The purpose of this evaluation is to compare the gross and histological observations of the HP and a commercially available PP (Bio-Pyrig®) plug. Adhesions to the spermatic cord, ovarian and vaginal ligaments, and inguinal rings were assessed. Histologically, examined collagen deposition, necrosis, extrusion, erosion of the cord structures, and overall cellular response to each device. These devices were evaluated in a porcine model of inguinal herniography at 3 and 6 months post-implantation.

MATERIALS AND METHODS

The ten (10) adult male, reproductively intact, mini-pigs, approximately 45 kg in weight, were obtained from an approved laboratory animal supplier. The left device consisted of the new HP and the control device consisted of a commercially available Bio-Pyrig® plug. Animals were sacrificed at 3 months (n=6) and 6 months (n=4) for histological analysis.

Surgical Procedure

The animals were placed in dorsal recumbency and the groin area grasped in standard orthopedic technique for a right 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 create a 3 mm or 4 mm defect as per Gilbert classification (Table 1). Hemostasis and drape were performed in the same fashion as described in the previous study. The devices were alternated to the right and left sides of the inguinal ring. A mesh was not employed.

RESULTS

Table 1: Gilbert’s classification (modified by Rubow and Robbins)

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>Indirect hernia, internal ring not enlarged</td>
</tr>
<tr>
<td>Ib</td>
<td>Indirect hernia, internal ring enlarged (exceeding the tip of one finger)</td>
</tr>
<tr>
<td>Ic</td>
<td>Indirect hernia, internal ring extremely enlarged (exceeding the tip of two or more fingers)</td>
</tr>
<tr>
<td>IIa</td>
<td>Direct hernia, large direct</td>
</tr>
<tr>
<td>IIb</td>
<td>Direct hernia, small direct</td>
</tr>
<tr>
<td>IIc</td>
<td>Direct hernia, hernial cord</td>
</tr>
<tr>
<td>IIIa</td>
<td>Falciform ligament hernia</td>
</tr>
<tr>
<td>IIIb</td>
<td>Rectocutaneous hernia</td>
</tr>
</tbody>
</table>

Conclusion

Biodegradable plugs seem to avoid potential complications compared to PPs, such as migration and adhesions to intraperitoneal asepsis, and to reduce the possibility of chronic inguinal pain related to these implants. Chronic inflammatory response decreases and invasion of the inguinal canal and not as well as adhesions. The amount of collagen generated by the biodegradable 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 at over 60,000 and 700,000 groin hernioplasty repairs are performed in Europe and North America respectively every year. 17 This has further estimated that approximately 40% of these repairs involve some type of prosthetic device.

Pain and other various complications of plug-and-patch hernia repairs have been previously reported. A new prosthetic mesh made of polypyrrole mesh. Polypyrrole is known to be less to cause adhesions and extraperitoneal response and occurring, which is known to cause PP to shrink.11 There are reports of PPs migrating to the scrotum,12 small bowel,3 and into the hernial canal.13

The HP was developed with the goal of repairing the hernia defect in the short term while eliminating or mitigating chronic complications associated with permanent plugs. The HP is composed of the polypyrrole study and extracellular matrix (ECM), which is known to cause adhesions to shrink. HP is designed to be biodegradable, thus allowing the device to completely resolve and be replaced by the surrounding tissue. This study was designed to test the ability of a new device to fill a defect and extraperitoneal tissue regeneration. Additionally, no new animal study has been performed evaluating the post-operative effects of permanent, polypyrrole hernia plugs.

Implant Retention

A hernia repair was accomplished in order to visualize the intra-abdominal aspect of the inguinal region. The inguinal region was then reconstructed and repaired. The entire hernia area was removed en bloc and immersed in appropriate fixatives. The defect was filled with 10% buffered formalin for 7 days.

Histological Examination

Histological parameters included 1) inflammation; 2) assessment of in-growth; 3) image analysis to determine amount/degree of collagen in defect; 4) detection of foreign body reaction; 5) granulomas; 6) necrosis; 7) cellular response; and P1/2 reactions (i.e., mineralization, infection, etc.).

CONCLUSIONS

Gross and histological findings demonstrate that none of the PPs used across the performance, 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 these polypropylene prosthetic devices presenting.

Conversely, with the Biodegradable hernia plug, we observed that the inflammation and fibrosis, the defect was filled with largely intact extracellular tissue that maintained the architecture of the posterior inguinal wall. The inflammatory response associated with the material was known to be biodegradable.

We observed that the biodegradable plugs restored the posterior inguinal wall while protecting the nerve fibers by distributing the material with collagen and nerve tissue. In addition, a persistent foreign body response, which may have contributed to the persistent foreign body observed in 40% of the animals. The production of the PP was associated with the inflammation of the plug to the abdominal cavity, which resulted in erosion of the peritoneum, and adhesions to internal organs in 40% of the animals.

Based on these results, biodegradable plugs appear to avoid the potential complications associated with permanent polypropylene plugs, such as erosion, migration and entrapment, and extraperitoneal tissue regeneration. Additionally, no new animal study has been performed evaluating the post-operative effects of permanent, polypyrrole hernia plugs.

REFERENCES