



Pelvic Floor Surgery versus Non Invasive Laser Treatment for Vaginal Relaxation Syndrome And Stress Incontinence

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Abstract: Background: vaginal relaxation syndrome is a quite medical condition commonly correlated with vaginal childbirth and natural senility **Aim of this work:** to study the effectiveness and safety of non- invasive laser in the treatment of vaginal relaxation syndrome, stress incontinence and compare it to surgical correction. **Patient's and methods:** study of 150 cases who were complaining of vaginal relaxation syndrome and attended Al Zahra'a University Hospital in the period from 1st of October 2014 to the end of April 2015. **Results:** In our results we found marked improvement in both studied groups as 100% of our cases had improvement in surgical group and 91% of cases improved in Laser group. **Conclusions:** Laser treatment is safe and effective in cases of vaginal relaxation syndrome .

[Zainab Zaki Soliman, Hanaa Farouk Ahmed, and Aida Abdel Mageed. **Pelvic Floor Surgery versus Non Invasive Laser Treatment For Vaginal Relaxation Syndrome And Stress Incontinence.** *Life Sci J* 2021;18(10):11-16]. IS SN 1097-8135 (print); ISSN 2372-613X (online). <http://www.lifesciencesite.com>. 3.doi:[10.7537/marslsj181021.03](https://doi.org/10.7537/marslsj181021.03).

Keyword: Laser treatment, pelvic floor surgery, vaginal relaxation syndrome, urinary stress incontinence

1. Introduction:

As pelvic floor disturbances contain urinary disturbances, pelvic organ prolapse, and fecal incontinence, all these disturbances rise extremely with age. Urinary incontinence has been documented to be having a passive effect on women erotic life (1).

Stress urinary incontinence is known as the involuntary seepage of urine during incremented abdominal pressure (like a sneeze, a cough or unexpected effort) by the International Continence Society. About 63% of all females with urinary incontinence were detected by stress urinary incontinence (2).

However, a women first vaginal child delivery routinely includes soft tissue compression enduring for hours. The second pushing phase of labor causes pressure between the foetal head and vaginal wall averaging 100 mmHg and reaching come up to 230 mmHg (3).

Vaginal relaxation syndrome is defined as the lack of the optimum structural architecture of the vagina. This method commonly correlated with natural senility and is especially influenced by child delivery, whether vaginal or not. Multiple pregnancies further increment the alteration of these structures. Through the vaginal relaxation process, the vaginal muscles become relaxed with poor tone, strength control and support (1).

Actually the propose of operation is to return the natural anatomy, normal vaginal length should be preserved with its axis directed towards S3-S4. So for vaginal prolapse repair, it is important to identify whether the deficiency is in the central or lateral compartments (4).

Many references revealed that SUI and pelvic floor disorder are correlated with reduced collagen content and production of pre-urethral or pelvic connective tissue and ligatures. Actually, lasers have been vastly applied in the field of dermatology and aesthetic medicine because lasers not only promote collagen structures but also induce neocollagenesis. (5)

Fistonic et al. applied the Er: YAG vaginal laser to cure females with SUI and shown that the thermal energy impacts of the Er: YAG vaginal laser can enable collagen reconstruction and neo-collagenesis in vaginal mucosa. They have recommended non-ablative Er: YAG laser application as a successful, safe and comfortable treatment option for symptom relief in clients with systemic urinary incontinence (6)

Laser procedures for vaginal rejuvenation are currently the most popular one. Non ablative laser treatment would have several advantages, tissue is coagulated to cause shrinkage but tissue is not eliminated. The total effect burden on the patient

organ would therefore be considerably decreased, but at the same time the treatment would yield good outcomes correlated with high therapy safety (7).

Two newly minimally invasive non ablative Er: YAG laser procedures have been established as a vaginal tension treatment (Intimal Lase TM) and stress incontinence treatment (Inconti Lase TM). Both treatment methods extend photo-thermal impact of laser beam on mucosal tissue (8).

Possible mechanisms of effects of the Eb:YAG vaginal laser with treatment of stress urinary incontinence might be as follows: The Eb:YAG vaginal laser triggers collagen rebuilding and synthesis of vaginal mucosa, which may strengthen the flexibility and tissue density underneath the urethra to reform the structure and return its function(9).

Aim of this work:

We aimed to study the efficacy and safety of non- invasive laser in the treatment of vaginal relaxation syndrome, stress incontinence and compare it to surgical correction.

2. Patient and methods:

This is longitudinal prospective interventional study included 150 cases who complained from vaginal relaxation syndrome, stress urinary incontinence (SUI), attended Al Zahra' a University Hospital in the period from 1st of October 2014 to the end of April 2015.

Inclusion criteria:

Vaginal canal, introitus and vestibule free of infections

Normal menstrual cycle

Normal cervical cytology

Normal urine analysis

Sexual activity at least once per month

Vaginal prolapse and stress urinary incontinence must be confirmed by Urodynamic studies and sexual dysfunction

Exclusion criteria;

Pregnancy or active infection in vulva, vagina and cervix

These women will be subdivided into 2 groups

1st group: (Laser group); consists of 70 patients

30 patients treated by intimal Laser sessions for vaginal tightening.

40 patients of them proved to be having urinary incontinence treated by incontinence Laser sessions.

2nd group; (surgery group): consists of 80 patients treated by surgical correction and vaginal repair.

Ethical committee approval;

Verbal consent was taken from every patient after explanation of the procedure.

History taking:

Full history taking (personal, menstrual, obstetric, contraceptive, past surgical and medical history), sexual history using **PISQ-12 questionnaire** designed to evaluate sexual function in cases of urinary incontinence and or pelvic organ prolapse described by Rogers et al., (10).

Examination:

General examination; general, abdominal, and back examination

Local examination: for external genitalia, introitus using POP-Q measuring points , vagina and cervix, bimanual examination, recto-vaginal examination for detection of pelvic floor defect as hernia of Douglas pouch and or rectocele.

Examination of stress incontinence: patient was asked to cough with full bladder to detect stress incontinence,

Preoperative preparation:

Hemoglobin level, liver, kidney function, random blood sugar chest X ray ECG, pelvic ultrasound, complete urine analysis, urine culture and sensitivity and urodynamic studies

Perineometric measurements;

Measurement of muscle strength with Peritron 9300 V Perineometer (cardio design Australia)

The Peritron comprises of a – 28 mm – diameter compressible probe attached with a handheld microprocessor.

The probe is introduced into the vagina, compressed so, the pressure is expressed as centimeter of water to calculate muscle strength.

Laser treatment;

The first phase:

Put the patient in lithotomy position after complete sterilization topical anesthesia composed of Lidocain cream was applied to the vestibule and introitus prior session. Then a specially intended Laser speculum was introduced into the patient vagina to serve as an evidence for the Laser beam. Laser irradiation of the anterior vaginal wall starts from the distal end of the vaginal canal towards its upper end.

The second phase: removal of the speculum and hand piece

Remove the adaptor from the speculum and withdraw the speculum from the vagina. Exchange the R11 Hand piece with the PSO3 Hand piece equipped with the standard straight adaptor.

Laser action by straight irradiation of the vestibule and introitus

Apply Laser pulses on the exposed vestibule, including the urethral meatus, by depositing a patterned laser beam across the whole vestibule and introitus area with the aim to follow and through heat these areas, depositing approximately 10J of laser

energy in each Laser sequence and thus induce collagen shrinkage, remodeling and new collagen synthesis.

On each spot location 2-3 smooth pulses should be delivered before moving to the next spot, slight overlap of the spots by approximately 10% may be occurred.

As the urethral orifice is more sensitive, less Smooth pulses should be delivered to this area, depend on patient's sensitivity. Three full passes across the vestibule and introitus area should be performed.

Surgical treatment;

The second group (80) patient treated by surgical correction classical repair, Kelly's suture, posterior colpopoeroraphy, and colposacropexy

Statistical analysis

Data collected and entered for Statistical analysis using SPSS version 12, presented as numbers and percentages, compared using Chi-square test. P value <0.05 accepted to be significant.

3. Results:

This is longitudinal study of 150 cases were complaining of vaginal relaxation syndrome and attended Al Zahra' a University Hospital in the period from 1st of October 2014 to the end of April 2015.

These women were subdivided into 2 groups

1st group: (Laser group); consists of 70 patients

30 patients treated by intimalse Laser sessions for vaginal tightening.

40 patients of them proved to be having urinary incontinence treated by incontilase Laser sessions.

2nd group; (surgery group); consists of 80 patients treated by surgical correction and vaginal repair.

in the current study the age group (35-49yrs) 70% included in surgery group and 50% in laser group the other age group(20-34yrs) represented by less percentage table (1).regarding to parity distribution,

para (1-4) it represented 75.7% and 45% in laser and surgery groups respectively while grand mulipara 5+ represented 55%in surgery group and 18.6% in laser group table(2).the percentage of normal body math index (BMI) in laser group was 51.4% and in surgery group was 73.8% while the sum of overweight and obase patients were more in laser group 48.6% compared to 26% in surgery group table (3).more than one complain(vaginal swelling, SUI, widening, sexual and dragging pain) had been documented in all patients in varying proportions table (4).Grading of vaginal prolapse by POP-Q in the study groups revealed that grade 1&2 (90%) in laser group while grade 3&4 (52.5%) in surgery group before treatment, then it had been noted that all patients in surgery group (100) their Grading improved from 3&4 to become 1&2 while 5 patients (7.1%) in laser group her Grading changed to advanced one (3&4) table (5&6). Peritron measurement in laser group before treatment registered as follow 22(31%) had poor muscle strength, 48(68.6%) had good muscle strength, one month later after treatment good muscle strength representend in 64 (91.4%) and 6(8.6%) had strong muscle strength while in surgery group 28(35%) had poor strength, 52(65%) had good strength and after surgery 73(91.2%) had strong muscle strength and 7(8.8%) had good strength with highly significance difference (p-value <0.001 table (7&8), three months later the all patients in surgery group had strong muscle strength (100%) table (9). In current study the cure rate of SUI by surgery was (100%) with no residual complain while in laser group it was (70%) with 9 cases (30%) still had SUI table (11).our study reported that sexual life improvement had been notified to change from moderate sex 8.6% (6) patients to had better sex (40%) 28 patients in laser group, while in surgery group it changed from 91.2% to 100% after one month and three months respectively from treatment either laser or surgical table (12).

Table I: age (yrs) in the studied groups

Age	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
20 – 34 yr.	23	32.9	10	12.5	9.497	0.009
35 – 50 yr.	35	50	56	70		
More than 50yr	12	17.1	14	17.5		

P >0.05: NS, P < 0.05: S, P < 0.01: HS.

Table II: Parity in both groups

Parity	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Nulliparous	4	5.7	0	0.0	23.545	<0.001
Para 1-4	53	75.7	36	45		
Para 5 +	13	18.6	44	55		

Table III: Comparison between our patients as regards to BMI

Parity	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Underweight	0	0.0	0	0.0	13.352	0.001
Normal	36	51.4	59	73.8		
Over weight	24	34.3	8	10		
Obese	10	14.3	13	16.2		
Morbid obese	0	0.0	0	0.0		

Table IV: Comparison between our patients as regards to Complaint

Complaint	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Vaginal Swelling	20	28.5	72	90	59.4	<0.001
Widening	36	51.4	0	0.0	54.1	<0.001
Sexual complain	32	45.7	54	67.4	7.24	0.007
Dragging pain	8	11.4	11	13.8	0.18	0.670
Stress urinary incontinence	30	42.9	33	41.2	0.04	0.842

Table V: Grading of POPQ in both groups before treatment

POPQ	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Grade 1	18	25.7	4	5	46.7	0.000
Grade 2	45	64.3	26	32.5		
Grade 3	7	10	40	50		
Grade 4	0	0.0	10	12.5		

Table VI: Grading of POPQ in both groups after treatment

POPQ	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Grade 1	45	64.3	56	56	0.25	0.01
Grade 2	20	28.6	24	24		
Grade 3	5	7.1	0	0		
Grade 4	0	0.0	0	0		

P > 0.05: NS, P < 0.05: S, P < 0.01: HS.

Table VII: Pelvic Floor muscle strength(contraction) measured by peritron in CMH2O in both studied groups before treatment

Peritron	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Poor (< 20 cm H2O)	22	31.4	28	35	0.214	0.643
Good (20- 40 cm H2O)	48	68.6	52	65		
Strong (> 40 cm H2O)	0	0.0	0	0.0		

Table VIII: pelvic floor muscle strength (contraction) measured by Peritron in CMH2O after one month of treatment

Peritron	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Poor (< 20 cm H2O)	0	0.0	0	0.0	10.372	<0.001
Good (20- 40 cm H2O)	64	91.4	7	8.8		
Strong (> 40 cm H2O)	6	8.6	73	91.2		

P > 0.05: NS, P < 0.05: S, P < 0.01: HS.

Table IX: pelvic floor muscle strength measured by peritron in CMH2 after 3 month after treatment

Peritron	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
Poor (< 20 cm H2O)	0	0.0	0	0.0	66.667	<0.001
Good (20- 40 cm H2O)	42	60	0	0.0		
Strong (> 40 cm H2O)	28	40	80	100		

P > 0.05: NS, P < 0.05: S, P < 0.01: HS.

Table X: the incidence (%) of stress urinary incontinence in both groups by urodynamic study before treatment

stress incontinence	Laser group		Surgery group		Chi-square test	
	NO	%	NO	%	X2	P Value
No stress	40	57.1	47	58.8	0.04	0.842
Urinary stress	30	42.9	33	41.2		

Table XI: Comparison between our patients as regards to stress incontinence before and after treatment

stress incontinence	Laser group		Surgery group	
	NO	%	NO	%
Before treatment	30	100	33	100
After treatment	9 still had stress	30	0 No stress	100

Table XII: PISQ-12 Questionnaires before and after treatment in both groups

PISQ-12 Questionnaire		Laser group		Surgery group		Chi-square test <	
		No	%	N	%	X2	P-Value
Pretreatment	Bad sex	22	31.4	28	35	0.214	0.64
	Moderate sex	48	66.6	52	65		
	Better sex	0	0.00	0	0.00		
1 month	Bad sex	0	0.00	0	0.00	10.37	< 0.001
	Moderate sex	64	91.4	7	8.8		
	Better sex	6	8.6	73	91.2		
3 month	Bad sex	0	0.00	0	0.00	66.66	<0.001
	Moderate sex	42	60	0	0.00		
	Better sex	28	40	80	100		

P > 0.05: NS, P < 0.05: S, P < 0.01: HS.

4. Discussion:

Vaginal relaxation syndrome is a quite medical condition usually associated with vaginal child delivery and natural aging. Female organ prolapse, urinary incontinence and fecal incontinence are dramatically increased with age.

This study was conducted on 150 cases were complaining of vaginal relaxation syndrome and attending Al Zahra'a University Hospital in the period from 1st of October 2014 to the end of April 2015.

These women were subdivided into 2 groups:

1st group: (Laser group): consists of 70 patients

30 patients treated by intimate Laser sessions for vaginal tightening.

40 patients of them proved to be having urinary incontinence treated by incontinence Laser sessions.

2nd group; (surgery group): consists of 80 patients treated by surgical correction and vaginal repair

In the present study the age group between our patients from 20 to 34 years formed 32.9 % in laser group compared to 12.5 in surgery group and patient age between 35 to 49 years formed 50% I laser group and 70 % in surgery group.

As regarded to parity the nulliparous mother were 5.7 % in laser group and 0% in surgery group while parity from 1 to 4 formed 75.7 in laser group and 45 % in surgery group while multiparous mothers have more than 5 deliveries formed 18.6% in laser group and 55% in surgery group.

In the current study 51.4% of our patient having normal body mass index compared to 73.8% in

surgery group while obese patients were 48.6% in laser group compared to 26% in surgery group.

This is in agreement with *Aniuliene (2015)* who concluded that the major potential risk factors for pelvic organ prolapse are vaginal birth, number of childbirths, age, enhanced intra-abdominal pressure and fatness. (10)

Most of the patients in our study were having more than one complaint urinary stress incontinence formed 42.9% in laser group compared to 41.2 in the surgery group. Sexual complaints

Form 45.7 % among laser group compared to 59.4% in surgery group. Swelling form 28.5 % among laser group compared to 67.5% in surgery group. Dragging pain form 11.4 % among laser group compared to 13.8% in surgery group.

This is in coincide with *Aniuliene (2015)* who found that the main possible complaints are vaginal swelling, dysfunction of urination, bowel movement and sexual dysfunction. (10)

In the present study we assessed our patients by pelvic organ prolapse quantification exam (POPQ) showed that 90% of the laser have POPQ grade 1& 2 while in the surgery group 52.5% have the same grade, the improvement after 3 month as regards to POPQ test were 100% in surgery group and 92.9 in laser group.

Fistonc et al (2012) studied thirteen participants with different degree of prolapse most of them (nine patients) had stage1 prolapse while 3 patients had stage2 and 1 patient stage3 treated by laser. On follow up 6weeks after treatment for 12 patient revealed that

6 patient had 50% in their prolapse degree and 5 patients had one stage of improvement. (11)

As regards to our work we found marked improvement in pelvic floor muscle contraction 1 month after treatment by 91.4% in laser group and 100% in surgery group but this improvement decreased to 40 % in laser group only after 3 month of treatment which may raise the question if these patient need more session of laser treatment. Also we found marked improvement in pelvic floor muscle contraction in both group but complete stratification in laser group after two sessions.

Our study in correlation with *Sarcoglu (2011) (12) and Fistonc et al (2012) (11)*; they reported that Periometric measurements appeared increments in all measures values : maximum squeeze on average incremented from 18 to 23.8mm Hg, average squeeze from 11.2 to 17.9, while the period of pressure on average incremented from 5.1 to 5.3 second.

In our results, we revealed that the cure rate of urinary stress incontinence is 100% in surgery group and 70% in laser group. This in agreement with *Maher (2013)* who reported an improvement in urodynamic results in 20 patient (68%) while there is no improvement in 8 patients (32%) from totally 28 patients treated by IncontiLase TM protocol (13).

In correlation to our study *Sarcoglu (2011)* from Numune Research and Training Hospital who concluded that treatment of stress incontinence and laser vaginal tension utlizing single session on IncontiLase TM or IntiLase TM protocols, subjecting to patient indication. (12)

Many possible techniques of impacts of the Eb: YAG vaginal laser in applying SUI might be as follows: The Eb: YAG vaginal laser triggering collagen reconstruction and formation of vaginal mucosa.

This may strengthen the flexibility and tissue density underneath of the urethra to reform the structure and restore its function. (14)

Gaspar and Brandi 2017 appeared that non-ablative intra-urethral Er:YAG laser also has a safe and effective results in curing patients with intrinsic sphincter deficiency. (16)

Conclusions:

We concluded that the IntimaLase and IncontntiLase are safe treatment with good results in mild and moderate degree of vaginal prolapse.

Laser treatment improved sexual function and sexual stratification increased by laser as 91% and by surgery 100% after 3 months.

Laser treatment improve stress urinary incontinence by 91.2% while surgery have 100% cure rate

10/12/2021

Recommendation:

Further studies to evaluate Lase efficacy in treatment of vaginal relaxation syndrome and stress incontinence on large scale with longer period of follow up

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