The Long-Term Results of Pubovaginal Sling Surgery Using Acellular Cross-Linked Porcine Dermis in the Treatment of Urodynamic Stress Incontinence

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Purpose: Acellular cross-linked porcine dermis is a potential substitute for rectus fascia as a sling material with the advantage of decreased morbidity. However, the long-term efficacy is unknown. We compared the 3-year efficacy of PD vs autologous rectus fascia as a sling material for pubovaginal sling surgery in the treatment of urodynamic stress incontinence.
Materials and Methods: Between July 2000 and December 2001 a total of 101 consecutive, nonrandomized patients with USI underwent a PD (51) or RF (50) sling procedure. Patients were assessed at 6 weeks, and at 3, 6 and 12 months postoperatively. Urodynamic study was repeated in cases of treatment failure. A detailed survey questionnaire was mailed to all patients at least 36 months after surgery and all responders were then retested by telephone interview by a blinded assessor. The primary outcome measure was patient perceived success rate (cured or improved) at least 36 months after PVS. Secondary outcome measures were patient satisfaction 36 months after surgery, durability of success with time and reoperation rate.
Results: Complete data were available on 94 patients (48 treated with PD and 46 treated with RF sling). The groups were well matched for age, leak point pressure, prior incontinence surgery and urge symptoms. Pubovaginal sling was successful (cured or improved) in 37 (80.4%) patients treated with RF but in only 26 (54%) patients treated with PD 36 months after surgery (Fisher's exact test $p = 0.009$; 95% CI 8.03, 44.4). Treatment failure occurred by 9 months after RF and by 24 months after PD sling procedure. Repeat urodynamic study showed USI to be the cause of treatment failure in 18 (37.5%) of 20 patients treated with PD but in only 3 (6.5%) of 8 patients treated with RF.
Conclusions: We have shown that use of the PD sling, although reducing early morbidity, results in a significantly inferior long-term cure rate in comparison to the RF sling. Therefore, acellular cross-linked porcine dermis should not be used as a substitute for rectus fascia.

Key Words: dermis, urinary incontinence, fascia

The pubovaginal sling has become the first line surgical treatment for all types of USI at many institutions. Modifications in sling technique have resulted in broader indications,[1] reduced morbidity and shorter hospital stay.[2] Autologous rectus fascia remains the gold standard sling material for the surgical treatment of USI with a 4-year durability of 88%.[3] However, the Pfannenstiel incision used for harvesting autologous fascia often results in considerable postoperative morbidity and prolongs patient recovery time. Attempts have been made to reduce morbidity by introducing various readymade sling materials.[4] The main disadvantage of synthetic material is the risk of urogenital tract erosion (0.3% to 23 %).[5] Compared to synthetic material, biological sling materials offer the promise of increased biocompatibility and a much reduced erosion risk. Among the most popular alternative biological sling materials are cadaveric fascia allografts. Although cadaveric fascia lata was initially used with success, more recently Carbone et al reported a 37.6% recurrence rate of moderate to severe stress incontinence at 6-month followup.[6]

Cell-free, cross-linked collagen isolated from porcine sources (eg Stratasis®, Pelvicol®) has been used extensively throughout the human body.[7] Acellular porcine dermal collagen (Pelvicol®) is one such new biological sling material. However, it is important that in providing a substitute biological material for rectus fascia to reduce morbidity, long-term efficacy is not compromised. Therefore, we prospectively compared the long-term efficacy of PD with that of RF as a sling material in the treatment of USI.

PATIENTS AND METHODS

Consecutive patients were recruited from outpatient clinics in a nonrandomized fashion once a decision was made for anti-incontinence surgery. The inclusion criteria were patients with urodynamically proven stress urinary incontinence. Patients with neuropathic bladder, uterovaginal prolapse, DI and preoperative voiding dysfunction (maximum urine flow rate less than 15 ml per second, detrusor pressure at maximum flow more than 40 cm H_2O, post-void residual more than 50 ml) were excluded from this study.

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Study received ethical approval from the local Ethics Committee.
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Ethical approval was obtained from the local Ethics Committee. Our unit has performed rectus fascia slings since 1996. Between July 2000 and December 2001 a total of 101 consecutive patients met our inclusion and exclusion criteria. The December 2001 cutoff was drawn to allow a minimum 3-year followup. From July 2000 to December 2000 all of these patients underwent PVS using RF only (in 37). Then from January 2001 to December 2001 all patients were offered the option of PVS using PD. RF sling was performed only in those who declined the PD sling. Thus, 51 patients overall underwent the PD sling and 50 underwent the RF sling procedure in the study period. All data were accrued prospectively.

Preoperative Evaluation

Preoperatively all patients were evaluated by a complete history, physical examination, urinalysis and urodynamic study. All patients had a pelvic examination to assess pelvic floor defects and bladder neck motion. After free uroflowmetry and post-void residual measurements, all patients had medium fill subtracted cystometry using a 6Fr double lumen bladder catheter and a cuffed, fluid filled 4Fr rectal catheter. Cystometric parameters measured included sensation, presence of detrusor stability, compliance and capacity. Urethral sphincter competency was assessed in the semi-recumbent or standing position using the Valsalva maneuver or cough at 50 ml intervals from 150 ml of filling to obtain abdominal leak point pressure.

Patients were counseled regarding the possible need for clean intermittent self-catheterization postoperatively and were briefly taught the technique. Explanatory pamphlets were given to each patient. Informed consent was obtained from all patients.

Operative Procedure

All patients received thromboprophylaxis with 20 mg subcutaneous enoxaparin**,** and preoperative antibiotic prophylaxis with 1 gm intravenous ceftriaxone and 240 mg gentamicin. All operations were performed by HDF with the patient under general anesthesia.

The technique of PVS used was a minor modification of the technique described by McGuire and Clemens.[8] The sling was prepared using an 8×2 cm strip of autologous RF or PD secured at each end with 1-zero polypropylene suture. After paraurethral dissection the endopelvic fascia was perforated in a superolateral direction. A Yachia needle was passed through the suprapubic incision and guided digitally behind the pubic ramus into the vaginal incision bilaterally. One end of the polypropylene suture was then passed through the eyelet in the needle which was then withdrawn upward. The procedure was repeated on the opposite side. Cystoscopy was performed to rule out any bladder injury. The sling was then placed under the proximal urethra at the urethrovesical junction with appropriate tension. The details of the PD sling technique have been described previously.[9] A Foley catheter was placed in the bladder and a vaginal pack was inserted. The operating time and intraoperative blood loss were recorded. Any intraoperative complications were also recorded.

Postoperative Care

The vaginal pack was removed on postoperative day 1. When the patient was ambulatory (usually later on postoperative day 1 or 2), the urethral catheter was removed. Patients were considered suitable for discharge from hospital when emptying efficiently[1] or when self-catheterizing confidently with adequate pain control in the absence of any significant complication.

TABLE 1. *Baseline patient characteristics*

	PD	RF
Median age (IQR)	46 (34–52)	48 (36–56)
Median parity (IQR)	3 (2–4)	3 (2–4)
No. postmenopausal (%)	15 (31.2)	14 (30.4)
No. previous hysterectomy (%)	9 (18.7)	8 (17.4)
Median preop pad use (IQR)	3 (1–6)	3 (1–6)
No. prior incontinence surgery (%)	4 (8.3)	5 (10.8)
Median cm H_2O abdominal leak point pressure (IQR)	90 (60–110)	85 (55–108)

Followup

Patients were assessed by symptom review, clinical examination and questions about recovery at 6 weeks, and 3, 6 and 12 months postoperatively in the outpatient clinics. Urodynamic study was repeated when the patients complained of treatment failure or had persistent obstructive symptoms.

To evaluate long-term outcome and patient satisfaction a detailed survey questionnaire was mailed to all patients at least 36 months after surgery, and all responders were then retested by telephone interview by a blinded assessor. The questionnaire was similar to a previously validated questionnaire of Haab et al with the addition of question 5 (see Appendix).[10]

Results of PVS were stratified as success (cured or improved) or failure. Cured was defined as patient report of 90% or greater improvement in urine leakage or the patient considered herself totally cured. Improved was defined as 50% or more improvement, or patient response as much improved. Failure was defined as less than 50% improvement in urine leakage or patient response as only slight improvement or no improvement.[11] The primary outcome measure was patient perceived success rate (cured or improved) at least 36 months after PVS. Secondary outcome measures were patient satisfaction 36 months after surgery, durability of success with time and reoperation rate.

Statistical Analysis

Data obtained from case report forms were transferred to a computer spreadsheet. Entries were then checked for any errors. All data were tested where appropriate for normality. P values less than 0.05 were considered statistically significant. Statistical significance was calculated using the chi-square test, Fisher's exact test or Mann-Whitney U test where appropriate.

RESULTS

Three patients treated with PD sling and 4 patients treated with RF sling did not return the final questionnaire 36 months after surgery. Thus, complete data were available on 94 patients (48 treated with PD sling and 46 treated with RF sling). Table 1 shows that the baseline characteristics of the 2 study groups were similar. Operative and postoperative details are shown in table 2. As expected, median operation