Clinically available reinforcing materials for soft tissue reconstruction

Abstract

Navigating the rapidly evolving field of materials for soft tissue reinforcement is challenging given the volume of clinically available options. Additionally, the current generally accepted classifications of these mesh materials confound the understanding of their utility by grouping disparate materials that have attributes overlapping category boundaries and that do not fully consider their clinically functionality. This review article highlights, from a materials science perspective, the most important attributes of these materials to improve the clinical decision-making process in the selection of the most appropriate features and design for the patient, surgery and clinical need. These characteristics include the physical attributes that directly impact the surgical procedure and immediate postoperative mechanical requirements as well as the post-implantation properties such as an adequate reinforcement time, strength of the resulting tissue and infection risk profile.

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Introduction

The clinically available technologies for surgical repair and reinforcement of soft tissues are varied and rapidly changing. Often these materials are used interchangeably within broad, ill-defined categories. This review article highlights, from a materials science perspective, the important clinical attributes and post-implantation properties of these materials to improve the clinical decision-making process in the selection of the most appropriate features and design for the patient, surgery and clinical need.

Soft tissue reinforcement materials

Sheet materials, or meshes, are used to reinforce soft tissue for a wide range of plastic and reconstructive procedures. Although first introduced for hernia repairs, the technology has evolved and uses have expanded to other indications. In addition to hernia repair and complex abdominal wall reconstruction (Garvey et al, 2017), they are approved and used widely across Europe for submuscular breast reconstruction and more recently in prepectoral breast reconstruction (Eichler et al, 2017; Mazari et al, 2018; Scheflan et al, 2018). Other reported uses include correction of synmastia (Maxwell and Gabriel, 2011; Becker and Lind, 2013), chest wall reconstructions (Raz et al, 2017), diaphragmatic reconstructions (Bassuner et al, 2017), lower eyelid cicatricial ectropion repair (Barmettler and Heo, 2017), and head and neck reconstructions (Tracy et al, 2014).

Following the industrialisation of medical plastics after World War II, meshes derived from permanent synthetic polymers were introduced (Read, 2004). This was followed by the degradable synthetics, beginning most notably with sutures made from polyglycolic acid (PGA) in the early 1970s, and then subsequently meshes (Read, 2004). In the early 2000s, soft tissue repair devices derived from processed human or animal tissues were introduced as alternatives (Cornwell et al, 2009). More recently, degradable synthetics with slower resorption times than PGA have been rebranded as biosynthetics or bioresorbables and marketed for similar applications (Petro and Rosen, 2018).

Several authors have attempted to catalogue existing mesh materials (Cornwell et al, 2009; Smart et al, 2012; Deeken and Lake, 2017), but an exhaustive review is challenged by the large quantity of available devices (including many which have entered and left the market or lost favour), as well as the limited clinical data comparing them in any specific application. With an overwhelming list of options, it is human nature to attempt to reduce the complexity by categorisation and simplify the decision process. Unfortunately, most mesh classification systems are not based on clinically relevant parameters, with convenient impractical features

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driving product grouping. In academia, there is often a desire to preclude the use of brand names in published literature, with positive or negative outcomes being broadly applied to an entire category regardless of the true applicability. This review discusses the available information on materials for reinforcing soft tissue reconstructions from a materials science perspective, with an emphasis on clinically relevant and definable characteristics. Key examples of well-known materials with product names will be used to highlight these characteristics.

Existing classification

Sheet materials for reinforcing soft tissues are broadly classified by regulatory agencies as meshes for soft tissue reinforcement and have similar cleared indications. Materials within this group are commonly categorised in the literature as synthetic, biosynthetic, biologic, or hybrid, as summarised in Table 1.

Synthetic meshes

Synthetic meshes are then defined as materials made from permanent vs hydrolytically unstable polymers, mostly derived from petrochemicals. These plastic meshes can range in porosity and mechanical properties, from macroporous knitted polypropylene (Prolene, Ethicon), to microporous expanded polytetrafluoroethylene (Gore-Tex, Gore Medical), and may even contain adhesion-reducing barrier membranes (Deeken et al, 2011a,b).

Biosynthetic meshes

Biosynthetic meshes are derived from hydrolytically unstable polymers. These mostly aliphatic polyesters have long molecular chains that, in an aqueous environment, are

Table 1. Current mesh classification, by material source

			Physical properties		Post-implantation properties	
Types	**Definition**	**Origin**	**Porosity**	**Strength**	**Mechanism of change**	**Biologic response**
Permanent synthetic	Non-absorbable synthetic polymers	Typically high molecular weight, long chain polymers created by synthetic polymer chemistry	Non-porous to macroporous	Highly variable, potential strong anisotropy	None, hydrolytically and enzymatically stable	Variable, typically foreign body encapsulation and potential contraction
Degradable synthetic or biosynthetic	Absorbable synthetic polymers	Long chain polymers, typically polyesters (polyglycolic acid, poly-4-hydroxybuturate), assembled via synthetic polymer chemistry	Microporous to macroporous	Highly variable, potential strong anisotropic	Degradation, hydrolytically unstable (occasionally accelerated enzymatically)	Variable by biochemistry, porosity, and rate of hydrolytic degradation, typically inflammatory with fibrous encapsulation
Biologic	Extracellular matrix biopolymers	Primarily collagen derived from processed human or animal tissue preserved in its native architecture	Microporous to macroporous	Highly variable, typically low-to-moderate anisotropy	Remodeling, active via cell-derived enzymatic processes, hydrolytically stable	Highly variable by biochemistry, processing and physical characteristics. Can be rapidly resorbing, encapsulated or gradual assimilation
Hybrid	Combination of two of the above	Combination of the above	Combination of the above	Combination of the above	Combination of the above	Combination of the above

By the common mesh classification, grouped materials share similar origin or manufacture, but are otherwise disparate, with clinically relevant features such as physical properties and post-implantation properties often overlapping with other groups.

broken down or degraded into smaller molecules that can eventually be excreted (Petro and Rosen, 2018). Similar to permanent synthetics, these degradable mesh materials can range in porosity, mechanical strength and physical characteristics, with hydrolytic degradation times that range from months to years (Petro and Rosen, 2018).

Biologic materials

Biologic materials are those derived from processed or treated human or animal tissues, better termed extracellular matrix biomaterials (Cornwell et al, 2009). While the term 'biologic' in a regulatory connotation refers to substances with a biological origin and metabolic mode of action, surgical meshes of biological origin are almost always 'medical devices' that augment native tissue or organ structure and function without a metabolic mode of action. The physical and post-implantation properties of biologic meshes are dictated by the species and characteristics of the source tissue, as well as the processing methodology. These predominantly collagen-based materials are hydrolytically stable and are enzymatically modifiable by host cells, and therefore neither persist like permanent synthetic meshes nor degrade like biosynthetics (Cornwell et al, 2009). The timeframe of persistence can range from rapid degradation within weeks (eg Veritas, Baxter) to very little degradation (eg Permacol, Covidien) (Melman et al, 2011). Turnover of biologic meshes can be catabolic (with degradation and resorption leading to net loss of mesh material, strength and volume), or anabolic (with newly synthesised host tissues replacing the matrix to retain strength and volume to varying degrees based on various host and implant site conditions) (Cornwell et al, 2016).

Hybrid meshes

Hybrid meshes combine a synthetic polymer, either permanent or degradable, with a processed animal tissue. There is little published information on these materials (Melman et al, 2011), but their features are likely to comingle the positive and negative characteristics of the individual materials combined.

Limitations of existing classification systems

The major limitations of this existing categorisation system are that it is assumed that within each category, group members have clinical features and benefits that are distinct from the other groups; but also, within any category, it is often assumed that the clinical features and benefits are the same. Unfortunately, neither assumption is completely accurate. Some materials have similar features that cross categories. For example, some devices classified as biologic mesh (SurgiSis, Cook) degrade and are resorbed on a timescale akin to a short-term degradable synthetic polyglycolic acid mesh (Vicryl, Ethicon) (Rice et al, 2010). Conversely, some degradable synthetics (eg Phasix, Bard) encapsulate and contract while remaining in the body for up to 3 years, yielding a biologic response more akin to permanent synthetics (Martin and Williams, 2003; Petro and Rosen, 2018). Within categories, materials may have very different features. For example, within synthetic meshes the porosity and strength profiles can vary dramatically (Deeken et al, 2011a,b; Klinge et al, 2012). Similar disparities exist among biologic meshes, making broad assumptions about their performance as a group problematic.

Key soft tissue reinforcement material characteristics are summarised below.

Physical properties

The physical properties of mesh materials are defined by their underlying material chemistry, manufacture and design. These devices all share similarities with fabrics, whereby the type of fibre and organisation of those fibres ultimately dictates the attributes, following fundamental principles of material science where microstructure explains material properties.

Permanent or degradable synthetic polymers can be formed into fibres and subsequently into fabrics. The strength of the underlying polymer supports the manufacture of thin filaments that can be woven, knitted or braided (Prolene or Vicryl, Ethicon). Therefore these materials are usually thin sheets, with the pore size controlled by design and spacing of the fibres to balance strength, flexibility and minimisation of the foreign material (Rastegarpour et al, 2016). However, some synthetics are extruded, electrospun into fibrous mattes, or expanded into sheets

leading to microscopic pores and in some cases increased thickness (Gore-Tex and Gore Bio-A, Gore Medical). This engineered fibre organisation delineates the macroscopic mechanical properties of the mesh, often with specific anisotropic strength, stiffness, tear resistance and suture retention characteristics (Table 2). The shape, area and overall size are limited only by design, with small and large sheets as well as pre-cut shapes for specific applications.

Despite the commonly held belief of being weaker, extracellular matrix biomaterial properties encompass a similar range of strength, thickness and mechanical property profiles as permanent or degradable mesh materials (Table 2). However, they are all composed of predominantly fibrillar collagen, preserved in its native organisation and structure following processing and decellularisation (Cornwell et al, 2009). The material properties, including thickness, dimension, strength and tear resistance, are then dependent on the source or origin of the processed tissue including species, tissue type and age, and the preservation of these properties by the manufacturing process. The framework for design is then restrained by the source. For example, smaller source tissues, such as bovine pericardium (Veritas, Baxter), can limit the available size and thickness of devices, or may require layering and lamination into

Table 2. Examples of physical properties by common classification

					Mechanical properties			
Category	**Example**	**Material**	**Porosity**	**Thickness (mm)**	**Suture retention strength (N)**	**Tear resistance (N)**	**Uniaxial tensile strength (MPa)**	**References**
Permanent synthetic	Entire category	Variable	Non-porous, micro, and macro	0.16–0.73, 2*	20–90	14–54	0.08–16	Deeken et al (2011a), Deeken and Lake (2017)
	Prolene	Polypropylene	Macro	0.53	61.2 (L), 70.49 (T)	33.66 (L), 39.33 (T)	0.76 (L), 16.06 (T)	
	Ultrapro	Polypropylene with poliglecaprone-25	Macro	0.50	15.08 (L), 16.74 (T)	10.47 (L), 5.07(T)	13.52 (L), 0.08 (T)	
Degradable synthetic	Entire category	Variable	Micro and macro	0.07–1.57	40–60	16–33	0.2–7	Deeken and Matthews (2013), Deeken and Lake (2017)
	Bio-A	PGA/TMC	Micro	1.57	45	16.6	4.5	
	Phasix	P4HB	Micro	0.51	59.2 (L), 49.1 (T)	30.3 (L), 29.5 (T)	4.25	
Biologic	Entire category	Variable	Micro and macro	0.47–4.5	20–150	10–85	2–20	Adelman et al (2014), Deeken and Lake (2017)
	SurgiMend	Fetal/neonatal bovine dermis	Micro	~1.0	87.85	27.86	18–28	
			Micro and macro	~2.0	112.36	50.95		
			Micro	~3.0	153.02	86.89		
			Micro	~4.0	>153, exceeds test limits	100.02		
	Strattice	Porcine dermis	Micro	1.76	63.76	27.54	9.92	
	Permacol	Crosslinked porcine dermis	Micro	0.91	23.75	10.1	8.22	
Hybrid	Ovitex	Ovine rumen and polypropylene or PGA	Micro	0.9–1.6	~42	n/a	n/a	Deeken and Lake (2017)

**generally thin, with the exception of Goretex and Gore Dualmesh (up to 2 mm). L = longitudinal; n/a = not available upon search of peer-reviewed literature or corporate marketing materials; P4HB = poly-4 hydroxybuturate; PGA = polyglycolic acid; T = transverse; TMC = trimethylene carbonate.*

larger sheets as occurs with products from porcine intestinal submucosa (Biodesign, Cook) or porcine urinary bladder (Gentrix, Acell) (Deeken et al, 2012; Rastegarpour et al, 2016). Larger sizes are available from dermal sources, with options thicker than 2–3 mm currently only available from bovine dermis (SurgiMend, Integra LifeSciences) (Cornwell et al, 2009).

The mechanical properties of strength and stiffness are directly correlated with the organisation and alignment of the collagen fibre network of the source tissue, rather than the processing methodology. A study using synchrotron-based small-angle X-ray scattering to investigate collagen fibre organisation of extracellular matrix biomaterials derived from the dermis of three different species found significantly increased tear resistances and suture retention strengths in bovine and human dermis, compared to porcine dermis, that were correlated to a strongly bimodal and isotropic distribution of fibres in porcine dermis (Wells et al, 2015). Additionally, increasing thickness of an extracellular matrix biomaterial is correlated with increased load-bearing capacity (Adelman et al, 2014) and should be considered for more challenging surgical applications (Clemens et al, 2013).

Processing and decellularisation can alter material characteristics; for example, lyophilisation of materials for long-term shelf-stable storage may also increase matrix porosity as a result of ice crystal sublimation. However, some processing steps, such as chemical crosslinking (eg porcine dermis, Permacol, Covidien), have not been shown to increase the initial strength of these biomaterial significantly (Deeken et al, 2012; Dunn, 2012), but may adversely affect their biocompatibility. With better understanding of these inherent material properties, newer versions of extracellular matrix biomaterials have been introduced with designs tailored to surgical techniques. Examples include thicker versions with a multitude of perforations for a macroporous design (for enhanced fluid flow), as well as 2:1 meshed configurations that can expand to cover larger areas with improved conformability over convex shapes (Figure 1).

Post-implantation properties

The second major consideration for a soft tissue reinforcement device involves understanding what happens to the material following implantation. The key attributes affecting this behaviour include the biochemistry of the underlying material(s) and inflammatory profile,

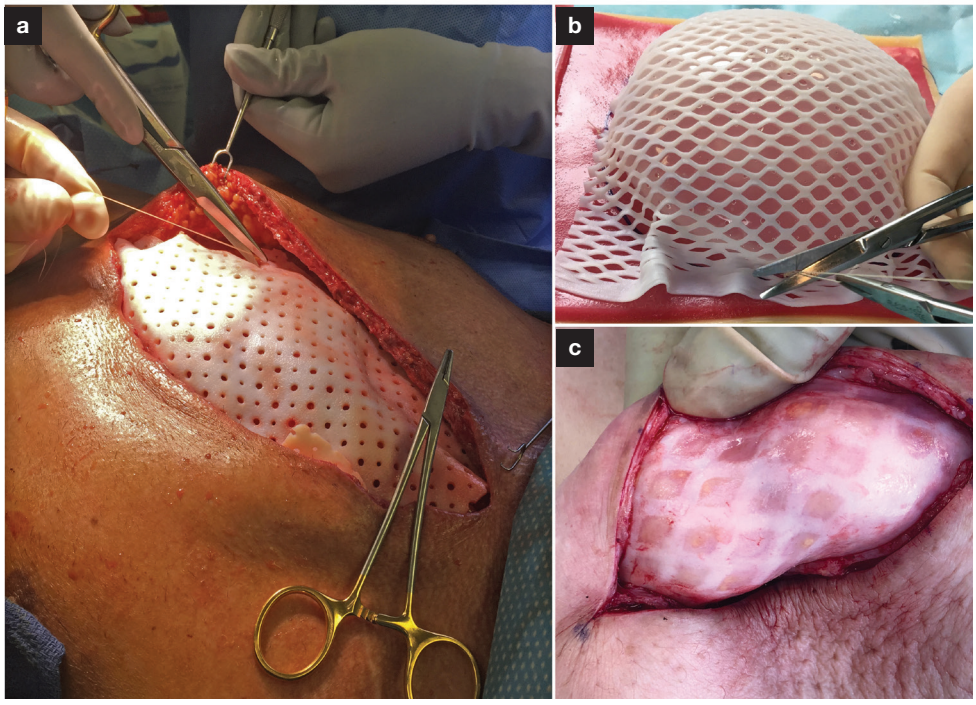

Figure 1. Novel configurations of extracellular matrix biomaterials with physical attributes often associated with synthetic or degradable synthetic materials including macroporous designs. a. SurgiMend MP in a chest wall reconstruction. b. SurgiMend PRS Meshed expanded 2:1 with increased conformability. c. Expanded SurgiMend PRS Meshed adherent to a mastectomy skin flap following 4 months implantation.

the mechanism of transformation (encapsulation or contraction, degradation, remodelling or assimilation), the porosity and the mechanical stiffness. All these attributes eventually affect material behaviours under normal conditions, but also differ in the presence of microbial contamination, infection or digestive fluids.

Biochemistry and inflammatory profile

Three generally recognisable pathways have been described for the host following implantation of soft tissue repair devices: foreign body encapsulation, degradation or absorption, and remodelling or assimilation.

Encapsulation

The classic foreign body response is experienced with most permanent synthetic materials, metals and ceramics, and well-reviewed elsewhere (Anderson et al, 2008). In brief, it involves the traditional wound healing cascade leading to an accumulation of macrophages that fuse to form foreign body giant cells with the intent to phagocytise the object (Anderson et al, 2008). When the giant cells are unable to consume and remove the material, they recruit fibroblasts and ultimately wall off the implant with a fibrous capsule (Anderson et al, 2008). Within this capsule surrounding the foreign body, fibroblasts can differentiate into myofibroblasts and begin to contract and squeeze the implanted device.

With silicone breast implants, this phenomenon is recognisable as capsular contracture, which can progress to explantation to treat aesthetic deficits and pain.

With porous, non-degradable materials for soft tissue reinforcement, the fibrous encapsulation surrounds the individual fibres of mesh. If the myofibroblast contraction is strong, or the mechanical resistance of the mesh to the forces are weak, the mesh can contract and in some cases begin deforming (Gonzalez et al, 2005). This is sometimes confusingly referred to in the literature as 'tissue ingrowth' (Gonzalez et al, 2005), because the collagen tissue wraps the fibres in porous constructions. However, the resultant scar tissue is asymmetric and circumferential to the individual fibres, rather than a uniform laminar structure like fascia or aponeuroses (Figure 2). Therefore, the strength and sustained reinforcement of the soft tissue is provided by the polymer, not the generated fibrous tissue. With non-porous materials, or some cross-linked extracellular matrix biomaterials, the fibrous tissue deposition is typically limited to a peripheral encapsulation of the device, as the pore structure does not support cell penetration into the device (Dwyer, 2006; Broderick et al, 2012).

Absorption

The second response is absorption, and is seen with some degradable polymers and rapidly degrading extracellular matrix biomaterials. Like the classic foreign body response, early inflammation is followed by macrophage accumulation in and around the material (Figure 2). However, as the material degrades, increased chronic inflammation persists, associated with an increased microvascular network and phagocytosis of the polymer fragments, leaving behind 'only loose granulation tissue with low collagen content and many infiltrating leukocytes, histocytes, and giant cells' (Laschke et al, 2009). In essence, the material is

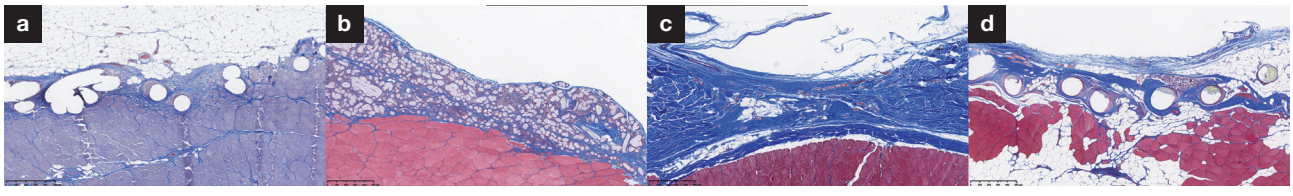

Figure 2. Histological images of the various materials stained with Masson's trichrome in a small animal model of muscle reinforcement at 12 weeks. a. The classic foreign body response can be observed with fibrous encapsulation of macroporous polypropylene mesh (Prolene) including foreign body giant cells and loose collagen surrounding the polypropylene circumferentially. b. The electrospun matte fibres of the remaining polyglycolic acid/trimethylene carbonate mesh (Bio-A, Gore) are seen surrounded by macrophages and giant cells in the process of phagocytosing the particles of the degrading polymer. c. Aligned, fibrillar collagen is being deposited with the large pore of a macroporous extracellular matrix biomaterial (SurgiMend MP, Integra LifeSciences), occurring in the absence of a foreign body encapsulation response. d. Although ultimately degrading and absorbing, the macroporous poly-4-hydroxybuturate is still present at 12 weeks and the polymer fibres are circumferentially encapsulated with loose collagen being deposited to wall off the material, similar to the classic foreign body response seen with permanent synthetic mesh.

degraded, either hydrolytically or enzymatically, with the byproducts metabolised and little substantive tissue remaining (Hwang et al, 2007; Peeters et al, 2013; Carey et al, 2014).

The length of time for maintenance of strength, degradation and complete absorption can vary widely from weeks to years based on the biochemistry of the hydrolytic degradation process with absorbable synthetic polymers or the processing methodology of the extracellular matrix biomaterial, especially where the latter retains inflammatory, non-collagenous components of the source tissue or otherwise damages or denatures the source collagen.

The organisation and collagen content of the loose granulation tissue following resorption can be different among materials, but remains weak overall and is typically incapable of maintaining structural domain. Long-term resorbable polymers (eg Phasix, Bard or TiGR, Novus Scientific) appear to follow the same process, albeit delayed, with an extended early phase mimicking the classic foreign body encapsulation response followed much later by the degradation response (Deeken et al, 2013; Martin et al, 2013; Peeters et al, 2013). A porcine study of soft tissue reinforcement with slow resorbing synthetic mesh (Phasix, Bard) showed extended strength maintenance followed by a return to baseline strength after polymer degradation, indicative of a delayed but otherwise typical degradation response (Martin et al, 2013).

Remodelling or assimilation

The third possible response is a remodelling or assimilation process that is seen with well-processed, non-crosslinked extracellular matrix biomaterials. This process includes early inflammation and revascularisation of the matrix, but is absent of chronic inflammation (Cornwell et al, 2009, 2016; Adelman and Cornwell, 2018). The matrix is ultimately repopulated with predominantly fibroblasts along with some macrophages and histocytes, and the matrix is very slowly enzymatically broken down concomitant with new collagen deposition (Cornwell et al, 2016). In the absence of the foreign body response or chronic inflammation, the fibroblasts within the matrix can respond to the mechanical loading environment, a well-known and strong stimulus of aligned collagen deposition, to lay down organised, isotropic fibrous connective tissue. The strength of this generated tissue can provide sustained, durable reinforcement of soft tissue (Garvey et al, 2017; Scheflan et al, 2018).

Additionally, while independent of vascularity in strongly inflammatory materials, the rate of revascularisation in the assimilation process seen with low-inflammatory materials appears dependent on the vascularity and approximation to de-epithelialised host tissue (Adelman and Cornwell, 2018). The insertion of larger diameter perforations or macroporous extracellular matrix designs have been demonstrated to increase the rate of revascularisation and host cell repopulation as well (**Figure 3**, DM Adelman, KG Cornwell, unpublished data, 2018).

Post-implantation properties with infection

Unlike the idealised descriptions of the post-implantation properties described above, in the presence of significant bioburden or when an infection occurs, each of the materials may behave differently and pose different risks. Synthetic polymers harbour infections by accumulation and formation of a biofilm on the surface of the polymer (Sanchez et al, 2011). While not common in clean surgical procedures, when synthetic polymer mesh does become infected, the treatment often requires surgical removal of the mesh with devastating consequences as a result of the need to excise large areas of tissue (Hawn et al, 2011; Sanchez et al, 2011; Vagholkar et al, 2016). With degradable synthetic polymers, the risks appear similar until the material is degraded and absorbed and therefore can vary by the absorption time (Sahoo et al, 2017; Stoikes et al, 2017).

With these permanent or degradable synthetic meshes, macroporous meshes may be better designed for reducing this complication because there is more empty space between fibres and less total polymer introduced overall (Klinge and Klosterhalfen, 2012). Extracellular matrix biomaterials are collagen based and in the early phase can break down in the presence of certain bacteria, or as collateral damage during the host response to the infection. Areas of degraded material are no longer able to reinforce, but reoperation to remove the material is typically unnecessary as any secondary procedures required can be accomplished with the original mesh in situ (Garvey et al, 2014). Extracellular matrix

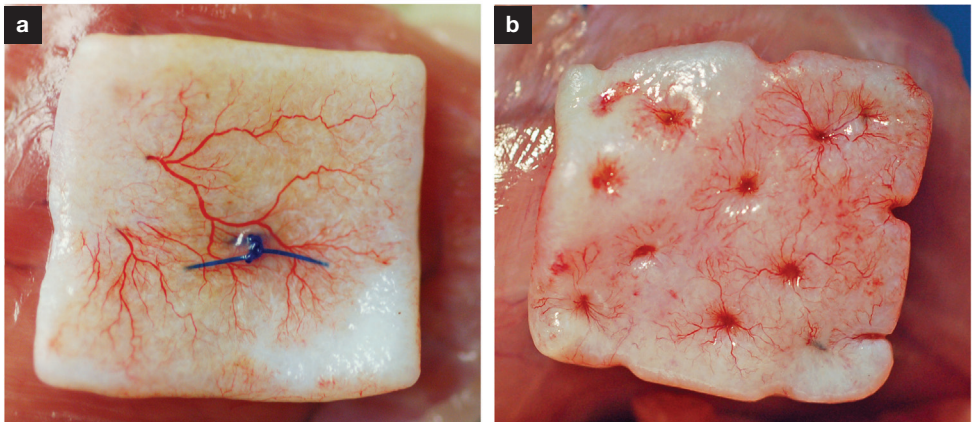

Figure 3. Similar to other categories of reinforcing materials, the revascularisation is affected by porosity, with (a) a microporous extracellular matrix biomaterial at 10 weeks in an intra-abdominal implant model and (b) the same material with large perforations on the right at 4 weeks.

mesh degradation is rarely seen in later phases once revascularisation of extracellular matrix biomaterials has occurred.

Conclusions

Although the classic soft tissue reinforcement categories are potentially problematic for clinical decision making, they are engrained and unlikely to depart soon. Regardless, evaluation of these materials should be individual, not categorical, and based on considerations relevant to the patient and procedure. Key characteristics therefore include the strength profile to match the surgical demands, available size and configuration to match the procedure, an adequate length of reinforcement time, strength of the resultant tissue, and an infection risk profile to match the patient's needs.

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Figure 1a is reproduced courtesy of Ernesto Hayn, MD

Conflicts of interest

Dr KG Cornwell and Dr C Bret Jessee are employees of Integra LifeSciences, Dr DM Adelman is a research advisor and consultant for Integra LifeSciences.

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Key points

- Materials used to reinforce soft tissues are commonly categorised as synthetic, biosynthetic, biologic or hybrid.
- Their physical properties are defined by the underlying material chemistry, manufacture and design.
- It is important to consider properties affecting post-implantation behaviour when selecting a soft tissue reinforcement device.

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