Hypothesis / aims of study

Compare the subjective and objective outcomes between patients who underwent a transvaginal Cooper’s ligament sling procedure for urodynamic stress incontinence with a low-pressure urethra using either porcine dermis or cadaveric fascia lata.

Study design, materials and methods

All patients (N=232) underwent a transvaginal Cooper’s ligament sling procedure using either porcine dermis or cadaveric fascia lata within our Division between July, 2000 and May, 2003. Indication for surgery was urodynamic stress incontinence with low-pressure urethra (max Urethral Closure Pressure \( \leq \) 20 cm H\(_2\)O). Patients were seen in an ambulatory setting at two, six, twelve and fourteen weeks postoperatively. The fourteen-week postoperative visit included multichannel urodynamics. Both preoperative and postoperative multichannel urodynamics were performed in a consistent manner and consisted of cystometry, static and dynamic (cough and Valsalva) urethral closure pressure profiles, and micturition studies. Stress urinary incontinence (SI), urge urinary incontinence (UI) and detrusor overactivity (DO) were compared subjectively and objectively using a retrospective cohort study design. Subjective outcome variables included patient reported stress and/or urge incontinence at the 14 weeks postoperative urodynamics visit or, if unavailable, at the 12 weeks post-operative follow-up visit. Objective outcome variables included: support provided by the sling (Q-tip test); presence of stress incontinence or detrusor overactivity on post-operative multichannel urodynamics; and, post-operative urinary retention (post void residual (PVR) \( \geq \) 50cc or urethrolysis). Statistical analysis of variance compared subjective and objective outcomes of the 2 different materials.

Results

At baseline, the cohorts were similar with respect to age, parity, body-mass index, and menopausal status. The cadaveric fascia lata cohort had a significantly higher percentage of subjects with prior incontinence surgery including anterior colporrhaphy (45/165 [27%] vs. 8/67 [12%] for porcine dermis, p 0.01), and the rates of other prior surgeries were similar in the cohorts. There was a significantly higher rate of baseline subjective UI (124/165 [75%] vs. 39/67 [61%], p 0.03) in the cadaveric fascia lata. There
was also a higher rate of baseline DO in that cohort (125/165 [77%] vs. 40/67 [66%], p 0.09), but the difference did not reach statistical significance. Two hundred ten patients (91%) completed fourteen-week postoperative urodynamics. Follow-up was similar in the cohorts. Among patients completing fourteen-week postoperative urodynamics, there was a significant difference in the rate of DO (119/153 [78%] cadaveric fascia vs. 35/57 [60%] porcine dermis, p 0.009) but no difference in the rate of postoperative urodynamic SI (43/153 [28%] vs. 17/57 [30%], p 0.81). Two hundred and seventeen patients completed twelve to fourteen week subjective follow-up. Postoperative subjective SI (30/155 [19%] vs. 18/62 [29%], p 0.12) and UI (96/155 [62%] vs. 39/57 [63%], p 0.89) were similar in both cohorts. There was no significant difference between cohorts with respect to mean Q-tip straining angle (10° fascia vs. 11° porcine dermis, P > 0.2). Overall post-operative retention (PVR ≥ 50cc) was similar between cohorts (24% fascia vs. 31% porcine dermis, p > 0.2) but there was a significant difference with respect to post-operative retention requiring urethrolysis (1% fascia vs. 6% porcine dermis, p 0.02).

**Interpretation of results**

When used during a Cooper's ligament sling procedure, porcine dermis is similar to cadaveric fascia lata fourteen-weeks post-operatively in subjective and objective cure of stress urinary incontinence, post-operative suburethral support and urinary retention. Porcine dermis was superior to cadaveric fascia lata fourteen-weeks postoperatively in objective rate of DO. Post-operative bladder neck support was similar between cohorts. Also similar were post-operative complications, except for urethrolysis, which was significantly more common in the porcine dermis cohort. The study was limited by preoperative subjective UI being reported more in the cadaveric fascia lata cohort. That baseline difference may have biased the results and may have shown a statistically significant benefit to porcine dermis in the treatment of DO when it does not exist. The cadaveric fascia lata cohort was more difficult to treat based on the higher percentage of prior incontinence surgery in this cohort. This may have diluted a possible advantage of cadaveric fascia lata in the treatment of SI.

**Concluding message**

When used during a Cooper’s ligament sling procedure, porcine dermis is equivalent to cadaveric fascia lata fourteen-weeks post-operatively but may offer better treatment of concurrent DO in patients with mixed incontinence. Future work will include long-term follow-up of the cohorts.