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REVIEW PAPER / GYNECOLOGY

Current approach to the use of transvaginal mesh systems in pelvic organ prolapse

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ABSTRACT

Pelvic organ prolapse (POP) involves the descent of vaginal walls, uterus, or vaginal apex. Traditional native tissue repair techniques, while low in complications, exhibit significant relapse rates. To enhance durability of surgical repair, synthetic mesh systems were adopted. However, early generations faced complications such as vaginal mesh exposure and dyspareunia, leading to critical reevaluation and regulatory actions.

The Food and Drug Administration issued first warning in 2008 and reclassified mesh as high-risk in 2016, banning it for transvaginal anterior compartment prolapse in 2019. European and Canadian regulations similarly increased scrutiny, with prominent professional organizations and regulatory bodies endorsing limited use and thorough counseling.

Subsequent innovations introduced lighter mesh systems with sacrospinous ligament fixation, which improved anatomical outcomes and reduced adverse effects. Recent studies on these

systems demonstrate promising success rates, with notable reductions in prolapse recurrence and improved quality of life.
Given these developments, current perspectives advocate for selective use of advanced mesh systems in POP surgery, emphasizing rigorous patient selection, informed consent, and meticulous surgical technique. This careful approach, as opposed to a categorical ban, aims to balance the therapeutic benefits with potential risks, ensuring optimized patient outcomes in POP management.

Keywords: pelvic organ prolapse; transvaginal mesh repair; sacrospinous ligament fixation

INTRODUCTION

According to the International Continence Society glossary, pelvic organ prolapse (POP) is the descent of the anterior, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy) [1]. Symptomatic cases of POP require treatment. Whenever conservative management proves ineffective or is not accepted by the patient, surgical procedures become the treatment of choice.

The results of surgical treatment are not always long-lasting- according to available data, up to 30% of patients may need a reoperation due to recurrence within five years following the initial procedure [2].

Native tissue techniques are considered safe and attractive since they are associated with a low risk of complications and at the same time offer the benefits of transvaginal approach. However, authors reported a considerable risk of POP relapse following these procedures [3]. High success rates of synthetic mesh for hernia repair resulted in the idea of transvaginal use of grafts for prolapse. The aim of implementing mesh systems in POP surgery was to enhance the long-term stability of the repair, reduce morbidity and invasiveness, enable the use of regional anesthesia, and effectively target the specific anatomical defects associated with pelvic floor dysfunction [4]. In 2001, the Food and Drug Administration (FDA) approved vaginal mesh for surgical treatment of POP. The first systems were introduced in the USA in 2005. Since then, grafts have been utilized in various locations, including the anterior and

posterior vaginal walls, the vaginal apex (either vault or uterus), or a combination of these sites [5].

Initially, mesh materials used in transvaginal surgery were classified into four categories based on their pore size (macro- or microporous), composition (mono- or multifilament), and structure (knitted or woven). Type 1 meshes were macroporous (> 75 nm), type 2 was microporous (< 10 nm), type 3 contained both macro- and microporous components, and type 4 featured very small pores and was seldom utilized in prolapse surgery. The macroporous material, with its larger pore size, is believed to facilitate the movement of macrophages and other leukocytes through the mesh, thereby reducing the risk of infection [6]. Today, type 1 polypropylene macroporous mesh is the most used. The initial transvaginal meshes were meant to be placed between the vagina and bladder or rectum to reinforce the anterior or posterior vaginal wall. The early systems aimed to mimic the pubocervical or rectovaginal fascia with four fixation points anchored at the obturator foramen. Newer mesh systems have special devices designed to facilitate the placement of a pulley stitch through the supportive connective tissue. These systems allow the mesh to be positioned via a single incision in the vaginal mucosa, eliminating the need for trocars. Additionally, they include apical fixation points and cover a reduced surface area [7].

A Cochrane database metaanalysis published in 2016 summarized and confirmed the benefits of POP repair with the use of synthetic mesh compared to NTR. The likelihood of experiencing recurrent objective prolapse, defined as stage 2 or higher in any compartment during examination, was reduced by 60%. This reduction was even more significant when focusing on anterior compartment repairs, with the mesh group showing a substantial benefit (RR 0.33). In the multicompartment repair group, defined as apical, anterior, and/or posterior mesh repairs, the advantage of mesh persisted but was less pronounced (RR 0.59). The subjective outcome rates (awareness of prolapse) were also better: women who underwent permanent transvaginal mesh repair being less likely to report prolapse awareness compared to those who had NTR (RR 0.66). These results were similar in the anterior group and multicompartment group [3]. Furthermore, the rate of repeat surgeries for prolapse was lower in the mesh group, with a relative risk of 0.53. It should be stressed, however, that the metaanalysis investigated various mesh systems that were difficult to compare, and that most of those analyses investigated older mesh systems that did not include sacrospinous ligament (SSL) fixation [3].

MESH COMPLICATIONS AND INSTITUTIONAL WARNINGS

Soon after introducing transvaginal mesh systems, there was a notable increase in the reports of postoperative complications. The most common and at the same time bothersome side effect of mesh surgery was vaginal mesh exposure. As far as repair of the anterior vaginal wall is concerned, Hiltunen et al. observed a mesh exposure rate of 17.3% in their randomized controlled trial (RCT) assessing a self-tailored low-weight monofilament polypropylene mesh [8]. A comprehensive review highlighted exposure rates ranging from 8% to 24% [6]. In the posterior compartment, Lim et al. reported a mesh exposure rate of 12.9% within a 6-month follow-up period among 31 patients who underwent rectocele repair using Vypro II mesh, which is composed of a combination of vicryl and prolene materials [9]. The previously cited Cochrane database meta-analysis estimated the rate of mesh exposure at approximately 10% [3]. Interestingly, in a multicenter prospective cohort study by Withagen et al., involving 294 women who underwent anterior or posterior POP repair with the polypropylene Prolift system, it was found that mesh exposure occurred in 30% of smokers compared to just 9% of nonsmokers [10]. Additionally, Sokol et al. performed a multicenter randomized controlled trial (RCT) to evaluate the effectiveness of the Anterior Prolift procedure in comparison to traditional anterior colporrhaphy. Despite similar cure rates, the Anterior Prolift group experienced higher reoperation rates, and the trial was prematurely halted due to a 15.6% incidence of vaginal mesh exposure in the mesh group (5 out of 32 women) [11]. Further, Feiner et al. performed a prospective study comparing two polypropylene systems — the Anterior Prolift and the Perigee system — and found that vaginal exposures occurred in 6% of the former group and 4% of the latter group [12].

Concern was also raised since cases of dyspareunia, either associated with or independent of vaginal mesh exposure, were being reported after the introduction of mesh systems. Baessler reported a high incidence of this symptom, reaching up to 38% of cases [13]. In the previously cited analysis, de novo dyspareunia was observed in 11% of patients who underwent the Anterior Prolift procedure and in 16% of those treated with the Perigee system [12]. A study conducted by Lim reported a 3% incidence of de novo dyspareunia in a cohort of 90 patients who had rectocele repair using a mesh composed of both vicryl and prolene materials [14].

Stress urinary incontinence occurring de novo is another potential complication of vaginal mesh implantation. An analysis indicated that this condition developed in 23% of patients who had mesh repair, while only 10% of those who underwent traditional anterior repair

experienced it [8]. In addition, detrusor overactivity increased in 34% of women after undergoing prolene mesh repair for anterior vaginal wall prolapse [15].

Despite initial enthusiasm and acclaim for the surgical treatment of POP using transvaginal synthetic mesh, driven by good anatomical results, the significant incidence of complications led to a reevaluation of this initial optimism. Authors assessing this innovative method during that period particularly advised against the use of type II and III micro-porous and multifilament meshes [6].

Further, in 2013, Lee et al. [16] reviewed complications from transvaginal mesh procedures managed at two tertiary institutions. All patients had undergone mesh excision due to complications arising from the initial prolapse surgery. The average time between the original surgery and the mesh excision was 21 months, with a range from 2 to 60 months. Of the 58 women included in the study, 35 (60%) had also undergone concurrent midurethral sling surgery along with the transvaginal mesh implantation. Additionally, 21 of these women (36%) had previously attempted mesh removal before being referred to the tertiary institutions. The most common complaint was mesh exposure, reported by 43 women (74%). Seventeen women (29%) required further mesh re-excision — 13 of them once and 4 twice. Moreover, five women (7%) experienced a recurrence of symptomatic pelvic organ prolapse. Persistent dyspareunia was reported by 14% of the patients, and pelvic pain by 22%. The authors concluded that patients should be informed that some complications arising from transvaginal mesh procedures can be life-altering and may not always be rectifiable through surgery [16].

The repercussions of mesh-related issues extended beyond physical discomfort of the affected women, intensifying the distress associated with the initial pelvic floor dysfunction. This compounded into a sequence of escalating health difficulties, marked by increasing anxiety and feelings of despair [17].

In 2008, the FDA issued a warning citing over 1000 complications between 2005 and 2008 from different mesh manufacturers. These complications included mesh exposure, infections, pain, urinary issues, and recurrence of prolapse or incontinence [18]. In 2012, the agency mandated postmarket surveillance studies. By 2016, surgical mesh for POP was reclassified as high-risk [19]. In 2019, the FDA banned mesh for transvaginal anterior compartment prolapse due to uncertain benefits versus risks [19]. In Europe, regulation mirrored the FDA's scrutiny. The Medicines and Healthcare Products Regulatory Agency (MHRA), which supervises the

UK, endorsed the use of vaginal mesh for prolapse repair but recommended further research into the types of implants and their application techniques [20]. Similarly, SOGC in Canada issued guidelines in 2017, limiting mesh use to high-risk patients and advocating for thorough counseling [4]. The 2019 NICE guideline did not ban mesh but urged decision aids, detailed counseling, and data tracking for women considering mesh-based procedures [21].

NEW TRANSVAGINAL MESH SYSTEMS

In order to mitigate certain risks associated with first-generation kits while preserving the potential benefits of using mesh in the treatment of POP, 6-point transvaginal mesh systems were developed. These kits not only mimic the pubocervical or rectovaginal fascia but are also anchored to the SSL and to the respectively arcus tendineus fascia pelvis or iliococcygeus muscle which involves secure attachment of the mesh without tension. These grafts incorporate lighter, less-dense type I polypropylene mesh and utilize a single-incision vaginal access approach.

Recently, a study analyzing the results of a 6-arms mesh kit (InGYNious Anetrior — A.M.I. Austria) ultralightweight (21 g/m^2) mesh, consisting of large micropores and macropores (of 100–150 mm and 1.9–2.8 mm, respectively)) was published. It was a multicenter analysis performed in 6 hospitals that investigated 195 cases. At the 3-year follow-up, anatomical (objective) success, defined as POP-Q Ba < –1 and C < –1, was achieved in 77% of cases in the anterior compartment, 82% in the apical compartment and in 72% in both the anterior and apical compartments. If success had been set to any point < 0, then anatomical success would have been achieved in 91% for the treated compartments. As far as urinary and bowel function are concerned, the implantation of a 6-point mesh also improved symptoms in this study: 37% of patients had urge urinary incontinence (UUI) before POP surgery. This number decreased significantly to 11% at the 3-year follow-up. Similarly, voiding dysfunction decreased significantly from 38 to 3%. Also, obstructed defecation showed a significant improvement, decreasing from 9 to 3%. The rate of de novo SUI was 23% in women without reoperation for SUI and/or POP and without primary SUI. In the study, quality of life of the treated patients was also assessed, with the use of the P-QoL (Prolapse Quality of Life questionnaire). According to the results, the quality of life measured for 3 years post-surgery increased significantly in all subdomains [22]. No serious adverse events were reported within 36 months after the mesh repair. 10 patients (6%) suffered from recurrent urinary tract

infections (UTI), whereas 6 women had subjective voiding dysfunction. At the 3-year follow-up, no new mesh exposures were observed. 24 patients (13%) reported pain, but 14 patients rated it with VAS score 1 (hence, the median pain score of VAS was 1). At the 3-year follow-up, the rate of de novo dyspareunia was 3% (170 women having sexual activity with or without a partner were included in the analysis of this parameter). Other mesh-related complications such as infection, abscess formation or mesh contraction were not reported in the study [22].

Another study, that also investigated the effects of a lightweight 6-point fixation kit (TiLOOP ® PRO A), found that the objective success rates were also satisfactory: at the 12-month follow-up, 54.3% of patients showed no signs of cystocele, while 41.3% had a grade I cystocele. Regarding apical prolapse, 69.6% of patients had no apical prolapse, and 26.1% had a grade I apical prolapse. Additionally, 4.3% of women were diagnosed with a recurrent grade II cystocele combined with a grade II apical prolapse and prolapse in the posterior compartment. In terms of the posterior compartment, 37% of patients had no prolapse, 43.5% had a grade I prolapse, and 19.6% had a grade II prolapse at the 12-month mark. Notably, preoperative evaluations showed that 86.5% of all patients exhibited a prolapse in the apical compartment, either of the uterus or vaginal stump (grade I–III). Anatomical success, as measured by the POP-Q system, was achieved in 77% of cases for the anterior compartment, 82% for the apical compartment, and 72% for both the anterior and apical compartments combined [23]. Another study evaluating the same 6-arm mesh kit (TiLOOP® PRO A) found a recurrence rate of 4.5% in the anterior compartment (follow-up was performed 36 months postoperatively). The authors did not, however, specify the degree of POP preoperatively as far as the apical compartment was concerned (patients with cystocele or POP-Q ≥ grade II or with grade I prolapse accompanied by symptoms that necessitated surgical intervention). The study also evaluated the impact on quality of life. Prior to surgery, 48.6% of patients reported that their sex life was adversely affected; however, after 36 months, only 14.4% indicated a negative impact on their sex life [24].

In another study, that included 9 hospitals in Germany (289 women) and aimed to prospectively evaluate quality of life after implantation of the same 6-arm mesh, a significant positive effect of mesh implantation on pelvic floor-related quality of life as well as sexual function was observed [25]. The complication rates were also low: bladder lesions occurred in 1.7% of cases, while ureteral injury or bleeding that required a transfusion was reported in 0.3% of the women who underwent surgery. Urinary tract infection (UTI) or an infected

hematoma was diagnosed in 0.3% of patients, and 0.3% of women experienced positional pain. Overall, 22 adverse events were recorded in 21 patients between the 12-month and 36-month follow-up periods, although none of these events could be definitively linked to the mesh implant. However, 8 of the reported events were clearly associated with the surgical method: one patient experienced pain around mesh implantation, and mesh exposure was observed in 7 patients [24].

Another mesh providing an SSL fixation point- Elevate- was associated with a low risk of recurrence. Among the 317 of women in whom the procedure was performed, the anatomical success rate after 3 years was 87.5%. Although this rate significantly decreased over time, it remained high after 5 years, with 78.6% of women with POPQ < 2 (the definition of success in the study). The authors also provided data collected 9 years post-surgery, showing a success rate of 66.8% [26]. In fact, this system had been investigated even earlier — in 2012, Moore et al. reported on a series involving sixty women who underwent surgical repair of stage 2 or higher anterior and/or apical compartment prolapse using the Elevate system were evaluated. After an average follow-up period of 13 months, 91.7% of these patients achieved an objective cure, defined as reaching POP-Q stage 0 or 1. None of the women had experienced vaginal mesh extrusion or significant buttock or leg pain [27].

In 2015, Huang et al. also published a study investigating the results of the Elevate mesh implantation. The mean follow-up duration was 28 months (range: 15–45 months). The anterior vaginal wall was corrected successfully in 190 patients (95%), whereas the posterior vaginal wall was repaired successfully in 198 patients (99%), and the apical compartment – in 194 patients (94%). After prolapse surgery, relevant questionnaires showed significant improvements in incontinence-related quality of life [28].

In a new study investigating the outcomes of implantation of the Elevate system in 130 women, at a median follow-up of 33.6 months, anatomical recurrence was found in 13.8% of patients: 5.3% of women reported isolated recurrence in the anterior compartment, 3.8 % showed an isolated apical compartment recurrence, and 4.6 % reported combined anterior and apical relapse. As far as functional outcome is concerned, among women with anatomical relapse, 5 of them reported symptoms associated with lack of satisfaction of the surgery, attesting the functional success rate at 96.2 % [29]. The same mesh kit was also investigated by Rogowski et al. In the study, published in 2019, 50 cases were analyzed. Follow-up was performed 18 months after the procedure. Postoperatively, POP-Q anterior or apical stage 0 or I was reported in 92% of the patients. The subjective cure rate, i.e. absence of vaginal bulging,

was 78% [30]. Very recently, a retrospective study conducted at a single center reviewed the outcomes of 350 women who underwent Elevate mesh reconstruction for POP between 2006 and 2016. The authors assessed intra- and peri-operative complications, including those related to mesh, at intervals of 6 weeks, 1 year, and 5 years post-surgery. The mesh exposure rate was found to be 1.1%. The authors concluded that, due to the low rates of morbidity and mesh-related complications, this mesh should be considered at least a viable alternative treatment option for POP [31]. The other recent analysis of outcomes and complications of the Elevate system revealed that the most frequently observed short-term complications were urinary bladder injuries (3.0%) and temporary urinary retention (6.9%). Over the longer term (median follow-up of 33.6 months), the most prevalent complications included the development or persistence of symptomatic stress urinary incontinence (10.8%) and the extrusion of vaginal mesh (3.8%) [29]. The Elevate system was, however, proven by other authors to be a procedure associated with a relatively low risk of vaginal exposition of the mesh [29, 32]. The rate of dyspareunia was 3,4% in the abovementioned study, where 238 women who underwent implantation of the Elevate system without concomitant MUS implantation and were followed-up for 5-9 years [26].

In a 2015 study conducted by Huang et al. on the Elevate mesh kit, the observed rate of mesh extrusion was 2% over a mean follow-up period of 28 months. The postoperative urgency and urgency incontinence rates were 9.5 % and 24 % respectively [28].

Meanwhile, in a study by Rogowski et al. involving 50 women who underwent Elevate mesh insertion, there was no incidence of vaginal exposure of the mesh after 18 months of follow-up. De novo SUI occurred in 18.5% of patients, de novo OAB in 12%, dyspareunia in 8%, and the rate of postoperative pelvic pain was 8% [30].

Recently, a novel, ultralight transvaginal mesh option has emerged for the treatment of anterior wall vaginal prolapse. The Self-Retaining-Support technology (Lyra) mimics pubocervical fascia and eliminates the need for advanced anchoring techniques.

In a 2017 study conducted by Levy et al., a group of 20 women diagnosed with POPQ stage 2 or higher underwent surgical repair utilizing the SRS device [33]. After a 2-year follow-up period, results revealed that 17 patients (84.2%) achieved stage 0 prolapse, while 3 patients (15.8%) presented with stage 1 prolapse. Notably, there was one documented case (5%) of frame exposure, which occurred 8 months post-surgery. The exposure was successfully

managed through the removal of the affected portion under local anesthesia, resulting in symptom resolution.

In the most recent study led by Levy et al., which encompassed a cohort of 67 patients, the 36-month follow-up revealed an impressive 94.3% rate of anatomical success (defined as POPQ stage 0 or 1 or a Ba score of ≤ –2) [34]. Post-operative complications were limited and included two cases of urinary retention, one minor instance of frame exposure, one case of delayed voiding dysfunction, and two instances of de novo stress urinary incontinence. These findings suggest that this method may offer advantages in terms of ease of adoption by operators and enhanced safety for patients, resulting in fewer complications both during and after surgery.

SUMMARY

Considering the above data on the effectiveness and safety of modern, 6-point transvaginal mesh systems for treating POP, their use should not be completely banned but rather carefully evaluated. The foundation of this evaluation is proper diagnosis and understanding of the indications and damage mechanisms leading to prolapse. Justifying the use of mesh is crucial. Careful patient selection for implant-based surgical treatments, including a thorough assessment of medical history and pelvic floor function, along with providing comprehensive information about potential complications, should ensure high satisfaction with this treatment method while maintaining a low incidence of complications. In our opinion, older systems that do not include apical compartment fixation may need to be withdrawn.

Article information and declarations

Author contributions

Monika Pycek — project development, manuscript writing, data collection; Justyna Zarzecka — data collection, data analysis; Wojciech Majkusiak — manuscript editing; Ewa Barcz — project development, manuscript writing; Aneta Zwierzchowska — concept, project development, mansucript writing, data analysis.

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Conflict of interest

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Supplementary material

None.

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