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Is a softly knitted polypropylene tape a better choice than a laser cut polypropylene tape for the treatment of female urinary stress incontinence?

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ABSTRACT

Objectives: Urinary stress incontinence (USI) is a discomforting condition that negatively affects the quality of life of many female individuals and frequently treated by surgical intervention. The incontinence curative operations revolutionized at 1995, with the introduction of the first retro-pubic sub-mid urethral synthetic slings, intra-vaginal sling-plasty (IVS) and tension free vaginal tape (TVT), by Ulmsten and Petros. This was later proposed to be done trans-obturator (TOT), for avoiding operative bladder injuries such as perforation (5.5% were attributed to the older technique and 0.3% to TOT) according to Cochrane review in 2009. Among other peri-operative untoward outcomes attributed to the commonly used anti-incontinence TOT are the dyspareunia, thigh and groin pain. This current study aims to compare TVT-Abbrevo procedure (12 cm polypropylene laser cut tape) to Serasis procedure (softly knitted monofilament non-absorbable polypropylene) for the cure of USI. The purpose of this study is to evaluate the feasibility, the safety, the cure rate, and postoperative pain of both procedures, as well as digital ability to palpate the implanted tapes and on physical examination. We assume that production of pain during palpation of the tape might predict dyspareunia in our patients.

Materials and Methods: This is a two arm, prospective and randomized comparative study. Ninety-nine women were recruited for the study and followed for one year after the surgery. Data was collected from the patient's medical charts and, in addition, the patients were interviewed by using three different questionnaires [Pain Questionnaire (Pain Q), Urinary Distress Inventory - Short Form (UDI-6), Incontinence Impact Questionnaire - Short Form (IIQ-7)] at different time intervals. In addition, physical examinations were performed before and after the operations.

Results: Cure rates at three months and one-year post surgery were similar between both groups based on questionnaires and physical exams. A trend of higher palpation score was documented with TVT-Abbrevo group vs. Serasis group (5.6% vs. 0.0%, p=NS) one-year post surgery. Replies to the pain questionnaire showed no significant difference between the two groups. Surgery characteristics-needle passing in the tissue was more difficult in Serasis group (23.4% vs. 0.0%, p=NS) than in TVT- Abbrevo group, however, blood loss was more prominent in TVT-

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Abbrevo group (1- sided *p*-value 0.046). One procedure failed in TVT-Abbrevo and Serasis groups meaning inadequate improvement, leakage persisted one year after the surgery.

Conclusion: Based on the results, Serasis softly knitted polypropylene tape might be a better choice than TVT-Abbrevo laser cut polypropylene for the treatment of female USI due to less unfavorable outcomes.

Keywords: Serasis; TVT-Abbrevo; USI; pain; groin; thigh; dyspareunia; safety

Introduction

The International Uro-gynecological Association (IUGA) and International Continence Society (ICS) defined urinary stress incontinence (USI) as urine loss condition with sudden pressure on the bladder or urethra during effort, physical exertion such as sports activities, or while sneezing or coughing.[1] USI is not a life-threatening condition, yet, if left untreated, it might have a significant negative impact on quality of life of many patients. According to epidemiologic studies woman's age, multi-parity and menopausal status are all risk factors for USI.[1,2] Treatment options offer changes in life style, and nonsurgical modalities such as pelvic floor muscle training which can be useful in mitigating discomforting symptoms. However, upon failure of conservative treatment, surgery will be recommended for women who are unsuccessful in coping with USI.[3]

Intravaginal sling-plasty retro-pubic surgical procedure was reported by Ulf Ulmsten and Peter Petrous at 1995 for treating urinary stress incontinence[4]. Soon after, a study was done on this new procedure now called TVT, which was concluded to be a safe and an efficient ambulatory procedure.[4-6] This led to a major change with the uro-gynecologic operation preferences, that was previously based mainly on open retro-pubic operations. Trans-obturator sub mid urethral tape procedures (TOT) for treating female urinary stress incontinence were reported thereafter, first by Delorme,[7] then by De Leval.[8] The TOT procedures were designed in order to minimize the incidence of urinary tract injuries, urinary outlet obstruction, bowl penetration and intra-operative bleeding.[9,10] The TOT procedures' efficacy was claimed to be non-inferior to the TVT, therefore became greatly adopted by uro-gynecologists world-wide.[9] The proximity of the TOT needle to the obturator vessels and nerves, might explain the incidental post-operative thigh pain.[10]

Despite the fact that TOT is reported to have a low complication rates, there are still complaints on post-operative thigh and groin pain as well as dyspareunia.[11] A study on a mini TVT, using a single incision sling that does not pass through the obturator membrane, found reduced post-operative pelvic and thigh pain, yet many surgeons are reluctant to use mini TVT implants because of the expected reduced cure rates. Dyspareunia, occurred with TVT, TOT and mini TVT procedures causing concern with sexually active patients.[11] Thigh and groin pains are complications caused by trans-obturator passage of the sling close to the obturator nerve. The typical TOT post-operative pain is at the thigh, uni or bilateral, yet it was described even at the lumbar spine or hip regions. This might have been due to patient's hips position during operation, but more likely to intra-operative obturator nerve injury or post-operative neuralgia, due to a direct pressure or tape foreign body reaction.[9] Jean de Leval, Alexandre Thomas and David Waltregny proposed a modified TOT[9], the TVT-Abbrevo (Ethicon J&J Somerville, NJ, USA). The polypropylene tape's length was reduced to 12 cm. The TVT-Abbrevo was developed in order to avoid extensive tape trans-obturator traumatic passage, thus reducing the amount of mesh in the aponeurotic tissues, and this way to reduce the postoperative pain in the thigh and groin areas.[9] The post TVT Obturator thigh pain might be due to nerve injury or compression, or might it be due to irritation of the adductor muscle components. Anyhow, this thigh pain was shown to be significantly reduced with the Flam modification.11

Their results showed that the group that underwent modified TVT-Abbrevo procedure experienced less pain on day 0 than the TVT-Obturator group but not thereafter.[9,12] In addition to thigh and groin pain, Sue Ross, in his clinical study was concerned to find that a significant number of women in TOT group (80%) had a palpable polypropylene tape at vaginal examination one year after the surgery vs. TVT group (27%).[13] These findings are rather concerning because risk factors for unfavorable outcomes of tape surgeries such as dyspareunia, erosions are not completely understood.[13,14]

The Serasis (Serag-Wiessner, Naila, Germany) is composed of soft knitted sling implant, potentially able to reduce the occurrence and severity of post-operative pain. The ratio is that the tape softness will reduce tissue trauma when the tape is introduced through the obturator plat and maybe less fibrotic tissue reaction as well. There are no comparative studies performed on effectiveness of Serasis tape implantation as an anti-USI procedure, neither a comparison to other polypropylene tapes.

In this prospective study we compared the Serasis to the TVT-Abbrevo, for the treatment of USI. Firstly, we evaluated feasibility, the safety and the effectiveness of both procedures including the post-operative immediate and long-term pain levels as well as the dyspareunia developed after the insertion of the devices.

Secondly, we evaluated differences in the ability to palpate the Serasis and TVT-Abbrevo tapes and possibly produce local pain at vaginal examination in both groups one-year post surgery. We focused our attention on rigidity of the Serasis tape, a soft knitted sling, versus the common polypropylene tape, which is provided with the TVT-Abbrevo. Previous studies showed that the TVT-Abbrevo caused less immediate post-operative thigh and groin pain. There was no pain found in the long term.[12,15] This current study hypothesis is that being gently knitted, the Serasis tape, would be superior to the TVT-Abbrevo tape, in terms of post-operative pain levels and severity. We think that Serasis might be an effective solution for the above stated post-operative complications due to its softer monofilament non-absorbable polypropylene tape.

We presumed that the objective and subjective cure rates may be around 85% in Serasis group and in TVT-Abbrevo group. Early postoperative pain levels, caused probably by operative trauma, will be the same in Serasis and TVT-Abbrevo groups of patients. Finally, the long term post-operative pain levels, dyspareunia and ability to palpate the implanted tape at vaginal examination will be reduced with the Serasis patients' group in comparison to the TVT-Abbrevo groups of patients. The significance of this study is that the effectiveness, immediate and long term post-operative outcomes and vaginal tape palpability and exposure can improve the choice of the tape.

MATERIALS AND METHODS

Study Design

This is a two arm, prospective and randomized comparative study.

The enrolled patients were given detailed, explanation regarding the study. Patients signed an informed consent and got randomized onto one of the two study groups, to have either Serasis or TVT-Abbrevo.

The operations were performed under general anesthesia and the patients were discharged 8 hours after surgery.

The operations were performed according with previously medially deviated trans-obturator needle passage. The TVT-Obturator Flam which is a medial deviation of the de-Leval surgical needle pass. The needle is inserted perpendicularly through the medial section of the structures.[15]

Data such as history of health was extracted from patient's medical folders that were created by the researchers for this particular study, collected on interviews by using three questionnaires [Pain Questionnaire (Pain Q), Urinary Distress Inventory - Short Form (UDI-6), Incontinence Impact Questionnaire - Short Form (IIQ-7)] and physical exams.

Validation of the urogenital distress inventory (UDI-6) and incontinence impact questionnaire (IIQ-7) standardized questionnaires that are composed of multiple-choice questions ordered based on the severity of the condition. For example, UDI 6- Frequent urination? 0- not at all, 1- a little bit, 2- moderately, 3- greatly.

Chronbach's Alpha was calculated 1 month and 3 months after the surgery for both questionnaires. UDI-6=0.628, IIQ-7=0.802 and UDI-6=0.535 and IIQ-7=0.879. Pain questionnaire was written by the researchers. Chronbach's Alpha was calculated for pain questionnaire before release from the hospital 0.734 and after the release 0.665.

Study's detailed steps:

Pre-operation: interview + physical exam + (Pain Q, UDI-6, IIQ-7).

Intra-operative estimate of feasibility and safety: needle passage ease and adjustment using (modified visual analog scale (VAS) system: 0- not at all, 1- slightly, 2- moderately, 3- greatly), estimate blood loss (cc).

Before discharge from the hospital: chart data download, interview + physical exam+ pain questionnaire.

Early postoperative follow up: interview and a pain questionnaire by telephone on the 1st post-operative day.

1 month follow up: interview + physical exam + Pain Q, UDI-6, IIQ-7 questionnaires, palpability score was determined at physical exam.

3 months follow up: interviewed by telephone + Pain Q, UDI-6, IIQ-7 questionnaires

12 months follow up: interview + Pain Q, UDI-6, IIQ-7 questionnaires, physical exam including objective palpability score determination.

Data was collected, reviewed and investigated by the researchers.

Subjects

Inclusion criteria: Women suffering from urinary incontinence during physical exertion proved by clinical examination such as supine cough stress test. This study enrolled 99 patients, 52 women to TVT-Abbrevo group and 47 to the Serasis group. Sample size was calculated according to the difference in pain levels between women in TVT-Abbreveo and Sersis groups. The difference of 50% in pain levels between the two groups was considered as a significant difference (for example, 1.2±2 on 0 to 3 scale, 3=great pain).[15] Based on the Independent sample t-test, 2-sided hypothesis, 5% significance for approximately 40 patients in each group, the power is 96%. With intention to use a parametric test as Mann–Whitney according to the A.R.E rule, it is required at least 46 patients in each group to achieve the same

power of 96%. The sample size analysis was calculated with the IBM SamplePower software (Endicott, New York, United States), version 1.2.

The exclusion criterion:

Women younger than 30 and older than 80 years old.

Women who had previous surgical procedures involving the pelvic floor, either for the treatment of USI or for pelvic organ prolapse (POP).

Women who suffered from advanced POP [POP-Quantification System (POP-Q) stage more than 2].

Patients who had absent or incomplete medical records regarding their history of health.

Women who refused to participate with the study.

Women who were not able to give informed consent or participate with this randomized research study for any other reason.

Variables

Demographic data was collected such as age, background illness, etc.

Preoperative/intraoperative/postoperative data collection: medical records created by the researchers for this particular study which included health background, demographic data and personal information such as contact numbers, and other relevant information. Questionnaires on quality of life (IIQ-7), urogenital distress (UDI-6) and sexual functioning, surgical procedure that was undertaken, clinical postoperative analysis, pain levels and other intra and post-operative complications were evaluated using VAS.

Pain location, severity, onset and duration were determined at thorough examination by the main researcher. The ability to identify the implant upon digital vaginal palpation (VAS)-zero "not at all" palpable and three "greatly/very" palpable.

The primary outcome measures were the cure or failure of the operation, as well as any adverse effects such as dyspareunia or pain. This was based upon interview and questionnaires. The second outcome measure was the ability to palpate on the polypropylene tape at vaginal examination.

Statistical Analysis

Quantitative data is presented using mean and standard deviation, median and ranges, while qualitative data is presented using frequencies and percentages. Comparison of quantity data between the groups was examined by comparisons tests: Independent sample t-test or Mann–Whitney U test (if the normality assumption was violated). Qualitative data was compared among/between groups using chi-square test or Fisher's exact test (if expectancy <5). Changes over time were examined. Quantity data was compared by Wilcoxon signed ranks test, as appropriate. Ordinal data was compared by Freidman test (comparison test of a rank variable between different time points. Sometimes it is also used for the purpose of comparing quantitative data between different time points when the assumptions that are required for parameter tests in this case do not exist.) or Wilcoxon signed ranks test.

Estimation of feasibility and safety of the procedures: blood loss (cc)-estimated clinically by the main surgeon based on his experience and judgment, needle passage ease (VAS) – 0 to 3. Zero meaning "not at all" difficult and three meaning "greatly/very" difficult was estimated by the main surgeon based on experience of how much force needed to be applied in order to pass a needle through the tissue.

Estimation of pain level at: intercourse, vaginal examination, and of constant pelvic, thigh and groin pain follow up 1 month, 3 months and 12 months after the surgery (VAS).

Estimation of tape palpability: 1 month and 12 months using (VAS).

Estimation of cure rate: cure-no leakage at all, failure-inadequate improvement, leakage remained one year after the surgery. Recurrence; completely dry, based on questionnaires; physical exams.

Ethical Aspects

Following the protocol for performing clinical human research, this MD Thesis was approved by board of Helsinki on 03.02.2016 and extended on 23.07.2017, 0141-15-NHR. NIH registration code: NCT02867748.

RESULTS

A total of 99 women were recruited to the study. Forty-eight women were lost during the 12 months follow up due to personal issues such as new personal or family member's health problems, changing home location and not being able to make to the doctor's office, lack of commitment to the study. Eight out of 51 women left were interviewed by phone only at 12 months follow up and did not visit at doctor's office. Forty-three women completed 12 months follow up including visits at physician's office.

Ninety-nine women were randomly assigned into two groups. Fifty-two women in TVT-Abbrevo group and Forty-seven in Serasis group. Data based on demographic information showed no significant difference between the two groups ($p>0.05$) (Table 1).

Table 1. Preoperative information

Demographic data		TVT-ABB (n=52)	Serasis (n=47)	*p*-value (2-sided)
Age	Mean (SD)	54.8 (13.7)	51.7 (10.1)	0.178*
BMI	Mean (SD)	27.7 (3.07)	26.8 (2.8)	0.106*
Duration of urinary incontinence	Median (range)	2 (0.16–30)	2 (0.16–15)	0.979**
Parity	median (range)	3 (1–6)	3 (0–6)	0.901**

*Independent Sample T-test; **Mann–Whitney U test; TVT: tension free vaginal tape; ABB: Abbrevo; BMI: Body Mass Index; SD: standard deviation; n: number

Data collected for blood loss during surgery, difficulty passing a needle during surgical procedures, and additional necessary procedures such as anterior and posterior colporraphy showed no difference between the two groups ($p>0.05$) (Table 2). Blood loss category during surgery showed significant difference between the groups for 1 tailed *p*-value calculation ($p=0.042$) but not for 2-tailed.

Based on a raw data we noticed that passing a needle in the Serasis group appeared to be more difficult than in TVT-Abbrevo group. It got "2"-moderate as opposed to "0"-not difficult at all as defined in methods section.

On a visit to physician's office before the surgery, physical examination was performed to estimate the degree of incontinence, posterior, anterior and uterine prolapses (meaning the degree of uterine complete/incomplete descend into the vaginal cavity). Patients were followed for one year after the surgery and physical examination was performed and recorded using VAS grading system at 1st, 3rd and 12th months as mentioned before. Percentage of improved cases was calculated and compared between TVT-Abbrevo and Serasis groups. Improvement is considered a reduction by one in the grading system (Table 3). Friedman test was used to show significant statistical improvement (*p*-value <0.001) over time for each group with an exception of few cases. Urinary stress incontinence category score was" 2"– moderate on a grading scale 12 months after the surgery for few patients in both groups. Finally, Fisher's exact test and Pearson chi square test were used to calculate p-value which showed no significant difference between the two groups.

Pain questionnaire was administered before and after discharge from the hospital, 1, 3 and 12 months after the surgery (Tables 4a-g). The following data shows total number of patients and their pain scale choices based on VAS grading system. There was no significant difference in pain levels between the two groups based on calculated Pearson chi-square, Mann-Whitney U test and Fisher's exact test (*p*-value> 0.05). Friedman test was calculated for each group and showed significant statistical improvement overtime in pain scale (*p*-value<0.05).

Palpation of TVT-Abbrevo and Serasis tapes on physical exam were performed at doctor's office at the discharge from the hospital, and then during follow up visits at 1 month and 12 months. Improvement in palpation showed reduction by one in the grading system (VAS). Friedman test was used to show significant

Table 2. Surgery characteristics

Variables		TVT-ABB (n=52)	Serasis (n=47)	*p*-value
Blood loss (cc)	Median (range)	47.5 (10–180)	40 (10–160)	0.092 (2-sided)** 0.046 (1-sided)**
Difficulty passing a needle (VAS system)	0	10 (19.2%)	13 (27.7%)	0.29**
	1	42 (80.8%)	23 (48.9%)	
	2	0 (0.0%)	11 (23.4%)	
Additional procedures				1.00***
	Without additional	22 (42.3%)	20 (42.6%)	
	Procedures	-	-	
	Posterior colporrhaphy	1 (1.9%)	0 (0.0%)	
	Anterior and posterior	29 (55.8%)	27 (57.4%)	
	colporrhaphy	-	-	

**Mann–Whitney U test; ***Fisher's exact test; TVT: tension free vaginal tape; ABB: abbrevo; VAS: Visual Analogue Scale; n: number

improvement in palpation for each group over the year (*p*-value <0.001). Based on Mann–Whitney U test (*p*-value >0.05) there was no significant difference between the two groups. In TVT-Abbrevo group at 12 months physical exam two patients received higher palpation scores as opposed to Serasis group (Table 5).

In order to estimate the degree of improvement of USI and quality of life as defined in the methods section for each group, the mean was calculated for each questionnaire, UDI-6 and IIQ-7. A decrease in mean (answers for each question in the questionnaire summed and mean calculated), at one and three months is shown in (Table 6) indicating improvement. A slight increase in mean is seen at 12 months, which was due to the fact that few patients suffered from urinary urgency at the time of filling out UDI-6 and IIQ-7 standardized questionnaires. Patients presenting with urinary urgency were further evaluated before choosing a proper treatment. Based on patient's condition treatment consisted either of antibiotic drugs for UTI, anticholinergic drugs for overactive bladder, or other behavioral strategies until resolution of urinary incontinence symptoms. *P*-value is showed in (Table 7).

Questionnaires comparison by timeline for TVT-Abbrevo and Serasis groups showed that there was a significant improvement in USI cure rate and overall quality of life 12 months after the surgery for each group. Answers for each question in the questionnaires UDI-6, IIQ-7 were summed, results summarized, and *p*-value was calculated.

Table 3. Physical examination timeline

		Timeline							
		0		1		3		12	
Variable	Score	TVT-ABB	Serasis	TVT-ABB	Serasis	TVT-ABB	Serasis	TVT-ABB	Serasis
Urinary stress incontinence	0	0 (0.0%)	0 (0.0%)	52 (100%)	46 (97.9%)	52 (100%)	47 (100%)	16 (88.9%)	24 (96.0%)
	1	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	1 (4.0%)
	3	52 (100%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anterior prolapse	0	20 (38.5%)	13 (27.7%)	51 (98.1%)	44 (93.6%)	51 (98.1%)	47 (100%)	17 (94.4%)	25 (100%)
	1	3 (5.8%)	7 (14.9%)	1 (1.9%)	3 (6.4%)	1 (1.9%)	0 (0.0%)	1 (5.6%)	0 (0.0%)
	2	24 (46.2%)	24 (51.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	3	5 (9.6%)	3 (6.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Posterior prolapse	0	19 (36.5%)	14 (29.8%)	51 (98.1%)	44 (93.6%)	51 (98.1%)	47 (100%)	18 (100%)	25 (100%)
	1	3 (5.8%)	9 (19.1%)	1 (1.9%)	3 (6.4%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	2	26 (50.0%)	21 (44.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	3	4 (7.7%)	3 (6.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Uterine prolapse	0	37 (71.2%)	30 (63.8%)	49 (94.2%)	40 (85.1%)	52(100%)	47 (100%)	18(100%)	25 (100%)
	1	14 (26.9%)	17 (36.2%)	3 (5.8%)	7 (14.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	3	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4a. Groin pain

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	39 (75.0%)	10 (19.2%)	3 (5.8%)	0 (0.0%)	39 (83.0%)	7 (14.9%)	1 (2.1%)	0 (0.0%)
After release from the hospital	47 (90.4%)	5 (9.6%)	0 (0.0%)	0 (0.0%)	45 (95.7%)	2 (4.3%)	0 (0.0%)	0 (0.0%)
1 month follow-up	52 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	52 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	22 (95.7%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	27 (96.4%)	0 (0.0%)	0 (0.0%)	1 (3.6%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4b. Vaginal pain at intercourse

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	-	-	-	-	-	-	-	-
After release from the hospital	-	-	-	-	-	-	-	-
1 month follow-up	50 (98.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	44 (95.7%)	2 (4.3%)	0 (0.0%)	0 (0.0%)
3 months follow-up	51 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	22 (95.7%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	27 (96.4%)	0 (0.0%)	0 (0.0%)	1 (3.6%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4c. Vaginal pain

Pain scale	TVT- ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	8 (15.4%)	31 (59.6%)	13 (25.0%)	0 (0.0%)	7 (14.9%)	32 (68.1%)	8 (17.0%)	0 (0.0%)
After release from the hospital	20 (38.5%)	27 (51.9%)	5 (9.6%)	0 (0.0%)	26 (55.3%)	19 (40.4%)	2 (4.3%)	0 (0.0%)
1 month follow-up	51 (98.1%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	27 (96.4%)	0 (0.0%)	0 (0.0%)	1 (3.6%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4d. Pelvis pain

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	24 (46.2%)	20 (38.5%)	8 (15.4%)	0 (0.0%)	21 (44.7%)	22 (46.8%)	4 (8.5%)	0 (0.0%)
After release from the hospital	36 (69.2%)	13 (25.0%)	3 (5.8%)	0 (0.0%)	36 (76.6%)	9 (19.1%)	0 (0.0%)	0 (0.0%)
1 month follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	0 (0.0%)	1 (2.1%)	0 (0.0%)
3 months follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	45 (95.7%)	1 (2.1%)	1 (2.1%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4e. Thigh pain

Pain scale	TVT- ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	37 (71.2%)	9 (17.3%)	6 (11.5%)	0 (0.0%)	34 (72.3%)	12 (25.5%)	1 (2.1%)	0 (0.0%)
After release from the hospital	40 (76.9%)	12 (23.1%)	0 (0.0%)	0 (0.0%)	41 (87.2%)	6 (12.8%)	0 (0.0%)	0 (0.0%)
1 month follow up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
3 months follow up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
12 months follow up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	27 (96.4%)	1 (2.1%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4f. Radiating pain

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	40 (76.9%)	9 (17.3%)	3 (5.8%)	0 (0.0%)	43 (91.5%)	4 (8.5%)	0 (0.0%)	0 (0.0%)
After release from the hospital	47 (90.4%)	5 (9.6%)	0 (0.0%)	0 (0.0%)	44 (93.6%)	3 (6.4%)	0 (0.0%)	0 (0.0%)
1 month follow-up	51 (98.1%)	0 (0.0%)	1 (1.9%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	52 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	46 (97.9%)	0 (0.0%)	1 (2.1%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 4g. Coital pain (partner)

Pain scale	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	-	-	-	-	-	-	-	-
After release from the hospital	-	-	-	-	-	-	-	-
1 month follow-up	51 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months follow-up	51 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 months follow-up	23 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 5. Palpation of a tape on physical exam

Palpation score								
Timeline	TVT-ABB				Serasis			
	0	1	2	3	0	1	2	3
Before release from the hospital	0 (0.0%)	0 (0.0%)	0 (0.0%)	52 (100%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	46 (97.9%)
1 months follow-up	16 (30.8%)	33 (63.5%)	3 (5.8%)	0 (0.0%)	36 (76.6%)	11 (23.4%)	0 (0.0%)	0 (0.0%)
12 months follow-up	11 (61.1%)	5 (27.8%)	1 (5.6%)	1 (5.6%)	23 (92.0%)	2 (8.0%)	0 (0.0%)	0 (0.0%)

TVT: tension free vaginal tape; ABB: abbrevo

Table 6. Improvement analysis for each group based on UDI-6 and IIQ-7 questionnaires

	TVT-ABB					Serasis				
Questionnaire	n	Mean	SD	Median	Min-max	n	Mean	SD	Median	Min-max
UDI-6 before surgery	52	0.98	0.4	1	0.5–2.0	47	0.84	0.31	0.83	0.5–1.67
UDI-6 1 month follow-up	52	0.18	0.2	0	0–0.67	47	0.09	0.18	0	0–0.67
UDI-6 3 months follow-up	52	0.18	0.2	0	0–0.67	47	0.14	0.24	0	0–0.67
UDI-6 12 months follow-up	23	0.63	0.6	0.5	0–2.50	28	0.39	0.47	0.25	0–1.5
IIQ-7 before surgery	52	2.12	0.6	2.1	0.86–3.00	47	1.99	0.59	2.15	0.43–3.0
IIQ-7 1 month follow-up	52	0.17	0.4	0	0–1.71	47	0.03	0.13	0	0–0.86
IIQ-7 3 months follow-up	52	0.11	0.3	0	0–1.00	47	0.05	0.15	0	0–0.86
IIQ-7 12 months follow-up	23	0.37	0.6	0.1	0–2.43	28	0.19	0.31	0	0–1.0

UDI-6: Urinary Distress Inventory - Short Form; IIQ-7: Incontinence Impact Questionnaire - Short Form; TVT: tension free vaginal tape; ABB: abbrevo; SD: standard deviation; min: minimum; max: maximum; n: number

We calculated *p*-value for UDI-6, IIQ-7 questionnaires before the surgery and 12 months after the surgery for both groups in order to assess the improvement of USI over time for both groups. Both groups showed neither significant difference before the surgery, nor 12 months post -surgery meaning that the improvement of USI was equal for both groups, *p*-value (2-sided=NS) (Table 8).

Additional information (Table 9) - one erosion and one failure in TVT-Abbrevo group and one failure in Serasis group overall. Erosion means that the tape extruded into the vaginal cavity or other adjacent tissue/organ and was palpable on the physical exam 12 months after the surgery. Cure rate evaluated based on the questionnaires and physical exam 12 months after the surgery. Only 43 women were physically examined at 12 months after the surgery. The rest answered questionnaires.

Table 7. Statistical difference between the questionnaires at different timeline points in each group

Questionnaire comparison by timeline	TVT-ABB &*p*-value	Serasis &*p*-value
UDI-6 before surgery vs.1 month	<0.001	<0.001
UDI-6 1month vs. 3 months	1	0.245
UDI-6 3 months vs. 12 months	0.001	0.007
UDI-6 before surgery vs. 12 months	0.039	0.004
IIQ-7 before surgery vs. 1 month	<0.001	<0.001
IIQ-7 1 month vs. 3 months	0.561	0.266
IIQ-7 3 months vs. 12 months	0.027	0.058 (2-sided)
		0.029 (1-sided)
IIQ-7 before surgery vs. 12 months	<0.001	<0.001

&Wilcoxon signed ranked test; UDI-6: Urinary Distress Inventory - Short Form; IIQ-7: Incontinence Impact Questionnaire - Short Form; TVT: tension free vaginal tape; ABB: abbrevo; SD: standard deviation; min: minimum; max: maximum; n: number

DISCUSSION

It has already been discussed that TVT-Abbrevo was developed to reduce post-operative thigh and groin pain and has the same efficacy as TVT-Obturator tape in treatment of USI.[15,16] Based on recent randomized trial conducted by Zullo et al.[16] efficacy, safety and complications were analyzed prospectively for 3 years and showed 87% percent cure rate in TVT-Abbrevo as in TVT-Obturator group. Significant difference was noted between the groups in postoperative pain. In TVT-Abbrevo group only one patient reported postoperative groin pain vs. nine patients in TVT-Obturator group.[16]

In our prospective randomized study, we followed patients for one year and evaluated the cure rate and pain side effects by comparing between two groups: one using TVT-Abbrevo and the other- Serasis tapes for treatment of USI. The cure rate after one year was 96% in Serasis group vs. 88.9% in TVT-Abbrevo group. There was no significant difference in postoperative pain between the two groups. Vaginal pain at intercourse, vaginal and groin pain was given a higher score in 3.6% of patients in Serasis group one-year post surgery. Palpability score of the tape at 12 months follow up was high in TVT-Abbrevo group for (5.6%) of patients including one complication-erosion into the vaginal cavity.

Pre-operative information such as age, BMI, duration of urinary incontinence and parity showed no significant difference between TVT-Abbrevo and Serasis groups, *p*-value >0.05. Background illnesses were not presented in the results chapter, however, there was no significant difference between the two groups as well. Conditions such as hypertension, diabetes mellitus, hypothyroidism and asthma were the common ones among our patients.

Blood loss in TVT-Abbrevo and Serasis showed no significant difference based on 2-sided *p*-value=0.092, however, 1-sided

Table 8. Statistical comparison between questionnaires for TVT-Abbrevo and Serasis groups before the surgery and 12 months after the surgery

		n	Mean	SD	*p-value (2-sided)	*p-value (1-sided)
UDI-6 before surgery	ABB-TVT	52	0.96	0.40	0.098	0.049
	Serasis	47	0.84	0.31		
IIQ-7 before surgery	ABB-TVT	52	2.12	0.59	0.301	
	Serasis	47	1.99	0.59		
UDI-6 12 months after the surgery	ABB-TVT	23	0.63	0.61	0.106	0.053
	Serasis	28	0.39	0.47		
IIQ-7 12 months after the surgery	ABB-TVT	23	0.38	0.62	0.205	
	Serasis	28	0.19	0.31		

*Independent sample t-test; UDI-6: Urinary Distress Inventory - Short Form; IIQ-7: Incontinence Impact Questionnaire - Short Form; TVT: tension free vaginal tape; ABB: abbrevo; SD: standard deviation; n: number

Table 9. Additional information		
Variables	**TVT-ABB (n=52)**	**Serasis (n=47)**
Erosion	1 (1.9%)	0 (0.0%)
Failure	1 (1.9%)	1 (2.1%)
	TVT-ABB (n=18)	**Serasis (n=25)**
Completely dry	16 (88.9%)	24 (96.0%)
TVT: tension free vaginal tape; ABB: abbrevo; n: number		

p-value=0.046 showed significant difference between the two groups. In TVT-Abbrevo median blood loss was 47.5 vs. 40 in Serasis group. Difficulty passing a needle showed no significant difference between the two groups *p*-value >0.05, however, in Serasis group we see higher difficulty score in (23.4%) of patients vs. (0.0%) in TVT-Abbrevo group. This difference could be attributed to the technique used while passing Serasis tape through the tissue and its attachment. In addition, anterior and posterior colporrhaphy was performed in both groups during the surgery for USI and there was no significant difference between the two groups, *p*-value >0.05.

On physical examination before the surgery, 1,3 and 12 months later we objectively evaluated USI improvement/cure, posterior, anterior prolapse and uterine prolapse using our grading system. Each group showed significant statistical improvement over the year on physical examination, *p*-value <0.001. USI evaluation was performed by supine cough stress test and results showed 96.0% cure rate in Serasis group vs. 88.9% in TVT-Abbrevo group 12 months after the surgery. One and three months after the surgery results showed 97% cure rate of USI or higher for both groups. Higher cure rate (96%) in Serasis group could be explained by the fact that the sample size after 12 months was significantly smaller than that of the previous months since half of the patients were lost to follow one year after the surgery. Therefore, a larger sample of patients is still needed in order decide whether there is a significant difference in cure rate between the TVT-Abbrevo and Serasis groups.

The rest of the categories showed equal results for both groups. No anterior, posterior or uterine prolapses were identified in both groups 12 months after the surgery.

Post-operating immediate and long-term pain was evaluated based on pain questionnaire and both groups did not show any significant difference in pain levels immediately after the surgery or 12 months after the surgery, *p*-value >0.05. There was a significant improvement in pain overtime for each group *p*-value <0.05. However, few patients (3.6%) in Serasis group reported significant vaginal, vaginal pain at intercourse and groin pain at one year follow up vs TVT-Abbrevo group. This slight difference could as well be attributed to a small sample of patients at 12th months follow up, other anatomical, physiological or psychological factors.

We evaluated the ability to palpate the Serasis and TVT-Abbrevo tapes one-year post-surgery. In TVT-Abbrevo as in Serasis group high palpation score was given right after the surgery and before release from the hospital with no significant difference between the two groups as expected. We showed an improvement in palpation score one-year post-surgery for each group, *p*-value <0.001. At 12th months follow up, in TVT-Abbrevo group (5.6%) of patients were given high palpation scores and included one erosion of the polypropylene tape into the vaginal cavity. Palpation scores were low in Serasis group 12 months post-surgery.

These results made us believe that Serasis, a soft knitted and less rigid tape, might result in more favorable outcomes in a long term, less dyspareunia or erosions. Further research is needed to evaluate the ability to palpate, produce local pain with the Serasis tape on a larger sample of patients.

Improvement/cure of USI was evaluated objectively as mentioned before and subjectively based on UDI-6 and IIQ-7 questionnaires before the surgery 1, 3 and 12 months after the surgery. Mean was calculated for each questionnaire and analyzed. A decrease in mean was noted at 1st and 3rd months after the surgery as we expected meaning that there was a significant improvement of USI in both TVT-Abbrevo and Serasis groups (p<0.05). Slight increase in mean was noted 12 months after the surgery and was attributed to urinary urgency that was reported by several patients. Those patients were treated for urinary urgency and the problem resolved. They did not repeat the questionnaires since then.

Overall, two procedures failed in TVT-Abbrevo group and one in Serasis group. Erosion of a tape in TVT-Abbrevo group into the vaginal cavity is a serious complication that we attribute to the stiffness of the tape.

CONCLUSION

This study shows that Serasis tape is as effective as TVT-Abbrevo tape for treatment USI. The soft nature of Serasis tape, however, did not alleviate completely postoperative pain such as vaginal or groin pain 12 months after the surgery in few patients, and needs a further research on a larger sample of patients. Cure rate based on physical exam and questionnaires was the same in both groups. Palpation scores were higher in TVT-Abbrevo group one-year post surgery as we expected. We attribute it to the stiffness of the tape that might have also led to the erosion of the TVT-Abbrevo tape into the vaginal cavity in one patient. Stiffness

could be one of the causes in addition to the age of a patient, background illnesses, BMI, etc. This needs further investigation in order to make correct selection of patients and to choose the best tape to use in order to reduce post-operative complications and increase effectiveness in a long term. Erosion complication was not observed in Serasis group one year after the surgery. Further research is needed on a larger sample of patients in order to conclude that Serasis has low rate of serious complications such as erosion/exposure of the tape into the vaginal cavity. Overall satisfaction of quality of life one year after the surgery was equal for both groups based on statistical analysis of questionnaires.

ETHICS

Ethics Committee Approval: This Medical degree thesis was approved by board of Helsinki on 03.02.2016 and extended on 23.07.2017, 0141-15-NHR. NIH registration code NCT02867748.

Informed Consent: Informed consents were obtained from the patients.

Peer-review: Externally peer-reviewed.

Contributions

Concept: Y.T.H., M.N., J.B.; Design: Y.T.H., M.N., J.B.; Data Collection or Processing: Y.T.H., M.N., J.B.; Analysis or Interpretation: Y.T.H., M.N., J.B.; Literature Search: Y.T.H., M.N., J.B.; Writing: Y.T.H., M.N., J.B.

DISCLOSURES

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