

Patient Satisfaction with Vaginal Erbium Laser Treatment of Stress Urinary Incontinence, Vaginal Relaxation Syndrome and Genito-urinary Syndrome of Menopause

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ABSTRACT

Introduction: Increasing demand in the field of cosmetic gynecology, together with the trend toward minimally invasive procedures in clinical gynecology and the appearance of new devices designed for these procedures, have led to a change in perspective toward this gynecological subspecialty.

Objective: To identify the impact and evaluate the degree of satisfaction among patients, after the introduction of a new 2940 nm erbium laser device in one gynecology center, for the treatment of vaginal relaxation syndrome, genito-urinary syndrome of menopause, and urinary incontinence.

Materials and methods: A prospective descriptive study of the first 40 consecutive cases treated in our center with said device and our experience in its use.

Results: All subjects completed the treatment without reporting adverse events. Clinical improvements in the pathologies present were noted in 78% of patients receiving the treatment, and the degree of satisfaction was greater than 90%.

Conclusions: This procedure is a quick and minimally invasive in-office alternative treatment, without side effects, that is effective and easily tolerated by patients. The patients reported a level of satisfaction greater than 90%, and 98% would recommend the treatment to other patients.

Key words: laser; erbium laser; vaginal relaxation syndrome; stress urinary incontinence; genito-urinary syndrome of menopause.

Article: J. LA&HA, Vol. 2016, No.1; OnlineFirst.

Received: September 18, 2016; Accepted: December 1, 2016

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Printed in Europe. www.laserandhealth.com

I. INTRODUCTION

A history of obstetric vaginal birth and

chronological ageing result in an increased laxity of the pelvic connective tissue and can lead to vaginal relaxation syndrome [1-3]. This loss of normal vaginal architecture results in a loss of tension that principally manifests with a loss of “friction” during sexual relations and a resulting loss of sexual gratification [4]. The laxity of the pelvic floor and periurethral connective tissue are also related to the appearance of stress incontinence [5]. Likewise, aging precipitates a lower production of female hormones, which is causative of the so-called genito-urinary syndrome of menopause [6] and consistent with the appearance of vulvo-vaginal atrophy [7], which manifests clinically as dryness, burning, irritation, discomfort during sexual intercourse, and urinary symptomatology. The recent appearance of laser photothermal treatments that produce a “shrinking” effect on the vaginal mucosa opens the door to alternatives to existing treatments [8].

II. MATERIALS AND METHODS

This prospective, descriptive study was conducted in only one center and included a total of 240 “in-office” procedures performed with a 2940 nm Erbium-YAG laser during the period from January 2014 to August 2015. A total of 82 of these cases were vaginal treatments. Of these cases, 40 were patients treated consecutively. All patients were evaluated by the same doctor, who performed anamnesis and gynecological explorations, including vaginal speculosity, cytology sampling, and ultrasound studies of the internal genital structure. During this consultation, the Sandvik test was performed to evaluate the degree of stress incontinence in patients who reported this symptom, including for patients with a result of less than 6 [9] (Table 1). Table 2 shows a summary of the inclusion/exclusion criteria applied for this study. Subsequently, results regarding vaginal tension, stress incontinence, genito-urinary syndrome, and the patients’ degrees of satisfaction with the treatments performed were graded using a previously designed questionnaire. Patients affected with slight or moderate stress incontinence were included, whereas patients diagnosed with mixed incontinence and severely affected patients were excluded.

Table 1. Sandvik's severity test for urinary incontinence.

How often does urine escape?	
Less than once a month	1
A few times a month	2
A few times a week	3
Every day and/or night	4
How much urine escapes each time?	
Drops (very small quantity)	1
A small stream (moderate quantity)	2
A large quantity	3

The severity index is calculated by multiplying the result of the two questions and then categorizing according to the following scale: 1-2 = slight, 3-6 = moderate, 8-9 = severe, 12 = very severe.

Table 2. Inclusion and exclusion criteria for erbium laser treatment.

Inclusion criteria
Vaginal relaxation syndrome
Slight-to-moderate stress urinary incontinence
Genito-urinary syndrome
Examination and cytology without pathologic findings
Introitus, vestibule, and vagina free of blood or lesions
Exclusion criteria
Age greater than 70 years
Pregnancy
Taking of medications causing photosensitivity
Menstruation
Active infections
Diabetes mellitus
Morbid obesity

The patients were given appointments for clear explanations of the treatments to be performed and received forms with post-treatment recommendations. Informed consent forms for treatment were signed. All procedures were performed by the same obstetrics & gynecology specialist, who had surgical experience and training specific to this device. A topical anesthetic (EMLA®) was recommended. After situating the patients in the dorsal lithotomy position and proceeding to disinfection, followed by a thorough drying of the area, the minimally invasive non-ablative thermal treatment was performed using a 2940 nm Erbium-YAG (FotonaSmooth™ XS, Fotona, Slovenia) laser device in SMOOTH mode.

The use of the device complied with the protocols recommended by Fotona in each case, including the protocols for IntimaLase®, IncontiLase®, and RenovaLase®.

Two identical treatment sessions separated by a 30-day interval were performed. After each session, the patients were given a one-week follow-up appointment with the goal of early detection of possible complications produced by the treatment with the new laser device. Subsequently, a four-month follow-up evaluation was performed, and patient satisfaction questionnaires (Suppl. 1) were delivered to assess the treatment for vaginal relaxation syndrome, urinary incontinence, or genito-urinary syndrome. These questionnaires were designed specifically for this study and were based on examples published by other authors [10,11].

III. RESULTS

Since the acquisition of the FotonaSmooth™ XS erbium laser device in 2013, we have performed a total of 240 different outpatient gynecological procedures in office. A total of 40 patients with vaginal relaxation syndrome (27% n=11), slight-to-moderate stress urinary incontinence (52% n=21), or genito-urinary syndrome (20% n=8) were consecutively included in our study. Other indications or combinations of the above treatments were excluded from the study. In all cases, we successfully completed the minimally invasive treatment with the 2940 nm erbium laser. Subsequently, the impacts of this treatment on different patient quality of life measures were evaluated, including general satisfaction, the effect on vaginal tension in sexual relations, improvement of stress incontinence, and other factors in the scope of genito-urinary syndrome, such as vaginal dryness, leucorrhea, and recurrent infections.

The average patient age was 47.6 years (range from 30 to 61 years). Of the patients included in the study, 92% had undergone vaginal births; of these patients, 50% had undergone two or more births. After treatment, 80% of patients whose indication had been a loss of vaginal tension (n=8/11) reported improvement; 70% of these saw their improvement as "important" (Fig. 1). This value increased to 82% when the partner was questioned (Fig. 2). 70% of patients with vaginal laxity experienced improvements in their sex lives, and 20% reported increases in sexual desire (Fig. 2). Urinary incontinence improved in 75% of the patients (n=15/21) suffering from SUI; 86% (n=13/15) of these referred to the improvement as important (Fig. 1). More than 80% of patients presenting with vaginal dryness experienced

improvement after the procedure and 85% of these achieved important improvement (Fig. 1).

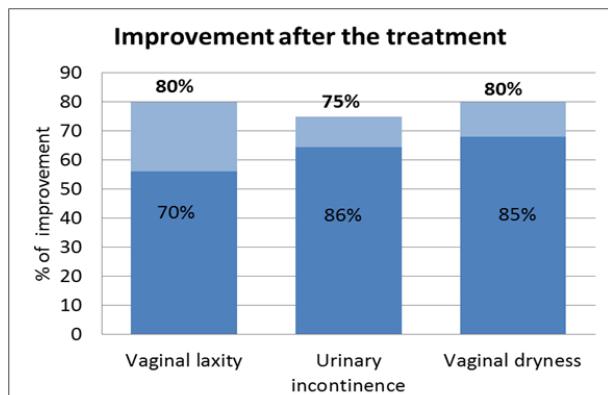


Fig. 1: Improvement Results. Group 1: Vaginal laxity; Group 2: Urinary incontinence; Group 3: Vaginal dryness

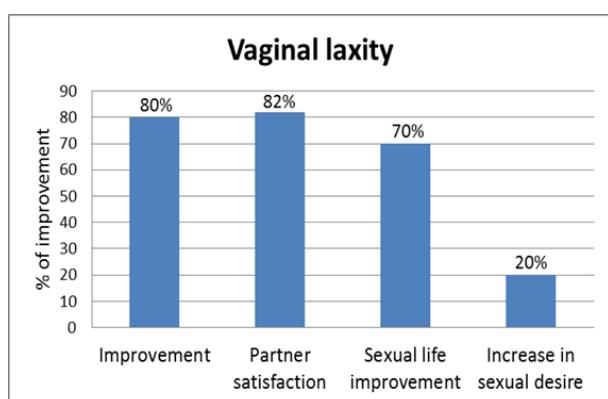


Fig. 2: Vaginal laxity: improvement after the treatment with Er:YAG laser

When evaluating treatment tolerance and patient satisfaction, 90% of the patients reported little or no discomfort. Only 10% of the patients reported the moment of treatment as painful. Only 10% of the patients reported any complaints after treatment, including discomfort or mild pain, which were of very minimal impact in the days following treatment. All patients reported that they were able to proceed with their normal lives the same day, indicating that this treatment was well tolerated, practically painless and without a convalescent period. In reference to overall satisfaction with the treatment, despite an overall improvement reported by 78.3% of patients, 90% of the patients considered the treatment useful, 98% would recommend the treatment to a friend, and the overall degree of satisfaction was 90%.

IV. DISCUSSION

The loss of anatomical support of the periurethral structures due to age and damage of these areas is very likely due to alterations in collagen quantity or quality [12-14]. The use of lasers can improve these

alterations in connective tissue [15-17]. The exposure of collagen to a thermal effect produces an immediate contraction of collagen fibers and a shrinkage of the irradiated tissue [18]. Additionally, the long-term effects result in remodeling and collagenogenesis, which entails the generation of new collagen fibers and general improvements in the elasticity and tension of the treated tissues [19-23].

After using the FotonaSmooth™ XS 2940 nm erbium laser device for the treatment of patients with vaginal relaxation syndrome with loss of sexual gratification, García et al. [24] reported improvements not only in sexual relations, but also secondarily with respect to the urinary incontinence with which these patients presented, very possibly due to the existence of a close relationship between the two conditions. Different authors have demonstrated the effectiveness of treatment with erbium laser for a loss of vaginal tension [25], urinary incontinence [26], and genito-urinary syndrome [27-29]. This evidence suggests the utility of incorporating these devices into our daily practice in the field of gynecology. Gaviria et al. [10] described erbium laser treatment for the loss of vaginal tension as a safe modality with minimal discomfort for the patient. We conducted weekly follow-ups with our patients after each of the two sessions and did not encounter any complications following treatment. As a result, this procedure is positioned as a valid alternative to standard treatments. The procedure was performed under topical anesthetic (EMLA® 25 g/g), and very little discomfort was experienced during its performance; furthermore, the results showed high patient satisfaction. Gaviria et al. [10] also reported improvements of 95% in vaginal tension and sexual satisfaction. In our study, sexual improvements were reported for only approximately 75% of the patients and were confirmed by the partner at a similar percentage.

In another report studying 39 patients affected with slight to moderate stress incontinence who were treated using the same system, Fistonic et al. [11] also demonstrated that the procedure was safe. The same author treated 73 women affected with incontinence in another prospective study in only one center and found improvements in 67% of women with a normal body mass index, and in 100% of women when the treated patients were younger than 39 years of age [30]. Ogrinc et al. [31] used an erbium laser to treat 175 consecutive patients affected with incontinence, including 114 women with stress incontinence, and demonstrated that this method was effective with at least one year of positive effects. This report also demonstrated that this method was not suitable for mixed incontinence cases. In our study, only patients

with stress incontinence of the slight or moderate type were included, whereas patients diagnosed with mixed incontinence or severely affected patients were excluded. Generally, we demonstrated improvement in vaginal tension and urinary incontinence (80% and 75%, respectively). These results were comparable to the results described with other surgical techniques without the same possibility for complications [3].

Regarding vaginal dryness, the erbium laser is proposed as a good alternative to other existing medical treatments [32-35]. Gaspar [36] published better results with laser treatment versus local estrogen treatment to improve symptoms such as dyspareunia, vaginal dryness, burning sensation, or irritation. After performing laser treatment on 48 menopausal patients for genito-urinary syndrome, Perino et al. [27] demonstrated that the treatment was reliable and safe. Finally, Salvatore et al. [28] also showed improvement in vulvo-vaginal atrophy and sexual relations in menopausal patients after laser treatment. Although our objective was to evaluate patients with vaginal relaxation syndrome and urinary incontinence, the data gathered included the degrees of improvement in vaginal dryness, vaginal discharge, and recurrent infections. Of the three indications studied for vaginal erbium-laser treatment, genito-urinary syndrome was the most infrequent; only 20% of the patients presented with this clinical indication, very possibly due to the average age of the treated patients. The improvement reported was 80%.

In our center, the introduction of laser treatments has not produced any complications in our daily routine. Moreover, this novel method appeared to be well received by the clientele based on the number of cases seen in the given period and the great satisfaction of the patients who had the treatment (90%). Vizintin et al. [37] was in agreement with this conclusion and suggested that the erbium laser was effective and safe for the treatment of vaginal relaxation, stress urinary incontinence, pelvic-organ prolapse, and vaginal atrophy. These data together with the social changes seen in gynecological consultations where patients increasingly request solutions for the loss of vaginal tension, urinary incontinence, or genital dryness [37,38] indicate that this type of treatment should be included in the alternatives currently offered for the treatment of these conditions. Classically, different treatments are available for vaginal rejuvenation, although these procedures are invasive and have a surgical risk and long periods of convalescence [39]. Based on our results, we found that this method represented an easily performed and easily learned in-office procedure without significant reported complications that offered

good results and yielded great patient satisfaction. Due to these factors, this procedure should be considered as an important treatment alternative.

V. CONCLUSIONS

We propose offering 2940 nm erbium laser treatment as a minimally invasive and safe treatment for the loss of vaginal tension and deterioration in sexual relations, slight-to-moderate urinary incontinence, and vaginal dryness caused by genito-urinary syndrome. This procedure is associated with a significant degree of patient satisfaction, with 90% overall satisfaction and 98% of the patients reporting that they would recommend the treatment to others. The procedure can be integrated into the daily activities of any obstetrics and gynecology center and can be presented as an alternative to other medical or surgical treatments.

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SUPPLEMENT 1: SATISFACTION QUESTIONNAIRE

A-MEDICAL INDICATION

What was the reason for the laser vaginal tightening?

- a) Urinary incontinence.
- b) Interest in improving sexual relations
- c) Vaginal dryness
- d) Recurrent vaginal-urinary infections

B-URINARY INCONTINENCE

What changes occurred in your urinary incontinence following the laser treatment compared to before the treatment?

- a) No pre-treatment incontinence was presented
- b) No change
- c) Slight
- d) Moderate
- e) Great change

What were the results following the laser treatment in relation to your urinary incontinence?

- a) No pre-treatment incontinence was presented
- b) Still very wet
- c) Slightly wet (sometimes)
- d) Rarely wet (practically dry)
- e) Totally dry

What were the results following the laser treatment in relation to urine loss during sexual activity?

- a) I have never presented urine loss
- b) I continue to lose urine during sexual intercourse
- c) I do not lose urine during sexual intercourse

C-SEXUAL ACTIVITY

What changes occurred in your vaginal tension following the laser treatment compared to before the treatment?

- a) No change
- b) Slight
- c) Moderate
- d) Great change

What changes in your vaginal tension were perceived by your partner following the laser treatment compared to before the treatment?

- a) No change
- b) Slight
- c) Moderate
- d) Great change

How has vaginal laser tightening improved your sex life?

- a) It has not improved at all
- b) More vaginal friction during sexual intercourse
- c) Better orgasms
- d) More orgasms
- e) Other (If other, explain the reason).....

Has the vaginal laser tightening improved your sexual interest in some way?

- a) Same sexual interest
- b) Less sexual interest
- c) Greater sexual interest
- d) Much greater sexual interest

D-VAGINAL DRYNESS

What changes occurred in your vaginal dryness/lubrication following the laser treatment compared to before the treatment?

- a) No vaginal dryness was presented
- b) No improvement of vaginal dryness-lubrication
- c) Mild-moderate improvement of vaginal dryness-lubrication
- d) Significant improvement of vaginal dryness-lubrication

E-VAGINAL-URINARY INFECTIONS

What changes in your flow (leucorrhoea)/repetition of infections were perceived by your partner following the laser treatment?

- a) No recurrent infections were presented
- b) Improvement in the flow-repetition of infections
- c) No improvement in the flow-repetition of infections

F-TREATMENT

Did you find the laser treatment annoying/painful?

- a) Nothing annoying
- b) Slightly annoying
- c) Very annoying

Did you present discomfort/pain following the laser treatment?

- a) No discomfort/pain
- b) A little discomfort/pain
- c) Much discomfort/pain

How long did it take for you to consider that you were in a position to continue your normal life?

- a) The same day
- b) In one day
- c) In two days
- d) In more days

G-SATISFACTION

Do you think the treatment you received has been useful?

- a) Yes
- b) No

Would you recommend the treatment to a friend?

- a) Yes
- b) No (If no, explain the reason).....

What degree of satisfaction would you express?

- a) None
- b) A little bit
- c) Much