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I-Stop® for Treatment of Stress Urinary Incontinence: High Satisfaction Rate and Low Morbidity

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Abstract: *Objective*: The objective of this study was to investigate patient satisfaction and stress urinary incontinence (SUI) cure rates in females who underwent a midurethral I-Stop® sling insertion. It is well established in current literature that midurethral sling insertion is a highly efficacious treatment for female SUI. The challenge with sling insertion is to find a product that addresses SUI caused by both urethral hypermobility and intrinsic sphincter deficiency (ISD). Thus, this study aims to highlight the success of an I-Stop® midurethral slings for treatment of SUI in females with ISD and urethral hypermobility, while demonstrating low patient morbidity. *Methods*: Three hundred females who underwent midurethral I-Stop® sling insertion from August 2011 through December 2019 were included in this retrospective chart review. Females with diagnosed SUI and ISD were included in this study. Females with ISD underwent retropubic sling insertion approach while all other patients diagnosed with SUI underwent a transobturator (TO) approach. Patients scheduled follow-up visits 2-, 6-, 12-, and 24-weeks post-procedure and then yearly thereafter. Statistical analysis was completed with a paired t-test. *Results*: This retrospective review yielded 300 females who underwent sling insertion with a mean age of 66.6 years and median follow up of 37 months. Satisfaction rate was rated 4 or 5 on a 5-point Likert scale by 91.7% of patients, and SUI correction rate was 95%. Highest satisfaction rates were reported by patients in the 65–75-year-old age group. No statistical significance was identified between any of the variables analyzed with the exception of reported SUI after sling insertion and satisfaction rate, $p=0.048$. Nine patients (3.0%) required sling lysis secondary to inability to void or difficulty voiding resulting in elevated post-void residual values >200cc. Ten patients had sling exposure requiring revision. No vaginal, urethral, or vesical perforations, and no persistent pain post-procedure was reported. *Conclusion*: Midurethral I-Stop® sling insertion results in high patient satisfaction and SUI cure rates while maintaining low post-operative complications.

Keywords: Stress Urinary Incontinence, Midurethral Sling, Incontinence, Transobturator Sling, Retropubic Sling

1. Introduction

Treatments for stress urinary incontinence (SUI) have undergone several minimally invasive iterations since the idea's first conception proposed by Petros and Ulmsten [1] in the early 1990's and first introduction with the first tension-free vaginal tape in 1996 [2], and echoing DeLorme's work with the transobturator technique [3]. Every new minimally-invasive concept introduced has brought inherent questions regarding safety and efficacy. The concept of the transobturator approach was to preserve the pre-vesicular space and reduce vascular and visceral complications caused by open procedures [3]. Likewise, the retropubic approach with the minimally invasive trocar usage helps to minimize these complications as well by preventing open dissection of the pre-vesical space. In 2011, the United States Food and Drug Administration (FDA) issued a statement declaring the use of mid-urethral polypropylene mesh sling to be safe and effective in the treatment of SUI [4]. Thus, the midurethral mesh sling remains a mainstay of treatment for many women who fail more conservative therapies for treatment such as pelvic floor physical therapy and biofeedback.

The challenge becomes to find an acceptable sling product that can address SUI caused by both urethral hypermobility and intrinsic sphincter deficiency (ISD) with excellent outcomes and safety. The combination of safety and efficacy is of utmost importance when offering treatment options to patients and counseling patients about post-surgical

expectations and longevity of treatment.

The I-Stop® midurethral sling (CL Medical, Lyon, France) is a monofilament, macroporous, and inelastic sling made of polypropylene mesh. It has been well-established that these are superior characteristics of sling material by reducing infection rate and allowing incorporation of the tissue within the mesh to reduce sling exposure and compromised healing [5-7].

The objective of this paper is to demonstrate that the I-Stop® midurethral sling remains a highly effective treatment for SUI with low morbidity and a high rate of satisfaction. Specifically, the I-Stop® midurethal sling by CL Medical not only demonstrates superior safety but also superior efficacy, durability, and patient satisfaction with an exceptionally low morbidity rate.

2. Materials and Methods

Patients undergoing midurethral I-Stop® sling insertion from August 2011-December 2019 were included in this retrospective chart review design with a total of 300 females who underwent I-Stop® sling insertion out of 322 total female patients. All procedures were performed by a single surgeon who is Fellowship trained in Female Pelvic Medicine and Reconstructive Surgery and underwent the procedure under general anesthesia. The Internal Review Board (IRB) was consulted, and the IRB confirmed that IRB approval was not required for this study. Each patient included in this study underwent the procedure with an inelastic, looped-edge macroporous sling constructed of polypropylene (I-Stop®, CL Medical, Lyon, France) for diagnosed SUI. Patients with SUI were diagnosed by urodynamic studies, noted urethral hypermobility, and/or SUI visualized during physical exam. Patients with ISD were diagnosed by urodynamic studies revealing VLPP <=60cm H_2O. All multichannel urodynamic studies were performed using air-charged catheters and were all performed according to standard protocol in the same clinic. However, not all patients underwent urodynamic testing prior to their surgical procedure.

Patients diagnosed with ISD underwent retropubic sling insertion (24 patients) while all other patients with diagnosed SUI underwent a transobturator approach (276 patients). Patients who required pelvic organ prolapse (POP) concomitantly were included in this review as were patients who had previously undergone prior anti-incontinence procedures and confirmed overactive bladder by urodynamic studies. Patients were excluded from this review if they underwent sling insertion using any other product other than I-Stop® or underwent autologous sling insertion. Patients with prior sling insertion were included as the sling revision was performed with I-Stop® sling.

All patients were evaluated and physically examined by the primary surgeon prior to surgery and at each subsequent follow up appointment. Every patient's follow up visits was scheduled at 2, 6, 12, 24 weeks, and then yearly thereafter. Patient data considered included age at time of procedure, prior history of anti-incontinence procedure, and diagnosis of overactive bladder, complications of procedure, persistent pain, persistent urinary retention/incomplete bladder emptying, persistent SUI, and satisfaction rate as measured on a 5-point Likert scale. Patients reported their satisfaction rates by telephone follow-up. Success was measured by those patients who reported a 4 or a 5 on a 5-point Likert scale. Patients also self-reported the presence or absence of post-operative SUI at each of their scheduled follow up visits or at the time of telephone follow up. For patients who were not seen within the last two years, a telephone follow-up was conducted at the time of writing this manuscript to assess patient satisfaction rates.

Additionally, patient charts were reviewed for patients being treated for overactive bladder (OAB), those who experienced sling exposure and if it was repaired in the office or operating room setting, those who needed sling revision and the reason for revision, and those patients who underwent urethral bulking agent (UBA) post-sling.

Statistical analysis of the collected data was completed with a paired *t*-test. Normal and continuous data was reported as mean and standard deviation. A p value <0.05 was considered significant. The data analysis for statistical significance was conducted for comparison of each of the following variables: Age, BMI, SUI after sling insertion, follow up, prior sling, sling exposure, persistent pain, need for UBA, OAB treatment, sling revision, and satisfaction rate.

3. Results

This retrospective review had a total of 322 total patients. Twenty-two patients were excluded secondary to sling insertion with a different brand/type of sling. Thus, we yielded 300 patients who underwent I-Stop® sling insertion with a mean age of 66.6 years and median follow-up period of 37 months (Table 1). The follow-up duration was not normally distributed. The median BMI of patients included in this study was 28.4±6.19. Three patients were lost to follow up and one patient was deceased at the time of this review, so satisfaction rate was taken from the verbal report given at their last follow up appointment.

Of the 300 procedures, there were no vaginal, urethral, or vesical perforations. Additionally, there was no report of uncontrolled pain post-procedure. One patient suffered from a hematoma of the retropubic space following retropubic sling insertion that required evacuation 2 days post-procedure. This patient gave a low satisfaction rate despite successful hematoma evacuation and no persistent SUI reported after the procedure. Patient pelvic operation history was indicated by whether the patient had a prior sling. Of the 300 patients, only 57 of the women were pre-menopausal (less than 55 years of age). 243 women were post-menopausal (greater than 55 years of age at the time of publication).

Nine patients (3.0%) required sling lysis secondary to inability to void, or difficulty voiding, resulting in elevated post-void residual values >200cc that were symptomatic (Table 2). Ninety-five percent (95%) of patients who underwent sling insertion did not have SUI after surgery. Of those 15 patients who reported persistent SUI after sling insertion, 12 of those patients (4.0%) opted to undergo UBA

injection (Table 2). Additionally, only 10 patients (3.3%) had a sling exposure requiring revision (Table 2). Of those 10 patients with exposure, 6 of those patients successfully underwent revision in the office setting with local anesthesia. The remaining 4 patients who underwent revision for exposure had a successful revision in the operating room setting; 2 secondary to body habitus preventing office revision and 1 patient had exposure located in an area in the vagina that could not be accessed easily in the office. The one remaining patient requiring revision could have been revised in the office, but she required another surgery and opted to have it repaired in the operating room concomitantly. All sling exposures were revised.

Table 1. *Patient Demographics and Follow up.*

Age (years)	N		Minimum	Maximum	Mean
	300		30 years old	93 years old	66.6 years old
Age group	25-35	1	41 months	41 months	41.0 months
	35-45	15	7 months	67 months	32.6 months
	45-55	42	7 months	96 months	36.8 months
	55-65	57	7 months	96 months	41.6 months
	65-75	97	4 months	103 months	35.1 months
	75-85	72	5 months	96 months	39.5 months
	85-95	16	10 months	100 months	39.0 months
Follow up (months)		300	4 months	103 months	37.7 months
Median Follow up (months)		37 months			
BMI (median)	28.4±6.19				
Pre-Menopausal Women (N)	57				
Post-Menopausal Women (N)	243				

Table 2. *Operative Variables of Patients Undergoing Sling Insertion.*

Category	Yes		No	
	Frequency	Percentage (%)	Frequency	Percentage (%)
Prior Sling	40	13.3	260	86.7
SUI After Sling	15	5.0	285	95.0
Urethral Bulking Agent After Sling	12	4.0	288	96.0
OAB Treatment	141	47.0	159	53.0
Sling Exposure	10	3.3	290	96.7
Persistent Pain	3	1.0	297	99.0
Sling Revision	9	3.0	291	97.0

As referenced in Table 2, 99% of patients reported no persistent pain after sling insertion. The remaining 1% of patients had resolution of symptoms with pelvic floor physical therapy. We considered patients who underwent prior midurethral sling insertion for this study, which comprised 40 patients (13.3%). Evaluation of SUI after surgery was indicated by subjective self-report during each of the patient's scheduled follow up visits. Subjectively, most SUI symptoms had resolved within 6 weeks to 3 months post-operatively. Of the 300 patients included in this study, 141 patients (47%) required OAB treatment with medications.

Table 3. *Patient Satisfaction Rate on a 5-point Likert Scale.*

Age Group (Years)		25-35	35-45	45-55	55-65	65-75	75-85	85-95	Total
Level	1	0	0	1	0	2	3	0	6
	2	0	0	1	1	1	0	2	5
	3	0	0	1	2	4	5	2	14
	4	0	2	5	4	15	8	2	36
	5	1	13	34	50	75	56	10	239
Total		1	15	42	57	97	72	16	300

The satisfaction rate after sling insertion of patients reporting satisfaction of 4 or 5 was high at 91.7% as illustrated by Table 3. Additionally, the highest rate of satisfaction reported in Table 3 was in the age group of 55–85-year-old patients with the highest rate of satisfaction being reported by those in the 65–75-year-old age group. There was no statistical significance noted between any of the variables analyzed except for the report of SUI after sling insertion and patient satisfaction rate, $p=0.048$.

4. Discussion

The objective of this study was to evaluate patient satisfaction rate of those patients who underwent an I-Stop® midurethral sling insertion for SUI. As previously supported by Krauth *et al.,* midurethral sling insertion has demonstrated to be a very effective treatment for SUI [3]. Krauth *et al.,* discovered that patients had an 85.5% satisfaction rate after one-year post-surgery [3]. Similarly, Gomelsky reviewed 55

studies comparing retropubic (RP) to transobturator (TO) midurethral slings that further solidify previous patient satisfaction rates. This study examined patient satisfaction rate during three post-operative periods: short-, medium-, and long-term follow-up. Mean subjective cure rates were found to be 83%, 87%, and 84%, respectively [11]. Our results demonstrated a 91.6% patient satisfaction rate for a median of 37 months post-surgery (ranging from 4-103 months). We found that 95% of patients who underwent I-Stop® sling insertion did not report SUI after surgery. This successfully highlights a positive correlation between satisfaction rating and resolution of SUI for which this retrospective study found significance. Glass et al. found that patients who underwent previous incontinence surgery had a negative SUI cure rate and thus a lower satisfaction rate than patients who did not have previous incontinence surgery [10]. Conversely, our study found no association with prior sling surgeries and subjective cure rates among those patients.

Differences in patient satisfaction among older patients can be complicated by several factors. First, concomitant SUI and OAB likely alter a patient's interpretation of the procedure's success if they are still experiencing leakage resulting from OAB. This is, perhaps, secondary to a lack of patient understanding of the various types of incontinence. Mallett et al. found that a significant number of women expected resolution of symptoms that were not associated with SUI; notably, 92% of women expected that SUI surgery would improve urinary urgency and 74% of women expected resolution of urinary frequency [12]. Nettleman explains that patient satisfaction is directly related to the patient's post-procedural expectations [13]. Furthermore, older patients historically have an increased percentage of concomitant OAB, which leads to more residual leaks compared to younger patients. As Ulrich et al. explains, de novo OAB could develop in older women, thereby decreasing subjective satisfaction ratings [11]. Contrastingly, Shin et al. found that out of 76 patients with SUI who underwent midurethral sling operations, 5 patients (6.6%) developed *de novo* urgency, and the remaining 71 patients did not develop *de novo* urgency [15]. Shin et al. expanded on this finding by stating that the *de novo* urgency was tolerable in 5 patients [15], however, the impact on satisfaction rating remains plausible.

Younger patient populations that have uncomplicated SUI are often cured by sling insertion, thereby increasing satisfaction ratings. We, however, did not find a significant difference when comparing patient age to patient satisfaction. It seems that our findings could be affected by the patients who also require treatment for OAB, as some patients conflate SUI symptoms with OAB symptoms and, thus, were not optimally satisfied post-procedure. This is more prominent in older patient populations, as evidenced by 47% of patients requiring OAB treatment with medications in our study. Because we did not find a significant correlation between age and patient satisfaction, we can therefore imply that OAB presence had minimal impact on patient satisfaction. The success of surgery for SUI is further compromised by performing it in older populations, as Lo et al. found that both subjective and objective cure rates were significantly lower in older populations compared to younger populations [14]. They further posit that age has a negative impact on lower urinary tract symptoms (LUTS) and this can persist even after I-Stop® midurethral sling surgery [14]. Nevertheless, we found that I-Stop® midurethral sling insertion demonstrates a 91.6% satisfaction rate for treating patients with SUI.

This study further elaborates on previous study findings that suggest I-Stop® midurethral sling insertion has a very low complication rate. As demonstrated by Ulrich *et al.,* there were no reported hemorrhage or hematoma formation at the time of surgery [11]. Similarly, Jijon et al. and Krauth et al. found that one and five patients developed a hematoma, respectively [7, 11]. Our study further supports a low post-surgical complication rate. Our outcomes found only one patient (0.3%) developed a hematoma that was successfully evacuated two days post-procedure without further complication. Additionally, our study expands on previous evidence that suggests I-Stop® midurethral sling insertion has a low risk of both revision and exposure rate. Jijon et al. and Ulrich et al. demonstrated that 7.7% and 7% of patients required reintervention, respectively [7, 11]. However, our results were much lower. Our patients required a revision rate of 3.3%, secondary to exposure. Our low exposure rate can potentially be explained, in part, to surgical technique, as more occurrences happened in a cluster of five exposures at post-op within six weeks. The surgeon in our study had been using a running Vicryl suture and changed to an interrupted Vicryl suture with fewer exposures thereafter. This would suggest the possibility of exposure potentially secondary to causes such as faulty suture material, hematoma formation that could not spontaneously evacuate, or less tension on the suture line.

Our study further supports a low rate of sling exposure, as ten patients (3.3%) in our study experienced sling exposure. Sling exposure was identified during proper pelvic examinations at each of the patient's scheduled follow up visits and often occurred in clusters of five. Of these, six patients underwent in-office repair, and four patients had their slings revised in the operating room. Patients underwent sling revisions in the operating room for various reasons. Two patients had increased body habitus preventing revision in the office, one patient had devascularized tissue needing augmentation, and one patient had an upcoming surgery who elected to revise the sling in the operating room concomitantly. The latter patient would have otherwise been a candidate for in-office sling. In-office sling revisions are important because it highlights that when exposures happened, they were not complicated and are revised easily. Additionally, in-office revisions are much more accessible for patients rather than revisiting the operating room. All 10 patients in this study who had sling exposure underwent sling revision.

As previously discussed by Glass et al., 67.5% of patients in their study underwent a concomitant surgery at the time of SUI repair, which included both hysterectomies and pelvic organ prolapse (POP) repair [10]. They found that concomitant POP repair along with midurethral sling placement improves the subjective cure rate for SUI [10]. Our

study expands on this previous research, as we also included patients with concomitant POP undergoing retropubic I-Stop® midurethral sling placement with similar findings.

Strengths of this study include a large dataset of patients and consistent periods of follow-up with every patient. Glass et al., discusses single-surgeon procedures as a limitation in the study design [10]. However, single-surgeon procedures can also be interpreted as a strength as this controls for variability in surgical techniques or patient selection. For example, Krauth et al. included both urologists and gynecologists in their study and found patient satisfaction rate to be 85.5% [3]. Perhaps a difference in patient satisfaction rate could be attributed to the surgeon's specialty, as they could have different parameters for patient selection and utilize different surgical techniques. One potential limitation of this study is that it is a retrospective cohort study and, thus, the results could not be compared to a control group. Another limitation of this study is that patients with both RP sling insertion and TO sling insertion were included. Gomelsky's previous review found inconsistent subjective and objective outcomes when comparing both TO and RP midurethral slings [11]. Thus, it would be an interesting avenue to study satisfaction rates of the two different groups using the same I-STOP® sling. A third limitation of this study is that validated questionnaires to assess patient satisfaction and the resolution of SUI symptoms was not used. However, a Likert scale allows us to easily operationalize and quantify patient satisfaction and could be interpreted as a strength in this study.

In future studies, it would be interesting to examine the extent of patient education of OAB symptoms more completely in comparison to SUI and potential leakage. Shin et al. examined 78 patients with SUI with urgency who underwent midurethral sling operations and found that 51 (65.4%) patients had resolved urgency, but 24 (30.8%) of patients had persistent urgency after midurethral sling insertion [15]. Due to the similarities of both SUI and OAB symptoms causing leakage, it would be of interest to investigate differences more extensively in studies comparing pre- and post-surgical satisfaction rates. Perhaps, in the future, it would be useful to further categorize SUI symptoms and observe how this impacts satisfaction rating. This would serve to help direct patient-doctor conversations prior to surgery with the hope that the patient will be able to further understand the differences in symptoms. In addition to urodynamic studies, we would observe if this would increase a patient's overall satisfaction rate of the procedure.

5. Conclusion

Our study using an I-Stop® midurethral sling for treatment of SUI supports previous research that demonstrates high patient satisfaction and high cure rates of midurethral sling insertion. Our study demonstrates high patient satisfaction rate even after nine years of follow up while also limiting patient morbidity and post-operative complications. Out of 300 patients, we yielded an overall satisfaction rating of 91.7% and an SUI correction rating of 95%. Notably, we maintained very low post-surgical complications, highlighting that I-Stop® midurethral sling insertion is an excellent procedure for treating SUI in patients with ISD and urethral hypermobility.

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References

[1] Sivaslioglu AA, Unlubilgin E, Aydogmus S, et al. A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results. *J Urol*. 2012; 188 (1): 194-199.

[2] Ross S, Tang S, Eliasziw M, et al. Transobturator tape versus retropubic tension-free vaginal tape for stress urinary incontinence: 5-year safety and effectiveness outcomes following a randomised trial. *Int Urogynecol J*. 2016; 27 (6): 879-886.

[3] Krauth JS, Rasoamiaramanana H, Barletta H, et al. Sub-urethral tape treatment of female urinary incontinence--morbidity assessment of the trans-obturator route and a new tape (I-STOP): A multi-centre experiment involving 604 cases. *Eur Urol*. 2005; 47 (1): 102-107.

[4] Considerations about surgical mesh for SUI. fda.gov. https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui. Updated April 16, 2019. Accessed February 21, 2021.

[5] Nazemi TM, Kobashi KC, Govier FE. Synthetic sling options for stress urinary incontinence. *Curr Bladder Dysfunct Rep.* 2007; 2 (2): 79-85.

[6] Amid, PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia.* 1997; 1 (1): 15–21.

[7] Ogah J, Cody DJ, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. *Neurourol Urodyn*. 2011; 30 (3): 284-291.

[8] Jijon A, Hegde A, Arias B, et al. An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency. *Int Urogynecol J*. 2013; 24 (8): 1325-1330.

[9] Ulrich D, Tammaa A, Hölbfer S, et al. Ten-year followup after tension-free vaginal tape-obturator procedure for stress urinary incontinence. *J Urol*. 2016; 196 (4): 1201-1206.

[10] Glass A, Durbin-Johnson B, Rothschild J, et al. SEAPI incontinence classification system: 1-year postoperative results following midurethral sling placement. *Female Pelvic Med Reconstr Surg*. 2020; 26 (11): 671-676.

[11] Gomelsky A. Midurethral sling: is there an optimal choice?. *Curr Opin Urol*. 2016; 26 (4): 295-301.

[12] Mallett VT, Brubaker L, Stoddard AM, et al. The expectations of patients who undergo surgery for stress incontinence. *Am J Obstet Gynecol*. 2008; 198 (3): 308. e1-308. e6.

[13] Nettleman, MD. Patient satisfaction--what's new?. *Clin Perform Qual Health Care*. 1998; 6 (1): 33-37.

[14] Lo TS, Shailaja N, Tan YL, et al. Outcomes and failure risks in mid-urethral sling insertion in elderly and old age with urodynamic stress incontinence. *Int Urogynecol J*. 2020; 31 (4): 717-726.

[15] Shin JH, Choo MS. *De novo* or resolved urgency and urgency urinary incontinence after midurethral sling operations: How can we properly counsel our patients?. *Investig Clin Urol*. 2019; 60 (5): 373-379.