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ORIGINAL ARTICLE

Effects of laser procedure for female urodynamic stress incontinence on pad weight, urodynamics, and sexual function

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Abstract
Introduction and hypothesis The impact of the IncontiLase™ procedure on lower urinary tract symptoms (LUTS) remains unclear. Our aim was to evaluate the effects of the IncontiLase™ procedure for urodynamic stress incontinence (USI).
Methods All consecutive women with USI prospectively underwent the IncontiLase™ procedure. Urodynamic studies, pad testing, LUTS, and sexual function questionnaires were assessed before and after treatment.
Results Thirty-five women underwent the IncontiLase™ procedure. Among the 28 women with baseline pad weights >1 g, 11 (39.3 %) were objectively cured and 11 (39.3 %) improved. Among the 18 women with mild USI (i.e., baseline pad weight 1–10 g), nine (50 %) were cured and five (27.8 %) improved. Among ten women with baseline pad weight >10 g, two (20 %) were cured and six (60 %) improved. Among the 32 women with complete questionnaire data at 6 months, seven (21.9 %) were subjectively cured, and four (12.5 %) improved. Regarding LUTS, the majority of domains on the King's Health Questionnaire and female sexual desire and function exhibited significant improvements. Forty percent (12/30) of the partners of these patients felt their sexual function had improved at 6 months. Nonetheless, urodynamic values did not differ across the timeline.
Conclusions The effect of the IncontiLase™ procedure for mild USI was moderate at 6-month follow-up but was not effective for pad weight >10 g. Moreover, it improved LUTS, quality of life, QoL, and sexual function of both partners. Further studies should be performed to assess long-term sustained efficacy.

Keywords Laser therapy · Sexual dysfunction · Physiological · Urinary incontinence · Stress · Urodynamics

Introduction

For women with stress urinary incontinence (SUI), initial nonsurgical management includes behavioral therapy, pelvic floor muscle exercises, and continence pessary. Pelvic floor muscle training combined with bladder training has been reported to be more effective for SUI than bladder training alone; however, only 50 % of patients have reported being cured by this combination therapy [1]. Continence pessaries combined with behavior therapy have been reported to be more effective than pessaries alone; however, only 53 % of patients feel "much better" or "very much better" by the combination therapy [2]. Thus, a significant percentage of patients need other nonsurgical treatment. The heat of laser treatment may induce collagen denaturation, shorten collagen along the longitudinal axis, and result in subsequent collagen remodelling and collagen neogenesis [3]. The treated tissue may then become enriched with new collagen, making it tighter and more elastic days later [4]. Radiofrequency ablation has been used to treat with SUI and can be classified into the following routes: laparoscopic, transurethral, or transvaginal [5–11]. Fulmer et al. used laparoscopic radiofrequency ablation

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to shrink the endopelvic fascia of the bladder neck and urethra of women with urethral hypermobility, and urodynamic evaluation at 12 months showed no urine leakage during the Valsalva maneuver in 78 % of cases [5]. Transurethral radiofrequency collagen denaturation was reported to achieve a 50 % or greater reduction in the severity of SUI in 46.7–72 % of women at 12–36 months' follow-up [6–8]. Nonetheless, 2015 Cochrane database review reported that evidence is insufficient to show whether transurethral radiofrequency collagen denaturation improves disease-specific quality of life (QoL) [9]. After vaginal incision and dissection to expose the endopelvic fascia, transvaginal radiofrequency remodelling of endopelvic fascia was reported to have a cure rate of 45.8–76.0 % [10, 11].

One of the minimally invasive laser techniques that enable collagen remodelling is known as the IncontiLase™ procedure [4, 12]. Fistonic et al. reported that the procedure effectively improved SUI symptoms [4]; however, the assessment tools used by these authors were limited to the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form and the Q-tip test [4]. We sought to evaluate the therapeutic effect with comprehensive assessment tools. Thus, the main purpose of this study was to evaluate the effect of the IncontiLase™ procedure on female urodynamic stress incontinence (USI) as assessed with pad weights and urodynamic values. The secondary purpose was to evaluate the effect of the procedure on lower urinary tract symptoms (LUTS) and sexual function for both partners, as tested by validated questionnaires.

Materials and methods

All consecutive sexually active women with a diagnosis of USI were enrolled at the obstetrics and gynecology department of a medical center from May 2014 to January 2015. Women who had never been sexually active and those with undiagnosed abnormal vaginal bleeding were excluded. The research ethics committee of the hospital approved this study, which had been registered at ClinicalTrials.gov with an identifier of NCT02130375. Written informed consent was obtained from each participant. Patients were evaluated before treatment (visit 1) and re-examined at 3 months (visit 2) and 6 months (visit 3) postoperatively. All three visits included a clinical examination, a 3-day bladder dairy, a urodynamic study, a 20-min pad test [13], and an interview regarding LUTS, sexual function, and adverse effects.

Urodynamic studies were performed with a Life-Tech six-channel monitor with computer analysis and Urolab/Urovision System V (Houston, TX, USA), with patients in a seated position. The studies included uroflowmetry, both filling (at a rate of 60 ml/min) and voiding cystometry with infusion of 35 °C distilled water, and stress urethral pressure profiles with distilled water in the bladder. The pad test was performed after the stress urethral pressure profiles study. We adopted the method provided by Sand [13]. Each patient returned to a standing position with a preweighed perineal pad placed inside the underwear. Each patient was asked to cough ten times, bear down ten times, perform ten deep knee bends, jump up and down in place ten times, wash her hands under cold water for 1 min, walk up and down five stairs ten times, walk in the hall for 10 min, then return for pad removal. The pad was weighed, and net weight was calculated by subtracting the original dry weight to achieve a measure of the total urine lost during the 20-min exercise. A positive pad weight result was defined as >1-g leakage [13]. USI was diagnosed as involuntary leakage of urine during filling cystometry associated with increased intra-abdominal pressure in the absence of a detrusor contraction [14].

The Chinese versions of the Patient Perception of Bladder Condition (PPBC) [15], Urgency Severity Scale (USS) questionnaire [16], Overactive Bladder Symptom Score (OABSS) questionnaire [17], Urogenital Distress Inventory-6 (UDI-6) [18], Incontinence Impact Questionnaire-7 (IIQ-7) [18], King's Health Questionnaire (KHQ) [19], Female Sexual Function Index (FSFI) [20], and a modified Male Sexual Activity questionnaire [21] were used to assess LUTS, health-related QoL, and the patients' and their partners' sexual function. Higher FSFI scores represented greater positive effects on sexual function. The modified Male Sexual Activity questionnaire [21] included the following questions:

(1) How would you describe having sexual intercourse after the treatment (better than before; worse than before, or no difference)?
(2) Did you experience vaginal narrowing during intercourse?
(3) Did you experience vaginal dryness during intercourse?
(4) Did you experience pain during sexual intercourse?

Treatment procedure

Every patient received with one treatment by a Fotona Dynamis Er:YAG laser (2940 nm) system (XS Dynamis, Fotona, Slovenia). The nonablative thermal SMOOTH mode, two Er:YAG collimated handpieces (R11 full-field and PS03 pixelated beams), and three handpiece adaptors (circular, straight, and angular) were used [4, 12]. The patient was placed in the lithotomy position, and the vaginal canal and perineum were disinfected and dried. Topical anesthesia with 2 % lidocaine jelly was applied to the vestibule and introitus area before treatment. A specially designed laser speculum was inserted into the s vagina as a guide for the laser delivery adaptors. The procedure consisted of three phases. In the first phase, the R11 full-field handpiece with a circular adaptor was used to irradiate the full circumference of the vaginal canal. Three passes were executed. In the second phase, the PS03

handpiece with an angular adaptor was used to irradiate the anterior vaginal wall. Five passes were executed. The speculum was removed. In the third phase, a pixelated, nonablative SMOOTH-mode laser irradiation with the PS03 handpiece with a straight adaptor was delivered to the mucosa of the vestibule and the introitus in three passes. At the time of writing, the National Health Insurance in Taiwan did not cover the cost of this procedure (~US $800 per procedure). Nonetheless, patient expenses were waived. Results were classified as either objective or subjective. An objective cure was defined by pad weight ≤1 g after the 20-min pad test at 6 months after treatment, and improvement was indicated by a >50 % decrease in pad weight at 6 months compared with preoperative data. Objective failure was defined by a ≤50 % decrease in pad weight relative to preoperative data at the 6-month follow-up [22]. A subjective SUI cure following surgery was indicated by a score of zero on the third question of the UDI-6: subjective improvement was characterized by an improvement in the score for the third question on the UDI-6.

One of the main hypotheses of this study was that baseline pad weights would be different from postoperative pad weights. Data gathered from the first 15 women with complete 3-month follow-up data were used to estimate the sample size. Mean difference between baseline and the 3-month pad weight was 9.2 g [standard deviation (SD) 15.7 g]. Calculation with a significance level of 0.05 and a power of 0.9 suggested that at least 31 individuals were required to test the null hypothesis.

The Skillings–Mack test, Wilcoxon signed-rank test, and McNemar's test were used for statistical analyses, as appropriate. The Skillings–Mack test is used for comparison of three or more groups of paired samples with ordinal or continuous data. The Wilcoxon signed-rank test is a nonparametric test for comparison of two groups of paired samples. The McNemar's test is used for comparison of paired samples with nominal data. STATA software (Version 11.0; Stata Corp, College Station, TX, USA) was used for statistical analyses. *P* values <0.05 were considered statistically significant.

Results

Thirty-five women, including 14 with concomitant overactive bladder syndrome (OAB) underwent treatment. Mean age was 43.3 ± 7.2 years; mean baseline pad weight was 14.0 ± 18.2 g (Table 1). Three women were lost to follow-up at the 3-month visit, and one woman did not receive an urodynamic study at her 6-month visit (Table 1 and Fig. 1). Significant improvements in the pad weights were noted in the follow-up visits ($P < 0.001$, Table 1 and Fig. 2a).

Twenty-eight women with baseline pad weights >1 g with complete 6-month follow-up data were evaluated for objective treatment efficacy. The objective cure and improvement rates were both 39.3 % (11/28). Objective success rate (cure and improvement rate) was 78.6 % (22/28, Table 2). However, urodynamic values did not differ along the timeline (Table 1).

Table 1 Baseline characteristics of women with urodynamic stress incontinence (USI) and comparisons of clinical outcomes, pad weights, and urodynamic effects between baseline and posttreatment time points

Variables	Baseline ($n = 35$)[a]	3 months after treatment ($n = 32$)[b]	6 months after treatment ($n = 32$)[c]	*P* value*	Post hoc analysis**
Age (years)	43.3 ± 7.2	–	–		
Parity	1.8 ± 1.2	–	–		
Body mass index (kg/m^2)	24.0 ± 3.2	–	–		
Menopause	7 (20)	6 (18.8)	6 (18.8)		
Pad weight (g)	14.0 ± 18.2	6.1 ± 13.1	3.1 ± 5.6	<0.001	a vs. b, c: all *P* <0.001
Q_{max} (ml/s)	23.9 ± 7.6	24.6 ± 9.1	23.4 ± 8.0	0.92	
Voided volume (ml)	334.6 ± 156.2	291.8 ± 111.0	312.5 ± 196.3	0.95	
PVR (ml)	25.2 ± 7.7	25.0 ± 8.6	23.6 ± 9.4	0.20	
Strong desire (ml)	267.0 ± 50.4	278.9 ± 52.7	278.9 ± 55.6	0.74	
P_{det} Q_{max} (cm H_2O)	31.6 ± 11.3	38.1 ± 13.1	31.0 ± 19.1	0.39	
MUCP (cm H_2O)	74.0 ± 24.8	66.1 ± 20.5	67.8 ± 29.9	0.50	
FPL (cm)	2.9 ± 0.6	3.0 ± 1.2	3.2 ± 1.3	0.52	
PTR at MUP (%)	126.5 ± 92.1	113.5 ± 62.0	104.9 ± 44.8	0.79	

Values expressed as mean ± standard deviation or number (%)

FPL functional profile length, *MUCP* maximum urethral closure pressure, Q_{max} maximum flow rate, P_{det} Q_{max} detrusor pressure at maximum flow rate, *PTR* pressure transmission ratio, *MUP* maximum urethral pressure, *PVR* non-post-void residual volume

*Mack test

**Wilcoxon signed-rank test

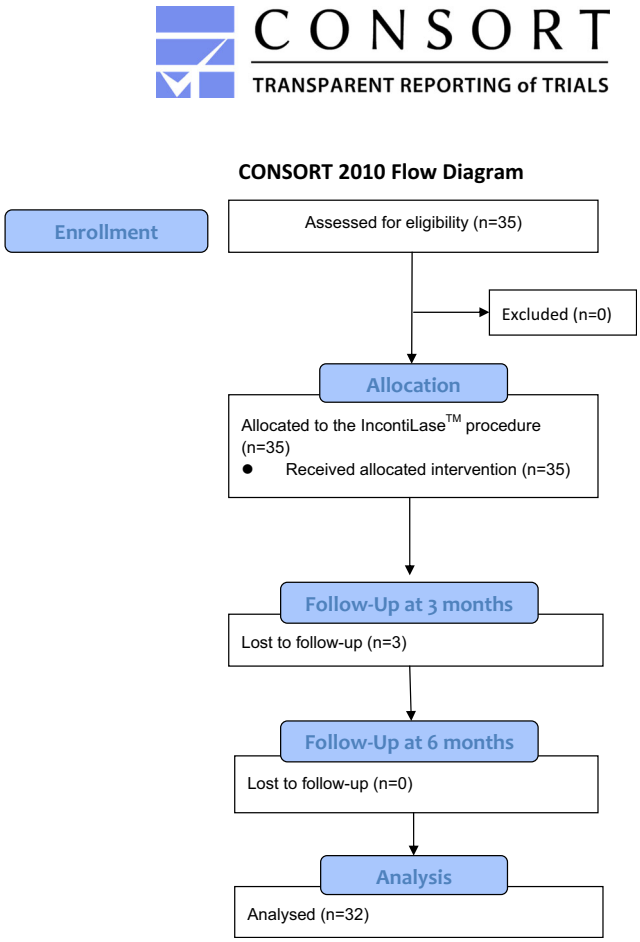

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram for study participants

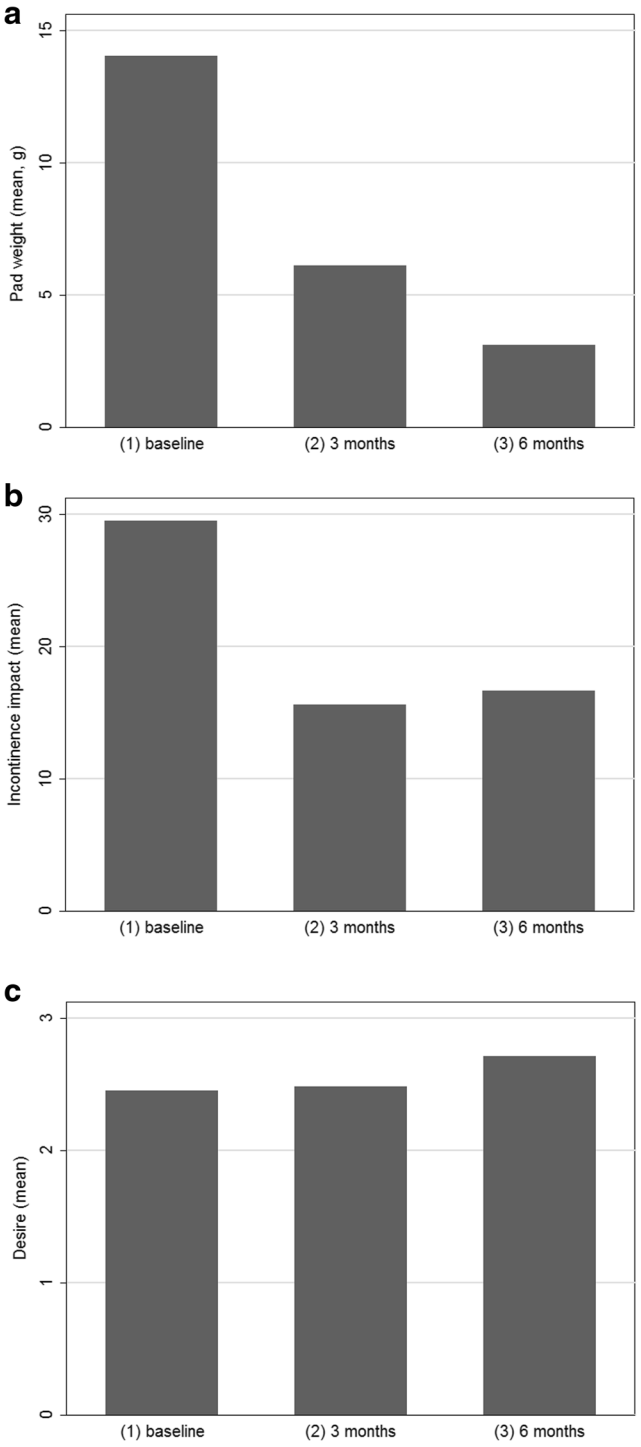

Fig. 2 **a** Pad weights, **b** incontinence impact scores form the King's Health Questionnaire, **c** sexual desire scores from the Female Sexual Function Index (FSFI) at baseline and 3 and 6 months after therapy

Among women with mild USI at baseline (i.e., baseline pad weights 1–10 g, $n = 18$), nine (50 %) were cured, and five (27.8 %) exhibited improvement at 6 months (Table 2). Among the other ten women who had moderate or severe USI at baseline (i.e., baseline pad weights ≥10 g), only two (20 %) were cured; six (60 %) exhibited improvement at 6 months (Table 2). Thirty-two women with UDI-6 data at 6 months were evaluated for subjective treatment efficacy. Subjective cure rate was 21.9 % (7/32), and subjective improvement rate was 12.5 % (4/32). Subjective success rate (cure and improvement rates) was 34.4 % (11/32). Clinical subjective outcomes from the PPBC, USS, OABSS, UDI-6, IIQ-7, and the majority of variables of the KHQ (including the general health perceptions, incontinence impact, role limitations, physical limitations, emotions, sleep/energy and severity measures) and bladder dairies (including nocturia episodes, daytime frequency episodes, and incontinence episodes) revealed improvements (Table 3 and Fig. 2b).

The desire domain of FSFI exhibited a significant improvement at visit 3 (Table 4 and Fig. 2c); the other domains did not. Sexual activity improved for 53.3 % of male partners (16/30) at visit 2 and 40 % (12/30) at visit 3 (Table 4).

There were no adverse events during treatment or follow-up periods.

Table 2 Clinical outcomes at 6 months after treatment based on changes in pad weights

Variables	6 months after treatment [*n* (%)]
Baseline pad weight >1 g (*n* = 28)	
Cure	11 (39.3)
Improvement	11 (39.3)
Failure	6 (21.4)
Baseline pad weight 1–10 g (*n* = 18)	
Cure	9 (50)
Improvement	5 (27.8)
Failure	4 (22.2)
Baseline pad weight ≥10 g (*n* = 10)	
Cure	2 (20)
Improvement	6 (60)
Failure	2 (20)

Cure = < 1 g pad weight at 6 months; improvement = >50 % pad weight reduction from baseline at 6 months; failure = ≤50 % pad weight reduction from baseline at 6 months

Discussion

Pad weight, LUTS, health-related QoL, and sexual function of both partners improved following laser treatment (Tables 1, 3, and 4). The pad weight test was used to quantify the amount of urine lost over the duration of testing [13, 14]; thus, our results revealed that SUI improved after laser treatment. Although there were no differences in urodynamic values between baseline and post-treatment time points, the possibly tighter and more elastic collagen may have acted as an effective hammock, preventing urine leakage [23] and reducing pad weights. Fistonic et al. reported decreases in scores on the Incontinence Questionnaire-Urinary Incontinence Short Form scores and Q-tip angles following IncontiLase™ treatment [4]. The findings obtained through our objective assessment methods (e.g., the pad test and the bladder diary) should make the finding that pad weight improved after laser treatment reliable.

Most domains on the KHQ improved after laser treatment (Table 3), which is used to measure health-related QoL. Thus, our findings indicate that laser treatment may improve health-

Table 3 Comparison of subjective outcomes and bladder diaries of women with urodynamic stress incontinence (USI) between baseline and posttreatment time points

Variables	Baseline (*n* = 35)[a]	3 months after treatment (*n* = 32)[b])	6 months after treatment (*n* = 32)[c]	*P* value*	Post hoc analysis**
PPBC	2.7 ± 1.0	2.0 ± 1.2	2.0 ± 1.1	0.01	a vs. b, c: all $P < 0.001$
USS	1.3 ± 0.8	0.6 ± 0.8	0.8 ± 0.7	0.004	a vs. b, c: all $P < 0.01$
OABSS	4.1 ± 2.8	3.1 ± 2.9	2.7 ± 2.6	<0.001	a vs. b, c: all $P < 0.001$
UDI-6	4.1 ± 2.9	2.8 ± 3.0	3.1 ± 3.1	0.001	a vs. b, c: all $P < 0.001$
IIQ-7	3.2 ± 4.2	2.2 ± 4.2	2.7 ± 4.9	0.02	a vs. b, c: all $P < 0.05$
General health perceptions	36 ± 20	30 ± 20	30 ± 24	0.046	a vs. b: $P = 0.03$
Incontinence impact	30 ± 30	16 ± 24	17 ± 25	<0.001	a vs. b, c: all $P < 0.01$
Role limitations	25 ± 24	11 ± 23	13 ± 26	<0.001	a vs. b, c: all $P < 0.01$
Physical limitations	27 ± 26	14 ± 23	12 ± 22	<0.001	a vs. b, c: all $P < 0.01$
Social limitations	12 ± 17	9 ± 21	11 ± 21	0.56	
Personal relationships	11 ± 24	10 ± 25	14 ± 28	0.29	
Emotions	23 ± 25	14 ± 25	16 ± 25	0.002	a vs. b, c: all $P < 0.05$
Sleep/energy	29 ± 22	22 ± 22	20 ± 24	0.03	a vs. c: $P = 0.02$
Severity measures	30 ± 18	20 ± 24	20 ± 24	<0.001	a vs. b, c: all $P < 0.01$
Nocturia episodes (72 h)	2.9 ± 4.8	1.4 ± 1.8	1.8 ± 2.5	0.006	a vs. b, c: all $P < 0.05$
Daytime frequency episodes (72 h)	21.8 ± 9.1	19.8 ± 6.7	19.7 ± 7.0	0.03	a vs. b, c: all $P < 0.05$
Urgency episodes (72 h)	4.1 ± 6.3	2.8 ± 5.1	1.9 ± 3.4	0.06	
Incontinence episodes (72 h)	1.3 ± 4.6	0.0 ± 0.2	0.1 ± 0.4	0.001	a vs. b, c: all $P < 0.05$

Values are expressed as mean ± standard deviation or numbers

IIQ-7 Incontinence Impact Questionnaire-7, *OABSS* Overactive Bladder Symptoms Score Questionnaire, *PPBC* Patient Perception of Bladder Condition Questionnaire, *UDI-6* Urinary Distress Inventory-6 Questionnaire, *USS* Urgency Severity Scale Questionnaire

*Skillings–Mack test

**Wilcoxon signed-rank test

Table 4 Comparisons of sexual functions of women with urodynamic stress incontinence (USI) between baseline and post-treatment time points

Variables	Baseline ($n = 35$)[a]	3 months after treatment ($n = 32$)[b]	6 months after treatment ($n = 32$)[c]	*P* value	Post hoc analysis
Desire	2.5 ± 0.7	2.5 ± 0.9	2.7 ± 1.0	0.03	a vs. c, P = 0.02; b vs. c, *P* = 0.04
Arousal	3.0 ± 1.2	3.0 ± 1.3	3.0 ± 1.4	0.64	
Lubrication	3.3 ± 1.4	3.6 ± 1.4	3.4 ± 1.4	0.56	
Orgasm	3.3 ± 1.4	3.6 ± 1.3	3.6 ± 1.4	0.28	
Satisfaction	3.7 ± 1.0	3.8 ± 1.2	3.9 ± 1.2	0.11	
Pain	3.6 ± 1.4	3.7 ± 1.5	3.8 ± 1.6	0.13	
FSFI total score	19.4 ± 6.3	20.2 ± 6.8	20.5 ± 7.3	0.052	
Male sexual activity	($n = 35$)	($n = 30$)	($n = 30$)		
Better than before		16	12		
No difference		14	18		
Worse than before		0	0		
Vaginal narrowing during intercourse	7	10	11	a vs. b: *P* = 0.37 a vs. c: *P* = 0.32	
Vaginal dryness during intercourse	13	6	5	a vs. b: *P* = 0.052 a vs. c: *P* = 0.02	
Pain during intercourse	4	4	2	a vs. b: *P* = 1.00 a vs. c: *P* = 0.32	

Values are expressed as mean ± standard deviation or numbers

FSFI Female Sexual Function Index questionnaire

*Skillings–Mack or McNemar's test

related QoL of SUI women. Improvements in the incontinence QoL score following transurethral radiofrequency remodelling have been reported [7, 8]. Nonetheless, their Cochrane database review, Kang et al. reported that there is insufficient evidence that transurethral radiofrequency collagen denaturation can improve disease-specific QoL [9].

A positive effect on OAB was also found in this study, as evidenced by the improvements in USS, OABSS, nocturia episodes, and daytime frequency episodes (Table 3). The majority of women with stress-predominant mixed urinary incontinence (MUI) experience significant improvement in OAB symptoms following incontinence surgery [24]. We also found that changes in daytime frequency episodes were well correlated with changes in incontinence episodes (Spearman correlation test, rho = 0.64, $P = 0.0001$). These findings may be at least partly related to SUI improvements following laser treatment. The desire domain of female sexual function and male sexual activity improved following the IncontiLase™ treatment (Table 4). Gaspar et al. described another minimally invasive laser therapy for vaginal rejuvenation treatment performed with a fractional ablative CO_2 laser, and beneficial effects were found in the three layers of the vaginal tissue and in sexual function [25]. Additionally, anti-incontinence surgeries can improve female patients' sexual function and even improve their partners' sexual function [21, 26]. The abovementioned findings may partially explain our findings regarding improvement of sexual function following laser treatment. It is worth noting that the change in desire score was small (Table 4) and may not have clinical significance. In addition, male sexual activity improved in only 40 % of male partners at 6 months, and female arousal, lubrication, orgasm, satisfaction, and pain were not improved to a level that is either clinically relevant or statistically significant (Table 4).

Notably, subjective and objective improvements in SUI symptoms were not as extensive as those that follow midurethral sling surgeries [22], especially in moderate and severe cases. Midurethral sling (MUS) surgery, which has a long-term subjective cure rate of 77–85 % [27, 28], remains one of the first-line surgeries for SUI. Thus, the IncontiLase™ procedure should not replace MUS surgery as standard therapy for SUI patients who fail to improve following first-line therapy. In addition, the injection of bulking agents has been reported to have a cure rate of 53–73.2 % [29, 30], which is better than the cure rate of the IncontiLase™ procedure (Table 2). Thus, the IncontiLase™ procedure should not replace the injection of bulking agents as the sole minimally invasive procedure for SUI.

The strength of this prospective study is that objective and subjective measurements were used to evaluate therapeutic efficacy. Nonetheless, this study is limited by a short-term

follow-up period, lack of a control group, and the small sample size. However, serial comprehensive follow-up assessments should make our results reliable.

Conclusions

The effect of the IncontiLase™ procedure for mild USI was moderate at the 6-month follow-up, but the procedure was not effective for pad weight >10 g. Moreover, LUTS, health-related QoL, and sexual functions were significantly improved following treatment. Based on its minimally invasive nature and the lack of significant adverse effects, the IncontiLase™ procedure may be used as an alternative therapy for mild USI cases. Nonetheless, results from only 6 months of follow-up results were obtained; therefore, further studies should be performed to assess long-term sustained efficacy and negative effects of the IncontiLase™ procedure.

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Compliance with ethical standards

Conflicts of interest This study was partially funded by Dynamic Medical Technologies Inc., Taipei, Taiwan. However, the company was not involved in the study design, data collection, or manuscript preparation.

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