



## URODYNAMIC CHANGES FOLLOWING THE USE OF FRACTIONAL CO<sub>2</sub> LASER THERAPY IN FEMALES WITH MIXED URINARY INCONTINENCE – A PILOT STUDY

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### Abstract

**Objective:** A pilot study was conducted to determine the efficacy of fractional CO<sub>2</sub> laser intravaginally for the management of mixed urine incontinence (MUI).

**Materials and methods:** This is a prospective, experimental study. An overall of 13 patients with confirmed urodynamic MUI were included. All patients received two sessions of FRAXIS fractional CO<sub>2</sub> laser, model FRX-C1 separated by 4 weeks. Three months after second laser therapy, Patients were requested to come in for a clinical evaluation by urodynamics. Also, adverse events were recorded.

**Results:** Approximately two thirds of patients reported variant degrees of improvement up to 3 months after the second laser session [5 (38.5%) patients showed improvement od MUI symptoms and 3 patients stated that they have no more incontinence (23.1%)]. Furthermore, urodynamics study showed that 3 patients had no more SUI by Abdominal Leak Point Pressure (ALPP) and 2 patients had no Detrusor Overactivity (DO). During the course of the study, there were no major adverse events.

**Conclusions:** the use of Transvaginal fractional CO<sub>2</sub> laser may be an effective treatment for MUI. It is expected to be a less invasive, safe, and quicker-recovery alternative to traditional management.

**Keywords:** bladder symptoms; urinary mixed incontinence; urodynamic assessment; vaginal CO<sub>2</sub> laser.

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## 1. BACKGROUND

In women, the prevalence of urinary incontinence (UI) is 45%<sup>1</sup>. UI can have negative effects on one's social, physical, emotional, and sexual health, and can cause depression as well as social isolation<sup>2-3</sup>. As a result of stigma along with embarrassment, many women stop getting healthcare when they need it<sup>4</sup>.

Stress incontinence as well as urgency incontinence are the two most common forms of urine incontinence. The International Continence Society (ICS) in addition to the International Urogynecological Association (IUGA) agree on a definition for stress urinary incontinence (SUI) as the involuntary release of urine caused by coughing, sneezing, or just physical exertion, and for urge urinary incontinence (UUI) as the involuntary release of urine caused by an urgent need to urinate that cannot be delayed. Due to the high prevalence of both forms, they are frequently found together in a pattern known as mixed urine incontinence (MUI)<sup>5</sup>.

First-line care options for UI in women suggest non-invasive solutions include behavioural therapy, pelvic floor muscle exercise, as well as functional electrostimulation of the pelvic floor (FES)<sup>5</sup>. Surgery to reinforce the urethra or to improve the bladder capacity is commonly used to treat UI, but this operation is not without a number of risks and complications<sup>6-7</sup>.

Recently, investigators have found transvaginal laser as a less invasive treatment tool for UI<sup>8</sup>. The laser's ability to cause thermal changes in tissues may trigger an inflammatory healing cascade, leading to changes in histology, cytology, metabolism, as well as gene expression that regenerate and remodel tissues through increased collagen synthesis as well as structural remodelling of collagen fibers<sup>9-10-11</sup>.

In this study, we described the preliminary findings of the vaginal CO<sub>2</sub> laser to treat women with MUI.

## 2. METHODOLOGY

a single-centre prospective experimental pilot study recruited 13 women having MUI received transvaginal CO<sub>2</sub> laser during period from Jan 2022 to March 2023. Participants were given a written informed consent before treatment. The study protocol and urodynamics for the outcome measurement got approval by the Research Ethics Committee of National Research Centre in Egypt with approval number (16/070). The patients who participated in the study received no financial compensation.

**Inclusion criteria** involved women who reported symptoms of MUI (urgency besides frequency, urge form as well as stress form UI) and urodynamics findings of MUI (Abdominal leak point pressure (ALPP) with values more than 60 cmH<sub>2</sub>O and detrusor overactivity (DO)). It is worth mentioning that patients with ALPP values less than 60 cmH<sub>2</sub>O reflect more severe stress incontinence and suggest that there is intrinsic sphincter deficiency and advanced prolapse which in most cases require invasive management.<sup>12</sup>

**Exclusion criteria** involved pelvic organ prolapse stage > II based on the pelvic organ prolapse quantification (ICS- POP- Q) system (to ignore severe prolapse, for which surgery is usually the preferred therapeutic option), existing malignancy, well-known dysplasia of the cervix, acute urinary tract infections, active genital infections, past history of heat- brought herpes virus infection previous pelvic reconstructive surgery, chronic conditions that may affect study participation, current pregnancy, undiagnosed abnormal uterine bleeding.

• **Study procedure:**

All participants underwent: complete history taking, general and abdominal examination, pelvic examination including assessment of the degree of uterovaginal prolapse according to POP-Q system, and the exclusion of vaginal injury and/or pathology, complete urine analysis, pelvic ultrasound to exclude organic lesions, and urodynamic studies with ALPP more than 60 cmH<sub>2</sub>O and detrusor overactivity for all patients.

In this study, we used the Laborie, Solar blue wireless urodynamic suite. With the patient seated, we introduced a 6Fr double lumen catheter transurethraly entering the bladder while recording a water cystometry at a fluid rate of 20 ml each minute. A rectal catheter was inserted into the rectum to measure abdominal pressure at the same time. A number of urodynamic variables were assessed: Bladder sensations (volume of 1st desire to void, normal desire to void, strong desire, as well as urge to void). Maximum Cystometric Capacity (MCC) (ml): Whenever a patient exhibiting normal sensation reaches a point where she can no longer hold her urine, her bladder has reached this volume. Maximum Flow Rate (Q<sub>max</sub>) (ml/sec): is the highest flow rate that was measured. All patients

had Q-max over 20 ml/sec to exclude bladder outlet obstruction. Abdominal leak point pressure (ALPP) (cmH<sub>2</sub>O): it is a dynamic test to determine the minimum intravesical pressure required to induce urine leakage in a lack of detrusor contraction, Detrusor overactivity: when the detrusor muscle contracts involuntarily during a cystometric filling. On the cystometrogram, such contractions (which can be either spontaneous or induced) appear as a wave form of varying duration as well as amplitude, and Post-void residual (PVR) is the amount of urine remaining within the bladder after urination has stopped, expressed in milliliters (mL).<sup>13</sup>

All participants underwent transvaginal laser treatment (FRAXIS fractional, gynecological, and surgical CO<sub>2</sub> laser, model FRX-C1, with RF laser tube with the patented Gynolaser applicator including the I-slide applicator), with the following settings in the first treatment session: energy level of 72 mJ, distance 0.8mm, I-stack 1-2 and overlap 1x. In the second session, the energy level increased by 20% to 102 mJ.

Overall, patients received two treatments, four weeks apart. Before treatment, the vaginal canal was cleaned and dried, in order to avoid reduction in the penetrability of the tissue by laser beams. No oil or gel was used before insertion of the applicator. Vaginal treatment consisted of the use of the applicator with the patented I-slide applicator. The applicator was lightly introduced into the vagina until the tip hits the distal end of the vagina. A burst of laser pulse was fired, then (rotation of the handpiece clockwise I notch (30o) and firing again was done 7 times) so that a full circle rotation of 360o was achieved. Then the handpiece was retracted 8mm and rotation and firing repeated 7 more times to complete another circle. The same procedure repeated several times until the applicator retracted to the introitus. For the next 72 hours, patients were asked to stay away from all sexual activity. No medicine was given to the patients after each treatment session. Patients received treatment twice, with an interval of 28 days between sessions to avoid treatment during the patient's menstrual cycle. Following each laser treatment, patients were instructed to wait five days before engaging in sexual activity there.

Follow-ups were scheduled for three months following the end of two treatment sessions. Subjective outcomes were recorded in the form of (cure, improved, same and worse). On the other hand, objective outcomes were recorded in the form of urodynamics for all participants. Adverse events were also recorded and classified in to 3 categories: a- During application of laser probe, b- immediately after application and c- few days after the procedure.

**Statistical analysis** executed by using Megastat® (Microsoft 365 latest version for education)

whereas graphs was plotted by R version 4.2.1. Numerical values are expressed as mean and standard error (mean ± SE) whereas count and percentage (count (%)) was used to express categorical variable. Furthermore, paired values were compared with paired t test (Pt) if the parametric assumptions met otherwise Wilcoxon sign ranked test (W) were used. In the case of comparing paired categorical variables, Fisher's test (F) was executed by R version 4.2.1. In all tests, p-Value less than 0.05 is considered significant.

### 3. RESULTS

**Table 1 and 2** reveals demographic data of the patient in the group who completed 3 – months of following-up. The mean age was 42 (ranging from: 27: 58) years old, parity was 2.5 (1–4), and the mean BMI was 33 (21-41). As shown in **Table 2**, around two third of patients (61.5%) used to drink a cup or more of caffeine per day, and only 15.4% were smokers.

**Table (1):** Demographic characteristics of the study population. Data are given as mean ± standard error (SE)

Variable	Mean ± SE	(Min: Max)
Age (years)	42±2.5	(27: 58)
BMI	33±2.0	(21: 41)
Parity (number)	2.5±0.31	(1: 4)

**Table (2):** Baseline habitual characteristics of the study population. Data are given as count %

Variable	Categories	Count (%)
Caffeine (cups/day)	0	2 (15.4%)
	1-2	11(84.6%)
Smoking	No	12 (92.3%)
	Yes	1 (7.7%)

There were no major side effects during the treatment or the 3-month follow-up. Minor side effects that were concerned to treatment were classified as follows: During application, most of the population (76.9%) didn't suffer from any adverse effects, although the other quarter had mild discomfort (23.07%). Furthermore, most of patients (92.3%) didn't find any adverse effects

immediately after application whereas only one patient (3.3%) had vulval discomfort. However, more than two third of patients didn't have any adverse effects in the first few days after application, where about one third (30.8%) suffered from change in vaginal discharge and only one patient had both dysuria and change in vaginal discharge (0.07%) **Table 3**.

**Table (3):** Adverse events during, immediately and few days after application of laser therapy. Data are given as count (%)

During application		Immediate after application		First few days after application	
None	10 (76.9%)	None	12(92.3%)	None	8(66.6%)
Mild Discomfort	3(23.07%)	Vulval discomfort	1(0.07%)	Change in vaginal discharge	4 (30.8%)
				Change in vaginal discharge & dysuria	1(0.07%)

Data are given as count (%).

Our preliminary results showed that more than two thirds of patients reported variant degrees of improvement in their condition as follows: 23.1% stated that they have no more incontinence, and

38.5% reported some improvement in the condition. However, the remaining (38.5%) of participants were neither improved nor worsen as shown in **Table 4**.

**Table (4):** Improvement status of the patients

Improvement status			
Cure	Improved	Same	Worse
3 (23.1%)	5 (38.5%)	5 (38.5%)	None

As far as urodynamics before and after laser therapy is concerned, the following changes were recorded in table 5. Bladder sensations showed the

following changes: First desire increased from 118±14.4Cm prior to therapy to 137±16.4 Cm which were statistically insignificant P value 0.19

Pt). On the other hand, strong desire and bladder capacity were increased from 238±22.9 and 259±25.8 before treatment to 274±23.1 and 302±26.7 3 months after the second laser therapy respectively which were statistically significant (P values 0.039 W and 0.019 Pt).

On the other hand, ALPP (which represents the stress component of MUI) showed no leakage in 3 patients (23.1%) 3 months after laser therapy. However, the other 10 patients mean ALPP increased from 73.2±3.31 to 75.7±3.55 which is

statistically non-significant. On the other hand, Detrusor overactivity (which represents the urge part of the MUI) showed no leakage in only 2 patients (15.4%). Which is also statistically insignificant (P value 0.240 F)

Despite the need for further randomized, controlled, as well as prospective data with a greater number of individuals and also longer follow-up, these findings suggest that the CO<sub>2</sub> vaginal laser may be a potential option in treatment mild to moderate mixed UI.

**Table (5):** Pre and post treatment comparison

Variable	Pre	Post	P-value
Q-max	24.7±0.74	26.3±1.04	0.02 <sup>F</sup>
First desire (ml)	118±14.4	137±16.4	0.19 <sup>Pt</sup>
Strong desire (ml)	238±22.9	274±23.1	0.039 <sup>W</sup>
Bladder capacity (ml)	259±25.8	302±26.7	0.019 <sup>Pt</sup>
ALPP (CmH <sub>2</sub> O) *	73.2±3.31	75.7±3.55	0.833 <sup>W</sup>

**Table (6):** comparing count and percentage of ALPP and Detrusor overactivity pre and post to laser therapy

Variable	Pre	Post	P-Value
ALPP: No Leakage	0(0%)	3(23.1%)	0.110 <sup>F</sup>
Absence of Detrusor overactivity	0(0%)	2(15.4%)	0.240 <sup>F</sup>

#### 4. DISCUSSION

This pilot study utilized a complete subjective and objective evaluation of vaginal CO<sub>2</sub> laser on patients suffering from MUI for 3 months.

Within the 3-month follow-up, 61% of patients reported improvement, half of them reported complete cure, indicating that the positive subjective improvement persisted for at least 3 months.

There were also objective improvements in urodynamic study 3 months post second laser therapy in 3 main points: 1) Bladder sensations and maximum bladder capacity: our study showed improvement in bladder sensations and maximum bladder capacity after the second laser therapy. Although First desire improvement was not statistically significant, the changes in the strong desire as well as bladder capacity were statistically significant. 2) ALPP (the test performed to provoke urinary leak in lack of a detrusor contraction to diagnose the stress component of MUI) was done before and after laser treatment. 3 out of 13 patients (23.1%) showed no leakage at all. 3) Detrusor overactivity also recorded before and after laser treatment. Two out of 13 patients (15.4%) showed no leakage at all.

There are a number of non-invasive methods for treating MUI, but they all rely on the patient participation. Pessaries (an intravaginal device that raises the vesico-urethral angle) as well as pharmaceuticals such as serotonin and

noradrenaline reuptake inhibitors (SNRIs) along with topical oestrogen are examples of such strategies that can improve urethral sphincter muscle tone. Pessaries are a frequent solution, but they come with their own set of problems, such as the discomfort of having to insert and remove the devices on a frequent basis, the high expense, and the low rate of compliance seen with behaviorally based therapy<sup>14-15</sup>.

Previous studies, such as that by **Blaganje et al.**<sup>16</sup> which found that 21.4% (12/56) of individuals in the laser group were dry three months following one session of Er:YAG laser treatment, and also by **Bizjak-Ogrinc et al.**<sup>17</sup> which found that 60% of 175 women suffering from SUI or mixed incontinence informed no incontinence following two sessions, and that this stage stayed identical at the 12-month follow-up, provide support and expansion.<sup>17</sup> Moreover, it is also similar to **Alcalay et al.**<sup>18</sup> who evaluated 52 individuals suffering from SUI, 48 of whom finished a 6-month follow-up along with 42 of whom finished a 12-month follow-up, after receiving a total of 3 Fractional - Pixel CO<sub>2</sub> laser treatments. At 3 months, PGII improved by 75.0%; at 6 months, by 61.9%; and in 12 months, by 64.3%. From beginning to 12 months, PFDI increased significantly and continuously (37.2 ± 3.89 to 16.1 ± 3.7, <0.05). Similar results were seen with PFIQ, which improved significantly after the first treatment and persisted for 12 months<sup>18</sup>.

However, **Dabaja et al.** found that vaginal CO<sub>2</sub> laser was not as beneficial, and that measurements had returned back to baseline after 6 months.<sup>19</sup>

Our results were inferior to, **Alcalay et al.** who showed that at the 6 months follow-up, out of 29 patients who received repeat urodynamic testing, 12 (or 41.4% of the total) no longer leaked. Patients with leakage showed no change in mean CLPP (117) or VLPP (104) from starting at 6 months. This might be related to the number of laser sessions as they had 3 laser sessions and the limited number of patients.<sup>17</sup>

Our findings suggest that the fractional vaginal CO<sub>2</sub> laser could be used as a conservative treatment option for MUI and should be considered a viable therapeutic method in the management toolbox.

Epithelium as well as lamina propria are two layers of vaginal tissue that the vaginal CO<sub>2</sub> laser is recognized to influence. Although vaginal CO<sub>2</sub> laser's impact on tissue is well documented, its mechanism of action on urine incontinence is unknown. Collagen denaturation, shortened collagen fibrils, as well as following collagen remodeling and neogenesis have all been hypothesized as mechanisms by which laser treatment alters tissue laxity. The treatment has been shown to increase urethral support 20, which may be due to a change in collagen composition. Others have found that variations in intravaginal pressure alter the vaginal muscle contractions, therefore increased muscle strength could be a possible explanation.<sup>16</sup>

Our study followed a treatment procedure that was consistent with the manufacturer's recommendations for the laser equipment utilized, and was also consistent with methods advised by other laser manufactures. However, many questions remain about the efficacy of vaginal laser treatment for stress as well as mixed urinary incontinence, including whether or not only the anterior vaginal wall needs to be treated (as we performed in our study), how long between treatments the patient should wait and number of sessions.

It is widely accepted that the laser's trophic impact on vaginal tissue gradually wears off over time; regular maintenance treatments are required to maintain the desired outcome. **González et al.** found that a 3-year clinical impact may be maintained with extra annual treatment.<sup>21</sup>

**Athanasiou et al.** demonstrated that greater than three sessions could provide a better therapeutic benefit than three sessions in menopausal women, while **Pitsouni et al.** found that 3 treatment sessions are suggested in the majority of treatment protocols<sup>22,23</sup>. The majority of studies are lacking long-term follow-up as well as control groups, although a recent consensus report published by **Alshiek et al.** indicated that short-term improvement could be achieved after a fractional laser<sup>24</sup>.

Our study has limitations due to the fact that it is a pilot study with a small sample size. Furthermore, there were many patients who did not complete the study's follow-up mainly due to noncompliance, and it wasn't a comparative evaluation of alternative treatment approaches. However, the strength of our study is the use of urodynamics as an objective outcome. Therefore, further evaluations in a larger sample size and during a longer follow - up period, is required. Studies should consider not only how long participants report feeling better, but also how long they report needing follow-up care.

## 5. CONCLUSION

Based on our pilot study, fractional CO<sub>2</sub> intravaginal laser may help reduce symptoms of mild MUI. The fractioned CO<sub>2</sub> intravaginal laser is a non-surgical option for alleviating the symptoms associated with MUI. Our findings show that additional studies are required to determine the efficacy of vaginal laser treatment as an adjunctive therapy for MUI, and we recommend that this study include comparisons to pelvic floor exercises as well as other ambulatory treatments.

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