Experience with the GORE® BIO-A® Hernia Plug in Inguinal Herniorrhaphy

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**Introduction**

In 2005, more than 750,000 inguinal hernia repairs were performed in the United States. Since Lichtenstein popularized outpatient tension-free repair in 1989,1 several inventive operations for inguinal defects have been described. The goals of all such repairs are to return the patient to full activities as soon as possible, decrease the risk of hernia recurrence, and limit the possibility of long-term inguinal pain from the repair.

An anterior approach remains the most common hernioplasty technique. All modern hernia repairs have the following similarities:

- Hernia sacs are not resected or ligated
- Hernia defects are not closed; instead, the wall is replaced with no-tension mesh
- Polypropylene remains the mesh with which all others are compared
- There is a tendency toward using larger pieces of mesh
- There is less fixation of the mesh
- The type of fixation is often absorbable

An anterior approach to inguinal hernia repair has several advantages:

- The anatomy is familiar to surgeons
- Recurrence rates should be acceptably low
- There is less risk of injury to viscera or vessels

The disadvantage of a pure Lichtenstein repair is that sutures are often placed circumferentially. In the early postoperative period, when a patient strains or coughs, tension returns to the inguinal area, thereby causing tension-related pain at the fixation site. Moreover, because the Lichtenstein repair does not include an entry into the preperitoneal space, the surgeon may overlook a femoral hernia. There have been reports of sublay hernias through the defect and posterior to the mesh.2

The mesh plug and patch repair described by Rutkow and Robbins in 19933 has several advantages over the Lichtenstein procedure. First, because the preperitoneal space is entered, an evaluation for a femoral defect can be performed. Second, because the mesh holds the hernia sac in place, less fixation is required for the overlay patch. Third, when a patient coughs or strains early postoperatively, the plug dissipates the force so that little tension is transmitted to the overlay mesh and fixation sutures. As a result, there is less early postoperative pain (the plug allows fewer sutures to be used for fixation of the overlay mesh).

Once the overlay mesh has been incorporated into the tissue, the mesh plug no longer participates in the repair. In fact, its continued presence places the patient at risk for erosion into viscera or vessels,4-6 migration into the scrotum,7 small bowel obstruction,8,9 and embolization.10 The most concerning long-term consequence of the mesh plug and patch repair is inguinodynia, which in the author’s experience is most likely to occur in a thin male patient with a Gilbert type I or type II hernia. Possible theories regarding the cause of chronic inguinodynia include erosion of the plug into nerves, contraction of the plug with nerve entrapment, and inflammatory cells that irritate nerve endings.
Why Not an Absorbable Plug?

The GORE® BIO-A® Hernia Plug (W.L. Gore & Associates, Inc., Flagstaff, AZ) became available for clinical use in April 2005. The plug is made of a copolymer of 67% polyglycolic acid, a strong soluble polymer, and 33% trimethylene carbonate, which imparts softer and suppler properties. The copolymer has been available for medical use since 1986 in a monofilament suture form. In a web-based sheet form, it has been used in periodontal reconstructive products since the mid-1990s and in staple-line reinforcement products since 2003. The plug was evaluated for tissue response at 3 and 6 months post-implantation in an experimental study using a porcine model. This study demonstrated that the plug material was replaced by collagen on an approximately equal volume basis throughout the absorption process, and was essentially fully absorbed at 6 months. Histologically, the collagen had the appearance of normal healing tissue.

Use of a bioabsorbable plug instead of a permanent prosthesis does retain the advantages of a traditional plug and patch repair. The hernia is completely reduced into the preperitoneal space, and wall tension is dissipated by the plug in the immediate postoperative period, thereby decreasing the risk of both early recurrence and sublay recurrence. Thus, the overlay patch can be affixed with a minimum number of absorbable sutures during tissue incorporation. The repair is easy, and the time in the operating room is short. Most important, the potential for erosion, migration, and nerve entrapment in the long term is markedly reduced because the bioabsorbable plug is replaced with native tissue by 6 months after surgery.

A “Standardized” Technique

The “standardized” procedure for using the hernia plug begins with a 5- to 7-cm groin incision. Electrocautery is used to traverse the subcutaneous tissue. The external oblique fascia is opened, and the ilioinguinal nerve is identified and left alone. The spermatic cord is then encircled with a penrose drain, and the defect (indirect or direct) is identified. For an indirect defect, the sac and preperitoneal fat are separated from cord structures, dissected “high” through the internal ring, and then reduced through the internal ring into the preperitoneal space. For a direct defect, the attenuated transversalis fascia is opened, exposing the yellow fat of the preperitoneal region. The preperitoneal space is developed with a dry Ray-Tec gauze and should be bloodless. With use of a headlight, the pubis, iliopectineal line, femoral vessels, epigastric vessels, and cord structures are identified.

The plug is then inserted “dry” through the defect and held in place with a stitch or two of 3-0 absorbable suture. The keyhole in the mesh is used to encircle the cord, and the tails are overlapped and sutured together with 2-0 absorbable suture so that the keyhole is positioned snugly around the cord structures. The overlay mesh is positioned so that the medial blunted end extends a centimeter or two medial to the pubic tubercle. The mesh is held in place medially with a stitch of 2-0 absorbable suture near the pubis, but is inserted in the rectus fascia rather than the periosteum. Four interrupted stitches of 2-0 absorbable suture
are used to affix the caudal edge of the mesh to the iliopubic tract. The last stitch should be lateral to the external ring. Two stitches can be used to affix the cephalad portion of the mesh to the internal oblique fascia, with care taken not to catch the underlying nerves. The volume of the plug creates a natural “dome” for the mesh. This tenting of the overlay mesh has a cupping effect, so that when the patient is upright, the fixation sutures should not be under tension. The plug and mesh operation is usually performed in under 30 minutes.

Postoperatively, an ice bag is placed over the groin area the day of the procedure and, if requested by the patient, the next day as well. Propoxyphene is used on an as-needed basis, and ibuprofen is administered three times a day until there is no pain. Twenty-four hours after the operation, the patient is allowed to shower and resume activities as tolerated; there are no lifting restrictions after 24 hours. Full activities are allowed by the second day and encouraged before the fifth day. No local anesthesia is used because patients who have no postoperative pain the day of the procedure may be more active, and this can result in postoperative edema and a prolonged convalescence.

Clinical Experience

Participation in a Multicenter Study
At SurgiCare of Missouri, P.C. (Jefferson City), the first implantation of a GORE® BIO-A® Hernia Plug and overlay mesh took place in August 2004. SurgiCare is a participant in a prospective, multicenter study of the plug. This study, which includes 132 patients in seven centers in the United States and Europe, is investigating the efficacy of the plug and polypropylene patch repair, with the primary endpoint being freedom from hernia recurrence and the secondary endpoints being freedom from pain and complications. Patients are reexamined in the clinic 14 days and 1, 3, 12, and 24 months postoperatively. The study has the following inclusion criteria: patient age at least 18 years, primary defect (or secondary defect not previously repaired with mesh) smaller than 3 cm by 3 cm, and body-mass index below 40. Exclusion criteria are a previous herniorrhaphy with a prosthesis, defect larger than 10 cm², wound healing or autoimmune disorder, preexisting infection, bowel strangulation, or need for emergency herniorrhaphy. Enrollment in the study was closed in December 2005. The final results will be reported at the end of the 24-month follow-up period. SurgiCare contributed data on 29 male patients (30 defects) to the multicenter study (Table 1).
Table 1. Patient demographics and perioperative findings

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients/defects</td>
<td>29/30</td>
</tr>
<tr>
<td>Mean age (range), years</td>
<td>51.3 (21-77)</td>
</tr>
<tr>
<td>Mean (range) body-mass index</td>
<td>26 (21-34)</td>
</tr>
<tr>
<td>No. of left-sided/right-sided defects</td>
<td>14/16</td>
</tr>
<tr>
<td>Mean (range) defect size, cm²</td>
<td>6.2 (2-10)</td>
</tr>
<tr>
<td>Gilbert/Rutkow-Robbins hernia type</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>II</td>
<td>16</td>
</tr>
<tr>
<td>III</td>
<td>2</td>
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<td>V</td>
<td>3</td>
</tr>
<tr>
<td>VI</td>
<td>3</td>
</tr>
<tr>
<td>VII</td>
<td>0</td>
</tr>
<tr>
<td>Mean (range) operating time, minutes</td>
<td>30.1 (20-62)*</td>
</tr>
<tr>
<td>Mean (range) convalescence time, days</td>
<td>5.8 (1-26)</td>
</tr>
<tr>
<td>Mean (range) time to return to work, days</td>
<td>6.3 (1-26)</td>
</tr>
</tbody>
</table>

* One operation was extended to accommodate creation of a training videotape; there were no problems with the surgical procedure.

Additional Experience
Since the release of the GORE® BIO-A® Hernia Plug for unrestricted clinical use, the device has been employed at SurgiCare of Missouri in an additional 106 patients not included in the multicenter study; thus, one surgeon (C.R.D.) at SurgiCare has treated a total of 135 patients with the plug. No patient scheduled to receive the plug and patch repair required a different repair on presentation in the operating room. At their follow-up visits, all patients stated that they had resumed full activities by 5 days after surgery. The mean time to return to work in this series was 6.2 days.

Freedom from Complications
As of May 2006, none of the 135 patients who underwent inguinal herniorrhaphy using the bioabsorbable plug and overlay mesh technique at SurgiCare of Missouri have had an infection, seroma, or hematoma. There was one hernia recurrence, which developed 13.5 months postoperatively in a patient who had previously undergone a preperitoneal varicocelectomy. On reoperation using an open preperitoneal approach, the recurrence was found to be through the keyhole of the overlay mesh, beside the skeletonized preperitoneal spermatic cord. A gross examination revealed that the hernia plug was fully absorbed. A tissue sample was obtained from the plug.
implantation site for histologic analysis (see below). The recurrence was unrelated to the plug; instead, it was associated with the skeletonized preperitoneal spermatic cord and placement of the keyhole too loosely around the cord. Therefore, careful attention should be paid to the positioning of the keyhole around an atypical cord and keeping any portions of the plug from traversing the internal ring.

**Histologic Analysis of the Explanted Plug**

The histologic analysis of the tissue from the plug implantation site was performed by W. L. Gore & Associates. A section of tissue stained with Milligan’s trichrome (Figure 1) showed collagen and a few artifacts of the plug. Immunohistochemical staining with anticollagen types I (Figure 2) and III (Figure 3) revealed a predominance of type I collagen and very little type III collagen in the space previously occupied by the plug.

This analysis shows that when implanted into an inguinal defect, the bioabsorbable plug serves as a scaffold for generation of type I collagen. The collagen remains after the plug has been absorbed, functioning, in essence, as a collagen autograft.

![Figure 1. 4X, Milligan’s trichrome. Arrow points to remaining bioabsorbable material](image1)

![Figure 2. 10X, Anti-Collagen Type I. Brown extracellular material is type I collagen.](image2)

![Figure 3. 10X, Anti-Collagen Type III. Faint brown staining of less abundant Type III collagen.](image3)

**Absence of Long-Term Pain**

Evaluations of long-term inguinodynia after hernia repair are done either by gathering specific data or by reviewing clinical outcomes. In the multicenter study, data on preoperative (baseline) pain and postoperative pain were recorded by using the McGill Pain Questionnaire. Most SurgiCare patients enrolled in that study reported their baseline present pain intensity (PPI) as being either “mild” or “discomforting.” The larger group of patients treated outside the study had similar responses. As of May 2006, there have been no reported complaints of pain (corresponding PPI = 0) beyond 3 months postoperatively among the patients treated at SurgiCare. The patients in the multicenter study will be followed for up to 2 years postoperatively, in accordance with the protocol of that investigation. Patients treated outside the study are routinely followed until they report no pain, and none have required follow-up care after 3 months postoperatively. Because an absence of pain 3 months after an inguinal hernia repair is a strong predictor of an overall pain-free outcome in the author’s experience, none of our patients is anticipated to develop chronic debilitating inguinodynia.
Conclusions

The bioabsorbable plug and overlay mesh technique is suitable for the repair of 85% of primary inguinal hernias. It is the first choice for inguinal herniorrhaphy at SurgiCare of Missouri, when appropriate. It is not used for large incarcerated scrotal hernias because repairs of such defects (eg, Stoppa repairs) should employ large pieces of mesh. In our experience with 135 patients both within and outside a multicenter study, there has so far been a low incidence of recurrence. Patients enrolled in the multicenter study will be followed for a full 2 years postoperatively.

In summary, inguinal herniorrhaphy using a bioabsorbable plug with a permanent patch is:

- Simple
- Mastered after a short learning curve
- Usually performed in 30 minutes or less
- Associated with a low risk of complications
- Safe for the patient, with a reduced risk of erosion, migration, or embolization of the plug
- Conducive to an early return to full activities and work
- Anticipated to reduce long-term inguinodynia and eliminate meshoma

References
