

Evaluation of the Rebound Hernia Repair Device for Laparoscopic Hernia Repair

Gonzalo Torres-Villalobos, MD, Laura Sorcic, BS, George R. Ruth, DVM, PhD, Rafael Andrade, MD, Luis A. Martin-del-Campo, MD, J. Kyle Anderson, MD

ABSTRACT

Background: The characteristics of the ideal type of mesh are still being debated. Mesh shrinkage and fixation have been associated with complications. Avoiding shrinkage and fixation would improve hernia recurrence rates and complications. To our knowledge, this is the first study of a device with a self-expanding frame for laparoscopic hernia repair.

Methods: Six Rebound Hernia Repair Devices were placed laparoscopically in pigs. This device is a condensed polypropylene, super-thin, lightweight, macroporous mesh with a self-expanding Nitinol frame. The devices were assessed for adhesions, shrinkage, and histological examination. Laboratory and radiologic evaluations were also performed.

Results: The handling properties of the devices facilitated their laparoscopic placement. They were easily identified with simple x-rays. The mesh was firmly integrated within the surrounding tissue. One device was associated with 3 small adhesions. The other 5 HRDs had no adhesions. We noted no shrinkage or folding. All devices preserved their original size and shape.

Conclusions: At this evaluation stage, we found that the Rebound Hernia Repair Device may serve for laparoscopic hernia repair and has favorable handling properties. It prevents folding and shrinkage of the mesh. It may eliminate the need for fixation, thus preventing chronic

pain. The Nitinol frame also allowed radiologic evaluation for gross movement. Further studies will be needed to evaluate its clinical application.

Key Words: Hernia, Laparoscopic hernia repair, Mesh, Pig.

INTRODUCTION

Hernia repair techniques using mesh have been associated with hernia recurrence rates that are up to 50% lower compared with those for tissue-to-tissue sutured hernia repair. Numerous experiments have sought the ideal mesh for laparoscopic hernia repair, but this question is still unanswered. By far, the most widely used material is polypropylene (PP). Prosthetics made from PP induce biologic reactivity, which varies depending on their weight, filament size, pore size, and architecture of the prosthetic, as well as on the individual host response. Heavyweight PP meshes have properties that lead to excellent fibrous ingrowth but also may induce a brisk fibrous reaction and tissue ingrowth into the mesh. It has been demonstrated that decreasing the amount of biomaterial content of mesh reduces inflammatory response and shrinkage.¹ To reduce the inflammatory response, the trend has been to use lighter weight, more porous PP mesh that enhances the formation of a scar net rather than a scar plate. The type and amount of material and the structure of the mesh are also of critical importance for the development of adhesions.¹⁻³ Further optimization of mesh materials is still needed.^{4,5}

The optimal method for mesh fixation has been debated. Mechanical anchorage of the mesh is intended not only to reduce mesh migration, shrinkage, and folding, but also to enhance the bursting strength of the repair.^{6,7} The main concern about mesh fixation is the development of chronic pain.⁸⁻¹⁰ Pain might be due to nerve entrapment associated with the use of sutures or staplers. The potential complications of mesh fixation and the risk of mesh folding or migration have led to the consideration of alternative methods. The ideal mesh should have good biocompatibility coupled with good handling properties.

Department of Surgery, University of Minnesota, Minneapolis, Minnesota, USA (Drs Torres-Villalobos, Andrade).

Department of Experimental Surgical Services, University of Minnesota, Minneapolis, Minnesota, USA (Ms Sorcic, Dr Ruth).

Department of Urology, University of Minnesota, Minneapolis, Minnesota, USA (Dr Anderson) Experimental Surgery Department, Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran (Dr Martin-del-Campo).

This work was supported by Minnesota Medical Development, Inc., (MMDI) Minneapolis MN. The authors wish to thank Therese Swan and Mary E. Knatterud for the editorial review.

Address correspondence to: J. Kyle Anderson, MD, Department of Urology, University of Minnesota Medical Center, 420 Delaware St SE, Box 394 Mayo, Minneapolis, MN 55102, USA. E-Mail: Ande.1821@umn.edu

DOI: 10.4293/108680810X12674612014824

© 2010 by JSLs, Journal of the Society of Laparoendoscopic Surgeons. Published by the Society of Laparoendoscopic Surgeons, Inc.

In our study, we evaluated the Rebound Hernia Repair Device (HRD) in pigs. The Rebound HRD uses a Nitinol (Nickel Titanium Naval Ordinance Laboratory) frame to make a self-expanding support for the mesh. The objectives included evaluating laparoscopic deployment of the device, verifying the device location with postoperative x-rays, and evaluating the shape, hernia recurrence rates, tissue ingrowth, and changes in the area surrounding the implant and hernia defect.

MATERIALS AND METHODS

Experimental Protocol

The use and care of all the pigs in our study were in accordance with the *Guide for the Care and Use of Laboratory Animals* (National Institute of Health publication No. 86–23). The protocol was approved by the Institutional Animal Care and Use Committee (IACUC) of the University of Minnesota. This investigation was conducted in compliance with the regulations for *Good Laboratory Practice for Nonclinical Laboratory Studies* (21 CFR [Code of Federal Regulations] 58). The study was monitored by an independent quality assurance unit. All procedures were conducted at the Experimental Surgical Services of the University of Minnesota.

We gave antibiotics to 3 female adult pigs (weight range 49 kg to 57 kg) and monitored their preoperative health. Their scheduled survival time postoperatively was 90 days. We implanted 2 Rebound HRDs bilaterally in the preperitoneal space of each pig. Immediately after implantation and on postoperative days 7, 30, 60, and 90, we obtained x-rays. A complete blood count was obtained before surgery, on the day of implantation, and at sacrifice. At 90 days, necropsies were performed and tissue blocks containing the patches were explanted. A radiographic image of each device was made in a Faxitron 805 x-ray system (Field Emission Corp., McMinnville, OR) to evaluate the shape of the devices.

Mesh Types and Characteristics

Rebound HRD (Minnesota Medical Development, Inc., Minneapolis MN) are made with a condensed PP, super-thin, lightweight, macroporous mesh. It has 2 different shapes: the Hybrid Small (8.81 cm x 11.28 cm) and the Dog Bone (7.65 cm x 10.24 cm). Both have a PP mesh with a pore size of 2410 μm , a thickness of 250 μm , and a density of 52.0 g/m^2 .

The devices have a self-expanding multistrand Nitinol frame designed mainly for the laparoscopic repair of both inguinal and ventral hernias. The mesh is tied to the Nitinol frame by a polyethylene polyblend braided suture. The superelastic Nitinol frame allows the device to be folded and inserted laparoscopically by using the loading cannula through a 10-mm port. The HRDs can also be folded and placed via a small incision. Once deployed, it fully unfurls or “rebounds” back to its original shape and conforms to the patient’s preperitoneal anatomy. Before implantation, the device was evaluated for magnetic resonance (MR) safety by using a 3-Tesla MR system (General Electric Healthcare, Milwaukee, WI). The Rebound HRD was recognized as the 2006 Innovation of the Year by the Society of Laparoendoscopic Surgeons (SLS) (SLS does not endorse or approve any products).

Operative Technique

Before anesthesia induction, each pig received Telazol (tiletamine-zolazepam) at 6 mg/kg and xylazine hydrochloride at 1.2 mg/kg. Anesthesia was induced with 1 mg/kg to 2 mg/kg of propofol intravenously; additional amounts were given if needed. The animals were intubated, and mechanical ventilation was maintained with 4 liters per minute of O_2 and isoflurane (1.5% to 2%). Ceftiofur at 5 mg/kg and gentamicin at 3 mg/kg were used for antibiotic coverage and Buprenorphine at 0.03 mg/kg was administered as an analgesic.

Implantation of the devices was accomplished laparoscopically. With the pig in the supine position, pneumoperitoneum was established with a Veress needle. Two 5-mm trocars and one 10-mm trocar were placed.

Two hernia defects were made bilaterally on the abdominal wall of each pig. First, the peritoneum was incised with a Harmonic scalpel (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) to perform a preperitoneal dissection. Then, the fascia was incised to create a hernia defect. After that, the devices were introduced into the abdominal cavity via the 10-mm trocar using the Rebound HRD 10-mm loading cannula.

The devices were positioned to cover the defect with at least 1cm beyond the border of the defect circumferentially. The mesh side of the devices (opposite to the Nitinol frame) was placed adjacent to the fascia. The devices were not sutured to surrounding tissue. The peritoneum was sutured over the devices with 2–0 Vicryl (Ethicon, Inc., Somerville, NJ), and 2 or 3 Ligaclips (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) were applied in the peritoneum to complete the closure. For all 3 animals, each hernia repair proceeded independently of

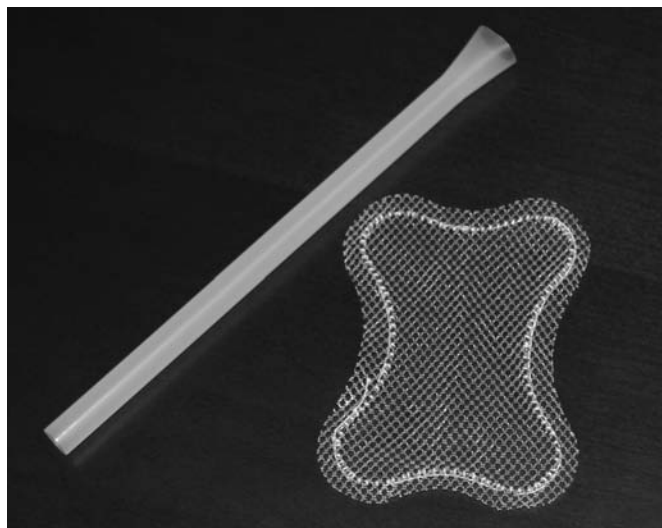


Figure 1. Dog Bone Shape Rebound HRD with 10-mm loading cannula.



Figure 2. Hybrid Small Shape Rebound HRD with 10-mm loading cannula.

the other (ie, the second hernia defect was not made until the first hernia repair was completed). Each animal received 2 Rebound HRD: 1 Dog Bone shape (**Figure 1**), and the other a Hybrid Small (**Figure 2**) shape. Because the peritoneum in the inguinal area of the pig was very thin and difficult to suture, the hernia site was advanced proximally according to the quality of the peritoneum. Only 1 of the HRDs was placed in the inguinal area. One of the pigs had the device placed invertedly on the mesh side, to ascertain the effects of improper orientation. The

trocars were removed under direct vision, and the skin was closed. The handling and laparoscopic deployment was also evaluated.

Immediately after surgery, we obtained baseline postoperative x-rays to document the position of the HRDs. All animals were observed on a daily basis. Postoperative medications included amoxicillin/clavulanate at 14 mg/kg, twice a day for 7 days to 10 days (for antibiotic prophylaxis) and buprenorphine at 0.03 mg/kg intramuscularly or subcutaneously as needed (for analgesic therapy).

Necropsy and Radiological Evaluation

Postoperatively x-rays were performed immediately after implantation and at 7, 30, 60, and 90 days. The pig was placed in the supine ventral-dorsal abdominal position. We used an x-ray 903, type B-85 portable large animal veterinary unit (MinXRay Inc., Northbrook, IL). We used bony landmarks (pelvis and spinal column) as references for potential movement of the device.

The pigs were euthanized 90 days after the HRDs were implanted. Prior to euthanasia, the animals were given Telazol (tiletamine and zolazepam) at 6 mg/kg and Xylazine at hydrochloride 1.2 mg/kg IM. After approximately 5 minutes, we administered 300 units/kg of heparin IV. The pigs were then euthanized with an IV injection of Beuthanasia-D (pentobarbital sodium and phenytoin sodium) solution at 1 mL/5kg to 10 kg.

At necropsy, adhesion areas and the dimensions of the mesh were measured in the fresh specimen. The HRDs were removed with at least 2.5 cm of normal tissue at its margins. In the fresh specimen, the shape and area of the devices were evaluated. To assess shape and area with the greatest accuracy, we used the Faxitron. We recorded descriptive features and photographic images, and then fixed the specimens in 10% neutral buffered formalin (NBF).

After fixation for at least 48 hours, we obtained a radiographic image of each HRD in a Faxitron (40 KVP for 1.5 min). We trimmed a minimum of 6 sites and processed them for histologic examination by routine procedures, staining them with hematoxylin and eosin (H&E) and Masson's trichrome. Samples from the cable coupling site and the cable-mesh-thread site were collected for embedding in methylmethacrylate, then ground and stained with H&E and Masson's trichrome. A complete blood count was obtained before surgery, on the day of implantation,

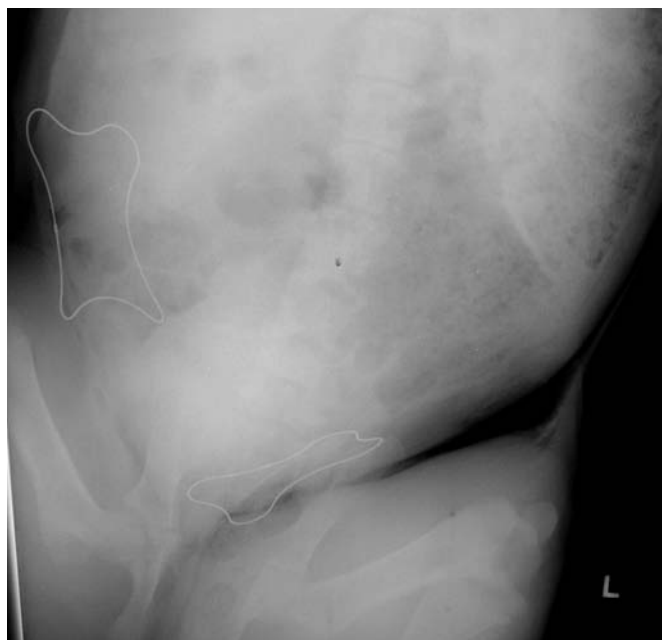


Figure 3. Supine ventral-dorsal abdominal x-ray. The device on the left (Dog Bone Shape) is implanted in the inguinal area; the device on the right (Hybrid Small Shape) is implanted proximal to the inguinal area.

and at sacrifice. Testing was done at Marshfield Laboratories in Marshfield, WI.

RESULTS

Surgery, Radiologic and Laboratory Evaluation

We performed all of the laparoscopic deployments of the HRDs without complications. Their handling properties facilitated their placement. The Nitinol frame prevented folding and allowed easy manipulation of the mesh into the abdomen. Only the first HRD of the first pig was implanted in the inguinal area (**Figure 3**); the remaining HRDs were implanted proximal to the inguinal area (**Figure 4**).

The HRDs were easily identified on the radiographic prints (**Figure 4**). However, evaluating the potential movement of the HRDs was difficult because of the inconsistency in the pigs' positioning between radiography time points, along with their fast growth rate and size. Slight discrepancies in rotation and position between the time points decreased the usefulness of bony landmarks as references, but still we did not find any gross movement of any of the HRDs. The shape of the mesh was completely preserved.



Figure 4. Supine ventral-dorsal abdominal x-ray immediately after surgery. In the right abdominal wall is a Small Hybrid Rebound HRD. In the left side is a Dog Bone Rebound HRD.

The MR evaluation showed that the HRD was safe. It was considered "MR-conditional" according to the terminology specified by the American Society for Testing and Materials.¹¹⁻¹⁴ A patient with this HRD could be scanned safely, immediately after placement. All the parameters of the complete blood count were within normal limits, with no difference in the mean values at the 3 evaluation time points.

Necropsy and Histologic Findings

All 3 pigs were in good health, and their weights were 115 kg, 108 kg, and 106 kg. Of the 6 HRDs implanted, 5 were in appropriate sites, covering the hernias with a margin of more than 1.5 cm. In 1 implantation site, the border of the mesh was slightly <1 cm from the hernia margin. It was not easy to determine whether the mesh migrated after the procedure or whether it was implanted "off center" during surgery. Because, the largest amount of mature fibrous tissue was located at the center of the HRD, it would seem more likely that the implantation of the device was "off center." If migration did occur, then the HRD moved very slightly ventrally.

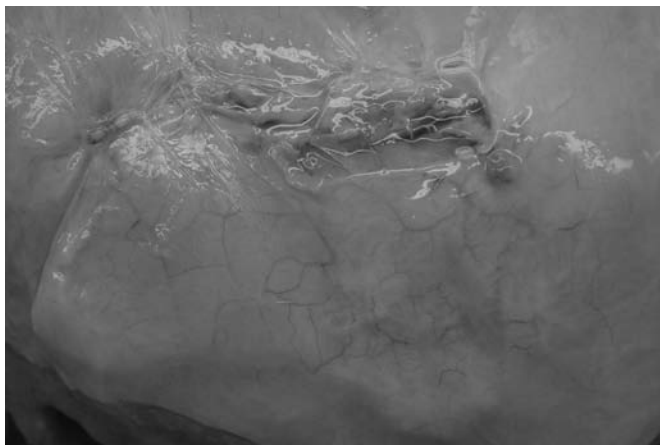


Figure 5. Fresh specimen with a Dog Bone Shape Rebound HRD. The mesh is flat, unwrinkled, and completely covered by mesothelium.

When we evaluated the HRDs directly in the fresh specimen and with the Faxitron, their shape and area were preserved (**Figure 5**). The mesh held firmly to the Nitinol frame and was flat and unwrinkled. The peritoneal surface of the HRD placed in the inguinal area had 3 band-adhesions of about 1.5 mm in diameter, 2 of them to the urinary bladder and 1 to the spiral colon. The peritoneum covering the mesh in this area had some small sites where the suturing was not able to completely close the gap between the 2 peritoneal edges. It was difficult to evaluate whether the adhesions were caused by incomplete peritoneal coverage. However, the HDRs and the wound surface were all completely covered by mesothelium. No intraabdominal adhesions were associated with the other HRDs. No lesions were detected in any organ. The mesh was firmly integrated within the surrounding tissue. Each individual fiber was surrounded by connective tissue and covered with peritoneum.

The microscopic slides showed the mesh firmly integrated within the surrounding tissue (**Figure 6**). The mesh was embedded in mature fibrous tissue of variable thickness (0.2 mm to 4 mm) and was separated from the peritoneal surface by fibrous tissue and histiocytes. The sites of the coupling-thread-mesh complex seemed to stimulate the thickest fibrous reaction, with sites up to 4-mm thick (**Figure 6**). The host tissue response to the cable-mesh-thread junction site was a mild fibrogranulomatous reaction with a narrow layer of histiocytes and occasional multinucleated giant cells adjacent to the HRD and fibroblasts at the periphery.

Small nodules of osseous metaplasia were present in

some areas associated with the fibrous tissue. The size of the nodules varied (0.5 mm to 5 mm). Small nodules formed by the Ligaclips on the peritoneum surface (**Figure 7**). They were about 3 mm to 4 mm in diameter and covered with fibrous tissue. These Ligaclips were used to assist with the peritoneal closure; they were not part of the HRDs. We intentionally implanted 1 HRD upside down; We found no discernible difference in that HRD outcome compared with outcome at the other sites.

DISCUSSION

The search continues for the ideal hernia repair. This search has shifted away from discussing the type of repair and has turned instead to an evaluation of the type of mesh used in the repair.¹⁵ The characteristics of the ideal type of mesh are still being debated. A better mesh should show better biologic tolerance. To evaluate the biocompatibility of an implant, the mesh needs to fulfill its predetermined function, achieving a high level of tissue incorporation and causing as few local or systemic side effects as possible.

Nevertheless, mesh always induces an inflammatory foreign-body reaction.¹⁶ This reaction might be associated with a higher rate of chronic pain and local discomfort, in relation to the amount of material in the mesh and its surface structure. Heavyweight, small-pore mesh tends to cause a more pronounced inflammatory reaction. In contrast, large-pore, lightweight mesh produces less inflammatory reaction and less scar formation.^{17,18}

The size of the pores seems to be the main factor in successful incorporation and diminished foreign-body reaction. The structure of the mesh appears to be of greater importance than the material itself in terms of adhesion formation and mesh shrinkage.¹⁹ Incorporation of mesh could be improved by enlarging mesh pores and by using thinner fibers to have smaller knots and prevent the bridging effect.¹⁶ Pores $>1,000 \mu\text{m}$ produce a more physiologic wound healing, avoiding scar overgrowth.²⁰ Large pores in the mesh allow the individual mesh fibers to become incorporated in the neoperitoneum. Reducing the material amount and increasing pore size have led to a considerable advancement in biocompatibility.^{4,15,17,18} On the other hand, the reported theoretical advantages of light meshes have been questioned in some prospective randomized studies and some animal experiments.^{15,21} Moreover, some evidence suggests that reducing the material amount leads to a greater risk of hernia recurrence.²²

All available types of mesh, regardless of composition,

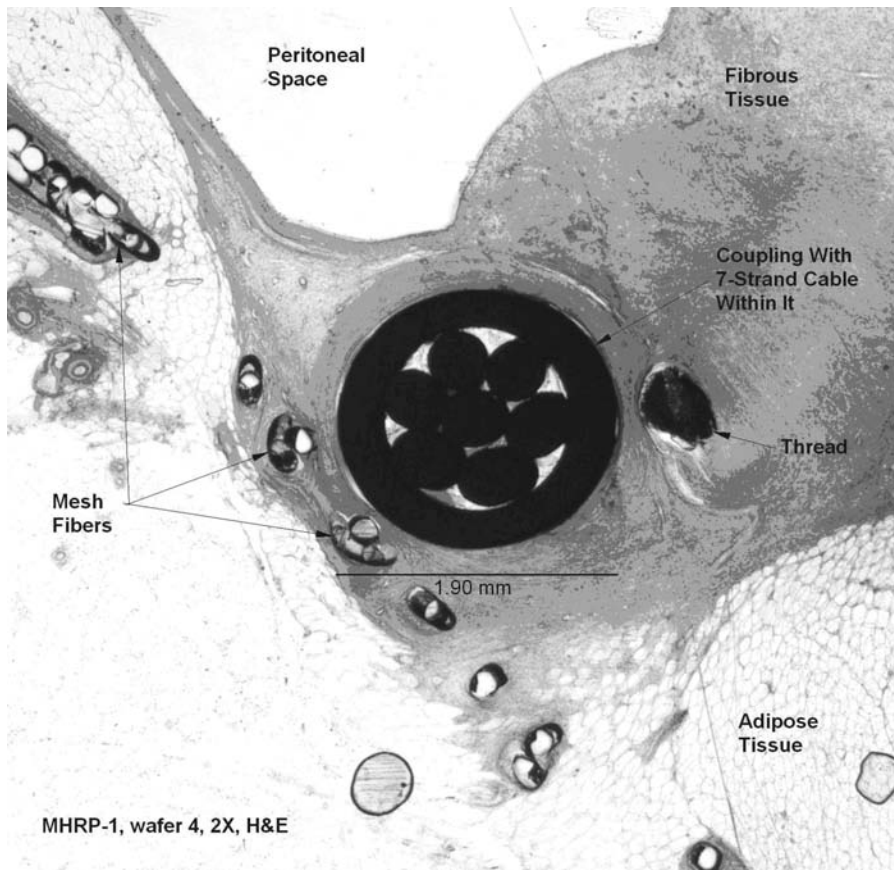


Figure 6. Frame coupling-mesh-thread junction site methylmethacrylate (plastic) embedded section stained with H&E. The Rebound HRD is firmly integrated within the surrounding mature fibrous tissue.

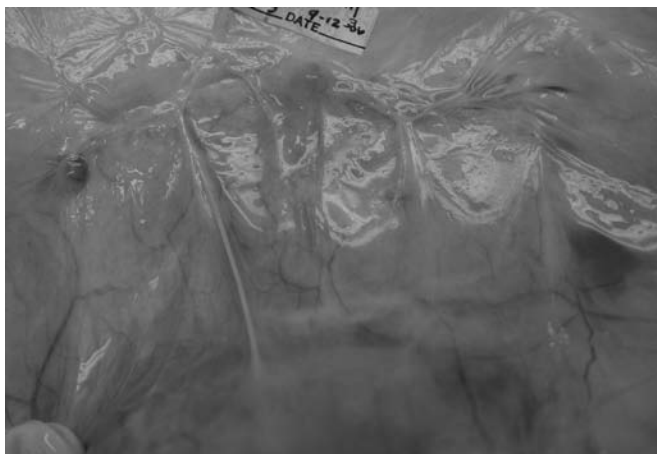


Figure 7. Fresh specimen with a Hybrid Small Shape Rebound HRD. The peritoneum is covering the device completely. A small nodule was formed by Ligaclips used to close the peritoneum.

experience significant reduction in their initial size after implantation. Physiologic wound contraction has been associated with considerable mesh shrinking and folding.

It is not the mesh itself that shrinks, rather, the surface reduction is caused by connective tissue contraction during the consolidation of scar tissue. The pronounced shrinkage of heavyweight meshes appears to be of crucial importance in hernia recurrence. Lightweight monofilament large-pore PP mesh has less of a tendency to shrink,¹⁵ thus reducing the theoretical risk of hernia recurrence.

Even with the reduction in the material amount and with the increase in pore size, mesh can still shrink considerably.^{4,19} With large-pore mesh, the bridging effect is reduced and the shrinkage is also reduced,⁴ resulting in more of a scar “net” (rather than a scar “plate”). Some authors have attributed shrinkage to the bridging effect. In our study, the HRDs showed no shrinkage, a most desirable effect because of the known association between shrinkage and hernia recurrence. The HRD with macroporous (2410 μ m) mesh showed some bridging effect in parts of the pathology samples. Independently of this finding, the HRD did not show shrinking or folding, and the mesh was always completely flat, maintaining its orig-

inal shape. This advantage may be attributed, in part, to the mesh characteristics,^{1,17} but the most important factor appeared to be the Nitinol frame that prevented the mesh from shrinking. One of the reasons for hernia recurrence after hernia repair has been mesh shrinkage. The Nitinol frame might represent an advantage that could diminish or eliminate mesh folding during the desufflation process, considered an important factor for hernia recurrence.²³ Long-term clinical studies investigating this aspect are, however, currently not available.

Nitinol has been safely used and proven reliable in several specialties, such as cardiac surgery, orthopedics, and interventional radiology.^{28–30}

Mesh shrinking has also been associated with inadequate mesh fixation.¹⁹ Fixation is intended not only to reduce mesh migration, shrinkage, and folding, but also to enhance the bursting strength of the repair.^{6,7} The Nitinol frame has a good tensile strength that allows it to keep the mesh in a constant shape, thus preventing shrinking. The main complication associated with mechanical mesh fixation is the development of chronic pain caused by nerve entrapment. The elasticity of the Nitinol frame may allow the HRDs to easily adjust to human anatomy, offering a potential way to diminish the need for fixation and its possible complications.

We found metaplastic bone in the fibrous tissue associated with the HRDs. This was found mostly located in the area of cutting and hernia creation site made by the Harmonic scalpel and may have some association with the trauma and the heat generated. Osseous metaplasia is a common response to trauma and foreign material in the abdominal wall of pigs.^{24–26} Calcifications have also been reported in humans, mostly associated with long-term implantation of heavyweight microporous mesh.²⁷ The significance of this finding is still to be determined.

The handling properties associated with the mesh are important during laparoscopic placement. The considerable increase in flexibility of the lightweight macroporous mesh makes it difficult for surgeons to handle or manipulate it in the operating room.¹⁵ Some types of mesh incorporate absorbable filaments into their weave, to add stiffness and facilitate implantation, but doing so may contribute to increased surface area and potentially to a higher infection risk.¹⁵ In our study, we placed the HRDs laparoscopically to reproduce, as closely as possible, the conditions of laparoscopic hernia repair in human patients. The stabilization of the mesh and the stiffness provided by the addition of the Nitinol frame remarkably made it easy to handle.

The possibility of identifying the HRD with a simple x-ray may represent a favorable property of this device. We found that the exact position of the HRD was difficult to evaluate, but its gross position and its shape were easily evaluated.

On the basis of our results, we conclude that at this stage of evaluation, the Rebound HRD may be suited for laparoscopic hernia repair. It may help reduce or eliminate shrinkage, which in the long-term may be associated with other benefits. Its handling properties facilitated laparoscopic placement; the elimination of fixation should help prevent chronic pain in the long term. The Nitinol frame may represent an advantage in terms of radiologic evaluation for gross movement, mesh shrinkage, and mesh folding. Long-term clinical studies are needed to confirm our favorable results in pigs with the Rebound HRD.

References:

1. Klinge U, Klosterhalfen B, Muller M, et al. Shrinking of polypropylene mesh in vivo: an experimental study in dogs. *Eur J Surg*. 1998;164(12):965–969.
2. Bellon JM, Jurado F, Garcia-Honduvilla N, et al. The structure of a biomaterial rather than its chemical composition modulates the repair process at the peritoneal level. *Am J Surg*. 2002;184(2):154–159.
3. Coda A, Bendavid R, Botto-Micca F, et al. Structural alterations of prosthetic meshes in humans. *Hernia*. 2003;7(1):29–34.
4. Scheidbach H, Tamme C, Tannapfel A, et al. In vivo studies comparing the biocompatibility of various polypropylene meshes and their handling properties during endoscopic total extraperitoneal (TEP) patchplasty: an experimental study in pigs. *Surg Endosc*. 2004;18(2):211–220.
5. Schumpelick V, Klosterhalfen B, Muller M, Klinge U. [Minimized polypropylene mesh for preperitoneal net plasty (PNP) of incisional hernias]. *Chirurg*. 1999;70(4):422–430.
6. Dion YM, Laplante R, Charara J, Marois M. The influence of the number of endoclips and of mesh incorporation on the strength of an experimental hernia patch repair. *Surg Endosc*. 1994;8(11):1324–1328.
7. Hollinsky C, Gobl S. Bursting strength evaluation after different types of mesh fixation in laparoscopic herniorrhaphy. *Surg Endosc*. 1999;13(10):958–961.
8. Bay-Nielsen M, Perkins FM, Kehlet H. Pain and functional impairment 1 year after inguinal herniorrhaphy: a nationwide questionnaire study. *Ann Surg*. 2001;233(1):1–7.
9. Liem MS, van Duyn EB, van der Graaf Y, van Vroonhoven TJ. Recurrences after conventional anterior and laparoscopic

inguinal hernia repair: a randomized comparison. *Ann Surg.* 2003;237(1):136–141.

10. Poobalan AS, Bruce J, King PM, et al. Chronic pain and quality of life following open inguinal hernia repair. *Br J Surg.* 2001;88(8):1122–1126.

11. Shellock FG. Metallic surgical instruments for interventional MRI procedures: evaluation of MR safety. *J Magn Reson Imaging.* 2001;13(1):152–157.

12. Shellock FG. Biomedical implants and devices: assessment of magnetic field interactions with a 3.0-Tesla MR system. *J Magn Reson Imaging.* 2002;16(6):721–732.

13. ASTM. *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.* 2005.

14. Shellock FG, Shellock VJ. Metallic stents: evaluation of MR imaging safety. *AJR Am J Roentgenol.* 1999;173(3):543–547.

15. Cobb WS, Kercher KW, Heniford BT. The argument for lightweight polypropylene mesh in hernia repair. *Surg Innov.* 2005;12(1):63–69.

16. Weyhe D, Schmitz I, Belyaev O, et al. Experimental comparison of monofile light and heavy polypropylene meshes: less weight does not mean less biological response. *World J Surg.* 2006;30(8):1586–1591.

17. Greca FH, de Paula JB, Biondo-Simoes ML, et al. The influence of differing pore sizes on the biocompatibility of two polypropylene meshes in the repair of abdominal defects. Experimental study in dogs. *Hernia.* 2001;5(2):59–64.

18. Klinge U, Klosterhalfen B, Birkenhauer V, et al. Impact of polymer pore size on the interface scar formation in a rat model. *J Surg Res.* 2002;103(2):208–214.

19. Schug-Pass C, Tamme C, Tannappel A, Kockerling F. A lightweight polypropylene mesh (TiMesh) for laparoscopic intraperitoneal repair of abdominal wall hernias: comparison of biocompatibility with the DualMesh in an experimental study using the porcine model. *Surg Endosc.* 2006;20(3):402–409.

20. Junge K, Klinge U, Rosch R, et al. Functional and morphologic properties of a modified mesh for inguinal hernia repair. *World J Surg.* 2002;26(12):1472–1480.

21. Weyhe D, Belyaev O, Muller C, et al. Improving outcomes in hernia repair by the use of light meshes—a comparison of different implant constructions based on a critical appraisal of the literature. *World J Surg.* 2007;31(1):234–244.

22. O'Dwyer PJ, Kingsnorth AN, Molloy RG, et al. Randomized clinical trial assessing impact of a lightweight or heavyweight mesh on chronic pain after inguinal hernia repair. *Br J Surg.* 2005;92(2):166–170.

23. Katkhouda N, Mavor E, Friedlander MH, et al. Use of fibrin sealant for prosthetic mesh fixation in laparoscopic extraperitoneal inguinal hernia repair. *Ann Surg.* 2001;233(1):18–25.

24. LeBlanc KA, Booth WV, Whitaker JM, Baker D. In vivo study of meshes implanted over the inguinal ring and external iliac vessels in uncastrated pigs. *Surg Endosc.* 1998;12(3):247–251.

25. Jubb KVF, Kennedy PC, Palmer N. *Pathology of Domestic Animals.* 4th ed. San Diego: Academic Press; 1993.

26. Nieberle K, Cohrs P. *Textbook of the Special Pathological Anatomy of Domestic Animals.* Rev. by Paul Cohrs. 1st English ed. Oxford, New York: Pergamon Press, 1967.

27. Klosterhalfen B, Junge K, Klinge U. The lightweight and large porous mesh concept for hernia repair. *Expert Rev Med Devices.* 2005;2(1):103–117.

28. Roukis TS. A 1-piece shape-metal nitinol intramedullary internal fixation device for arthrodesis of the proximal interphalangeal joint in neuropathic patients with diabetes. *Foot Ankle Spec.* 2009;2(3):130–134.

29. Park JG, Jung GS, Oh KS, Park SJ. Double-layered PTFE-covered Nitinol stents: experience in 32 patients with malignant esophageal strictures. *Cardiovasc Intervent Radiol.* 2009.

30. Sadowski J, Kapelak B, Pfitzner R, Bartus K. Sutureless aortic valve bioprosthesis '3F/ATS Enable' - 4.5 years of a single-centre experience. *Kardiol Pol.* 2009;67(8):956–963.