BIOABSORBABLE vs POLYPROPYLENE PLUG FOR THE "MESH AND PLUG" INGUINAL HERNIA REPAIR

S. Morales-Conde, M. Flores, V. Fernández, S. Morales-Méndez – Department of Surgery, University of Sevilla, Spain

ABSTRACT

Objective: To compare integration and to detect complications related to two different plugs used to repair inguinal hernias: one plug of polypropylene, normally used for the "mesh and plug" repair, and a new bioabsorbable plug.

GORE Bioabsorbable Hernia Plug

Material and Methods: An experimental study was conducted using 10 adult male pigs. Two incisions were performed in both inguinal areas of the pig, identifying both inguinal rings, placing a polypropylene plug (PP) and a GORE Bioabsorbable Hernia Plug (HP) in each inguinal canal. Explants were performed at 3 months after surgery in 5 pigs, and at 6 months in the other 5. Macroscopic and histologic study was performed.

Results: Macroscopic evaluation showed adhesions from the PP to the bladder in one case at 3 months and in 3 pigs at 6 months, while no adhesions were found to the bioabsorbable plug. Two PPs migrated into the abdominal cavity, being exposed to intrabdominal viscera in two pigs, one at 3 months and another one at 6 months, while the bioabsorbable plug was difficult to distinguish from the surrounding tissue 6 months after surgery. The inguinal canal with the PP was open in 4 out of 5 pigs at 6 months after surgery, while the canal where the bioabsorbable plugs were implanted were completely closed in all cases. Histological study showed how the acute inflammatory response was maintained where the PP was implanted 6 month after surgery, and how the amount of collagen was greater at 3 and 6 months where the bioabsorbable plugs were implanted, decreasing the amount of material through time. Polypropylene fibers were observed to be in contact and to invade structures of the inguinal cord, nerve fibers and blood vessels.

Conclusions: Bioabsorbable plugs seem to avoid potential complications compared to PPs, such as migration and adhesions to intrabdominal viscera, and to reduce the possibility of chronic inguinal pain related to these plugs since the inflammatory response decreases and invasion of the inguinal cord and nerves is avoided. The amount of collagen generated by the bioabsorbable plug seems to maintain the inguinal canal closed while the integration of the mesh occurs during the "mesh and plug" inguinal repair, being an option to consider in the near future.

INTRODUCTION

It is estimated that over 800,000 and 700,000 inguinal herniorrhaphy are performed in Europe and the United States, respectively, every year. It is further estimated that approximately 90% of these repairs involve some type of prosthetic device.

Pain and other serious complications of plug-and-patch hernia repairs have been specifically associated with use of a nonabsorbable prosthesis made of polypropylene. Polypropylene is known to provoke an intense, continuous fibroblastic response and scarring, which is known to cause PPs to shrink.[1,3] There are reports of PPs migrating to the scrotum,[2,4] small bowel,[2,5] and into the abdominal cavity.[6]

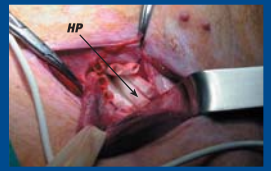
The HP was developed with the goal of repairing the hernia defect in the short term while eliminating the potential of chronic complications associated with permanent plugs. The HP is composed of the copolymer polyglycolic acid:trimethylene carbonate (PGA:TMC); a synthetic material which has a long history of use in medical devices. To validate its effectiveness as a hernia plug, an animal study was designed to test its ability to fill a defect and encourage tissue regeneration. Additionally, no known animal study has been performed evaluating the post-operative effects of permanent, polypropylene hernia plugs.

The purpose of this evaluation is to compare the gross and histological observations of the HP and a commercially available PP (BARD® PERFIX® Plug). Adhesions to the spermatic cord, erosion into the inguinal ring, and intrusion into the abdominal cavity were assessed. Histology examined collagen deposition, nerve entrapment, erosion of the cord structures, and overall cellular response to both devices. These devices were evaluated in a porcine model of inguinal herniorrhaphy at 3 and 6 months post-implantation.

MATERIALS AND METHODS

Ten (10) adult, male, reproductively intact, mini-pigs, approximately 45 kg in weight, were obtained from an approved laboratory animal supplier. The test device consisted of the new HP and the control device consisted of a commercially available BARD® PERFIX® plug. Animals were sacrificed at 3 months (n=5) and 6 months (n=5) to evaluate the healing response.

Surgical Procedure:
The animals were placed in dorsal recumbency and the groin area prepped in standard aseptic technique for a bilateral inguinal hernia repair. A standard surgical approach was used to access the right and left inguinal canal and internal ring. Digital manipulation was used to widen the internal ring to mimic a Type II or III indirect hernia as per Gilbert's classification (Table I). Implant position and order of implantation were predetermined with the Gore and Bard device alternating between the left and right sides. Overlay mesh was not employed.



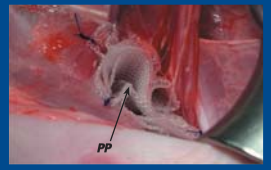


Table I Gilbert's classification (modified by Rutkow and Robbins)

Type I	Indirect hernia, internal ring not enlarged
Type II	**Indirect hernia, internal ring enlarged (passable for the tip of one finger)**
Type III	**Indirect or scrotal hernia, insufficient Internal ring (passable for two or more fingers)**
Type IV	Direct hernia, large defect
Type V	Direct hernia, small defect
Type VI	Combined direct/indirect hernia
Type VII	Femoral hernia

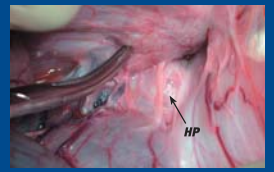
Implant Retrieval:
At 3 and 6 month intervals, a laparotomy was performed in order to visualize the intra-abdominal aspect of the inguinal region. Photos of the inguinal region were taken to demonstrate any difference in device behavior. The entire inguinal region was removed en bloc and immersed in appropriate quantities of 10% neutral buffered formalin for 7 days.

Histological Evaluation:
Histological parameters included 1) inflammation, 2) assessment of in-growth, 3) image analysis to determine amount/distribution of collagen in defect, 4) thickness of fibrous capsule/peri implant membrane, 5) foreign body response, 6) vascular response and 7) other reactions (i.e., mineralization, infection, etc.).

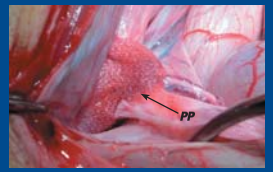
RESULTS

Adhesions to the Bladder

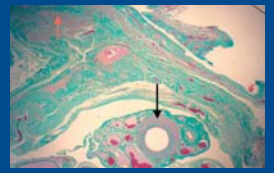
0/10 Cases (0%) HP



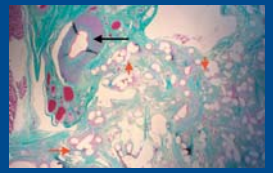
4/10 Cases (40%) Polypropylene



Histology – 6 Months

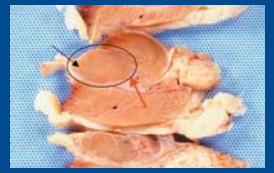


Black arrow illustrates spermatic cord, red arrow illustrates remnants of the HP. No adhesions to cord are present. Milligan's trichrome 2.5x

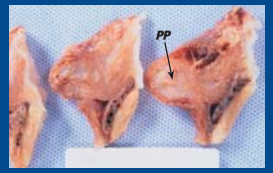


Black arrow illustrates spermatic cord, red arrow illustrates polypropylene fibers. Polypropylene plug is adhered to the cord. Milligan's trichrome 2.5x

Explant – 92 Days



***HP –** Void space completely filled with bland, fibrocollagenous tissue; complete incorporation of the resorbable mesh (arrows). No evidence of mesh erosion or inflammation of adjacent tissues.*



***PP –** Intense inflammation of tissue within the stiff polypropylene mesh. Dark brown areas, indicative of persistent granulation tissue, indicating ongoing inflammatory response to the polypropylene fibers.*

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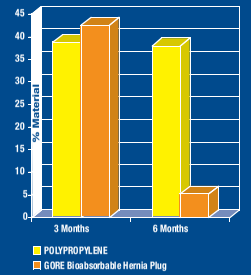
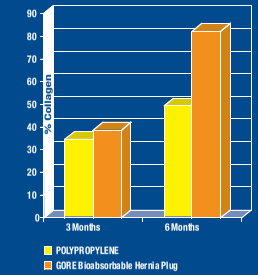


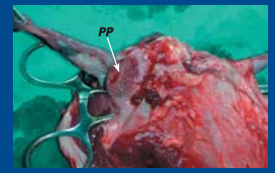


CONCLUSIONS

Gross and histological findings demonstrate that when a PP is used, erosion into the peritoneum, cord structures, and bladder can occur. Additionally, histology showed impingement and entrapment of nerve fibers, and a persistent inflammatory and foreign body response as a direct result of the polypropylene material being present.

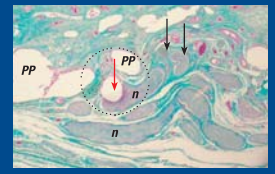
Conversely, with the GORE Bioabsorbable Hernia Plug, we observed that as the material bioabsorbed, the defect was filled with highly vascularized, collagenous tissue that maintained the architecture of the posterior inguinal wall. The inflammatory response subsided as the material bioabsorbed.

We observed that the bioabsorbable plugs restored the posterior inguinal wall while closing the inguinal canal by substituting the material with collagen and new tissue. In contrast, PPs caused a persistent foreign body response, which may have contributed to the patent inguinal canals observed in 40% of the animals. The protrusion of the PP below the transversalis fascia exposes the plug to the abdominal cavity, which resulted in erosion of the peritoneum, and adherence to bladder in 40% of the animals.



Open Inguinal Ring
4/10 Cases (40%) Polypropylene

Histology – 6 Months



The advancing fibrosis from the PP (PP) entraps the nerve fibers (black arrows). The stiff polypropylene fibers impinge (red arrow) on a nerve bundle (n). Milligan's trichrome 25x

Based on these results, bioabsorbable plugs appear to avoid the potential complications associated with permanent polypropylene plugs, such as erosion, migration, nerve entrapment, and adherence to intrabdominal viscera. Additionally, the GORE Bioabsorbable Hernia Plug may reduce chronic inguinal pain, attributed to the chronic inflammatory response and invasion of the spermatic cord structures associated with PPs. Integration of the bioabsorbable plug during wound healing makes its use a viable option in the repair of inguinal hernias.