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Original Article

Efficacy and Safety of "I-Stop-Mini Adjustable" Sling System versus Transobturator Midurethral "Obtryx" Sling System in Stress Urinary Incontinence: A Retrospective Cohort Study

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ABSTRACT **Study Objective:** To compare the safety, efficacy, and adverse events of the new mini-adjustable sling system "I-stop-mini" with transobturator midurethral slings "Obtryx" (Boston Scientific, Marlborough, MA) in women with stress urinary incontinence.

Design: A single-center, retrospective cohort study.

Setting: Department of Obstetrics and Gynecology, Taipei Veterans General Hospital, Taiwan.

Patients: A total of 347 patients who underwent I-stop-mini or Obtryx for stress urinary incontinence treatment.

Interventions: Midurethral sling with either I-stop-mini or Obtryx.

Measurements and Main Results: The primary outcomes were objective success and subjective cure rates between the 2 groups. Objective success was evaluated using a 1-hour pad test, and subjective cure was evaluated using a questionnaire score (Incontinence Impact Questionnaire, Urinary Distress Inventory, and International Consultation on Incontinence Questionnaire Short Form). Secondary outcomes were the evaluation of surgical outcomes, operative data, and adverse events between the 2 groups. In total, 171 of 200 I-stop-mini subjects and 127 of 147 Obtryx subjects completed 12 months of follow-up. Regarding the objective success between the I-stop-mini group and the Obtryx group, 1-month postoperative (3.6 ± 5.2 vs 3.9 ± 12.6; $p = .765$), 6-month postoperative (3.9 ± 5.1 vs 4.2 ± 12.6; $p = .848$), and 12-month postoperative (4.6 ± 5.6 vs 4.5 ± 13.6; $p = .980$) 1-hour pad tests showed no significant difference. The 12-month subjective cure rates decreased from 94.7% (1-month postoperative) to 91.2% (12-month postoperative) in the I-stop-mini group and 95.2% (1-month postoperative) to 85.0% (12-month postoperative) in the Obtryx group. Similar and durable efficacy was observed between the 2 groups. The I-stop-mini group had shorter operative times and hospital stays than the Obtryx group; however, both groups showed similar adverse event rates.

Conclusion: The objective success and subjective cure rates of I-stop-mini did not differ to those of Obtryx. However, long-term data and further prospective studies on I-stop-mini are necessary to arrive at a definite conclusion. Journal of Minimally Invasive Gynecology (2022) 29, 519−527. © 2022 Published by Elsevier Inc. on behalf of AAGL.

Keywords: Midurethral slings; Objective success; Tension-free vaginal tape

The authors declare that they have no conflicts of interest.

The study was approved by the Institutional Review Board of Taipei Veterans General (approval number: TPEVGHIRB: 2021-06-012AC).

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Fig. 1

I-stop-mini adjustable sling system.
*Mesh delivery device
→Adjustable tape.

Stress urinary incontinence (SUI) is a prevalent and inconvenient problem affecting approximately 50% of the general population of women during their lifetime [1−3]. SUI prevalence in adults is approximately 4% to 35% and is estimated to increase by 47% between 2010 and 2050 [4−6]. Since the introduction of a tension-free vaginal tape in 1996, the midurethral sling became the most common surgical treatment for females with SUI. It became the gold standard treatment, replacing the Burch colposuspension and autologous fascial sling with equivalent efficacy [1,7,8].

In the tension-free vaginal tape procedure, the synthetic tape is passed from the vagina through the retropubic space to support the midurethra. In 2001, Delorme [9] introduced the transobturator approach, which showed similar effects and less complications such as retropubic hematoma and bladder perforation [10,11)]; however, the incidence of chronic pelvic or thigh/groin pain increased.

To maintain the efficacy and reduce the risk of complications, "single-incision slings" (SIS) or "mini-slings" were developed; these instruments reduced groin and lack of penetration through the adductor muscle and also reduced the risk of obturator neuropathy. Several studies have demonstrated comparable efficacy and safety between mini-slings and transobturator midurethral slings (TMUS) for more than 1 year [2,4,12−17].

However, the present study used a new SIS, mini-adjustable sling system, "I-stop-mini" (CL Medical, Winchester, MA) (Fig. 1 and Supplemental Video 1), to compare the efficacy and safety with the TMUS system, "Obtryx" (Boston Scientific, Marlborough, MA). To the best of our knowledge, this is the first 12-month retrospective study to examine a new mini-adjustable sling system. We hypothesized that the I-stop-mini system would show noninferior efficacy and safety compared with Obtryx.

Materials and Methods

This was a single-center, retrospective cohort study conducted at the Taipei Veterans General Hospital, northern Taiwan, between June 2018 and June 2020. The study was approved by the institutional review board of Taipei Veterans General (institutional review board approval number: TPEVGHIRB: 2021-06-012AC). An informed consent for publication was obtained from all the patients.

The inclusion criteria of study patients were as follows: (1) women aged ≥ 18 years, (2) women who were not currently pregnant or planning for a future pregnancy, and (3) women with predominant SUI greater than urgency urinary incontinence who failed conservative treatments. Patients presenting with concomitant pelvic organ prolapse and previous surgery for urinary incontinence were eligible. The exclusion criteria were as follows: (1) recurrent urinary tract infection, (2) malignant disease, (3) chronic pelvic pain, and (4) psychiatric disorders that could not give a clinical history.

A preoperative, full, multichannel, urodynamic study was performed. Bladder capacity ≥ 300 mL and adequate bladder emptying with postvoiding residual urine ≤ 150 mL were confirmed. Preoperative baseline data were evaluated, including maximal urethral closure pressure, Valsalva leak point pressure, and concomitant prolapse assessed with the Pelvic Organ Prolapse Questionnaire. A full clinical history was recorded in outpatient clinics. We queried patients about their distressed experiences, urgency incontinence, stress incontinence during

physical activities, voiding difficulty, and genital discomfort; all patients answered these questions with "not at all," "slightly," "moderately," and "greatly." Furthermore, we also inquired about the patient's frequency of experiencing an SUI, the time of day, the amount of urine leakage (none to a large amount), interference on daily life activities (scale: 0−10), and subjective feelings with their experiences. All patient responses were recorded in medical charts.

All procedures were performed by 2 senior surgeons (H.C.H and C.P.C) with expertise in the anti-incontinence sling procedure. The procedure steps of I-stop-mini (Supplemental Video 1) were as follows: (1) infiltration with vasopressin for hydrodistension of the periurethral tissues, (2) a 1-cm vaginal midline incision was made starting 1 cm below the urethral meatus, (3) construction of the tunnel at a 45-degree angle with Mayo scissor on bilateral sides, (4) insertion and adjustment of the sling's tension, and (5) assessment for vaginal closure with a cystoscope. Estimated blood loss, operative time, and cystoscopy assessment were done on the day of surgery and hospital stay, and residual urine was recorded at the time of patient discharge. Residual urine was assessed after bladder backfill and spontaneous voiding.

During the postoperative clinical follow-up, a 1-hour pad test was performed and recorded on the medical chart for the patients with SUI complaints. Subsequent postoperative outpatient clinic assessment, including pelvic examination for mesh erosion and clinical history taking for SUI recurrence, urgency, urinary tract infection (culture proven), and pelvic/groin pain, was performed using the visual analog scale (VAS); dyspareunia was evaluated 1, 6, and 12 months postoperatively.

The primary aim of this study was to compare the efficacy and safety of the 2 devices. Objective success was evaluated by postoperative 1-hour pad tests at 1, 6, and 12 months. In the pad test, the patient wore a pad and walked or climbed the stairs for 1 hour after drinking 500 mL of water. One-hour pad test was performed by weighing the pad to quantify urine loss. Subjective success and improvement in SUI were evaluated by reviewing the medical chart and transferring the patient subjective self-report to the scores of validated questionnaires, including the Incontinence Impact Questionnaire, Urinary Distress Inventory, and International Consultation on Incontinence Questionnaire Short Form. Subjective cure was defined as a patient's response "urine dose not leak" or no stress urine leakage after the procedure. The full clinical history was taken preoperatively and at 1, 6, and 12 months postoperatively.

The secondary outcomes were surgical outcomes, hospital stay, and adverse events including postoperative SUI, urgency, pelvic/groin pain (VAS >5), mesh erosion, and urinary tract infection. Mesh revision was defined as the need for sling revision because of urinary retention who

Fig. 2

Retrospective flow diagram (from June 2018 to June 2020). SUI = stress urinary incontinence

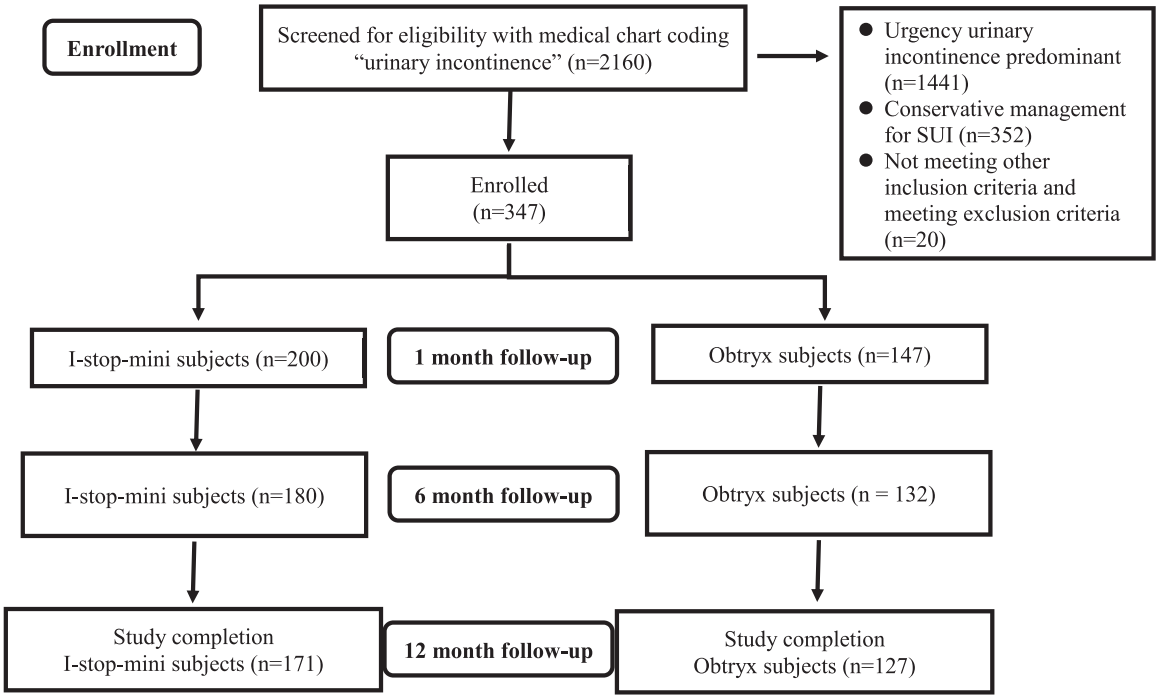


Table 1

Baseline characteristics

Adjustable mid-urethral slings for stress urinary incontinence	Single-incision sling (I-stop-mini)	Transobturator midurethral sling (Obtryx)	p value
Age, yrs	58.7 ± 12.8 (171)	61.7 ± 13.2 (127)	.05
Body mass index	25.3 ± 3.9 (171)	26.4 ± 4.4 (127)	.03*
Parity	2.5 ± 1.1 (171)	2.6 ± 1.3 (127)	.546
Menopause	65.5% (112/171)	79.5% (101/127)	.08
Estrogen use	10.5% (18/171)	9.4% (12/127)	.76
Previous urinary incontinence surgery	3.5% (6/171) (Sparc × 2, Solyx × 2, Monarc × 2)	12.6% (16/127) (Solyx × 9, Needleless × 3, Monarc × 2, Burch × 2)	.003*
Maximal urethral closure pressure (cm H_2O)	50.6 ± 35.8 (171)	45.2 ± 23.2 (127)	.138
Valsalva leak point pressure (cm H_2O)	73.6 ± 33.3 (171)	66.3 ± 52.7 (127)	.146
Concomitant prolapse			.828
Anterior compartment prolapse	29.8% (51/171)	31.5% (40/127)	
Apical compartment prolapse	12.3% (21/171)	11.8% (15/127)	
Posterior compartment prolapse	3.5% (6/171)	5.5% (7/127)	

complain of the inability to pass urine despite persistent effort.

The analytic statistics for continuous variables were described as mean ± standard deviation or median (minimum to maximum), and nominal variables were described as percentages (%). The difference between the mean values of the 2 groups was analyzed using Student's *t* test. Categorical data were analyzed using the chi-squared distribution. Statistical significance was set at $p < .05$. Statistical analyses were performed using IBM SPSS Statistics version 26 software.

Results

In the initial study period, 2160 women were screened for eligibility using medical chart coding for "urinary incontinence." A total of 1441 women with predominant urgency incontinence, 352 women with conservative management for SUI, and 20 women who did not meet the inclusion criteria were excluded from the study. The remaining 347 patients were included in the study and were divided into the I-stop-mini group (N = 200) and the Obtryx group (N = 147). During the postoperative 12-month follow-up, 29 patients from the I-stop-mini group and 20 from the Obtryx group were not followed up because they did not return to outpatient clinic. Fig. 2 shows the retrospective flow diagram of all patients, including enrollment and follow-up at 1, 6, and 12 months.

Baseline Characteristics

Between the I-stop-mini and Obtryx groups, age, parity, menopausal status, hormone replacement therapy, maximal urethral closure pressure, Valsalva leak point pressure, and concomitant prolapse status were shown to be similar (Table 1). However, patients in the Obtryx group (body mass index [BMI]: 26.4 ± 4.4) were more overweight than those in the I-stop-mini group (BMI: 25.3 ± 3.9, p = .03), and more patients in the Obtryx group (Solyx × 9, Needleless × 3, Monarc × 2, Burch × 2) underwent previous urinary incontinence surgery compared with the I-stop-mini group (Sparc × 2, Solyx × 2, Monarc × 2) (12.6% vs 3.5%, p = .003).

Primary Outcome

In total, 171 of 200 I-stop-mini subjects and 127 of 147 Obtryx subjects completed 12 months of follow-up (Fig. 2). In regard to the objective success between the I-stop-mini

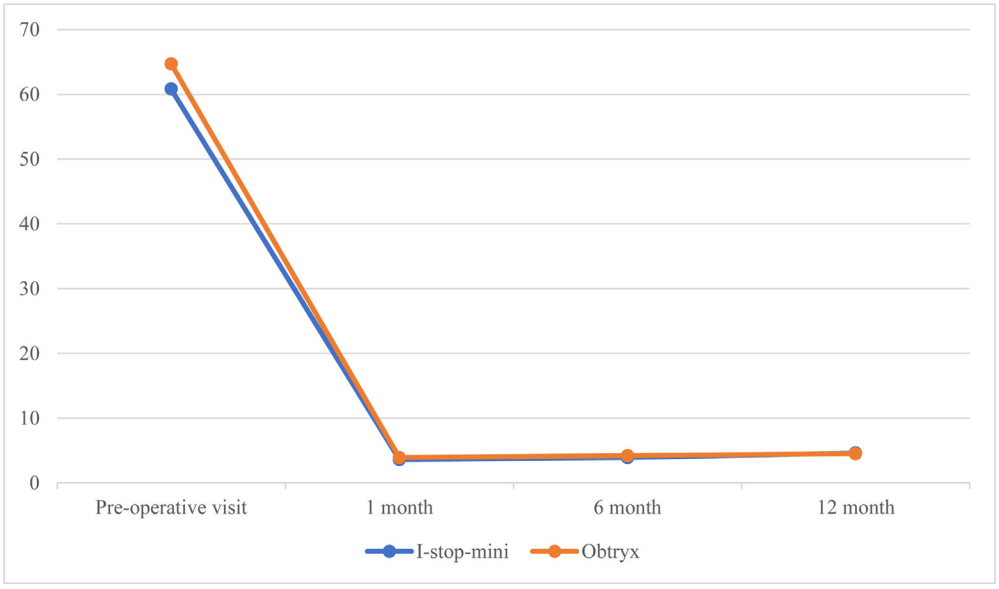
Table 2

One-hour pad test of enrolled cases

Adjustable mid-urethral slings for stress urinary incontinence	Single-incision sling (I-stop-mini)	Transobturator midurethral sling (Obtryx)	p value
Preoperative	60.8 (21−265)	64.7 (20−300)	.585
Postoperative, 1st mo	3.6 (2−52)	3.9 (0−80)	.765
Postoperative, 6th mo	3.9 (3−58)	4.2 (0−81)	.848
Postoperative, 12th mo	4.6 (2−63)	4.5 (0−88)	.980

Fig. 3

One-hour pad test from available cases.



group and the Obtryx group, 1-month postoperative (3.6 ± 5.2 vs 3.9 ± 12.6, p = .765) (Table 2), 6-month postoperative (3.9 ± 5.1 vs 4.2 ± 12.6; p = .848), and 12-month postoperative (4.6 ± 5.6 vs 4.5 ± 13.6; p = .980) 1-hour pad tests showed no significant differences (Fig. 3). A significant decrease in the 1-hour pad test from the preoperative to postoperative period and similar objective success were noted in the 2 groups. Regarding self-reported subjective cure rates between the I-stop-mini group and Obtryx group, no statistically significant differences were observed at 1-month postoperative (94.7% vs 95.2%; p = .833), 6-month postoperative (93.0% vs 89.0%; p = .216), and 12-months postoperative tests (91.2% vs 85.0%; p = .097) (Table 3 and Fig. 4). The 12-month subjective cure rates decreased from 94.7% to 91.2% in the I-stop-mini group and from 95.2% to 85.0% in the Obtryx group. There were no significant

Table 3

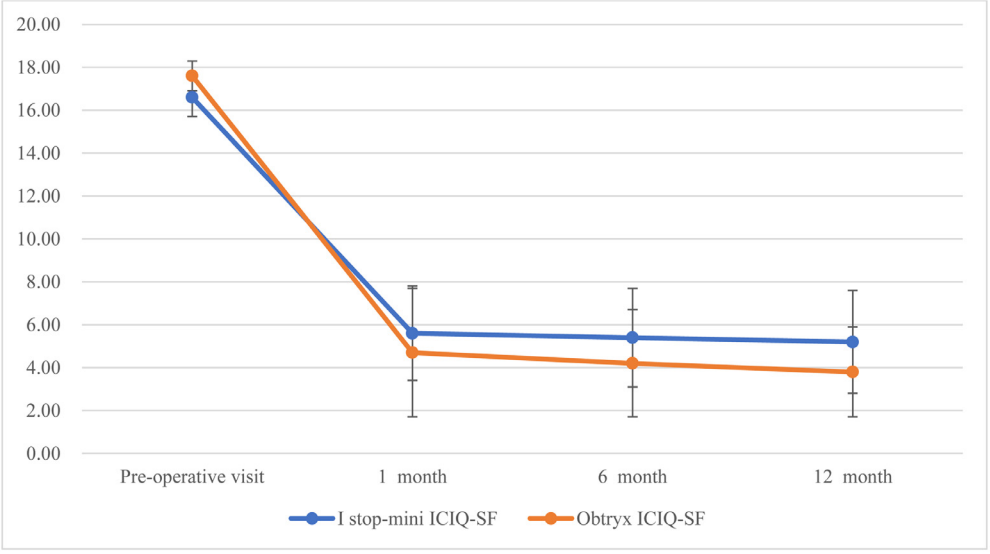
Short Form Questionnaire comparison (IIQ-7, UDI-6, ICIQ-SF) between I-stop-mini and Obtryx

Adjustable mid-urethral slings for stress urinary incontinence	Single-incision sling (I-stop-mini)	Transobturator midurethral sling (Obtryx)	p value
IIQ-7 (preoperative)	18.3 ± 0.5	17.1 ± 1.2	.005*
IIQ-7 (postoperative, 1st mo)	5.3 ± 1.6	4.5 ± 2.5	.098
IIQ-7 (postoperative, 6th mo)	5.6 ± 1.7	4.5 ± 2.5	.254
IIQ-7 (postoperative, 12th mo)	5.7 ± 1.2	4.3 ± 2.2	.083
UDI-6 (preoperative)	15.7 ± 1.0	15.4 ± 0.7	.407
UDI-6 (postoperative, 1st mo)	3.8 ± 2.7	3.1 ± 2.4	.506
UDI-6 (postoperative, 6th mo)	4.0 ± 2.8	3.4 ± 2.8	.599
UDI-6 (postoperative, 12th mo)	3.4 ± 2.5	3.2 ± 2.2	.791
ICIQ-SF (preoperative)	16.6 ± 0.9	17.6 ± 0.7	.002*
ICIQ-SF (postoperative, 1st mo)	5.6 ± 2.2	4.7 ± 3.0	.447
ICIQ-SF (postoperative, 6th mo)	5.4 ± 2.3	4.2 ± 2.5	.200
ICIQ-SF (postoperative, 12th mo)	5.2 ± 2.4	3.8 ± 2.1	.114
Subjective cure rates (postoperative, 1st mo)	94.7% (189/200)	95.2% (140/147)	.833
Subjective cure rates (postoperative, 6th mo)	93.0% (167/180)	89.0% (117/132)	.216
Subjective cure rates (postoperative, 12th mo)	91.2% (156/171)	85.0% (108/127)	.097

ICIQ-SF = International Consultation on Incontinence Questionnaire Short Form; IIQ-7 = Incontinence Impact Questionnaire; SUI = stress urinary incontinence; UDI-6 = Urinary Distress Inventory.
Subjective cure: Absence of SUI according to questionnaire.

Fig. 4

Relationship between ICIQ-SF. ICIQ-SF = International Consultation on Incontinence Questionnaire Short Form; SUI = stress urinary incontinence.



differences in the Incontinence Impact Questionnaire (p = .083), Urinary Distress Inventory (p = .791), and International Consultation on Incontinence Questionnaire Short Form scores at 12 months postoperatively (p = .114) between the 2 groups, even though the scores were slightly favorable for the Obtryx group. Overall, objective success and subjective cure rates over the 12-month study showed similar and durable efficacy between the 2 groups. When adjusting for confounding factors such as BMI (defined as 18.5−24.9 or ≥ 25) and previous anti-incontinence surgery by restriction, our analyses also demonstrated similar objective success and subjective cure rates between the 2 groups (Supplemental Tables 1−4).

Secondary Outcome

The operative time in the I-stop-mini group was significantly shorter than in the Obtryx group (15.3 ± 5.5 vs 23.9 ± 7.5, min, p = .001), and hospital stay was significantly shorter in I-stop-mini group (3.0 ± 0.9 vs 3.4 ± 0.8, days, p = .001) (Table 4). Intraoperative blood loss between the 2 groups showed no significant differences. We evaluated the postvoid residual urine by ultrasound examination before discharge and observed slightly more residual urine in Obtryx group than I-stop-mini group (57.6 ± 78.5 vs 51.4 ± 87.2, mL, p = .525); however, there were no significant differences. No viscus or bladder perforation was noted in either group. In the overall operative data, the I-stop-mini group showed a shorter operative time (min) and hospital stay (days). When controlling the confounding factors, we also observed similar results (Supplemental Table 5 and 6).

Regarding postoperative SUI, 16 of 171 patients (9.4%) in the I-stop-mini group and 13 of 127 patients (10.2%) in the Obtryx group were identified (Table 5). The results were similar and showed no significant differences (p = .800). The time to postoperative SUI (months) showed no significant difference in I-stop-mini group and Obtryx group (3.1 ± 3.7 vs 8.0 ± 11.7, p = .235); however, the Obtryx group demonstrated slightly more durable and

Table 4

Overall proportion of operative data

Adjustable mid-urethral slings for stress urinary incontinence	Single-incision sling (I stop-mini)	Transobturator midurethral sling (Obtryx)	p value
Operative time (min)	15.3 ± 5.5	23.9 ± 7.5	.001*
Blood loss (mL)	42.5 ± 21.5	42.6 ± 14.0	.948
Hospital stay (d)	3.0 ± 0.9	3.4 ± 0.8	.001*
Residual urine (mL)	51.4 ± 87.2	57.6 ± 78.5	.525
Bladder perforation	0.0% (0/171)	0.0% (0/127)	

Table 5

Overall proportion of adverse events

Adjustable mid-urethral slings for stress urinary incontinence	Single-incision sling (I stop-mini)	Transobturator midurethral sling (Obtryx)	p value
Postoperative SUI	9.4% (16/171)	10.2% (13/127)	.800
Time to postoperative SUI (mo)	3.1 ± 3.7	8.0 ± 11.7	.235
Mesh revision	1.8% (3/171)	3.9% (5/127)	.249
Mesh erosion	2.3% (4/171)	2.4% (3/127)	.542
Urgency	25.7% (44/171)	31.5% (40/127)	.274
Urinary tract infection	8.2% (14/171)	10.2% (13/127)	.542
Pelvic/groin pain > 5 on VAS	9.9% (17/171)	11.0% (14/127)	.759
Dyspareunia	1.8% (3/171)	0.8% (1/127)	.473

SUI = stress urinary incontinence; VAS = visual analog scale.

favorable effects over I-stop-mini. The rate of mesh revision because of urinary retention showed no significant difference between the I-stop-mini (3 of 171, 1.8%) and Obtryx (5 of 127, 3.9%) groups (p = .249). However, a higher trend of urinary retention in Obtryx (Table 5) was noted, which was compatible with slightly more residual urine (Table 2). I-stop-mini (4 of 171, 2.3%) and Obtryx (3 of 127, 2.4%) had similar mesh erosion rates without significant differences (p = .542). There was a higher tendency of urgency in the Obtryx (40 of 127, 31.5%) than in the I-stop-mini (44 of 171, 25.7%) group, but the difference was not statistically significant (p = .274). A similar phenomenon was also observed in urinary tract infections (13 of 127, 10.2% vs 14 of 171, 8.2%; p = .542). A slightly higher rate of pelvic/groin pain (VAS > 5) in the Obtryx (14 of 127, 11.0%) than in the I-stop-mini (17 of 171, 9.9%) group was noted (p = .759). The opposite result was observed for dyspareunia between the Obtryx (1 of 127, 0.8%) and I-stop-mini (3 of 171, 1.8%) groups (p = .473). In terms of overall adverse effects, Obtryx showed a more durable effect but a higher tendency of mesh revision, urgency, urinary tract infection, and pelvic/groin pain (VAS > 5); however, there were no significant differences between these 2 groups. When controlling for confounding factors, the adverse events between the 2 groups showed no significant differences (Supplemental Table 7 and 8).

Discussion

This is the first retrospective study on the efficacy and safety of the new mini-adjustable sling system (Fig. 1). I-stop-mini is a SIS with a tape that can adjust tension on the midurethra during the surgery; Table 6 illustrates the comparison between the I-stop-mini and the SIS made available by the U.S. Food and Drug Administration.

In our retrospective study, the durable objective success (p = .980) and subjective cure rates (p = .097) of the new SIS "I-stop-mini" did not differ compared with the TMUS "Obtryx." The I-stop-mini demonstrated a shorter operative time (p = .001) and a shorter hospital stay (p = .001), and the adverse event rates between the 2 groups were similar.

SIS is known to be as efficient as classic midurethral slings, and several studies have compared it with TMUS. Schellart et al [18] and Fernandez et al [19] showed comparable objective (74% vs 73%; 80.9% vs 88.5%) and subjective cure rates (71% vs 76%; 83.9% vs 91.6%) between SIS and TMUS. Dogan et al [4] also showed a durable objective and subjective cure of SIS in a 24-month follow-up study.

Table 6

Comparison between I-stop-mini and available U.S. Food and Drug Administration SIS

Sling	I-stop-mini	Altis	Solyx	MiniArc
Material of mesh	Macroporous monofilament polypropylene	Macroporous monofilament polypropylene	Monofilament polypropylene	Macroporous monofilament polypropylene
Length (mm)	450	77.5	90	85
Attachment	Anchoring barbs	Anchoring barbs	Anchoring barbs	Anchoring barbs
Adjustability	Yes	Yes	None	None
Timing of tension adjustment	Perioperative cough test	Perioperative cough test	None	None

SIS = single-incision sling.

Luo et al [20] conducted a meta-analysis that showed durable subjective cure rates (66.7% to 93.6%) in SIS, which was compatible with the subjective cure rates of our study in I-stop-mini (91.2%).

According to the meta-analysis by Luo et al, [20] 4 previous studies showed significant shorter operative time between SIS (8.3 to 15.56 min) and TMUS (16.4 to 21.47 min) ($p < .0001$), which is consistent with the results of our study. However, in contrast to our result, previous studies have shown no significant difference in the length of hospital stay between the 2 groups; our study demonstrates that the trend of shorter hospital stays in the SIS group is consistent.

Few previous studies have investigated the time to postoperative SUI. In our study, there was no significant difference, but the Obtryx group showed a slightly long-lasting anti-incontinence effect. In previous studies, the rate of postoperative urinary retention showed no difference between the SIS (0% to 5.6%) and TMUS (0% to 7.4%) groups ($p = .34$) [4,18,20–24]. We approached the rate of mesh revision to evaluate urinary retention and showed no significance between the 2 groups ($p = .249$). Compared with the durable effect of TMUS, the mesh revision rate of Obtryx (3.9%) was slightly higher than that of the I-stop-mini group (1.8%).

In a previous study, a significant difference in pelvic/groin pain between the TMUS (0% to 11%) and SIS (0% to 3%) groups was noted ($p < .05$) [4,17,25]. In contrast, our study showed no significant difference in pelvic/groin pain (VAS > 5) between the 2 groups ($p = .759$). This was related to the higher rate of pelvic/groin pain (VAS > 5) in the I-stop-mini group (9.9%) than in the SIS study group (0% to 3%). However, a slightly lower tendency of pelvic/groin pain (VAS > 5) was noted in the I-stop-mini group (9.9%) than in the Obtryx group (11.0%).

A previous study showed no significant difference in mesh erosion rate between SIS (0% to 5.6%) and TMUS (0% to 7.1%) ($p = .87$) [4,18,20,21,25], which is consistent with our results. In a meta-analysis, no significant difference was found in the urgency and urinary tract infection rate between SIS (7.7% to 10.6%; 0% to 4.3%) and TMUS (9.3% to 16.6%; 0% to 1.4%) ($p = .11$; $p = .32$), which is in accordance with our results. However, in our study, the Obtryx group showed a slightly higher trend of urgency and urinary tract infection rate. In addition, the urgency and urinary tract infection rates of I-stop-mini (25.7% and 8.2%, respectively) and Obtryx (31.5% and 10.2%, respectively) in our study group were higher than those in previous studies.

Compared with the adjustable sling for SUI, the Remeex readjustable sling allows the regulation of the tension not only during sling placement but also at any time after the operation. This product can be considered for treatment of recurrence after previous anti-incontinence surgeries or cases of intrinsic sphincter deficiency [26]. It is different from I-stop-mini that the timing of tension adjustment is perioperative cough test (Table 6).

Table 6 illustrates the comparison between the I-stop-mini and the SIS made available by the U.S. Food and Drug Administration. The benefit of the I-stop-mini, relative to Solyx or MiniArc, is that the length of the 2 latter instruments is fixed whereas the I-stop-mini has the ability to adjust the tension at the moment of placement. Compared with other adjustable SIS, such as Ajust or Altis, these are allowed for a perioperative cough test to adjust the tension until continence is reached [27]. However, the length of I-stop-mini is longer than Altis (450 mm vs 77.5 mm). According to study by Bai et al [28], adjustable SIS had equally efficacy for SUI compared with TMUS and Solyx and MiniArc. However, the significantly shorter operative time and lower postoperative pain score than TMUS supported the clinical application of adjustable SIS. In conclusion, the aim of our research is not to assertively describe which instrument is superior, but rather we present the efficacy and safety of these alternative kinds of commercial kits, some which may benefit the patient based on their medical needs and familiarity with the instrument.

Our study has several limitations. First, we conducted a retrospective study, and the questionnaire scores were transferred by reviewing the patient's medical charts. Although the questions, response and scores of questionnaires were standardized, patients answered with the description, and we recorded it in the medical charts. It could have caused reporting bias in the analysis. Second, failure to be followed up (because of no return to the outpatient clinic) in the I-stop-mini and Obtryx group could have resulted in selection bias. Third, because of the limited amount of anti-incontinence surgeries, this study contains a small study sample that may influence the study's generalizability. Fourth, the study had a short follow-up period of 12 months and caution should be exercised when interpreting our results. Finally, we did not exclude patients with concomitant pelvic organ prolapse, previous surgery for urinary incontinence, and intrinsic sphincter deficiency, which may be confounders for operative time, blood loss, and vaginal anatomic variation and influence the efficacy and safety of both procedures. However, we tried to control for several other confounding factors (BMI, previous anti-incontinence surgery) by restriction; these data are presented in the Supplemental Tables 1-8.

In conclusion, the objective success and subjective cure rates of I-stop-mini did not differ to those of Obtryx. Compared with Obtryx, I-stop-mini demonstrated reduced operative times and hospital stays, while resulting in similar adverse event rates. However, long-term data and further prospective studies on I-stop-mini system are required to examine the potential benefits of the I-stop-mini.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.jmig.2021.12.005.

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