Weighing The Options

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Having a basic understanding of the different surgical implants and grafts available—both biologic and synthetic—is the first step to help a surgeon decide which material is right for the patient and procedure.

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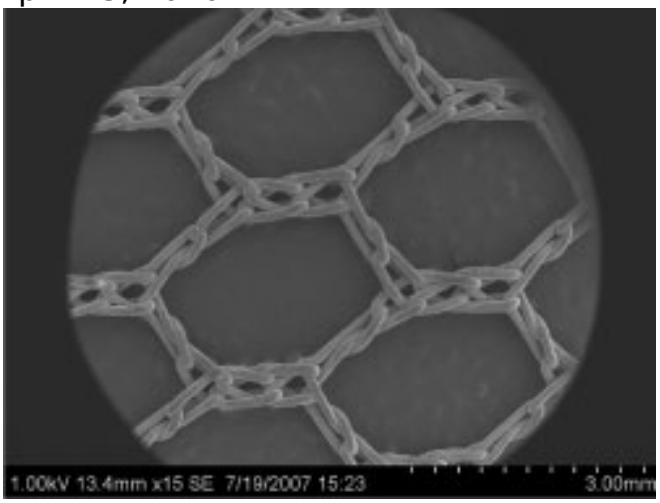


With an array of materials and structures to consider, the options for surgical implants and grafts for surgeons can be “dizzying” at times, says Alfredo M. Carbonell, II, DO, FACS, FACOS, assistant professor of clinical surgery at the University of South Carolina School of Medicine and co-director of the Hernia Center at the Greenville Hospital System University Medical Center in Greenville, SC.

For nearly 50 years, surgical tissue implants and grafts have been the solution for surgeons to replace or augment part of a patient’s body that is weak or defective. Several different options have been developed over the years, and they have largely involved synthetic materials. However, in the last 10 years, biologic materials derived from a human or animal source have emerged, providing surgeons even more options and tougher choices in deciding which material is best for their patient.

Synthetic Options

As Dr. Carbonell explains, synthetic surgical implants have been the standard of care in hernia and soft tissue repair. Historically, these materials have proven to be durable, having been well-researched for years. Still, with a multitude of manufacturers, as well as varying materials and structures, surgeons using synthetic materials still have decisions to make.

According to Tiffany Brown, Ph.D., a product specialist at W. L. Gore & Associates, a manufacturer of synthetic materials, most synthetic options for soft tissue repair are permanent devices used to replace part of the body and remain implanted for

the long-term. In the United States, there are three main base polymers from which permanent synthetic surgical implants are manufactured:

1. Polytetrafluoroethylene (PTFE)
2. Polypropylene
3. Polyester

Each is a polymer with different chemical properties, and each carries slightly different handling characteristics. The materials may heal, look and react differently in each patient's body. Deciding which material or structure is often up to surgeon preference, Dr. Carbonell notes.

Along with being made from different polymers, another consideration for permanent synthetics involves how the structure of the material has been created. As Brown explains, the material can be knitted together or woven. It can also be expanded, which means solid material is taken under very high temperatures and pressure, and made into a material that is much more open and fluffy. If the tissue implant or graft has been knitted or woven, it could be done with a single strand—monofilament—or more than one strand—multifilament.

Depending on the structure of the implant, it may feature different porosity. Pores are simply the holes in the material. As Brown says, a macroporous material typically means the pores can be seen through with the naked eye. Meanwhile, microporous material has smaller pores that can only be seen under a microscope. The porosity of the material is important in terms of whether the patient's tissue can attach to the material once in the body. In a macroporous material, the pores are large enough for cells to grow into, and the patient's tissue can attach to the implant or graft. Meanwhile, a microporous structure prevents tissue attachment. The pores are too small for cells to grow into and adhere. This type of porosity can be useful in instances in which tissue attachment is avoided, such as in hernia repair in which the surgical implant contacts the intestines.

Dr. Carbonell says he mainly uses synthetics in his practice because their durability with good surgical technique has been proven for many years. However, one of the concerns associated with synthetics is potential infection.

"One of the risks associated with any implanted foreign body is that, once it is implanted, bacteria can adhere to the surface of the permanent material and create a biofilm that can hide from antibiotics," says Brown. "Surgeons worry about patients that have a history of infection or presence of bacteria when they're using permanent synthetic material."

Dr. Carbonell adds that often it can be difficult to treat the infection unless the entire graft is removed. Patients particularly at-risk include those who are morbidly obese, have diabetes, take steroids or smoke.

Non-permanant synthetic options have been developed to help combat these infection risks by being partially resorbable or completely bioabsorbable. According to Dr. Carbonell, there are synthetic implants that contain a partially absorbable polymer. After about 90 days, the resorbable component goes away and leaves

behind a light weight skeleton of permanent synthetic mesh that allows for better tissue ingrowth and may be less likely to become infected.

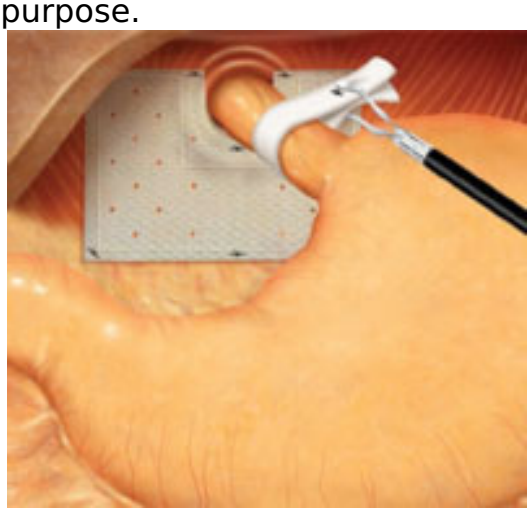
W. L. Gore makes a completely bioabsorbable synthetic 3D tissue scaffold that utilizes the bioabsorbable polymers polyglycolic acid (PGA) and trimethlyene carbonate (TMC) which naturally break down in the body after about six months. This option leaves nothing behind but the patient's own tissue.

Since non-permanent synthetic options are more recent developments among surgical implants and grafts, additional research, such as animal labs and viable human studies, is needed to prove the efficacy of these new solutions.

For Brown, the key to knowing when a synthetic material may be used and if it should be permanent or non-permanent is to ask, "How is it being used, and what is it being asked to do?" According to George Foutrakis, Ph.D., product specialist coordinator at W. L. Gore, a permanent implant may be needed when long-term strength is required to maintain a repair. It can be used to "bridge a gap" of missing or weak tissue.

Brown adds, "If you are going to replace a piece of the body, you need something that is going to permanently serve that function, whereas if you need to augment something and add additional tissue, you probably don't need a permanent device itself."

A non-permanent material may be used to build strength or build tissue volume in an area, says Foutrakis. While this can be done through a non-permanent synthetic material, surgeons can, and often do, turn to biologic material to serve this same purpose.



Biologic Considerations

Among the biological surgical tissue implants and grafts, there are three main choices for surgeons in terms of the source of the material.

1. **Allograft tissue** is human tissue recovered by a tissue bank from a deceased donor and processed through tissue banks to be transplanted back into a human.

According to Frederic Peycelon, senior director of marketing & client services at LifeNet_Health®, the process of recovering human tissue to be used for

transplantation is careful to ensure infection control and safety. From donor screening to recovery to quality testing, tissue banks are required by the FDA, the American Association of Tissue Banking and often by the bank's own internal guidelines to gather and test all necessary material before processing the implant for use. After recovery and processing, tissue is manufactured—cleaned, sized and some times pieced together—into a product to be used by a surgeon as a bioimplant.

2. **Xenograft tissue** is animal derived, often bovine- or porcine- derived, tissue to be used in a human. According to Mark Bleyer, president of Cook Biotech, which manufactures biologic tissue from porcine small intestine submucosa, xenografts are gathered and harvested from, in Cook's case, a closed herd of pigs raised to precise specifications. The animals are used for pork production, but the company takes the intestine and begins to control it from that point on as a medical-grade raw material. Various carefully controlled "rinse cycles" are performed to remove all the cells and make sure any bacteria or contamination has been rendered sterile. Then, this base raw material is used to make different product designs for numerous clinical applications.

It's worth noting that allografts, because they come from human tissue, require additional tracking once in the hospital. Meanwhile, xenografts are cleared by the FDA as sterile manufactured medical devices and do not require additional tissue tracking.

3. The third option for biologic surgical tissue implant and graft material is **autograft tissue**, which involves taking the patient's own tissue from elsewhere in the body for the repair.

According to Dr. Carbonell, it's particularly in the biologic realm of surgical tissue implants and grafts that surgeons have a lot of choices to make. Since this is a newly emerging field with many biologic products being brought to market within the last 10 years, long-term data is just now being published to show these materials' true effectiveness. While some of the newest entries into this field of biologic tissue implants have little supporting clinical evidence, a few players hold the support of clinical studies. Cook, Bleyer says, carries more than 800 peices of clinical research on its biologic products.

There are some patients and procedures in which biologics are a good fit. David S. Edelman, MD, FACS, a board-certified general surgeon and general surgeon for the Miami Heat NBA professional basketball team, has found using biologics in young, healthy patients results in quicker recoveries. A synthetic material, he says, can lengthen recovery time as the material is stiff, hard and can cause discomfort.

As Dr. Carbonell mentions, biologics can be a good option for patients prone to infection. Dr. Edelman adds that biologics are remodeled over time, meaning the body helps with the repair. In a few months, the material is incorporated and replaced with the patient's own tissue, so it lessens the chance of becoming infected.

In fact, there are certain clinical circumstances in which infection is especially a concern and a biologic may be a better solution. For example, in a contaminated case where there is bowel content spillage because a portion of the intestine is resected—this type of procedure would warrant concern about the chance of infection of a synthetic. That said, biologics have their complications, too. They can get overwhelmed by bacteria that may digest the biologic mesh and completely degrade it.

For successful incorporation, the biologic implant needs to be in contact with tissue. As Bleyer explains, biologic implants, both xenograft and allograft, are composed of an extracellular matrix that allow this incorporation to happen. The extracellular matrix is the cells' platform on which they adhere and establish a signaling pathway. "Cells are giving out little chemical packets that enter into the matrix and other cells pick them up. These signals tell cells across and around from each other how and what they're doing," he says. "It's an amazing complex communication system."

Making The Decision

How a surgeon decides which of the multitude of surgical tissue implant and graft materials to use comes down to a host of factors, including the patient, procedure, surgeon comfort and price.

"It is really beneficial for the surgeon to have a basic understanding of the material, and the features and benefits of the material, so they can incorporate that decision into the big picture of caring for the patient," Brown says.

"Considerations include co-morbidities of the patient, the disease being addressed, the surgical technique, and then finally, the device."

Dr. Edelman adds, "Every patient responds differently, and there is no test for me to say, 'You're going to have less pain with a biologic mesh vs. synthetic.' Both meshes may cause pain, but it's different in every patient."

He recommends to surgeons trialing biologic mesh to first try the materials on young, healthy patients to gain a certain amount of comfort with the material. Then, move on to older patients and more complex cases.

In terms of technique, synthetics may lend themselves better to minimally invasive approaches than biologics, simply because of their handling characteristics and the ability to put them through a laparoscopic trocar, says Dr. Carbonell.

As for the future, it may come down to what the literature reveals as more data is published on the effectiveness of biologic implants and grafts in surgical patients. In addition, Dr. Carbonell offers a couple tips:

1. **Be critical.** "Be very, very critical of what you use," he says. "Learn as much as you can about the product, and don't just go by what the company's representative tells you. Do your own research, go to the surgical meetings, listen to what the experts have to say and read what has been published in the surgical literature."

2. **Follow your patients.** “If you are an early adopter of a material, follow your patients critically,” Dr. Carbonell explains. “Create your own database, document which product you used, under what clinical scenario, technical details of the operation and track your outcomes. When you come to settle on one or a variety of products, you can see what you’ve had the best results with.”

In the end, choosing the right surgical tissue implant and graft material is about being an informed consumer, Dr. Carbonell says.

"We are the end user,” he says. “The onus is on us because it’s patients that we are treating. We have to do our due diligence. We are the consumer.”

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