

WOMEN'S SEXUAL HEALTH

Treating Vaginal Laxity Using Nonablative Er:YAG Laser: A Retrospective Case Series of Patients From 2.5 Years of Clinical Practice



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ABSTRACT

Introduction: Vaginal laxity drastically impairs women's quality of life, suggesting there is a need for effective noninvasive treatments.

Aim: The aim was to retrospectively assess the effectiveness and safety of a nonablative Er:YAG IntimaLase laser procedure for vaginal laxity in patients treated in our clinical practice during a 2.5-year period.

Methods: Laser treatment for vaginal laxity was performed using an intravaginal nonablative Er:YAG laser. Effectiveness was assessed using a Patient Satisfaction Questionnaire and also by independent evaluation of before and after treatment photographs of the patients' introitus. The safety and tolerability of the procedure was monitored in all patients.

Main Outcome Measure: The study showed an improvement of sexual gratification and improvement of vaginal tightness, as assessed by patients. The tightness of the introitus was also improved, as assessed by independent evaluators.

Results: As assessed by the Patient Satisfaction Questionnaire, we show that 92.7% of patients experienced improvement of sexual gratification after IntimaLase laser treatment. The results of the visual evaluation of the grade of laxity improvement in the introitus area, when open introitus photos were evaluated, show that 69% (n = 20/29) of patients had an improvement of laxity. Nonablative Er:YAG treatment seems to be an effective and safe treatment for vaginal laxity. As it is a noninvasive procedure, it should be considered before any vaginoplasty surgery. The study included all the patients treated in clinical practice and observed very few adverse effects. The results were comparable with other published data. Because it is a retrospective study, there is a lack of a control group.

Conclusion: The results have confirmed that patients suffering from vaginal laxity can be effectively treated using the nonablative Er:YAG IntimaLase procedure without adverse effects. **Mitsuyuki M, Štok U, Hreljac I. Treating Vaginal Laxity Using Nonablative Er:YAG Laser: A Retrospective Case Series of Patients From 2.5 Years of Clinical Practice. Sex Med 2020;8:265–273.**

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Key Words: Vaginal Laxity; ER:YAG Laser; Sexual Gratification; Quality of Life

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INTRODUCTION

Vaginal laxity has long been an underreported problem, mainly due to the societal stigma associated with women's sexuality. As vaginal laxity has not been historically recognized as a treatable condition, there are still no existing objective criteria or standardized questionnaires for determining the impact of vaginal laxity on sexual function in women. The prevalence of vaginal laxity has started to be systematically addressed only recently, with 2 studies showing that 28–40% of surveyed women (patients in urogynecological clinics) suffered from a degree of vaginal laxity that negatively affects their quality of life (QoL).^{1,2} In the study by Dietz et al,² the women rated the

problem a score of 5.7 on a 0-10 Visual Analog Scale (VAS) scale. In the study by Campbell et al,¹ 48% of surveyed women reported symptoms of vaginal laxity and almost 90% of these women reported vaginal laxity as a presenting a problem. Physicians have also started to recognize vaginal laxity as a bothersome symptom in their patients—Pauls et al³ published a survey of urogynecologists' perception of vaginal laxity issues. The study included answers from 563 urogynecologists spanning 6 continents. A vast majority (87%) of the surveyed physicians agreed that vaginal laxity is underreported by their patients; 57% thought that it is a bothersome QoL condition that impacts relationship happiness; and 95% felt that vaginal laxity impacts sexual function. A majority of respondents recommended Kegel muscle training (75.5%), while surgical repair was offered by 54% of respondents, with North American doctors more inclined to perform surgeries than their counterparts on other continents. Despite these results showing an awareness of the problem, there is still no standardized definition of vaginal laxity, or guidelines for diagnosis and treatment. Because vaginal laxity is a QoL issue but is not life-threatening, noninvasive methods are the main treatment of choice both for patients and doctors. Traditional noninvasive methods include physical therapy and Kegel exercises, which have limited efficiency due to poor patient compliance. Invasive surgical methods have been proven effective. Vaginoplasty is a joint term for surgical tightening of the vaginal canal that involves different surgical procedures aimed to decrease the diameter of the vaginal canal and reduce excessive vulvar tissue. These procedures include excision of redundant vaginal tissues, muscular tightening by imbrication of the median levator ani muscles, remodeling of the perineal body, and excision of surplus skin.⁴ However, there is reluctance in offering surgical treatments for QoL problems, such as vaginal laxity.

In the last decade, new energy device-based therapies have become available, including radiofrequency, high-focused ultrasound, and different laser therapies.^{5,6} These methods are minimally invasive and offer better efficiency than traditional noninvasive methods. 2 different laser technologies have been proposed to treat genitourinary problems—microablative fractional CO₂ lasers and Er:YAG lasers. Microablative fractional CO₂ laser works by creating superficial microablation zones on the mucosal surface—as a result, a healing response is triggered, resulting in new collagen formation. Nonablative Er:YAG laser works by creating rapid sequential heat pulses, which are compounded and transferred deeper into the mucosa. The fast heat pulsing results in tightening of the mucosa and stimulation of new collagen formation, without injuring the tissue surface. Er:YAG laser incorporating Fotona SMOOTH technology effectively restores tissue quality, but it works in a nonablative manner, leaving the surface intact. In this way, the risk of unwanted side effects, especially after multiple repeated treatments, is greatly reduced. For the aforementioned reasons, we have chosen the nonablative Er:YAG IntimaLase treatment as our noninvasive treatment of choice for vaginal laxity patients.

In the present study, we report on a retrospective case series of patients treated in our clinic, which included patients with vaginal laxity from our clinical practice who received the IntimaLase treatment during a 2.5-year period.

PARTICIPANTS AND METHODS

This study is a retrospective case series, based on a chart review of patients treated in our clinic in Tokyo. A total of 364 patients suffering from vaginal laxity were treated in our clinic using a nonablative Er:YAG treatment protocol—IntimaLase (XS Dynamis, Fotona, Slovenia) between October 2013 and February 2016.

All treated women had complained about symptoms of vaginal looseness, which negatively impacted their QoL. They were older than 18 years, with normal cell cytology (Papanicolaou smear), negative for urinary infections, with a vaginal canal and introitus free of injuries. Pregnant women and active users of photosensitive drugs or women having any genitourinary infection and/or injury were deemed ineligible for the treatment.

All patients were provided with detailed information about the treatment. Telephone follow-ups were scheduled for all patients after 48 hours and at 3 and 12 months after the final treatment to obtain data on treatment safety and efficacy.

Informed consent for inclusion of their data into the retrospective case series was obtained from all individual participants included in the study, and ethical approval was obtained for this retrospective study.

The efficacy of vaginal tightening was assessed using a subjective patient's evaluation of improvement after the laser treatment—a Patient Satisfaction Questionnaire (Table 1); the patients completed question 1 at the follow-up 3 months after the treatment (question 1), whereas they answered question 2 before the treatment and at every telephone follow-up. The questionnaire comprised 2 questions: the first question asking for information about improvement of sexual gratification after the laser treatment and the second question about the sensation of the degree of the tightness of the vagina after the laser treatment (see Table 1). The numbers of patients who answered both questions of the questionnaire greatly differed—that is why the patients were retrospectively divided into 2 different subgroups—group 1 including patients who answered question 1 and group 2 including patients who answered question 2. The analysis was performed using anonymized data retrieved from patient charts.

Effectiveness of the treatment on the tightening of the introitus was also determined in a subgroup of patients (group 3) that had introitus pictures taken before and after the procedure. The evaluation was carried out by blinded analysis of standardized photographs of open introitus that were taken before the treatment and 12 months after the final treatment. All the photographs were taken by the lead investigator. The camera

Table 1. Patient Satisfaction Questionnaire

Patient Satisfaction Questionnaire	
Q1. How do you assess improvement of sexual gratification after laser treatment?	
0	No sexual relations since treatment
1	No improvement
2	Noticeable improvement
3	Large improvement
Q2. How do you assess the tightness of your vagina?	
1	very loose
2	loose
3	normal
4	tight
5	very tight

Question 1 was used to assess improvement of sexual gratification, whereas question 2 was used to assess vaginal tightness by patients who have undergone the IntimaLase procedure.

used was a RICOH CX5 digital camera with 10 megapixel resolution.

2 independent evaluators were given a pair of before and after photos for each patient and were asked to (i) determine whether a photo was taken before or after the treatment and (ii) evaluate the level of improvement on a Likert scale (0: no change, 1: mild, 2: moderate, 3: excellent change).

Hundred forty-eight women were included in the retrospective efficacy assessment, as they have either filled out one or both questions of the Patient Satisfaction Questionnaire (group 1 and 2) or had photographs evaluated by blinded reviewers (group 3).

All statistical analysis was performed using GraphPad Prism statistical software.

The safety and tolerability of the treatment were monitored in all treated patients (N = 364). The tolerability of the procedure was assessed by measuring patient discomfort data on a 0-10 VAS scale. Safety was measured by monitoring and documenting side effects during and after the procedure.

The IntimaLase treatment protocol was performed using a 2,940 nm Er:YAG laser using a unique nonablative Fotona SMOOTH mode (XS Dynamis, Fotona, Slovenia). In this SMOOTH modality, one pulse sequence comprises a train of

several micropulses, resulting in a gradual temperature increase in the vaginal mucosa, enabling controlled heating of the lamina propria to a range between 45 and 65°C, which is the optimal temperature range for collagen remodeling. The IntimaLase protocol consists of 2 steps. In the first step, a full-beam handpiece (R11) was used together with a circular intravaginal adapter, which delivers a 360° laser beam to the whole circumference of the vaginal canal. The whole length of the vagina was treated by sequentially moving the handpiece outward by 5 mm until the entrance to the vaginal canal had been reached. 250 joules of energy was delivered per pass, corresponding to 3 J/cm² of fluence per one SMOOTH pulse. 2 complete passes along the length of the vaginal canal were completed in the first step. In the second step, a fractional handpiece (PS03) was used to deliver laser pulses to the entrance of the vaginal canal. 3 passes of the whole vestibule and introitus area were completed in this step, each pass depositing around 10 J of laser energy. The patients received 2-3 IntimaLase sessions with 30 days interval between the sessions.

Before the treatment, topical anesthesia (10% lidocaine cream) was applied to the introitus and the distal portion of the vaginal canal. The anesthetic was left for 10 minutes and then wiped off. Before the laser treatment, the patients' vestibule, introitus, and the vaginal canal were washed with physiological solution and carefully dried off. After the procedure, the patients were advised to avoid sexual intercourse for at least 3 days. Other post-operative precautions were not necessary.

RESULTS

In the period between October 2013 and February 2016, 364 patients underwent a noninvasive Er:YAG laser treatment with the aim to reduce symptoms of vaginal laxity (IntimaLase, Fotona, Slovenia). Demographic characteristics of the patients are summarized in Table 2. Patients who were evaluated using one or more efficacy measures (148 patients in total—some patients were included in more than one subgroup as they had been evaluated by more than one efficacy method) were divided into 3 groups, depending on the efficacy assessment method. The first subgroup of patients comprised individuals who responded to the first question of the Patient Satisfaction

Table 2. Demographic data on patients involved in the study

Group demographics	Total	Group 1	Group 2	Group 3
Number of patients	364	144	11	29
Mean age (95% CI)	42.8 (41.7–43.8)	44.7 (43.2–46.3)	42.9 (37.1–48.6)	43.5 (40.1–46.7)
Mean BMI (95% CI)	20.2 (19.9–20.4)	20.5 (20.1–20.9)	19.8 (18.2–21.3)	19.5 (18.8–20.2)
Parity (95% CI)	1.40 (1.3–1.5)	1.53 (1.4–1.7)	1.55 (0.7–2.3)	1.52 (1.1–1.9)
% menopause patients	19.5	18.8	18.2	20.7

Three hundred sixty-four patients in total underwent IntimaLase procedure in our clinic. Group 1 included patients who have answered the question 1 of the Patient Satisfaction Questionnaire, group 2 included patients who have answered question 2, and group 3 included patients who were included into visual evaluation of improvement laxity at the introitus. There were no significant demographic differences between groups.

BMI = body mass index.

Questionnaire (see Table 1) at their 3-month follow-up ($n = 144$); the second, a much smaller subgroup included the patients who responded to the second question before treatment, at the 3-month follow-up and at the 12-month follow-up ($n = 11$); and the third subgroup included patients who were evaluated using the independent blinded evaluation of before and after pictures of the open introitus ($n = 29$). There were no statistically significant differences between the groups in any of the collected demographic parameters (analysis was performed using the Kruskal-Wallis one-way analysis of variance with multiple comparisons test).

Group 1 included 144 patients who answered question 1 at the follow-up 3 months after the treatment. Thirty-four patients were excluded from the analysis of group 1, as they had marked 0 on the questionnaire, indicating that they had no sexual relations since the treatment. Of the remaining patients, 32.7% ($n = 36/110$) reported a large improvement of sexual gratification after the laser treatment, 60% ($n = 66/110$) reported noticeable improvement, and only 7% ($n = 8/110$) reported no improvement. Together, 92.7% ($n = 102/110$) of patients in group 1 claimed improvement of sexual gratification after the laser treatment (Figure 1).

Group 2 ($n = 11$, except at the 12-month follow-up, where $n = 10$) (Table 3) consisted of a small subgroup of 11 patients

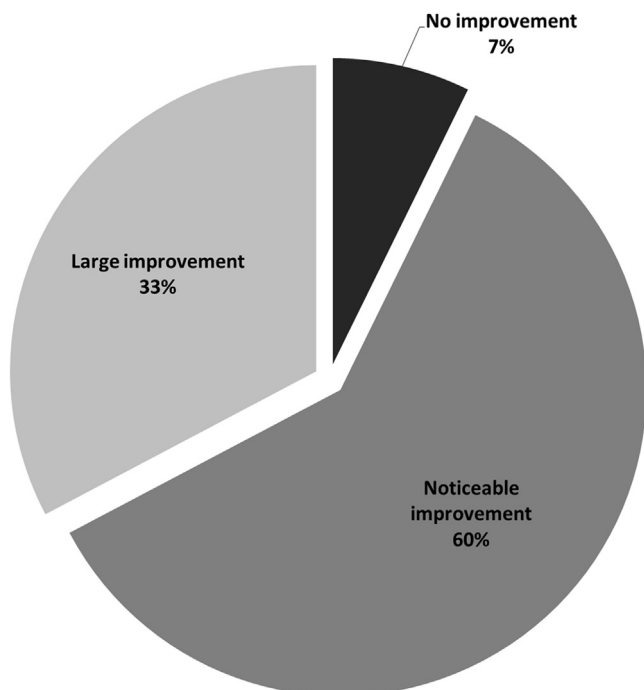


Figure 1. Patients' improvement in sexual satisfaction after the vaginal laser tightening as assessed by question 1 from the Patient Satisfaction Questionnaire. The numbers represent percentages of sexually active patients in group 1 ($n = 110$) by estimated levels of improvement. Thirty-three percent of patients ($n = 36$) reported large improvement, 60% of patients ($n = 66$) reported noticeable improvement, and 7.3% of patients ($n = 8$) reported no improvement.

who also responded to the second question, which asked them to estimate the degree of their vaginal tightness before the treatment and at each follow-up at 3 and 12 months after treatment. At the second follow-up at 12 months, 60% ($n = 6/10$) of patients in group 2 evaluated their vaginal canal to be tight or very tight, whereas before the treatment, none of the patients considered their vaginal canal to be tight or very tight (Figure 2, Table 3). Of the patients in group 2, 36.4% ($n = 4/11$) reported their vaginal canal to be very loose before the treatment; however, none of the patients considered it loose anymore at the follow-ups 3 months and 12 months after the treatment (Figure 2, Table 3).

Group 3 consisted of a subgroup of patients ($n = 29$) who were also evaluated using the objective visual evaluations of the grade of laxity evaluated by 2 independent reviewers on the basis of the patients' introitus photographs taken before and 3 months after treatment (Figure 3). The objective visual assessments had shown improvements in laxity at the introitus after IntimaLase treatment. The results of the visual evaluation of the grade of laxity improvement in the introitus area have shown that when open introitus photos were evaluated, 69% ($n = 20/29$) of patients had an improvement of laxity. The differences between the 2 evaluators' assessments of the pictures were checked for both groups using the Wilcoxon matched-pairs signed rank test and were not significant. Figure 4 shows examples of the assessed photographs from 2 patients.

Tolerability and safety of the treatment were evaluated for all treated patients ($n = 364$). Treatment-associated pain was estimated on average as 1 on a VAS 0-10 scale. All patients experienced transient edema after the treatment, which receded after 1–2 days. Stronger vaginal discharge was reported by 40% of patients, while transient urge incontinence was reported by 3% of patients. All adverse effects were mild and transient.

DISCUSSION

Vaginal laxity significantly impairs patients' sexual function and reduces their QoL.³ Recently, different studies suggested promising short-term results with treating vaginal laxity using energy-based devices such as lasers and low-dose radio-frequency.^{5,6} In the present study, we aimed to retrospectively extract and analyze the safety and efficacy data of the nonablative Er:YAG IntimaLase treatments performed in our clinical practice during a 2.5-year period. The results of our retrospective case series indicate that the nonablative Er:YAG laser produced favorable results without serious adverse effects.

The effect on sexual gratification was assessed using a Patient Satisfaction Questionnaire. The results have shown that 92.7% of patients in group 1 experienced an improvement of sexual gratification after receiving IntimaLase laser treatment. Our results are in accordance with previously published studies; Gaviria and Lanz⁷ have shown improvement in vaginal laxity, high patient satisfaction, and also calculated the duration of the

Table 3. Assessment of vaginal laxity in group 2 (n = 11 patients who answered question 2 of the Patient Satisfaction Questionnaire) before and at the 3- and 12-month follow-ups

Patient no.	Before	3 months FU	12 months FU
1	2	4	5
2	2	3	4
3	3	4	4
4	1	2	2
5	3	3	3
6	2	3	4
7	2	3	
8	2	3	4
9	1	2	2
10	1	3	5
11	1	2	3
Average (95% CI)	1.82 (1.31–2.32)	2.91 (2.44–3.38)	3.60 (2.83–4.37)
P-value (FU vs before)		0.029*	0.0006 [†]

ANOVA = analysis of variance; FU = follow-up.

Increasing numbers denote increasing sensation of vaginal tightness (see Table 1). Statistical significance was determined using the Kruskal-Wallis one-way ANOVA with multiple comparisons test.

* $P < .05$.

[†] $P < .001$.

treatment's effects in a retrospective study with a 3-year follow-up period.⁸ Pardo and Dalenz⁹ evaluated sexual satisfaction before and after the IntimaLase treatment and also the patient's satisfaction with the procedure. They found that the mean level of improvement in sexual satisfaction was 70% and the mean level of satisfaction with the laser vaginal tightening procedure was 75%. All the aforementioned studies have shown a

significant improvement of symptoms without adverse effects even after repeated treatments and prolonged periods of time.^{8,10} Our results strongly indicate that the laser treatment improved the sexual gratification of the treated patients; however, it was recorded only using a self-reported questionnaire. Owing to the absence of a control group, other factors that might have influenced sexual gratification in women may have been overlooked.

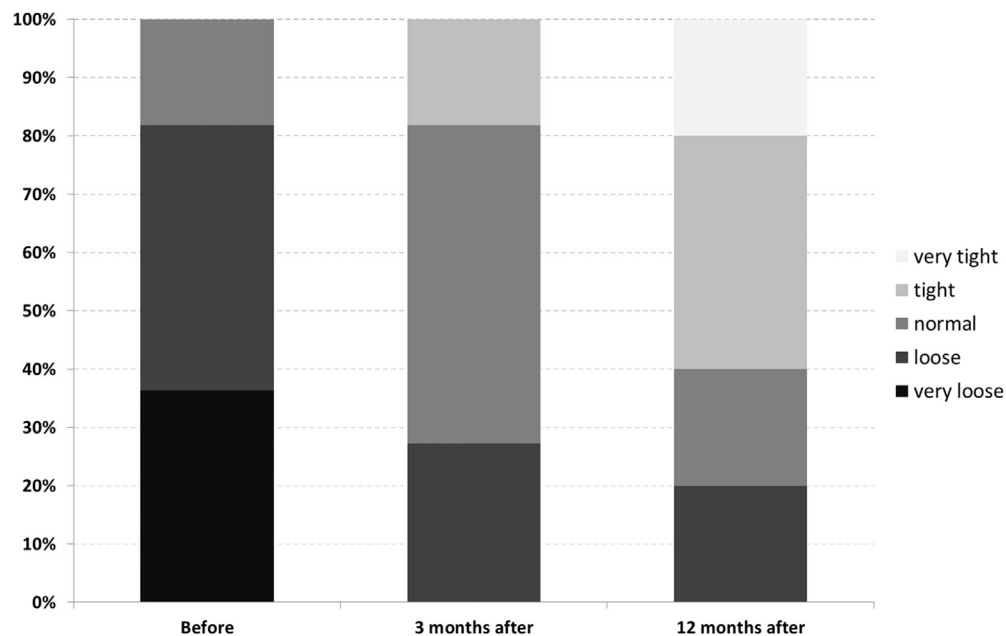


Figure 2. Distribution of the group 2 patient population (n = 11) by the estimated levels of vaginal tightness as assessed by question 2 of the Patient Satisfaction Questionnaire. The columns represent results taken before and at follow-ups 3 and 12 months after the IntimaLase vaginal laser treatment. Before treatment, 36.4% of patients (n = 4) reported their vagina to be very loose, whereas 45.5% of patients (N = 5) reported their vagina as loose. At both follow-ups, none of the patients reported their vagina as very loose. At the 12-month follow-up, 80% of patients reported their vagina as either normal, tight, or very tight.

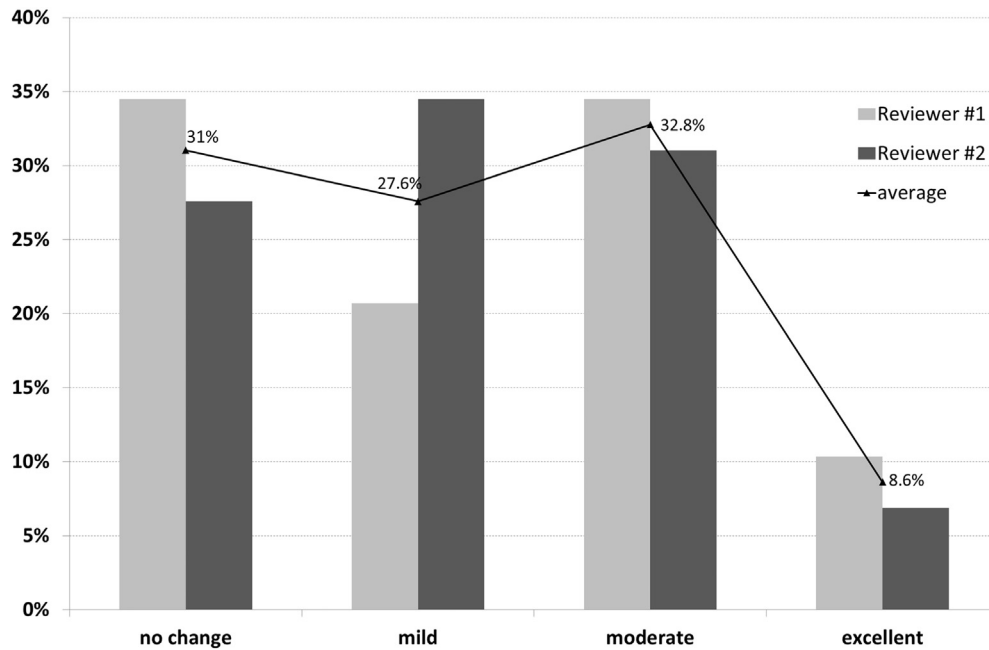


Figure 3. Results of objective visual estimation of improvement of the tightness of the introitus after the IntimaLase treatment. Measurements were based on pictures of open introitus in the patient group 3 ($n = 29$). The numbers represent the estimated percentage of patients as per levels of improvement, as estimated by 2 independent reviewers on the basis of before and after (12-month follow-up) treatment photographs of the open introitus. The lines on the graphs represent the average of both reviewers' estimate. On average, the change in laxity at the introitus was estimated as excellent in 8.6% of patients, as moderate in 32.8% of patients, and as mild in 27.6% of patients. No change in laxity was estimated in 31% of the patients' photographs.

These may include higher motivation for sexual intercourse of the patients and their partners because of the received treatment and selection bias of patients who are motivated to change their sexual life, as these patients would be highly motivated to come for treatment and expect improvement.)

Vaginal laxity was estimated using a modified 5-point vaginal laxity scale—question 2 of the Patient Satisfaction Questionnaire. Patients who answered that question (group 2) had reported significantly improved symptoms of vaginal laxity at the 3- and 12-month follow-ups after receiving the IntimaLase treatment. None of the patients in group 2 had categorized their vagina as very loose at the 1-year follow-up. All patients in group 2 reported an improvement of vaginal laxity. The results of our retrospective case series are in accordance with other studies, where the improvement of vaginal laxity symptoms assessed by patients was in a range of 80–95%.^{7–9,11,12} This level of effectiveness is comparable with that of surgical procedures.⁴

The visual evaluations of laxity, which were performed using independent blind evaluation of before and after photographs of the introitus, showed an improvement of laxity in 69% of the evaluated patients (group 3). These results are also in accordance with the other aforementioned studies.

All 364 treated patients were asked about tolerability and side effects, which were mild and rare.

Although our results indicate a high effectiveness of the IntimaLase treatment for treating vaginal laxity, these would have to be further confirmed in a randomized controlled trial setting.

2 different laser technologies have been used in the treatment of genitourinary problems connected to pelvic floor dysfunction: microablative fractional CO₂ lasers and Er:YAG lasers. A comparative study on the efficacy of CO₂ vs Er:YAG treatments has not yet been performed, although there is an ongoing randomized controlled trial to compare the effectiveness of these 2 lasers on the treatments of genitourinary syndrome of menopause/vaginal atrophy.¹³ Both technologies have separately shown to be effective for the treatment of genitourinary conditions. Microablative fractional CO₂ laser, which produces laser light in the wavelength of 10.6 μm , works by creating microablation zones on the surface of the mucosa. In these zones, microscopic punctures with coagulated edges are created; these stimulate the regenerative response in the skin/mucosal surface, increasing the synthesis of collagen, the formation of new vessels, and tightening of the tissue.¹⁴ Even though CO₂ treatments have been shown effective in treating some genitourinary conditions, there is concern about the side effects of long-term repetitive microwounding of the mucosa, as the laser treatments need to be repeated to maintain symptom free results. There were several reported cases of pain and burning sensation lasting up to 5 days after fractional CO₂ laser treatment.¹⁵

Contrary to fractional microablative CO₂ laser, nonablative Er:YAG laser with Fotona SMOOTH technology does not injure the tissue surface. Delivering the energy in SMOOTH pulses heats the epithelial surface up to 500 μm deep into the mucosa, while at the same time prevents overheating of the surface because of the optimal spacing between the

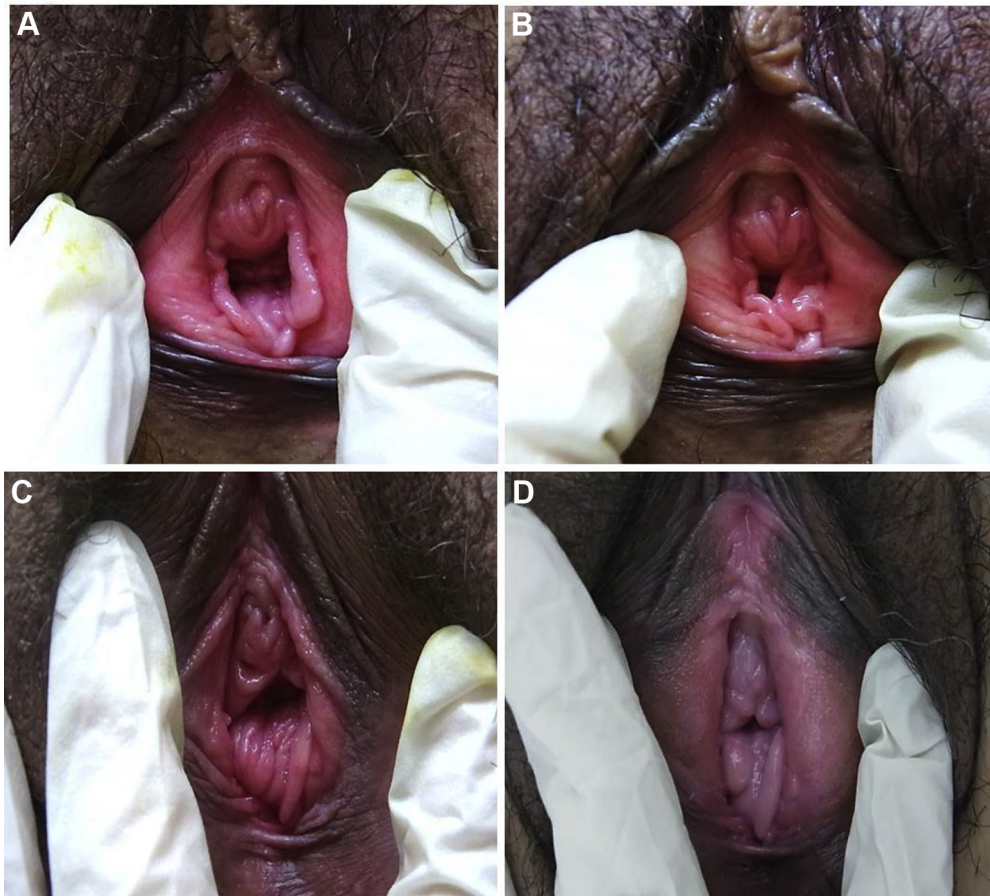


Figure 4. Examples of photographs used in objective estimation of laxity of the introital area before and after treatment (group 3, N = 29). Images show the vulvar area of 2 patients (first patient: A and B; second patient: C and D) before nonablative Er:YAG laser treatment (A) (C) and 12 months after the second treatment (B) (D) in open introitus view.

micropulses.^{12,16} The treatment results in shrinkage of collagen fibers and the induction of neocollagenesis.^{17,18}

This distinction is important to understand in light of the Food and Drug Administration (FDA) warning letter of July 2018, which was sent to 7 energy-based device manufacturers that market lasers and other energy-based devices, such as radio-frequency, for indications of vaginal rejuvenation. The FDA warning letter resulted in an increased level of skepticism for all such treatments internationally, even in countries where they have been approved for clinical use. We disagree with the FDA's generalized warning about vaginal laser procedures, as different lasers have different mechanisms of action and risk profiles. In contrast to ablative lasers, the laser that we used in our study—vaginal nonablative erbium laser with Fotona SMOOTH mode—does not physically harm the tissue surface but creates only controlled heating of the mucosal surface. It therefore does not pose any of the safety risks that are connected with tissue ablation, such as scarring or infection. The safety data from our study and all other cited clinical trials have shown that all adverse effects are of a mild and transient nature. Over the past years, nonablative Er:YAG laser with SMOOTH technology has been used to safely and effectively treat various genitourinary conditions, such as stress

and mixed urinary incontinence, genitourinary syndrome of menopause, and pelvic organ prolapse, as well as vaginal laxity.^{7–12,16–21}

The limitations of our study include the small number of patients in subgroups (group 2 and 3) that estimated efficacy in improving vaginal laxity; this is due to cultural reasons, as many Japanese patients are reluctant to respond to such questions. A somewhat larger (n = 144) subgroup of patients answered the question regarding the improvement of sexual gratification after the laser treatment. Despite the low number of patients in the 3 subgroups evaluated for efficacy, they have included different assessment methods, which have shown consistent improvement in all analyzed groups, comparable with published data. Our results give us an indication that the treatment is highly effective—this will, however, need to be confirmed in further prospective controlled trials.

The major limitation of this study is that it is not a randomized controlled trial, but a retrospective case-series, without a control group or a comparator. In order to confirm the effect of the non-ablative vaginal Er:YAG laser on vaginal laxity with the highest level of clinical evidence, randomized controlled trials should be performed.

Conditions related to age- and childbirth-related pelvic floor dysfunction affect hundreds of millions of women worldwide.²² These conditions are interconnected, as their major cause is weakening of the pelvic floor support. One of the main factors in pelvic floor dysfunction is the laxity in the vagina and its supporting ligaments due to increasing age and vaginal childbirth. Dietz et al² have found strong concurrence of vaginal laxity with early pelvic prolapse stages, and even proposed that vaginal laxity may be the first stage in the development of pelvic organ prolapse. Hence, we can speculate that the treatment of this bothersome condition may not only improve women's QoL but may also improve the symptoms or delay the progress of developing more serious and difficult-to-treat conditions.

CONCLUSIONS

Vaginal laxity is detrimental to quality of life and may be an early or a concurrent symptom in more conditions related to pelvic dysfunction. Our data indicates that Er:YAG laser treatment is an effective and safe method for treating vaginal laxity symptoms, with our results being comparable to other published studies. Randomized controlled trials are necessary to confirm these results with highest level of clinical evidence.

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Conflict of Interest: Irena Hreljac and Zdenko Vizintin are currently employed by Fotona d.o.o., a medical laser company and manufacturer of the laser used in the study.

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