



Partially absorbable lightweight sub mid-urethral sling implant (serasis) for female stress urinary incontinence treatment - 355 operations

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ABSTRACT

Objectives: Serasis is a partially absorbable lightweight sub mid-urethral sling for treating female stress urinary incontinence (SUI). Its placement is considered less traumatic than other mid-urethral slings as, due to its nature of weaving and soft edges it causes less damage to the tissue, diminishing post-operative pain and the extent of tissue scarring. The aim of the study was to evaluate the efficacy and safety of treating SUI using the partially absorbable lightweight mid-urethral sling Serasis placed at the sub mid-urethra.

Materials and Methods: This is a retrospective study. Pre-operative, intra-operative and post-operative data was retrieved from patients' electronic files. The patients reported their subjective functional outcomes on the first post-operative day, one month, and four months after surgery. The reported intra- and post-operative complications, post-operative lower urinary tract symptoms, bowel symptoms, dyspareunia, functional results, were tabulated and assessed. Physical evaluation on the first post-operative month were tabulated as well.

Results: The study of SUI reporting female study population (n=355) had a mean age of 50.1 ± 10.3 years, 4.5% had previous hysterectomy, 118 patients (33.2%) reported pre-operative overactive bladder. Concomitant anterior and posterior colporrhaphy was performed in 230 (64.8%) cases. No significant intraoperative complications were recorded. 95.9% of the patients were satisfied with the procedure at the 4-month follow-up (F/U). The recurrence rate was 3.7%. Ten patients were lost to F/U. There were 2 (0.4%) reported incidents of implant exposure in the 4-months F/U that were successfully treated surgically.

Conclusion: The Serasis partially absorbable lightweight sub mid-urethral sling for treating SUI is safe and efficient and carries a minimal risk of complications upon short term F/U period.

Keywords: Mesh; sling; urinary stress incontinence

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INTRODUCTION

In the past 3 decades, efforts have focused on creating less invasive and safer techniques that mimic the high success rates of colposuspension for curing stress urinary incontinence (SUI), with low rates of morbidity and shorter hospitalization and recovery time.¹ In the 1980s, there was a shift toward less invasive surgical treatment for SUI. Procedures based upon needle mediated suspensions reasonably were widely used as they were simple to perform and provided good short-term results. Medium- and long-term pain, dyspareunia, persistent urine incontinence, and erosion or exposure of the sutures led later to abounding these techniques.²

The next generation of anti-incontinence operations were the sub mid urethral sling (SMUS) era. Again, medium term pain, dyspareunia, persistent urine incontinence, and erosion or exposure after SMUS insertion raise concerns.³ Yet, the evidence from randomized clinical trials regarding these longer-term outcomes is limited.⁴

As the objective of surgical SUI treatment in women is to regain continence while minimizing treatment related morbidity. With this perspective and given the known risks of complications associated with the common anti-incontinence surgical techniques today, we searched for safer SMUS that might help to reduce intra- and postoperative complications. The Serasis tape (Serag-Wiessner, Naila, Germany), knitted of partially absorbable material to form light-mesh of soft fabric, potentially causes less trauma and damage to the tissues, diminishing post-operative pain and the extent of tissue scarring was developed.⁵

The Serasis was placed as a trans obturator tape (TOT) implant. This technique of sling passage through the obturator foramina - close to the medial border, from the inside to the outside was described earlier (2003).⁶ The outcomes of 107 consecutive patients show that this surgical procedure is fast, easy, precise, and feasible. Furthermore, this method prevents harm to the bladder and urethra, which eliminates the need for cystoscopy.

In 2022, a comparison of the Serasis and TVT-Abbrevio tapes demonstrated that being related to fewer adverse effects, the Serasis softly knitted partially absorbable tape might be a better option for treating female USI than TVT-Abbrevio (Ethicon, Johnson & Johnson, Summerville, USA) laser cut polypropylen.

The aim of this study was to assess the effectiveness and safety of using the Serasis lightweight mid-urethral sling to treat female SUI.

Our hypothesis was that the use of Serasis would lead to a decrease in the frequency and intensity of post-operative dyspareunia and other post-operative pain, as well as bowel and lower urinary tract symptoms.

MATERIALS AND METHODS

This is a retrospective study. Data was collected from electronic medical records prior to, during and after surgery. The inclusion criteria were clinical stress incontinence, and the exclusion criteria were previous pelvic irradiation and/or pelvic inflammatory disease. Patient's remote follow-up was performed on the first day following surgery, as well as one and four months later, patients' follow-up physical pelvic examinations and questionnaires form filling was conducted one month after surgery. The following were designated as outcome measures: Urinary and bowel symptoms, post-operative pain and dyspareunia levels, anatomical and functional cure rates, and the nature, rate and severity of post-operative complications. Patients were asked to rate pain or discomfort according to the visual analogue scale (VAS). The primary outcome measure was post-operative pain during the first month after surgery. Secondary outcomes were relief of SUI symptoms, dyspareunia or bowel discomfort, and the occurrence of post-operative complications during the first 4 months after surgery.

Being a retrospective study, the ethical committee waved us the need for informed consent. Helsinki Committee's approval 29:5:24, for Prof. Menahem Neuman, Assuta Medical Centers: We were convinced that your study about curing female USI with sub mid urethral sling placement is in accordance with the 1980 regulations of ethics of medicine and you can now proceed with your research. Your study no is 013-24-ASMC, version no 2. discussed on 12:4:24, approved on 29:5:24. Dr. Shiri Shulman, Assuta.

Statistical Analysis

Preoperative demographic and clinical characteristics: General demographic data of the Serasis patients (n=355) were provided with the use of mean, range, and standard deviation; continuous data such as age, and the discrete data of parity were given in this format. Other general, preoperative data included the categorical, nominal information of symptoms, prior surgical procedures, and concomitant diseases/conditions. These were displayed using frequency (n) and their respective proportions in percentages (%).

Postoperative outcomes: The postoperative complication data were represented as categorical, nominal data with frequency (n) and proportion as a percentage (%). Symptoms and conditions at the second and third follow-ups (one and four months, respectively) fell into this category, as did complication data at the first (one day), second and third follow-ups. Pain intensity (VAS) was treated as discrete data, so it was also displayed with a mean and range.

Of the aforementioned, the categorical data [namely, SUI, dyspareunia, overactive bladder (OAB), Bowel symptoms, Stage 1 apical prolapse, cystocele, and rectocele] were summarized in a combination-bar chart, where they were shown as proportions (%) before and after the Serasis procedure, with a trendline displaying the differences ($\Delta\%$). All of the postoperative (“after”) data represent proportions of patients at the third (four month) follow-up event, with the exception of the cystocele and rectocele conditions, which represent the proportion of patients at the second (one month) follow-up event.

The statistical test used to demonstrate the differences in pre- and post-operative data regarding the symptoms and conditions, was the McNemar’s test, which yielded the outcomes of the symptoms of SUI and OAB to be “extremely” and Bowel symptoms “very” significant, whereas the difference in dyspareunia proved “not significant”. For the conditions apical prolapse (Stage 1), cystocele, and rectocele, the test also showed an “extremely significant” difference. A two-tailed *p*-value of 0.05 was regarded as significant.

RESULTS

Three hundred fifty-five women were included in the study and had the Serasis light-weight mid-urethral sling for treating SUI performed between October 2013 and December 2015. No intraoperative complications were recorded. Ten patients were lost to F/U. 95.9% of the patients were satisfied in the 4-month follow-up (F/U). The recurrence rate was 3.7%. There were 2 (0.6%) reported incidents of implant exposure in the 4-months F/U that were successfully treated surgically. The preoperative patient characteristics are listed in Table 1. The mean age of the study population at the time of the procedure was 50.1 ± 10.3 years (range 29-79). All patients had urinary stress incontinence (SUI) symptoms prior to surgery. One hundred eighteen (33.24%) patients had OAB symptoms prior to surgery, and 16 (4.5%) patients had a previous hysterectomy. 78.6% of the patients had one of the following or a combination of apical, anterior and/or posterior pelvic organ prolapse (POP). Concomitant anterior and posterior colporrhaphy was performed in 230 (64.8%) cases. The mean duration surgery time was 18.3 min (range 10-25) with mean blood loss averaging at 22.1 mL (range 10-30).

Table 1. Patients preoperative demographic and clinical characteristics, total n=355

Demographic data (mean, range, SD)	Mean	Range	SD
Age	50.1	29-79	10.3
Parity	2.8	0-7	1.1
SUI duration	3 years, 1 month	1 months-30 years	4.0
Procedures/symptoms (n, %)	n	%	
SUI	355	100.0%	
Previous hysterectomy	16	4.5%	
Dyspareunia	17	4.8%	
OAB	119	33.2%	
Bowel symptoms	13	3.7%	
Apical prolapse			
0	170	47.9%	
1	185	52.1%	
Rectocele			
0	119	33.5%	
1	99	27.9%	
2	137	38.6%	
Cystocele			
0	76	21.4%	
1	74	20.9%	
2	204	57.5%	
3	1	0.3%	

SUI: stress urinary incontinence; SD: standard deviation; OAB: overactive bladder

Table 2. Success rate of USI, OAB, pain, dyspareunia, bowel symptoms, POP symptoms

	Preoperative			Postoperative			Calculations			
	Before (n)	%	Total (n)	After (n)	%	Total (n)	D (%)	p-values	Test done	Significance
SUI	355	100.0	355	20	5.6	355	94.4	<0.0001	McNemar's test	Extremely
Dyspareunia	17	4.8	355	15	4.2	355	0.6	0.8445	McNemar's test	Not
OAB	118	33.2	355	43	12.1	355	21.1	<0.0001	McNemar's test	Extremely
Bowel symptoms	13	3.7	355	2	0.6	355	3.1	0.0055	McNemar's test	Very
Apical POP	185	52.1	355	1	0.3	355	51.8	<0.0001	McNemar's test	Extremely
Cystocele	279	78.6	355	0	0.0	355	78.6	<0.0001	McNemar's test	Extremely
Rectocele	236	66.5	355	0	0.0	355	66.5	<0.0001	McNemar's test	Extremely

POP: pelvic organ prolapse; OAB: overactive bladder; SUI: stress urinary incontinence

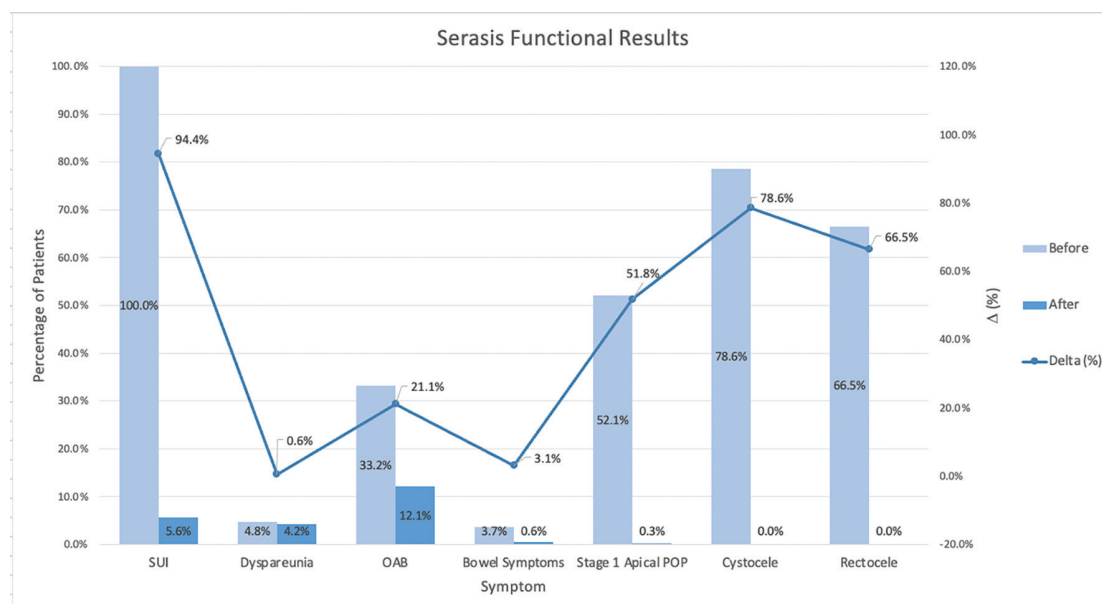
The functional and anatomical data is shown in Table 2, comparing these parameters before and after surgery. The outcome measures, including urinary, bowel, and pain symptoms, and the subjective and objective success rates are shown in Figure 1. Significant reductions were observed with OAB symptoms after surgery, including urgency, frequency and nocturia, as well as urinary stress incontinence. The occurrence of adverse events and both subjective and objective success proves over-all positive results.

Despite a general decline in SUI and OAB symptoms, there were still 13 (3.7%) recurrence cases in 4 months follow-up. The unfavorable results rate was 2.5%, including 5 (1.4%) cases of surgery failure and 3 (0.9%) cases of urinary tract infection (UTI) in 4-month follow-up. All the complications are listed in Table 3. Three days of oral antibiotics were used to treat postoperative fever of unknown origin; hemostatic sutures were used

to treat intraoperative bleeding; low hemoglobin was carefully watched until spontaneous recovery; leg edema, vaginal bleeding and hematuria were resolved spontaneously; retropubic TVT was used for patients suffering SUI recurrence; surgical apical suspension was used to treat POP; analgetics were used to treat low back pain; and exposed tape segments as well as granulation tissue were resected, antibiotics were used to treat UTI.

At the 4-month follow-up, the patient's satisfaction rating was 95.9%.

At the postoperative pelvic examination, 1 month after the treatment, there was a significant improvement in SUI, apical, anterior and posterior defects (Figure 1). There was a significant positive correlation between anatomical and functional success rate, the correlation coefficient is significantly different from zero ($p < 0.0001$). Functional outcomes are also associated with higher ratings for anatomical results.

**Figure 1.** Postoperative functional results at 4th month follow-up

POP: pelvic organ prolapse; OAB: overactive bladder; SUI: stress urinary incontinence

Table 3. Complications rate

	n	%
1 day after surgery		
Intra operative bleeding (>100 cc.)	1	0.3%
Low hemoglobin <10 gr %)	1	0.3%
Fever (>38.0)	2	0.4%
Leg edema	1	0.3%
1 month after surgery		
Vaginal bleeding	1	0.3%
Hematuria	1	0.3%
4 months after surgery		
SUI recurrence	13	3.7%
UTI	3	0.9%
Vaginal tap exposure	2	0.6%
LBP	1	0.3%
Granulation tissue formation	1	0.3%
POP	2	0.6%
SUI: stress urinary incontinence; POP: pelvic organ prolapse; UTI: urinary tract infection; LBP: low back pain		

DISCUSSION

Seraxis is a partially absorbable light-weight mid-urethral sling for treating SUI, used here with the transobturator approach. Being gently weaved rather than laser cut and composed of soft fabric, its edges are soft – making the insertion significantly less traumatic than other mid-urethral slings, causing less damage to the tissue, diminishing post-operative pain and the extent of tissue scarring, as well less tap exposure occurrence rate. Both, pain intensity and duration were low, when compared to previous clinical reports. The fact that some patients had improved SUI, yet not completely cured explains the reported 95.9% patient satisfaction compared to the 94.4% SUI cure rate. The data reported here agrees with former comparison of Seraxis to other TOT taps, showing that the Seraxis related post-operative discomfort occurs less frequently and at lower levels.

We strongly believe that concomitant prolapse repair improves the patients centered subjective satisfaction of anti-incontinence surgery. Thus, concomitant anterior and posterior colporrhaphy was performed in 64.8% cases. POP surgery together with MUS were compared in an RCT by Van der Ploeg et al., which showed that POP surgery plus MUS improved post-operative USI.

Our study shows excellent results in terms of the post-operative success rate and the occurrence of subjective and objective side effects.

Long-term follow-up studies on efficacy and adverse effects following Seraxis sling implantation are not available currently.

Study Limitations

Due to its descriptive and retrospective nature, the current study has a few limitations: The retrospective nature of the study, no control group in this descriptive trial to compare our surgical technique to, a rather short follow-up period and lack of use validated questionnaires to assess the outcome results. The strengths of the study are the large patient's group and the large data amount reported here.

CONCLUSION

The use of a partially absorbable, light-weight carefully weaved tape for anti-incontinence procedure results in reduced morbidity while preserving treatment effectiveness. This current study shows that the Seraxis mid-urethral sling is a safe, efficient procedure that has a minimal risk of complications.

ETHICS

Ethics Committee Approval: Helsinki Committee's approval 29:5:24, for Prof. Menahem Neuman, Assuta Medical Centers: We were convinced that your study about curing female USI with sub mid urethral sling placement is in accordance with the 1980 regulations of ethics of medicine and you can now proceed with your research. Your study no is 013-24-ASMC, version no 2. discussed on 12:4:24, approved on 29:5:24. Dr. Shiri Shulman, Assuta.

Informed Consent: Being a retrospective study, the ethical committee waved us the need for informed consent.

FOOTNOTES

Contributions

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

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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