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Self-Fixing Anchoring Mechanism for a Minimally-Invasive Non-Mesh Incontinence Sling

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Abstract

Mesh mid-urethral incontinence slings are unavailable in many nations, and reducing in popularity elsewhere. Harm from surgical mesh is a significant concern, and older procedures such as colposuspension and fascial slings are being reinstituted as replacements. We assessed the feasibility of a minimally invasive technique resembling the mid-urethral sling using absorbable barbed suture to simplify the placement and tensioning of a fascial sling. Five participants were treated with a fascia lata sling using a barbed suture for tensioning. All participants reported a reduction in urinary leakage related to physical activity (UDI-6 score median pre-op 3-"greatly bothered" and median 0 post-op-"not at all bothered") and no bother with difficult urination at 6 month follow-up. This method is feasible for fascial sling placement and tensioning.

Keywords

Urinary Incontinence, Stress Incontinence, Fascial Sling

1. Introduction

The International Continence Society defines stress urinary incontinence as "the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction". The most commonly used surgical treatment for this is the mesh mid-urethral sling. Harm from implanted surgical mesh for the treatment of stress urinary incontinence has become a controversial topic worldwide and patients are increasingly mesh-averse. Harm from implanted surgical mesh can include exposure of the mesh into the vagina, erosion into the bladder or other surrounding structures and pain.

In response, countries such as New Zealand underwent a restorative justice approach to people injured by surgical mesh [1], and several countries have either placed a pause or an outright ban on the use of mesh for pelvic organ prolapse and stress urinary incontinence procedures [2] [3].

Presently in New Zealand, there is a newfound interest in stress urinary incontinence procedures that preceded the shift to routinely using polypropylene mesh slings [4] as first line treatment. These procedures that have since become the "new" standard of treatment in New Zealand include the Burch colposuspension [5] and the fascial sling, utilising harvested autologous fascia from the rectus abdominus or fascia lata [6]. Many gynaecologic surgeons trained since the 2000s have not learned the techniques of colposuspension or fascial slings, and with the loss of the mesh mid-urethral sling, access to care can be compromised.

As a result, suitable alternatives for the treatment of stress urinary incontinence are needed to replace the mesh mid-urethral sling, particularly in locations that can no longer access this treatment.

We sought to develop a meshless sling that mirrored the technical aspects of the mesh mid-urethral sling procedure. This would preserve the minimally invasive attributes of the procedure and avoid the abdominal incision typically used to anchor and tension a fascial pubovaginal sling. The goal is to develop a safe, minimally-invasive incontinence procedure that would include technical steps similar to a mid-urethral sling, and offer a short operating time and rapid hospital discharge.

As a preliminary evaluation, we developed a technique of sling fixation using an existing absorbable barbed suture product, Stratafix Symmetric PDS (Ethicon, Bridgewater, NJ) size 2-0. We first assessed the grip security of the barbed suture compared to the uncovered mesh from a commercially available sling kit. We tested the pull-through force of the materials after they were passed through synthetic cloth, using a calibrated push-pull force gauge (Wedderburn. Ingleburn, NSW, Australia). The barbed suture holding strength was up to 19 Newtons, whereas the mesh sling pull through force was measured at 3 Newtons. By estimating the surface contact area of a mid-urethral sling at 4.5 cm^2, we converted these forces to holding pressures: 430 cm H_2O for the barbed suture and 68 cm H_2O for the mesh.

Following this mechanical assessment, we conducted a small observational feasibility study of five participants to test the function of barbed suture as a fixation technique for a pubovaginal sling.

2. Materials and Methods

All procedures were completed under general anaesthesia. The sling used in the study was derived using harvested fascia lata taken from a small incision along the lateral lower thigh. We chose to use fascia lata so the sling anchoring point at the abdominal wall could be configured in a way that would avoid an abdominal incision larger than a simple skin puncture. A 2-0 Stratfix Symmetric PDS absorbable suture was affixed to each end of an 8 - 10 cm long, 1.5 - 2 cm wide strip of

fascia lata. The fixation point of the suture was doubly thrown to avoid relying entirely on the tab at the end of the suture for the fixation.

The sling was placed through a 1.5 - 2 cm long sub-urethral incision in the vaginal epithelium, exiting the abdominal wall just above the pubic symphysis on each side, with 7 cm separation between the exit points. The bladder was reflected away from the trocar path using the sheath of the cystoscope. The fixation sutures were passed retropubically (**Figure 1**) using a reusable trocar (CAL-TV02 Caldera Medical, Westlake Village, CA, USA).

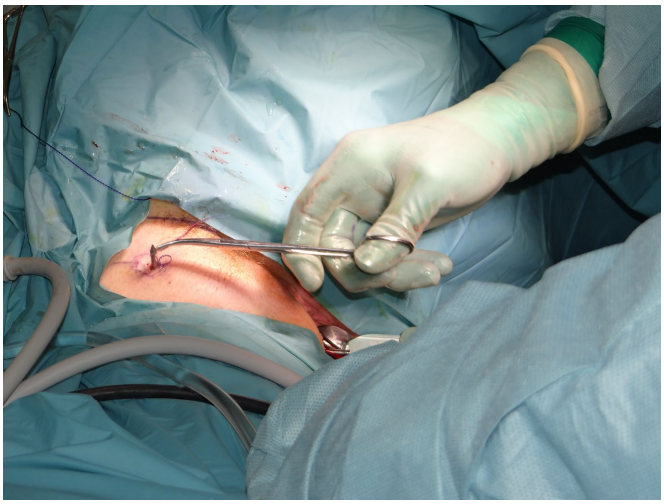

Figure 1. Trocar passage.

Cystoscopy was performed using a 70 degree cystoscope visualising the lateral distal bladder from posterior to anterior along the trocar path to ensure the trocar did not puncture the bladder.

The sling was then tensioned in a mid-urethral position by placing a pair of Metzenbaum scissors with the blades opened widely between the urethra and the graft. The anchoring sutures were then pulled through from the abdominal punctures to adjust the sling tension with the separated scissors maintaining a tension free position of the graft. Once positioned, the sutures were cut flush with the skin, and the puncture sites closed with skin glue. The vaginal incision was closed with 2-0 Vicryl suture (Ethicon, Bridgewater, NJ).

Post-operative care consisted of a voiding trial prior to same-day discharge from hospital. Participants requiring catheter drainage were seen weekly for voiding assessment. Participants still requiring catheter use two weeks after the procedure were taught clean intermittent self-catheterisation.

The evaluation study was approved by the New Zealand Northern A Health and Disability Ethics Committee, reference 20/NTA/57. The study was prospectively registered with the Australian New Zealand Clinical Trials Registry, trial number ACTRN12620000900910.

Inclusion criteria included adults with purely urodynamic stress urinary incontinence who would otherwise be candidates for a mid-urethral sling procedure.

Exclusion criteria were: mixed incontinence symptoms, post-void residual volume of urine greater than 100 mL, body mass index greater than 35, prior significant pelvic or urinary tract reconstructive surgery, age under 18 years, chronic vaginal or pelvic pain and inability to provide informed consent.

Outcome evaluation was performed by post operative examination and by using the Urogenital Distress Inventory-Short Form UDI-6 pre-operatively, postoperatively at 42 - 56 days and at 6 months. Permission to use the UDI-6 was granted by license from the Mapi Research Trust.

3. Results

Five participants were enrolled in the evaluation study between April 2021 and November 2022. Four participants reported New Zealand European ethnicity, while one participant reported New Zealand Māori ethnicity. All participants provided written informed consent to participate in the study and four of five participants also consented to surgical photography for the study. All participants had the procedure performed per protocol and completed all study follow-up evaluations. One participant delayed the 42 - 56 day in-person follow-up visit to post-op day 67 due to having contracted COVID-19. All other follow-up procedures were kept to the study protocol timeframes.

For the efficacy measure of "Physical Activity Leakage," all participants reported an improvement at both 6 weeks and 6 months post-operatively (median of 0—bothered not at all for both) as compared to baseline (median 3—bothered greatly).

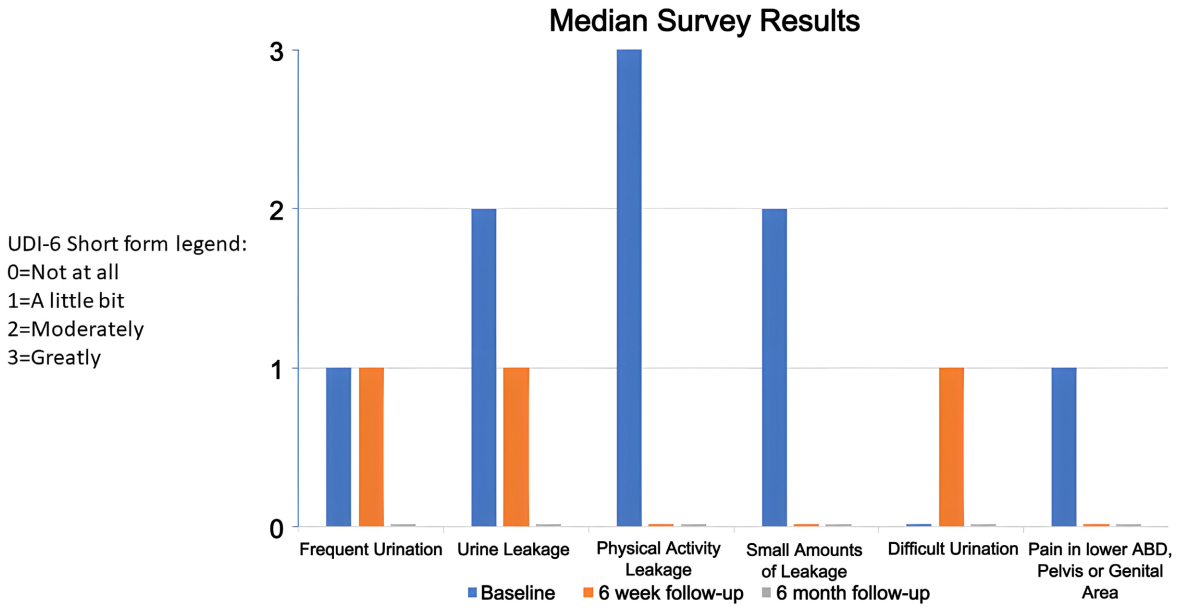

Figure 2. Median results for all survey outcome measures.

Short-term urinary retention was common, all participants discharged on the day of surgery required the use of a catheter for bladder drainage. The duration of

catheter usage was for a median of 28 days post-operatively, with a range of 5 - 45 days. All participants reported no bother with difficult urination at the 6-month follow-up UDI-6 short-form survey.

There were no bladder perforations or other adverse events.

The UDI-6 shortform survey median values for all measures are shown in **Figure 2**.

4. Discussion

Absorbable barbed suture used as an anchoring device for a fascial sling provides suitable sling fixation with a minimally invasive technique with procedural steps similar to a mesh mid-urethral sling.

With mesh mid-urethral slings becoming a less desirable treatment option and even unavailable in numerous places around the world relating to increasing reports of harm from mesh, a suitable alternative for treatment of stress urinary incontinence is urgently needed. The ideal alternative would be safe, efficacious, minimally invasive, have standardized and reproducible technique, require a short operative time and not contain permanent synthetic mesh. Previous iterations of stress urinary incontinence procedures were developed six to eight decades ago. The Burch colposuspension [6], first reported in 1961, utilises sutures placed into the vaginal tissue lateral to the urethra and anchored to the pectineal ligament on each side. More recently this procedure has been performed laparoscopically. Other historical operations for stress incontinence include the Marshall-Marchetti-Kranz [7] retropubic suspension from 1949, the Pereyra transvaginal needle suspension (1959) [8], and the resurgent fascial sling procedure (1942) [9] Suture materials and surgical instrumentation have changed significantly since these operations were first conceived. Incorporating modern suture materials and instrumentation into the classic fascial sling procedure has potential to improve upon its results and make its re-adoption an acceptable replacement for mesh mid-urethral sling procedures.

This is a small feasibility study that shows efficacy with participant reported reduction in leakage events related to physical activity. We have shown that the fascial sling procedure can be modernized using updated retropubic access techniques and securely anchored using absorbable knotless barbed suture.

As this was a small feasibility study, the findings are less generalisable due to the limited ability to statistically analyse results due to the sample size. The length of time to resuming normal voiding function was considerably longer than expected. All participants did void with complete emptying without any sling adjustment or division interventions required. We plan to alter the tensioning technique in future studies by adjusting the graft with a visible gap between the urethra and the sling.

Future modifications are being targeted at finding a suitable absorbable replacement for harvested fascia lata, further reducing operative and recovery times. These findings require larger controlled studies to confirm these benefits.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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