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ORIGINAL ARTICLE

Outcomes following sacrocolpopexy using ultralight and lightweight mesh

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Abstract

Introduction and hypothesis This study reports the long-term anatomic and subjective outcomes following sacrocolpopexy based on mesh weight and provides device-specific data.

Methods This cohort study compared ultra-lightweight (≤ 20 g/m^2) with lightweight mesh (≥ 25 g/m^2). The primary outcome was composite failure defined as at least one of $\geq$ stage 2 apical prolapse, anterior or posterior vaginal wall beyond hymen, complaint of bulge or retreatment. Effect measure estimates were calculated as the incidence rate ratio of composite failure comparing the use of ultra-light with lightweight mesh. Crude and adjusted incidence rate ratios (IRRs) were obtained using uni- and multivariable Poisson regression models.

Results Of 358 women who met inclusion criteria, 220 (61%) agreed to attend for review; 95 (43%) had ultra-lightweight mesh and 125 (57%) had lightweight mesh including Upsylon^{TM}. Median follow-up for ultra-light and lightweight mesh was 36 (IQR 22–42) and 63 (IQR 48–87) months, respectively ($p < 0.001$). Accounting for differences in follow-up time, there was no significant difference in composite failure between ultra-light and lightweight mesh groups (IRR 1.47, 95% CI 0.83–2.52, $p = 0.15$). This persisted after adjustment for age, body mass index, parity, smoking and presence of advanced prolapse prior to surgery (IRR 1.52, 95% CI 0.94–2.47, $p = 0.087$). Mesh exposure for both groups was mostly asymptomatic, and the rate was 7% for the ultra-light group and 8% in the lightweight group. Overall, repeat surgery for recurrent apical prolapse and mesh exposure occurred in 4% and 2%, respectively.

Conclusions Ultra-lightweight mesh appears to have similar incidence rate of failure compared to lightweight mesh. Upsylon^{TM} mesh has a similar low rate of recurrent apical prolapse and mesh exposure.

Keywords Prolapse · Sacrocolpopexy · Mesh weight · Long-term outcomes

Introduction

The abdominal sacrocolpopexy procedure was developed to manage post-hysterectomy prolapse as an alternative to the vaginal approach and to manage failed vaginal surgery. This approach employs the retroperitoneal interposition of a suspensory prosthesis (synthetic, autologous, allograft or xenograft) between the vaginal apex and the sacrum. Abdominal sacrocolpopexy was originally described by Huguier in 1957 and later by Lane in 1962 [1, 2]. Indications for sacrocolpopexy (SCP) include apical or multicompartment prolapse. Although SCP is an extensively studied and highly effective procedure [3], significant heterogeneity exists in surgical technique [4]. Outcomes could be influenced by intraoperative choices including the mesh weight, pore size and material used. The stiffness of a device directly impacts the remodelling response following implantation [5] and mesh stiffness is highly correlated with mesh weight, pore size and porosity [6]. Human and animal studies have shown that heavier mesh may be associated with chronic inflammation and poor remodelling of the vagina contributing to

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mesh complications [7]. This led to development of lighter weight mesh, in an attempt to minimise these complications. Lighter weight meshes with higher porosity and lower stiffness achieve more favourable host responses and better tissue in-growth compared with heavier weight, reducing mesh complications.

However, anatomical outcomes need to be assessed when comparing lighter versus heavier mesh. In 2018, Askew et al. compared the anatomic failure rates between ultralight mesh ($\leq 20 g/m^2$) and heavy mesh ($\leq 35 g/m^2$). Ultralightweight mesh was twice as likely to fail within three years compared to heavy weight mesh ($p = 0.03$) though it was associated with a lower mesh exposure rate (1.6% vs. 6.0%, $p = 0.01$) [8].

Complications reported by patients for transvaginal mesh repair for pelvic organ prolapse (POP) have led to concerns regarding the use of mesh for SCP. The Therapeutic Goods Administration (TGA) and European regulatory bodies have since classified all mesh as type 3, requiring device-specific data for the specific surgical indication. Historically, mesh SCP was performed using hernia polypropylene mesh, which has become lighter in the last 2 decades. As a result of these regulatory requirements, some parent companies have made the decision to abandon the approval process in some countries or states rendering their product not for use in urogynaecological procedures. This has left some countries, like Australia, with no currently approved mesh for SCP, despite the proven efficacy and safety of the procedure.

The US Food and Drug Administration (FDA) found that the safety and effectiveness of abdominal placement of surgical mesh for apical POP repair was well established and recommended reclassification to class III for SCP mesh [9]. In contrast, transvaginal mesh was discontinued.

This study aims to assess the long-term anatomic and subjective outcomes following SCP based on mesh weight and to provide device-specific cohort data as requested by regulatory bodies.

Methods

This cohort study derived from a single surgeon series in two private hospitals and a public tertiary hospital pelvic floor unit in Melbourne, Australia. The latter included a number of urogynaecology subspecialists and trainees. The study included all women who underwent SCP for symptomatic POP. Patients were identified using electronic search of institutional and medical practice databases. Medical records were available for patients who underwent SCP between January 2000 and December 2019 for the tertiary public hospital and between January 2006 and December 2019 for the private series. Pre-, intra- and postoperative data were collected. Preoperative data included demographics, medical and surgical history and preoperative stage of prolapse. Intraoperative data recorded concurrent procedures, type of mesh and intraoperative complications. Postoperative data included postoperative complications, follow-up duration and reoperation for prolapse recurrence, stress incontinence or complications. All identified patients were invited to participate in the study for review; this clinical evaluation was performed by an independent assessor who did not perform the index surgery.

For patients who were unable to be contacted, their last follow-up data were obtained from the medical records and their outcomes are reported separately.

Ethics approval was obtained from the local Ethics Committee (RES-19-0000330A).

The primary outcome was composite surgical failure following SCP using ultra-lightweight mesh ($\leq 20 g/m^2$, Restorelle® Y) compared with lightweight mesh ($\geq 25 g/m^2$, Upsylon™, Ultrapro™, Intepro™, Gynemesh®, Vypro®). Composite failure was defined as at least one of: ≥ stage 2 apical prolapse, anterior or posterior vaginal wall beyond hymen, complaint of bulge on questionnaire or retreatment (including pessary). Staging for POP was assessed using the Pelvic Organ Prolapse Quantification (POP-Q) system [10]. A response of 'daily' or 'frequently' to the question in the Australian Pelvic Floor Questionnaire (APFQ) prolapse domain 'Do you have a sensation of tissue protrusion/lump/bulging in your vagina?' was regarded as a complaint of bulge. Secondary outcomes included the Patient Global Impression of Improvement (PGI-I), subjective outcomes using APFQ and complications.

The PGI-I is a validated seven-point questionnaire on a scale from 1 = very much better to 7 = very much worse [11]. Functional outcomes were assessed using the APFQ, a validated, reliable tool to assess symptoms, severity and quality of life impact due to pelvic floor dysfunction [12]. Complications are reported as per the Clavien-Dindo surgical complication grading system and the IUGA/ICS joint terminology for complications related to mesh [13, 14].

Finally, Upsylon™ mesh (the only mesh under consideration by the TGA for use at SCP at time of writing) was also compared with non-Upsylon™ mesh for primary and secondary outcomes.

Statistical analysis

Categorical variables were expressed as number and percentage and compared between the groups with the chi-squared test or the Fisher's exact test, as appropriate. Normally distributed continuous variables were reported as mean and standard deviation and compared between the groups with independent-samples *t*-tests. Non-normally distributed variables and ordinal variables were expressed as median and interquartile range and compared between

the groups with the Wilcoxon rank-sum test. Normality was assessed by inspection of histograms. To account for different lengths of follow-up, we calculated the incidence rate of the composite failure outcome per person per month of follow-up in the two groups. Effect measure estimates were calculated as the incidence rate ratio (IRR) of composite failure comparing the use of ultra-light with the lightweight mesh group. Crude and adjusted incidence rate ratios (controlling for age and body mass index at follow-up, parity, smoking and the presence of advanced prolapse prior to surgery), along with the respective 95% confidence intervals (CI), were obtained using univariable and multivariable generalised linear models with a Poisson family and a log link function accounting for follow-up time with robust estimation of the variance.

Results

Three hundred fifty-eight patients were eligible for inclusion. Two hundred twenty (61%) participants attended for review with questionnaire and POP-Q examination. The remaining 138 (39%) were contacted but were unavailable for review for various reasons including being unwell from other health problems, having moved interstate, being deceased, declining examination, not being interested in ongoing follow-up or not wanting to attend because of COVID-19 concerns. Their outcomes are reported separately based on review of the medical record.

During the study period, the type of mesh used varied depending on surgeon preference, availability and TGA approval. Table 1 displays the type of mesh used, baseline demographic characteristics, and preoperative anatomic and subjective data using POP-Q and APFQ. The groups are similar in terms of stage of POP, body mass index (BMI), previous prolapse or incontinence surgery, parity and mode of delivery. Women undergoing SCP using ultra-light mesh were older and had better bladder and prolapse domain scores on APFQ. There were no differences between the groups for concomitant hysterectomy, vaginal repair and stress urinary incontinence procedures and for being more likely to have a robotic procedure (Table 1).

Within the ultra-lightweight group, 119 (88%) had sacrocolpopexy, 10 (7%) sacrocervicopexy and 7 (5%) sacrohysteropexy.

In the lightweight group, 188 (85%) underwent sacrocolpopexy, 10 (4%) sacrocervicopexy and 24 (11%) sacrohysteropexy. Intraoperative and immediate postoperative data (≤ 6 weeks) are described in Supplementary Table 2, classified as per Clavien-Dindo criteria. Overall, there was a 4% Clavien-Dindo Grade III and above complication rate.

Outcomes

Of 220 patients reviewed, 95 (43%) had ultra-lightweight mesh and 125 (57%) lightweight mesh. The median follow-up for ultra-light and lightweight mesh was 36 (IQR 22–42) and 63 (IQR 48–87) months, respectively ($p \leq 0.001$). There was no statistical difference in the composite failure between the groups (23% vs. 33%, $p = 0.11$) (Table 2). Total length of follow-up for ultra-light mesh was 3249 and 8884 person-months for lightweight mesh. Accounting for differences in follow-up time, there was no difference between the incidence rates of composite failure between the ultra-light and lightweight mesh groups (6.7 per 1000 persons per month in the ultra-light mesh group, 4.6 per 1000 persons per month in the lightweight mesh group: IRR 1.47, 95% CI 0.83–2.52, $p = 0.154$). After adjusting for age and BMI at follow-up, parity, smoking, the presence of advanced prolapse prior to surgery and route of surgery, there was no difference in rates between groups (aIRR 1.52, 95% CI 0.94–2.47, $p = 0.087$) (Table 3). At review, of the 220 women which included those who had repeat surgery for recurrence, only 3 (1.5%) had apical recurrence of stage ≥ 2 or more, 1 was asymptomatic, and the other 2 declined any treatment at the time of review.

Eighty-five (90.4%) in the ultra-light group and 94 (64%) in the lightweight mesh group reported an improvement in outcome of 'very much better' or 'much better' ($p = 0.002$) in PGI-I. The difference remained significant after accounting for difference in follow-up time and route of surgery (aIRR 2.2, 95% CI 1.65 to 3.05, $p < 0.001$) . There was no significant difference in the PGI-I based on route of surgery. In terms of functional outcomes, there was significant improvement in all domains of the APFQ (Table 2). There was a relative improvement in the prolapse domain of 100%, the sexual domain up to 50 %, the bladder domain of 33% and the bowel domain of 14 % but no difference was seen between groups. Figure 1 illustrates sexual function for the groups pre- and post-surgery for participants that completed the sexual function domain of the APFQ. Question 39 of the APFQ assesses for dyspareunia: '*Do you experience pain with sexual intercourse*' and the responses can vary from 0–4 (never to always).

From index surgery to follow-up, within the ultra-light group, five (5%) had surgical treatment for recurrent POP; two required apical suspension with sacrospinous fixation and concomitant posterior repair. Sixteen (13%) had repeat prolapse surgery in the lightweight mesh group; eight required apical suspension. Five patients in the ultra-light group underwent further incontinence surgery and seven in the lightweight group. There was no statistically significant difference between the groups for recurrent POP and SUI surgery (Table 2).

In terms of mesh complication, seven (7%) cases of mesh exposure were noted in the ultra-light group; one (1%) was

Table 1 Baseline demographics, pre- and intraoperative data

	Ultra-light mesh^{++} n = 136	Lightweight mesh^{+} n = 222	*P*-value
Age in years, median (IQR)	65.7 (56.7–70.1)	63.0 (53.5–69.1)	**0.04**
BMI in kg/m^2, median (IQR)	25.7 (22.6–28.6)	26.6 (23.3–30.1)	0.08
Menopause, *n* (%)	105/120 (87.5)	168/202 (83.2)	0.30
Sexually active, *n* (%)*	61/115 (53.0)	85/157 (38.3)	0.86
Parity, median (IQR)	2 (2–3)	3 (2–3)	0.61
Previous vaginal deliveries, median (IQR)	2 (2–3)	2 (2–3)	0.61
Previous hysterectomy, *n* (%)	111 (81.6)	174 (78.4)	0.46
Previous prolapse operation, *n* (%)	55/128 (43.0)	71/194 (36.6)	0.25
Previous urinary incontinence operation, *n* (%)	15 (11.0)	21/220 (10.0)	0.65
Point Ba, median (IQR)	2 (0–3)	1 (0–3)	0.56
Point C, median (IQR)	0 (–2–2)	0 (–2–2)	0.18
Point Bp, median (IQR)	0 (–1–1)	0 (–1–2)	0.75
Stage ≥ 3 POP, *n* (%)**	95 (69.9)	146 (65.8)	0.42
APFQ*			
Bladder domain, median (IQR)	2.9 (1.3–3.8)	3.1 (1.8–4.7)	**0.05**
Bowel domain, median (IQR)	2.1 (1.3–3.5)	2.4 (1.2–3.5)	0.78
Prolapse domain, median (IQR)	5.3 (4.0–6.7)	6.0 (4.7–7.3)	**0.05**
Sexual function domain, median (IQR)	1.9 (1.0–3.3)	2.4 (1.0–3.8)	0.55
Route of surgery, *n* (%)			
Open	0	6 (2.7)	0.09
Laparoscopic	82 (60.3)	181 (81.5)	**< 0.001**
Robotic	54 (39.7)	35 (15.8)	**< 0.001**
Concomitant hysterectomy, *n* (%) Subtotal; total	12 (8.8) 8; 4	24 (10.8) 18; 6	0.54
Concomitant vaginal repair, *n* (%)	58 (42.7)	91 (41.0)	0.75
Concomitant SUI surgery, *n* (%)	19 (14.0)	31 (14.0)	1.00
Conversion to laparotomy, *n* (%)	2 (1.5)	10 (4.5)	0.12
Intraoperative complications, *n* (%)	5 (3.7)	15 (6.8)	0.22

BMI body mass index, *IQR* interquartile range, *POP* pelvic organ prolapse, *APFQ* Australian Pelvic Floor Questionnaire, *SUI* stress urinary incontinence

*Preoperative APFQ completed by 280 participants

**Any compartment prolapse stage ≥ 3

$^{+}$Ultrapro^{TM} 103 (46.0%), Upsylon^{TM} 91 (41.0%), Gynemesh^{TM} 10 (4.5%), Vypro^{TM} 9 (4.0%), Intepro^{TM} 6 (3.0%), Biodesign^{TM} 2 (1%) and Atrium^{TM} 1 (0.5%)

$^{++}$Restorelle® Y-136 (100.0%)

managed with surgical excision. Within the lightweight group, ten (8%) cases of mesh exposure occurred; four (3%) had surgical excision. The remainder were treated conservatively. There was no statistical difference between the groups for exposure or surgery for mesh exposure/pain (Table 2).

Outcomes for patients who declined review

Review of the medical record was conducted for 41 in the ultra-light and 97 in the lightweight group who were unable to be reviewed. The median follow-up was longer in the lightweight mesh group compared to the ultra-light group: 10 (IQR 6–24) and 6 (IQR 2–8) months, respectively ($p = 0.006$). One patient had an apical recurrence in the lightweight mesh group (1/85, 1.2%) and none in the ultra-light group (0/33, 0%; $p = 0.53$). Two patients in the lightweight group (2/85, 2.3%) and none in the ultra-light group (0/33, 0%; $p = 1.0$) had repeat apical surgery.

Six in the lightweight group (6/76, 8%) had mesh exposure compared to one in the ultralight group (1/36, 2.7%; $p \leq 0.0001$). Exposure in the ultralight group was managed with topical oestrogen while two (2.6 %; $\leq = 1$) in the lightweight group needed surgical excision vaginally.

Table 2 Outcomes of respondents at follow-up, ultra-light versus lightweight mesh

	Ultra-light mesh $n = 95$	Lightweight mesh $n = 125$	*P*-value
Composite failure*, *n* (%)	22/95 (23.2)	41/125 (32.8)	0.11
Bulge on APFQ	11 (11.6)	22 (17.6)	0.21
Retreatment	7 (7.4)	16 (12.8)	0.19
Apical ≥ stage 2	1 (1.1)	2 (1.6)	0.72
Ant > 0	5 (5.3)	14 (11.2)	0.12
Post > 0	1 (1.1)	4 (3.2)	0.29
Follow-up in months, median (IQR)	36 (22–42)	63 (48–87)	**< 0.001**
Age in years, median (IQR)	68.8 (62.1–78)	68.1 (57–74.1)	0.89
BMI in kg/m^2, median (IQR)	25 (22.3–28.5)	26.5 (23.6–29.7)	**0.02**
Sexually active *n* (%)	41/92 (44.6)	66/125 (52.8)	0.231
Point Ba, median (IQR)	–2 (–2—0.5)	–1 (–2–0)	**0.05**
Point C, median (IQR)	–7 (–7—6)	–6 (–7—5)	**0.01**
Point Bp, median (IQR)	–2 (–3—2)	–2 (-2—1)	**< 0.01**
Any compartment stage 2 POP, *n* (%)	53 (39)	83 (37.4)	0.77
Stage ≥ 3 POP	0 (0)	4 (1.8)	0.12
APFQ			
Bladder domain, median (IQR)	1.6 (0.9–2.7)	1.7 (0.9–3.1)	0.22
Relative improvement (preop vs. postop %)	33.3 (–16.7–56.3)	25 (–7.1 – 68.4)	0.83
Bowel domain, median (IQR)	2.1 (1.2–3.5)	2.1 (0.9 – 3.2)	0.36
Relative Improvement (preop vs. postop)	14.3 (–33–38.5)	12.5 (–20–50)	0.54
Prolapse domain, median (IQR)	0 (0–1.3)	0 (0–2)	0.11
Relative improvement (preop vs. postop)	100 (71–100)	100 (61.5–100)	0.21
Sexual function domain	1 (0.5–2.4)	1.9 (0.5–3.3)	0.11
Relative improvement (preop vs. postop)	50 (–29.2–77.5)	33.3 (–11.1–75)	0.80
Mesh exposure, *n* (%)	7/95 (7.4)	10/125 (8.0)	0.86
Surgery for mesh exposure	1/95 (1)	4/125 (3.2)	0.39
rPOP operation	5/95 (5.3)	16/125 (12.8)	0.10
Recurrent apical surgery	2/95 (2.0)	8/125 (6.4)	0.19
SUI operation	5/136 (3.7)	7/222 (3.2)	0.77

BMI body mass index, *IQR* interquartile range, *POP* pelvic organ prolapse, *APFQ* Australian Pelvic Floor Questionnaire, *SUI* stress urinary incontinence, *rPOP* recurrent pelvic organ prolapse

*Composite measured in 220 women who attended in-person follow-up visit defined as at least one of ≥ stage 2 apical prolapse, anterior or posterior wall beyond hymen, complaining of a bulge on questionnaire or retreatment

Table 3 Adjusted incidence rate ratios comparing the ultra-light mesh group with lightweight mesh group

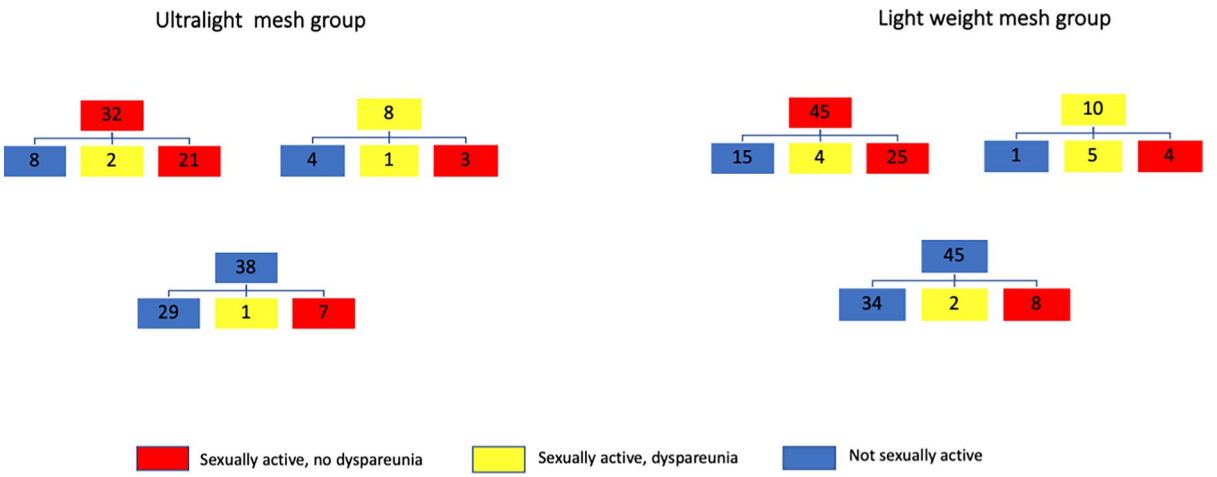
	Adjusted IRR (95% CI)	*P* value
Composite failure*, *n* (%)	1.53 (0.94–2.47)	0.08
Bulge on APFQ	1.23 (0.57–2.65)	0.59
Retreatment	1.72 (0.70–4.22)	0.23
Apical ≥ stage 2	4.22 (0.75–23.88)	0.10
Ant > 0	0.90 (0.32–2.52)	0.84
Post > 0	3.50 (0.16–76.50	0.42

*IRR adjusted for follow-up time and age at follow-up, BMI, parity, smoking and severity of POP prior to surgery

Outcomes for patients with Upsylon™ mesh compared to non-Upsylon™

We performed a subgroup analysis for the 91 (25%) patients who had Upsylon™ mesh SCP and compared outcomes with the remainder of the cohort (non-Upsylon™ group) (Table 4). There were no significant differences in preoperative POP stage, BMI, previous prolapse or incontinence surgery, parity or mode of delivery between the groups (Supplementary table 1).

Composite outcomes at follow-up were available for 67 (74%) in the Upsylon™ group and 153 (57%) in the non-Upsylon™ group. The median follow-up for Upsylon™ and non-Upsylon™ group was 50 (IQR 41–60) and 44 (IQR 30–80) months, respectively ($p = 0.88$). There was no



Dyspareunia defined as a response of 'frequently' or 'always' to the APFQ question 'Do you feel pain with sexual intercourse'. No dyspareunia was a response of 'never' or 'occasional' to the same question. One participant did not complete sexual function domain at follow-up.

Fig. 1. Sexual function pre-surgery and at follow-up for ultra-light and lightweight mesh group. Dyspareunia defined as a response of 'frequently' or 'always' to the APFQ question 'Do you feel pain with sexual intercourse'. No dyspareunia was a response of 'never' or 'occasional' to the same question. One participant did not complete sexual function domain at follow-up

statistically significant difference in the composite failure between the groups (25% vs. 30%, $p = 0.48$). After adjusting for age and BMI at follow-up, parity, smoking and the presence of advanced prolapse prior to surgery, there was no significant difference in rates between groups (aIRR 0.85, 95% CI 0.51–1.42, $p = 0.54$) (Table 5).

Sixty-eight percent (48/71) in the Upsylon^{TM} group reported to be 'very much better' or 'much better' compared to 87% (131/150) in the non-Upsylon^{TM} ($p \leq 0.001$) group. This difference lost significance after accounting for follow-up time (IRR0.90, 95% CI 0.63–1.26, $p = 0.52$).

At review in the Upsylon^{TM} group there were four (6%) cases of mesh exposure, all < 0.5 cm, asymptomatic and managed with topical estriol. No patient required surgery for mesh exposure. Two patients had repeat surgery for prolapse recurrence: posterior repair at 6 months and posterior repair and sacrospinous fixation at 55 months. One other patient had recurrence which was managed with a pessary.

Discussion

A similar rate of composite failure is observed when using ultra-lightweight mesh compared to lightweight mesh for sacrocolpopexy. Both groups reported improvement in functional outcomes, demonstrated across all domains of the APFQ. No statistically significant difference was observed between lightweight and ultra-lightweight mesh in the incidence of long-term mesh complications and the need for surgery for recurrent prolapse. At a median follow-up of 3–5 years, the overall rate of retreatment for apical failure was 4.5%, and the overall rate of repeat surgery for mesh complication was 2.2%. For Upsylon^{TM}, at a median follow-up of 4 years, the reoperation rate for apical prolapse was 1.5% and there was no repeat surgery for mesh complication.

Our findings are similar to those of Giugale et al., who reported no difference in composite anatomical failure between ultra-lightweight mesh and lightweight mesh after minimally invasive SCP (7.2% vs. 6.6%, $p = 0.68$) [15]. Their primary outcome based on chart review only was a composite of anatomical recurrence defined as any prolapse beyond the hymen or retreatment with surgery or pessary. They also found shorter time to recurrence in the ultra-lightweight group; however, the significance of this is unknown as subjective outcomes were not reported and, overall, there was no difference in prolapse recurrence [15]. Their study found reduced mesh complication and reoperation rates for mesh complication in the ultra-light group compared to the lightweight group (1% vs. 6%, $p < 0.01$, and 0.6% vs. 4%, $p < 0.01$, respectively). We found no significant differences in rates of mesh exposure or reoperation for mesh complication between the groups. Within their study, however, > 50% had a concomitant subtotal hysterectomy (compared with 9% in this study), which is known to be associated with lower mesh exposure rates [16]. In addition, their follow-up

Table 4 Outcomes of respondents at follow-up, Upsylon™ with non-Upsylon™

	Upsylon™ n = 71	Non-Upsylon™ n = 153	*P*-value
Composite failure*, *n* (%)	17/67 (25.4)	46/153 (30.1)	0.47
Bulge on APFQ	11/67 (16.4)	22/153 (14.4)	0.69
Retreatment	3/67 (4.5)	20/153 (13.1)	0.05
Apical ≥ stage 2	0/67	3/153 (2.0)	0.24
Ant > 0	7/67 (10.5)	12/153 (7.8)	0.52
Post > 0	0/67	5/153 (3.3)	0.13
Follow-up in months, median (IQR)	51 (41–60)	44 (30–80)	0.87
Age in years, median (IQR)	64.3 (54.8–69.3)	64.3 (55.9–69.6)	0.99
BMI in kg/m^2, median (IQR)	26.7 (23.4–29.9)	26.1 (22.9–29.4)	0.34
Sexually active, *n* (%)	44/75 (58.7)	101/197 (51.8) wrong	0.30
Point Ba, median (IQR)	–1.5 (–2–0)	-1 (–2–0)	0.80
Point C, median (IQR)	–6 (–7—6)	–7 (–7—6)	0.47
Point Bp, median (IQR)	–2—2—1)	–2—2—1)	0.88
Any compartment stage 2 POP, *n* (%)	40/67 (59.7)	96/153 (62.8)	0.66
Stage ≥ 3 POP	2/67 (3)	2/153 (1.3)	0.39
APFQ			
Bladder domain, median (IQR)	1.8 (1.1–3.3)	1.6 (1.9–2.9)	0.13
Relative improvement (preop vs. postop %)	21 (–9.5–68.4)	33.3 (–5.9–56.3)	0.99
Bowel domain, median (IQR)	2.1 (0.9–3.2)	2.1 (1.2–3.2)	0.65
Relative improvement (preop vs. postop)	27.3 (–8.4–50)	2.9 (–36.4–38.5)	**0.03**
Prolapse domain, median (IQR)	0 (0–2)	0 (0–2)	0.73
Relative improvement (preop vs. postop)	100 (63.7–100)	100 (66.7–100)	0.72
Sexual function domain	1.9 (0.5–3.3)	1.0 (0.5–2.9)	0.38
Relative improvement (preop vs. postop)	50 (0–75.0)	50 (–75–80)	0.65
Mesh exposure, *n* (%)	4/67(6.0)	13/153 (8.5)	0.60
Surgery for ME	0/67 (0)	5/153 (3.2)	
rPOP operation	2/71 (2.8)	19/153 (12.4)	**0.03**
Surgery for apical rec pop	1/67 (1.5)	9/153 (5.8)	0.28
SUI operation	1/71(1.4)	11/153 (7.2)	0.11

*Composite measured in women who attended in-person follow-up visit defined as at least one of ≥ stage 2 apical prolapse, anterior or posterior wall beyond hymen, complaining of a bulge on questionnaire or retreatment

was significantly shorter and based only on review of the medical record.

In our population, the patient-reported global improvement (PGI-I) was higher in the ultra-light group even after adjusting for follow-up time. Route of surgery was not associated with significant improvement in PGI-I, and ultra-lightweight mesh remained associated with significant improvement in PGI-I (IRR 2.2, 95% CI 1.65 to 3.05, $p < 0.001$) after controlling for route of surgery.

Table 5 Adjusted incidence rate ratios comparing the Upsylon™ mesh group with non-Upsylon™

	Adjusted IRR (95% CI)	*P* value
Composite failure*, *n* (%)	0.85 (0.51–1.42)	0.53
Bulge on APFQ	1.12 (0.54–2.34)	0.76
Retreatment	0.32 (0.08–1.32)	0.11
Apical ≥ stage 2	-	0.49
Ant > 0	1.54 (0.65–3.63)	0.32
Post > 0	-	0.20

*IRR adjusted for follow-up time and age at follow-up, BMI, parity, smoking and severity of POP prior to surgery

All POP-Q points were better in the ultra-light group on review. It is difficult to attribute this finding to the mesh weight alone. There are other factors that could potentially contribute to global improvement that have not been assessed. In addition, the ultra-lightweight mesh group had better preoperative bladder and prolapse domain scores on APFQ, which influences better overall subjective improvement scores. Even though PGI-I has been shown to measure objective, subjective and quality of life outcomes, it does not specifically define the reason for failure or success. Pelvic floor dysfunction is a complex condition, and patient dissatisfaction may be due to conditions other than

prolapse. Amongst the patients that attended for follow-up, 20 (9%) reported 'no change' to 'very much worse' on the PGI-I scale. Of these, nine (45%) did not meet the definition of composite failure, indicating other causes of low satisfaction.

Our study found overall higher failure rate for both groups, 23% in the ultra-light and 32% in the lightweight mesh group, compared to other literature. This may be attributed to our use of composite failure as the primary outcome measure over anatomic or subjective only outcomes. In addition, the assessment was not undertaken by the primary surgeons, reducing bias in both subjective and objective findings. Pelvic organ prolapse is dynamic in nature; it has been suggested that the use of composite outcome to define surgical failure may lead to an overestimation of failure [17]. As described by Jelovsek et al., failures can be intermittent and can transition between success and failure over time [17]. Only 7% of our population met both the objective and subjective definitions of failure. Anatomic and subjective findings for POP may not always align [18]. For the patients that attended follow-up, 33 (15%) had a complaint of bulge, but on examination only 24 of these (73%) had prolapse beyond the hymen. Similarly, amongst the 24 (11%) that had prolapse beyond the hymen, 14 (58%) did not complain of bulge.

In all patients there was a statistically significant improvement in all domains of the APFQ following surgery and there was no difference between the ultra-lightweight mesh and lightweight mesh groups. The minimally important difference in the prolapse domain for APFQ after prolapse surgery is reported as 1, which was achieved in both groups [19] with a 100% relative improvement for both groups. The bowel domain had only a 12-14% relative improvement, which may depend on the severity of bowel dysfunction preoperatively, severity of posterior compartment POP, variation in surgical technique in terms of concomitant posterior repair or mesh attachment or the possibility of de novo bowel dysfunction.

Overall, there was a low major intraoperative complication rate. This is in line with other studies that have reported on long-term outcomes after abdominal and laparoscopic sacrocolpopexy [20, 21].

The strengths of this study include a medium-sized cohort with long-term follow-up. These results include subjective patient-reported outcomes using validated questionnaires. Sexual function is often not considered after POP surgery; this has been reported using a validated questionnaire specifically addressing dyspareunia. In addition, participants were examined by an independent assessor at follow-up who was blinded to the type of mesh used. The limitations of this study include shorter follow-up in the ultra-lightweight mesh group as this was a relatively newer device. However, this has been considered when reporting outcomes. There was difficulty recruiting participants willing to attend in person during the COVID-19 pandemic and outcomes based only on chart review have been reported for this cohort. Other limitations include the cohort representing a mixture of open, laparoscopic and robotic procedures. The number of open procedures is too small to comment on; our results mainly apply to laparoscopic and robotic procedures and therefore generalisability may not be possible.

Although a randomised controlled trial has reported that the route (laparoscopic versus robotic) of surgery does not affect outcomes [22], a recent systematic review of surgical management of apical prolapse reported that minimally invasive SCP had less overall and posterior anatomic recurrence compared with open SCP [23]. The study population is heterogenous as it includes women who underwent concomitant hysterectomy and sacrohysteropexy. Our study also included flat or Y mesh; however, a recent RCT by Ferrando et al. found no differences in subjective outcomes and prolapse recurrence in patients who underwent sacrocolpopexy with the Restorelle® Y mesh versus dual flat mesh at 24 months [24].

In conclusion, sacral colpopexy is an efficacious procedure with an overall repeat prolapse surgery rate of 9%. The use of ultra-lightweight mesh does not lead to increased failure, including objective and subjective outcomes compared to lightweight mesh. During the same time period, there was no difference in the rate of surgery for mesh complication, which was 2% overall. This study adds to the literature of mesh-specific outcome data for sacrocolpopexy including for Upsylon, which can be used to inform appropriate regulatory bodies. Unfortunately, in November 2021 Boston Scientific withdrew all its mesh products from Australia and New Zealand and described this as a commercial decision. It is assumed this is a result of the costs associated with the class action brought by Shine and of regulatory compliance in a relatively small population. At the time of writing, Australia has no approved SCP mesh by the TGA despite the evidence in favour of sacral colpopexy in both the Cochrane review and International Consultation on Incontinence (ICI).

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Authors participation 1. M Kulkarni: Study design, recruitment, follow-up, database, manuscript preparation
2. D Rolnik: Statistical analysis, manuscript preparation
3. J Alexander: Recruitment, follow-up, database, manuscript preparation
4. F McGannon: Follow-up, database
5. Y Liu: Follow-up, database
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Declarations

Conflicts of interest None.

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