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Vaginal reconstruction effectiveness and safety: Comparison of anterior versus posterior pelvic floor compartment reinforcement with partially absorbable mini mesh implant in 500 cases of apical pelvic organ prolapse

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ABSTRACT

Objective: To assess the vaginal reconstruction effectiveness and safety, comparing anterior versus posterior pelvic floor compartment reinforcement with partially absorbable mini mesh implant in 500 cases of apical pelvic organ prolapse (aPOP).

Materials and Methods: The seratom PA MR MN® (Serag Wiessner, Naila, Germany) lightwheight partially absorbable mini mesh implants were used to treat stage II or greater apical and anterior or posterior pelvic floor compartment prolapse in women with aPOP. The patients were divided into two groups: Those with anterior prolapse predominance, for whom an anterior mini-mesh was implanted, and those with posterior prolapse predominance, for which a posterior mini-mesh was placed. The patients reported their functional outcomes on the first post-operative day (POD1) after surgery, one month, and four months afterwards. Anatomical outcomes were evaluated 1 month after surgery, using POP quantification (POP-Q) staging system. The reports of intra and post-operative (post-op) complications, post-op lower urinary tract symptoms, bowel symptoms and dyspareunia, anatomical and functional cure rates, were tabulated and assessed. The absence of bulging symptoms combined with no protrusion past the hymenal ring upon physical examination along with absence of surgery related adverse events or complications was considered success. Patient was considered satisfied if the operation was successful and subjective ecpectations were fulfilled at >80%.

Results: The study population (n=500) had a mean age of 62.7±9.4 years. Concomitant anterior and posterior colporrhaphy was performed in all cases. Four hundred fifty-two patients had completed medical files and follow-up (F/U) records, 48 patients (9.6%) had missing files or were lost to F/U. Three hundred ten individuals made up the anterior mini mesh group the first group. 12% of the patients of the first group had prior hysterectomies, 114 patients (36.7%) reported urgency-related stress incontinence (USI). The preoperative mean POP-Q C point was

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1.1 [0-(+)15], the Ba point was 4.01 [(-)2-(+)10], and the Bp was 0.8 [(-)3-(+)10]. 95.2% of the patients were satisfied at the 4-month F/U. Of the 142 patients in the second group, 28 (20%) had a prior hysterectomy, 48 (33.8%) reported USI. The preoperative POP-Q C point mean was 1.66 [0-(+)12], the Ba point was 1.27 [(-)2-(+)3], and the Bp was 1.9 [(-)2-(+)3]. At the 4-month F/U, the patient's satisfaction rating was 88.65%.

Conclusion: Excellent anatomical and quality of life outcomes were seen in patients treated with the seratom PA MR MN® mini-mesh system for POP, according to this current study. Within the 4-months after surgery, there was only one report of mesh exposure that was successfully treated surgically, and no other mesh related complications.

Keywords: Cystocele; mesh; pelvic floor; rectocele

INTRODUCTION

A complex network of muscles, ligaments, and connective tissues supports the reproductive organs of women and keeps them in their anatomical location in the pelvis. When one or more of these support structures are damaged due to aging, childbirth, or elevated intra-abdominal pressure, the condition known as pelvic organ prolapse (POP) occurs. Consequently, the vagina descends and there may be a varying degree of loss of normal pelvic function. About 50% of patients will have a vaginal bulge discovered during a routine gynecological checkup.[1] Urinary tract infections, obstructed defecation, pain, and, less frequently, urine retention can all be consequences of prolapse. Prolapse treatment is determined by the extent of the prolapse, its symptoms, the overall health of the woman, and the surgeon's skill and choice. Treatment options include conservative measures, mechanical treatments, and surgical procedures.[2,3] The U.S Food and Drug Administration (FDA) revolutionized the surgical treatment of genital prolapse with its recommendation in January 2016 to reclassify surgical mesh for transvaginal repair of POP to the highest risk class of devices (class III). The FDA also directed the manufacturers of all surgical mesh products that remained recommended for POP transvaginal repair to cease marketing and distributing their products in the United States by April 2019.[4,5] Similarly, guidelines for patient selection and informed consent for vaginal mesh placement have been issued by the International Urogynecological Association.[6,7] This emphasizes the necessity of modifying implants, which might be accomplished via bettering the dissection process or surgical delivery.[8] Our major goal was to create an implant that is more ligamentous than fascial, with the hope that it would better mimic the architecture of the connective tissues in the pelvic floor and drastically lower the overall bulk of the mesh implant. This may make it easier to reduce surgical risks related to mesh while maintaining the benefits of reinforcement in pelvic floor reconstruction. Examining the viability, safety, and surgical result of a novel skeletonized mesh fastened to the sacrospinous ligaments for advanced apical pelvic organ prolapse (aPOP) repair, comparing anterior versus posterior mini mesh placement, was the aim of this study. Efficacy and safety of skeletonized mini mesh implants for advanced POP with 12-month follow-up were published earlier (2013).[9]

MATERIALS AND METHODS

A cohort of women who had significant aPOP and thus undergone POP reconstruction with seratom PA MR MN® mini-mesh reinforcement, was enrolled into this study. All patients gave their informed permission. The requirements of the ethics committee were all met.

The seratom PA MR MN® operations were conducted by an experienced urogynecology surgeon (MN), from October 2013 to December 2015. The study included 500 individuals with substantial POP symptoms who had been diagnosed with aPOP (based on POP-Q). An anterior mini-mesh was implanted for patients with anterior prolapse predominance, while a posterior mini-mesh was put for those with posterior prolapse predominance. The patients were divided into these two groups according with the mini-mesh compartment placement. On first post-operative (POD1), one month, and four months following surgery, the patients reported their functional results. Physical examination for prolapse evaluation was conducted at the 1st post-op month, including office pelvic examination included a maximum Valsalva maneuver and a preoperative, site-specific vaginal examination using a Sim's speculum in the lithotomy position. Using the conventional scoring system of the International Continence Society, we assessed POP-Q. The study's inclusion criteria were POP-Q stage II-IV and agreement to the POP reconstructive operation using the seratom PA MR MN® mini-mesh. This research did not include women with reproductive tract abnormalities, those who had previously pelvic radiation therapy, those who had a history of significant pelvic inflammatory disease or pelvic cancer, or those who were incapable of providing informed consent.

This skeletonized mini-mesh was designed to offer ligamentary qualities and a lower overall mesh mass. Seratom PA MR MN® mini mesh (Serag-Wiessner, Naila, Germany) was utilized. The partially absorbable materials used to make seratom PA MR

MN® mini implants generate a lightweight mesh that loses 50% of its bulk over the course of six months. The central section of the sacrosciatic ligament (SSL) was sutured to the mini-mesh using a specifically designed re-usable suturing device named SERAPRO® RSD-Ney (Serag-Wiessner, Germany). In order to correct both anterior compartment and apical prolapse, the mesh can be introduced through a longitudinal anterior vaginal wall incision and fastened to the SSL, or it can be put through a posterior vaginal wall incision to treat both apical and posterior compartment prolapse. The prolapsed compartment might be supported by the skeletonized mesh once the cystocele, rectocele, or enterocele was decreased by paravesical or pararectal dissection. Generally, the uterus was preserved throughout the study. When necessary, anti-incontinence surgery was added.[9] As the data was retrieved out of the patient's medical records retrospectively with no active patient's participation. The operations were done in a routine manner, and as the patient's identity was kept discreet, this study was exempt of the need for the ethical committee approval. This study conduction was approved by the Asssuta Medical Centers Ethical Committee (ASMC- 0117-23).

Statistical Analysis

Preoperative demographic and clinical characteristics: General numerical data of the two groups (n=452) were provided with the use of mean, range, and standard deviation (SD). Continuous data such as age, and the discrete data of parity were given in this format. Other general, preoperative data included categorical, nominal information of symptoms and prior surgical procedures. These are displayed using frequency (n) and their respective proportions in percentages (%). The preoperative data belonging to group 1 (n=310) and group 2 (n=142) were displayed in the same way as previously described, with the addition of POP-Q points as numerical, continuous information being also presented with mean, range, and SD.

Post-op outcomes: The postoperative complication data for both group 1 (n=310) and group 2 (n=142) were represented with categorical, nominal data with frequency (n) and proportion in percentage form (%). Anatomical positions of POP-Q points were displayed on a chart using the mean values calculated from the numerical, continuous data collected at every follow-up.

All of the aforementioned data were summarized in a combination-bar chart, where categorical data of symptoms and numerical data of POP-Q points were shown as proportions (%) before and after the seratom procedure, with a trendline displaying the differences (D%) [POP-Q points Ba, C, and Bp were converted into categorical data, based on whether the numerical value would be considered a prolapse or not. e.g., if C >0, it would be tallied as a data point in the "failure" category and presented on the chart after conversion to proportion (%)].

Statistical tests were used to show these data in a different way categorical data was analyzed with McNemar's test to see if the change in symptom frequency was significant, and the paired numerical data of POP-Q (prior to categorical conversion) was analyzed with a paired t-test to see if the before/after means of the points differed significantly. A two-tailed *p*-value of 0.05 was regarded as significant. In group 1, the outcomes yielded the difference in symptoms of urgency-related stress incontinence (USI), overactive bladder (OAB), and bowel symptoms to be "extremely significant", dyspareunia as "very", and pelvic pain as "not significant". All POP-Q points had "extremely significant" outcomes. In group 2, the difference in symptoms of USI and OAB were "extremely significant", bowel symptoms "very", and dyspareunia and pelvic pain as "not significant". The comparison of means of POP-Q points were "extremely significant" here too.

RESULTS

Five-hundred women were included in the study and had the seratom PA MR MN® lightwheight partially absorbable mini-mesh procedure performed between October 2013 and December 2015. Forty-eight patients had missing data or were lost for follow-up. The pre-operative (pre-op) patient characteristics are listed in Table 1 [pre-op demographic and clinical characteristics of the study population with available data (452)]. The mean age

Table 1. Preoperative demographic and clinical characteristics of the study population with available data (452)

Demographic data (mean, range, SD)	**Mean**	**Range**	**SD**
Age	62.7	39.0-88.0	9.4
Parity	3.3	0-13	1.7
Procedures/symptoms (n,%)	**n**	**%**	
Previous hysterectomy	64	14%	
Prior TVT	30	6.7%	
Prior colporrhaphy	15	3.3%	
Prior POP reconstruction	19	4.2%	
USI	161	35.9%	
Dyspareunia	43	9.6%	
OAB	104	23.0%	
Bowel symptoms	32	7.1%	
Pelvic pain	14	3.1%	

SD: Standard deviation, TVT: Tension-free vaginal tape, POP: Pelvic organ prolapse, USI: Urgency-related stress incontinence OAB: Overactive bladder

of the study population at the time of the procedure was 62.7 SD ±9.4 years (range 39-88). Sixty-four (14.3%) patients had a previous hysterectomy and 161 (35.9%) patients had stress urinary incontinence (SUI) symptoms. Three hundred ten individuals made up the anterior prolapse group in the first group. Patients' characteristics are listed in the Table 2 (pre-op demographic and clinical characteristics of the 1 group, total n=310). 11.6% of the patients had prior hysterectomies. Before surgery, 114 (36.8%) patients had SUI. The pre-op POP-Q C point mean was 1.1 (-5-15), the Ba point was 4.0 (-2-10), and the Bp was 0.8 (-3-10) (Table 2). All patients had concomitant colporraphy. In 117 (37.7%) of patient's concomitant sub midurethral sling was performed.

Regarding the occurrence of side effects and both subjective and objective success, the post-op, F/U records were good. Data on functional results and POP-Q points C, Ba, and Bp are shown in Table 3 (correlation of pre-op and post-op anatomical and functional results) both before and after surgery. The outcome measures, including urinary, sexual, bowel, and pain symptoms, and the subjective and objective success rates are shown in Figure 1. Significant reductions were observed in symptoms of bladder overactivity, including urgency, frequency, and nocturia, as well as urinary stress incontinence. Constipation, pelvic discomfort, and fecal incontinence were also decreased. Despite a general decline in bowel symptoms and overactive bladder, there were still 11 (3.6%) and 4 (1.3%) *de novo* occurrences, respectively. Of the patients, 18 (5.8%) experienced *de novo* SUI, 10 (3.2%) had *de novo* dyspareunia, and 11 (3.6%) had persistent pelvic discomfort. 95.2% of the patients were satisfied at the 4-month F/U. At the POD pelvic examination, 4 months after the treatment, there was a significant improvement in the anterior defect; the average POP-Q Ba point was -2.7 cm, Bp point was -2.8 cm, and C point was -5.4 cm (Figure 2). There was a significant positive correlation between anatomical and functional success rate because the correlation coefficient is significantly different from zero ($p<0.0001$). Higher scores are given to anatomical outcomes, which also lead to functional successes.

Table 2. Preoperative demographic and clinical characteristics of the 1st group, total n=310

Demographic data (mean, range, SD)	**Mean**	**Range**	**SD**
Age	63.6	39-88	8.7
Parity	3.4	0-13	1.8
Prolapse duration	2 years, 11 months	1.2 months-32 years	4.6
Procedures/symptoms (n, %)	**n**	**%**	
Previous hysterectomy	36	11.6%	
Prior TVT	16	5.2%	
Prior colporrhaphy	7	2.3%	
Prior POP reconstruction	11	3.5%	
USI	114	36.8%	
Dyspareunia	27	8.7%	
OAB	68	21.9%	
Bowel symptoms	21	6.8%	
Pelvic pain	9	2.9%	
POP-Q (mean range, SD)	**Mean**	**Range**	**SD**
Point C	1.1	0.0-(+)15.0	3.1
Point Ba	4.0	(-)2.0-(+)10.0	1.5
Point Bp	0.8	(-)3.0-(+)10.0	1.7

SD: Standard deviation, TVT: Tension-free vaginal tape, POP: Pelvic organ prolapse, USI: Urgency-related stress incontinence, OAB: Overactive bladder, POP-Q: Pelvic organ prolapse quantification

Table 3. Correlation of preoperative and postoperative anatomical and functional results

	Preoperative			**Postoperative**			**Calculations**			
	Before (n)	**%**	**Total (n)**	**After (n)**	**%**	**Total (n)**	**D (%)**	***p*-values**	**Test done**	**Significance**
USI	114	36.8	310	18	5.8	309	31.0	<0.0001	McNemar's	Extremely
Dyspareunia	27	8.7	310	10	3.2	309	5.5	0.0021	McNemar's	Very
OAB	68	21.9	310	26	8.4	309	13.5	<0.0001	McNemar's	Extremely
Bowel symptoms	21	6.8	310	4	1.3	309	5.5	0.0005	McNemar's	Extremely
Pelvic pain	9	2.9	310	11	3.6	304	-0.7	0.8137	McNemar's	No
Ba	295	95.2	310	0	0.0	309	95.2	<0.0001	Paired T	Extremely
C	139	45.1	308	1	0.3	309	44.8	<0.0001	Paired T	Extremely
Bp	133	42.9	310	3	1.0	309	41.9	<0.0001	Paired T	Extremely

USI: Urgency-related stress incontinence, OAB: Overactive bladder

The complication rate was less than 2%, including urinary retention in 3 (1.0%) patients and mesh exposure in 1 (0.3%) woman, that was successfully treated surgically, and 6 cases (1.9%) of surgery failure in 4-month follow-up (Table 4).

One hundred fourty-two patients were included in the second group, 28 (19.7%) had a prior hysterectomy, 48 (33.8%) reported USI. The preoperative POP-Q C point mean was 1.7 (-5-12), the Ba point was 1.3 (-10-3), and the Bp was 1.9 (-10-3). 100% of patients had concomitant colporraphy. In 48 (33.8%) of patient's concomitant sub midurethral sling was performed (Table 5).

Regarding the occurrence of side effects and both subjective and objective success, the post-op follow-up records showed high patients' satisfaction. Data on functional results and POP-Q points C, Ba, and Bp before and after surgery are shown in Table 6. Figure 3 shows the outcome measurements, including bowel, sexual, urine, and pain symptoms, as well as the subjective and objective success rates. Urinary stress incontinence and other symptoms associated with overactive bladder, such as urgency, frequency, and nocturia, were significantly reduced. Fecal incontinence, pelvic pain, and constipation were also reduced. Despite a general decline in bowel symptoms and overactive bladder, there were still 2 (1.4%) and 14 (9.9%) *de novo* occurrences, respectively. Of the patients, 5 (3.5%) experienced *de novo* SUI, 9 (6.4%) had *de novo* dyspareunia, and 6 (4.2%) had *de novo* pelvic pain. At the 4-month F/U, the patient's satisfaction rating was 88.7%.

At the post-op pelvic examination, four months after the treatment, there was a significant improvement in the anterior defect; the average POP-Q Ba point was -2.1 cm, Bp point was -2.7 cm, and C point was -5.1 cm (Figure 4). There was a significant positive correlation between anatomical and functional success rate, because the correlation coefficient is significantly different from zero ($p<0.0001$). Functional outcomes are also associated with higher ratings for anatomical results.

The complications rate included defecation difficulties in 1 (0.7%) patient, cystocele occurrence in 12 (8.5%) of patients and 10 cases (7.0%) of surgery failure in 4-month follow-up (Table 7).

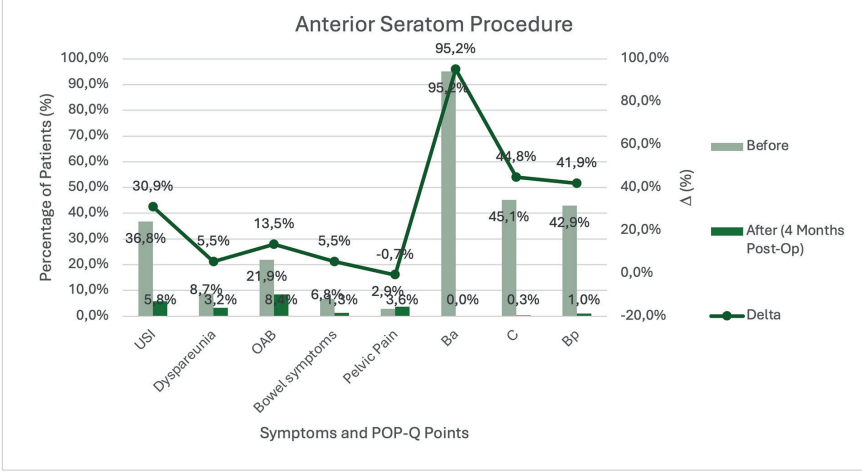

Figure 1. Postoperative outcomes in the 1st group
POP-Q: Pelvic organ prolapse quantification, USI: Urgency-related stress incontinence, OAB: Overactive bladder

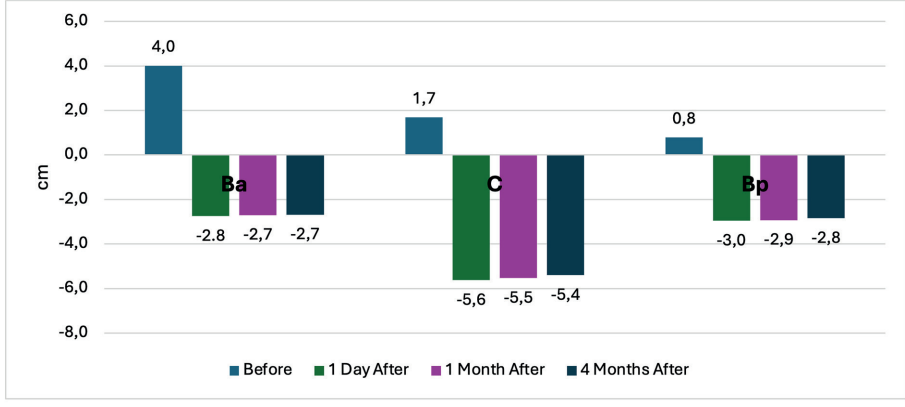

Figure 2. Anatomical results during follow-ups

Table 4. Complications rate, total n=310		
Complications 1 day after surgery	**n**	**%**
Hemoglobin below 10 gr %	3	1.0
Fever above 38 °C	3	1.0
Hematoma	1	0.3
Urinary obstruction	1	0.3
Bleeding after emesis (treated by hemostatic sutures)	1	0.3
Complications 4 months after surgery	n	%
UTI	3	1.0
Urinary retention	3	1.0
Fever above 38 °C	3	1.0
Reoccurrence	8	2.6
Vaginal pain (>2 according to VAS)	2	0.7
USI	2	0.7
Rectocele	7	2.3
Cystocele	4	1.3
Mesh exposure	1	0.3
Cervical elongation	1	0.3
Constipation	2	0.7

UTI: Urinary tract infection, VAS: Visual analogue scale, USI: Urgency-related stress incontinence

Table 5. Preoperative demographic and clinical characteristics of the 2nd group, total n=142			
Demographic data (mean, range, SD)	**Mean**	**Range**	**SD**
Age	60.9	39-88	10.5
Parity	3.06	1-11	1.5
Prolapse duration	2 years, 3 months	1.2 months-17 years	2.8
Procedures/symptoms (n, %)	**n**	**%**	
Previous hysterectomy	28	19.7%	
Prior TVT	14	9.9%	
Prior colporrhaphy	8	5.6%	
Prior POP reconstruction	8	5.6%	
USI	48	33.8%	
Dyspareunia	16	11.3%	
OAB	36	25.4%	
Bowel symptoms	11	7.7%	
Pelvic pain	5	3.5%	
POP-Q (mean, range, SD)	**Mean**	**Range**	**SD**
Point C	1.7	0.0-(+)12.0	3.5
Point Ba	1.3	(-)3.0-(+)10.0	2.3
Point Bp	1.9	(-)3.0-(+)10.0	2.2

SD: Standard deviation, TVT: Tension-free vaginal tape, POP: Pelvic organ prolapse, USI: Urgency-related stress incontinence, OAB: Overactive bladder, POP-Q: Pelvic organ prolapse quantification

Table 6. Correlation of the preoperative and postoperative anatomical and functional results

	Preoperative			Postoperative			Calculations			
	Before (n)	**%**	**Total (n)**	**After (n)**	**%**	**Total (n)**	**D (%)**	***p*-values**	**Test done**	**Significance**
USI	48	33.8	142	5	3.6	141	30.3	<0.0001	McNemar's	Extremely
Dyspareunia	16	11.3	142	9	6.4	141	4.9	0.1904	McNemar's	No
OAB	36	25.4	142	14	9.9	141	15.4	0.0020	McNemar's	Very
Bowel symptoms	11	7.8	142	2	1.4	141	6.3	0.0077	McNemar's	Very
Pelvic pain	5	3.5	142	6	4.2	142	-0.7	1.0	McNemar's	No
Ba	73	51.4	142	11	7.8	141	43.6	<0.0001	Paired T	Extremely
C	76	53.5	142	1	0.7	141	52.8	<0.0001	Paired T	Extremely
Bp	82	57.8	142	1	0.7	141	57.0	<0.0001	Paired T	Extremely

USI: Urgency-related stress incontinence, OAB: Overactive bladder

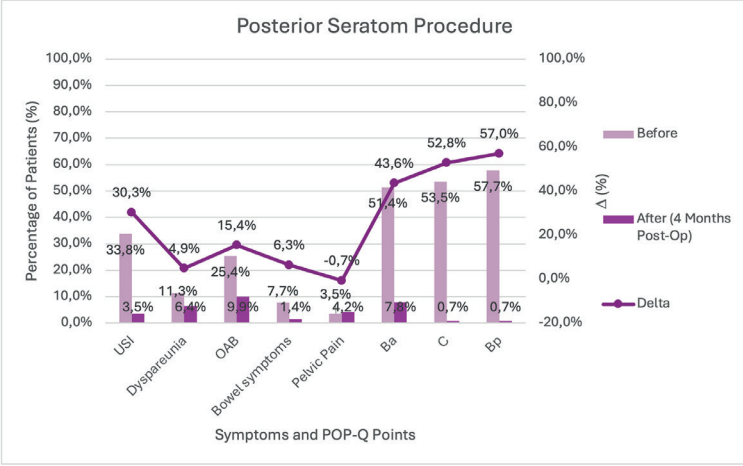

Figure 3. Postoperative outcomes in the 2nd group
POP-Q: Pelvic organ prolapse quantification, USI: Urgency-related stress incontinence, OAB: Overactive bladder

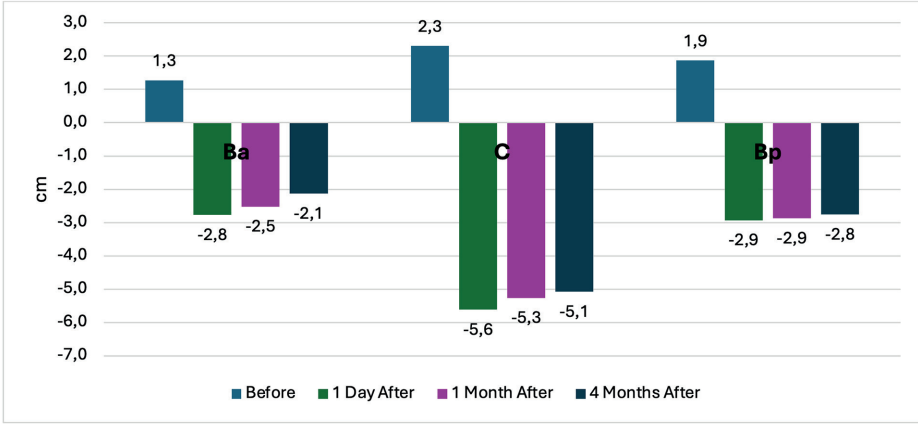

Figure 4. Anatomical results during follow-ups in the 2nd group

Table 7. Complications rate, total n=142		
Complications 1 day after surgery	**n**	**%**
Low hemoglobin below 10	2	1.4
Vaginal bleeding-moderate	1	0.7
Fever above 38 °C	1	0.7
Complications 4 months after surgery	**n**	**%**
Cystocele	12	8.5
Thigh pain (> 2 according to VAS)	1	0.7
Cervical elongation	1	0.7
USI	2	1.4
Exposure of TVT	1	0.7
OAB	1	0.7
Digital assistance during defecation	1	0.7
Fever above 38 °C	2	1.4
Failure	10	7.0

VAS: Visual analog scale, USI: Urgency-related stress incontinence, TVT: Tension-free vaginal tape, OAB: Overactive bladder

DISCUSSION

The lifetime probability of women requiring surgery for pelvic floor disorders varies from 6% to 18%. Many women will not respond well to conservative treatments (such as pessaries or pelvic floor muscle training) or would want more conclusive treatment. Regretfully, following native tissue healing, recurrence rates are estimated to reach over 40%, with the anterior compartment accounting for around 13% of recurrences. While some research has demonstrated that mesh enhanced repairs in the anterior compartment yield superior subjective and objective results than native tissue repair, other studies have revealed that transvaginal mesh is associated with a greater risk of problems, including mesh exposure and dyspareunia. Compared to the more recent generation of transvaginal mesh, several of the meshes utilized in these studies were denser and bigger.[10] Low mesh exposure rates have been found in randomized controlled studies, with even lower reoperation rates of 6% or below.[11,12] Vaginal reconstruction using mesh is a very controversial procedure. The FDA publications express concern about possible

significant consequences and the lack of evidence supporting better subjective outcomes related to transvaginal mesh insertion for POP. Many surgeons have stopped using mesh in POP repair as a consequence. Nevertheless, rather than coming from specific long-term research, a large number of these issues are the result of voluntary reports made through the FDA's manufacturer and user facility device experience database.[13] For patients and surgeons to make informed decisions, public objective and subjective data must be made available.[9]

In response to previous suggestions, we designed a mini lightwheight implant that is more ligamentous than fascial made to resemble the natural structure of the connective tissues in the pelvic floor in order to reduce the mesh implant's overall size and foot print, yet to provide reinforcement in pelvic floor restoration while lowering the surgical risks associated with mesh. This study results show the feasibility, safety, and good surgical objective and subjective outcome of this new skeletonized mesh attached to the sacrospinous ligaments for advanced POP repair. No significant difference was noted when comparing mini-mesh placement with the anterior or posterior pelvic floor compartments. Hence, we conclude that vaginal implantation of the seratom PA MR MN® lightwheight partially absorbable mini-mesh for the reinforcement of advanced POP reconstruction is a good treatment option, and that the surgeon might chose to implant it anteriorly or posteriorly. All surgical operations in our research were carried out by the highly experienced surgeon in accordance with the FDA's recommendations. However, the fact that the same physician (MN) conducted every surgical procedure is also a research limitation, together with the retrospective nature and shortF/U of the study. Nevertheless, the strengths of the study are the large group, extensive data collection, and the assessment of self-reported patient-centered outcomes. Furthermore, we aim to have provided some overview into how mesh-related problems can be decreased with skeletonized and reduced mesh surgery. When patients with different stages of POP were treated with a skeletonized and reduced mesh system, the current study demonstrated extremely low rates of mesh-related complications while guaranteeing good results for both anatomical findings and quality of life. Within the 4 months following surgery, there was only one report of mesh exposure.

CONCLUSION

This recent study reports excellent anatomical and quality of life short term results in women treated with the seratom PA MR MN® mini-mesh device for POP-both anterior and posterior compartments. There was just one case of mesh exposure in the four months follow-up after surgery, and it was successfully treated surgically. No other mesh-related complications were reported.

ETHICS

Ethics Committee Approval: This study conduction was approved by the Asssuta Medical Centers Ethical Committee (ASMC- 0117-23).

Informed Consent: All patients gave their informed permission.

FOOTNOTES

Contributions

Surgical and Medical Practices: M.N., Concept: N.S., S.F.S., Design: N.S., S.F.S., Data Collection or Processing: J.N., R.F.K., Analysis or Interpretation: N.S., Literature Search: N.S., Writing: N.S.

Conflict of Interest: Authors N.S., J.N., R.F. have nothing to declare. M.N. receives royalties from Serag-Wiessner.

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