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Laser Vaginal Tightening (LVT) – evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome

Jorge E. Gaviria P, Jose A. Lanz L
Aldana Laser Center, Caracas, Venezuela

ABSTRACT

The objective of this study was to evaluate the safety and efficacy of a novel laser treatment for vaginal relaxation syndrome.

Method: A pilot study was conducted on 21 patients who received the novel laser treatment (IntimaLase) for vaginal tightening with a 2940 nm Er:YAG laser between June 2011 and January 2012. All patients received two treatment sessions with an interval between sessions of 15 to 30 days. In a non-ablative, thermal-only mode, laser energies of approx. 90 J per treated area in the vaginal canal and of approx. 10 J per treated area at the vestibule and introitus were delivered to the patient's vaginal mucosa. A special Laser Vaginal Tightening (LVT) questionnaire was designed for assessing the improvement of vaginal tightness via patient self evaluation and by their sexual partner's assessment. POP-Q measurements were also performed prior to both treatment sessions in an attempt to objectively assess the change in vaginal tissue structure. Additionally, a PISQ-12 questionnaire was also used as a standard assessment tool for pelvic organ prolapse, urinary incontinence and sexual gratification. Patients were also asked about treatment discomfort, potential adverse effects, and their general satisfaction with the treatment.

Results: Twenty of twenty one patients (95%) reported significant (moderate and strong) improvement of their vaginal tightness, and also all of their partners confirmed an improvement of vaginal tightness during sexual intercourse (85% reported significant improvement and 15% reported mild improvement). All patients but one (95%) reported better sex after the treatment. Five patients had prolapses (of stages 1-3) before receiving the treatment, which improved in all of these patients, leaving just two of them with prolapses (one with stage 1 and one with stage 2). Three patients suffering from SUI before the treatment reported significant improvement (2) and complete healing (1). There were no adverse effects and patient discomfort was assessed as minimal.

Conclusions: The novel laser vaginal tightening therapy (IntimaLase) is an effective and safe method for the treatment of vaginal relaxation syndrome.

Key words: vaginal relaxation syndrome, laser treatment, Er:YAG laser, collagen remodeling and synthesis

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I. INTRODUCTION

Vaginal Relaxation Syndrome (VRS) is a quite common medical condition described as a loss of the optimal vaginal structure and is usually associated with vaginal child delivery and natural aging. Multiple pregnancies and deliveries contribute to a worsening of the VSR condition, as well as the onset of menopause, which causes a decline in hormone levels and vaginal atrophy. Most women (and their husbands or partners) refer to vaginal relaxation syndrome as "loose vagina" [1], complaining of a loss of vaginal tightness, which is directly related to the reduction of friction during intercourse and thus to a decrease or loss of sexual gratification [2].

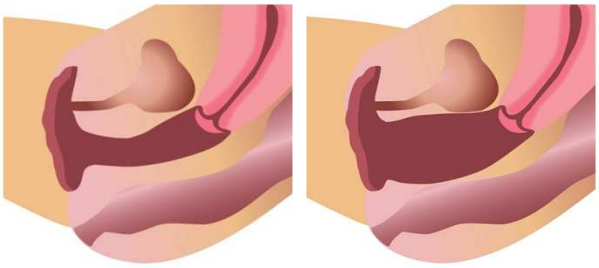

Fig. 1: Tight vs. expanded (relaxed) vagina

There is a large spectrum of various VRS treatment options on the market ranging from behavioral (Kegel exercises) through pharmacological therapies (hormonal, tightening creams and sprays) to various more-or-less invasive surgical procedures. While behavioral and pharmacological therapies are noninvasive and safe, they have limited efficacy. On the other hand, various surgical procedures promise a much better final result at the price of higher associated risks.

Surgical procedures require the cutting and rearrangement of vaginal and peripheral tissue in order

to reduce the size of the vaginal canal. Operating on or near sensitive vaginal tissue is inherently risky and can cause scarring, nerve damage and decreased sensation. Furthermore, patients require an extended recovery period.

The most popular among the surgical procedures are those performed with lasers, where the laser is used instead of scalpel [3]. However it is still a relatively aggressive surgery with a long and painful recovery period.

This is why many clinical researchers are still searching for a non-invasive or minimally invasive treatment method for VRS that would offer good efficacy combined with a high level of safety and a short recovery period.

There are several novel therapies on the market, among them is IntimaLase - a minimally-invasive, non-ablative Er:YAG laser vaginal tightening procedure utilizing photothermal laser-mucosa tissue interaction. Precisely controlled VSP [4,5] laser energy pulses delivered to the vaginal canal and introitus area cause heating of the tissue and collagen within. Heating of collagen causes its immediate contraction, fibers become shorter and thicker and consequently the irradiated tissue contracts and shrinks [5]. Aside from a momentary collagen and tissue shrinkage reaction, the processes of collagen remodeling and neocollagenesis start [6-11] and at the end of these processes the treated tissue becomes enriched with new collagen, appearing younger, tighter and more elastic, thus improving vaginal laxity and reducing the effects of vaginal relaxation syndrome.

The purpose of this study was to assess the efficacy and safety of this new laser treatment.

II. MATERIALS AND METHODS

Twenty one (21) patients suffering from vaginal looseness were submitted to IntimaLase treatment with an Er:YAG 2940 nm laser (XS Dynamis, Fotona, Slovenia).

All treatments were executed at a single location, the Aldana Laser Center in Caracas, Venezuela in the period between June 2011 and January 2012.

a) Inclusion and Exclusion Criteria

At the baseline consultation visit patients were examined to determine their suitability according to the inclusion and exclusion criteria. All patients submitted to treatment had passed inclusion criteria and had provided written informed consent forms.

All patients testified to suffering from vaginal relaxation syndrome or had otherwise acquired "loose vagina" and diminished sexual gratification, and expressed their desire to improve their vaginal tightness.

The inclusion criteria were: normal cell cytology (PAP smear), negative urine culture, vaginal canal, introitus and vestibule free of injuries and bleeding, sexual activity at least 1/month.

The exclusion criteria were: pregnancy, intake of photosensitive drugs, injury or/and active infection in the treatment area, undiagnosed vaginal bleeding, and active menstruation.

At the beginning of this study patients were aged between 22 and 61 years (average 37.7). A total of 19 (90.5%) were premenopausal and 2 (9.5%) postmenopausal. The patients' average body mass index was 24.15 (range 19.25-30.49) and parous status as follows: 13 patients (61.9%) had single or multiple child deliveries, 3 among them (14.3%) with caesarean section, while 8 patients (38.1%) were nulliparous. All patients were sexually active having on average 2 vaginal intercourses per week (ranging from 1 in two weeks to 4 times in week). All patients except one (4.8%) were non-smokers.

Table 1: Patients' demographic data

BMI	24.15 (19.25-30.49)
Parous status	
0	8 (38.1%)
1	2 (9.5%)
2	7 (33.3%)
3	3 (14.3%)
4	1 (4.8%)
Delivery type	
Vaginal	10 (47.6%)
Caesarean	3 (14.3%)
Menstrual status	
Premenopausal	19 (90.5%)
Postmenopausal	2 (9.5%)
Sexually active	21 (100%)
Frequency of sexual activities / week	(1x/2w – 4x/w)
Smoking	1 (4.8%)

b) Treatment procedure

The IntimaLase treatment consisted of two treatment sessions with an interval time between the sessions of 15 to 30 days.

Prior to treatment and at follow-up before the second session, patients completed a PISQ-12 questionnaire [12]. A pelvic organ prolapse quantification (POP-Q) exam [13] was also performed before each session. Aside from these two standard and well-known assessment tools, a special Laser vaginal Tightening (LVT) questionnaire was designed for assessment of treatment efficacy and was used on follow-up at 3 months after treatment completion.

The LVT questionnaire consists of five questions, two of which are four grade scales for assessment of patients' and their sexual partners' subjective evaluation of treatment efficacy. Patients were asked to evaluate the vaginal tightness sensation as 0 *(no change*), 1 (*mild improvement*), 2 (*moderate improvement*) and 3 (*strong improvement*), while their partners were asked to assess their sensation of the patient's vaginal tightness with the same grades on the same scale. The next two questions were about satisfaction and willingness to recommend this treatment to friends and about the worthiness of the procedure. The last question was aimed at determining a patients' assessment of changes in their sexual gratification after the treatment. The question offers five categories of answers: *no improvement*, *more friction/sensation*, *better orgasm*, *more orgasms* and *other* (an answer under which the patients were asked to give their description of the change).

The IntimaLase treatment had two phases. In the first phase, the complete length of the vaginal canal was subjected to laser irradiation, while in the second phase the introitus and vestibule were irradiated as well. To perform the first phase – the irradiation of the vaginal canal, specially designed accessories were used – a laser speculum and a circular beam delivery adapter – enabling quick and easy irradiation of the vaginal canal in its full circumference. For execution of the second phase, another accessory – a fractional straight shooting handpiece was used.

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

In the next step, a specially designed laser speculum was introduced into the patient's vagina to serve as a guide for the laser beam delivery system. When the laser speculum is properly positioned into the patient's vagina, the laser beam delivery system (a handpiece with a circular adapter) is introduced into the laser speculum. The circular adapter enables 360 degree laser irradiation of the vaginal canal. Laser energy is applied on the vaginal walls in 360° belt-shaped patterns, deposited successively along the vaginal canal without overlapping via a simple step-by-step withdrawal of the laser handpiece outwards from the laser speculum. Depending on the vaginal canal length, one full irradiation pass could consist of a different number of irradiation locations (belt-shaped energy stamps). 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.

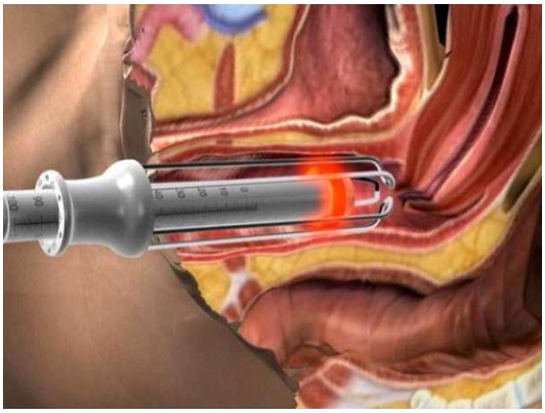

Fig. 2: The first phase of IntimaLase treatment: laser speculum and circular adapter enable delivery of a 360° radial laser beam.

After the completion of the first phase of the IntimaLase procedure, the laser handpiece and laser speculum are removed and the second phase of the procedure is executed using a straight-shooting fractional laser handpiece. Fractionated 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.

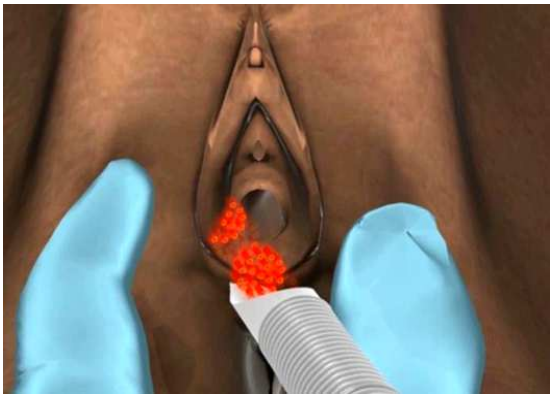

Fig. 3: Treatment detail of the second phase of IntimaLase treatment – irradiation of the introitus.

The safety and tolerability of the procedure was assessed by observation and documentation of potential adverse effects during and after the procedure and by

assessment of the patients' discomfort (pain) level using an 11-grade (0-10) visual analog scale.

Topical anesthesia (a cream composed of 2% Lidocain combined with Prilocain) was applied to the vestibule and introitus area before each session.

No special post-op therapy was needed. Patients were only requested to restrain from 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, prior to the second treatment session (15-30 days after the first session) and at 3 months after the completion of therapy when patients were asked to answer the LVT questionnaire and self-assess the efficacy of the IntimaLase laser vaginal tightening treatment.

III. RESULTS

POP-Q measurements were made on all 21 patients before the treatment and prior to the second treatment session. The first measurement before the treatment showed that 16 patients (76.2%) didn't have any prolapses (POP-Q stage zero), while 5 of them (23.8%) had prolapses of stages 1 to 3, as shown in Table 2.

Table 2: POP-Q stages before and after the first session

POP-Q Stages	Before	After
Stage 0	16	19
Stage I	2	1
Stage II	2	1
Stage III	1	0
Stage IV	0	0

Upon the second measurement after the first treatment session, all patients with prolapses showed improvement; four of them improved by one stage and one showed improvement of two POP-Q stages.

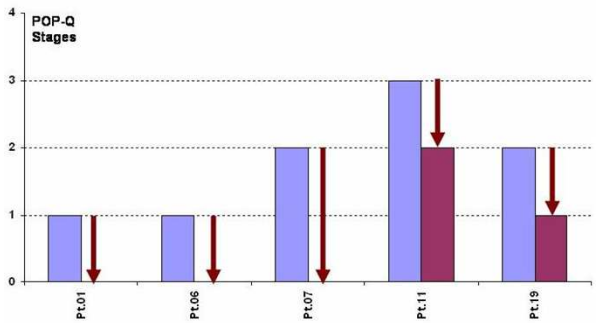

Fig. 4: All five patients having prolapses showed improvement after the first treatment session. One of them (patient No. 07) improved by two stages, while the other four improved by one stage.

All 21 patients responded to the PISQ-12 questionnaire before the treatment and prior to the second treatment session. However, two of the patients had more than two missed responses and were excluded from this measurement in accordance with PISQ-12 scoring instructions [12]. The average PISQ-12 score before the treatment was 40.1 points (with a range of 29-48), while after the second measurement it was 40.5 points (range of 32–48). Three of nineteen patients (15.8%) showed an improvement of 2 to 4 points.

At approximately 3 months after the completion of both treatment sessions, patients were asked to assess their treatment results and satisfaction by answering the LVT questionnaire. All 21 patients responded to the LVT questionnaire.

Responding to the first question of the LVT questionnaire – to assess the change in their vaginal tightness after the IntimaLase treatment, all 21 patients assessed their tightness as improved. One patient (4.8%) assessed the improvement as mild, 16 patients (76.2%) as moderate and 4 (19%) as strong. The results of the patients' self-assessments are presented in Fig. 5.

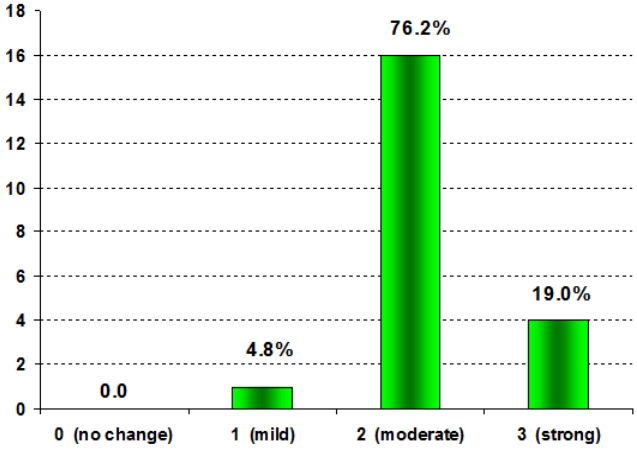

Fig. 5: Patients' self-assessment of improvement in vaginal tightness after IntimaLase treatment. All patients reported improvement, with 95% assessing the improvement as "moderate and strong."

The patients' sexual partners were also asked to evaluate the changes in their sensation after the patients were submitted to IntimaLase treatment. Twenty out of twenty one partners responded to this question. The non-responding partner was a new partner of one of the patients who didn't have the opportunity to compare the sensation with the previous situation. The results of the partners' assessments are presented in Fig. 6.

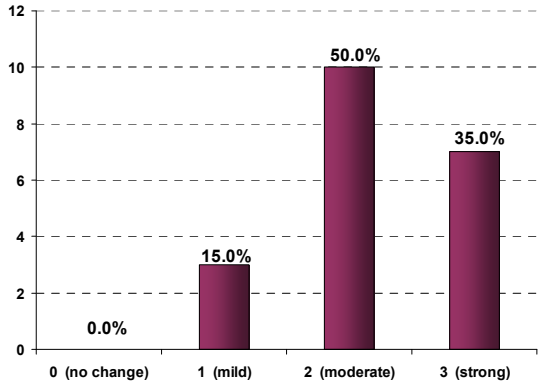

Fig. 6: Patients' sexual partners' assessment of improved sensation after IntimaLase treatment. All partners recognized the improvement, with 85% assessing it as "moderate or strong."

All patients replied positively to questions 3 and 4 of the LVT questionnaire, confirming that they would recommend the IntimaLase treatment to their friends and that they considered it a worthy treatment.

The last question of the LVT questionnaire asked the patients if the IntimaLase treatment improved their sexual gratification, and if yes, in which way. There were four offered answers: *no improvement, more friction/sensation, more orgasms and better orgasms*. Additionally for the fifth answer option (*"other"*) patients were invited to provide additional comments and a description of how their sexual gratification changed or improved. Multiple answers were allowed and 17 patients (81%) used this opportunity, giving two (15) or even three (2) answers.

Twenty patients (95.2%) reported an improvement of sexual gratification after the IntimaLase treatment. All of the 20 who had reported improvement (95.2%) selected the answer "more friction/sensation", while 12 patients (57.1%) also selected the answer "better orgasm", and 3 (14.3%) also selected "more orgasms". Just one patient (4.8%) selected the answer "no improvement" (of sexual gratification) although the same patient (No. 11) when answering the first question of the LVR questionnaire testified about moderate improvement of her vaginal tightness.

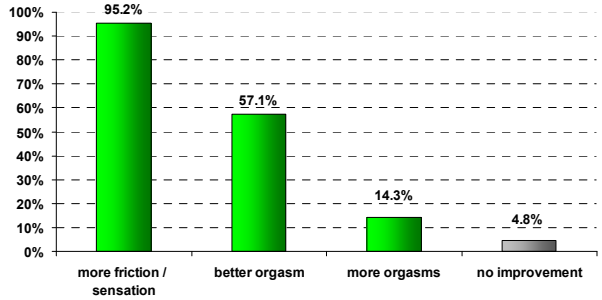

Fig. 7: Patients' assessment of sexual gratification improvement after IntimaLase treatment. Out of 21 patients, 20 reported better sex due to: better sensation (95.2%), better orgasm (57.1%) and more orgasms (14.3%).

Five patients (23.8%) gave additional comments under the answer "other". Three of them (patients No. 07, 12 and 14) reported that aside from improved vaginal tightness and sexual gratification, they experienced improved (2) or healed (1) stress urinary incontinence, which they had prior to the treatment. Two patients (No. 06 and No. 21) reported that aside from their satisfaction with the improved sexual gratification, their husbands were "very satisfied" and "happy" as well.

All patients replied to questions about treatment discomfort and made assessments of pain immediately after both treatment sessions. A visual analog scale [14] as presented in Fig. 8 was used for pain assessment.

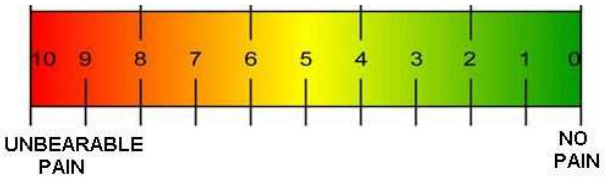

Fig. 8: Visual Analog Scale for measurement of pain during the laser treatment.

Almost half of the patients (10 or 47.6%) assessed the IntimaLase treatment as totally painless, while the other half (11 or 52.4%) reported very mild pain during the treatment of the introitus area.

The discomfort sensation in these 11 patients was present only during the execution of the treatment and was reported to immediately disappear after the completion of the laser irradiation.

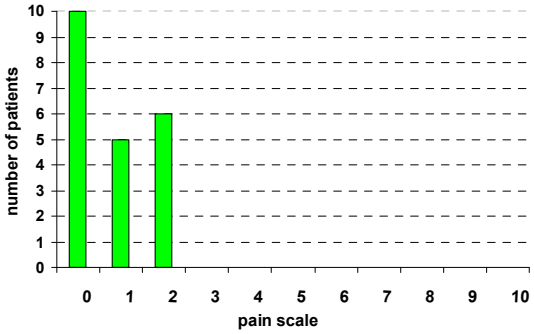

Fig. 9: Patients' assessment of pain during IntimaLase treatment. Ten of 21 patients assessed the treatment as totally painless, while the rest (11/21) reported very mild pain during treatment of the introitus region.

No adverse effects were detected by the clinician or reported by patients on inspection immediately after the treatment and on follow-ups at 48 hours, before and after the second session, at 15-30 days, as well as on the last follow-up at 3 months after treatment completion.

IV. DISCUSSION

Female sexual dysfunction is a complex psychophysiological problem involving psychological, neurological, hormonal, and physiological aspects [15, 16]. A patient's sexual history and relationship with their sexual partner play very important roles in female sexual health and influence the experience of sexual gratification.

Although physiological changes, like vaginal relaxation syndrome and vaginal looseness, are important factors contributing to female sexual dysfunction [17-22], these are just a part of the complete picture, and any correction of this part alone will not necessarily improve a patient's sexual gratification. However, many women are seeking treatments for loose vaginas predominantly with the aim of improvement of their sexual life. Due to increased interest, many approaches and techniques for correction and repair of VRS have been developed and are in everyday use all around the world.

Various surgical techniques are still the mainstream of vaginal repairs. There are quite some articles describing various techniques of vaginal repair [23-25] claiming good results and low levels of complications. Pardo et al. [26] reported satisfactory improvement of sexual gratification in 74% of patients submitted to surgical narrowing of wide vaginas, similarly Moore and Miklos [27] further elaborated on the positive impact of prolapse repair on sexual function. However, all of these surgical therapies are associated with risks of serious adverse effects and require relatively long recovery periods and restraining from sexual activities during this period. For example in Pardo's paper [26], patients were requested to restrain from sexual activities for a period of six weeks after the surgery.

There have been several attempts to design a new procedure that would overcome the problems of surgical repair and at the same time achieve comparable improvements of vaginal relaxation but with no adverse effects and with a minimal recovery time.

Among several minimally invasive procedures claiming to fulfill these criteria, the IntimaLase procedure and the initial reports of its application and results [28-30] attracted our attention and led to our decision to do this pilot study with the aim to evaluate its efficacy and safety.

When designing this pilot study we faced several challenges regarding the assessment tools available. Among the standardized questionnaires we decided to use the PISQ-12 questionnaire, hoping to be able to compare our results with the results of two other clinical researchers who also used PISQ-12 to evaluate the IntimaLase procedure [29, 30]. However, analyzing our results, which showed a minimal increase and non-significant improvement in PISQ-12 score, and comparing it with results of Fistonic [29] and Saracoglu [30], we noticed that both of them had patient populations in which Stress Urinary Incontinence (SUI) was much more present than in our patient population (just 3 patients with SUI) and that it was probably the improvement in SUI which was also reflected in the greater improvement of PISQ-12 scores in their studies.

For objective measurement of structural tissue changes many researchers [28-30, 31, 32] have used perineometer assessment of pelvic floor muscle strength and endurance, which was not available to us at the beginning of the study. Instead, we decided to measure POP-Q stages, another objective measure of vaginal structural changes. Although we had a relatively small number of patients (5 or 23.8%) having any measurable prolapses (of stages 1-3) our results showed improvement in all of these five patients, and in one case even an improvement by two stages. These results are comparable with the POP-Q improvements achieved by Saracoglu [30].

Not being able to find an appropriate questionnaire that would capture the patients' self-assessment of the improvement of their vaginal tightness and sexual gratification, we decided to create a special LVT questionnaire as presented in second chapter (Materials and Methods) of this paper. Analyzing some other authors' papers [26, 31, 32] we found that it is not uncommon to use a procedure-specific self-assessment tool.

We believe that the LVT questionnaire we used in this pilot study gave a good subjective assessment of the efficacy of the IntimaLase treatment. The results achieved (95% of patients reporting moderate and strong improvement of their vaginal tightness, 85% of their partners confirming the feeling of moderate or strong improvement in the patients' vaginal tightness during sexual intercourse, and lastly 95% of patients reporting better sex after the treatment) exceeded the expectations we had at the beginning of this study. We found our results from the evaluation of short-term IntimaLase treatment efficacy fully comparable with Rivera's [28] and even better than the results achieved by Fistonic [29] and Saracoglu [30]. We are aware that our follow-up after the treatment was short and we plan to continue and expand this study with the aim to get an assessment of the longevity of the achieved results.

Regarding the safety, tolerability and return to sexual activity, we found the IntimaLase treatment to be much safer (no adverse effects, minimal discomfort, return to normal sexual activities 72 hours after the treatment) than any of other of analyzed procedures. In a paper describing another minimally invasive laser therapy for vaginal rejuvenation treatment performed with a fractional ablative CO_2 laser, Gaspar et al. [31] reported several cases of bleeding, pain and burning. Also, according to their method description (3 sessions, 60 days apart) one can conclude that quite a long time had to pass before patients' could return to normal sexual activity.

As already mentioned, Pardo et al. [26] also reported 6 weeks of restraining from sexual activities as well as two minor surgical complications. For pain management they used spinal or general anesthesia. Common occurrences in surgical treatments for VRS are dyspareunia, keloids, infection, post-op bleeding or suture dehiscence. Being a non-surgical approach, the IntimaLase laser treatment avoids all of these unwanted side effects.

We found the IntimaLase treatment quick and easy to perform in ambulatory conditions. During the learning curve we needed approximately 20-25 minutes to complete the laser irradiation part of one treatment session. Measurements of the laser session duration during the execution of second session resulted in an average laser treatment duration of only 8 minutes (range 6 – 10).

We are aware that this pilot study has several shortcomings including the relatively small size of the study group, the lack of a control group, the use of a non-validated questionnaire and the very short follow-up time. However we believe that the initial (very encouraging) results we obtained from this study will be confirmed in further studies that will follow shortly.

V. CONCLUSIONS

This pilot study of the efficacy and safety of a novel non-invasive Er:YAG laser treatment for vaginal relaxation syndrome demonstrated very good efficacy in improvement of vaginal tightness with minimal patient discomfort during the treatment and no adverse effects.

Further prospective studies are in preparation, which would include the use of additional assessment tools like a perineometer and some additional validated questionnaires. Also additional follow-ups of the existing patient population at 6, 12 and 24 months are planned.

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