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Prosthetic material in incisional hernia surgery

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There are different designs of prosthesis for use in the repair of incisional hernia, and it is often difficult to choose the most appropriate. The biological behaviour of the material must be a key part in the selection, although this behaviour will vary depending on what materials are available. A proper understanding of the relationship of the material with the abdominal wall dynamics is another important factor in this selection. Finally we need a stable repair without long term side effects. This paper analyses the prostheses more commonly available for incisional hernia surgery in the non-emergency situation.

Prótesis en el tratamiento de las eventraciones

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R E S U M E N

Diferentes y numerosas prótesis han sido diseñadas para facilitar la reparación de las eventraciones y es de esperar que se diseñen más en el futuro. En este contexto es difícil escoger la más adecuada. El comportamiento biológico del material debe ser una parte fundamental en la selección, aunque este comportamiento variará en función de las características de las diferentes prótesis de que se dispone. Un adecuado conocimiento de la relación del material con la dinámica de la pared abdominal es otro elemento importante a la hora de seleccionar. Finalmente, se ha de tener una idea de lo que se puede esperar de las prótesis para una reparación estable y sin efectos secundarios a largo plazo. En este trabajo se analiza el panorama protésico más comúnmente disponible para la cirugía de las eventraciones en situación no urgente.

Introduction

The current use of prosthetic material to repair incisional hernias is well founded, but one single, ideal prosthesis has yet to be found.[1] For this reason, many different prostheses have been designed to help to close these defects of the abdominal wall, and it is expected that more prostheses will be designed in the future. Each new product will probably be marketed as having substantially improved biomaterial, although many of these new products will lack

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the experimental and/or clinical data to effectively support their use.[1] It is difficult to understand this market.

A surgeon in training who sees this wide range of products has to know and keep sight of the different prostheses. However, maybe they should know that, no matter the type of prosthesis, it is vitally important to use the right technique to insert it. A trained surgeon must decide which technique and prosthetic material are the most suitable for each specific clinical situation.

The aim of this study is to analyse the present situation of the prostheses most commonly available for surgeons in non-urgent incisional hernias, by answering the following questions: What are the biological repercussions of inserting prosthesis? What material is available? What is hoped to be achieved by implanting prosthesis? Which prosthesis should we use?

What are the biological repercussions of inserting a prosthesis?

Inserting prosthetic material into the surgical wound of a hernia repair causes a unique tissue environment whereby the normal scarring sequence (coagulation, inflammation, angiogenesis, epithelialisation, fibroplasia, extracellular matrix formation and contraction[2]) is in close contact with the foreign material. This material will determine the start of the inflammatory response, where the cellular components involved include platelets, monocytes, macrophages and polymorphonuclear leukocytes. There will also be other cells such as fibroblasts, endothelial cells and smooth muscle cells.

The inflammatory response normally takes place in 4 stages: an acute inflammatory response, a chronic inflammatory response, the reaction to the foreign body and, finally, fibrosis.

Immediately after implantation, the prosthetic material is covered (adsorption) by palmatic proteins (mainly albumin, IgG and fibrinogen[3]), which are distributed on the basis of their electrical affinities and biochemical properties, which, in turn, vary depending on the prosthetic material (Vroman effect[4]). These proteins interact with the cellular components involved in the inflammatory response. Since the concentration of proteins adsorbed depends on the type of prosthetic material, their interaction is also different. Furthermore, prosthetic surfaces activate both the classic and alternative complement pathways (especially generating factor C5a). The extent of this activation again depends on the type of prosthetic material. The generation of C5a has important implications, the main one being that it is a powerful chemotactic factor for inflammatory cells.

The main cellular components involved in the inflammatory response are platelets, monocytes, macrophages, and polymorphonuclear leukocytes. Each of these cells plays a different role with regard to the prosthetic material.

The activated platelets release substances (serotonin, epinephrine, adenosine-diphosphate, etc.) which attract more platelets and other cellular elements which increase the acute stages of scarring.[5] Polymorphonuclear leukocytes, while not able to phagocytose the prosthetic material, are activated and secrete substances (proteolytic enzymes) which play an important role in "cleaning" the wound and removing dead tissue.[6] Monocytes differentiate into inflammatory monocytes, these into macrophages, and these into activated macrophages. Again, the degree of macrophage infiltration depends on the material's characteristics.[7] Activated macrophages liberate substances (leukotriene B_4, platelet-derived growth factor [PDGF], fibroblast growth factor [FGF], transforming growth factor β [TGFβ], interleukin 1 [IL1], and interleukin 6 [IL6]) which maintain and modulate cellular response in the prosthesis/blood/tissue interface.

There are numerous biologically-active factors which are released by the different cells and which affect the biological response to the prosthetic material. However, the so-called growth factors play an important role. There are five big groups of growth factors with an important role in the biological response to a prosthesis,[8] some of which have already been mentioned: 1) PDFG promotes the proliferation of smooth muscle cells and fibroblasts, 2) FGF is a potent mitogen for smooth muscle cells, endothelial cells and fibroblasts, and its production can be increased in the presence of prosthetic material,[9,10] 3) TGFβ, promotes the production of fibroblasts, attracts and activates monocytes, and the prosthetic material can increase its expression,[11] 4) insulin-like growth factor (IGF), produced by platelets and fibroblasts, is a potent chemotactic for endothelial cells,[12] 5) epidemic growth factor (EGF) is found in high concentrations in platelets and is involved in the migration and proliferation of endothelial cells, promoting the production of extracellular matrix proteins; its role in connection with a prosthesis is not completely known, although it may promote endothelialisation.[13,14]

A few hours after inserting a synthetic prosthesis to repair an incisional hernia the prosthesis-tissue interface is densely populated by inflammatory cells and the previously mentioned mediators of inflammation. Around a week after implanting the prosthesis, the population of cells is composed extensively of mononuclear phagocytes which, later, differentiate into macrophages. These cells secrete a wide number of effectors which help to modulate the biological response.[15,16] The inflammatory reaction seals the foreign body in an epithelioid granuloma. In the presence of indigestible prosthetic material, the macrophages coalesce into foreign-body giant cells.[17] The role of these cells is not clear, but they stay indefinitely in the presence of a non-absorbable prosthesis.

The final stage of the biological response is the synthesis of connective tissue. The fibroblasts synthesise and excrete collagen in its monomeric form to the extracellular space. Here, it polymerises into an insoluble helicoidal structure. A collagen network is produced for around 21 days, then there is a decrease in the ratio of immature collagen (type III), and an increase in mature collagen (type I). The three-dimensional collagen network grows around and through the prosthesis. As a consequence of this remodelling, its mechanical strength increases progressively until approximately 6 months after performing the surgical wound. However, at the end of this

period, the newly formed tissue only has 80% of the normal mechanical strength of the skin or fascia. Other properties, such as its elasticity or energy absorption capacity will be even lower. The final result is a weaker and more fragile tissue than normal. A non-absorbable prosthesis covered by the newly-formed tissue will help to improve these weaknesses.[18]

As mentioned above, the intensity and duration of all this host/prosthesis reaction depend on the type and quantity of material used.[18] In turn, this affects the following factors: the greater or lesser rigidity of the abdominal wall after the operation, the long-term pain or the sensation of noticing the material in the area of the surgery, and the greater or lesser contraction of the prosthesis/tissue with its possible influence on recurrence.

What material is available?

The risks and benefits of the prosthetic material are based on specific aspects of its biological response and handling characteristics, which are related, in turn, to the structure of the material itself. As this is never the same, due to variations in manufacturing, it is very difficult, if not impossible, to compare existing prostheses. The most commonly available ones are: non-absorbable and synthetic; non-absorbable and synthetic with a barrier; and synthetic and partially absorbable. This study does not analyse reabsorbable or biological prostheses which at the present have limited, specific use in daily practice.

Non-absorbable synthetic prostheses

These are the most commonly used. This may be why they are the ones which have been most studied with regard to their biological properties and clinical results.

Polypropylene

This is the most extensively used material for synthetic prostheses.[19] It is reticular, hydrophobic, electrostatically neutral and resistant to biological degradation.[20] Nevertheless, in electronic microscope analyses of polypropylene (PP) explanted from patients, alterations have been observed in the material, but with no clinical repercussions.[21]

It is made in a variety of forms, each one with its mono- or multifilament, and with a unique density (weight) and size. However, the optimal density and porosity remain unknown.[22] PP displays an intense biological response, which means that, in the end, it is covered with thick scar tissue, causing a solid incorporation of the prosthesis to the abdominal wall. This response can vary depending on its density, filament size, pore size, architecture, and the individual response of each carrier.[23,24] The clinical repercussions of an intense biological response can be chronic pain, discomfort and/or the sensation of feeling the material.[25,26] For this reason, if the PP is in direct contact with the abdominal viscera, it can give rise to intestinal obstruction or a fistula.[25]

Polyester

This is the textile term for polyethylenterephthalat. It is reticular, hydrophilic and its biological response in terms of scar formation is similar to that of PP.[27,28] The clinical repercussions in the form of possible long-term complications are also similar to PP.[25] It has been reported to degrade over time, especially in infections.[29] However, the clinical significance of this degradation is doubtful in terms of the repair of abdominal wall hernias.[30] Like PP, it is produced in a wide variety of forms.

Expanded polytetrafluoroethylene

This is a hydrophobic laminar material whose biological response causes a minimal inflammatory reaction, and a scar density lower than that of the non-absorbable materials described above.[18] New tissue develops across the surface of the material, but causing minimal distortion and very little contraction of the scar.[31] Due to its insignificant inflammatory reaction and few adhesions, it has been widely used for inserting in the intraperitoneal position.[18] It is manufactured in different ways and with different architectures. The characteristics of the different varieties were compared in abdominal wall defects in rabbits,[32] no advantages were observed for any particular variety in that experimental model. Due to the limited inflammatory reaction and density of the scar generated, this material's incorporation to the abdominal wall can be easily broken, so the right fixation is quite important.[33]

Non-absorbable synthetic prostheses with barrier

In response to the challenge of inserting PP or polyester into the abdominal cavity and in contact with its contents, some prostheses have been designed from these materials, which include a barrier on one of their faces which enables direct contact with the viscera. This barrier is used to minimise the biological response, reducing the initial adhesion to the material of mediators of inflammation and inflammatory cells, and thus partially inhibiting the onset of the inflammatory cascade, reducing the overall intensity of the response. The barrier can be physical (non-absorbable) or chemical (absorbable): expanded polytetrafluoroethylene, polyurethane, oxidised regenerated cellulose, omega-3 fatty acids, collagen, or beta glucan. Numerous experimental studies show the anti-adhesive properties of these compounds, both with physical or chemical barriers.[32,34-38] On the other hand, the literature is scarce regarding their observed clinical behaviour in reoperations.[39]

Partially-absorbable synthetic prostheses

To reduce the density of the material and the resulting inflammatory response, while maintaining the intraoperative ease of use and long-term strength of the prosthesis, designs have been developed with a mixture of non-absorbable (PP) and absorbable material (polyglactin 910, poliglecaprone 25).[40,41] From an experimental viewpoint, these prostheses

seem to show differences in a variety of inflammatory markers, showing less biological response than non-absorbable compounds such as PP.[42,43] The advantages seen in the laboratory seem to be confirmed in randomised clinical studies,[44] which show less pain and discomfort when these prostheses are used, although they also report a greater likelihood of a hernia relapse. However, the authors put this down to a faulty technique being used to insert the material, rather than to the material itself.[44] In any case, to confirm its possible negative influence on relapse, further clinical studies are necessary with long-term monitoring.

What is hoped to be achieved by implanting prosthesis?

It is obvious that the main aim of implanting a prosthesis in the surgical operation for an incisional hernia is to achieve a long-lasting, stable repair, with no long-term side effects for the patient. In other words, a repair with no relapse or chronic pain.

Is it possible to achieve an absence of relapse? The only population-based study which exists in this regard provides contradictory data.[45] After analysing 10 822 patients, the accumulated incidence of relapse with or without prostheses showed a linear increase over the years, the 2 procedures giving similar results. This study suggests that the prosthesis can only aim to delay a relapse for a few years since this does not depend solely on inserting material into the abdominal wall, but also on a complex biological disorder. It is only palliative treatment for a complex disease.

If it is possible that relapse can not be avoided but only delayed by using a prosthesis then, should we focus on preventing the appearance of long-term side effects? Reference was made above to the biological and resulting clinical effects that the different prosthetic designs can have. For this reason, it is advisable to choose the prosthesis bearing in mind 2 premises which probably have a direct influence on the reduction of long-term side effects. On the one hand, it is necessary to chose prostheses which meet the mechanical needs of the abdominal wall, and on the other, select prosthetic designs which, in the light of current data, produce the least biological effects.

Characteristics of the prosthesis with regard to the mechanics of the abdominal wall

When a prosthesis is inserted into the abdominal wall it is important to know what is being replaced and what is being strengthened. The abdominal wall develops strength and has elasticity. Furthermore, it is subjected to intraabdominal pressure. The strength and elasticity of the abdominal wall have been studied, the strength being calculated at 16 N/cm. The mean elasticity of the wall of a male at 16N/cm was 23 (7)% in the vertical direction and 15 (5)% in the horizontal direction. The mean elasticity of the wall of a woman at 16 N/cm was 23 (7)% in the vertical direction and 15 (5)% in the horizontal direction.[46] The intraabdominal pressure that the abdominal wall can withstand (coughing, jumping, lifting weights) can reach up to 252 mm Hg, which correlates with abdominal wall strengths of up to 27 N/cm.[47] Bearing in mind these values of between 16 and 27 N/cm, they can be related to the force necessary to break the prostheses which are normally used to repair incisional hernias. One study showed that non-absorbable synthetic prostheses break at a force of around 56N/cm,[48] and the same study observed that relapses in humans are produced in the material/tissue interface (margin of the prosthesis). Then, experimental models[49] confirmed that the prostheses do not break at intraabdominal pressures of 200 mm Hg, but they become detached at the edges of the hernia defect, except when the prosthesis has a wide margin (at least 4 cm) with regard to the edge. Furthermore, this phenomenon is more frequent if the more elastic direction of the prosthesis is not placed parallel to the direction of the defect's longest diameter. Other studies with experimental animals (pigs) which studied mechanical resistance to rupture observed that tissue without a prosthesis broke at 232 N/cm, absorbable partially-synthetic prostheses at 576 N/cm and non-absorbable synthetic ones needed forces between 590 and 1218 N/cm to break them.[50] From the data described above, we can say that most of the more commonly used prostheses for the treatment of incisional hernias have overdimensioned properties with regard to the mechanics of the abdominal wall that they are used to strengthen and/or replace. Also, from the point of view of abdominal wall dynamics, when an incisional hernia is repaired, it may be advisable to position the prosthesis with its more elastic direction parallel to the defect's longest diameter and with a minimum margin from the edge of the defect of 4 cm.

Prosthesis characteristics with regard to long-term side effects (chronic pain and abdominal rigidity)

The current tendency in the design of non-absorbable synthetic prostheses, non-absorbable synthetic prostheses with a barrier, and partially absorbable ones is to reduce the amount of material used, this being the case with both laminar and reticular ones.[51] In the case of reticular prostheses, this is achieved by reducing the diameter and number of the fibres, leading to a reduction in density or weight and an increase in pore size. The aim of this tendency is to manufacture prostheses with a weaker biological response, which results in a lower incidence of undesirable clinical symptoms and, in turn, the prosthesis adapts to the physiological dynamics of the abdominal wall.[40,52] Thus, in the face of the classic overdimensioned, high-density heavyweight prosthesis, so-called low-density, lightweight ones have emerged, meaning less material and bigger pores.[50] Unfortunately, as mentioned above, the optimal density and porosity remain unknown.[21] These low density prostheses have been proven not to be so overdimensioned, producing less inflammation and better tissue integration than the classic materials and, furthermore, they have been associated with reduced long-term pain, less paraesthesia and/or reactions to foreign bodies, and with improved abdominal wall elasticity but with no reduction in the material's necessary tensile strength.[26,40-42,44,46,48,50]

Which prosthesis should we use?

The most extensively used material nowadays for repairing incisional hernias is still classic PP.[19] Being dense and with a high degree of rigidity, this material is easy to handle and can give the sensation of having performed a "solid" and "consistent" repair of the incisional hernia. Obviously, this is why most surgeons find it extremely comfortable to use and are satisfied with the technique. However, as mentioned above, this classic material is overdimensioned, and this can cause potential complications. Low-density prostheses can now offer an alternative which is not overdimensioned with less long-term complications and without losing the mechanical effect that a prosthesis must exert in the repair of an incisional hernia. Bearing this in mind, it is possible that surgeons interested in abdominal wall surgery could develop a standardised technique for the immense majority of elective incisional hernias that they perform. The chosen technique could be the one that they master most effectively and efficiently, be it laparoscopic or open (prefascial, retromuscular or intraabdominal), as at the present time no technique exists for repairing incisional hernias that has been proven to be better than the others.[53] Standardising the technique for most patients may improve short- and long-term results, and also reduce the number of prostheses needed as surgeons will end up choosing the one that most suits the operation to be carried out, potentially reducing the number of side effects. This might also lead to a reduction in the cost of operations requiring prosthetic material. Obviously, there will be incisional hernias which are not suited to this standardised technique and require another more suitable technique and prosthesis. Surgeons must weigh up the usefulness of the new products available in the light of the scientific evidence they have, whether this is experimental or clinical. If no evidence exists for these new prostheses, maybe they should only be used for research purposes at first, either in the context of a clinical or experimental study.[54]

Conflicts of interests

The authors affirm that they have no conflicts of interests.

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