Autologous, cadaveric, and synthetic materials used in sling surgery: Comparative biomechanical analysis

Article *in* Urology · October 2001

DOI: 10.1016/S0090-4295(01)01205-5 · Source: PubMed

Laura James
Shriners Hospital for Children Cincinnati, Ohio

AUTOLOGOUS, CADAVERIC, AND SYNTHETIC MATERIALS USED IN SLING SURGERY: COMPARATIVE BIOMECHANICAL ANALYSIS

JONG M. CHOE, RUPA KOTHANDAPANI, LAURA JAMES, AND DOUG BOWLING

ABSTRACT

Objectives. To compare the biomechanical properties of allografts, autografts, and synthetic materials used in sling surgery using the Instron tensinometer.

Methods. The sling grafts we studied consisted of autologous tissues (dermis, rectus fascia, and vaginal mucosa), cadaver tissues (decellularized dermis and freeze-dried, gamma-irradiated fascia lata), and synthetics (Gore-Tex and polypropylene mesh). The sling grafts were constructed into two types of slings: full strip sling (FSS) versus patch suture sling (PSS). The slings were loaded onto the Instron tensinometer and uniaxially loaded in tension until failure. From the load deformation curve, the mechanical properties of the sling grafts were compared.

Results. A total of 140 sling grafts were analyzed. In rank order for the FSSs, cadaver allografts had the strongest tensile strength followed by the synthetics and autologous tissues ($P < 0.05$). The tensile strength of the FSSs was greater than for the PSSs for all groups ($P \leq 0.001$). In rank order for the PSSs, the synthetics and dermal tissues (autograft and allograft) had the highest tensile strength followed by cadaver fascia lata, rectus fascia, and vaginal mucosa ($P < 0.05$).

Conclusions. The tensile strength of the FSS was greater than that of the PSS for the autograft, allograft, and synthetic tissues. The autograft and allograft tissues were significantly weaker as a PSS. The synthetics were more durable as a PSS compared with the organic tissues. When a PSS is constructed from autograft and allograft tissues, the risk of suture pull-through and recurrent stress incontinence must be considered. UROLOGY **58:** 482–486, 2001. © 2001, Elsevier Science Inc.

Sling procedures have been shown to be effective for treatment of all types of female stress incontinence.[1] Slings vary in configuration, materials used, and method of fixation. A pubovaginal sling may be constructed from a long strip, a medium ribbon, or a short patch of supporting material. The supporting materials used include autologous, cadaver, and synthetic grafts. Slings may be fixed into position by sewing both arms of the sling directly to the rectus fascia, by tying the suspension sutures over the rectus fascia, or by using bone anchors (suprapubic or transvaginal). The type of construction, materials used, and methods of fixation vary. Most recently, cadaver slings have come under scrutiny because of the inconsistency in cure rates.[2–5]

This study was performed to determine whether the supporting materials currently in use have inherently differing tensile strengths and whether the architectural construction (full strip versus patch suture) of the sling or the type of suspension sutures used would affect the tensile strength of the sling studied.

MATERIAL AND METHODS

Sample Grafts

A total of 140 sample grafts were analyzed in a randomized, prospective fashion. Two independent investigators performed this study to eliminate intraobserver bias. The sample grafts consisted of autologous tissues (dermis, n = 20; rectus fascia, n = 20; vaginal mucosa, n = 20), cadaver tissues (decellularized dermis, n = 20; freeze-dried, gamma-irradiated fascia lata, n = 20), and synthetics (Gore-Tex, n = 20; polypropylene mesh, n = 20). Nonfrozen cadaveric fascia lata was not studied because it was not commercially available

From the Urodynamics and Continence Center, Division of Urology, University of Cincinnati College of Medicine, Cincinnati, Ohio

Reprint requests: Jong M. Choe, M.D., Division of Urology, University of Cincinnati Medical Center, 231 Bethesda Avenue, ML-0589, Cincinnati, OH 45267

Submitted: November 10, 2000, accepted (with revisions): April 19, 2001

0090-4295/01/$20.00
PII S0090-4295(01)01205-5

owing to an allograft shortage at the time of this study. The sample graft dimensions were 2 × 5 cm; this size was chosen because suburethral patch slings in clinical use employ grafts that approximate this size.[6]

Dermis, rectus fascia, and vaginal mucosa were harvested from 20 consecutive women undergoing vaginal prolapse surgery by way of special consent. Their mean age was 61 years (range 40 to 76) and their mean parity was 2.6 (range 0 to 3). Seven women had a history of vaginal surgery: anterior repair (n = 1), bladder neck suspension (n = 1), and hysterectomy (n = 5). All three tissues were harvested from the same individual, placed in normal saline, and studied within 2 hours of harvest. Autologous tissues were full-thickness in depth: dermis, 4 mm; rectus fascia, 3 mm; and vaginal mucosa, 4 mm. Of the study subjects, 16 women were premenopausal and 4 were postmenopausal. All premenopausal women had normal ovarian hormonal function and 4 postmenopausal subjects received 6 weeks of preoperative topical estrogen therapy.

The cadaver tissues consisted of decellularized dermis (Alloderm; Life Cell, Woodlands, Tex) and freeze-dried, gamma-irradiated fascia lata (Faslata; C. R. Bard, Covington, Ga). The cadaver allografts (1-mm thickness) were rehydrated as per the manufacturer's recommendations and studied within 1 hour. The synthetic materials (1-mm thickness) included polytetrafluoroethylene (W. L. Gore & Associates, Phoenix, Ariz) and polypropylene mesh (Ethicon, Cincinnati, Ohio).

We also analyzed the comparative biomechanical properties of No. 1 Prolene suspension suture (n = 10) versus No. 1 Vicryl suspension suture (n = 10). The suspension sutures were compared with each other independent of the graft material.

TABLE I. *Displacement and maximum load of full strip slings and patch suture slings*

	Displacement (mm)	Maximum Load (N)
FSS (n = 70)		
Fascia lata (n = 10)	1.36 ± 0.78	217 ± 66
Alloderm (n = 10)	3.12 ± 1.89	144 ± 44
Gore-Tex (n = 10)	57.0 ± 12.5	136 ± 17
Prolene mesh (n = 10)	28.3 ± 1.45	134 ± 5
Dermis (n = 10)	8.83 ± 5.68	122 ± 64
Rectus fascia (n = 10)	5.87 ± 3.8	42 ± 50
Vaginal wall (n = 10)	6.25 ± 3.97	42 ± 28
PSS (n = 70)		
Fascia lata (n = 10)	31.5 ± 3.49	58 ± 22
Alloderm (n = 10)	27.8 ± 1.46	68 ± 10
Gore-Tex (n = 10)	51.8 ± 13.9	76 ± 10
Prolene mesh (n = 10)	67.8 ± 3.09	63 ± 15
Dermis (n = 10)	48.9 ± 22.4	75 ± 6
Rectus fascia (n = 10)	30.7 ± 12.0	38 ± 21
Vaginal wall (n = 10)	15.5 ± 9.29	21 ± 18

KEY: FSS = full strip sling; PSS = patch suture sling.
When full strip sling grafts were reconstructed into patch suture slings, the tensile strength of cadaver grafts and autografts decreased dramatically ($t = -7.2241$, $P \leq 0.0001$)*; incidence of suture pull-through for cadaver fascia lata patch suture sling vs. autologous rectus fascia patch suture sling vs. vaginal wall patch suture sling was 70% vs. 80% vs. 100%; all patch suture grafts (100%) remained intact; and the incidence of suture pull-through was 0% for cadaver dermis, autologous dermis, Prolene mesh, and Gore-Tex patch slings.*

Tensinometer

The Instron tensinometer No. 4465 (maximum load 400 lb) was used to study the biomechanical properties of both slings (full strip sling and patch suture sling) and the suspension sutures. For the full strip sling, the ends of the graft were loaded onto the tensinometer and gripped by two grippers at a 10-mm gauge length. For the patch suture sling, the suspension sutures were tied to the ends of the grippers. For the sutures, each end of the suspension suture was tied to the grippers. Slings and sutures were uniaxially loaded in tension with a crosshead speed of 5 mm/min until either the graft tore or the suspension suture broke. From the load deformation curve, the mechanical properties of the slings and sutures were calculated: displacement at maximum load (in millimeters) and maximum load to failure (in newtons).

Definitions

The sling materials for the 140 sample grafts were constructed in two architectural forms—the full strip sling and the patch suture sling. The full strip sling was defined as a 2 × 5-cm graft without suspension sutures. The patch suture sling was defined as a 2 × 5-cm graft suspended by No. 1 Prolene sutures. To construct the patch suture sling, No. 1 Prolene suture was sewn to the patch at a distance of 4 mm proximal from the lateral edge using three helical bites. For the patch sling constructed from cadaver fascia lata, a cross-folded technique was used to place the suspension sutures. The size of the full strip sling was 5 cm because autologous tissues were in limited supply and the same tissues were being used for vaginal reconstruction during the harvest. Prolene was used as a suspension suture, since it is the most commonly advocated material for use.[7]

Statistical Analysis

We compared the tensile strength and elasticity of the sling materials within each subgroup (autograft, allograft, and synthetic). Then, we compared the tensile strength and elasticity of the sling construction (full strip sling versus patch suture sling) between each subgroup. The tensile strength and elasticity of two types of suspension sutures (No. 1 Prolene versus No. 1 Vicryl) were also compared. A two-way analysis of variance followed by Tukey's test was performed.

RESULTS

We analyzed 140 sling materials for comparative biomechanical properties using the Instron tensinometer. When full strip sling grafts were compared among each other as a group (cadaver versus synthetic versus autografts), cadaver grafts had the strongest tensile strength followed by synthetics and autografts, in rank order. Specifically, cadaver fascia lata grafts had a significantly higher mean maximum load to failure (217 N) followed by cadaver dermis (144 N), Gore-Tex (136 N), Prolene mesh (134 N), human dermis (122 N), rectus fascia (42 N), and vaginal mucosa (42 N) ($P < 0.05$). Within the autograft slings, human dermis had the highest mean maximum load to failure, followed by rectus fascia and vaginal mucosa ($P < 0.05$) (Table I).

When full strip sling grafts were reconstructed into patch suture slings, the tensile strength of the cadaver grafts and autografts decreased dramatically ($t = -7.2241$, $P \leq 0.0001$). As a patch suture sling, Gore-Tex had the highest mean load to failure (76 N) followed by human dermis (75 N), cadaver dermis (68 N), Prolene mesh (63 N), cadaver fascia lata (58 N), rectus fascia (38 N), and vaginal mucosa (21 N). As a group, no statistical difference was found in the mean maximum load to failure among cadaver, synthetic, and human dermis patch slings. However, a significant difference in the mean maximum load to failure was seen with the human dermis patch suture sling compared with vaginal mucosa and rectus fascia patch suture slings ($P < 0.05$) (Table I).

Of the 10 cadaver fascia lata patch suture slings, 7 (70%) experienced suture pull-through; Prolene sutures broke in 3 (30%) of 10 samples. Of the 10 autologous rectus fascia patch suture slings, 8 (80%) experienced suture pull-through; Prolene sutures broke in 2 (20%) of 10 samples. All 10 vaginal mucosa patch suture sling grafts (100%) experienced suture pull-through. The Prolene suspension sutures broke and the grafts remained intact in all 10 cadaver dermis patch suture slings, all 10 autologous dermis patch suture slings, all 10 Gore-Tex patch suture slings, and all 10 Prolene mesh patch suture slings (all 100%).

The elasticity of the sling grafts varied within each subgroup. The type of construction (full strip sling versus patch suture sling) also affected the elasticity (Table I). When constructed as full strip slings, Gore-Tex had the greatest displacement or elasticity (57.0 mm), followed by Prolene mesh, human dermis, rectus fascia, vaginal mucosa, cadaver dermis, and cadaver fascia lata (1.4 mm). When the supporting grafts were constructed into patch suture slings, the Prolene mesh had the greatest displacement (67.8 mm) followed by Gore-Tex, human dermis, cadaver dermis, cadaver fascia lata, rectus fascia, and vaginal mucosa (15.5 mm).

When we compared the biomechanical properties of the suspension sutures, No. 1 Vicryl suture had a significantly higher mean maximum load to failure than did No. 1 Prolene suture (89 N versus 54 N; $P < 0.05$). However, both sutures had similar displacements (98 mm versus 102 mm).

COMMENT

Pubovaginal slings have become a common means of correcting all types of female stress urinary incontinence. Aldridge[8] first reported the use of rectus fascia as a pubovaginal sling in 1942. He detached a strip of rectus fascia bilaterally, passed both ends of the rectus flap under the bladder neck, and tied them at the midline. McGuire and Lytton[9] reported their version of the pubovaginal sling, which was to implant a long strip of harvested rectus fascia under the bladder neck. The ends of the fascial sling were directed through the space of Retzius and then sewn directly to the anterior abdominal wall.[9]

Since its introduction in 1978, by McGuire and Lytton,[9] the rectus fascia pubovaginal sling has undergone many modifications. Slings in use today are constructed from long strips,[10] medium-size ribbons,[11] and short patches[6,12,13] of supporting material. We define a pubovaginal sling as a long strip of supporting material (ie, 2 × 14 cm) that spans from one edge of the rectus abdominis to the other. Both ends of the sling are affixed to the lateral edge of the rectus abdominis, and the belly of the sling supports the bladder neck. A medium-size ribbon is defined as graft material between 2 × 14 cm and 2 × 4 cm (eg, 2.5 × 7 cm).[11] A patch sling is defined as a sling with a short graft (ie, 2 × 4 cm) hung by suspension sutures. In this situation, the supporting material is positioned immediately under the bladder neck and only the suspension sutures enter the space of Retzius. In turn, the suspension sutures are secured to the abdominal fascia, Cooper's ligament, or bone anchors.

The success or failure of sling surgery depends on several factors—its weakest link, scarification, and the use of suspension suture and its insertion site. A sling is as strong as its weakest link. The weakest link may be the graft material, the suspension suture, or the origin or insertion site of the suspension sutures. We theorized that scarification of both sling arms within the space of Retzius causes a "cementing effect" and glues the sling into place. The success of a pubovaginal sling is predicated on having the sling become completely engrafted or scarred in the retropubic space as the tissue remodels postoperatively. The success of a patch sling relies on the strength of the suspension sutures and the origin and insertion site of the suspension sutures. For the patch suture sling, urinary incontinence may recur if the suspension sutures break or tear through the origin or insertion sites during the early postoperative period of tissue remodeling.

The supporting materials in use include autografts, synthetics, and commercially processed cadaver tissues. The autologous tissues in use include rectus fascia, fascia lata, and vaginal mucosa. The synthetics in use include Gore-Tex, antimicrobial impregnated MycroMesh, and polypropylene mesh. Commercially available human cadaver allografts include dermis and fascia lata.

The advantages of synthetic materials include a decreased operating time, less morbidity (eg, smaller incision), and the potential for better long-term durability. The potential risks are sling infection and tissue erosion. The advantages of allografts include a shorter operating time and decreased morbidity. The disadvantages include the risk of bacterial infection and early degradation. Autologous tissues have the advantage of having the best biocompatibility with the host. The disadvantages include an increased operating time, postoperative pain, and delayed convalescence.

In clinical practice, the dimensions of the patch slings are approximately 2 × 5 cm. It has been our experience that recurrent stress incontinence occurs more commonly in women who undergo implantation of autologous and cadaveric patch slings than do those who undergo implantation of full strip slings. Thus, we wanted to know whether changing a full strip sling into a patch sling with long suspension sutures would alter the overall tensile strength of the sling. In this study, all the patch suture slings were constructed by placing the sutures at an equidistance—4 mm from the lateral edge. The results of our study demonstrated that when full strip slings were constructed, the cadaver allografts had a significantly higher maximum load to failure followed by the synthetic and autologous tissues. However, when full strip sling grafts were reconstructed into patch suture slings, the tensile strength of the cadaver grafts and autografts decreased dramatically. Although this laboratory finding cannot be directly translated into a clinical scenario, one can glean some important information on how the tensile strength of a sling may be affected by its architecture. It allowed us to identify the potential sites of weakness of a patch sling—that is, sutures can rip out at the insertion point of a sling as opposed to the sling giving way at its center.

With respect to the cadaver tissues, the method of tissue processing may weaken the tensile strength of allograft slings. Webster *et al.*[3] evaluated the outcomes of pubovaginal slings constructed from freeze-dried, nonirradiated, allograft fascia lata (2 × 15-cm fascia with 1-0 polyglycolic acid suture) from a sling tissue bank. At a mean follow-up of 19.4 months, 76 (84%) of 91 women reported being cured or improved.[3] They surmised that their success was due to a special method of processing the cadaver tissue that resulted in preservation of its tensile strength. Secrest and Paige[2] compared the autologous rectus fascia and allograft fascia lata pubovaginal slings. The allografts used included Mentor Tutoplast (n = 32), Bard University of Florida (n = 11), and other (n = 8). Absorbable braided suture was used to secure the sling in both groups. At a minimum follow-up of 6 months, 50 (86%) of 58 patients who received the autologous fascia graft reported "positive outcomes" versus 33 (65%) of 51 patients who received the allograft fascia lata. The investigators theorized that the autologous fascial grafts survive as true fascial structures and the allograft slings work primarily through scarification with fibroblast ingrowth and scar replacement of the allograft material.

The method of affixing the suspension sutures to the cadaver allograft is especially important in maintaining durable cure rates. Chaikin and Blaivas[5] reported cadaver fascia lata sling failure from suture pull-through. Human allograft (2 × 14-cm freeze-dried fascia lata) was constructed into a pubovaginal sling using 2-0 polyester sutures on either end with two rows of horizontal mattress sutures. Recurrent stress incontinence immediately occurred on postoperative day 3 because of suture pull-through from both sides of the graft. Sutaria and Staskin[14] reported that the technique for securing the suture to the fascial edge has a definite effect on the "pull-through" strength. A comparison of four different suture techniques revealed that forces applied parallel to the fascial grain cause separation of the fibers and tissue failure. When a cross-fold technique was used to reorient the fascial grain 45° to the applied force, the tendency to "pull through" between the fibers decreased.

For synthetic slings, the cure rate for stress incontinence remains high, independent of the sling architecture. The cure rates for the synthetic slings (patch slings and pubovaginal slings) have been reported to be 77% to 90% at a mean follow-up ranging from 4 to 8 years.[15–18] However, the infectious complications of synthetic slings are well-known. Silastic, polytetrafluoroethylene (Gore-Tex), and polyester (Protegen) have the highest incidence of erosion, ranging from 11% to 71%.[19–22] Conversely, the reported erosion rates for polypropylene mesh range from 0% to 3%.[19–22] The incidence of sling erosion is proportional to the size of the synthetic material used.[20,23] Furthermore, Choe *et al.*[24] have reported that three factors may decrease erosion rates: small graft size, antibacterial properties, and a mesh-like configuration.

Our laboratory findings revealed that when a full strip sling is converted to a patch suture sling, the tensile strength of the sling decreases precipitously, especially when organic materials are used as the supporting material. Patch suture slings are weaker than pubovaginal slings because of the high rate of suspension suture pull-through. We surmise that the difference in tensile strength between the full strip sling and patch suture sling may be due to the composition of the graft in combination with how and where the suspension sutures were placed. With respect to the suspension sutures, it has been a common belief that the Prolene suture was inherently stronger than Vicryl. However, the results of this study revealed that No. 1 Vicryl was stronger than No. 1 Prolene suture. On the basis of these data, it may appear that the risk of suture pull-through by Vicryl suture should be greater than that of Prolene suture. However, Vicryl undergoes hydrolysis in situ and, as a result, the risk of suture pull-through may actually be less than for nonabsorbable Prolene suture.

CONCLUSIONS

In this series, we were able to show that the full strip sling has greater tensile strength than the patch suture sling within each graft subgroup, regardless of the material studied. Furthermore, patch suture slings were weaker compared with full strip slings when constructed from autograft and allograft tissue. We realize that it is difficult to apply this type of laboratory data to the clinical setting. However, on the basis of this information, one cannot help but wonder whether the variability in the tensile strengths of the supporting material and suspension suture is a contributing factor to early failure after sling surgery. More studies are needed using animal models to confirm these findings.

REFERENCES

1. Leach GE, Dmochowski RR, Appell RA, *et al:* Female Stress Urinary Incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence. J Urol **158:** 875–880, 1997.
2. Secrest CL, and Paige CW: Comparison of autologous and allograft fascia in pubovaginal sling for stress urinary incontinence (abstract). J Urol **163:** 165, 2000.
3. Webster GD, Visco AG, Ruiz H, *et al:* Outcome in 104 pubovaginal slings using freeze dried allograft fascia lata from a sling tissue bank (abstract). J Urol **163:** 165, 2000.
4. Carbone JM, Kavaler E, and Raz S: Disappointing early results with bone-anchored, cadaveric fascia pubovaginal slings (abstract). J Urol **163:** 166, 2000.
5. Chaikin DC, and Blaivas JG: Weakened cadaveric fascial sling: an unexpected cause of failure. J Urol **160:** 2151, 2000.
6. Karram MM, and Bhatia NN: Patch procedure: modified transvaginal fascia lata sling for recurrent or severe stress urinary incontinence. Obstet Gynecol **75:** 461–463, 1990.
7. Raz S: Instrumentation for vaginal surgery, in Raz S (Ed): *Atlas of Transvaginal Surgery*. Philadelphia, WB Saunders, 1992, pp 23–29.
8. Aldridge AH: Transplantation of fascia for relief of urinary stress incontinence. Am J Obstet Gynecol **44:** 398, 1942.
9. McGuire EJ, and Lytton B: Pubovaginal sling procedure for stress incontinence. J Urol **119:** 82–84, 1978.
10. Carr LK, Walsh PJ, Abraham VE, *et al:* Favorable outcome of pubovaginal slings for geriatric women with stress incontinence. J Urol **157:** 125–128, 1997.
11. Hassouna ME, and Ghoniem GM: Long-term outcome and quality of life after modified pubovaginal sling for intrinsic sphincteric deficiency. Urology **53:** 287–291, 1999.
12. Tsung-Hsien S, Jian-Pei H, Yeou-Lih W, *et al:* Is modified in situ vaginal wall sling operation the treatment of choice for recurrent genuine stress incontinence? J Urol **162:** 2073–2077, 1999.
13. Ogundipe A, Rosenweig BA, Karram MM, *et al:* Modified suburethral sling procedure for treatment of recurrent or severe stress urinary incontinence. Surg Gynecol Obstet **175:** 173–176, 1992.
14. Sutaria PM, and Staskin DR: Cadaveric allograft strength: an assessment of the effects of preservation techniques and the methods of suture fixation using two separate experimental models (abstract). Neurourol Urodyn **18:** 324, 1999.
15. Staskin DR, Choe JM, and Breslin DS: The Gore-Tex sling procedure for female sphincteric incontinence: indications, technique, and results. World J Urol **15:** 295–299, 1997.
16. Yamada T, Arai G, Masuda H, *et al:* The correction of type 2 stress incontinence with a polytetrafluoroethylene patch sling: 5-year mean followup. J Urol **160:** 746–749, 1998.
17. Morgan JE, Farrow GA, and Stewart FE: The Marlex sling operation for the treatment of recurrent stress urinary incontinence: a 16-year review. Am J Obstet Gynecol **151:** 224–226, 1985.
18. Bryans FE: Marlex gauze hammock sling operation with Cooper's ligament attachment in the management of recurrent urinary stress incontinence. Am J Obstet Gynecol **133:** 292–294, 1979.
19. Chin YK, and Stanton SL: A follow up of silastic sling for genuine stress incontinence. Br J Obstet Gynaecol **102:** 143–147, 1995.
20. Bent AE, Ostergard DR, and Zwick-Zaffuto M: Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: clinical and histologic study. Am J Obstet Gynecol **169:** 1198–1204, 1993.
21. Leach GE, Kobashi KC, Mee SL, *et al:* Erosion of woven polyester synthetic ("Protegen") pubovaginal sling (abstract). J Urol **161:** 106, 1999.
22. Duckett JR, and Constantine G: Complications of silicone sling insertion for stress urinary incontinence. J Urol **163:** 1835–1837, 2000.
23. Choe JM, and Staskin DR: Gore-Tex patch sling: 7 years later. Urology **54:** 641–646, 1999.
24. Choe JM, Ogan K, and Bennett S: Antibacterial sling: a prospective outcomes analysis. Urology **55:** 515–520, 2000.