# **Original articles**

# Parietal reinforcement prostheses: an original intraperitoneal experimental study

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**Summary:** The use of prosthetic materials is widely accepted for incisional and complex hernias, but the type of prosthesis in the abdominal wall still arouses acute controversy. We report an original experimental protocol testing three material placed intraperitoneally in the rat: a polyester mesh, a compound prosthesis (juxtaposition of a polyester mesh and a mesh of polyglactin 910) and a composite prosthesis (where fibers of polyester and polyglactin 910 were woven in the same mesh). There were two main criteria for assessment: the biologic tolerance to the material on the one hand, characterized histologically by the ratio of the surface of fibrosis to the surface of the inflammatory granuloma in contact with the material, and the nature of the adhesions between prosthesis and abdominal wall and the intraperitoneal viscera on the other. Statistical analysis of the results led to a preference for the homogeneous polyester prosthesis, compared with compound and composite prostheses (polyester and polyglactin 910) and to abandonment of the intraperitoneal site for insertion of such materials.

Key words: Hernia – Incisional hernia – Prosthesis – Polyglactin – Polyester

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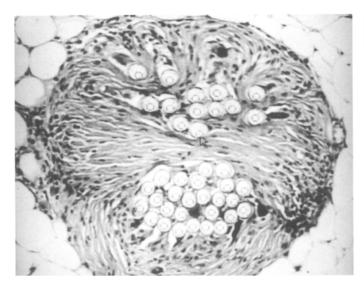
Hernia

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The use of prosthetic materials in the treatment of incisional and certain hernias is very widely accepted by the majority of authors. The type of material and the site of implantation, however, remain controversial. Placed intraperitoneally, prosthetic materials have been responsible for problems, sometimes life-threatening, caused by migration into the hollow viscera [Chevrel 1990, Darmaillacq 1966, Smith 1971, Griffe 1974, Stoppa 1990].This persuaded us to use the cleavable retroparietal spaces [Odimba 1980]. But these last procedures are often complex and require major dissection, the cleavable spaces often having been modified by previous operations, and are the source of postoperative morbidity. The aim of this study is to suggest a histomorphometric protocol and to compare the biologic tolerance and the formation of adhesions using three materials implanted at the intraperitoneal site:

- A compound prosthesis, prepared at the time of operation, formed

of the juxtaposition of polyester mesh, a terephthalic polymer of ethylene glycol, woven by the interlock procedure (Laboratoire Ethicon, Mersilene TS53) and a mesh of polyglactin 910, a polymer of glycolic acid and lactic acid (Laboratoire Ethicon, mesh of Vicryl VM94), the polyglactin mesh being positioned in contact with the viscera. This concept had already been used in a small number of patients [Loury and Chevrel 1983] and by ourselves [Soler 1993].



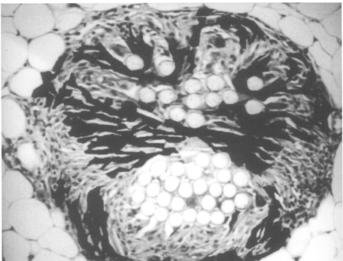


Fig. 2 Transverse section of a bundle of polyester fibers: the fibrous reaction (collagen fibers) is shown in black

Transverse section of a bundle of polyester fibers

- A composite prosthesis (Laboratoire Ethicon, composite vicryl VD14) where the fibers of the polyglactin and the polyester were woven into a single mesh.

- These two materials were compared with a mesh of polyester used by itself, a reference material employed by one of us since 1967 [Stoppa 1982].

#### **Material and methods**

#### Experimental protocol

We have developed an original experimental protocol [Soler 1993], all of the animal manipulations and the preparation of the histologic specimens up to fixation in Boin's fluid being made by the same operator. The remaining procedures leading to the obtaining of stained histologic specimens were made by another worker, whose chief concern was to secure good orientation of the sections to allow comparable measurements. Wistar rats of both sexes were used, weighing between 200 and 300 g, the animals being anesthetized by intraperitoneal injection of nembutal in a dose of 1 ml/kg. After shaving and skin asepsis, a median longitudinal laparotomy was performed and one of the prosthetic materials studied was inserted.

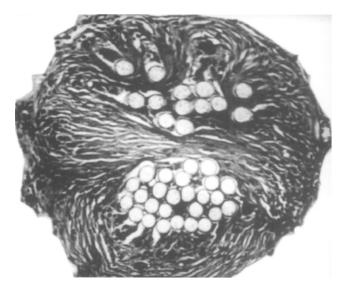
This consisted of a mesh of 5 x 4 cm attached to the deep aspect of the peritoneum by 10 interrupted sutures of polyglactin 910 3/0 at regular intervals around the prosthesis. Each suture caught the prosthesis at a distance from its free margin and transfixed the entire abdominal wall. The sutures were tied subcutaneously through short cutaneous counterincisions. Closure was made in two planes, one peritoneo-aponeurotic and the other intradermal (polyglactin 910 3/0). Groups of 10 rats were used and sacrificed at 3 and 6 months for each type of prosthesis.

After sacrificing the animals at 3 and 6 months, the anterior abdominal wall was removed as a whole, laid flat on a cork surface and fixed in 10% formol solution for 48 hours. The rigid block thus obtained was sectioned longitudinally and perpendicularly to the peritoneal plane to isolate three parts of the abdominal wall, which were then fixed in Boin's fluid for 24 hours. After dehydration with alcohol and clearing with toluene, the fragments were embedded in paraffin. Sections 3µ thick were then made and stained with phloxinhematin saffron and Masson's trichrome. The microscopic study used an optical microscope of Labolux type, brand Leica, fitted with a plane achromatic objective connected to a CCD

video-camera 3, JVC brand, model KY 15. The video images were handled with a histomorphometric software (Samba 2000, TITN), using a microcomputer fitted with a Matrox map for numeration.

The surface of fibrosis and that of the inflammatory cells in contact with a polyester fiber cut transversely (Fig. 1) were calculated for each rat. For this, the image of the microscopic preparation was transferred from the optical microscope to a monitor. By the use of histomorphometric software, it was possible to draw the contours of the surfaces occupied by the fibrosis (collagen fibers). The zones so demarcated were then darkened and their surfaces calculated (Fig. 2) The calculation of the surface occupied by the inflammatory granuloma was made semi-automatically by the software, which colored the inflammatory structures in red (Fig. 3). The operator had to calibrate this coloration in order to allow for all the inflammatory cells, but without counting artefacts. This calibration was made by comparing the microscopic preparation directly visible to the optical microscope with the numerated image in process of coloration. The ratio of the surface of fibrosis to the surface of inflammatory cells was then calculated.

Fig. 1



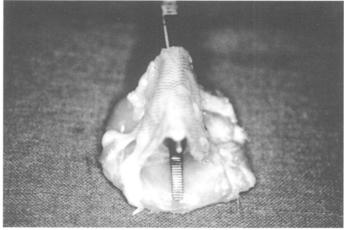




Fig. 3 Transverse section of a bundle of polyester fibers: the inflammatory granuloma is shown in black



#### Fig. 5

Adhesions between prosthesis and intraperitoneal viscera: note a lax adhesion between the large intestine and the prosthesis

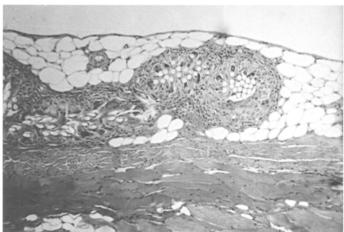


Fig. 6 Peritonization of implanted material: this section perfectly shows the neoperitoneum covering the prosthesis

#### Criteria of study

#### There were two main criteria:

- the fibrosis and inflammatory granuloma, defining the biologic tolerance to the material. We have already redefined the concept of biologic tolerance of a biomaterial [Soler 1993]. The studies already published on this matter did not quantify the collagen fibrosis [Petit 1974, Adloff 1976, Arnaud 1977, Amid 1997, Wantz 1994, Rath 1996, Trabucchi 1998]. The asessment criteria were the formation of a stable fibrous scar in contact with the material, capable of giving all its resistance to the parietal repair (collagenous), the inflammatory granuloma (consisting of mononuclears or foreignbody giant-cells) being the reflection of an active defense by the organism against the material, capable of causing its rejection. Essentially, we chose to consider the ratio of the surfaces of fibrosis and inflammatory granuloma, this ratio taking as its numerator the sound scarring in contact with the material, and as its denominator the persistence of undesired granuloma. The higher this ratio, the better is the biolgic tolerance for the material [Soler 1993].

- the adhesions between the prosthesis and abdominal wall and between the

prosthesis and the intraabdominal viscera (Figs. 4, 5). At autopsy, the adhesions of the prostheses with the abdominal wall were noted, distinguishing between prostheses exhibiting only punctate adhesions with the wall (listed as +) and those showng adhesions exceeding 50% of their surface (lisited as ++). In each group of rats the prostheses adherent to the intraabdominal viscera were counted, the nature of the viscera being stated.

Regular physical examination of the animals was carried out, monitoring the appearance of the abdominal wall. Any rats dying during the experiment were listed.

 Table 1. Fibrosis, inflammation and biologic tolerance related to the type of intraperitoneal prosthesis and the duration of implantation

Type of prosthesis	Polyester mesh		Compou	nd mesh	Composite mesh		
Duration	3 months	6 months	3 months	6 months	3 months	6 month	
N	10	9	10	7	11	14	
Surface of fibrosis							
$= F(\mu m_2)$	10277	25943	6269 <sup>a</sup>	14069	22366	21496	
Surface of inflam- matory granuloma = I (µm2)	14956	5863 <sup>b</sup>	13311	11525	52843	23654	
Biologic tolerance = ratio F/l	0.68	4.42	0.47	1.22	0.42	0.90	

<sup>a</sup> p < 0.001, <sup>b</sup> p < 0.002

Table 2. Adhesion of prosthesis to abdominal wall related to type of prosthesis and duration of implantation (n = 62)

Duration of implantation	Polyester		Compound		Composite	
	3 months	6 months	3 months	6 months	3 months	6 months
Punctate adhesions (+)	10	6	4	2	9	4
Adhesions > 50% of surface (++)	0	4	6	5	2	10
N	10	10	10	7	11	14

No statistically significant difference

Table 3. Number of prostheses adherent to intraabdominal viscera related to material used and duration of implantation (n = 62)

Duration of implantation	Polyester		Compound		Composite	
	3 months	6 months	3 months	6 months	3 months	6 months
No of prostheses adherent to viscer	a 6	3	3	2	3	5
N	10	10	10	7	11	14

No statistically significant difference

#### Associated histologic criteria

Peritonization of the implanted material: in the various sections made a neo-peritoneum was sought with the optical microscope on the deep aspect of the implanted prosthetic material (Fig. 6). The thickness of the tissue reaction between the superficial muscular plane and the deep aspect of the colonized material was measured. Measurements were made for each rat, retaining the mean. The incorporation and encapsulation of the prosthetic material by the host tissues were noted.

Statistical analysis: The prosthesisabdominal wall adhesions and prosthesis-visceral adhesions were compared with the chi<sup>2</sup> test. The surfaces of fibrosis and of inflammation, the biologic tolerances, and the thicknesses of the different prostheses were compared by the nonparametric test of Kruskal-Wallis.

#### Results

## Microscopic results

Fibrosis in contact with the prosthesis (Table 1)

At 3 months a fibrous reaction developed in contact with the compound prosthesis that was less marked than that in contact with the composite or polyester prosthesis (p<0.001). At 6 months the fibrous reaction was more marked in contact with the polyester prosthesis, but not to a statistically significant degree.

Inflammatory granuloma in contact with the prosthesis (Table 1)

At 3 months the inflammatory granuloma was more marked in contact with the composite prosthesis than with the polyester and compound prostheses, but without statistically significant differences. At 6 months the inflammatory reaction was statistically less marked in contact with the polyester prosthesis than with the composite and compound prostheses (p < 0.002).

#### Biologic tolerance (Table 1)

At 3 months the polyester prosthesis showed the best biologic tolerance: 0.68, tolerance for the composite prosthesis being 0.42 and for the compound prosthesis 0.47. However, the statistical analysis showed these differences not to be significant. At 6 months the polyester prosthesis showed a biologic tolerance of 4.42, statistically greater than the composite prosthesis (0.90) and the compound prosthesis (1.22) (p < 0.001). Further, the compound prosthesis was better tolerated than the composite prosthesis (p < 0.001).

#### Macroscopic results

No rats died during the experiment. Examination of the abdominal wall was always normal.

### Adhesions between prosthesis and abdominal wall (Table 2)

At 3 months the adhesions between the prosthesis and the wall remained punctate (+), opposite the points of fixation of the polyester mesh (10/10) and the composite prosthesis (9/11). Adhesion of the compound mesh was more marked (++) (6/10), but the difference was not statistically significant. At 6 months the polyester prosthesis had contracted mainly punctate adhesions (+) (6/10), while the compound prosthesis showed more marked adhesions (++) (5/7), as did the composite prosthesis (10/14), none of these differences being significiant.

Table 4. Thickness of tissue reaction related to duration of implantation and type of material

Duration of implantation	Poly	Polyester		Compound		Composite	
	3 months	6 months	3 months	6 months	3 months	6 months	
Thickness of tissue reaction	291	362	254	318	315	312	
Ν	10	9	9	9	11	14	

No statistically significant difference

 Adhesions between prosthesis and intraperitoneal viscera (Table 3)

Adhesion of the great omentum to the intraperitoneal prosthesis was constant, except for one compound prosthesis at 6 months and one polyester prosthesis at 6 months. The number of prostheses adherent to the intraabdominal viscera was not statistically different for the three materials. In every cases there were adhesions requiring to be freed by scissors.

 Interposition of small intestine between prosthesis and abdominal wall

The interposition of one or more loops of small intestine between the prosthesis and the abdominal wall was noted on four occasions. This was probably due to poor tension of the prosthesis at the time of its insertion, and to poor adhesion between the prosthesis and the wall. In two cases this was with a compound prosthesis at 6 months and in another two with a polyester prosthesis at 3 months.

- Peritonization of the implanted material

A neoserosa covering the deep aspect of the three types of materials was constantly found (Fig. 6).

- Thickness of the tissue reaction (Table 4)

At 3 months and 6 months the mean thickness of the cellular reaction measu-

red between the superficial muscular plane and the deep aspect of the three types of prostheses showed no significant difference.

- Incorporation of prostheses

The three meshes used were always widely colonized by the tissue reaction and in the same manner, the width of the meshes seeming to favor this incorporation.

#### Discussion

There were two main criteria of the experimental study. The first was a study of the biologic tolerance of the material by comparing a classical prosthesis (polyester) with two more recent materials: one prepared on the spot by superimposing a polyester and a polyglactin mesh, the other using the same polymers but assembled industrially in a single mesh. The polyester mesh led on contact to the formation of a scar rich in collagen fibers and poor in inflammatory elements, thus showing its good biologic tolerance. The addition of a mesh of polyglactin 910 perpetuated within the compound and composite prostheses a more marked inflammatory granuloma, with a lesser fibrous reaction. This is consistent with the results of Rath [1996], i.e, there is an incompatibility between the polyester and polyglactin 910. This phenomenon could be the

cause of rejection of the material, after a decrease in the collagen matrix and an influx of inflammatory cells in contact with the polyester mesh, as noted by Adloff [1976] and also by Trabucchi [1998]. We therefore do not recommend the use of materials combining polyester and polyglactin 910.

The second criterion studied was adhesion in contact with the prosthesis. It led us to conclude that there were no major adhesions between the prostheses, whatever the type, and the abdominal wall. This would probably favor displacement of the material and the interposition of loops of bowel. It also showed the presence of adhesions between all three types of prostheses and the intraperitoneal viscera. Polyglactin 910 disappeared completely without any new replacement tissue, so that a nonabsorbable material is preferable. The poor adhesion of the wall and the adhesion to the viscera may be the cause of accidents due to migration, with their ominous clinical consequences. On the basis of these results and in the light of our clinical experience [1993] we have decided to abandon the intraperitoneal site for the insertion of this type of material, preferring the subparietal cleavable spaces.

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