THE EFFECT OF VAGINAL CO_2 LASER TREATMENT ON STRESS URINARY INCONTINENCE SYMPTOMS

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Abstract

Background

Stress urinary incontinence (SUI) in women leads to physical discomfort, deteriorate quality of life and emotional burden. While pelvic floor exercises have been advocated as initial treatment, surgical interventions have demonstrated better efficacy and durable results. However, the possible morbidity of even the most minimally invasive surgical interventions, make many patients reluctant to undergo surgery. Recently, vaginal CO_2 laser treatments have been introduced as a conservative option to treat SUI. This study aimed to assess the effect of vaginal CO_2 laser on bladder and vaginal symptoms in patients with SUI.

Methods

This was a retrospective, multi-center evaluation of 133 consecutive patients with SUI symptoms, who underwent vaginal Pixel CO_2 laser treatments (FemiLift hand piece, Alma Lasers). Patients were interviewed 3-12 months following completion of treatment to evaluate their symptoms and satisfaction.

Results

Eighty percent of the 133 participating patients had SUI symptoms and 20% had mixed incontinence symptoms. The 105 patients successfully contacted to complete the post-treatment questionnaires, reported a significant decline in number of pads used per day, with 80.6% of patients requiring no pads following treatment, in contrast to the 47.8% of patients requiring no pads before treatment ($p<0.0001$).

Significant reductions in urinary urgency and frequency were reported, with >97% patients reporting no or mild urgency and frequency following treatment, versus 7.9% and 5.3%, respectively, reporting moderate symptoms before treatment ($p=0.03$ and 0.04, respectively).

In addition, 91.4% of the patients reported no pain during intercourse following laser treatment, while the remaining 8.6% experienced mild pain only ($p=0.04$).

Satisfactory global improvement was reported by 66.7% of the patients, with a higher incidence of such reports among women with SUI versus other types of urinary incontinence. No significant changes in nocturia were noted by patients following treatment. No adverse events were reported by any patients or recorded in patient charts

Conclusions

The vaginal CO_2 laser treatment yielded promising initial results in treatment of stress urinary incontinence symptoms and vaginal symptoms, with no adverse events.

The potential benefits of this outpatient treatment include improved patient compliance, alongside a high safety profile. Further studies are needed to prospectively assess the long-term efficacy of the pixelated laser treatment on SUI.

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Introduction

Stress urinary incontinence (SUI) is often initially addressed via pelvic floor exercises and behavioral modification. However, surgical interventions continue to be the mainstay of SUI therapy, as they provide the most effective long-term cure[1]. Midurethral slings are the most common surgical interventions today for SUI treatment, and are well accepted as minimal invasive procedures.

A recent meta-analysis of the prospective randomized controlled trials comparing midurethral slings to Burch or pubovaginal sling showed that mean objective and subjective cure rates for midurethral slings were 86.3% and 71.6%, without significant differences from Burch colposuspension.[2] However, these minimal invasive procedures are not free of complications, as reported in a perspective survey of the Nationwide Inpatient Sample database, which included 147,473 SUI surgery patients[3]. The overall complication rate was 13%, with bleeding (4.4%) and urinary/renal (4.3%) complications being most common.

Laser-based treatments have been reported to stimulate collagen neogenesis and skin and tissue remodeling and rejuvenation in wound healing, dermatological, gynecological and dental applications[4-14]. When recruiting this technology for intravaginal gynecological treatments, it is expected to exploit natural healing responses to trigger epithelial tissue regeneration, that may strengthen urethral support.

Recent application of endovaginal Er:YAG laser-based treatment to treat SUI symptoms, brought to significant decreases in urinary incontinence severity and to significantly improved quality of life, within one month of treatment, which were maintained throughout the 6-month follow-up period.[15] Improved SUI symptoms, including first sensation, first desire and maximal urethreral closure pressure were reported following application of an Er:YAG laser treatment regimen in 50 female patients.[11] Similarly, distinctive symptomatic improvement was reported following a three-series deployment of the FemiLift CO_2 laser to treat SUI symptoms in a 50-year-old woman with a 6-year history of urinary leakage.[16] The aim of this retrospective, multicenter audit, was to assess the efficacy of vaginal CO_2 laser treatment in SUI patients.

Methods

Patients:

Treated patients (n=133) suffered from symptoms of urinary stress incontinence. Patients concomitantly taking medicines that induce photosensitivity, with an active vaginal infection, active urinary infection, diagnosed collagen disease, herpes infection, undergoing corticoid therapies and/or with gynecological oncological pathologies were not treated. Pregnant women were not treated either.

The Technology:

The FemiLift CO_2 laser (Alma Lasers) delivers energy to the deep submucosal vaginal tissue through a holographic lens, which pixelates the beam into 81 microscopic pixels in a 9x9 mm pattern (Figure 2). The thermal effect is achieved in microscopic columns, while the surrounding tissue remains intact. In consequence, existing fibers contract and neocollagenesis is stimulated, while cells located in the unaffected tissue hastens the healing process, finally leading up to vaginal wall rejuvenation.

Ablative Laser Treatment:

Treatment was performed in an outpatient setting, without sedation or local anesthetics. The treated area was cleaned of mucus secretion with a gauze pad before treatment. Oral prophylactic antiviral agents to prevent outbreak of herpes simplex virus, were administered. FemiLift (by Alma Lasers) is a CO_2 laser with a single-use hygienic probe that delivers pixelated laser energy. The probe, lubricated with baby oil, was set at a low to moderate (Figure 1) energy setting (30-40 mJ/pixel) before being positioned under the mid-urethra location, with the laser's energy window oriented at 12 'o clock position.

It was then rotated by one hour at a time after each laser pulse, between positions 10 o' clock to 2 o' clock to address the urethra up to the bladder neck. After completing the 10-2 o'clock rotation, the handpiece was pulled back by one centimeter and the rotation was repeated. Three such passes were repeated. The energy intensity and pulse durations were only increased if the patient expressed no signs of discomfort.

The maximum energy setting was 70 mJ/pixel for postmenopausal women and 100 mJ/pixel, for premenopausal women. Pulse duration varied (130 - 270 ms).

A minimum interval of 30 days was required between 3 sessions.

Figure 1: FemiLift handpiece with a single-use hygienic probe

Questionnaires:

Patients were interviewed retrospectively with questionnaires, which included selected questions from the Pelvic Floor Distress Inventory (PFDI) questionnaire, and the 10-cm visual analog scale (VAS) Vulvo Vaginal Atrophy symptoms questionnaires about their symptoms before and after treatment. Patients were interviewed 3-12 months following treatments.

Statistical Analysis:

Statistical analyses were performed with SAS v9.3 (SAS®, SAS Institute Cary, NC USA) software. Study data was tabulated and summarized by data type, continuous variables with a mean and standard deviation and discrete data by a count and percentage. Bowker's test of symmetry was used to assess if there was a statistically significant change in clinical symptoms. A p-value of 0.05 or lower was considered statistically significant. Nominal p-values are presented.

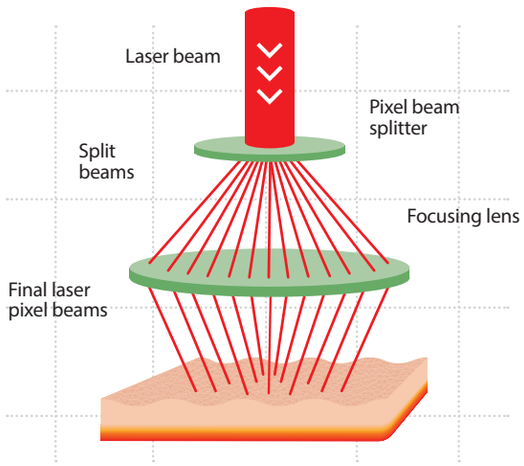


Figure 2:

The FemiLift CO_2 microablative laser. The laser beam is passed through a pixelating holographic lens, forming a 9x9 mm spot size.

The thermal effect is achieved in microscopic columns surrounded by spared tissue, from which healthy cells are recruited to accelerate the healing process

Results

Patients:

The patients participating in this survey included women with stress urinary incontinence (72.2%), urge incontinence (1.0%) or mixed urinary incontinence (19.6%) (Table 1). At baseline, 21.1% of patients reported mild to moderate urinary urgency, 24.2% mild to moderate urinary frequency and 10.1% complained of grades mild-moderate nocturia.

In addition, before treatment, 52.2% of the patient population reported use of protective pads, with 40.3% requiring two or more pads per day, and 20% reported some degree of vaginal dryness and painful intercourse.

Following treatment, significant improvements in urinary urgency and frequency were reported, with 97% of patients reporting no or mild urinary urgency and frequency (p=0.03 and 0.04, respectively) (Table 2).

No cases of moderate nocturia were reported post-treatment and only 5 (4.6%) of the 109 evaluated patients reported mild symptoms. Vaginal itching, reported by 8 patients at baseline, manifested following treatment among three patients only. Moreover, the number of reported pads used per day declined significantly, with 80.6% of the treated patients requiring no pads following treatment and the remainder requiring up to two pads per day (p<0.0001, figure 3).

Similarly, a 13% rise (p=0.009) in the number of post-treatment reports of no vaginal dryness was observed, with a total of 93.6% patients reporting no dryness and 6.4% reporting mild dryness only. In addition, 91.4% of the patients reported no pain during intercourse following laser treatment, while the remaining 8.6% experienced mild pain only (p=0.04).

When assessing the Vulvovaginal Atrophy questionnaire scorings 66.7% of the women reported moderate to significant responses to treatment (Figure 3), with a greater percentage of SUI patients reporting such marked effects (72.9%), when compared to women with other types of urinary incontinence (50%).

Discussion

Implementation of CO_2 (CO_2; 10,600 nm) laser therapy has been previously reported in gynecological applications, and has been shown to restore the vaginal epithelium and provide symptomatic relief of vaginal atrophy.[17] Following selective absorption of CO_2 illumination by tissue water, increased fibroblast and epithelial cell activity have been reported, with enhanced synthesis and deposition of extracellular matrix and vascular components[18], and eventual improvement in tissue function.

The fractionated CO_2 laser therapy reported here, maximized therapeutic efficacy, via a long-pulsed, fractionated illumination regimen, yielding deeper, yet safe (<500 microns) penetration and more intense heating of the high water-content submucosa.

The resulting thermal and ablative effects led to rejuvenation of the treated tissue and eventual refirming of the vaginal and mid-urethra structures, as manifested by symptomatic improvement of clinical vaginal and bladder parameters. More specifically, significant patient-rated improvements in urinary urgency and frequency were recorded as well as a 59.1% rise in the number of patients requiring no pads following treatment.

Moderate to significant global improvements were noted by 66.7% of the women. Of note, SUI patients were more satisfied with the treatment compared to patients with other types of UI, a difference which may have been incidental due to the small sample size of women with mixed urinary incontinence.

Self-managed lifestyle modifications and conservative SUI treatments, such as pelvic floor training, are typically adopted as first-line treatments. While cost-effective and relatively free of side effects, they rely heavily on patient compliance and adherence over time, and have been shown to be of greatest impact in younger patients19 and when performed under supervision and for at least three months.[20] Weighted vaginal cones provides similar efficacy to pelvic floor muscle training, but is associated with a 25% drop-out rate.[21] Occlusive continence devices demand a high degree of patient motivation and clinical trials assessing their effectiveness have reported marked drop-out rates.[1]

In addition, as they are typically disposable and replaced after each void and during sexual activity, they incur substantial costs and inconvenience.[1] Most importantly, as the devices fail to treat the underlying problem, they leave patients indefinitely dependent on them to maintain continence.

Pharmacological agents have been associated with a high rate of adverse events and unsatisfactory clinical outcomes. In their systematic review of nine trials, evaluating the efficacy and tolerability of duloxetine, a serotonin and noradrenaline reuptake inhibitor, in management among of over 3000 SIU cases, Mariappan et al. report significantly improved quality of life and rates of symptom improvements when compared to placebo-treated patients. However, 71% of the population suffered from side effects, leading to discontinuation of treatment in one in eight patients [22].

Stimulation of bladder neck and urethra a-adrenergic receptors, by various pharmacological agents, have led to low cure rates (£14%), a 19-60% reduction in incontinence and side effects in 5-33% of patients.[23]

While the optimal treatment for UI is determined by a spectrum of factors, and will differ between types of UI, there exists a consensus that surgical approaches provide the most effective and enduring therapies. However, they come hand-in-hand with morbidity, cost and inconvenience.

There exist over 200 surgical options for SUI management, many of which are associated with poor long-term success rates and are associated with significant complications. While minimally invasive options also exist, few studies have demonstrated their superiority or equivalence to conventional surgery.[24-26] The tension-free vaginal tape method incurs significantly less pain and morbidity, when compared to other surgical options, and has been associated with a high (84.7%) 5-year cure rate, with minimal complications when implemented in 90 SUI patients.[27] Injectable bulking agents have gained popularity, but have failed to demonstrate significant effectiveness over time and come along with significant pain during injection.[28-30] In addition, transient urinary retention and voiding dysfunction following treatment are commonly reported.

The CO_2 laser-based minimally invasive, outpatient approach, requires no anesthesia and provides immediate results, with no adverse events and no reliance on patient compliance and adherence to treatment regimens. In addition, the unique matrix design of the illuminating pixels and the extended pulse length avoided severe and long-lasting complications (e.g., hypertrophic scarring, ectropion formation, disseminated infection) which have been reported for fractionated laser skin resurfacing devices.[31] While its long-term effectiveness remains to be determined, it reduced clinical symptoms and improved patient quality of life.

The limitations of this study include its retrospective nature and the absence of objective evaluations of clinical symptoms.

TABLE 1.

Patient demographics and baseline characteristics (N=133)

AGE (YEARS)	
Mean (SD)	51.2 (11.7)
Min, Max	34.0, 86.0
URINARY INCONTINENCE, n (%)	
Mixed	26 (19.6)
Stress	96 (72.2)
Urge	1 (0.8)
Unknown	10 (7.5)
HRT USE PRETREATMENT, n (%)	
None	2 (1.8)
Local	109 (98.2)
SEXUAL ACTIVITY PRETREATMENT, n (%)	
No	17 (14.4)
Yes	101(85.60)

TABLE 2.

Clinical symptoms before and after CO_2 laser treatment

SYMPTOM	PRETREATMENT % (n)	POSTTREATMENT % (n)	BOWKER'S TEST
Pads per day			
None	47.8 (32)	80.6 (54)	p=0.0001
1	11.9 (8)	10.5 (7)	
2	31.3 (21)	9.0 (6)	
3	9.0 (6)	0.0 (0)	
Urinary urgency			
None	79.0 (90)	82.5 (94)	p=0.0341
Mild	13.2 (15)	14.9 (17)	
Moderate	7.9 (9)	2.6 (3)	
Urinary frequency			
None	76.1 (86)	82.3 (93)	p=0.0377
Mild	18.9 (21)	15.0 (17)	
Moderate	5.3 (6)	2.7 (3)	
Nocturia			
None	89.9 (98)	95.4 (104)	p=0.0719
Mild	7.3 (8)	4.6 (5)	
Moderate	2.8 (3)	0.0 (0)	
Vaginal itching			
None	91.4 (85)	96.8 (90)	p=0.4232
Mild	5.4 (5)	3.2 (3)	
Moderate	2.2 (2)	0.0 (0)	
Severe	1.1 (1)	0.0 (0)	
Vaginal dryness			
None	79.6 (74)	93.6 (87)	p=0.0093
Mild	10.8 (10)	6.5 (6)	
Moderate	8.6 (8)	0.0 (0)	
Severe	1.1 (1)	0.0 (0)	
Dyspareunia			
None	80.7 (75)	91.4 (85)	p=0.0430
Mild	11.8 (11)	8.6 (8)	
Moderate	6.5 (6)	0.0 (0)	
Severe	1.1 (1)	0.0 (0)	

TABLE 3.

Vulvovaginal atrophy questionnaire ratings after CO_2 laser treatment, by type of urinary incontinence

		Stress UI		Other UI		Overall	
		N	%#	N	%#	N	%#
GLOBAL IMPROVEMENT ASSESSMENT*	1-5	26	27%	18	50%	44	33%
	6-10	70	73%	18	50%	88	67%
Dysuria**	1-5	76	96%	16	100%	92	97%
	6-10	3	3.8%	.	.	3	3.2%
Vaginal Itching**	1-5	79	99%	16	100%	95	99%
	6-10	1	1.3%	.	.	1	1.0%
Vaginal Dryness**	1-5	80	98%	15	94%	95	97%
	6-10	2	2.4%	1	6.3%	3	3.1%
Dyspareunia**	1-5	78	99%	16	100%	94	99%
	6-10	1	1.3%	.	.	1	1.1%

The presented percentages represent the percentage of each column for each assessed parameter.
* 1-10 scale, where 1=no change and 10=significantly better
** 1-10 scale, where 1=absence of symptoms and 10 = symptoms as bad as it could be

FIGURE 3.

Number of pads used per day before versus after treatment, as reported by patients (p<0.0001)

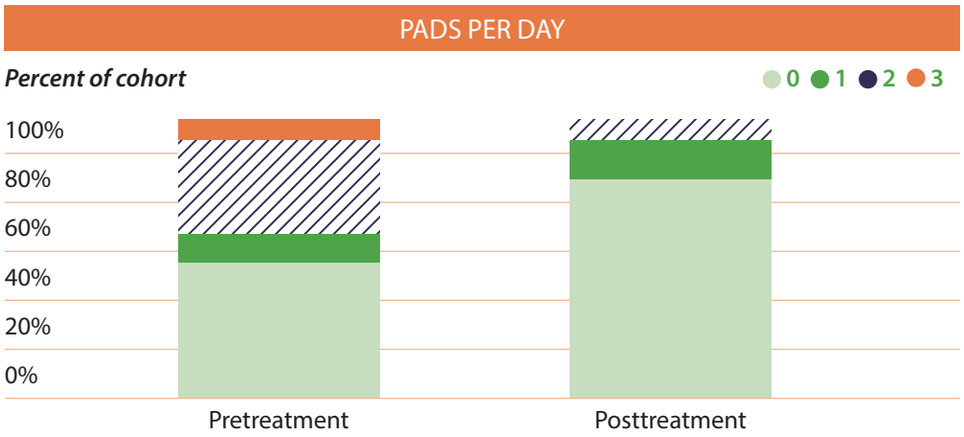
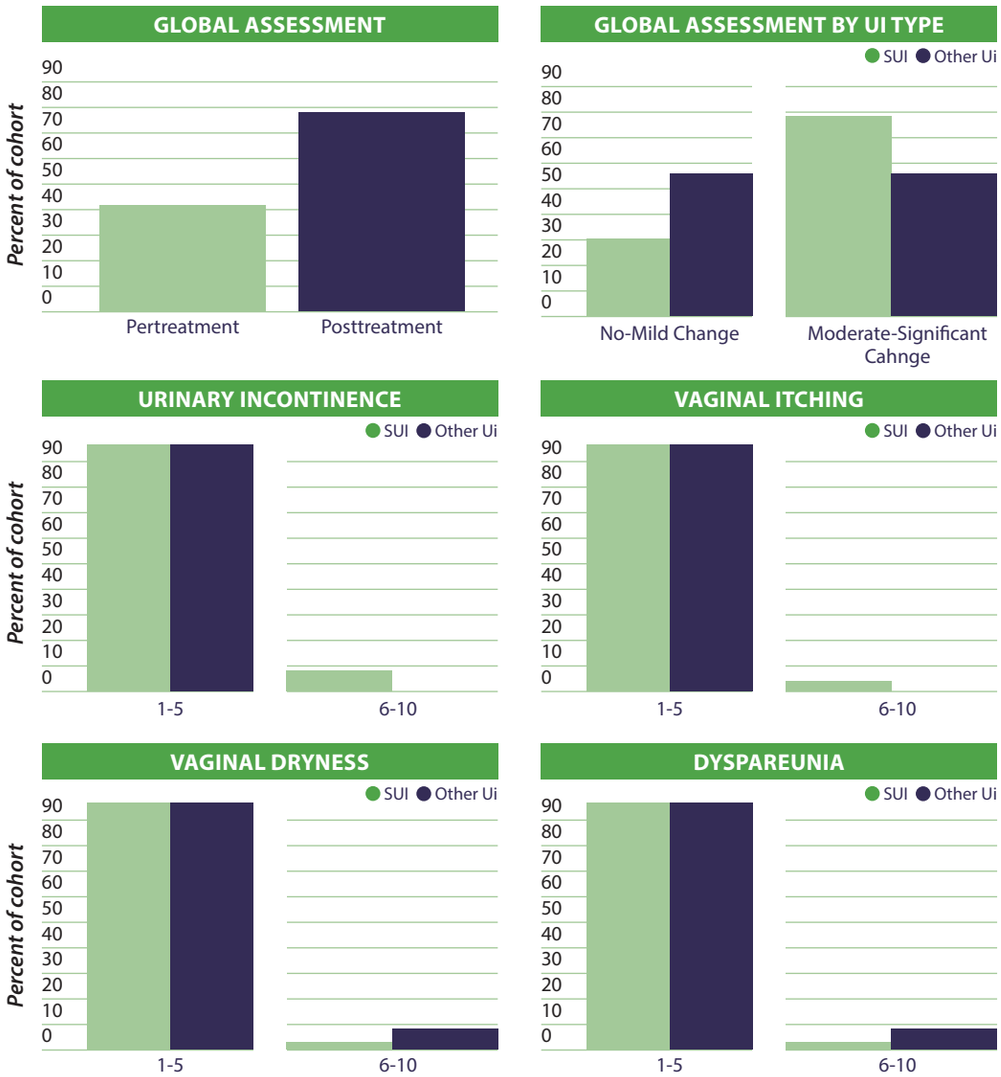


FIGURE 4.

Vulvovaginal atrophy questionnaire ratings after CO_2 laser treatment, by type of urinary incontinence



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