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# Laser Vaginal Tightening with Non-ablative Er:YAG for Vaginal Relaxation Syndrome. Evaluation of Patient Satisfaction.

**Jack I. Pardo[1], Vicente Solá Dalenz[2]**
*[1]Clinica Sara Moncada, Santiago 7700668, Chile*
*[2]Clinica Las Lilas, Santiago 7700668, Chile*

## ABSTRACT

The main reason patients seek vaginal tightening surgery is because they feel loose or large and/or wish to increase friction and enhance sexual pleasure for themselves and their partner. In light of the possible side effects of surgery, there is a need for an effective minimally-invasive treatment. Non-ablative, thermal-only, minimally invasive Laser Vaginal Tightening (LVT) was evaluated in 50 consecutive patients in our practice. All patients were treated using 2940 nm Er:YAG laser according to the IntimaLase® protocol for LVT. Patient satisfaction after the procedure was evaluated by a questionnaire 1-8 months after the procedure. Patients were asked to rate their satisfaction with the LVT procedure and to rate the improvement of their sexual satisfaction after the procedure on a scale from 0 to 10. They were also asked whether they would be willing to repeat the procedure and whether they would recommend the procedure to others. 42 out of 50 patients (84%) responded to the questionnaire. The mean level of improvement in sexual satisfaction was 7 (SD=3.1) and the mean level of satisfaction with the LVT procedure was 7.5 (SD=3.1). 34 patients (81%) would be willing to repeat the procedure and recommend the procedure to others. There were no side effects. Non-ablative LVT should be offered to patients who seek surgery because of a sensation of wide vagina. Most patients are likely to be satisfied with the results of LVT and thus avoid the risks and/or cost of surgery.

**Key words:** vaginal tightening, laser, non-ablative treatment, Er:YAG, patient satisfaction.

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## I. INTRODUCTION

Vaginal relaxation is the loss of the optimum structural architecture of the vagina [1]. Changes in connective tissue, usually associated with the normal aging process, may cause laxity of the vaginal wall. The condition is further exacerbated by pregnancies and deliveries, whether vaginal or caesarean [2]. Loss of vaginal tightness can result in a reduction of friction during intercourse and a decrease or loss of sexual satisfaction [3].

The most common current vaginal tightening technique (vaginoplasty and/or perineoplasty) is a surgical procedure that requires the cutting and rearrangement of vaginal and peripheral tissue in order to reduce the size of the vaginal canal [4]. Regional (spinal) or general anesthesia is required [5]. Risks of the procedure include bleeding, infection, scarring, dyspareunia, alteration in sensation, pain, wound dehiscence, a decrease in sexual pleasure, and possible dissatisfaction with the results [4–7]. Patients require an extended recovery and a sexual abstinence period of at least 6 weeks [5, 7].

There is controversy over the issue of whether the indication is strong enough to balance the risks of an operation [4–6]. Concerns were raised regarding the effects of the physiological changes associated with pregnancy and childbirth or menopause on the postoperative outcomes of perineal or vaginal cosmetic surgeries [6]. Less invasive solutions are therefore desired.

A few papers have been published proposing laser vaginal rejuvenation treatment performed with fractional $CO_2$ or Er:YAG lasers, which is based on the ablation of mucosal tissue aimed to stimulate collagenesis of the mucous layer of the vagina [8, 9]. They are described as minimally invasive, however, due to the ablative component, a long recovery time is still needed. There were several cases of pain and burning sensation lasting up to 5 days after fractional $CO_2$ laser treatment [8]. Nonsurgical low-energy radiofrequency thermal therapy has been used successfully for vaginal tightening after vaginal delivery [10, 11]. Subjects tolerated the treatment well and resumed vaginal intercourse after 10 days. The treatment was limited to vaginal introitus.

A non-ablative erbium-doped yttrium aluminum garnet (Er:YAG) 2940 nm laser vaginal tightening therapy (LVT) technique (IntimaLase®, Fotona, Slovenia) has been shown to be effective in several studies [1,12–14]. LVT works by means of photothermal tightening of vaginal tissue. Using special SMOOTH mode pulses, thermal energy is delivered to the mucous tissue of the vaginal canal and introitus area without any ablation [15]. Shrinkage of the endopelvic fascia and pelvic floor tissue is based on thermally-induced collagen coagulation and remodeling [16]. LVT treatment is minimally-invasive compared to surgical or ablative laser vaginal tightening procedures. It has a much lower complication rate and is well tolerated by patients. Moreover, recovery time is very short – in three days the patient may resume normal sexual activity [1, 12–14].

The main reason patients seek vaginal tightening surgery (vaginoplasty and/or perineoplasty) is because they feel loose or large and/or they wish to increase friction and enhance sexual pleasure both for themselves and for their partner [4, 5]. In light of the possible side effects of surgery, they should first be offered a minimally-invasive treatment with the potential to increase their satisfaction. We evaluated the effectiveness of the LVT procedure with the outcome measure that is most relevant in this case – patient satisfaction – with 50 consecutive patients undergoing LVT in our practice.

## II. MATERIALS AND METHODS

This pilot descriptive study included 50 consecutive patients that underwent the laser vaginal tightening procedure between April 2014 and June 2015 in Clinica Sara Moncada, a private health center in Santiago, Chile. The inclusion criterion for this study was complaint of vaginal relaxation. The exclusion criteria were: sexual dysfunctions such as primary anorgasmia, dyspareunia, vaginismus and/or libido dysfunctions, incontinence, severe prolapse, pregnancy, previous surgery due to a treated condition, patients with severe neurological conditions, vaginal lesions, genitourinary tract infections, abnormal vaginal bleeding, a history of photosensitivity disorder or the use of photosensitizing drugs and hematuria. Patients were contacted after the procedure and asked to complete the interview and to provide a written informed consent, voluntarily. 8 patients (16%) failed to respond to follow-up inquiries and were excluded from the analysis.

All patients were treated using 2940 nm Er:YAG laser (FotonaSmooth™ XS, Fotona, Ljubljana, Slovenia) in non-ablative thermal-only mode according to the two-step IntimaLase® protocol suggested in the manufacturer's application manual. In the first step, the whole vaginal wall was circularly irradiated using a full-beam handpiece (7 mm spot size; 3 J/cm2 fluence) with a circular adapter. Three passes were performed and the speculum was rotated by 30° after each pass. In the second step, the vestibule and the introitus were irradiated with a straight-shooting patterned handpiece (7 mm spot size; 10 J/ cm2 fluence). The therapy consisted of two treatment sessions with 1 month interval between sessions.

The treatment was performed using an outpatient clinical setting and no specific preparations were needed. Although no regional or general anesthesia was required, we used topical anesthesia (1% procaine, 1% benzocaine, 1% lidocaine), which was applied with vaginal gauze impregnated 20 min prior to the procedure. All the postmenopausal women with vaginal atrophy and no hormonal replacement therapy were treated with local estrogen (estriol) before the treatment. Patient discomfort, treatment tolerability, as well as adverse effects were monitored during and after the treatment. No special post-operative therapy was needed; patients were advised to avoid sexual intercourse for 3 days after the treatment. They were discharged immediately after the procedure.

Patient satisfaction after the procedure was evaluated by a questionnaire a few (1-8) months after the procedure. Patients were asked to rate their satisfaction with the LVT procedure on a scale from 0 (not satisfied at all) to 10 (completely satisfied). They were asked to rate the improvement of their sexual satisfaction after the procedure on a scale from 0 (no improvement) to 10 (completely satisfied). They were also asked whether they would be willing to repeat the procedure and whether they would recommend the procedure to others (possible answers were "yes", "no" and "I don't know").

Descriptive statistics were produced in Excel. Agreement between the different patient satisfaction measures was tested by correlation in R 17. The effect of follow-up time (months after the end of treatment), patients' age and parity on the satisfaction with the procedure were explored by multiple regression in R 17.

## III. RESULTS

42 out of 50 patients (84%) responded to the questionnaire. The questionnaire was applied 1-8

months after the final laser session (Table 1). 50% of the patients were followed up at 6 months. The mean age of the respondents was 42 years (SD=8, range=28-61). The mean parity was 2 (SD=1.4, range=0-5). Most women (40%) had 2 children and most of the births (85%) were vaginal.

**Table 1. Follow-up time in months after the laser vaginal tightening procedure.**

| Follow-up time (months) | n | % |
|---|---|---|
| 1 | 1 | 2% |
| 2 | 5 | 12% |
| 3 | 5 | 12% |
| 4 | 6 | 14% |
| 5 | 3 | 7% |
| 6 | 21 | 50% |
| 7 | 0 | 0% |
| 8 | 1 | 2% |

Answers to the two yes/no questions indicated a high level of satisfaction with the procedure (Table 2). Patients were asked whether they would be willing to repeat the procedure and whether they would recommend the procedure to others (possible answers were "yes", "no" and "I don't know"). 34 patients (81%) would be willing to repeat the procedure whereas 8 patients would not (19%). 34 patients (81%) would recommend the procedure to others, 7 would not recommend it (17%) and 1 patient (2%) answered "I don't know". There was perfect correlation between the responses to these two questions; all patients who would repeat the procedure would also recommend it to others and vice versa.

Most patients expressed a high level of sexual satisfaction augmentation after the procedure (Table 2). They were asked to rate the improvement of their sexual satisfaction after the procedure on a scale from 0 (no improvement) to 10 (completely satisfied). The mean level of improvement of sexual satisfaction was 7 (SD=3.1, range=0-10). 32 patients (76%) were satisfied (score 7-10), 3 patients (7%) were somewhat satisfied (score 4-6) and 7 patients (17%) were not satisfied (score 0-3) after the procedure. Only 1 patient (2%) reported 0 improvement in sexual satisfaction, whereas 12 patients (29%) were completely satisfied (score 10).

**Table 2. Patients' satisfaction after the laser vaginal tightening procedure. 42 of 50 patients responded to the questionnaire.**

| Question | n | % |
|---|---|---|
| Please rate the improvement of your sexual satisfaction after the procedure: | | |
| 0 (no improvement) | 1 | 2% |
| 1 | 4 | 10% |
| 2 | 1 | 2% |
| 3 | 1 | 2% |
| 4 | 0 | 0% |
| 5 | 3 | 7% |
| 6 | 0 | 0% |
| 7 | 5 | 12% |
| 8 | 9 | 21% |
| 9 | 6 | 14% |
| 10 (completely satisfied) | 12 | 29% |
| Please, rate your satisfaction with the procedure: | | |
| 0 (not satisfied at all) | 1 | 2% |
| 1 | 4 | 10% |
| 2 | 1 | 2% |
| 3 | 1 | 2% |
| 4 | 0 | 0% |
| 5 | 2 | 5% |
| 6 | 1 | 2% |
| 7 | 3 | 7% |
| 8 | 7 | 17% |
| 9 | 7 | 17% |
| 10 (completely satisfied) | 15 | 36% |
| Would you repeat the procedure? | | |
| Yes | 34 | 81% |
| No | 8 | 19% |
| I don't know | 0 | 0% |
| Would you recommend the procedure? | | |
| Yes | 34 | 81% |
| No | 7 | 17% |
| I don't know | 1 | 2% |

Most patients were satisfied with the LVT procedure (Table 2). They were asked to rate their satisfaction with the LVT procedure on a scale from 0 (not satisfied at all) to 10 (completely satisfied). Mean level of satisfaction was 7.5 (SD=3.1, range=0-10). 32 patients (76%) were satisfied (score 7-10), 3 patients (7%) were somewhat satisfied (score 4-6) and 7 patients (17%) were not satisfied (score 0-3). Only 1

patient (2%) reported 0 satisfaction, whereas 15 patients (36%) were completely satisfied (score 10).

There was a strong correlation between patient-reported improvement in sexual satisfaction after the procedure and satisfaction with the LVT procedure (correlation: r=0.97, df=40, t=24.3, p<0.001). Furthermore, there was a strong relationship between sexual satisfaction/satisfaction with the procedure and willingness to repeat/recommend the procedure (Fig. 1, Fig.2). All patients with either sexual satisfaction or satisfaction with the procedure rating >5 would recommend the procedure. All patients with either sexual satisfaction or satisfaction with the procedure rating <5 would not recommend the procedure. Of the two patients that rated 5 on both scales, 1 would recommend the procedure and 1 would not.

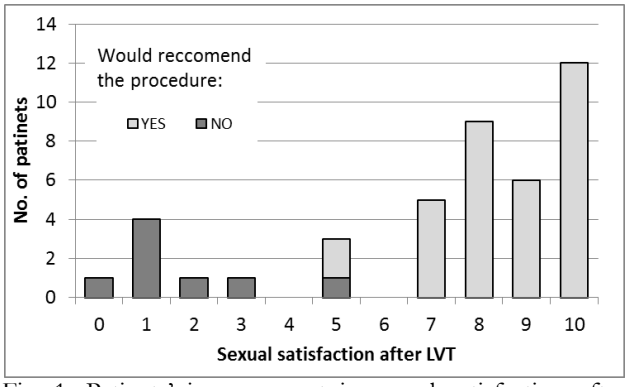


Fig. 1: Patients' improvement in sexual satisfaction after laser vaginal tightening (LVT) compared to their willingness to recommend the procedure.

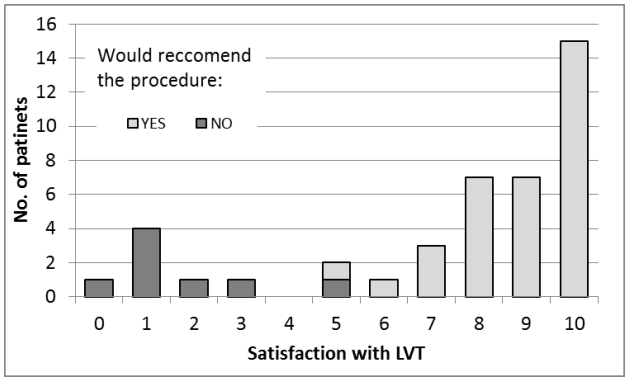


Fig. 2: Patients' satisfaction with laser vaginal tightening (LVT) compared to their willingness to recommend the procedure.

Satisfaction with the procedure decreased with follow-up time. Of the 20 patients contacted up to 5 months after the treatment, 19 (95%) would repeat/recommend the procedure. On the other hand, only 68% (15 out of 22) of patients contacted 6 months or longer after the procedure would repeat/recommend it. The effect of follow-up time on satisfaction with the procedure was statistically significant (multiple regression coefficient=-0.79±0.27, t=-2.96, p=0.005). On the other hand, satisfaction with the procedure did not depend on the patient's age or parity (multiple regression; p>0.05).

## IV. DISCUSSION

The success rate of LVT procedures reported in the literature is 83-100% [1, 12, 13]. Our results fall within this range. 81% of our patients would recommend/repeat the procedure and 83% of them had their expectations at least partially met. This level of effectiveness is comparable to that of surgical procedures. In a previous study [5], we reported our results of colpoperineoplasty in women with a sensation of a wide vagina. 6 months after the surgery, 90% of women reported at least sufficient or better improvement in their sexual activity. 95% felt their expectations were at least partially fulfilled. 96% were satisfied about undergoing the surgery. Literature information also indicates a high success rate of surgical vaginal tightening procedures [4, 7, 18, 19] with 83-97.5% of patients at least partially satisfied with the results and/or willing to recommend the procedure to others. In contrast, after ablative Er:YAG vaginal rejuvenation treatment, only 70% of patients considered themselves at least somewhat improved. Non-ablative radiofrequency treatment resulted in at least moderate improvement in only 41-52% of patients [10, 11].

There was some indication in our study that the effects of the LVT procedure may decrease with time. Nevertheless, in a recent report by Gaviria et al. with a longer follow-up of up to 3 years 89% of participants indicated moderate to high satisfaction with the results of the treatment and 83% of them would be willing to repeat the therapy [13]. Furthermore, non-ablative Er:YAG LVT is minimally invasive and so the procedure may be repeated without excessive risk to or inconvenience for the patient if the effects have faded over time due to ageing, menopause or childbirth. Once the operator is trained, the procedure can be accomplished in under 10 minutes [12]. Gaviria et al. suggest a follow up evaluation at 8 months followed by a maintenance session if needed, to increase the duration of the results [13].

Risk factors associated with vaginal relaxation (e.g. age or parity) appear to have no influence on the outcome of the LVT procedure. Gaviria et al. did not find any correlation between the persistence of the results and either age, presence of pelvic organ prolapse and/or incontinence, menopause,

constipation or smoking [13]. There was also no effect of a patient's age or parity on the outcome of LVT in this study. Vaginal relaxation symptoms like loss of vaginal tightness, stress urinary incontinence (SUI) or pelvic organ prolapse (POP) can be important contributing factors in female sexual dysfunction (FSD) [3, 20, 21]. In our previous study 82% of sexually active women reported high or moderate improvement in sexual gratification after Er:YAG treatment of SUI 22. Nevertheless, FSD is a multifactorial problem with biological, sociocultural, medical, and interpersonal factors 20, and any correction of vaginal tightness alone will not necessarily improve a patient's sexual satisfaction.

Because LVT was well tolerated by the patients, we have recently changed the method of application of topical anesthesia; now we apply anesthetic in the introitus only, and only for 5 minutes. The immediate results of LVT are even better this way, so we hypothesize that the anesthesia cream may decrease the effect of the laser. We plan to repeat the follow-up study with the new anesthesia procedure in order to formally compare the results of both.

Only subjective assessment tools were used in this study. Nevertheless, it is highly unlikely that improvement rates over 80% are due to placebo alone [23]. Additionally, other symptoms of vaginal relaxation syndrome, such as stress urinary incontinence (SUI) and pelvic organ prolapse (POP), the improvement of which can be evaluated objectively, have been treated successfully by similar non-ablative Er:YAG procedures relying on the same mechanism of action [14]. Furthermore, the sensation of wide vagina is unlikely to improve spontaneously. In our previous study, the median duration of the sensation of wide vagina was 8 years (range 1-30 years) before the patients resorted to surgery [5].

While randomized controlled trials would be preferable in terms of the quality of evidence, it may be difficult to find an appropriate control. While a sham LVT procedure is not problematic due to the minimal invasiveness of the procedure itself, it would be difficult to recruit patients for trials with inactive controls. On the other hand, a comparison of different methods of vaginal tightening may not really satisfy the critics who question the effectiveness of all available treatments [6].

General validated questionnaires that focus on sexual function (e.g. the Female Sexual Function Index and the Sexual History Form 12) are not condition-specific and may not be sensitive enough to detect differences due to pelvic floor dysfunction [21]. Condition-specific validated questionnaires focused on sexual function exist for women with POP or/and SUI. The Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ) or its short form with 12 questions (PISQ-12) are the most commonly applied 21. PISQ-12 has been used in other studies evaluating the LVT procedure, however, its usefulness for this purpose appears to depend on the percent of patients undergoing LVT who also suffer from some degree of POP and SUI [12]. Since our patients did not suffer from POP or SUI, we decided to use a procedure specific questionnaire comparable to the questionnaire used in our previous study 5 as well as those used by other authors evaluating vaginal tightening procedures [1, 4, 7, 10–13, 18, 19].

Concerns have been raised regarding the relative risks and benefits of surgical vaginal tightening procedures [6]. The application of surgical procedures is questionable in patients who might subsequently undergo vaginal birth or menopause [6]. LVT has several advantages in this context due to its minimal invasiveness. The possible side effects and complications of anesthesia and surgery are absent in LVT. Surgical patients may suffer from prolonged healing and pain, localized infection, vaginal bleeding, de novo dyspareunia and decrease of vaginal lubrication [4, 7, 18, 19]. The non-ablative Er:YAG LVT procedure is well tolerated, and in our study there were no side effects. The adverse effects reported in the literature were limited to mild and transient edema [13]. The procedure is relatively painless, rating 1 on a 0-10 VAS scale [13]. Sexual intercourse may be resumed after 3 days compared to a minimum downtime of 6 weeks after surgical vaginal tightening [5, 7]. Furthermore, non-ablative laser treatments may be repeated over time if the results fade because of pregnancy or ageing, with minimum risk for the patient. Non-ablative LVT should therefore be the first-choice procedure offered to patients who seek surgery because of a sensation of wide vagina. Over 80% of patients are likely to be satisfied with the results of LVT and thus avoid the risks and/or cost of surgery.

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