Vaginal Sacrospinous Ligament Fixation Using Tissue Anchoring System Versus a Traditional Technique for Women With Apical Vaginal Prolapse: A Randomized Controlled Trial

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Objective: The aim of the study was to compare the efficacy and safety of the tissue anchoring system (TAS) kit versus the traditional technique for sacrospinous ligament fixation (SSLF) to treat apical vaginal wall prolapse.

Methods: A prospective randomized controlled multicenter study of noninferiority involving women with apical prolapse (C-point≥+1). Primary outcome is surgical success as C-point≤−4 at the 1-year follow-up. Secondary outcomes are success according to the composite criteria as C-point≤−4, Ba-point ≤0, and Bp-point ≤0; POP-Q measures of the vaginal compartments; intraoperative findings, complications; reoperation rate; hospital stay; and quality of life and sexual functioning (PISQ-12). It was estimated that 50 individuals per group would yield an 80% power for a noninferiority margin of 15%.

Results: Ninety-nine women were randomized: TAS (n = 55) and traditional SSLF (n = 44). The groups' preoperative data were similar. Drop-out rate was 11% for 12-month follow-up. Success rates were 90% for TAS and 80% for traditional SSLF (P = 0.0006; absolute difference, 9.8%; 90% confidence interval, −5.2 to 24.8) with the sensivity analyses per-protocol considering only the subjects that completed the 12-month follow-up and 80% versus 73%, respectively (P = 0.0048; absolute difference, 7.3%; 90% confidence interval, −9.6 to 24.2) by sensivity analyses considering the total number of participants randomized and treated with drop-out cases as failure. We detected shorter intraoperative time to dissect and reach the SSL, shorter length of hospitalization, lower rates of urinary tract infection, and lower pain scores in the first 30 days postoperative in the TAS compared with the traditional SSLF groups (P < 0.05). There was an improvement in women's quality of life that did not differ between groups.

Conclusions: The modified technique of SSLF using the TAS kit is noninferior to the traditional technique for the treatment of apical compartment in 12-month follow-up.

Key Words: sacrospinous fixation, sacrospinous ligament fixation, suture device, apical prolapse, pelvic organ prolapse

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Pelvic organ prolapse (POP) is the descent of one or more of the anterior and posterior vaginal walls, the uterus (cervix), or the apex of the vagina.[1] Pelvic organ prolapse affects 41% of women aged 50 to 79 years,[2] and approximately 11% will undergo surgery for POP and/or SUI sometime during their lives.[3]

The loss of apical support is usually present in women with POP extending beyond the hymen.[4] Adequate support for the vaginal apex is an essential component of a durable surgical repair. Numerous procedures are described to address the apical defect, with 80% to 90% of these performed transvaginally in clinical practice.[3,5]

Sacrospinous ligament fixation (SSLF) is an effective and widely used vaginal procedure for correcting apical prolapse with the incidence of recurrence approximately 5% to 15%.[6–8] First described by Amreich[9] and later modified by Richter and Albrich,[10] the technique accesses the SSL under the surgeon's direct view through the dissection of the pararectal space posteriorly. Many modifications have taken place regarding the sutures, needles, and instruments used and whether to use unilateral or bilateral fixation to the sacrospinous ligament (SSL), attempting to optimize its performance and results in terms of operative time, decrease tissue dissection, and minimize complications. In this context, surgical devices have been incorporated into POP treatment.

A POP Tissue Anchoring System (TAS) kit (Promedon, Córdoba, Argentina) is a new, minimally invasive device to perform apical suspension. It was developed to allow a single apical transvaginal incision for SSLF via an anterior or posterior approach in which the surgeon achieves the SSL guided by his index finger with less dissection of the pararectal space. The kit includes a retractable insertion guide for placing the tissue anchoring devices.

Regulatory agencies have required trials of noninferiority for new technologies to be used in health care in which a new treatment modality or device is confronted with the effective standard treatment. There are no previously studies evaluating colpopexy using TAS. We tested the hypothesis that SSLF using TAS is noninferior to the traditional SSLF for treating apical vaginal wall prolapse. The aim of this trial was to compare the efficacy and safety of both operations after 12 months of follow-up.

MATERIALS AND METHODS

This study was a randomized, controlled, multicenter trial performed in 6 tertiary urogynecological centers. The study protocol was approved by the Institutional and National Ethics Committee before the study was started (CEP184.671). Promedon donated the devices for the study and provided the training on the new technology TAS but had no role on the study design and data analyses.

From February 2014 to December 2015, consecutive women aged 50 to 80 years presenting at the urogynecological clinics with bothersome POP symptoms were evaluated and assessed for eligibility. Those with a C-point≥+1 by POP-Q[1] were enrolled as candidates. Patients with or without uterus, either primary or recurrent POP, and with or without concomitant stress urinary incontinence (SUI), were included.

Women with malignant urogenital disease or previous pelvic radiotherapy, clinical contraindications to an operation, connective

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tissue disorders, systemic glucocorticoid treatment, and/or an acute genitourinary infection were not included. All women agreed to participate and signed an informed consent form.

Randomization

Patients were randomly assigned to undergo either SSLF with TAS or traditional SSLF by a computerized randomization table in a 1:1 ratio. The blocked size was 10, and each block was randomly chosen to determine the assignment of all subjects. Each center had separated randomization table, which was managed by a unique and common research coordinator who had no contact with the participants. The surgeons were only aware of the procedure in the operating room by telephone contact. The enrollment was equally distributed among the 6 centers, each one treated a minimum of 15 participants.

Statistical Analysis

All statistical analyses were performed with InfoStat Software (Version 2016). Demographic information was calculated using conventional descriptive statistics. For the analyses, we used Student *t* test or Wilcoxon nonparametric test for continuous variables and the χ^2 test or Fisher exact test for categorical variables. Preoperative and postoperative data were analyzed with the paired Wilcoxon test, using different models of sensitivity analyses such as, per protocol, when only subjects that completed the follow-up were evaluated, and as sensitivity analysis considering all subjects that were randomized and treated with imputation of failure for missing data for not completing the follow-up.[11] Normality of continuous data distribution was assessed using the Shapiro-Wilks test.

The efficacy was evaluated using a noninferiority test,[12] considering the null hypothesis as Traditional SSLF - TAS ≥15%, and the alternative hypothesis as Traditional SSLF - TAS <15%, and a 2-sided 90% confidence interval (CI). It was adopted a 15% noninferiority margin as the investigators estimated a priori that a surgical success difference of less than 15% would not change clinical practice. The null hypothesis is rejected in favor of the noninferiority of the TAS (the noninferiority margin is met) when the upper bound of the CI of the difference between the Traditional SSLF and TAS is less than 15%. A *P* value of less than 0.05 indicates that the study group is not inferior to the control group confirming the study hypothesis, and *P* values greater than 0.05 mean that the hypothesis of noninferiority cannot be proven.

Presuming objective cure rate of 90% for the SSLF, it was estimated that 50 individuals per group would yield an 80% power for a noninferiority margin of 15%. Assuming a 10% loss to follow-up rate, total enrolment goal was 110 patients.

Outcomes

The overall objective was to compare the efficacy and safety of the SSLF with TAS versus the traditional technique for treating apical vaginal wall prolapse at the 1-year follow-up. The primary outcome was surgical success measured objectively and defined as no apical descent into more than one-third of the vaginal canal, with the C-point≤−4.

Secondary outcomes included surgical success according to a composite criteria as C-point≤−4, and no anterior or posterior vaginal wall beyond the hymen (Ba point ≤0 and Bp-point ≤0); a comparison of individual anatomical measures of all vaginal compartments, intraoperative findings, complications, reoperation rate, hospital stay, and subjective findings related to quality of life and sexual function.

Preoperative Assessment

The patients underwent the standard anamnesis and general physical and gynecological examinations including POP-Q quantification. Postmenopausal patients underwent preoperative and postoperative local estrogen treatment.

Quality of life and sexual function were measured using the pelvic organ prolapse quality of life (P-QoL) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) questionnaires respectively, validated to Portuguese or Spanish languages.[13–16] The P-QoL questionnaire has 20 questions, and higher total scores indicate a poorer quality of life.[13,14] The PISQ-12 questionnaire contains 12 questions, and higher total scores indicate a better sexual quality of life.[15,16]

Intraoperative Assessment

The procedures were performed by surgeons who had extensive experience in SSLF surgeries and had performed at least 10 procedures of both traditional SSLF and the new TAS procedure before the study. All surgeons received previous training on the new technology by a proctor that developed the product. Demonstrative videos with the technique were circulated among the investigators before the trial begins to standardize the methodology.

The operations were performed from February 2014 to December 2015. All patients were given spinal anesthesia along with intravenous cefazolin (2 g) and metronidazole (500 mg) for antibiotic prophylaxis. Intraoperative complications were assessed. Increased bleeding was characterized by blood loss of greater than 300 mL estimated by pad weight. We measured the overall operative time and the net time for SSF, as well as the time to access and reach the SSL starting from the initial posterior vaginal wall dissection up to 2 sutures to the SSL being placed unilaterally (traditional suture or using TAS).

FIGURE 1. Tissue Anchoring System.

Surgical Techniques

Traditional SSLF

Patient was placed in lithotomy position. The SSL was accessed through an incision following the length of the posterior vaginal wall and extending up to the vaginal vault. Blunt dissection was used to open the right space and locate the ischial spine. A window was created through the rectal pillar that was large enough for 2 fingers. Just lateral to the rectum and above the puborectal muscle, the right SSL–coccygeus muscle complex was exposed. Three Breisky speculums were positioned, after which 2 Prolene 1-0 sutures were placed under direct vision of the surgeon. The sutures were placed bilaterally into the SSL approximately 0.5 cm apart, with the lateral suture being placed approximately 2 cm from the ischial spine. The sutures were attached to the vault on the suture line where the vault was closed after hysterectomy, seeking the portion with most connective tissue or remaining ligament. Alternatively, the sutures were attached to the uterosacral ligaments. The sutures were tight with no tensioning of the vagina, allowing bridges up to the SSL.

Sacrospinous Ligament Fixation With TAS

The TAS kit includes 3 tissue-anchoring polypropylene system anchors each with suture material and a retractable insertion guide (RIG). The TAS anchors are specifically designed for fixation at the SSL, with 6 concentrically located spikes arranged at 360 degrees and a base with a flat rim to limit the depth of insertion into the ligament. The TAS anchors are attached to a 0-0 polypropylene thread that is subsequently used for fixation on the vaginal vault (Fig. 1).[17]

The patient was placed in lithotomy position. A vertical incision was made in the posterior vaginal wall. Using the index finger, the surgeon performed blunt dissection at the medial edge of the ischiopubic rami, progressing toward the ischial spine until the bilateral SSLs are identified. First, the TAS was loaded on the retractable tip of the insertion guide, and the RIG was then introduced and directed toward the ischial spine guided by the surgeon's index finger but not under direct view. It was implanted in the SSL 2.5 cm medial to the ischial spine. Once the TAS was in the ligament, the tip of the RIG was gently retracted by sliding the knob on the handle to release the TAS. The TAS were placed bilaterally, 2 for each SSL. Once they were correctly placed, 2 stitches were made on the vaginal vault or the uterosacral ligament bilaterally, leaving a space of 1 cm between them. Next, the pericervical ring was reconstructed, and the vaginal incision was closed in the usual manner. The sutures were tight enough to elongate the vagina and considering their length, in the way they were not tensioning the vagina. In all the cases, suture bridges were left, and the knot did not reach the SSL. If the surgeon

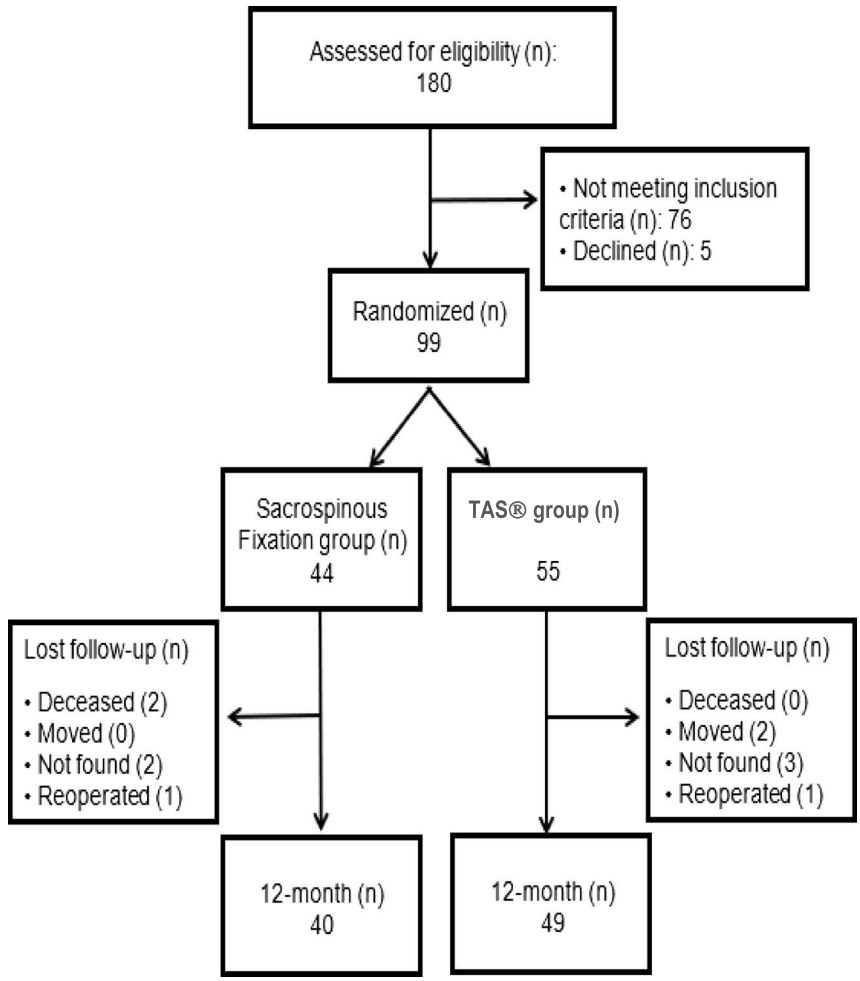

FIGURE 2. Consolidated Standards of Reporting Trials diagram of participants.

accidentally introduces the anchor into the SSL but in wrong position, it is not recommended the anchor removal but place another anchor in the right position and leave the last one to avoid complications. If necessary, vaginal hysterectomy, colporrhaphies, and/or midurethral sling was added to both procedures to correct more complex cases at the surgeon's discretion. If possible, patients were given the option to decide for a hysterectomy or a hysteropexy.

Postoperative Protocol

The postoperative assessors were unmasked to the procedures because of the differences in both techniques (TAS is bilateral and traditional SSLF is unilateral) that would be perceived by the examiner during the physical examination. The participants were blinded to their interventions.

Postoperative protocol and criteria for discharge were the same for both procedures. A 14F Foley vesical catheter and a vaginal tampon that had been inserted after the surgery were removed 24 hours later. Postoperative complications were evaluated. Urinary retention and voiding dysfunction were considered if patient was unable to void properly (postvoid residual >150 mL) at postoperative #1. Discharge occurred according to the individual's clinical condition and the length of hospital stay was assessed.

Follow-up appointments were scheduled for day 7, 1 month, and 12 months postoperatively when anamnesis, visual analog scale (VAS), and physical examination were carried out. The impact of the procedures was assessed by P-QoL and PISQ-12 at the 12-month visit. Adverse events and time to return to normal daily activities (regular but not physical or sexual activities) were also evaluated. Urinalysis with urine culture was ordered if the patients presented with dysuria in conjunction with irritative urinary symptoms, such as urgency and frequency, suprapubic pain, and/or hematuria, new or persistent, at any moment after the discharge and during the follow-up. Once urinary tract infection (UTI) was suspected, patients were given antibiotic course until urine culture confirms the infection. We considered UTI related to surgery if it occurred within 30 days postoperatively.

RESULTS

A total of 180 women were assessed, 99 of whom were randomly assigned to either the TAS (n = 55) or the traditional SSLF groups (n = 44). At this point, the study had to be interrupted because of time constraint as the recruitment was longer than it was originally anticipated. There was no protocol deviation, and all the patients underwent the treatment according to the randomization. Six patients from the TAS and 5 from the traditional SSLF groups did not attend the 12-month follow-up visit (11% overall dropout rate). Two participants from the SSLF group died during the follow-up for reasons not related to the surgery (Fig. 2).

Both groups were similar regarding demographic or clinical preoperative parameters, except that patients from traditional

TABLE 1. Preoperative Demographic and Baseline Clinical Data

Variable	TAS (n = 55)	Traditional SSLF (n = 44)	*P*
Age, mean ± SD, y	63 ± 8	64 ± 8	0.6136*
BMI, mean ± SD, kg/m^2	26 ± 4	29 ± 4	0.0067*
Vaginal parity, median (min-max)	3 (0–11)	3 (1–8)	0.5775†
Menopausal status, n (%)	51 (93)	42 (95)	0.6899‡
HRT, n (%)	3 (5)	3 (7)	1‡
Sexual activity, n (%)	15 (27)	17 (39)	0.2815‡
Comorbidities total, n (%)	40 (73)	35 (80)	0.4856‡
Diabetes, n (%)	13 (24)	12 (27)	0.8164‡
Hypertension, n (%)	30 (55)	28 (64)	0.4149‡
Smoking status, n (%)			
Present	5 (9)	3 (7)	0.7296‡
Past	10 (18)	5 (11)	0.4079‡
Previous anti-incontinence surgery, n (%)	1 (4)	2 (4)	0.5834‡
Previous POP surgery, n (%)	15 (27)	14 (32)	0.6614‡
Previous hysterectomy, n (%)	22 (40)	23 (52)	0.2322‡
Preoperative pain (VAS), median (min-max) (n)	2 (1–9) (55)	3 (1–9) (44)	0.8185*
Apical compartment			
Stage 0–1	0 (0)	0 (0)	1‡
Stage 2–4	55 (100)	44 (100)	1‡
Anterior compartment			
Stage 0–1	25 (45.45)	27 (61.36)	0.1563‡
Stage 2–4	30 (54.55)	17 (38.64)	0.1563‡
Posterior compartment			
Stage 0–1	3 (5.45)	8 (18.18)	0.0575‡
Stage 2–4	52 (94.55)	36 (81.82)	0.0575‡

Normality test for continuous variables: modified Shapiro–Wilks.

**T* test for independent samples.

†Wilcoxon test for independent samples.

‡Fisher exact test.

HRT, hormone replacement therapy.

SSLF group had higher mean body mass index (BMI, 29 vs 26; $P = 0.0067$). However, both groups belong to the same BMI category as overweight (BMI: 25–29.9). Twenty-nine subjects (29%) had undergone POP surgery before the study (Table 1).

Mean operation time, concomitant surgeries, and time to return to normal activity were similar in both groups. However, the net time to SSL suture placement was significantly shorter for the TAS compared with traditional technique group (11 and 20 minutes, respectively; $P = 0.0001$). We did not experience severe adverse events in this trial. Increased bleeding occurred in 2 patients in the Traditional SSLF and none in the TAS groups ($P = 0.195$). No visceral injuries were reported in either group (Table 2).

Urinary tract infection was diagnosed in 6 patients who received TAS and in 12 patients who received traditional SSLF ($P = 0.04$). All patients suspected were treated and further had the urine culture positive, confirming the postoperative uncomplicated UTI. The length of hospitalization was shorter in the TAS compared with traditional SSLF groups (24 and 48 hours, respectively; $P = 0.0484$). Lower pain scores were evidenced in the TAS group at 7 and 30 days postoperatively ($P = 0.0154$ and $P = 0.003$, respectively), although no difference was observed at the 12-month follow-up among the groups (Table 2).

No differences in preoperative points between groups were observed, except for the Ba point ($P = 0.0265$). All anatomical objective measurements in both groups changed significantly when comparing preoperative with postoperative values, except for point PB in the traditional SSLF group ($P = 0.138$). Anatomical improvement after both procedures was reflected in the similar POP-Q measures (Table 3).

Success rates for apical compartment (C≤−4) were 90% for TAS and 80% for traditional SSLF ($P = 0.0006$; absolute difference 9.8%; 90% CI, −5.2 to 24.8) with the per-protocol analysis, and 80% versus 73% considering all participants with imputation for failure for the missing data, respectively ($P = 0.0048$; absolute difference 7.3%; 90% CI, −9.6 to 24.2). Considering the composite criteria for anatomical cure (C≤−4, Ba≤0, Bp≤0), the absolute difference rate among the 2 techniques exceeded 15%, the cutoff point for noninferiority. With that, statistical significance was not reached, and the noninferiority could not be proven (Table 4). After 1 year, one patient from each group required a revision procedure because of anterior vaginal wall prolapse.

For quality of life, no significant difference was observed between groups neither preoperative ($P = 0.4365$) nor postoperative time ($P = 0.5039$), and both procedures showed significant improvement after 1 year compared with the baseline P-QoL scores ($P < 0.0001$). Considering sexual function, only the TAS group showed significant improvement ($P = 0.032$) after the procedure compared with baseline. Although there was no significant difference between groups preoperative and postoperative (pre, $P = 0.9748$; post, $P = 0.4672$; Table 5).

DISCUSSION

Vaginal SSLF is a standard operation for apical prolapse. A literature review indicates that overall SSLF has a subjective success rate of 84% to 99% and an objective success of 67% to 93% according to various criteria.[18] Its success and durability are due to the high quality of the anchoring system, which allow them to

TABLE 2. Operative and Postoperative Data

Variable	TAS (n = 55)	Traditional SSLF (n = 44)	*P*
Operative time, median (min-max)	68 (14–130)	72.5 (20–135)	0.1488*
Net time for SSLF, median (min-max), min	11 (2–35)	20 (5–60)	<0.0001*
Concomitant surgery, n (%)	49 (89)	36 (82)	0.3875†
Hysterectomy	8 (15)	4 (9)	0.5402†
Enterocele repair	—	—	—
Posterior colporrhaphy	34 (62)	27 (61)	1†
Anterior colporrhaphy	33 (60)	26 (59)	1†
Midurethral sling	13 (24)	7 (16)	0.4516†
Operative adverse events, n (%)	0	2 (5)	0.195†
Increased bleeding	0	2 (5)	0.195†
Bladder perforation	0	0	0
Postoperative adverse events, n (%)			
Urinary retention	0	2 (5)	0.195†
Urinary infection	6 (11)	12 (27)	0.04†
New-onset dyspareunia	1/15 (6.6)	4/17 (23.5)	0.34†
New-onset SUI	5/42 (12)	2/37 (5.4)	0.4574†
Total complications, n (%)	21 (38)	22 (50)	0.3081†
Pain (VAS), median (min-max) (n)			
7 d	3 (1–8) (55)	4 (1–10) (44)	0.0154*
1 mo	1 (1–10) (55)	3 (1–8) (43)	0.003*
12 mo	1 (1–5) (49)	1 (1–4) (40)	0.4701*
Length hospitalization, median (min-max), h	24 (18–72)	48 (18–72)	0.0484*
Return to normal daily activities, median (min-max) (n)	7 (1–10) (42)	7 (1–10) (29)	0.528*

Sensitivity analyses for pain and return to activities variables: missing data, analyzed only completed cases.

*Wilcoxon test for independent samples.

†Fisher exact test.

TABLE 3. Anatomical Analysis of Objective Measurements at the 12-Month Follow-up

	TAS				Traditional SSLF					
Point	**Pre**	**Post**	**Mean Diff**	***P****	**Pre**	**Post**	**Mean Diff**	***P****	***P**** **(Pre)**	***P**** **(Post)**
Aa	1	−1	2.35	<0.0001	0	−2	1.6	<0.0001	0.0635	0.9758
Ba	3	−1	3.86	<0.0001	2	−2	2.9	<0.0001	0.0265	0.3106
C	2	−5	7.41	<0.0001	2	−5	6.4	<0.0001	0.3774	0.9232
GH	4	3	0.95	<0.0001	4	3	0.93	<0.0001	0.5009	0.6239
PB	3	3	−0.42	0.002	3	3	−0.24	0.138	0.7989	0.7667
TVL	8	7	0.78	0.0036	8	7	0.78	0.0048	0.8959	0.601
Ap	−1	−2	1.53	0.0001	0	−2	1.38	0.0001	0.4619	0.0534
Bp	0	−2	2.07	<0.0001	0	−2	2.18	<0.0001	0.2021	0.1247
D	−2	−6	4.82	0.0001	−1	−7	9.77	<0.0001	0.0625	0.1788

Values expressed in median.

Sensitivity analyses for anatomical points: per-protocol analyses, including only subjects that completed the 12-month follow-up.

*Wilcoxon test (paired samples).

withstand the high pressures that affect the pelvic floor during efforts.[8] Although SSL suture can be done using a regular needle holder, some specially designed instruments are currently available.[19,20] In this study, we present the 12-month outcomes of the SSLF using the TAS kit. We developed a noninferiority randomized controlled trial to compare this new device for SSLF with the standard traditional SSLF.

We detected that SSLF using TAS is not inferior to traditional SSLF for the treatment of the apex of the vagina. Evaluating only the participants who completed 12-month follow-up, scenario that which would best reproduce the treatment differences, success rate reached 90% for TAS and 80% for traditional SSLF (10% difference). The analysis of all participants randomized and treated would best reflect the practical clinical scenario because it considers protocol deviations giving an unbiased estimate of treatment effect. When considering missing data as failures, we also found noninferiority of the technique using the device compared with standard SSLF with regular needle holder, although cure rates were lower as expected by using a more conservative analysis (80% for TAS and 73% for traditional SSLF; 7% difference). The same conclusions found by both sensitivity analyses increase the confidence in our results.[21] The high rates of objective success we observed after SSLF, irrespective of the technique, were in accordance with the literature.[18,22,23]

For anatomical recurrence after SSLF procedures, it is noted that the vaginal apex is generally well fixed deep inside the pelvis, although the weak point seems to be the anterior compartment. It is described that approximately 29% of the patients usually develop an anterior prolapse in the first few years after surgery.[23] In our study, 2 patients (2%) required revision procedure because of anterior compartment recurrence.

The TAS and traditional SSLF groups had similar improvement in all anatomical objective measurements. The study failed to show noninferiority of TAS considering the composite anatomical criteria for success. We acknowledge that concomitant native tissue procedures were performed to repair the multiple defects of the pelvic floor when applicable, and that would explain our positive results for all vaginal compartments. In addition, our study may be underpowered to conclude about composite anatomical end points in this model.

A noninferiority study aims to show that the experimental treatment is not unacceptably less efficacious than an active control treatment in use. With continuous improvements in health technologies, standard care, and clinical outcomes, the incremental benefits of newly developed treatments may be only marginal over existing treatments. Considering the success rate only, a new noninferior technique, such TAS, potentially would not change the clinical practice. However, usually new technologies come to the market because of other better properties. In our study, TAS was associated with shorter net time to dissect and reach the SSL, shorter length of hospitalization, lower rates of UTI, and lower pain scores in the first 30 days postoperative. Although not statistically significant, there was increased bleeding in 2 patients who received traditional SSLF and none in the TAS

TABLE 4. Objective Success Rates Considering Different Anatomical Criteria at the 12-Month Follow-up

	Analyses	**TAS**	**Traditional SSLF**	***P****	**Absolute Difference % (90% CI)**
C<=−4	PP (n: 89)	44/49 (90)	32/40 (80)	0.0006	9.80 (−5.2 to 24.8)
	SA (n: 99)	44/55 (80)	32/44 (73)	0.0048	7.3 (−9.6 to 24.2)
C<=4; Ba<=0; Bp<= 0	PP (n: 89)	38/49 (77.5)	31/40 (77.5)	0.9953	0.10 (−17.4 to 17.5)
	SA (n: 99)	38/55 (69.1)	31/44 (70.4)	0.0709	−1.30 (−19.6 to 16.8)

Results are expressed as n/n total (%).

Sensitivity analyses PP: per protocol considering only the subjects that completed the 12-month follow-up.

Sensitivity analyses SA: sensitivity analyses considering the total number of participants randomized and treated with drop-out cases as failure.

* Pearson's X2 test.

TABLE 5. Preoperative and 12-Month Postoperative P-QOL and PISQ-12 Scores

	TAS				Traditional SSLF					
Questionnaire	**Pre**	**Post**	**Mean Diff**	***P****	**Pre**	**Post**	**Mean Diff**	***P****	***P*† (Pre)**	***P*† (Post)†**
P-QOL (n:49 × 40)	360	67	259.98	<0.0001	324.5	69	224.05	<0.0001	0.4365	0.5039
PISQ-12 (n:14 × 9)	24.5	10	12.22	0.032	23	13	7.33	0.053	0.9748	0.4672

Values expressed in median.

Sample size for the analysis: (n: TAS × Traditional SSLF).

Sensitivity analyses for P-QoL scores: per protocol analyses, including only subjects that completed the 12-month follow-up.

Sensitivity analyses for PISQ-12 scores: including only sexually active subjects that completed the 12-month follow-up.

*Wilcoxon (paired samples).

†Wilcoxon for independent samples.

group. This finding is in accordance with the literature that emphasizes that newer disposable devices facilitate blind suture application using minimal dissection and are associated with decreased blood loss.[24–26] Taken together, those findings might influence the surgeon practice and bring the light for potential role of TAS in pelvic floor reconstruction.

Overall, quality of life related to POP equally improved for both procedures, in accordance with the subjective outcomes observed by others.[27] Sexual function improved only after TAS in our study when comparing preoperative and postoperative time, although comparison between groups showed no significant difference. However, we acknowledge that sample size was small to make final conclusions regarding sexuality as few women included were sexually active.

As strengths of our trial we can highlight that it is a randomized controlled and multicentric trial with appropriate allocation concealment and randomization methods with low dropout rate and involves objective anatomical outcomes measurements together with subjective outcomes as sexual function and quality of life by means of validated tools. We also acknowledge some limitations such as the use of only anatomical end point as primary outcome for SSLF by the time the study was designed in 2011, whereas nowadays is recommended to consider anatomy. Our study did not reach the sample sized expected because of time constraints and drop-out. However, this was enough to test and proof the original hypothesis that TAS is noninferior to the traditional SSLF for the treatment of apical compartment (C-point) in 12-month follow-up. On the other side, we may have had false-negative results or have not shown noninferiority of the device when the analyses of the secondary outcomes that included success as composite anatomical end points as well as the sexual function and quality of life. Increasing the number of participants would potentially provide complement data.

Although this trial showed very good outcomes for both SSLF procedures, a recent publication revealed that the number of admissions for SSLF grew more than 3-fold over the years after a substantial decline in the use of transvaginal mesh and a stable number of sacrocolpopexies, mainly because the US Food and Drug Administration's safety warnings about the use of mesh and the prolonged operative and recovery time after sacrocolpopexy.[28] With that, SSLF remains a useful procedure for prolapse when a vaginal approach is desired. Innovations in suturing devices have smoothed the technique.

CONCLUSIONS

The modified technique of SSLF using the TAS is noninferior to the traditional SSLF for the treatment of apical compartment in 12-month follow-up. Both techniques proved to be effective and safe for women with apical vaginal prolapse.

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