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ORIGINAL ARTICLE

The new 4DDome prosthesis: an original light and partially absorbable composite mesh for hernia repair

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Abstract
Introduction The use of non-absorbable meshes for the repair of inguinal hernias has become standard; however, these meshes have been associated with complications including long-term postoperative pain. To this end, a new partially absorbable composite mesh has been developed, and the aim of this study was to investigate its efficacy in animal and human trials.
Materials and methods Sixty male Wistar rats were used to evaluate the behavior of the newly designed composite mesh. Composite meshes were implanted in the extra-peritoneal plane for 2, 4 and 8 weeks and compared to a standard polypropylene mesh. Forty patients with symptomatic inguinal hernias were treated using a new 4DDome designed prosthesis. Follow-up was by clinical and ultrasound examination at 1, 6 and 12 months.
Results The animal study demonstrated that the inflammatory reaction associated with the new composite mesh was significantly lower than a standard polypropylene mesh, characterized by a lower macrophage infiltrate ($P < 0.001$). The mesh did not shrink over the 8-week period, unlike the polypropylene mesh ($P < 0.05$). The human study showed that there were three minor postoperative complications, no recurrences and the mesh was well tolerated. Follow-up with serial ultrasound showed that at 10 days and 1 month the dome was clearly visible in position; however, by 6 months it had flattened out, been partially absorbed and become incorporated into the repair.
Conclusion These experimental and clinical studies have validated the concept of the new 4DDome composite mesh. It was well tolerated and was associated with good short-term results. The combination of the dome shape and the new composite mesh means that less polypropylene is required and represents a significant advance in anterior hernia repair.

Keywords Hernia · Repair · Mesh · Plug · Composite · Polypropylene · PLLA dome

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Introduction

The repair of abdominal wall hernias using a prosthetic mesh is one of the most common procedures performed in general surgery. The aim of using a mesh is to achieve a mechanical as well as a physiological reinforcement of the abdominal wall through the induction of fibrosis [1]. This leads to better outcomes than the techniques performed without meshes, including lower recurrence rates and less postoperative pain [2–4]. Non-absorbable mesh materials have received global acceptance [5–7] and are currently considered to be the optimal material for inguinal hernia repair.

The use of mesh is associated with a very low recurrence rate, but it does not guarantee an ideal outcome for all patients [8–10]. Postoperative pain can be a significant problem, and disabling postoperative pain has been observed at rates ranging from 8.6 to 38.3% [11–14]. The origin of this pain is uncertain and may be secondary to surgical neural injury or foreign body inflammatory reaction associated with the prosthetic

material [15]. Peri-prosthetic inflammation can persist for many years and lead to long-term sequellae such as persistent pain, mesh migration and erosion, late-onset infection and adherence of the mesh to the surrounding tissues, including nerves and vessels [15–18]. Such observations have led to research efforts worldwide to identify the ideal prosthetic material associated with a low foreign-body inflammatory reaction, and it is now apparent that the extent of peri-prosthetic foreign-body reaction is related to the amount of non-absorbable prosthetic material used [16, 19]. This has led to the development of light polypropylene (LgPP) meshes with increased pore sizes [20]. However, the main concern regarding this is that their inflexibility results in difficulties placing the mesh. The 4DDome mesh is proposed as a potential solution to achieve the needs of an absorbable mesh to reduce inflammation and a non-absorbable mesh to provide strength. It is manufactured from the biomaterial poly-L-lactic acid (PLLA) and a light amount of woven polypropylene. The PLLA is an absorbable polymer of the naturally occurring amino acid lactate, which has a slow degradation profile [29]. It has generated interest in tissue engineering because of its use as scaffolding for the cellular regeneration of bone, cartilage, vessels, nerves and muscle [21–25], and it has been used in orthopedic surgery, plastic surgery, pediatric surgery, neurosurgery and cardiac stenting [26–30]. This mesh is considered to optimize the balance between a reduced foreign body inflammatory reaction and the requirement for mechanical strength to reinforce the abdominal wall.

The study is divided into two parts: an animal study and human study. The objectives of the animal study were to evaluate the macroscopic and microscopic changes that occur following implantation of the new composite mesh and to compare these to a standard polypropylene mesh as used in the reference technique, the Plug and Patch (Bard).

The objectives of the human study were to determine whether the 4DDome mesh provided a robust repair, how the mesh evolved with time and the incidence of postoperative complications and pain.

Materials and methods

Mesh and prosthesis specifications

An original mesh was designed for the study and consisted of two layers: one layer of pure PLLA and a scaffolding layer of mixed LgPP and PLLA (Fig. 1). The mesh is pre-molded, and the overall content of polypropylene is 10%. The polypropylene mesh (PP mesh) used in controls was the commercially available mesh Prolene manufactured by Ethicon, Cornelia, USA. The textile properties of both meshes are given in Table 1. The new 4DDome prosthesis is manufactured from the new prosthetic mesh made of 90% PLLA and 10% LgPP (COUSIN BIOTECH, Wervicq Sud—France). The prosthesis is molded into a dome shape in order to provide support to the area of the hernia defect. It is presented with a 6-mm strip placed in the concavity of the dome, allowing easy manipulation and placement. It is made in three diameters to adapt precisely to the size of the hernia defect: 24, 30 and 38 mm (Fig. 2).

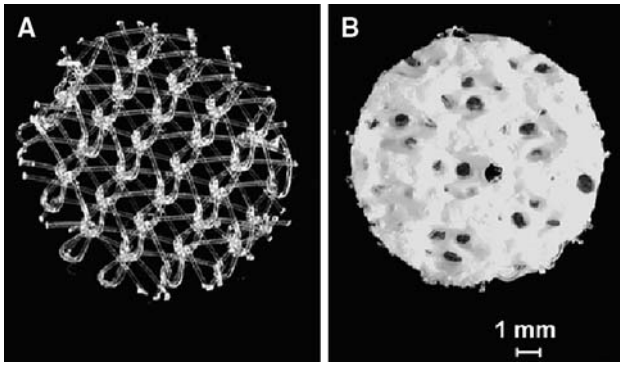

Fig. 1 Magnified photographs of inserted mesh pieces: **a** polypropylene mesh (prolene, Ethicon, Cornelia—USA); **b** composite poly-L-lactic acid and light polypropylene mesh

Animal study

A total of 60 male Wistar rats weighing 250–300 g each (Janvier, Le Genest-St-Isle, France) were housed in standard cages under cycled light and conditioned temperature (22±2°C) with unrestricted access to a balanced pellet diet and water. All animal experiments were in agreement with state laws for animal use and

Table 1 Textile properties of standard polypropylene and composite PLLA + light polypropylene meshes

Characteristics	Standard polypropylene	Composite poly-L-lactide with light polypropylene
Material	100% polypropylene	90% poly-L-lactide, 10% polypropylene
Filament	Monofilament	Multifilament, monofilament
Weight (g/m^2)	80	310 (280 PLLA + 30 PP)
Proportion of pores (%)	80	74
Mean pore size (mm)	500	500
Thickness (mm)	0.45	0.80–1.00

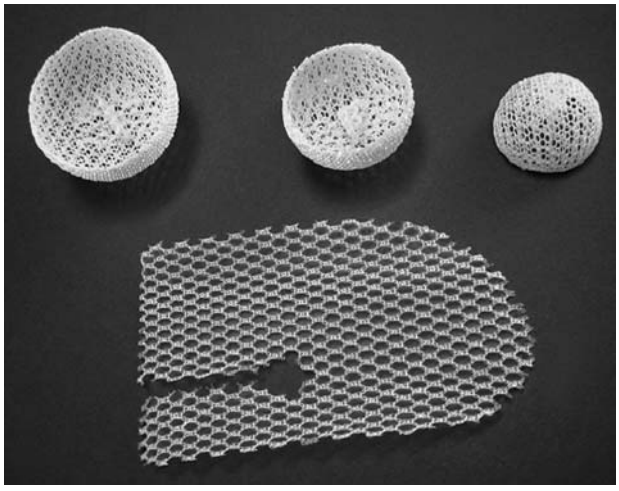

Fig. 2 The new 4DDome shaped prosthesis is proposed in three sizes: 24, 30 and 38 mm. The anterior prosthesis is made of light polypropylene

care. The rats were anesthetized with 2% isoflurane (Aerrane; Baxter, Maurepas, France) and oxygen. The skin over the abdomen was shaved and disinfected with povidone-iodine solution. A 3-cm midline laparotomy was performed in each rat followed by dissection of the extraperitoneal space between the abdominal muscle layers in order to create space for insertion of the mesh. Animals were randomly assigned into two groups of 30 animals, receiving either 2 PLLA composite meshes or 2 Prolene meshes. Two circular pieces of mesh, each measuring 1 cm in diameter, were implanted in the preperitoneal space in each rat on both sides of the midline under sterile conditions. The pieces of mesh were inserted and fixed to the abdominal wall muscle with three intermittent stitches of 5/0 Prolene (Ethicon, Cornelia, USA). The peritoneum and skin were closed separately using 3/0 Polysorb (Tyco Healthcare, Plaisir, France). No antibiotic treatment was given before or during the experiments. The operated rats were observed three times per week postoperatively. There were no perioperative complications or deaths.

Ten rats from each group were sacrificed under anesthesia at 2, 4 and 8 weeks after mesh insertion for retrieval of meshes and evaluation. The samples of meshes were excised with the surrounding abdominal wall. For each animal, one specimen was used for evaluation of adherence and size immediately after sampling, and the other was kept for pathological analysis. The rats were sacrificed after mesh sampling by anesthetic overdose.

Macroscopic evaluation looked for the presence of seroma, infection or adhesions surrounding the mesh. Following resection, the mesh specimens were dissected to separate the mesh from the muscular layers to assess the strength of adherence of the mesh to the abdominal wall. The adherences were scored on a scale of 0–3 (0, no adherence; 1, filmy adherence and mesh easily detached; 2, moderate adherence, but mesh removable; 3, dense adherence requiring sharp dissection for removal of mesh). After the evaluation of adherence, the maximal diameter of the retrieved pieces of mesh was measured in order to assess intra-corporal shrinkage.

Mesh specimens were fixed with 10% formalin and embedded in paraffin for microscopic evaluation. Serial sections of 2–4 μm were cut from the paraffin-embedded blocks and stained with hematoxylin and eosin (H and E). Light microscopy was performed at 20-fold magnification looking at the interface between mesh and tissue in three separate areas on each mesh. Inflammatory cellular reaction was evaluated using a semi-quantitative score. The density of neutrophils, lymphocytes and macrophages was determined and scored on a pre-determined scale of 0–3 (0, none; 1, small; 2, moderate; 3, large). The average number of foreign body giant cells present was also recorded. The extent of fibrosis was scored on a predetermined scale. The thickness of fibrotic tissue surrounding the mesh as well as the density of fibroblasts were taken into account, and a combined score between 0 and 3 was given (0, none; 1, small; 2, moderate; 3, large).

Patient study

A total of 40 patients were included in the study. Inclusion criteria were age over 18 years, unilateral or bilateral and primary or recurrent inguinal hernia. Femoral hernia and emergency operation were excluded. All patients agreed to participate in the study. Demographic data, hernia type according to Nyhus classification, operative and perioperative outcomes were prospectively registered. Three consultant surgeons performed the procedures following a standard surgical technique.

The technique is briefly described: the patient was placed in the supine position and the groin prepared in the usual fashion. After incising the skin and the subcutaneous tissue, the external oblique aponeurosis was opened, and the spermatic cord was elevated from the posterior wall of the inguinal canal. The hernia sac was isolated by blunt dissection and reduced. The dome-shaped mesh was inserted at the level of the defect and fixed by four absorbable sutures (Polysorb 3/0). In direct hernias, the dome was placed in the direct defect, pushing on the fascia transversalis and allowing a tension-free positioning of the anterior mesh. The

onlay light-weight polypropylene mesh was then placed around the spermatic cord. The split section was sutured lateral to the spermatic cord. Its inferior edge was secured to the inguinal ligament with a continuous suture (prolene 2/0). Its superior aspect was fixed by three separated absorbable stitches on the internal oblique aponeurosis (Polysorb 3/0). Finally, the aponeurosis of the external oblique and the subcutaneous layers were closed with two continuous sutures (Polysorb 2/0). The skin was closed by subcuticular absorbable suture (Monocryl 3/0).

The clinical follow-up was done at 10 days, 1 month, 6 months and 1 year after the operation. The patients underwent outpatient clinical examination and inguinal ultrasonography at 1 month, 6 months and 1 year. Local and general complications, recurrences and pain according to the visual analogic scale VAS (from 0–10) were evaluated. Ultrasonography was performed by an expert radiologist using a 7.5-MHz linear probe in order to evaluate physical changes of the dome-shaped mesh over time and to check for the presence of postoperative hematoma and seroma.

Results

Animal study

On macroscopic inspection, there was no seroma, infection, visible peritoneal inflammation or intra-peritoneal visceral adhesion observed in any of the rats with either mesh. Adherence scores were significantly lower for the PLLA mesh compared to the PP mesh at 2 weeks ($P < 0.01$) and 4 weeks ($P < 0.05$) (Fig. 3a). The difference did not reach statistical significance at 8 weeks. The mesh size on retrieval was measured (Fig. 3b): there was no change in size of the PLLA mesh, measured at 2, 4 and 8 weeks; however, the mean diameter of the PP mesh decreased and was significantly smaller after 8 weeks ($P < 0.05$). There was no significant difference in lymphocyte infiltration between the different time periods and meshes (Fig. 4a), and overall lymphocyte infiltration was observed to decrease over time. The number of infiltrated foreign body giant cells was low at all times of retrieval and did not vary over time (Fig. 4c). Macrophage infiltration was significantly lower around the PLLA mesh compared to the PP mesh at all times of retrieval (2 weeks $P < 0.0001$, 4 weeks $P < 0.001$, 8 weeks $P < 0.0001$) (Fig. 4b and Table 2). Fibrosis was significantly more extensive around the PLLA mesh compared to the PP mesh at 2 and 4 weeks (2 weeks, $P < 0.01$; 4 weeks, $P < 0.05$), although the difference did not reach statistical significance at 8 weeks (Fig. 5).

Patients

The study was carried out in a single teaching institution. Between September 2003 and November 2004, 41 hernias were operated on in 40 patients, 36 of whom were male. The mean age was 66.7 years (23–90). Mean weight was 72.6 kg (55–98) with a mean BMI of 24.9 (22–32). The mean ASA (American Association of Anesthesiologists) score was 1.8 (1–3). In 55% of the cases (22 patients), the inguinal hernia was on the right side, in 42.5% (17 patients) on the left side, and in one case the patient presented with a bilateral hernia. Five patients had a recurrent hernia (12.1%). In three cases this occurred after the Lichtenstein technique, in one case after the Bassini technique and in one case after laparoscopic TAPP repair. Patients were operated on under local anesthesia in 30 cases (75%) and general anesthesia in 10 (25%). The mean operative time was 38 min with a range between 25 and 50 min. There were no intraoperative complications. According to the Nyhus classification, the types of primary hernia

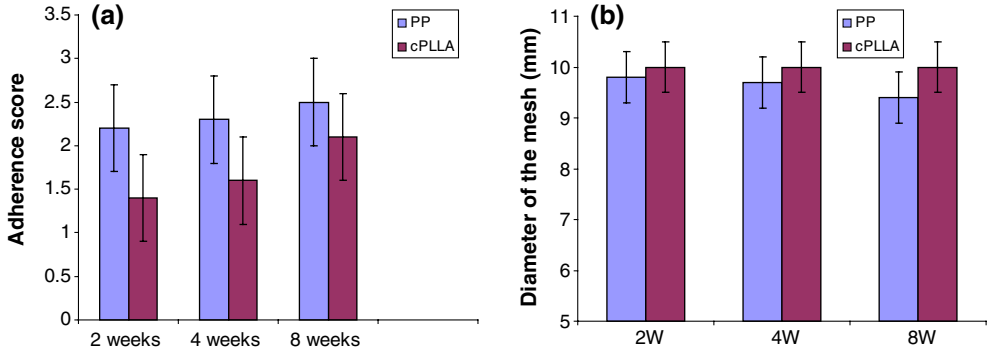

Fig. 3 Animal study: macroscopic evaluation of the adherences (**a**) diameter of the meshes (**b**); results are presented as the mean value ± standard deviation. *$P < 0.05$

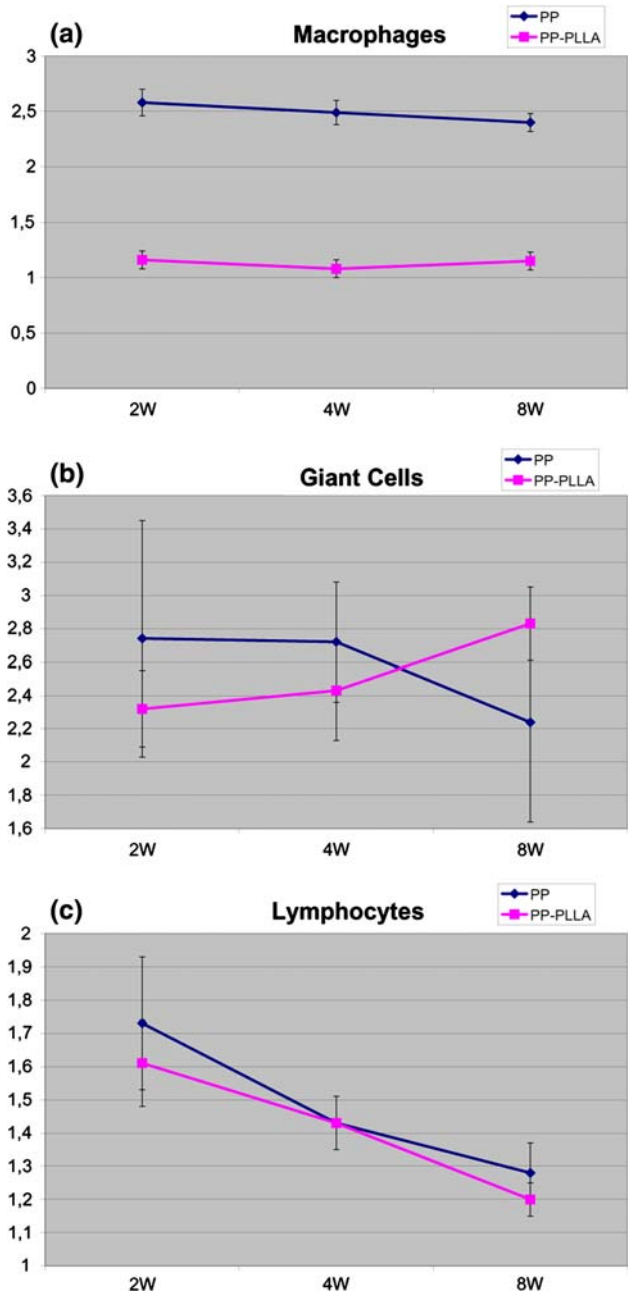

Fig. 4 Animal study: microscopic evaluation. Results of the lymphocyte (**a**), macrophage (**b**) and foreign body giant cell (**c**) quantification according to time of retrieval. Results are the mean ± standard deviation

were : type III A in 16 cases (39%), type III B in 23 cases (56%) and type II in 2 cases (5%).

There was no perioperative mortality. Minor postoperative complications occurred in three cases for an overall morbidity rate of 7.5%: two patients had a seroma and one patient a sub-cutaneous hematoma; these were treated conservatively. There were no infections, and the median postoperative hospital stay was 1 day (range 0–10 days).

Table 2 Results of the microscopic evaluation of immune cell stimulation (lymphocyte index) and of inflammation (macrophage and foreign body giant cell indexes)

Morphometric index	Week of implantation	Polypropylene	Composite mesh
Lymphocyte	2	1.73 ± 0.20	1.61 ± 0.13
	4	1.43 ± 0.08	1.43 ± 0.08
	8	1.28 ± 0.09	1.20 ± 0.05
Macrophage	2	2.58 ± 0.12	1.16 ± 0.08
	4	2.49 ± 0.11	1.08 ± 0.08
	8	2.40 ± 0.08	1.15 ± 0.08
Foreign body Giant cell	2	2.74 ± 0.23	2.32 ± 0.08
	4	2.72 ± 0.12	2.43 ± 0.10
	8	2.42 ± 0.20	2.83 ± 0.08

Indices are expressed on a 0–3 scale (specifications are given for each of them in Materials and methods). Data are shown as the mean ± SEM of ten animals. Microscopic changes were scored in ten separated fields of three different H and E-stained slices originating from the same animal and averaged to a single value

At the 12-month follow-up, there were no recurrences, and pain evaluated by the VAS score (0–10) was a median of 0 (range 0-2).

At the ultrasound examination at 10 days, the dome-shaped plug was clearly visible and correctly in place in all cases, and the onlay LgPP mesh was also clearly identified as a thin, corrugated hyperechogenic layer (Fig. 6). In most of the patients, the radiologist reported a small superficial collection of fluid that was not clinically evident. At 1 month, the meshes were unchanged on ultrasound examination. A total of 30 patients underwent a further ultrasound examination at 6 months, and this demonstrated a flattening of the dome-shaped prosthesis. In 50% of the patients, the image of the dome was replaced

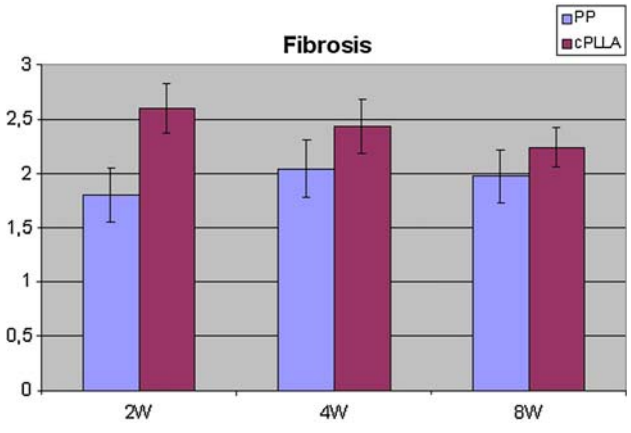

Fig. 5 Animal study: microscopic evaluation. Fibrosis score according to time of retrieval. Results are the mean ± standard deviation

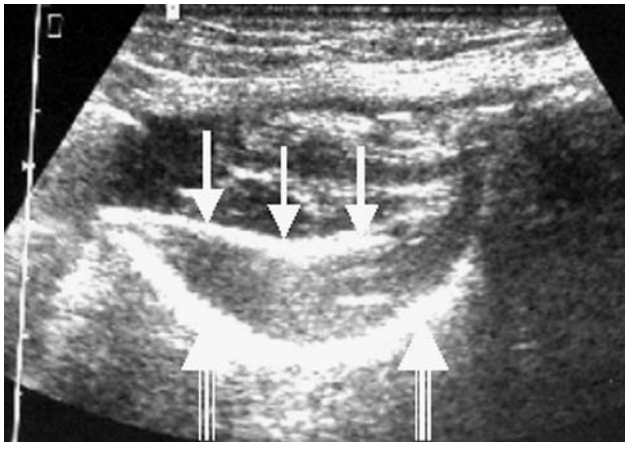

Fig. 6 Ultrasonography after 1 month. The dome shape of the 4DDome prosthesis is well identified (→ anterior mesh, ⇒ dome shaped mesh)

either by a small hyperechogenic spot with a posterior cone or by a small, thin, flattened hyperechogenic layer, similar to that of the on-lay mesh. However, in the remaining patients, there were no specific images associated with the dome (Fig. 7). In all cases, the on-lay LgPP mesh was identified showing the same previously reported characteristics. No seroma or hematoma were observed, and no recurrent hernias. The same observations were made in 24 patients at 1 year, and both clinically and ultrasonographically no recurrences were observed.

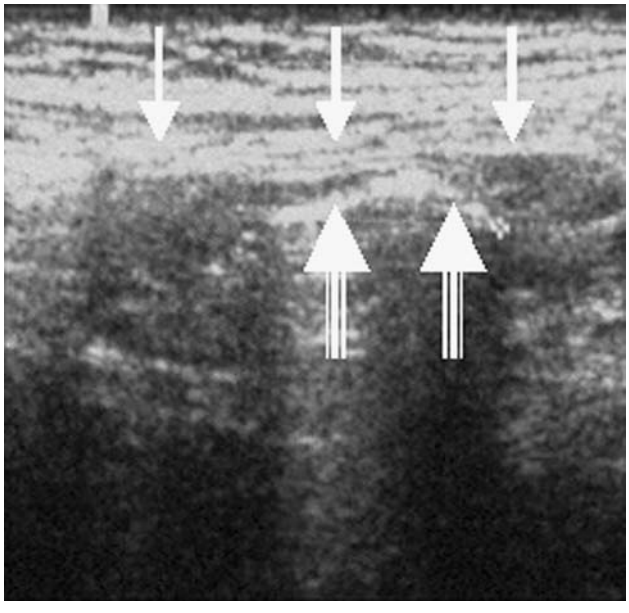

Fig. 7 Six-month ultrasonographic control: the dome shape is no longer identified. The prosthesis appears as a hyperechogenic layer. (→ anterior mesh, ⇒ flattened dome mesh)

Discussion

The reinforcement of the abdominal wall with prosthetic mesh occurs by the increased tensile strength of the prosthesis and the result of the fibrotic plate related to the mesh [16]. Bio-integration occurs as a result of inflammatory cell infiltration and the laying down of connective tissue [31]. However, the inflammatory cell infiltrate also appears to be responsible for most complications as well as mesh shrinkage, and solutions are currently being investigated in order to try to avoid these problems. One of the solutions is to limit the proportion of polypropylene in the mesh and hence the inflammatory reaction, although the downside of this has been that significant reductions in the amount of polypropylene has resulted in the meshes being difficult to place in situ. Therefore, an intermediate solution is proposed in this study in the form of a low-density polypropylene mesh reinforced by an absorbable biomaterial that will provide initial strength, but soon be absorbed, hence limiting local inflammation and foreign body reaction. The aim of this study was to investigate the efficacy and safety of this new low-density polypropylene and absorbable biomaterial (PLLA) composite mesh.

The findings from the animal study demonstrate that the acute inflammatory response, signified by inflammatory cell infiltration, remains very low and does not increase with time with the PLLA composite mesh. The macrophage counts from the retrieved PLLA composite mesh were significantly lower than the polypropylene-only mesh, hence it would appear the composite mesh limits the inflammatory response around polypropylene and increases the tissue tolerance of the mesh. This may explain the low adhesion rate. One criticism of the polypropylene mesh has been its tendency to shrink, and this was confirmed in the animal experiments performed in this study. However, encouragingly, the new composite mesh did not shrink and was significantly larger when retrieved at 8 weeks in comparison to the polypropylene mesh. The low inflammatory reaction does not alter the quality of the fibrotic reaction, linked to the slow absorption of the PLLA.

The animal experimental study validated the composite polypropylene/PLLA mesh, and the next phase of the study was to introduce the concept of molding the mesh into a dome shape in order to provide greater support to the area of the hernia defect. A dome is an almost spherical structure based on a network of struts arranged on circles (geodesics) lying on the surface of a sphere. The geodesics intersect to form triangular elements that create local triangular rigidity and distribute

the stress (described by Richard Buckminster Fuller in the late 1940s), and it is the only man-made structure that gets stronger as it increases in size. The geodesic dome gives maximum structural advantage, thus theoretically the use of a dome should allow the mesh to be made using the least material possible. The Perfix plug and patch hernia repair could be considered to be based on similar principles to the dome approach. However, although good results have been reported, there have also been significant complications, most of which are related to the amount of polypropylene used to create the plug [32].

The originality of the composite mesh consists in the fact that the initial resistance offered by the PLLA does not result in a major inflammatory reaction. The progressive absorption of the PLLA results in a very thin layer of polypropylene finally reinforcing the most fragile part of the hernia defect. Furthermore, during its initial presence and before absorption, the anterior mesh made of light and woven polypropylene has the ability to be at the origin of resistant fibrotic scar tissue. The low amount of implanted polypropylene fulfills the current requirement of reducing mesh masses in order to avoid their specific complications. Nevertheless, lightweight mesh has not demonstrated its ability to offer strong long-term healing. The presence of two meshes in the fibrosis could be considered as a guarantee for definitive parietal wall reinforcement; with a weight of only 60 g/m^2, it is lower than standard PP, which is 80 gm^2.

The human study revealed that the mesh was well tolerated and did not result in any adverse reactions. It was found that the mesh provided a sound hernia repair, and there was a low complication rate. The concept of the dome shape seemed to work to good effect, providing the initial reinforcement, but then with time altering in shape to a flat mesh that was incorporated into the repair and reinforced the abdominal wall long term. It would appear from the results that the composite mesh allows less polypropylene to be used, but still maintains the strength of repair. One of the perceived advantages of this was the potential for less long-term postoperative pain due to a lower inflammatory reaction. Although this was not a randomized controlled trial versus a standard polypropylene mesh, the outcomes regarding long-term pain appear to be very encouraging. There were no clinical or radiological recurrences; nevertheless, since the current recurrence rate is estimated between 1 and 2%, only a larger trial with longer follow-up would be able to evaluate this aspect.

In conclusion, this study has validated a new type of composite partially absorbable mesh by showing that it is effective and safe. The combination of the geodesic dome shape and the composite mesh using a low amount of polypropylene provides the initial strong resistance against intra-abdominal pressure as well as an effective longer term reinforcement of the anterior abdominal wall.

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