



## Stress Urinary Incontinence Treatment Using Vaginal Fractional CO<sub>2</sub> Laser (10600nm)

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**Abstract:** Stress urinary incontinence (SUI) is involuntary urine leakage during activities that increase abdominal pressure such as coughing, sneezing and lifting of heavy weights. This is a very common disorder among women with history of multiple vaginal deliveries with an obstructed labor. SUI is considered one of the most distressing problems, especially for younger women, with severe quality of life implications, it caused by the loss of urethral support, usually as a consequence of the supporting structural muscles in the pelvis. **Objective:** To prove and demonstrate the effect of a fractional CO<sub>2</sub> micro-ablative laser (10600nm) in intra vaginal therapy for treating SUI and achieve a clinical improvement of the urogenital system support. **Methods:** This is a prospective, observational study which was conducted over six month from the 1<sup>st</sup>. of July to 29<sup>th</sup> of December 2016 in Consultation Gynecologist Clinic in Al-Hila city, Iraq, in patients who complain of SUI. Twenty female patients were included in the study, their age ranged from 30-69 year, at range (49.5 year ) fifteen patient delivered vaginally, two delivered by cesarean section, two had combined delivery and one was Nulliparous ,all of them received the same treatment protocol. Detailed history about continence assessment, quality of life and sexuality before and after therapy. The fractional CO<sub>2</sub> Aphrodite laser was used. The parameters used in each session were energy/(dot)pixel 119.4mJ, pulse duration 900 μs, frequency 1000Hz, and exposure time 300ms /shot with average of shots 34 and in range 26-42, in three sessions four weeks apart between them. The patients were followed for three months started from the beginning of the second session to one month after the last session. **Results:** Thirty-five percent of patients 35%(n=7) were cured ,and these 35% included all patients delivered by cesarean section and one third of patients who delivered vaginally and extensively most of patients were 60%(n=12) improved of their SUI. Patient reported no leakage any more while coughing or sneezing. Only 5%(n=1) not responded was menopause women. **Conclusions:** This study shows that micro-ablative fractional CO<sub>2</sub> laser is effective can produce a remodeling of vaginal connective tissue without causing damage to surrounding tissue and the group of patients with continence disorder without vaginal delivery achieved marked improvement .

**Keywords:** Fractional CO<sub>2</sub> laser, Stress urinary incontinence, Pelvic organ prolapse.

### Introduction

Urinary incontinence affect millions of people worldwide, seriously impairing their quality of life[Jorge Alberto Elías MD. et al., 2015]. Epidemiology of urinary incontinence in western societies is 5-55% and stress urinary

incontinence (SUI) represent 29-75% of cases.[John O. schorge, ., et al.,2008] SUI is a complaint of involuntary loss of urine with physical exertion (i.e. , walking, straining, exercise) or with sneezing/coughing or other activities that cause arise in intra-abdominal

pressure.[ Alan j. Wein , et al.,2016 ] It is usually a result of weakness/disruption of the pelvic floor muscle and ligaments leading to poor support of the vesicourethral sphincteric unit[Jack W. Mcaninch, et al., 2013 ] Risk factors include age, Long Term Care Functional screen( LTCFs), pregnancy and postpartum, parity ,race/ethnicity, hormonal therapy, obesity, smoking and medical conditions such diabetes and depression.[ Alan j. Wein , et al.,2016 ] The main treatment options for SUI consist of either minimal invasive surgery: Urethral bulking injection therapy and retropubic suspension using laparoscopy or robotic assistance or more invasive surgery: Open retropubic suspension and Sling.[ Alan j. Wein , et al.,2016 ]

A new idea that has recently been applied for improving or treating female stress incontinence involve the application of CO2 laser in patient with symptoms of relaxation of the pelvic floor and the vaginal wall under the urethra.[ Bader Alexandros 2015]

#### **The Rationale for laser treatment for SUI:**

The endopelvic fascia is rich in collagen, making up 80% of its protein content [Fistonic, N., et al.2015,]. Collagenesis decreases with the aging process but is also affected by the destruction of collagen fibrils due to vaginal birth [Mannella, P., G. Palla, and M. Bellini;2013 ] and can even be associated with certain genetic polymorphisms[Campeau, L., et al., 2011]. One theory suggests that SUI occurs due to an alteration of collagen arrangement and metabolism.[ Chen, B. and J. Yeh, 2011] .Pelvic organ prolapse( POP) and SUI patients had diffuse atrophy of smooth muscles, active fibroblast metabolism, swollen metabolism and visible Golgi apparatus. The collagen fibril diameters were greater and the levels of Type I and Type III collagen were significantly lower in the SUI and POP group. Lastly, pelvic tissues were frail and smooth muscle cells were disorganized. [Chen, Y., et al.,2004 ]. This suggests that increased breakdown, rather than decreased synthesis, may be responsible for these changes. In fact, these hyper metabolic changes may be a result of increased fibroblast activity and subsequent increased fibroblast secretion of matrix metalloproteinase 1 (MMP-1), the enzyme responsible for collagen breakdown [Colaco, M., J. Mettu, and G. Badlani, 2015]. Application of the CO2 laser to vaginal canal, can yield healthier and more elastic tissue of the anterior wall which in turn,

may serve as a strong support to the urethral support mechanism. In addition, the external treatment to the vestibule area, may penetrate to the lower pelvic floor muscles, and supply a more comprehensive treatment that can increase the elasticity of the pelvic floor muscle, and potentially increase the efficacy of the external urethral sphincter, yielding again, better support, and potentially better control of urine emptying .[ Jamie M. Bartley ., et al.,2016]

#### **Patients, materials and method**

In this prospective study which was conducted over six month from December 2016 in Consultation Gynecologist Clinic in Al-Hila city, Iraq

#### **Patients selection**

Twenty patients women complaining of SUI with two to five years duration were recruited via gynecologist clinic advertisements. The features of the trial were well explained and the patient provided informed signed consent before treatment.

#### **Clinical assessment includes:**

##### **History**

- 1- The degree of leakage; its relation to activity, position, and state of bladder fullness; the timing of its onset, and the course of its progression.
- 2 - Past surgical and obstetric history.
- 3 - Medications taken such  $\alpha$ -blocker (e.g. prazosin) and dietary habits.
- 4 - Systemic diseases such diabetes mellitus.
- 5 - History degree of bother and effect on quality of life

##### **Examination**

- 1-Inspection of external genitalia.
- 2-Per-vaginal exam was demonstrated the laxity of pelvic support, presence of any degree of prolapse, cystocele and mobility of the anterior vaginal wall.
- 3-Casco-speculum examination.
- 4 -Stress test in supine and standing positions to demonstrates SUI.

Stress test: The patient was examined with a moderately full bladder in the lithotomy position while observed the urethral meatus, the patient was asked to cough. SUI occur if short spurts of

urine escaped simultaneously with each cough. [Neville F. Hacker, et al., 2010]

**ISI : Incontinence Severity Index for urinary incontinence:**

**Question 1:How frequent are the episodes of urine loss?**

- (1)less than once a month.
- (2)one or more times a month.
- (3) One or more times a week
- (4)every day.

**Question 2:How much urine is lost each time?**

- (1)1drop or less
- (2)2 drops or more

**The Severity Index is the product of the answers to Question 1&2:**

- 1-2:mild urinary incontinence
- 3-4:moderate urinary incontinence
- 6-8:sever urinary incontinence.[<https://www.pdfFiller.com>]

**Investigations**

**\*General urine examination with, culture and sensitivity** to exclude urinary tract infection.

**\*Pelvic ultrasound** to exclude poor bladder empty (i.e. post void residual) and bladder pathology.

Fifteen patients were with moderate severity of stress urinary incontinence and five patients were with mild severity.

**Exclusion cases:**

- 1.Women with urinary tract infection
- 2.Neuropathic diseases
- 3. Pelvic muscle diseases
- 4.Pregnant women
- 5.Women equal and over to70 years.
- 6. Severe stress urinary incontinence (6-8 score of ISI )
- 7.Advanced genital prolapse
- 8.Injury and/or active infection in treated area.
- 9. Women with undiagnosed uterine bleeding.

**Table (1): Patients distribution regarding age and mode of delivery.**

Age of patients (year)	No. of the patients	No. mode of delivery			Nulliparous
		No. of vaginal delivery (only)	No. of cesarean delivery (only)	No. of combined delivery (vaginal and cesarean)	
30-39	9	9	0	0	0
40-49	6	3	2	1	0
50-59	4	3	0	1	0
60-69	1	0	0	0	1
<b>Total</b>	<b>20</b>	<b>15</b>	<b>2</b>	<b>2</b>	<b>1</b>
<b>percentage %</b>	<b>100%</b>	<b>75%</b>	<b>10%</b>	<b>10%</b>	<b>5%</b>

Twenty patients at different age group arranged in four classes, 75% of them were delivered vaginally and 10% delivered by cesarean only and 10% have combined delivery with 5% was

nulliparous , as show in table (1) 95% of them were grand multipara and 5% was nulliparous .

**Parameters used:**

The parameters used in the procedure were the following:

- power:** max. output, continuous: 40 W
- \* **Frequency :**1000Hz\* Interval time:4 week
- \* **Pulse duration :**900 μs
- \* **Exposure time:**300ms
- \* **Energy/dot(pixel):**119.4mJ
- Pass:** two pass
- \* **Total session:**3

**Total duration of each application was 10 min. to completion.**

**Pre-treatment instruction:**

Preparation of the patients: two days after menstruation and later on period.

**Procedure treatment**

Include the following:

- 1.Few minutes before starting, asked patient to empty bladder.
- 2.In lithotomy position.
- 3.Mobing vagina with piece of cotton socked with normal saline.
- 4.Insert 25mg lidocain cream at the introits, then ask the patient to wait 10 mint to anaesthetized area.
5. Wearing the Google and safety glass to the patient.
6. Introduced SUI hand piece to the vagina ,at the median anterior vaginal wall from up down to the introits with half centimeter withdrawing to the outside completed with two passes, delivering laser energy to each irradiation location.
7. The operative time was 10 minutes to complete.



**Fig. (1):** vaginal CO2 laser during operation.

**Post-operative instruction**

All patients were advised to avoid intercourse 3 days only and no need any medical treatment.

**Results:**

Twenty patients at age range between 30 – 69 year with average 49.5 year , 95% of them had parity and 75% of them were delivered vaginally, 10% of them delivered by cesarean and 10% had combined delivery, the remaining 5% was nulliparous.

Regarding response to laser treatment from those 95% of patient ,35% of them had marked resolution including all patients delivered by cesarean and third who were delivered vaginally , that was during the period of the follow up (three month ).

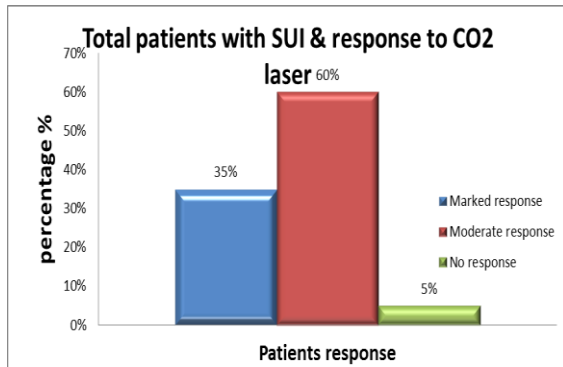
And 60% had moderate resolution including all patients had combined delivery and two third of patients delivered vaginally and 5% had no response who was nulliparous as show in table (2).

**Table (2): Patients distribution and response to laser treatment**

Patients		Average	Range	Marked improvement	Moderate improvement	No resolution
Age		49.5	30-69			
Parity	19	6.15789	4-10	7(35%)	12(60%)	
Vaginal	15	6.2	4-10	5(25%)	10(50%)	
Cesareans	2	5	4-6	2(10%)	0	
Vaginal-cesarean	2	7	6-8	0	2(10%)	
Nulliparous	1					1
<b>Total</b>				<b>7 (35%)</b>	<b>12(60%)</b>	<b>1(5%)</b>

Sample is represented in table (2) show the influence of parity and the relationship with vaginal delivery is clearly seen.

Upon analysis of stress incontinences symptoms only (35%) marked improvement (n= 7) and moderate improvements (n= 12), were observed, demonstrating a resolution rate of 60% as show in (Figure 2.1).



**Fig. (2):** Total patients with SUI and response to CO<sub>2</sub> laser.

#### Follow up:

The patients were followed for three months starting from the second visit i.e. before doing the 2<sup>nd</sup> session and continue for one month after last session. The total sample (n=20) had stress urinary incontinence, (5) patients started to d response after one session, most of them (14) were starting improvement after two sessions and with one case not improved after three sessions was being referred for surgery

#### Discussion

When discus current study results, found most of the patients in current study 15, (75%) where delivered vaginally ,vaginal childbirth is the most frequently cited risk factor associated with POP[John O. schorge, ., et al.,2008] . POP and SUI patients had diffuse atrophy of smooth muscles [Chen, Y., et al., 2004] . Childbirth may result in damage to the pelvic floor musculature as well as injury to pudendal and pelvic nerves [Keith Edmonds ;2007]. Pelvic floor dysfunction (PFD) can also lead to POP, POP and SUI coexists in 15 to 80 percent of women with PFD. [ Bai SW 2002].

Application of the CO<sub>2</sub> laser to vaginal canal, can yield healthier and more elastic tissue of the anterior wall which in turn, may serve as a strong support to the urethral support mechanism.[ Jamie M. Bartley., et al.2016]

Regarding the response of patients who delivered by cesarean 2, (10%) were markedly improved this may be due to absence of mechanical injuries and denervation of pelvic floor that cause by vaginal delivery[Sally Collin., et al.,2010] [Bader Alexandros 2014]., in addition to the effects of lasers are well established in terms of biochemical, ablative and thermal effects. Thermal energy from the laser source, especially in moist environments, enhances collagen structure and stimulates neocolagenesis. [Mohamed M Khalafalla1, ., et al., 2015 ]. Cesarean section, when compared to vaginal delivery, appears to confer an advantage with regard to the later development of urinary incontinence. This advantage may be lost with even one vaginal delivery in addition to the cesarean section [Alan j. Wein , et al.,2016 ].

Regarding the age, found the high percent of women with SUI coming at age ranged (30-49 year) which represent 15, (75%) most of them 12, (80%) are vaginally delivered .

Regarding the multiparty ,all the women 19, (95%) were grand- multipara and 15 (78.94%) of them delivered vaginally, that is mean the most predisposing factor for SUI is multiparty and the explanation of that frequent pregnancy cause frequent stretching effect on pelvic floor muscle that lead to weakness of the pelvic floor muscle. Numerous studies have clearly shown that childbirth does increase women propensity for developing POP[ John O. schorge, ., et al.,2008 ]. When we compares with other study, the influence of parity and the relationship with vaginal delivery is clearly seen.[ Jorge Alberto Elías MD. et al., 2015].

#### Conclusion

We have concluded that the laser is an effective and safe in treatment of stress urinary incontinence and that patients find it comfortable and noninvasive.

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## علاج السلس البولوي الاجهادي باستخدام ليزر ثنائي اوكسيد الكربون التجزيئي المهبلي (10600 نانومتر)

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**الخلاصة :** الخلفيه: السلس البولوي الاجهادي هو نزول الادرار بصورة لا ارادية خلال نشاطات التي تزيد من ضغط البطن الداخلي مثل السعال ، العطاس وحمل الاوزان الثقيلة . يعتبر السلس البولوي الاجهادي من الاضطرابات الشائعة جدا بين النساء اللواتي لديهن تاريخ ولادات طبيعية متكررة او عسر ولادة وهو يعتبر من اكبر المشاكل المزعجة وخاصة النساء الشابات مع تأثير كبير على نوعية ومتطلبات حياتهن ويحدث ذلك بسبب فقدان الاسناد الاحليلي البولوي نتيجة لفقدان الاسناد التركيبي العضلي في الحوض. **الهدف من الدراسة :** لاثبات وتبيان تأثير ليزر ثنائي اوكسيد الكربون (10600 نانومتر) المجزئي في العلاج المهبلي الداخلي لعلاج السلس البولوي الاجهادي والحصول على تحسن السريري لاسناد الجهاز البولوي . **الطريقة والعمل :** هي دراسة حالية رقابية تمت خلال ستة اشهر ابتداء من الاول شهر تموز الى التاسع والعشرين من شهر كانون الاول سنة 2016 في العيادة الاستشارية النسائية في مدينة الحلة للمرضى الذين جاءوا بسبب السلس البولوي الاجهادي. كل المرضى الذين يبلغ عددهم عشرون مريضا تم ادخالهم في الدراسة . النساء اللواتي تم تضمينهم هم في عمر يتراوح ما بين (30-69) سنة ، جميع النساء تم اعطاءهم نفس البروتوكول العلاجي وتم اخذ التاريخ المرضي كاملا للجميع لغرض تقييم السلس البولوي الاجهادي وطبيعة الحياة المعيشية والجنسية قبل وبعد العلاج لليزر ثنائي اوكسيد الكربون (النبضي) الذي استخدم. **المقاييس التي استخدمت في كل جلسة كانت :-** طاقة النبضة : 119,4 ملي جول ، عرض النبضة : 900 مايكرو ثانية ، التردد : 1000 هيرتز ، وقت التعرض : 300 ملي ثانية ، معدل الجرع : 34 جرعة ويتراوح بين 26 – 42 جرعة في ثلاث جلسات مع فارق 4 اسابيع بين الجلسات ، **النتائج:** 35% من المرضى تم شفاءهم ومعظم المرضى كانوا قد تم تحسنهم من السلس البولوي الاجهادي وقد ذكر المرضى في عدم نزول الادرار حينما يحدث السعال او العطاس وعند تحليل الولادات طبقا لطريقة الولادة وعمر المريض تم ملاحظة شفاء 25% من النساء اللواتي تم شفاءهن قد ولدن ولادة طبيعية . 10% منهن ولدن ولادة قيصرية 60% من المرضى كانوا قد تحسنا ، 50% منهم قد ولدن ولادة طبيعية ، و 10% منهن يمكن كل من ولادات طبيعية وقيصرية . فقط 5% من المرضى لم يتم استجابتهن وقد كانوا في سن اليأس . **الاستنتاج:** توضح لنا هذه الدراسة ان ليزر ثنائي الكربون يستطيع ان ينتج تجديد في النسيج اللبني المهبلي بدون ان يسبب تلف للانسجة المحيطة وان مجاميع المرضى الذين يعانون من اضطرابات السيطرة البولية يحصلون على تحسن ملحوظ بدرجة عالية جدا اذا لم يكن عندهم ولادات طبيعية.