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Tissue Strength Analysis of Autologous and Cadaveric Allografts for the Pubovaginal Sling

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The aim of this study was to compare the mechanical properties of autologous rectus fascia (ARF), two groups of commercially available cadaveric fascia lata commonly used in pubovaginal sling surgery [freeze-dried (FD) and solvent-dehydrated (SD)], and commercially available cadaveric dermal grafts (DG) evaluate differences in tissue strength and stiffness. We prospectively studied the maximum load to failure (MLF) and stiffness in 20 specimens of ARF, 20 specimens of FD, 20 specimens of SD, and 10 specimens of DG. Autologous fascia was obtained from patients undergoing pubovaginal sling operation utilizing rectus fascia. Cadaveric fascia was re-hydrated in saline. All specimens were then tailored into 1 × 1-cm samples and mounted onto the Instron tensiometer. Samples were loaded to failure at a 100% strain rate and force-elongation curves were generated. MLF was defined as the minimum force needed to tear the tissue. Stiffness was determined by the slope of the linear portion of the force/elongation curve between 5 and 15% strain. Statistical analysis was performed using Student's *t*-test. There is no statistical difference in both MLF and stiffness among ARF, SD, and DG. These data show that MLF and tissue stiffness of SD and DG are comparable to that of ARF. FD has a significantly lower MLF and is significantly less stiff than ARF, SD, and DG. The SD cadaveric fascia lata allograft and the cadaveric dermal allograft may be suitable alternatives to ARF for pubovaginal sling surgery. *Neurourol. Urodynam. 18:497–503, 1999.*

Key words: stress incontinence; tensile strength; fascia lata; dermal graft

INTRODUCTION

There has been a resurgence in the use of the pubovaginal sling since McGuire and Lytton reported an 80% overall success rate using their modification of the pubovaginal sling in patients with type III stress incontinence with minimal morbidity. Success rates for this procedure range from 73 to 100% [Ghoneim and Shaaban, 1994; McGuire and O'Connell, 1995; Chaikin et al., 1998]. Since its original description, the procedure has undergone some modifications, with alterations in both the technique and the choice of sling material [Ghoneim and Shaaban, 1994]. Typically, the sling used is autologous and is harvested from either the anterior rectus fascia via an abdominal incision or from the fascia lata via an incision in the lateral

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thigh. Numerous different non-autolgous materials have also been used for the sling with the aim of limiting the operative time and surgical morbidity. Substitution with synthetic materials, such as polytetrafluoroethylene, silicone, mersilene, and polyethylene, has been associated with increased rates of infection and erosion [Bent et al., 1993; Ghoneim and Shaaban, 1994; Chin and Stanton, 1995]. Recently, we and others have begun to use cadaveric fascia for the sling material in selected patients, primarily those with multiple medical co-morbidities and those whose body habitus makes fascia harvesting difficult [Wright et al., 1998]. The benefit of using this tissue is the elimination of the abdominal dissection to harvest the rectus fascia or the thigh dissection to harvest the fascia lata and, thus, to lessen the morbidity for the patient. The disadvantage of using this cadaveric tissue, although mostly theoretical, is the risk of transmissible disease from the donor, graft rejection, and the lack of long-term results. Fascia lata allografts have been successfully used in a variety of orthopedic and ophthalmologic procedures for nearly 20 years with a minimal risk of tissue rejection and disease transmission [Cooper et al., 1985; Ho et al., 1985; Bedrossian, 1993; Noyes and Barber-Westin, 1996].

The applicability of cadaveric fascial allografts in stress urinary incontinence surgery is hampered by the lack of long-term data supporting its efficacy and safety. A recent study with short-term follow-up demonstrated success using allograft fascia lata in the treatment of intrinsic sphincter deficiency without complications related to the cadaveric origin of the allograft [Wright et al., 1998]. Additionally, there are no standards regarding the necessary tensile strength of cadaveric tissue required for a successful outcome with the pubovaginal sling procedure. These standards are critical, especially as many new commercially available organic products are becoming available as sling alternatives. Variations in harvesting site and processing techniques will inevitably result in products that have variable tissue properties. The purpose of this study, therefore, is to compare the mechanical properties of autologous rectus fascia, two groups of commercially available cadaveric fascia lata (freeze-dried and solvent-dehydrated), and commercially available dermal grafts to evaluate differences in tissue strength and stiffness.

MATERIALS AND METHODS

Autologous rectus fascia was obtained from 20 consecutive female patients who presented with stress urinary incontinence and underwent a transvaginal pubovaginal sling procedure with rectus fascia, as described previously by Chaikin et al. [1998]. Patient age ranged from 32 to 76 years (mean, 56 years). Patients were evaluated pre-operatively with a history, physical examination, 24-hr pad test, voiding diary, and video-urodynamics. Fourteen of 20 (70%) patients were found to have intrinsic sphincter deficiency and seven of 20 (30%) patients were found to have urethral hypermobility as the primary diagnosis for their stress urinary incontinence. All patients had informed consent approved by the New York Presbyterian Hospital Institution Review Board to use their fascia for ex vivo tensile strength measurements. Procured tissue was trimmed of adherent fatty tissue and muscle fibers. Each patient specimen yielded from five to eight 1 × 1-cm square sections. Tissue remained in normal saline at 20°C until tested.

Solvent dehydrated, gamma-irradiated, Tutoplast®-processed cadaveric fascia lata was obtained from Mentor Corporation (Santa Barbara, CA). Twenty packages of

TABLE I. Mechanical Properties (Mean ± SD)

Sling material	Maximum load (N)	Maximum load/ graft width (N/mm)	Stiffness (N/mm)
Autologous rectus fascia	332 ± 17	33.2 ± 1.7	113.0 ± 21.3
Solvent-dehydrated fascia lata	319 ± 34	31.9 ± 3.4	114.5 ± 11.8
Freeze-dried fascia lata	250 ± 29[a]	25.0 ± 2.9[a]	89.2 ± 9.5[a]
Dermal graft	319 ± 18	31.9 ± 1.8	118.3 ± 6.0

[a]$P < 0.005$, freeze-dried vs. autologous, solvent-dehydrated, and dermal graft.

2 × 4-cm fascial strips were reconstituted in normal saline for 30 min. Eight 1 × 1-cm square sections were cut from each strip to be tested. Freeze-dried cadaveric fascia lata, which had been treated by a tissue process developed by the American Association of Tissue Banks in 1984 and subsequently modified in 1993, was obtained from the Northern California Transplant Bank (San Rafael, CA) [Food and Drug Administration, 1993]. Twenty 2 × 3-cm strips were obtained and reconstituted in normal saline for 30 min. Six 1 × 1-cm sections were cut from each strip to be tested. Cadaveric dermal grafts treated by the AlloDerm® Process™ were obtained from LifeCell Corporation (The Woodlands, TX). Each of 10 solvent-dehydrated 2 × 3-cm dermal grafts were reconstituted for 30 min in normal saline and then cut into six 1 × 1-cm sections to be tested.

Tissue specimens (1 × 1 cm) were sequentially loaded into the Instron Mini 55 tensiometer. The gripping clamps of the tensiometer that secures both ends of each specimen were reinforced with heavy steel clamps to prevent tissue slippage. A 10-N preload was applied. Specimens were loaded to failure at a 100% strain rate, and force-elongation curves were generated (Series IX, Merlin software). Slippage was monitored by sudden changes in tracing patterns. Tests were performed at room temperature.

The mechanical properties evaluated for each specimen were 1) maximum load to failure, defined as the minimum force needed to tear the graft; 2) maximum load per unit width of graft; and 3) stiffness, as determined by the slope of the linear portion of the force/elongation curve between 5 and 15% strain.

Student's *t*-test data analysis was used to assess data from the four tissue groups. Findings were considered significant if $P < 0.05$.

RESULTS

The means and standard deviations for the evaluated mechanical properties are presented in Table I. The mean values for maximum load to failure, maximum load/graft width, and stiffness were not statistically different among the autologous rectus fascia group, the solvent-dehydrated fascia lata group, and the dermal graft group (332 ± 17 vs. 319 ± 34 vs. 319 ± 18, respectively; 33.2 ± 1.7 vs. 31.9 ± 3.4 vs. 31.9 ± 1.8, respectively; and 113.0 ± 21.3 vs. 114.5 ± 11.8 vs. 118.3 ± 6.0, respectively). The mean values for maximum load to failure, maximum load/graft width, and stiffness were all significantly lower for the freeze-dried fascia lata group compared to the autologous rectus fascia group (250 ± 29 vs. 332 ± 17, 25.0 ± 2.9 vs. 33.2 ± 1.7, and 89.2 ± 9.5 vs. 113.0 ± 21.3, respectively; $P < 0.005$). The mean values for the mechanical properties of the freeze-dried fascia lata group were also significantly

TABLE II. Variability of Sections Within Individual Specimens (Mean ± SD)

	Autologous rectus fascia	Solvent-dehydrated fascia lata	Freeze-dried fascia lata	Dermal graft
Maximum load (N)	18.9	18.5	27.7[a]	8.9[b,c]

[a] $P < 0.02$, freeze-dried vs. autologous and solvent-dehydrated.
[b] $P < 0.04$, dermal graft vs. autologous and solvent-dehydrated.
[c] $P < 0.0002$, freeze-dried vs. dermal graft.

lower than for both the solvent-dehydrated fascia lata group and the dermal graft group (Table I).

To assess the consistency of a tissue's strength and stiffness throughout its entire length, the standard deviation of the five to eight sections within an individual specimen was evaluated (Table II). The mean standard deviations of maximum load to failure of autologous fascial specimens and cadaveric, solvent-dehydrated fascial specimens were not significantly different (18.9 vs. 18.5, respectively). The mean standard deviation of maximum load to failure of freeze-dried fascial specimens was significantly greater than for autologous fascial specimens and cadaveric, solvent-dehydrated fascial specimens (27.7 vs. 18.9 vs. 18.5, respectively; $P < 0.02$). The mean standard deviation of maximum load to failure of freeze-dried fascial specimens was even greater compared to that of dermal graft specimens (27.7 vs. 8.9, respectively; $P < 0.0002$). Individual dermal graft specimens demonstrated the least amount of intra-tissue variability among the four sling materials tested (Table II).

DISCUSSION

We sought to compare autologous rectus fascia used in pubovaginal sling surgery and other allograft products that are increasingly being substituted for autologous tissue in terms of tensile strength and tissue stiffness. The mechanical properties of two cadaveric products, solvent-dehydrated fascia lata and dermal grafts, were statistically indistinguishable from the mechanical properties of autologous rectus fascia. The tensile strength and stiffness of cadaveric freeze-dried fascia lata were significantly lower than the corresponding properties of the other three products tested. Maximum load of freeze-dried fascia lata was 25% less than the maximum load of autologous rectus fascia (250 ± 29 vs. 332 ± 17) and stiffness of freeze-dried fascia lata was 22% less than the stiffness of autologous rectus fascia (89.2 ± 9.5 vs. 113 ± 21.3).

We also examined the variability in mechanical properties among sections of individual specimens in each of the four sling groups. Specimens in the dermal graft group had the greatest degree of intra-tissue consistency. Autologous rectus fascial specimens and solvent-dehydrated, cadaveric fascial specimens had virtually the same degree of intra-tissue consistency, although less than for the dermal graft specimens. Freeze-dried cadaveric fascial specimens demonstrated the least amount of consistency along the length of the tissue.

Although early experiments in the orthopedic literature suggested no difference between fresh and freeze-dried fascia lata [Thomas and Grasham, 1963], there is some concern that ice crystal formation during the freeze-drying process may weaken the collagen structure in the fascia. Solvent-dehydration may represent a superior tech-

nique in tissue preservation. Our experiments suggest that solvent-dehydrated fascia lata is a stronger cadaveric allograft than its freeze-dried counterpart and has less tissue variability. We are unable to predict, however, whether other commercially available solvent-dehydrated products are equivalent to the Mentor Tutoplast®–processed tissue that we tested.

To our knowledge, the use of dermal grafts in pubovaginal sling surgery has not been previously reported. Dermal grafts differ from fascial allografts in that they are not derived from fascia at all but rather are derived from skin that is processed to eliminate the epidermis and all immunogenic cellular elements. The dermal graft has been used extensively in the field of plastic surgery for tissue grafting [Achauer et al., 1998; Harris, 1998; Hein et al., 1998; Chen and Yeow, 1999]. It provides a protein matrix that serves as a collagen scaffold for the host's own cellular matrix. The present study shows that dermal grafts are as strong as autologous rectus fascia and have the least amount of specimen variability. Based on their mechanical property profile, dermal grafts may be an appropriate alternative to fascia for pubovaginal sling surgery. Results in the plastic surgery literature support the use of dermal grafts as safe and not complicated by rejection, absorption, extrusion, or herniation [Achauer et al., 1998; Hein et al., 1998; Harris, 1998; Chen et al., 1999].

It must be emphasized that our experiments demonstrate tensile strength measurements of tissue products before surgical placement into patients. No studies have been conducted to evaluate the magnitude and direction of the mechanical force vectors sustained by the in situ sling grafts and how, if at all, these change with time. It is not known whether all allografts become incorporated similarly in the host. Furthermore, it is not known whether long-term success in patients depends on the initial strength of the implanted sling material or on a secondary fibrotic process that occurs in response to the graft and incorporates the graft into the surrounding native tissues. Animal studies in which the anterior cruciate ligament was reconstructed with a freeze-dried fascia lata allograft show that the restraining forces 24 weeks after transplant are only 51% as high as the initial restraining forces [Curtis et al., 1985]. Histological inspection of freeze-dried fascia lata allografts and autologous fascial grafts indicates that both groups undergo the same type of initial degeneration, revascularization and fibrotic proliferation, and ultimate tissue reorganization [Curtis et al., 1985; Iaconis et al., 1987]. It is unclear from the data in this report what is the minimum tissue strength necessary for a pubovaginal sling to be effective. In fact, in a large series by Morgan et al. [1998], using Mersilene mesh instead of fascia, the sling is simply positioned as a hammock beneath the urethra and not even sutured in place.

Wright et al. [1998] recently published a report that retrospectively compared the success of pubovaginal sling surgery in incontinent women who received either autologous or cadaveric freeze-dried allograft fascia lata. At a mean follow-up of 11.5 months, SEAPI scoring system showed that there was no statistical difference between the groups with respect to overall success rates. There were no cases of sling erosion or infection and no patient reported vaginal pain with either sling. Long-term studies using questionnaire analysis are critical to evaluate whether these success rates are durable. It is clear that cadaveric slings have the advantage of decreasing the operative time, since the sling itself does not need to be harvested. Wright et al. [1998] reported that the mean operative time with allograft sling placement was 87 min, whereas the operative time in surgery requiring fascia harvesting required 111 min (*P*

< 0.0001). In contrast, Chaikin and Blaivas [1998] reported a case in which an implanted cadaveric fascial sling broke soon after surgery.

More than one million tissue transplants and 60,000 organ transplants have been performed since 1985. Despite this popularity, there is still concern over transmission of infectious disease with transplantation. In an attempt to eradicate the possibility of transmission, tissue banks have instituted stringest criteria to screen prospective donors and procured tissues. Transplant material is now processed by a protocol, developed by the American Association of Tissue Banks in 1984 and subsequently modified in 1993, that incorporates a multi-step process of tissue high-pressure agitation, dehydration, and gamma-irradiation to eliminate human immunodeficiency virus (HIV), hepatitis virus, and other infectious pathogens [Mowe, 1992; Henkel, 1994]. To date, there has only been one documented case of HIV transmission from a bone transplant in 1985, and no cases have been documented since more sophisticated screening has been instituted [Simonds et al., 1992]. These data support continued use of cadaveric tissue allografts in pubovaginal sling surgery with negligible risk to the patient of viral or bacterial transmission.

CONCLUSIONS

Fascial allograft products are increasingly being substituted for autologous fascial tissue in pubovaginal sling surgery. The use of cadaveric allografts minimizes surgical dissection and patient morbidity and is associated with a negligible risk of disease transmission and graft rejection. Solvent-dehydrated cadaveric fascia lata and acellular dermal grafts are indistinguishable from native autologous rectus fascia, in terms of tensile strength and tissue stiffness. The freeze-dried cadaveric fascia lata allograft, commonly available from tissue banks, is significantly less strong than native fascia or other allograft alternatives. Solvent-dehydrated cadaveric fascia lata and cadaveric dermal allografts may be suitable alternatives to autologous rectus fascia for pubovaginal sling surgery.

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