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Prospective Pilot Study of 30 Patients on the Use of Vaginal Pixelated CO2 Laser for the Treatment of Stress Urinary Incontinence

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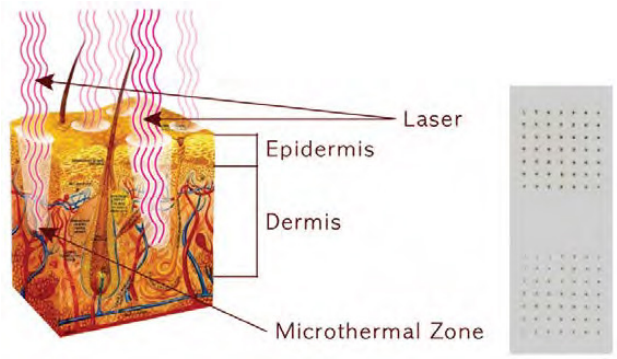
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Keywords
Dermatology, Latin white women, re-construction.

Introduction
Urinary incontinence [1] is a problem affecting millions of people seriously impairing their quality of life; its prevalence is not well established and ranges from 5% to 40% in different studies in relation to age and gender and also to racial and geographic factors. Higher incidences are seen in Latin white women [2-8]. In accordance to different studies, UI leads to consultation in less than 30% of the cases even when it is effectively present and usually (even nowadays) is a problem that only the person who suffers it knows [9].

This problem has an economic impact on health systems due to the high number of visits and increasing expenses for treatments [10]. Undoubtedly, this is going to increase so as the amount of patients seeking for solutions; therefore, this will be detrimental for the sanitary burden of costs.

The knowledge of the Modern Theory of Continence [11-13] and the mechanism of anti-incontinence action of suburethral tapes [14] lead to consider that improving the suburethral fascia and the supportive layers of medial urethra and bladder floor and neck using biological materials might be effective for treating UI. At this point, the progress in the knowledge of medical use of laser energy and its proved ultra-structural actions on collagen and extracellular matrix [15-18], lead us to conduct this trial to assess the outcomes of the use of CO2 fractional laser with the aim to achieve a "re-construction" and "rejuvenation" [19] of anterior vesicovaginal fascia and thus achieving a more appropriate support of the urogenital system correcting the continence disorder.

Materials and Methods


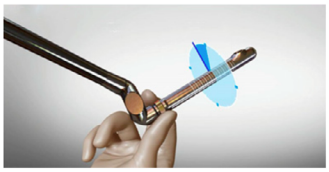
Graph 1: This is a prospective, observational, descriptive, pilot study of a patient series suffering urine incontinence treated with the surgical laser system Pixel **CO2,** together with a vaginal hand-piece **Femilift ®** *ad hoc*, from **Empresa Alma Lasers (Alma Lasers Ltd., Caesarea, Israel)** [20].

This equipment uses a technology implemented for dermatology since long ago for causing thermal ablation damage in dermis and epidermis [21,22]. The system Pixel CO2 delivers fractional laser energy through special lenses which split the energy beam in a 9x9 matrix originating 81 very small spots called pixels (Graph 1). These pixels cause thermal damage points in tissues, leaving health tissue between them allowing a rapid health process from collagen regeneration.

The operator may select the energy level (high, medium or low) and the individual energy of each beam in MilliJoules. Energy ranges from 10 to 500 mJ/Pixel. Thus, the operator may decide causing higher or lower thermal damage. Energy levels low, medium and high correspond to different exposure times or pulses by second.

"High" corresponds to an increase in laser emission strength which causes a rapid vaporization at the tissue level leaving a residual heat deposit in dermis. On the other hand, selection of the "low" program causes a higher thermal effect in the tissue and lower vaporization.

The vaginal hand-piece developed by the company **ALMA LASER** uses Pixel technology with a 9 x 9 shot through lateral window (81 impact point's emission). The hand-piece has a rotational mechanism which allows moving the laser emission output window from the outside towards each area to be radiated (Graph 2). It has a disposable acrylic cylindrical cover (Graph 3) which fits to the hand-piece and allows absolutely aseptic treatments without the need to sterilize the equipment head.



Graph 2



Graph 3

Patients, tests and treatments

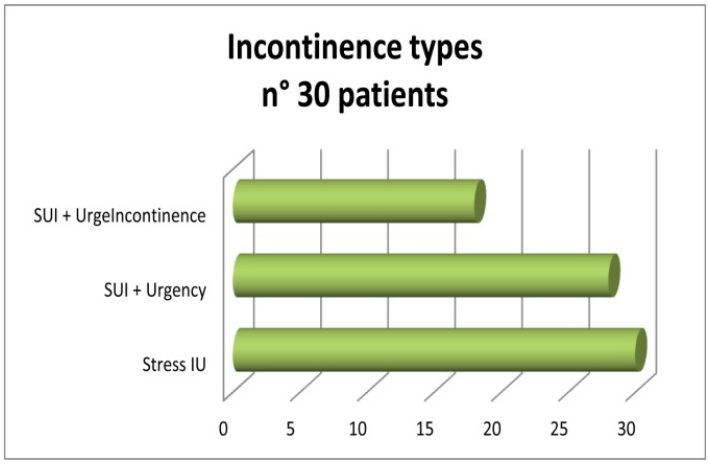
30 patients were treated and enrolled into the protocol by order of arrival to the Site without any exclusion. The patients were appointed for performing treatment by a Web publication. They were informed that it was an investigational treatment at no cost. The features of the trial were well explained and the patient signed and informed consent. They also completed validated questionnaires used for analyzing this trial.

Questionnaires selected for this study were as follows:
1.- ICIQ-SF questionnaire for incontinence diagnosis [23].
2.- Overactive bladder and Quality of Life questionnaire (Potenziani QOL-HV-26) [24].
3.- Bladder control self-assessment questionnaire (E.Andersson-L.Cardozo-B-SAQ) [25].
4.- Pelvic organ prolapse/Urinary incontinence sexual questionnaire (PISQ-12) [26].

For confirming incontinence diagnosis we used questioning and genitourinary physical exam assessing incontinence by stress test in supine and standing position; lesion of pelvic floor by POPQ classification [27] ; Qtip test; Pad Test 24 hours analyzing by number and humidity of pads reported by the patient; three days mictional diary; validated questionnaires and urodynamic tests in a smaller group. Patients were subjected to intravaginal pressure measurement at rest and under Kegel contraction by Aguilera's tonometer.

Through these analyses we initially obtained three groups in relation to the incontinence type (Figure 4). 30 presented SUI, 28 presented SUI plus urgency, and 18 had SUI + Urge incontinence

With the aim to analyze the results involving also the anatomical structural injuries we used the Blaivas' [28] classification (Graph 5). A split of Blaivas' Type I and II was added clinically assessing the support Level II status described by John De Lancey [29,30]. So, those two groups were divided in patients with 1.- II Level healthy and patients with 2.- II level Impaired.



Graph 4: Groups in relation to the incontinence type.

Clasification 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 symphisis
II B		BN below inferior border of pubic symphisis
Type III	ISD	BN and proximal urethral are open. Urethra fixa. Urodynamic pressure VLPP minor 60

Graph 5: Blaivas clasification SUI.

Patients		n°	Average	Range	Dry	Enhanced	Student
Age		30	52	28-72			
Parity	29	61	2,1	1-5.	17(58,62%)	12(41,38%)	
Vaginal	20	45	2,25	1-5.	11(55%)	9(45%)	
Cesarea	6	8	1,3	1-2.	6(100%)	0	
Vag-Ces	3	8	2,66	1.4.	0	3(100%)	
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	

Graph 6: Patient´s simple.

Patient's sample is represented in Graph 6. The influence of parity and the relationship with vaginal delivery and high weight of the gestational product is clearly seen. Six patients from the sample had previous surgeries related with incontinence and were analyzed in

the same treatment protocol assessing the individual response in accordance to surgeries performed (tape, colpoperineoplasty and vesicovaginal fistula repair).

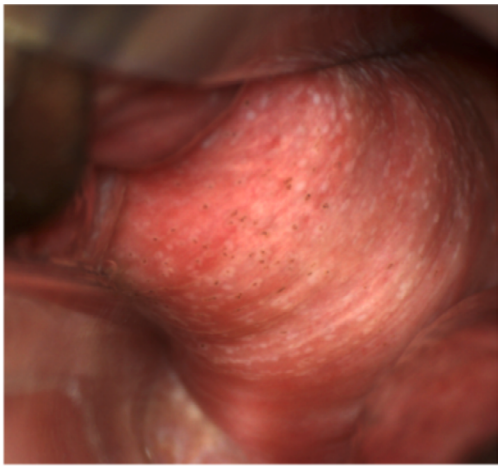
After 60 days, patients returned for completing questionnaires which graded the status at that time. Outcomes were statistically compared and analyzed. For statistical analysis, mean and standard deviation were calculated before and after treatment; the same was done with values of vaginal pressure. These values were compared and a Student t test was performed for proving the statistical significance of the results considering an alpha value of 0.05.

Urodynamic assessment

A group of three patients had an urodynamic assessment before admission to the investigational protocol; urodynamic is indicated in patients with urgency or urge incontinence associated to stress incontinence and those patients with unclear clinical diagnosis; so, other 11 patients had indication of the assessment. Due to the lack of medical cover and monetary reasons, 6 patients did not undergo the assessment; therefore, at last **we could perform urodynamic assessment before and after laser in a total of 8 patients.** Patients underwent the assessment at different sites and this caused that urodynamic tests had not the same methodology and report format.

Treatment protocol

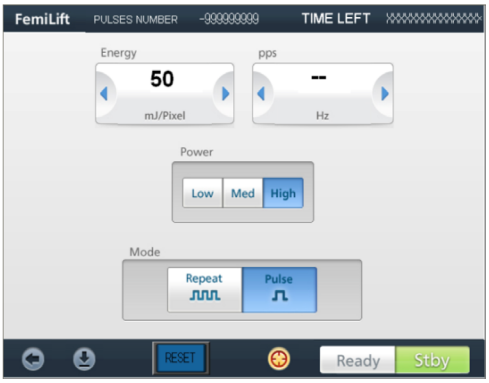
The protocol consisted in three treatment sessions with a period of 14 days between them (0-14-28 days) and finally a total reassessment of the case at 45 days since the second session (60 day from treatment initiation). This schedule and the amount of sessions were stated considering the needed time for fibroblastic stimulation and collagen production by laser challenge and the natural time of a healing process needed by a multiple micro-ablation caused in the vaginal wall by LASER (Graph 7).



Graph 7

At each session we shot from the vaginal fundus up to introitus every 1 cm while the hand-piece was moved out, repeating this sequence at 12 - 3 - 6 – 9 o´clock and then repeating them between already performed lines (between 1 and 2, between 4 and 5, between 7 and 8, and between 10 and 11).

Finally, after treating all the vaginal cavity an anti-incontinence protocol was applied: 3 laser shots at 12 o´clock at urethral area since the bladder neck up to introitus; 3 laser shots at right and left paraurethral area since the deep to introitus (towards retro-pubic palpating the arch of the pubic descendent rami, with no laser shots ahead of inferior bone border of pubic symphysis).



Graph 8

The equipment was set (Graph 8) in High Power throughout the treatment with a delivered energy of 50 mJ/pixel in pulsated mode with 1 Hz. Femilift® is a 40 Watts device. This makes it act in ablative and thermal mode. In cases where a 70 Watts device was used, setting at Med Power was proved to be the appropriate to deliver the same fluency at each impact point.

Results

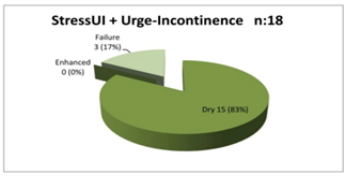
Blaivas Clasification		N°	DRY	ENHANCED	FAILURE	Student
Type 0		0				
Type I		3	3(100%)			
Type IIA	Total	13	11(84,6%)	2(15,38%)		
IIA	II°N healthy	8	7(87,5%)	1(12,5%)		
	II°N Impaired	5	4(80%)	1(20%)		
Type IIB	Total	10	3(30%)	7(70%)		
IIB	II°N healthy	7	2(28,57%)	5(71,4%)		
	II°N Impaired	3	1(33,3%)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

Graph 9: Global results after laser treatment.

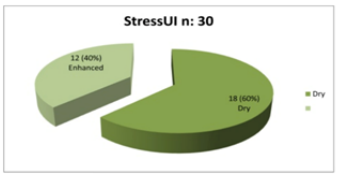
Global analysis of the sample showed an effectivity of 100% for CO2 LASER in stress incontinence pathology (SUI) if this symptom is analyzed alone (Graph 9), causing complete resolution (n= 18) or significantly improving the stress loss (n= 12), which stated a resolution of 60% (Graph 10). Patients who presented stress incontinence concomitantly with urgency (n= 28) showed an 82% response of urgency (n= 23) with 71% of resolution (n= 20) and 18% failure (n= 5) (Graph 11). All 28 patients presented response of SUI. Failure was determined by the need to receive anticholinergics (Darifenacin 15 mg/day).

In patients with Urge incontinence (n: 18) we had response in 15 patients (83%) with resolution of the symptom. There was no response in 3 patients 17%) (Graph 12).

The assessment of symptoms and response in relation to the injury



Graph 10



Graph 11

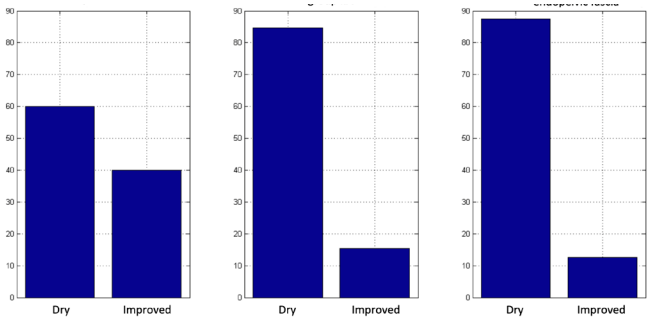


Graph 12

level of the pelvic floor (Graph 9) is shown as the status assessment of the elevator muscle of anus in its pubococcigeal muscle and endopelvic fascia **(II° level of John De Lancey).** Assessing the group of patients **Type IIA** we can see that the **resolution percent was 84.6% and the remaining 15.4% showed improvement.** Adding the assessment of the **endopelvic fascia (II° level), indemnity shows 87.5% resolution and when impaired, it falls to 80%.**

Graph 13 **(graphic column)** shows the difference that splitting the results by injury in supporting structures groups, causes in the results. The difference between globally dry patients (60%) and those with injury assessment is clear and obvious.

The group Type IIB, where fascias presented more lesions and there is an evident prolapse, resolution ratio suddenly falls to 30%, which undoubtedly shows the importance of a good clinical assessment of the pelvic floor for indicating Laser therapy in SUI.



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

In Urgency (U) and Urge Incontinence (UI) the analysis is the same when assessing fascia and pelvic floor support indemnity (Graph 14). Of course, here the neurogenic effect is present. Improving anatomy favors pudendal plexus function due to the lack of traction and elongation stimuli, but the laser effect on the nervous plexus is the major contributor to this improvement.

A global resolution of the urgency symptom of 71.42% and 83.3% of urge incontinence, both higher to that of 60% total resolution of SUI referred, clearly shows that not only the anatomy correction is important; however the importance is patent when we see that patients with elevator indemnity had a higher response that the global mean (urgency: Type II global resolution 72.7% and Type II with healthy elevator reaches 87.5%).

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	
	II° L. Impaired	5	3(60%)	1(20%)	1(20%)	
Type IIB	II° L. Healthy	7	5(71,42%)		2(28,57%)	
	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%)**	

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	
	II° L. Impaired	3	2(66,6%)	0	1(33,4%)	
Type IIB	II° L. Healthy	4	4(100%)	0	0	
	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%)**	

Graph 14: Analysis results after laser treatment in U and UI.

At post-treatment and follow-up, one of the clinical criteria which changed most was the incontinence pads or female pads analysis: the **PAD TEST**, with a 24 hours endpoint which considers the number of needed pads and their humidity, showed almost 60% of dry users (22 of 30 patients) and 36% improved (decrease in the pad number and their humidity). Only one patient remained without changes (Graph 15).

Graph 15

PAD TEST. Number and condition PAD before and after LASER					
	Patients	PADS n°	Dry	Dank	Wet
Type I	1	6		1	0
Type IIA	12	2,8	9(75%)	3	0
Type IIB	7	2,4	4(57%)	3	1
Type III	2	3	1	1	0
Total	22	3,55	13(59,10)	8(36,4%)	1(4,5%)

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Presurometry (Aguilera)		BASAL TENSION mmHg					PC CONTRACTION mmHg			
Blaivas		N°	Pre	Post	%+	Student	Pre	Post	%+	Student
Type 0		0								
Type I		3	2,3	10,3	339		8,6	16	86	
Type IIA	Total	13	2,8	10,7	282		12,9	20,5	59	
IIA	II°N healthy	8	3,5	9,25	164		13,5	19,1	41	
	II°N Impaired	5	1,6	13	712		12	22,8	90	
Type IIB	Total	10	3,4	9,9	191		13,7	19,1	39	
IIB	II°N healthy	7	3	10,1	236		14,4	19,3	34	
	II°N Impaired	3	4,3	9,3	116		12	18,6	55	
Type III		4	4,5	8,5	88		10,25	14	37	
		30	3,25	9,8	85		11,36	17,4	52	
					85%				52%	

Graph 16: Presurometrics changes.

Vaginal pressure recording (Graph 16) performed at rest and at Kegel contraction before and after Laser treatment showed an increase both in basal pressure (85% mean increase) and at contraction (52% increase). Percent mean increase is clearly related to the anatomical damage; so, the table shows a 339% improvement of basal pressure in Blaivas' Type I with a lower response at higher damage.

Student test statistical analysis of pressure recording changes **(Graph 17)** is shown at **Graph 18 and Graph 19**; statistically significant differences are seen at both times (rest and contraction).

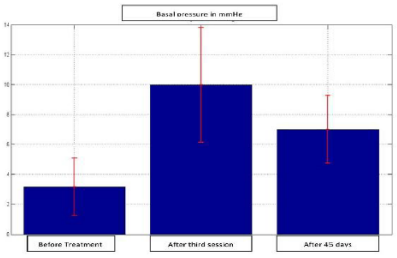
	Media BEFORE treatment	Media AFTER treatment	Value of p	
measurement of pressure basal	3.1	9.9	2.0 x	It can be seen that p is much smaller than 0.05 in all cases, therefore all differences are statistically significant.
measurement of pressure in Kegel contraction	12.0	18.7	3.9 x	

Graph 17: Statistical analysis.

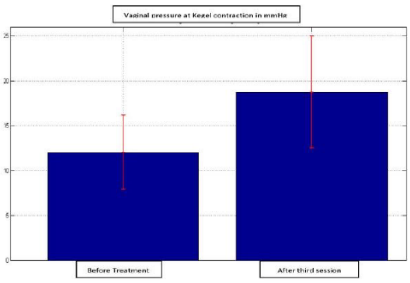
Analysis of validated questionnaires used

1. ICIQ-SF: International Consultation on Incontinence Questionnaire. Any grade which is higher than 1 is diagnosis of incontinence. At higher score, higher severity. Pretreatment mean score was 12.36 (range 5 - 21), while final treatment score had a mean of 3.73 (range 1 - 12). **Graph 20** show the standard deviation, mean and **"p" of 3.2 x 10^{-11}** with statistically significant differences (p: <0.05) which clearly confirm the beneficial effect of the LASER for this disorder.

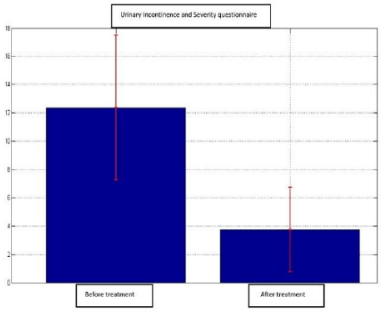
2. QOL-HV-26 POTENZIANI. Quality of Life impairment by overactive bladder questionnaire pre- and post- treatment. Pre Laser mean was 23 points (moderate impairment) ranging between 8 and 38 and post-treatment score was 10 (mild impairment) ranging between 2 and 25. **Estimated "P" was 3.0 x 10^{-9} (Graph 21).**



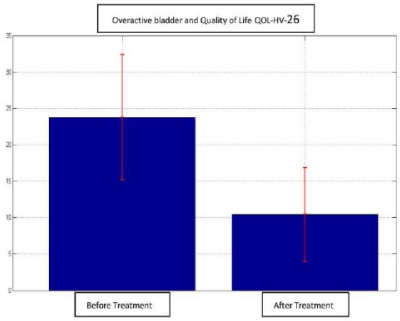
Graph 18: Graphic column of pressurometry changes in repose after laser treatment



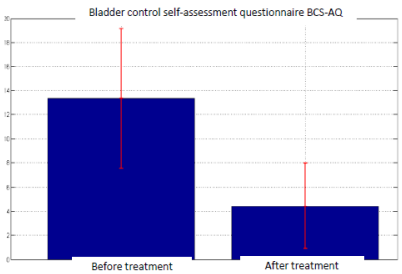
Graph 19: Graphic column of pressurometry changes in Kegel Contraction after laser treatment



Graph 20: Statistical analysis ICIQ-SF



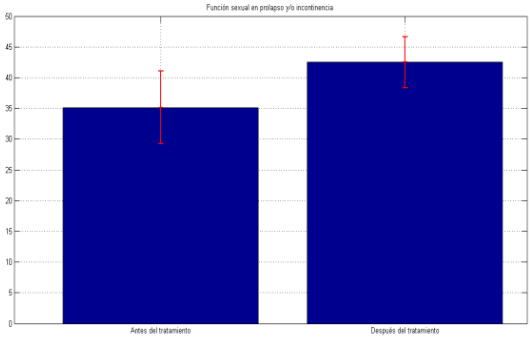
Graph 21: Statistical analysis QUOL-HV26



Graph 22: Statistical analysis BCSA-AQ

3. B-SAQ. Bladder Control Self-Assessment Questionnaire. This questionnaire grade from 0 to 3 in relation to the symptoms and intensity of discomfort; the scores are added to have a bladder control score. Pre-treatment mean score was 13.33 with a range of 3 - 24 points and post-treatment mean was 4.43 with a range of 0 - 15. The 4 points mean (lower than the mean) further shows the benefit of the Laser treatment in the total sample. **Estimated "P" was 7.8 x10^{-10} which is statistically significant (Graph 22)**.

4.- PISQ-12. Questionnaire for sexual function evaluation in women with genital prolapse and/or incontinence. This questionnaire confirms the improvement of the vaginal atrophy attributed to Laser treatment by some publications and also lubrication and vaginal tension which would cause an improvement of sexuality. Questionnaires related to sexuality completed after treatment show its quality improvement in almost all patients. Patients' pre-treatment PISQ 12 mean score was 35.14 (range 26 - 44) while at post-treatment the score showed a mean of 42.48 (range 34 - 47). Three patients did not complete the questionnaire giving as a reason that they thought it was not related to the nature of the trial (two of them had not sexual activity). Improvement showed by PISQ-12 **score is also statistically significant (P: 1.2 x 10-6)** ***(Graph 23).***



Graph 23: Statistical analysis PISQ-12.

Analysis of patients with pre- and post-treatment urodynamic tests

We did not draw conclusions about urodynamic due to the reasons already listed in "Material and Methods"; however, as shown in ***Graph 24***, changes in VLPP values were seen in six patients and also uninhibited contractions (UIC) in 3 out of the total patients. The same happens with bladder maximum capacity which in 6 of the patients increased after Laser. These changes are clearly in line with favorable clinical changes seen. This was only an observation which led as to begin a new trial with an evaluable, non- debatable urodynamic analysis with urodynamic tests before and after Laser treatment performed by the same operator, with the same equipment and same reporting criteria; this study is ongoing by now.

Analysis of patients with previous surgery

In this sample we had six (6) patients with SIUR (recurrent incontinence) and history of vaginal surgery. From this group, two (2) were recurrences from suburethral tape placement (one TOT and one TVT); two (2) were recurrences from traditional surgeries (Marshal Marchetti Krantz) and the remaining two (2) were surgeries for obstetric complications which caused vesicovaginal fistulas requiring correction surgery. From the group of urethral media tape, one (1) patient dried and the other presented such a significant improvement that she did not accept the complementary treatment with a new sling placement. One out of two MMK also dried but required five sessions and the other improved and continues on treatment due to evidence a progress towards healing (at the time of this script, 5 sessions were done). Patients with fistula surgery were those who presented less response with a regular improvement in one case and mild in the other case.

"n"	Blaivas Clasification	Initial Diagnosis and Outcome	Urodynamics Before Treatment	Urodynamics After Treatment
1	Type IIA elevator healthy	UI Dry. SUI-U very enhanced	MBC 220 CNI 30 CC LPP 70	MBC 350 CNI (-) LPP 100
2	Type IIB elevator impaired	SUI+U+UI very enhanced	MBC 400 CNI(-) SUI(-)	MBC 410 CNI (-) SUI (-)
3	Type IIA (Recurrence TVT)	SUI+U: Dry	MBC 250 CNI(-) LPP 100	MBC 380 CNI(-) SUI (-)
4	Type IIA elevator impaired	SUI+U: Dry	MBC 420 CNI (-) LPP 90	MBC 400 LPP 120
5	Type IIA elevator impaired	SUI+U+UI Dry	MBC 200 CNI 30	MBC 370 CNI (-)
6	Type IIB elevator healthy	SUI+U+UI very enhanced	MBC 220 CNI 25 LPP 60	MBC 350 CNI 90 LPP 90
7	Type IIA elevator healthy	SUI+U+UI Dry	MBC 200 CNI (-) LPP 100	MBC 380 CNI (-)
8	Type I	SUI+U Dry	MBC 300 CNI (-) LPP 140	MBC 360 CNI (-)

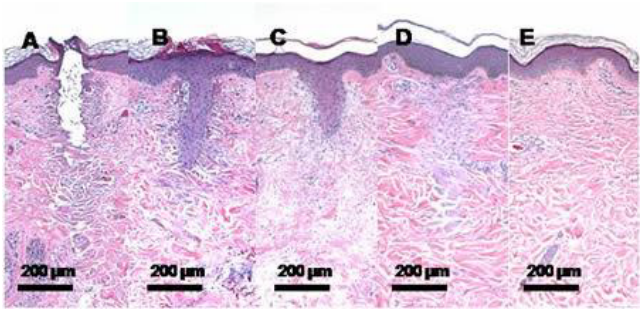
Graph 24: Urodynamic analysis before and after laser treatment.

Discussion and Conclusion

Urine incontinence is a severe problem for health systems. Treatment costs are increasing [10,31,32] and also are progressively increasing the prevalence and incidence of this disorder. More women each day leave hiding this disorder forgetting her embarrassment and giving priority to her quality of life; also, the increase in lifespan expectation and the changes in social, work and sexual activities at fifth decade of life are transforming this issue in a "true epidemic" [33].

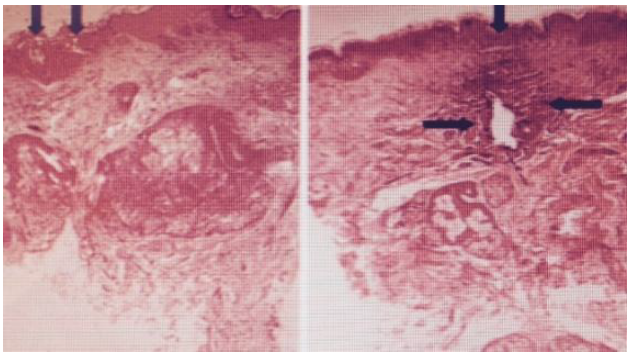
At year 2011 appeared the first reports of intravaginal Laser effect for continence disorders, almost by chance, treating patients with the novelty for that time which was vaginal tensing for genital rejuvenation [34-38].

At **Graph 25** from A to E, histological HE samples photographs show from the time just after the ablative effect (A), the filling of the "vaporized space" as a column shape (B) at 72-96 h, the progress of the healing in the vaporized area (C) (D) at 14 and 28 days respectively, and finally the rejuvenated fascia at two months (E).



Graph 25: Histological changes after laser treatment.

Simultaneously to this study, we are also analyzing the use of the Diode Laser 1470 (with promising results) with circumferential fiber for obtaining a thermal effect only and may compare this effect to the ablative and thermal effect from CO2 together (Graph.26), with which we worked for this presentation. In the first photograph we can see the "notch" caused by the ablation of the tissue columns and in the second slide a transversal area stained with HE shows the coagulation effect (marked with arrows) peripheral to the vaporized area.



Graph 26: Histological changes after laser treatment.

Discussion and Conclusions

Urine incontinence is a severe problem for health systems. Treatment costs are increasing [10,31,32] and also are progressively increasing the prevalence and incidence of this disorder. More women each day leave hiding this disorder forgetting her embarrassment and giving priority to her quality of life; also, the increase in lifespan expectation and the changes in social, work and sexual activities at fifth decade of life are transforming this issue in a "true epidemic" [33].

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Several publications support the concept of the thermal effect for fibroblastic stimuli for collagen production at temperatures between 45 and 60°C [39], but the ablative method acts faster, almost immediately by the immediate "inflammatory" process originated by vaporization ablation, and leucocytes and macrophages cell migration for "repairing" the area with a rapid neo-angiogenesis and neocollagenesis production.

Urethral medial tape is no under discussion; both TVT and TOT are considered the gold standard for SUI treatment, but we have no doubts that the Laser is coming to avoid surgery in a non-minor group of patients who can be cured or significantly improved with it. Clearly, a non-minor group of patients is favored with the Laser treatment due to its tensional effect on anterior fascia, and elevation and support of the bladder floor and urethra, achieving a decrease of hypermovility and therefore improving urethral closure function. Ablative and thermal effect from CO2 is able to stimulate the formation of a new urethrovaginal fascia and vesicovaginal fascia, elastic, young, which acts as a tensional free tape placed in medial urethra supporting the effort of all vesicourethral critical area related to incontinence: bladder neck and medial and posterior urethra.

Based on these observations, this treatment would be indicated for patients where anatomical injury of the pelvic floor is not severe; incontinence grade was not seen as related to problem resolution, both severe and mild responded to the Laser if the patient does not present an anterior prolapse seen at rest or Valsalva descending below the level of the inferior border of pubic symphysis (descended more than 2 cm). If also the II level of the pelvic floor (endopelvic fascia and puborectalis muscle of levator ani) is healthy, the possibility of cure is significantly higher. Because all previously discussed and using Blaivas' classification, we think that patients with continence disorders included in Blaivas 0, I or IIA are undoubtedly ideal for fractional Laser treatment and in accordance to our study more than 80% of cure can be predicted. Within Blaivas' IIA group, if the levator ani is healthy and presenting contraction strength, cure prediction is almost 90%.

Conclusions are similar in relation to urgency and urge incontinence disorders. Anatomical injury is a predictive factor for assessing response, but undoubtedly the Laser also has a modulator effect on pudendal plexus fibers, because resolution or improvement global percentages of these symptoms are higher to SUI symptom, seeing also a higher positive effect than that achieved in SUI in patients with evident or demonstrable prolapse.

We concluded that:

1. Based on this analysis, we can say that for SUI, fractional CO2 Laser has a place for treating patients with minimal anatomical injury regardless the clinical or urodynamic grade of incontinence. 80 to 87.5% of dry patients into these groups undoubtedly indicate its use and, at first, exclude the idea to lead them to surgery for TVT or TOT placement.

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, have a better response than

those having natural births. Multiple vaginal parity with big fetuses is related to injuries in endopelvic fascia and have to lead to a detailed analysis of supporting elements of the pelvic floor to accurate classify the extent of the injury of the patient and make a right potential 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 indication, 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. We does not recommend Laser in SUI in patients with prolapse higher than POP-Q grade I or Blaivas' IIB. In accordance to our study, 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. Fractional Laser is certainly entering as the gold standard within which is a possible rehabilitation of the pelvic floor in symptomatic post-partum patients. The clear demonstration of its beneficial effect on the anterior fascia and also on the endopelvic fascia at DeLancey's level II, makes it imperative for rehabilitation tasks over any other method due to achieve its effects spending lower patient's time and with minimum therapy time (less than a month and only in three sessions of 10 minutes each).

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

7. 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 those patients selected for the treatment and also for health systems which might decrease treatment costs for this disorder of increasing prevalence 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. Assessing all these, we estimate that the cost of a Laser is equivalent of an average of 10 to 20 surgeries, depending of the country. This analysis closes the cost-benefit calculation.

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