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A new type of polytetrafluoroethylene prosthesis (Mycro Mesh): an experimental study

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Comparisons were made of the tissue response to the implantation of two different polytetrafluoroethylene prostheses: Soft Tissue Patch (STP) and Mycro Mesh (MM). A 7 × 5 cm prosthesis of STP ($n = 12$) or MM ($n = 12$) was implanted into a defect of the same size (involving all layers except skin) created in the anterior abdominal wall in 24 New Zealand rabbits. The prostheses were anchored to the recipient tissue, in direct contact with the intestinal loops and connective tissue. After 14, 30, 60 and 90 days, groups of six implants were studied macroscopically and samples were taken to be processed by light microscopy, scanning electron microscopy (SEM), immunohistochemical studies and tensiometry. All animals were valid for the study. In three cases STP implants presented very loose adhesions in the peripheral zones corresponding to the sutures. They were also observed on three MM implants, in the area of the perforations. Light and scanning microscopy revealed the formation of a capsule of scar tissue surrounding both types of prosthesis. At day 90, bridges of connective tissue had formed in the perforated areas of MM. Good vascularization was established in the areas of recipient tissue corresponding to both implants. The macrophage reaction to both biomaterials was maximal at 14 days, after which it progressively decreased until day 90. Tensile testing revealed no significant differences between the two biomaterials. It is concluded that (a) behaviour in the peritoneal interface is similar in the two prostheses, (b) both biomaterials become encapsulated rather than integrated into the recipient tissue, (c) the foreign body reaction does not determine the success or failure of the implants, (d) The perforations of the MM prosthesis do not increase its resistance to stress, or at least not after 90 days of implantation into rabbit abdominal wall.

1. Introduction

The use of prosthetic materials to repair defects in abdominal wall tissue is increasingly common [1, 2]. This has led to the development and introduction of new biomaterials or modification of existing ones in the attempt to improve their integration with tissue. One of the most widely used materials is the polytetrafluoroethylene (PTFE) prosthesis known as Soft Tissue Patch (STP). Recently, a modification, Mycro Mesh (MM), also made of PTFE, has appeared. The STP is completely microporous while MM is pierced through by numerous 2 mm perforations. Their surface also differ, that of STP being smooth and that of MM, rough on one aspect. The objective of this study was to assess the process of integration of these biomaterials after implantation into rabbit abdominal wall.

2. Material and methods

2.1. Experimental animals

Twenty-four male New Zealand white rabbits weighing 1800–2000 g were studied. All of the animals were caged and kept in constant light and temperature conditions in accordance with EEC norms (28871-22A9) during the study.

2.2. Prosthesis

The prosthetic material implanted were the polytetrafluoroethylene mesh Mycro Mesh® (Gore-Tex) ($n = 12$) and the polytetrafluoroethylene prosthesis Soft Tissue Patch® (Gore-Tex) ($n = 12$). MM is a layered biomaterial. It has regularly spaced perforations 2 mm in diameter, a rough-textured face, and a smooth-textured face.

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2.3. Surgical technique

Anesthesia was induced with a mixture of ketamine chlorhydrate (70 mg/kg), diazepam (1.5 mg/kg), and chlorpromazine (1.5 mg/kg) injected intramuscularly. Some rabbits required an additional intraperitoneal dose of anesthetic.

Using sterile surgical technique, a full-thickness (except skin) 7 cm × 5 cm defect was created in the anterior wall of the animals. Prosthetic implants cut to the same size were used to close the defect and were placed in direct contact with intestine (inner side) and subcutaneous tissue (outer side). The implant was sutured to the edges of the defect using continuous polypropylene 4/0 suture.

Preoperative cefazolin prophylaxis was given (0.125 mg) to each animal.

2.4. Study times

Six rabbits were killed at 14, 30, 60, and 90 days post-implantation. Tolerance of the biomaterial was evaluated on the basis of the presence of infection or rejection, zones of relaxation of the abdominal wall, and adhesions to viscera. Samples were obtained from the interfaces between the prosthesis and visceral peritoneum, subcutaneous tissue, and receptor tissue, respectively.

2.5. Morphologic study

Specimens for light microscopy study were fixed in 10% formaldehyde, embedded in paraffin and cut into 5 μm thick slices. Hematoxylin-eosin and Masson's trichrome stains were used.

Specimens for SEM were sliced for optimal interface study. They were fixed in 3% glutaraldehyde and stored in Milloning's buffer (pH 7.3), then dehydrated in a graded acetone series. The critical point was determined in a Polaron E-3000 with CO_2. Sections were metallized with gold palladium and studied under a Zeiss DSM-950.

2.6. Immunohistochemical study

The immunohistochemical study used RAM-11 (DAKO M-633), a monoclonal antibody specific for rabbit macrophages, and the avidin-biotin technique with alkaline phosphatase, as has been described previously [3].

2.7. Tensiometric study

Tensile strength was measured using an Instron tensiometer (frame: F-DM-H 1072; console: TT-DM-1118). For the measurements the scale was adjusted for 5 kg intervals. The crosshead speed was 5 cm/min and the chart speed was 2 cm/min.

Measurements were made on 2 cm wide strips obtained after the rabbits were killed. Strips were taken parallel to the shorter axis of the implant and included the prosthesis and two anchor zones. Before testing, tissue strips were kept in culture medium (MEM). Specimens were not fixed to avoid altering results. All tests (three per animal) were made within 12 h of the rabbits' death.

2.8. Statistical study

The macrophages labelled with RAM-11 were counted at every study period in 80 microscopic fields for each type of implant (40 ×). Using the data obtained, the arithmetical mean and standard deviation were calculated. Means were compared using the Student–Newman–Keuls test performed independently for each type of implant and with the Mann–Whitney U test to compare both STP and MM.

The tensiometric results were analyzed with the Mann–Whitney U test.

3. Results

3.1. Macroscopic results

All animals were suitable for study. Three cases STP implants presented very loose adhesions in the peripheral zones corresponding to the sutures. They were also observed on three MM implants, in the area of the perforations.

None of the animals showed signs of infection or rejection.

3.2. Microscopic results

Formation of an organized repair tissue was evident 14 days after implantation of both the STP and MM grafts. The repair tissue was lax and had an important cellular component that consisted of cells typical of foreign-body reactions (lymphocytes, monocytes/macrophages, plasma cells) and fibroblasts. These cells were accumulated on prosthesis surfaces, including both the outer face and inner face, and incipient interstitial cell penetration was visible in both types of prosthesis. The MM perforations contained a very lax, highly cellular repair tissue; the cell types seen were those described earlier.

The neoformed tissues were even more organized at 30 and 60 days post-implantation. A monolayer of mesothelial cells limited the neoformed peritoneum in both the STP and MM implants. The fibres of the neoperitoneum were arrayed parallel to the graft surface. On the outer surface of the graft, the tissue had become more compact and extended since the beginning of the study; this tissue was much more abundant on the MM implants, possibly because of the rough texture of the outer face of the MM. Within the MM perforations, collagen bridges connected the tissue formed on both faces of the prosthesis. The cellularity of this tissue decreased notably after day 14 post-implantation, with the number of foreign-body cells decreasing and the number of fibroblasts increasing. On the other hand, vascularization, consisting of small and medium-calibre vessels irrigating the repair zone, increased greatly. Cell colonization differed somewhat between the two types of prosthesis. Cells penetrated the external third of STP implants on both faces, whereas they penetrated only the surface in contact with the neoperitoneum in the MM implants.

Moreover, the MM implants showed rows of cells in the contact areas between the different layers of PTFE composing the MM prosthesis.

At 90 days, both implants were integrated into an organized, well-vascularized repair tissue that showed no sign of foreign-body reaction and a homogeneous neoformed peritoneum (Figs. 1 and 2).

The macrophage reaction was similar in the STP and MM implants, showing a decrease in the number of RAM 11-labelled macrophages between day 14 and day 90 (Fig. 3, Table I). This decrease was statistically significant in every case (Student–Newman–Keuls test $p = 0.01$). The Mann Whitney U test showed $p > 0.05$ (not significant) in all cases.

The tensiometric studies showed a similar pattern of results in terms of tensile strength (Fig. 4). Tensile strength increased from day 14 to day 90 post-implantation (Table II). However, comparative statistical study did not show any significant difference between the STP and MM implants at any stage (Mann–Whitney U test, $p > 0.05$).

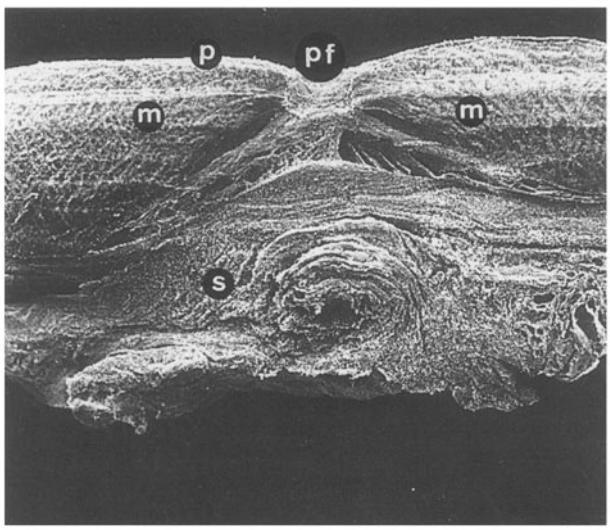

Figure 1 General aspect of the Mycro Mesh prosthesis at 90 days post-implantation (m = Mycro Mesh, s = subcutaneous tissue, p = peritoneum, pf = perforation) (× 20).

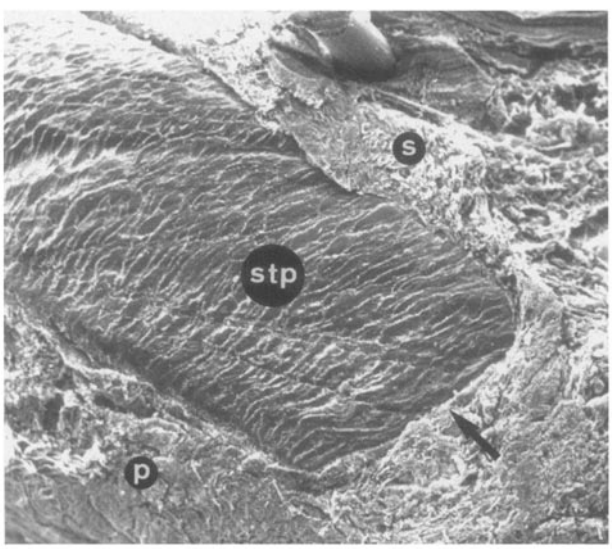

Figure 2 Microphotograph showing integration of a Soft Tissue Patch prosthesis in the abdominal wall at 90 days post-implant (anchorage zone: ➡, stp = Soft Tissue Patch, s = subcutaneous tissue, p = peritoneum) (× 38).

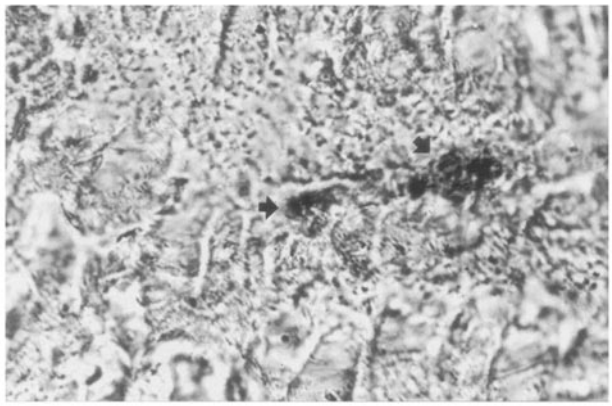

Figure 3 RAM-11 labelled macrophages (➡) in the interstices of the Mycro Mesh prosthesis (× 40).

TABLE I Labelled macrophage count for the Soft Tissue Patch and Mycro Mesh implants (mean ± SD)

Prosthesis	Time (days) 14	30	60	90
Soft Tissue Patch	33 ± 7.26	21.9 ± 3.3	13 ± 2.54	5.9 ± 2.5
Mycro Mesh	35.3 ± 3.4	23.35 ± 2.5	14 ± 1.61	6.75 ± 2.18

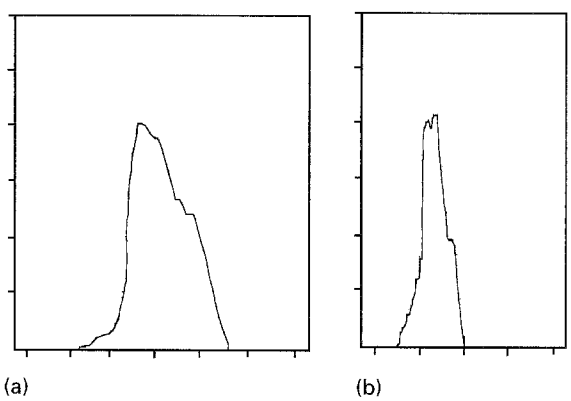

Figure 4 Tensiometric results for (a) the Mycro Mesh (20.1 N) and (b) Soft Tissue Patch (21.56 N) implants at 90 days post-intervention.

TABLE II Tensiometric results obtained with Soft Tissue Patch and Mycro Mesh at each study period (Newtons) (mean ± SD)

Prosthesis	Period (days) 30	60	90
Soft Tissue Patch	12.46 ± 1.58	19.94 ± 1.9	22.81 ± 2.35
Mycro Mesh	13.31 ± 0.61	18.03 ± 3.8	22.65 ± 2.81

4. Discussion

The behaviour of different types of prosthesis used to repair abdominal wall defects is an interesting topic, particularly when the prosthesis has to be placed in contact with the abdominal viscera.

Different experimental studies have demonstrated that reticular and macroporous prostheses, such as polypropylene mesh (Marlex), behave very well in terms of tissue integration [4, 5]. However, the rate of adhesion formation between Marlex prostheses and viscera is very high [6, 7]. At the other extreme are the layered, microporous materials, such as STP. Although the tissue integration of STP is not as good, the rate of adhesion formation is very low [8]. As a result, STP is considered the material of choice in most cases, although its lower-grade tissue integration, particularly in the receptor-tissue anchor regions, has been criticized by some authors [9]. In any case, it is evident that the structure of prosthetic biomaterials conditions the repair process. Our results show that the MM prostheses integrated better than the STP prostheses. The MM perforations permitted the formation of scar-tissue bridges linking the two sides of the prosthesis, but did not alter the repair process characteristic of STP implants. The repair process on these implants lead to progressive formation of layers of organized tissue with mild integration with the prosthesis, which tended to discourage adhesion formation. Vascularization was moderate, but perfectly established by day 90 post-implantation.

The macrophage reaction induced by different types of prosthesis should be evaluated to detect possible disturbances, such as persistence of a chronic foreign-body reaction, which could produce alterations in the biomaterials [10]. Likewise, measuring the amount of macrophages at each study time is an indirect indicator of the continuity and intensity of the repair process. It is known that animals that have a disturbed macrophage response also have repair disorders [11]. Likewise, the substances that originate directly or indirectly from macrophage actions modulate the repair process [12, 13]. Our results show that the number of macrophages decreased with time in both implants (confirmed by the Student–Newman–Keuls test), which demonstrated that both types of prosthesis were well tolerated.

The tensiometric study showed a significant increase in the tensile strength of the graft zone with both types of implants, undoubtedly as a result of the tissue reorganization and maturation observed. However, in contrast with the results obtained by other authors in a model that was similar to ours except for the use of a conventional perforated STP prosthesis [14], we found no significant differences in the tensile strength of the graft zones formed on these two biomaterials. It is interesting to note that although the MM perforations improved its integration, they did not enhance tensile strength. This is probably due to a comparable degree of integration in the anchor zone produced by both prostheses.

We conclude: (a) abdominal wall implants of Soft Tissue Patch and Mycro Mesh behave similarly, yielding a repair process characterized by the progressive formation of an organized scar tissue on both faces of the prosthesis; as such, both biomaterials are suitable for use in contact with abdominal viscera; (b) the perforations in Mycro Mesh improve its tissue integration; (c) the macrophage reaction presented no disturbances that might influence the success or failure of repair; (d) perforations did not increase the tensile strength of Mycro Mesh compared to Soft Tissue Patch in the first 90 days post-implantation in rabbits.

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