The Use of CO_2 laser for patients with Stress Urinary Incontinence

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Introduction

Stress Urinary Incontinence (SUI) affects 35%-40% of women worldwide[1,2], it occurs when a woman experiences involuntary leakage of urine during physical activities that increase intra-abdominal pressure such as exercise, cough, sneeze, or laugh[3]. Risk factors include age, parity, pregnancy, vaginal delivery, chronic cough, constipation, obesity, pelvic floor weakness, post-menopausal state and prior pelvic surgery.

SUI can significantly affect the quality of life since women may avoid certain activities or exercises that cause leakage or they may be embarrassed to go out in public due to fear of leakage.

The ideal treatment for SUI is a therapy that is effective at relieving symptoms, one that is minimally invasive, nearly painless, durable and would restore normal urethral supportive function.

Currently, the main treatment options for SUI consist of a vaginal approach and placement of a synthetic midurethral slings (MUS), a biologic bladder neck sling or urethral bulking agents. However, there are limitations to slings and not every patient with SUI may be a candidate for one. Some patients may require a tight bladder neck slings which can be associated with urgency-frequency, obstructive voiding and post-operative pain, especially if autologous fascia is used. Urethral bulking agents are minimally invasive but durability is lacking and repeat injections are typically necessary.

The synthetic MUS may carry its own unique set of risks, including mesh exposure, mesh erosion into surrounding organs, dyspareunia, pelvic pain, and need for further surgery. Despite the proven safety and efficacy of mesh MUS, an aggressive mesh MUS legal environment exists, thus the ideal treatment of SUI is still lacking.

CO_2 Laser Therapy for patients suffering from SUI

The CO_2 laser is considered the gold standard for high precision incisions, skin resurfacing and tissue remodeling, and has already proven to reach depths of several hundred microns in preclinical and clinical work exploring the effect on the vaginal tissue. The CO_2 energy is delivered in a fractional manner which generates controlled and precise tissue damage. The fractional pattern is important as it maintains a healthy tissue surrounding each micro ablation zone enabling rapid and complete epithelial repair. The fractional scanner of the CO_2 laser is fast to deploy the exact amount of energy, the depth of penetration is controllable and can be adjusted in order to receive the desired tissue / clinical effect. Controlled small ablation/coagulation zones are created within the lamina propria using various energy levels. The different energy settings allow an effective tissue remodeling while ensuring the safety of the fibromuscular layer.

In this white paper, we present the preliminary scientific evidence supporting CO_2 laser treatment for patients suffering from SUI based on a recently-conducted clinical study.

FemTouch and CO_2 laser treatment for patients with SUI

We conducted a prospective pilot study between April 2016 and April 2017 at the Center of Women's Health and Wellness, New Jersey - USA. The study included twenty eight postmenopausal women with one or more of the GSM-related symptoms (e.g. dryness, itching, burning, dysuria or dyspareunia). Among this study population, nine women had suffered from SUI (Stamey classification grade =1) and were taken for this further analysis. Women with transvaginal mesh implants, systemic steroid use, and vaginal lubricants within seven days prior to enrollment were excluded.

Treatment included three CO_2 laser treatments with four weeks apart and follow ups (FU) that were done at one, three and six months following the third treatment. The treatment of the vaginal canal was administered with the FemTouch™ handpiece in conjunction with the Lumenis AcuPulse™ system. The FemTouch™ handpiece was inserted into the vaginal canal and the fractional CO_2 laser energy was transmitted through the handpiece along the vaginal canal in a retrograde manner (treatment parameters were Energy 10 -12.5mJ, and Density 10%). Post procedure instructions were to avoid heat exposure in the treated area and refrain from sexual activity up to 72 hours following treatment. Following each procedure, women were asked to assess the level of pain and discomfort that was procedure-related using a Pain Visual Analogue Scale (VAS). In addition, they were asked to report the post procedure discomfort. The procedure was associated with only minimal discomfort. About half felt no discomfort post procedure and the other half felt discomfort up to 24 hours post procedure. No related adverse events were reported up to the six months follow up visit.

Urinary Incontinence Quality of Life Scale (I-QOL)

The evaluation of Urinary incontinence was done using the Urinary Incontinence Quality of Life Scale (I-QOL) questionnaire along the study visits. This is a disease-specific, 22-item, self-administered questionnaire that evaluates the effects of urinary incontinence overall and in three domains, which has demonstrated psychometric properties of validity, reliability, and responsiveness[4,5]. It includes questions that evaluate both the distress and impact of urinary incontinence, with a score of 100 being the best possible and a score of 0 being the worst possible quality of life. It has been shown that statistically significant improvements in I-QOL scores should generally exceed 6.3 points to be considered as clinically important[6].

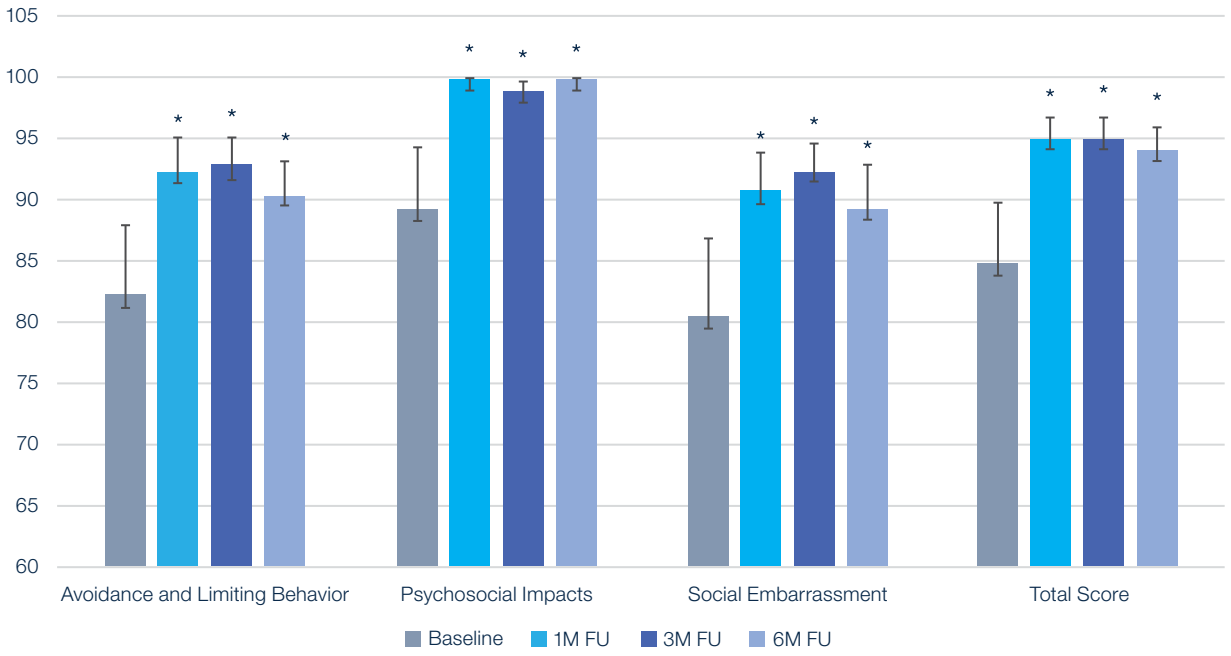
Significant improvement in the I-QOL total score was already noted at the one month follow up visit (1MFU) (95.13 ±4.24) compared to baseline (84.85±14.9) (Table 1), demonstrating more than 10 point increase, which is regarded as clinically significant. In addition, all I-QOL domain scores were significantly improved at one month following treatment and this was sustained up to the six months following treatment. The most profound change was reported by the women in the domain of Social Embarrassment (Figure 1).

Table 1: I-QOL Total and Domain Scores

Before Treatment	Baseline	1MFU	3MFU	6MFU
Total Score	84.85 ± 14.90	95.13 ± 4.24*	95.27 ± 3.40*	94.18 ± 4.91*
Avoidance and Limiting Behavior	82.29 ± 16.90	92.41 ± 7.18*	92.71 ± 5.82*	90.63 ± 7.65*
Psychosocial Impacts	89.51 ± 14.35	100.00 ± 0.00*	99.07 ± 1.43*	100.00 ± 0.00*
Social Embarrassment	80.56 ± 19.11	90.71 ± 8.38*	92.50 ± 5.24*	89.38 ± 9.80*

Data is presented as mean ± standard deviation. *Significantly different from baseline, p <0.05.

Figure 1: I-QOL Total and Domain Scores



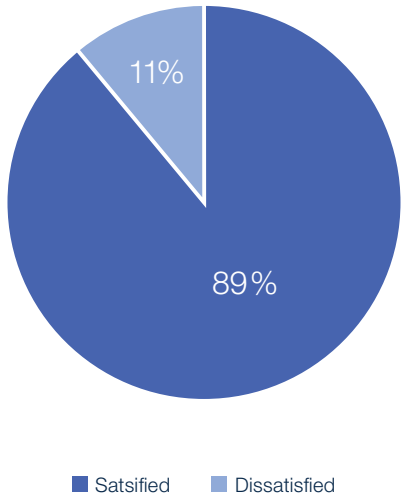
Data is presented as mean ± standard deviation.

*Significantly different from baseline, p <0.05.

Patient satisfaction

The patients overall satisfaction level with the treatment procedure and outcome was assessed based on a 5-point Likert scale (very dissatisfied, dissatisfied, uncertain, satisfied, very satisfied) at one, three and six months following treatments. As can be seen in Figure 2, at the first month follow up 89% of women were satisfied with the treatment.
At three and six months follow up, about 80% of women expressed satisfaction with the treatment.

Figure 2: Patient satisfaction at one month follow up visit.



Conclusion

The minimally invasive Lumenis CO_2 laser treatment may offer a unique therapeutic option for women with SUI. As seen in this prospective pilot study, the treatment was safe, well tolerated and women experienced an improvement in SUI symptoms as evaluated by the I-QOL questionnaire. The statistically significant improvement in the I-QOL total score following FemTouch™ laser treatment could already be seen at one month and was sustained until six months following treatment. According to Yalcin et al[6,7], statistically significant improvements in I-QOL scores should generally exceed 6.3 points to be considered as clinically important, thus the improvement of more than 10 points in the current study is considered to have significant clinical importance. In addition, improvement in the episodes of urine loss was reported and women's satisfaction with the treatment was high. Therefore, we may conclude that the FemTouch™ treatment provides a statistically-significant and clinically-meaningful improvement of the incontinence-related quality of life.
The results of this pilot study demonstrated that the FemTouch™ handpiece of the Lumenis AcuPulse™ system is an easy to use, minimally-invasive, and effective treatment option for post-menopausal women with SUI. Further study is needed in order to support these initial results.

Warnings and risks

CO_2 lasers are intended solely for use by physicians trained in the use of the Carbon Dioxide laser (10.6 µm) wavelength. Incorrect treatment settings or misuse of the technology can present risk of serious injury to patients and operating personnel. Risks that may be associated with any CO_2 laser procedure may include change of pigmentation, infection, erythema, skin induration or scarring. Read and understand the CO_2 systems and accessories operator manuals for a complete list of intended use, contraindications and risks. The use of Lumenis® CO_2 laser is contraindicated where a patient has taken Accutane (Isotretinoin) within the past 6-12 months, has a history of keloid formation and demonstrates excessive or unusually prolonged erythema.

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PB-2008898 Rev A