

Single-Incision Mini-Sling for the Treatment of Female Stress Urinary Incontinence: Is it Actually Inferior to Transobturator Vaginal Tape and Tension-Free Vaginal Tape?

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Abstract

Objectives: The aim of the study was to report the extended long-term results of the use of single-incision mini-sling (SIMS), tension-free vaginal tape (TVT), and transobturator tape (TOT) for the treatment of female stress urinary incontinence (SUI) at the Department of Gynecology and Obstetrics of the University Medical Center Ljubljana.

Materials and Methods: Enrolled women were evaluated by Patient Global Impression of Severity (PGI-S), Patient Global Impression of Improvement (PGI-I), Sandvik severity scale, Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), and Incontinence Questionnaire-Urinary Incontinence (ICIQ-UI) Short Form and data about diagnosis, procedures, complications, reoperations, postoperative results, and satisfaction with procedure were recorded.

Results: In analyzed group of patients ($n = 357$), 116 (32%) underwent SIMS procedure, 189 (53%) TOT, and 52 (15%) TVT. The SIMS, TOT, and TVT groups did not differ significantly from each other in PGI-S, PGI-I, Sandvik severity scale, UDI-6, IIQ-7, and ICIQ-UI Short Form or in postoperative complication rate. Repeat surgery was needed in 9.5% after SIMS, in 13.2% of TOT patients and in 23.1% of TVT patients ($P = 0.194$). Urinary retention occurred in 9.5% of the SIMS patients, in 9.5% of the TOT patients, and in 13.5% of the TVT patients ($P = 0.682$). Mesh erosion/inflammation occurred in 3.4% of the SIMS patients, in 6.3% of the TOT patients, and in 3.8% of the TVT patients ($P = 0.485$).

Conclusion: The efficacy and safety of SIMS, TOT, and TVT in the surgical treatment of SUI are comparable. The choice of the technique should be based on the relative pros and cons of techniques and the surgeon's experience.

Keywords: Complications, mini-sling, outcomes, stress urinary incontinence, tension-free vaginal tape, transobturator tape

INTRODUCTION

Operative techniques for female stress urinary incontinence (SUI) has changed over the last decades,^[1] aiming to improve symptoms and quality of life.^[2,3] For a long time, Burch colposuspension was the gold standard for SUI.^[4] Nevertheless, this procedure was associated with more complications, prolonged hospital stay and a high rate of anterior vaginal wall prolapse.^[5] Nowadays,

Burch colposuspension is replaced by minimally invasive procedures using mesh sling, a new surgical technique with minimal surgical trauma access, performed under local anesthesia, that has been found to significantly improve the quality of life,^[6] similarly to what has been found for native tissue repair^[7] and other techniques.^[8] Several studies have shown that the transobturator procedure is associated

Article History:

Submitted: 27 August 2019

Revised: 4 February 2020

Accepted: 17 March 2020

Published: 1 August 2020

Access this article online

Quick Response Code:



Website:
www.e-gmit.com

DOI:
10.4103/GMIT.GMIT_78_19

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How to cite this article: Keršič M, Keršič M, Kunič T, Garzon S, Laganà AS, Barbič M, *et al.* Single-incision mini-sling for the treatment of female stress urinary incontinence: Is it actually inferior to transobturator vaginal tape and tension-free vaginal tape? *Gynecol Minim Invasive Ther* 2020;9:123-30.

with postoperative pain in the inner thigh, but it shows high percentage of cure rates (up to 90%), shorter operation time, less blood loss as compared to retropubic route.^[5] The single-incision mini-sling (SIMS) was introduced in 2008 with the aim to further decrease potential complications from retropubic and transobturator approaches (such as bladder or bowel perforation and vessel injury).^[9] There is no blind passage of the needle introducer through the retropubic space when inserting the tension-free vaginal tape (TVT) nor the passage of trocars through the obturator or adductor muscles when inserting the transobturator tape (TOT). Instead, the SIMS requires only a single suburethral incision and the adjacent creation of a tunnel in either a “U-type” or “H-type” where the sling would lie. Therefore, this eliminates the potential complications associated with these trajectory paths.^[10] Mini-slings utilize only small tape strips, potentially avoiding problems inherent in the Food and Drug Administration (FDA) warnings.^[10] Unlike the TVT and TOT which have long lengths of tape, mini-slings rely on the anchor “grip” to resist restorative forces from tissues they compress. Anchor grip varies with different “kits” as do results reported. In general, achieving the correct tension is difficult with untensioned mini-slings, as insertion and tightening are done simultaneously.^[11] They compress the periurethral tissue and so are subject to restorative tissue elastic forces postoperatively, which tend to loosen the tape. Tensioned mini-slings work on a different principle:^[12] Soft-tissue anchors with high pull-out strength are inserted and the tape is tightened as a separate movement; the midurethral tissue fixation system tensioned mini-sling is inserted exclusively from the vagina at midurethra in the exact position of the pubourethral ligament; it is tightened over an 18-gauge Foley catheter; the anchors are at all times below the Space of Retzius and in this way, bladder perforation, hemorrhages, and major blood and nerve damage are avoided. Finally, only a few cm of a 0.7 cm wide mesh is required.^[13] So far, there is no consensus regarding long-term outcomes of SIMS for women with SUI. Some authors report comparable outcomes of SIMS for woman with SUI,^[14-16] but other authors report inferior outcomes as compared to TOT and TVT.^[17,18] Based on the lack of robust evidence to draw firm conclusion, our study was aimed to compare cure rates, urogynecological symptoms, complications, patient satisfaction and safety of SISM, TVT, and TOT procedures for female SUI.

PATIENTS AND METHODS

The retrospective observational study was performed from January to August 2017 at the Department of Gynaecology and Obstetrics, University Medical Center Ljubljana, comparing outcomes of SIMS, TVT, and TOT operations. All women included had stressed or mixed urinary incontinence

associated with urethral hypermobility (the stress component was clinically predominant, defined as more episodes of leakage due to coughing or physical effort). All women included had SUI confirmed by a positive standardized cough test and had failed or declined pelvic floor muscles training.^[19] Urinary incontinence was classified as recommended by the International Continence Society.^[20] Preoperative assessment included women’s detailed medical history, clinical, neurological and urogynecological examination. A preoperative assessment of the endometrium, possibly associated with an endometrial biopsy, was also performed for women with a history of endometrial hyperplasia or any episode of abnormal uterine bleeding as recommended.^[21-23]

Before the surgery, the patients filled out a 3-day diary, and we performed an ultrasound examination and examination of the pelvic static. If overactive bladder was diagnosed, patients received appropriate medication therapy (anticholinergics and betamimetics).

All enrolled women were re-evaluated in the postoperative period with the same tests.

We excluded women who underwent surgery more than 10 years before, older than 80 years, previous anti-incontinence surgery and/or pelvic organ prolapse (POP) more than stage I at the POP-Quantification system^[24] in any vaginal compartment. After inclusion and exclusion criteria, all women were invited to complete the following questionnaires: Patient Global Impression of Severity (PGI-S),^[25] Patient Global Impression of Improvement (PGI-I),^[25] Sandvik incontinence severity index,^[26] Urogenital Distress Inventory (UDI-6),^[27] Incontinence Impact Questionnaire (IIQ-7),^[27] and Incontinence Questionnaire-Urinary Incontinence (ICIQ-UI) Short Form.^[28] In addition, data about diagnosis, procedures, complications, reoperations, postoperative results, and satisfaction with procedure were recorded. Finally, data on body weight, body height, previous gynecological procedures, type of intervention, year of birth, year of operation, level of education, number of vaginal births, previous gynecological operations, conservative treatment of urinary incontinence, menopausal status, intraoperative and postoperative complications were also obtained from our electronic database of the University Medical Center Ljubljana.

Standard operating techniques were used as described by Petros and Papadimitriou,^[13] Ulmsten,^[29] and Delorme.^[30,31] The surgeons involved in this study had experience with all surgical the abovementioned techniques. The surgical procedures were performed under local anesthesia. After the procedure, residual urine volume was measured. In the case of residual urine volume above 50%, we advised intermittent catheterization until the first postoperative control after 1 week.

Ophira® Mini Sling System (Promedon, Córdoba, Argentina) has blue loosening sutures inserted in the base of both fixation arms, giving the ability to correct tension during the procedure. The fixation system has multiple fixation points along its self-fixating arms. The system includes a “retractable insertion guide” to improve control and ease when inserting the sling and releasing it in the correct position. The connectors located at the ends allow the retractable insertion guide to be inserted easily and safely. The delivery trocar is inserted in the small vaginal incision and guided by the surgeon toward the obturator internus. When half of the mesh is within the incision, the deployment button on the needle is pressed and the sling is kept in place by the self-anchoring fishbone columns.^[32]

In the TOT procedure, we used the GYNECARE TVT ABBREVO® system (Johnson and Johnson, Somerville, NJ: Ethicon, Inc), which has the same mesh design as the laser cut mesh used in the obturator systems for pelvic organ prolapse surgery. A thread is threaded through the end of the tape, which is removed at the end of the procedure. Depending on the stability of the position in the obturator membrane, it is comparable to the transobuturator mesh, where the mesh is in the whole course. The GYNECARE TVT ABBREVO® system uses less mesh but provides the same tension-free support.

In retropubic approach (TVT), we used the GYNECARE TVT EXACT® system (Johnson and Johnson, Somerville, NJ: Ethicon, Inc.,) with a rigid 3 mm diameter trocar shaft designed to maintain control during passage while reducing penetration force. The trocar features a smooth surface from handle to closed tip, to reduce tissue drag during needle passage. The trocar curvature and tip radius are designed so that the trocar maintains contact with the posterior aspect of the pubic bone.^[33]

The objective of the retrospective study was to test hypothesis that single-incision SIMS is not inferior to TVT or TOT. In particular, the scores of PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6, IIQ-7, ICIQ-UI Short Form questionnaires were considered as primary outcomes, whereas complication rate and patient’s subjective satisfaction were considered as secondary outcomes of the study.

Statistical analysis

To compare the ordinal categorical variables, we used the Mann–Whitney U-test. Other categorical variables were analyzed using a Chi-squared test or a Fisher’s exact test, as appropriate. Linear variables were analyzed with the Student’s *t*-test. The threshold for statistical significance was set at $P < 0.05$. All statistical calculations were performed using IBM SPSS Statistics, edition 24 (IBM Corp, Armonk, NY, USA).

Ethics statement

The design, analysis, interpretation of data, drafting and revisions conform the Helsinki Declaration and the RECORD (reporting of studies conducted using observational routinely-collected health data) statement,^[34] available through the enhancing the quality and transparency of health research network (www.equator-network.org). The study was approved by the independent Institutional Review Board National Medical Ethics Committee of the Republic of Slovenia (approval protocol: 0120-565/2016-2). Each patient enrolled in this study signed an informed consent for all the procedures and to allow data collection and analysis for research purpose. The study was nonadvertised, and no remuneration was offered to encourage patients to give consent for collection and analysis of their data. The study was not funded.

RESULTS

After the inclusion and exclusion criteria were taken into account, there were 1104 patients left, who were sent questionnaires. In August 2017 (6 months after sending), we received 466 completed questionnaires (42.2% response rate), of which 109 (23%) were excluded from further analysis due to insufficient data. Therefore, we could analyze 357 adequately filled questionnaires.

First, we have demonstrated the representativeness of the sample. Among the women who have responded to the questionnaires and among those who have not, there were no statistically significant differences in type of intervention, year of birth, year of surgery, present age, the level of education, job, number of vaginal births and Caesarean sections before the procedure, previous gynecological operations, conservative treatment of urinary incontinence, menopausal status, type of anesthesia, and intraoperative and postoperative complications ($P > 0.15$).

The average age of patients at surgery was 56.2 years (standard deviation 9.0).

Among the women who returned adequately filled questionnaires ($n = 357$), the treatment with SIMS approach was performed in 116 (32%) of cases, TOT in 189 (53%) of cases, and TVT in 52 (15%) of cases [Table 1].

In selecting surgical techniques, surgeons relied primarily on their opinion of relative advantages and disadvantages of different technique and his/her own experience.

Groups did not significantly differ in body weight during surgery ($P = 0.788$), in body weight when filling questionnaires ($P = 0.274$), in body height ($P = 0.054$) or time from the surgery (5.6 years; 5.1 years; 5.1 years; $P = 0.443$). In addition, the groups did not significantly differ in the

answer to the question: did your mother have problems with urine leakage? ($P = 0.782$).

Figure 1 shows the distribution of SIMS, TOT and TVT procedures over time: random distribution of procedures over time is apparent, without an obvious trend.

An analysis of the responses to structured questionnaires (PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6, IIQ-7, ICIQ-UI Short Form) and the following additional questions in the questionnaire are presented in Table 2.

Table 3 shows complications and patient satisfaction rates.

Table 1: Information about patients who returned complete questionnaires ($n=357$)

Type of incontinence	
Stress	233 (66)
Stress with urgent component	124 (34)
Type of surgical approach	
Transobturator approach (TOT)	189 (53)
Retropubic approach (TVT)	52 (15)
Mini-sling	116 (32)
Previous operations	
No	256 (71)
Total abdominal hysterectomy	49 (14)
Vaginal hysterectomy with anterior colporrhaphy	34 (10)
Other procedures (Burch, Wertheim, Stamey)	18 (5)
Previous pharmacological treatment for SUI	
Yes	23 (9.87)
No	210 (90.12)
Age at surgery (minimum; maximum)	55.0±9.21 (31; 78)
Parity	2.09±1.81
Mean BMI	27.48±4.75
BMI >30 (obese)	97 (17.2)

TOT: Transobturator tape, TVT: Tension-free vaginal tape, SUI: Stress urinary incontinence, BMI: Body mass index. Data are expressed as number and percentages for categorical variables, and as means and standard deviations for continuous variables

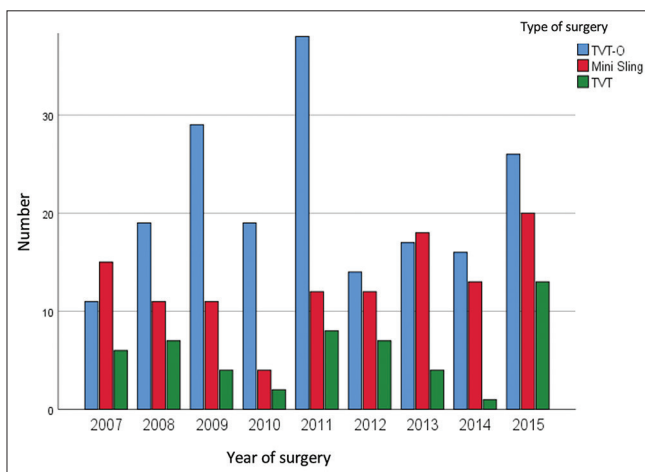


Figure 1: Distribution of single incision mini sling, transobturator vaginal tape (TOT) and tension-free vaginal tape (TVT) procedures over time

DISCUSSION

Urinary dysfunction represents one of the most common problems in women, due to different conditions.^[35,36]

Our retrospective study confirms that the efficacy and safety of SIMS, TOT, and TVT in surgical treatment of SUI are comparable. After analyzing the responses to structured established questionnaires (PGI-S, PGI-I, SANDVIK SEVERITY SCALE, UDI-6, IIQ-7, ICIQ-UI Short Form), we found that there were not significant differences for the investigated parameters. In addition, there were no significant differences between groups in the answers to the questions “How much does the urine leaks now?” ($P = 0.798$) and “Does the urine leaks during cough if your bladder is full?” ($P = 0.954$).

With the regression models, we also checked the possible impact of the time that passed from the operation on the individual results and we did not find any impact on current condition.

The incidence of complications after surgery ($P = 0.194$), urine leakage ($P = 0.682$), erosion of the vaginal tape into the vagina ($P = 0.485$) also did not significantly differ between the groups. Our findings are in accordance with published studies, which also report the incidence of erosion of the tape in the vagina from 3.8% to 15%.^[37,38]

The type of synthetic mesh, surgical experience, and type of intervention affect the incidence of erosion of the tape in the vagina. Possible causes are different: rubbing of the mesh against the epithelium of vagina; mesh tension that could trigger a stronger inflammatory response; subclinical inflammation of the mesh and poor wound healing; compromised vascularization and consequent ischemia in the tissue around the mesh. The size of the pores in the monofilament mesh is very important, multifilament meshes, knitted materials, and silicone-coated implants are associated with a higher risk of erosion of the tape into the vagina.^[39,40]

The advantage of our research was that in all groups (SIMS, TVT, and TOT) we used meshes with the same material (polypropylene) to avoid this important potential bias, which is the problem of some other studies.^[41] In this regard, Rechberger *et al.*^[42] compared monofilament mesh with multifilament mesh at the same type of operation and found different incidence of postoperative urine retention, although the success rate of both the approaches has been found comparable,^[15,43] which is similar to what is possible to obtain with other approaches.^[44]

In the case of erosion of the synthetic mesh in the vagina, local excision, antiseptic washing, and re-closure of the wall of the vagina are not always sufficient. Sometimes, it is

Table 2: Patient global impression of severity, patient global impression of improvement, Sandvik severity scale, urogenital distress inventory, incontinence impact questionnaire, and incontinence questionnaire - urinary incontinence short form questionnaires analysis

Check the number that best describes how your urinary symptoms are now (PGI-S)	TOT (%)	TVT (%)	SIMS (%)
Normal	63 (33.3)	15 (28.8)	41 (35.3)
Mild	59 (31.2)	13 (25.0)	37 (31.9)
Moderate	35 (18.5)	17 (32.7)	23 (19.8)
Severe	21 (11.1)	6 (11.5)	9 (7.8)
No data	11	1	6
<i>P</i>		0.510	
Check the number that best describes how your postoperative condition is now, compared with how it was before you had the surgery (PGI-I)	TOT (%)	TVT (%)	SIMS (%)
Very much better	73 (38.6)	21 (40.4)	53 (45.7)
Much better	39 (20.6)	11 (21.2)	14 (12.1)
A little better	34 (18.0)	7 (13.5)	19 (16.4)
No change	14 (7.4)	6 (11.5)	10 (8.6)
A little worse	6 (3.2)	1 (1.9)	4 (3.4)
Much worse	9 (4.8)	3 (5.8)	4 (3.4)
Very much worse	5 (2.6)	2 (3.8)	3 (2.6)
No data	9	1	9
<i>P</i>		0.825	
Sandvik severity scale	TOT (%)	TVT (%)	SIMS (%)
Slight	119 (63.0)	27 (51.9)	73 (62.9)
Moderate	45 (3.8)	12 (23.1)	32 (27.6)
Severe	25 (13.2)	13 (25.0)	11 (9.5)
<i>P</i>		0.101	
UDI-6	TOT	TVT	SIMS
Mean score	35.29	31.20	33.38
<i>P</i>		0.539	
IIQ-7	TOT	TVT	SIMS
Mean scores	30.95	28.39	26.08
<i>P</i>		0.402	
ICIQ-SF	TOT (%)	TVT (%)	SIMS (%)
Mean scores	7.30	8.65	7.48
<i>P</i>		0.329	
How often do you experience urinary leakage now?	TOT	TVT	SIMS
Never, I do not leak urine	45 (25.0)	13 (26.0)	29 (25)
Leaks with severe coughing or sneezing	88 (48.9)	22 (44.0)	43 (37.1)
Leaks already with minor coughing or sneezing	17 (9.4)	4 (8.0)	13 (11.2)
Leaks for no obvious reason	22 (12.2)	10 (20.0)	17 (14.7)
Leaks all the time	8 (4.4)	1 (2.0)	8 (6.9)
No data	9	2	6
<i>P</i>		0.798	
Does your urine leaks with a half full bladder if you sneeze?	TOT (%)	TVT (%)	SIMS (%)
Yes	36.6	38.8	36.4
No	63.4	61.2	63.6
<i>P</i>		0.954	

Data are expressed as number and percentages for categorical variables, and as means and standard deviations for continuous variables. Data are expressed as *n* (%). PGI-S: Patient global impression of severity, PGI-I: Patient global impression of improvement, UDI-6: Sandvik severity scale, Urogenital distress inventory, IIQ-7: Incontinence impact questionnaire, ICIQ-UI: Incontinence questionnaire - Urinary incontinence, short form questionnaires analysis, TOT: Transobturator tape, TVT: Tension-free vaginal tape, SIMS: Single-incision mini-sling, ICIQ-SF: International consultation on incontinence - short form

necessary to perform total mesh removal and many of these patients need reoperation for establishing continence.^[45] Erosion and secondary infection of the mesh can also appear

18 years or more after the procedure.^[46,47] In addition, urinary retention could occur even as a consequence of vaginal vault prolapse.^[48]

Table 3: Postoperative complication and satisfaction rates

Postoperative complications	TOT (%)	TVT (%)	SIMS (%)	P
Erosion of the tape in the vagina	12 (6.7)	2 (3.9)	4 (3.7)	0.485
Infection	12 (6.7)	2 (3.9)	6 (5.5)	0.762
Difficulties with urine leakage	18 (10.0)	7 (13.7)	11 (10.1)	0.682
Re-operation needed	25 (13.9)	12 (23.5)	16 (14.7)	0.194
No complications	118 (65.6)	29 (56.0)	74 (67.9)	0.598
Postoperative pain	TOT (%)	TVT (%)	SIMS (%)	P
Thigh pain	17 (9.7)	3 (6.4)	2 (1.9)	0.037
Groin pain	23 (13.1)	3 (6.4)	11 (10.3)	0.379
Abdominal pain	19 (10.9)	2 (4.3)	16 (15.0)	0.145
No pain	118 (67.4)	39 (83.0)	79 (73.8)	0.204
Are you satisfied with the operation?	TOT (%)	TVT (%)	SIMS (%)	P
Yes	161 (86.6)	41 (80.4)	95 (84.1)	0.271
No	25 (13.4)	10 (19.6)	18 (15.9)	
No answer	3	1	3	
Would you decide for the operation again?	TOT (%)	TVT (%)	SIMS (%)	P
Yes	163 (89.1)	37 (75.5)	96 (83.5)	0.014
No	20 (10.9)	12 (24.5)	19 (15.5)	
No answer	6	3	1	
Would you recommend this procedure to a friend with the same problem?	TOT (%)	TVT (%)	SIMS (%)	P
Yes	167 (90.8)	39 (81.3)	99 (88.4)	0.063
No	17 (9.2)	9 (18.8)	13 (11.6)	
No answer	5	4	4	

Data are expressed as n (%). TOT: Transobturator tape, TVT: Tension-free vaginal tape, SIMS: Single-incision mini-sling

Among the weakness of our study, we lack data of objective methods of evaluation (cystometry) and the retrospective nature of our research. However, the questionnaires represent an added value as not only the improvement of urodynamic and cystometric outcomes but also patient satisfaction is an important variable to be considered in clinical practice.

Most women did not have pain due to procedure, but patients who underwent SIMS had significantly ($P = 0.037$) less thigh pain (1.9%) as compared to TVT (6.4%) and TOT (9.7%).

The most common complication at retropubic approach is urinary retention (17%–50%).^[24,29] In de Tayrac's study,^[49] urinary retention was reported in 13.3% of women after TOT and 25.8% of women after TVT. Similar to that, urinary retention in our study was present in 10.0% of women after TOT procedure, 10.1% after SIMS and at 13.7% of women after TVT procedure. Also for this parameter, we did not find significant difference among the groups ($P = 0.682$), confirming what was previously found by others.^[50,51]

Finally, the groups did not significantly differ in the satisfaction with the procedure ($P = 0.265$). In the group of women with TOT, there were statistically significant higher percentage ($P = 0.014$) of those who would decide again for

the operation and would recommend a procedure to a friend with the same problem ($P = 0.08$).

Considering together the data analysis of our study, the use of SIMS, TOT, and TVT techniques seems to lead to similar outcomes in terms of safety, efficacy and patient's subjective satisfaction rate. Nevertheless, we acknowledge that our results need to be confirmed in a larger setting and a long-term follow-up. In particular, the use of surgical mesh intended for transvaginal repair of anterior compartment prolapse and different techniques should be considered in the light of the warning by the FDA, which reclassified them into Class III.^[52]

CONCLUSION

Our data analysis allows us to conclude that the efficacy and safety of SUI surgery in women with SIMS, TOT and TVT are comparable. Most women do not have pain due to procedure, but patients undergoing SIMS had significantly less thigh pain as compared to TVT and TOT.

When choosing a surgical technique for the treatment of female SUI, we solicit to take into consideration the relative advantages and disadvantages of different technique and the surgeon's skills.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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