Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Outcomes of supercritical carbon dioxide-processed cadaveric fascia lata pubovaginal sling for female stress urinary incontinence: a prospective single-surgeon cohort

Hnin Yee Kyaw
h.kyaw@griffith.edu.au
Griffith University
Hannah Krause
Greenslopes Private Hospital
Yu Hwee Tan
Greenslopes Private Hospital
Vivien Wong
Bond University
Judith Goh
Greenslopes Private Hospital

Research Article

Keywords: Stress urinary incontinence, pubovaginal sling, cadaveric fascia lata, allograft, supercritical carbon dioxide

Posted Date: November 17th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11621335/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: Competing interest reported. Judith Goh has previously delivered unpaid educational presentations for Samson Medical Technologies, Australia. The remaining authors declare no competing interests.

Title Page

Title

Outcomes of supercritical carbon dioxide-processed cadaveric fascia lata pubovaginal sling for female stress urinary incontinence: a prospective single-surgeon cohort

Authors

Hnin Yee Kyaw[1,2]
Hannah Krause[1,3,4]
Yu Hwee Tan[1,3,4]
Vivien Wong[1,5]
Judith Goh[1,2,4]

Affiliations

[1] Department of Urogynaecology, Gold Coast University Hospital, Queensland, Australia
[2] Griffith University School of Medicine, Queensland, Australia
[3] Faculty of Health, Medicine and Behavioural Sciences, The University of Queensland, Queensland, Australia
[4] Greenslopes Private Hospital, Brisbane, Queensland, Australia
[5] Bond University Faculty of Health Sciences & Medicine, Gold Coast, Queensland, Australia

Corresponding Author

Hnin Yee Kyaw
Department of Urogynaecology
Gold Coast University Hospital
Queensland, Australia
Email: hninyk13@gmail.com

ORCID IDs

Hnin Yee Kyaw: https://orcid.org/0009-0006-8001-3531
Yu Hwee Tan: https://orcid.org/0000-0002-1425-5501
Vivien Wong: https://orcid.org/0000-0003-1007-3783
Judith Goh: https://orcid.org/0000-0002-6486-5359

Title:
Outcomes of supercritical carbon dioxide-processed cadaveric fascia lata pubovaginal sling for female stress urinary incontinence: a prospective cohort study

Abstract:
Purpose
Supercritical carbon dioxide ($SCCO_2$) processing may preserve the structural properties of cadaveric fascia while avoiding donor-site morbidity associated with autologous fascial harvest. Clinical outcomes of $SCCO_2$-processed fascia lata have not previously been reported in continence surgery. Our study evaluated efficacy and safety outcomes following $SCCO_2$-processed cadaveric fascia lata pubovaginal sling (PVS) surgery for female stress urinary incontinence (SUI).

Methods
This prospective, single-centre, single-surgeon observational cohort included 24 consecutive women undergoing $SCCO_2$-processed fascia lata PVS surgery. Patient-reported outcomes were assessed using the International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF) and Patient Global Impression of Improvement (PGI-I) at 6 weeks, 6 months and 12 months. Primary outcome was change in ICIQ-UI SF and PGI-I from baseline to 12 months. Perioperative and graft-related complications were recorded prospectively.

Results
Baseline median ICIQ-UI SF was 15.5 (IQR 14–16). Twelve-month outcome data were available for 18 participants with a median ICIQ-UI SF of 4 (IQR 0–6), and a median within-participant improvement of 11 points (IQR 9–15; $p<0.001$). Thirteen (72.2%) reported being “very much better” on PGI-I; subjective SUI cure / improvement were reported by 17/18 (94.4%). Graft exposure occurred in 3/24 (12.5%).

Conclusion
$SCCO_2$-processed cadaveric fascia lata PVS was associated with substantial improvement in patient-reported continence outcomes at 12 months. These preliminary findings support further prospective evaluation with larger comparative cohorts and longer follow-up.

Keywords:
Stress urinary incontinence; pubovaginal sling; cadaveric fascia lata; allograft; supercritical carbon dioxide

Introduction

Stress urinary incontinence (SUI) is a common condition among women and surgical interventions is an option when conservative measures fail. Established operations include synthetic midurethral slings, autologous fascial pubovaginal slings (PVS), colposuspension, and urethral bulking agents [1]. In many parts of the world, concerns regarding transvaginal mesh [2] and subsequent restrictions in device availability have increased interest among patients and clinicians regarding non-mesh continence procedures.

Autologous fascial PVS is an established treatment option for SUI, with durable continence outcomes [3-5]. However, fascia harvest increases operative time, postoperative pain, and donor-site morbidity [6, 7]. Cadaveric fascia lata has emerged as an alternative to avoid tissue harvest [6, 8-10], however earlier preservation techniques for allografts such as freeze-drying or irradiation have shown variable durability, with reports of graft degeneration and early failure [11-15]. Processing methods may influence the mechanical properties of fascia lata allografts [14].

Supercritical carbon dioxide ($SCCO_2$) processing is a low-temperature supercritical-fluid technique used in the processing of biological allografts [16]. $SCCO_2$ can reduce bioburden and has been used for terminal sterilisation of musculoskeletal allografts at physiological temperatures. Studies demonstrate $SCCO_2$ processing can preserve important aspects of collagen architecture and graft strength without ionising radiation, although effects on tissue stiffness have varied between studies [17, 18]. To our knowledge, $SCCO_2$-processed fascia lata has not previously been clinically evaluated in continence surgery.

This study prospectively evaluated the efficacy and safety of $SCCO_2$-processed cadaveric fascia lata PVS surgery for female SUI together with a comparison of perioperative resource utilisation against autologous fascial PVS surgery performed by the same surgeon.

Materials and Methods

Study design and participants

This prospective, single-centre, single-surgeon observational cohort study was conducted at Greenslopes Private Hospital, Queensland, Australia. All consecutive women undergoing $SCCO_2$-processed cadaveric fascia lata PVS surgery for SUI between July 2024 and May 2026 were included. Women undergoing concomitant pelvic surgery and those with previous anti-incontinence surgery were included. The only exclusion criterion was inability to provide informed consent. No formal sample size calculation was performed for this pilot study.

The study was approved by the institutional Human Research Ethics Committee (HREC 2024/ETH/0064). All participants provided written informed consent. An audit of hospital records of isolated autologous rectus fascia PVS procedures performed by the same surgeon was undertaken for comparison of perioperative resource utilisation.

Pre-operative assessment

All participants underwent preoperative assessment including standardised clinical history, pelvic examination, International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF) and multichannel urodynamic studies.

Surgical technique and graft

All procedures were performed by a single urogynaecologist (JG) using a standard retropubic PVS technique. The $SCCO_2$-processed 10 cm x 1.5cm cadaveric fascia lata graft (Samson Medical Technologies, Australia) was thawed in sterile room-temperature saline before implantation. Intravenous antibiotics were administered, and the bladder emptied. Following local anaesthetic infiltration, a 1.5-cm midline anterior vaginal incision was made at the level of the mid-urethra and bilateral paraurethral tunnels were developed towards the perineal membrane. A 3–4-cm low transverse suprapubic incision was made and the rectus fascia exposed. Each end of the fascia lata graft was

secured with 0-polydioxanone suture and passed retropubically from the vaginal to the suprapubic incision using a sling needle passer. Cystoscopy was performed following each retropubic passage to exclude bladder or urethral injury.

The sling was positioned suburethrally without tension with a suture bridge of 3-4 cm between the rectus fascia and polydioxanone suture knot, after which the vaginal and abdominal incisions were closed. An indwelling urinary catheter was left overnight. A trial of void was performed the following morning according to institutional protocol.

Follow-up and outcome measures

At 6 weeks, 6 months and 12 months post-operative review, ICIQ-UI SF and Patient Global Impression of Improvement (PGI-I) were completed. Patient-reported SUI cure and improvement were recorded. Perioperative, postoperative and graft-related complications were prospectively documented throughout follow-up.

Primary outcomes were change in ICIQ-UI SF score from baseline to 12 months and PGI-I at 12 months. Secondary outcomes included change in ICIQ-UI SF from baseline to 6 weeks and 6 months, PGI-I at 6 weeks and 6 months, subjective SUI cure and improvement at 12 months, trial-of-void outcome, catheter requirement at discharge, 30-day unplanned clinical representation, and postoperative and graft-related complications. Operative time was assessed separately for procedures performed without concomitant surgery.

For assessment of perioperative resource utilisation, a retrospective sample of isolated autologous rectus fascial PVS procedures performed by the same surgeon was identified. Procedures involving concomitant surgery were excluded to permit comparison of operative time and other perioperative resource measures with isolated allograft sling procedures.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics, version 32.0.0.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarised as mean with standard deviation (SD) when approximately normally distributed and as median with interquartile range (IQR) or range when distributions were skewed or discrete. Categorical variables were reported as counts and percentages.

Changes in ICIQ-UI SF scores from baseline to 6 weeks, 6 months and 12 months were calculated within individual participants. Because postoperative ICIQ-UI SF scores and change scores were not normally distributed, paired comparisons with baseline were performed using the Wilcoxon signed-rank test. The 12-month comparison represented the primary efficacy analysis; earlier time-point comparisons were secondary. A reduction of ≥ 5 points from baseline at 12 months was classified as a clinically meaningful improvement according to the published minimum important difference for surgically treated women with SUI [19]. PGI-I and subjective SUI cure and improvement were analysed descriptively.

Analyses at each postoperative time point used available paired data. Participants who had not yet reached a scheduled follow-up time point were excluded from that time-point analysis and were not classified as having missing data.

Comparison between isolated allograft and autologous fascial PVS procedures were performed for perioperative resource utilisation. Operative time was compared using Welch's independent-samples t-test, and length of hospital stay using the Mann–Whitney U test. All tests were two-sided, with statistical significance defined as $p<0.05$.

Results

Participants and baseline characteristics

Between July 2024 and May 2026, 24 women underwent $SCCO_2$-processed cadaveric fascia lata PVS surgery and were included. Baseline characteristics are presented in Table 1. Eight women (33.3%) had undergone previous anti-incontinence surgery (Table 1).

Urodynamic stress urinary incontinence was demonstrated in 23/24 women (95.8%). The remaining woman without demonstrable incontinence had bladder outlet obstruction from a previous synthetic mid-urethral sling. She requested and underwent total removal of the mesh sling with concomitant insertion of the allograft sling. Median baseline ICIQ-UI SF score was 15.5 (IQR 14–16).

Primary outcomes

At study completion, 18 participants had reached 12 months after surgery (Table 2). Median ICIQ-UI SF score decreased from 15.5 (IQR 14–16) at baseline to 4 (IQR 0–6) at 12 months. The median within-participant improvement was 11 points (IQR 9–15; Wilcoxon signed-rank $p<0.001$). Seventeen of 18 participants (94.4%) achieved a reduction of at least 5 points, meeting the predefined threshold for clinically meaningful improvement.

At 12 months, 16/18 participants (88.9%) rated their condition as “very much better” or “much better” on the PGI-I. No participant reported worsening.

Secondary patient-reported outcomes

Improvement in ICIQ-UI SF scores (Table 2) and PGI-I responses were evident at earlier follow-up and maintained at 12 months. No participant reported worsening at either time point.

At 12 months, subjective SUI cure was reported by 12/18 participants (66.7%), while 17/18 (94.4%) reported subjective improvement.

During follow-up, two participants (8.3%) underwent further treatment for recurrent SUI, receiving urethral bulking with polyacrylamide hydrogel (Bulkamid; Contura International A/S, Denmark) between 9-10 months after sling surgery. Two participants developed de novo urgency, both responded to conservative management. Two participants continued pre-existing intradetrusor botulinum toxin A treatment during follow-up; neither were considered de novo treatment. No participant reported persistent voiding dysfunction at subsequent follow-up.

Perioperative and safety outcomes

Nine women (37.5%) underwent one or more concomitant procedures, including hysterectomy with bilateral salpingo-oophorectomy, native-tissue vaginal repair, rectovaginal fistula and anal sphincter repair, mesh MUS excision, and intradetrusor botulinum toxin A injection. Among the 15 women undergoing an isolated allograft PVS procedure, mean operative time was 36.3 minutes (SD 8.3) (Table 3).

Twenty-two women (91.7%) passed their trial of void within 24 hours and one (4.2%) was discharged with an indwelling urinary catheter. This participant subsequently underwent surgical exploration on postoperative day 17 for persistent voiding difficulty; the sling and suspension sutures were found to be loose, and no sling loosening was required. She passed a trial of void the following day and subsequent transperineal ultrasonography demonstrated a sling-pubis gap of 13mm on Valsalva.

During follow-up, graft exposure occurred in three women (12.5%). Of the three graft exposures, one (2mm exposure) resolved with conservative antibiotic treatment, one underwent partial graft excision and vaginal closure, and one associated with significant graft exposure with infection required complete explantation at 6 weeks. The participant who underwent graft explantation was subsequently lost to follow-up.

Autologous sling comparison

Six isolated autologous rectus fascial PVS procedures performed during the same time frame were available for comparison with 15 isolated allograft procedures. Mean operative time was 36.3 minutes (SD 8.3) for allograft sling surgery compared with 60.0 minutes (SD 7.0) for autologous sling surgery, representing a mean difference of 23.7 minutes (95% CI 15.8–31.5; $p<0.001$). Median length of hospital stay was 1 day (range 1–2) following allograft sling surgery compared with 3 days (range 2–4)

following autologous sling surgery ($p<0.001$). Mean BMI was similar between the allograft and autologous groups (29.2 [SD 6.5] versus 28.0 [SD 5.8] kg/m², respectively).

Discussion

In this prospective cohort of women undergoing $SCCO_2$-processed cadaveric fascia lata PVS surgery, there was significant improvement in patient-reported continence outcomes at 12 months. Median ICIQ-UI SF score improved by 11 points, with 17/18 women (94.4%) achieving the published ≥5-point minimum important difference; 72.2% reported being "very much better" on PGI-I, and subjective SUI cure and improvement were reported by 66.7% and 94.4%, respectively. These efficacy findings were accompanied by graft-related morbidity: graft exposure occurred in 3/24 women (12.5%), two required graft revision of whom one required complete graft explantation.

The early efficacy observed in this cohort is broadly consistent with favourable patient-reported outcomes described in autologous fascial PVS. Long-term autologous fascial sling series have reported durable cure/improvement in more than 90% of women, including complex and previously operated populations [3]. Wright et al. found similar short-term outcomes between allograft and autograft slings [20]. However, outcomes with cadaveric fascia have been inconsistent. Carbone et al. reported recurrent moderate-to-severe SUI in 37.6% of women and found fragmented, attenuated or absent graft material at reoperation [21]. Another study demonstrated recurrent SUI in 41.7% of allograft recipients compared with none receiving autologous fascia despite similar subjective continence outcome [15]. These historical findings emphasise that outcomes from one allograft preparation cannot necessarily be extrapolated to another, particularly where processing methods differ. The favourable 12-month outcomes observed with $SCCO_2$-processed fascia lata are therefore encouraging, however require longer follow-up.

In the SISTEr trial, two sling exposures were reported among 326 women undergoing autologous rectus fascial sling, alongside other vaginal and abdominal wound complications [22]. At 24 months following retropubic MUS, the TOMUS trial demonstrated mesh exposure occurred in 4.4% of women and 2.7% following transobturator MUS, while contemporary reviews estimate vaginal mesh exposure after MUS at approximately 2% [23, 24]. Comparatively, the 12.5% rate of graft exposure was high in our study, with 2/24 participants requiring graft revision surgery. A possible theory is that concomitant excision of the vaginal portion of the TOT was performed in one participant, and the larger vaginal incision may have contributed to the graft vaginal exposure. However, this was not the case in the participant requiring graft explantation.

A potential practical advantage of the allograft technique is avoidance of fascial harvest. In our single-surgeon comparison, isolated allograft procedures were a mean 23.7 minutes shorter than autologous rectus fascial sling procedures, and median hospital stay was 1 versus 3 days, respectively. Additional benefits of the allograft technique include reduced donor-site morbidity and convalescence; British Society of Urogynaecology patient guidance for autologous fascial sling surgery advises return to light work at approximately 6 weeks and to more physically demanding work at around 12 weeks [25]. This prolonged recovery has potential indirect economic implications through time away from employment and normal activities.

Strengths of this study include its prospective design, use of validated patient-reported outcome measures, predefined follow-up intervals, and consistent surgical technique. The study also included women with previous continence surgery and concomitant pelvic procedures, reflecting a clinically heterogeneous population. However, the small sample size, single-centre and single-surgeon design limit precision and generalisability. Follow-up was short-term and performed within the treating clinical service which meant these outcomes were potentially subjected to bias, and outcomes were predominantly patient-reported, without a standardised objective continence assessment at 12 months. Finally, 12-month follow-up is insufficient to establish graft durability, particularly given historical concerns regarding late failure of cadaveric fascia.

These findings suggest that $SCCO_2$-processed cadaveric fascia lata may provide meaningful continence improvement while avoiding autologous fascial harvest, with potential advantages in operative time and hospital stay. Larger comparative multicentre studies with longer follow-up, standardised objective and patient-reported outcomes, and direct comparative assessment of graft-related morbidity and durability are required before its role in routine continence surgery can be defined.

Conclusion

$SCCO_2$-processed cadaveric fascia lata PVS appears to be associated with significant improvement in patient-reported continence outcomes at 12 months. Larger comparative studies with longer follow-up are required before the role of this graft in routine SUI surgery can be established.

Reference

1. Kim A, Kim S, Kim HG (2020) Current Overview of Surgical Options for Female Stress Urinary Incontinence. Int Neurourol J 24:222-30. https://doi.org/10.5213/inj.2040052.026
2. Australia. Parliament. Senate. Community Affairs References C. Number of women in Australia who have had transvaginal mesh implants and related matters. Canberra: Commonwealth of Australia; 2018.
3. Chaikin DC, Rosenthal J, Blaivas JG (1998) Pubovaginal fascial sling for all types of stress urinary incontinence: long-term analysis. J Urol 160:1312-6.
4. Cross CA, Cespedes RD, McGuire EJ (1998) Our experience with pubovaginal slings in patients with stress urinary incontinence. J Urol 159:1195-8.
5. Aldridge AH (1942) Transplantation of fascia for relief of urinary stress incontinence. American Journal of Obstetrics and Gynecology 44:398-411. https://doi.org/10.1016/S0002-9378(42)90477-0
6. Flynn BJ, Yap WT (2002) Pubovaginal sling using allograft fascia lata versus autograft fascia for all types of stress urinary incontinence: 2-year minimum followup. J Urol 167:608-12. https://doi.org/10.1016/s0022-5347(01)69095-5
7. Larouche M, Zi Zheng MM, Yang EC, Konci R, Belzile E, Gill PK, et al. (2024) Synthetic vs nonsynthetic slings for female stress and mixed urinary incontinence: a systematic review and meta-analysis. Am J Obstet Gynecol 231:166-86.e8. https://doi.org/10.1016/j.ajog.2024.02.306
8. Richter HE, Burgio KL, Holley RL, Goode PS, Locher JL, Wright KC, et al. (2003) Cadaveric fascia lata sling for stress urinary incontinence: a prospective quality-of-life analysis. Am J Obstet Gynecol 189:1590-5; discussion 5-6. https://doi.org/10.1016/j.ajog.2003.08.016
9. Walsh IK, Nambirajan T, Donellan SM, Mahendra V, Stone AR (2002) Cadaveric fascia lata pubovaginal slings: early results on safety, efficacy and patient satisfaction. BJU Int 90:415-9. https://doi.org/10.1046/j.1464-410x.2002.02913.x
10. Elliott DS, Boone TB (2000) Is fascia lata allograft material trustworthy for pubovaginal sling repair? Urology 56:772-6. https://doi.org/10.1016/s0090-4295(00)00825-6
11. Huang YH, Lin AT, Chen KK, Pan CC, Chang LS (2001) High failure rate using allograft fascia lata in pubovaginal sling surgery for female stress urinary incontinence. Urology 58:943-6. https://doi.org/10.1016/s0090-4295(01)01430-3
12. FitzGerald MP, Mollenhauer J, Bitterman P, Brubaker L (1999) Functional failure of fascia lata allografts. Am J Obstet Gynecol 181:1339-44; discussion 44-6. https://doi.org/10.1016/s0002-9378(99)70374-1
13. Soergel TM, Shott S, Heit M (2001) Poor surgical outcomes after fascia lata allograft slings. Int Urogynecol J Pelvic Floor Dysfunct 12:247-53. https://doi.org/10.1007/s001920170047
14. Hinton R, Jinnah RH, Johnson C, Warden K, Clarke HJ (1992) A biomechanical analysis of solvent-dehydrated and freeze-dried human fascia lata allografts. A preliminary report. Am J Sports Med 20:607-12. https://doi.org/10.1177/036354659202000521
15. McBride AW, Ellerkmann RM, Bent AE, Melick CF (2005) Comparison of long-term outcomes of autologous fascia lata slings with Suspend Tutoplast fascia lata allograft slings for stress incontinence. Am J Obstet Gynecol 192:1677-81. https://doi.org/10.1016/j.ajog.2005.01.078
16. Bernhardt A, Wehrl M, Paul B, Hochmuth T, Schumacher M, Schütz K, et al. (2015) Improved Sterilization of Sensitive Biomaterials with Supercritical Carbon Dioxide at Low Temperature. PLoS One 10:e0129205. https://doi.org/10.1371/journal.pone.0129205

17. Irani M, Lovric V, Walsh WR (2018) Effects of supercritical fluid CO(2) and 25 kGy gamma irradiation on the initial mechanical properties and histological appearance of tendon allograft. Cell Tissue Bank 19:603-12. https://doi.org/10.1007/s10561-018-9709-y
18. Farey JE, Salmon LJ, Roe JP, Russell V, Sundaraj K, Pinczewski LA (2024) Outcomes of ACL Reconstruction Utilizing Supercritical CO(2)-Sterilized Allografts. Orthop J Sports Med 12:23259671241254115. https://doi.org/10.1177/23259671241254115
19. Sirls LT, Tennstedt S, Brubaker L, Kim HY, Nygaard I, Rahn DD, et al. (2015) The minimum important difference for the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form in women with stress urinary incontinence. Neurourol Urodyn 34:183-7. https://doi.org/10.1002/nau.22533
20. Wright EJ, Iselin CE, Carr LK, Webster GD (1998) Pubovaginal sling using cadaveric allograft fascia for the treatment of intrinsic sphincter deficiency. J Urol 160:759-62. https://doi.org/10.1016/s0022-5347(01)62779-4
21. Carbone JM, Kavaler E, Hu JC, Raz S (2001) Pubovaginal sling using cadaveric fascia and bone anchors: disappointing early results. J Urol 165:1605-11.
22. Albo ME, Richter HE, Brubaker L, Norton P, Kraus SR, Zimmern PE, et al. (2007) Burch colposuspension versus fascial sling to reduce urinary stress incontinence. N Engl J Med 356:2143-55. https://doi.org/10.1056/NEJMoa070416
23. Albo ME, Litman HJ, Richter HE, Lemack GE, Sirls LT, Chai TC, et al. (2012) Treatment success of retropubic and transobturator mid urethral slings at 24 months. J Urol 188:2281-7. https://doi.org/10.1016/j.juro.2012.07.103
24. Welk B, Dmochowski R, McCarthy K, Keck J, Mourad S, Hashim H (2024) Complications associated with the use of mesh to treat female urinary incontinence and pelvic organ prolapse. Continence 12:101713. https://doi.org/10.1016/j.cont.2024.101713
25. British Society of Urogynaecology. Autologous fascial sling. United Kingdom: British Society of Urogynaecology; 2018 2018/03.

Table 1 Baseline characteristics

Baseline characteristics	
Age, years, mean (SD)	53.6 (12.2)
BMI, kg/m^2, median (IQR)	27.5 (26.2-30.1)
Parity, median (range)	2 (1-5)
Previous surgery	
Previous abdominal surgery, n (%)	11 (45.8%)
Previous POP surgery, n (%)	4 (16.7%)
Previous SUI surgery, n (%)	8 (33.3%)
Previous hysterectomy, n (%)	7 (29.2%)
Urodynamic findings	
Detrusor overactivity, n (%)	3 (12.5%)
Urodynamic stress incontinence, n (%)	23 (95.8%)
Maximum flow rate, mL/s, mean (SD)	29.0 (12.8)
PVR > 150 mL, n (%)	0 (0.0%)
MUCP, cmH_2O, mean (SD)	68.6 (26.4)
Baseline ICIQ-UI SF, median (IQR)	15.5 (14–16)
Previous anti-incontinence procedures	
Retropubic MUS insertion; subsequent sling division; later excision of vaginal mesh component	
Retropubic MUS; mesh excision and urethrovaginal fistula repair; subsequent complete retropubic mesh excision with labial fat flap; urethral bulking	
Retropubic MUS; total sling excision; urethral bulking	
Transobturator MUS; total sling excision; urethral bulking; autologous rectus fascial sling; repeat urethral bulking	
Transobturator MUS (2 participants)	
Retropubic MUS	
Retropubic MUS; partial mesh excision; urethral bulking	

BMI, body mass index; POP, pelvic organ prolapse; SUI, stress urinary incontinence; PVR, post-void residual; MUCP, maximum urethral closure pressure.

Table 2: Patient-reported outcomes following allograft fascial pubovaginal sling surgery

Outcome	Baseline	6 weeks	6 months	12 months
ICIQ-UI SF				
Available ICIQ data, n	24	24	20	18
ICIQ-UI SF, median (IQR)	15.5 (14–16)	0 (0–1.5)	3.5 (0–7.5)	4 (0–6)
Improvement from baseline, median (IQR)	—	15 (9.5–16)	11 (8.3–14.3)	11 (9–15)
Wilcoxon signed-rank p-value vs baseline	—	<0.001	<0.001	<0.001
PGI-I				
Available PGI-I data, n	—	23	20	18
Very much better, n (%)	—	20 (87.0%)	14 (70.0%)	13 (72.2%)
Much better, n (%)	—	2 (8.7%)	4 (20.0%)	3 (16.7%)
A little better, n (%)	—	1 (4.3%)	2 (10.0%)	1 (5.6%)
No change, n (%)	—	0 (0.0%)	0 (0.0%)	1 (5.6%)
Worse, n (%)	—	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subjective SUI outcomes				
Subjective cure, n/N (%)	—	21/22 (95.5%)	14/20 (70%)	12/18 (66.7%)
Subjective improvement, n/N (%)	—	22/22 (100%)	19/20 (95%)	17/18 (94.4%)

Table 3: Perioperative outcomes.

Characteristic	Overall (N = 24)
Perioperative outcomes	
Concomitant surgery, n (%)	9 (37.5%)
Discharged with indwelling urinary catheter, n (%)	1 (4.2%)
Operative time for sling-only procedure, min, mean (SD)	36.3 (8.3)
Postoperative safety outcomes	
Urinary tract infection, n (%)	2 (8.3%)
Blood transfusion, n (%)	0 (0.0%)
Abdominal surgical-site infection (minor), n (%)	1 (4.2%)
DVT/PE, n (%)	0 (0.0%)
Unplanned re-presentation within 30 days, n (%)	3 (12.5%)
Graft-related outcomes during available follow-up	
Graft exposure, n (%)	3 (12.5%)
Graft revision, n (%)	2 (8.3%)
Graft explantation, n (%)	1 (4.2%)

Operative time was calculated only for women undergoing sling insertion without a concomitant surgical procedure (n=15). DVT, deep vein thrombosis; PE, pulmonary embolism. Graft revision includes partial excision for graft exposure and surgical exploration for voiding difficulty.

Statements and Declarations

Funding
No funding was received for conducting this study.

Competing interest
Judith Goh has previously delivered unpaid educational presentations for Samson Medical Technologies, Australia.
The remaining authors declare no competing interests.

Ethics approval
This study was approved by the institutional Human Research Ethics Committee (HREC 2024/ETH/0064)

Consent to participate
Written informed consent was obtained from all participants included in the prospective study.

Data availability
The datasets generated and analysed during this study are not publicly available due to participant privacy and ethical restrictions. De-identified data may be made available upon reasonable request, subject to institutional approval.

Author contributions
Hnin Yee Kyaw: Data collection or management, Data analysis, Manuscript writing/editing.
Hannah Krause: Protocol/project development, Manuscript writing/editing.
Yu Hwee Tan: Protocol/project development, Manuscript writing/editing.
Vivien Wong: Manuscript writing/editing.
Judith Goh: Protocol/project development, Manuscript writing/editing, Other (Surgical procedures).