

Case study:

Use of Biodesign™ (Surgisis®) Advanced Tissue Repair Products in Vaginal Paravaginal Repair of Anterior Prolapse

Introduction

The prevalence of pelvic floor disorders is greater than 25% in childbearing women; up to 50% of patients repaired with anterior colporrhaphy experience a recurrence within 5 years.¹ In addition to the significant impact pelvic floor disorders have on patient activity and quality of life, these disorders contribute to an annual economic cost in excess of U.S. \$1.5 billion, with further increases expected as the population ages.²

Most cystoceles arise through the shearing of the central pelvic support from its lateral attachment to the pelvis and from its proximal attachment to the pericervical ring and uterosacral ligaments as a complication of vaginal childbirth.³ Current trends in reconstructive gynecology have led surgeons to turn from fascial plication to defect-specific repairs, where the fascial tears causing support failure are identified and corrected.

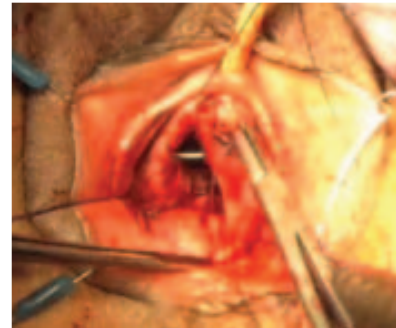
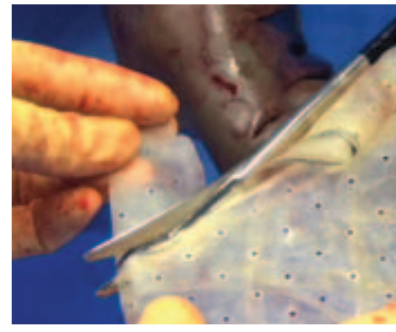
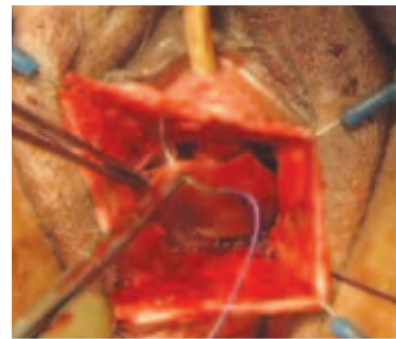
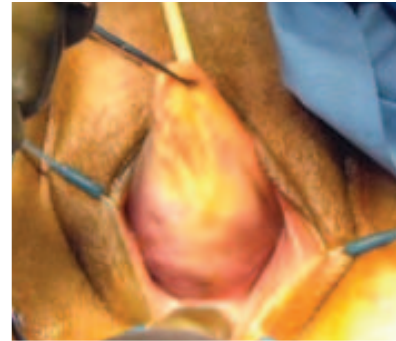
Vaginal paravaginal repair (VPVR) is one method used to perform defect-specific anatomic reconstruction and is reported to have a 78% rate of anatomic control.⁴ However, there has been poor surgeon acceptance of this technique because of complications reported in the literature and the relative complexity of the surgery. A second drawback of traditional VPVR has been that aggressive resuspension of avulsed anterior suspensory support can create suture-line tension that exceeds the strength of aging tissues, leading ultimately to repair failure.

Preliminary studies using a VPVR technique in combination with the Biodesign Anterior Pelvic Floor Graft have shown a success rate as high as 92%.⁵ The improvement of the VPVR technique using Biodesign reduces the risk of known complications of the use of synthetic materials, and greatly simplifies the procedure. The problem of aging tissues is addressed by the use of Biodesign as a bridging graft to augment the suture line. This paper discusses the graft, outlines the surgical technique, and provides two illustrative cases for how this procedure and material can be used in cystocele repair.

Biodesign Advanced Tissue Repair

Biodesign was developed to reinforce soft tissues that have been shown to be insufficient in withstanding physiological pressures. Because pelvic floor prolapse is caused by muscular defects usually resulting from obstetric trauma, Biodesign can possibly help restore the suspensory support for the endopelvic fascia and improve the degree of prolapse following surgical placement of the graft.

A naturally derived, acellular biologic scaffold, Biodesign is not chemically cross-linked during processing. Unlike synthetic mesh, it communicates with the body, signaling surrounding tissue to grow across the scaffold. It remodels into vascularized host tissue, providing strength. As a result, Biodesign provides not only mechanical strength, but also includes growth factors and cytokines that actively modulate cell behavior and direct the healing process.⁶



Operative Technique

The anterior repair/paravaginal repair was performed first. After the patient was placed in the dorsal lithotomy position, she was prepped and draped in the normal sterile fashion. The bladder was drained with a Foley catheter, and a self-retaining retractor was subsequently placed to provide countertraction for the dissection.

Two Allis clamps were used to grasp the vaginal apex. Hydrodissection with 75 to 200 mL normal saline and/or 0.5% lidocaine/epinephrine was then performed to help dissect the underlying tissue away and to help with hemostasis. A scalpel was then used to make a vertical incision at the apex roughly 3 cm in length. Metzenbaum scissors were used for sharp dissection of the vaginal mucosa away from the pubocervical fascia. In addition, some blunt dissection with a moist 4x4 was used.

Next, sharp dissection close to the pelvic bone (to avoid tearing of the connective tissue or muscle) was used to enter the paravaginal space. Once this space was entered, the index finger was used to sweep the tissue off the bone.

Anatomic landmarks were then identified: the sacrospinous ligament, the ischial spine (spinous process) and the arcus tendineus fascia pelvis (ATFP). The ATFP may be felt as a band of connective tissue or may be very attenuated and thin in nature. If it is attenuated severely, accurate identification of the ATFP may be difficult or impossible. As an alternative, the obturator internus muscle can be used as an attachment point.

If the prolapse was severe, the pubocervical fascia was then plicated with interrupted 2-0 absorbable/delayed absorbable sutures to reduce its size. The sacrospinous ligament, which acts as the apical support structure for

the graft, was identified. A delayed absorbable suture (1 fingerwidth medial to the spinous process) was placed through the sacrospinous ligament on each side. An absorbable suture was subsequently placed through the ATFP and then through the lateral vaginal mucosa apex.

After a 2 minute rehydration, the Biodesign Anterior Pelvic Floor Graft was laid flat and cut to size for the patient's pelvis, taking into consideration that the average patient's ischial spine width is 10.5 cm and that the graft may shrink up to 30% in vivo. An apical arch was cut out of the graft in order to wrap around the vaginal apex and decrease the stress on the sacrospinous graft arm attachment. Both ends of the sacrospinous sutures were placed through the graft, leaving approximately 1 cm distance between them to help prevent suture pull out. After both sutures were placed through, tension was released from the self-retaining retractor and the sutures were secured to the sacrospinous ligament. A stay suture of absorbable suture was then placed at the vaginal apex and the periurethral space.

At the distal ATFP, a delayed absorbable suture was placed on each side, approximating the correct distance by having the graft rest tension-free at the proximal bladder neck. This suture was then placed through the Biodesign Anterior Pelvic Floor Graft distally. Vaginal mucosa trimming was then performed as needed, and the vaginal mucosa was reapproximated with absorbable suture. Tension from the self-retaining retractor was then released, and the sutures that were attached to the ATFP and subsequently placed through the vaginal mucosa were tied.

Discussion

If a mesh or graft is to permanently reinforce soft tissue, it must be able to support cell growth, proliferation and collagen deposition. What makes Biodesign unique and advantageous over synthetic mesh, chemically cross-linked biologic grafts, and other biologic grafts used in gynecologic surgery is its ability to not only provide the mechanical support necessary to reduce the incidence of recurrence, but to also facilitate the remodeling of strong, organized interstitial tissue and muscle at the site of the defect. Synthetic mesh and chemically cross-linked collagen-based materials are unable to promote tissue regeneration because they don't signal surrounding tissue, and thus only provide mechanical support that might eventually erode into surrounding tissues.

Because Biodesign signals the body to stimulate natural healing processes, the graft acts as a scaffold for tissue remodeling and cellular differentiation.⁷ In various animal models, it has been shown to restore fascia, smooth muscle, skeletal muscle, cardiac muscle tissue, bone, dura mater, and even functional nervous tissue. As cells and blood vessels grow into the graft,

Biodesign effectively becomes "self" during the process of natural tissue turnover.⁸ As such, no Biodesign permanently remains in the body, but it is gradually incorporated into a strong repair. Its unique design means that postoperative discomfort, encapsulation and erosion are less likely to occur than with chemically cross-linked biologic grafts or synthetic mesh.

In summary, the Biodesign Anterior Pelvic Floor Graft embodies the characteristics of an ideal graft. It signals the body to grow across the scaffold, remodeling completely into vascularized, infection-resistant tissue for a lasting repair without a permanent material.⁸ It assists in restoring normal pelvic anatomy by first reinforcing the pelvic floor and then in aiding the deposition of new connective tissue in an area that has become significantly attenuated or torn. We advocate its use in conjunction with VPVR to restore normal pelvic floor anatomy while reducing the likelihood of mesh erosion and recurrence following alternative procedures.

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COOK MEDICAL INCORPORATED

P.O. Box 4195, Bloomington, IN 47402-4195 U.S.A.
Phone: 812.339.2235, Toll Free: 800.457.4500, Toll Free Fax: 800.554.8335

COOK (CANADA) INC.

111 Sandiford Drive, Stouffville, Ontario, L4A 7X5 CANADA
Phone: 905.640.7110, Toll Free: 800.668.0300

WILLIAM A. COOK AUSTRALIA PTY. LTD.

95 Brandl Street, Brisbane Technology Park, Eight Mile Plains
Brisbane, QLD 4113 AUSTRALIA, Phone: +61 7 3841 1188

COOK IRELAND LTD.

O'Halloran Road, National Technology Park, Limerick, IRELAND
Phone: +353 613 34440

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