#### **Clinical Trial**

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## Pubovaginal sling using cadaveric allograft fascia for the treatment of intrinsic sphincter deficiency

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#### Abstract

**Purpose:** Pubovaginal sling is the definitive management of female stress urinary incontinence due to intrinsic sphincter deficiency. Customarily, autologous fascia has been used, although synthetic material has its proponents. Harvesting autologous fascia at surgery is associated with postoperative discomfort, and synthetic material has a history of infection and erosion. To assess whether allograft fascia is free from these drawbacks, we retrospectively compared the outcome of women undergoing pubovaginal sling using either autologous or cadaveric allograft fascia.

**Materials and methods:** We reviewed our experience during the last 28 months with patients treated with the pubovaginal sling for intrinsic sphincter deficiency. All patients underwent preoperative video urodynamics. The outcome was assessed using the SEAPI scoring system. Special attention was devoted to local sling tolerance. Operative time and length of hospital stay were compared between patients with allograft and autograft pubovaginal sling.

**Results:** A total of 92 women (mean age 60 years) underwent allograft (59) or autograft (33) pubovaginal sling. Preoperative parameters, such as percent of patients who had had previous incontinence surgery, mean leak point pressure and SEAPI incontinence score, were similar in both populations. Mean followup was 11.5 months (range 1 to 28) for the overall population. The SEAPI scoring system showed that patients were markedly improved, with no significant difference between the allograft and autograft groups. Allograft and autograft pubovaginal slings were equally well tolerated, and no infection or erosion was encountered. Mean operative time and hospital stay were significantly shorter when using allograft compared to autograft fascia.

**Conclusions:** The success rates of allograft and autograft pubovaginal sling were equally high, and no complications related to the cadaveric origin of the allograft fascia were observed. Allograft pubovaginal sling was well tolerated, and its use significantly shortened operative time and hospital stay.

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# Pubovaginal sling using allograft fascia lata versus autograft fascia for all types of stress urinary incontinence: 2-year minimum follow up

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## Abstract

**Purpose:** Allografts have been substituted for autografts as a pubovaginal sling to decrease postoperative morbidity, although to our knowledge their long-term durability is unknown. Since 1997, we have offered allograft fascia lata as an alternative to autograft fascia in women undergoing the pubovaginal sling procedure. We describe our continued experience with those with a minimum 2-year followup.

**Materials and methods:** We retrospectively reviewed the records of 134 consecutive women with all types of stress urinary incontinence but without neurovesical voiding dysfunction or a significant degree of pelvic prolapse who underwent pubovaginal sling (allografts in 63 and autografts in 71) performed by a single surgeon. Rectus abdominis or fascia lata autograft and freeze-dried, gamma irradiated allograft slings were placed using identical techniques and a 2 x 12 cm. piece of fascia. Outcome analysis included a chart review, third party telephone interview and selective videourodynamics. Surgical outcome was categorized by daily pad use as cured-0, improved-1 or failed-greater than 1 pad.

**Results:** Of 140 women who received a pubovaginal sling 134 were still evaluable. Preoperative parameters were similar in each group. Mean followup plus or minus standard deviation was less in the allograft group (29 +/- 3 versus 44 +/- 7 months, p < 0.05). There was no statistical difference in the overall stress and urge incontinence cure rate in the allograft and autograft groups (45 of 63 cases and 55 of 71, p = 0.42), nor was there a difference in the total number with recurrent stress urinary incontinence (8 and 7, respectively, p = 0.58). In 24% and 16% of cases postoperative incontinence was due to urge incontinence in the allograft and autograft groups, respectively. Using allografts instead of autografts resulted in a significantly decreased postoperative pain and disability (p < 0.05).

**Conclusions:** Using allograft fascia lata as an alternative to autologous fascia for a pubovaginal sling significantly decreases postoperative pain and disability without compromising efficacy at 2 years. Therefore, we believe that allograft fascia should remain a suitable alternative to autografts for pubovaginal slings.

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**Comparative Study** 

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# Cadaveric versus autologous fascia lata for the pubovaginal sling: surgical outcome and patient satisfaction

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## Abstract

Purpose: We report our initial experience with cadaveric fascia lata in pubovaginal sling procedures.

**Materials and methods:** We compared 121 consecutive women who underwent a sling procedure using cadaveric fascia lata from February 1997 through June 1999 (group 1) with 46 consecutive women who underwent a sling procedure using autologous fascia lata from May 1994 through July 1997 (group 2).

**Results:** Mean followup was longer in group 2 (44 versus 12 months). A total of 104 of the 121 group 1 patients (86%) responded to the questionnaire, of whom 85% were cured of stress incontinence, 83% reported overall improvement in urinary control and 74% had no or minimal leakage not requiring pads. Median catheterization time was 9 days (range 4 to 120). Overall 89% of the women were satisfied with the results and 83% would recommend this surgery. A total of 30 of the 46 group 2 patients (65%) responded to the questionnaire, of whom 90% were cured of stress incontinence, 90% reported overall improvement in urinary control and 73% had no or minimal leakage not requiring pads. Median catheterization time was 14 days (range 6 to 180). Overall 90% of the women were satisfied with the results and 83% would recommend this surgery.

**Conclusions:** Cadaveric fascia lata pubovaginal slings appear to be safe. Early experience suggests that cadaveric fascia lata may be considered an alternative to autologous fascia. Cadaveric and autologous fascia lata appear to have a high success rate.

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# Is fascia lata allograft material trustworthy for pubovaginal sling repair?

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## Abstract

**Objectives:** In a recent publication, cadaveric fascia lata used for pubovaginal sling procedures was reported as having an early, rapid, and high failure rate. Recurrent incontinence was reported to occur from 1 week to 5 months after surgery. The study concluded that cadaveric tissue should not be used for urogynecologic procedures. Their results, however, were significantly different from what we found in clinical practice. We reviewed our series of cadaveric pubovaginal slings to determine the occurrence of rapid breakdown of cadaveric sling tissue leading to recurrent stress urinary incontinence.

**Methods:** At our institution, since June 1998, pubovaginal slings have been performed using only cadaveric fascia lata. Because all of the failures in the aforementioned study occurred within 5 months (mean 11 weeks) of surgery, we included in our series only patients with a minimum of 12 months of follow-up to ensure a long enough follow-up period for failure of the donor tissue to occur. Duration of follow-up and current continence status was documented.

**Results:** Twenty-six patients, with a mean follow-up of 15 months (range 12 to 20), were evaluated. Twenty-four of 26 (92%) patients used one or fewer pads per day: 20 of 26 (77%) were completely dry and 4 of 26 (15.4%) used only one pad per day. Two of 26 (7.7%) required two pads per day. Twenty-five of 26 (96%) reported being "significantly improved" and were "very pleased and satisfied" with the results of surgery.

**Conclusions:** We found no evidence of rapid degradation of solvent-dehydrated cadaveric tissue resulting in early recurrent incontinence. We think these data support the continued use of cadaveric allograft material, especially given its intraoperative and postoperative advantages. Clearly, long-term evaluation of the durability of the cadaveric slings in comparison with autologous fascia is warranted.

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