

PELVICOL™: INITIAL RESULTS OF A NOVEL XENOGRAFT IMPLANT IN PELVIC FLOOR RECONSTRUCTION

Aims of Study

Pelvic floor reconstruction is associated with approximately 20% rate of recurrence (1). With the goal to achieve more long lasting results, implantation of porcine acellular collagen matrix (Pelvicol™) has been introduced (2). Pelvicol™ is an approved biocompatible, non-allergenic acellular porcine dermal matrix. Cross-linking of the implant using hexamethylene diisocyanate provides resistance to enzymatic attacks as well as preservation of the integrity of the material. We determined the efficacy and safety of transvaginal pelvic floor reconstruction using porcine xenograft acellular collagen matrix (Pelvicol™).

Methods

From April 2001 to August 2002, 32 patients underwent transvaginal pelvic floor reconstruction with Pelvicol™ and all of them were available for follow-up. Mean age was 62 years (range 33 to 87 years). Forty-two implants were placed: 29 (91%) for anterior defects, 1 (3%) for posterior defect, and 12 (38%) as pubovaginal slings. Ten patients (31%) had simultaneous cystocele repair and pubovaginal sling with Pelvicol™. Presenting symptoms included frequency/urgency in 25 (78 %), obstructive symptoms in 16 (50 %), vaginal mass in 12 (38 %), bowel complaints in 7 (22 %), stress urinary incontinence (SUI) in 5 (16 %) and urge urinary incontinence (UUI) in 6 (22 %). Patients were prospectively evaluated using validated Stress, Emptying, Anatomy, Protection and Instability (SEAPI) scores. Associated procedures were the following: rectocele in 19 (59 %), enterocele in 6 (19 %), and hysterectomy in 4 patients (13 %). Combined procedures were elected in 27 patients (84 %).

Results

Mean follow-up was 8 months (range from 4 to 15). Preoperative and postoperative 0 (no complaints) scores were: S0=28%, E0=53%, A0=6%, P0=31%, I0=21% and S0=84%, E0=91%, A0=85%, P0=66%, I0=66% respectively. Comparison of pre and postoperative SEAPI scores showed a statistically significant improvement in all the SEAPI domains ($p<0.001$) using Mc Nemar's analysis. Cystocele recurred in 4 patients (13%) (3 in grade IV, 1 in grade III), none of which required surgery. There was no symptomatic recurrence of rectocele or enterocele. SUI persisted in 2 patients (16%) who had a pubovaginal sling procedure. De novo urge incontinence occurred in 2 patients (6%). No retention, infection, erosion, fistula or vaginal stenosis was noted.

Conclusions

The use of the porcine xenograft acellular matrix (Pelvicol™) has shown satisfactory safety profile in transvaginal pelvic floor reconstruction. Follow-up is ongoing to evaluate the durability of the technique.

References

- 1- Weber AM., Walters M.: Anterior vaginal prolapse: review of anatomy and techniques of surgical repair. *Obstet Gynecol* **89:2** 311, 1997
- 2- Harper C.: Permacol™: clinical experience with a new biomaterial. *Hops Med* **62:2**, 90, 2001