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Up to 3-year Follow-up of Patients with Vaginal Relaxation Syndrome Participating in Laser Vaginal Tightening

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ABSTRACT

Vaginal Relaxation Syndrome (VRS) is defined as a laxity of the vaginal wall due to changes in connective tissue, usually associated with the normal aging process. Laser vaginal tightening with non-ablative, minimally invasive Er:YAG laser using the IntimaLase® protocol has been performed in our practice since 2011, with over 1000 patients treated since then. After 3 years of performing laser treatments, a telephone follow up of 60 patients was performed to overview the results and to evaluate the long-term efficacy of laser vaginal tightening. Telephone interviews were obtained asking patients to answer the LVT questionnaire and self-assess the efficacy of the IntimaLase® laser vaginal tightening treatment, based on 6, 12, 18, 24 and 36-month follow ups. According to the patients' evaluation of the results, the average duration of effect after the therapy was 16 months, with significant improvement of stress urinary incontinence and prolapse. Adverse effects were limited to mild and transient edema and a tolerable heating sensation in a few cases. Further, results also showed that 83.33% of participants would be willing to repeat the therapy. From our observation we can suggest that two treatments are sufficient for obtaining a long-lasting improvement of vaginal relaxation syndrome, and a follow-up evaluation visit 8 months after the second treatment would be recommended, followed by a maintenance session if needed. The vast majority of patients find the concept of IntimaLase® therapy appealing, and the brief and painless ambulatory procedure motivates them to comply with a yearly maintenance.

Key words: Vaginal Relaxation Syndrome, Er:YAG laser, non-ablative treatment, Laser Vaginal Tightening.

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I. INTRODUCTION

Vaginal Relaxation Syndrome (VRS) is defined as a laxity of the vaginal wall due to changes in connective tissue, which is usually associated with the normal aging process. Multiple pregnancies and deliveries as well as the onset of menopause, which causes a decline in hormone levels and vaginal atrophy, can contribute to a worsening of the VSR condition [1]. Other potential medical consequences associated with vaginal relaxation syndrome are also pelvic organ prolapse, stress urinary incontinence, bowel incontinence, altered sexual function, dyspareunia, and chronic pelvic pain [2,3].

Loss of vaginal tightness can result in the reduction of friction during intercourse and a decrease or loss of sexual satisfaction [4], which are referred to as female sexual dysfunction. This condition is rarely discussed, possibly because of the embarrassment as well as the lack of evidence-based treatment options; this is why the incidence of vaginal relaxation syndrome is unknown.

Various treatment options are available for VRS treatment, ranging from non-invasive behavioral and pharmacological therapies to more invasive surgical procedures. Nonsurgical treatments for vaginal relaxation syndrome included Kegel exercises or pelvic floor therapy with electrical stimulation of the vaginal musculature to promote perineal muscle strength. Many pharmacological therapies are under investigations, but there are only a few approved by the FDA so far [5]. Although behavioral and pharmacological treatments are non-invasive and safe, they have limited efficacy. Surgical procedures promise much better and longer-lasting results, but are usually associated with a higher risk of scar formation, nerve damage and decreased sensation as well as an extended recovery time required [6,7]. Laser surgical procedures are the most popular VRS treatment options currently available, but are still a relatively aggressive with a long recovery period [8].

This is why non-invasive or minimally invasive treatment methods for VRS that offer good efficacy combined with a high level of safety and a short recovery period were recently developed. A few papers have been published proposing laser therapy for vaginal rejuvenation treatment performed with fractional CO_2

or Er:YAG lasers, based on ablation of mucosal tissue, and although described as minimally invasive, a long recovery time is still needed [9,10]. There were several cases of bleeding, pain and burning reported by Gaspar et al. using fractional CO_2 laser treatment [10]. On the other hand, a minimally-invasive, non-ablative Er:YAG laser vaginal tightening procedure (IntimaLase®) was introduced recently that utilizes photothermal laser-mucosa tissue interaction [11–13]. Using special SMOOTH mode pulses, precisely controlled Variable Square Pulse (VSP) Er:YAG [14] laser energy is delivered to the vaginal canal and introitus area, creating a temperature increase within the mucous tissue without any resulting ablation. Heating of mucous induces immediate contraction of collagen; the fibers become shorter and thicker and consequently the irradiated tissue contracts and shrinks [14]. Additionally, the processes of collagen remodeling and neo-collagenesis are also induced [15–19], and at the end of these processes the treated tissue becomes enriched with new collagen, resulting in vaginal laxity improvement and a reduction of vaginal relaxation syndrome. Known as IntimaLase®, the treatment presents a quick and easy-to-perform ambulatory procedure with minimal patient discomfort and no adverse effects observed [11–13].

Laser vaginal tightening has been performed in our practice since 2011 and over 1000 patients were treated since then, of which 103 patients have been included in this study. After 3 years of treatments, a telephone follow up has been performed to overview the results to evaluate the long-term efficacy of laser vaginal tightening with non-ablative, minimally invasive Er:YAG laser using the IntimaLase® protocol.

II. PARTICIPANTS AND METHODS

103 patients suffering from vaginal relaxation syndrome has been treated using IntimaLase® treatment protocol with a 2940 nm Er:YAG laser (XS Dynamis Fotona, Slovenia) between June 2011 and May 2014.

All patients testified having VRS or had otherwise acquired "loose vagina" and diminished sexual gratification, and expressed their desire to improve their vaginal tightness.

The inclusion criteria included normal cell cytology (PAP smear), negative urine culture, a vaginal canal, introitus and vestibule free of injuries and bleeding, sexual activity at least once per month. Pregnant women and women taking photosensitive drugs or with injury or/and active infection in the treatment area, undiagnosed vaginal bleeding, and active menstruation were excluded from the treatment.

Before the treatment, detailed information about the treatment was provided and signed informed consent forms were obtained from all patients.

The IntimaLase® treatment consisted of one to four treatment sessions with 15 to 30 days interval between the sessions.

Prior to treatment and at follow-up before the second session, patients completed a PISQ-12 questionnaire [20]. A pelvic organ prolapse quantification (POP-Q) exam [21] was also performed before each session. For better assessment of the long-term efficacy of laser vaginal tightening, a special laser vaginal tightening (LVT) questionnaire was designed and used on telephone follow-ups based on a survey of closed Likert response. The LVT questionnaire consists of several questions assessing the duration of the results, satisfaction and absence of symptoms associated with vaginal laxity. The first set of questions was designed to assess satisfaction and willingness to repeat and recommend this treatment to friends. The next set of questions were designed to evaluate the changes of life quality after the treatment and the last set of questions were designed to evaluate the presence of symptoms associated with vaginal laxity, such as prolapse and urinary incontinence. The analysis, including patient phone interviews and data processing, were conducted by gynecologists at the University Hospital of Caracas who did not treat the patients.

a) Treatment protocol

The IntimaLase® treatment protocol was performed in two steps with a 2940 nm Er:YAG laser (XS Dynamis, Fotona, Slovenia), using SMOOTH mode, which delivers laser energy in a non-ablative, thermal-only technique achieving a heating of the vaginal mucosa to around 60°C. In the first step, the complete length of the vaginal canal was subjected to laser irradiation using a specially designed circular beam delivery adapter, while in the second step the introitus and vestibule were irradiated as well. To perform quick and easy irradiation of the vaginal canal in its full circumference, the circular beam delivery adapter is guided by a speculum. For performing the second step, a patterned straight-firing handpiece was used.

Immediately before the laser treatment, the patient's vagina (vestibule, introitus and vaginal canal) was thoroughly washed and the disinfecting solution was carefully dried off and removed from the mucosa.

The circular adapter used in the first step of the procedure enables 360 degree laser irradiation of the vaginal canal without overlapping via a simple step-by-step withdrawal of the laser handpiece outwards from

the laser speculum. Laser energy of approximately 90 J is delivered to each irradiation location (belt) in a special, proprietary sequence (developed by the laser manufacturer, Fotona) producing a non-ablative, precisely controlled, thermal-only effect on the vaginal wall that causes immediate tissue shrinkage and initiates collagen remodeling and new collagen synthesis in the vaginal mucosa. Two complete passes of laser irradiation of the whole vaginal canal was performed in the first step. Additionally, two short passes as reinforcement of the lower vaginal third was performed. The speculum was rotated during the procedure to optimize the exposure to the tissue. The second step of the IntimaLase® procedure is performed using a straight-firing patterned laser handpiece. Patterned laser-beam energy is delivered to the whole area of the vestibule and introitus with the manufacturer's same proprietary sequence, depositing approximately 10 J of laser energy in each laser sequence.

The safety and tolerability of the procedure was assessed by the monitoring and documentation of potential adverse effects during and after the procedure, and by assessment of the patients' discomfort (pain) level on an 11-grade (0-10) visual analog scale.

Before each session topical anesthesia was applied to the vestibule (Lidocaine 2%) and to the introitus area (Lidocaine spray 10%).

No special post-op therapy was needed. Patients were only advised to avoid sexual activities for a period of 72 hours after each of the treatment sessions.

Follow-ups were scheduled at 48 hours after each session (via telephone interview with the patient), during the second visit, and prior to the second treatment session (15-30 days after the first session). Telephone interviews were obtained asking patients to answer the LVT questionnaire and self-assess the efficacy of the IntimaLase® laser vaginal tightening treatment, in order to evaluate our three-year experience with IntimaLase® therapy based on 6, 12, 18, 24 and 36-month follow ups..

III. RESULTS

Among the 103 patients treated for Vaginal Relaxation Syndrome in the past three years in our clinic, 60 patients (58.25% of the participants) participated in the telephone interview. The remaining 43 patients (41.75%) were withdrawn from the study since they did not answer the telephone (72.09%) or changed their telephone number (23.26%); only two patients (4.65%) refused to participate in the follow-up interview. According to symptoms, participants were divided into four groups. The first group involved patients with different stages of prolapse (POP) and Stress Urinary Syndrome (SUI), the second group involved patients with POP and an absence of SUI, the third group consisted of patients with SUI and an absence of POP, and the fourth group consisted of participants with no POP or SUI symptoms present according to the obtained questionnaire. The mean age of participants was 39 years and ranged from 20 to 74 years. On average, participants had 1.5 children (ranging from 0 to 5). Body mass index (BMI) varied from 17.58 to 40.58 and was on average 25.66 (Table 1).

Table 1: Demographic data of patients involved in the study

Patients (n=60)	Patients with POP and SUI (n=5)	Patients with POP without SUI (n=11)	Patients with SUI without POP (n=5)	Patients without POP or SUI (n=39)
Average age	44	51.1	35.8	36.2
Age range	(33-51)	(33-74)	(22-53)	(20-64)
BMI	25.27 (22.38 – 27.27)	27.39 (25.97 – 28.8)	26.95 (23.04 – 37.22)	24.92 (17.58 – 40.58)
Parous status				
No. of Parous patients	4 (80%)	10 (91%)	5 (100%)	22 (56%)
Average pregnancies	2.4 (1-4)	2.55 (0-5)	1.8 (1-3)	1.13 (0-3)
Delivery type				
Vaginal	4 (80%)	10 (91%)	5 (100%)	37 (95%)
Caesarean	1 (20%)	1 (9%)	0 (0%)	2 (5%)
Menopausal status				
Pre-menopausal	4 (80%)	7 (64%)	5 (100%)	37 (95%)
Post-menopausal	1 (20%)	4 (36%)	0	2 (5)
Sexual activity				
Frequency of sexual activities / week	1 (0.25-2)	2 (0.5-4)	3 (1-5)	2 (0.25-7)
Smoking	2 (40%)	1 (27%)	1 (20%)	6 (15%)

On the basis of the amount of time after the therapy at follow up, participants were divided to five groups (Table 2).

Table 2: Result of three-year experiences obtained from telephone interviews.

Group	Time after therapy (Follow-up time)	Percentage of participants	Average No. of sessions	The effect of the therapy at follow-up
Group A	36 months	8 (13.3%)	1.5	7 (87.5%)
Group B	24 months	27 (45%)	1.6	13 (48.1%)
Group C	18 months	7 (11.6%)	2.3	5 (71.4%)
Group D	12 months	15 (25%)	1.8	8 (53.3%)
Group E	6 months	3 (5%)	1.3	2 (66.7%)

According to the patients' evaluation of the results, the average duration of effect after the therapy was 16 months; only 1 participant reported no effect after the therapy. The majority of results (30%) persisted 18 to 24 months followed by 12 to 17 months (28.3%) (Figure 1).

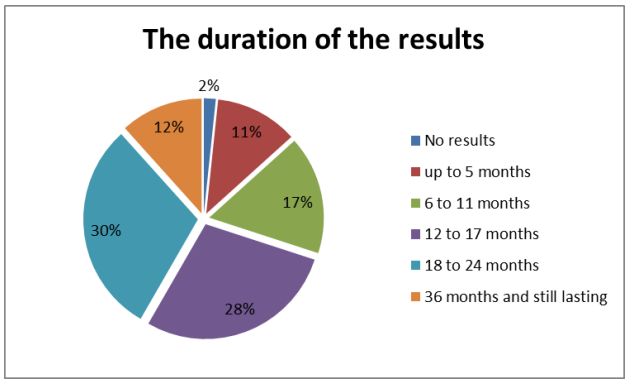

Fig. 1: Duration of the effect of IntimaLase® therapy

It should be mentioned that in 33% of the participants, the results of the laser therapy are still persisting, regardless of the follow up, so it could be predicted that the percentage in the long-lasting results category would be even higher at the end of this study. It is also interesting that in 87.5% of the patients with a three year follow up, the results still persisted, and a majority (67%) of them received only one treatment (Table 2).

We also looked for correlation between risk factors and persistence of the results, but neither age ($p = 0.975$), nor number of sessions ($p = 0.502$), nor prolapse and/or incontinence ($p = 0.071$), menopause ($p = 0.388$), presence of constipation ($p = 0.341$) nor smoking ($p = 0.825$) showed a direct correlation with the decline of the results.

58% of all participants indicated high satisfaction with the results of the treatment, 31% described moderate satisfaction and only 11% of participants were poorly satisfied with limited or no (in only one patient) treatment outcomes (Figure 2). Further, results also showed that 83.33% of participants would be willing to repeat the therapy. While the majority (60%) of the participants did not specify the reason for rejecting the repetition of the procedure, the pain (in 30% of participants) and poor results (in 10% of participants) were stated as reasons for not repeating the therapy. 90% of the participants would also recommend the treatment. The average pain evaluated by the patients was 1 (range 0-10). Adverse effects were limited to mild and transient edema and a tolerable heating sensation in a few cases.

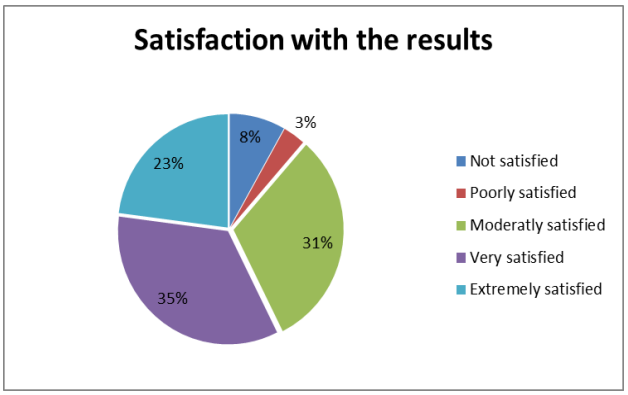

Fig. 2: Satisfaction with the results of IntimaLase® therapy

Although this study is centered on the analysis of VRS, all patients included information regarding symptoms of urinary incontinence and prolapse. Following Petro's law, a change in the longitudinal axis of the vaginal canal may improve SUI and POP [22]. It seems relevant to highlight that among patients with stress urinary incontinence diagnosed before the treatment, symptoms of SUI were absent at follow up interviews in 21.43% of the patients, and only three patients (13.63%) out of 22 with prolapses diagnosed before the therapy reported prolapse symptoms at the follow up interview. Urinary incontinence recurred in 78.57% of patients at the follow-up interview. Improved intercourse after treatment persisted in 28.57% of cases.

IV. DISCUSSION

Vaginal relaxation syndrome is most often associated with a reduction in a patient's quality of life and is rarely correlated with severe clinical conditions. Therefore, the need for minimally invasive therapies has generated increasing interest for the treatment of vaginal relaxation syndrome using less invasive techniques. Recently, several studies reported promising short-term results using different thermal therapies such as laser vaginal treatment [11–13, 22–24]. Recent studies on ovine vaginal introitus biopsies have shown histological changes leading to fibroblast stimulation and subsequent collagen replacement and augmentation using low-dose radiofrequency therapy [23]. A low-dose radiofrequency (RF) therapy is a nonsurgical outpatient procedure with limited treatment options, since it treats only the vaginal introitus tissue in women who experienced vaginal introital laxity after vaginal childbirth [23–25]. Recently, a novel non-invasive therapy has been proposed using Er:YAG laser in non-ablative thermal-only mode, allowing the treatment of the whole vaginal canal as well as introitus, and several preliminary studies using this approach have shown promising results confirming the safety as well as efficacy of the procedure [9, 10]. The first results using

the IntimaLase® protocol with Er:YAG laser were reported by Dr. Mario A. Rivera D. [12]. The first group of 135 patients was treated in the period from June 2009 to September 2010 in the GynDermo Laser Clinic and 122 patients (90.4%) expressed their satisfaction with the tightening improvement at 1 month after the first session of the IntimaLase® treatment. 13 patients (9.6%) declared less improvement, and a second treatment was performed to improve the results. On the subsequent follow-up interviews at 3 and 6 months, all patients expressed their satisfaction with vaginal tightening improvement with the IntimaLase® therapy. In a second study, Dr. Rivera used some additional measuring methods for better evaluation of the results, such as the McCoy Female Sexuality Questionnaire (MFSQ) to measure changes in sexual gratification, as well as measurements of the shrinkage of the vaginal canal. An average shrinkage of the vaginal canal of 17% (3-28%) was achieved in all patients and results of the MSFQ showed an average improvement of 8.5 points on a 36-point scale [12]. Our preliminary study performed on 21 patients between June 2011 and January 2012 using two sessions of IntimaLase® treatment showed an improvement in all participants, and a large majority of the patients (20/21 or 95%) assessed the improvement of vaginal tightness as strong or moderate. An improved sensation of tightness was also reported by the patient's partners. According to the patients' description, improvement was reflected in better sensation (95.2%), better orgasm (57.1%) as well as an increased number of orgasms (14.3%). Results of POP-Q measurements also showed an improvement of prolapse, which was present in 5 patients (23.8%) before treatment. Three patients suffering from SUI before the treatment reported significant improvement (2 patients) or even complete healing (1 patient) after IntimaLase® therapy [11]. Regarding the safety, tolerability and return to normal activity, the IntimaLase® treatment was proven to be safer than any other available procedures described so far, with minimal discomfort for the patients and adverse effects limited to a burning sensation and edema lasting up to 48 hours, allowing for a return to normal sexual activities within 72 hours after the treatment. Research has shown that with the SMOOTH mode pulses, human tissue is non-ablatively heated to a depth of 300 microns, resulting in collagen remodeling even at 100 μm below the epidermal-dermal junction, which is just what is required for a depth-controlled thermal treatment of vaginal mucosa tissue [16–18].

Recent pilot studies have reported significant improvement with laser vaginal tightening, but no study evaluating long-term efficacy has been reported to date. In this article we have described the results of a retrospective study evaluating the long-term effect of the IntimaLase® therapy conducted from our data collected after three years of our experience with the IntimaLase® protocol.

From our observation that the majority (67%) of the patients with persisting results received two treatments, we can suggest that two treatments are sufficient for achieving a long-lasting improvement of vaginal relaxation syndrome, and a follow-up evaluation visit 8 months after the second treatment would be recommended, followed by a maintenance session if needed. Since the majority of the results persisted 18 to 24 months and the effect of the therapy starts to fade two years after the treatment, a maintenance therapy after two years would be recommended as a solution to enable longer persistence of the results. This recommendation would be feasible since according to a follow-up interview, 83.33% of the participants agreed to return to the therapy. The vast majority of patients find the concept of IntimaLase® therapy appealing and the brief and painless ambulatory procedure motivates them to comply with maintenance therapies.

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