

## Adjuvant Dermal Graft for Advanced Anterior Compartment Prolapse: Comparison to Standard Anterior Colporrhaphy

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### Objective

Compare preliminary outcomes for patients receiving an anatomically-anchored acellular dermal matrix, to age matched controls receiving standard anterior colporrhaphy, for the repair of cystoceles extending to the hymenal ring or beyond.

### Methods

59 patients with > Stage II anterior prolapse (Aa or Ba 0) underwent anterior compartment repairs augmented with an acellular dermal implant, between 11/2003 to 11/2004. 42 patients had completed 12-week follow up at the time of this assessment. The dermal graft (4 x 7 cm) was placed longitudinally and attached at 3 levels to ATFP, re-establishing bilateral paravaginal supports. The proximal graft was anchored to the posterior vaginal apex or paracervical fascia across the midline. Standard anterior colporrhaphy was performed along with graft placement in all cases. Forty-two age matched controls with > Stage II prolapse (Aa or Ba 0), who had received standard anterior colporrhaphy alone, were identified for comparison of outcomes at 12 weeks. POP-Q staging was performed preoperatively and at 6 and 12 weeks postoperatively. Objective recurrence was defined as > Stage II (Aa or Ba -1). Secondary outcomes included subjective stress and/or urge incontinence, dyspareunia, EBL, and time to normal voiding. QOL assessments included the PFDI, PISQ-12 and IIQ-7, administered before and after surgery. Chi2, McNemar's and student t-tests were used.

### Results

The dermal graft and colporrhaphy groups were comparable in terms of mean age (60.6 vs. 62.8,  $p=0.54$ ), parity (2.5 vs. 2.8), BMI (26.4 vs. 25.5), prior recurrences ( $p=0.69$ ), prior SUI surgery ( $p=0.29$ ), and concomitant surgeries with the exception of more bladder neck slings in the colporrhaphy group ( $p=0.002$ ).

At 12-weeks postoperatively, significantly fewer recurrences were identified in the dermal graft group vs. the colporrhaphy group (12 vs. 29%,  $p=0.05$ ). This represents an overall 58.6% reduction in overall cystocele recurrence, associated with the graft technique. Recurrent prolapse to the hymenal ring or beyond was observed in 5% vs. 17% in the graft and colporrhaphy groups, respectively ( $p=0.06$ ). This represents a 70.5% reduction in 'advanced' cystocele recurrence, associated with the graft.

Time to normal voiding (9 vs. 8 days), retention ( $p=0.57$ ), subjective SUI ( $p=0.35$ ), urge incontinence ( $p=0.37$ ), detrusor overactivity ( $p=0.20$ ), EBL (287 vs. 302cc) and hospital stay (1.5 vs. 1.7 days) did not differ between groups. There were no erosions or adverse events related to the graft. QOL scores improved significantly.

### Conclusions

These findings suggest that anchored acellular dermal grafts, when anatomically anchored to the ATFP and vaginal apex, result in markedly improved outcomes for the management of cystoceles extending to the hymenal ring or beyond, without significant complication or discomfort.

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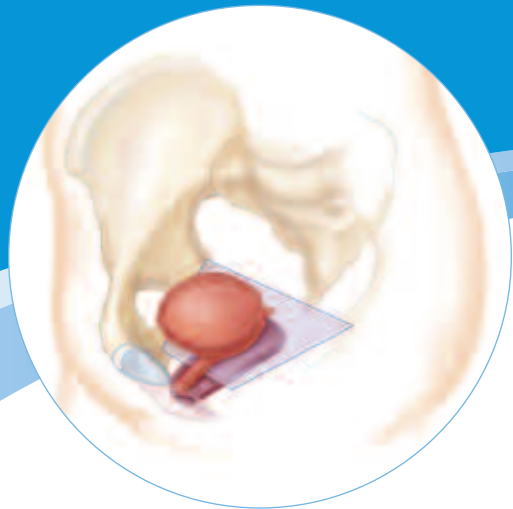
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# Managing the Advanced Cystocele:

Improved Outcomes With Repliform® Graft Augmentation

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### **Introduction**

Advanced cystoceles represent one of the most challenging aspects of pelvic surgery, with traditional anterior colporrhaphy associated with failure rates exceeding 50%<sup>1</sup>. Emerging data indicates that Repliform graft augmentation results in up to a 70% reduction in advanced cystocele recurrence compared to standard colporrhaphy after 3 months follow-up.

The procedure achieves an anatomically correct repair of both central and paravaginal defects, requiring minimal dissection beyond that performed during anterior colporrhaphy, no extra incision, no trocar insertions, and no risk of synthetic mesh erosion.

In this technical spotlight, a minimally invasive, trocar-free surgical approach to Repliform graft placement is outlined, placing potentially better anatomic outcomes and fewer failures within the reach of surgeons familiar with standard “anterior repair”.

<sup>1</sup> Weber AM, *Am J Obstet Gynecol* 2001;185:6

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## Arcus to Arcus Graft: The Simplified 5-Step Approach

### Step 1

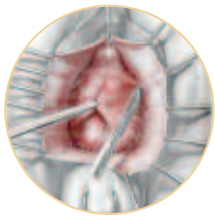


Figure 1

**Start with a Standard Colporrhaphy Dissection.** Dissect the the vaginal epithelium away from the bladder and its surrounding endopelvic connective tissue, just like an anterior colporrhaphy. For graft placement, blunt dissection will be carried *further laterally on both sides*, beyond the descending pubic ramus which can be easily palpated. The obturator internus (OI) is now exposed. The OI muscle surface is the anatomic insertion point for the *pubocervical fascia*, the physiologic ‘hammock’ of connective tissue support beneath the bladder – and also the insertion point for your graft. These structures are readily accessible, and are associated with no major blood vessels. *Figure 1* illustrates this simple and safe anatomic area.

### Step 2



Figure 2

**Palpating Simple Bony Landmarks.** Two easily palpable bony ‘notches’ are your most reliable fixed reference points for confirming the position of the OI and arcus tendineus. These are the *ischial spine*, and *pubic tubercle*. Between these bony notches lies the soft muscular surface of the OI, where your stitches will be placed to anchor the graft. The connective tissue remnant of the arcus tendineus *fascia pelvis* can often be seen or palpated overlying this portion of the obturator internus; however for cases involving pronounced paravaginal defect, the arcus may be absent, as this connective tissue remnant has been completely attenuated or detached. Whether the arcus is well defined or absent, the surgeon should be aware that graft sutures rely upon the tensile strength of the OI muscle and not the overlying arcus tendineous connective tissue remnant for their support. Palpation of the bony landmarks, and their relation to the OI, ATFP, and Repliform graft sutures, are illustrated in *Figure 2*.

### Step 3



Figure 3

**Placing the Sutures.** The Capio® suturing device is now used to anchor sutures into the OI. This most commonly involves 3 sutures on each side (although at physician discretion 2 may be used), anchoring the graft to the (1) proximal, (2) mid and (3) distal areas of the OI and overlying arcus tendineous fascia pelvis. Place a finger on the desired target site and advance the Capio head to your finger. The push-and-catch Capio system delivers suture placement with controlled depth, requiring minimal dissection and a trocar-free approach.

### Step 3A

**Colporrhaphy.** At the discretion of the physician, standard colporrhaphy is now performed at this time.

**Step 4**

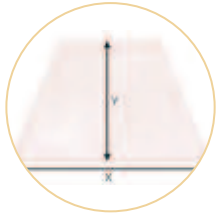


Figure 4

**Preparing the Graft.** Repliform acellular tissue grafts are available in several sizes – including 5x10cm and 6x12cm. This allows the surgeon to customize according to patient dimensions, avoiding ‘one size fits all’ mismatches. The graft should be immersed in sterile saline solution for approximately 20 minutes before placement into the surgical site. A typical trapezoidal shape appropriate for most anterior compartment repairs, along with dimensions, is illustrated in *Figure 4*.

**Step 5**



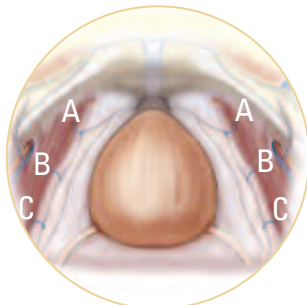
Figure 5

**Securing the Graft.** The free ends of each anchoring suture are now carried through the graft corners, using an ordinary free tapered suture needle, 1cm from each corner. Sutures are sequentially tied, fastening the graft into place. Excessive tension and laxity should be avoided, the graft should lay flat. As the graft is being fixed into position, it can be further tailored to the patient’s anatomy by trimming excess width or by repositioning the site of suture placement. A safety stitch can be used by placing a free suture between the knot and graft, before final tie down, to release the knot if necessary. *Figure 5* illustrates final graft placement. Standard closure of the vaginal incision is now performed.

*Given the incidence of stress urinary incontinence associated with prolapse repair, a sling procedure may now be performed.*

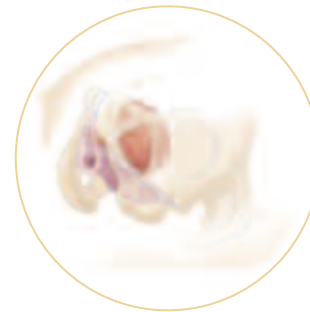
**Anchoring Sites Along ATFP**

Sites A,B,C are illustrated



A: Proximal Arcus B: Mid-Arcus C: Distal Arcus

**Final Placement**



**Why a Repliform Graft for Cystocele Repair?**

**1. Anatomically Correct.**

A ‘hammock’ of natural regenerative tissue provides anatomical correction of both central and paravaginal defects.

**2. Excellent Safety Profile.**

- Trocar-free technique.
- No blind insertion.
- No extra incision beyond that required for anterior colporrhaphy.
- No perforation through the levator ani muscles or pelvic sidewall.
- No proximity to major blood vessels, or abdominal cavity.

**3. Short Procedural Time.**

Performed in approximately 20 minutes.

**4. Promising Results.**

59-70%\* reduction in cystocele recurrence at three months, when compared to traditional colporrhaphy.

\* Presented AUGS 26 Annual Scientific Meeting. Journal of Pelvic Medicine and Surgery 2005; 11 (Supplement 1); S51.