Original Article

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# Impact of Subablative Erb:Yag Laser Applications on Vaginal Resting and Contraction Pressures

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## Abstract

**Aim:** The existing data on vaginal laser treatment in pelvic floor dysfunction is encouraging and shows improvement in urinary incontinence (UI) and genital prolapsus symptoms. The aim of this study was to examine the effects of subablative Erb:Yag laser applications for incontinence and vaginal laxity (VL) in terms of changes in vaginal resting and contraction pressures.

**Methods:** This observational, assessor-blind study was conducted in the Women's Health Clinic of the American Hospital from 2015 to 2017. Data from 176 patients, aged 18 to 55, were analyzed. Each patient received a total of two laser applications, performed six weeks apart. The indications were UI or VL. The pre- and post-treatment vaginal pressures during resting and contraction were measured with a perineometer (Peritron 9300 Perineometer Laborie). All the laser procedures were performed by the same physician, and measurements were carried out by another physician. Laser applications were performed with an Er:YAG laser SMOOTH, Fotona SP Dynamis (Fotona, Slovenia).

**Results:** The age of patients showed a high correlation with the pre-treatment resting and contraction vaginal pressure values (r=-0.23, p=0.002, and r=-024, p=0.002, respectively). After evaluation of all cases, vaginal pressure values measured during rest and contraction showed a significant increase. The correlation coefficient was 0.67 for resting pressure values and 0.72 for contraction pressure values before and after treatment. There was no significant difference between the VL and UI groups in terms of the increase in pre- and post-treatment resting and contraction pressures (p=0.957 and p=0.743, respectively). After analyzing the effect of age, no difference was observed between the VL and UI groups in terms of pressure increase (p=0.515 and p=0.568, respectively). A total of 115 patients, or 61.8% of the cases, stated that they were "satisfied" or "very satisfied" with the treatment.

**Conclusion:** We observed significant improvements in intravaginal resting and contraction pressure values, which we interpreted as an objective strengthening effect of laser treatments on the pelvic floor.

**Keywords:** Vaginal laser, perineometer, pelvic pressure, vaginal pressure, vaginal laxity, urinary incontinence, pelvic floor

## Introduction

Interest in non-invasive or minimally invasive treatment options in all areas of medicine and the frequency of their application are increasing. In gynecology, vaginal laser applications ($CO_2$ laser, Erb:Yag laser) are still controversial, but they continue to gain extreme popularity (1). The frequency of application is increasing in cases of all types of incontinence (mix, urge, or stress incontinence), vaginal laxity (VL), the genitourinary syndrome of menopause, and pelvic organ prolapse, although there is not enough evidence for the beneficial effect (2). The Er:YAG laser exerts a gradual thermal effect. After breaking the cross-connections of collagen in the subepithelial connective tissue-which is rich in water-and shortening the collagen fibrils, the thermomechanical interaction, which spreads to deeper tissues, causes tissue contraction and stretching, and then produces the formation of new collagen fiber. The effect of both mechanisms of action on the reshaping of connective tissue has been shown histologically (3).

A guideline has not yet been established regarding the place of laser applications for incontinence or pelvic organ prolapse in the treatment steps, as there is no FDA approval for these treatments. While informing the patient about possible treatment modalities, unless the patient's specific situation requires otherwise, the general tendency

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is to start with non-invasive or minimally invasive methods before requiring surgery. Thus, when recommending laser, it is possible to consider it as a minimally invasive application that can be offered to the patient after other non-invasive treatment modalities such as lifestyle modification, Kegel exercises, and pelvic floor exercises. Because of general practices, this ranking is more a reported opinion than a guideline.

Laser therapy can effectively improve trophism through a restorative reaction consisting of collagenesis, elastogenesis, and angiogenesis. This creates a warming process at the level of the lamina propria (3). Thus, without acting on the fascia, the collagen and elastin fibers in the mucosa are tightened and the support function is strengthened. In a recent prospective multicentric randomized placebo-controlled trial to evaluate the efficacy and safety of non-ablative Er:Yag laser for the treatment of stress urinary incontinence (SUI), O'Reilly describes the effect of laser as increasing the support of the connective tissue around the bladder neck, reducing urethral hypermobility, and contributing to pelvic floor support (4).

In our study, the effects of laser applications for UI and VL on vaginal resting and contraction pressures were examined. All participants reported experiencing discomfort due to incontinence or VL in their daily lives. Since the pelvic floor resistance of each patient was evaluated on its own before and after therapy, parity, body mass index (BMI), and additional pathologies were not considered.

## Materials and Methods

### Compliance with Ethical Standards

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and all its revisions. The data were generated, documented, and processed in accordance with good clinical practice (GCP). Extensive written informed consent for laser treatments was obtained from all subjects before every laser session. The patients also agreed to participate in the study and gave consent to publish their data. The study was approved by the Scientific Ethics Committee of Koç University (2022.273.IRB1.114).

### Study Design

This observational, assessor-blind data analysis was conducted at the American Hospital. Data from 176 patients, aged between 18 and 55, treated between 2015 and 2017 were analyzed.

The patients complained of UI or VL. The pre- and post-treatment vaginal pressure values during resting and contraction were measured with a perineometer (Peritron 9300 Perineometer Laborie). The Peritron perineometer had a tapered vaginal probe with a measurable length of 55 mm and was connected to the main body by an 80 cm plastic tube, and when the vagina was compressed, the pressure sensor measured the vaginal pressure in cm $H_2O$. A medium-sized vaginal probe was used in this study.

Vaginal pressure measurements were performed in the supine lithotomy position. The probe -condom and gel-applied- was placed in the mid-part of the vagina, and the pressure values during rest and contraction were measured.

All the laser procedures were performed by the same physician, and measurements were carried out by another physician. Before laser applications, local anesthetic cream (EMLA 5% cream; 25 g lidocaine and 25 mg prilocaine) was applied to the introitus and distal 1/3 of the vagina and kept at a minimum for 10 min to take effect. Laser applications were performed with an Er:YAG laser SMOOTH, Fotona SP Dynamis (Fotona, Slovenia). The Er:YAG laser we used has a wavelength of 2940 nm (Er:YAG laser SMOOTH Fotona, Slovenia); it is the patented "SMOOTH MODE" that exerts a non-ablative effect on tissues and results in a controlled warm-up, creating a gradual thermal effect.

Two laser sessions, performed six weeks apart, were described as "treatment", and the data from patients who completed two sessions were included in the study. During rest and contractions, pre-treatment vaginal pressure measurements were taken with a perineometer. Then, two laser sessions six weeks apart were performed as per indication. The second measurement was carried out 6-8 weeks after the second laser application. None of the patients received pelvic floor muscle (PFM) exercises before or between laser sessions. Since each patient was its own control, parity, BMI, and concomitant diseases were not subject to evaluation.

In addition to the pre- and post-treatment pressure value comparison, the patients were asked to evaluate the treatment results using the 5-point Likert scale (1= very dissatisfied; 2= dissatisfied; 3= no change; 4= satisfied; 5= very satisfied). There was no separate symptom-based assessment.

**The laser protocols used in the study were as follows:**

For urinary incontinence, a total of three steps were applied as per the protocol determined on the device.

Step 1: Linear from proximal to distal, clockwise, by delivering energy to the entire anterior vaginal wall surface, 6 passes.

Step 2: Linear from proximal to distal, by delivering the energy with a 360°, 3 passes.

Step 3: Delivering energy, clockwise at the introitus with 3 passes.

For vaginal tightening: a total of two steps were applied according to the parameters determined in the device for that indication.

Step 1: Linear, by delivering energy to the entire vaginal wall, three passes.

Step 2: Introitus and the outer 1/3 of the vagina, delivering energy clockwise, three passes.

All laser parameters used are listed in Tables 1 and 2.

### Statistical Analysis

Continuous variables were defined by means and standard deviations, and categorical variables were defined by numbers and ratios. Pre- and post-treatment measurements were compared using a Paired sample t-test, and categorical variables were compared using Fisher's exact test. The variance in measurements was evaluated using the Pitman-Morgan test.

The relationship between the measurements and the subject's age was evaluated by correlation analysis and expressed with Pearson r values. The change between pre- and post-procedure measurements was evaluated by the mean difference and correlation coefficient. Regression analysis was performed on a general linear model to control the female age variable. In the context of two-way hypothesis evaluation, $p<0.05$ was considered statistically significant. Statistical analysis and figures were performed with the Statistical Package for the Social Sciences (SPSS, 24.0) and GraphPad Prism (9.0.0) applications.

The primary outcome measure was the difference between rest and contraction pressures in the vagina, and the secondary outcome measure was the feedback received from the treatment.

## Results

The laser procedures were held between March 2015 and February 2017. Vaginal laser applications were performed twice, six weeks apart, on 176 patients aged between 27 and 55.

Of the 176 patients involved, 94 (53.4%) and 82 (46.6%) were treated for VL and UI, respectively. The mean age of patients was 39.6±7.6 (27-55). VL cases were younger than UI cases (36.6±6.1 vs. 43.0±6.6, $p\leq0.0001$).

We observed that the age of patients showed a high correlation with the pre-treatment resting and contraction vaginal pressure values ($r=0.23$, $p=0.002$, and $r=-024$, $p=0.002$, respectively). The correlation persisted to a limited extent with the post-treatment values ($r=-0.15$, $p=0.046$, and $r=-0.16$, $p=0.033$, respectively).

The violin plot graph of the measurements made before and after the treatment is presented in Figure 1. When all cases were evaluated together, vaginal pressure values measured during rest and contraction showed a significant increase (Tables 3 and 4). The correlation coefficient was 0.67 for resting pressure values and 0.72 for contraction pressure values before and after treatment.

While there was a decrease in pressure values in 11 cases (6.2%) in pre- and post-treatment resting pressure measurements, no change was observed in 20 cases (11.4%). Again, in pre- and post-treatment contraction pressure measurements, a decrease in pressure values was observed in 6 cases (3.4%), while no change was observed in 17 cases (9.7%). The distribution of the calculated average changes between the measurements, as shown in Figure 2.

There was no significant difference between the VL and UI groups in terms of the increase in pre- and post-treatment resting and contraction pressures ($p=0.957$ and $p=0.743$, respectively). After analyzing the effect of age, no difference was observed between the VL and UI groups in terms of pressure increase ($p=0.515$ and $p=0.568$, respectively).

Patients' subjective perceptions were scored on a 5-point Likert scale, with 1 being the worst and 5 being the best. The results are shown in Figure 3. A total of 115 people, or 61.8% of the cases, stated that they were "satisfied" or "very satisfied" with the treatment.

**Table 1. Laser parameters for urinary incontinence**

| Handpiece | Speculum | Mode | Spot | Fluence | Repetition | Stacking | Passes |
|---|---|---|---|---|---|---|---|
| PS03+ GAc | Glass | Smooth | 7 mm | 6 J/cm² | 2 Hz | 7 | 6 |
| R11+ GCc | Glass | Smooth | 7 mm | 3 J/cm² | 2 Hz | 7 | 3 |
| PS03 | | Smooth | 7 mm | 10 J/cm² | 1.6 Hz | 7 | 3 |

**Table 2. Laser parameters for vaginal laxity**

| Handpiece | Speculum | Mode | Spot | Fluence | Repetition | Stacking | Passes |
|---|---|---|---|---|---|---|---|
| R11+ GCc | Glass | Smooth | 7 mm | 3 J/cm² | 2 Hz | 7 | 4 |
| PS03 | | Smooth | 7 mm | 10 J/cm² | 1.6 Hz | 7 | 3 |

| Table 3. Resting (vaginal pressure measurements pre and post treatment) | | | | | | |
|---|---|---|---|---|---|---|
| | Number | Rest before treatment (cm $H_2O$) | Rest after treatment (cm $H_2O$) | Average difference | 95% CI | p-value |
| Vaginal laxity | 94 | 6.85±5.14 | 10.63±5.30 | 3.77 | 2.89-4.66 | <0.0001 |
| Incontinence | 82 | 6.12±4.58 | 9.87±4.65 | 3.74 | 2.94-4.54 | <0.0001 |
| Total | 176 | 6.51±4.89 | 10.27±5.01 | 3.76 | 3.16-4.36 | <0.0001 |
| Paired samples t-test, values represent mean -/+ 2SD and mean difference (95% confidence interval)<br>CI: Confidence interval, SD: Standard deviation | | | | | | |

| Table 4. Contraction (vaginal pressure measurements pre and post treatment) | | | | | | |
|---|---|---|---|---|---|---|
| | Number | Pre-treatment contraction (cm $H_2O$) | Post-treatment post-treatment contraction (cm $H_2O$) | Average difference | 95% CI | p-value |
| Vaginal laxity | 94 | 23.04±11.40 | 33.47±13.32 | 10.42 | 8.49-12.36 | <0.0001 |
| Incontinence | 82 | 17.83±10.45 | 27.78±13.17 | 9.95 | 7.82-12.08 | <0.0001 |
| Total | 176 | 20.61±11.25 | 30.82±13.51 | 9.53 | 8.79-11.6 | <0.0001 |
| Paired samples t-test, values represent mean -/+ 2SD and mean difference (95% confidence interval)<br>CI: Confidence interval, SD: Standard deviation | | | | | | |

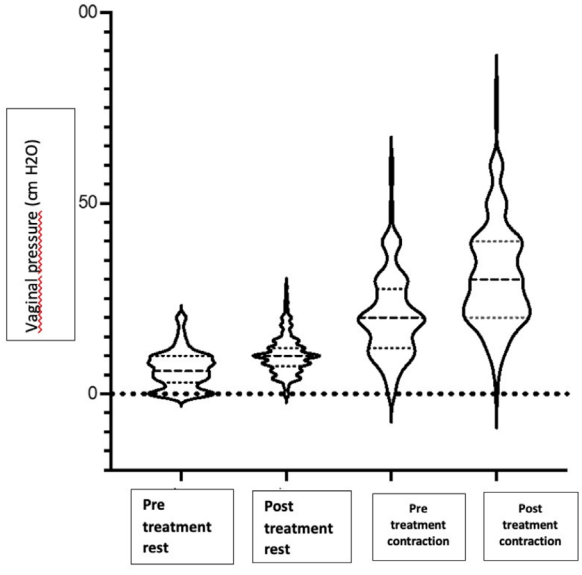


**Figure 1.** Violin plot chart pre-post treatment vaginal pressures mean and 25%-75%

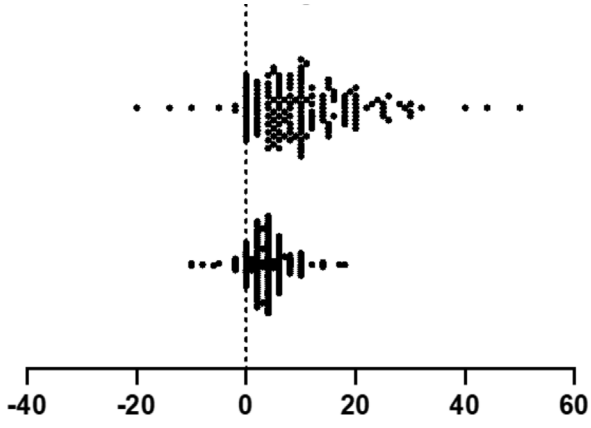


**Figure 2.** Distribution of pre and post treatment mean pressure differences (cm $H_2O$)

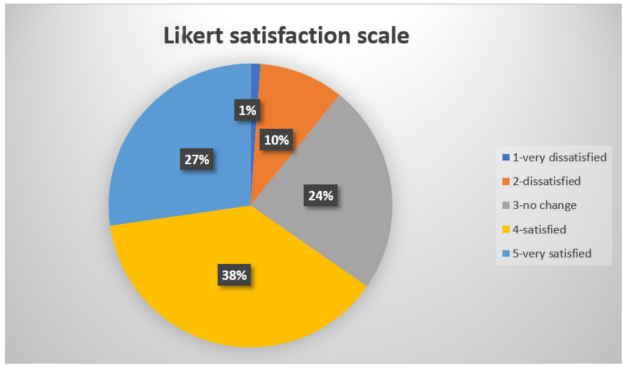


**Figure 3.** Likert 5-digit satisfaction scale options for patients (1- very dissatisfied, 2- dissatisfied, 3- no change, 4- satisfied, 5- very satisfied)

## Discussion

This study differs from many other laser studies in that it uses a very simple method to show the effect of laser, which is applicable and affordable in every clinical setting. Our study is focusing on the changes in pelvic floor pressures after laser treatment, not only during contraction but during resting as well. Resting pelvic floor capacity is important for maintaining support for the pelvic organs. We observed a decline in pre-treatment resting and contraction vaginal pressure values with age, which can be interpreted as an age-related worsening in the contractile capacity of the tissue. But regardless of age, there was a significant increase in pre- and post-treatment pressure values in both groups.

Beside many observational and few randomized controlled trials (5-9), a recently published randomized, double-blind, sham-controlled study from Page used patient symptoms, validated screening tests, standard evaluation forms, and microscopy to demonstrate the effects of laser. There has been a lot of research done on the laser treatment of incontinence and genitourinary syndrome (10).

In PUBMED, there are a very limited number of publications "Lee (11), Fistonić et al. (12), Blaganje et al. (13)" on the use of perineometers for measuring pelvic floor pressures in laser applications. In Fistonić et al's. (12) study, they analyzed 42 women with SUI and reported a significant improvement in perineometry values after Er:YAG treatment. In another randomized, sham-controlled study by Blaganje et al. (13) in 2018, 114 cases of SUI and vaginal relaxation were evaluated. Patients were clinically examined at baseline and 3 months after treatment. They also answered questionnaires for SUI severity and sexual function assessment, and the PFM function was assessed with perineometry. Improvements in PFM strength and maximum pressure in the laser group were significantly better than those in the sham group (13).

Some recent studies used the vaginal tactile imager (VTI) technique to evaluate the vaginal elasticity and strength. Vaginal tactile imager allows biomechanical evaluation of soft tissue along the anterior, posterior, and lateral vaginal walls. The vaginal probe comprises a tactile sensor array, which is installed on the probe surface and is in contact with the vaginal wall during the examination procedure. The implemented VTI software allows real-time visualization of the pressure pattern on the probe head and stores the data in a digital format (14). An increase in vaginal pressures and elasticity has been reported in two recent studies using this measurement technique used by Gao et al. (15) and Lauterbach et al. (16) to evaluate the effects of $CO_2$ laser in SUI.

Of course, whether the significant difference in vaginal pressure levels observed after treatment is clinically reflected in the functions remains to be determined. The sole purpose of our study was to show vaginal pressure changes before and after the laser. Since the changes in symptom severity were not the main subject of this study, unlike many other laser studies, no distinction was made for the type of incontinence.

The study group consisted of a mixed group of patients with incontinence and VL, and as a single common evaluation criterion, patients were asked to subjectively evaluate the treatment outcomes and improvement in their complaints. To assess treatment success, we used a 5-digit Likert scale, which showed that 65% of patients were satisfied or very satisfied with the treatment. Even though there is no other screening test for symptom severity, this is an important outcome because it reflects patient satisfaction.

Simultaneously, additional applications to extend the duration of this positive effect should be determined. For example, it may be useful to teach patients regular Kegel exercises to get the maximum benefit from the pressure change obtained from the treatment. Combining physiotherapy practices with laser treatment in the patient's treatment program can be another option. Doing the pelvic floor exercises properly plays a crucial role, as the treatment will not bring any benefit if they are performed incorrectly. PFM training is shown as a Class A recommendation by the International Continence Society for treating stress, urinary incontinence, and pelvic organ prolapse (17-19).

However, the fact that patients must go to the hospital for the exercises several days a week is the biggest obstacle to compliance with the treatment. Hence, strengthening the supportive tissues of the pelvic fascia with laser applications that can be performed 4-8 weeks apart can provide us with satisfactory results that can be achieved in a shorter time interval. Laser treatments in gynecology are criticized for the superficial mucosal and submucosal effects, which do radiate to the pelvic fascia, but as an objective finding, the support in the connective tissue and the presence of the strengthening effect of laser, which means an increase in vaginal pressure values, were clearly observed in our study group. If the success and effectiveness of PFM training (the recommended treatment modality in pelvic organ prolapse) are objectively measured by the improvement in vaginal pressures, any other method resulting in an increase in vaginal pressures should be beneficial as well.

We know that pelvic relaxation is the weakness of the pelvic fascia, and this problem can manifest itself as pelvic organ prolapsus. Although the target areas of vaginal laser treatment are the mucosa and submucosa, we see the effect of treatment as a significant increase in vaginal resting and contraction pressures.

Effective measurement of vaginal pressure must assess the treatment's success. Physiotherapy and

biofeedback applications are important invasive treatment modalities for pelvic floor rehabilitation. The objective assessment of the success and effectiveness of these applications is based on the measurement of vaginal resting and contraction pressures. For this purpose, the Oxford scale, which provides a subjective evaluation, and validated perineometric measurements are frequently performed as well (20-22). In our study, we preferred perineometric measurements as an objective scale.

The measurement of PFM resistance depends on the size and location of the probe, the cooperation of the patient, and the experience and skills of the examiner assessing the vaginal pressures (22,23). This was not the case in our study, as the measurements were performed by a single examiner.

### Study Limitations

The major limitation of the study can be seen in the lack of a control group with another treatment method and a validated questionnaire for symptom severity measurements before and after treatment. The study group consisted of a mixed group of patients with incontinence and VL, and as a single common evaluation criterion, patients were asked to subjectively evaluate the treatment outcomes and improvement in their complaints, and the patient's satisfaction was the benchmark of treatment success. Besides these limitations, there are certain strengths in our study. First, all vaginal pressure measurements were performed by a single examiner, who was blinded to the type and stage of the patient's treatment. All laser treatments were applied by another physician. The sample size is another study strength; the large sample size compared to similar studies and the easily applicable, objective measurement method for the laser effect make this study valuable for further research.

### Conclusion

Our findings regarding the changes in vaginal pressure after laser irradiation are promising for the use of vaginal laser treatments, alone or along with pelvic floor physiotherapy, as a new treatment protocol in pelvic floor rehabilitation. The perineometer, as an assessment tool for pelvic pressure, is useful and easy to use. By increasing the support of the connective tissue around the bladder neck and contributing to pelvic floor support, non-ablative Er:YAG laser therapy is a promising option as a non-surgical treatment and should be offered to patients suffering from UI and VL.

### Ethics

**Ethics Committee Approval:** The study was approved by the Scientific Ethics Committee of Koç University (2022.273.IRB1.114).

**Informed Consent:** Extensive written informed consent for laser treatments was obtained from all subjects before every laser session.

**Peer-review:** Externally and internally peer-reviewed.

### Authorship Contributions

Concept: E.A., S.A., Design: E.A., S.A., Data Collection or Processing: E.A., S.A., Analysis or Interpretation: E.A., S.A., Literature Search: E.A., Writing: E.A.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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