Comparison of Efficacy of Solyx™ Single Incision Sling and TO-TVT for Female Stress Urinary Incontinence

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Research Article

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Abstract

Introduction To compare the efficacy, safety, and complications of the trans-obturator mid-urethral sling (TO-TVT) and Solyx^{TM} single-incision sling for treatment of female SUI

Methods The clinical data of 92 patients who underwent urinary incontinence surgery in the Affiliated Hospital of Xuzhou Medical University were retrospectively analyzed. The groups were divided on surgical techniques such as TO-TVT and the Solyx single-incision sling groups. Preoperative evaluation included patient's history, urodynamic evaluation, clinical examination results, I-QOL, and UDI-6 scores. The operative time, intraoperative blood loss, complications, and hospital stay were recorded. At six months follow-up, the patient was re-evaluated for I-QOL, UDI-6 scores, and urodynamics and clinical examinations. The PGI-I questionnaire assessed subjective cure rates at six months postoperatively.

Results Patients in the TO-TVT and Solyx single-incision sling groups had similar subject cure rates six months after surgery. There was no statistical significance in intraoperative blood loss, length of hospital stay, I-QOL and UDI-6 scores between the two groups except for operation time .There was no significant difference in the incidence of intraoperative and postoperative complications between the two groups.

Conclusion In terms of the effect and complications, the TO-TVT is similar to Solyx^{TM} single incision sling. Nevertheless, Solyx^{TM} single incision sling is shorter in operation time, more minimally invasive, and has a definite curative effect worthy of clinical promotion.

Introduction

Urinary incontinence (UI) is a prevalent disease that seriously bothersome middle-aged and older women, and the incidence of UI is gradually increasing with age[1]. A large meta-analysis showed that older Asian women had the highest incidence of urinary incontinence, which is about 45.1%[2]. Urinary incontinence includes stress incontinence, urge incontinence, and mixed incontinence[3]. The incidence of stress urinary incontinence (SUI) is the highest, about 50% of the overall incidence of urinary incontinence. Its symptoms gradually worsened with the increase in age and severe impact on the social and personal life[4–5]. Urinary incontinence is the unintentional loss of urine or involuntary urine leakage from the ureteral orifice during physical activity or exertion(coughing, walking quickly, sneezing), leading to increased abdominal pressure. The risk factors of its incidence are age, pregnance, vaginal delivery, parity, obesity and so on[6]. Risk gynecological operations, especially hysterectomy, can also double the risk of SUI[7].

First-line treatment for SUI includes conservative treatment (pelvic floor muscle training, drugs, laser therapy, etc.), and surgical is reserved for intractable SUI. Previous studies believe that conventional treatment is generally adopted for mild SUI, and surgical treatment can be considered if conservative treatment is ineffective or for moderate to severe SUI[8]. Over the years, different Surgical technique has been described for stress incontinence. Trans-vaginal tension-free mid-ureteral suspension (TVT), proposed by Uimsten in 1996, is the most commonly performed procedure to treat SUI. In addition,

through a three-year follow-up study, Uimsten proved that this surgical method of mesh implantation in the posterior pubic space could effectively treat SUI patients, with an effective rate of over 97% and a complete cure rate of 86[9]. However, due to blind penetration of TVT surgery, complications such as bladder perforation and retropubic may be caused[10]. In order to reduce the occurrence of such complications, Delorme et al. Proposed the transforaminal urethral sling (TOT/TVT-O) based on TVT surgery, nevertheless at the same time, it also increased the risk of groin pain, nerve and vascular injury, and other related complications [11–12]. Single-incision sling (SIS) has been introduced to ensure the surgical effect and reduce the complications of the tension-free mid-urethral sling. Although the initial single-incision sling products such as TVT-Secure (Gynecare) were not as effective as the standard mid-urethral sling and were withdrawn from the market, there is not enough evidence to make a reliable comparison on other single-incision slings [13]. With the continuous improvement of technology, the second generation of the single-incision sling in treating female stress urinary incontinence has been no less than the traditional surgical method[14]. In this paper, a total of 92 patients admitted to the Affiliated Hospital of Xuzhou Medical University from October 2018 to January 2021 who received TO-TVT and SolyxTM single-incision sling suspension for urinary incontinence were compared. The results are reported as follows.

Objects And Methods

1. General information

A total of 92 patients with SUI were included in this study. Inclusion criteria: (1) Patients with urine leakage when abdominal pressure increases, such as coughing, sneezing, running, etc., and urine leakage stops when abdominal pressure disappears, and cough pressure test results are positive, laboratory examination, imaging examination, and urodynamics examination ruled out urinary tract infection and obstruction; (2) Patients with indications of surgery who accept and tolerate surgery; (3) Patients who can complete the questionnaire independently. Exclusion criteria: (1) Patients with severe detector instability, mainly non-stress urinary incontinence, and other urinary diseases; (2) Patients who had undergone previous anti-urinary incontinence surgery or pelvic floor surgery with mesh implantation; (3) Patients with malignant tumors. If one of them is satisfied, it is excluded. All patients signed informed consent before surgery. According to different surgical methods, 54 cases were divided into TO-TVT, including 49 cases of simple stress urinary incontinence and 5 cases of mixed urinary incontinence (mainly stress urinary incontinence). SolyxTM single-incision sling was performed in 38 cases, including 36 simple stress urinary incontinence cases and 2 cases of mixed urinary incontinence (mainly stress urinary incontinence). All patients were positive for the cough-induced test, and there was no significant effect after systematic Kegel pelvic floor function training preoperatively. The preoperative urodynamic examination was performed in both groups to exclude detrusor weakness and bladder outlet obstruction. The general clinical data of the patients in the TO-TVT group and the SolyxTM single-incision sling group are shown in Table 1. According to the classification of Valsalva leak point pressure (VLPP), the patient in the TO-TVT group was divided into type 19 cases (VLPP90 cmH_2O), type 31 cases(60≥VLPP≤90

cmH_2O□, □ type 4 cases□VLPP□60 cmH_2O□. SolyxTM single-incision sling group was divided into □type 14 cases, □type 22 cases, □ type 2 cases.

Table 1
Comparison of general clinical data

variable	TO-TVT(54 patients)	SolyxTM(38 patients)	P
Age(years)	54.6 ± 6.94	54.1 ± 6.93	0.750
BMI(kg/cm2)	25.1 ± 3.39	24.3 ± 2.45	0.211
Vaginal delivery	2.0 ± 0.78	1.8 ± 0.79	0.242
Course of the disease(years)	5.9 ± 5.93	4.9 ± 4.37	0.349
VLPP(cmH_2O)	87.8 ± 22.9	92.1 ± 29.2	0.428
Classification of SUI			
□Type	19(35.2%)	14(36.8%)	0.785
□Type	31(57.4%)	22(57.9%)	
□ Type	4(7.4%)	2(5.3%)	
Types of UI			
SUI	49(90.7%)	36(94.7%)	0.479
MUI	5(9.3%)	2(5.3%)	
Prolapse of the anterior vaginal wall (<2 degrees)			
Yes	22(40.7%)	12(31.6%)	0.373
No	32(59.3%)	26(68.4%)	
Follow-up time(weeks)	51.0 ± 15.40	47.0 ± 9.36	0.124
PVR(ml)(preoperative)	8.5 ± 11.1	9.6 ± 11.5	0.639
Qmax(ml/s)(preoperative)	14.8 ± 5.1	14.7 ± 5.1	0.936
I-QOL (preoperative)	52.3 ± 9.0	54.6 ± 13.3	0.362
UDI-6 (preoperative)	7.7 ± 1.3	8.0 ± 1.2	0.213

BMI: body mass index; VLPP: abdominal leak point pressure; SUI: Stress urinary incontinence; MUI: Mixed urinary Incontinence; PVR: bladder residual urine; I-QOL: incontinence questionnaire short form; UDI-6: the urogenital distress inventory.

2. Surgical methods

Patients in both groups underwent surgery for the first time for SUI. All patients preoperative received vaginal wash with iodophor for three days and mixed urinary incontinence patients oral tolterodine tartrate one week. Patients in the two groups were treated with TO-TVT and Boston Scientific Corp: SolyxTM single-incision sling from the USA.

All the operations took place under general anesthesia. For both techniques, the patients were placed in lithotomy position, with hips flexed at 90 degrees, legs in stirrups, and buttocks at the edge of the table. Surgery began with bladder emptying with catheterization. A longitudinal incision of about 1.5 to 2 cm was made in the anterior vaginal wall about 1.0 cm from the external orifice of the urethra to separate the urethra and vaginal mucosal space. A tension-free mid-urethral sling (TOT) needle was inserted through the obturator "from outside to inside" to the ischiopubic ramus. From outside to inside, puncture transversely through the skin and subcutaneous tissue, and then pass through the obturator external muscle, obturator membrane, and obturator internus muscle in the direction of the inferior pubic rami, and enter the urethrovaginal space through the front of the ischiorectal fossa. The "inside-out" trans-obturator tension-free middle urethral sling (TVT-O) passes through the obturator internal fascia, obturator muscle, obturator anteromedial area, and obturator outside the obturator. The needle is inserted at a 1-1.5cm incision in the skin at a distance of about 2cm from the level of the urethral orifice and 5cm outside the urethral orifice. During puncture, the needle insertion point into the vagina should be maintained within 2.0-2.5cm according to the distance from the external opening of the urethra. To avoid penetrating injury to the levator ani muscle, blood vessels, and nerves of the obturator membrane, the angle between the puncture direction and the longitudinal axis of the urethra should be about 45 degrees. Then, the strip was adjusted in pulling on the suture loop, until tension is obtained desired. Mayo scissors were placed between the urethra and the strip to obtain a flat position without tension. Once the loop was adjusted, the suture loop was cut and removed.

The SolyxTM single incision sling procedure was performed using the method described in reference [14]. In brief, On the midline of the anterior vaginal wall, 1-1.5cm below the external orifice of the urethra. A 10ml syringe needle to penetrate the entire thickness of the anterior vaginal wall and inject 10-20ml of normal saline around the vaginal urethral space evenly to separate the urethrovaginal space. A longitudinal incision of 0.5 to 1 cm is made at 1 to 1.5 cm below the urethra external orifice, and the full thickness of the anterior vaginal mucosa is incised. At a 45-degree angle to the midline, use tissue scissors to separate the urethra and vagina to the inner and posterior border of the descending pubic branch and separate a urethra-vaginal space about 1.0 cm wide that can accommodate a sling, and separate the opposite side in the same way. In the direction extending at a 45-degree angle to the midline, use tissue scissors to separate the tissue between the urethra and the vagina to the lower part of the descending pubic branch, and separate a 1.0-1.2cm wide urethra-vaginal space that can accommodate a sling. Side; insert the tip of the delivery device into the anchors on each side of the sling. The device was then inserted into the isolated urethrovaginal space at a 45° angle, and the implanted device was advanced laterally of the inferior pubic ramus to the obturator internus muscle until the midline marking on the device was approximately midline below the urethra. The anchor is placed by holding the deployment mechanism with one hand and pulling the delivery device handle back with the other hand. In

this way, the anchor is fixed into the surrounding musculature. After exiting the handle, you can gently pull the mesh to check whether the mesh is tightly fixed, and adjust the mesh to prevent the mesh from curling.

Place the contralateral side in the same way. Before puncturing the contralateral side, Aili's forceps can be used to clamp 2 ~ 2.5mm on both sides of the midline of the mesh to retain an appropriate length to prevent excessive tension after the sling is fixed, resulting in postoperative urinary retention or dysuria. Complication. After the contralateral puncture is completed, Aili's forceps can be released, and the tip of tissue scissors is placed between the urethra and the mesh. A leak test was performed by Injecting 300–400 ml of normal saline into the bladder And removing the urinary catheter. Appropriate pressure was applied above the suprapubic and abdomen. The anterior vaginal incision was suture, urinary catheter in-situ, and iodophor gauze was placed in the vagina to compress the incision and stop minor bleeding.

3. Postoperative Management and follow-up

After anesthesia recovery, patients returned to the ward, diets were allowed according to gastrointestinal tolerance. The patients' urination 48h after removal of the catheter was observed. Six months after surgery, the maximum urine flow rate and residual urine in the bladder were reviewed by urological color Doppler ultrasound and urodynamics. The objective cure was evaluated by cough induced test, and the subjective cure was evaluated by filling in the general condition improvement questionnaire (PGI-I) after anti-urinary incontinence. I-QOL and UDI-6 scores were filled in preoperatively and six months after surgery.

4. Statistical approach

SPSS 25.0 statistical software was used to process the data. Measurement data were expressed as Mean ± SD, and components were compared by independent sample T-test or Non-parametric test. $P<0.05$ was considered statistically significant.

Result

In this study, 92 patients were successfully operated. The mean operation time was 55.3±12.5min vs 35.5±7.1min（P＜0.05）, the average intraoperative blood loss was 22.7±4.4ml vs 24.7±6.8ml（P=0.133）, the mean catheterization time was 49.5±9.2H vs 47.0±2.7H（P=0.064）, the mean hospital day was 7.8±2.7D vs 7.0±1.8D（P=0.087）in these two groups. All patients were followed up. And the mean follow-up time was 51.0±15.40weeks vs 47.0±9.36weeks（P=0.124）in these two groups.

Six months after the operation, the cough-induced test was negative in 51 patients in the TO-TVT group. Regular family work and mild physical activities were allowed. 1 patient was positive for cough induced test, but the symptoms were reduced. Symptoms were still severe in 2 patients. The objective cure rate was 96.3% six months after the operation. The PGI-I questionnaire showed that compared with the preoperative treatment, 51 patients thought the symptoms were significantly improved, 1 patient thought

they were improved, 1 patient thought they were slightly better than the preoperative treatment, and 1 patient thought there was no significant change. The subjective cure rate was 98.1%. One case of obturator artery bleeding occurred in the TO-TVT group. After re-puncture and compression, the affected side's lower limb was immobilized after the operation, and the bleeding stopped. Two cases developed medial thigh pain after the operation, which was improved 3–4 weeks after treatment with hot compress and physiotherapy. Two patients with new frequency and urgency of urination with or without urgent urinary incontinence subside with anticholinergic treatment. No postoperative urinary retention was found.

On Six months follow-up, in Solyx™ single-incision sling suspension group, 36 patients were negative in the cough-induced test and were able to carry out regular family work and mild physical activities. One patient was positive in the cough-induced test, but the symptoms were significantly reduced than before, and the other one patient was still severe. The objective cure rate was 94.7 six months after the operation. The PGI-I questionnaire showed that compared with preoperative treatment, 34 patients thought their symptoms were significantly improved, 2 patients thought they were improved, 1 patient thought they were slightly better than preoperative treatment, and 1 patient thought there was no significant change. The subjective cure rate was 97.4%. 1 patient with urinary retention after catheter removal 48 hours after surgery was not effective after intermittent catheterization for a week, the sling was excised, and the broken ends of both sides were connected with 1 − 0 absorbable sutures and recovered. One patient developed anteriorvaginal mesh exposure one month after surgery. The exposed mesh was excised, and the wound was sutured again in the outpatient department. The patient was treated with estrogen ointment and recovered. After surgery, one patient developed mycotic vaginitis and recovered after vaginal scrubbing and clotrimazole suppository treatment.

Comparison of various indicators six months follow-up between the TO-TVT group and the SolyxTM single-incision sling group is shown in Table 2 and Table 3, and the intraoperative and postoperative complications are shown in Table 4.

Table 2
Comparison of surgical indexes

variable	TO-TVT group(54 patients)	Solyx group(38 patients)	P
Operating time(min)	55.3 ± 12.5	35.5 ± 7.1	<0.05
Introperative blood loss(ml)	22.7 ± 4.4	24.7 ± 6.8	0.133
Catheterization time(hours)	49.5 ± 9.2	47.0 ± 2.7	0.064
Duration of hospital stay(days)	7.8 ± 2.7	7.0 ± 1.8	0.087

Table 3
Comparison of Qmax、PVR、I-QOL and UDI-6 scores 6 months after the operation.

variable	TO-TVT group(54 patients)	Solyx group(38 patients)	P
Qmax(ml/s)	13.3 ± 4.9	15.9 ± 5.9	0.067
PVR(ml)	7.0 ± 8.7	8.2 ± 10.6	0.578
I-QOL	83.8 ± 8.2	85.2 ± 7.6	0.390
UDI-6	0.8 ± 0.78	1.1 ± 0.99	0.219

Table 4
Comparison of complications

variable	TO-TVT group(54 patients)	Solyx group(38 patients)	P
Obturator vessel injury	1(1.9%)	0(0.0%)	0.402
Groin pain	2(3.7%)	0(0.0%)	0.233
Urinary retension	0(0.0%)	1(2.6%)	0.233
Mesh exposure	0(0.0%)	1(2.6%)	0.233
De novo UI	2(3.7%)	0(0.0%)	0.233
Vaginal infections	0(0.0%)	1(2.6%)	0.233
Total	5(9.3%)	3(8.7%)	0.820

Discussion

Surgical procedures for women with SUI are designed to improve pelvic floor anatomy stability and correct urethral closure to increase urethral closure pressure. In 1914, Kelly first used the folding method to improve the vesicourethral segment, curing mild stress urinary incontinence[15]. Since then, many surgical methods have been reported successively. Currently, more than 200 surgical methods for SUI treatment have been reported in the medical literature[16]. Transpubic retrovesiconeck urethral suspension (MMK) and trans-pubic retro-urethral fixation and suspension (Burch) were the first surgical procedures to use a suprapubic approach to raise the paraurethral tissue and fix it to Cooper's ligament or the periosteum of the pubis. These two procedures were used as the first-line treatment for SUI in the past, but other procedures later replaced them due to the high incidence of postoperative complications of retropubic vesiconeck sling (MMK) and a large amount of intraoperative bleeding and long postoperative recovery[17].

Transvaginal middle urethral suspension (tension-free vaginal tape, TVT) was first proposed by Ulmsten et al. in Sweden in 1996 as a new surgical method for treating women with SUI. Unlike the traditional

surgical treatment principle, it does not restore the angle and position of the urethra nor significantly increase urethral resistance. Instead, it is based on the "hammock theory" to achieve the purpose of urine control by strengthening the supporting force of the female middle urethra[18]. Hence TVT has become the standard surgical method for SUI with less traumatic, short recovery, and high long-term cure rate[19]. However, TVT is performed with a blind needle puncture in the retropubic space, which increases the risk of bladder, intestinal, and vascular injuries[10, 20]. Because of the above shortcomings of TVT operation, De Leval et al. Proposed TO-TVT based on the TVT operation in 2003, which can be further divided into TVT-0 and TOT according to the puncture direction. The advantages of this operation are as follows: (1) The method of implantation is simple: the arc of the bending needle through the sling crosses the subpubic physiological curve, avoiding the retropubic space, bladder, and the blood vessels near the bladder, reducing the potential risk of bladder, urethra, blood vessels, intestine or nerve injury, and shorting the operation time. (2) There is no need for cystoscopy: therefore, it has been routinely used in many hospitals to treat women with SUI, and the treatment effect is satisfactory. At the same time, short learning curve, cystoscopy is not required during the operation, and postoperative recovery is fast. It is a highly repetitive and accurate tension-free urethral sling operation of the amorioclastic foramis. At the same time, TO-TVT is associated with the risk of postoperative complications such as groin pain, reticular erosion, and obturator nerve injury[12].

In order to further reduce the postoperative complications caused by traditional SUI surgery and reduce the difficulty of surgical operation while ensuring the surgical effect, a single-incision sling (SIS) has been developed. The TVT-Secur sling is one of the earliest clinical applications and one of the most widely studied single-incision sling. However, its therapeutic effect is not as good as standard TO-TVT, so it has been withdrawn from the clinical application[13]. With the continuous improvement of technology, more new single-incision sling products have been applied in clinical practice and produced a considerable clinical effect. After constant optimization and update of suspension systems such as TVT-Secur, Mini-Arc, and Ajust, the SolyxTM demonstrated a high subjective cure rate of 97.4%, comparable to the 98.1% subjective cure rate of TO-TVT. Meschina M et al. also pointed out in literature reported that the average follow-up of 63 Solyx single-incision sling patients was 6.5 months, and both subjective and objective cure rates reached 95%[14]. Lenz et al. suggested that the high cure rate of the Solyx single-incision sling is primarily related to the more substantial grip and optimal placement of the obturator internus muscle provided by the automatic anchor bolt[21]. A previous study also demonstrated that the SolyxTM single-incision sling provides greater tension than the Mini-Arc and Ajust sling[22].

In this study, among the 54 patients with TO-TVT, one patient suffered obturator artery bleeding during the operation. After re-puncture and compression, the lower extremity on the affected side was immobilization after the operation, and the bleeding stopped. Two patients developed medial thigh pain after the operation, which was improved 3–4 weeks after hot compress therapy. Two patients developed new frequent and urgent urination with or without urgent urinary incontinence, which improved after anticholinergic therapy. Among the above complications, obturator artery bleeding and postoperative groin pain is common in TO-TVT. It is speculated that the obturator vessels and nerves of the obturator canal can be easily damaged during the puncture route. Zahn et al. found in the cadaver puncture

experiment that the incidence of groin pain after TOT was lower than that of TVT-O, which was related to the distance between the TOT sling and the obturator canal being farther than that of the TVT-O sling[23]. One of the 38 patients with SolyxTM single-incision sling had postoperative urinary retention, which was a depression in the middle part of the urethra after intraurethral ultrasound examination, which was supposed to be caused by excessive sling tension. After the sling was cut off for a second operation, the symptoms of urinary retention disappeared after connecting the two broken ends with 1 – 0 absorbable suture (Figure 1). For complications of postoperative urinary retention, Mingping Wu et al. suggested adding tension release sutures at one end of the sling. For patients with postoperative urinary retention due to overly tight sling, tension release sutures can be used to reduce the tension and avoid the possibility of a second operation[24]. One month after surgery, the anterior vaginal incision dehiscence due to premature sexual activity, resulting in mesh exposure. The exposed mesh was excised in the outpatient operating room, and the wound was sutured. The patient was treated with estrogen ointment for one month and recovered. One patient had a positive cough-induced test after surgery, which was presumed to be related to severe vaginal tearing during vaginal delivery. However, after evaluation, the symptoms of urinary incontinence were significantly improved compared with preoperative symptoms.

This figure is our own, drawn by Li Shuaishuai and Ashok Raj.

This study showed no significant differences in efficacy, intraoperative blood loss, postoperative residual urine volume, length of hospital stay, and incidence of postoperative complications between TO-TVT and SolyxTM single-incision sling surgery ($P>0.05$). However, SolyxTM single-incision sling surgery is shorter in operation time and less minimally invasive.

In conclusion, SolyxTM single-incision sling and TO-TVT have similar short-term efficacy and safety, but the former has minor surgical trauma, a short learning curve, and a shorter operation time, worthy of active clinical promotion long-term follow-up is needed for other effects.

Declarations

Availability of data and materials:

The data that support the findings of this study are available from [third party name] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [third party name].

Ethics declarations:

Ethics approval and consent to participate:

The study was approved by the Clinical Trial Ethics Committee, Affiliated Hospital of Xuzhou Medical University. All patients have signed informed consent forms. The final protocol, any amendments, and

informed consent documentation was reviewed and approved by the Institutional Review Boards. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication:

Informed consent to publish was obtained.

Contribution of Each Author:

Li Shuaishuai: Data Collection, Manuscript Writing, Data Analysis

Ashok Raj: Data Collection, Manuscript Writing, Data Analysis

Xue Ning: Data Collection

Zhao Fangzheng: Data Collection

Chen Rui: Data Collection

Zhu Haitao: Manuscript Writing

Competing interests:

The authors declare no conflict of interest.

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Figures

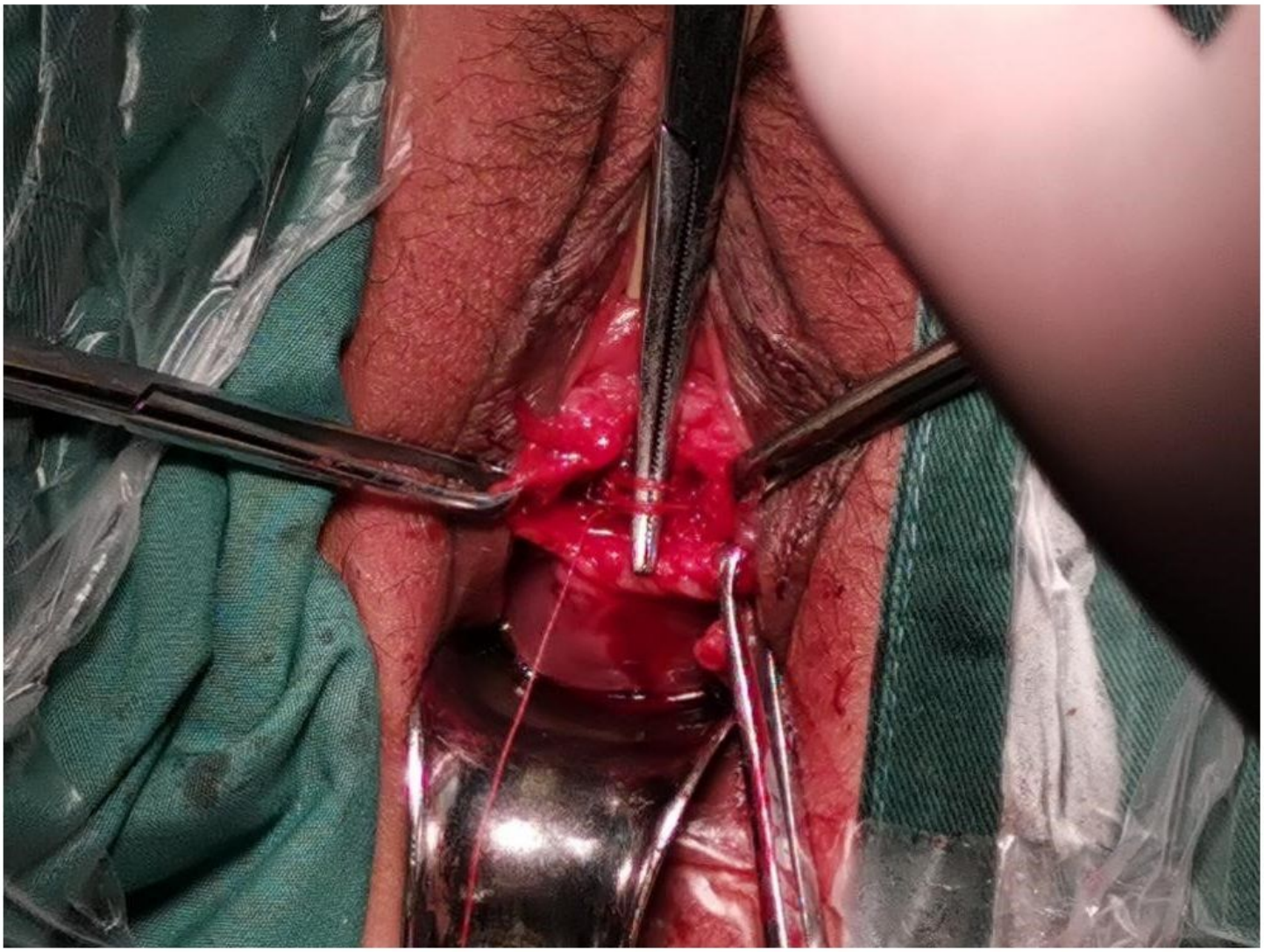

Figure 1

Legend not included with this version.