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A comparison of the use of mesh to native tissue in the management of vaginal vault prolapse

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A B S T R A C T

Vaginal vault prolapse afflicts millions of women and evokes significant psychosocial and pelvic floor dysfunction. The risk factors and modalities of conservative management are discussed in this study. There remains controversy in the optimal surgical management. This review serves to study the clinical conundrum of the decision-making process to utilize the mesh and the approach. In-depth evaluation of mesh-related postsurgical complications as compared to those associated with the native tissue is explored.

Vaginal vault prolapse (VVP) is defined as the downward or forward displacement of the pelvic viscera into the vaginal canal from their normal positions, involving anterior (bladder), apical, and posterior (rectum) compartments. Symptoms elicited can be quite debilitating and disrupt daily activities, including (a) vaginal bulge or protrusion, (b) pelvic pressure, (c) lower back pain, (d) urinary symptoms (such as stress urinary incontinence (SUI) or incomplete emptying), (e) need for self-digitation for rectal or bladder evacuation, and (f) sexual dysfunction. Fig. 3 demonstrates a patient with stage IV VVP.

Primarily through magnetic resonance imaging and pathophysiological studies, Dr John Delancey has defined three levels of lower genital tract support [1] as shown in Fig. 1: (i) level I provides apical support to the uterosacral and sacrospinous ligaments, (ii) level II provides mid paravaginal support laterally to the arcus tendineus fascia pelvis through the paravaginal fascia, and (iii) level III provides support distally through the perineal membrane. These segments have been well classified and utilized in guiding surgical procedures to correct respective compartmental defects.

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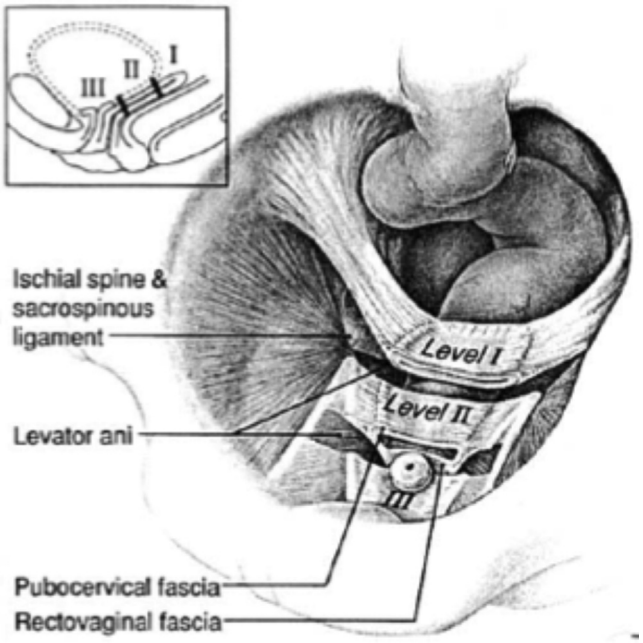

Fig. 1. DeLancey levels of support.

Pelvic organ prolapse (POP) is estimated to affect a third of adult women [2] and 50% of women more than 50 years of age [3]. The prevalence of women seeking care for POP peaks in their sixth decade of life [4]. In 2000, there were 23 million women more than 65 years of age in the United States suffering from the symptoms of POP, and this is estimated to almost double to 43 million by 2030 [5]. In 2010, more than 5000 surgical procedures for POP were performed in Canada, and 29% involved the use of mesh (Canadian Institute for Health Information Data). Vaginal parity is the biggest risk factor for the development of POP; the relative risk (RR) of POP is 10.7 from 1 to 4 or more vaginal deliveries [6]. There is an odds ratio (OR) of 1.82 (95% CI 1.04–3.19) when comparing the risk of developing POP postvaginal delivery to that of elective cesarean section [7]. Other risk factors include age, physical activity, prior pelvic surgery, menopause, obesity, smoking, genetic factors, and neuropathy [8].

Pelvic floor dysfunction

The etiologies of pelvic floor dysfunction share significant commonality. There is an intricate interplay of factors predating, confounding, and affecting the evolution of pelvic floor disorders that is both patient specific and unpredictable in evolution for each specific patient. The complexity of these variables is outlined in the schematic of Fig. 2 [9].

There are multiple predisposing factors to pelvic floor dysfunction that can alter how a patient presents with her particular problem and how she responds to the given therapy. These factors include (a) neurologic factors, (b) family history, (c) collagen disorders, (d) race, (e) anatomic variation, (f) environmental elements, (g) cultural issues, and (h) muscular disparity. Subsequent to this, there are numerous inciting factors that vary the presentation and response of the patient. These factors comprise (a) childbirth, (b) radiation, (c) neurologic damage, (d) muscular damage, (e) tissue disruption, and (f) radical pelvic surgery. Then, there exist promoting factors, which often exacerbate the presenting symptoms and can expedite deterioration at different rates following treatment. These factors are (a) obesity, (b) pulmonary dysfunction, (c) smoking, (d) menses, (e) constipation, (f)

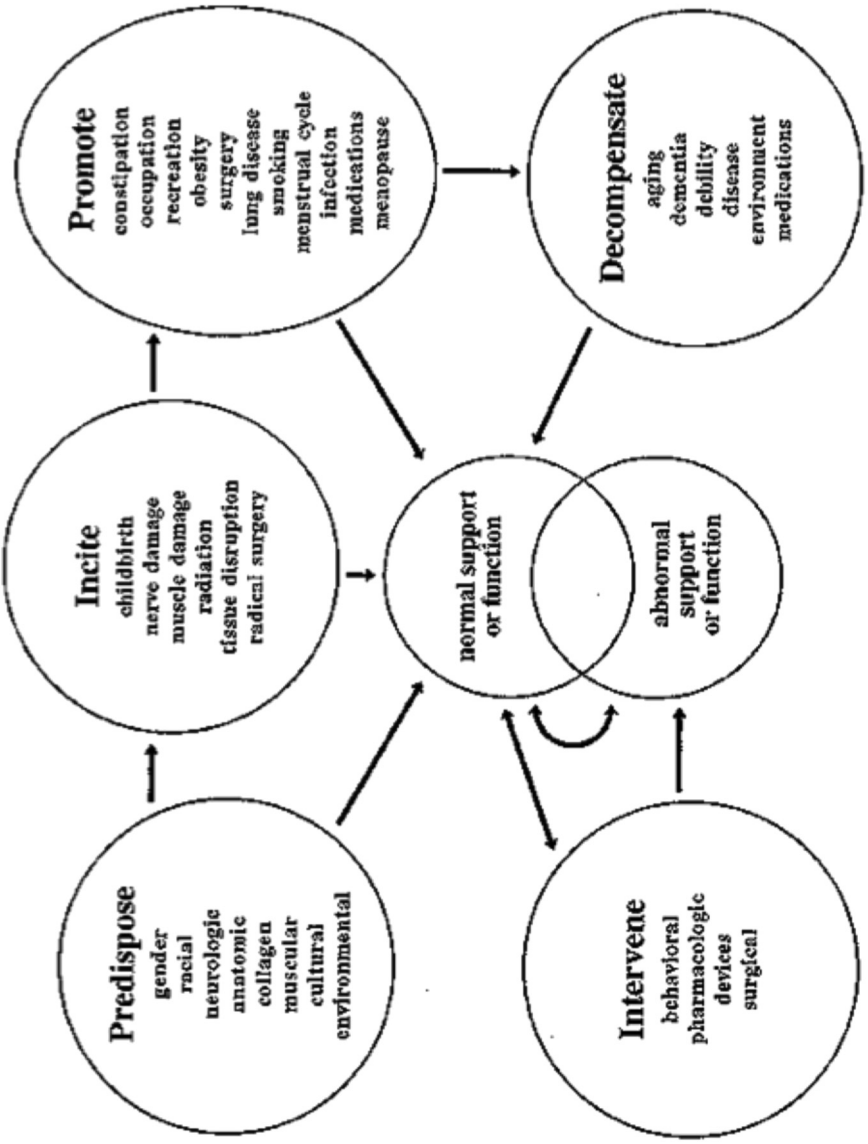

Fig. 2. Risk factors for pelvic floor dysfunction.

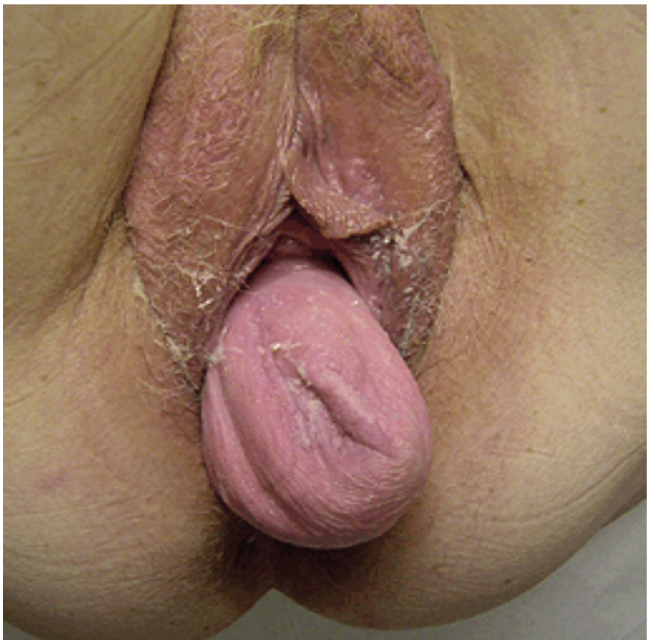

Fig. 3. Stage IV vaginal vault prolapse.

recreational activity, (g) occupation, (h) medications, (i) menopause, (j) infection, and (k) surgery. Finally, there are decompensating factors that culminate the whole cycle of pelvic floor dysfunction predisposition. These factors include (a) aging, (b) dementia, (c) debility, (d) disease, (e) environmental factors, and (f) pharmacologic components [9].

Conservative management of POP

If it is possible to ensure that there is no obstruction of the upper urinary tract, no evidence of recurrent urinary tract infections, and no interference with bowel or sexual function, then the pelvic floor physician has the option of offering expectant management in the form of observation. If the patient seeks active management, then either pessary fitting or surgical treatment can be provided.

Pessaries are silicone devices placed intravaginally to fix malpositioning of the uterus and/or vaginal walls. They can be used in patients who either are poor surgical candidates, awaiting surgery, or wish to avoid surgery. There are various sizes, shapes, and mechanisms of action that facilitate relief of VVP symptoms. Their care depends upon the specific pessary used and the estrogenization status of the lower genital tract, but generally, they are removed, cleaned, and reinserted at least every 3 months. Attention needs to be paid to check for vaginal irritation, vaginitis, erosion, and fistulization. Fig. 4 demonstrates multiple pessaries available for VVP management.

The successful fitting of a pessary occurs in 71%–90% of patients [10], and the specific prolapse symptoms of pressure and bulging are reduced in 70%–90% and 29%–49% of those patients successfully fitted [11], respectively. If successful relief of bothersome symptoms continues to 4 weeks postfitting, then the majority of patients continue their use for at least 5 years [12]. Ring pessaries (with or without covers) are the most commonly used and may be replaced by a more space-occupying pessary, such as a Gellhorn or Donut pessary, if protrusion of any VVP compartment persists or the ring spontaneously expels. Surgical options are pursued if the pessary fails to execute its function of improving lower urinary tract symptoms, relieving bulge or pressure, and/or improving general activity [13]. Predictors of unsuccessful pessary fitting and/or discontinuation of pessary use include patient-specific factors

Fig. 4. Vaginal pessaries.

such as a shortened vagina less than 6 cm, a widened introitus greater than 4 fingerbreadths, the presence of a rectocele, prior vaginal surgery, coexisting SUI, less than 65 years of age, and discomfort [11,14–17].

Surgical management of VVP

Approximately 11%–20% of women will undergo surgery in their lifetime for the repair of either POP or SUI [18,19]. There are several general factors to consider when deciding upon embarking on surgical repair of VVP. These factors include (a) patient characteristics such as age, medical comorbidities, sexual activity, and history of prior pelvic floor surgery; (b) preservation of uterus or not; (c) graft augmentation of repair or not; (d) surgical approach (vaginal, abdominal, and laparoscopic); (e) compartment involved; (f) stage of prolapse; (g) potential for de novo stress incontinence; and (h) the addressing of coexisting risk factors for recurrence as previously outlined.

There are approximately one-quarter of a million pelvic floor reconstructive procedures performed annually in the United States [20], and it is estimated that more than 7 million such procedures will be performed annually by 2030 [21]. Traditionally, surgical repairs of VVP involve plication of existing pubocervical or rectovaginal fascia with or without apical suture suspension to deep ligamentous pelvic structures. Between 29% and 40% of these traditional native tissue procedures will require surgical reintervention for failure within 3 years [18,22]. Specifically, the anterior compartment carries an up to 70% risk of recurrence [23] and 32.5% of prolapse recurrences occur in a different compartment due to unmasking of an occult support defect [24].

Multiple studies have demonstrated that patients with pelvic floor dysfunction have structurally altered collagen fibers [25–28]. General surgery experience has demonstrated an inguinal hernia risk of recurrence reduction of approximately 50% after 3 years following repair with a polypropylene mesh

[29]. A permanent monofilament macroporous polypropylene mesh carries the added benefits of being readily available, being of relatively low risk, having consistent tensile strength, failing to remodel, having limited stretch properties, and demonstrating predictable in vivo clinical tissue response [30,31]. Many authors have demonstrated a higher rate of cure of the anterior compartment with repairs augmented by the mesh as shown in Table 1

Mesh augmentation in VVP repair can be facilitated through either mechanical support or as a bridging material for the fascial defect. The early landmark study of mesh use in the anterior compartment demonstrated a 31.8% reduction in the risk of recurrence, with the use of mesh overlying a standard anterior repair as compared to that of a standard repair without mesh [32]. Attempts were then made to standardize repairs of the anterior compartment augmented with mesh, which resulted in the development of transvaginal mesh systems for prolapse repair (TVM). The SOGC recognized them as techniques for pelvic floor repair, which demonstrate high rates of anatomical cure in uncontrolled short-term case series [33]. It was also felt wise that training specific to transvaginal mesh procedures be undertaken before performing them. As illustrated in Table 2, multiple authors have demonstrated high rates of cure of anatomical prolapse using these techniques.

These findings were confirmed by a multicenter parallel group randomized controlled trial conducted by the Nordic Transvaginal Mesh Group. A total of 389 patients were randomized to undergo either an anterior trocar-guided, transvaginal polypropylene-mesh system (Prolift™) or a traditional anterior colporrhaphy. The findings demonstrated a combined objective and subjective OR of success after 12 months of 3.6 (95% CI 2.2–5.9) [34]. Mesh revision for vaginal exposure was only required in 3% of the TVM cases. A total of 524 patients were followed up for 3 years following transvaginal Prolift™ mesh implantation [35]. Of these patients, only 16 (3%) required repeat surgery for prolapse recurrence, 36 (6.9%) required intervention for urinary incontinence or voiding dysfunction, and 19 (3.6%) underwent revision for mesh-related complications (exposure, contraction, infection, and rectal compression). The mean presentation time for mesh exposure was 13 months. The global reoperation rate of 11.6% ($^{61}/_{524}$) is far less than that estimated for native tissue repairs (29%–40%) [18,22].

As with all surgical procedures, these standardized transvaginal mesh systems do not come without risk. The mere fact that patients experience an operative complication is not inherently related to the properties of the mesh itself. Previous studies have demonstrated the following potential complications of: (a) mean mesh exposure rate of 4.7% (1%–12%), (b) mesh contraction of up to 17%, (c) de novo dyspareunia in up to 13% of cases, (d) de novo SUI, (e) alternate compartment recurrence in 5%–8%, (f) visceral and vascular injuries up to 1.4%, and (g) lower genital tract fistulae [36,37].

When further evaluating the issue of mesh contraction, we found interesting results. It is known that in traditional trocar-based transvaginal mesh procedures, there is an element of tissue contraction resulting in mesh shrinkage. Ultrasonographic images of transobturator-placed anterior compartment mesh procedures demonstrated a 26% reduction in total mesh length in week 6 as compared to postoperative day 3 [38]. However, these findings do not necessarily correlate to clinical findings. A large cohort of patients with mesh complications was evaluated ultrasonographically to assess size and positioning of their mesh. Contrary to prior hypotheses that postoperative pain was associated with mesh shrinkage and folding, these findings differ. Posterior compartment meshes were associated with

Table 1
Cystocele repairs with mesh augmentation.

Author	Mesh	n	F/U	Success	Erosion	Other
Julian '96	Marlex	12	24 m	100%	25%	
Flood '98	Marlex	142	38 m	100%	2.1%	94% subj. cure rate Mesh excised
Migliari '00	Prolene	12	20 m	75%	-	
Dwyer '04	Prolene	81	28 m	88%	0	
Hung '04	Prolene	38	21 m	87%	10.5%	4 cornered anchored mesh
DeTayrac '05	Gynemesh	87	24 m	91.6%	8.3%	
Ng '06	Prolene	37	16 m	76%	0	Grade 4 cystoceles
Sola '06	Gynemesh	31	5 m	100%	0	Ant + Post
Achtari '06	Prolene Vypro 2	198	6 m	-	7.1%	Ant + Post, no diff RF: age and surgeon
Deffieux '07	Gynemesh	138	32 m	95%	20%	Gynemesh = GM soft

Table 2
Anatomical cure rates of transvaginal mesh procedures.

Author	Journal	Design	N	Device	F/U (m)	Anatomic Qjre
Gauruder-Burm ester	*Int Urogynecol J Pelvic Floor Dysfunct* 2007	Retrospective	120	AMS	12	93%
Fatton	*Int Urogynecol J Pet vie Floor Dyfunct* 2007	Retrospective	110	Prolift	6	96.3%
Altman	*Int Urogynecol J Petvic Floor Dysfunct* 2008	Prospective cohort	123	Prolift	2	87–91%
Abdel-Fattah	*BJOG* 2008	Retrospective cohort	289	Prolift/AMS	3	94–100%
Shek	*Ultrasound Obstet Gynecol* 2008	Retrospective	46	Perigee	10	87%
Van Raalte	*J Pelvic Med Surg* 2007	Observational	350	Prolift	6	90%
Hinoul	*J Muvm Invasive Gynecol* 2008	Observational	48	Prolift		95.2%
Lucioni	*Can J Urol* 2008	Observational	12	Prolift	10	92%
Gabriel	*Acta Otstet Gyrvool Scand* 2007	Case series	73	Avaulta	4	100%
Nguyen	*Otstet Gywcoi* 2008	RCT cf AR	75	Perigee	12	93.3% vs 61.5%
Murphy	*Am J Otstet Gynacol* 2008	Retruspective cohort cf colpoclcius	90	Prolift	24	97.8% vs 93.3%
Cosson	*Neurourol Urodyn* 2005 abs	Retrospective	687	Prolift	3	94%
Meschi	*Int Urogynecol J* 2007 abs	RCT cf fascial plication	38	AMS	3	NS
Davila	*J Minim Invasive Gynecol* 2005 abstract	Observational	55	Apogee	3	91%
Balakrishnan	*Int Urogynecol J* 2006 abs	Observational	70	Perigee	3	97%
Moore	*Int Urogynecol J* 2006 abs	Observational	42	Perigeec	12	93%
Dietz	*Int Urogynecol J* 2006 abs	Observational	48	Perigee	11	85%
Davila	*Int Urogynecol J* 2006 abs	Observational	298	AMS	9	96%

higher rates of pain but were found to be significantly longer than those with anterior meshes (42.1 [SD, 11.9] mm versus 25.8 [SD, 9] mm; $p < 0.0001$) and had a higher rate of "flat" pattern as opposed to the greater folding in the anterior compartment ($p = 0.013$). Native tissue repairs can be associated with intravaginal fibrosis and caliber reduction associated with excessive excising of vaginal mucosa.

Vaginal mesh exposure is a complication unique to pelvic floor reconstructive procedures that use synthetic mesh material. The average reported incidence after either trocar-guided system or self-tailored transvaginal mesh procedures is 12% [39]. Mesh exposures usually present with vaginal discharge, bleeding, pain, dyspareunia, or partner discomfort with intercourse. Average time to presentation is 5 months, ranging from a few days to 5 years postoperatively; the most consistently cited risk factors for transvaginal mesh complications are concomitant hysterectomy (OR 3.72–5.17) and smoking (OR 3.1 to 3.7) [40]. The management of mesh exposure varies depending on its presentation. The majority of small (<0.5 cm) vaginal mesh exposures can be managed conservatively with topical estrogenization and/or in-office trimming [41]. Often, minor exposures can be managed under local anesthesia in the office, and the number of revisions requiring main operating room time remains relatively low [32].

Patient response to implantation is essential to the clinical outcome of the TVM. A pre- and post-operative prospective trial evaluating sexual function with transvaginal mesh surgery for pelvic prolapse demonstrated no difference in validated questionnaire responses [42]. A second prospective trial in women undergoing trocar-based transvaginal mesh systems demonstrated improvements in physical function and no difference in dyspareunia rates [43]. In addition to these findings, we have observed increased rates in dyspareunia with native tissue repairs. A cohort study evaluating sexual function in patients undergoing anterior, apical, and posterior compartmental repairs without mesh augmentation demonstrated higher rates of dyspareunia with the group undergoing posterior repair [44]. Clearly, this demonstrates that other factors are involved other than placement of the mesh foreign body that leads to de novo dyspareunia, such as patient response to scarification, patient healing responses, and surgical technique. Tissue contraction with mesh placement is ultimately a natural process involved in the repair of POP and does not necessarily evoke sexual dysfunction.

A recent meta-analysis was conducted evaluating 37 randomized controlled trials comparing native tissue repair to TVM placement [39]. The findings demonstrated a statistically significantly higher rate

of both objective and subjective success of prolapse repair when comparing trocar-guided or self-tailored TVM to native tissue repair (OR 1.37 [95% CI 1.30–1.45] and OR 1.07 [95% CI 1.04–1.12], respectively). There was an RR of 0.66 (95% CI 0.54 to 0.81) when comparing the awareness of prolapse after native tissue repair (18.8%) to that of TVM (12.4%). De novo SUI and musculoskeletal pain were slightly higher in the TVM group (13.3%, 3.6%) than in the native tissue repair cohort (9.6%, 1.5%) with RRs of 1.39 (95% CI 1.06–1.82) and 2.44 (95% CI 1.03–5.74), respectively. However, no difference was found in rates of de novo dyspareunia between the TVM (8.8%) and native tissue (9.5%) groups (not statistically significant) [39].

Trocarless transvaginal mesh systems (such as Uphold Lite™ by Boston Scientific, Fig. 5) have demonstrated equivalent short-term efficacy with minimal morbidity [45]. In fact, in a recent retrospective cohort trial comparing the trocarless to trocar-based TVM systems, similar subjective success rates were reported (93.4 versus 81.6%, $p = 0.1$) with fewer surgical reinterventions (OR 0.17; 95% CI 0.05–0.62) for recurrent POP, latent SUI, and mesh complications [46]. A total of 115 patients underwent bilateral sacrospinous ligament utero-vaginal suspensions with a trocarless transvaginal mesh system [47]. At 23 months, 93% of patients obtained objective anatomic success and 95% reported subjective success. The reoperation rate for mesh-related complications was 3.4%, and 8% of patients experienced de novo dyspareunia. The aforementioned meta-analysis also reviewed the data associated with trocarless TVM systems [39]. The overall mesh exposure rates with trocarless TVM systems was 4.8%. The rates of de novo dyspareunia with native tissue repairs (9.5%) actually greatly exceed those associated with trocarless TVM systems (4.8%). Similarly, rates of de novo SUI for the native tissue (9.6%) exceeded those of trocarless TVM systems (8.7%). Incidences of de novo musculoskeletal pain (1.5%) and re-operation rates (4.8%) within the native tissue group were similar to those (3.1% and 5.8%, respectively) of the trocarless TVM group [39]. Such variances occur in outcomes and complications when comparing trocar-based to trocarless TVM systems, whereas the mesh material characteristics remain relatively similar, which would indicate that surgical technique and approach carry significant impact on these differences as opposed to the nature of the material used.

A total of 78.4% of Canadian pelvic floor surgeons feel that success rates of anatomical cure are higher with TVM systems than with traditional repair [48]. The 2010 Canadian Institute of Health

Fig. 5. Uphold Lite™ TVM.

Information Data documented 5000 annual procedures for POP repair, with 29% having used mesh and more than 25,000 annual procedures for SUI with 93% having used synthetic mesh mid-urethral slings. In general, vaginal mesh use in POP surgery results in a 30% reduction in the risk of recurrence. Patient characteristics that may render the surgeon to prefer mesh augmentation include (a) recurrent apical and/or anterior compartmental prolapse, (b) severe prolapse (stages III to IV), (c) uterine preservation, (d) older patients, (e) obese patients, (f) occupational risk factors (i.e., lifting), and (g) medical comorbidities.

In 2011, the FDA released an update to their advisory of 2008 indicating that serious complications associated with surgical mesh for transvaginal repair of POP are not rare. The FDA feels that there is not sufficient evidence to claim that POP repair with mesh is more effective than that of traditional repairs without mesh. During the period reviewed (January 2008 to December 2010), more than 225,000 transvaginal mesh procedures were performed for POP. Thus, the 1503 reported mesh complications represented only a 0.67% ($^{1,503}/_{225,000}$) overall mesh complication rate with mesh the placed through transvaginal mesh systems in that period. In addition, the mesh complication rate for tension-free vaginal slings was 0.021% during the same timeframe. These are both very acceptable surgical mesh complication rates.

The most commonly reported complications associated with transvaginal mesh surgery for POP (for all manufacturer's prolapse mesh) according to the 2011 FDA Advisory Update include (a) mesh exposure, (b) pain, (c) infection, (d) bleeding, (e) dyspareunia, (f) visceral injury, (g) lower urinary tract symptoms, (h) recurrent prolapse, (i) neuromuscular problems, (j) vaginal scarring, and (k) emotional issues. Recommendations were made to undertake mesh augmentation only after weighing the risks and benefits and to recognize the permanency of mesh implantation with implications of subsequent surgical technical difficulty for revision or removal.

One must compare the complications of transvaginal mesh systems used for VVP surgery to those of traditional repairs and dissect which are truly attributable to the mesh material itself or the associated tools in each system, which elicit a complex interplay of various patient and surgical factors, and which are due to the need for recurrent surgery to correct an identifiable issue. Before doing so, we must understand the nature of and long-term experience with a synthetic mesh placed intra-abdominally as a bridging mechanism for the repair of VVP.

The sacral colpopexy was developed in 1962 by Lane, and it creates a mesh bridge between the vaginal vault and the sacrum. It is a procedure that requires an abdominal approach to secure two strips of the mesh on the anterior and posterior walls of the vagina to support it to a strong ligament on the sacral surface. Extensive retroperitoneal dissection, mobilization of the bowel, avoidance of prominent presacral vessels, identification of ureteric course, burying of the mesh under peritoneal cover, and potential concurrent hysterectomy are all involved in the procedure. Traditionally, it has been performed through a laparotomy, but more minimally invasive approaches are currently used. Regardless, it has been a procedure requiring hospital stay and carrying significant potential morbidity but demonstrating durable results. A comprehensive review of 98 studies with a 3-year follow-up in 2004 demonstrated surgical success rates between 78% and 100% [49]. The reoperation rate was 4.4% (0–18.2%), and overall mesh exposure was 3.4% (0.5–5.6%). However, when the type I macroporous polypropylene mesh was evaluated in isolation, the risk of mesh exposure was only 5 in 1000 [49]. Short-term complications included urinary tract infection (10.9%), hemorrhage (4.4%), cystotomy (3.1%), bowel injury (1.1%), ureteral injury (1.0%), ileus (3.6%), and thromboembolism (3.3%). Long-term complications included small bowel obstruction (1.1%) and incisional hernia (5.0%). Sexual function parameters after sacral colpopexy have been shown to all significantly improve postoperatively. These include (i) vaginal symptoms interfering with sex (7.1% versus 30.4%, $p < 0.001$), (ii) incontinence restricting sexual function (3.1% versus 10.3%, $p = 0.003$), (iii) avoidance of sex due to bulge (45% versus 47.8%, $p < 0.001$), and (iv) intercourse limited by pain (21% versus 38.8%, $p < 0.001$) [50].

Long-term success is demonstrated as 95% at 3 years, 84% at 5 years, and 74% at 14 years [51]. Three randomized trials have compared sacral colpopexy to sacrospinous vaginal vault suspension, the previously accepted gold standard for apical vaginal vault suspension. Lower risk of recurrence (RR 0.23; 95% CI 0.07–0.77) and less postoperative dyspareunia (RR 0.39; 95% CI 0.32–0.95) were consistently shown with sacral colpopexy [52–54]. The laparoscopic version (see Fig. 6) has also shown high short-term success rates of 97% in 24 months [55] and 79% at 5 years [56]. A meta-analysis

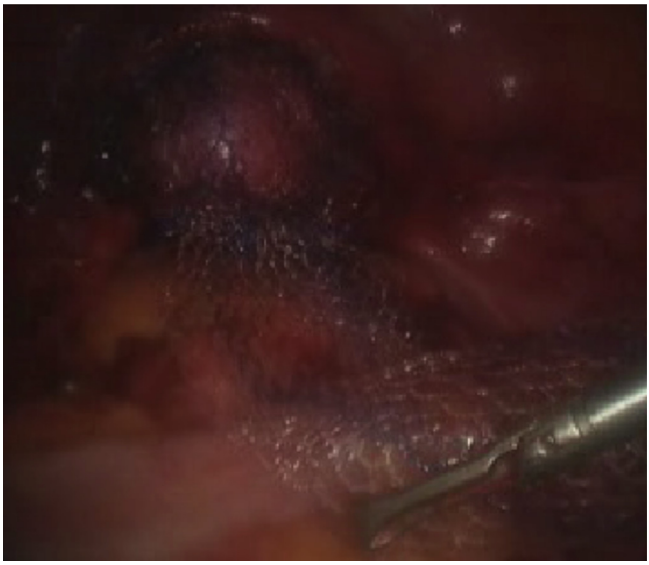

Fig. 6. Laparoscopic sacral colpopexy.

involving 12 studies and 4757 patients comparing open to laparoscopic sacral colpopexy discovered equivalent effectiveness in cure rates and risk of recurrence, with the minimally invasive counterpart being attributable for a lower transfusion rate (OR 0.41, 95% CI 0.20–0.83), a shorter length of hospital stay (mean −1.57 days, 95% CI −1.91 to −1.23), less blood loss (mean −113.27 cc, 95% CI −163.67 to −62.87), and a slightly longer operative time (mean 87.47 min, 95% CI 58.60 to 116.34) [57]. In fact, when randomized for a 2-year period to trocar-based transvaginal mesh systems in one study, laparoscopic sacral colpopexy reportedly had similar satisfaction rates but less risk of reoperation for recurrent POP, SUI, or mesh complication (5 versus 22%, $p < 0.006$) [58].

With an armamentarium of surgical tools previously available, the pelvic floor surgeon would need to decide which technique to use. Once it was felt appropriate that mesh augmentation was necessary, the mental decision algorithm used would include multiple factors including both patient-based and surgical technique-based factors. Primarily, the patient factors age and medical comorbidities would enable a choice between vaginal and abdominal approaches, with the latter reserved for slightly younger and healthier patients. Extensive patient counseling would be required to elucidate the established yet invasive nature of the sacral colpopexy and the novel yet promising techniques of the transvaginal approaches. Whether or not the patient had prior mesh procedures would also enable a surgeon-based informed decision, as repeat procedures of the same type tend to be more technically demanding. Finally, surgeon experience and comfort with each individual procedure remains a key component to the decision-making process.

Complication rates of mesh compared to those of native tissue repair for prolapse

The 2011 FDA advisory reported pain or dyspareunia as the most frequently cited cause of complications [($^{590}/_{1503}$(38.6%)] with the use of transvaginal mesh for prolapse surgery. A 2013 Cochrane review evaluated 56 trials including 5954 patients for the use of mesh in pelvic floor surgery [59]. The trials that evaluated the anterior vaginal compartment demonstrated no removal of mesh for pain or dyspareunia. This in itself is the verification of the drastic contrast in clinical results that we see from different trials, from different surgeons, and with different patients. There clearly are too many confounding variables (mesh properties, patient tissue-healing properties, patient comorbidities, and

surgical technique alterations) to attribute any potential postoperative complication solely to the mesh itself.

Sexual function has been evaluated before and after reconstructive procedures, and the vast majority of studies demonstrate improved sexual function postoperatively. In a randomized trial evaluating sacral colpopexy with or without concurrent incontinence surgery, sexual function-validated questionnaires were used before and after surgery. Dyspareunia rates were reduced from 39.9% to 21.6% 1 year postoperation, and more women were sexually active (76.3% versus 66.1%) [50]. Similarly, in patients undergoing transobturator mesh implantation, pain-free intercourse improved at 2 years postoperation ($p = 0.023$), despite the transient increase at 3 months [60]. This indicates an effect of healing and scarification on sexual function and not necessarily the mesh itself. Supporting this conclusion is a meta-analysis of studies comparing sexual function in patients undergoing anterior compartment mesh implantation to those with traditional colporrhaphy. There was no difference between the two groups in neither a worsening in sexual function nor an increase in postoperative or de novo dyspareunia [61].

Pain following pelvic floor reconstructive surgeries generally follows two presentations: painful intercourse (dyspareunia) and chronic pain without specific provocation. Predating transvaginal mesh procedures postoperative dyspareunia was predominantly due to scarring at the fourchette of the vagina, potentially related to overzealous plication of the levator ani muscles. Lately, with improved apical suspension techniques available (including transvaginal mesh), this has become less of an issue, as there is less reliance upon genital hiatus reduction for presumed reduction of prolapse recurrence risk. The dyspareunia associated with transvaginal mesh is more likely to be related to scarring around the arms that provide apical support to either the sacrospinous ligaments or proximal insertion into the arcus tendineus. Such dyspareunia usually occurs with less frequency than that associated with levatorplasty, but because there is an associated foreign body, more attention may be paid to this by the medical literature, patients, and indeed legal representatives. We know that rates of de novo dyspareunia are equivalent between TVM implants and native tissue repairs [39]. In fact, when performing isolated repairs of posterior compartmental defects through either a midline plication or site-specific approach, the mean postoperative rates of de novo dyspareunia approach 18% [62]. This may be increased further when levatorplasty is performed. Again, these rates of de novo dyspareunia far exceed any rate experienced in the trials of TVM systems. Clearly, other factors associated with vaginal axis, elevator strain, and scarification play roles in the development of de novo dyspareunia as opposed to the nature of implanted mesh materials.

In comparing complications of traditional procedures for pelvic floor repair to those associated with mesh use, one must evaluate the available literature and assess whether or not this proves to be clinically significant despite appropriate statistical analyses. For example, operating time seems to be significantly reduced in statistical analyses when comparing the time for traditional native tissue repairs to the time for polypropylene mesh repair (−16 min, 95% CI −18 to −13) [34,63–65]. Several studies demonstrated an increase in blood loss of 35 ml (95% CI −47 to −23) with mesh use as compared to that in native tissue repairs [34,63,65,66]. It is difficult to theorize and demonstrate that an additional 16 min of operating time and 35 ml of blood loss could have clinically significantly detrimental impacts on patient outcomes.

A comparison of validated quality of life questionnaires used postoperatively between the mesh and traditional procedures identifies similar long-term outcomes, thus diminishing the argument of maintained adverse complications. The PFIQ-7 (Mean difference 9, 95% CI −4 to 22) and PFDI-20 (Mean difference 11, 95% CI −3 to 25) failed to demonstrate a difference in quality of life between the two groups [63]. Use of the UDI (Mean difference 0.00, 95% CI −1.57 to 1.57) detected no difference between the groups using the UDI [34,67]. Finally, the P-QOL (Mean difference 0.22, 95% CI −0.21 to 0.65) was also unable to demonstrate a difference in quality of life outcomes [68].

De novo SUI has been estimated to occur in 31% of patients with severe POP undergoing surgical correction [75]. There appears to be a lower rate of de novo SUI in women undergoing anterior colporrhaphy than in those undergoing transvaginal polypropylene mesh for anterior compartment prolapse ($^{26}/_{324}$, 8% versus $^{41}/_{320}$, 13%) (RR 0.6, 95% CI 0.4–0.9) [34,64,66,68]. However, further incontinence surgery was only performed in $^{15}/_{368}$ (3.1%) women in the native tissue repair and $^{12}/_{380}$ (4.1%) after polypropylene mesh augmentation. These data need to be interpreted with caution, as

there existed variations in concurrent surgeries, and the increase in 1% requiring incontinence surgery does not likely carry any clinical significance.

Qualified urogynecologists and pelvic floor reconstructive surgeons often argue that the most significant complication in prolapse surgery is recurrence. The literature seems to be clearly attributing a higher risk of this complication to traditional repairs. Subsequent surgery to repair failures inherently possesses a higher risk of intraoperative complication and subsequent failure. Multiple patient-based and surgical technique-based factors abound, which limit this interpretation, and it would be inherently feasible to conclude that this risk could not solely be attributed to the mesh alone. Data from 8 of 10 trials on transvaginal polypropylene mesh demonstrated a higher recurrence rate on examination following anterior colporrhaphy ($^{220}/_{478}$, 46%) than any transvaginal polypropylene mesh ($^{69}/_{498}$, 14%) (RR 3.3, 95% CI 2.6–4.2) in the management of anterior compartment prolapse [34,63,64,66,68,70–72]. Results from five trials demonstrated that significantly more women had an awareness of prolapse (subjective failure) after the anterior colporrhaphy ($^{118}/_{430}$, 27.4% as compared to $^{86}/_{436}$, 18.3%) than after anterior compartment graft repair (RR 1.5, 95% CI 1.2–1.9) [34,65,66,73,74]. To reiterate, a recent meta-analysis was conducted evaluating 37 randomized controlled trials comparing native tissue repair to the TVM placement [39]. The findings demonstrated a statistically significantly higher rate of both objective and subjective success of prolapse repair than trocar-guided or self-tailored TVM to native tissue repair (OR 1.37 [95% CI 1.30–1.45] and OR 1.07 [95% CI 1.04–1.12], respectively). There was an RR of 0.66 (95% CI 0.54 to 0.81) when comparing the awareness of prolapse after native tissue repair (18.8%) to that after TVM (12.4%).

Whether mesh is an independent risk factor for surgical complication

We have now extensively determined the evolution of the use of transvaginal mesh and its inherent potential complications in pelvic floor reconstructive surgery from perspectives of both prolapse and SUI. Therefore, it becomes necessary to formulate a global assessment and evaluation of whether or not specific mesh characteristics contribute to determining whether there exists an inherent risk of overall complication with the use of TVM and whether there are clinical implications that could facilitate in optimizing patient outcome and/or management in such potential complications. It would appear a difficult task, as individualization remains a common theme in patient care. One must contemplate whether addressing the issue of transvaginal mesh being associated with a materially increased risk of complication as compared to traditional approaches renders assistance in determining causality or likelihood of any patient's potential complication.

Epidemiological data evaluating pelvic floor reconstructive procedures, and in particular those involving TVM, are evolving. The recent meta-analysis conducted by Maher reviewed 37 level I randomized controlled trials comparing the use of TVM to native tissue repairs. The findings have been reviewed above in that they found a statistically significantly higher rate for both objective and subjective success rates of prolapse repair when comparing trocar-guided or self-tailored TVM to native tissue repair (OR 1.37 [95% CI 1.30–1.45] and OR 1.07 [95% CI 1.04–1.12], respectively). There was an RR of 0.66 (95% CI 0.54–0.81) when comparing the awareness of prolapse after native tissue repair (18.8%) to that of any form of TVM (12.4%). De novo SUI and musculoskeletal pain were slightly higher in the TVM group (13.3%, 3.6%) than in the native tissue repair cohort (9.6%, 1.5%) with RRs of 1.39 (95% CI 1.06–1.82) and 2.44 (95% CI 1.03–5.74), respectively. However, there was no difference found in rates of de novo dyspareunia between the TVM (8.8%) and native tissue (9.5%) groups (not statistically significant) [39]. These brief categories of complication are reviewed to outline the point that these trials were powered from a statistical perspective to evaluate outcomes of anatomical cure rates and quality of life parameters. None of these trials were powered to specifically compare rates and patterns of complications, hence rendering the ability to allocate causality quite poor. This is the fundamental fault with the literature that we have available to us as pelvic floor reconstructive surgeons. The available evidence is insufficient to demonstrate a significant RR of each complication occurring and inherent causality. Indeed, these results in the literature lack in optimizing the management of individual clinical cases.

Practice points

- Pre-existing sexual dysfunction does not need to be a contraindication to transvaginal mesh placement for the correction of vaginal vault prolapse.
- Laparoscopic placement of mesh may result in lower recurrence risk than that placed vaginally for the management of vaginal vault prolapse.
- Evolution of graft materials and techniques needs to be continuously evaluated scientifically in an ongoing basis to optimize surgical repairs.

Research agenda

• A pelvic floor surgeon assesses 35 patients in her postoperative clinic. The first 34 of them have an optimal anatomical result without complication and two-thirds of them have undergone mesh augmentation. Patient number 35 presents 8 months after a transvaginal mesh procedure for recurrent pelvic organ prolapse. Her surgeon performs 15 such procedures annually. She is morbidly obese with reasonably controlled hypertension and adequate diabetic control. She has reduced her cigarette smoking to 5 per day, and her previous hysterectomy and suspension was 7 months before this recent procedure. She demonstrates an asymptomatic 4 mm anterior mesh exposure. What ultimately leads to the occurrence of this extrusion?

• It would appear that there exist multiple factors involved in the development of the mesh extrusion associated with this patient. Clinical entities that apparently contribute to this possible scenario include the following:

- **the relative lack of surgical expertise of her pelvic floor reconstructive surgeons**: she only performs 15 procedures per year; does this allow for adequate submucosal dissection into full-thickness planes for mesh placement and apical ligamentous access?
- **morbid obesity**: this contributes to poor tissue healing and suboptimal healing phase due to increased intra-abdominal pressure
- **smoking**: cigarette consumption clearly reduces the quality of type III collagen and promotes coughing, which increases intra-abdominal pressure
- **recent pelvic floor surgery**: she underwent her prior pelvic floor procedure only 7 months prior; perhaps, inadequate surgical site healing leads to the suboptimal conditions for her subsequent procedure
- **perioperative factors**: a subclinical hematoma was formed and subsequently became super infected or released to promote superficial separation of suture lines leading to the mesh extrusion
- **polypropylene mesh degradation**: would it be possible for the clinician managing this patient to allocate potential scanning electron microscopic surface cracking of the mesh as the ultimate culprit in this scenario?

• The aforementioned clinical entities demonstrate a typical scenario encountered in pelvic floor reconstructive surgery. We are infrequently clinically aware of the direct cause or causes motivating potential complications of our procedures but are ultimately faced with the medical directive of managing our patients. Each patient we manage brings forth a new constellation of contributory factors that ultimately contribute to their individual postoperative evolutions. The development of a potential mesh complication is far too complex and multifactorial to be able to allocate a single factor such as mesh degradation as the inciting factor that leads to it. We possess no insightful literature to decipher any possible single etiology of mesh complications, and we have no insightful literature to suggest that there are more optimal techniques than mesh augmentation that clearly reduce the risk of recurrence of either POP or SUI. This remains a clinical enigma, but mesh characteristics do not remain the isolated contributory factor.

Conflict of interest

None.

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