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Special article

The labyrinth of composite prostheses in ventral hernias

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ARTICLE INFO

Article history:

Received July 1, 2008

Accepted January 9, 2009

Online June 21, 2009

Keywords:

Abdominal wall

Incisional hernia

Composite prosthesis

Biomaterials

A B S T R A C T

Reinforcement or replacement are increasingly being used in the repair of incisional hernias. In many occasions it is necessary to place the prosthesis in the intraperitoneal plane, for which the so called «composite» or bilaminar prostheses have been designed.

A terminological precision is made in this article, defending the denomination of dual or «composite» prosthesis for these materials, and the different commercial available options at present are related. The numerous suitable alternatives on the market can do that the surgeon is in a labyrinth.

A review of the experimental and clinical studies that support their use, efficiency, safety and complications is included. It concludes by recommending the prostheses for which there is consistent documentary evidence: Bard Composix, Dual Mesh, Parietex Composite, Parietene Composite, and Proceed. However, longer term studies and randomised clinical trials are needed to make stronger recommendations.

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El laberinto de las prótesis composite en las eventraciones

R E S U M E N

Los materiales protésicos de refuerzo o sustitución se emplean cada vez con mayor frecuencia en el tratamiento de las eventraciones. En muchas ocasiones es necesario ubicar la prótesis en plano intraperitoneal, para lo cual se han diseñado las llamadas prótesis composite o bilaminares.

En este artículo se realiza una precisión terminológica, defendiendo la denominación de prótesis dual o *composite* para estos materiales y se relacionan las diferentes opciones comerciales disponibles en la actualidad. Las numerosas alternativas elegibles en el mercado pueden hacer que parezca al cirujano que se encuentra en un laberinto.

Se añade una revisión de los estudios experimentales y clínicos que avalan su utilización, su eficacia, su seguridad y sus complicaciones. Se concluye recomendando las prótesis sobre las que existe un acervo documental más consistente: Bard Composix, Dual Mesh, Parietex, Parietene Composite y, recientemente, Proceed. No obstante, son necesarios estudios a largo plazo y ensayos clínicos aleatorizados para proporcionar recomendaciones de mayor potencia.

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Palabras clave:

Pared abdominal

Eventraciones

Prótesis composite

Biomateriales

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Introduction

The results of traditional surgical treatment for ventral hernia were very unfavourable, with high complication and relapse rates, until prosthetic material began to be used for repairing defects in the abdominal wall. The characteristics of the prosthesis and where it should ideally be located along different planes of the abdominal wall are topics for constant debate.¹ At times, whether due to the extension of the defect or to the use of the laparoscopic approach, it is necessary to place the prosthesis intraperitoneally, and therefore right against the abdominal organs. Furthermore, the laparoscopic method is gaining an increasing number of supporters because it adheres closely to the principles of minimally invasive surgery.²⁻⁴ When the prosthesis will be in contact with the abdominal viscera, which type should be used? Surgeons' fear of peritoneal adhesion, intestinal obstruction, fistulisation, etc, has brought about research and design of materials that may be ideal for the abdominal wall-peritoneal interface. We will now review the concepts including mesh, prosthesis, etc, the meaning of "composite," the different models that exist on the market, and some of the experimental and clinical studies that have taken place with these biomaterials.

Basic concepts

We frequently hear or read the terms "mesh," "prosthesis," "laminar," "hybrid," "dual," "composite," etc. Let us take a moment to clarify these concepts. Mesh: fabric made of thread or wire with an open weave that leaves holes⁵; prosthesis: artificial part that replaces or reinforces part of the body⁵; hybrid: generally refers to items stemming from 2 different sources or having 2 different natures⁵; dual: applying to items that have or contain 2 aspects or which refer to 2 things, etc⁵; laminar: having a leaf-shaped form (a thin, flat section of any material)⁵; composite: signifying a material made up of two or more distinct parts).⁶

When referring to a prosthetic reinforcement or replacement for intraperitoneal use, it is common to use the terms "composite mesh," "bilaminar/dual-layer mesh," or "bilaminar match." However, all of these terms are conceptually incorrect; as we all know, one of the components of these prostheses is a sheet, rather than a mesh, and no prosthesis contains 2 sheets. Therefore, more appropriate terms would be "compound prosthesis," "dual-layer patch," or the more common "composite prosthesis." The term "hybrid" is only used when 2 materials are present within the same structure (a mesh for example), and normally one is absorbable and the other is not.

Composite prostheses

As stated above, these materials are necessary for repairing defects in the abdominal wall when the prosthesis is attached within the peritoneal cavity. These biomaterials are

designed to have 2 properties: on their parietal side, excellent integration into the abdominal wall, lending it strength and resistance; and on the visceral side, good interaction with the visceral peritoneum, meaning that it would provoke a minimum amount of adhesion and its sequelae, intestinal obstruction, or fistulisation.

Biomaterials used in the abdominal wall are continuously being perfected⁷ and for now, the ideal dual-layer or composite prosthesis does not exist. As for the behaviour of the prosthesis, the importance of its structure has been evaluated more than the importance of its composition.⁸ Consequently, reticular or macroporous materials with a pore size >75 µm (polypropylene or polyester mesh) have shown excellent parietal integration, but on the contrary, they may generate some concern about their effects on the peritoneum (adhesion, obstruction, erosion, fistula, etc). Laminar or microporous materials (ePTFE with pores from <10 to 75 µm) are known for their good coexistence with the peritoneum, but they lead to worse parietal integration with a risk of encapsulation.⁹ This is how the idea arose of designing a dual-property prosthesis by modifying the structure or composition of the available materials to make a dual composite prosthesis (DCP). The first, or parietal component of a DCP is the reinforcement, made from ePTFE, polypropylene or polyester; the second, visceral component is an anti-adhesive barrier that may be chemical (absorbable) or physical (non-absorbable).

E-PTFE is a special case, because is a single material that can be used to make a DCP. During the search for solutions to its problems, the prosthesis evolved from the single-sheet of ePTFE (Soft Tissue Patch) to the perforated sheet (Micro Mesh) and subsequently became composed of 2 face-specific layers: a textured parietal side to promote integration, and an anti-adhesive sheet on its visceral side (DualMesh Corduroy).¹⁰

The rest of the DCPs are made of polypropylene or polyester mesh as a reinforcing component with an added chemical or physical anti-adhesive barrier on the visceral side. The chemical or absorbable products include sheets of collagen-polyethylene glycol-glycerol, hyaluronic acid-carboxymethyl cellulose, oxidised regenerated cellulose, and omega-3 acid. The physical or non-absorbable products include silicone, polyurethane, and ePTFE once again. The different DCPs that are on the market are listed in Table 1.

New materials exist based on lightweight concepts and including a smaller proportion of non-absorbable material in the prosthesis, which is thought to decrease the local inflammatory reaction and increase postoperative well-being.¹¹ We also find acellular biological prostheses that may be either xenogenic (Surgisis)¹² or allogenic (AlloDerm)¹³ which foster integration, vascularisation and infection resistance, and bioactive materials with the ability to liberate growth factors locally. However, giving details about these devices is not within the scope of this article.

Experimental studies in animals

Numerous studies¹⁴⁻⁴⁹ have been carried out to evaluate DCP behaviour in the abdominal-peritoneal wall interface

Table 1 – Dual-layer or composite prostheses. Alphabetical order

	Manufacturer	Parietal side	Visceral side
Bard Composix LP	CR Bard	Polypropylene	ePTFE
C-QUR Edge	Atrium	Polypropylene	Omega 3 fatty acids
DualMesh	WL Gore & Associates	Textured ePTFE	Smooth e-PTFE
HI-TEX Endo IA	Bioser	Polyester	Polyurethane
Intramesh T1	Cousin-Biotech	Polypropylene	ePTFE
Microval Intro	Microval	Polypropylene	Silicone
Parietex Composite	Sofradim, Covidien	Polyester	Collagen, polyethylene glycol, glycerol
Parietex Composite	Sofradim, Covidien	Polypropylene	Collagen, polyethylene glycol, glycerol
PL-PU 99	JM Bellón	Polypropylene	Polyurethane
Proceed	Ethicon	Polypropylene and PDS	Oxidised regenerated cellulose
Sepramesh	Genzyme Surgical Corporation	Polypropylene	Hyaluronic acid and carboxymethyl cellulose
Surgimesh WN Non-Stick	Aspide Medical	Polypropylene	Silicone
Ti-Mesh	GfE Medizintechnik GmbH	Polypropylene	Titanium ^a

^aAlthough this prosthesis is manufactured for intraperitoneal use, the titanium covers a lightweight polypropylene mesh with no anti-adhesive layer on the visceral side.

with regard to reinforcement and integration, creation of neoperitoneum, induction of the adhesion phenomenon, and resistance to bacterial contamination and infection (Table 2). This research has generally been done on a short-term basis in small animals and with small amounts of biomaterial, and results have been highly variable if not contradictory. Contrasted, acceptable results exist for Dual-Mesh, Parietex, and Parietene Composite, Bard Composix, and most recently, Proceed. The advantage of this last prosthesis is that its reinforcing component is made of low-density polypropylene mixed with absorbable polydioxanone (PDS). All of the above products, which obtain better or worse results depending on the study, are sufficiently strong, foster new peritoneal formation over the prosthesis in 1-2 weeks with very little adhesion, and provide a good defence against bacterial contamination. In general, macroporous prostheses are better at integrating and resisting infection than microporous or laminar prostheses. In practice, there have not been enough studies to evaluate other DCPs.

Clinical studies

There is already a significant body of work available⁵⁰⁻⁸³ containing studies on the clinical results for strength, integration, adhesion syndrome (and its complications, such as obstruction or fistulisation) and local infection in conjunction with DCP use. Some investigations evaluate a single prosthesis type and others compare different materials. In addition, the approach may vary from open surgery in some to laparoscopic surgery in others (Table 3). The most widely-used material is e-PTFE and the composite prostheses Bard Composix and Parietex Composite; clinical references to Proceed^{84,85} are also beginning to appear.

With regard to strength and integration and the relapse rate, studies are not conclusive. Among other reasons, this is because multiple factors—such as the hernia and patient characteristics, the surgical technique that is used, the

infection, etc—exert a significant influence on results. With respect to the adhesion syndrome, which is an obvious cause of concern for the surgeon, studies using dynamic ultrasound, and findings from abdominal reinterventions^{68,86,87} give significant adhesion rates between 5% and 15%; here, the greatest problem is adhesion of the mesh to the viscera (fundamentally the intestinal loops), resulting in added difficulty for new procedures and the risk of fistulation. In either case, incarcerated ileum or subsequent/recurring intestinal obstruction have not been recorded more frequently than after any other similar type of procedure.

The troublesome enterocutaneous fistulae are absent or have a frequency of less than 2% in most series (when they do arise, it tends to be in cases where open surgery was performed), and it is difficult to determine whether they are caused by the DCP itself, its attachment mechanisms, loss of serous membrane, or by infection. Either way, there is a risk and the patient should be informed.

With regard to infection, the use of composite prostheses is accompanied by a higher risk during healing than if no prosthesis was used, but it is similar to the risk involved when implanting any foreign material. Infection is clearly associated with open surgery techniques and can reach a rate of 5%, particularly when ePTFE is used (for which reason this material now tends to be impregnated with an antimicrobial agent). Infection is very rare if the procedure uses the laparoscopic approach: about 1%. In either case DCPs should not be used to treat hernias in infected or potentially contaminated sites. For cases like these, modern absorbable biological prostheses that leave no permanent material behind may come to play a major role.^{12,13}

Other complications and sequelae from DCP use are hernia sac seroma (very frequent following laparoscopic repair), shrinkage or retraction of the prosthesis, and postoperative pain. It seems that seroma is more persistent following the use of microporous material, but there are no conclusive studies. Shrinkage or retraction of biomaterial may range between 10% and 40%, and therefore a wide overlapping

Table 2 – Experimental studies in animals

	PLP	DM	BCx	PtxC	PtnC	SM	ProC	PU99	TiM
Amid, 1995 ¹⁴	X	X (v)							
Malazgirt, 2000 ¹⁵						X (v)			
Baptista, 2000 ¹⁶	X					X (v)			
Greenawalt, 2000 ¹⁷	X		X			X			
Bellón, 2001 ¹⁸		X (v)		X					
Ferrando, 2002 ¹⁹	X	X(v)	X						
Bellón, 2002 ²⁰			X (v)						
Bellon, 2002 ²¹	X							X	
Bellón, 2002 ²²			X	X				X	
van Riet, 2003 ²³	X			X		X			
Matthews, 2003 ²⁴	X	X							
González, 2004 ²⁵	X	X	X	X	X	X			
Jhonson, 2004 ²⁶		X				X			
Young, 2004 ²⁷		X				X			
Borrazo, 2004 ²⁸	X	X				X			
Duffy, 2004 ²⁹			X	X					
Felemovicus, 2004 ³⁰	X					X			
McGinty, 2005 ³¹	X	X		X					
Matthews, 2005 ³²		X	X			X			
Kayaoglu, 2005 ³³	X	X(v)		X		X			
Bellón, 2005 ³⁴								X	
Bellón, 2005 ³⁵			X (v)	X		X		X	
Bellón, 2005 ³⁶	X					X			
Demir, 2005 ³⁷	x		x				X (v)		
Harrel, 2006 ³⁸	X	X	X				X		
Schönleben, 2006 ³⁹	X				X (v)				
Burger, 2006 ⁴⁰	X	X		X		X	X		X
Martín, 2006 ⁴¹	X	X							
Schug-Pass, 2006 ⁴²		X							X
Bellón, 2006 ⁴³	X	X				X			
Sikkink, 2006 ⁴⁴	X		X		X	X			
Novitsky, 2006 ⁴⁵	X		X				X		
Bellón, 2007 ⁴⁶	X	X	X	X				X	
Judge, 2007 ⁴⁷				X		X			
Jacob, 2007 ⁴⁸	X			X			X		
Olmi, 2007 ⁴⁹				X					

The boxes corresponding to the materials being used are marked. Some investigations use other materials which are not listed in the table in order to simplify this article.

(v) indicates variants; BC, Bard Composix; DM, Dual Mesh; PL, polypropylene, Pro, Proceed; PtnC, Parietene Composite; PtxC, Parietex Composite; PU-99, PL-PU 99; SM, Sepramesh; TiM: Ti-Mesh.

margin is required at the time of implantation; it also appears that this affects ePTFE even more. Post-op pain has no significant relation with the type of DCP described; rather, it seems to be related to the attachment procedure (transfacial sutures, tackers, nitinol staples, etc) and also to the amount of implanted biomaterial. For this reason, prostheses that incorporate lightweight or hybrid material in the reinforcing component^{88,89} appear to have a promising future.

Finally, we must point out that the complication rates that have been recorded are not what one might expect from a technique that leaves material in the peritoneal cavity. There are even some articles that describe the use of polypropylene mesh with no added protection and without higher complication rates.⁹⁰ Other studies, however, warn that its use in this area is not appropriate.⁹¹⁻⁹³ There are no definitive studies of this topic. From a monetary viewpoint, DCPs are expensive, but no more so than the materials used

in other specialties. For example, a reinforcement measuring 20×25 cm is priced at 1000 to 1200 euros, although this sum may vary according to the agent and manner of purchase.

Conclusions

The surgeon who enters the world of DCPs for the first time goes deep into a labyrinth and may feel lost among the many available options. Experimental and clinical studies have shown that these dual-layer patches are effective and safe. However, there are no powerful, evidence-based data to show which is the best, and therefore the choice rests on the surgeon's opinion alone at this moment. As we wait for long-term studies and randomised trials, it seems sensible to recommend the DCPs that are the most widely-used and best known. These are, in alphabetical order: Bard Composix,

Table 3 – Clinical investigations

	Method	Cases	DM	BC	PtxC	PtnC
LeBlanc, 1993 ⁵⁰	Lap	5	X(v)			
Heniford, 2000 ⁵¹	Lap	100	X			
Carbajo, 2000 ⁵²	Lap	100	X			
LeBlanc, 2000 ⁵³	Lap	100	X			
Balique, 2000 ⁵⁴	Lap/Om	80			X	
Heniford, 2000 ⁵⁵	Lap	407	X			
Crisos, 2000 ⁵⁶	Om	52	X			
de María, 2000 ⁵⁷	Om/Lap	39	X			
Moreno Egea, 2001 ⁵⁸	Lap	20			X	
Parker, 2002 ⁵⁹	Lap	50	X	X		
Aura, 2002 ⁶⁰	Lap	86	X			
Ben-Haim, 2002 ⁶¹	Lap	100	X (v)			
Moreno-Egea, 2002 ⁶²	Lap	55			X	
Cobb, 2003 ⁶³	Om	95		X		
Heniford, 2003 ⁶⁴	Lap	850	X			
Díaz, 2004 ⁶⁵	Om	55	X			
Ammatur, o 2004 ⁶⁶	Om	26			X	
Balique, 2004 ⁶⁷	Lap/Om	80			X	
Lermite, 2004 ⁶⁸	Om	26			X	
Moreno-Egea, 2004 ⁶⁹	Lap	86			X	
Denué, 2005 ⁷⁰	Om	52			X	
Edwards, 2005 ⁷¹	Lap	65	X	X		
Yavuz, 2005 ⁷²	Lap	150	X	X		X
Topart, 2005 ⁷³	Lap	146	X			
Morales-Conde, 2005 ⁷⁴	Lap	146	X			
Olmi, 2006 ⁷⁵	Lap	178			X	
Johanet, 2006 ⁷⁶	Lap	222			X	
Hadi, 2006 ⁷⁷	Om	51		X (v)		
Beldi, 2006 ⁷⁸	Lap	49				X
Lomanto, 2006 ⁷⁹	Om/Lap	100			X	
Chelala, 2006 ⁸⁰	Lap	400			X	
Cobb, 2006 ⁸¹	Lap	120	X			
Stickel, 2007 ⁸²	Lap	62	X			
Bernard, 2007 ⁸³	Om	61		X		

(v) indicates variant; BC, Bard Composix; DM, Dual Mesh; Lap, laparoscopic method; Om, open method; PtnC, Parietene Composite; PtxC, Parietex Composite.

DualMesh and Parietex, and Parietene Composite. Proceed may also be heading toward an important role. Lastly, it is very important that all groups using these patches publish the results from their studies, as well as any adverse effects that may arise.

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