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ORIGINAL ARTICLE

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Medium-term follow-up on use of freeze-dried, irradiated donor fascia for sacrocolpopexy and sling procedures

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Abstract The aim of this study was to document longer-term follow-up of patients in a previously reported series who underwent either sacrocolpopexy (SCP) or suburethral sling procedures utilizing freeze-dried, irradiated donor fascia. Subjects from the initial series of 67 SCPs and 35 slings were included in this retrospective chart review of postoperative follow-up where surgical follow-up longer than 3 months from the procedure was available. Subjects undergoing SCP were examined at the time of any clinical visit and their pelvic organ support evaluated utilizing the POP-Q system. The SCP procedure was considered to be unsuccessful if any anterior vaginal wall point (Aa or Ba) was at the hymen or beyond, or if the vaginal apical point (C or D) descended to a point at least halfway to the hymen from a position of perfect apical support. Subjects who did not return for clinical examination after their 3-month postoperative visit but who had been in telephone contact with the clinic stating that they had experienced symptomatic recurrence of their POP were also included as having unsuccessful SCP procedures. Those similarly in contact with the office by telephone, but not clinically examined, who indicated no subjective return of their POP, were coded as successful. The outcome of the sling procedure was primarily evaluated subjectively, with the patient indicating that stress incontinence symptoms were present or absent. Follow-up was available for 75 patients, who had undergone 54 SCP and 27 sling procedures (6 patients had undergone both SCP and sling procedures). When failure was defined according to any of the criteria listed in the methods section, 45 (83%) patients experienced SCP failure at a median of 12 months after surgery. A total of 14 (52%) sling procedures were failures, with recurrent SUI symptoms experienced from 2 weeks to 24 months (median 3 months) after the procedure. One year after surgery, 23 (43%) SCPs were known to be failures, and 11 (41%) slings were known to be failures. The remaining 13 (48%) slings were subjectively successful when last seen 7–51 months after surgery. We reoperated on 21 (40%) patients. At the time of repeat SCP (chosen by 16 patients) we found graft between the sacrum and vagina in just 3 patients (19%). The use of freeze-dried, irradiated donor fascia for both SCP and sling procedures was associated with an unacceptably high failure rate in our series.

Keywords Donor fascia · Sacrocolpopexy · Sling procedure

Abbreviations SCP: Sacrocolpopexy

Introduction

We previously reported on the use of freeze-dried, irradiated fascia lata allografts in 67 sacrocolpopexy (SCP) and 35 suburethral sling procedures [1, 2]. In that initial series, with a mean follow-up of 1 year, a 31% failure rate was detected for suburethral slings.

Since that report, several other centers have reported their surgical outcomes (Table 1), with wide ranges of early and long-term success with the use of donor fascia for pubovaginal slings [3, 4, 5, 6, 7, 8, 9, 10]. Because of the different tissue processing utilized, the length of follow-up and inconsistent outcome variables, many pelvic surgeons have come to question what is the appropriate material to use for suburethral slings [11, 12]. Although personal communications with other reconstructive pelvic surgeons have confirmed that donor fascia lata grafts are being used for abdominal sacrocolpopexies, we could not find other published data

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Table 1 Previously reported success rates of donor fascia lata

Author, year, country	No. tissue processing	How success determined	Outcome: improved/cured	Mean follow-up Range
Handa et al. 1996, USA	16 freeze-dried	Office questionnaire Multichannel Urodynamics	86% subjective cure 79% objective cure	12 month
Elliott/Boone 2000, USA	26 solvent-dehydrated, gamma-irradiated	Third party Phone questionnaire	96%/77%	15 months 12 to 20 months
Amundsen/Webster 2000, USA	91 freeze-dried	Physical exam, patient questionnaire, pad usage	85%/63%	19 months 3 to 37 months
Brown/Govier 2000, USA	121 fresh-frozen, freeze-dried (One gamma-irradiated)	Mail Questionnaire Failure = ≥3 pads daily	85%/74%	12 months, no range given
O'Reilly/Govier 2002, USA	update on 121	8 additional failures from original report	−/66%	4 to13 months
Huang et al, 2001, Taiwan	18 solvent-dehydrated, gamma-irradiated	Mail questionnaire with urodynamics on failures only	72% improved/cured 28% failed within 6 months	7–12 months
Soergel, Shott, Heit 2001, USA	7 freeze-dried, gamma-irradiated	Multichannel	−/33%	6 months
	4 freeze-dried	Urodynamics	−/100%	6 months
Flynn, Yap 2002, USA	63 freeze-dried, gamma-irradiated	Chart review Third-party phone questionnaire	71% cured (half of failures with urge incontinence only)	24 months

on the surgical outcomes of SCP using donor fascial grafts.

The purpose of this report is to provide medium-term follow-up on the use of freeze-dried, irradiated fascia lata allografts for abdominal SCP pubovaginal sling at one institution.

Materials and methods

Subjects from the initial surgical series of 67 SCPs and 35 slings performed by three urogynecologists at one institution between 1997 and 1999 were included in this retrospective review if (a) their surgical procedure was successful and follow-up was available for more than 3 months after surgery, or (b) they had been followed until the time of surgical failure (including those who failed prior to 3 months postoperatively).

The method of donor fascia use in these procedures has been described previously [1]. Briefly, freeze-dried, γ-irradiated donor fascia from an approved tissue bank was reconstituted in saline and then used to construct a Y-shaped SCP graft for vaginal suspension, unless SCP was performed with the uterus in situ, in which case a graft was applied only to the posterior vagina. Two pieces of fascia approximately 6x8 cm and 6×16 cm were used to construct the Y-shaped graft. Permanent sutures were used to secure the graft to the vagina and sacrum. A pubovaginal sling procedure was performed using a strip of freeze-dried, irradiated donor fascia approximately 3×10 cm, being passed through a midline or U-shaped vaginal incision periurethrally to the space of Retzius and sutured via permanent suture arms to the rectus fascia. The sling was secured under no tension at the urethrovesical junction, with interrupted, absorbable suture.

Subjects undergoing SCP were examined at the time of any clinical visit and their pelvic organ support evaluated utilizing the pelvic organ prolapse quantification (POP-Q) system [13]. An SCP procedure was considered to be unsuccessful if any anterior vaginal wall point (Aa or Ba) was at the hymen or beyond, or if the vaginal apical point (C or D) descended to a point at least halfway to the hymen from a position of perfect apical support. Subjects who did not return for clinical examination beyond their 3-month postoperative visit, but who had been in telephone contact with the clinic stating that they had experienced symptomatic recurrence of their POP, were also included as having unsuccessful SCP procedures. Those similarly in contact with the office by telephone but not clinically examined, who indicated no subjective return of their POP, were coded as successful.

Patients who reported a return of symptoms of stress urinary incontinence at any time after initial subjective or objective cure of those symptoms were coded as experiencing sling failure at the time recurrent stress incontinence was experienced.

Results

Follow-up beyond the 3-month postoperative visit was available for 74 patients who had undergone 53 SCP and 27 sling procedures (6 patients had undergone both).

Sacrocolpopexy

The median age of the 53 patients who underwent SCP was 59 years (range 33–75) and median follow-up was 17 months (range 3–54). Five patients (9%) were premenopausal, 39 (74%) were postmenopausal on HRT, and 9 (17%) were postmenopausal not on HRT. Forty-four (83%) patients had previously undergone hysterectomy.

Three patients had a preoperative POP stage II, 41 (77%) were stage III and 9 (17%) were stage IV. Hysterectomy was performed at the time of SCP in 6 patients, and sacrocolpopexy was performed with the uterus in situ for 3 women.

The outcome of SCP is recorded in Table 2. When failure was defined according to any of the criteria listed in the Methods section, 45 (83%) patients experienced SCP failure. By 1 year after their surgery, 23 (43%) SCP procedures were known to be failures. A Kaplan–Meier plot of SCP failures is drawn in Figure 1.

We reoperated on 21 (40%) SCP patients, with 2 choosing colpocleisis, 1 choosing transvaginal vault suspension, 2 choosing anterior colporrhaphy only, and the remaining 16 choosing repeat SCP with synthetic mesh placement. At the time of repeat SCP we found graft between the sacrum and vagina in just 3 (19%) patients. In one of these the graft appeared to be reasonably thick and viable; in the other two, a band approximately 5 mm in diameter was all that linked the vagina and sacrum. In all other patients remnants of graft were evident in the posterior, subperitoneal vagina, but no graft linked the vagina to the sacrum.

Suburethral sling

The median age of the 27 patients with follow-up after sling procedure was 59 years (range 38–79) and median follow-up was 12 months (range 0.5–51). Twenty patients (74%) were postmenopausal, of whom 17 (85%) were on HRT. Ten (37%) patients had undergone previous incontinence surgery. One patient underwent transvaginal division of the sling 4 weeks after the procedure for persistent urinary retention. She experienced recurrence of her symptoms of SUI, but was not counted as a failure for the purposes of this review.

A total of 14 (52%) sling procedures were failures, with recurrent SUI symptoms experienced 2 weeks to 24 months after the procedure. Three patients had recurrent SUI symptoms within 3 months of surgery, with the remaining 11 experiencing recurrence of their SUI symptoms after 3 months. The remaining 13 (48%) of slings were subjectively successful 7–51 months after surgery. Ten (37%) patients elected to undergo repeat pubovaginal sling procedures with autologous rectus fascia.

By 1 year after surgery, 11 (41%) slings were known to be failures. A Kaplan–Meier plot of sling failure is drawn in Figure 2.

Discussion

The rate of surgical failure obviously depends upon the definition of the term. Most would agree that a need for reoperation constitutes failure, implying a 60% success rate in this series of SCP procedures. In addition, most would agree that protrusion of the anterior vaginal wall beyond the hymen constitutes SCP failure, dropping the success rate to 32%. Again, defining anterior vaginal wall points to the hymen or beyond, or apical descent of half vaginal length or more, drops the success rate of SCP even further, to 19%. Alarmingly, the success rate may be even lower, depending on the status of those lost to follow-up. Even if all those lost to follow-up were successful, the success rate remains as low as 34%. Similarly, even if all those lost to follow-up were successful, the pubovaginal sling success rate would be only 60%.

The unacceptably high failure rates for SCP and pubovaginal sling reported in this series indicate failure of the graft material and are well below the usual 5%–15% failure rates reported by this group and many others when using synthetic or autgraft material for the same surgical procedures [14, 15, 16]. Further, the inability to find any remaining graft material at the time of reoperation in the majority of patients confirms degradation and resorption of the fascial graft.

Banked human fascial tissue has been commonly used for years by orthopedic surgeons, opthalmologists and cardiac and vascular surgeons as replacements or supports for natural tissues. It is unfortunate that their largely successful use of donor fascia apparently does not translate into success with vaginal reconstruction. The advantage of these tissues over synthetic materials with their risks of infection, erosion and rejection is well documented [17].

Our high failure rates appear to be similar to those reported by Soergel et al. [9] using freeze-dried, irradiated cadaveric fascia lata. Other case series using tissue that is freeze dried but not irradiated apparently yield better results, but even with non-irradiated tissue more surgical failures are being seen with longer and more careful follow-up [7]. These findings are consistent with tissue analysis comparing freeze-dried and solvent-dehydrated cadaveric fascia with cadaveric dermal grafts and autologous rectus fascia [18]. Lemer [18] found in laboratory testing that freeze-dried cadaveric fascia was significantly weaker and less stiff and had significantly more tissue variability.

Table 2 Outcome of SCP and how defined

SCP outcome: *n* (%)	How outcome defined	*n* (%)
Success 10 (19%)	Clinical examination	8 (80%)
	Phone report no problem	2 (20%)
Failure 43 (81%)	Clinical exam with anterior wall at hymen	4 (7%)
	Clinical exam with anterior vaginal wall beyond hymen	36 (68%)
	Apex descended more than half total vaginal length	9 (17%)
	Phone report of POP recurrence	2 (4%)

Among patients with failures, some demonstrated both apical and anterior vaginal wall failure

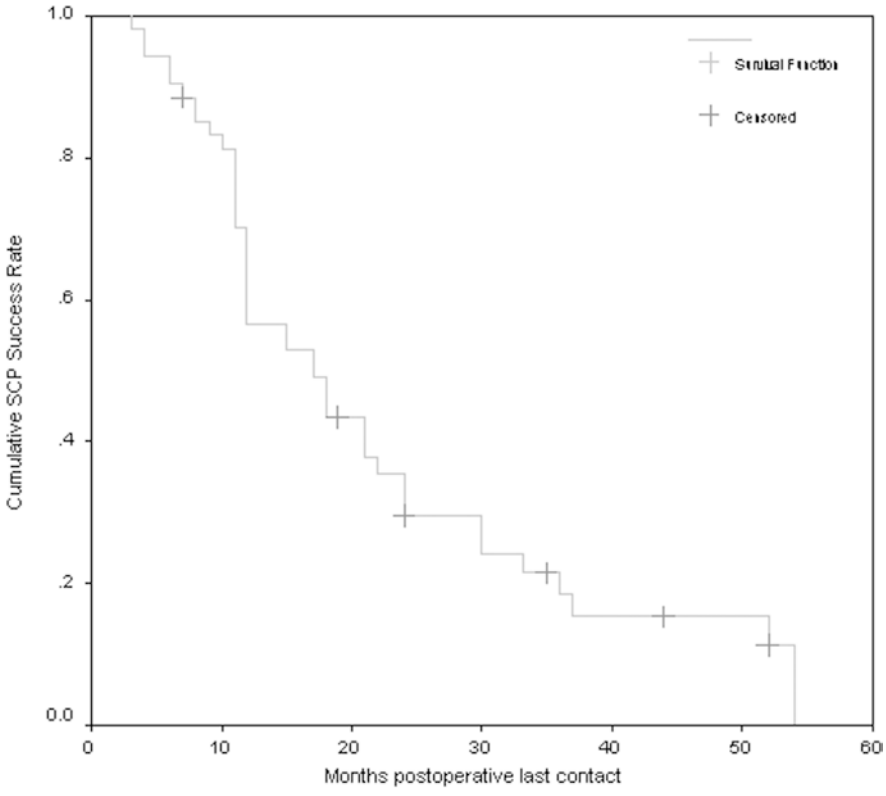

Fig. 1 Kaplan–Meier plot describing the time of sacrocolpopexy failure

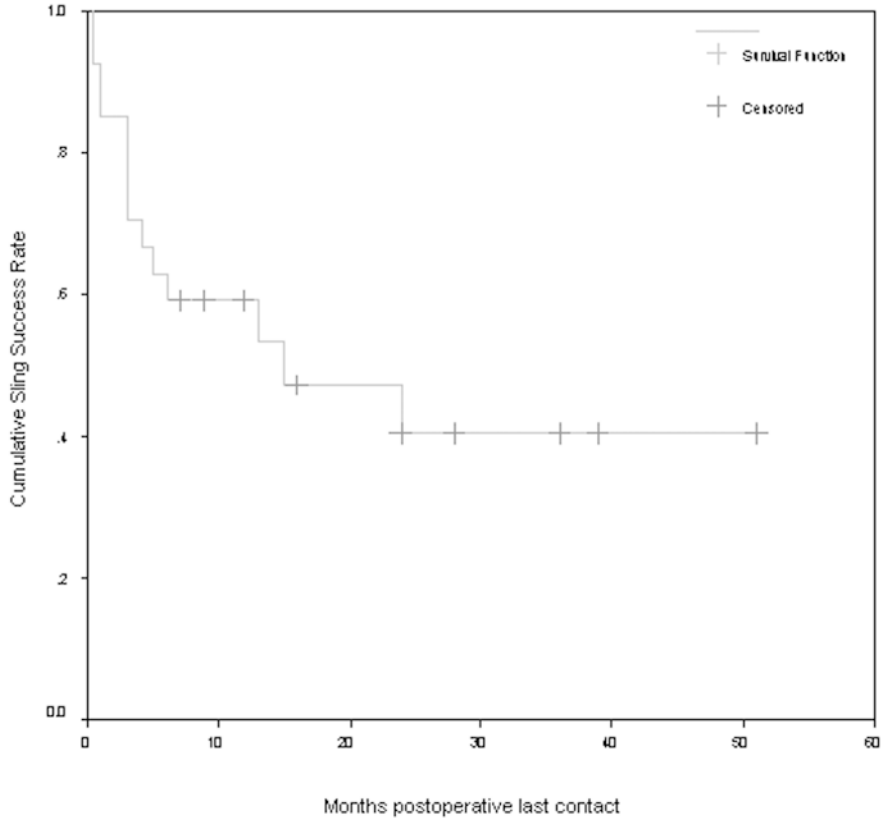

Fig. 2 Kaplan–Meier plot describing the time of suburethral sling failure

In reviewing the published surgical experience with the use of cadaveric donor fascia for pubovaginal slings there appear to be differences in outcomes by geographic region, suggesting some dependence on the source of the tissue. Although there are standards monitored by the American Association of Tissue Banks, a wide range of

procedures is acceptable for tissue procurement, processing, sterilization and reconstitution. Each step in this process may be important in determining the integrity of the tissue, its long-term strength and its ability to promote fibroblast growth and proliferation. Unfortunately, most published reports give little information about the exact processes used to obtain, sterilize and reconstitute the tissue. In addition, many commercial tissue preparation techniques are proprietary. Without processing information, one cannot necessarily generalize reports concerning the use of 'cadaveric fascia' for reconstructive surgery, or compare outcomes between centers.

As more xenograft and allograft tissues become available, surgeons must be aware of the specific tissue qualities, sterilizing techniques and specific applications in vaginal reconstructive and incontinence procedures. One cannot always assume that they are using the same tissue that another surgeon used, or that results reported at 1 year will hold over time. Similarly, it may be that graft suitable for the anterior wall is not suited for apical suspension or for the posterior compartment.

We are aware that our methods of describing pelvic organ support and subjective postoperative symptoms are not standard, and would not be acceptable if we were staking claim to a successful surgical technique. We hope the publication of our poor results will prompt others to critically examine their own surgical outcomes with donor materials and to report both promising and regrettable results. While continuing to search for new and improved techniques and materials to help our patients, we must be cautious and scientifically evaluate each new material prior to suggesting its widespread clinical use.

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Editorial comment

In this paper the authors present the follow-up results of 67 sacrocolpopexy and 35 sling procedures. Follow-up was available in 73% of cases and ranged between 3 and 54 months, with an average of 17 months. The cases are identical to those presented in an earlier work entitled 'Functional failure of fascia lata allografts', published in the *American Journal of Obstetrics and Gynecology* in 1999, in which the focus was on 12 reoperations done for failures encountered up to that point. The histologic and gross appearances of utilized allografts were the focus of that earlier work. In the latest manuscript 21 patients from the same original pool of 102 cases had undergone reoperation. The focus of this article is on their failure rate over the aforementioned time period.