Urological Science 28 (2017) 135–138

Contents lists available at ScienceDirect

Urological Science

journal homepage: www.urol-sci.com

Original article

Long-term outcomes of autologous fascia lata sling for stress incontinence secondary to intrinsic sphincter deficiency in women

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ARTICLE INFO

Article history:
Received 8 September 2016
Received in revised form
30 December 2016
Accepted 6 March 2017
Available online 20 April 2017

Keywords:
fascia lata
functional outcomes
intrinsic sphincter deficiency
long term
pubovaginal slings

ABSTRACT

Objective: To report our long-term pubovaginal sling (PVS) outcomes using fascia lata for stress urinary incontinence (SUI) secondary to intrinsic sphincteric deficiency (ISD).
Methodology and methods: Following Institute Review Board approval, charts from women undergoing PVS with fascia lata, with at least 6 months of follow up, were reviewed. Preoperative and postoperative data collected included demographics, validated questionnaires, prior anti-incontinence procedures, associated repairs, urodynamic findings, and reoperation procedures for SUI. Success was defined as cure of SUI (no pad, UDI-6 Question 3 related to SUI at $\leq$ 1, and no SUI reoperation).
Results: Between 1997 and 2013, 22 women met the inclusion criteria with mean age of 73 (52–88) years, mean BMI 29 (17–38) and mean parity 2.7 (1–4). Mean follow up was 96 months (8–190). Indication for fascia lata sling included obesity (13) and prior abdominal procedures (9), including abdominoplasty. Fifteen women had received one or more prior antiincontinence procedures and five a prior injectable agent. No perioperative complications were noted. Overall, 14 of 22 women met success criteria [UDI-6 Question 3 at 0 (10) and at 1 (4)]. Three women underwent a subsequent procedure for residual SUI with periurethral bulking agent and one is awaiting an artificial urinary sphincter.
Conclusion: At long-term follow-up of over 8 years after fascia lata sling, women who underwent fascia lata sling had acceptable continence outcomes with minimal complications.

1. Introduction

The autologous fascia pubovaginal sling (PVS) has long been an established surgical technique used to treat stress urinary incontinence (SUI). However, PVS is often criticized for its invasive nature including perioperative morbidity and extended hospital stay. Its use declined substantially in the late 1990s following the introduction of synthetic mid urethral sling (MUS) as the preferred treatment approach. Recently, the US Food and Drug Administration's concerns with regards to transvaginal mesh for prolapse repair have impacted on the use of synthetic MUS despite a joint statement from American Urogynecologic Society/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction supporting its safety and efficacy.[1] There is an emerging interest in re-establishing autologous sling techniques to either avoid these adverse events altogether or to address residual bothersome stress urinary incontinence (SUI) from intrinsic sphincteric deficiency (ISD) when it occurs after MUS removal. However, there is a dearth of long-term data on autologous slings, especially involving fascia lata. Therefore, our objective was to report on our long-term outcomes in women undergoing autologous fascia lata sling (AFLS) for ISD proven SUI.

2. Materials and methods

Data collection and database use was approved by our institutional review board and compliant with the terms of Health Insurance Portability and Accountability Act (HIPAA). We retrospectively reviewed a prospective PVS database of women who underwent PVS for clinically proven SUI by a single surgeon (P.Z.) between 1997 and 2013 with a minimum of 6 months follow-up. The AFLS was indicated for SUI secondary to ISD with a well-supported urethra as documented on vaginal examination with no urethral descent on Valsalva and on standing lateral voiding view in a micturating cystogram. Selection of patients for AFLS are targeted primarily at women in which the harvest of rectus fascia

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http://dx.doi.org/10.1016/j.urols.2017.03.002

maybe operatively challenging. This included women with morbid obesity [defined by the World Health Organization as body mass index (BMI) $\geq$ 30 kg/m^2] and/or previous complicated abdominal surgeries such as abdominoplasty. Women with: (1) urethral hypermobility; (2) abdominal leak point pressure > 60 cmH_2O; and (3) mobility and gait issues were excluded from the study. Pre- and postoperative data collected by a third-party investigator (D.L.) who did not participate in the surgeries included demographics, validated questionnaires, prior anti-incontinence procedures, associated repairs and reoperation procedures for SUI.

Women were seen in follow-up at 6 weeks, 6 months and yearly thereafter. The patients completed preoperative validated questionnaires including the short forms of the urogenital distress index (UDI-6) and incontinence impact questionnaire (IIQ-7). All patients with postoperative validated questionnaire scores at their latest clinical visits were analyzed. Definition of surgical success included the following: (1) no pad, (2) UDI question 3 on SUI $\leq$1 and (3) no retreatment/operation.

2.1. Operative technique for autologous fascia lata sling

Patient is positioned in high lithotomy with careful pressure-area protection of feet and ankle with foam pads in adjustable stirrups allowing fascia lata harvest followed by the performance of the PVS itself. The fascia lata is harvested from the lower limb by convention with the stirrups lowered to straighten the leg. A short transverse incision is made two fingerbreadths above the knee joint along the course of the fascia lata (Figure 1A). Following division of the distal end of the fascia lata, holding sutures are placed to lift off the fascia and dissected upwards for a 6 cm $\times$ 2cm strip (Figure 1B).[2] The fascial strip is divided (Figure 1C) cephalad, marked in the midline and secured with nonabsorbable suspension sutures at each extremity. Meticulous hemostasis is performed progressively. The fascial edges are not re-approximated and the skin incision is closed over a small Penrose drain.

Compression bandage is applied and the patient is re-adjusted in a high lithotomy position. An inverted U-shaped anterior vaginal incision is made with the top of the U located at the level of the midurethra. A vaginal flap is then dissected to the level of the bladder neck. Next, using a combination of blunt and sharp dissection the endopelvic fascia is perforated and the retropubic space entered. A Raz double prong ligature carrier is used to transfer the suspension sutures at the ends of the fascia lata strip from the vaginal incision to the suprapubic region under finger control. The fascia lata strip is then secured under the proximal urethra with several interrupted absorbable sutures, thus keeping the strip flat and avoiding a bunching effect.

Cystoscopy is then performed with a 30° and 70° lens to exclude bladder or urethral injury. Following closure of the vaginal incision, the sutures are tied loosely over a rubber shod right angle clamp leaving 2 cm between the knots and the tendinous portion of the anterior rectus fascia at the back of the pubic symphysis. Vaginal packing and an indwelling Foley catheter are left in place for 24 hours.

3. Results

From a prospective longitudinal database on PVS slings, 22 women met the study criteria with mean age of 73 years (range, 52–88 years), mean BMI 29 kg/m^2 (17–38 kg/m^2) and mean parity 2.7 (1–4; Table 1). Mean follow-up was 96 months (8–190). Indication for fascia lata sling (over traditional rectus fascia) was related to overweight (n =13) and to prior abdominal procedures,

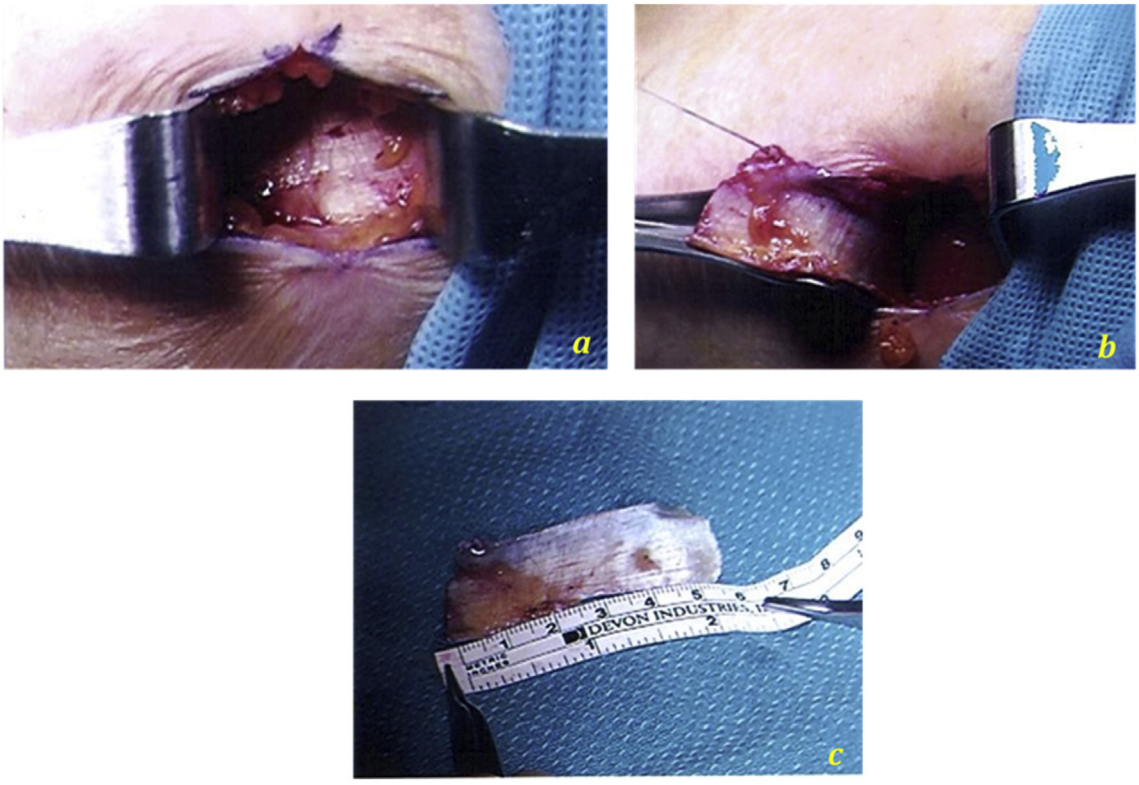

Figure 1. (a) Small transverse incision is made above knee with exposure of fascia lata; (b) distal end is detached with cephalad mobilization of the fascia lata strip; (c) completion of 6 cm $\times$ 2 cm sling harvest.