

Predictors of Clinical Response to Fractional CO₂ Laser Therapy in Women with Mild-to-Moderate Stress Urinary Incontinence: A Two-Center Pilot Study

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ABSTRACT

Background. Stress urinary incontinence (SUI) is a common urogynecological condition with a substantial impact on quality of life. Fractional CO₂ laser therapy has emerged as a minimally invasive treatment for mild-to-moderate SUI; however, data on predictors of treatment response remain limited. This study aimed to assess clinical, questionnaire-based, and ultrasound parameters associated with outcomes following CO₂ laser therapy.

Material and methods. This prospective two-centre study included 31 women aged 33–66 years with grade 1–2 SUI. Participants completed validated questionnaires, including the Urogenital Distress Inventory (UDI-6), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), and visual analogue scales (VAS) for urogynecological symptoms. Pelvic floor ultrasound evaluated urethral length, resting position, and mobility during voluntary contraction and Valsalva. All patients underwent three sessions of fractional CO₂ vaginal laser therapy at 28–30-day intervals. Statistical analysis was performed using SigmaPlot 11.0, with $p < 0.05$ considered significant.

Results. CO₂ laser therapy resulted in significant improvement in VAS-assessed symptoms, including vaginal atrophy, dryness, itching, dyspareunia, and SUI severity. Total UDI-6 scores decreased significantly after treatment. Ultrasound assessment showed a significant reduction in urethral descent during Valsalva. Baseline urethral mobility during voluntary contraction emerged as a potential predictor of therapeutic response. Improvement in sexual function was observed but did not reach statistical significance.

Conclusions. Fractional CO₂ laser therapy appears to be an effective minimally invasive option for women with mild-to-moderate SUI and vulvovaginal atrophy. Pretreatment urethral functional parameters may help identify patients most likely to benefit. Further large-scale randomized studies are needed to confirm these findings.

Introduction

Stress urinary incontinence (SUI) is a common urogynecological disorder affecting approximately 40% of women worldwide [1]. Numerous studies have demonstrated that SUI significantly impairs quality of life in women of all ages. Beyond its impact on physical activity, SUI often negatively affects social interactions and sexual functioning [2,3]. Previous research has shown reduced sexual satisfaction and intimacy among women with SUI, as reflected by lower scores on the Female Sexual Function Index (FSFI) [3–6].

The aetiology of SUI is multifactorial and primarily involves damage or weakness of the pelvic floor muscles. Major risk factors include vaginal delivery, pregnancy, high birth weight, obesity, and smoking. Hormonal changes, particularly estrogen deficiency, also play a significant role by contributing to reduced collagen quality and vaginal tissue atrophy, thereby impairing pelvic support mechanisms.

Pelvic floor muscle training remains the first-line treatment for women with SUI across all age groups and aims to restore pelvic floor strength and function. Electrostimulation is also commonly used as an adjunctive conservative therapy. In cases of moderate to severe SUI, additional treatment options include pessary use, pharmacotherapy, and surgical interventions. In recent years, minimally invasive modalities have gained increasing attention, particularly within the expanding field of aesthetic gynaecology.

Since 2012, several studies have reported promising outcomes of laser-based therapies for the management of SUI, particularly using the erbium-doped yttrium aluminium garnet (Er:YAG) laser [7,8]. Other thermal energy-based modalities, such as carbon dioxide (CO₂) laser therapy and radiofrequency ablation (RFA), have also been introduced. The proposed mechanism of action involves controlled thermal stimulation of vaginal tissue, leading to collagen fibre contraction, neocollagenesis, improved tissue elasticity, and neovascularisation [9,10]. Enhanced periurethral vascularisation is believed to play a key role in increasing urethral closure pressure and improving continence mechanisms [11].

Despite growing clinical interest, evidence regarding the long-term efficacy and safety of thermal energy-based treatments for SUI remains

limited. In 2018, the U.S. Food and Drug Administration (FDA) issued a statement highlighting the lack of sufficient high-quality data supporting the effectiveness of vaginal laser therapies for urinary incontinence [12]. Therefore, further well-designed clinical studies are needed to clarify their role in SUI management.

The present study aimed to evaluate SUI symptoms, sexual satisfaction, and changes in urethral mobility following vaginal CO₂ laser treatment. These findings are preliminary and intended to contribute to the ongoing discussion on the clinical utility of thermal energy-based therapies in SUI.

Materials and methods

Study design and participants

A retrospective, two-centre analysis of medical records was conducted involving 31 women aged 33–66 years who underwent treatment between January 2024 and September 2025. Inclusion criteria comprised stress urinary incontinence (SUI) grade 1 or 2 according to the Stamey classification, with or without concomitant cystocele up to pelvic organ prolapse quantification (POP-Q) stage 1.

All patients had provided written informed consent to undergo the laser treatment. According to the decision of the local Bioethics Committee, the study was classified as a retrospective analysis of medical records, was non-experimental, and did not require formal ethical approval (decision no. 385/24).

Clinical assessment

Validated questionnaires were used to assess urinary and sexual symptoms, including the Urogenital Distress Inventory short form (UDI-6) and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Symptom severity related to SUI, vaginal dryness, atrophy, dyspareunia, and vaginal itching was additionally evaluated using a visual analogue scale (VAS). Complete remission was defined as no reported urine leakage (VAS scoring = 0); partial remission was defined as any improvement in UDI-6 scoring and subjective VAS score simultaneously.

Pelvic floor ultrasound examinations (PFS-TV) were performed using introital ultrasound by two operators trained in pelvic floor sonogra-

phy. All assessments were conducted according to a standardised (PFS) protocol described by Kociszewski et al., with patients examined in the same position and using identical measurement landmarks at both study centres [3–5]. Urethral position and mobility were assessed at rest, during voluntary pelvic floor muscle contraction, and during the Valsalva manoeuvre. Due to the multicenter design, two different ultrasound systems were used (Voluson S8 and Voluson S7, GE Healthcare, Zipf, Austria). However, the examination protocol and measurement methodology were standardised across centres.

Intervention

All patients underwent a series of three vaginal laser treatments performed at intervals of 28–30 days. Carbon dioxide (CO₂) laser treatment was applied along the entire length of the vaginal canal. Follow-up evaluation was performed 4 weeks after completion of the third treatment session.

The study was carried out at two clinical centres. At the Milbrandt Institute, treatments were performed using the Bioxel CO₂ laser system (Metrum Cryoflex, Poland). At the Złotowska Plastic Surgery Clinic, the Finixel Evero CO₂ laser system (SNJ Medical, South Korea) was used. Identical treatment protocols, technical parameters, and application techniques were applied at both centres. Laser settings included a total energy of 90–100 mJ per pulse, an energy density of 17, a treatment area of 5 × 5 mm, and a two-step application protocol.

Statistical analysis

Statistical analysis was performed using SigmaPlot version 11.0 (Systat Software, USA). Data distribution was assessed using the Shapiro–Wilk test. As most variables did not follow a normal distribution, non-parametric tests were primarily applied. For paired comparisons (before vs after treatment), the Wilcoxon signed-rank test was used (VAS, UDI-6, PISQ-12). For normally distributed ultrasound parameters, the paired Student's t-test was applied. Between-group comparisons (complete remission, partial remission, no improvement) were performed using one-way ANOVA or Kruskal–Wallis test, as appropriate, followed by post hoc Holm–Šidák correction. Due to multiple comparisons across questionnaire domains and ultrasound variables, a cautious

interpretation of p-values was adopted. Formal corrections for multiple testing were not applied systematically due to the exploratory nature of the study; however, relevant post hoc corrections (Holm–Šidák) were used where appropriate. Effect sizes were calculated using Cohen's d to assess clinical relevance. Additionally, 95% confidence intervals (95% CI) for mean differences were calculated to improve interpretation of treatment effects. Predictive analysis was exploratory. Variables potentially associated with treatment response were initially assessed using univariate comparisons (ANOVA or Mann–Whitney U test). Due to the limited sample size, multivariate regression analysis was not performed. Therefore, the results should be interpreted as hypothesis-generating. Potential confounding variables (e.g., age, BMI, parity) were evaluated descriptively but not formally controlled in a multivariate model. A p-value < 0.05 was considered statistically significant.

Results

Changes in subjective symptoms assessed by VAS

Visual analogue scale (VAS) assessment demonstrated a significant reduction in multiple urogynecological symptoms following laser therapy. Statistically significant improvements were observed in symptoms of vaginal atrophy (p = 0.031), vaginal laxity ("loose vagina") (p = 0.002), vaginal itching (p = 0.031), vaginal dryness (p = 0.016), dyspareunia (p = 0.039), and SUI severity (p < 0.001) (**Table 1**).

UDI-6 questionnaire outcomes

Results of the UDI-6 questionnaire revealed a significant reduction in the total score after treatment compared with baseline (p < 0.001). Significant improvements were observed for items 1, 3, and 4 (frequent urination, stress urinary leakage, and small-volume urinary leakage, respectively; all p < 0.001) (**Table 2**).

Sexual function assessment

Analysis of the PISQ-12 questionnaire showed a non-significant increase in mean total scores following laser therapy (36.1 ± 6.1 vs. 37.9 ± 4.4; p = 0.13) (**Figure 1**).

Table 1. Urogynecological symptoms were assessed using a visual analogue scale (VAS) before and after fractional CO₂ laser therapy (n = 31). Values are presented as mean ± SD. Statistical significance was assessed using the Wilcoxon signed-rank test.

Disorder assessed on a VAS scale	Before laser therapy (n = 31)	After laser therapy (n = 31)	p (Wilcoxon test)
Symptoms of vaginal atrophy	17.8 ± 30.1	9.7 ± 21.4	0.031
„Loose vagina”	24.2 ± 31.3	9.4 ± 19.6	0.002
Itching	15.1 ± 31.5	4.7 ± 16.5	0.031
Dryness	21.3 ± 31.7	7.8 ± 23.5	0.016
Dyspareunia	15.2 ± 30.6	4.5 ± 10.3	0.039
SUI	50.9 ± 28.6	22.2 ± 22.1	<0.001

VAS – visual analogue scale; SUI – stress urinary incontinence

Table 2. Changes in Urogenital Distress Inventory-6 (UDI-6) scores before and after fractional CO₂ laser therapy in women with mild-to-moderate stress urinary incontinence (n = 31). Data are presented as mean ± standard deviation (SD). Statistical significance was assessed using the Wilcoxon signed-rank test

UDI-6 questionnaire	Before laser therapy (n = 31)	After laser therapy (n = 31)	p (Wilcoxon test)
Summary	34.6 ± 21.9	15.1 ± 17.1	<0.001
1	1.2 ± 1.2	0.4 ± 0.7	<0.001
2	1.1 ± 1.2	0.7 ± 1.2	0.67
3	1.9 ± 1.2	0.9 ± 1.3	<0.001
4	1.4 ± 1.4	0.2 ± 0.6	<0.001
5	0.2 ± 0.7	0.1 ± 0.5	1.000
6	0.9 ± 0.9	0.2 ± 0.8	0.625

UDI-6 – Urogenital Distress Inventory-6. Items 1–6 correspond to individual questionnaire questions. Higher scores indicate greater symptom severity

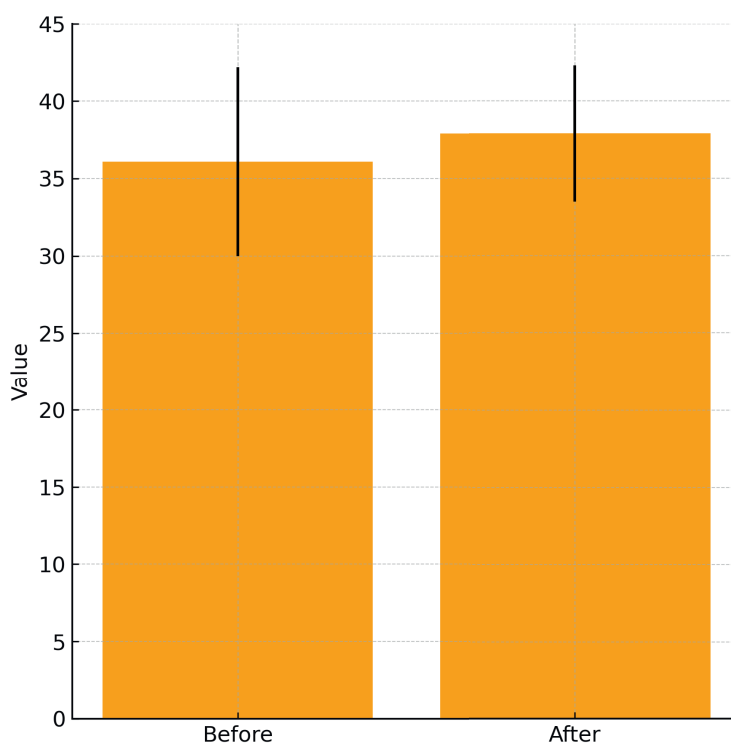


Figure 1. PISQ-12 scores before and after fractional CO₂ laser therapy (n = 31). Bars represent mean values, and error bars indicate standard deviation. Mean scores increased from 36.1 ± 6.1 to 37.9 ± 4.4; however, the difference was not statistically significant (Wilcoxon signed-rank test, p = 0.13)

Ultrasound assessment of pelvic floor and urethral mobility

Transvaginal pelvic floor ultrasound showed no significant changes in resting urethral position or urethral position during pelvic floor muscle contraction after treatment. Urethral mobility during the Valsalva manoeuvre changed significantly ($p = 0.003$), whereas resting urethral position and urethral mobility during contraction did not. Post-treatment urethral length was not reported in the available dataset (Table 3).

Factors associated with improvement in SUI symptoms

Patients were stratified into three groups based on post-treatment outcomes: complete remission, partial remission, and no improvement in SUI symptoms. Comparison of demographic, obstetric, lifestyle, and ultrasound parameters

among these groups revealed no statistically significant differences (Table 4).

Analysis of baseline UDI-6 domain scores across the three outcome groups showed a significant overall difference only for item 3 (stress urinary leakage; $p = 0.003$). The exact pairwise comparison and multiplicity-adjusted p value require verification against the statistical output (Table 5).

Comparison between patients with and without improvement

Further comparison between patients who demonstrated improvement in SUI symptoms and those who did not showed a statistically significant difference in urethral mobility during pelvic floor muscle contraction ($p = 0.039$) (Table 6). Exploratory univariate analysis of demographic, obstetric, lifestyle, and ultrasound parameters

Table 3. Pelvic floor ultrasound parameters before and after fractional CO₂ laser therapy in women with mild-to-moderate stress urinary incontinence ($n = 31$). Values are presented as mean $\pm$ standard deviation (SD). Statistical significance was assessed using the paired Student's t -test

Ultrasound assesement	Before laser therapy ($n = 31$)	After laser therapy ($n = 31$)	p (paired t -Student test)
Length of the urethra [mm]	25.8 $\pm$ 3.1	–	Not applicable
Resting position of the urethra [mm]	10.1 $\pm$ 4.3	9.3 $\pm$ 3.9	0.286
Constriction of the urethra [mm]	12.8 $\pm$ 4.2	12.6 $\pm$ 4.2	0.777
Valsalva position of the urethra [mm]	1.4 $\pm$ 5.6	3.1 $\pm$ 5.2	0.058
Urethral mobility (constriction) [mm]	2.6 $\pm$ 1.6	3.2 $\pm$ 1.8	0.203
Urethral mobility (Valsalva) [mm]	-8.4 $\pm$ 4.4	-6.0 $\pm$ 4.1	0.003
Post-void residual volume (PVR)	<30 ml	<30 ml	Not applicable

Post-void residual volume (PVR) was <30 mL both before and after treatment

Table 4. Baseline clinical and ultrasonographic parameters according to treatment outcome following fractional CO₂ laser therapy. Patients were categorized into three groups: complete remission of stress urinary incontinence (SUI) symptoms ($n = 7$), partial remission of SUI symptoms ($n = 19$), and no improvement ($n = 5$). Values are presented as mean $\pm$ standard deviation (SD). Comparisons between groups were performed using one-way analysis of variance (ANOVA)

Predictive parameter	Group: Complete remission of SUI symptoms ($n = 7$)	Group: Partial remission of SUI symptoms ($n = 19$)	Group: no improvement In SUI symptoms ($n = 5$)	ANOVA (p -value)
Length of the urethra [mm]	25.9 $\pm$ 3.2	25.8 $\pm$ 3.3	25.0 $\pm$ 2.4	0.883
Resting position of the urethra [mm]	7.5 $\pm$ 7.0	10.4 $\pm$ 6.5	9.3 $\pm$ 6.5	0.911
Constriction of the urethra [mm]	11.6 $\pm$ 10.1	12.8 $\pm$ 11.1	11.6 $\pm$ 8.9	0.546
Urethral position during Valsalva [mm]	-0.6 $\pm$ 5.1	1.73 $\pm$ 6.2	2.3 $\pm$ 5.1	0.613
Urethral mobility (constriction) [mm]	3.2 $\pm$ 1.5	3.0 $\pm$ 1.7	1.4 $\pm$ 1.1	0.118
Urethral mobility (Valsalva) [mm]	-9.6 $\pm$ 5.2	-9.1 $\pm$ 4.2	-5.9 $\pm$ 3.7	0.319
BMI	26.7 $\pm$ 3.0	24.4 $\pm$ 2.6	23.7 $\pm$ 3.5	0.257
Number of deliveries	1.5 $\pm$ 0.5	1.8 $\pm$ 0.6	1.75 $\pm$ 0.5	0.507
Number of natural deliveries	1.33 $\pm$ 0.8	1.8 $\pm$ 0.9	1.25 $\pm$ 0.5	0.457

BMI – body mass index; SUI – stress urinary incontinence. Urethral mobility was calculated as the difference between urethral position at rest and during pelvic floor muscle contraction or Valsalva maneuver

Table 5. Baseline UDI-6 scores and clinical characteristics according to treatment outcome following fractional CO₂ laser therapy. Patients were categorized into three groups: complete remission of stress urinary incontinence (SUI) symptoms (n = 7), partial remission of SUI symptoms (n = 19), and no improvement (n = 5). Values are presented as mean ± standard deviation (SD). Group comparisons were performed using one-way analysis of variance (ANOVA), followed by Holm–Sidak post hoc testing when appropriate

Predictive parameter	Group: Complete remission of SUI symptoms (n = 7)	Group: Partial remission of SUI symptoms (n = 19)	Group: No improvement in SUI symptoms (n = 5)	ANOVA
UDI-6 Item 1: Frequent urination	1.57 ± 1.21	1.26 ± 1.22	1.20 ± 1.30	p = 0.829
UDI-6 Item 2: Urgency urinary leakage	0.85 ± 1.01	1.46 ± 1.40	0.80 ± 1.30	p = 0.439
UDI-6 Item 3: Stress urinary leakage	1.00 ± 1.29	2.66 ± 0.60	1.60 ± 1.34	p = 0.003 (Holm-Sidak test: no improvement vs improvement p < 0.001)
UDI-6 Item 4: Small-volume urinary leakage (dribbling)	1.85 ± 1.46	1.66 ± 1.49	0.40 ± 0.89	p = 0.163
UDI-6 Item 5: Difficulty emptying the bladder	0.00 ± 0.00	0.33 ± 0.90	0.40 ± 0.89	p = 0.535
UDI-6 Item 6: Lower abdominal pain or discomfort	0.28 ± 0.48	0.40 ± 1.05	0.60 ± 1.34	p = 0.817
UDI-6 total score	20.9 ± 19.9	43.3 ± 19.7	27.7 ± 20.7	p = 0.198
Age	49.4 ± 4.1	45.2 ± 9.9	48.5 ± 14.7	p = 0.244
SUI VAS scale	39.5 ± 20.3	67.4 ± 19.4	36.4 ± 33.8	p = 0.01 (test Holm-Sidak no improvement vs partial improvement, separately t-Student test no improvement vs full resolution: p = 0.97, no improvement vs partial improvement p = 0.019)

UDI-6 – Urogenital Distress Inventory-6; SUI – stress urinary incontinence; VAS – visual analogue scale. Higher UDI-6 scores indicate greater symptom severity

Table 6. Baseline clinical and ultrasonographic predictors of treatment outcome following fractional CO₂ laser therapy. Patients were categorized into two groups according to treatment response: improvement of stress urinary incontinence (SUI) symptoms (n = 26) and no improvement of SUI symptoms (n = 5). Values are presented as mean ± standard deviation (SD). Comparisons between groups were performed using the independent-samples Student's t-test

Predictive parameter	Improvement of SUI symptoms	No improvement of SUI symptoms	Test t-Studenta
Length of the urethra [mm]	25.8 ± 3.4	25.0 ± 2.4	p = 0.61
Urethral position at rest [mm]	8.3 ± 6.8	9.3 ± 6.5	p = 0.93
Urethral position during pelvic floor muscle contraction [mm]	12.3 ± 10.4	11.6 ± 8.6	p = 0.52
Urethral position during Valsalva maneuver [mm]	0.9 ± 5.8	2.3 ± 5.1	p = 0.67
Urethral mobility (constriction) [mm]	3.1 ± 1.06	1.4 ± 1.1	p = 0.039
Urethral mobility (Valsalva) [mm]	-9.2 ± 4.4	-5.9 ± 3.7	p = 0.13
BMI	25.4 ± 2.9	23.7 ± 3.5	p = 0.35
Number of deliveries	1.7 ± 0.6	1.7 ± 0.4	p = 0.90
Number of natural deliveries	1.6 ± 0.8	1.2 ± 0.4	p = 0.49
Weight of the largest newborn [grams]	3565 ± 513	3337 ± 437	p = 0.46
Age at first delivery [years]	25.7 ± 3.6	29.5 ± 4.0	p = 0.12
Age at last delivery [years]	28.8 ± 4.5	33.6 ± 4.1	p = 0.13
Physical activity (h/week)	4.0 ± 4.5	2.5 ± 2.5	p = 0.74
Coffee cups per day	2.7 ± 2.3	2.8 ± 1.1	p = 0.87
Alcohol units per week	0.9 ± 2.0	0.6 ± 0.8	p = 0.68

BMI = body mass index; SUI = stress urinary incontinence. Urethral mobility was calculated as the difference between urethral position at rest and during pelvic floor muscle contraction or Valsalva maneuver

did not identify statistically significant predictors of treatment response. Due to the limited sample size, multivariate regression analysis was not performed, and these findings should be interpreted cautiously.

Comparison of baseline UDI-6 questionnaire results between patients with any improvement (complete or partial remission; $n = 26$) and those with no improvement ($n = 5$) revealed no statistically significant differences in the total score or individual items (**Table 7**).

Effect size analysis

Effect size analysis demonstrated a moderate effect for improvement in UDI-6 scores (Cohen's $d = 0.65$) and vaginal dryness assessed by VAS (Cohen's $d = 0.58$), and a small effect for changes in sexual function assessed by PISQ-12 (Cohen's $d = 0.32$) (**Table 8**).

Safety outcomes

All participants completed the full course of treatment. No treatment-related adverse events, serious adverse events, treatment discontinuations, or unplanned medical visits were observed during the study period.

Discussion

In this retrospective, uncontrolled pilot study, fractional CO₂ laser therapy was associated with short-term improvement in several self-reported urinary and vulvovaginal symptoms. Sexual-function scores increased modestly but not significantly ($p = 0.13$). Because the study had no sham-control group, included only 31 participants, and assessed outcomes four weeks after treatment, efficacy and durability cannot be inferred.

Table 7. Comparison of baseline UDI-6 scores and selected clinical parameters between women with improvement of stress urinary incontinence (SUI) symptoms ($n = 26$) and those with no improvement ($n = 5$) following fractional CO₂ laser therapy. Values are presented as mean $\pm$ standard deviation (SD). Comparisons between groups were performed using the independent-samples Student's t -test

Predictive parameter	Group: Improvement of SUI symptoms ($n = 26$)	Group: No improvement in SUI symptoms ($n = 5$)	Statistical test (p value)
UDI-6 Item 1: Frequent urination	1.3 $\pm$ 1.1	1.1 $\pm$ 1.1	$p = 0.82$
UDI-6 Item 2: Urgency urinary leakage	1.2 $\pm$ 1.2	0.8 $\pm$ 1.1	$p = 0.52$
UDI-6 Item 3: Stress urinary leakage	2.1 $\pm$ 1.1	1.1 $\pm$ 1.2	$p = 0.43$
UDI-6 Item 4: Small-volume urinary leakage (dribbling)	1.7 $\pm$ 1.4	0.4 $\pm$ 0.8	$p = 0.061$
UDI-6 Item 5: Difficulty emptying the bladder	0.2 $\pm$ 0.7	0.4 $\pm$ 0.8	$p = 0.56$
UDI-6 Item 6: Lower abdominal pain or discomfort	0.4 $\pm$ 0.8	0.6 $\pm$ 1.2	$p = 0.89$
UDI-6 total score	39.3 $\pm$ 19.7	27.7 $\pm$ 18.5	$p = 0.257$
Age	46.6 $\pm$ 8.4	48.4 $\pm$ 13.1	$p = 0.71$
SUI VAS scale	58.6 $\pm$ 22.7	36.4 $\pm$ 30.2	$p = 0.089$

UDI-6 – Urogenital Distress Inventory-6; SUI – stress urinary incontinence; VAS – visual analogue scale. Higher UDI-6 scores indicate greater symptom severity

Table 8. Effect sizes for selected clinical outcomes following fractional CO₂ laser therapy ($n = 31$). Mean differences represent baseline minus post-treatment values for UDI-6 and VAS dryness, and post-treatment minus baseline values for PISQ-12. The effect-size formula and confidence intervals must be verified using paired individual-level change data

Outcome	Mean Difference	Cohen's d
PISQ-12 score	1.8	0.32
UDI-6 total score	19.5	0.65
VAS dryness	13.5	0.58

PISQ-12 – Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; UDI-6 – Urogenital Distress Inventory-6; VAS – visual analogue scale. Positive or negative values indicate the direction of change according to the scoring system used

The exploratory effect-size estimates suggested greater changes in UDI-6 and vaginal-dryness scores than in PISQ-12 scores. These estimates require verification using paired individual-level changes and should be interpreted as hypothesis-generating rather than confirmatory.

First-line management of SUI includes lifestyle measures and supervised pelvic floor muscle training. These established conservative options should remain the clinical reference standard when interpreting investigational energy-based treatments [13].

The articles by Tadir et al. and Salvatore et al. described a potentially favorable role of vaginal laser therapy in genitourinary syndrome of menopause. However, heterogeneity in study design, comparators, follow-up, and outcome definitions limits direct comparison with the present SUI cohort [14,15].

Histological studies have reported connective-tissue remodelling after laser exposure. Such mechanistic observations do not establish clinical efficacy or long-term safety and should not be extrapolated beyond the studied tissue and treatment settings [16].

A systematic review by Ruffolo et al. reported possible improvement in SUI symptoms after vaginal laser therapy, but the included studies were generally small and methodologically heterogeneous [11]. These limitations reinforce the need for adequately powered sham-controlled trials.

Comparison with existing therapies

Current international guidelines recommend pelvic floor muscle training (PFMT) as the first-line conservative treatment for women with stress urinary incontinence. The European Association of Urology (EAU) recommends supervised intensive PFMT for at least three months as first-line therapy for all women with SUI, while NICE guidelines similarly support supervised PFMT as the primary conservative treatment option [17,18]. PFMT has demonstrated significant efficacy in reducing urinary leakage episodes and improving quality of life and therefore remains the gold-standard conservative treatment for SUI. Consequently, CO₂ laser therapy should currently be considered a potential adjunctive treatment rather than a replacement for guideline-recommended pelvic floor rehabilitation. Recent evi-

dence suggests that energy-based therapies may improve symptoms in selected patients [19,20]. However, the available evidence remains limited and heterogeneous, highlighting the need for further high-quality comparative studies.

Evidence suggests that physiotherapy-based interventions, particularly pelvic floor muscle training, can significantly improve FSFI scores and overall sexual well-being in women with SUI. Improvements in quality of life and reduction of urinary leakage episodes have been consistently reported following structured rehabilitation programs, highlighting the role of conservative management in symptom control. These findings underscore the importance of considering baseline pelvic floor function and adherence to physiotherapy as predictive factors when evaluating outcomes of laser therapy. Integrating physiotherapy with laser treatment may offer synergistic benefits, optimizing both continence and sexual health outcomes in women undergoing minimally invasive SUI management [3–6].

There are only a few studies concerning the impact of CO₂ laser treatment for SUI [21–24].

Seki et al. analysed a three-arm, double-blind RCT involving CO₂ laser, radiofrequency ablation (RFA), and sham treatment groups. They conducted three treatment sessions at monthly intervals and observed subjective improvements (76.2%) as evaluated on a Likert scale and objective improvements (45.2%), which were defined as a composite outcome according to negative stress tests, voiding diaries, and pad tests in the CO₂ laser group [21].

Alexander et al. found no significant difference in subjective or objective cure of SUI at 3 months after CO₂ laser treatment: three treatments, four weeks apart, with increasing energy and density settings [22].

Hrefna B'öel Sigurdardóttir et al. reported no difference in subjective cure (ICIQ-IU SF scores). The main result indicated a mean score of 12.2 for the laser group vs 12.7 for the sham group (mean difference, 95 % CI: 2.15 to 3.15; p-value 0.70) [23].

All the results are reported in **Table 9**.

Clinical implications

To our knowledge, this study is among the first to explore urethral mobility before and after three fractional CO₂ laser sessions. Associations

Table 9. Summary of Clinical Studies Evaluating CO₂ Laser Therapy for SUI

Study	N	Laser CO ₂ therapy	Method	Results
Seki et al. 2022 [22]	76 Double-blind RCT questionnaire	CO ₂ "Alma-Femilift (mode medium, 1 Hz, 100-W potency, and 100-mJ/1.0-cm ² fluency" Pixelated beam to "81 microscopic pixels in a 9_9 ablation pattern"	12 months of observations Plus "behavioral therapy" and pelvic floor exercises	Subjective improvement: Laser: 76.2 % Shame: 30 % Objective cure: Laser: 45.2 % Shame: 14 %
Alexander et al. 2022 [22]	101 Single-blinded, shamcontrolled trial questionnaire	CO ₂ FemTouch (Lumenis) delivery system with the AcuPulse CO ₂ laser system, "from 7.5e12.5 mJ with a 10%e 15% density and a fixed penetration depth of 600 microns	3 months	No difference
Hrefna B'oeel Sigurdard'ottir et al. 2025 [23]	37 Single-blinded, shamcontrolled trial questionnaire	CO ₂ SmartXide2 MonaLisa Touch, DEKA M.E.L.A Srl, Florence, Italy) 30 W power, dwell time 1000 µs, 1000 µm spacing, using normal scan mode	4 months	No difference

between baseline urethral functional parameters and response were examined only in exploratory univariable analyses. They should not be described as independent predictors without a prespecified multivariable model and external validation.

Fractional CO₂ laser treatment was associated with short-term symptomatic improvement in this selected group of women with vaginal atrophy and mild-to-moderate SUI. The uncontrolled design does not allow the observed changes to be attributed to the intervention.

Conclusions

These findings are preliminary and hypothesis-generating. They require confirmation in adequately powered, sham-controlled randomised trials with prespecified outcomes, transparent statistical reporting, systematic safety assessment, and substantially longer follow-up before clinical efficacy, durability of treatment effects, and long-term safety can be established.

Limitations and perspectives

The main limitations of this study include a small sample size, lack of randomisation, and a short follow-up period. The relatively small sample size increases the risk of a type II error, particularly for outcomes that approached statistical significance, such as sexual function as assessed by the PISQ-12. The lack of a control or sham-treatment group precludes definitive conclusions regarding causality. Therefore, placebo

effects, behavioural modifications, and spontaneous symptom variation cannot be excluded as contributing factors. Additionally, the lack of multivariate modelling limits the ability to control for potential confounders. Future research should involve multicenter RCTs with sham controls, standardised laser settings, and objective measures such as pad tests and urodynamics. Long-term outcomes and safety profiles must be established before routine clinical use.

Statements

Ethics approval

The study was reviewed by the Ethics Committee of the Poznań University of Medical Sciences, and the project was classified as non-experimental and did not require formal ethical approval (decision no. 385/24).

Data availability

Data is available upon reasonable request.

Author contributions

P.R.: Study design, ultrasound evaluation, data collection, data interpretation. K.T.: Data collection, manuscript drafting, corresponding author.

Conflict of interest statement

The authors declare no conflict of interest.

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