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Original Article

Effects of Single Vaginal Incision Technique on Quality of Life in Women with Stress Urinary Incontinence

Ates Karateke, MD, Cetin Cam, MD, Sule B. Ince, MD, Niyazi Tug, MD, Selcuk Selcuk, MD*, Mehmet R. Asoglu, MD, and Dogan Vatansever, MD

From the Division of Urogynecology, Department of Obstetrics and Gynecology, Zeynep Kamil Women's Hospital, Istanbul, Turkey (all authors).

ABSTRACT **Study Objective:** To estimate the short-term effects of a minimally invasive single vaginal incision technique without passing through the abdomen or groin (ContaSure Needleless System) on the quality of life in women with incontinence.
Design: Prospective cohort study (Canadian Task Force classification II-2).
Setting: Tertiary referral urogynecology clinic.
Patients: 50 consecutive patients with urodynamically proved stress urinary incontinence from October 2008 to March 2009.
Interventions: Preoperative and postoperative scores on the short forms of the IIQ-7 (Incontinence Impact Questionnaire, UDI-6 (Urinary Distress Inventory) PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Function), and long form of the P-QOL (Prolapse Quality of Life) were evaluated in 50 patients with urodynamically proved stress urinary incontinence. Scores were compared with postoperative urodynamic findings.
Measurements and Main Results: Mean (SD) follow-up was 433.5 (44.1) days (95% CI, 420.1–445.1). Patients showed statistically significant improvement insofar as preoperative and postoperative scores on the IIQ-7, P-QOL, and PISQ-12 and the irritative and stress subgroups of UDI-6. Obstructive score of UDI-6 worsened, consistent with the findings of pressure-flow studies. Postoperatively, 40 patients (80%) were urodynamically continent. Eight patients (16%) were still incontinent; however, their quality of life scores (IIQ-7 and UDI-6 stress) improved. Two patients (4%) continued to experience leakage, with equal or worsened quality-of-life scores.
Conclusion: Early clinical results of the present trial demonstrate that the ContaSure Needleless System seems to be capable of improving significantly all aspects of quality of life in women with incontinence. To improve the willingness for treatment of women with stress incontinence, this minimally invasive technique should be encouraged after confirming its efficacy in larger prospective, randomized, comparative trials. Journal of Minimally Invasive Gynecology (2011) 18, 634–639 © 2011 AAGL. All rights reserved.

Keywords: Minimally invasive surgery; Quality of life; Stress urinary incontinence

DISCUSS You can discuss this article with its authors and with other AAGL members at **http://www.AAGL.org/jmig-18-5-1707**

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Pelvic floor disorders are common in women; however, affected women seem to be reluctant to seek medical help for their debilitating condition. Nearly half of affected women cope alone with their symptoms, and those who receive social or medical help decide to do so after 2 years of onset of symptoms [1]. Lack of information about treatment methods, fear of surgery, and belief that any treatment is useless may be key factors in the reluctance of women to seek treatment [2]. Pelvic floor disorders seldom cause significant morbidity or even mortality, and it is the degree of impairment of quality of life (QoL) that urges the decision to seek medical help. Therefore, surgical treatment methods should be as noninvasive as possible, with the objective to restore QoL without compromising the efficacy of the procedure.

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Corresponding author: Selcuk Selcuk, MD, Department of Urogynecology, Nuh Kuyusu Cad Uskudar, 34668 Istanbul, Turkey.
E-mail: md_sel@hotmail.com

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Stress incontinence is one of the commonest pelvic floor disorders, and can be cured surgically. Surgical treatment may involve placing several sutures between the periurethral area and the pubic bone or ligaments, necessitating abdominal incision, and so-called mini-invasive techniques such as use of tension-free vaginal tape via an abdominal route and transobturator tape via the groin. Evidence for the effectiveness and benefits to QoL of these procedures are well presented in the literature [3]; however, demand for and research on lesser invasive techniques continues [4]. The search for development of a less invasive approach to placement of tension-free vaginal tape resulted in techniques that use only a single vaginal incision without any needle passage through the abdomen or groin, with adequate fixation of the tape in a similar position [5,6].

In the present study, validated questionnaires were used to evaluate prospectively the short-term effects on QoL after treatment with a minimally invasive technique (ContaSure Needleless System; Neomedic International SL, Barcelona, Spain) that involves a single vaginal incision without passing through the abdomen or groin [7].

Materials and Methods

From October 2008 to March 2009, patients with urodynamically proved stress urinary incontinence were entered in the study. The study was approved by our institution review board, and signed informed consent was obtained from all patients. Exclusion criteria included detrusor overactivity (n = 6), symptoms of overactive bladder (n = 12), urinary retention (peak flow rate <15 mL/s) (n = 3), previous anti-incontinence surgery including anterior colporraphy (n = 7), and neurologic bladder (n = 1). Detrussor overactivity was defined as involuntary contractions during the filling phase that may be spontaneous or provoked during urodynamic examination [8], and overactive bladder as urgency, with or without urge incontinence, usually with frequency and nocturia [8]. The degree of pelvic organ prolapse was evaluated using the pelvic organ prolapse quantification system [9]. Urethrovesical junction hypermobility was evaluated using the cotton swab test [10]. Urethral hypermobility was defined as a maximal straining angle of 30 degrees or greater [11]. Urodynamic evaluations were performed in accordance with criteria established by the International Continence Society [12]. Valsalva leak point pressure was recorded by using a 9F urethral catheter and the Valsalva maneuver to provoke stress urinary incontinence. The intravesical pressure was used to calculate the Valsalva leak point pressure at 300 mL bladder volume with gradually increased increments of intraabdominal pressure with the Valsalva maneuver until stress urinary incontinence was demonstrated.

Preoperative assessment included history and physical examination, urogynecologic clinical examination, and urodynamic evaluation including filling cystometry and pressure-flow studies and measurement of post-void residual urine.

Outcome Measures

Outcome measures included preoperative and 6-month postoperative scores on validated versions of the IIQ-7 (Incontinence Impact Questionnaire), UDI-6 (Urogenital Distress Inventory) [8], P-QOL (Prolapse Quality of Life Questionnaire (P-QOL) [9], and PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) [13], along with urodynamic findings.

The IIQ and UDI were developed and combined to assess the effect of urinary incontinence on QoL [14], and short versions of the IIQ and UDI composed of seven and six questions, respectively, with a high degree of correlation with the longer forms were developed [15]. The short forms, IIQ-7 and UDI-6 were developed in combination to measure the life effect of incontinence in women. The UDI-6 can be divided into 3 subscales to evaluate, respectively, irritative symptoms (urgency, frequency, and pain; questions 1 and 2), stress symptoms (questions 3 and 4), and obstructive or discomfort or voiding deficiency (questions 5 and 6).

The P-QOL questionnaire was first developed to measure the effect of urogenital prolapse on QoL in women. Question 1 describes the general health of the woman; question 2 assesses the effect of urogenital prolapse on QoL; questions 3 and 4 evaluate the limitations on normal daily activities caused by urogenital prolapse; and questions 5 through 8 assess the physical and social limitations caused by urogenital prolapse. Questions 9 through 11 assess the effect of uterovaginal prolapse on personal relationships. Questions 12 through 14 evaluate the effect of urogenital prolapse on emotional life. Questions 15 and 16 assess sleep and energy disturbances, and questions 17 through 20 assess symptom severity [16].

The PISQ is a condition-specific questionnaire that includes 31 questions in the behavioral/emotive, physical, and partner-related domains. It is the first validated, self-administered, condition-specific sexual questionnaire for women with urinary incontinence or pelvic organ prolapse [17]. The PISQ-12 is a validated short form of the questionnaire and contains 12 questions [18].

Beginning after postoperative month 12, patients were evaluated urodynamically and asked to answer the IIQ-7, UDI-6, P-QOL, and PISQ-12. The cotton swab test and measurements of post-void residual were performed. Preoperative and postoperative scores on the questionnaires were compared, and urodynamic findings were recorded.

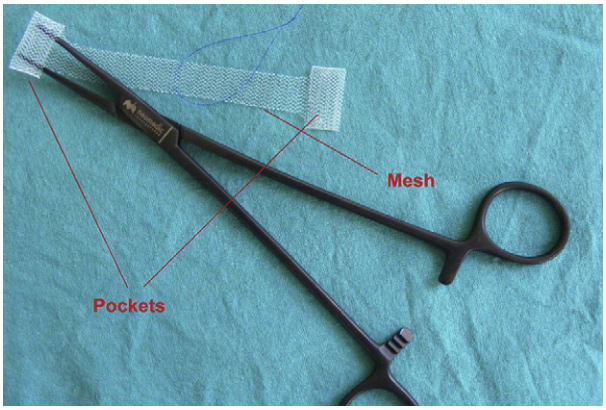
Operative Procedure

The ContaSure Needleless System (Neomedic International SL) is a macroporous, monofilament, knitted, polypropylene sling 14 cm long and 1.4 cm wide and includes the concept of pocket positioning and fixation that avoids passage of needles [7] (Fig. 1).

The procedure consisted of placing the system through a minimally invasive single vaginal incision, avoiding the

Fig. 1

Mesh and pockets.



passage of any needles through the abdomen or groin. The patient was placed in a dorsal lithotomy position. After administration of spinal anesthesia, a transverse 1.5- to 2-cm incision was made in the anterior vaginal wall. Through this incision, bilateral scissors dissections into the paraurethral spaces up to the ischiopubic ramus were made at 45-degree angles. A Kelly clamp was introduced in the "pocket system" at the edge of the mesh, and was introduced through the dissected spaces perforating the fascia of the internal obturator muscle. After perforation of the fascia of the internal obturator muscle, the Kelly clamp was opened and the end of the mesh left in place, and the clamp was withdrawn. No manipulation of the bladder was needed with use of the urethral route. The correct location of the mesh was confirmed, with the blue polypropylene string knotted in the middle of the mesh, and the tension was adjusted by pulling this string, which was left in situ, with the extension of its knotted ends through the closed vaginal incision for possible adjustment after the operation. No cystoscopy was performed. The patient was reevaluated the following day, and if no signs of outflow obstruction were observed, the strings were cut and removed.

Table 1

Preoperative characteristics in 50 patients who underwent needleless procedure

Variable	Mean (SD)	Variable	No. (%)
Age, yr	50.84 (8.1)	Menopause	27 (54)
BMI	28.32 (4.08)	COPD	5 (10)
Parity	3.44 (1.47)	Diabetes	5 (10)
Follow-up, day	433.5 (44.1)	Constipation	4 (8)
PFM strength[a]	2.96 (0.83)	Anterior prolapse[b]	30 (60)
VLPP, mm H_2O	146.38 (34.81)	Previous hysterectomy	3 (6)
Cotton swab test, degree	53.06 (13.96)	Previous cesarean section delivery	3 (6)

BMI = body mass index; COPD = chronic obstructive pulmonary disease; POP-Q = Pelvic Organ Prolapse Questionnaire.
[a] Oxford scale.
[b] POP-Q stage II or higher.

Statistical Analysis

Paired *t* tests and the Wilcoxon signed rank test were performed by using commercially available software (SPSS version 13.5; SPSS, Inc, Chicago, IL). All p values were 2-tailed. and p = .05 was considered significant.

Results

From October 2008 to March 2009, 50 consecutive patients with urodynamically proved stress urinary incontinence were included in the study. Patient characteristics are given in Table 1.

Thirteen women (26%) underwent concomitant operations. Vaginal hysterectomy was performed in 8 women. Anterior colporraphy was performed in 9 patients, and posterior colporraphy in 3 patients. McCall culdoplasty was added to 6 prolapse interventions, and 1 woman underwent the LeForte operation. After excluding the additional operations, mean operation time for needleless surgery was 24.4 minutes (6.17; 22.61–26.16). No intraoperative complications were recorded.

Five women (10%) women demonstrated post-void residual urine greater than 100 mL; however, this condition resolved in 4 patients on postoperative day 2 and in 1 patient on postoperative day 4. Patients who did not undergo additional procedures and demonstrated adequate post-void residual measurements were discharged within 24 hours postoperatively. The early postoperative course was uneventful; however, 4 women developed a urinary infection after postoperative day 15, which responded to antimicrobial therapy. Mesh exposure was observed in 3 patients (6%) in the first 8 weeks, which responded to primary mucosal repair. No mesh was removed. No de novo overactivity was observed.

Patients exhibited statistically significant improvement in preoperative and postoperative scores on the IIQ-7 and the irritative and stress subdomains of the UDI-6, P-QOL, and PISQ-12. The obstructive subdomain of the UDI-6 demonstrated a slight but significant elevation. Comparison of IIQ-7, subgroups of UDI-6, P-QOL, and PISQ-12 are given in Table 2. Preoperative and postoperative pressure-flow studies demonstrated that maximum flow rates decreased significantly; however, no difference was found between preoperative and postoperative mean flow and detrussor pressure at maximum flow rates (Table 3).

Postoperatively, 40 patients (80%) were urodynamically continent. Eight patients (16%) still had incontinence; however, their QoL scores (IIQ-7 and UDI-6 stress) were

Table 2

Comparison of preoperative and postoperative IIQ-7, UDI-6, P-QOL, and PISQ-12 Scores[a]

Questionnaire	Preoperative score	Postoperative score	p value
IIQ-7	11.35 (6.46)	3.09 (4.57)	<.001[b]
UDI-6			
Irritative	5.09 (1.58)	1.79 (1.81)	<.001[b]
Stress	5.09 (1.43)	1.49 (2.03)	<.001[b]
Obstructive	0.60 (1.33)	2.72 (2.12)	<.001[b]
P-QOL	46.82 (22.15)	17.88 (10.56)	<.001[b]
PISQ-12[c]	27.12 (6.62)	30.86 (5.65)	.007[b]

IIQ-7 = Incontinence Impact Questionnaire; P-QOL = Prolapse Quality of Life Questionnaire; PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire; UDI-6 = Urogenital Distress Inventory.
[a] Values are given as mean (SD).
[b] p <.05.
[c] Eleven patients had no sexual activity.

Table 3

Comparison of preoperative and postoperative parameters of pressure-flow studies[a]

Variable	Preoperative value	Postoperative value	p value
Q_{max}, mL/s	22.54 (7.14)	17.00 (7.54)	.000[b]
Q_{mean}, mL/s	8.52 (3.24)	8.63 (3.26)	.87[b]
P_{det} Q_{max}, mm H_2O	31.19 (27.66)	35.03 (16.04)	.54[b]

Q_{max} = maximum flow rate; Q_{mean} = mean flow rate; P_{det} Q_{max} = detrussor pressure at Q_{max}.
[a] Values are given as mean (SD).
[b] p <.05.

improved. Two patients (4%) continued to experience leakage, with equal or worsened QoL scores (Table 4).

Discussion

Urinary incontinence in women can have devastating psychological implications. It is embarrassing, threatens self-esteem, and may result in social isolation, adversely affecting QoL [19]. It has been proved that treatment options for incontinence are not able to provide a cure in all patients; however, a substantial number of women who could benefit from treatment are not aware of treatment methods, have irrelevant ideas about the intervention, or believe that no treatment will alleviate the condition [2]. These thoughts may further contribute to the decrease in QoL because failure to use treatment strategies or the lack of belief in the effectiveness of these strategies may result in depression. When individuals are exposed to uncontrollable events, they may believe they can do nothing to change the outcome of those events and may develop inappropriate expectations that outcomes of future events will also be beyond their control [20]. Offering less invasive treatment methods with low morbidity and high clinical efficacy to women who seek help for incontinence could negate their feeling of helplessness and increase the number of women who seek medical care.

Revolutionary changes have occurred in the last decade that introduce safe and effective minimally invasive techniques such as tension-free vaginal tape and transobturator tape procedures, but with complications including bladder injury and voiding dysfunction [21,22]. Although the transobturator sling seems to be a safer approach with fewer adverse effects than retropubic placement, postoperative groin or thigh pain has been reported, in particular with use of the "inside-to-out" transobturator approach [23]. Passage of the needle through the groin with exit closer to the obturator nerve is explained as the cause of the pain. To eliminate needle passages through the groin, single-incision slings without "turning around" any pubic bone and secondary incisions in the abdomen or groin have been developed [24,25].

The new ContaSure Needleless System uses the same positioning of the sling in a subfascial hammock-type position as the transobturator tape approach. It consists only of the mesh itself, and requires neither a needle nor a fixating tip. A unique pocket system at both ends eliminates the need to pass needles through the groin, obturator space, or medial adductor muscles. Consequently, the device results in less trauma than procedures that require turning around of the

Table 4

Comparison of preoperative and postoperative IIQ-7 and UDI-6 scores for patients with postoperative urodynamic stress incontinence[a]

Questionnaire	Preoperative score	Postoperative score	p value	Improved	Unchanged	Worsened
IIQ-7	13.22 (6.72)	6.55 (5.72)	.07	8	1	1
UDI-6						
Irritative	5.30 (1.06)	3.10 (1.60)	.02[b]	8	1	1
Stress	5.70 (0.67)	3.50 (2.01)	.03[b]	8	1	1
Obstructive	1.00 (2.07)	3.75 (1.58)	.02[b]	6	3	1

IIQ-7 = Incontinence Impact Questionnaire; UDI-6 = Urogenital Distress Inventory.
[a] Values are given as mean (SD).
[b] p <.05.

pelvic bones to eliminate the cause of groin pain. In the present study, no patient reported any postoperative groin pain attributable to the sling.

The 6% mesh exposure rate may seem extremely high for a sling procedure, especially when compared with other prolapse treatment procedures that use meshes. It should be noted that all of the 3 patients were asymptomatic for their exposure, which was less than 1 cm, and were diagnosed during routine postoperative examination within 8 weeks after the operation. Recently, a new classification of complications related to use of meshes has been released, and is based on category (C), time (T), and site (S), and divisions which create a CTS code for each complication involving 3 (or 4) letters and 3 numerals [26]. According to this classification, lesions in all 3 of our affected patients can be coded as C2/1A/T2/S1, indicating that vaginal epithelial separation is 1 cm or less, an asymptomatic lesion generally was diagnosed by the physician at any episode of clinical care, the clinical diagnosis was made less than 6 months after surgery, and the lesion is at the area of the suture line in the vagina. It has been argued that lesions falling in category 1A may be considered not real complications because the patient is not bothered by the potential problem. Therefore, the characteristics of the mesh exposure in our series may be interpreted as not so troublesome as is observed in other prolapse procedures using meshes.

Although in our series the follow-up was relatively short and the number of patients was limited, this single-incision procedure demonstrated promising data insofar as efficacy and effect on QoL. The improvement in the P-QOL score can be attributed to concomitant prolapse operations, which also demonstrate that this procedure can be combined with other interventions to treat pelvic floor disorders. Another important finding is that no patient reported any postoperative groin pain attributable to the sling.

Conclusion

The ContaSure Needleless System is a new minimally invasive single-incision sling for treatment of stress urinary incontinence in women. Early clinical results of the present trial show it to be a safe and effective minimally invasive procedure capable of substantially improving all aspects of QoL in women with incontinence. This minimally invasive technique performed using a single incision may introduce a new era in the treatment of stress urinary incontinence and should be encouraged after confirming its efficacy in larger prospective, randomized, comparative trials with other tension-free procedures and mini-sling systems.

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