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REVIEW: BIOMATERIALS FOR ABDOMINAL WALL RECONSTRUCTION

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Abstract

The reconstruction of large abdominal wall defects still is a major surgical problem. Many different techniques have been developed for this purpose, most of which appeared to be unsatisfactory. The lack of sufficient tissue requires the insertion of prosthetic material. Non-absorbable prostheses used to reconstruct abdominal wall defects showed the best results. Polypropylene mesh (PPM) and expanded polytetrafluoroethylene (ePTFE) soft-tissue patch are the most frequently used materials for this purpose. However, PPM induces extensive visceral adhesions and erosion of the skin, whereas ePTFE is insufficiently anchored to the adjacent tissue and therefore both materials are not ideal. As a result of own clinical and experimental studies, we constructed a new prosthesis that combines the favourable properties and avoids the drawbacks of PPM and ePTFE and tested it in an experimental study in the rat. The results are promising and warrant future study to find the ideal non-absorbable prosthesis to reconstruct large abdominal wall defects.

Key Words: Biomaterials, abdominal wall defects, polypropylene mesh, expanded polytetrafluoroethylene, double-layer patch.

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Introduction

Reconstruction of large abdominal wall defects either resulting from longstanding incisional hernias, trauma, infection or tumor resection, remains a challenging problem. Primary closure, the traditional way of handling abdominal wall defects (70), is only possible if the wound edges can be approximated without tension. Closure of the abdominal wall under undue tension will lead to a high rate of wound infections (89) and recurrences (8, 32, 50, 51, 58, 71, 73, 104), even when holding sutures are used (12, 66, 94, 108). Moreover, primary closure is associated with an increase of intra-abdominal pressure which may result in circulatory, pulmonary and renal problems (6, 41, 55, 56, 72, 78, 88, 91, 109, 111). Therefore, the fascial gap in patients with large abdominal wall defects should be bridged, either with autologous or heterologous material.

Reconstructions with autologous material, such as free human dermis (33, 61, 74, 75, 109) and free fascial (38, 78, 87) or musculofascial flaps (40, 67, 68), are not satisfactory. Free human dermis is too weak to resist the intra-abdominal pressure on the long term, resulting in bulging of the abdominal wall. Moreover, persistent production of sebaceous cysts may result in infections (88). The operations of free fascial transplant-harvesting are time-consuming and frequently followed by functional deficits at the donor-site (37, 40, 65, 67, 75, 89, 110). The functional results of those reconstructions are mostly disappointing because of bulging of the denervated muscles (65, 87, 88), and high reherniation-rates up to 20% (49, 59, 65). Moreover, reexplorations are difficult because of firm adhesions between the autologous material and the viscera (33). For these reasons, prosthetic materials are preferred in the repair of abdominal wall defects (49). Two kinds of prosthetic materials can be distinguished: absorbable and non-absorbable.

Absorbable Prostheses

The use of absorbable prostheses in the repair of abdominal wall defects was inspired by the idea that the prosthesis, would be replaced by autologous fibro-collagenous tissue, thus resulting in a lower infection-rate.

However, the reherniation-rate after the use of absorbable prostheses is nearly a hundred percent, because the prosthesis itself hampers the formation of properly orientated collagenous fibers by neutralizing the forces of the abdominal wall musculature, which are inevitable for the formation of collagenous fibers that are strong enough (34, 36). Thus, after absorption of the prosthesis, the newly formed fibro-collagenous tissue will be unable to resist the intra-abdominal pressure, resulting in reherniation (23, 37, 52). As a result, most surgeons have abandoned the use of absorbable prostheses for the reconstruction of large abdominal wall defects.

Non-absorbable Materials

Non-absorbable prosthetic materials, used for the repair of abdominal wall defects, should fulfill several of the criteria which were originally proclaimed by Cumberland (22) and Scales (80), and later completed by Arnaud *et al.* (3, 4). According to these criteria the ideal prosthesis should be **[1]** chemically inert, **[2]** non-carcinogenic, **[3]** resistant to mechanical strain, **[4]** sterilizable, **[5]** unmodified by tissue fluids, **[6]** hypoallergenic, **[7]** non-inflammatory, **[8]** conformable to different shapes, **[9]** non-rigid, **[10]** be incorporated into the host-tissue, **[11]** not adherent to or damage underlying viscera, **[12]** not expensive, and **[13]** resistant to infection (1, 4, 8, 19, 22, 23, 57, 60, 76, 80, 89).

Metal meshes made of silver, tantalum and stainless steel were the first non-absorbable prostheses that were used for abdominal wall repair (15, 17, 45, 46, 48). They, however, were abandoned (59) because of their tendency to corrode (15) or break (1, 4, 71, 93, 110), thereby endangering the overlying skin (2, 19, 39, 48, 49, 88) or underlying viscera (13).

The introduction of plastics, as for example, polyamide (Nylon®, Supramide®), polyester (Dacron®, Mersilene®, Ticron®), polypropylene (Marlex®, Prolene®) and polytetrafluoroethylene (Teflon®, Gore-tex®), started a new era in the repair of abdominal wall defects. However, many of these materials proved to be unsatisfactory. Polyamide evokes an extensive acute inflammatory reaction (43, 106) and is unstable after implantation and, therefore, not strong enough on the long term (1, 29). Polyesters also evoke a chronic inflammatory reaction (43, 106) resulting in dense adhesions (3, 56) and an increased risk for infection (35, 47). Silastic and silicone prostheses appeared to be unsuitable for the abdominal wall repair because 82% of the prostheses were extruded with subsequent visceral dehiscence (42), or migrated into the peritoneal cavity (4). Carbon fibers showed degradation (63). Nowadays, only two materials, polypropylene and polytetrafluoroethylene are used with any frequency for abdominal wall reconstruction because they nearly fulfill all criteria. Therefore, they deserve special attention.

Polypropylene-mesh

The introduction of polypropylene mesh by Usher and Wallace in 1958 (96) is a milestone in the development of abdominal wall prostheses. It is still the most widely used material for hernia repair (3, 16, 18, 20, 25-27, 48, 51, 53, 59, 62, 73, 76, 77, 81, 96, 100-102, 104, 105, 111). Polypropylene meshes, better known as Marlex®- or Prolene®-mesh, are made of knitted monofilament fibers produced out of ethylene gas, which have a high tensile strength (96). Its implants in human tissue, show a mild reactivity (18, 95, 106) and a low infection potentiating ability. Due to its macroscopically open structure, fibrous tissue readily grows into the mesh interstices, incorporating the material within the adjacent host tissues [Fig. 1]. According to the criteria of Cumberland (22) and Scales (80), it is nearly ideal, because, besides the above mentioned qualities, polypropylene mesh is pliable, flexible with a limited degree of elasticity with a two-way stretch (100), and holds sutures well. The material can be (re)sterilized with autoclavation or ethylene oxide (96). It does not disintegrate with age and does not fray or fragment even after long periods of implantation (28). When used in the repair of groin hernias (20, 28, 97, 99, 102), the results are excellent. Usher *et al.* (97) reported no recurrences in his own series. Berliner *et al.* (9) observed a 1.4% failure rate in 1084 patients who had a Marlex® mesh for primary inguinal hernia repair, and Barnes (7) noticed 3 recurrences in 227 repaired groin hernias after an eleven years follow-up.

Polypropylene mesh used as an overlay-prosthesis in the repair of incisional or ventral hernias also shows good results (25, 53, 97, 98) with a low recurrence rate. Molloy *et al.* (62), and Larson and Harrower (51) had a 8% reherniation-rate which is favorable compared to incisional hernia repair without mesh, which has a 30%-reherniation rate (62). Furthermore, Marlex® is a good fascial substitute in the repair of abdominal wall defects after tumor-resection (11, 44).

Polypropylene mesh also appeared usable in the reconstruction of contaminated abdominal wall defects after war-time trauma (58, 81, 82) and for closure of the abdominal wall in the semi-open treatment of generalized peritonitis (34, 111). Even in a heavily contaminated environment, the mesh is incorporated in granulation tissue (79). Afterwards, it can be covered with a split skin graft. Although the short term results are good, the long term results were disappointing. Polypropylene mesh used as an inlay prosthesis appeared to initiate the formation of dense adhesions between the mesh and the viscera, sometimes leading to ileus or bowel fistulas (33, 83, 89) which is a major drawback (14, 47). When covered with a split-skin graft Marlex®-mesh, due to wound retraction, tends to wrinkle which may result in erosion of the skin (14, 36). In these circumstances, chronic infection with sinus formation will occur, which ultimately will result in loss of the patch. This complication is not observed if the mesh is covered with full thickness skin. If the mesh erodes into the bowel, it causes bowel fistulas, which will never heal in the presence of the mesh. Then the mesh has to be removed, which carries a high risk of iatrogenic bowel perforation due to the adhesion-formation.

In conclusion, polypropylene meshes have a proven validity in the treatment of groin hernias (91) and in the reinforcement of incisional hernia-repair as on overlay. It also is suitable for the reconstruction of abdominal wall defects when covered with full thickness skin although it gives dense adhesions between the bowel and the mesh.

Polytetrafluoroethylene

Two kinds of polytetrafluoroethylene (PTFE) prosthetic materials for abdominal wall reconstructions are available: Teflon®-mesh and Gore-tex®-soft-tissue patch. Teflon®, made of solid fibers woven in a cloth structure (106), was used in the repair of inguinal hernias (64) and abdominal wall defects. The material was not satisfactory because of a very high reherniation-rate, up to 40% (28), and a high incidence of infection, nearly 50%. The high reherniation-rate may be explained by the fact that the mesh tends to ravel because it is impossible to interconnect Teflon® fibers (39). The high infection rate is probably a result of the extensive granulomatous reaction around the Teflon®-prosthesis which leads to dense visceral adhesions (106). Teflon-mesh is satisfactory in a contaminated environment. Harrison (39), and Koontz and Kimberly (47) had a universal failure in infected wounds.

Recently expanded polytetrafluoroethylene (ePTFE)-patch (Goretex® Soft Tissue Patch, W.L.Gore and Associates, Inc., Flagstaff, AZ, USA) has been introduced for the repair of abdominal wall defects (37, 52, 84, 89). ePTFE is a microporous material composed of nodules of solid polytetrafluoroethylene interconnected by thin flexible fibrils of the same material [Fig. 2]. The material can be manufactured in various fibril lengths, which determine the size of the internodal spaces or pores (65). The internodal space of the ePTFE patches suitable for the repair of large abdominal wall defects is about 20 μm. The material was first used in vascular surgery (21, 30, 53, 90, 93) and subsequently introduced for abdominal wall reconstructions because of its favorable mechanical properties. The material hardly provokes any tissue reaction after implantation (31, 52, 54, 96), is easy to handle because it is soft and pliable yet at the same time very strong (92), it is resterilizable, it can easily be cut in the proper shape, and exhibits a low rate of adhesion formation when used as an inlay fascial substitute (24, 95).

So far 11 reports of clinical and experimental use of ePTFE in the repair of tissue defects are published (8, 23, 24, 27, 31, 35, 42, 69, 84, 92, 107). Most of these reports show favorable results of ePTFE when compared to other materials. However, three out of twelve patients from our clinic, who had been treated with an ePTFE soft-tissue patch, developed one or more buttonhole hernias at the fascia/patch-interface within the first year after repair of their abdominal wall defect (103). These herniations appeared between the intact sutures which were approximately 2 cm apart. All three patient were reoperated which gave us the opportunity to take biopsies of the material.

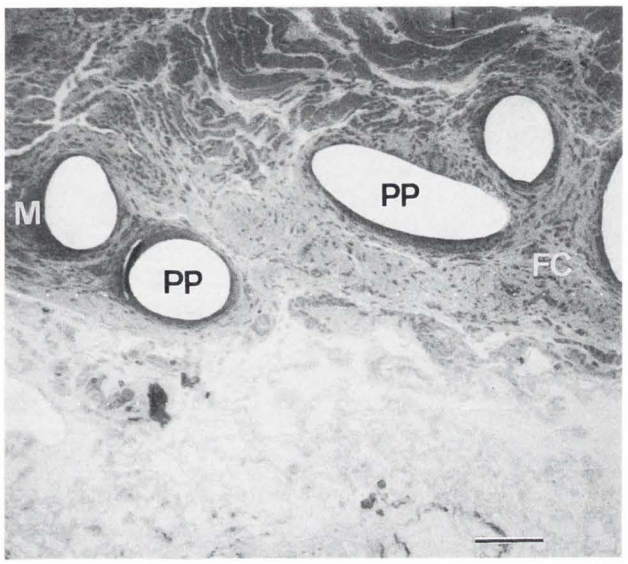


Figure 1. Light micrograph of a polypropylene-mesh 12 weeks after implantation. The circular and oval structures are polypropylene fibers (PP) in transverse and oblique sections. The fibers are embedded in fibro-collagenous tissue (FC). Each fiber is surrounded by a zone of macrophages (M). Toluidine/alkaline fuchsine staining. Bar = 80 μm.

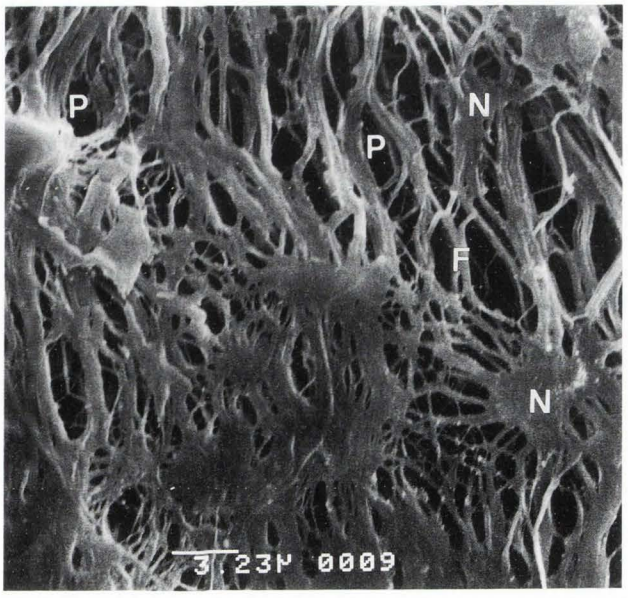


Figure 2. Scanning electron micrograph of an ePTFE-patch. The patch is composed of nodules (N) of solid polytetrafluoroethylene connected by thin flexible fibrils (F) of the same material. The fibril length determines the size of the pores (P).

Histologically, no ingrowth of fibro-collagenous tissue into the pores of the ePTFE-patch could be detected [Fig. 3], resulting in unsatisfactory anchorage. Our clinical data were later confirmed by others (8, 65, 69, 95, 107, 112). There are four methods to improve the results when using the Gore-tex® soft tissue patch. First, one may use a running suture. We, however, used interrupted sutures because a running suture does not permit sufficient overlap between the patch and the adjacent aponeurosis. Furthermore, a running suture leaves one completely dependant on the strength and quality of that suture (27). Second, a double row of sutures in combination with sufficient overlap of the patch and the adjacent aponeurosis is effective in preventing reherniations (103). Third, we have tried to improve the anchorage of the patch by modifying it mechanically and physically. In an experimental study in the rat, ePTFE-patches were perforated with a 22 gauge needle (25 perforations per square centimeter). Implanted subcutaneously in the rat, ingrowth of fibro-collagenous tissue into the perforations could be detected (85). In the same study, ePTFE-patches, physically modified by a pretreatment with 96% ethanol in order to make the material less hydrophobic, did not show improvement of the fibro-collagenous tissue ingrowth into the patch. Finally, using ePTFE-patches with a pore-size of 90 μm revealed better anchorage of the patch to the adjacent aponeurosis but also initiated firm bowel adhesions. Besides this, the ePTFE-patch completely fails when used in a contaminated area (10). It then is extruded or, surprisingly enough, falls apart in layers [Fig. 4]. Therefore, ePTFE too, is not the ideal material to bridge large abdominal wall defects.

Development of a New Patch

Summing up the numerous reports on the repair of large abdominal wall defects with non-absorbable prostheses as a substitute for the lost abdominal fascia, it may be stated that incorporation into the host-tissue and avoidance of visceral adhesions appear to be crucial problems. Obviously the basic structure of the material determines to what extent incorporation and visceral adhesions will appear. (Porous) meshes show good incorporation into adjacent tissue but also guarantee adhesion formation whereas, hydrophobic microporous materials, like ePTFE, do not show adhesion formation but will not be incorporated into the host-tissue. Since, according to Cumberland (22), Scales (80) and Arnaud *et al.* (3, 4), both contradictory criteria have to be fulfilled by the ideal material in the repair of abdominal wall defects, the solution, on a theoretic basis, should be a double layer prosthesis: macroporous and hydrophilic on the dermal side, microporous and hydrophobic on the visceral side.

This principle was tested using a prosthesis made of a macroporous polyurethane (PU) outer layer and a microporous ePTFE inner layer (Epigard®). In an experimental study performed by our group this PU/ePTFE double layer patch was used to bridge 20 x 30 mm abdominal wall defects in rats. The inlay-technique was used. The patch was placed intraabdominally in such a way that the microporous ePTFE layer faces the viscera, whereas the macroporous PU-layer faces the defect and the inner side of the anterior abdominal wall. The patches used were 25 x 35 mm so that there was an overlap on every side. The patch was fixed with interrupted non-absorbable sutures. The animals were sacrificed after 8 weeks, and herniations and adhesions were scored. Biopsies were taken from the margins to be evaluated histologically. We observed 30% button-hole herniations, which is less than we found clinically (103). There were some adhesions comparable to ePTFE abdominal wall repairs. Histologically the PU-layer is invaded by fibro-collagenous tissue [Fig. 5] which is continuous to the adjacent connective tissue, whereas again there was no ingrowth into the ePTFE-layer.

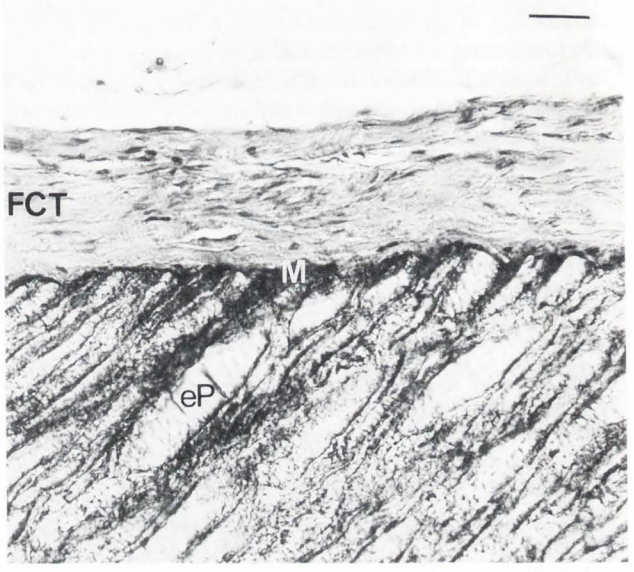
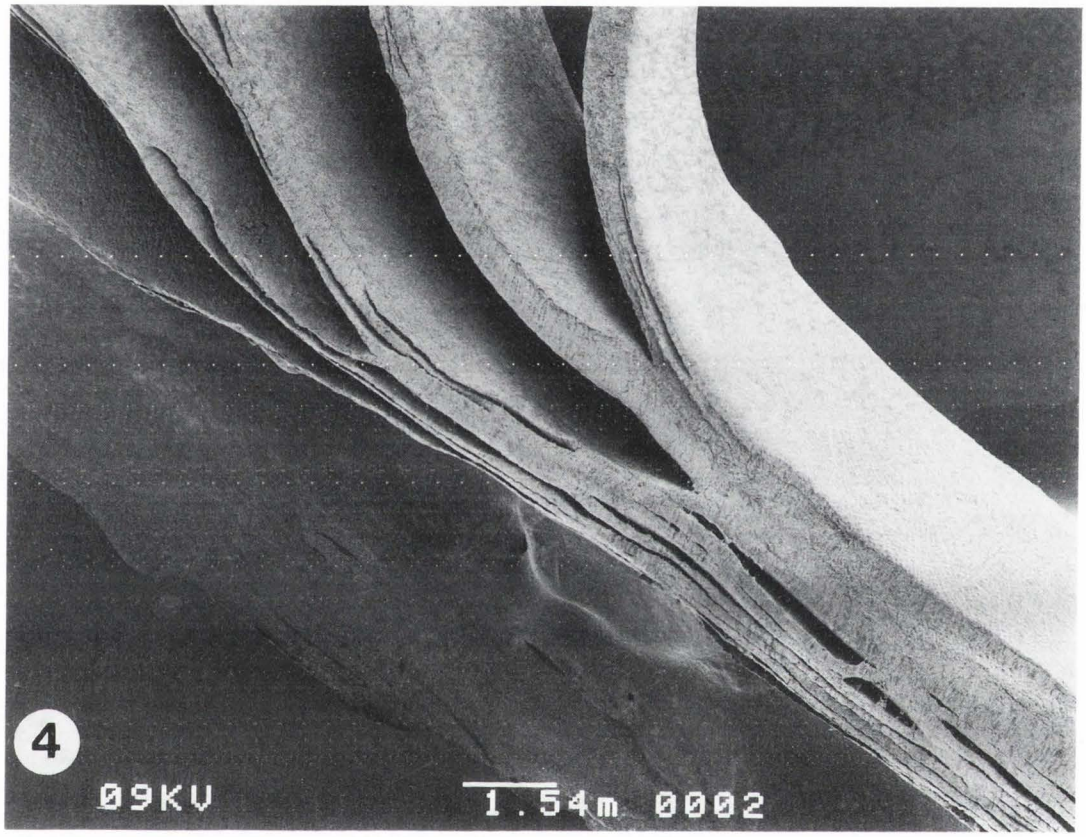


Figure 3. Light micrograph of a ePTFE patch 12 weeks after implantation, The ePTFE patch (eP) is separated from the adjacent fibro-collagenous tissue (FCT) by a thin layer of macrophages (M). There is no ingrowth of fibro-collagenous tissue into the patch. Toluidine/alkaline fuchsine staining. Bar = 80 μm.

Figure 4 (facing page, top). Expanded polytetrafluoroethylene soft tissue patch six weeks after implantation in a contaminated wound. The patch is completely disintegrated and can be separated in different layers.

Figure 5 (facing page, bottom). Light micrograph of a part of the polyurethane/ePTFE double layer patch. Fibro-collagenous tissue (FCT) completely fills up the pores of the macroporous polyurethane-layer (PU). The ePTFE-layer (eP) does not show cellular ingrowth. Bar = 100 μm.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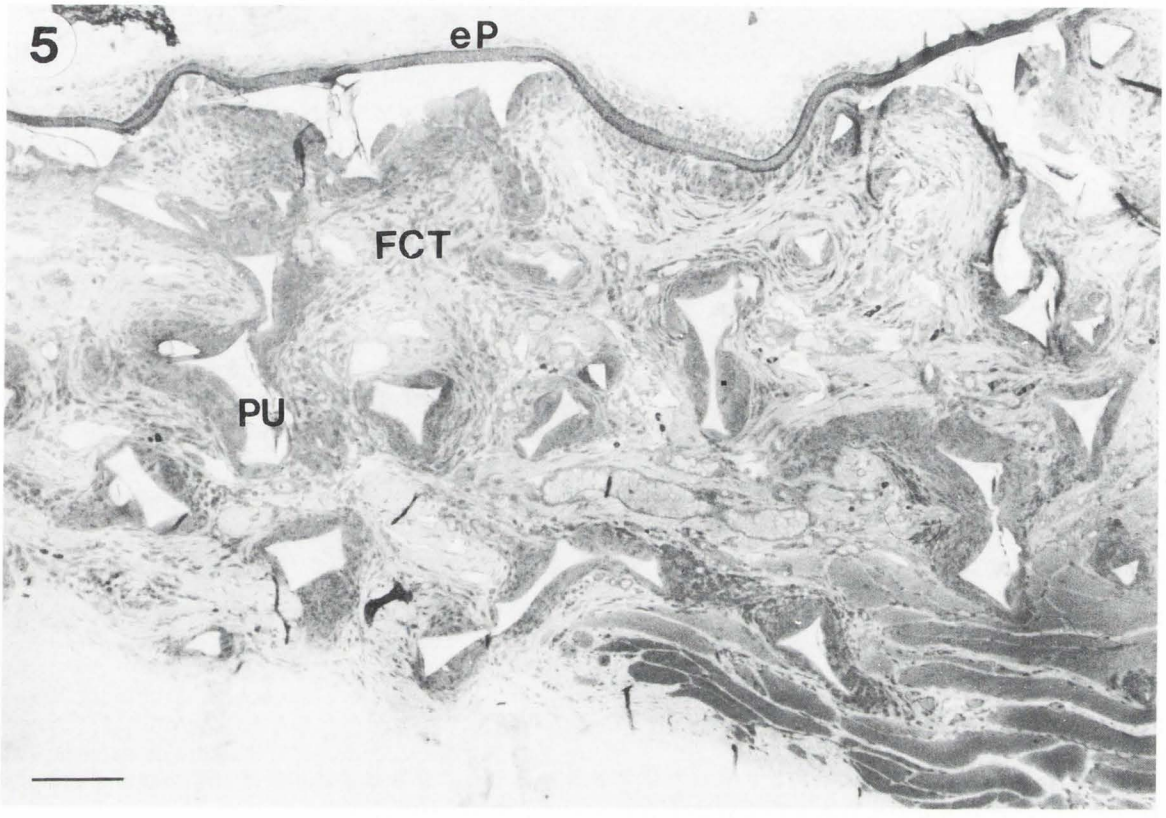
5
eP
FCT
PU

This patch originally was constructed as a temporary cover of skin wounds preventing infection due to the impenetrable ePTFE layer. Therefore, this patch does not need to be strong. That is the reason why it is unsuitable for the repair of abdominal wall defects, even in rats (86). Some of the herniations seen in this study are due to breakage of the material.

However, the principle of the double-layer patch, showing ingrowth of fibro-collagenous tissue in a macroporous outer polyurethane layer and inhibition of ingrowth of cells into the inner microporous ePTFE-layer, appeared to be fulfilled. Recently, we designed a polyurethane patch which has a gradual increase in pore-size. Very small on the visceral side to prevent adhesion-formation, to very large on the outer side to allow ingrowth of fibrous tissue. This patch proved to anchor firmly to the aponeurosis but there was some adhesion-formation at the visceral side (5). So further study will be done to prevent adhesion-formation at the visceral side.

Conclusions

There seems to be nearly universal agreement that large abdominal wall defects should be bridged with a non-absorbable prosthesis because only they provide a sufficiently strong reinforcement of the abdominal wall. The ideal material, however, has not yet been found since, up to now, it appeared to be impossible to construct a material that is well incorporated into the host tissue without inducing adhesions to the viscera.

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Discussion with Reviewers

S.K. Williams: How does the incorporation of polypropylene, PTFE and ePTFE in abdominal wall reconstruction compare to incorporation of these materials in other applications (e.g., vascular)?
Authors: Incorporation of polypropylene in adjacent fibro-collagenous tissue, as we saw it in the repair of abdominal wall defects in rats, has been reported in many other studies on the repair of abdominal wall defects, but also in the repair of thoracic wall defects and rectopexia posterior in the repair of rectal prolapsus (79). The behaviour of ePTFE in the repair of abdominal wall defects cannot really be compared to the use of ePTFE in vascular surgery because in the latter application the pore-size is about 60 μm which is three times the pore-size of the ePTFE-patch used for abdominal wall repair. However, there are some reports suggesting cellular ingrowth into the ePTFE vascular prosthesis (26, 31) as there are also reports stating the opposite (21, 90, 93). In an experimental study we used the ePTFE-vascular prosthesis in the repair of abdominal wall defects in the rat. We will report on this in a future paper.

S.K. Williams: The delamination of the ePTFE is quite dramatic. Is this not unusual for ePTFE which is generally considered non-degradable in most applications?
Authors: Indeed, delamination of ePTFE when infected is previously not reported and dramatic. Therefore, we suppose that ePTFE-prostheses usable for the repair of abdominal wall defects are not homogeneous but manufactured by "gluing" multiple very thin layers, probably under high pressure, together. Up till now, the manufacturer did not want to comment on this.

S.K. Williams: Prosthetic material centered infections are a major problem related to the use of synthetic implants. What approaches must be taken to reduce the incidence of prostheses infection in abdominal wall reconstructions?
Authors: Our clinical experience with ePTFE indicates that the use of certain synthetic implants, for example ePTFE, in the repair of large abdominal wall defects, is only possible in a non-contaminated area and probably should be accompanied by the use of prophylactic antibiotics and laminar flow in the operating theater similar to that for the use of implants in orthopedic surgery.

S.K. Williams: How was the identification of cells, in association with polymer in Figure 1, as macrophages carried out? Were these cells identified cytochemically?
Authors: We did not identify the cells adjacent to the prosthetic material immunocytochemically or histochem-

ically. Owing to their characteristic morphological appearance they could easily be identified directly in the microscope.

E.J. Guilbeau: Could you please provide a photomicrograph of the new patch material you have developed to show its macro- and microstructure?
Authors: We decided not to include a scanning electron micrograph (in addition to the light micrograph, Figure 5) of the new patch material. We do not think that such a micrograph will provide better information on the structure of this material because it would not show the absence of cellular ingrowth into the inner microporous layer **together** with the ingrowth of fibrocollagenous tissue into the pores of the outer macroporous layer.

M.P. Elliott: The paper appears to be objective in its evaluation of the materials and to contain a clever attempt at producing a hybrid material incorporating the advantages of a widely porous material with that of a less porous material to reduce adhesions on the visceral side and increase adhesions on the superficial side of the prosthesis. The paper also candidly admits that the new material is not a solution to the problem. One alternative, that was not presented by the authors, was to take the PTFE material and create an open mesh with scissors. In my experience, this has worked for several very major abdominal defects. It tends to solve the problems posed by the author. First of all, by creating large meshed surfaces, it is possible for a large amount of tissue adhesion to occur between the underlying structures and the superficial subdermal fat. This has two positive effects: (1) it produces superb tissue adhesion between the graft and underlying structures; and (2) it promotes adhesion with a firm stable framework between the deep fascial structures and the more superficial, less strong structures. This adhesion and lack of dead space makes the material less prone to produce seroma and probably less likely to cause infections due to prolonged dead space maintenance. I can only address this issue with the experience of three cases. I do not have a large series of results to present. At this time, while not sold in open mesh configuration by the manufacturer, PTFE open mesh material can easily be made with a pair of scissors in a few minutes of the surgeon's time. While no material, as yet, is perfect for this purpose, it may be that this configuration is certainly superior to the non-perforated PTFE sheet. It should be considered for use by those people dealing with difficult abdominal wall repair problems.
Authors: We thank Dr. Elliott for his suggestion to make an open mesh PTFE-patch by using scissors. Unfortunately he does not tell us whether to use PTFE (Teflon®) or ePTFE (Gore-Tex®). In both cases, adhesion by incorporation will certainly occur, however, we want to control and even prevent adhesion-formation at the visceral side of the patch because visceral adhesions attached to the patch might create major clinical problems like ileus or gut-perforations.

C.A. van Blitterswijk: Much research has been dedicated to the effects of porosity on infection. Apparently introducing pores can have an initial negative effect (large surface area) followed by a favorable effect (good vascularization). If, in your concept, pores are used that gradually decrease in size it might be possible that vascular ingrowth is inhibited at those smaller pore sizes thus making the implants more infection-prone. How do you plan to deal with that?
Authors: It is our intention to inhibit vascular or any other ingrowth in the visceral part with smaller pore-size because we want to prevent adhesion-formation at that site. The surface of the visceral side of the new patch should be impenetrable and therefore, only needs to be 0.5 or 1 mm thick. We do not expect that this part will be very infection-prone as it is far away from the potential source of infection, the skin.

C.A. van Blitterswijk: In the past we have performed several studies with porous polyurethanes and to our surprise these showed high degradation rates. Since you seem to agree with many other authors that resorbable materials cannot be used in this type of surgery I wonder whether such a "degradable" polyurethane graft would not cause the same complications.
Authors: The polyurethane we use for the recently designed patch for the repair of large abdominal wall defects is non-degradable as was found in long-term animal experiments by others.