosthetic size is not very clinically relevant, it answers some important questions about the basic principles of prosthetic delivery. On the contrary, a recent study by Buck and colleagues compared NOTES<sup>®</sup> mesh placement to

laparoscopic mesh placement and found that NOTES<sup>®</sup> mesh placement had a significantly increased rate of infection, despite gastric irrigation [27]. This study also utilized a non-clinically relevant mesh size. This implies the need for a sterile delivery device, such as the one we describe. Miedema et al. [18], despite using a biologic prosthetic placed in a transgastric fashion, found micro-abscesses in three of five animals, indicating a likely source of contamination during prosthetic delivery.

Given that there were no infectious problems when a solid polytetrafluoroethylene prosthetic was used to repair iatrogenic colonic defects in a dog model, one wonders if there is a difference between the gastric and colonic flora as it relates to prosthetic infection. There are obviously many unanswered questions about this concept [28]. One problem encountered during the transanal prosthetic placement was locating the prosthetic after delivery. The use of a unique magnetic system to assist in prosthetic location was successfully employed [26]. We have not found this necessary, as the prosthetic was easily located with the endoscope after delivery with the device via a transgastric approach, likely due to the larger prosthetic size, in addition to the predictable fashion with which the delivery system placed the prosthetic. To solve problems with contamination, we modified an esophageal stent delivery device by removing the esophageal stent, and placing the prosthetic with anchoring sutures in the chamber that housed the stent in a sterile fashion. A particularly useful property of the stent delivery device is that the wire guide is completely separate from the chamber that houses the prosthetic, further reducing the contamination risk. During deployment of the prosthetic, however, the cap is pushed off the device by a rod that also pushes the prosthetic against the cap, thus dislodging it. With the cap off, and pushed away from the delivery device, the potentially contaminated wire is briefly exposed to the prosthetic. A brief exposure to a relatively low inoculum size would theoretically reduce the chance for clinical infection, although the recent work of Buck et al. [27] seems to contradict this. One concept that we have considered is the use of an overtube, to allow a relatively smooth, less contaminated pathway for prosthetic delivery. Changing the wire once the delivery device is placed through the visceral wall may be another strategy to reduce contamination. Further modifications of the stent delivery device as such are ongoing as well. Survival studies will be needed to discover whether or not these strategies will reduce or eliminate infectious complications related to prosthetic delivery.

Manipulating the prosthetic into the correct orientation can sometimes be challenging, even during laparoscopic hernia repair. When utilizing a NOTES<sup>®</sup> technique, this challenge is magnified. In order to facilitate prosthetic manipulation, we drew from our extensive clinical



experience with laparoscopic ventral hernia repair. Marking the prosthetic at the site of the first suture to pull out was difficult, so we adapted our technique to use different color sutures, determining which color would be the primary suture pulled out. The looped spinal needle technique [3] proved quite easy when performed in conjunction with a skilled flexible endoscopist.

Using both full thickness abdominal wall sutures in combination with tacks, we aimed to replicate the currently most commonly used method of prosthetic fixation for ventral hernia repair. Once the suture anchors were brought through the abdominal wall, the prosthetic was relatively flat against the anterior abdominal wall, and ready to be tacked. We utilized endoscopically delivered Nitinol anchors (Cook Medical) to tack the prosthetic between the full thickness anchoring sutures. Once all the tacks were in place, we concluded the experiment. We first evaluated this proprietary tack design and delivery system with four survival swine where the anchors were placed in the abdominal wall without a prosthetic. At necropsy 2 weeks after implantation, there were no adhesions to the tacks, which remained fixed well in the abdominal wall, and one microabscess. These animals had their gastrotomies closed using the loop-anchor purse-string system we developed previously [2]. We have since developed an alternative to the technique to place full thickness tacks through the abdominal wall and prosthetic with a needle-based delivery system directly through the abdominal wall without an incision.

Only the development of new working platforms and tools will enable more widespread use in humans that require lysis of adhesions. Adhesions not only pose a risk with abdominal wall exposure, a NOTES<sup>®</sup> approach must also consider intra-visceral adhesions for peritoneal cavity entry. The clinical benefits will also have to be studied, and may not be realized until the advent of new prosthetic and anchoring technology.

In summary, we have demonstrated the feasibility of a NOTES<sup>®</sup> ventral hernia repair by developing a reproducible technique in a porcine model that utilizes a clinically relevant prosthetic and commonly employed fixation methodology. Survival studies need to be performed to assess issues related to infection, durability of prosthetic fixation, adhesions, and visceral closure. Once fully addressed in the laboratory, human studies could be done to assess whether or not there are clinically relevant benefits.

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