Polypropylene Mesh for Pelvic Organ Prolapse Surgery

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Abstract During the past 2 years, there has been a dramatic reduction in the employment of transvaginal mesh in the United States and simultaneously a doubling in the number of sacral colpopexies performed annually. While sacral colpopexy has strong Level 1 evidence supporting its use for posthysterectomy prolapse, the evidence supporting sacral colpopexy in those with uterine prolapse is limited. Hysterectomy performed at sacral colpopexy for uterine prolapse results in a fourfold increase in rate of mesh exposure compared with sacral colpopexy for posthysterectomy prolapse. The data supporting subtotal hysterectomy at sacral colpopexy and hysterectomy for uterine prolapse are Level 3 and derived from very limited numbers. With the withdrawal of commercial transvaginal polypropylene mesh products from the market, the Level 1 evidence relating to these products is derived from only 242 cases and demonstrate only an objective advantage over native tissue repairs in the anterior vaginal compartment. No Level 1 data are available to support transvaginal polypropylene mesh in multicompartiment or posterior compartment vaginal prolapse.

Keywords Sacral colpopexy · Transvaginal mesh · Transvaginal polypropylene mesh · Prolapse surgery · Pelvic organ prolapse surgery · Pelvic organ prolapse

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Introduction

The transvaginal mesh decade commenced in 2002 with the first transvaginal mesh approved by the Federal Drug Administration (FDA) specifically for pelvic organ prolapse surgery (Gynemesh, Ethicon, Somerville, NJ) and culminated in 2012 with manufacturers removing transvaginal mesh products from the market and commencement of transvaginal mesh class actions with patients seeking compensation from mesh manufacturers. While the FDA estimated that 75,000 transvaginal polypropylene mesh kits were implanted in 2010, this number has fallen to less than 30,000 of any transvaginal grafts in 2012 [1].

In 2012, multiple transvaginal polypropylene mesh products were voluntarily removed from the market, including Gynemesh PS, Prolift Anterior, Posterior, Total, +M and Prosima (Ethicon, Johnson and Johnson (Somerville, NJ); Avaulta (Bard, Covington, LA) and Pinnacle Posterior (Boston Scientific, Marlborough, MA) in the American market.

Our 2013 Cochrane systematic meta-analysis of randomised, controlled trials (RCT) made conclusions on the surgical management of prolapse based upon data from transvaginal mesh products that are now not available [2]. The goal of this article was to reevaluate the evidence with data on products that have been removed from the market excluded. This will allow a clear picture of efficacy and safety of products that are currently available for the surgical management of pelvic organ prolapse.

Transvaginal Mesh Data in 2012

To refresh, the 2013 Cochrane review of Level 1 data on the surgical management of anterior compartment prolapse reviewed 10 trials: Ali 2006 [3]; El-Nazer 2012 [4]; Altman 2011 [5]; Carey 2009 [6]; Nguyen 2008 [7]; Nieminen 2008 [8]; Menefee 2011 [9]; Sivaslioglu 2008 [10]; Thijs 2010 [11]; Vollebregt 2011 [12]) and evaluated 1,237 women. The review found that a standard native tissue anterior repair

was associated with more anterior compartment prolapse on examination than for any polypropylene mesh repair (relative risk (RR) 3.15, 95 % confidence interval (CI) 2.5–3.96). Awareness of prolapse also was higher after the anterior repair compared with polypropylene mesh repair (28 % vs. 18 %, RR 1.57, 95 % CI 1.18–2.07). However, the reoperation rate for prolapse was similar at 14/459 (3 %) after the native tissue repair compared with 6/470 (1.3 %) (RR 2.18, 95 % CI 0.93–5.1) after the anterior polypropylene mesh repair and no differences in quality of life data or de novo dyspareunia were identified. Blood loss (mean difference 64 ml, 95 % CI 48–81), operating time (mean difference 19 min, 95 % CI 16–21), recurrences in apical or posterior compartment (RR 1.9, 95 % CI 1.0–3.4), and de novo stress urinary incontinence (RR 1.8, 95 % CI 1.0–3.1) were significantly higher with transobturator meshes than for native tissue anterior repair. Mesh erosions were reported in 11.4 % (64/563), with surgical interventions being performed in 6.8 % (32/470) [2]. {AU Query: Is [2] the correct reference citation?} Data summarising outcomes from the ten RCTs comparing anterior compartment native tissue repair compared with anterior transvaginal polypropylene meshes are recorded in Table 1.

Data from three trials (Halaska 2012 [13]; Iglesia 2010 [14]; Withagen 2011 [15]) evaluated 383 women and compared native tissue repairs with a variety of total, anterior, or posterior polypropylene kit meshes. Although no difference in awareness of prolapse was able to be identified between the groups (25/132, 19 % vs. 18/123, 15 %) (RR 1.3, 95 % CI 0.8–2.3), in two trials (Iglesia 2010; Withagen 2011) the recurrence rate on examination was higher in the native tissue repair group compared with the transvaginal polypropylene mesh (native tissue 103/18, 55 % vs. polypropylene mesh kits 74/194, 38 %) (RR 1.4, 95 % CI 1.0–2.0). The mesh erosion rate was 35/194 (18 %) and 18/194 (9 %) underwent surgical correction for mesh erosion. The reoperation rate was higher after the combined polypropylene mesh kits (22/194, 11 %) compared with native tissue procedures (7/189, 3.7 %) (RR 1.1, 95 % CI 1.0–1.2) [2].

Transvaginal Mesh Data 2013

When RCTs that included anterior transvaginal mesh that have been removed from the market were excluded from the 2013 Cochrane analysis on the surgical management of prolapse, five RCTs remained (Table 2), which evaluated 510 women, 242 of whom underwent anterior transvaginal mesh. The reanalysis demonstrates that standard native tissue anterior repair was associated with more anterior compartment prolapse on examination than for polypropylene mesh repair (RR 3.3, 95 % CI 2.2–4.1). However, awareness of prolapse was only reported in one study and was not

significantly different between the groups (RR 1.9, 95 % CI 0.9–4.0). The rate of reoperation for prolapse remained not significantly different at 11/225 (5 %) after the native tissue repair compared with 6/232 (2.6 %) (RR 1.9 95 % CI 0.7–4.7) after the anterior polypropylene mesh repair. Again, no differences in quality of life data or rate of de novo dyspareunia were identified between the groups. Perioperative outcomes were similar in the reanalysis with reduced blood loss (mean difference 76 ml, 95 % CI 54–98) and operating time (mean difference 15 min, 95 % CI 7–22) in the anterior colporrhaphy group. Also in the reanalysis, no difference between the groups was identified in the rate of posterior or apical prolapse (RR 1.6, 95 % CI 0.7–3.4) or de novo stress urinary incontinence (RR 1.3, 95 % CI 0.1–16). The rate of mesh erosions was higher in the reanalysis at 14 % (37/260), with surgical interventions being performed in 10 % (23/232).

The 2013 Cochrane findings on surgical management of multicompart prolapse were unable to be verified, because the three RCTs (Halaska 2012; Iglesia 2010; Withagen 2011) all involved transvaginal mesh products that have been removed from the market. A variety of transvaginal polypropylene mesh products remain on the market that have not been evaluated under the auspices of a RCT.

Anterior Elevate (American Medical Systems, Minnetonka, MN) using a lightweight polypropylene graft (24 g/m²) and is a single-incision kit with the mesh secured to the sacrospinous ligament apically and to the arcus tendineus fascia pelvis in the anterior compartment. Clearance from Federal Drug Administration was obtained in 2008, and in 2012 Moore et al [16], reported a 92 % objective success rate at 13 months in 60 patients with anterior and/or apical prolapse. No mesh exposures were reported, and the authors who reviewed the patients reported a financial relationship with the company that manufactured the product being evaluated.

A similar lightweight polypropylene mesh kit, Elevate Posterior (American Medical Systems), is available for management of posterior or apical prolapse. Lukban et al [17], in a prospective, multicentre, international evaluation of 139 women with stage 2 or greater posterior or apical prolapse reported that at 1 year the objective success rate was 92 % in the posterior compartment and 90 % for the vaginal apex with a 6.5 % mesh extrusion rate. Many of the authors reported a conflict of interest with the manufacturer of the product that was being evaluated.

Azais et al [18], reported on 70 women undergoing a combination of anterior, posterior, or combined anterior and posterior Elevate for prolapse at the hymen or beyond in a single French site with authors reporting no conflict of interest. At 1 year, the success rate was lower than in previous reports at 69 %; however, the definition of success

Table 1 Outcomes of randomized, controlled trials comparing native tissue repair and transvaginal mesh for anterior compartment vaginal prolapse

Author	Awareness prolapse		Objective Anterior Recurrence		DE novo Dyspareunia		Reoperation Anterior prolapse		Mesh exposure		Sx for Mesh		Reoperation rate	
	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh
Al Nazer 2012*	6/19	1/18			1/23	0/21			1/20				0/19	0/20
Ali 2006*			5/43	3/46					3/46					
Altman 2011**	64/174	44/179	96/183	33/186	2/101	8/110	1/183	0/186	21/183		6/183		0/183	11/186
Carey 2009*	10/60	7/62											4/60	3/62
Menefee 2011***			14/24	5/28					5/28				0/24	2/28
Nguyen† 2008			20/38	5/38	4/26	2/22	1/38	0/37	2/37				2/38	2/37
Nieminen ‡2008	18/96	10/104	40/97	14/104			10/97	6/104	18/104		14/104		19/97	25/104
Sivaslioglu‡ 2008			12/42	4/34	0/42	2/43	0/42	0/43	3/43		3/43		0/42	3/43
Thijs 2010							0/48	0/48	9/48		4/48		0/48	4/48
Vollebregt 2011††			33/51	5/53	2/21	3/20	2/51	0/53	2/53		2/53		7/51	4/53
Total	98/349	62/363	220/478	69/498	9/213	15/216	14/459	6/471	64/563		31/468		32/562	54/581
	RR 1.6 (1.2-2.2)		RR 3.2 (2.5-4.1)		RR 0.6(0.3- 1.3)		RR2.2(0.9- 5.1)						RR 0.6(0.4-0.9)	

Blanks represent missing data. †American Medical Systems, Minnetkato, MN;

‡Parientene, Sofradim, Trevoux, France; ††Bard, Covington, LA.

was stricter than previous studies (no stage 2 prolapse at any POPQ site) and no patients underwent subsequent prolapse surgery. The mesh extrusion rate remained low at 4.5 %, and there was an improvement in pelvic floor function on validated questions postoperatively.

Vu et al [19]. reported a retrospective evaluation of a new reduced-size transvaginal polypropylene mesh product Uphold (Boston Scientific, Marlborough, MA) with only apical fixation in 115 patients with a mean review of 12 months. No inclusion or exclusion criteria were specified, and patients were reviewed by fellows and the senior author who reported receiving royalties from the product being evaluated. The success rate was high at 98 % on examination and the mesh exposure rate was low at 2.8 %. Postoperative dyspareunia occurred in 9 % and was lower than the 13 % reported preoperatively. The validated prolapse specific questionnaire Pelvic Floor Distress Inventory demonstrated an improvement in all domains postsurgical intervention.

Both of these newer transvaginal polypropylene mesh kits had FDA approval by the 510 K process that required them to be similar to previously approved predicate cases. Following the FDA 2011 [20] reclassification of transvaginal polypropylene mesh from a Class II to Class III product, it is mandatory for new devices to undergo significant comparative premarket testing. Products, such as Uphold and Pinnacle (Boston Scientific) and Elevate (American Medical Systems), that already had received FDA clearance are required to provide postmarket data of efficacy or safety to FDA. Elevate achieved FDA clearance in 2008, and 4 years later the first reviews with excellent outcomes were reported by authors who declared financial conflict of interest (COI) with the

manufacturer of the product being evaluated [17, 21]. The outcomes of the first independent evaluation of Elevate by authors without a COI have not been as promising [18].

This pattern of excellent initial clinical outcomes reported by authors with a COI with the manufacturers of the product being evaluated and subsequent poorer outcomes when later evaluated independently is not new in pelvic floor surgery and has been seen previously with the Intravaginal Slingplasty [22, 23] (Tyco Healthcare, Norwalk, CT) cleared for continence and prolapse surgery in 2001 and more recently with Prolift [24, 25] (Ethicon, Somerville, NJ). Unfortunately, the new 522 k postmarket surveillance process for transvaginal mesh products already approved under the old 510 K process, such as Uphold, Pinnacle, and Elevate, is concerning in two ways. First, there is at least a 5-year time period between clearance from FDA and first independent evaluation of products that allows products to be utilized that may not be as effective or safe as first envisaged and potentially exposing women to unknown risk. Second, the potential problem of reviewer bias when products are evaluated by clinicians with a conflict of interest with the manufacturers of the product has not been addressed in the new FDA clearance processes for transvaginal mesh.

Sacral Colpopexy

Lane first described the sacral colpopexy in 1962 as an abdominal vault suspending procedure and since that time sacral colpopexy has gained in popularity with 35,000 procedures performed in the United States in 2010 and 75,000

Table 2 Outcomes of RCTs comparing native tissue repairs and transvaginal meshes that are currently available for the surgical treatment of anterior compartment prolapse

Author	Awareness prolapse		Objective Anterior Recurrence		de novo Dyspareunia		Reoperation Anterior Prolapse		Mesh exposure		Sx for mesh exposure		Reoperation rate	
	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh	NT	Mesh
Menefee 2011			14/24	5/28						5/28			0/24	2/28
Nguyen 2008†			20/38	5/38	4/26	2/22	1/38		2/37				2/38	2/37
Nieminen 2008‡	18/96	10/104	40/97	14/104			10/97	6/104		18/104		14/104	19/97	25/104
Sivaslioglu‡ 2008			12/42	4/34	0/42	2/43	0/42	0/43		3/43		3/43	0/42	3/43
Thijs 2010†							0/48	0/48		9/48		4/48	0/48	4/48
Total	18/96	10/104	86/201	28/213	4/68	4/65	11/225	6/232		64/563		31/468	21/249	36/260/581
	RR 1.9(0.9- 4.0)	RR 3.3(2.2-4.1)	RR0.9(0.2- 3.2)	RR1.9(0.7- 4.7)					RR 0.6(0.4-1.0)					

Blanks represent missing data. †American Medical Systems, Minnetonka, MN;

‡Parientene, Sofradim, Trevoux, France; ††Bard, Covington, LA.

in 2012 from industry estimates [26]. The efficacy of the sacral colpopexy has been well-established and Level 1 evidence from 2013 Cochrane review [2•] reported abdominal sacral colpopexy was associated with a lower rate of recurrent vault prolapse (Benson et al. 1996 [27]; Maher et al. 2004 [28]), reduced grade of residual prolapse (Lo and Wang 1998 [29]), greater length of time taken to recurrence of prolapse (Benson et al. 1996 [27]), and less dyspareunia (Benson et al. 1996; Lo and Wang 1998 [29]; Maher et al. 2004 [28]) compared with vaginal sacrospinous colpopexy. However, the abdominal sacral colpopexy was associated with a longer operating time (Benson et al. 1996 [27]; Lo and Wang 1998 [29]; Maher et al. 2004), a longer time for recovery (Maher et al. 2004 [28]), and it was more expensive (Benson et al. 1996 [27]; Maher et al. 2004 [28]) than the vaginal approach. Polypropylene mesh had superior anatomical outcomes as the graft material at sacral colpopexy at 5 years compared with fascia lata graft (Tate et al. 2010 [30]).

In a single study at 1 year, Rondini et al [31]. demonstrated that the sacral colpopexy was superior to vaginal uterosacral colpopexy with a higher objective success rate and lower reoperation rate. The operating time, admission days, and postoperative complication rate were all higher after sacral colpopexy compared with vaginal uterosacral colpopexy. These findings mirror the outcomes of sacral colpopexy compared with sacrospinous colpopexy.

In a small, single study, Freeman et al [32]. compared open and laparoscopic sacral colpopexy and the outcomes were similar except for reduced blood loss, analgesic requirements, and inpatient days in the laparoscopic group. Again, in a single trial, Maher et al [34]. demonstrated that laparoscopic sacral colpopexy (LSC) took longer to perform than total vaginal polypropylene mesh repair and had reduced blood loss, admission days, and reoperation rate. The recurrent prolapse rate, both on examination and subjectively, was lower after the laparoscopic sacral colpopexy. Paraiso et al [33]. demonstrated that robotic sacral colpopexy (RSC) had increased operating time, postoperative nonsteroidal anti-inflammatory drug (NSAID) use, and costs compared with LSC, with no difference in anatomical or functional outcomes. However, significant questions remain unanswered regarding the sacral colpopexy.

Who Should Undergo Sacral Colpopexy?

The Cochrane Level 1 evidence supporting anatomical superiority of sacral colpopexy over sacrospinous colpopexy for apical prolapse comes from three RCTs. The literature is unclear whether this relates to both vault (posthysterectomy) and uterine prolapse. Maher et al [28]. included only those with posthysterectomy prolapse, whereas Benson et al [27].

and Lo and Wang [29] performed hysterectomy concomitantly in those with uterine prolapse, which accounted for approximately 50 % of cases. There is concern that the introduction of a polypropylene mesh over a healing sutured incision plus exposure to vaginal microbes theoretically increases the risk of mesh exposure when hysterectomy is performed at the time of sacral colpopexy.

Table 3 from the 5th International Consultation on Incontinence reviewed the rate of mesh erosions after sacral colpopexy with and without hysterectomy and demonstrated that the rate of mesh exposure at sacral colpopexy alone was 2.2 % and increased to 8.6 % if a hysterectomy is performed concomitantly [34]. The near fourfold increase in the rate of mesh exposure if a hysterectomy is performed concomitantly brings the rate of mesh exposure associated with sacral colpopexy and hysterectomy to similar levels seen with transvaginal polypropylene mesh. There also is increasing evidence that the morbidity associated with partial or complete mesh excision after sacral colpopexy, especially if abdominal approach is required, is significant [35]. Tjldink et al. retrospectively reviewed 75 patients who underwent 30 complete and 51 partial mesh excisions for complications

after prior continence tapes (n=15), transvaginal mesh (n=48), or sacral colpopexy (n=12). The vaginal approach was utilised in 72 cases and abdominal approach in 9. The abdominal approach to mesh complications following sacral colpopexy was associated with intraoperative complications in 23 % and postoperative complications in 46 %, which was significantly greater than experienced with vaginal surgery to manage complications. For these reasons, until more definitive evidence is available on the role of sacral colpopexy in women with uterine prolapse, the current literature is only supportive of sacral colpopexy for posthysterectomy prolapse.

This leads us to discuss how sacral colpopexy is employed in those with uterine prolapse and what evidence supports this approach? Following the 2011 FDA transvaginal mesh alert and subsequent litigation, there has been more than a twofold increase in the numbers of sacral colpopexy procedures performed in the United States in the 2 years from 2010 to 2012 and it is likely that many of these were performed in women with uterine prolapse. Gynaecologists are performing hysteroscaptopexy or a subtotal hysterectomy and sacral colpopexy with the goal to achieve the excellent outcomes

Table 3 Compares the rate of mesh exposure in those undergoing sacral colpopexy with and without hysterectomy and with subtotal hysterectomy

Author, year	Design	Follow-up (mo)	Surgery	Mesh	No hysterectomy	Concomitant total hysterectomy	Concomitant subtotal hysterectomy	<i>p</i>
Jeon, 2009 [36]	Retrospective comparative	36	Open	Teflon Marlex PP	2/35	5/63	MD*	-
Cundiff 2008 [37]	Prospective comparison	24	Open	Mersilene PP Goretex	8/239	12/83		
Wu 2006 [38]	Retrospective comparative	15	Open	Goretex Mersilene PP	10/212	7/101	MD	-
Costantini 2005 [39]	Prospective non randomised	50	Open	Marlex	0/34	3/38	MD	-
Bensiger, 2005 [40]	Retrospective comparative	12	Open	PP	0/35	4/49	0/37	-
Brizzolara 2003 [41]	Retrospective Comparative	35	Open	80 % PP 20 % allografts	0/64	1/60		
Culligan 2002 [42]	Retrospective	24	Open	Synthetic mesh	3/234	3/11		
Total for open SC	-	-	-	-	23/853 (2.7 %)	35/405 (8.6 %)	0/37	.001
Stepanian 2008 [43]	Retrospective	12	Lap	PP	2/272	3/130		
Tan Kim, 2011 [44]	Retrospective comparative	15	Lap	PP	MD	13/57*	1/21	-
Total	-	-	-	-	25/1125(2.2 %)95 % CI(1.4-3.1)	51/592(8.6 %)95 % CI(6.3-11 %)	1/58	.001

MD, missing data.

Table 4 Compares success rate and mesh exposure rate for abdominal sacrohysteropexy (ASHP) and sacral colpopexy and hysterectomy (TAHSCP) for uterine prolapse

Author	Study Type	Surgery	Follow-up(mo)	ASHP Success rate	TAH SCP Success rate	ASHP Mesh	TAHSCP Mesh	Complications
Roovers 2004 [45]	Multicentre RCT		12	26/41 (63 %)		2/41		1 Transfusion, 2 vault abscess & Infected implant
Constantini 2005 [39]	Prospective		51	31/34(91 %)	35/38(92 %)	0/34	3/38	ASHP group 2 Transfusion 2 Incisional hernia
Jeon 2008 [46]	Retrospective Cohort		36(1- 84)	35/35(100 %)	60/63 95 %	0/35	5/63	TAH: 1 DVT, 3 SBO, 1 ureteric obstruction
Bai 2005 [47]	Retrospective cohort		12	10/10(100 %)	18/19 0(95 %)	0/10	3/19	Transfusion: 3 /5 Wound dehiscence secondary closure: 0/2 Ileus: 1 ASHP
Constantini 2011 [48]	Prospective observational	ASHP (47) LSHP (8)	64(12-146)	45/52(87 %)		2/52		De novo constipation 5, Persistent sexual dysfunction 24 %(4/17) Wound hernia 2 PE 1
Price 2010 [49]	Prospective LSHP		3-6	50/51 (98 %)		0/51		2 dyspareunia,
Demirci 2006 [50]	Prospective ASHP		25(3-60)	19/20(95 %)		0/20		Wound infection 2 Incisional hernia 1 Dyspareunia 3
Barranger 2003 [51]	Prospective ASHP		45(2-156)	(28/30)(93 %)		1/30		Hematoma 1, Presacral Hemorrhage 1 Wound Incisional hernia 1, Incisional hernia 1, infection 1, SBO 1, Sciatic pain 1, De novo dyspareunia 2
Constantini 1998 [52]	Retrospective ASHP		32 (12-68)	7/7	8/9 (89 %)	0/7	0/9	DVT/PE 2 (10 %), Femoral neuropathy 1 (5 %), Incisional hernia 2 (10 %)
Rosenblatt 2008 [53]	Retrospective LSHP		8	40/40(100 %)		0/40		1 rectal injury, umbilical hernia transfection
Banu 1997 [54]	Retrospective ASHP		36-60	19/19(100 %)		0/19		significant complications"
Total				310/339(91 %)	121/129(94 %)	5/339(1.5 %)	11/129(8.5 %)	

of sacral colpopexy for posthysterectomy prolapse and avoid the increased risk of mesh exposures associated with sacral colpopexy and hysterectomy.

Table 4, reproduced from Maher et al [34], in the 5th International Consultation on Incontinence, demonstrates that both hysterectomy and hysteropexy at time of sacral colpopexy for uterine prolapse achieve a successful anatomic outcome in approximately 90 % of cases. The rate of mesh exposure increases from 1.5 % at hysteropexy to 8.5 % if hysterectomy is performed at the time of sacral colpopexy. These findings need to be viewed cautiously because they are based on only 129 cases of sacral colpopexy and hysterectomy and 339 cases of hysteropexy, of which 99 were performed laparoscopically, in the peer-reviewed literature. As seen in Table 3, subtotal hysterectomy and sacral colpopexy is associated with a low mesh erosion exposure rate of 1.7 % (1/58); however, this finding is based on only 58 cases in the literature and needs further evaluation.

Sacral Colpopexy: What Approach?

The original Level 1 data on efficacy of sacral colpopexy over vaginal sacrospinous colpopexy all arose from open sacral colpopexy. The open approach in these three RCTs may have accounted for some of the increased perioperative morbidity, including longer admission time, slower return to activities of daily living, and greater cost of the sacral colpopexy.

Many surgeons choose to perform the LSC to minimise the perioperative morbidity of the laparotomy. Table 5 compares the outcomes of open sacral colpopexy from our 2004 RCT [28] with the LSC group from our 2011 RCT [25] with a mean review time of 24 months in each group. We found very similar rates of satisfaction, anatomical outcomes, operating time, and complications with the laparoscopic arm having

significantly reduced blood loss, admission days, and time to recovery. These outcomes were replicated by Freeman et al [32], in a prospective evaluation of 51 women undergoing either the open or laparoscopic sacral colpopexy in England.

Anecdotally many of the 75,000 sacral colpopexy undertaken in the United States {AU Query: As meant: the United States?} in 2012 were performed robotically. In the only randomised comparison of RSC to date, Paraiso et al. provides Level 1 evidence that RSC results in longer operating time and increased pain and cost compared with LSC [33]. This single-center, blinded, randomised trial compared RSC (n=40) with LSC (n=38) in women with stage 2–4 posthysterectomy vaginal prolapse. Total operative time was chosen as the primary outcome for this study serving as a proxy measure for surgical efficiency. Total operative time was significantly longer in the robotic group compared with the laparoscopic group (+67-minute difference; 95 % CI 43–89; $P<0.001$) [33]. Anaesthesia time, total time in the operating room, total sacral colpopexy time, and total suturing time were all significantly longer in the robotic group. Participants in the robotic group also had significantly higher pain at rest and with activity during weeks 3–5 after surgery and required longer use of nonsteroidal anti-inflammatory drugs (median, 20 compared with 11 days, $P<0.005$). The robotic group incurred greater cost than the laparoscopic group, even though the significant purchase and maintenance cost of Da Vinci Robot (Intuitive) were not included (mean difference+\$1,936; 95 % CI \$417–\$3,454; $P=0.008$) [33]. Both groups demonstrated significant improvement in vaginal support and functional outcomes 1 year after surgery with no differences between groups.

A meta-analysis of observational studies on robotic gynaecological surgery found that the currently available evidence shows that for most gynaecological procedures studied, robotic surgery achieved a shorter hospital stay and less

Table 5 Contrasts outcomes of open and laparoscopic sacral colpopexy

Outcome	Open SC 2004 ²⁸	Laparoscopic SC 2011 ²⁵
Number	46	53
Operating time	106	97
Blood loss	362	100
Inpatient days	5.4	2
Days to return ADL	34	21
Transfusion	1	1
Intraoperative complications	1 cystotomy	cystotomy, enterotomy
Complications reoperation	2 incisional hernia 1 removalmesh, 2 POP surgery	1 trocar hernia, 1 mesherosion, 1 TVT
Mesh erosions	1	1
Patient satisfaction	85	87
Overall success rate	76 %	77 %
Length of review	24 months	24 months

blood loss than open surgery [55]. However, no clinically significant improvements were noted when robotic surgery is compared with conventional laparoscopic surgery in benign gynaecological procedures [55]. The current evidence, although limited, suggests that these conclusions also are applicable for RSC. RSC probably has a shorter learning curve than LSC and thus may be more generalizable; however, published evidence for this is currently lacking. In surgeons with advanced laparoscopic skills, RSC offers no clinical benefit compared with LSC and results in longer operating times, greater cost, and greater postoperative pain.

Conclusions

- There has been a rapid decline in transvaginal polypropylene mesh kits from 2010 to 2012.
- With the withdrawal of some commercial transvaginal polypropylene mesh products from the market, the Level 1 evidence relating to these products is derived from only 242 cases and demonstrates only an objective advantage over native tissue repairs in the anterior vaginal compartment.
- No Level 1 data are available to support transvaginal polypropylene mesh in multicompartiment or posterior compartment vaginal prolapse.
- There is only limited Level 3 evidence to support the use of newer transvaginal mesh products that have received 510 K clearance from the FDA and are awaiting further postmarket surveillance. The early data are encouraging; however, the reader must be mindful that the authors of these studies reported COI with the manufacturers of the product that was evaluated. Very early independent evaluation of one of these products is not as encouraging.
- It is preferable that conflicts of interest did not exist between authors evaluating commercial products and the manufacturers of those products. Efforts to establish an “arms-length” relationship between researcher and industry would be beneficial to establish greater transparency and integrity to pre- and postmarket surveillance undertaken in the future.
- There has been more than a twofold increase in sacral colpopexy performed in the United States between 2010 and 2012.
- The sacral colpopexy has strong Level 1 evidence supporting its use for posthysterectomy prolapse.
- Hysterectomy performed at sacral colpopexy for uterine prolapse results in a fourfold increase in the rate of mesh exposure compared with sacral colpopexy for posthysterectomy prolapse.
- Both hysterectomy and subtotal hysterectomy at the time of sacral colpopexy reduce the rate of mesh exposures compared with sacral colpopexy and hysterectomy

in those with uterine prolapse. The data supporting subtotal hysterectomy at sacral colpopexy and hysterectomy for uterine prolapse are Level 3 and derived from very limited numbers.

- Anecdotally, there has been a dramatic increase in sacral colpopexy performed robotically in the United States. Limited Level 1 evidence indicates that RSC has greater cost and perioperative morbidity than does LSC.

Compliance with Ethics Guidelines

Conflict of Interest Nir Haya and Christopher Maher declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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