

Fractional CO2 Laser for treatment of urinary continence disorders (SUI, U and UI). Pilot study, early results and 1-year follow-up.

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ABSTRACT

OBJECTIVE:

To demonstrate effectiveness of a fractional CO2 micro-ablative laser used in intra-vaginal therapy for treating urine continence disorders (stress, urgency and urge incontinence) and prove an improvement of the urogenital support system. Our main goal was to determine a group of patients that can be cured by laser treatment in a similar percentage compared with surgery (TOT or TVT). To finally analyze early result and follow-up to 6 and 12 months.

METHODS:

This is a prospective, observational study on patients who consulted for stress urinary incontinence (SUI). All 30 patients involved in the study presented SUI, 28 of them also had urgency, and 18 urge incontinence added. All of them received the same treatment protocol but were split for result analysis in relation to their pelvic floor condition (damage evaluated by the classification of Blaivas). They completed four questionnaires to assess the results of laser treatment (ICIQ-SF, QOL-HV-26, B-SAQ and Sexual Questionnaire PISQ12) before and after therapy. Laser therapy (FemiLift, by Alma Lasers) was applied in three sessions separated by three weeks each. Sex and quality of life were also assessed due to the known laser effect for treating vaginal atrophy and the improvement in the walls tension, lubrication and mucosa quality. The patients were followed up after treatment by bi-monthly appointment and telephone contact and attended a global control at 6 and 12 months.

RESULTS:

All 30 patients responded to SUI treatment. Globally, 60% presented resolution and 40% improved significantly. When pelvic floor injury was analyzed in accordance to Blaivas classification, those patients without prolapse or prolapses above the edge of the pubic symphysis and healthy *levator ani* muscle and endopelvic fascia (Blaivas type IIa) showed an 87.5% resolution. The same group but with a *levator ani* or endopelvic fascia impaired, presented only 80% resolution. Biggest prolapse patients (Blaivas classification type IIb or higher) responded only 30%. Globally, urgency responded in a 71% of patients and urge incontinence in 83%. The four questionnaires used for patient's assessment showed statistically significant improvements.

Six-month follow-up global cure showed a slight decrease to 53,3% (immediately after treatment 60%), but the group of patients in Blaivas IIa with healthy *levator ani* muscle and endopelvic fascia maintained the percentage of 87,5% cure. With a year follow-up to global healing decreases to 46,7% (after laser 60%, six-month 53,3%), but in group with fascia and muscle healthy the cure rate persists in up to 75%. Patients with higher prolapse grade-I (Blaivas IIa or more) showed the follow-up at one year persistence of cure to SUI in 10% only (immediately after laser 30%)

CONCLUSIONS:

Intravaginal laser treatment (FemiLift) demonstrated effectiveness to cure or improve continence disorders by a percentage similar to the TVT or TOT surgery in the group of patients without or with minimal damage to the pelvic floor (without prolapse or following the classification of Blaivas SUI and Prolapse types I and IIa). Patients with prolapse higher than grade I by POP-Q or Type 1Tb by Blaivas classification are not candidates for laser treatment if their expectation is to cure the disorder of continence. However, many chose to try a minimal invasive method that has the added value of lower cost and no serious complications compared to surgery. Taking these concepts intravaginal laser is one more tool to treat urinary continence problems

Keywords: Incontinence urinary. Treatment with Laser CO2 pixel

INTRODUCTION

Urinary continence disorders affect millions of women around the world and seriously impact their quality of life. The prevalence of the disease is not well established existing reports ranging from 5% to 40% where factors such as age, hormonal status, racial and geographical factors, obstetrical and/or surgical history have great impact on these statistics

¹ (1)(2)(3)(4)(5)(6)(7) A Higher incidence in white and latin woman is reported in several studies.

Changes in lifestyle and the pursuit of quality of life of modern peri and postmenopausal women between the fourth and fifth decade of life, lead to a high number of consultations in search of a solution for this pathology and became a serious economic problem for

Healthcare system¹. The principles of modern theory on continence and knowledge of sub

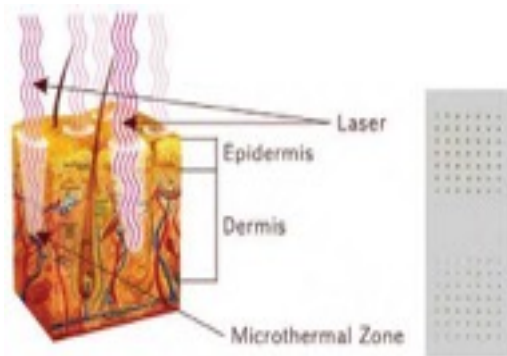
urethral tapes mechanisms for incontinence^{(9) (12) (11) (12)} allowed us to establish the hypothesis that the thickening and rejuvenation of vesico-vagina l fascia⁽¹³⁾ generates better support to the urethra, bladder neck and bladder allowing interaction of the forces to act

more in line with women without pathology correcting the flaws that lead to continence disorders. It is at this point that the great development of knowledge on fractional CO2 laser action for skin (in dermatology) and proven structural rejuvenating action by neocollagenesis and neo-angiogenesis of treated tissues^{(14) (15) (16) (17) (18)}

applying this technology to improve the support system of urethra and bladder.

MATERIALS AND METHODS

This is a prospective, descriptive, observational pilot study developed with a series of patients suffering stress urinary incontinence treated with CO2 Laser and Femilift vaginal hand piece (Alma Lasers Ltd, Caesarea, Israel)⁽¹⁹⁾. This is the same device used by dermatologists to induce thermal and ablative effect for facial rejuvenation by neo collagenesis and neo-angiogenesis making structural changes in tissues and already proven



by scientific evidence of more than a decade.

The CO2 laser delivers fractional energy through special lenses which split the energy beam into a 9x9 matrix, generating 81 very small spots called Pixels (Fig.1). These pixels cause thermal damage points in tissues, leaving healthy tissue between them, promoting rapid collagen

regeneration. The operator can select the energy level (high, medium or low) and the individual energy (mJ) of each beam (10 to 500 mJ/Pixel). Energy levels correspond to different exposure times (pulse duration). The "high" setting delivers the same amount of energy in a shorter pulse, corresponding to an increase in laser emission strength, which causes rapid vaporization at the tissue level, leaving a residual heat deposit in the dermis.



Fig. 2



Fig.3

On the other hand, the "low" program uses a longer pulse, causing a greater thermal effect in the tissue and less vaporization. The vaginal hand-piece uses Pixel technology with a 9 x 9 shot through the lateral window (81 impact point emission). The hand-piece has a rotational mechanism which allows the laser

emission output window to be moved from the vagina outside towards each area to be radiated (Fig.2). It has a disposable acrylic cylindrical cover (Fig.3) which supports aseptic treatments without the need sterilization the device head.

Patients, definitions, tests and treatments

30 patients were enrolled in order of arrival to the site, without any exclusion criteria. The patients were recruited via online advertisements. They were informed that it was an investigational treatment at no cost.

All patients had lower urinary tract symptoms (LUTS) and for the purposes of this study, we analyzed three groups:

- a.- Patients with Stress urinary Incontinence (SUI);
- b.- Patients with SUI plus Urgency (U);
- c.- Patients with SUI plus Urge Incontinence (IUU)

All according to the following definitions ⁽²⁰⁾⁽²¹⁾

Stress Urinary Incontinence (SUI) is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing

Urgency (U): Is the complaint of a sudden compelling desire to pass urine, which is difficult to defer

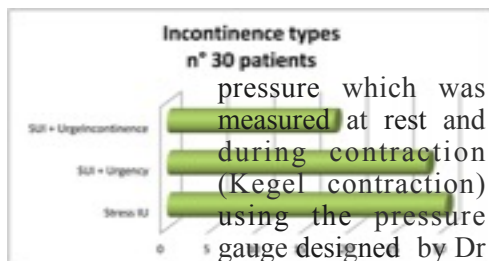
Urge Urinary Incontinence (IUU): Is the complaint of involuntary leakage accompanied by or immediately preceded by urgency.

The features of the trial were well explained and the patient provided informed signed consent before treatment. They also completed the following validated questionnaires

ICIQ-SF questionnaire for incontinence diagnosis ⁽²²⁾

Overactive bladder and Quality of Life questionnaire (Potenziani QOL-HV-26) ⁽²³⁾ **Bladder control self-assessment questionnaire (E.Andersson-L.Cardozo -B-SAQ)** ⁽²⁴⁾ **Pelvic organ prolapse/Urinary incontinence sexual questionnaire (PISQ-12)** ⁽²⁵⁾

Incontinence diagnosis was confirmed by interrogation and a genitourinary physical exam, assessing incontinence by stress test in supine and standing positions, Q-tip test and lesion of pelvic floor by Blaivas classification ⁽²⁶⁾. This classification was chosen for considering incontinence in relation to pelvic floor damage. We also assessed intravaginal



pressure which was measured at rest and during contraction (Kegel contraction) using the pressure gauge designed by Dr Oscar Aguilera and Marco Pelosi TI (Aguilera's Tonometer).

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At 30 days from final of treatment, patients

returned to complete the questionnaires listed above.

All patients (n = 30) presented stress urinary incontinence (SUI), most of them (28 patients) had as a Urgency (U) associated symptoms, and only 18 had urge incontinence symptoms (IUU) too (Table 1). We do not use classification IUGA, ICS or ACOG urinary incontinence because they are declarative and prefer to seek a more clinical and anatomical criteria (that point directly towards a therapy), we believe that it Blaivas Classification is the best with what we have today (Table 2).

Clasificación SUI		
Type Blaivas	Urethral	Characteristics
Type 0	Urethral Hypermobility	Normal anatomy. Without clinical or urodynamic SUI
Type I	Urethral Hypermobility	Less than 2 cm descent of bladder neck (BN) during Valsalva
Type II	Urethral Hypermobility	More or equal 2 cm descent of bladder neck during Valsalva
II A		BN above inferior border of pubic symphysis
II B		BN below inferior border of pubic symphysis
Type III	ISO	BN and proximal urethral are open. Urethra fixa. Urodynamic pressure V/LPP minor 60

Table 2. Classification Blaivas-Olson

This study aimed to analyze the effect of laser treatment

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1.

Patients	n*	Average	Range	Dry	Enhanced	Student
Age	30	52	28-72			
Parity	29	6,1	2-1	17(58,62%)	12(41,38%)	
Vaginal	20	4,5	2-5	11(55%)	9(45%)	
Cesarea	6	8	1-2	6(100%)	0	0
Vag-Ces	3	8	2-6	3(100%)	0	0
Weight		3604	2400-4290			
Status Hormonal						
Pre	20(62,5%)			11(55%)	9(45%)	
Post	10(37,5%)			5(50%)	5(50%)	
Surgery	6				2	4
TVT-TOT	2				1	1
Prolapso	2				1	1
Fistula	2					2

in weakened anatomical structures causing urethral hypermobility and different degrees of prolapse. All know that damage to the pubo-urethral ligament, causing posterior displacement of the urethra.

Impairment of the lateral supports, affecting the hammock back-plate provided by the vagina. Deficient in the endopelvic fascia, associated with descent of the proximal portion of the urethra, reducing the direct transmission of the intra-abdominal pressure enhancing urethral closure. Damage to the levator ani, allowing descent of the bladder base and outlet, placing several aspects of the continence mechanisms at risk⁽²⁷⁾ Therefore, patients were classified using the Blaivas classification⁽²⁶⁻²⁸⁾. To better assess the results of treatment in accordance with anatomical damage, subdivisions were added to Blaivas classes IIA and IIB, to differentiate between the anatomical status of the levator ani muscles and/or the endopelvic fascia (11 level pelvic floor support - John DeLancey^{(29) (30)} Namely, both groups were divided into two subgroups: patients with level II healthy, and patients with level IIO impaired.

Table 3. Patients. Features

The influence of parity and the relationship with vaginal delivery and high weight of the gestational product is clearly seen in the samples presented in Table 3. Six patients had previous incontinence related surgeries and were analyzed in the same individual response in

Accordance to surgeries performed (tape, colpoperineoplasty and vesicovaginal fistula repair).

Statistical analysis

Data are presented as per group means and standard deviation. These values were compared and a Student t test was performed to establish statistical significance of the results, considering an alpha value of 0.05.

Treatment protocol

Treatment was administered in 3 sessions, performed at 14 day intervals (Days 0-14-28)

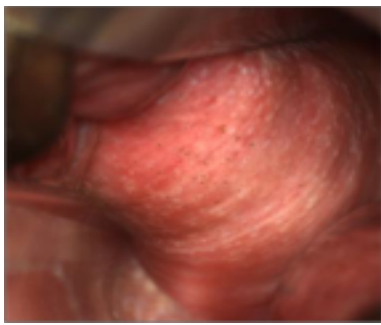


Fig.4 Photo vaginal wall after laser

and outcomes were assessed 45 days after treatment session 2 (Day 60 of the study). This schedule was chosen to allow for fibroblastic stimulation and collagen production in the post-laser challenge healing process in the vaginal wall (Fig.4)

At each session, shots were made from the vaginal fundus to the introitus, at 1 cm intervals, while the hand piece was moved out. The sequence was repeated at 12-3- 6-9 o'clock and then between 1 and 2, between 4 and 5, between 7 and 8, and between 10 and 11 o'clock.

Fig.5 Parameters used in treatment



Finally, after treating the entire vaginal cavity, an anti incontinence protocol was applied: 3 laser shots at 12 o'clock in the media

urethral area and 3 laser shots in the right and left paraurethral areas. Hand pick was lubricated following recommendation (oil cream) and topical anaesthesia was applied to introit. The device was set (Fig.5) on High Power throughout the treatment, with a 50 mJ/pixel delivered in a pulsed mode, with 1 Hz. In this trial Femilift® is a 40 Watt device (Fig.5)

Follow-Up

Monitoring and minimum control post treatment was one year. All patients were followed up by telephone every two months and clinically analysed in relation to the therapeutic result at six and twelve months after the end of treatment using the same tests and

questionnaires used before and after laser protocol. Patients who were lost to follow-up monitoring were considered treatment failures.

RESULTS

Upon analysis of stress incontinence symptoms only complete resolution (n= 18) or

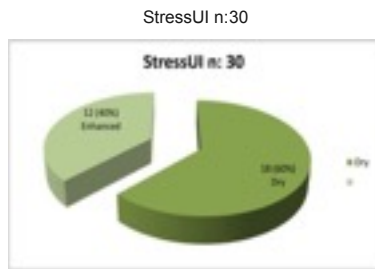


Fig.6 Patients SUI after laser



Fig.7 Patients SUI+U after laser



Fig 8 Patients SUI+IUU after laser

significant improvements (n= 12) were observed, demonstrating a complete resolution rate of 60% (Fig.6) When considering cases concomitantly presenting stress

incontinence -SUI and urgency -U (n: 28), 71% (n:20) reached complete resolution for urgency symptom, 11% (n:3) showed significant improvements and 18% failed to see any changes (n:5) (Fig.7); a 11 patients exhibited an SUI response.

Among patients presenting urgeincontinence IOU (n:18), 83% (n:15) experienced full resolution of the symptoms. The remaining three patients showed no response (Fig.8) and failure was determined by the need to receive anticholinergics (Darifenacin 15 mg/day).

Treatment response in relation to the level of damage of the pelvic floor (Table 4) in the levator ani and especially in their pubococcygeus fascicle and/or the endopelvic fascia (level J1^o John De Lancey) was clearly different even among Blaivas Ila patients. In this

group the resolution rate was 84.6% and the remaining 15.4% showed improvement. When evaluating the healthy levator ani muscle resolution was obtained in 87.5% of patients and

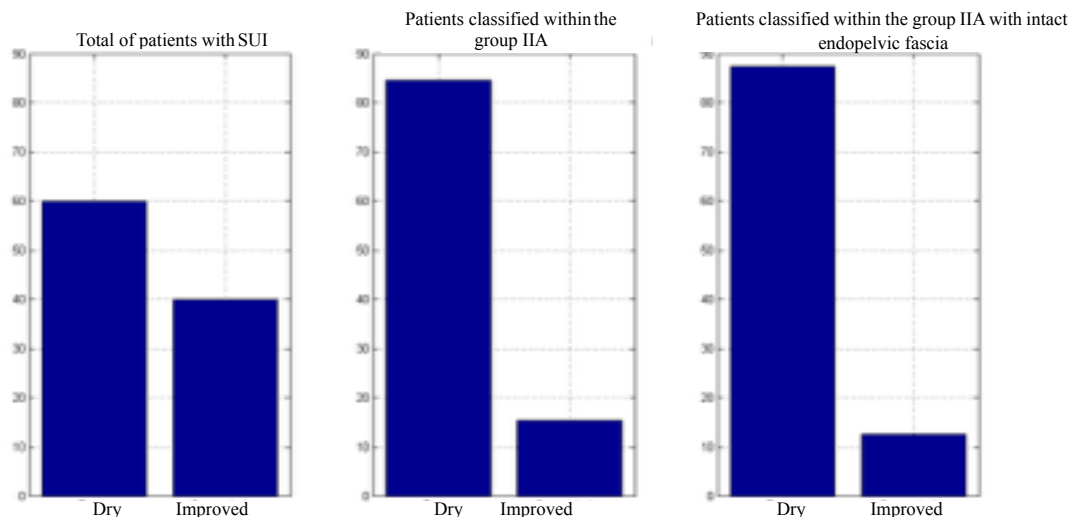
Table 4. Patients. Features

Blaivas Clasification	N*	DRY	ENHANCED	FAILURE
Type 0	0			
Type I	3	3(100%)		
Type IIA	13	11(84,6%)	2(15,38%)	
IIA	II*N healthy	8(87,5%)	1(12,5%)	
	II*N Impaired	5(80%)	1(20%)	
Type IIB	10	3(30%)	7(70%)	
IIB	II*N healthy	7(28,57%)	5(71,4%)	
	II*N Impaired	3(33,3%)	2(66,6%)	
Type III	4	1(25%)	3(75%)	
	30	18(60%)	12(40%)	

when damaged was reduced to an 80% resolution rate. shows the difference that splitting the patients by type of injury in pelvic floor supporting structures does to the treatments results . The difference between total

dry patients (60%) and those categorized by the state of pelvic floor injury is clear. In the Type IIB group which presented fascias with more lesions and an evident prolapse, the resolution ratio fell to 30%, which undoubtedly shows the importance of pelvic floor status in defining the indications of Laser therapy in SUI (Table 5).

Table 5. Difference results by injury in supporting structures of pelvic floor (After laser treatment)



Graph 13: Difference results by injury in supporting structures of pelvic floor (After laser)

An identical analysis was run on data collected from urgency and urge incontinence patients (Table 6). Of course, the neurogenic effect of the laser was observed as well.

Table 6. Analysis results after laser treatment in U and IUU

Blaivas - Urgency	N*	Dry	Enhanced	Failure*	Student
Type I	3	2(66,6%)	1(33,4%)		
Type II	22	16(72,7%)	2(9,1%)	4(18,18%)	
Type IIA II* L. Healthy	8	7(87,5%)	1(12,5%)	0	
Type IIA II* L. Impaired	5	3(60%)	1(20%)	1(20%)	
Type IIB II* L. Healthy	7	5(71,42%)		2(28,57%)	
Type IIB II* L. Impaired	2	1(50%)		1(50%)	
Type III	3	2(66,6%)		0	1(33,4%)
	28	20(71,42%)	3(10,71%)	5(17,86%)	

Improving anatomy favors pudenda) plexus function by traction and elongation stimuli, but we think the laser effect on the nervous plexus is the major contributor to this functional improvement.

Blaivas - U.Incontinence	N*	Dry	Enhanced	Failure*	Student
Type I	1	1(100%)			
Type II	15	13(86,6%)		0	2(13,33%)
Type IIA II* L. Healthy	4	4(100%)		0	0
Type IIA II* L. Impaired	3	2(66,6%)		0	1(33,4%)
Type IIB II* L. Healthy	4	4(100%)		0	0
Type IIB II* L. Impaired	4	3(75%)		0	1(25%)
Type III	2	1(50%)		0	1(50%)
	18	15(83,3%)		0	3(16,6%)

A global resolution of the urgency symptom among 71.42% and 83.3% of urge incontinence patients, was higher than the 60% total resolution observed for SUI and clearly shows that not only the anatomy correction is important;

however the importance is patent when we see that patients with levator indennity had a higher response that the global mean (urgency: Type II global resolution 72.7% and Type II with healthy elevador reaches 87.5%).

	Media BEFORE treatment	Media AFTER Treatment	Value of P	It can be seen that "P" is much smaller than 0,05 in all cases, therefore all differences are statistically significant
measurement of pressure basal	3.1	9.9	2.0×10^{-12}	
measurement of pressure in Kegel contraction	12.0	18.7	3.9×10^{-6}	

Table 7. Statistical analysis vaginal pressurometry

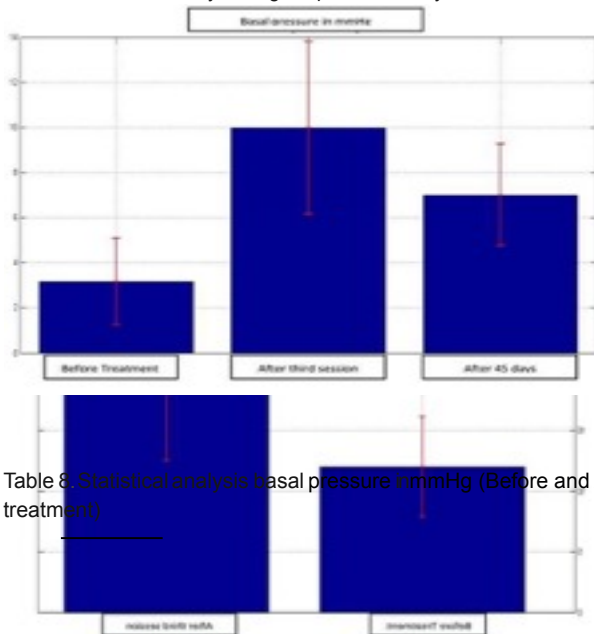


Table 8. Statistical analysis basal pressure in mmHg (Before and After treatment)

pressure in Blaivas classification Type I (339% increased pressure) and a lower response at patients with greater baseline damage Type IIb and Type III (increased pressure 88%). Statistical analysis of pressure recording changes is shown in Tables 8 - 9; statistically significant differences are seen at both times (rest and contraction).

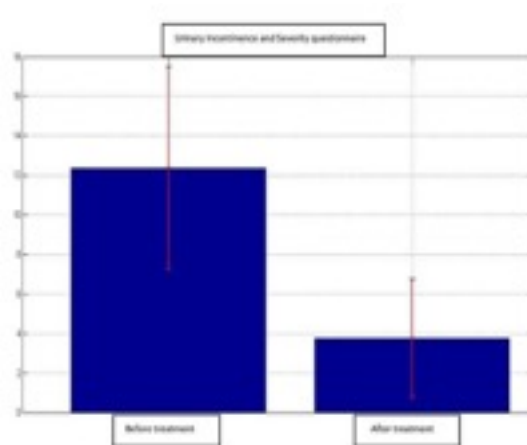
Table 9. Statistical analysis Pressure Kegel contraction in mmHg

Vaginal pressure recordings performed at rest and at Kegel contraction before and after laser treatment showed a statistically significant increase in basal pressure at rest and at contraction (Table 7). The percent mean increase is clearly related to the anatomical damage; so, with greater improvement of basal

Analysis of validated questionnaires used

1. ICIQ-SF²²: Any grade which is higher than 1 is an indication of incontinence with higher

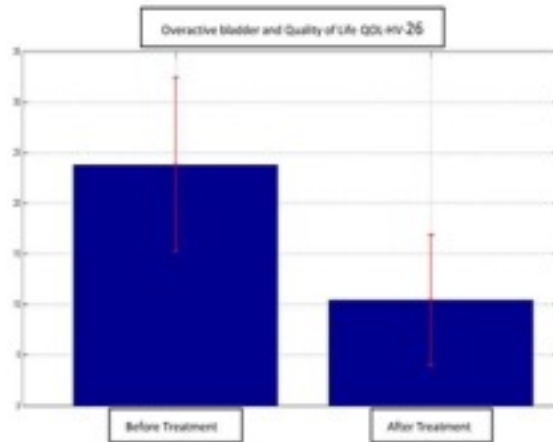
International Consultation on Incontinence Questionnaire (ICIQ-SF)



Scores directly correlating with symptom severity. The mean pretreatment score was 12.36 (range 5 - 21), while the mean final treatment score (60 days) was 3.73 (range 1-12). Figure 13 shows the standard deviation and mean value. The "p" was 3.2×10^{-11} with statistically significant differences ($p: <0.05$), which clearly confirms the beneficial effect of the LASER in treating this disorder

2. QOL-HV-26¹²³; The mean pretreatment score was 23 points (moderate impairment) range:

Overactive bladder and Quality of Life (QOL-HV-26)



8-38 and the mean post-treatment score was 10 (mild impairment) range: 2-25. The "p" was 3.0×10^{-9}

3. BC-SAQ¹²⁴: This three-point scale grades the symptoms and intensity of discomfort and

Bladder control self-assessment questionnaire (BC-SAQ)

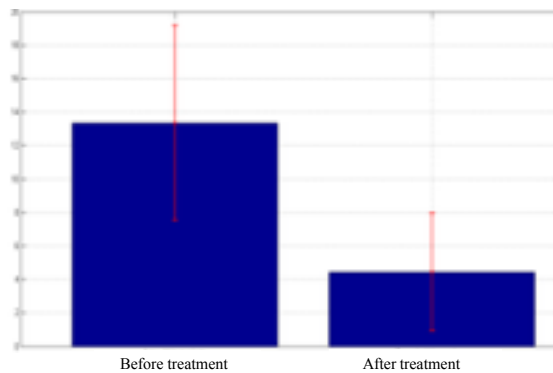


Table 12. Statistical analysis BC-SAQ

provides a bladder control score when summed up. The mean pretreatment score was 13.33 (range of 3 - 24 points), and the mean post-treatment was 4.33 (range of 0 - 15). The "p" was 7.8×10^{-10} which is statistically significant

4. PISQ-1⁽²⁵⁾ : This questionnaire assesses vaginal atrophy, as well as lubrication and vaginal

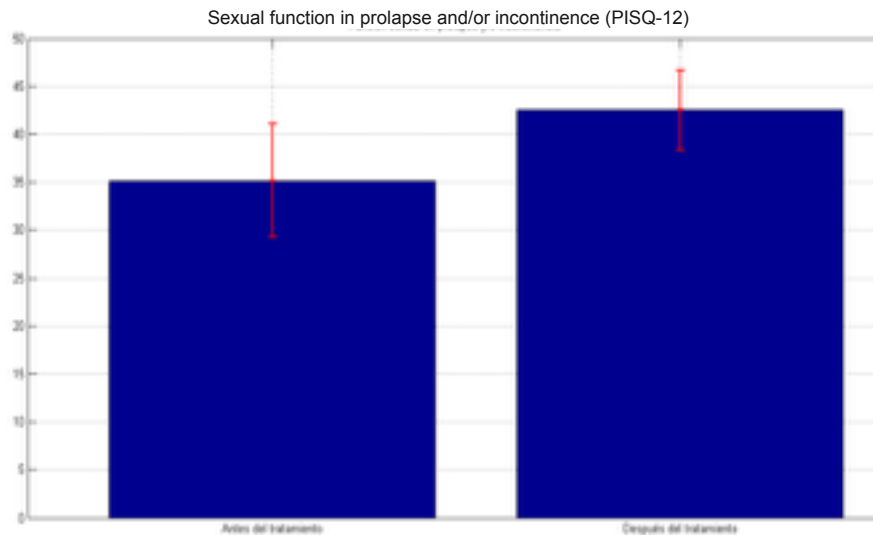


Table 13. Statistical analysis PISQ-12

tension, which significantly improved ($p = 1.2 \times 10^{-6}$) in almost all patients. The mean pre

treatment PISQ-12 score of 35-14 (range 26-44), which rose to 42-48 (range 34-47) following treatment. Three patients did not complete the questionnaire, as they thought it was not related to the nature of the trial (two of them had no sexual activity during the study (Table 13))

Analysis of patients with previous surgery

The sample included six patients with SIUR (recurrent incontinence) and a history of vaginal surgery. Of this group, two were recurrent cases after placement of suburethral tape (one TOT and one TVT), two were recurrences following traditional surgeries (Marshall Marchetti Krantz) and the remaining two surgeries were directed to obstetric vesico-vaginal fistula causing complications requiring surgical correction. In the group with urethral means taping history, one patient was dried and the other had a very significant improvement refused adjuvant therapy with repositioning sling. One of the two patients was operated with MMK dry well, but required five sessions of laser treatment and the other improved and continued on treatment due to evidence of progress (at the time of this presentation, 5 sessions had been conducted). Patients with fistula surgery had no satisfactory answers.

Follow-Up

In valuations of patients at six months 53.3%¹² of the total were "dry" (Table 14). Taking into account the state of the pelvic floor 76.9% of Ila Blaivas overall and 87.5% with

Healthy level II^o were cured; almost all percentages similar to those obtained when the immediate evaluation after laser treatment. No treatment failures and / or relapses were reported. Two patients were lost to follow-up (group A Blaivas Ila and another in Blaivas Jib) reason that determined the small percentage change again considered and patient with SUI which was not controlled by exit tracking was said.

Lost patient is considered failure

Table 14. Follow-Up six months

	N°	6 to Months	Dry	Enhanced	Lost	Failure*	
Type 0	0	0	0	0		0	
Type I	3	3	3	0		0	
Type Ila	Total	13	12	10	2	1	0
	11° Healthy	8	8	7	1		0
	11° Impaired	5	4	3	1	1	0
Type Iib	Total	10	9	2	6	1	1
	11° Healthy	7	6	1	4	1	1
	11° Impaired	3	3	1	2		0
Type III	4	4	1	2		1	
Total	30	28	16 (53,3%)	10 (33,3%)	2 (6,66%)	2 (6,66%)	

Table 14. Follow-Up one year

	N°	12 months	Dry	Enhanced	Lost	Failure*	
Type 0	0	0	0	0		0	
Type I	3	3	3	0		0	
Type Ila	Total	13	11	9	2	2	0
	11° Healthy	8	7	6	1	1	0
	11° Impaired	5	4	3	1	1	0
Type Iib	Total	10	9	1	6	1	2
	11° Healthy	7	6	1	4	1	1
	11° Impaired	3	3	0	2		1
Type III	4	4	1	2		1	
Total	30	27	14 (46,7%)	10 (33,3%)	3 (10%)	3 (10%)	

Analyzed at one year follow-up (Table 15), a total of three (3) were lost so they were 27 to assess results. There 2 lost patients were taken as treatment failure (again symptomatic patients). The persistence of healing in the total group (dry patients) was 46.7 % without considering the degree of

damage to the pelvic floor. When we evaluate and analyze types Blaivas the group with less damage pelvic floor classified (Blaivas IIa) the percentage of patients with persistent healing was 69.2 %. Within this group, we evaluated the subgroup with Endopelvic fascia and levator ani (pubo - coccygeal) without damage (II O Level Healthy) and the persistence of healing was 75 %. In the patients of group IIb healing Blaivas only persisted in 10%

COMMENT

Urinary incontinence is a severe problem for health systems. Treatment costs are increasing (8-31-32) as are the prevalence and incidence of this disorder. More women each day choose to stop hiding this disorder, forgetting her embarrassment and giving priority to her quality of life. In addition the increase in lifespan expectancy and the changes in social, work and sexual activities in the fifth decade of life are transforming this issue in a "true epidemic" (John DeLancey).⁽³³⁾

The reports of the intravaginal laser effect on continence disorders observed almost by chance, upon vaginal tensine treatment for genital rejuvenation were first reported in 2009 at 2012 (34-35-36-37)

Figure 9. Reparative changes after laser ablation

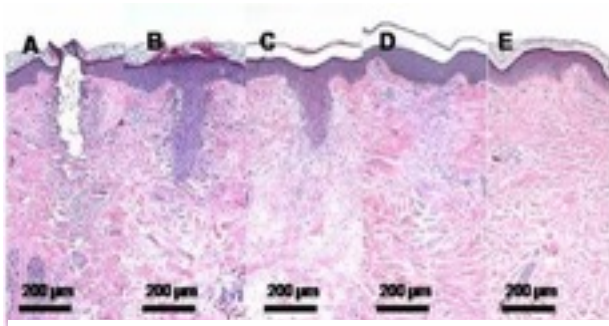
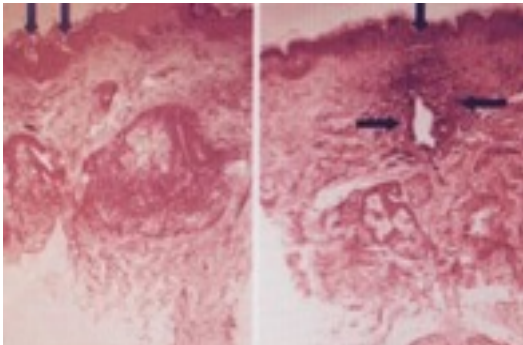


Figure 10. Histological changes after laser treatment



Histological analyses demonstrated the ablative lesion, which was later filled within 72-96hs of treatment culminating in a rejuvenated fascia at two months (Figure 9)

Several publications support the concept of the thermal effect serving as a fibroblastic stimulus for collagen production at temperatures between 45 and 60°C⁽¹³⁻³⁸⁾, but the ablative method acts faster, almost immediately by the immediate "inflammatory" process triggered by macrophage cell migration to "repair" the area with a rapid neo-angiogenesis neocollagenesis production (Figure 11)

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The last photo (Figure I0) shows the area of ablative effect (yellow arrow) and the area of thermal effect with dark red in the color of the histological technique (black arrows)

While both TVT and TOT are considered the gold standard for SUI treatment, we have no doubts that the laser is coming to avoid surgery in a significant group of patients whose symptoms can be cured or significantly improved with it. Clearly, the laser treatment provides a favorable effect, due to its tensional effect on anterior fascia, and elevation and support of the bladder floor and urethra, achieving a decrease of urethra hypermobility and therefore improving urethral closure function. Ablative and thermal effects of CO2 stimulate the formation of a new, elastic and young urethrovaginal fascia and vesicovaginal fascia, which act as a tensional-free tape placed in medial urethra supporting the critical vesicourethral area related to incontinence, i.e, bladder neck and medial and posterior urethra.

Incontinence grade was not a determinant of resolution, both severe and mild incontinence cases responded to laser treatment, so long as the patient did not present an anterior prolapse seen at rest or a valsalva descending below the level of the inferior border of pubic symphysis (descended more than 2 cm). Furthermore, the prospects of cure were significantly higher if the II0 level of the pelvic floor (endopelvic fascia and puborectalis muscle of levator ani) is healthy. In summary, Blaivas 0, I o Ila patients are undoubtedly ideal for fractional laser treatment, with a predicted > 80% chance of cure. Within Blaivas Ila group, if the levator ani is healthy and has good contraction and strength, cure prediction is almost 90%.

The monitoring of this patient shows us that healing is sustained over time in most patients followed for a year without negative changes at six months and minimum decay at one year results.

Conclusions are similar in relation to urgency (U) and urgeincontinence (UUT) disorders. Anatomical injury is a predictive factor of response, but undoubtedly the laser also has a modulator effect on pudenda) plexus fibers, because global percentages of resolution or improvement of these symptoms were higher for SUI symptoms, seeing also a higher positive effect than that achieved in SUI in patients with evident or demonstrable prolapse.

CONCLUSIONS

1.- Based on this analysis, we can say that CO2 Laser fractional Femilift has a place for treating SUI patients with minimal anatomical injury regardless of the clinical or urodynamic grade of incontinence. 80-87.5% of dry patients undoubtedly support its use and, at first, exclude surgical alternatives for placement TVT or TOT.

2.- Prediction of a positive result is magnified with the analysis of patient's parity. Those with cesarean section only, even as a product of an obstructed parturition, had a better response than those who had natural births. Multiple vaginal parity with big fetuses is related to injuries in endopelvic fascia and has led to a detailed analysis of supporting elements of the pelvic floor to accurately classify the extent of the injury in attempt to further define the indication of the fractional Laser.

3.- For patients presenting urgency, the Laser may be an alternative even with a prolapse higher than POP-Q Grade I and before anticholinergics are indicated, if micturition kinesiology and reeducation did not solve the problem. Besides, we believe that it can be indicated as primary treatment of urgency, if it is the main symptom.

4.- Laser is not recommended in SUI patients with prolapse higher than POP-Q grade I or Blaivas IIB. In accordance with our findings, these patients should be treated with medial urethral tapes and the appropriate surgery in relation to the associated anatomical injury, which causes incontinence and prolapse.

5.- Recurrent SUI patients after incontinence and/or prolapse surgery, either suburethral or old classic surgery (Kelly, MMK, Burch, etc.) benefit from fractional Laser therapy and may be indicated in repeated sessions achieving improvements and sometimes complete resolution without a new surgery.

6.- This is a very low-cost therapy, almost negligible because the fractional Laser has not supplies which increase costs. Fractional Laser will be certainly useful for patients selected for the treatment and also for health systems due to reduced treatment costs for this disorder of increasing prevalence and due to a clear decrease in surgery indication. If the investment for the equipment acquisition is considered as the therapy cost, we should say that the fractional Laser mean value is not higher than the cost of 60 suburethral tapes; only the tapes without considering surgical expenses, fees, complication treatment, costs due to patient's activity impairment, etc. Evaluations of these factors, which estimate the cost of a laser is equivalent to an average of 10-20 surgeries, demonstrate a very positive cost-benefit ratio.

7.- Our experience leads us to conclude that the laser treatment and subsequent monitoring and re-treatment every 12 months or on relapses is an effective treatment for SUI (in the group of patients already described: without prolapse) is clearly cost-effective for patients and health systems.

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