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Comparing the host tissue response and peritoneal behavior of composite meshes used for ventral hernia repair

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ABSTRACT

Background: The use of a prosthetic material is the best treatment option for ventral hernia repair; one of the most frequently performed abdominal surgery procedures. This preclinical study compares the behavior of a new mesh (Parietex composite ventral patch [Ptx]) with that of two existing meshes used for ventral hernia repair.

Materials and methods: Fifty-four New Zealand White rabbits (3000 g) were used in an experimental model of umbilical hernia repair (diameter 1.5 cm). The materials tested were: Ventralex ST hernia patch (Vent) (Bard Davol Inc, Warwick, RI) ($n = 18$); Proceed ventral patch (Ethicon, Somerville, NJ) (PVP) ($n = 18$) and Ptx (Covidien, Sofradim, Trevoux, France) ($n = 18$). At 3, 7, 14 d, and 6 wk after implant, peritoneal behavior and adhesion formation were assessed by sequential laparoscopy. Mesh mesothelial cover was determined by scanning electron microscopy. Host tissue ingrowth (collagens I and III) and the macrophage response were assessed by immunohistochemical labeling. Animals were euthanized at 2, 6 wk, and 6 mo after surgery. Data were compared using the Mann–Whitney *U* test.

Results: Adhesion formation from 3 d–6 wk was significantly greater ($P < 0.05$) for PVP compared with Vent or Ptx. Three encapsulated PVP implants showed "tissue-integrated" adhesions affecting the intestinal loops. All three implant types showed similar patterns of collagen l and III deposition. The PVP mesh elicited the greater macrophage response both at 2 wk and 6 mo.

Conclusions: Ptx and Vent showed excellent mesothelialization, which led to minimum adhesion formation. The appropriate tissue integration of Ptx in the parietal neoperitoneum is likely attributable to its deployment system.

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1. Introduction

In 2009, the European Hernia Society issued a classification system for ventral hernias [1]. According to this system, epigastric and umbilical hernias are considered primary ventral hernias if they are not caused by an incision. Both hernia types are a common indication for surgical intervention in a setting of general surgery. Data available for the United States indicate that 180,730 umbilical hernias and 8994 epigastric hernias were surgically treated in 2012 [2].

Despite the possibility of a laparoscopic approach to hernia repair, conventional open surgery to implant a prosthetic material continues to be the most common option for the repair of both umbilical and epigastric hernias. The drawbacks of laparoscopic surgery are mainly its high cost [3] and adverse effects such as port-site hernia and bulging [4,5].

Conventional repair techniques involving simple suture closure or the Mayo technique for umbilical hernia repair are associated with a recurrence rate of 10%–30% [6,7]. The use of a prosthetic material, even for the repair of a small defect, has reduced the incidence of hernia recurrence to around 1%–2% [8–11].

The materials used for ventral hernia repair have evolved over time from the conventional polypropylene meshes in the shape of an "H" [12] or a "plug" [13], to today's new designs created specifically for these types of hernia. A basic requirement is that one of the surfaces of the repair mesh should make adequate contact with the visceral peritoneum. This determines the composite nature of the mesh such that one of its components should show optimal behavior at the peritoneal interface. This is achieved through the use of laminar materials, reabsorbable or nonreabsorbable that induce the deposition of a smooth mesothelial layer and thus avoid adhesion formation or other complications.

A further characteristic feature of prosthetic mesh implants is the way in which they are placed or deployed. Although most meshes available today are not technically demanding for the surgeon to implant, complications may arise if the mesh is not positioned to make intimate, uninterrupted contact with the parietal peritoneum. Efficient deployment of the mesh during placement is therefore critical.

The objective of the present study was the preclinical assessment of a new prosthetic design (Parietex Composite Ventral Patch) that has a deployment device designed for optimal intraperitoneal placement. This new composite mesh also has a reabsorbable collagen film barrier to prevent adhesions. The post-implant behavior of the mesh was laparoscopically monitored and compared with that of two meshes used in current clinical practice. In parallel, host tissue incorporation into both the intraperitoneal and abdominal wall sides of each mesh was assessed in the short- and long-term in an experimental abdominal wall defect model.

2. Materials and methods

2.1. Experimental animals

Fifty-four male New Zealand white rabbits of mean weight 3000 g were housed and handled during the entire study period in accordance with the recommendations detailed in the Guide for the Care and Use of Laboratory Animals of the National and European Institutes of Health (Spanish Law 32/2007, Spanish Royal Decree 1201/2005, European Directive 2010/63/UE, and European Convention of the Council of Europe ETS123). All procedures were performed at the Animal Research Centre of the Alcalá University. The study protocol was approved by a local Committee on the Ethics of Animal Experiments.

2.2. Biomaterials

- Ventralex ST Hernia Patch (Vent) (Bard Davol Inc). The Ventralex patch is composed of polypropylene monofilament and absorbable polyglycolic acid (PGA) fibers. The mesh is coated on its PGA surface with an absorbable, chemically modified hydrogel containing sodium hyaluronate, carboxymethylcellulose, and polyethylene glycol. For placement, the patch has two main features: a fully absorbable (polydioxanone) SorbaFlex Memory Technology ring, which makes the patch "spring open" when deployed, and two straps used to secure the position and suture the mesh to the margins of the defect.
- Proceed ventral Patch (PVP) (Ethicon Johnson & Johnson, Somerville, NJ). This patch is a flexible mesh made of multiple layers of absorbable and nonabsorbable materials laminated together with an absorbable polydioxanone polymer. The bottom layer of the patch facing underlying tissue and organ surfaces is composed of oxidized regenerated cellulose (ORC) fabric bonded to Prolene Soft Mesh (Ethicon, Somerville, NJ), a nonreabsorbable, macroporous polypropylene mesh. The polypropylene mesh side of the product allows for tissue ingrowth. The ORC side of the patch provides a bioreabsorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the critical wound healing period. The polypropylene mesh layer is encapsulated with layers of PDS (polydioxanone) film. The parietal side of the mesh contains a polydioxanone polymer reinforcement film and positioning ring, which provide memory to the patch. Vicryl Mesh (Ethicon, Somerville, NJ) is placed on top of the polydioxanone polymer reinforcement film to facilitate placement of the mesh. The Vicryl Mesh layer is encapsulated within layers of PDS film. Anchoring straps of the patch are designed to facilitate placement and fixation of the mesh device.
- Ptx (Covidien Sofradim Production). The Parietex patch is a dual-facing mesh composed of a nonreabsorbable, three-dimensional monofilament polyester material coated with an absorbable hydrophilic collagen film, based on Parietex Composite technology. Instead of straps, the patch has a fixation system composed of four monofilament polyester flaps. Two removable handles complete the device. This fixation system and the three-dimensional reinforcement material are assembled with absorbable poly (glycolide-co-L-lactide) (PGLA) expanders ("ring"). This system facilitates the placement and fixation of the mesh (Fig. 1).