BJU International (2002), **90**, 415–419 doi:10.1046/j.1464-4096.2002.02913.x

Cadaveric fascia lata pubovaginal slings: early results on safety, efficacy and patient satisfaction

I.K. WALSH, T. NAMBIRAJAN*, S.M. DONELLAN, V. MAHENDRA* and A.R. STONE

*Department of Urology, University of California, Davis, Sacramento, CA, USA, and *Department of Urology, Belfast City Hospital, Belfast, UK*

Objective To prospectively evaluate and quantify the efficacy of cadaveric fascia lata (CFL) as an allograft material in pubovaginal sling placement to treat stress urinary incontinence (SUI).

Patients and methods Thirty-one women with SUI (25 type II and six type III; mean age 63 years, range 40–75) had a CFL pubovaginal sling placed transvaginally. The operative time, blood loss, surgical complications and mean hospital stay were all documented. Before and at 4 months and 1 year after surgery each patient completed a 3-day voiding diary and validated voiding questionnaires (functional inquiry into voiding habits, Urogenital Distress Inventory and Incontinence Impact Questionnaire, including visual analogue scales).

Results The mean (range) operative time was 71 (50–120) min, blood loss 78.7 (20–250) mL and hospital stay 1.2 (1–2) days; there were no surgical complications. Over the mean follow-up of 13.5 months, complete resolution of SUI was reported by 29 (93%) patients. Overactive bladder symptoms were present in 23 (74%) patients before surgery, 21 (68%) at 4 months and two (6%) at 1 year; 80% of patients with low (< 15 cmH_2O) voiding pressures before surgery required self-catheterization afterward, as did 36% at 4 months, but only one (3%) at 1 year. Twenty-four (77%) patients needed to adopt specific postures to facilitate voiding. After surgery there was a significant reduction in daytime frequency, leakage episodes and pad use ($P < 0.05$). The severity of leak and storage symptoms was also significantly less ($P < 0.002$), whilst the severity of obstructive symptoms remained unchanged. Mean subjective levels of improvement were 69% at 4 months and 85% at 1 year, with corresponding objective satisfaction levels of 61% and 69%, respectively. At 1 year, ≈ 80% of the patients said they would undergo the procedure again and/or recommend it to a friend.

Conclusion Placing a pubovaginal sling of CFL allograft is a highly effective, safe surgical approach for resolving SUI, with a short operative time and rapid recovery. Storage symptoms are significantly improved, and subjective improvement and satisfaction rates are high.

Keywords urinary incontinence, pubovaginal sling, cadaveric fascia lata

Introduction

Sling procedures, first introduced in the early 1900s, are the oldest known surgical approach for treating female stress urinary incontinence (SUI) [1]. Whilst pubovaginal slings were introduced in the 1970s for treating women in whom previous anti-incontinence surgery had failed, in the last decade slings were shown to be effective in treating all types of SUI [2].

Slings act by providing urethral support and a 'backboard' plate, which prevents the transmission of intra-abdominal pressure to the bladder neck and proximal urethra. These mechanisms ideally result in urethral coaptation and bladder neck stabilization during stress manoeuvres [3]. Accurate sling placement beneath the bladder neck and proximal urethra is most commonly undertaken by a combined abdominal and transvaginal approach. Placement can also be facilitated by minimally invasive transvaginal needle techniques and the use of bone anchors to fix the sling to the pubis. Materials used for the sling may be autologous, heterologous, homologous or synthetic. To date, such materials have included rectus fascia or fascia lata, vaginal wall, or synthetics, e.g. polypropylene mesh [4,5]. Overall cure rates exceed 80%, with prolonged retention or de novo detrusor instability occurring in up to 10% and 20% of patients, respectively [6]. Autologous fascia demands surgical tissue harvesting, and *in situ* vaginal wall slings can be associated with vaginal foreshortening and occasional flap dehiscence [7]. Synthetic materials are hampered by an increased risk of infection and erosion [8,9]. Recently, cadaveric fascia lata (CFL) has been introduced as a suitable sling material. CFL is attractive because it is strong and avoids fascial harvest-

Accepted for publication 10 June 2002

ing, which potentially reduces morbidity, postoperative discomfort and operating time [10].

The aims of the present study were to prospectively evaluate and quantify the efficacy of CFL pubovaginal slings for surgical complications, the resolution of SUI, the incidence and severity of voiding dysfunction, and patient satisfaction.

Patients and methods

The study included 31 women (mean age 63 years, range 40–75) with SUI; their mean (range) duration of symptoms was 82 (6–360) months and 20 (65%) gave a history of previous incontinence surgery, most commonly in the form of a suspension procedure. Eight (26%) patients had previously undergone conservative treatment with pelvic floor exercises and bladder retraining, with no success. Seventeen (55%) patients were taking anticholinergic drugs for concomitant overactive bladder symptoms. The diagnosis of SUI was confirmed in all patients by a full history and physical examination, multichannel video urodynamics and cysto-urethroscopy. Twenty-five (81%) patients were diagnosed as having type II SUI and six (19%) type III.

Surgery was undertaken or supervised by the same surgeon (A.R.S.) in all cases. Through an inverted U-shaped anterior vaginal wall flap, a plane was developed on each side of the catheterized urethra so that the inferior pubic ramus could be palpated. The periurethral fascia was then perforated on each side to enter the retropubic space. Through a separate 3 cm transverse suprapubic incision, Stamey needles were introduced on each side through the rectus fascia, via the retropubic space into the vaginal incision under digital control. The absence of bladder perforation was confirmed by cysto-urethroscopy. Polypropylene (#1) was then sutured to the end of each 9–11 cm CFL sling (non-proprietary, gamma-irradiated, lyophilized CFL, Tissue Bank, University of California, Davis; Fig. 1) and the suture ends passed through the eyes of the Stamey needles. Each suture was brought through the vaginal incision up into the suprapubic area by withdrawing the Stamey needles (Fig. 2). The sling was then anchored at the bladder neck with several polyglactin sutures into the adjacent periurethral tissue. The polypropylene sutures were then tied with no tension over the rectus fascia across the mid-line. Six (19%) patients also underwent concurrent vaginal repairs (three cystoceles, two urethral diverticula and one rectocele). The surgical field was irrigated with antibiotic solution before closure and an antibiotic-impregnated vaginal pack inserted. Vaginal packs were removed the morning after surgery and the patients discharged on oral antibiotics for 48 h with an indwelling 16 F urethral catheter, which was removed at an outpatient voiding trial 5 days after surgery. The operative duration, blood loss, surgical complications and mean hospital stay were documented.

Fig. 1. A 10-cm CFL sling prepared with helical polypropylene sutures for subsequent retropubic placement.

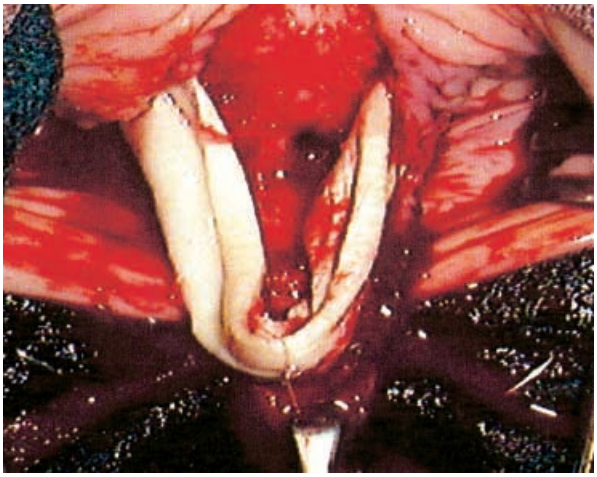

Fig. 2. The CFL sling is brought out through the vaginal incision with Stamey's needles.

Each patient completed the following self-administered documents at 1 week, 4 months and 1 year after surgery: (i) a 3-day voiding diary to document their frequency, nocturia, leakage episodes and pad usage; (ii) standardized voiding questionnaires including (a) a functional inquiry into voiding habits, focusing on leak severity, obstructive and storage symptoms, and (b) the Urogenital Distress Inventory and the Incontinence Impact Questionnaire, both validated and disease-specific quality-of-life instruments [11,12]; (iii) visual analogue scales (VAS) to quantify the degree of subjective improvement and overall patient satisfaction. Patients were also asked if they would undergo surgery again and if they would recommend the procedure to a friend. The patients were surveyed by a surgeon (S.M.D.) not associated with the surgical procedure. In the event of a patient not returning or failing to complete their questionnaires, the patient was contacted by telephone to complete data collection.

The incontinence and pad use before and after surgery were compared by univariate analysis (unpaired two-tailed Student's *t*-test), questionnaire responses were analysed using contingency tables and the chi-square cross-table analysis was used to investigate relationships between categorical preoperative and outcome variables. Statistical significance was assumed throughout at $P < 0.05$.

Results

The mean (range) follow-up was 13.5 (12–14) months, the operative duration 71 (50–120) min, the blood loss 78.7 (20–250) mL, and the hospital stay 1.2 (1–2) days; there were no surgical complications, e.g. bleeding, wound infection or erosion. Complete resolution of SUI was reported by 29 (94%) patients at both 4 months and 1 year (Table 1). Storage symptoms such as frequency and urgency declined after surgery. Two (6%) patients before and four (13%) after surgery were noted to have low-pressure detrusor instability (in a urodynamic study after surgery in seven patients whose symptoms failed to respond to anticholinergic medication). The reduction in the incidence and severity of urgency and urge incontinence was further reflected in the use of anticholinergic medication before and after surgery (Table 1).

Twenty (65%) patients failed the voiding trial at 5 days and 11 (35%) were still self-catheterizing at 4 months. Of these 11 patients, eight had had voiding pressures of < 15 cmH_2O before surgery; only one (3%) patient was still catheterizing at 1 year. The need to adopt specific postures to void (usually leaning forward) increased after surgery, but overall there was a significant subjective improvement in most patients at 4 months and at 1 year (Table 1).

From the voiding diaries, there were reductions in daytime frequency, nocturia episodes, leak episodes and pad use (Table 1). From the questionnaires, the severity of leak was also reduced at 4 months and 1 year. Obstructive symptom severity was slightly worse at 4 months but had returned to preoperative values by 1 year. The severity of overactive bladder symptoms was improved at 4 months and 1 year (Table 1). The VAS scores showed mean subjective levels of improvement of 69% at 4 months and 85% at 1 year; the respective mean subjective satisfaction levels were 61% at 4 months and 69% at 1 year; 23 (74%) patients at 4 months and 25 (81%) at 1 year stated that they would undergo the procedure again. At 4 months, 22 (71%) patients stated that they would recommend the procedure to a friend, compared with 24 (77%) at 1 year.

Discussion

Pubovaginal slings have historically been reserved for patients with previously failed anti-incontinence surgery, those with intrinsic sphincter deficiency, or complex incontinence cases [13,14]. More recently, sling procedures have been shown to be an effective treatment for both types II and III SUI [15]. Whilst autologous fascia has been the most commonly used sling material, attempts have been made to obviate the need for fascial harvesting by using alternative materials, e.g. vaginal wall or syn-

Table 1 The overall results of the CFL pubovaginal sling placed in 31 women with SUI

Variable	*Before*	*4 months*	*1 year*
N (%):			
Infection/erosion	–	0	0
Resolution of SUI	–	29 (94)*	29 (94)*
Storage symptoms	23 (74)	21 (68)	12 (39)*
Anticholinergic use	17 (55)	10 (32)	8 (26)*
Need to self-catheterize	0	11 (36)*	1 (3)
Postural voiding	7 (23)	24 (77)*	24 (77)*
Subjective improvement	–	23 (74)*	28 (90)*
Voiding diary, mean [% change]:			
frequency /day	8.4 (2.9)	7.3 (2.5) [−14]*	6.1 (2.5) [−28]*
nocturia /night	2.7 (1.7)	1.8 (1.1) [−33]*	1.9 (2.4) [−30]*
leakage episodes /day	5.3 (1.6)	1.9 (2.2) [−64]†	1.6 (2.4) [−70]†
pad use /day	3.2 (2.6)	1.2 (1.5) [−62]†	0.8 (0.9) [−75]‡
Voiding questionnaire, % change in severity of			
leak	–	−48.7‡	−59.9‡
obstruction	–	+16.2	+0.4
urge	–	−23.4*	−34.3*

*$P < 0.05$; †$P < 0.01$; ‡$P < 0.001$.

thetics. As the latter are known to be associated with the risk of vaginal foreshortening or infection/erosion, respectively, an ideal alternative has yet to be found.

Cadaveric fascia is an attractive allograft tissue because of its strength, biocompatibility and ready availability [16]. CFL has been shown to be an effective material in ophthalmic and neurosurgical reconstructive surgery [17,18]. Commercially available CFL for use in pubovaginal sling surgery is as strong as autologous rectus fascia but considerably more pliable [19].

Pubovaginal sling procedures, whilst having a favourable cure rate for SUI, have been perceived as having unacceptably high rates of prolonged urinary retention and secondary detrusor instability [15]; thus we prospectively investigated the efficacy of CFL as a pubovaginal sling allograft in resolving SUI, and the effect on overall voiding dysfunction. The results indicate that the operative duration and hospital stay were short and there were no surgical complications, e.g. infection or sling erosion. The relatively brief surgery and rapid postoperative recovery presumably reflect the avoidance of fascial harvesting, which is known to adversely affect morbidity, and to prolong surgery and recovery [10].

The CFL pubovaginal sling is effective in resolving SUI as shown by the complete absence of SUI episodes in 93% of patients, together with a significant reduction in leakage episodes, severity of leak and pad use after surgery (Table 1). These results compare very favourably with previous published reports using autologous fascia [3,20].

Interestingly, both the incidence and severity of overactive bladder symptoms (frequency, nocturia, urgency and urge incontinence) were reduced with surgery and further diminished with time (Table 1). This contrasts with the increased irritative voiding dysfunction, which is thought to be particularly prevalent after pubovaginal sling surgery [2,21]. Leakage into the proximal urethra during stress manoeuvres may either produce a sense of urgency or trigger the voiding reflex [22,23]. By effectively reducing stress leak, sling placement may serve to interrupt this mechanism. This might explain the relatively high incidence and severity of storage symptoms before surgery, with the significant reduction in such symptoms afterward.

Prolonged self-catheterization is known to be associated with pubovaginal sling surgery [15]. Whilst more than half the present patients failed to void on catheter removal and a third were still relying on catheterization at 4 months, only one was still catheterizing at 1 year. The incidence of self-intermittent catheterization at 4 months is higher than that in other studies [20,24], but interestingly eight of 11 of these patients had low preoperative voiding pressures ($< 15\ cmH_2O$). Although intervention such as urethrolysis has been advocated for patients using prolonged self-catheterization [25], the need for catheterization continued to decrease beyond 4 months. Low-pressure voiding therefore predicts that efficient emptying is unlikely in the early and intermediate postoperative period, but this should resolve. Notably, despite this drawback in those with inefficient voiding, most were highly satisfied, being willing to undergo the procedure again and recommend it to a friend.

Significantly many patients reported the need to adopt specific postures to void after surgery, continuing at 1 year. Whilst this did not appear to adversely affect the overall satisfaction, we now routinely explain this finding to patients before surgery.

Overall patient satisfaction was high, including those patients who required prolonged self-catheterization and those in whom overactive bladder symptoms worsened or appeared de novo. There was also a trend for subjective improvement and satisfaction to improve with time, presumably reflecting the discontinuance of catheterization in 10 patients and the resolution of storage symptoms in nine between the 4- and 12-month assessments.

Thus CFL appears to be an effective alternative to autologous fascia for pubovaginal sling placement, hastening surgery and hospital discharge. We encountered no surgical complications, and the overall symptomatic improvement and satisfaction were high. These results reflect only the 1-year follow-up but further prospective study will be necessary to determine the long-term efficacy and acceptability.

References

1 Kobashi KC, Leach GE. Stress urinary incontinence. *Curr Opin Urol* 1999; **9**: 285–90

2 Chaikin DC, Rosenthal J, Blaivas JG. Pubovaginal fascial sling for all types of stress urinary incontinence: long-term analysis. *J Urol* 1998; **160**: 1312–6

3 Das S. Dynamic suburethral suspension with pedicled external oblique aponeurosis in the management of female urinary incontinence. *J Urol* 1999; **162**: 469–73

4 Govier FE, Gibbons RP, Correa RJ, Weissman RM, Pritchett TR, Hefty TR. Pubovaginal slings using fascia lata for the treatment of intrinsic sphincter deficiency. *J Urol* 1997; **157**: 117–21

5 Ulmsten U, Johnson P, Rezapour M. A three-year follow-up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol* 1999; **106**: 345–50

6 Leach GE, Dmochowski RR, Appell RA *et al.* Female SUI Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence. The American Urological Association. *J Urol* 1997; **158**: 875–80

7 Vasavada SP, Rackley RR, Appell RA. In situ anterior vaginal wall sling formation with preservation of the endopelvic fascia for treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1998; **9**: 379–84

8 Barbalias G, Liatsikos E, Barbalias D. Use of slings made of indigenous and allogenic material (Goretex) in type III urinary incontinence and comparison between them. *Eur Urol* 1997; **31**: 394–400
9 Myers DL, LaSala CA. Conservative surgical management of Mersilene mesh suburethral sling erosion. *Am J Obstet Gynecol* 1998; **179**: 1424–8
10 Wright EJ, Iselin CE, Carr LK, Webster GD. Pubovaginal sling using cadaveric allograft fascia for the treatment of intrinsic sphincter deficiency. *J Urol* 1998; **160**: 759–62
11 Trockman B, Leach GE, Hamilton J, Sakamoto M, Santiago L, Zimmern P. Modified Pereyra bladder neck suspension: 10-year follow-up using outcomes analysis in 125 patients. *J Urol* 1995; **154**: 1841–7
12 Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. *Neururol Urodyn* 1995; **14**: 131–9
13 Haab F, Zimmern PE, Leach GE. Female stress urinary incontinence due to intrinsic sphincteric deficiency. recognition and management. *J Urol* 1996; **156**: 3–17
14 Farrell SA. Application of the concept of 'therapeutic index' to surgery for stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1998; **9**: 299–302
15 Sarver R, Govier FE. Pubovaginal slings. past, present and future. *Int Urogynecol J Pelvic Floor Dysfunct* 1997; **8**: 358–68
16 Burnett AL. Fascia lata in penile reconstructive surgery. a reappraisal of the fascia lata graft. *Plast Reconstr Surg* 1997; **99**: 1061–7
17 Prolo DJ, Pedrotti PW, White DH. Ethylene oxide sterilization of bone, dura mater and fascia lata for human transplantation. *Neurosurgery* 1980; **6**: 529–39
18 Mauriello JA Jr, Abdelsalam A. Effectiveness of homologous cadaveric fascia and role of suture fixation to tarsus in frontalis suspension. *Opthal Plast Reconstr Surg* 1998; **14**: 99–104
19 Lemer ML, Chaikin DC, Blaivas JG. Tissue strength analysis of autologous and cadaveric allografts for the pubovaginal sling. *Neurourol Urodyn* 1999; **18**: 497–503
20 Cross CA, Cespedes RD, McGuire EJ. Our experience with pubovaginal slings in patients with stress urinary incontinence. *J Urol* 1998; **159**: 1195–8
21 Fulford SC, Flynn R, Barrington J, Appanna T, Stephenson TP. An assessment of the surgical outcome and urodynamic effects of the pubovaginal sling for stress incontinence and the associated urge syndrome. *J Urol* 1999; **162**: 135–7
22 Park JM, Bloom DA, McGuire EJ. The guarding reflex revisited. *Br J Urol* 1997; **80**: 940–5
23 Jung SY, Fraser MO, Ozawa H *et al.* Urethral afferent nerve activity affects the micturition reflex; implication for the relationship between stress incontinence and detrusor instability. *J Urol* 1999; **162**: 204–12
24 McGuire EJ, Bennett CJ, Konnak JA, Sonda LP, Savastano JA. Experience with pubovaginal slings for urinary incontinence at the University of Michigan. *J Urol* 1987; **138**: 525–6
25 Cross CA, Cespedes RD, English SF, McGuire EJ. Transvaginal urethrolysis for urethral obstruction after anti-incontinence surgery. *J Urol* 1998; **159**: 1199–201

Authors

I.K. Walsh, MD, FRCS(Urol), Visiting Assistant Professor, and Consultant Urologist and Neuro-urologist.
T. Nambirajan, MS, MCh, FRCS(Edin, Glas), Specialist Registrar.
S.M. Donellan, MD, Visiting Assistant Professor.
V. Mahendra, MS, MCh, FRCS(Glas), Specialist Registrar.
A.R. Stone, MD, FRCS(Ed), Professor and Vice Chairman.
Correspondence: I.K. Walsh, Department of Urology, Belfast City Hospital, Belfast, UK.
e-mail: chwalshian@talk21.com

Abbreviations: **SUI**, stress urinary incontinence; **CFL**, cadaveric fascia lata; **VAS**, visual analogue scale.