Improved Pelvic Support and Urinary Symptoms Following Apical Mesh Reinforcement with a Partially Absorbable Lightweight Polypropylene Mini Mesh for Advanced Pelvic Organ Prolapse

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ABSTRACT **Background:** Studies have shown that approximately half of the female population may experience some degree of pelvic organ prolapse (POP) during their lifetime, although only 3–6% report symptomatic prolapse.

Objectives: To evaluate the clinical and adverse outcomes associated with transvaginal repair using partially absorbable lightweight polypropylene Seratom PA MR MN® mini mesh for enhanced apical support in the treatment of advanced POP.

Methods: A retrospective study was conducted on 114 patients who underwent transvaginal repair with the Seratom partially absorbable lightweight polypropylene mini mesh between August 2013 and January 2016. Data collected included demographic, surgical, adverse symptoms, and anatomical characteristics assessed via the modified Pelvic Organ Prolapse Quantification system (POP-Q). Postoperative pain was assessed using the Visual Analog Scale.

Results: Significant improvements were observed in POP-Q measurements (*P*-value < 0.001). Subjective outcomes demonstrated significant pre- to 4-month postoperative reductions in urinary stress incontinence and overactive bladder ($P < 0.001$). No cases of mesh erosion were reported. Immediate complications included bleeding (3.5%), fever (1.7%), and urinary obstruction (0.9%). The recurrence rate was 12.3%. Patient satisfaction scores were consistently high, with an average of 95.96% at 1 month, 94.73% at 4 months, and 91.33% at the most recent follow-up.

Conclusions: Transvaginal repair with the Seratom PA MR MN® partially absorbable mini mesh demonstrated significant improvements in anatomical and subjective outcomes, with few complications, and low recurrence rates. Further studies are necessary to validate these outcomes and optimize patient selection.

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KEY WORDS: lightweight polypropylene mini mesh, pelvic organ prolapse (POP), transvaginal repair

Pelvic organ prolapse (POP) refers to the descent of one or more pelvic organs into the vagina. It most commonly involves the uterus and/or nearby organs such as the bladder, rectum, or bowel [1]. POP is a prevalent condition, with studies suggesting that approximately half of the female population may experience some degree of prolapse during their lifetime, although only 3–6% report symptomatic prolapse. Despite its widespread nature, many women do not seek treatment for their symptoms [2]. POP may have a significant impact on quality of life (QoL), affecting both physical and emotional well-being. Women often experience symptoms such as vaginal bulging, pelvic pressure, urinary and bowel dysfunction, and sexual dysfunction, including dyspareunia, and reduced libido [1].

POP can be managed through non-surgical approaches, including pelvic floor muscle training, biofeedback, electrogalvanic stimulation therapies, and the use of pessaries [3]. Surgical treatment is indicated for women with POP who experience significant symptoms and have not benefited from nonsurgical treatments. Multiple surgical approaches, including vaginal and abdominal techniques, are available for managing POP [4]. Although most cases of POP are asymptomatic, approximately 12% of women may require surgical treatment for pelvic floor disorders over their lifetime [5].

Traditional anterior and posterior vaginal repair (colporrhaphy) and apical repair techniques aim to correct defects in the fascia by plicating and suturing native connective tissues to restore support to the bladder, rectum, and vaginal apex [6]. However, these methods often do not address the underlying pathophysiology of weak connective tissue, resulting in high recurrence rates. A 2024 Cochrane review [6] showed that native tissue re-

pairs were associated with significantly higher rates of prolapse awareness, repeat surgeries for prolapse, and prolapse observed on examination compared to mesh-based repairs. This updated analysis aligns with the 2016 Cochrane review [7] but offers greater certainty and precision due to a larger sample size. The 2024 Cochrane review also addressed absorbable meshes and biological grafts, concluding that there is no significant difference in outcomes with native tissue repair [6].

Based on the integral theory by Petros and Ulmsten [8], which highlights the importance of reinforcing pelvic ligaments to manage prolapse and functional symptoms, surgical mesh was introduced in the 1990s with the aim of restoring normal anatomy and minimizing prolapse recurrence. This development was followed by the production of surgical mesh kits designed to simplify the procedure [9].

However, the complication rates associated with vaginal mesh, including dyspareunia, mesh erosion (protrusion of the mesh through the surgical incision into the vagina), pain, damage to surrounding organs, and new urinary symptoms [10,11] led to regulatory warnings issued by the U.S. Food and Drug Administration (FDA) in 2008 [12] and 2011 [13]. Following the FDA's warnings, the use of mesh in POP procedures decreased, dropping from 30% in 2011 to 23% in 2013, as observed, for example, in New York State [14].

Since 2015, various international organizations have reviewed the use of transvaginal mesh for POP. These evaluations, in addition to subsequent reports, have led to global bans on transvaginal mesh for POP treatment [6]. Currently, transvaginal mesh for prolapse repair is banned in countries such as the United Kingdom, Australia, the United States, and Canada but remains available in certain European and Asian countries [6].

Despite these restrictions, as concluded in the 2024 Cochrane review [6], transvaginal mesh should still be considered in carefully selected cases where the risk-benefit profile justifies its use, in compliance with national regulatory standards. Further exploration on mesh safety, long-term outcomes, and advancements in mesh technology is essential for improving patient care and addressing the evolving challenges in POP treatment.

The aim of the study was to evaluate the clinical outcomes and adverse events in patients who underwent transvaginal repair with Seratom PA MR MN® (SERAG-WIESSNER, Naila, Germany) mini mesh for symptomatic advanced pelvic organ prolapse.

PATIENTS AND METHODS

We conducted a retrospective cohort study to analyze data from patients who underwent transvaginal repair with Seratom PA MR MN® mini mesh (Serag-Wiessner, Naila, Germany) between August 2013 and January 2016.

The study population included 114 consecutive patients presenting with advanced symptomatic POP with a C point > +4, according to the modified Pelvic Organ Prolapse Quantification system (POP-Q) classification. Inclusion criteria included age over 40 years. Exclusion criteria were active pelvic malignancy, active pelvic infection, significant pelvic anomalies, nitinol or nickel allergy, and missing data. Selection criteria were designed to limit confounders and focus on those with advanced POP most likely to benefit from the surgery.

The Seratom PA MR MN® mini mesh is lightweight, skeletonized, monofilament, partially absorbable, polypropylene/polyglycolic acid-caprolactone implant. Its material properties result in a lightweight mesh that gradually loses 50% of its mass over 6 months.

SURGICAL TECHNIQUE

All procedures included reinforced apical support with a mini mesh when the uterus was preserved and hysterectomy was avoided. Anti-incontinence surgery and native tissue colporrhaphies were added when indicated. Patients were administered 1 gram of Monocef® (Cefonicid, Beecham Healthcare, UK) intravenously one hour before the surgery and received an iodine antiseptic vaginal wash. General anesthesia was used. Urinary bladder catheterization and diagnostic cystoscopy were not routinely performed. The mesh was inserted through an anterior or posterior vaginal wall incision to correct anterior or posterior compartment and apical prolapse, accordingly.

The mesh has surface dimensions of 3 × 3 cm and is equipped with two pairs of enhanced sutures for para-vesical or para-rectal and sacrospinous ligament (SSL) fixation. One pair of sutures was fixed on the distal anterior or posterior part of the vagina on either side of the proximal urethra or rectum. The other pair of arms was fixed to the SSL with a reusable suturing device, SERAPRO® AR-SD-Ney TTT (Serag-Wiessner, Naila, Germany), designed to facilitate suture placement through SSL. It requires a relatively narrow transvaginal dissection toward the SSL, potentially reducing dissection-related complications. After dissection and reduction of the cystocele or enterocele, the skeletonized mini mesh provided sufficient material surface to support the prolapsed compartment. The com-

bination of a small mesh implant with minimal dissection reduces the invasiveness of the procedure.

All procedures were performed by a single surgeon, maintaining uniformity in surgical techniques. Follow-up assessments included evaluations at postoperative day one (POD1), one month, four months, and final telephone follow-up visit conducted until August 2024, with follow-up durations ranging from approximately 7 to 11 years.

Data collected included demographic details, surgical characteristics, adverse events and symptoms, and outcome measures including pelvic organ prolapse assessed using the modified POP-Q system [15], which evaluated points Ba, Bp, and C. Postoperative pain levels were evaluated using a standardized pain scale (Visual Analog Scale). In addition, adverse complications, recurrence of POP (including apical recurrence, defined as any return of prolapse measured by the POP-Q system), and patient satisfaction (rated by patients on a scale of 0–100%) were assessed during follow-up. Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 29 (SPSS, IBM Corp, Armonk, NY, USA). Categorical variables are presented as percentages and were analyzed using the chi-square test or Fisher's exact test, as appropriate. Continuous variables with a normal distribution are presented as means and standard deviations were analyzed using the paired Student's *t*-test. For continuous variables without normal distribution, medians and interquartile ranges are reported. To evaluate changes in paired categorical variables, McNemar's test was applied. A P-value < 0.05 was considered statistically significant. The study was approved by the institutional review board (ASMC 0117-23), and all data were anonymized.

Table 1. Preoperative demographic and clinical characteristics of 114 patients who underwent transvaginal repair with Seratom mesh

Characteristic	
Age, years, mean ± SD	62.68 ± 9.96
Parity, median (IQR)	3.0 (2.0–4.0)
Prolapse symptoms duration, median (IQR)	1.3 (1.0–3.0)
Obesity, n (%)	2.00 (1.75)
POP-Q points*, mean ± SD	
C	6.04 ± 2.04
Ba	2.77 ± 2.16
Bp	2.34 ± 2.07
Symptoms, n (%)	
Dyspareunia	10 (8.8)
USI	38 (33.3)
OAB	29 (25.4)
Defecation problems	5 (4.4)
Past pelvic surgeries, n (%)	
Previous hysterectomy	19 (16.7)
MUS	3 (2.6)
Transvaginal repair	8 (7.0)
POP reconstruction	4 (3.5)
ACSP with Gore-Tex**	1 (0.9)

ACSP = abdominal sacrocolpopexy, IQR = interquartile range, MUS = midurethral sling, OAB = overactive bladder, POP = pelvic organ prolapse, POP-Q = pelvic organ prolapse quantification, SD = standard deviation, USI = urinary stress incontinence

*Measurements of Ba, C, and Bp were recorded according to the POP-Q system: Ba anterior vaginal wall point, C cervix or vaginal cuff point, Bp posterior vaginal wall point

**Gore-Tex Polytetrafluoroethylene surgical mesh

RESULTS

A total of 114 patients underwent transvaginal repair with Seratom mesh between August 2013 and January 2016. Table 1 presents preoperative demographic and clinical characteristics of the study population. The mean age of the women at the time of surgery was 62.68 ± 9.96 years. The preoperative POP-Q measurements for the C, Ba, and Bp points were 6.04 ± 2.04, 2.77 ± 2.16, and 2.34 ± 2.07, respectively. Nineteen patients (16.7%) had a previous hysterectomy, three patients (2.6%) underwent a previous midurethral sling, and eight patients (7.0%) had a previous transvaginal repair.

Table 2 presents the perioperative characteristics of the study population. In all procedures, apical reinforcement was performed. In addition, 69 (60.5%) underwent anterior vaginal repair, 44 (38.6%) underwent posterior vaginal repair, and one (0.9%) underwent combined anterior and posterior repair with the Seratom mesh. Immediate postoperative complications at POD1 included bleeding in four patients (3.5%), although no blood transfusions or reoperations were required. Fever occurred in two patients (1.7%), while urinary retention, hematoma formation, and pneumonia presented in one patient each (0.9%). The median hospital stay was 2.0 days (IQR 2.0–3.0).

Table 3 presents adverse outcomes at the 4-month postoperative follow-up visit. Three patients (2.6%) reported dyspareunia, three patients (2.6%) experienced urinary stress incontinence (USI), six patients (5.3%) reported overactive bladder (OAB) symptoms, and one patient (0.9%) had defecation problems. No cases of mesh erosion were reported. The recurrence rate of POP, including

apical recurrence, was observed in 14 patients (12.3%). Patient satisfaction (0–100%) remained high, with mean patient satisfaction scores of 95.96% at 1 month, 94.73% at 4 months, and 91.33% at the latest follow up meeting.

Table 2. Perioperative characteristics of 114 patients who underwent transvaginal repair with Seratom mesh

Characteristics	
Additional compartment repair (beyond apical support), n (%)	
Anterior transvaginal repair	69 (60.5)
Posterior transvaginal repair	44 (38.6)
Anterior and posterior transvaginal repair	1 (0.9)
Intraoperative details, mean ± SD	
Amount of bleeding, ml	33.42 ± 26.23
Duration of surgery, minutes	29.61 ± 8.78
Concomitant MUS, n (%)	37 (32.5)
POD1 VAS score, median (IQR)	2.0 (2.0–3.0)
POD1 complications, n (%)	
Bleeding (> 50 ml, no more than 200 ml)	4 (3.5)
Fever (> 38°C, no more than 39.5°C)	2 (1.7)
Urinary retention	1 (0.9)
Hematoma	1 (0.9)
Pneumonia	1 (0.9)
Postoperative hospital stay duration, days, median (IQR)	2.0 (2.0–3.0)

IQR = interquartile range, MUS = midurethral sling, POD = postoperative day, SD = standard deviation, VAS = visual analog scale

Table 3. Adverse outcomes and patient's satisfaction in 114 patients who underwent transvaginal repair with Seratom mesh

Characteristics	
Adverse outcomes at 4 months n (%)	
Dyspareunia	3 (2.6)
USI	3 (2.6)
OAB	6 (5.3)
Defecation problems	1 (0.9)
Apical prolapse recurrence at 4 months	14 (12.3)
Patient satisfaction*, mean ± SD	
1 month postoperative	95.96 ± 6.91
4 months postoperative	94.73 ± 9.31
Latest telephone follow-up meeting (until August 2024)	91.33 ± 15.81

OAB = overactive bladder, SD = standard deviation, USI = urinary stress incontinence
*Scaled from 0% to 100%

Subjective outcomes demonstrated significant pre- to 4-month postoperative improvement in USI (from 39.98% to 3.12%, $P < 0.001$) and OAB symptoms (from 30.49% to 6.36%, $P < 0.001$). In contrast, postoperative improvement in dyspareunia (from 10.56% to 3.12%, $P = 0.092$) and defecation problems (from 5.28% to 1.08%, $P = 0.219$) showed no significant change. *P*-values were calculated using McNemar's test.

The anatomical results of surgery (POP-Q points Ba, C, and Bp) are depicted in Figure 1. The POP-Q point measurements showed significant improvement following surgery, with reductions observed in prolapse severity at the immediate postoperative, 1-month, and 4-month intervals ($P < 0.001$ for all points).

DISCUSSION

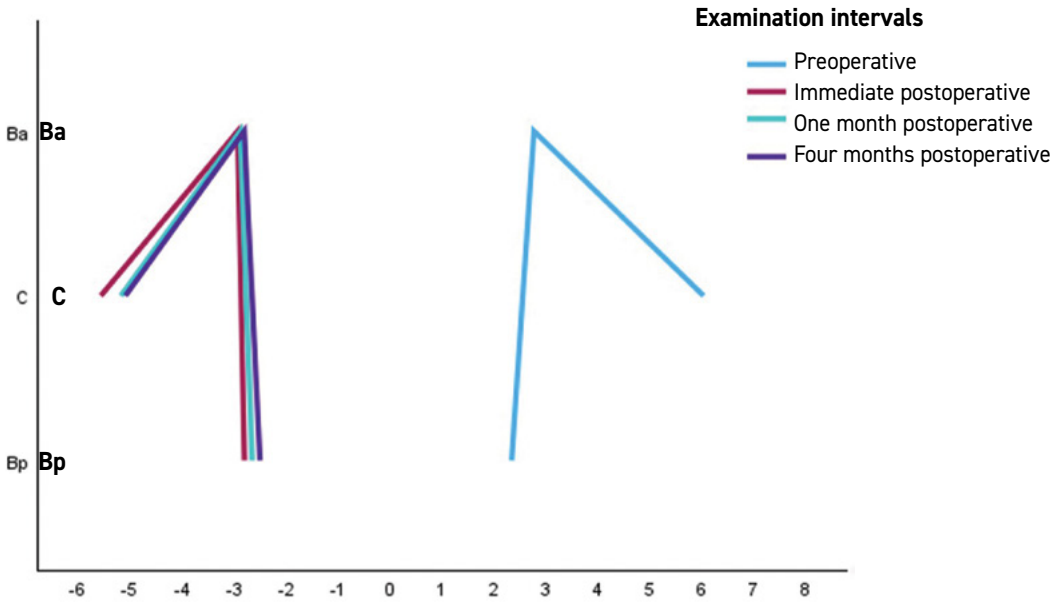
Surgical repair of POP remains a challenge even though a variety of surgical techniques are available [6]. Traditional native tissue repairs have shown limited long-term success, with high rates of recurrence and anatomical failure, as reported in the 2024 Cochrane review [6]. The introduction of synthetic mesh aims to address these limitations by providing enhanced pelvic organ support, consistent with the biomechanical principles and theories proposed by Petros and Ulmsten [8]. The Seratom PA MR MN® partially absorbable mini mesh represents an advanced synthetic mesh, which is designed to minimize potential mesh-related hazards for providing enhanced apical support.

In our study, we reported outcomes following transvaginal repair with the Seratom PA MR MN® mini mesh in patients presenting with advanced and significantly symptomatic POP. This mesh features a lightweight, skeletonized design that is partially absorbable and minimizes implant mass to reduce tissue trauma and foreign body reactions. This innovative design aligns with evolving trends in mesh technology, enhancing pelvic support while mitigating mesh-related complications.

In our study, significant anatomical improvements were observed, alongside subjective improvements in USI and OAB symptoms. A notable finding is that the mesh improved not only POP-related anatomical and symptomatic outcomes but also reduced USI symptoms. The improvement in USI symptoms may be attributed to enhanced support of the urethra and bladder neck, provided by the mesh's fixation at the level of the bladder neck. Dyspareunia and defecation problems did not exhibit significant changes, although their prevalence remained low after treatment. These findings align with

Figure 1. POP-Q point changes over preoperative and postoperative intervals

Measurements of Ba, C, and Bp were recorded according to the (POP-Q) system
P-values were calculated using paired *t*-test and are < 0.001 for Ba, C, and Bp
Ba = anterior vaginal wall point, C = cervix or vaginal cuff point, Bp = posterior vaginal wall point, POP-Q = Pelvic Organ Prolapse Quantification



a previous study by Weintraub and colleagues [16], which demonstrated significant anatomical improvements and reductions in OAB and USI after 12 months of follow-up using the same mesh, along with significant reductions in dyspareunia. Enhanced anatomical outcomes of transvaginal polypropylene mesh are supported by an increasing body of evidence [17,18].

The use of synthetic mesh in vaginal reconstruction has been controversial, largely due to concerns raised by regulatory bodies, including the FDA [12,13]. These concerns focus on complications such as mesh erosion, extrusion, and pain. In our study, a low percentage of intraoperative and immediate postoperative complications were observed, including 3.5% bleeding, 1.7% fever, and 0.9% urinary retention.

Importantly, no cases of mesh erosion were noted during the follow-up period. This finding highlights the potential of advanced mesh designs to reduce complications while providing effective pelvic support. These results are consistent with the findings of Weintraub et al. [16] and Levor et al. [19], which reported no mesh erosion at 12 months and 3 months of follow-up, respectively. However, older studies [18,20] involving smaller populations reported mesh erosion rates of 5–7.5% over follow-up periods of 12–24 months. These newer findings support the safety profile of lightweight polypropylene mesh.

The recurrence rate observed in our study was 12.3%, which is substantially lower than the nearly 20% recurrence for mesh repairs and up to 46.2% for native tissue repairs reported in the 2024 Cochrane review [6]. However, the certainty of this evidence was rated as very low, limiting its reliability and emphasizing the need for improved study designs to strengthen future evidence. The lower recurrence rate that we reported may be attributed to the advanced design of the mesh and careful patient selection, which could have minimized risk factors associated with recurrence.

Patient satisfaction scores remained consistently high, with 95.96% at 1 month, 94.73% at 4 months, and 91.33% at the last follow-up meeting. These results underscore the ability of transvaginal repair with lightweight polypropylene mesh to achieve improvements in both anatomical and subjective outcomes while maintaining a favorable safety profile.

The primary limitation of this study is the absence of a randomized control group, which limits the ability to directly compare outcomes with alternative treatment approaches. In addition, the follow-up period, while suffi-

cient for short-term outcomes, may not be long enough to assess long-term durability and complications, such as late recurrence or mesh erosion. The strengths of the study include comprehensive analysis of both objective and subjective outcomes, providing a comprehensive view of the procedure's effectiveness and safety.

CONCLUSIONS

Transvaginal repair with lightweight polypropylene mesh for enhanced apical support demonstrated significant improvements in both anatomical and subjective outcomes for patients with POP, while maintaining a favorable safety profile and maintaining patient satisfaction. Nevertheless, these findings should be interpreted cautiously given the limited follow-up and the retrospective, single-center design. Further studies with longer follow-up periods and controlled comparisons are needed to fully evaluate long-term outcomes and optimize patient selection.

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A teacher affects eternity; he can never tell where his influence stops.
Henry Adams (1838–1918), American historian and teacher