American Journal of Obstetrics and Gynecology (2005) **193**, 2112–6

ELSEVIER

American Journal of Obstetrics & Gynecology

www.ajog.org

Suburethral sling materials: Best outcome with autologous tissue

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KEY WORDS
Female stress urinary incontinence
Sling
Autograft
Allograft
Xenograft

Objective: This study was undertaken to assess the outcome of suburethral slings by type of sling material.

Study design: A retrospective review of women who underwent a suburethral sling between January 1997 and January 2003 with autograft, allograft or xenograft materials. Objective failure was defined as urinary leakage with cough stress testing at any time after 3 months, postoperatively. Objective cure was defined as no leakage with a standing cough stress test with at least 200 mL bladder volume at a minimum of 12 months postoperatively. Data were analyzed using Student *t*, Wilcoxon rank sum, and Kaplan-Meier survival tests.

Results: A total of 241 women were included in this study: 78 received autograft, 80 received allograft, and 83 received xenograft. Objective failure was 36% and 46% for allograft and xenograft, respectively compared with 13% for autograft ($P < .001$).

Conclusion: Autograft has a significantly higher cure rate when used for suburethral slings.

The best long-term results for urinary stress incontinence surgery are observed with the retropubic urethropexy or suburethral sling procedures.[1] Once considered only for recurrent incontinence or intrinsic sphincter deficiency, slings are now accepted as a primary procedure. Materials used in performance of slings have included autologous rectus fascia or fascia lata, allograft, or xenograft. There is extensive evidence in the literature supporting the use of native tissue with cure rates ranging from 80% to 93%.[2] The use of non-autologous materials is popular and attractive because it decreases operative time and avoids the possible morbidity associated with a second surgical site.[3] However, the efficacy of these materials for use as a sling has yet to be determined. There have been conflicting reports in the literature on whether outcomes are compromised with the use of cadaveric fascia, and there is a paucity of data on the use of porcine dermis for slings.[4] The aim of this study is to report on our experience using autograft, cadaveric fascia, and porcine dermis as sling material for the treatment of stress incontinence.

Presented at the 31st Annual Meeting of the Society of Gynecologic Surgeons, April 4-6, 2005, Rancho Mirage, CA.

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doi:10.1016/j.ajog.2005.07.072

Table I Demographics

	Autograft	Allograft	Xenograft	Significance
Mean age (y)	55 ± 10	59 ± 11	57 ± 10	< .05 autograft vs allograft
Mean BMI	28 ± 6	30 ± 6	30 ± 6	NS
Medianparity	3	3	3	NS
Prior surgery	24%	25%	14%	< .05 xenograft vs autograft and allograft
Attachment to rectus	74%	84%	57%	< .05 xenograft vs allograft and autograft
Concomitant surgery	77%	82%	81%	NS

Materials and methods

The Institutional Review Boards approved the study. Data were extracted from the San Diego Pelvic Floor Consortium database on all women who underwent a suburethral sling from January 1997 to January 2003 at Naval Medical Center San Diego and Kaiser Permanente Medical Center. Sling material consisted of autograft (rectus fascia or fascia lata), allograft (cadaveric fascia lata), and xenograft (porcine dermis). Cadaveric fascia was freeze-dried and irradiated (Allosource, Denver, CO). The porcine dermis used was Pelvicol, a cross-linked acellular collagen matrix (Bard, Covington, GA). The selection of the sling material for surgery was made by the patient after the study surgeon reviewed with her the options for materials. Of note, autologous tissue was uniformly offered throughout the study period. Allograft was initially offered during the early years of the study period; however, as data was published suggesting decreased efficacy with this material, we then transitioned to offering porcine dermis.

Preoperative evaluation included history, standardized written questionnaire, urogenital examination (including pelvic organ prolapse quantification [POP-Q] assessment), Q-tip angle, stress test, and multichannel urodynamics.[5] All patients had demonstrated stress urinary incontinence on filling cystometry and stress testing.

Surgeries were performed primarily by a resident surgeon under the supervision of 1 of 3 attending surgeons (A.J.S., C.R.P., S.A.M.). The senior surgeon (S.A.M.) had proctored the other 2 attendings over a 2- to 3-year period therefore techniques were similar. The slings were secured abdominally by tying the polypropylene attachment sutures across the rectus muscle, as described by McGuire, or by directly attaching the sling to Cooper's ligament, as described by Koduri.[6,7] Each of the surgeons performed the different attachment methods. Autologous tissue sling varied in length from 8 to 12 cm, and in width from 1.5 to 2 cm. Cadaveric tissue was standardized at 10 cm length × 2 cm width. Porcine dermis sling length was 12 cm and the width ranged 1.5 cm to 2 cm. The ends of the autologous and cadaveric tissue were folded over before suture placement to reduce risk of suture pull-through. In all cases, suture material for sling attachment was permanent 0-gauge.

Postoperative assessment was performed at 3, 6, and 12 months and annually thereafter. The evaluation included a history via standardized written questionnaire, physical examination, cough stress test, and Q-tip test. Objective failure was defined as any leakage of urine with cough stress test. Objective cure was defined as no leakage with standing cough stress test with a minimum of 200 mL bladder volume. Subjective failure was defined as a positive response to the question "do you ever leak with activity, cough or sneeze?" on a standardized written pelvic floor questionnaire, which had undergone face validation. A patient was not considered objectively cured until they were followed at least 12 months postoperatively; failures could be reported at any postoperative time period after 3 months with last observation carried forward (LOCF) as a failure.

Statistical analysis was performed with the use of *t* tests and Wilcoxon rank sum tests to compare the groups with respect to age, BMI, parity and concomitant surgery, and failure. Logistic regression analysis was used to determine the confounding effects of age, parity, body mass index (BMI), prior surgery, or sling material. Kaplan-Meier analysis was performed to assess sling "survival" over time on the basis of material group.

Results

Three hundred fifty-four patients underwent suburethral slings, with nonsynthetic material, for stress urinary incontinence from January 1997 to January 2003 at Naval Medical Center San Diego and Kaiser Permanente San Diego. Two hundred forty-one patients (68%) had a minimum of 12 months postoperative follow-up, or had failed before 1-year assessment thus qualifying them to be included in the outcome as LOCF.

Of the 241 patients, 78 received autograft, 80 received allograft, and 83 received xenograft. Of the 241 patients, 10 underwent sling takedown (4 autograft, 4 allograft,