Long-term Follow-up on the Effective Use of Biologic Grafts

Most surgeons agree that hernia repairs that incorporate a mesh or graft are superior to repairs made with sutures alone. Since the early 1960s, when polypropylene mesh became the favored choice for repair of groin hernias, a wide variety of synthetic mesh and, more recently, biologic grafts have become available to allow for a tension-free repair with a reduced risk for recurrence. With the availability of long-term data, biologic grafts, such as Biodesign® (SurgiSis®, Cook Medical), offer an effective means of repairing hernias while minimizing risk for infections and recurrence.4

Whether to use a synthetic mesh or biologic graft depends on the patient’s condition and the characteristics of the hernia. “The things that go into that thought process are how many operations the patient has had previously, why we are repairing the hernia, and whether it is a pure elective hernia [repair] or an acute hernia [repair] with incarceration and/or strangulated bowel and/or compromised tissue of any kind,” said Morris E. Franklin Jr, MD, director of the Texas Endoscopy Institute in San Antonio. “We also consider the size of the patient, if there is a fistula or gastrointestinal tract involvement, and a myriad of other contributing, though separate, issues.”

Biologic Grafts

Biologic grafts fall into 2 basic categories: human and animal–derived. “Clear indications for the use of a biologic [graft] include contaminated operations and exposed wounds,” said Eduardo Parra-Davila, MD, director of minimally invasive and colorectal surgery at Celebration Health–Florida Hospital in Celebration, FL. “Its placement assists in the prevention of evisceration and future enteric fistulas. Some surgeons feel that in potentially contaminated fields, such as in cholecystectomy, gastric bypass, and colon surgery, biologic [grafts] have a definitive role.”

Biologic grafts should be considered in clean, contaminated or potentially contaminated fields for repair of inguinal, hiatal and incisional hernias.4-6 “The time that I choose a biologic [graft] is if there is any question about an infection,” Dr. Franklin said. Likewise, in situations where the hernia is incarcerated or strangulated, biologic grafts such as Biodesign are an attractive option, assuming the graft lasts long enough in the patient’s body to result in a long–lasting repair; fully absorbable synthetic mesh, such as polyglactin 910, tends to fail early and often.7

Without a graft, the risk for incisional or ventral hernia recurrence is high and unacceptable to most surgeons and patients. With incisional hernia repair, there is a recurrence rate of approximately 50% and a reported infection rate of about 10%.8 Hernia development associated with laparotomy incisions necessitates approximately 90,000 incisional hernia repairs every year.9

When an original repair fails, the cost of correcting the repair is difficult to estimate, because it includes not only the hospital charge but the surgeon’s fee as well, “which is probably the least costly part of the procedure,” Dr. Franklin said, acknowledging the patient’s time away from work and the immeasurable cost of additional pain and suffering. “If the repair fails the first time, you have to start over again from ground zero,” he explained. “That means you double, triple, or quadruple the cost if you have to do something that has a 50%-plus chance of recurring.”

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Analyzing the Long-term Data

Although there had been little long-term data available on biologic grafts, Dr. Franklin and colleagues recently reported on their 5-year experience with patients who received Biodesign for a variety of repairs: incisional, umbilical, inguinal, femoral, spigelian, or parastomal.4-6 From May 2000 to October 2006, 133 procedures were carried out on 116 patients; 39 of these repairs took place in grossly infected fields and the rest in potentially contaminated fields.4 With a follow-up rate of 85% at 5 years, the researchers identified 7 recurrences, 11 seromas (all resolved), and 10 patients reporting mild pain. Of the 6 patients who underwent subsequent laparoscopic procedures, all but one showed the graft to be completely integrated into the tissue (Figure).

The team concluded that Biodesign is preferable to other prosthetic materials in contaminated or potentially contaminated fields, and that it is safe and feasible for hernia repair, with minimal recurrence rates and satisfactory follow-up results.4

More recently, a team of investigators led by Luca Ansaloni, MD, from St. Orsola–Malpighi University Hospital in Bologna, Italy, reported on the safety and efficacy of the Biodesign (Surgisis) Inguinal Hernia Graft compared with polypropylene (PP) in Lichtenstein’s hernioplasty.10 In this prospective, randomized, double-blind trial, 70 male patients underwent Lichtenstein’s hernioplasty with half receiving Biodesign and half receiving PP.4

At 1, 3, and 6 months and 1, 2, and 3 years after surgery, the Biodesign group experienced a significant decrease in the degree of postoperative pain when at rest, coughing and/or moving. Additionally, the Biodesign patients required significantly less pain medication in follow-up visits up to 6 months. Furthermore, from 3 months to 3 years post-op, those in the Biodesign group experienced a significant decrease in the incidence and degree of discomfort when coughing and moving. The authors concluded that the use of Biodesign was safe and effective since the recurrence rate appeared comparable between groups.

Selecting a Biologic Graft

All biologic grafts are not created equal. Dermis-based grafts, many of which are harvested from human cadaveric or porcine dermis tissue, contain collagen and elastin. The mechanical characteristics of the graft are determined by the ratio of these components, with collagen providing strength and elastin providing flexibility. However, elastin weakens over time, regardless of the quality, which makes dermis–based graft repairs vulnerable to stretching and can result in recurrence or pseudo–recurrence (laxity) requiring secondary repair.10-12

Complete remodeling of a biologic graft demands that the host be able to replace all parts of the graft over time with its own tissue. Elastin, however, does not turn over quickly—it has an average predicted residence of 74 years in the human body.13 The patient with a dermis-based repair may have a lifetime concern of that repair stretching. Biodesign, being derived from small intestinal submucosa, contains only a very small amount of elastin.

Additionally, some biologic grafts are exposed to chemical crosslinking agents, such as glutaraldehyde or hexamethylene disocyanate, resulting in a more stable product. “In theory, a controlled degree of crosslinking is introduced into the structure, making it resistant to collagenase enzymes responsible for the breakdown and resorption of implanted collagen,” Dr. Parra-Davila explained.

The downside to this durability is that chemical crosslinking renders the graft functionally nonporous; new tissue forms over the graft rather than through it, encapsulating it as with a synthetic mesh.14

“As crosslinking density of the mesh increases, so too does...
Once Biodesign is implanted in the body, these signaling factors encourage rapid infiltration of the graft scaffold and help guide the cells toward remodeling. Remodeling results in a robust repair that, being comprised of vascularized host tissue, resists infection. Remodeled tissue that forms around the scaffolding of a biologic graft shows the same characteristics of native tissue and is distinctly different from scar tissue.

The ideal biologic [graft] creates no allergic response; is readily available and inexpensive; allows for the most rapid vascular ingrowth; stays around long enough for the patient’s host tissue to grow in; resists infection; won’t wind up getting encapsulated; and hopefully is totally replaced with the patient’s host tissue, making the repair stronger than the tissue was initially.

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References