

THE TREATMENT OF URINARY INCONTINENCE WITH FRACTIONAL/PIXEL CO₂ LASER TECHNOLOGY

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Abstract

The aim of this study was to evaluate the efficacy of pixelated CO₂ laser therapy in treating urinary incontinence symptoms. Daily habits that increase intra-abdominal pressure, such as sneezing, coughing, laughing, jumping, and heavy lifting, may cause urine leakage. Ninety-four patient charts with a follow-up of up to 9 months were retrospectively analyzed. All patients underwent 2-3 treatment sessions with the pixel CO₂ laser (FemiLift™, Alma Lasers, Israel) by the same gynecologic surgeon. The largest age group was 40-49, and 44% of the patients were post-menopausal. The main indications for treatment were SUI (86%), and mixed UI (12%). Two patients had vaginal relaxation (2%) with no urinary incontinence.

Following treatment, almost twenty-five percent of the patients did not have SUI, frequency of leakage upon coughing or sneezing decreased, and 47% of the patients experienced only one episode of urinary leakage per week. Fifty-two patients reported vaginal laxity before treatment, whereas 36 patients made such reports following treatment. Similar improvements in vaginal dryness were noted. The impact of this treatment on patient's quality of life was notable. **CONCLUSION:** The ease of the procedure, with satisfactory outcome and minimal side effects, renders this new treatment modality a viable option for the treatment of urinary incontinence.

Introduction

Several types of urinary incontinence (UI) are listed in the medical literature. These include stress urinary incontinence (SUI), which relates to sudden increase of intra-abdominal pressure, urge incontinence (UI), defined as leakage caused by overactive bladder muscles, mixed incontinence (MUI), which is a combination of both SUI & UI, and overflow incontinence (OI), which is a steady loss of small amounts of urine when the bladder does not empty.

SUI is an embarrassing disorder, typically occurs when certain kinds of physical movement place pressure on the urinary bladder. Daily activities that increase intra-abdominal pressure such as sneezing, coughing, laughing, jumping and heavy lifting may cause urine leakage.

According to the American College of Obstetrics and Gynecology (ACOG) May 2014 SUI guidelines [1-2], SUI "is estimated to affect 15.7% of adult women. Among women with SUI, 77.5% report their symptoms to be bothersome, and of this group 28.8% report their symptoms to be moderately to extremely bothersome; the degree of bother is associated with the severity of UI." Classifying SUI relies on distinguishing between intrinsic sphincter deficiency, and urethral malposition, or hypermobility [3], however, in most clinical practices, urodynamics testing is not the routine.

The multifactorial etiology of the inability to control the urge to urinate involves anatomic failure of urethral support, and sphincter dysfunction interplay with dynamic pressure changes. There is a wide spectrum of treatment options to mention just few such as tension-free vaginal tape (TVT) [4], radiofrequency (RF), and injection of synthetic and biological biomaterials as urethral bulking agents [5].

Non-surgical approaches involve physiotherapy, and use of the recently developed, FDA-approved device (Poise Impressa™) in which a non-absorbable expandable device is inserted, like a tampon. The device places pressure on the urethra to help prevent leakage [6]. Non-surgical solutions require long-term commitment, typically associated with low patient compliance. The need for a simple, minimally invasive, outpatient procedure to improve quality of life still exist.

Recent developments in laser technology, and preliminary reports on improved control of urination following vaginal rejuvenation, led to this retrospective chart analysis. The aim was to evaluate the efficacy of minimally invasive pixel CO₂ laser therapy (FemiLift™) in treating urinary incontinence symptoms. The treatment exploits a unique combination of superficial ablation and deeper thermal deposition of the pixelated CO₂ laser energy, delivered via a probe designed specifically for the vaginal anatomy, aimed to tighten the vaginal wall and improve sub-urethral support.

Materials And Methods

Patient charts (n=94), documenting a follow-up period of up to 9 months, were retrospectively analyzed. All patients were treated with the pixel CO₂ laser (FemiLift™, Alma Lasers, Israel) by the same gynecologic surgeon. Indications for treatment were SUI (86%), Mixed UI (12%) and vaginal relaxation (2%).

The largest age group was 40-49 (**Figure 1**), 44% of the patients were post-menopausal, and most (58%) with a history of two vaginal births (**Figure 2**). Urinary leakage primarily provoked by coughing, sneezing and physical activity.

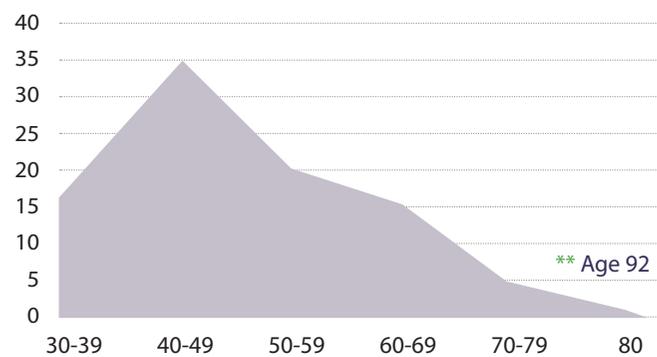
The oldest patient successfully treated for SUI was 92-years-old. Her charted data were used in the safety and efficacy analyses, however, as the case was unusual, her chart was excluded from data analysis.

FIGURE 1:

Patient's Age

In this 94 cases women were between 30 and 80 years old. Most between 40-59 (60%) 92% under 70 years old.

30-39 - 16% | 40-49 - 38% | 50-59 - 21% | 60-69 - 17% | 70+ - 8%



** Age of the oldest patient was 92 years. She was successfully treated, but excluded from this analysis.

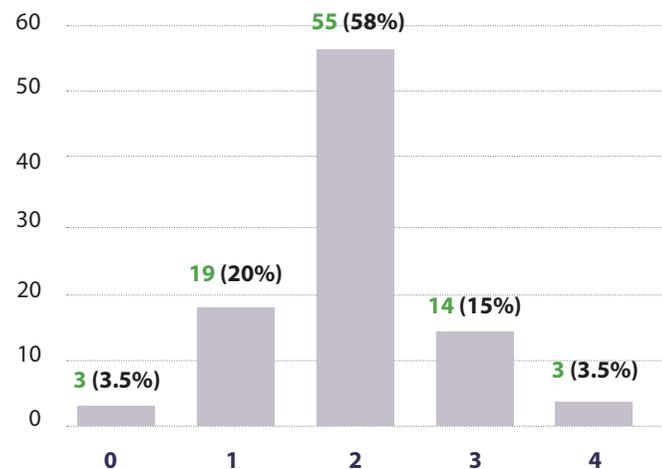
Urinary leakage occurring more than once a day was reported by 35% of patients and once a week by 34% of patients.

Volume of baseline urinary leakage (Small, Medium or Large) was typically small. Most patients reported the impact of urinary incontinence on the quality of life (QoL) on a scale of 1-10, as 1 being "minimal", and 10 as "terrible impact". More than 50% of patients reported need to urinate during the night.

Each patient underwent a gynecologic examination before every treatment, to rule-out inflammations, bleeding, or other abnormal condition. Vaginal laxity was scored on a 6-point scale, and cystocele/rectocele was score according to Pelvic Organ Prolapse quantification system (POP-Q) [7].

FIGURE 2:

Numbers of vaginal deliveries



0-4 = Number of deliveries ■ Number of Women
Only one delivery - Vacuum Extraction.

Treatment protocol

The vagina was cleaned with a dry swab, and anesthetic gel was topically applied on the introitus (Lidocain 22%, tetracaine 8%), to avoid pain or discomfort during probe insertion and treatment. The FemiLift Pixel CO₂ laser probe (**Figure 3**) was designed to allow for spread of laser pixel beams on the vaginal mucosa.

The FemiLift laser is focused through holographic lenses (**Figure 4**) to deliver microablative CO₂ laser energy (30 Watts, 60-110 mJ/Pixel high laser mode, 0.5 Hz), with an 81-pixel beam in a 9x9 mm template.

Five passes were performed at each treatment session, where the probe was rotated and retracted at 1 cm intervals after completion of each rotation at 45 degrees each, in order to cover the entire vaginal canal.

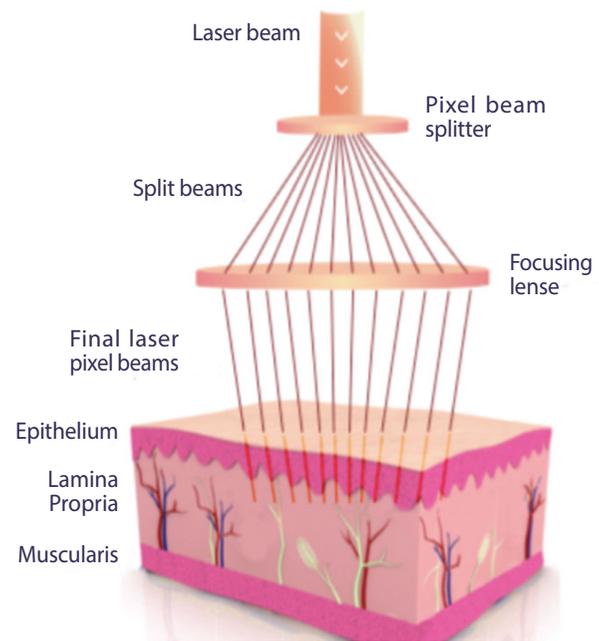
Energy for first application was between 60 to 100 mJ/Pixel, depending on the age at menopause onset, vaginal atrophy and patient-reported comfort. Laser energy was gradually increased to 110-120 mJ/Pixel. The standard protocol included two treatment sessions, performed at 4-week intervals. If needed, a third session was conducted six months later.

After each treatment, patients are advised to abstain from sexual activity for 7 days, avoid extreme physical activities for 2 days, and expect yellow or bloody discharge for 3-7 days. Intravaginal hyaluronic acid (vaginal ovules, Cicatridina, Farma-Derma S.R.L, Italy) was administered for 7 days, and vitamin C 500 mg supplement was prescribed for 6-8 months.

FIGURE 3



FIGURE 4



Results

Almost 25% Twenty-of the patients reported fully resolved UI symptoms following treatment, (**Figure 5**).

In analyzing the data of that main complaint related to uncontrolled urination, after shifting from one category to the other as a results of the Pixelated CO₂ laser, a marked pattern change is clearly demonstrated after two treatment sessions. A third treatment session was performed on 52 patients (52%).

The frequency of urine leakage is also changed after treatment (**Figure 6**). Before treatment, 35% of the patients reported at least one episode per day, and the frequency pattern is shifted to the left, i.e. towards 1-3 episodes per week.

Patients reported an improvement in their quality of life following

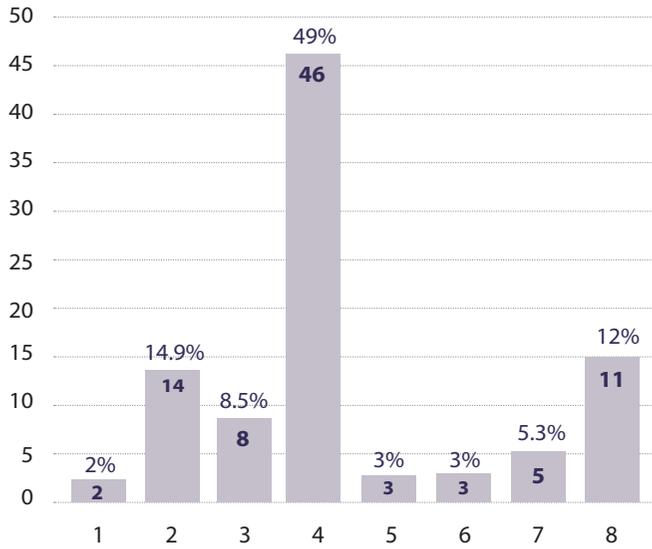
the two-session treatment regimen (**Figure 7**), with 82% of patients rating impact of UI on QoL to be ≤ 5 .

Following the laser treatment, about 45% of the patients had vaginal discharge for 3-7 days, 80% of them for just 3 days. Five patients reported uncontrolled urination in the 24-48 hours following treatment. Two patients reported an elevated body temperature for one day, and one patient experienced vaginal adhesiae, treated gently with hyaluronic acid, and confirmed good outcome on follow up.

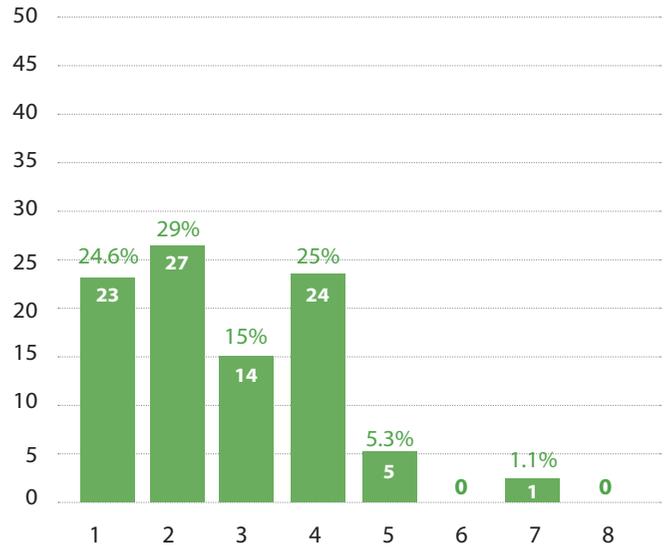
The oldest patient (92) treated for SUI was satisfied with the treatment outcome, mainly because SUI symptoms improved significantly, and she felt stronger pelvic support which helped in walking and improved her quality of life.

FIGURE 5:
Main Patient`s Complaint that provokes leakage:

before treatment:



After treatment:



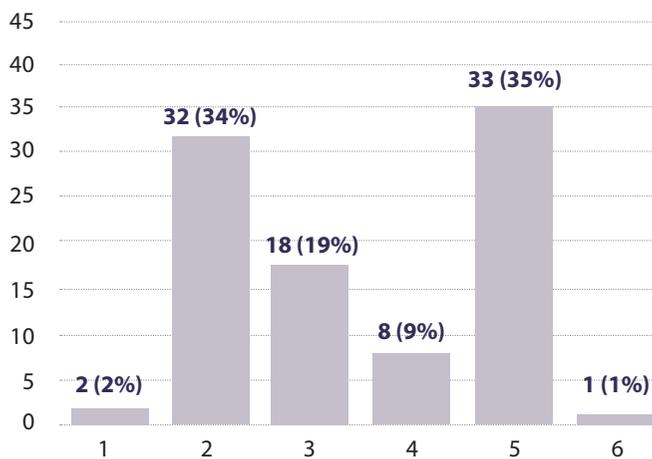
1. No SUI – just V.R	2 (2%)	5. 2+3+4 combined	3 (3%)
2. Caughing/sneezing	14 (14,9%)	6. 2+3+5 combined	5 (5,3%)
3. Physical activities	8 (8,5%)	7. 2 + 3 + 6 combined	5 (5,3%)
4. 2+3 combined	46 (49%)	8. 2-5: combined	11 (12%)

1. No SUI	23 (24,6%)	5. Post Void	5 (5.3%)
2. Caughing/sneezing	27 (29%)	6. 2+3+5 combined	0
3. Physical activities	14 (15%)	7. 2+3+6 combined	1 (1,1%)
4. 2+3 combined	24 (25%)	8. 2-5: combined	0

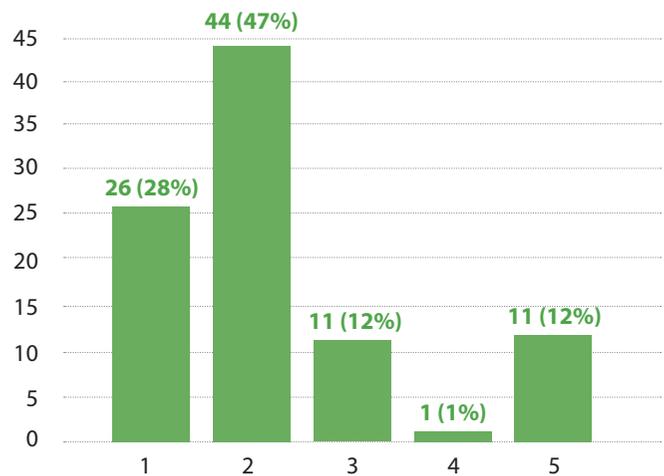
1 = No SUI, 2 =Caughing/Sneezing, 3 = Physical activities, 4 = During Intercourse, 5. Post void / geting up, 6 = No control of urination

FIGURE 6:
Frequency of urine leakage

before treatment:



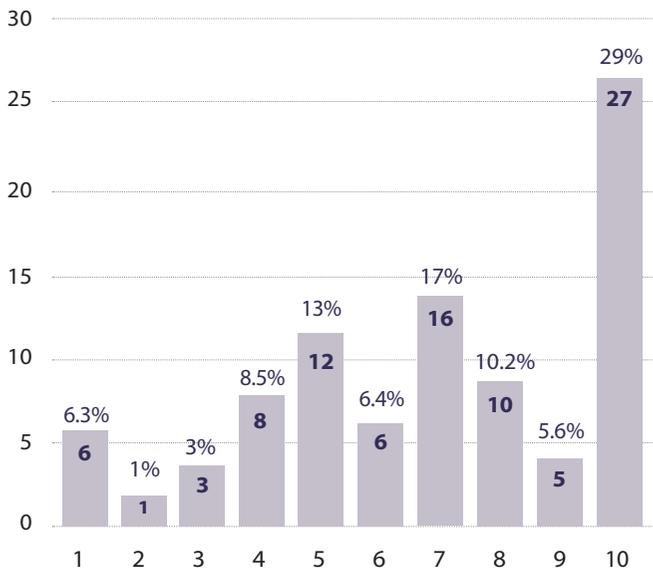
After treatment:



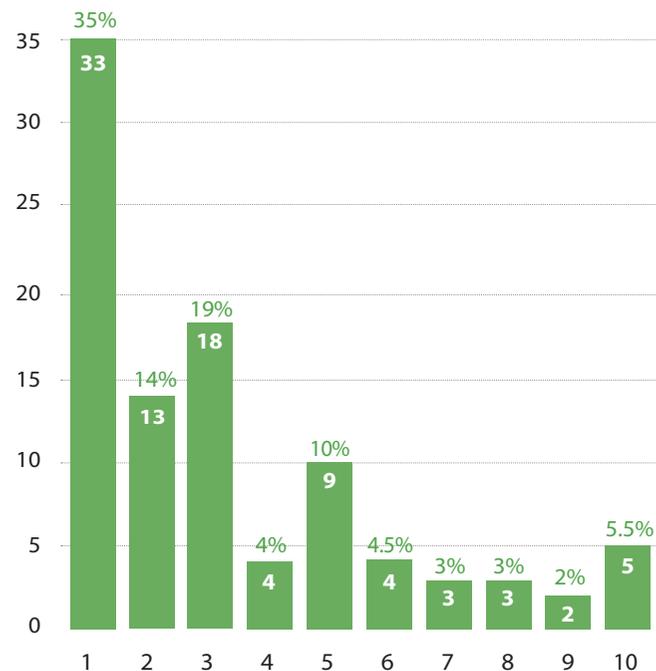
QoL: 1= Never, 2= 1/week, 3= 2-3/week, 4= 1/day, 5= >1/day, 6= at all time

FIGURE 7:
SUI Impact on Quality of Life.

before treatment:



After treatment:



QoL: 1 = minimum, 2-9* = various degrees, 10 = terrible. *As defined by patients, on a scale of 1-10.

Discussion

While no single therapy is optimal for all patients with various types of UI, when selecting an appropriate intervention, some symptomatic relief will be achieved. Oftentimes, the choice of intervention is made by the patient after appropriate diagnostic evaluation and counseling. Traditionally, treatment was tailored based on UI classifications, urodynamic testing and clinical staging. However, some argue that this concept now seems outdated in the era of so many non-surgical solutions and minimally invasive treatment options, especially for mild to moderate SUI.

Recent reports of the favorable impact of Fractional/Pixel laser-elicited vaginal rejuvenation, has added this treatment concept to the caregiver’s armamentarium. Ogrinc et al. [8] showed that deployment of the non-invasive Er:YAG laser brought to a lasting positive effect in 175 women suffering from SUI symptoms. Using the same laser system in a prospective International Consultation Incontinence Questionnaire – short form (ICIQ-SF)-based analysis of treatment effect on 42 women with SUI, Pardo et al.

[9] concluded that the procedure is safe and efficacious. The outcome of these two studies was corroborated by Fistonc et al. [10], who studied the safety and mechanism of action of the treatment in a group of 31 women, with follow-up of 6 month. In a prospective study Fractional/Pixel CO₂ laser treatment of 30 women presenting

genitourinary syndrome of menopause – GSM, Sokol and Karram concluded that the treatment is effective and safe [11]. Histological evaluation of the effects of microablative Fractional/Pixel CO₂ laser treatment has shown that this technique can stimulate vaginal connective tissue remodeling without damaging surrounding tissue [12]. The CO₂ laser was shown to improve the vaginal health of postmenopausal women by inducing repopulation of the vagina with Lactobacillus species, restoring the normal flora to its premenopausal status, and decreased vaginal pH from a mean of 5.5 to 4.7 [13].

This retrospective chart analysis confirms the efficacy of the pixel CO₂ laser in treating symptomatic, mild to moderate urinary incontinence, and to improved vaginal laxity. Meaningful impact was noted on patient’s quality of life, resulting from reduced urine leakage related to coughing, sneezing and physical activity. Using the 1-10 “subjective personal scale” might not be the most scientific mode of evaluation, however, since each patient used the same “personal” score, and served as her own control, the combined data is important and consequential to this group of patients.

The ease of the procedure, impressive outcome, and minimal side effects, render this new modality a viable option for the treatment of urinary incontinence and other GSM symptoms. A prospective study on similar parameters is in progress.

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