Which mesh or graft? Prosthetic devices for abdominal wall reconstruction

This article reviews the ever-increasing number of prosthetic devices – both synthetic mesh and biologic grafts – now in use for abdominal wall reconstruction. It also introduces a novel hybrid synthetic/biologic graft (Zenapro) and suture passer device (Novapass).

Despite the growing use of laparoscopy for many cases of intra-abdominal pathology, abdominal wall hernia remains one of the most challenging clinical problems for general surgeons. Hernia development can be primary from de novo defects of the abdominal wall, but more commonly this is acquired from prior abdominal surgery. While hernias may remain asymptomatic, over time patients can develop symptoms of chronic abdominal discomfort and a noticeable bulge. In severe cases, patients may present with acute incarceration of intra-abdominal contents leading to bowel obstruction. A combination of patient characteristics, severity of the defect and overall skill set of the surgeon often dictates the type of repair offered when surgery is indicated.

Historically, abdominal wall reconstruction involved primary suture repair of the abdominal wall defect under tension. Unfortunately, these repairs were associated with an unacceptably high recurrence rate. The introduction of prosthetic mesh implantation improved the recurrence rate, but there was a trade-off as mesh-related complications arose. The delicate balance between the desired clinical effect and avoidance of therapeutic harm has resulted in a significant evolution in the number and types of prosthetic materials available for abdominal wall reconstruction. There has also been a rapid increase in surgical approaches to abdominal wall reconstruction, including laparoscopy, robotics, open and hybrid. As stated by Bringman and colleagues (2010), 'surgical repair of hernias is one of the most common operative procedures performed, and there is no single gold-standard operative technique in hernia repair.' The varying approaches to abdominal wall reconstruction are covered in a separate article by Stylianides and Slade (p. 151).

Currently, there are over 200 options for prosthetic materials available to the general surgeon for abdominal wall reconstruction, all with varying composition, weight, cost and indications for use in the surgical field (Robinson et al, 2005; Le et al, 2013). Selecting the 'right mesh' for a patient can be a complex process – one size does not fit all. This article reviews the currently available mesh and grafts, discusses the clinical scenarios where use is indicated, and introduces a novel hybrid synthetic/biologic hernia device: Zenapro (Cook Medical, Bloomington, Indiana).

History of hernia biomaterials

To understand how we have come to the current state of having over 200 available prosthetic materials for abdominal wall reconstruction, it is helpful to look briefly at the history of hernia biomaterials. Before 1958, primary suture repair was the most common approach for abdominal wall reconstruction. FC Usher et al (1958) described the first use of synthetic mesh (Marlex), which was composed of high density polyethylene fibre. This material was initially shown to have a reasonable interaction with human tissue as well as markedly reduced recurrence rates (Usher et al, 1958; Patt, 1967). This standard Marlex mesh was used almost exclusively from 1958–62. The concept of 'tension-free' repair was popularized at this time, and the replacement of Marlex with polypropylene in 1962 offered a more malleable and heat-resistant solution (Usher, 1962). Around the same time, Stoppa and colleagues introduced polyester as another option in hernia repair, with claims of potentially improved post-implantation infection rates (Stoppa et al, 1975).

Polypropylene and polyester remained the two dominant mesh options until 1985, when expanded polytetrafluorethylene emerged as the third option, with some initial reports of improvement in adhesion formation (Bauer et al, 1987). Since 1985, various alterations of these three dominant materials have made up the backbone of the currently available synthetic materials. Modifications include, but are not limited to: weight, pore size, density, ability to biodegrade, and addition of composite adhesion or antimicrobial barriers (Zogbi, 2011). These modifications are highlighted in the following sections.

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Table 1. Classification of synthetic mesh-associated complications

Early	Late
Cellulitis 7%	Recurrence 17%
Ileus 8%	Infection 6%
Wound drainage or seroma 3–4%	Bowel obstruction 5%
	Enterocutaneous fistula 3.5%

What is the difference between a mesh and a graft?

The first tissue-based implant composed of porcine intestinal submucosa for use in abdominal wall reconstruction was approved in 1998 (Franklin et al, 2002). Subsequently, many other options became available and the era of biologics began. Because of these developments and increased clinical use, the important distinction between synthetic 'mesh' and biologic 'graft' should be clarified when discussing hernia materials. Generally speaking, the term mesh refers to all synthetic materials while graft refers to materials derived from animal (xenograft) and human (allograft) tissue.

Considerations when choosing between a mesh or graft

Choosing the right implant for the clinical scenario is a balance between patient factors such as comorbidities and cleanliness of the surgical field, and device-related factors such as weight, porosity and resistance to infection. It is also important to consider the desired outcome of an effective repair, low risk of complications, optimal quality of life and cost-effectiveness. Each of these aspects must be carefully considered when choosing between a mesh and a graft.

Early and ongoing modifications to synthetic materials are largely in response to increased rates of device-related complications, classified as early (<1 month) and long term (>1 month) (*Table 1*). Infection remains the most challenging complication of synthetic grafts and is associated with increased morbidity, health-care costs, and possibly increased need for future interventions (Brown et al, 2013).

Increasingly, quality of life is also being measured in patients undergoing abdominal wall reconstruction. While hernia recurrence is an important measure, chronic pain and decreased patient mobility also need careful monitoring. Chronic pain may result, either caused by device-related inflammation or infection, which may ultimately impair a patient's mobility (Bay-Nielsen et al, 2001; Novitsky, 2013).

Finally, overall cost must be weighed when selecting an appropriate device for abdominal wall reconstruction. There is a wide range of cost for various devices, with a general trend toward much higher costs for biologic *vs* synthetic materials. If two materials with vastly different prices offer comparable outcomes both in terms of hernia recurrence and the patient's quality of life, the less expensive option should be considered as the more valuable choice. That said, complications from abdominal wall reconstruction such as infections, readmissions and recurrence may lead to further operations and an overall increase in health-care costs. Poulose et al (2012) estimated that a 1% reduction in hernia recurrence could result in annual savings of $32 million.

To help assist clinicians with general clinical guidelines, the ventral hernia working group (VHWG) developed a grading system in 2010 to assist with mesh choice in various clinical scenarios. Patient characteristics and clinical scenarios were graded from 1–4, with grade 1 being low-risk patients in a clean environment while grade 4 scenarios were situations involving grossly infected fields. Grades 2 and 3 are cases with varying levels of patient comorbidities and contaminated surgical fields. The general consensus was to use permanent synthetic material in grade 1 and some grade 2 cases, with strong consideration for using biologic material in grade 3 and 4 cases (Breuing et al, 2010). Some of these considerations have been challenged, with reports of reasonable outcomes with the use of lightweight, macroporous permanent synthetic mesh in contaminated fields (Carbonell et al, 2014). Based on conflicting reports, an optimal mesh in these challenging cases, namely VHWG grades 2 and 3, remains elusive.

Over 200 to choose from, now what?

Once the above concepts have been considered, the surgeon is ultimately left with a large choice of devices to implant: permanent synthetic, absorbable synthetic or biologic?

Permanent synthetic mesh

Most data examining outcomes of abdominal wall reconstruction with mesh are retrospective, with short-term follow up, and limited variables studied. One exception was the landmark study by Luijendijk et al (2000) in which patients were randomized to undergo either primary suture repair or permanent synthetic mesh implantation. The results favoured permanent synthetic mesh implantation with a statistically significant decrease in hernia rates when compared to primary repair, even at 3 years and beyond.

Despite this favourable outcome with permanent synthetic mesh placement, numerous retrospective cohort studies reported mesh-related complications such as infection and adhesion formation, sometimes with the late development of bowel obstruction and enterocutaneous fistulae (Brown and Finch, 2010). When use of one of the four permanent synthetic meshes was studied in 200 patients, rates of short-term and long-term complications such as infection and recurrence were 18% and 27% of patients respectively (Leber et al, 1998). Among all synthetic mesh used, the most data are available for polypropylene. Multiple modifications including development of macroporous, three-dimensional constructs (i.e. knit, woven), and lighter weight options have been developed to improve rates of ingrowth and infection resistance (Cobb et al, 2009).

Efforts to decrease these complications ultimately led to the development of materials such as expanded polytetrafluorethylene (ePTFE) – a microporous material that prevents tissue in-growth and adhesion formation. Initial reports by Brown et al (1985) suggested that ePTFE was associated with fewer adhesions than polypropylene. The

trade-off with this material was lower tissue incorporation of the abdominal wall and ultimately questionable resistance to infection (Cortes et al, 2008). More recent advances with the various permanent synthetic meshes include added components for adhesion barrier and antimicrobial layers such as polypropylene with omega-3 fish oil, polypropylene with polyglycolic acid and hydrogel, polypropylene with submicron ePTFE, polyester with purified collagen, and polyethylene glycol and glycerol (Butler et al, 2013). These composite devices have been associated with low infection and recurrence rates and comparable hospital stays in clinical studies (Byrd et al, 2011).

These modifications have led to various improvements in mesh-related complications, although long-term outcomes of their use are lacking, with very few comparative studies. Amid (2001) developed a helpful classification system to further characterize various permanent synthetic mesh materials. *Table 2* summarizes this classification system with selected currently available permanent synthetic and composite mesh with associated characteristics.

Absorbable synthetic mesh

Absorbable synthetic mesh, also known as biosynthetic or bioabsorbable, is synthetic material that fully reabsorbs into the patient's tissues, ultimately leaving no foreign material behind. These devices are a scaffold of materials such as polyglycolic acid and poly-4-hydroxybutyrate (P4HB) which provide an environment for tissue in-growth and repopulation of host cells (Jacobsen and Chao, 2010; Ruiz-Jasbon et al, 2014). Advantages of these devices include a large range of sizes, full tissue incorporation, and overall decreased risk of infectious complications, as material will biodegrade over time. On the other hand, there is no long-term tensile strength and these should be used only when primary closure can be achieved. There is a potential advantage in contaminated fields for temporary closure in settings where formal abdominal wall reconstruction would be deferred to a later time (Bilsel and Abci, 2012). A snapshot of currently available absorbable synthetic meshes is shown in *Table 3*.

Biologic grafts

Since 1998, devices composed of extracellular matrices of human (allograft) or animal (xenograft) sources have been available for use in abdominal wall reconstruction (El-Hayek and Chand, 2010). Similar to the concept of absorbable synthetic mesh, these devices provide a scaffold for recipient cellular repopulation and integration into native tissue. Multiple retrospective studies showed safety and feasibility of these devices in standard hernia repair, but at a significant increase in overall cost when compared with synthetic mesh (Rosen et al, 2013). In many instances, these devices have only been approved for use in clean environments, but many studies report on their use in contaminated surgical fields. One study demonstrated reasonable efficacy in contaminated fields after 2-year follow up, but noted infection and recurrence rates of 28% and 30% respectively (Itani et al, 2012).

Table 2. Commonly used synthetic meshes and their characteristics

Types (examples)	Characteristics
Type I (Marlex, Prolene)	Macroporous (pore >75 µm), allow dense cellular infiltration
Type II (soft tissue patch, dual mesh)	Microporous (pore <10 µm)
Type III (Teflon, Mersilene, Sugipro, perforated expanded polytetrafluoroethylene (ePTFE))	Macroporous (multifilament) or microporous, braided polyester, microporous interstices
Type IV (polypropylene, preclude pericardial membrane and preclude dura structure)	Submicronic pores, form adhesion-free composites

Table 3. Currently available synthetic absorbable meshes and their characteristics

Mesh	Characteristics
Vicryl	Polyglactin mesh, tightly woven, less elasticity, degradation in 90 days
Dexon	Polyglycolic acid mesh, braided weave, soft, flexible, used for infected fields, biodegradation over 90 days
Bio A	Polyglycolic acid:trimethylene carbonate, three-dimensional matrix, consists of polymer matrix, flexible, dissolves gradually
TIGR	Copolymer of glycolide lactide and trimethylene carbonate, consists of slow and fast degrading copolymer, initial resorption 4 months, complete resorption 3 years

Emerging long-term data regarding biologic graft use have caused many surgeons to pause before using them in abdominal wall reconstruction. Most notably, the results of use within clean and some contaminated environments have not shown significant improvement in device-related complications compared with synthetic mesh, particularly lightweight macroporous mesh (Carbonell et al, 2014). Enzymatic cross-linking of these materials can result in a similar foreign body reaction as seen in permanent synthetic mesh (Novitsky, 2013), reducing the desired effect of the so-called 'biocompatibility'. Also, as discussed above with absorbable synthetic mesh, biologic grafts will ultimately completely degrade over time. They should therefore be used in a reinforcement setting and not a bridged setting to limit hernia recurrence (El-Hayek and Chand, 2010).

The final consideration in choosing a biologic graft is the markedly increased cost when compared to synthetic mesh. Biologic graft prices range from $16 to $30/cm^2 compared to synthetic mesh prices which range from $2 to $8/cm^2 (Deeken et al, 2012). These increased costs must be justified by an improved outcome and potential avoidance of synthetic mesh-related complications. Selected currently available biologic grafts are highlighted in *Table 4*.

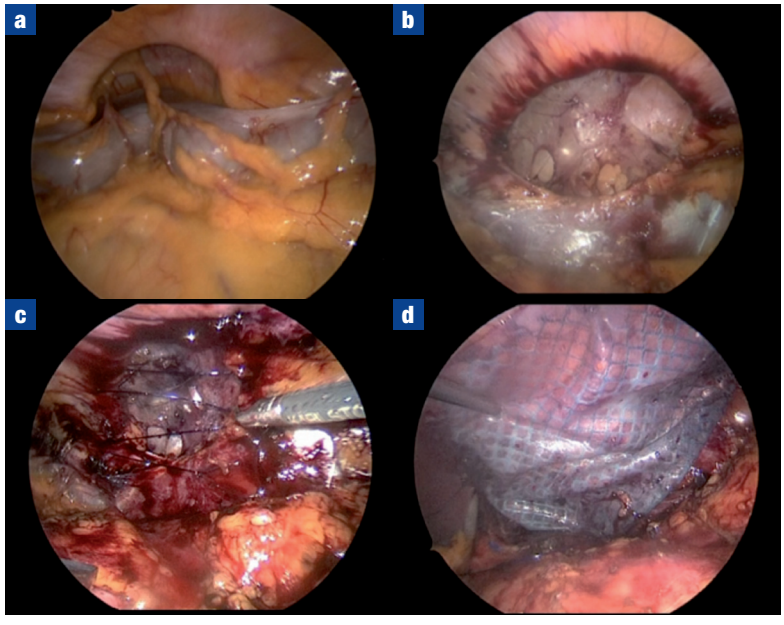
Future products and combination therapies

While products have come a long way since the first use of Marlex in 1958, the ideal mesh for every patient has likely not been produced, nor ever will be. Long-term benefits

Table 4. Available biologic grafts with their characteristics

Biologics	Source	Cross-linking	Sterilization
AlloDerm	Human dermis	No	None
AlloMax	Human dermis	No	Gamma irradiation
FlexHD	Human dermis	No	None
CollaMend	Porcine dermis	Yes	Ethylene oxide
Permacol	Porcine dermis	Yes	Gamma irradiation
Strattice	Porcine dermis	No	Electron beam
Biodesign	Porcine small intestinal submucosa	No	Ethylene oxide
XenMatrix	Porcine dermis	No	Electron beam
Peri-Guard	Bovine pericardium	Yes	Liquid alcohol
Tutopatch	Bovine pericardium	No	Gamma irradiation
Veritas	Bovine pericardium	No	Electron beam
SurgiMend	Fetal bovine dermis	No	Ethylene oxide

Figure 1. **a.** Initial hernia view. **b.** Hernia contents reduced. **c.** Transfascial closure of hernia defect. **d.** Intraperitoneal onlay of Zenapro mesh. From Wathen et al (2014).



of meshes or grafts depending on application are being regularly studied, but to date no one mesh or graft has been shown to have all the characteristics that surgeons would find beneficial. Each patient should be analysed individually to see which product best fits his/her needs; in some cases a combination of products or treatments may be best.

With advances in treatments come advances in technologies. The combination of a mesh and a graft has long been discussed, and to date there is only one device on the market that combines an extracellular matrix of small intestinal submucosa (SIS) or biologic and a permanent synthetic (*Figure 1*)(Zenapro, Cook Medical). This combination is currently being studied in a clinical trial with expected outcomes of 1-year follow up to be available in 2017. Bringing together two technologies has been described in other areas as well with synthetics and hydrogel coatings for minimizing attachment to surrounding viscera.

The future of combining two separate therapies for use could include use of meshes or grafts with a range of different therapies, such as adhesion barriers, patients' cells, blood or platelet therapy, antimicrobials, and other pharmaceuticals, that could benefit patients in the long and short term.

A word about device placement

Mesh placement is described based on its position in relation to the abdominal wall. Onlay placement refers to the most anterior placement, just deep to the subcutaneous tissue and anterior to the rectus sheath. Inlay placement refers to mesh that is sewn to the edges of the fascia in a 'bridge' method. Underlay or intra-peritoneal onlay refers to mesh that is exposed to the intra-abdominal viscera. Retrorectus position describes mesh that is placed within the layers of the abdominal wall, just posterior to the rectus muscle and anterior to the posterior rectus sheath. This mesh is ultimately covered both anteriorly and posteriorly and is not exposed to the skin or intra-abdominal viscera. Ideally, permanent synthetic mesh placement should be limited to onlay or retrorectus placement unless it has a composite anti-adhesion barrier. Composite mesh, synthetic absorbable, biologic and hybrid devices can be placed in any location.

Mesh fixation can be achieved by suture, fixation devices, glue and with self-fixation technology. A new fixation device called Novapass (Cook Medical) provides a curvature that allows passage of sutures through the abdominal wall in an antegrade fashion, and may provide more control than passage from skin to the intra-abdominal position (*Figure 2*).

Future developments

Surgeons and industry continue to work together in an effort to improve outcomes from this common clinical problem. Future developments are aimed at more individualized mesh and graft options such as targeted device integration, drug delivery and combination therapies. Surgical technique is also being refined to increase minimally invasive options, improve patient selection and preparation, and improve submission of cases to database registries for quality control. With such collaboration, the future is bright for patients suffering from abdominal wall hernias.

Conclusions

The number of mesh and graft options for abdominal wall reconstruction continues to grow, with modifications aimed at improving patient outcomes. An ideal mesh should have the following characteristics: strong, inert, resistant to infection, low recurrence rate, high quality of life and good value. Ongoing advancements in techniques and technology will continue to help surgeons tailor the hernia device to the clinical scenario. **BJHM**

Conflict of interest: none.

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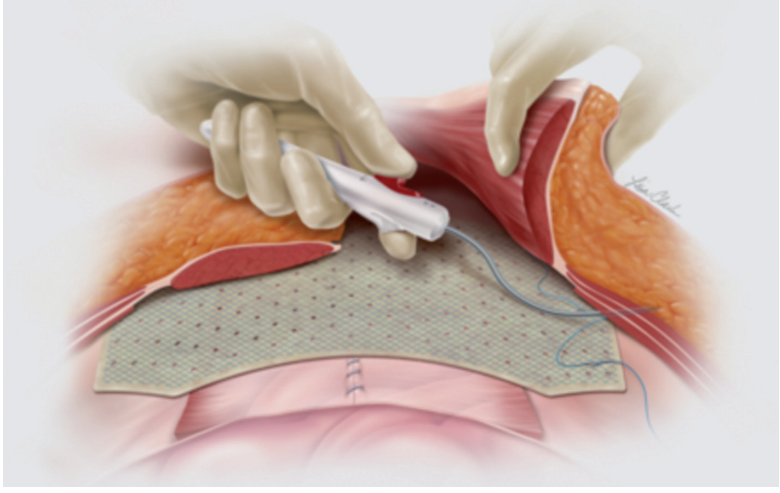
Figure 2. Use of Novapass suture device for mesh fixation.



KEY POINTS

- Current mesh or graft options include permanent synthetic, absorbable synthetic, biologic and hybrid devices.
- No single device has emerged as the optimal choice for every clinical scenario in abdominal wall reconstruction.
- An ideal hernia device should be strong, inert, resist infection, incorporate well into tissues and be cost-effective.
- A novel hybrid biologic and permanent graft (Zenapro) may combine the advantages of both biologic and permanent mesh in complex clinical settings.
- The Novapass suture device offers an alternative method for mesh fixation that may provide more control in suture passage.