

Optimal repair of pelvic organ prolapse: the debate continues

Pelvik organ prolapsının optimal onarımı: tartışma devam ediyor

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ABSTRACT

As the need for durable pelvic organ prolapse (POP) repairs continues to increase, greater scrutiny has been placed on finding the optimal repair. Evidence-based literature indicates that the durability of standard (plication-type) repairs in the anterior compartment is suboptimal and that graft augmentation, especially with non-absorbable, synthetic mesh, may be superior. However, while appealing, the transvaginal mesh used for POP repair may be associated with adverse sequelae, such as erosion, extrusion, and infection. Additionally, there is concern regarding the potential long-term outcomes, such as dyspareunia, chronic pelvic pain, and vaginal distortion, which may occur even in the absence of frank extrusion. Recent warnings by the U.S. FDA among other groups regarding adverse events after transvaginal mesh implantation have fueled the debate even further. Our aim is to summarize the available literature regarding the available surgical options for the repair of POP.

Key words: Female; pelvic organ prolapse; postoperative complications; treatment outcome.

ÖZET

Pelvik organ prolapsının (POP) kalıcı onarımı için ihtiyaç artmaya devam ettiğinden, optimal onarım üzerine daha detaylı inceleme yapılmaktadır. Kanıta dayalı literatür ön kompartmandaki standart (pilikasyon tipi) onarımların kalıcılığının optimalin altında olduğunu ve, özellikle absorbe olmayan, sentetik meş bir graft ile güçlendirmenin, daha üstün olabileceğini göstermektedir. Bununla birlikte çekici olmasına karşın, POP onarımı için kullanılan transvajinal meş, erozyon, ekstrüzyon ve enfeksiyon gibi advers sekellerle ilişkili olabilir. Ek olarak, cinsel ilişki sırasında ağrı, kronik pelvis ağrısı ve belirgin bir ekstrüzyon olmasa bile görülebilen vajina distorsiyonu gibi potansiyel uzun dönem sonuçlar hakkında kaygılar vardır. Transvajinal meş implantasyonundan sonra advers olaylarla ilgili diğer gruplar arasında ABD FDA'nın yakın zamandaki uyarıları tartışmayı daha da alevlendirmiştir. Amacımız POP'un onarımı için var olan cerrahi seçeneklerle ilişkili mevcut literatürü özetlemektir.

Anahtar sözcükler: Kadın; pelvik organ prolapsı; postoperatif komplikasyonlar; tedavi sonucu.

Introduction

Pelvic organ prolapse (POP) is a prevalent condition. An analysis of women who participated in the 2005–2006 National Health and Nutrition Examination Survey revealed the weighted overall prevalence of POP to be 2.9%.^[1] This prevalence increased with age, from 1.6% in women aged 20–39 years to 4.1% in women aged 80 years or older. Using recent population projections from the U.S. Census Bureau, Wu et al. estimated that the number of women with POP in the U.S. alone will increase by nearly 50% from 3.3 million to 4.9 million from the years 2010 to 2050.^[2] Some projections estimate that as many as 9.2 million women in the U.S. will have prolapse by the year 2050. As may be expected, the demand for services to

care for pelvic floor disorders is also likely to increase by 45% by the year 2030.^[3]

The cost of treating POP is also significant. In an analysis of the 1997 National Hospital Discharge Survey, Subak et al.^[4] estimated that the direct costs of prolapse surgery were 1012 million dollars and that this total would increase by 52% to 1543 million dollars if all operations were reimbursed by non-Medicare sources. Furthermore, women with POP have an impaired quality of life (QoL). Based on the Short Form Health Survey and the Pelvic Floor Distress Inventory–20 QoL scale, women with advanced POP seeking surgical correction were significantly more likely to feel self-conscious and less likely to feel physically and sexually attractive than normal controls.^[5]

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Because POP is clearly a prevalent and costly condition that greatly and negatively impacts a woman's well-being and QoL, the demand for efficacious, safe long-term surgical options will only continue to increase. The chief controversy in POP repair today is whether to proceed with traditional repairs or engage in augmented repairs, possibly with the addition of synthetic mesh. The recent debates and subsequent warnings regarding the complications of transvaginal mesh implantation for POP repair have shed an intense spotlight on the field of pelvic floor reconstruction. These questions are not easily answered; however, our objectives are to provide evidence-based information regarding POP repair and to attempt to reach conclusions regarding the roles of the different procedures in repairing pelvic floor defects.

Anatomy of pelvic prolapse

Before diving into an evaluation of the surgeries for POP, first describing the normal anatomy and subsequent anatomic variations responsible for POP is important. The pelvic organs are held in position by connections between the bony pelvis, musculature, and extensive connective tissue. A 3-level system is useful when considering normal vaginal support cephalad to caudad.^[6] The cardinal ligaments anchor the upper vagina and cervix to the pelvic sidewall (Level I support), while in the mid-vagina, the vesicopelvic ligament extends medially from the arcus tendineus fasciae pelvis (ATFP) to support the bladder base and anterior vaginal wall (Level II support). In the posterior compartment, level II support is provided by the direct attachment of the posterior vaginal wall laterally to the levator ani fascia. In the anterior vagina, the urethropelvic ligaments provide support to the urethra (Level III support). In the posterior compartment, the vagina is separated from the rectum by the rectovaginal septum, which is fused distally with the urogenital diaphragm and perineal body (Level III support).^[7] The septum is attached laterally to the arcus tendineus fasciae rectovaginalis in the distal one-third of the vagina and to the ATFP in the proximal two-thirds.^[6,8] Proximally, the septum fuses with the uterosacral ligaments laterally and the pericervical ring centrally.

Anterior compartment prolapse arises when the bladder and urethra herniate through a defect in the pubocervical fascia into the potential space of the vagina (Figure 1).^[9] While the loss of urethral support (Level III) may result in stress urinary incontinence (SUI), the loss of bladder support (Level II) may result in a central, lateral, or combined defect (often called a cystocele). Attenuation in the pubocervical fascia in the setting of an intact lateral attachment of the vesicopelvic ligament to the ATFP produces a central anterior compartment defect, while a lateral defect results from an intact pubocervical fascia and disrupted attachment of the vesicopelvic ligament to the ATFP. Central defects are often associated with the loss of Level I support at the cardinal ligaments, and patients may present with a concomitant enterocele. The traditional repair of a central cystocele has involved a plication of the pubocervical fascia in the midline

(anterior colporrhaphy) (Figure 2), while a lateral cystocele is repaired with a reattachment of the vesicopelvic ligament to the pelvic sidewall (paravaginal repair). The attachment of an interposition graft to the ATFP or obturator internus fascia has the potential to address central and lateral defects simultaneously.

As in the anterior compartment, a posterior compartment defect (rectocele) in the rectovaginal septum may be central, lateral, or combined. Likewise, the proximal detachment of the rectovaginal septum from the uterosacral ligaments may be associated with an enterocele, while the disruption of the distal attachment to the perineal body (Level III) may result in a perineocele. A reapproximation of the perineal body (perineorrhaphy) addresses a perineal weakness, while a plication of the rectovaginal fascia (posterior colporrhaphy) repairs a rectocele. A "site-specific" rectocele repair involves the reapproximation of discrete rents in the rectovaginal fascia instead of a midline plication.^[10] The attachment of a graft to the fascia of the levator ani may theoretically address all variations of a rectocele. Finally, vaginal suspension from the sacral promontory (abdominal sacral colpopexy; ASC), uterosacral or sacrospinous ligaments (sacrospinous ligament fixation; SSLF), or the iliococcygeus fascia may be performed to repair concomitant apical compartment defects (vaginal vault prolapse).

Outcomes of traditional POP repair

One of the reasons behind the debate regarding optimal POP repair is the perceived deficiency of traditional POP repairs, and there is now sufficient evidence in the literature to lend credence to these perceptions. In an analysis of approximately 400 women in the Kaiser Permanente Northwest database, Olson et al.^[11] found that nearly 30% underwent reoperation for incontinence or prolapse and that the time intervals between procedures decreased with each subsequent repair. Clark et al.^[12] determined that 13% of these women underwent reoperation within 71



Figure 1. Anterior compartment prolapse.

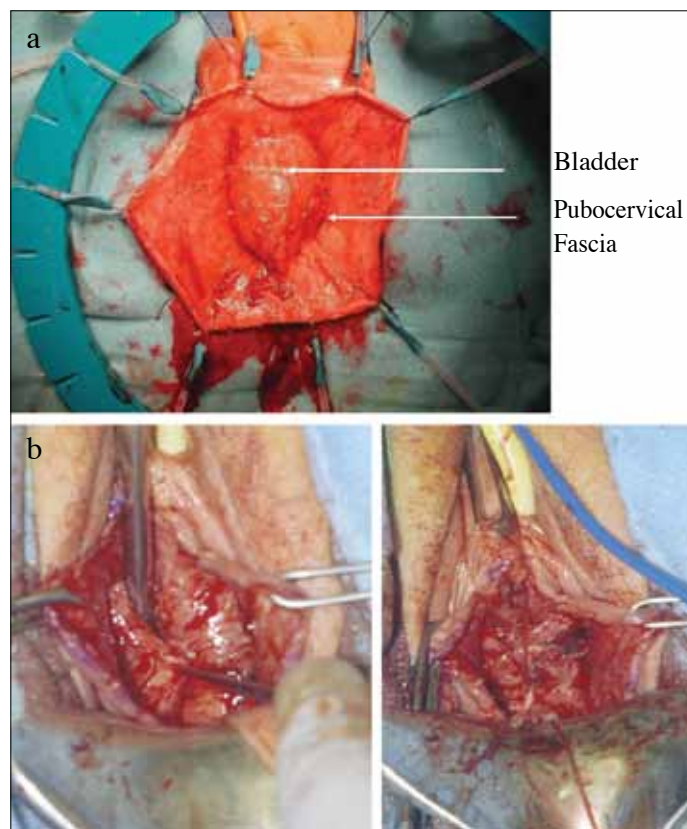


Figure 2. Traditional repair of a central cystocele (anterior colporrhaphy). (a) The procedures include complete detachment of the bladder from the vaginal wall and exposure of the pubocervical fascia and (b) plication of the pubocervical fascia in the midline.

months and that the risk of reoperation increased from 12% to 17% in those women who had already failed a previous procedure for SUI or POP. While 60% underwent reoperation at the same anatomic site, 32.5% of the women developed an occult support defect and underwent reoperation at a different site.

The reports of success after cystocele repair have been inconsistent. While some reports cite low long-term recurrence rates (> 5%) after anterior colporrhaphy, most publications cite > 40% anterior compartment recurrence rates.^[13-16] Although no long-term prospective trials are available, anatomic cure rates after isolated rectocele repair are relatively high and typically exceed 85%.^[10, 17-19] These figures suggest that plication-type repairs in the anterior compartment may be associated with high rates of recurrence, but these results should be interpreted cautiously. As in the SUI literature, published outcomes are often difficult to compare due to variations in the patient populations, surgical techniques, definitions of success and failure, and indications for repair. The outcomes of POP repair may be further confounded by concomitant repairs in other compartments.

ASC is considered the gold standard for the repair of POP in the apical compartment due to its low recurrence rate at the apex; however, these repairs are most commonly augmented with synthetic mesh. Transvaginal vault suspensions have likewise been associated with durable outcomes. Nygaard et al.^[20] assessed the ASC outcomes in MEDLINE articles from 1966 to 2004, and the follow-up for most studies ranged from six months to three years. When defined as lack of postoperative POP in the apical compartment and no POP in any compartment, the success rates ranged from 78-100% and 58-100%, respectively. The median reoperation rate for recurrent POP in the studies that reported

Total Prolift: Mesh Placement

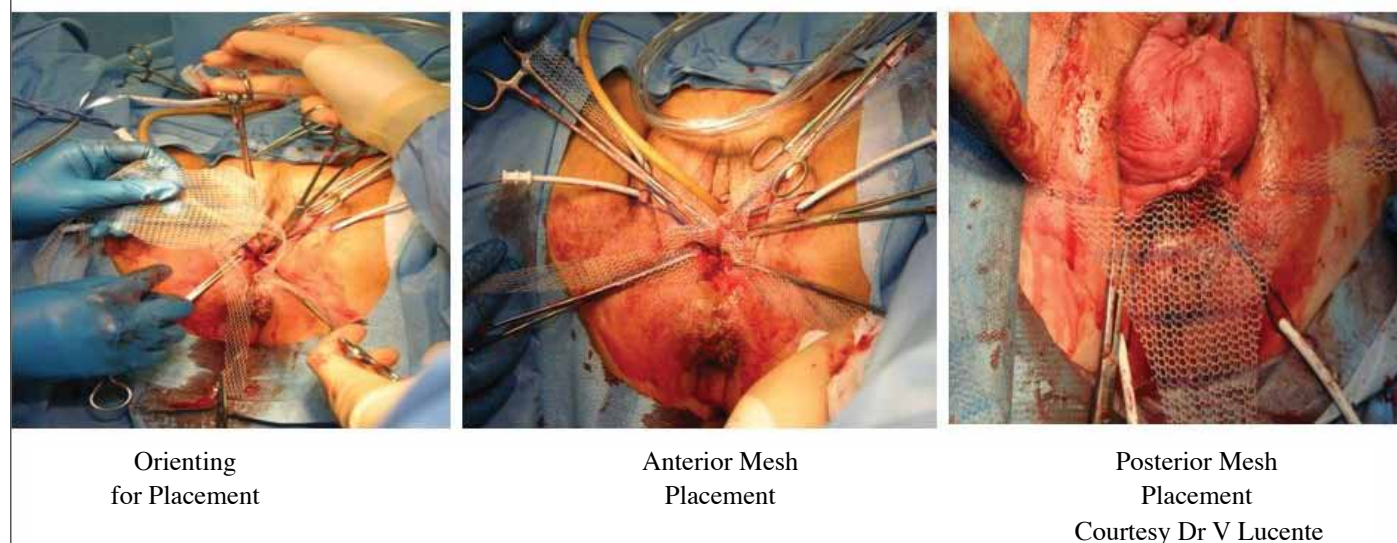


Figure 3. Combined mesh repair for simultaneous anterior and posterior compartment defects.

these outcomes ranged from 0–18.2% (median 4.4%). In a 2010 Cochrane review, ASC was associated with lower rates of recurrent vaginal vault prolapse and less dyspareunia compared with SSLF, but there was no statistically significant difference in the re-operation rates for prolapse between the two procedures.^[21] Conversely, SSLF was quicker and less expensive to perform and enabled women to return earlier to their daily living activities. Additionally, in another MEDLINE review from 1996 to 2010, Petri and Ashok^[22] confirmed that SSLF provides good long-term objective and subjective outcomes and improves the QoL of women with POP. The complication rates of SSLF were comparable with those of ASC and much less than those of transvaginal mesh procedures. Finally, Maher et al.^[23] randomly assigned 95 women to undergo ASC or SSLF. At a mean of two years, the subjective success rate was 94% and 91% in the ASC and SSLF groups, respectively, while the objective success rate was 76% and 69%, respectively. As previously mentioned, the ASC was associated with a significantly longer operating time, a slower return to daily living activities, and a greater overall cost than the SSLF. Both surgeries significantly improved the QoL of the patients.

Interposition grafts for POP repair

Because plication and reapproximation of potentially weak tissue, mainly in the anterior compartment, have been associated with widely variable degrees of success, novel techniques have been proposed to improve pelvic support. Taking a cue from inguinal hernia surgery, interposition grafting has become an attractive method to replace or augment standard plication-type repairs. One of the advantages of graft augmentation is that both central and lateral compartment defects can be repaired simultaneously by recreating entire pubocervical and rectovaginal connective tissue layers from pelvic sidewall to sidewall. Additionally, a graft may be anchored to an apical landmark, such as the SSL, or placed suburethrally to provide concomitant Level I and III support, respectively. Numerous biologic allografts and xenografts have been described for the repair of anterior and posterior compartment defects, and despite variations in the techniques and definitions of success, short-term anatomic cure rates have approached 90%.^[24] Unfortunately, the cure rates appear to decline with longer follow-up periods, mirroring the experience with many biologic materials for the surgical correction of SUI.^[25]

As with pubovaginal and midurethral (MUS) sling surgery, synthetic polymers have been used for the interposition repair of POP. Julian^[26] was the first to describe a polypropylene (Marlex) graft that was sutured to the obturator/levator fascia to address an anterior compartment defect. At two years of follow-up, none of the women had a recurrence of the POP. Since then, several authors have reported promising outcomes after interposition procedures employing synthetic materials in anterior and posterior compartment repairs.^[24] Because synthetic meshes may differ significantly by weave, fiber type, pore size, weight, and stiffness, the positive and adverse outcomes obtained with each synthetic may differ

substantially. Once again, an extensive experience with sling surgery has resulted in the conclusion that a macroporous, monofilament, polypropylene mesh has the most favorable biocompatibility profile of all of the current synthetics. The absence of interstitial pores allows native collagen ingrowth, and the large pores allow entry of macrophages and other immune mediators. However, even materials with the most favorable biocompatibility profiles, such as polypropylene, may induce a persistent chronic inflammatory and foreign body response long after implantation.^[27]

Commercial POP repair kits

Owing to the popularity and success of the “all-inclusive” MUS kits, the interest in POP kits has peaked in the last decade. These kits combine mesh for the repair of an anterior or posterior compartment defect, trocars for subcutaneously tunneling the mesh arms, and suture-capturing or -anchoring devices to provide simultaneous apical support (Figure 3). The concept behind the kits is the provision of a route for a “minimally invasive,” mesh-augmented, transvaginal POP repair using easily identified landmarks. The first kit, the posterior intravaginal slingplasty (PIVS; U.S. Surgical, Tyco Healthcare Group, Norwalk, CT), achieved Level I support by tunneling a nylon tape through the ischio-rectal fossa into an incision in the posterior vaginal fornix.^[28] The tunnelers exited through the iliococcygeus muscle near the ischial spines, and the deployed tape was sutured to the vaginal vault. After more than four years of follow-up, an apical recurrence was reported in only 6%, but mesh extrusion was observed in 5.3% and two intraoperative rectal perforations were reported. Several additional studies have since reported severe adverse outcomes after the PIVS, including retropubic abscess, vesicovaginal and rectovaginal fistulae, and sinus formation, with the reoperation rates for complications approaching 25%.^[24]

Several other manufacturers have introduced prolapse kits into the global marketplace. While a detailed discussion of specific kit properties is beyond the scope of this review, a comparison of mesh kits is available elsewhere.^[24] All of the currently available kits are constructed from Type I, macroporous, monofilament polypropylene, and as mentioned previously, mesh rigidity, mesh weight, mesh thickness, and total mesh load have not been investigated to date as predictive factors for efficacy or effective tissue integration. These properties may eventually play a significant role in the option to use one product over another in POP repair or to use a mesh interposition at all.

For the placement of mesh in the anterior compartment, two sets of trocars are typically advanced percutaneously through the obturator foramen into a vaginal incision. The superior trocars exit near the bladder neck, while the inferior trocars exit near the ischial spine. The mesh arms are advanced through the skin with the trocars until the body of the mesh is seated under the anterior compartment in a tension-free, wrinkle-free position. For posterior compartment repair, one set of trocars is passed through bilateral perianal incisions to exit near the ischial spine, and the

proximal part of the mesh is positioned as above. The second generation of kit procedures offers several modifications. All dissection is performed under direct vision, and there is no percutaneous mesh advancement. Additionally, suture passers or specialized trocars attach the mesh arms to the SSL for the repair of a concomitant apical defect. The anatomic outcomes associated with the use of transvaginal kit repairs have been promising in the short-term. A recent meta-analysis encompassing 30 studies with 2,653 patients calculated the objective success rates to be 87-95% for different kits.^[29]

Outcomes of standard vs. augmented POP repairs

Several studies have compared the outcomes of standard and augmented anterior compartment repairs. In a 2010 Cochrane Database review, anterior colporrhaphy was associated with more recurrent cystocele formation than standard repairs augmented with polyglactin mesh or porcine dermis inlay, polypropylene mesh as an overlay, or armed transobturator mesh.^[21] The review also emphasized that, although some data were limited, there were no differences in the subjective outcomes, QoL data, *de novo* dyspareunia, SUI, and reoperation rates for prolapse or incontinence between the augmented and standard procedures. Guerette et al.^[30] determined that the anatomic success rate at two years of follow-up was similar in women undergoing bovine pericardium interposition and those undergoing anterior colporrhaphy alone. At 12 months of follow-up, Carey et al.^[31] observed an anatomic success rate of 81% in women undergoing polypropylene mesh augmentation vs. 65.6% in the no-mesh group, with a high level of postoperative satisfaction and QoL improvement observed in both groups. Finally, a meta-analysis encompassing 49 studies and more than 4,500 women determined that nonabsorbable synthetic mesh had a significantly lower objective anterior compartment recurrence rate (8.8%) than either absorbable synthetic mesh (23.1%) or biological graft (17.9%).^[32]

RCTs comparing outcomes after a mesh kit repair and standard anterior colporrhaphy continue to emerge. Nguyen and Burchette^[33] cited a significantly higher anatomic success rate (89%) 12 months after Perigee (AMS Inc., Minnetonka, MN) compared with 55% after anterior colporrhaphy. The QoL indices were improved in both groups. More recently, Altman et al.^[34] randomly assigned 389 women to undergo anterior repair with a mesh kit or traditional colporrhaphy. At one year, the primary outcome (anatomical stage 0-1 per the Pelvic Organ Prolapse Quantification system and the subjective absence of vaginal bulging symptoms) was significantly more common in the women treated with transvaginal mesh repair (60.8%) than in those treated with colporrhaphy (34.5%).

There are fewer evidence-based studies comparing the outcomes after standard posterior colporrhaphy and graft-augmented repair.^[21] Sand et al.^[35] found that posterior compartment recur-

rence was similar after posterior colporrhaphy with or without polyglactin mesh reinforcement. Likewise, Paraiso et al.^[36] found that the addition of porcine small intestinal submucosa did not lead to improved anatomic outcomes after standard posterior colporrhaphy or site-specific repair. After one year, women undergoing graft augmentation had a significantly greater anatomic failure rate than those who underwent posterior colporrhaphy alone, but there were no differences in the subjective prolapse symptoms between the groups.

Complications of POP repairs

All POP repairs are associated with varying, but mostly minimal, degrees of significant intraoperative bleeding and inadvertent pelvic organ injury. The incorporation of synthetic grafts and the use of trocar-guided kits in particular may be associated with additional and unique complications. A recent meta-analysis of more than 70 studies and case reports assessed the rates of adverse events associated with graft use.^[37] These adverse events included bleeding (0-3%), visceral injury (1-4%), urinary tract infection (0-19%), graft extrusion (0-30%), and fistula formation (1%). These data were insufficient regarding sexual, voiding, and defecatory dysfunctions. Another recent systematic review identified 110 MEDLINE studies that reported on graft erosion, wound granulation, and/or dyspareunia after prolapse repair using graft materials.^[38] The rate of graft erosion was 10.3% (range 0-29.7%; synthetic 10.3%, biologic 10.1%), and the rate of wound granulation was 7.8% (range 0-19.1%; synthetic 6.8%, biologic 9.1%). Dyspareunia was described in 70 studies with a rate of 9.1% (range 0-66.7%; synthetic 8.9%, biologic 9.6%). For comparison, ASC has been associated with a 3.4% incidence of mesh erosion.^[20] Pelvic pain and dyspareunia in women with POP may be multifactorial and may persist or worsen regardless of the type of repair performed.^[39]

As the use of synthetic mesh for transvaginal POP repair has increased exponentially, the reporting of complications after these surgeries has been closely scrutinized. In the last few years, the French Health Authorities, the Society of Gynecologic Surgeons Systematic Review Group, and the U.S. Food and Drug Administration have all issued warnings regarding the unique complications associated with mesh use in the pelvis.^[24] The FDA recommended that surgeons do the following: (1) obtain specialized training for each mesh placement technique; (2) inform patients that surgical mesh implantation is permanent and that some mesh complications may require additional surgery; and (3) provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available. More recently, in July 2011, the FDA released an update to their 2008 warning in response to the reporting of more complications associated with transvaginal mesh placement.^[40] Although the issue continues to undergo investigation, transvaginal mesh may ultimately undergo device reclassification and require additional post-market surveillance.

Analysis and conclusions

The optimal repair of pelvic organ prolapse is a lofty goal. The ideal procedure should correct the inherent weaknesses in the woman's pelvic floor and minimize the chance of long-term anatomic recurrence in the corrected compartment. Additionally, the surgical repair should be safe and not be associated with significant immediate and long-term morbidity. Furthermore, the procedure should improve the woman's quality of life and the subjective symptoms of pelvic floor dysfunction. Because there are multiple options for surgical POP correction, the debate over the optimal repair persists. There are several facets of the debate that usually lead to agreement. First, standard anterior colporrhaphy has a high rate of anatomic recurrence but improvements in the subjective indices and QoL similar to those after augmented repairs. Second, biologic or synthetic interposition grafting in the anterior compartment significantly reduces anatomic recurrence rates, and non-absorbable synthetic mesh is associated with significantly lower anatomic recurrence rates than other grafts. Third, there is currently insufficient information to support interposition grafting of any type in the posterior compartment. Fourth, in experienced hands, both ASC and SSLF produce a durable resolution of apical prolapse, although SSLF is less invasive and quicker to perform and may lead to a more rapid return to daily activities. Although not a part of this review, the rapid advancement in laparoscopic and robotic-assisted technology may lead to a narrowing of the time and morbidity gap between transvaginal and transabdominal repairs of apical prolapse.

While augmented repairs may certainly be effective in minimizing anatomic POP recurrence, the U.S. FDA recently reminded the public that these repairs are associated with unique and serious complications. Although pelvic surgeons are already familiar with trocar injuries to neurovascular structures and solid organs from their initial experiences with midurethral slings, these complications are relatively rare compared with mesh-related sequelae. These adverse events may consist of erosion into the bladder or urethra or extrusion into the vagina as well as delayed effects, such as dyspareunia and pelvic pain. Although erosion is a potentially catastrophic complication, vaginal mesh extrusion may often be treated with mesh debridement and a reapproximation of the vaginal mucosa.

Several issues remain unanswered regarding mesh-augmented repairs. First, several authors have noted that even a well-placed vaginal mesh may contract significantly in both length and width over time.^[41,42] While mesh contraction may often be asymptomatic, it is not immediately clear whether this factor may affect coitus and lead to dyspareunia.^[43] Second, there is significant controversy over who is the ideal patient for mesh augmentation. While factors such as pelvic irradiation, severe urogenital atrophy, immunosuppression, and comorbidities, including poorly controlled diabetes, morbid obesity, and heavy smoking, may serve as relative contraindications to mesh implantation, women with these criteria are often the ones who have recurrent POP and may be at high risk for recurrence after standard repairs.^[44,45]

In conclusion, the optimal procedure for the repair of POP continues to be a source of great debate among pelvic surgeons worldwide. Although no one procedure satisfies all of the criteria, each has strong advantages and potential detractors. Here is where the surgeon's experience takes over and a detailed informed consent discussion should take place. Additionally, judicious patient selection, adequate surgeon training, and a solid comfort level with variations in pelvic anatomy are vital to the success of any POP surgery. Finally, the surgeon performing these procedures should be comfortable in treating postoperative complications as these may occur in even the most experienced hands.

Conflict of interest

No conflict of interest was declared by the authors.

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