

Transvaginal Repair of a Large Chronic Porcine Ventral Hernia with Synthetic Mesh Using NOTES

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ABSTRACT

Background: Ventral incisional hernias still remain a common surgical problem. We tested the feasibility of transvaginal placement of a large synthetic mesh to repair a porcine hernia.

Methods: Seven pigs were used in this survival model. Each animal had creation of a 5-cm hernia defect and underwent a transvaginal repair of the defect with synthetic mesh. A single colpotomy was made using a 12-cm trocar for an overtube. The mesh was cut to size and placed through the trocar. A single-channel gastroscope with an endoscopic atraumatic grasper was used for grasping sutures. Further fascial sutures were placed every 5cm.

Results: Mesh repair was feasible in all 7 animals. Mean operative time was 133 minutes. Technical difficulties were encountered. No gross contamination was seen at the time of necropsy. However, 5 animals had positive mesh cultures; 7 had positive cultures in the rectouterine space in enrichment broth or on direct culture.

Conclusion: Transvaginal placement of synthetic mesh to repair a large porcine hernia using NOTES is challenging but feasible. Future studies need to be conducted to develop better techniques and determine the significance of mesh contamination.

Key Words: Transvaginal, Hernia, Natural Orifice Transluminal Surgery.

INTRODUCTION

Ventral incisional hernias remain a common surgical problem with approximately 200 000 procedures performed annually at a cost of nearly 2.5 billion dollars.¹ Over time, ventral hernia repair options have evolved from open to laparoscopic repair. The laparoscopic approach demonstrates decreased morbidity² and equal² or lower recurrence rates,³ leading to wider acceptance. The standard laparoscopic ventral hernia repair requires 4 port sites in the anterior wall. These incisions are associated with pain and risk of infection or incisional hernia formation.

Natural orifice transluminal endoscopic surgery (NOTES) allows intraperitoneal operations without the need for abdominal wall incisions. This may ultimately result in decreased pain, faster recovery, fewer port-site hernias, and shorter hospital stay compared with laparoscopic surgery. In animal models, it has been demonstrated that a variety of procedures, like cholecystectomy,⁴ gastrojejunostomy,⁵ tubal ligation,⁶ splenectomy,⁷ and oophorectomy with salpingectomy^{8,9} can be performed in a transgastric manner using flexible endoscopy and without the need for abdominal wall incisions.

Transgastric repair of porcine ventral abdominal wall hernias with biologic mesh has been performed by our NOTES team. A previous survival study was performed involving 11 pigs with hernia creation and subsequent hernia repair. That study did demonstrate that transgastric repair was feasible in all of the animals, but there was a 100% infection rate even though a biologic mesh was used (Surgisis mesh, Cook Medical Inc. Bloomington, IN).

The vaginal route may have several advantages compared with the transgastric route. The peritoneum and the space of Douglas are opened under direct vision, and instruments are introduced parallel to the great blood vessels avoiding injury. The spacious pouch of Douglas allows direct application of larger multi-channel instruments. The vagina repairs easily, and the wound heals quickly and painlessly without visible scars and without long-term complications. The transvaginal approach provides a more ergonomic working platform for the surgeon, unlike the transgastric approach.

Our hypothesis was that a chronic ventral hernia could be

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repaired with a synthetic mesh in a porcine survival model by using one vaginal trocar and a transfacial suture passer. Study aims were technical feasibility and safety including mesh contamination and infection.

MATERIALS AND METHODS

Seven female Landrace/Yorkshire pigs weighing a mean of 94.5 lb with a standard deviation of 10.4 were used for initial hernia creation in this study. The swine were housed with a 12-hour dark/light cycle at a temperature of 65-degrees F. There was at least one week of acclimation to the on-campus housing with free access to food and water. This study was approved and performed in accordance with the University of Missouri Animal Care and Use Committee and USDA requirements.

Abdominal Wall Hernia Creation

All animals received fluids only for at least 36 hours before the operation and were kept NPO for 12 hours prior. General anesthesia was induced with IM Xylazine (2.2 mg/kg IM), atropine (0.05 mg/kg), and Telazol (2.2 mg/kg to 6.6 mg/kg, Fort Dodge Animal Health, Fort Dodge, IA). After endotracheal intubation, each animal was placed on the operating table on a warm water-circulating blanket and maintained on isoflurane (1% to 4%) inhalational anesthesia throughout surgery. Continuous pulse oximetry performed in the anesthetized animals confirmed stable hemodynamics. An intravenous line was placed in a superficial ear vein, and isotonic sodium chloride solution was infused throughout the operation. Preoperative antibiotics were administered in accordance with surgical prophylaxis for patients undergoing gynecologic surgery. The cephalosporins and cephamycins are the antibiotics most frequently used, because they have proved to be both efficacious and safe, and have been used by gynecologists to treat infections for many years.¹⁰ The success of these antibiotics is based on both their spectrum of antimicrobial activity and the status of the patient's endogenous vaginal microflora. All animals received 1 g of a preoperative dose of Cefoxitin intravenously before the start of the procedure.

After prepping and draping the animal with traditional Betadine prep, a 5-cm incision was made in the midline of the abdominal wall. A circle of muscle and fascia 5cm in circumference was then created with electrocautery in the midline. The peritoneum was closed with 3-0 Vicryl. One additional deep dermal layer of 3-0 Vicryl sutures was placed, and the skin was closed with skin staples. The animal had an abdominal binder placed and was awak-

ened. Animals were housed for 4 weeks and allowed free access to food and water until they were taken back for hernia repair.

Transvaginal Hernia Repair

Anesthesia was induced again and a standard prep and drape of the animal's abdomen was performed. The vagina was prepped with Betadine scrub followed by 10% Povidone iodine solution (standard gynecologic prep). An Olympus single-channel endoscope (Olympus GIF Q140, Olympus, Center Valley, PA) placed in 2.4% glutaraldehyde (Cidex, Johnson and Johnson, Langhorne, PA) for at least 10 hours was used in this study.

At this time, a posterior vaginal colpotomy was performed, and a tunnel formed to the pelvic peritoneum with a clamp. The scope was then placed in the tunnel, and a hole was made in the pelvic peritoneum with a rat-tooth grasper. The scope was then inserted into the peritoneal cavity. A 12-mm trocar (Excel, Ethicon Endosurgery), which had been back loaded, was placed over the scope into the abdominal cavity and pneumoperitoneum was created. The hernia defect was located and inspected. At that time, any adhesions to the mesh were taken down with endoscopic graspers. The hernia defect was measured and an appropriately sized Proceed mesh was cut to have 5-cm overlap on all sides of the hernia defect. 2-0 Prolene stay sutures were then placed in each corner of the mesh, and subsequently the mesh was rolled and placed in the peritoneal cavity with a laparoscopic grasper through the transvaginal trocar. The sites of transfacial fixation were marked on the abdominal wall, and the left superior suture was brought out through the abdominal wall first by using the GraNee needle. This was performed under transvaginal endoscopic visualization. Next, the left inferior stay suture was brought out of the abdominal cavity. At this point, the mesh was unrolled using the transcutaneous GraNee needle, and the endoscopic grasper to help manipulate the mesh. The final 2 stay sutures were brought through the abdominal wall. Next, further transfacial fixation was performed using 2-0 Prolene every 5cm along the mesh.

The pneumoperitoneum was then evacuated by using suction through the endoscope. The scope and trocar were removed, and the colpotomy was closed with a running 2-0 Vicryl suture. A binder was placed around the animal's abdomen, and the animal was subsequently awakened. Buprenex (0.01mg/kg) was given for pain, and the animal was returned to its housing site. Animals were provided fluids ad libitum after surgery, and a reg-

ular diet the next day. All animals were closely monitored by the veterinary staff for signs of distress or loss of appetite. No further Buprenex was given.

Four weeks following mesh placement, the pigs were placed under general anesthesia and euthanized. The abdomen was opened via a U-shaped incision incorporating the mesh. A random cross section of mesh as well as peritoneal fluid from the pouch of Douglas was sent for qualitative cultures.

RESULTS

No mortalities and no intraoperative and postoperative morbidity occurred during the observational period. Mean operative time was 133 minutes (standard deviation of 38.4). Total procedure time was measured from creation until closure of the colpotomy. Times for different parts of the procedure are shown in **Table 1**. Colpotomy creation and closure varied mostly due to the difficulty traversing the pelvic peritoneum due to the porcine anatomy. The pelvic peritoneum was strong yet mobile, making it difficult to cross by using a flexible endoscope and accessories. We have not found similar difficulties in humans.

Regarding hernia repair, mesh placement and transfacial mesh fixation was time consuming. Reasons were visual orientation, a mirror image, and poor precision of the tip of the endoscope and endoscopic accessories. It was challenging to take even thin filmy adhesions down with a conventional endoscopic grasper. The procedure time did decrease with experience (**Table 1**).

Findings on necropsy are shown in **Table 2**. None of the animals had intraperitoneal signs of infection at the time

of necropsy. The mesh was secure in each animal with good incorporation into the abdominal wall. Mesh adhesions were variable; however, most animals had filmy adhesions covering the mesh up to 20% of the surface area. **Figure 1** gives an accurate representation of what most adhesions looked like at necropsy. No subcutaneous abscess or pelvic abscess was seen in any of the pigs.

Mesh cultures and peritoneal cultures are shown in **Table 3**. One animal had bacterial growth on direct culture; however, 5 had growth only in enrichment broth. One specimen had no growth. Three animals had positive pelvic peritoneal cultures on direct culture, while 4 animals required enrichment broth for speciation.

DISCUSSION

Ventral incisional hernia repair continues to be a common procedure for general surgeons. Most patients request repair due to pain and quality of life issues as well as risk of hernia incarceration and increasing size. Both laparoscopic and open techniques for ventral hernia repair are usually successful in treating these patients but require an abdominal incision with its inherent risks. This study demonstrates that a chronic ventral hernia can be repaired with transvaginal placement of mesh and commercially available instruments by using a large-sized mesh.

We have shown the feasibility of a NOTES ventral hernia repair. No additional abdominal wall fascial incisions were created. Hence, the risk of abdominal surgical site complications, such as port-site hernias, and postoperative pain are reduced. We were able to achieve a 5-cm overlap for a 5-cm or greater chronic hernia defect by

Table 1.
Procedure Times (Min)

Pig #	Colpotomy Creation Until Pneumoperitoneum	Mesh Placement	Mesh Fixation	Colpotomy Closure	Total
1	50	45	35	25	155
2	78	30	50	32	190
3	51	40	30	18	139
4	45	30	33	10	118
5	30	55	60	11	156
6	20	10	35	10	75
7	5	50	35	12	102
Mean	39.9	37.1	39.7	16.9	133.6
SD	23.9	15.2	11.0	8.6	38.4

Table 2.
Necropsy Findings

Pig #	Evidence of Gross Infection	Adhesion Tenacity xy (1 to 4)	% Adhesions	Organs Adhered
1	No	1	10	Small bowel
2	No	2	15	Colon, omentum
3	No	2	20	Omentum, spleen
4	No	0	0	none
5	No	1	5	Omentum
6	No	2	5	Liver
7	No	1	5	omentum

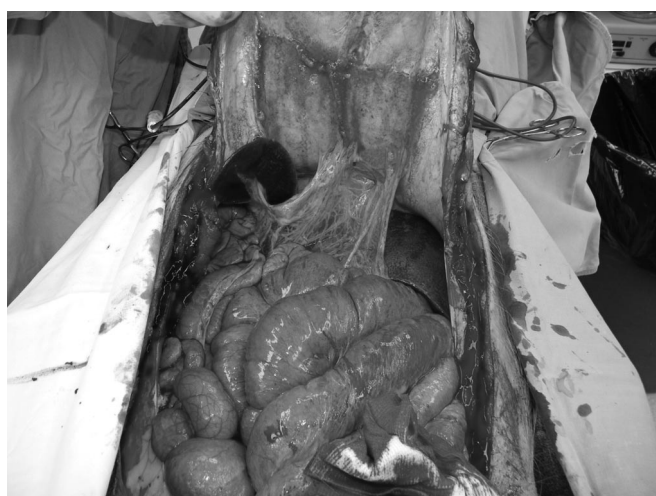


Figure 1. Necropsy showing a well incorporated mesh covering the defect with adhesions.

using a standard endoscope and other commercially available equipment without laparoscopic assistance. Transvaginal endoscopy is not a recent phenomenon; it has been used as an established methodology to perform pelvic exploration by gynecologists in the past. The vaginal route offers several advantages. Closure of the vagina is technically straightforward, repairs easily, and heals quickly without visible scars or long-term complications.

The feasibility of transgastric placement of mesh has been demonstrated¹¹ at our institution. In the transgastric approach, we used biologic mesh to repair a porcine hernia. Despite using a sterile overtube system for mesh insertion, we found a 100% clinical infection rate with gross contamination. The transvaginal technique might have more promise in that no gross contamination was present even though we used a synthetic mesh. Some previous studies have been done using smaller pieces of mesh in animal models, but this may not adequately evaluate the true

clinical scenario or infectious complications of such a technique. One recent study did demonstrate the feasibility of transvaginal mesh placement. However, this was an acute hernia model, and no cultures were taken at necropsy.¹² Only gross contamination and the number of adhesions were visualized, so mesh colonization rates are unknown.

Transvaginal incisional hernia repair with mesh placement has been accomplished in humans. Jacobson et al¹³ at the University of California San Diego described a case report using a 7 x 7 cm flex HD acellular human dermis mesh brought through the vaginal route and secured to the anterior abdominal wall with one 5-mm port for safety. Although current literature supports the feasibility of transluminal hernia repairs, all reported cases utilize a biological mesh. Most groups cannot advocate the placement of a prosthetic device in the setting of NOTES access, because of insufficient clinical data on infectious complications. For this procedure to have wide utilization, prosthetic materials will have to be used. Prosthetic mesh has been adopted as the gold standard for hernia repairs due to its ability to provide a tension-free repair and reduce recurrence. Hence, we used a lightweight polypropylene with cellulose covering in this feasibility model. In this study, the mesh appeared to perform well. There was no migration and little shrinkage after 4 weeks. Most of the bacteria were grown in enrichment broth, very little on direct culture. Thus, it is unclear from this study how clinically significant the positive cultures would be. Better techniques likely need to be developed prior to use in humans to help avoid infectious complications.

The obvious problems associated with transvaginal mesh placement would be chronic mesh infection. Placing a foreign body through a colonized natural orifice, with synthetic mesh may increase chronic mesh infection compared with laparoscopic techniques. For this technique to

Table 3.
Mesh Cultures and Rectouterine Space Cultures

Animal #	Mesh Culture	Rectouterine Space Culture
1	staph hyicus (EB)	staph hemolyticus (EB)
2	staph hyicus (EB)	staph hyicus (DC), epidermis (DC)
3	staph aureus (DC)	staph hyicus (DC), strep equisimilis (DC)
4	Staph hyicus, epidermis, xylosus (all EB)	Staph spp., bacillus thuringiensis
5	NG	Staph hyicus (EB), clos. Perf. (EB)
6	Staph chromogenes (EB)	Staph hyicus (EB), clos. Perf. (EB)
7	Bacillus	Staph xylosus (DC)

*EB = enrichment broth; DC = direct culture; NG = no growth.

become feasible, infection rates must be lowered to levels seen with laparoscopic repair to ever be feasible. Currently, there is no delivery system that allows for delivery of mesh sterilely through the stomach, vagina, or colon. Secondly, we do not know how significant mesh cultures on enrichment broth are in this setting. A metaanalysis comparing pooled data of laparoscopic versus open ventral hernia repair showed a greater than 2-fold increase in mesh infections for open ventral hernia repairs.¹⁴ Heniford et al¹⁵ reported their 9-year experience with over 800 laparoscopic hernia repairs and found an overall infection rate of 1.8%. Other studies¹⁴⁻¹⁷ have looked at various complication rates between open and laparoscopic repairs and report a mesh infection rate of <2% in the laparoscopic groups. However, the infectious complications of mesh placement using a natural orifice technique have not been thoroughly investigated.

The other drawback is the difficulty with lysis of adhesions with endoscopic instruments in a patient with multiple previous operations. We found that about half of our animals had one small filmy adhesion from making the hernia; even this small amount of adhesiolysis took a significant amount of time. In addition, we foresee even greater complexity to be encountered with the potential for bowel adhesions to be present. This would likely require a great amount of time, and it may not be possible to take down bowel adhesions with the current endoscopic instruments in a safe and feasible manner. Other techniques or instruments will likely need to evolve to allow for lysis of adhesions in a timely and safe manner compared with current technology.

Finally, it is difficult drawing conclusions about mesh infection in a short-term model in animals that have no clinical indication of mesh infection. Perhaps a chronic

model would allow better assessment of a true infection rate based on quantitative cultures in correlation with gross infection. This may allow us to delineate irrelevant contamination from postoperative infection with clinical significance. Secondly, a better adhesion model that replicates all of the complexities that can be present in a human model needs to be made to work on adhesiolysis through a natural orifice technique. Further studies still need to be performed after a mesh delivery system is introduced that helps with sterility. Currently, no delivery systems are available that can keep the mesh sterile and isolated from colonized vaginal flora. This delivery system might need to be a combination of an overtube with a bag type delivery vehicle. Current methods of deployment make hernia repair unsafe in humans due to the infection risk.

CONCLUSION

This study demonstrates the feasibility of transvaginal NOTES placement of intraabdominal synthetic mesh. Ongoing studies will need to be performed to continue to try to resolve contamination, and infectious and technical aspects. NOTES hernia repair may have the potential for large utilization in humans. However, multiple issues will need to be addressed before clinical application.

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