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Review article

Role of the new lightweight prostheses in improving hernia repair

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ABSTRACT

The use of a prosthetic material to treat abdominal and/or thoracic disease has, to a great extent, resolved the problem created by the tissue defect itself and complications of recurrence. The most commonly used of these materials has been polypropylene in the form of a reticular mesh. This biomaterial, which boasts optimal biocompatibility, has been the object of constant modification aimed at better adapting it to the functional needs of the host tissue. Hence, the classic prostheses, nowadays known as heavyweights, are being gradually replaced by lighter materials with a simple spatial configuration and, more importantly, with a larger pore size (lightweight prostheses). Lightweight meshes are able to preserve abdominal wall compliance by generating less post-implant fibrosis and rigidity. However, further studies are still needed to achieve the ideal balance between material density and pore size. These two factors will determine the behaviour of these new prosthetic designs.

Implicaciones de los nuevos diseños protésicos de baja densidad en la mejora de la reparación de defectos herniarios

RESUMEN

El empleo de materiales protésicos para tratar enfermedades de la pared abdominal y/o torácica ha resuelto, en gran medida, el problema creado por el defecto tisular y las complicaciones de recidiva. Clásicamente, el más empleado ha sido el polipropileno en forma de prótesis reticular. Este material, con una biocompatibilidad óptima, está sufriendo modificaciones, encaminadas a conseguir la mejor adaptación posible al tejido receptor y mantener las mejores propiedades funcionales en el lugar del implante. De esta forma, las prótesis clásicas denominadas de alta densidad están siendo sustituidas por otras más ligeras (de baja densidad), con una configuración espacial sencilla y un poro más amplio. Las prótesis de baja densidad mantienen su elasticidad, lo que genera menos fibrosis y

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rigidez tras el implante. De cualquier forma, son necesarios estudios que consigan una densidad de material y un tamaño de poro ideales, dos parámetros que condicionan el comportamiento de dichos biomateriales.

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Conceptual aspects

One of the most widely used biomaterials to repair abdominal wall defects is polypropylene, in a mesh format. In the middle of the last century, Usher^{1,2} began to use said material in the first hernia repair surgeries.

Over time, its use has been generalised and now it is considered as one of the best biomaterials to treat tissue/ tissue defects, even when they are infected.^{3,4} It is one of the few materials that allows for the "partial rescue" of the prosthesis when infection occurs.^{5,6} The only disadvantage of polypropylene is its poor performance in the peritoneal interface. Complications have been reported such as intestinal fistulae⁷ and emigrations to hollow organs.⁸ Therefore, its use in said interface should be avoided.

In vitro⁹ studies have demonstrated the bio-stability of polypropylene. In vivo, samples of implants from operated patients have recently described oxidation processes that may affect this material with slight bio-degradation which is only visible with scanning electron microscopy. ¹⁰ Nonetheless, the mechanical resistance of polypropylene remains unaltered over the years.

At present, the classical Marlex® type mesh polypropylene prostheses (Bard, New Jersey, United States) are being modified into prostheses made with less material, with larger pores and a tighter spatial organisation of filaments. In the terminology used by the Schumpelick¹¹¹ group, they would be prostheses with large pores and, consequently, needing less material for their fabrication, also called lightweight.

In this way, and according to the parameter indicative of the prosthesis weight g/m^2 , the mesh prostheses are classified in heavyweight prosthesis (HW) and lightweight prosthesis (LW). ^{12,13} Prostheses are considered HW when they weigh more than 80 g/m^2 , and LW when they weigh less than this amount. Recently, mediumweight prostheses have been included in the classification, including prostheses that weigh between 50 and 80 g/m^2 ; leaving the LW between 35 and 50 g/m^2 , and one last type, called ultra-lightweight, that would weigh less than 35 g/m^2 (Figure 1 and Table).

Something that must be taken into account is that, sometimes, the prosthetic weight is independent of pore size. This is due to the fact that there are prostheses with a small pore design, with a simple spatial structure and meshing, and in turn, a fine filament; these are considered as light weight for presenting, as a whole, a low weight in g/m².

This last aspect is important as, following the German school, 14,15 we consider that prosthetic pore size is the principle parameter to catalogue a prosthesis as heavy or lightweight. According to this concept, lightweight prosthesis would always present large pores.

Another modification that mesh polypropylene prostheses have undergone is the creation of hybrid or partially degradable prostheses. ^{16,17} These, aside from their polypropylene structure, have biodegradable polymeric elements as well. These prostheses, all lightweight, are characterised by presenting components that degrade in the middle to long term, and a smaller quantity of residual material is left in the receiving tissue.

As a result, in a generic manner, the lightweight prostheses could be fabricated using only polypropylene or using this polymer and some other biodegradable material.

Objectives of the lightweight prosthesis and possible advantages of its use

The objectives are, fundamentally, to reduce the quantity of foreign material that is left implanted in the host and to generate the minimum amount of fibrosis possible in receiving tissues, without producing deterioration of the mechanical resistance.

Although there are individual variations concerning the repair process after the implantation of these types of materials, ¹⁸ there is no doubt that the fibrosis generated by the conventional heavyweight prostheses would be decreased with the use of lightweight prostheses. We must not forget that the abdominal wall acts as a dynamic system that undergoes acute (coughing, vomiting, etc) or constant (obesity, pregnancy, etc) ^{19,20} pressure changes. Therefore, after inserting prosthetic material, a certain amount of distension capacity should be left to allow for unrestricted movement of the abdominal wall ^{14,21}; basically, after receiving an implant, the abdominal wall should maintain its function in the most physiological manner possible.

Research experience

Experimental research

The first experimental trials were carried out by Klinge et al, ²² in 1998; with a hybrid polypropylene and polyglactin prosthesis that was later commercialised as Vypro[®] (Ethicon, Johnson & Johnson, Somerville, United States). In this first bio-trial, these authors demonstrated lower rates of inflammatory reaction with the implants, as well as improved elastic integration.

This led to an improved adaptation of the abdominal wall as it allowed it to keep its distension capacity. In this first study, they proved that the LW prostheses should have a large pore size as well as less material.

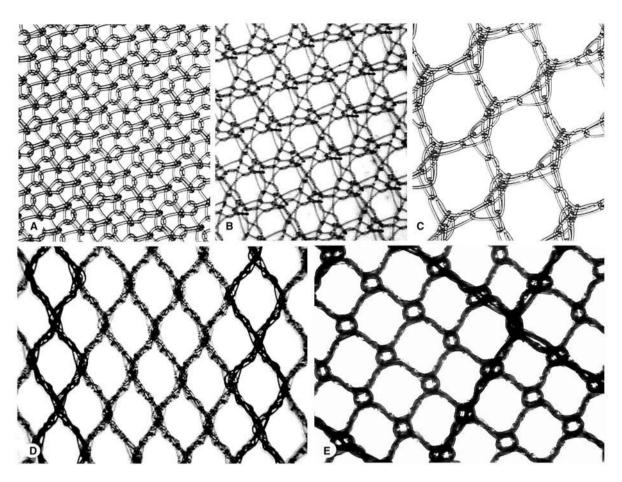


Figure 1 – A: conventional polypropylene prosthesis (HW), Surgipro® (Covidien, Mansfield, United States), with a density of 84 g/m² and a small pore size (0.26 [0.03] mm²). B: Parietene® (Covidien, Mansfield, United States) (LW), 38 g/m density and a pore size of 1.15 [0.05] mm². C: Optilene elastic® (B/Braun, Spangerwerg, Germany) (LW), with a density of 48 g/m² and a large pore size (7.64 [0.32] mm²). D: partially absorbable prosthesis, Ultrapro® (Ethicon, Johnson & Johnson, Somerville, United States) (LW), made of polypropylene and polyglecaprone-25 filaments with a density of 28 g/m² and a pore size of 3.45 (0.19) mm². E: prosthesis with absorbable polyglactin filaments, Vypro II® (Ethicon, Johnson & Johnson, Somerville, United States) (LW) with a density of 35 g/m² and a pore size of 4.04 (0.54) mm².

Table 1 – Classification of the prosthetic material according to density

Heavyweight >80 g/m² Mediumweight, 50–80 g/m² Lightweight, 35–50 g/m² Ultralightweight <35 g/m²

Modified from Earle et al. 13

In 2001, Greca et al,²³ using dogs as their experimental animals, were able to demonstrate that a large-pore prosthesis, by their design, induced a greater collagen I deposit than the implant of a conventional polypropylene prosthesis. From a bio-mechanical perspective, no differences were found between both prostheses.

Posterior studies, also from the German school, 15,16 demonstrated that large pores helped to avoid the "bridging

effect," that takes place in small pore prostheses (<1 mm). This phenomena causes the fibrosis and rigid scarring that can be found after the implant of this type of prostheses. Some prostheses that are considered as LW with small pores, as they present a low weight in g/m^2 , act, from a tissue integration perspective, like HW prostheses.

Ultimately, and following Klinge,²⁴ this type of prosthesis produce confusion about the concept of lightweight and heavyweight. Thus, in certain studies,²⁵ due to this peculiar phenomenon, LW prostheses have not been evaluated in a positive manner compared to the use of conventional HW prostheses.

Experimental studies carried out by our group have been able to identify a similar biomechanical phenomenon when comparing partially absorbable HW and LW prostheses.²⁶ In accordance with other authors,¹⁷ the biological behaviour of these partially absorbable prostheses is excellent. We have also recently demonstrated,²⁷ after using molecular biological techniques, the early deposit of collagen in LW prostheses,

Heavyweight prostheses Greater rigidness Less elasticity Less distension capacity More residues of external material Lightweight prostheses Less rigidness Greater elasticity Greater distension capacity Less residues of external material

Figure 2 - Schematic representation of the scarring process in HW and LW prostheses. A: scarring process in a HW type prosthesis, with a small distance between the prosthetic filaments (F) 14 days after insertion (Sirius red, ×50). B: LW prosthesis, where a greater distance can be observed between the filaments, at the same time of the study (Sirius red, ×50).

Collagen

without modifications in the biomechanical behaviour compared with HW prostheses (Figure 2).

Prosthetic filament

Clinical research

The clinical use of LW prostheses has yet to pass the sufficient follow-up time required for this type of implants. Indeed, there are discrepancies regarding the results. Certain retrospective studies²⁸ have demonstrated the benefits of these prostheses, although other prospective studies, with a short follow-up period (1 year, approximately),^{29,30} have shown a greater incidence of relapses after the use of this type of prosthetic material.

Akolekar et al,³¹ although they do not find differences regarding relapse with the use of HW and LW, they do however recommend the fixation of the LW prosthesis widely overlapping the hernia margins. Probably, the fixation of the LW prosthesis with very large pores at the edges of the hernia requires special care, as it is necessary to widely overlap said edges. In this respect, a recent experimental study published by Binnebösel et al³² has demonstrated, in an in vitro model, the need to overlap at least 3 cm of the edge of the hernia with the prostheses.

Other authors^{28,33-37} relate the clinical results of the LW prostheses with the well-being of the patient and post-operatory pain. It seems to be less in patients with LW implants, especially is they are of the partially-absorbable type (Ultrapro®, Ethicon, Johnson & Johnson, Somerville, United States).

Inflammatory cells

The clinical trials that use LW prostheses that are pretreated with titanium³⁸ have not shown any differences regarding relapse, when compared with conventional polypropylene prostheses, though their follow-up did not surpass one year.

For this reason, the clinical results should be evaluated over more time, in order to establish the final benefits of LW type prostheses.

Are there bio-mechanical reasons to defend the use of lightweight prostheses?

Considering the abdominal cavity like a cylinder, and according to the Pascal's hydrostatic principal, the maximum load for it to break would be between 11 N/cm and 27 N/cm. Abdominal pressures oscillate between 8 and 150 mm Hg.¹⁹

Klinge et al³⁹ demonstrate that heavyweight prostheses can withstand up to 10 times more than the above mentioned pressure breaking limits. Therefore, the HW prostheses are highly above the abdominal wall's own resistance. This could explain the fact that after insertion there is less elasticity in the natural tissue as the incorporation of the tissue of the prosthesis may create an incongruence of resistances between the receiving tissue and the biomaterial integrated into it. From the mechanical point of view, the insertion of a material that could withstand breaking limits highly above those required would be necessary. Therefore, the insertion of materials with a lower resistance to breakage and with greater elasticity⁴⁰ would be more logical. The LW prostheses meet this parameter. In experimental studies after the insertion of a LW prosthesis, compared to HW, we have been able to determine that there are no differences of mechanical resistance to breaking 90 days after the insertion of LW compared with HW, including the use of partially absorbable LW prostheses.²⁶

Future perspectives

Although polypropylene is still one of the polymers with the best bio-compatibility, tissue integration, tolerance to infection and mechanical resistance, studies are still needed that, in some way, find the ideal polypropylene prosthesis, ie, one which, with the least quantity of residues, ultimately obtains the best mechanical resistance. Most likely, the optimal solution will be found by determining the ideal pore size, with a correct spatial disposition of the filaments and, in this way, find a prosthesis that best adapts to the needs of patients. We must not forget that the abdominal wall functions like a dynamic structure and that the final objective in the repair process is to reach the total adaptation of the prosthesis to the receiving tissue.

Conflict of interests

The author declares that he/she has no type of affiliation or economic interest with any of the commercial organisations that provide the biomaterials described in this review.

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