

## IS ACELLULAR PORCINE DERMIS MATERIAL DURABLE FOR PUBOVAGINAL SLING SURGERY?

### Hypothesis / aims of study

Advances in alternative sling materials now offer the promises of simplifying the procedure and minimising morbidity. Proponents of alternative sling materials submit that they eliminate the need to harvest autologous fascia, saving valuable operation time and additional patient morbidity. Compared to synthetic material, organic sling materials offer the promise of increased biocompatibility.

We now have the opportunity to use xenograft collagen, which avoids the morbidity of harvesting autologous fascia, and the variability and infection risk of cadaveric fascia. Cell-free, cross-linked collagen isolated from porcine sources has been developed. Porcine dermal collagen (Pelvicol, Bard Urology, UK) is one such new biological sling material.

Thus, our primary research question for this study was whether introducing a biological sling material like acellular porcine dermis (PD), can we substitute autologous rectus fascia? While providing a substitute sling material for rectus fascia in an attempt to reduce morbidity, it is important that treatment safety and long term efficacy are not compromised.

The aim of our study was to compare the 3-year effectiveness and patient satisfaction of the PD with that of the autologous rectus fascia (RF) sling in the treatment of stress urinary incontinence (SUI).

### Study design, materials and methods

Between July 2000 and December 2001, 101 patients with SUI were randomly assigned to either RF (n=50) or PD sling (n=51). A 2X7 cm. strip of autologous RF or PD was used as sling material and was placed at the bladder neck. Patients were evaluated with a validated postoperative outcome questionnaire by a blinded assessor. All patients were asked to complete the questionnaire by telephone interview. Minimum time interval after surgery was 3 year. Primary outcome measures included continence rate and patient satisfaction on a linear analogue scale (0= not satisfied, 10=completely satisfied).

### Results

Complete data were available on 94 women (48 with PD and 46 with RF sling). The groups were well matched for age, menopausal status, hysterectomy, prior incontinence surgery and urge symptoms. Distribution of continence results and severity 3-year after PD and RF pubovaginal sling surgery is shown in the table 1 and 2 respectively. Operation time, duration of hospital stay, and return to normal activity were longer after RF than after PD sling procedure.

### Interpretation of results

Overall, SUI was cured or improved in 37 (80.4%) patients after RF and only 26 (54%) patients after PD sling (p= 0.009). Nine patients (19.6%) with RF and 22 (46%) patients with PD sling reported full recurrence of incontinence within 3 to 24 months after surgery. Median patient satisfaction was significantly lower after PD sling (7.0 vs. 9.0 for RF, p = 0.008).

### Concluding message

Acellular porcine dermis (PD) compromises efficacy of pubovaginal sling surgery when compared with the autologous rectus fascia. The higher failure rates and poorer patient satisfaction at longer term follow-up may prohibit its use in the operative management of SUI.

Table1. Distribution of continence results 3-year after acellular porcine dermis (PD) and autologous recus fascia (RF) pubovaginal sling surgery. Values are given as number.

Continence results	PD n=48	RF n= 46
Cured	15	26
Improved	11	11
Failure	22	9

Table 2: Showing distribution of severity of urinary incontinence 3-year after acellular porcine dermis (PD) and autologous recus fascia (RF) pubovaginal sling surgery. Values are given as number.

Urinary incontinence Severity	PD n=48	RF n=46
None	10	21
Mild	20	12
Moderate	11	12
Severe	7	1