

SURGICAL BIOLOGIC ALLOGRAFTS

OB-GYN Surgical Procedures

Clinical Case Examples Demonstrating the Use of Biologic Allografts as Barrier Membranes and Healing Adjuncts in Common OB-GYN Surgical Procedures

6Sixty Biologics Advanced Treatments

BIOLOGIC GRAFT

ADVANCED SURGICAL BIOLOGICS FOR OB-GYN PROCEDURES

What Is a Biologic Allograft?

A biologic allograft is a dehydrated human amnion/chorion membrane (dHACM) derived from donated placental tissue following healthy, full-term cesarean deliveries. The allograft is processed and preserved for surgical use and is available in multiple sheet sizes to accommodate a variety of pelvic and gynecologic procedures.

Biologic allografts are commonly utilized as a protective tissue barrier and healing adjunct in procedures where tissue has been incised, dissected, cauterized, or otherwise surgically manipulated.

Why OB-GYN Surgeons Use Biologic Allografts

Protective Tissue Barrier

- Provides a protective covering over surgically treated tissue
- Separates adjacent tissue planes during the critical healing period
- Supports the body's natural healing response

Preserved Extracellular Matrix & Regulatory Proteins

- Retains key extracellular matrix components
- Contains more than 300 identified regulatory proteins and signaling molecules naturally present within placental tissue

Designed for Surgical Workflow

- Easy to handle, trim, and place
- Conforms well to complex pelvic anatomy
- Available in multiple sheet sizes
- Shelf-stable with a long storage life
- Ready to use with no preparation required

Common OB-GYN Applications

Biologic allografts may be utilized in a wide range of pelvic and gynecologic procedures, including:

- Hysterectomy
- Endometriosis Excision
- Myomectomy
- Cesarean Section
- Ovarian Surgery
- Pelvic Reconstruction Procedures
- Complex Pelvic Dissections
- Revision Procedures
- Patients at Increased Risk for Fibrosis, Adhesion Formation, or Impaired Healing

Product Processing & Safety

Biologic Allograft is processed in accordance with American Association of Tissue Banks (AATB) standards using a proprietary preservation and sterilization process designed to maintain the structural integrity of the tissue while providing an additional level of safety.

The tissue is recovered exclusively from donated placentas following healthy cesarean deliveries in the United States. During processing, blood components and cellular debris are removed while preserving the extracellular matrix and naturally occurring regulatory proteins found within placental tissue.

Each graft undergoes terminal sterilization and is supplied ready for surgical use.

To find out more about
6Sixty Biologics products

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Biologic Graft as a Barrier & to Enhance Healing after Endometriosis Surgery

CHALLENGE — EXPEDITE HEALING & MINIMIZE SCAR TISSUE

Endometriosis is a painful disorder in which the endometrium grows outside the uterus, leading to irritation and adhesions of surrounding tissues. Surgery often requires stripping the peritoneal layer along with adhesions, and these surgically created wounds can scar to surrounding organs — potentially causing recurrence of chronic pain. Many barriers resorb too rapidly and do not enhance healing.

CLINICAL HISTORY

38-year-old female presented with severe, chronic pelvic pain with dyspareunia. On examination she exhibited pain when the uterosacral ligaments were palpated and the uterus manipulated. Surgical intervention was required.

TREATMENT

Single-port laparoscopic surgery. Endometrial lesions were present on the anterior and posterior peritoneum, several with adhesions (Fig. 1). Adhesions were released and the peritoneal layer resected in three locations (Fig. 2). Two 4×7 cm Biologic Graft sheets were applied as a barrier at each site, becoming “tacky” on rehydration and adhering without fixation (Figs. 3–5).

FOLLOW-UP

On post-op day 7 the patient felt well enough to return to work. At 12 weeks she remained pain-free and fully recovered.

CONCLUSION

Biologic Graft provided a barrier against surrounding tissues, enhanced healing at the surgical wounds, and reduced scarring — with reduced post-op pain and an expedited recovery.



Figure 1 Endometrial lesions and adhesions

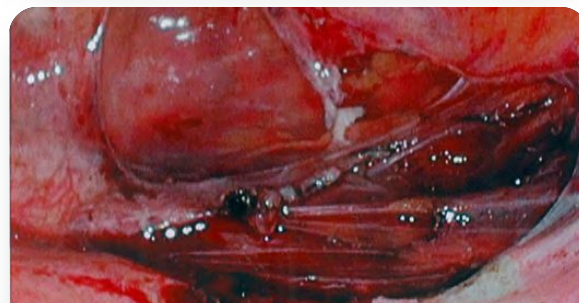


Figure 2 6 cm x 6 cm peritoneal excision



Figure 3–5 Biologic Graft applied to resection sites

Biologic Graft on the Vaginal Cuff after Hysterectomy in an Obese Patient

CHALLENGE — RISK OF IMPAIRED HEALING IN OBESE PATIENT

Many factors can impair wound healing. Obesity in patients undergoing hysterectomy can impair healing and recovery and raises intrapelvic pressure, increasing the risk of wound breakdown at the vaginal cuff closure and other post-operative complications.

CLINICAL HISTORY

53-year-old female (BMI 34) with endometrial hyperplasia and a positive family history of ovarian cancer, scheduled for total laparoscopic hysterectomy with bilateral salpingo-oophorectomy (Fig. 1).

TREATMENT

Single-port laparoscopic procedure. After the uterus was removed, the vaginal cuff was closed with resorbable sutures. Given the increased healing risk, Biologic Graft particulate (160 mg vial mixed with sterile saline to a flowable consistency) was deposited directly onto the cuff closure, adhering to the sutures and settling into the creases (Fig. 2).

FOLLOW-UP

At day 14 there was no vaginal bleeding, pain, or complications. The patient discontinued pain medication on day 4 and returned to work on day 14.

CONCLUSION

Across the author's prior cases, Biologic Graft on the cuff closure was associated with reduced post-op pain, decreased pain-medication use, and faster recovery, with no related adverse events.

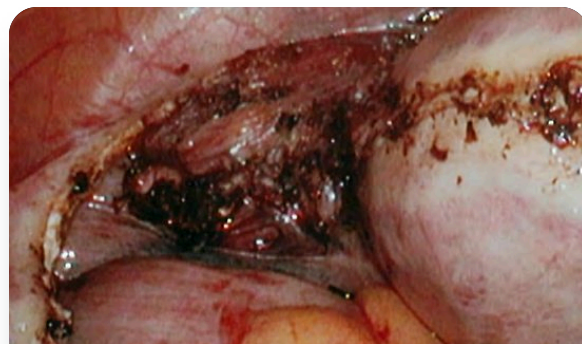


Figure 1 Total laparoscopic hysterectomy with BSO



Figure 2 Biologic Graft deposited on the cuff

Total Abdominal Hysterectomy with Bilateral Salpingectomy

Gerry L. Sotomayor, MD

CHALLENGE — FIBROID UTERUS, ADHESIONS & COMORBIDITIES

A 15-week-size fibroid uterus with extensive adhesions, complicated by obesity (BMI > 35), chronic anemia, and poorly controlled diabetes.

CLINICAL HISTORY

44-year-old with pelvic pain and menorrhagia; MRI revealed a 15-week fibroid uterus. History of chronic anemia and 3 prior Cesarean sections with postpartum sterilization.

SURGICAL INTERVENTION

Total abdominal hysterectomy with bilateral salpingectomy. Extensive adhesion formation was encountered; cell saver was used without need for transfusion. A 7×7 cm Biologic Graft covered the vaginal vault (Figs. 1–2) as well as the anterior abdominal wall. An On-Q system was used for pain management.

FOLLOW-UP

Minimal post-operative pain, with no infection or hernia. Follow-up visits at 7 and 40 days revealed excellent recovery and earlier-than-expected return to work.

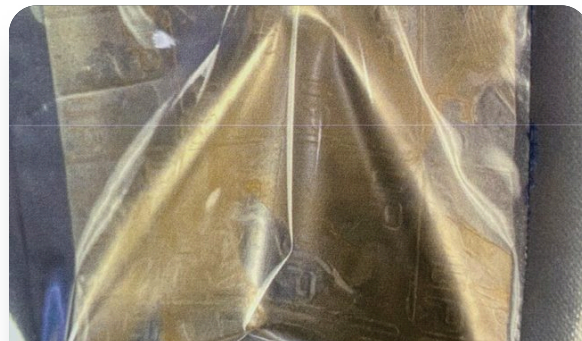


Figure 1 7 cm x 7 cm Biologic Graft



Figure 2 Placement on the vaginal vault

LAVH with Bilateral Salpingo-Oophorectomy & Lysis of Adhesions

Gerry L. Sotomayor, MD

CHALLENGE — ANEMIA, ADHESIONS & LARGE CERVICAL POLYP

Anemia, adenomyosis, pelvic adhesions, and a large cervical polyp (6×2 cm) not resectable in an office setting.

CLINICAL HISTORY

60-year-old with 6 months of post-menopausal bleeding, negative PAP and endometrial biopsy. A 6 cm uterine polyp was identified; the patient had lost 3 g hemoglobin since onset of bleeding.

SURGICAL INTERVENTION

LAVH with BSO and lysis of adhesions. Previous tubal ligation and infection had created extensive adhesions; the polyp had partially necrosed. A 7×7 cm Biologic Graft sheet was applied to the cuff prior to closure (Figs. 1–3).

FOLLOW-UP

24-hour hospitalization with no pain, bleeding, or infection. The vaginal cuff was observed at 2 and 6 weeks with proper resolution and granulation tissue noted.

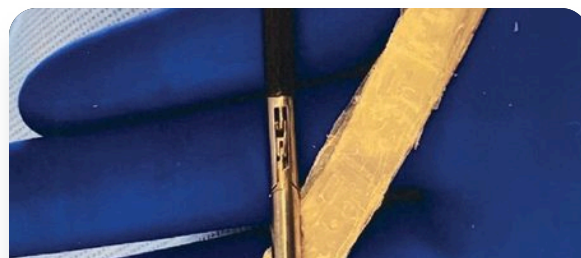


Figure 1 Rolled graft in atraumatic grasper

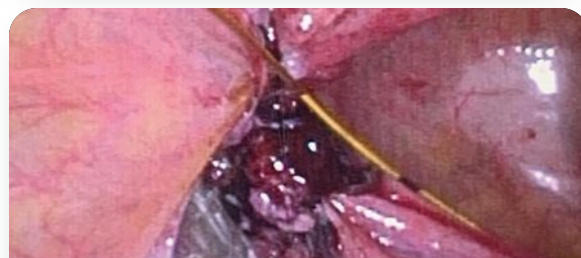


Figure 2 Cul-de-sac application

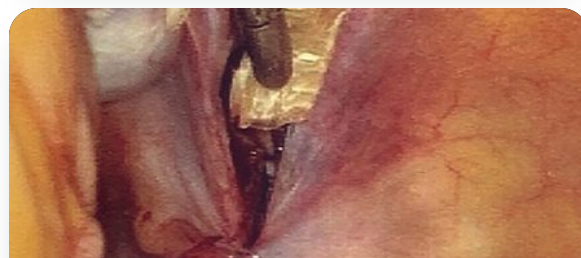


Figure 3 Two areas covered with allograft

Biologic Graft to Enhance Healing after a Challenging Myomectomy

CHALLENGE — DENSE ADHESIONS & MULTIPLE LARGE FIBROIDS

What should have been a routine myomectomy turned challenging due to dense adhesions from a prior myomectomy and an unexpected number and size of fibroids that had grown in only two years.

CLINICAL HISTORY

44-year-old female with a prior myomectomy presented with chronic pelvic pain. MRI revealed multiple uterine fibroids. She elected myomectomy over hysterectomy to preserve future fertility.

TREATMENT

Dense adhesions were encountered on entry; the bladder was adhered to the abdominal wall and a fallopian tube to a posterior fibroid (Figs. 1-2). After adhesiolysis, seven serosal and eight intramural fibroids were resected. Biologic Graft particulate was deposited into the larger uterine wounds (Fig. 3), and two 4×6 cm Biologic Graft sheets were placed over the serosal closures as a barrier to reduce adhesions (Fig. 4).

FOLLOW-UP

Discharged on day 3. At the day-13 follow-up the patient felt well and requested to return to work.

CONCLUSION

Biologic Graft's sheet and particulate forms offered the versatility to adapt to an unexpectedly complex case, providing a barrier and the much-needed enhanced healing.



Figure 1 Fibroid tumor excision

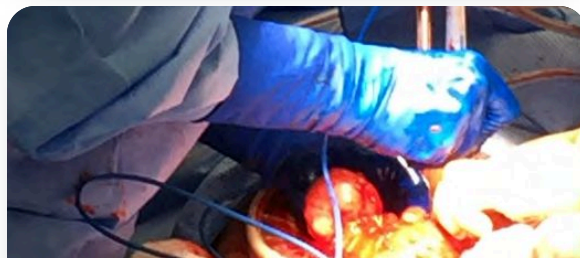


Figure 2 Multiple resected fibroid tumors

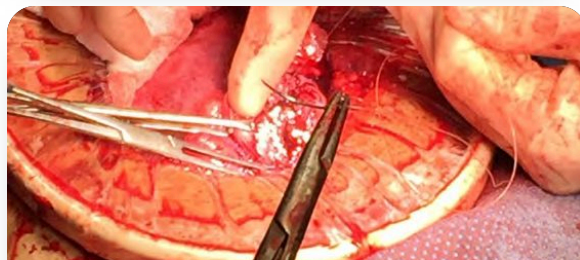


Figure 3 Dense adhesions from prior myomectomy



Figure 4 Biologic Graft sheet applied to suture lines

Biologic Graft as a Barrier & to Enhance Healing after Caesarean Section

CHALLENGE — OBESE PATIENT, TWO PRIOR C-SECTIONS, LARGE PANNUS

Adhesion incidence rises with each repeat C-section and increases OR time and the risk of organ injury. Obesity further raises the risk of wound infection, dehiscence, hematoma, and seroma.

CLINICAL HISTORY

31-year-old (BMI 46) scheduled for her 3rd full-term C-section and bilateral salpingectomy (Fig. 1). Adhesions were expected and there were concerns for post-op wound complications.

TREATMENT

Very dense bladder adhesions were lysed off the uterine wall, leaving a defect that was closed (Fig. 2). Biologic Graft was placed on each tubal excision site and the uterine defect. After fascial closure, a 2×12 cm Biologic Graft was placed in the incision before skin closure (Fig. 3).

FOLLOW-UP

At the 10-day follow-up the incision was fully healed without infection — impressive given the large pannus covering it. The patient reported less pain and faster recovery than her prior deliveries.

CONCLUSION

Biologic Graft is a versatile graft that can modulate inflammation, enhance healing, reduce scar tissue, and act as a barrier — here addressing multiple needs during one C-section.

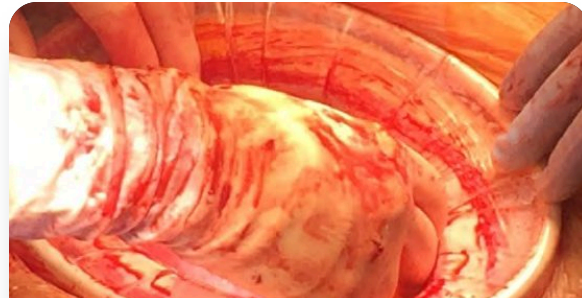


Figure 1 Caesarean section and bilateral salpingectomy

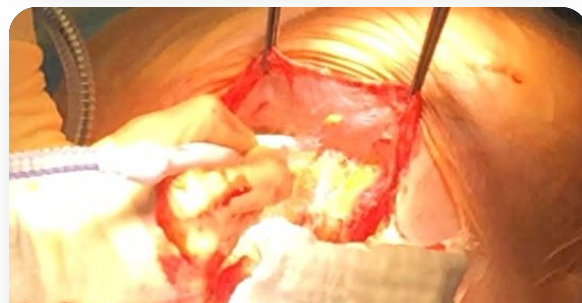


Figure 2 Dense adhesions after prior C-sections



Figure 3 Incision fully healed at 10 days post-op

Caesarean Section with Biologic Graft

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CHALLENGE — OBESITY & LARGE PANNUS WITH PRIOR C-SECTIONS

Adhesions were expected after two prior full-term Caesarean deliveries, with concerns for postoperative wound complications due to the patient's obesity and large pannus.

CLINICAL HISTORY

31-year-old G4, P2012 (BMI 46) scheduled for her 3rd full-term Caesarean section and bilateral salpingectomy.

SURGICAL INTERVENTION

Dense adhesions were present while gaining access to the uterus and between the bladder and uterus. Adhesiolysis left a uterine defect; bilateral salpingectomy was performed. Biologic Graft was placed on each tubal excision site and the uterine defect closure (Fig. 1). After fascial closure, a 2×12 cm Biologic Graft was placed in the incision site before the skin was closed (Fig. 2).

FOLLOW-UP

At the 10-day follow-up the incision was fully closed without signs of infection (Fig. 3) — impressive given the large pannus fully covering the site. The patient reported a faster recovery than her prior deliveries.

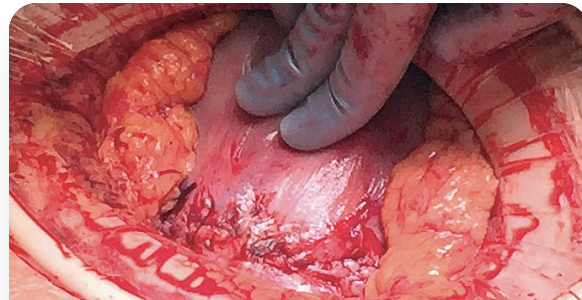


Figure 1 Biologic Graft on uterus defect closure



Figure 2 Biologic Graft in subcutaneous space



Figure 3 Incision 10 days postop

Laser Ablation Cone

Gerry L. Sotomayor, MD

CHALLENGE — RECURRENT CERVICITIS & FERTILITY PRESERVATION

Recurrent cervicitis/vaginitis with very friable tissue and extensive cervical intraepithelial neoplasia. The patient wished to preserve cervical canal function and desired future pregnancies.

CLINICAL HISTORY

31-year-old with an abnormal PAP smear; colposcopy revealed CIN II, HGSIL, with bacterial vaginosis and candida infection. Laser was preferred for rapid healing and less tissue trauma.

SURGICAL INTERVENTION

CO₂ laser ablation cone to a depth of 7 mm plus a 7 mm safety margin. After char removal, a 4×4 cm folded Biologic Graft was inserted into the endocervical canal and a 2×2 cm graft applied to the ectocervical tissue (Figs. 1–2).

FOLLOW-UP

At 6 weeks, significant granulation tissue was present over 60% of the treated areas (Fig. 3). Long-term PAP smears proved excellent repair of both endo- and ectocervical tissue.



Figure 1 Pre-surgery



Figure 2 4 cm x 4 cm Biologic Graft folded



Figure 3 6 week follow-up

Marsupialization of Recurrent Bartholin Cyst

Gerry L. Sotomayor, MD

CHALLENGE — RECURRENCE, SCARRING & DYSPAREUNIA

Risk of worse scar tissue formation, poor healing, recurrence of new Bartholin cysts, and possible future dyspareunia.

CLINICAL HISTORY

31-year-old with recurrent left Bartholin cysts, previously incised and drained, causing chronic dyspareunia and scarring.

SURGICAL INTERVENTION

Marsupialization with copious irrigation and proper cyst-wall approximation to mucosa. A 2×2 cm folded Biologic Graft was placed in the cavity, and the incision edges were loosely sutured to keep the allograft in place (Figs. 1–3).

FOLLOW-UP

Excellent recovery at the 2- and 6-week visits, with no scarring or infection. Dyspareunia resolved per the patient.



Figure 1 Folded Biologic Graft placed in the cavity

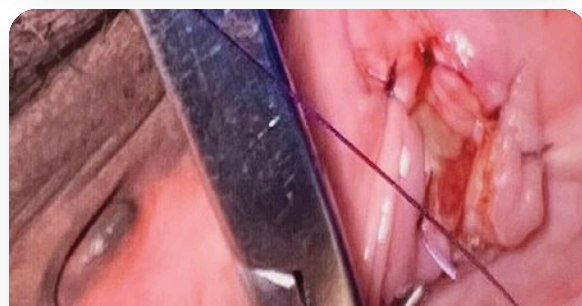


Figure 2 Edges loosely sutured to secure the graft



Figure 3 Approximation of the incision

Rectus Abdominis Diastasis at Laparotomy

Gerry L. Sotomayor, MD

CHALLENGE — SEVERE DIASTASIS & RECURRENT HERNIA RISK

Recurrent hernia formation was possible, and chronic pain might not resolve given the patient's physically demanding occupation requiring constant use of abdominal muscles.

CLINICAL HISTORY

45-year-old with diastasis recti admitted for total abdominal hysterectomy and BSO, suffering burning abdominal pain. Her work requires constant abdominal muscle use.

SURGICAL INTERVENTION

A Pfannenstiel incision revealed severe rectus abdominis diastasis. TAH and BSO were performed with Biologic Graft applied at the vaginal cuff. The abdominal wall was repaired with interrupted stitches and two 7×7 cm Biologic Graft allografts placed over the surgical site (Figs. 1–3). An On-Q pain-management system was used.

FOLLOW-UP

The 2- and 6-week visits revealed rapid recovery with minimal scarring; the incision closed very well.

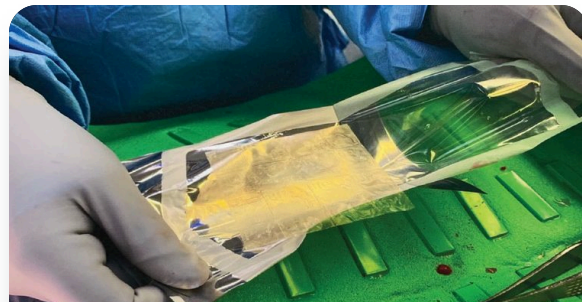


Figure 1 Biologic Graft allograft prepared

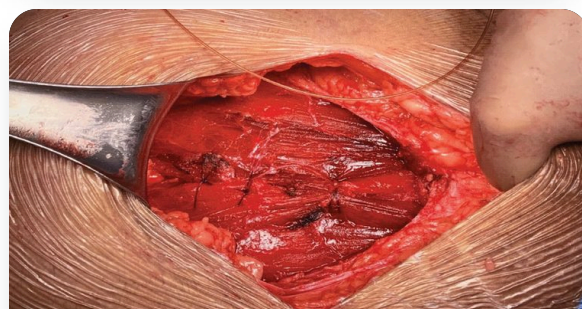


Figure 2 Allografts placed over the surgical site

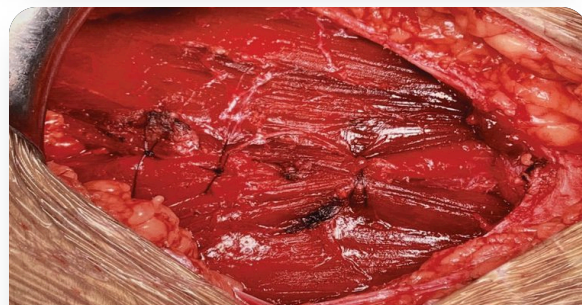


Figure 3 Rectus diastasis repair