Laser&Health
ACADEMY

Compendium of Clinical Studies

Er:YAG and Nd:YAG Laser Treatments in Gynelocogy

May 2025

Content

Foreword

Scientific Evidence Behind Laser Gynecological Treatments

For over a decade, the Laser and Health Academy (LA&HA) has been at the forefront of supporting and conducting numerous scientific studies exploring the safety and effectiveness of laser-based applications, including the notable non-ablative Er:YAG SMOOTH gynecological laser therapy introduced in 2012. Published in esteemed, peer-reviewed international journals, these studies have yielded clinically proven results, showcased in more than 100 publications. Among these, a meta-analysis of four randomized controlled trials (RCTs) confirms the effectiveness and safety of Fotona laser therapy for stress urinary incontinence (SUI), further strengthening the clinical credibility of laser-based therapy.

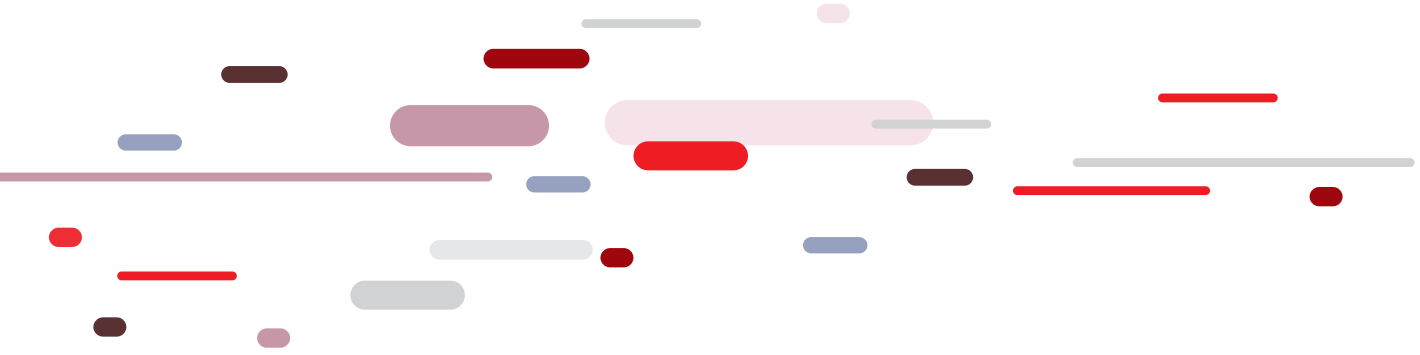
The newly updated compendium compiles the summaries of some of the most impactful published clinical studies that support the safety and efficacy of laser gynecological treatments using non-ablative Er:YAG SMOOTH and Nd:YAG PIANO laser technology. The first part of the compendium contains brief drafts from selected publications, outlining some of the key findings of each study. The second part presents the comprehensive collection of published studies, with QR codes added for easier access to the official online sources.

By encouraging the exchange and dissemination of scientific knowledge among peers, LA&HA strives to facilitate the widespread adoption of evidence-based laser medicine among the healthcare community and the general public. We believe this compendium will help bring crucial scientific evidence one step closer to users.

The LA&HA Clinical Affairs Team

The use of lasers for medical treatments is subject to local regulations, which may vary depending on your region. Please check with the manufacturer whether a specific product or application has been approved or cleared to be marketed in your country.

Short Drafts of Selected Scientific Publications



The Efficacy and Safety of Er:YAG Laser Therapy for Stress Urinary Incontinence: A Systematic Review and Meta-Analysis

Authors: Yan H, Wang J, Ding Y, Huang G, Ding H, Zhao W, Ma Y

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Published in: Lasers in Surgery and Medicine, 2025

1. REVIEWING ER:YAG LASER FOR SUI TREATMENT EFFECTIVENESS

This systematic review and meta-analysis aimed to evaluate the efficacy and safety of non-ablative Er:YAG laser therapy for women with stress urinary incontinence (SUI). It sought to consolidate findings from randomized controlled trials (RCTs) and clarify the clinical value of this non-surgical treatment approach.

2. META-ANALYSIS OF FOUR RCTS INVOLVING 390 PATIENTS

The authors included four RCTs with a total of 390 women diagnosed with SUI, comparing Er:YAG laser therapy (Fotona, Slovenia) to sham treatments or pelvic floor exercises. Key outcomes analyzed were objective measures like the 1-hour pad test, subjective cure rates via ICIQ-SF, changes in ICIQ-SF and PISQ-12 scores, pain levels (VAS), and reported adverse events.

3. LASER IMPROVED OBJECTIVE MEASURES, WITH MIXED SUBJECTIVE SCORES

Er:YAG laser therapy significantly improved the 1-hour pad test results and increased subjective cure rates compared to controls. However, the studies did not find statistically significant differences in the ICIQ-SF or PISQ-12 scores. No serious adverse events were reported, and the frequency of minor side effects (e.g., discharge, discomfort, suspected UTIs) was comparable between groups.

4. ER:YAG LASER IS EFFECTIVE AND SAFE FOR SUI TREATMENT

The meta-analysis supports Er:YAG laser as a safe and effective treatment option for SUI.

Vaginal Erbium Laser Versus Pelvic Floor Muscle Training for Stress Urinary Incontinence: A Randomised Controlled Trial

Authors: Page A-S, Borowski E, Bauters E, Housmans S, Van der Aa F, Deprest J

Published in: International Urogynecology Journal, 2025

1. COMPARING LASER AND PFMT FOR STRESS URINARY INCONTINENCE (SUI)

This randomized controlled trial aimed to compare the effectiveness of non-ablative vaginal Er:YAG laser therapy with pelvic floor muscle training (PFMT) in women with mild to moderate stress urinary incontinence (SUI). The study assessed whether laser therapy could serve as a viable alternative to PFMT, focusing on symptom relief, patient satisfaction, and long-term effectiveness over two years.

2. RANDOMIZED TRIAL WITH LASER AND PFMT GROUPS

A total of 60 women diagnosed with mild to moderate SUI were randomized into two groups: one receiving three to six laser treatments (SP Spectro, Fotona, Slovenia) and the other undergoing a structured PFMT program with nine to eighteen sessions. The primary outcome was symptom improvement at four months, measured by the Urogenital Distress Inventory-6 (UDI-6). Secondary outcomes included patient-reported quality of life, treatment satisfaction, and adverse events, with follow-ups extending to 24 months.

3. SHORT-TERM IMPROVEMENT WITHOUT SIDE EFFECTS

Both groups showed significant symptom improvement at four months, with no subjective or objective inter-group differences, confirming laser's non-inferiority to PFMT. No serious adverse effects occurred in either group.

4. LASER MATCHES PFMT FOR SYMPTOM RELIEF

The study concluded that laser therapy and PFMT offer comparable short-term benefits for mild to moderate SUI.

Efficacy and Safety of Non-Ablative Er:YAG Laser for Mild to Moderate Stress Urinary Incontinence: A Prospective, Multicenter, Randomized, Sham-Controlled Clinical Trial

Authors: Wang X, Zhang Z, Meng L, Xu S, Zheng J, Wang H, Lv J, Zhang Z, Yuan X, Zhang Y

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Published in: Lasers in Medical Science, 2025

1. EVALUATING LASER THERAPY FOR SUI

The study aimed to evaluate the efficacy and safety of non-ablative vaginal Er:YAG laser therapy in treating women with mild to moderate stress urinary incontinence (SUI). It also sought to provide more rigorous clinical data using a randomized, sham-controlled design in a Chinese patient population.

2. RIGOROUS MULTICENTER CLINICAL TRIAL DESIGN

A prospective, multicenter, randomized, sham-controlled clinical trial was conducted across four Chinese medical centers between 2020 and 2023. A total of 125 women diagnosed with mild to moderate SUI were randomized in a 2:1 ratio to receive either three monthly sessions of Er:YAG laser therapy (XS Dynamis, Fotona, Slovenia) or sham treatment. Efficacy was assessed using objective (urine pad test) and subjective (ICIQ-SF, I-QOL) outcomes over a three-month follow-up period.

3. SIGNIFICANT IMPROVEMENT WITH LASER TREATMENT

At three months post-treatment, the laser group showed a 71.43% treatment success rate versus 36.59% in the sham group, with a significant absolute difference of 34.84%. While both groups improved on quality-of-life and symptom severity scales, only the laser group showed significantly greater objective reductions in urinary leakage and incontinence frequency. Adverse events were mild and transient, mostly limited to discomfort and temporary discharge.

4. PROMISING NON-SURGICAL OPTION FOR SUI

Non-ablative Er:YAG laser therapy demonstrated significant short-term benefits in treating SUI, offering a non-invasive alternative with good safety and tolerability.

Urinary symptoms data between two groups after treatment.

	Experimental group (*n* = 84)	**Control group (*n* = 41)**	***P***
Treatment succes at 1 month after treatment, n (%)	56 (70.00%)	15 (38.46%)	= 0.001
Reduce rate of one hour urine pad test with leakage			
1 month after treatment	43%	31%	<0.05
3 months after treatment	45%	14%	<0.001
Reduce frequencies of UI compared to baseline			
1 month after treatment (Mean ± SD)	1.79 ± 4.05	0.24 ± 3.70	<0.05
3 month after treatment (Mean ± SD)	1.63 ± 4.61	2.08 ± 4.08	<0.05

Vaginal Erbium Laser Treatment for Stress Urinary Incontinence: A Multicenter Randomized Sham-Controlled Clinical Trial

Authors: O'Reilly BA, Viereck V, Phillips C, Toozs-Hobson P, Kuhn A, Athanasiou S, Lukanovic A, Palmer B, Dahly D, Daykan Y, Cardozo L

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Published in: International Journal of Gynecology and Obstetrics, 2023

1. EXAMINING THE EFFICACY AND SAFETY OF ER:YAG LASER FOR SUI TREATMENT

The aim of this multicenter study was to evaluate the efficacy and safety of non-ablative vaginal Er:YAG laser for the treatment of stress urinary incontinence (SUI).

2. 110 PARTICIPANTS IN A BLINDED RANDOMIZED SHAM-CONTROLLED TRIAL

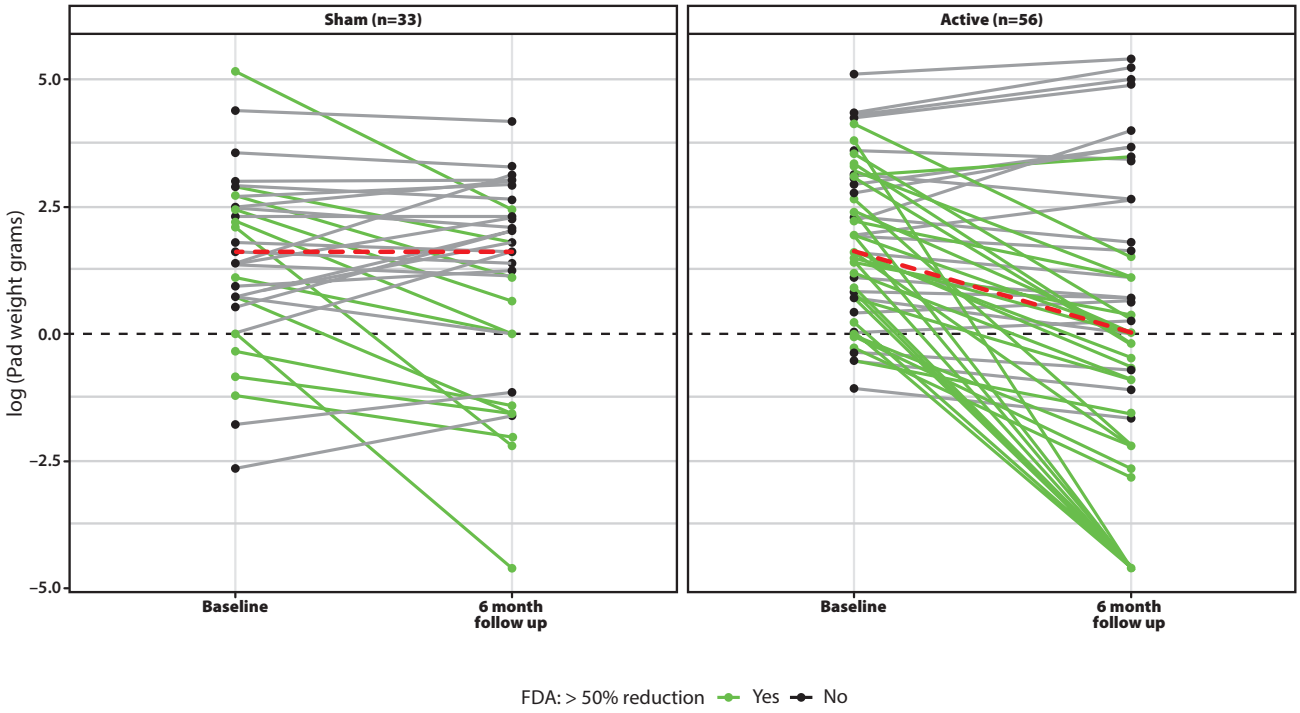
During this multicenter trial 110 participants with SUI were recruited, with 73 in an active arm and 37 in a sham arm. Patients received two treatments (XS Dynamis, Fotona, Slovenia) at 1 month apart. The primary outcome measure was the 1 h pad weight test measured at 6 months. Secondary outcomes were the durability of treatment success at 12 months, and questionnaires that assessed SUI severity (ICIQ-UI SF), sexual function (PISQ-12) and HRQoL (KHQ), and incidence and severity of device-related adverse events and pain (VAS).

3. RESULTS SHOW SIGNIFICANTLY HIGHER IMPROVEMENT IN THE ACTIVE ARM

The primary outcome data obtained from the trial revealed that treatment success was observed in 36% of the sham arm compared to 59% of the active arm that received Er:YAG laser treatment. Subjective patient assessment of general and sexual function improvement with PISQ-12 and PGI-I also showed superior effects compared to the sham (OR 2.8, 95% CI: 1.2–7.0, P = 0.02 and OR 0.13, 95% CI: 0.05–0.36, P < 0.001, respectively).

4. A SUCCESSFUL TREATMENT OPTION FOR SUI PATIENTS

The authors of the study conclude that non-ablative vaginal Er:YAG laser appears to be a safe and effective non-surgical treatment option for SUI, with a superior effect over sham as measured by the primary outcome measure, the 1-h pad weight test.



Treatment success demonstrated as log transformed pad weight at baseline and at 6 months follow-up (FU) in a control and laser arm. Green line – participants with treatment success >50% pad weight reduction from baseline at FU, gray lines – participants without treatment success. Dashed lines identifies the median.

Efficacy and Safety of Intraurethral Er:YAG Laser Treatment in Women with Stress Urinary Incontinence Following Failed Intravaginal Laser Therapy: A Retrospective Study

Authors: Tseng YL & Su CF

Published in: Lasers in Medical Science, 2023

1. EVALUATING INTRAURETHRAL ER:YAG LASER TREATMENT FOR FAILED INTRAVAGINAL THERAPY

This was a retrospective study that included 93 female patients with mild to moderate stress urinary incontinence (SUI) who had completed two courses of intravaginal Er:YAG laser treatment (SP Dynamis, Fotona, Slovenia) between January 2015 and June 2018. Of these patients, 22 (23%) who continued to experience persistent SUI at 4 weeks following the second intravaginal Er:YAG laser treatment were selected to receive intraurethral laser treatment in January 2019.

2. COMPARISON OF PRE- AND POST- INTRAURETHRAL TREATMENT ICIQ-UI SF SCORES

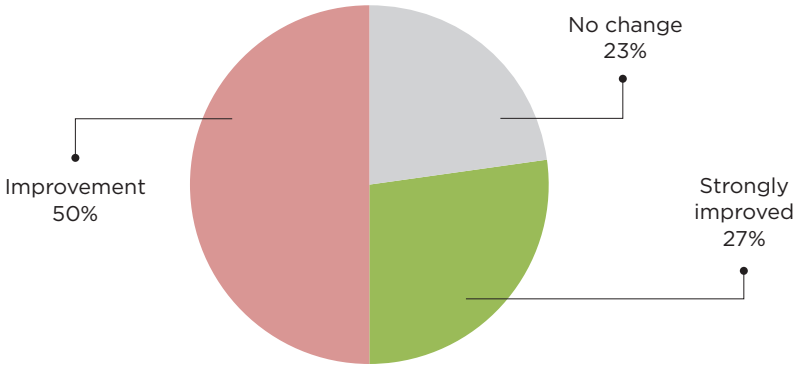
The 22 female patients with persistent SUI received intraurethral Er:YAG laser treatment using Er:YAG SMOOTH technology via a 4-mm cannula with fluence of 1.5 J/cm^2. Their average age was 47.5 years, with an average of 2 parities and a mean body mass index of 20.97. All patients completed the ICIQ-SF questionnaire before and 3 months after the procedure.

3. MAJORITY OF PATIENTS REPORTED IMPROVEMENT IN SYMPTOMS

Of the patients, 77% reported improvement in symptoms, with 6 reporting strong improvement and 11 reporting improvement. The treatment was well-tolerated, with mild and transient adverse effects such as urinary infection in 1 patient (4.5%) and mild pain in 7 patients (31.8%).

4. A PROMISING ALTERNATIVE FOR PATIENTS WITH PERSISTENT SUI

Intraurethral laser treatment may be helpful for many women with persistent SUI after vaginal laser treatment. Using intraurethral Er:YAG SMOOTH laser treatments to rejuvenate tissues and enhance structural support could be a promising avenue for managing stress urinary incontinence.



Improvement ratio after intraurethral laser treatment.

SUI in Postmenopausal Women: Advantages of an Intraurethral + Intravaginal Er:YAG Laser

Authors: Erel CT, Gambacciani M, Ozcivit Erkan IB , Gokmen Inan N , Hamzaoglu Canbolat K, Fidecicchi T

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Published in: Climacteric, 2023

1. INTRAURETHRAL + INTRAVAGINAL LASER TREATMENT FOR POSTMENOPAUSAL SUI

This study aimed to compare the efficacy of concomitant application of an intraurethral (IU) + intravaginal (IV) non-ablative Er:YAG laser with IV application in improving the symptoms of stress urinary incontinence (SUI) in women.

2. 122 SUI PATIENTS TREATED WITH ER:YAG LASER (62 WITH IU + IV AND 62 WITH IV ONLY)

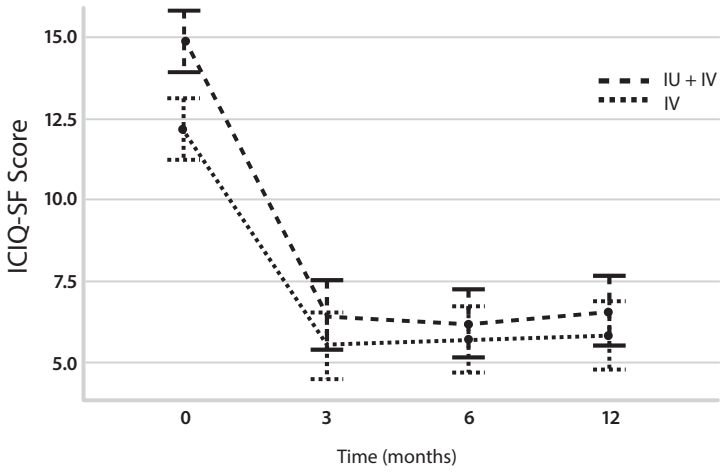
This observational retrospective cohort study included 122 SUI patients, 60 women in the IU + IV laser arm and 62 in the IV laser arm. The primary outcome was the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) score at entry and at 3, 6 and 12 months from baseline. The IV Er:YAG laser procedure (SP Dynamis, Fotona, Slovenia) was applied according to the setting for SUI. The IU SMOOTH mode Er:YAG laser was applied according to a procedure previously described by Gaspar and Brandi. Pelvic examination and ultrasound were done and a vaginal smear test was taken before the intervention. SUI was diagnosed by the history and pelvic examination along with the stress and Q-tip test.

3. CONCOMITANT APPLICATION OF IU + IV ER:YAG LASER SHOWED GREATER IMPROVEMENT

The results of the study showed that significant improvement in SUI symptoms was seen 3 months after the intervention and was sustained until the end of month 12 in both arms. The women who had severe SUI symptoms initially showed greater improvement. A higher number of women who initially had mild to moderate SUI symptoms were dry after treatment. Patients treated with IU + IV Er:YAG laser showed significant improvement in SUI symptoms compared to IV laser only, especially at postmenopausal state ($p = 0.003$).

4. COMBINED IU + IV LASER TREATMENT IS EFFECTIVE FOR POSTMENOPAUSAL SUI

Non-ablative Er:YAG laser appears to be an efficient method for the treatment of SUI. Concomitant application of an IU + IV Er:YAG laser is more effective in relieving SUI symptoms at a postmenopausal state.



Improvement in SUI symptoms in relation to treatment method – intraurethral (IU) + intravaginal (IV) vs. intravaginal (IV) alone.

Vaginal Er:YAG Laser for Treatment of Stress Urinary Incontinence: Optimization of Treatment Regimen for a Sustained Long-Term Effect

Authors: Gaspar A, Koron N, Silva J, Brandi H

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Published in: Lasers in Medical Science, 2022

1. ASSESSING THE LONG-TERM EFFICACY AND SAFETY OF ER:YAG LASER TREATMENT OF SUI

This prospective uncontrolled study was conducted to assess the long-term efficacy and safety of non-ablative Er:YAG laser treatment of Stress urinary incontinence (SUI), a common health problem that affects roughly 35% of women in the reproductive period.

2. FORTY-THREE SUI PATIENTS UNDERWENT THREE SESSIONS OF INCONTILASE®

The patients received three consecutive non-ablative Er:YAG laser (XS Dynamis, Fotona, Slovenia) treatments with 20-day intervals between sessions following the IncontiLase® protocol. The efficacy of laser treatment was assessed by 1-h pad test, 24-h pad test, 3-day voiding diary, and ICIQ-UI SF questionnaire at multiple follow-ups. Statistical analysis was performed using one-way repeated measures ANOVA. Patients were questioned about discomfort during treatment and any adverse events following the laser procedures.

3. RESULTS SHOW A SIGNIFICANT IMPROVEMENT OF SUI SYMPTOMS

All outcome measures showed a significant change over a period of the entire clinical trial. The eighteen-month follow-up revealed a fading of the effect, which was alleviated by single-session maintenance treatments every 6 months. There were no serious adverse events reported during the study. All reported side effects were mild and transient.

4. NON-ABLATIVE ER:YAG LASER IS AN EFFICACIOUS AND SAFE OPTION FOR TREATMENT OF SUI

The results of this study show that application of non-ablative Er:YAG laser for SUI treatment significantly improves SUI symptoms. High improvement rates and patient satisfaction can be maintained with single-session maintenance treatments performed every 6 months.

Improvement in outcome measures at three different time points (follow-ups). Data is presented as the percentage of patients with a corresponding improvement rate (n = number of patients).

Outcome Measure	ICIQ-UI SF			1-h pad test		
6-month FU	All (n = 43)	Group 1 (n = 28)	Group 2 (n = 15)	All (n = 43)	Group 1 (n = 28)	Group 2 (n = 15)
Dry[a] (%)	14	19	7	0	0	0
Improved[b] (%)	81	81	80	21	4	53
Not improved[c] (%)	5	0	13	79	96	47
Worse[d] (%)	0	0	0	0	0	0
Dry or improved (%)	95	100	87	21	4	53
12-month FU	(n = 43)	(n = 28)	(n = 15)	(n = 43)	(n = 28)	(n = 15)
Dry[a] (%)	14	18	7	0	0	0
Improved[b] (%)	53	54	13	40	25	67
Not improved[c] (%)	33	28	80	60	75	33
Worse[d] (%)	0	0	0	0	0	0
Dry or improved (%)	67	72	20	40	25	67
36-month FU	(n = 34)	(n = 21)	(n = 13)	(n = 34)	(n = 21)	(n = 13)
Dry[a] (%)	76	90	54	0	0	0
Improved[b] (%)	24	10	46	50	38	69
Not improved[c] (%)	0	0	0	50	62	31
Worse[d] (%)	0	0	0	0	0	0
Dry or improved (%)	100	100	100	50	38	69

ICIQ-UI SF International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form, FU follow-up
[a]1-h pad test < g, or ICIQ-UI SF score = 0
[b]If improvement at the follow-up was ≥ 50%
[c]If improvement at the follow-up was < 50%
[d]If improvement at the follow-up was negative (relative to baseline)

Changes in Sexual Function and Vaginal Topography using Transperineal Ultrasound after Vaginal Laser Treatment for Women with Stress Urinary Incontinence

Authors: Long C-W, Wu P-C, Chen H-S, Lin K-L, Loo Z, Liu Y, Wu C-H

Published in: Scientific Reports, 2022

1. ASSESSING THE EFFECTS OF ER:YAG VAGINAL LASER TREATMENT FOR SUI

This study aims to assess the changes in sexual function and vaginal topography using 3-D transperineal ultrasound in stress-incontinent women treated with Er:YAG vaginal laser.

2. A 6-MONTH STUDY USING VAGINAL TOPOGRAPHY AND 3-D TRANSPERINEAL ULTRASOUND

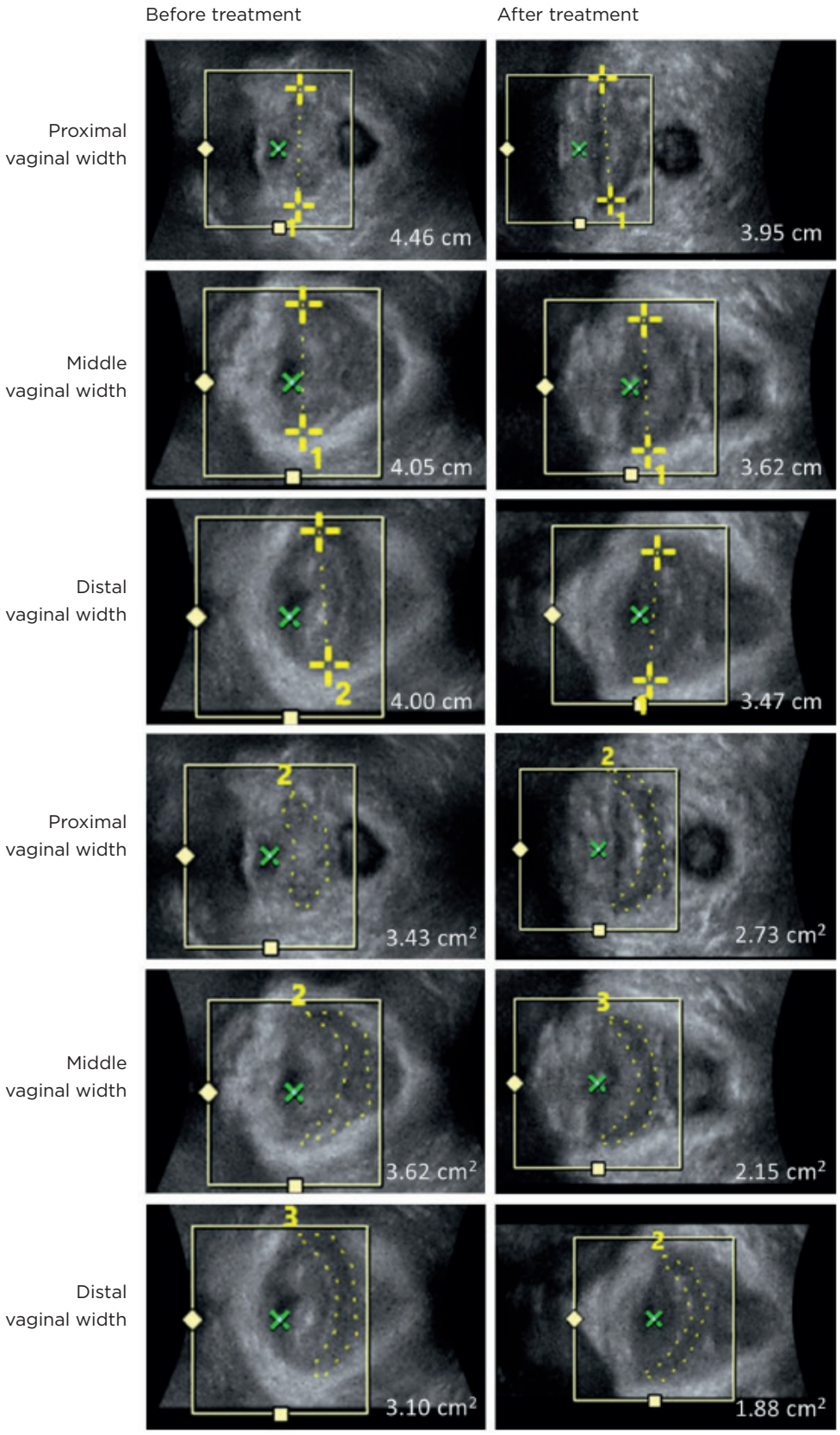
Two hundred and twenty women with stress urinary incontinence (SUI) treated with Er:YAG laser (FotonaSmooth XS, Fotona, Slovenia) were recruited. Assessment before and 6 months after the treatment included vaginal topography using 3-D transperineal ultrasound and sexual function using female sexual function index questionnaire (FSFI).

3. RESULTS SHOW SYMPTOMATIC IMPROVEMENT IN 74% OF WOMEN

A total of 50 women with complete data showed that the symptomatic improvement was noted in 37 (74%) women. After the Er:YAG vaginal laser treatment, a significantly decreased width and cross-sectional area in the proximal, middle, and distal vagina were found in women with SUI. Nearly all of the domains of FSFI improved significantly after the vaginal laser treatment, except sexual desire.

4. ER:YAG VAGINAL LASER TREATMENT PRODUCES FAVORABLE ANATOMICAL CHANGES

The study shows that following Er:YAG vaginal laser treatment, the anatomical changes of vaginal shrinkage and an improvement of female sexual function were both noted. The favorable outcome of sexual function partly related to the tightening of the vagina, as evidenced by the measurements of the 3-D transperineal ultrasound.



The sequential images of vaginal width and area of a same patient before and after treatment at different levels of vagina.

Comparison of Urethral Sling Surgery and Non-ablative Vaginal Er:YAG laser Treatment in 327 Patients with Stress Urinary Incontinence: A Case-matching Analysis

Authors: Okui NP, Miyazaki H, Takahashi W, Miyauchi T, Ito C, Okui M, Shigemori K, Miyazaki Y, Vizintin Z, Lukac M

Published in: Lasers in Medical Science, 2021

1. FIRST PS ANALYSIS COMPARING TVT AND VAGINAL ERBIUM:YAG LASER TREATMENT (VEL)

This study, published in Lasers in Medical Science, retrospectively compared tension-free vaginal tape (TVT) and non-ablative vaginal Erbium:YAG laser treatment (VEL) by propensity score (PS) analysis in women with SUI. No previous PS analysis studies have investigated urethral sling surgery using polypropylene TVT and VEL for SUI.

2. STUDY EXAMINED A LARGE NUMBER OF PATIENTS AT SEVERAL FACILITIES

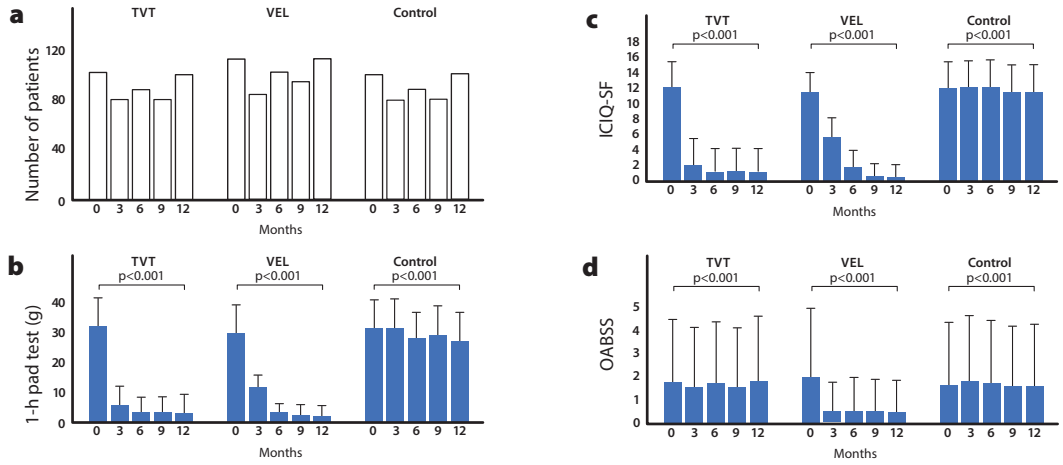
The study analyzed 102, 113, and 112 patients in the TVT, VEL, and control groups, respectively. The subjects were patients between 35 and 50 years of age at the time of treatment who (1) underwent TVT surgery, (2) received VEL treatment (XS Dynamis, Fotona, Slovenia) or (3) were placed under observation with no treatment (control) for SUI at several facilities, within a period of 15 years between 2004 and 2019. The choice of treatment type (VEL or TVT) was up to the patients after the consultations, at which they were informed in detail about both options.

3. RESULTS SHOW SIGNIFICANT IMPROVEMENT

Compared with the control group, the TVT and vaginal erbium laser VEL groups exhibited significant improvement in the 1-h pad test and ICIQ-SF. In the PS analysis, the TVT and VEL groups similarly improved in the 1-h pad test and ICIQ-SF. As for the OABSS, the VEL group showed significantly greater improvement than the TVT group.

4. A VIABLE OPTION FOR SUI TREATMENT

The results of this study demonstrate that vaginal Erbium:YAG laser (VEL) is a viable option for patients desiring SUI treatment. VEL may be an option for patients with both SUI and OAB symptoms, as TVT can worsen urinary urgency and frequency, and VEL could represent an option for patients who are concerned about artificial implants.



Treatment in the TVT and VEL groups. (a) The number of patients at 0, 3, 6 , 9 and 12 months in three groups. (b-d) The change over time for the 1-h pad test, ICIQ-SF, and OABSS. There was a significant difference between the start of treatment and 1-year post-treatment in the TVT and VEL groups. No significant difference was observed in the control. Only OABSS was significantly different between the two groups.

Er:YAG Laser Treatment of Urinary Incontinence After Failed TOT/TVT Procedures

Authors: Erel CT, Carazo Fernandez LD, Inan D, Makul M

Published in: European Journal of Obstetrics and Gynecology and Reproductive Biology, 2020

1. EVALUATING THE USE OF ER:YAG LASER FOR SUI AFTER FAILED TOT/TVT PROCEDURES

This study was performed to determine if non-ablative Er:YAG laser treatment can improve the symptoms of SUI patients who had previously experienced failed TOT/TVT procedures.

2. A RETROSPECTIVE STUDY WITH DATA FROM TWO OBSTETRICS AND GYNECOLOGY DEPARTMENTS

The retrospective study included 25 women with persistent SUI after failed TOT/TVT operations and 25 women who previously did not receive either any type of surgical or non-invasive treatment for SUI.

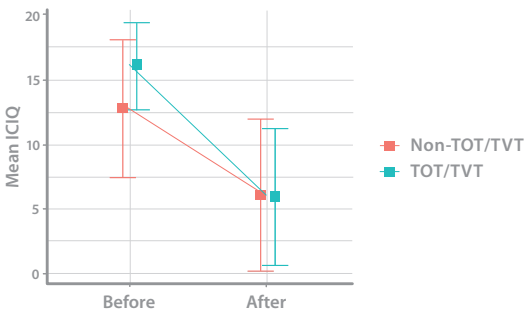
2940 nm Er:YAG laser (SP Spectro Dynamis, Fotona, Slovenia) was used in the treatment procedure for SUI. The patients were evaluated on the basis of ICIQ-UI SF before and after the procedure. According to the differences in the ICIQ-UI SF before and after, the percentage of improvement was graded as “good responders” (≥50 %) or “poor responders” (<50 %). The duration of the treatment effect was evaluated in follow-ups with relation to maximum improvement time (MIT) and total improvement time (TIT).

3. RESULTS SHOW SIGNIFICANT IMPROVEMENT

The SUI patients who previously had failed TOT/TVT operations had a significantly higher initial ICIQ-UI SF score ($p = 0.013$). Non-ablative Er:YAG laser treatment significantly and similarly improved the severity of SUI symptoms in both groups ($p = 0.000$ for failed TOT/TVT group and $p = 0.001$ for the non-TOT/TVT group, respectively). The women who were good responders were younger ($p = 0.012$) and had fewer years in menopause ($p = 0.011$). The effect of Er:YAG laser treatment lasted longer among the SUI women in the good responders group ($p = 0.000$ for MIT and $p = 0.000$ for TIT, respectively).

4. A PROMISING OPTION FOR SUI PATIENTS WITH FAILED TOT/TVT PROCEDURES

Non-ablative Er:YAG SMOOTH mode laser is an alternative choice of treatment for the SUI patients who previously had failed TOT/TVT procedures. Its effect lasts longer especially in younger and early postmenopausal women.



Mean ICIQ-SF scores in the TOT/TVT and non-TOT groups before and after the non-ablative Er:YAG laser treatment

Predictive Factors for the Efficacy of Er:YAG Laser Treatment of Urinary Incontinence

Authors: Erel CT, Inan D, Mut A

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Published in: Maturitas, 2020

1. DETERMINING THE PREDICTIVE FACTORS FOR ER:YAG LASER TREATMENT OF UI

The aim of this study was to determine the efficacy and predictive factors for the success of Er:YAG laser treatment in patients with urinary incontinence (UI).

2. EIGHTY-TWO PATIENTS TREATED AND EVALUATED BY ICIQ-SF AND KHQ-UI

Eighty-two patients with UI were treated by Er:YAG laser (SP Spectro Dynamis, Fotona, Slovenia) in this cohort study. The patients were evaluated by ICIQ-UI SF and KHQ before and after the procedure. Improvement was categorized as: none (0–25%), mild (26–50%), moderate (51–75%), or high (76–100%). The duration of the treatment effect was evaluated at follow-up in relation to the maximum improvement time (MIT) and total improvement time (TIT).

3. RESULTS SHOW SIGNIFICANT IMPROVEMENT, ESPECIALLY WITH YOUNGER PATIENTS

Forty-two patients were determined to have SUI and 40 patients MUI. The mean ICIQ-UI SF and KHQ scores significantly improved after the procedure ($p<0.0001$). The SUI patients responded to the laser treatment significantly better ($p<0.008$). Younger women had significantly better results ($p<0.008$), while premenopausal women ($p<0.032$) and women in the early postmenopausal years ($p<0.032$) also saw a positive response to the Er:YAG laser treatment. Women with a lower BMI had greater improvement ($p<0.011$). The total laser energy expenditure during the sessions may also be a predictive parameter for the success of Er:YAG laser treatment of UI ($p=0.059$). MIT and TIT were significantly longer among the patients in the high-improvement group.

4. ER:YAG LASER IS A SAFE AND EFFECTIVE TREATMENT FOR UI

Er:YAG laser treatment of the symptoms of UI, especially SUI, is more efficacious and of longer duration for younger, premenopausal or early postmenopausal women with normal BMI.

Er:YAG Laser in Hysterectomized Women with Stress Urinary Incontinence: A VELA Retrospective Cohort, Non-inferiority Study

Authors: Erel CT, Fistonic I, Gambacciani M, Oner Y, Fistonic N

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Published in: Climacteric, 2020

OPEN ACCESS

1. FIRST PS ANALYSIS COMPARING TVT AND VAGINAL ERBIUM:YAG LASER TREATMENT (VEL)

Many studies have confirmed the efficacy of Er:YAG SMOOTH® laser in the treatment of SUI, however, this retrospective cohort, non-inferiority study offers the first published data on laser treatment of SUI in hysterectomized women.

2. A MULTICENTER VELA STUDY CONDUCTED AT THREE OBSTETRICS/ GYNECOLOGY CLINICS

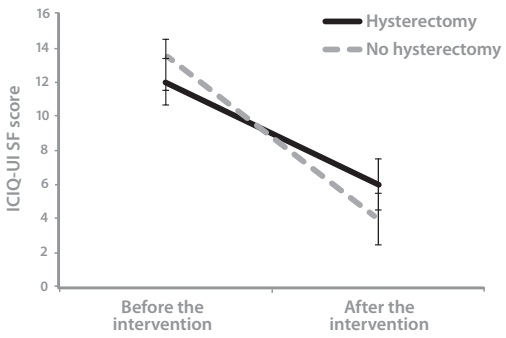
In this real-world, retrospective cohort study performed in Turkey, Croatia and Italy, a consecutive sample of 35 hysterectomized and 34 non-hysterectomized patients with SUI were treated with Er:YAG SMOOTH® laser (SP Spectro Dynamis, Fotona, Slovenia). All three centers are members of VELA (Vaginal Er:YAG SMOOTH® Laser Academy), which defined the criteria, procedures, the common informed consent form and instruments for measuring clinical outcomes.

3. RESULTS SHOW SIGNIFICANT IMPROVEMENT

The results of this study supported the hypothesis of non-inferiority of intravaginal Er:YAG SMOOTH® laser treatment efficacy on the symptoms of SUI in hysterectomized women compared to its already proven efficacy in non-hysterectomized patients. The primary outcome was median reduction of SUI symptoms measured by the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short-Form (ICIQ-SF). In hysterectomized patients, the ICIQ-SF was reduced by 5 points (95% confidence interval 3–8; p<0.001), a reduction of 45% (95% confidence interval 36–67%).

4. A VIABLE OPTION FOR SUI TREATMENT IN HYSTERECTOMIZED WOMEN

Based on the results of this study, Er:YAG SMOOTH® laser treatment appears to improve the symptoms of SUI in hysterectomized women to approximately the same degree clinically as in non-hysterectomized women.



The median ICIQ-SF scores in hysterectomized and non-hysterectomized women before and after the Er:YAG SMOOTH® treatment.

Er:YAG Laser Treatment of Female Stress Urinary Incontinence: Midterm Data

Authors: Kuszka A, Gamper M, Walser C, Kociszewski J, Viereck V

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Published in: International Urogynecology Journal, 2020

1. EXAMINING EFFECTS OF SUI SEVERITY AND NUMBER OF LASER INTERVENTIONS

This study examined how incontinence severity at baseline and the number of laser interventions may affect the treatment success rate, and whether the effect of laser therapy was obvious 6 months and 2 years after the final laser intervention.

2. THREE STAGES OF SUI TREATED WITH THE INCONTILASE® PROTOCOL

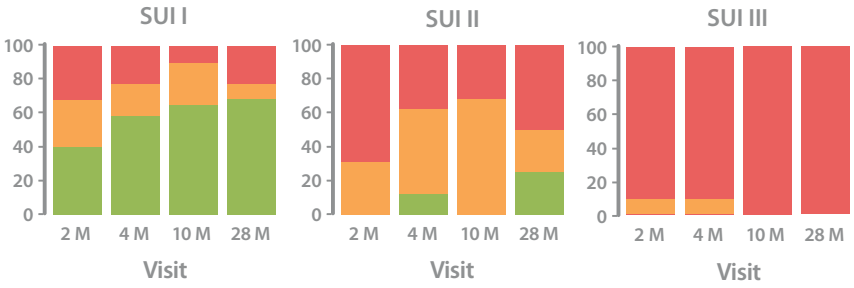
Fifty-nine women, 32 with SUI I, 16 with SUI II, and 11 with SUI III were treated using an Er:YAG laser following the IncontiLase® protocol (Dynamis, Fotona, Slovenia). Therapy included five laser sessions with a 1-month interval between sessions. Objective (1-h pad test) and subjective data (International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form [ICIQ-UI SF], Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire [PISQ-12]) were assessed at baseline, after two and four laser sessions and 6 months and 2 years after the fifth laser session.

3. RESULTS SHOW IMPROVEMENT FOR SUI I AND SIU II

The results of this study show that objective cure/improve rates for mild SUI I were 69%, 78%, 91%, and 78% after two, four, and five laser sessions at the 6-month and 2-year follow-ups. Subjective cure rates (ICIQ-UI SF) also improved: 53%, 69%, 72%, and 66%, as well as sexual function (PISQ-12). For SUI II, objective cure/improve rates were 31%, 63%, 69%, and 50%, with a subjective cure rate of 13% at the 2-year follow-up. For SUI III, only one patient had an objective improvement after two and four laser sessions.

4. INCONTILASE® IS A SUSTAINABLE SOLUTION FOR MOST CASES OF SUI

Intravaginal laser therapy led to cure/improvement for SUI I and SUI II, but not for severe SUI III. The outcome was better after four to five laser sessions than after two laser sessions. Follow-up data 6 months and 2 years after the final laser intervention showed sustainability of the treatment.



One-hour pad test. Objective cure rates (%) are shown for patients with initial stress urinary incontinence (SUI) I, SUI II or SUI III at the following time points: 1 month after two laser sessions (2 M), 1 month after four laser sessions (4 M), and 6 months and 2 years after the fifth laser session (10 M and 28 M). Green – cured (pad weight ≤2 g), orange – improved (pad weight reduction of > 50% compared with baseline), red – not cured (pad weight reduction of ≤50% compared with baseline).

Efficacy and Safety of Non-ablative Vaginal Er:YAG Laser Treatment as a Novel Surgical Treatment for Overactive Bladder Syndrome: Comparison with Anticholinergics and β3-adrenoceptor Agonists

Authors: Okui NP

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Published in: World Journal of Urology, 2019

1. IMPROVEMENT OF OAB SYMPTOMS

According to this large study with 150 patients, Er:YAG laser protocol (Dynamis, Fotona, Slovenia) demonstrated comparable efficacy to anticholinergics (fesoterodine, 4 mg) or β3-adrenoceptor agonists (mirabegron, 25 mg). Compared to both medicines, the Er:YAG laser was the only therapy to promote vaginal cell synthesis and improve VHIS scores.

2. BETTER VAGINAL HEALTH STATUS

Er:YAG laser therapy has been shown to significantly improve the vaginal tissue and its overall health status.

3. DIFFERENT SAFETY PROFILE

There have been no adverse effects reported in the laser group, but there were some observed in the pharmacotherapy groups. Mouth dryness, associated with the use of medications for example, led to a desire to change the treatment in up to 22% of patients.

4. NEW INSIGHTS INTO MECHANISMS OF ACTION

The results of the laser group may indicate the presence of a relationship between the vaginal condition and OAB, which from a different perspective can be considered a pathway that closely connects the vagina and bladder via the OAB mechanism. Er:YAG laser therapy can improve OAB symptoms through a different mechanism than that involved in pharmacotherapy.

Non-ablative Er:YAG Laser Therapy Effect on Stress Urinary Incontinence Related to Quality of Life and Sexual Function: A Randomized Controlled Trial

Authors: Blaganje M, Scepanovic D, Zgur L, Verdenik I, Pajk F, Lukanovic A

Published in: European Journal of Obstetrics and Gynecology and Reproductive Biology, 2018

1. FIRST EVER RANDOMIZED CONTROLLED TRIAL OF INCONTILASE® TREATMENT

The study presents the first ever randomized controlled trial which evaluates the efficacy and safety of non-ablative Er:YAG laser therapy as an alternative, non-invasive treatment of SUI and the improvement of sexual gratification in parous women.

2. STUDY EXAMINES A LARGE NUMBER OF PATIENTS

114 premenopausal parous women with SUI were randomized in two groups of 57 women: a laser intervention group and a placebo group. Both groups were treated according to the IncontiLase® clinical treatment protocol for SUI developed by Fotona, with an Er:YAG laser, except that there was no energy output when treating the placebo group and patients were not aware of this fact. At baseline and 3 months after treatment, patients were clinically examined, answered questionnaires for SUI severity and sexual function assessment, and their pelvic floor muscle function was assessed with perineometry. ICIQ-UI SF was used as the primary outcome measure. PISQ-12 and FSFI were used to assess the sexual function. Patients were monitored for discomfort and side-effects during treatment and in the follow-up period.

3. RESULTS SHOW SIGNIFICANT IMPROVEMENT IN THE LASER GROUP

3 months after treatment the ICIQ-UI SF ($p < 0.001$), PISQ-12 ($p = 0.014$) and FSFI ($p = 0.025$) scores collected were significantly more improved in the laser group than in the placebo control group. 21% of laser-treated patients were completely dry at follow-up (ICIQ-UI SF = 0), compared to only 4% of the placebo control patients. No serious adverse effects were observed or reported.

4. INCONTILASE® IS A MINIMALLY-INVASIVE SAFE TREATMENT ALTERNATIVE FOR SUI

The results of this randomized trial reveal that a single session of IncontiLase® treatment improves the impact of SUI symptoms on quality of life and sexual function in premenopausal parous women significantly better than a placebo treatment.

Preliminary Outcome of Non-ablative Vaginal Er:YAG Laser Treatment for Female Stress and Mixed Urinary Incontinence

Authors: Su C-F, Chen G-D, Tsai H-J

-

Published in: Taiwanese Journal of Obstetrics and Gynecology, 2019

1. A COMPARISON OF VAGINAL ERBIUM TREATMENT RESULTS FOR SUI AND MUI

This prospective study presents a preliminary result to compare the clinical efficacy of patients with stress urinary incontinence (SUI) and mixed urinary incontinence (MUI) using minimally invasive Er:YAG vaginal laser.

2. TWENTY PATIENTS UNDERWENT ER:YAG SMOOTH TREATMENT

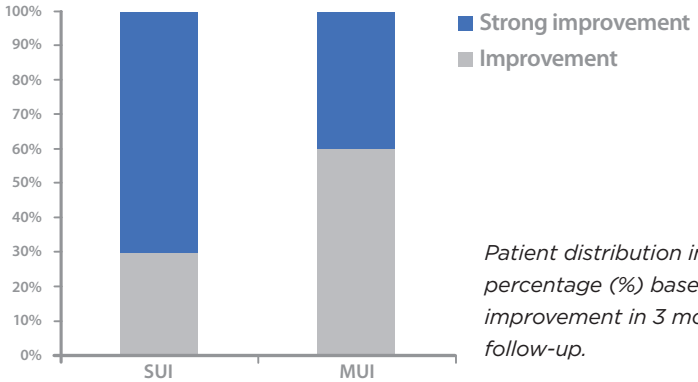
A total of 20 patients were included (10 patients with SUI and 10 patients with MUI) who underwent treatment using a 2940 nm Er:YAG laser (XS Dynamis, Fotona, Slovenia) with a special SMOOTH mode in an outpatient office without anesthesia or postoperative medications. All patients completed two sessions of treatment with an interval time of 28 days. At pretreatment and 3 months after the completion of two therapy sessions, the patients were asked to answer ICIQ-SF questionnaires. All the results were compared by Student's t test with two-way analysis of variance between the two groups.

3. RESULTS SHOW SIGNIFICANT IMPROVEMENT

A total of 20 patients presented with SUI symptom relief and improvement with treatment satisfaction. All 10 patients with SUI reported improvement after vaginal laser treatment, 70% with marked improvement and 30% with improvement. All 10 patients with MUI also had improvement, 40% with marked improvement and 60% with improvement. There was no statistically significant difference in the treatment outcome between the two groups.

4. A SAFE AND EFFECTIVE OPTION FOR SUI AND MUI TREATMENT

Vaginal Erbium laser provides vaginal collagen remodeling and synthesis that may repair and restore the pelvic floor function. Despite the sample size limitation and short follow-up, this procedure presented a good and a safe clinical outcome in patients with SUI and MUI by assessment of ICIQ-UI SF questionnaires.



Patient distribution in percentage (%) based on improvement in 3 months follow-up.

Non-ablative Er:YAG Laser for the Treatment of Type III Stress Urinary Incontinence (Intrinsic Sphincter Deficiency)

Authors: Gaspar A & Brandi H

Published in: Lasers in Medical Science, 2017


Non-ablative erbium YAG laser for the treatment of type III stress urinary incontinence (intrinsic sphincter deficiency)

OPEN ACCESS

1. NEW TREATMENT OPTION FOR TYPE III STRESS URINARY INCONTINENCE (SUI)

This pilot study aimed to determine the safety and efficacy of the IntimaLase® treatment for managing the symptoms of type III stress urinary incontinence (intrinsic sphincter deficiency) in women.

2. METHODOLOGY

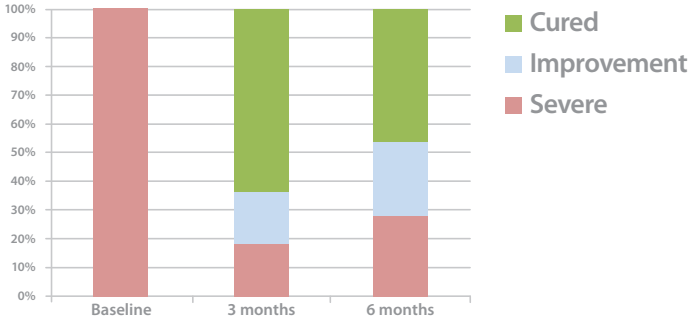
Twenty-two patients having diagnosed ISD participated in the study and were treated with the laser (SP Spectro Dynamis, Fotona, Slovenia) throughout the whole length of the urethra through a specially designed cannula. Treatment consisted of two laser sessions with a 3-week interval in-between. Therapeutic efficacy was assessed by the ICIQ-SF questionnaire for determining incontinence severity and quality of life, and the 1-h pad test for objective measure. Patients were followed for 6 months.

3. VERY PROMISING RESULTS

According to the ICIQ-SF questionnaire, 64% of patients were cured and 18% had improved at 3 months post-treatment, while at 6 months 46% were cured and 23% had improved. No change in SUI stage was observed in 18% at 3 months and 32% at 6 months. Importantly, however, even those patients that saw no improvement in their SUI stage had a slight improvement in their absolute ICIQ-UI SF scores. Furthermore, according to the Pad test, clinical improvement was shown in 82% of patients at 3 months and in 50% of patients at 6 months after the treatment.

4. NON-ABLATIVE ER:YAG TECHNOLOGY SEEMS TO WORK ALSO FOR TYPE III SUI

This study suggests that IntimaLase® treatment is a safe and efficacious alternative for patients with type III stress urinary incontinence. Future controlled studies will confirm this data and evaluate the long-term effects.



Patient distribution (in %) based on SUI improvement rates at 3 and 6 months following intraurethral Er:YAG laser treatment.

How do SMOOTH™ Treatments Affect the Vaginal Mucosa? This Paper Gives Mechanistic Data Along with Clinical Evidence in Patients with Stress Urinary Incontinence

Authors: Fistonic N, Fistonic I, Gustek SF, Bilajac Turina IS, Marton I, Vizintin Z, Kazic M, Hreljac I, Perhavec T, Lukac M

Published in: Lasers in Medical Science, 2016

1. INTERDISCIPLINARY APPROACH - PHYSICS AND MEDICINE WORKING HAND IN HAND TO SHOW INCONTILASE® MODE OF ACTION

The paper, published in a high-impact medical laser journal, combines computer modelling of the Fotona SMOOTH® thermal pulsing effect, confirms the numerical calculations using in vivo thermal camera imaging, and presents data from a pilot study of 31 patients suffering from stress urinary incontinence, proving that the delivery of gentle thermal pulsing to the vaginal wall's mucosa can improve the symptoms of stress urinary incontinence.

2. SMOOTH™ PULSES GENTLY HEAT THE VAGINAL MUCOSA TO THE IDEAL TEMPERATURE

Numerical modelling and *in vivo* thermal camera measurements showed that SMOOTH™ laser pulses warm up the vaginal wall mucosa to peak temperatures up to 65°C, which is ideal for collagen remodeling and strengthening of the tissue, without damaging the epithelium.

3. CLINICAL STUDY IN PATIENTS WITH STRESS URINARY INCONTINENCE

The pilot clinical study used the IncontiLase® protocol (Dynamis, Fotona, Slovenia), which delivers SMOOTH™ pulses to the vaginal canal using a patented pulsing sequence, with an emphasis on the anterior vaginal wall. One treatment session was performed and the results were evaluated up to 6 months after treatment. ICIQ questionnaire, perineometry and post void residual volume were among the study assessments.

4. PILOT CLINICAL STUDY HAS SHOWN SIGNIFICANT AND CLINICALLY MEANINGFUL IMPROVEMENT IN INCONTINENCE SYMPTOMS AFTER INCONTILASE® TREATMENT

Significant improvement of urinary incontinence symptoms was seen at all follow-ups. Patients also had significantly improved voiding function.

Hyaluronic Acid and Erbium Laser for the Treatment of Genitourinary Syndrome of Menopause

Authors: Fidecicchi T & Gambacciani M

Published in: Climacteric, 2024

1. TESTING COMBINED LASER AND HA FOR GSM SYMPTOMS

This randomized pilot study aimed to evaluate whether adding vaginal hyaluronic acid (HA) to vaginal erbium laser (VEL) therapy improves treatment outcomes for genitourinary syndrome of menopause (GSM) in postmenopausal women. The focus was on reducing vaginal dryness and dyspareunia, common and distressing symptoms of GSM.

2. RANDOMIZED STUDY COMPARING LASER ALONE VS. LASER PLUS HA

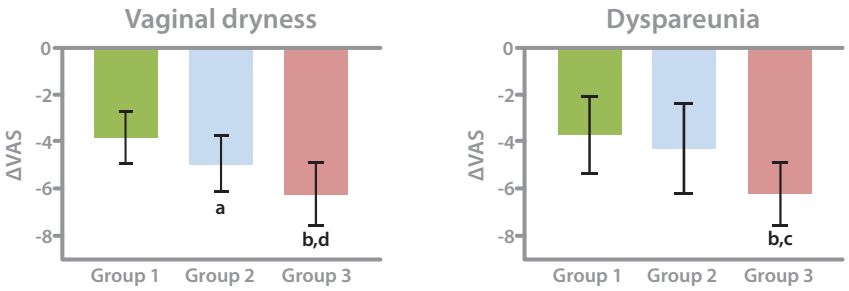
A total of 100 sexually active postmenopausal women with GSM were randomized into three groups: (i) VEL alone (Group 1), (ii) VEL plus HA after each session (Group 2) , and (iii) HA before and after each VEL session (Group 3). All participants received three laser treatments (SP Dynamis & XS Fotona Smooth, Fotona, Slovenia) at monthly intervals, and vaginal dryness and dyspareunia were assessed using visual analog scale (VAS) scores at baseline and during follow-up up to three months after treatment.

3. COMBINED HA AND LASER IMPROVED SYMPTOMS MORE EFFECTIVELY

All groups showed significant improvement in vaginal dryness and dyspareunia, but groups receiving additional HA (Groups 2 and 3) had greater and faster symptom relief than the laser-only group. Group 3, which used HA both before and after each laser session, showed the most substantial improvement in both outcomes, with statistically significant differences compared to the other groups. No serious adverse events occurred, and minor side effects were rare and self-limiting.

4. ADDING HA TO LASER BOOSTS GSM TREATMENT EFFECTIVENESS

The study suggests that vaginal HA enhances the effectiveness of vaginal erbium laser therapy in treating GSM, especially for relieving dryness and dyspareunia. Using HA both before and after laser sessions provided the best outcomes. This combination therapy may represent a more effective and patient-friendly approach for GSM.



Decrease in the visual analogue scale (VAS) score (mean3SD) at 3 months after treatment.
Group 1: laser
Group 2: laser + HA
Group 3: HA + laser + HA
[a]p < 0.01 versus Group 1. [b]p < 0.001 versus Group 1. [c]p < 0.05 versus Group 2
[d]p < 0.01 versus Group 2

A Novel Objective Evaluation Method, Shear Wave Elastography, in the Treatment of Atrophic Vaginitis by Nonablative Intravaginal Er:YAG Laser: A Randomized-Sham Controlled Pilot Study

Authors: Bayraktar E, Erel CT, Akturk H, Ozcivit Erkan IB, Hamid R, Alper E, Adaletli I, Urfalioglu M

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Published in: Menopause, 2024


ORIGINAL STUDY

A novel objective evaluation method, shear wave elastography, in the treatment of atrophic vaginitis by nonablative intravaginal Er:YAG laser, a randomized-sham controlled pilot study

Elif Bayraktar, MD,[1] C. Tamer Erel, MD,[1] Hayaleh Akturk, MD,[2] Ipek Betul Ozcivit Erkan, MD,[1] Rauf Hamid, MD,[3] Ebru Alper, MD,[1] Ibrahim Adaletli, MD,[3] and Mert Urfalioglu, MD[1]

OPEN ACCESS

1. EVALUATING LASER TREATMENT FOR POSTMENOPAUSAL ATROPHIC VAGINITIS

This study aimed to evaluate the effectiveness of intravaginal nonablative Er:YAG laser treatment for postmenopausal atrophic vaginitis using shear wave elastography (SWE) as a novel, objective assessment method. The goal was to determine whether Er:YAG laser therapy improves vaginal tissue elasticity and related clinical symptoms compared to a sham control.

2. DOUBLE-BLIND TRIAL USING LASER AND SHAM TREATMENTS

A randomized, double-blind, sham-controlled pilot study was conducted on 20 postmenopausal women diagnosed with atrophic vaginitis (12 in the laser group, 8 in the sham group). Participants underwent three laser (XS Dynamis, Fotona, Slovenia) or sham sessions at three-week intervals, and outcomes were measured using SWE to assess vaginal tissue elasticity, as well as vaginal pH, Vaginal Health Index (VHI), Female Sexual Function Index (FSFI), and Visual Analog Scale (VAS) for dyspareunia.

3. IMPROVED ELASTICITY, PH, PAIN, AND SEXUAL FUNCTION

The study found significant improvements in vaginal tissue elasticity (reduced stiffness) in the laser group compared to the sham group, as shown by SWE measurements. Additionally, participants in the laser group showed statistically significant improvements in vaginal pH, VHI, VAS scores, and FSFI scores, indicating better vaginal health and sexual function. Minor and transient side effects, such as slight discomfort and discharge, were noted but did not require treatment discontinuation.

4. LASER TREATMENT + SWE IS A PROMISING THERAPY

Intravaginal Er:YAG laser treatment appears to be an effective and safe option for improving vaginal tissue elasticity and alleviating symptoms of atrophic vaginitis in postmenopausal women. Shear wave elastography (SWE) presents a promising objective tool for evaluating intravaginal Er:YAG laser treatment efficacy.

		Laser treatment group (n = 12) Mean ± SD	Sham control group (n = 8) Mean ± SD	*P*[a]
Vaginal pH		5.1 ± 0.2	5.9 ± 0.4	<0.001[b]
VHI score		17.4 ± 2.2	12.6 ± 1.0	<0.001[b]
VAS score		2.1 ± 1.9	3.8 ± 3.6	0.04[b]
FSFI score improvement		3.20 ± 3.31	0.10 ± 0.53	0.02[b]
Anterior vaginal wall	SWE (baseline E_{mean})	27.9 ± 16.9	20.4 ± 3.9	0.27
	SWE (final E_{mean})	13.1 ± 6.3	20.0 ± 3.3	0.01[b]
	P	0.002[c]	0.48[c]	
Posterior vaginal wall	SWE (baseline E_{mean})	15.7 ± 5.6	19.0 ± 11.4	0.52
	SWE (final E_{mean})	12.7 ± 10.2	19.4 ± 6.9	0.04[b]
	P	0.05[c]	0.58[c]	

The vaginal pH, VHI score, VAS score, and SWE (E_{mean}) and the improvement in the FSFI score following laser and sham applications.

E, mean elasticity; FSFI, Female Sexual Function Index; SD, standard deviation; SWE, shear wave elastography; VAS, visual analog scale; VHI, Vaginal Health Index

[a]*Mann-Whitney U test was performed*

[b]*P<0.05: statistically significant*

[c]*Wilcoxon signed ranks test was performed*

A Study of the Objective Benefits and Safety of Er:YAG Laser in the Treatment of Genitourinary Syndrome of Menopause

Authors: Avul Z & Guven CM

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Published in: Lasers in Medical Science, 2023

1. EXAMINING THE EFFICACY AND SAFETY OF ER:YAG LASER FOR GSM TREATMENT

The aim of this study was to evaluate changes in vaginal pH and epithelium maturation after Er:YAG laser treatment, and to assess its safety and efficacy on the symptoms of genitourinary syndrome of menopause (GSM).

2. DATA USED FROM PATIENTS WHO OPTED FOR AN ESTROGEN FREE ALTERNATIVE

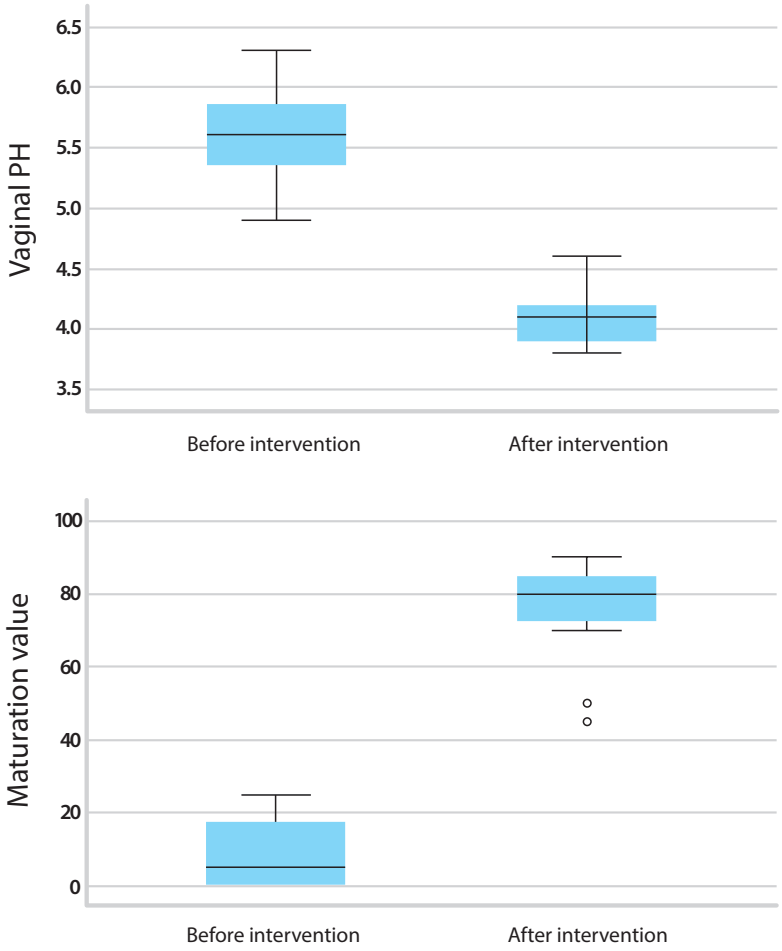
This was a retrospective study conducted between November 2019 and April 2022 that included 32 women diagnosed with GSM, with a mean age of 59.72 ± 5.66 years, who had not benefitted from lubrication treatment and could not or would not use estrogen. The patients had received three sessions of Er:YAG laser (SP Dynamis, Fotona, Slovenia). Vaginal maturation index (VMI), maturation value (MV) and vaginal pH values of the patients before and after laser treatment were compared.

3. GSM-RELATED SYMPTOMS DECREASED SIGNIFICANTLY

The study found a significant improvement in VMI, MV and vaginal pH at follow-up (5 months after treatment). After laser therapy, there was a significant decrease in vaginal pH ($p < 0.001$) and the proportion of parabasal cells in VMI ($p < 0.001$), while there was a significant increase in MV ($p < 0.001$) and the proportion of superficial cells in VMI ($p < 0.001$). In 84.4% of the patients, GSM-related symptoms regressed completely or decreased to a tolerable level.

4. ER:YAG LASER OFFERS AN EFFECTIVE TREATMENT ALTERNATIVE FOR GSM PATIENTS

Vaginal Er:YAG laser treatment offers a safe and effective alternative treatment method in a population of women with GSM who do not want to or cannot use estrogen therapy.



Vaginal pH and maturation value before and 5 months after laser treatment.

Sexual Function After Vaginal Er:YAG: The Results of a Large, Multicentric, Prospective Study

Authors: Gambacciani M, Albertin E, Torelli MG, Bracco GL, Casagrande AC, Martella L, Baiocchi G, Alfieri S, Russo N, Cervigni M

Published in: Climacteric, 2020

OPEN ACCESS

1. EXAMINING EFFECTS OF ER:YAG ON POSTMENOPAUSAL GSM

The aim of this multicentric, prospective study was to evaluate the effects of vaginal erbium laser (VEL-SMOOTH®) on sexual function in postmenopausal women suffering from genitourinary syndrome of menopause (GSM).

2. A LARGE, MULTICENTRIC STUDY OF 1081 POSTMENOPAUSAL WOMEN

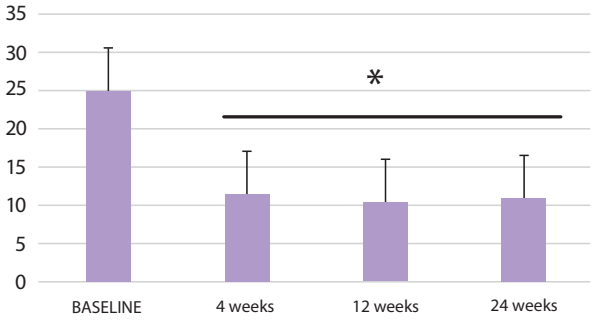
The study was performed on an outpatient basis without anesthesia or drug use before or after the intervention, using an erbium laser (XS Fotona Smooth®) in 1081 postmenopausal women (age 54.3 ±3.9 years) treated with up to three laser applications every 30 days. Patients were assessed using the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale-Revised (FSDS-R).

3. RESULTS SHOW IMPROVEMENT IN SEXUAL FUNCTION WITH NO SIDE EFFECTS

The FSDS-R scores significantly improved at all follow-ups ($p<0.01$ vs. corresponding basal values, see Chart). Also individual FSFI domain scores significantly ($p<0.01$, see Table) increased after VEL-SMOOTH® treatment, and remained significantly higher, up to the 24th week after the end of treatment. The total FSFI scores improved from basal values of 15.5 ±1.5 to 27.0 ±3.5 at the 24-week follow-up ($p<0.01$). No adverse events were recorded during the study.

4. VEL-SMOOTH® IS AN EFFECTIVE SOLUTION FOR GSM IN POSTMENOPAUSAL WOMEN

The results of this large, multicentric, prospective study show that VEL-SMOOTH® is effective in improving sexual function and overall satisfaction with sexual life in postmenopausal women suffering from severe GSM.



The values of 554 Female Sexual Distress Scale-Revised (FSDS-R) tests in baseline conditions and after treatment with vaginal erbium laser (VEL).
**p<0.01*

After VEL treatment, 4, 12 in 24 weeks

		After treatment		
FSFI domain	**Before treatment**	**4 weeks**	**12 weeks**	**24 weeks**
Desire	3.0 ± 0.5	4.0 ± 1.5	4.0 ± 1.5	4.7 ± 1.5
Arousal	2.7 ± 1.5	4.0 ± 1.5	4.0 ± 1.5	4.0 ± 1.5
Lubrication	2.1 ± 0.5	4.8 ± 0.5	4.9 ± 0.5	4.8 ± 1.5
Orgasm	2.7 ± 0.7	4.0 ± 0.5	4.0 ± 0.5	4.0 ± 1.5
Satisfaction	2.5 ± 1.5	4.9 ± 1.5	4.9 ± 1.5	4.9 ± 1.5
Pain	2.5 ± 0.5	4.8 ± 0.5	4.9 ± 0.5	4.7 ± 1.5
Total score	**15.5 ± 1.5**	**27.5 ± 2.5**	**27.6 ± 2.7**	**27.0 ± 3.5**

The values of 569 Female Sexual Function Index (FSFI) tests in baseline conditions and after treatment with VEL. Data are mean±SE the values of each specific domain and total score after the treatment and at the end of the observation period were significantly (p<0.01) different vs. corresponding basal values.

Histological Findings After Non-ablative Er:YAG Laser Therapy in Women with Severe Vaginal Atrophy

Authors: Gaspar A, Silva J, Calderon A, Di Placido V, Vizintin Z

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Published in: Climacteric, 2020

OPEN ACCESS

1. EVALUATING THE USE OF ER:YAG LASER FOR SEVERE VAGINAL ATROPHY

The aim of this study was to evaluate the effect of non-ablative erbium vaginal laser treatment on vaginal mucosa tissue affected by severe atrophy.

2. VAGINAL BIOPSIES PERFORMED BEFORE AND 3 MONTHS AFTER TREATMENT

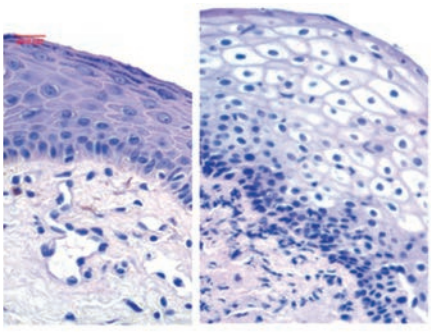
Ten patients with severe genitourinary syndrome of menopause were treated with two sessions of the Er:YAG (XS Dynamis, Fotona, Slovenia) separated by 4 weeks. Vaginal biopsies were performed before and 3 months after the second treatment. The improvement in vaginal atrophy was assessed using multiple measuring tools before and 6 months after the treatment. The degree of patient's satisfaction was also assessed.

3. RESULTS SHOW SIGNIFICANT IMPROVEMENT IN VAGINAL WALL MUCOSA

Microscopic examination showed significant changes in the main structural components of the vaginal wall mucosa after two non-ablative Er:YAG laser sessions. The epithelial thickness increased from 45 µm (10–106 µm) to 153 µm (97–244 µm) measured 3 months after the final laser treatment. Vaginal atrophy improved in all patients by all measured outcomes. The degree of patient satisfaction was very high (3.6 on the Likert four-point scale). No adverse events or complications were observed in any of the sessions.

4. ER:YAG LASER IS A SAFE AND EFFECTIVE TREATMENT FOR SEVERE VAGINAL ATROPHY

The non-ablative Er:YAG laser seems to be a safe and effective method to increase epithelial thickness of the vaginal mucosa in patients with severe vaginal atrophy.



40x magnification shows an average epithelial thickness before the treatment (left picture) of 106 µm (85-120 µm) with an average of 9 (7-11) layers of cells and no glycogenic load, and after the treatment (right picture) 183 µm (160-215 µm) average of epithelial thickness with an average of 21 (15-25) layers of cells, with a significant amount of glycogen and basal cell hyperplasia.

Thickness of endometrial epithelium	Before laser treatment	3 months after final laser treatment
Epithelial thickness (µm)	45.0 ± 33.4	152.9 ± 44.7
Number of cell layers	6.9 ± 2.4	18.9 ± 5.6

Long-term Effects of Vaginal Er:YAG Laser in the Treatment of Genitourinary Syndrome of Menopause

Authors: Gambacciani M, Levancini M, Russo E, Vacca L, Simoncini T, Cervigni M

Published in: Climacteric, 2018

1. TWO-YEAR FOLLOW-UP OF PATIENTS

First longitudinal study on the use of minimally invasive Er:YAG technology for the treatment of genitourinary syndrome of menopause (GSM), showing long-term efficacy of RenovaLase® (Dynamis, Fotona, Slovenia).

2. LARGE GROUP OF TREATED PATIENTS

205 postmenopausal women received three laser sessions of RenovaLase® at 30-day intervals. Study assessment was performed throughout the 24-month follow-up period and included the subjective visual analogue scale (VAS) and the objective vaginal health index score (VHIS). Furthermore, postmenopausal women suffering from stress urinary incontinence symptoms were evaluated with the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form (ICIQ-UI SF).

3. BETTER RESULTS COMPARED TO LOCAL TREATMENT

Non-ablative Er:YAG laser treatment induced a statistically significant ($p < 0.01$) decrease in VAS for vaginal dryness and dyspareunia, and VHIS was significantly increased ($p < 0.01$) up to the 12th month after the final laser treatment. Values reported after 18 and 24 months returned to the baseline level. Furthermore, 144 women suffering from mild to moderate SUI also showed improvement in urine leakage. No major adverse events were reported.

4. STRONG PROOF OF EFFICACY AND SAFETY OF THE RENOVALASE® TREATMENT

The efficacy of non-ablative Er:YAG laser treatment has been demonstrated by several clinical studies, but data on long-term effects was lacking to fully support it. This longitudinal study therefore fills an important gap in the story of non-invasive treatments for GSM.

Intraurethral Er:YAG Laser for the Management of Urinary Symptoms of Genitourinary Syndrome of Menopause: A Pilot Study

Authors: Gaspar A, Maestri S, Silva J, Brandi H, Luque D, Koron N, Vizintin Z

-

Published in: Lasers in Surgery and Medicine, 2018

1. ASSESSING THE SAFETY AND EFFICACY OF INTRAURETHRAL ER:YAG TREATMENT

There are several treatment methods available for the management of VVA symptoms of GSM, whereas urinary tract dysfunction often remains overlooked and undertreated. The objective of this pilot study was to assess the safety and efficacy of intraurethral Er:YAG laser treatment of urinary symptoms of GSM.

2. TWO ER:YAG SMOOTH™ MODE TREATMENTS

29 female patients, aged between 56 and 77 years, with diagnosed GSM, having less than 5% of vaginal superficial cells in the cytology, vaginal pH higher than 5, with urinary symptoms of GSM (dysuria, frequency, urgency) and impaired continence due to urethral atrophy, received two sessions of the intraurethral non-ablative Er:YAG SMOOTH™ mode laser therapy (SP Spectro Dynamis, Fotona, Slovenia), with a 3-week interval in-between the sessions. The therapeutic efficacy was determined using ICIQ-SF, the 1-hour pad test and VAS scores. Follow-ups (FU) were at 3 and 6 months.

3. ALL URINARY SYMPTOMS OF GSM IMPROVED

The intraurethral laser procedure performed in this study successfully reduced the symptoms of dysuria, urgency, and frequency in the treated patients. A statistically significant long-term effect was observed, and the positive effects appear to last up to 6 months following laser treatment.

4. AN EFFICIENT, SAFE AND RELIABLE TREATMENT ALTERNATIVE

Non-ablative Erbium SMOOTH™ mode therapy proves to be a valid and reliable alternative to traditional treatment options, as its positive effects last up to 6 months, and based on the modality, both VVA and urinary symptoms can be addressed. Most importantly, Erbium SMOOTH™ laser treatment can be used in patient populations for which other treatment methods are not recommended (e.g. breast cancer survivors).

Average improvement rates (%) from baseline values.
Results are presented as mean (SD).

	3-month FU	6-month FU
Dysuria	87 (12)	64 (25)
Urgency	79 (18)	44 (35)
Frequency	77 (18)	52 (23)
ICIQ-UI	64 (25)	40 (31)
1-h pad test (g)	59 (13)	42 (20)

Vaginal Er:YAG Laser as Second-generation Thermotherapy for the Genitourinary Syndrome of Menopause: A Pilot Study in Breast Cancer Survivors

Authors: Gambacciani M & Levancini M

Published in: Menopause, 2017

1. A MINIMALLY INVASIVE SOLUTION FOR BREAST CANCER SURVIVORS

The objective of the study was to evaluate the efficacy and acceptability of the RenovaLase® procedure for treating patients with premature GSM due to estrogen blocking therapy.

2. METHODOLOGY

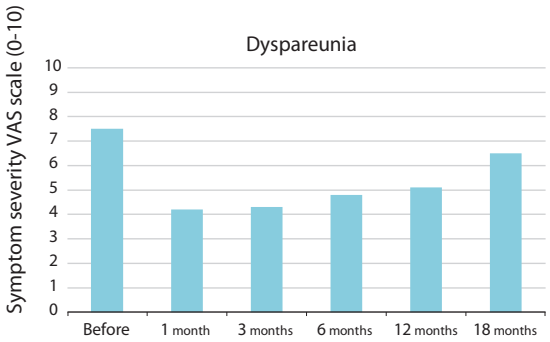
Forty-three postmenopausal breast cancer survivors received 3 RenovaLase® treatments (XS Dynamis, Fotona, Slovenia) with 30 days in-between the sessions. Symptoms were evaluated before the treatment and after 1, 3, 6, 12, and 18 months using two methods: subjective Visual Analog Scale (VAS) and objective Vaginal Health Index Score (VHIS).

3. VERY PROMISING RESULTS

VAS values for vaginal dryness showed a statistically significant reduction from baseline 8.5 ±1.0 cm to 4.4 ±1.2 cm after 3 months, to 5.5 ±1.5 cm after 12 months, and returned to nearly baseline levels at 18 months (NS vs basal values). VAS values for dyspareunia followed a similar pattern. VHIS score showed a statistically significant increase from baseline values of 8.1 ±1.3 to 21.0 ±1.4 after the third treatment and to 18 ±1.8 at twelve months from the final laser treatment. VHIS score was kept above baseline values even after 18 months from the final treatment (NS vs basal values).

4. RENOVALASE IS A SAFE TREATMENT FOR BREAST CANCER SURVIVORS

Results from this study indicate that RenovaLase® is a treatment option for GSM in breast cancer patients whose current treatment options are still very limited.



Effect of VEL on dyspareunia in postmenopausal breast cancer survivors.

RenovaLase® Treatment Induces Significant Improvement of Genitourinary Syndrome of Menopause (GSM)

Authors: Gambacciani M, Levancini M, Cervigni M

-

Published in:

Climacteric, 2015

1. HIGH IMPACT JOURNAL

Published in Climacteric, the Journal of the International Menopause Society (IMS). The journal was founded in 1998 and has become a leader in publishing peer-reviewed research on menopause.

2. HORMONE-FREE TREATMENT FOR THE SYMPTOMS OF GENITOURINARY SYNDROME OF MENOPAUSE (GSM)

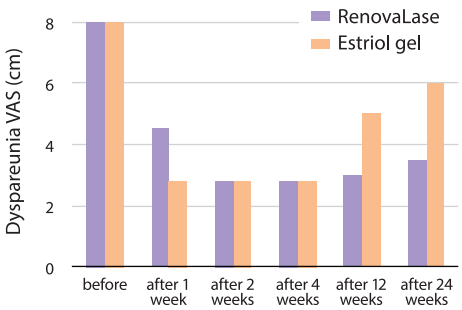
GSM (or vulvovaginal atrophy) is a chronic condition, which affects up to half of all postmenopausal women. Symptoms of GSM include dryness, burning, irritation, lack of lubrication and impaired sexual function. Traditional treatments have been limited to local or systemic estrogen therapy.

3. MATERIALS AND METHODS

45 postmenopausal women with symptoms of GSM were treated with a non-ablative vaginal erbium laser (XS Dynamis, Fotona, Slovenia). As a control group, 25 postmenopausal women were treated with an established treatment for GSM (1 g of vaginal gel containing 50 µg of estriol twice weekly, for 3 months).

4. SIGNIFICANT IMPROVEMENT OF VAGINAL DRYNESS AND DYSPAREUNIA

RenovaLase® treatment resulted in a rapid and long-lasting improvement in the signs and symptoms of GSM. This treatment is of special importance in the treatment of postmenopausal women who cannot be treated with hormones.



Effect of RenovaLase® therapy on dyspareunia using the visual analog score (VAS) on a 10-point scale for the women receiving laser treatment and the women receiving estriol. In the estriol group, a reduction of efficacy can be seen 12 weeks after the end of treatment. Conversely, the RenovaLase® group maintained the same positive results throughout the entire study period up to the 6-month follow-up.

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

Authors: Mitsuyuki M, Stok U, Hreljac I, Yoda K, Vizintin Z

Published in: Sexual Medicine, 2020

1. A MINIMALLY INVASIVE TREATMENT FOR VAGINAL LAXITY

The aim of this study was to retrospectively assess the effectiveness and safety of a nonablative Er:YAG laser procedure (IntimaLase®, XS Dynamis, Fotona, Slovenia). for vaginal laxity in patients treated in a clinical practice during a 2.5-year period.

2. A REVIEW OF 2.5 YEARS OF CLINICAL PRACTICE

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.

3. RESULTS SHOW IMPROVEMENT IN PATIENTS' VAGINAL TIGHTNESS SATISFACTION

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. 92.7% of patients experienced improvement of sexual gratification after the 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, showed that 69% (n = 20/29) of patients had an improvement of laxity.

4. ER:YAG LASER PROVIDES IMPROVEMENT OF SEXUAL SENSATION

The results of this study have confirmed that patients suffering from vaginal laxity can be effectively treated using the nonablative Er:YAG IntimaLase® procedure without adverse effects.

The Efficacy of Er:YAG Laser in the Treatment of Decreased Sexual Sensation: A Randomized, Placebo-controlled Trial

Authors: Sathaworawong A, Manuskiatti W, Phatihattakorn C, Ungaksornpairote C, Ng JN

Published in: Lasers in Medical Science, 2021


The efficacy of erbium-doped yttrium aluminum garnet (Er:YAG) laser in the treatment of decreased sexual sensation: a randomized, placebo-controlled trial

1. EXAMINING EFFECTS OF SUI SEVERITY AND NUMBER OF LASER INTERVENTIONS

The study is believed to be the first randomized, placebo-controlled trial comparing the efficacy and safety of Er:YAG laser (XS Dynamis, Fotona, Slovenia) in treating decreased sexual sensation. Vaginal laxity, a common cause of decreased sexual sensation, is a common problem affecting the quality of life of women worldwide.

2. THREE STAGES OF SUI TREATED WITH THE INCONTILASE® PROTOCOL

Forty-two patients with decreased sexual sensation were randomized into 2 groups: intervention (laser treatment) and control (placebo treatment). Both groups received two treatments, at 1-month interval. Subjective and objective evaluations were done at baseline, 1-, 3-, and 6-month follow-ups. Pain score and adverse effects were also recorded.

3. RESULTS SHOW IMPROVEMENT IN PATIENTS' VAGINAL TIGHTNESS SATISFACTION

In the laser group, there was significant improvement in the patients' vaginal tightness satisfaction at 1- and 3-month follow-ups (P = 0.002 and 0.004) and also in the patients' overall satisfaction at 1- and 3-month follow-ups (P = 0.003 and 0.001). Pelvic floor muscle contraction was significantly better in the laser group after the first treatment (P = 0.043). No serious adverse effects were noted.

4. ER:YAG LASER PROVIDES IMPROVEMENT OF SEXUAL SENSATION

The results of the study show that Er:YAG laser provides improvement of sexual sensation for an average of 3 months following 2 monthly treatments.

Patients' vaginal tightness satisfaction on all follow-up visits.

	1-month follow-up *n* (%)	3-month follow-up *n* (%)	6-month follow-up *n* (%)
Laser group			
Worst	0 (0.0)	0 (0.0)	1 (5.0)
No change	1 (4.8)	1 (5.3)	6 (30.0)
Slightly improved	6 (28.6)	6 (31.6)	2 (10.0)
Moderately improved	7 (33.3)	8 (42.1)	6 (30.0)
Significantly improved	7 (33.3)	4 (21.1)	5 (25.0)
Placebo group			
Worst	0 (0.0)	0 (0.0)	0 (0.0)
No change	4 (19.0)	7 (33.3)	7 (33.3)
Slightly improved	11 (52.4)	8 (38.1)	7 (33.3)
Moderately improved	6 (28.6)	6 (28.6)	6 (28.6)
Significantly improved	0 (0.0)	0 (0.0)	1 (4.8)
P value	0.002*	0.004*	0.318

*Statistically significant difference

Effect of Er:YAG Laser on Pelvic Floor Strength and Sexual Satisfaction in Women Complaining of Vaginal Looseness: A Randomized Controlled Trial

Authors: Ahmed SM, Kotb HG, Yousef AM, Ahmed H

Published in: Polish Journal of Physiotherapy, 2019

1. EXAMINING THE EFFECTIVENESS OF ER:YAG LASER FOR TREATING VAGINAL LOOSENESS

The study aimed to determine the effect of Er:YAG laser on pelvic floor strength as well as sexual satisfaction in women complaining of vaginal looseness.

2. A PROSPECTIVE, SINGLE-BLIND, RANDOMIZED CONTROLLED TRIAL WITH 30 PATIENTS

Thirty women complaining of vaginal looseness with a decrease in pelvic floor strength and sexual satisfaction, aged 40–50 years, were randomized into 2 equal groups. Group (A) received pelvic floor training exercise (kegel exercise) for 8 weeks, while group (B) received Er:YAG laser (Dynamis, Fotona, Slovenia) in addition to kegel exercise for 8 weeks. All women in both groups were evaluated before starting the study, after 4 weeks and after 8 weeks of the treatment with a Peritron device to assess pelvic floor strength and with the Millheiser sexual satisfaction scale to assess sexual satisfaction.

3. RESULTS SHOW IMPROVEMENT IN PELVIC FLOOR STRENGTH AND SEXUAL SATISFACTION

There was a highly significant increase in pelvic floor strength and sexual satisfaction at post 8 weeks and post 4 weeks of treatment, in favor of group (B) (P = 0.0001).

4. ER:YAG LASER THERAPY IS AN EFFECTIVE OPTION FOR TREATING VAGINAL LOOSENESS

Er:YAG laser represents an effective, safe and successful therapy adjunct to kegel exercise in treating vaginal looseness in women.

Pelvic floor muscle strength at different measuring periods for both groups.

Pelvic floor muscle strength	Pre treatment (Mean ± SD)	Post 4 weeks of treatment (Mean ± SD)	Post 8 weeks of treatment (Mean ± SD)
Group A	58.86 ± 4.27	69.33 ± 3.84	80.33 ± 3.75
Group B	58.86 ± 4.27	75.4 ± 4.06	88.13 ± 2.32
Within groups (Pre vs. Post) Multiple pairwise comparison (Post hoc tests) among different measuring periods for Pelvic floor muscle strength at both groups			
p-value	**Pre Vs. Post 4 weeks of treatment**	**Pre Vs. Post 8 weeks of treatment**	**Post 4 weeks of treatment Vs. 8 weeks of treatment**
Group A	0.0001 HS	0.0001 HS	0.0001 HS
Group B	0.0001 HS	0.0001 HS	0.0001 HS
Multiple pairwise comparison tests (Post hoc tests) for the Pelvic floor muscle strength between both groups at different measuring periods			
Group A Vs. group B	**Pre treatment**	**Post 4 weeks of treatment**	**Post 8 weeks of treatment**
P-value	1.00 HS	0.0001 HS	0.0001 HS

NS P >0.05=Non-significant, HS P < 0.01 = highly significant, P = Probability

Sexual satisfaction grades at different measuring periods for both groups.

Friedman test for sexual satisfaction grades						
		Group A			**Group B**	
	X2-value	21.535			30	
	p-value	0.0001 HS			0.0001 HS	
Wilcoxon Signed Rank tests (within groups)						
	Pre Vs. Post 4 weeks of treatment		**Pre Vs. Post 8 weeks of treatment**		**Post 4 weeks of treatment Vs. post 8 weeks of treatment**	
	Z-value	**p-value**	**Z-value**	**p-value**	**Z-value**	**p-value**
Group A	-2.828	0.005 HS	-3.638	0.0001 HS	-2.646	0.008 HS
Group B	-3.508	0.0001 HS	-3.453	0.001 HS	-3.52	0.0001 HS
Mann-Whitney tests between groups						
Group A Vs. group B	**Pre treatment**		**Post 4 weeks of treatment**		**Post 8 weeks of treatment**	
U-value	71.5		15		0.00	
Z-value	-1.818		-4.229		-5.06	
p-value	0.069 NS		0.0001 HS		0.0001 HS	

NS P >0.05=Non-significant, HS P < 0.01 = highly significant, P = Probability

Up to 3-year Follow-up of Patients with Vaginal Relaxation Syndrome Participating in Laser Vaginal Tightening

Authors: Gaviria PJE, Korosec B, Fernandez J, Montero G

-

Published in: Journal of the Laser and Health Academy, 2016


Up to 3-year Follow-up of Patients with Vaginal Relaxation Syndrome Participating in Laser Vaginal Tightening

OPEN ACCESS

1. MINIMALLY INVASIVE APPROACH TO SIGNIFICANTLY IMPROVE WOMEN'S QOL

Non-surgical treatments that promote perineal muscle strength and certain pharmacological agents are very safe, but offer limited efficacy. On the contrary, surgical interventions offer high efficacy but are at the same time associated with a high risk of nerve damage and therefore loss of sensation. The gap between both extremes has been filled with the IntimaLase® treatment, which offers minimal invasiveness but high efficacy.

2. A 3-YEAR FOLLOW-UP TO PROVE INTIMALASE® EFFICACY

Several other clinical studies have shown a positive effect of the laser treatment on vaginal tightness, however, data on the long-term effectiveness was missing. 60 patients received 1-4 laser sessions of IntimaLase® (XS Dynamis, Fotona, Slovenia) at 15 to 30-day intervals. Study assessment was performed throughout the 36 months and included laser vaginal tightening (LVT) questionnaires and self-assessment reports.

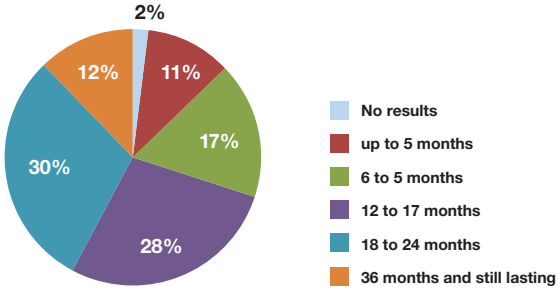
3. GREAT RESULTS

Patients reported the average duration of effect from the treatment was 16 months, with significant improvement of stress urinary incontinence and prolapse. No serious adverse effects were reported. Furthermore, data showed that 58% of patients were extremely satisfied or very satisfied with the treatment and 83.3% of participants would be willing to repeat the therapy.

4. INTIMALASE® TECHNOLOGY AS AN ALTERNATIVE FOR UNCOMFORTABLE, HIGH-RISK SURGICAL PROCEDURES

Because of its minimal invasiveness and positive results, a vast majority of patients finds the principle of IntimaLase® therapy very appealing. Longitudinal studies are bringing more evidence to the field and hopefully more women will stand a chance to undergo the laser treatment first before considering surgical intervention.

The duration of results



Vaginal Erbium Laser Versus Pelvic Floor Exercises for the Treatment of Pelvic Organ Prolapse: A Randomised Controlled Trial

Authors: Page A-S, Borowski E, Bauters E, Housmans S, Van der Aa F, Deprest J

Published in: European Journal of Obstetrics and Gynecology, 2024

1. COMPARING LASER VS. EXERCISES FOR PROLAPSE SYMPTOM RELIEF

This randomized controlled trial aimed to compare the effectiveness of vaginal erbium:YAG (Er:YAG) laser treatment with pelvic floor exercises (PFE) for improving symptoms of mild to moderate pelvic organ prolapse (POP). The goal was to assess if laser therapy is a viable alternative to standard conservative treatment using PFE, with a focus on patient-reported outcomes and safety over a 24-month period.

2. RANDOMIZED TRIAL COMPARING LASER AND PELVIC FLOOR EXERCISES

61 patients with grade II-IV cystoceles were treated (Dynamis, Fotona, Slovenia) 2-5 times at 2-month intervals. Prolapses were photographed and graded using the Barden-Walker scale.

3. LASER AND EXERCISES BOTH REDUCED SYMPTOMS

Both laser and PFE groups showed similar improvements in POPDI-6 scores at 4 months, confirming non-inferiority of laser to PFE. Approximately 65% of laser participants and 61% of PFE participants reported subjective improvement. By 24 months, around half of women in both groups sought additional, yet conservative treatment. No serious adverse events were reported.

4. LASER EQUALS EXERCISES IN SYMPTOM IMPROVEMENT

Vaginal erbium laser therapy and pelvic floor exercises offer comparable short-term symptom improvement for women with mild to moderate prolapse.


European Journal of Obstetrics & Gynecology and Reproductive Biology

Full length article

Vaginal erbium laser versus pelvic floor exercises for the treatment of pelvic organ prolapse: A randomised controlled trial

OPEN ACCESS

Non-Ablative Vaginal Er:YAG Laser Treatment of Patients with Cystocele and Stress Urinary Incontinence – a Retrospective Study

Authors: Novakov Mikic A , Lepes Bingold B, Hreljac I, Vizintin Z

-

Published in: European Gynecology and Obstetrics, 2023

1. EVALUATING SMOOTH® MODE ON PATIENTS WITH PELVIC ORGAN PROLAPSE & SUI

The study evaluated the efficacy of erbium laser treatment (VEL) using the non-ablative SMOOTH® mode procedure ProlapLase® (Fotona, Slovenia) on patients with pelvic organ prolapse (cystocele) and co-existing stress urinary incontinence (SUI).

2. A RETROSPECTIVE STUDY OF DATA RECORDED DURING A TWO-YEAR PERIOD

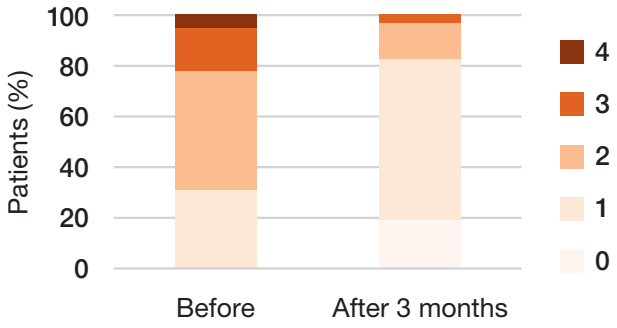
The study carried out by the analysis of data recorded during a two-year period from charts of 41 patients that completed VEL treatment for cystocele (Group A); 27 of these also had concomitant stress urinary incontinence (Group B). The average cystocele grade in Group A was 2, while in Group B it was 1.96.

3. CLINICALLY SIGNIFICANT IMPROVEMENT IN SYMPTOMS NOTED

The results showed that patients experienced a decrease in cystocele grade by an average of 0.95 after undergoing an average of 2.7 laser sessions. Among patients with both cystocele and SUI, there was a clinically significant improvement in SUI symptoms following the VEL treatment. The average ICIQ-UI short form score decreased from 11.33 at baseline to 3.56 after completing the treatment sessions.

4. ER:YAG SMOOTH® MODE TREATMENT IS AN EFFECTIVE AND SAFE OPTION

The study reported high patient satisfaction with the treatment results, indicating that vaginal non-ablative Er:YAG laser treatment using the SMOOTH® mode was well-received by the patients who underwent the procedure.



The effect of intravaginal non-ablative Er:YAG treatment on cystocele grade distribution (0-4).

Non-ablative Vaginal Er:YAG Laser for the Treatment of Cystocele

Authors: Bizjak Ogrinc U & Sencar S

Published in: Italian Journal of Gynaecology and Obstetrics, 2017

1. NEW MINIMALLY INVASIVE OPTION

The principle of non-ablative Er:YAG laser has been widely adopted for treating various conditions associated with pelvic floor dysfunction. Lately it has also been used to treat pelvic organ prolapse (POP). Since surgical treatments often come with the cost of long downtime and a high possibility of adverse events, developing alternative minimally invasive treatments is of a great importance.

2. METHODOLOGY

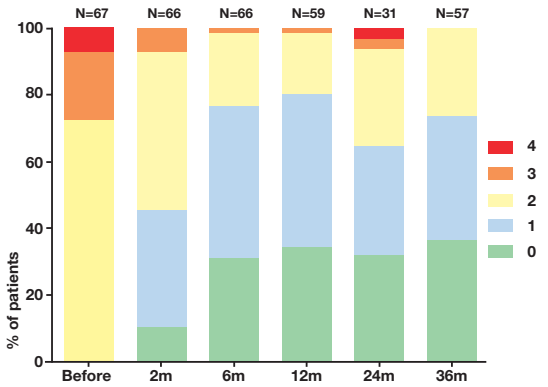
61 patients with grade II-IV cystoceles were treated (Dynamis, Fotona, Slovenia) 2-5 times at 2-month intervals. Prolapses were photographed and graded using the Barden-Walker scale.

3. EXCELLENT RESULTS

95% of the patients showed a reduction of at least one grade, 85% of which had achieved grade 0 or I, and 15% achieved grade II. 90% of the patients were very satisfied or satisfied with the treatment. No major adverse effects were noted.

4. PROLAPLASE® IS A BREAKTHROUGH, MINIMALLY INVASIVE OPTION FOR PATIENTS WITH POP

Clinical research supports the efficacy of the ProlapLase® treatment. With additional studies this innovative procedure may become a well-recognized minimally invasive alternative to surgery.



The effect of ProlapLase® on cystocele grade distribution at baseline and follow-ups.

Nd:YAG/Er:YAG Dual Laser Compared with Topical Steroid to Treat Vulvar Lichen Sclerosus: A Randomised Controlled Trial

Authors: Zivanovic I, Gamper M, Fesslmeier D, Walser C, Regauer S, Viereck V

-

Published in: BJOG: An International Journal of Obstetrics and Gynaecology, 2023

1. COMPARING DUAL ND:YAG/ER:YAG LASER TREATMENT WITH CORTICOSTEROID THERAPY

The aim of this randomised controlled trial was to evaluate the efficacy and safety of a novel non-ablative Nd:YAG/Er:YAG dual laser treatment for vulvar lichen sclerosus (LS) in comparison with the recommended first-line therapy with topical steroid.

2. CHANGES MEASURED IN OBJECTIVE VALIDATED CLINICAL LS SCORE

44 women were included in the laser group and 22 in the steroid group. Patients in the laser group received four laser treatments with a dual Nd:YAG/Er:YAG laser (SP Spectro Dynamis, Fotona, Slovenia), at baseline and after 1, 2 and 4 months. The comparison group received standardised topical steroid for 6 months. The primary outcome was the change in objective clinical LS score in the laser arm between baseline and 6 months. Secondary outcomes were changes in subjective and objective measures between baseline and 6-month follow-up, safety of the laser treatment and comparisons between laser and steroid outcomes.

3. LASER TREATMENT WAS EFFECTIVE, SAFE AND WELL TOLERATED

The total LS score decreased by −2.34 ± 1.20 (95% CI −2.71 to −1.98) in women treated with laser compared with a decrease of −0.95 ± 0.90 (95% CI −1.35 to −0.56) in those receiving steroid applications ($p < 0.001$). Subjective severity scores (on visual analogue scale) and vulvovaginal symptoms questionnaire scores improved similarly for the laser and steroid arms without significant differences between the two treatments. Patient satisfaction was higher in the laser arm than in the steroid arm ($p = 0.035$).

4. LASER IS A PROMISING ALTERNATIVE TO CORTICOSTEROID THERAPY

Non-ablative dual Nd:YAG/Er:YAG laser therapy was safe and significantly improved clinical outcomes and subjective symptoms at the 6-month follow-up. This suggests that laser may be a promising alternative to corticosteroid therapy.

Improvement of lichen sclerosus (LS) score, VAS symptoms and VSQ at six months follow-up.

Variable	Baseline, mean ± SD	Six months, mean ± SD	Change, mean ± SD	*p* value, within
LS score total				
Laser (n = 44)[a]	6.27 ± 1.25	3.93 ± 1.34	-2.34 ± 1.20	**<0.001**
Steroid (n = 22)	6.05 ± 1.50	5.09 ± 1.15	-0.95 ± 0.90	**0.014**
p walue between	0.397	**<0.001**	**<0.001**	
VAS total (itching, burning, pain)				
Laser (n = 44)[a]	11.59 ± 6.87	5.75 ± 6.50	-5.84 ± 6.19	**<0.001**
Steroid (n = 22)	9.36 ± 5.60	4.00 ± 3.12	-5.36 ± 6.33	**0.001**
p walue between	0.303	0.647	0.881	
VAS total (Q1–16)				
Laser (n = 44)[a]	8.11 ± 3.58	4.89 ± 4.42	-3.23 ± 3.21	**<0.001**
Steroid (n = 22)	7.68 ± 3.20	5.36 ± 4.27	-2.32 ± 3.43	**0.043**
p walue between	0.473	0.637	0.408	

Efficacy of Non-ablative Laser Therapy for Lichen Sclerosus: A Randomized Controlled Trial

Authors: Bizjak Ogrinc U, Sencar S, Luzar B, Lukanovic A

Published in: Journal of Obstetrics and Gynaecology Canada, 2019

1. COMPARING THE EFFECTS OF LASER TO TOPICAL CORTICOSTEROID TREATMENT

A total of 40 patients were included in the study and were randomized into the active group (combined treatment with topical corticosteroids and laser) or control group, who received treatment with topical corticosteroids only.

The patients in the active group received three Nd:YAG laser treatments (SP Spectro Dynamis, Fotona, Slovenia) every 14 days. One week before the first laser treatment, the patients in this group started pre-treatment with topical corticosteroid betamethasone (Diprosone) to alleviate symptoms and increase treatment comfort. This therapy lasted 3 weeks with decreasing dosage: twice daily during the first week, once daily during the second week, and every second day during the third week.

The control group received the topical corticosteroid betamethasone (Diprosone) for 4 weeks with decreasing dose: twice daily during the first 2 weeks, once daily during the third week, and every second day during the fourth week.

2. THE EFFECTS ARE HISTOLOGICALLY PROVEN

The thickness of sclerosis was reduced significantly after the combined treatment, but not after the corticosteroid treatment.

3. IMPROVEMENT HAS BEEN MEASURED OBJECTIVELY AND SUBJECTIVELY

Both the combined and corticosteroid treatments reduced the intensity of symptoms (itching, burning, pain) compared with the baseline, however, the reduction was statistically significantly better in the active group for all symptoms. The effect of LS on the quality of the patient's sex life was significantly reduced only in the active group.

4. ADDITIONAL ADVANTAGES OF LASER TREATMENT

Most patients have a negative attitude towards the long-term use of topical corticosteroids, so they seek better and more permanent solutions. Initial results regarding laser therapy appear promising not only due to its efficacy, but also its ease of use, as patients do not need to apply their medicine on a daily basis.

Use of Er:YAG Laser in the Treatment of Vulvar Lichen Sclerosus

Authors: Gomez-Frieiro M & Laynez-Herrero E

-

Published in: International Journal of Women's Dermatology, 2019

1. EVALUATING ER:YAG LASER FOR TREATMENT OF VULVAR LICHEN SCLEROSUS

The aim of this research was to evaluate the efficacy and safety of Er:YAG lasers to improve signs and symptoms of vulvar lichen sclerosus.

2. ONE OF THE FIRST STUDIES TO ASSESS ER:YAG FOR LICHEN SCLEROSUS

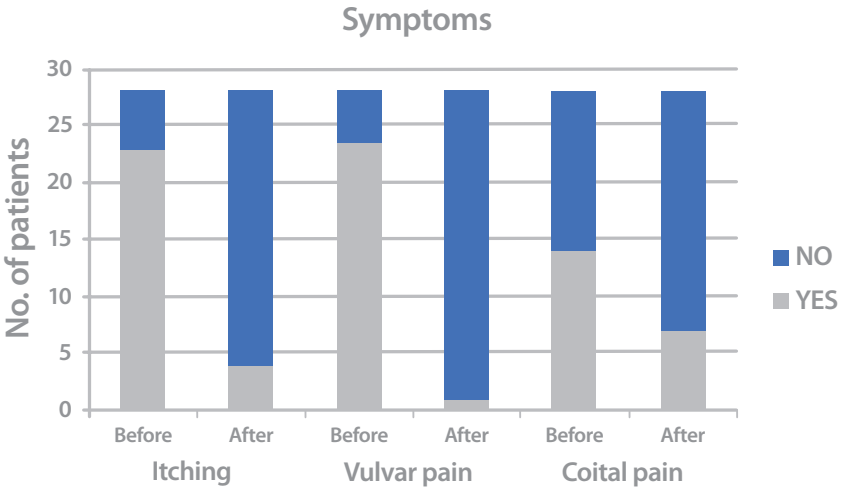
The study population consisted of 28 women with symptomatic vulvar lichen sclerosus. Three nonablative, thermal-only Er:YAG laser treatment (SP Spectro Dynamis, Fotona, Slovenia) sessions (7 J/cm², 2 Hz, 7 mm spot) were performed at 4-week intervals. Based on the presence of symptoms, lesions, and affected zones, a scale with a maximum of 14 scores was established for use before and after treatment. The impact of lichen sclerosus on patients' lives before and after treatment was evaluated with an 11-point visual analogue scale, and treatment discomfort was assessed at each session.

3. STATISTICALLY SIGNIFICANT IMPROVEMENTS OBSERVED POST TREATMENT

The results of this study showed that Er:YAG laser treatment significantly reduces symptoms of lichen sclerosus such as itching and vulvar pain, but not coital pain. After analysis of each scoring component, individual statistically significant reductions were observed in itching, pain, ecchymosis, excoriations, and hypopigmentation. Three sessions with monthly intervals using the indicated parameters quantifiably reduced the impact of lichen sclerosus on patients' lives.

4. ER:YAG LASER IS RECOMMENDED FOR ADJUVANT TREATMENT OF VULVAR LICHEN SCLEROSUS

The Er:YAG laser is a safe, well tolerated, and effective method for treatment of vulvar lichen sclerosus supplementary to topical steroids. The authors encourage doctors who have this technology to use it as a complementary and safe alternative that has proven to be effective.



Frequency of lichen sclerosus symptoms before and after laser treatment.

Efficacy of Two Laser Treatment Strategies for Breast Cancer Survivors with Genitourinary Syndrome of Menopause

Authors: Okui NP, Okui M, Kouno Y, Nakano K, Gambacciani M

Published in: Cereus, 2023

1. EVALUATING VEL VS. VEL+ND:YAG FOR PAIN IN BREAST CANCER SURVIVORS WITH GSM

The aim of this study was to compare the effectiveness of vaginal Er:YAG SMOOTH mode laser (VEL) treatment with a combined Nd:YAG laser + VEL treatment (Fotona, Slovenia) over time, with respect to therapeutic targets for pain in breast cancer survivors with GSM.

2. MORE THAN 200 WOMEN WHO RECEIVED EITHER VEL OR VEL+ND:YAG WERE ENROLLED

This retrospective, case-control study targeted sexually active breast cancer survivors who reported GSM with vulvodynia and dyspareunia. Propensity score (PS)-matching analysis was used to compare two-year postoperative data retrospectively. Symptoms were assessed using the visual analog scale (VAS) for vulvodynia before and after laser treatment for one, three, six, 12, and 24 months after completion. Female Sexual Function Index (FSFI) and Vaginal Health Index Score (VHIS) were also assessed.

3. RESULTS SHOW GREATER IMPROVEMENT FROM COMBINED TREATMENT

Comparing the two groups, the results confirmed that VEL+Nd:YAG treatment of the vaginal vestibule and vaginal opening reduced superficial vulvar pain more effectively, extensively, and over a longer period than VEL. FSFI improved significantly in the VEL+Nd:YAG group and persisted for two years. VHIS improved equally in both groups and was not significantly different. The VAS values in the VEL+Nd:YAG group and the VEL group decreased from the pre-treatment to 3.79 ± 0.63 ($p < 0.001$ vs. baseline) and 5.56 ± 0.89 ($p < 0.001$ vs. baseline) after the third treatments, respectively. After 24 months, the VAS value in the VEL+Nd:YAG group and the VEL group was at 4.43 ± 1.38 ($p < 0.001$ vs. baseline) and 5.56 ± 0.89 ($p < 0.001$ vs. baseline), respectively.

4. AN EFFECTIVE NOVEL TREATMENT FOR BREAST CANCER SURVIVORS WITH GSM

The study showed that VEL and Nd:YAG combination treatment is effective as a novel treatment for GSM with superficial vulvar pain and dyspareunia in breast cancer survivors. Over two years, the combination treatment was more effective than VEL alone. Combination therapy had no significant adverse events.

Laser Treatment for Patients With Vulvodynia and Interstitial Cystitis/Bladder Pain Syndrome: A Case Series (The UNICORN-3 Study)

Authors: Okui N, Okui MA, Kouno Y, Nakano K

-

Published in: Cureus, 2023

1. EXPLORING LASER THERAPY FOR IC/BPS AND VULVODYNIA

This study aimed to assess the effectiveness of combined vaginal erbium:YAG (VEL) and neodymium:YAG (Nd:YAG) laser treatments in women suffering from interstitial cystitis/bladder pain syndrome (IC/BPS) and vulvodynia. The goal was to determine if addressing both vaginal and vulvar tissues could alleviate symptoms that had not responded to conventional therapies.

2. CASE SERIES USING COMBINED VAGINAL AND VULVAR LASER TREATMENT

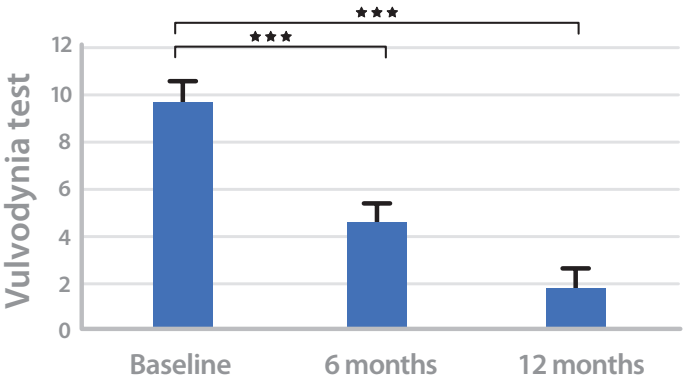
Fifteen women diagnosed with both IC/BPS and vulvodynia underwent three combined VEL + Nd:YAG laser sessions (SP Dynamis, Fotona, Slovenia) at one-month intervals. Clinical outcomes were assessed using pain scores (NRS-11), vulvodynia tests, bladder symptom indices (ICSI/ICPI), pelvic pain/urgency/frequency scores (PUF), and urination diaries. Follow-ups were conducted at 6 and 12 months to evaluate short- and long-term effects.

3. LASER REDUCED PAIN, URGENCY, AND FREQUENCY SIGNIFICANTLY

Significant improvements were observed in vulvodynia test scores, bladder pain (NRS-11), ICSI, ICPI, PUF scores, mean urination volume, and frequency, all showing sustained benefits at both six and 12 months.

4. COMBINED LASER EFFECTIVE, SUGGESTING SYNERGISTIC SHORT-TERM RELIEF

The combined VEL + Nd:YAG laser treatment appears effective for managing coexisting IC/BPS and vulvodynia, offering both genital and urinary symptom relief.



Vulvodynia test pain score before and after laser treatment.

Short-Term Effects of an Erbium/ Neodymium Laser Combination in Superficial Dyspareunia: A Pilot Study

Authors: Gambacciani M & Fidecicchi T

Published in: Climacteric, 2022

1. A NOVEL COMBINATION LASER THERAPY FOR SUPERFICIAL DYSPAREUNIA

This prospective pilot study aimed to evaluate the effects of combining Nd:YAG laser with vaginal erbium laser (VEL), as a non-ablative photothermal therapy for superficial dyspareunia in postmenopausal women (PMW) suffering from genitourinary syndrome of menopause (GSM).

2. SINGLE VS. DUAL TREATMENT COMPARED BEFORE AND AFTER 3 SESSIONS

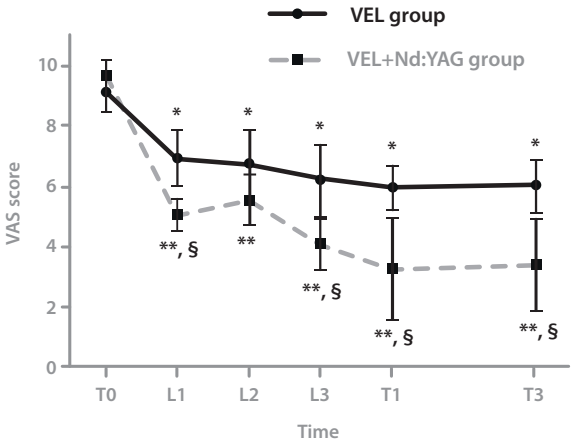
Two groups of sexually active PMW reporting superficial dyspareunia were selected: one (15 patients, VEL) was treated using an Er:YAG laser (XS Fotona SMOOTH; Fotona, Ljubljana, Slovenia) with a wavelength of 2940 nm; in the other group (15 patients, VEL + Nd:YAG), this treatment was followed by Nd:YAG laser (Fotona SP Dynamis, PIANO mode) treatment. Treatment consisted of three laser applications at 30-day intervals. Symptoms were assessed before, after each laser application and after 1 and 3 months from the end of the treatment, using the subjective visual analog scale (VAS) for superficial dyspareunia.

3. THE VEL + ND:YAG GROUP SHOWED GREATER IMPROVEMENT

The results of this study showed that both groups achieved a rapid and significant improvement of superficial dyspareunia over time ($p<0.001$) independently from age and years since menopause. The VEL + Nd:YAG group showed a greater improvement of superficial dyspareunia ($p<0.001$); this difference was evident since the first treatment and remained stable over time.

4. COMBINING ND:YAG WITH VEL OFFERS BENEFITS FOR TREATING SUPERFICIAL DYSPAREUNIA

The addition of Nd:YAG to the vaginal erbium laser (VEL) protocol may induce greater improvement of superficial dyspareunia in postmenopausal women with GSM.



Mean visual analog scale (VAS) score over time for the two treatment groups – vaginal erbium laser (VEL) group and VEL+ Nd:YAG group. T0, baseline; L1, laser session 1; L2, laser session 2; L3, laser session 3; T1, 1 month after treatment; T3, 3 months after treatment.

Superficial Dyspareunia Treatment with Hyperstacking of Er:YAG SMOOTH Laser: A Short-Term, Pilot Study in Breast Cancer Survivors

Authors: Fidecicchi T, Gaspar A, Gambacciani M

-

Published in: Menopause, 2022

ORIGINAL STUDY

Superficial dyspareunia treatment with hyperstacking of erbium: yttrium-aluminum-garnet SMOOTH laser: a short-term, pilot study in breast cancer survivors

OPEN ACCESS

1. TREATING SUPERFICIAL DYSPAREUNIA IN POSTMENOPAUSAL BREAST CANCER SURVIVORS

The purpose of this study was to evaluate the effects of a modified Vaginal Erbium Laser (VEL) protocol with hyperstack mode on the vaginal vestibulum and introitus to treat superficial dyspareunia in postmenopausal breast cancer survivors suffering from genitourinary syndrome of menopause (GSM).

2. ENHANCING THE VEL PROTOCOL WITH A SECOND STEP OF ERBIUM HYPERSTACKING

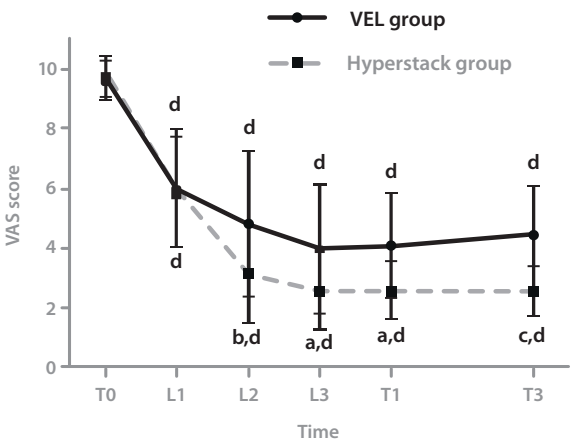
This prospective, randomized pilot study analyzed two groups of postmenopausal women suffering from superficial dyspareunia. 34 women (VEL group) were treated with 2,940 nm Er:YAG laser (XS Fotona SMOOTH; Fotona, Ljubljana, Slovenia), while a second group of 34 patients (hyperstack group) received the same treatment along with a modified second step of the VEL protocol for the treatment of the vestibulum and introitus, which consisted of hyperstacked subablative, long pulses with very low fluence. For each group, three laser applications at 30-day intervals were performed. Symptoms were assessed before, after each application, and after 1 and 3 months from the last laser application, using the visual analog scale score for superficial dyspareunia.

3. RESULTS SHOW GREATER AND MORE PERSISTENT IMPROVEMENT IN HYPERSTACK GROUP

The results of this study showed that superficial dyspareunia improved in both groups over time ($P < 0.001$), regardless of age and years since menopause status. The reduction in the visual analog scale score after the third laser application was 58% in the VEL group versus 73.5% in the hyperstack group. Since the first of the three laser sessions, the hyperstack group showed more notable ($P < 0.001$) and persistent improvement of superficial dyspareunia symptoms.

4. HYPERSTACK TREATMENT LEADS TO MORE SIGNIFICANT IMPROVEMENT

Adding a hyperstack treatment protocol to the standard VEL treatment may enhance the beneficial effects on superficial dyspareunia in breast cancer survivors. The hyperstack treatment of the introitus and vestibulum leads to a more significant improvement in superficial dyspareunia than VEL treatment alone.



Mean VAS score over time for the two treatment groups. T0, baseline; L1, laser session 1; L2, laser session 2; L3, laser session 3; T1, 1 month after treatment; T3, 3 months after treatment.

Exploring the Impact of Non-Ablative Erbium Laser Therapy on Recurrent Vaginal Candidiasis

Authors: Gaspar A, Calderon A, Vargas Mora J, Silva J, Bojanini JF, Araujo MJ, Lazzaleta Geada L, Ivanova E, Helvacioglu Y, Peña Coello P, Zelaschi D, Lucas MF, Mitraud L, Carneiro V, Cogorno M, Novakov Mikic A, Vasilescu M

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Published in: Lasers in Surgery and Medicine, 2025

1. TESTING LASER THERAPY FOR RECURRENT VAGINAL CANDIDIASIS (RVVC)

This study aimed to assess the safety and effectiveness of non-ablative Er:YAG vaginal laser therapy in treating women with recurrent vulvovaginal candidiasis (RVVC), a condition marked by multiple yeast infections per year. The goal was to evaluate its ability to reduce both symptoms and the presence of *Candida* and other pathogens.

2. MULTI-CENTER STUDY WITH SYMPTOM AND PATHOGEN MONITORING

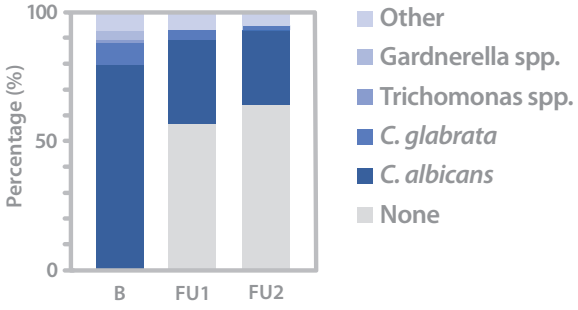
A total of 167 women with RVVC from 17 gynecological centers in 11 countries underwent four non-ablative vaginal Er:YAG laser sessions (SP Dynamis, Fotona, Slovenia) over four months. The study tracked microbiological cultures and five key symptoms (burning, itching, dyspareunia, dysuria, discharge) at baseline, 3 months, and 9 months post-treatment. Patient satisfaction and adverse effects were also recorded to evaluate safety and acceptability.

3. LASER REDUCED CANDIDA AND IMPROVED SYMPTOMS SIGNIFICANTLY

The therapy led to significant improvement in all bothersome symptoms, with complete symptom resolution (VAS = 0) in 38%–74% of women depending on the symptom, and reductions maintained at 9 months. *Candida albicans* prevalence dropped from 80% to 30%, with a complete pathogen elimination in 64% of participants. Patients reported high satisfaction (86% satisfied/very satisfied), and only minor, transient adverse effects were observed.

4. PROMISING, SAFE ALTERNATIVE TO CONVENTIONAL ANTIFUNGAL TREATMENTS

Non-ablative vaginal Er:YAG laser therapy appears to be a safe and effective treatment for RVVC, showing durable symptom relief and significant pathogen reduction. It may serve as a promising non-pharmacological option, especially for patients with recurrent infections resistant to standard treatments.



Microbiological findings in vaginal swabs of participants during the study. Data are given as prevalence of specific species (B, baseline; FU1, after 3 months, FU2, after 9 months).

Effects of Non-ablative Vaginal Er:YAG Laser Treatment for Interstitial Cystitis/Bladder Pain Syndrome: A Case Series (UNICORN-2 Study)

Authors: Okui NP, Okui M, Vizintin Z

-

Published in: Climacteric, 2020

1. EXAMINING THE EFFECTIVENESS OF NON-ABLATIVE ER:YAG LASER FOR PATIENTS WITH IC/BPS

There are no established treatments for interstitial cystitis/bladder pain syndrome (IC/BPS). The authors conducted a study to verify the effectiveness of non-ablative vaginal Er:YAG laser (VEL) treatment for patients with IC/BPS who were resistant to conventional treatments.

2. A YEAR-LONG STUDY OF 12 IC/BPS PATIENTS

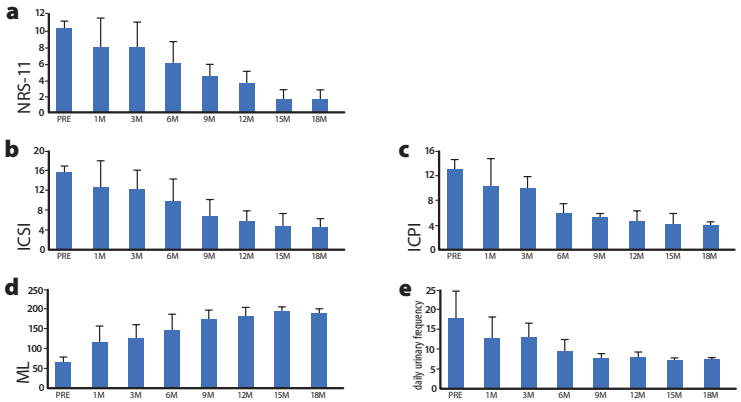
A total of 12 patients without improvement after several treatments underwent nonablative vaginal Er:YAG laser treatment (XS Dynamis, Fotona, Slovenia) once a month for 12 months. The numeric rating scale-11 (NRS-11), O'Leary–Sant interstitial cystitis symptom and problem indexes (ICSI and ICPI), functional bladder capacity, and daily urinary frequency were recorded.

3. RESULTS SHOW IMPROVEMENT IN 9 OF 12 PATIENTS

VEL treatment demonstrated efficacy for both ulcerative and non-ulcerative patients with IC/BPS. The response rate was 75% (9 out of 12). The NRS-11 scores and ICSI and ICPI improved in all responders. The bladder capacity and urinary frequency also normalized. The residual effect lasted for 18 months from the first treatment, without long-term side-effects.

4. A PROMISING TREATMENT OPTION FOR PATIENTS WITH IC/BPS

Nonablative vaginal Er:YAG laser treatment is a safe and effective treatment for patients with IC/BPS.



Effect of VEL treatment according to (a) the numeric rating scale-11 (NRS-11), (b) the O'Leary-Sant interstitial cystitis index (ICSI), (c) the O'Leary-Sant interstitial cystitis problem index (ICPI), (d) functional bladder capacity (IVIL) in ml and (e) daily urinary frequency. The x-axis of all graphs indicates time, showing progress from before VEL treatment to 1, 3, 6, 9, 12, 15, and 18 months.

Er:YAG Treatment for Relief of Long-term Symptoms Related to Episiotomy Scars - 1-Year Follow-up

Authors: Novakov Mikic A, Pajk F, Vizintin Z

-

Published in: European Gynecology and Obstetrics, 2022

1. ASSESSING THE EFFICACY OF ER:YAG TREATMENT FOR EPISIOTOMY SCAR SYMPTOMS

The purpose of this study was to evaluate Erbium:YAG (Er:YAG) laser treatment for relief of long-term symptoms related to episiotomy scars.

2. 110 PATIENTS RECEIVED THREE ER:YAG LASER TREATMENT SESSIONS IN A TWO-STEP PROTOCOL

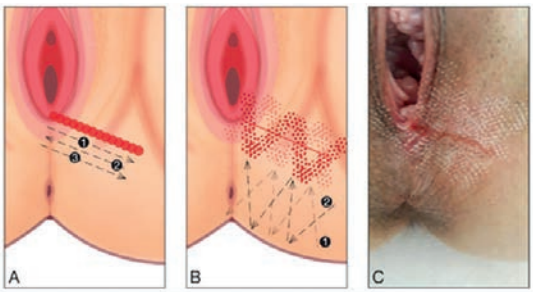
This single-arm study included patients with episiotomy scars complaining of at least one of the following: dyspareunia, pain while sitting, pain at pressure, pulling, bumps at perineum, and bleeding after intercourse. 110 patients aged 22–50 years (mean age 33 years) received three Er:YAG laser treatment sessions (XS Dynamis, Fotona, Slovenia) in a two-step protocol: full-spot cold ablation along the scar, and fractional ablation across the whole episiotomy surface.

3. RESULTS SHOWED SIGNIFICANT IMPROVEMENT WITH MINIMAL SIDE EFFECTS

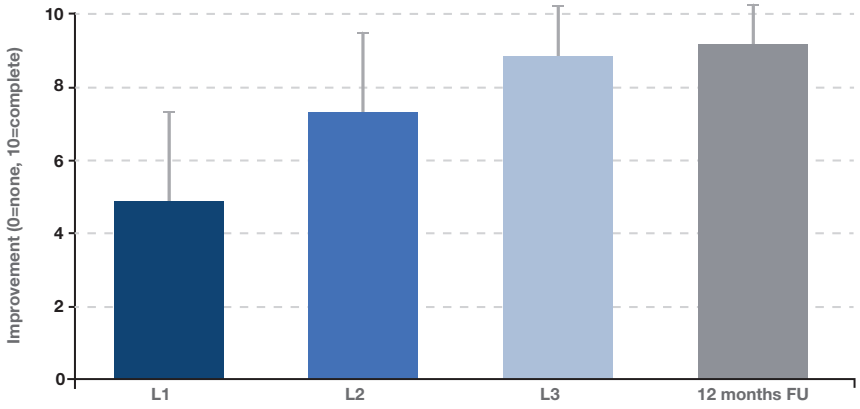
Improvement and side effects were monitored at every treatment and 3 and 12 months after the last procedure. Average improvement increased with each treatment session and was maintained during 12 months of follow-up (average improvement at 12 months was 9.1±1.1 on a 0–10 scale). All patients achieved improvement and 52.7% became symptom free. Average pain during the procedure (without anesthesia) was 5.4/10. Side effects were mild and transient.

4. LASER TREATMENT FOR EPISIOTOMY SCARS IS AN EFFECTIVE ALTERNATIVE TO SURGERY

The study confirmed that Erbium laser treatment is an excellent candidate as a less invasive alternative to surgery for relief of long-term symptoms related to episiotomy scars.



Two-step protocol for Er:YAG laser resurfacing of episiotomy scar. A) Full spot cold ablation along the scar with non-overlapping pulses. B) Fractional ablation across the whole episiotomy surface with 2 cm margins. C) Immediately after the procedure.



Improvement in episiotomy scar symptoms (mean±SD) after each of three laser treatment sessions (L1, L2, L3) and at 12 months follow-up (FU).

Sutureless Laser Labiaplasty of Labia Minora

Authors: Bizjak Ogrinc U & Sencar S

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Published in:

Sexual Medicine, 2021

1. EXAMINING THE EFFICACY AND SAFETY OF SUTURELESS LASER LABIAPLASTY

The purpose of this study is to report on a "sutureless" laser labiaplasty and to evaluate the efficacy and safety of this technique. Vaginal labiaplasty, the surgical reduction of the labia minora as a treatment for labia hypertrophy, has become a common procedure, with many different techniques yet no optimal approach suggested.

2. A RETROSPECTIVE ANALYSIS OF 80 FEMALE PATIENTS

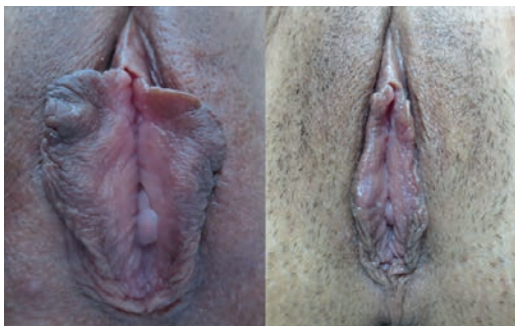
A retrospective chart review analysis of 80 female patients who underwent laser labiaplasty with 2940 nm Er:YAG laser (SP Dynamis, Fotona, Slovenia) between February 2015 and April 2018 was conducted. The labiaplasty procedure was carried out in around 30-40 minutes, and there were no intraoperative complications. The patients were asked about or checked for side effects and answered a questionnaire regarding their satisfaction.

3. THE MAJORITY OF PATIENTS SHOWED HIGH SATISFACTION, WITHOUT SIDE EFFECTS

The majority of women (71 or 89%) did not experience any side effects, 7 (9%) developed wound infection, bleeding was reported by 1 patient, and 1 woman reported hematoma formation. All of the patients reported high satisfaction. There were no partly satisfied or dissatisfied patients.

4. SUTURELESS LASER LABIAPLASTY CAN BE CONSIDERED SAFE AND EFFECTIVE

Sutureless laser labiaplasty is a safe and effective way of improving women's lives and is associated with a high degree of patient satisfaction.



Patient before and 3 weeks after procedure.

Effectiveness and Safety of Ablative Er:YAG Laser Treatment for External Genital Warts

Authors: Bizjak Ogrinc U & Sencar S

Published in: Slovenian Medical journal, 2020

1. EXAMINING THE USE OF ER:YAG LASER FOR REMOVING GENITAL WARTS

The aim of this study is to evaluate the effectiveness and safety of using ablative Er:YAG laser for removal of external genital warts (EGW), also called condylomata acuminata (CA).

2. MORE THAN 100 FEMALE PATIENTS INCLUDED IN RETROSPECTIVE COHORT STUDY

This was a retrospective cohort study performed at the Juna Gynecology Clinic in Ljubljana, Slovenia. A total of 133 female patients older than 18 years (mean age 39.6 ±12.9 years, range: 19–80) that were clinically diagnosed with EGW and were treated with ablative Er:YAG laser (Dynamis, Fotona, Slovenia) between January 2012 and December 2017 were included in the study. EGW had been present from one to seven months, with a mean presence of 2.1 ±2.0 months. The majority of the warts were on the labia majora with some also on the mons pubis. The size of the lesions was 2–8 mm.

3. THE MAJORITY OF PATIENTS SHOWED COMPLETE CLEARANCE, WITHOUT RECURRENCE

The majority of the 116 patients who completed therapy (74 patients) received only one treatment and 82 of the patients (n = 95) showed complete clearance of the lesions, without recurrence observed to date of analysis. Complete clearance was achieved after an average of 1.33 treatment sessions. Recurrence was reported by 21 patients (18). Recorded adverse effects of laser treatment were mild and transient.

4. ER:YAG LASER IS A SIMPLE, QUICK AND SAFE PROCEDURE FOR REMOVAL OF EGW

Er:YAG laser removal of EGW is a simple, quick and safe procedure, particularly suitable for large volume EGW or those that are located in anatomical sites difficult to access by other techniques.

Age group	No. of patients [n]	Mean no. of treatments (95% CI)	Patients requiring single treatment [n, (%)]	Effectiveness of treatment CC [n, (%; 95% CI)]	Mean no. of treatments needed for CC[b] (95% CI)
19-29	26	1.96 (1.43-2.49)	14 (54.8)	21 (80.7;73.6-89.9)	1.62 (1.11-2.13)
30-39	35	1.63 (1.26-1.99)	24 (68.6)	27 (77.1; 79.5-84.8)	1.19 (0.94-1.43)
40-49	31	1.45 (1.15-1.75)	21 (67.7)	29 (93.5; 89.1-98.0)	1.34 (1.09-1.60)
50-59	12	1.25 (0.96-1.54)	9 (75.0)	10 (83.3; 76.6-90.1)	1.10 (0.87-1.33)
60-69	8	1.50 (1.05-1.95)	4 (50.0)	4 (50.5; 40.9-59.1)	1.00 (1.00-1.00)
70-80	4	1.50 (0.58-2.42)	2 (50.0)	4 (100; 100-100)	1.50 (0.58-2.42)
Overall	**116**	**1.60 (1.42-1.78)**	**74 (63.8)**	**95 (81.9; 74.9-88.9)**	**1.33 (1.17-1.48)**

Effectiveness (Complete Clearance (CC)) of Er: YAG laser treatment within the age groups.

Safety of Vaginal Erbium Laser: A Review of 113,000 Patients Treated in the Past 8 Years

Authors: Gambacciani M, Cervigni A, Gaspar A, Novakov Mikić A, Gaviria PJE, Koron N, Vizintin Z

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1. EVALUATING THE FREQUENCY OF ADVERSE EFFECTS FROM VAGINAL ERBIUM LASER (VEL)

The aim of this study was to obtain information on the frequency of occurrence of adverse effects (AEs) related to vaginal erbium laser (VEL) treatment.

2. LARGEST SURVEY ON AES FOR PROCEDURES PERFORMED IN GYNECOLOGY WITH EB DEVICES

A global survey was conducted among practitioners using the non-ablative VEL treatment. Users were invited to provide the number of patients treated with VEL (Fotona, Slovenia) and the number of observed laser-related AEs.

The survey was conducted from August 2018 to April 2019. Responses from 535 practitioners were collected, with a total of 113,174 patients treated in the period from 2012 to 2019.

3. AES WERE MILD TO MODERATE, TRANSIENT AND APPEARED WITH LOW FREQUENCIES.

Out of 535 respondents, 160 (30%) shared detailed information about the indications they treated in a population of 62,727 patients, whereas 188 respondents (35%) provided information on the frequency of AEs observed in their treated population of 43,095 patients. All observed AEs were mild to moderate, transient and appeared with low frequencies.

4. VAGINAL ERBIUM LASER (VEL) TREATMENTS APPEARS TO BE VERY SAFE

Minimally invasive thermal-only laser treatments using the non-ablative VEL procedure appear to be safe, and carry a very low risk profile.

Reported adverse effect (AEs), mean frequency of AE occurrence, range of reported frequencies, and calculated overall frequency.

Adverse effect	Number of respondents reporting the AE (n)	Mean of frequencies (%)	Range of frequencies (%)	BCa bootstrap interval[a]	24 weeks frequencies (%)[b]
Vaginal discharge	47	6.53	0.00–100	3.69–9.67	4.01
Edema	23	3.72	0.00–100	1.80–5.86	3.45
Pain (during treatment)	30	1.92	0.00–50.0	1.09–2.92	1.44
Pinpoint bleeding	33	1.55	0.00–50.0	0.87–2.36	1.16
Dryness	14	0.22	0.00–7.37	0.10–0.36	0.48
De novo urinary incontinence	13	0.28	0.00–14.3	0.12–0.49	0.21
Burns	7	0.10	0.00–10.0	0.02–0.22	0.16
Post-operative pain	7	0.47	0.00–37.7	0.07–1.06	0.10
Mild irritation of the introitus	4	0.56	0.00–70.0	0.007–1.70	0.44
Discoloration	2	0.10	0.00–16.7	0.003–0.32	0.02
Itching	2	0.06	0.00–10.0	0.001–0.24	0.01
Infection	4	0.03	0.00–3.33	0.001–0.07	0.01
Abnormal bleeding	1	0.04	0.00–6.67	0.04–0.16	0.005
Dyspareunia	1	0.004	0.00–0.69	0.04–0.17	0.002

[a]BCa, bias-corrected and accelerated (BCa) bootstrap interval, based on 1000 bootstrap samples (999 for burns, 982 for introital irritation, 985 for infection, 866 for itching, 653 for abnormal bleeding, 637 for dyspareunia, 858 for discoloration); [b]calculated as the number of AEs per patients included in the safety analysis (n=43,095)

Effects of Non-ablative Er:YAG Laser on the Skin and the Vaginal Wall: A Systematic Review of the Clinical and Experimental Literature

Authors: Hympanova L, Mackova K, El-Domyati M, Vodegel E, Roovers J, Bosteels J, Krofta L, Deprest J

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1. EVALUATING THE EFFECTS OF NON-ABLATIVE ER:YAG LASER ON THE SKIN AND THE VAGINAL WALL

The aim of this systematic review was to summarize current knowledge about the effects of non-ablative Er:YAG laser on the skin and vaginal wall.

2. A REVIEW OF STUDIES FROM MEDLINE, EMBASE, COCHRANE, AND THE WEB OF SCIENCE

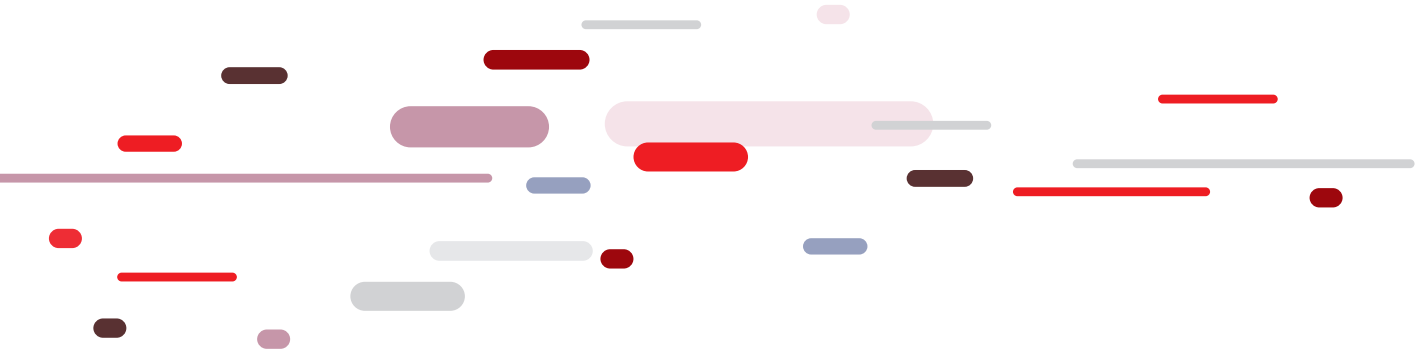
Studies investigating objectively measured effects of non-ablative Er:YAG laser on the skin or vaginal wall were included. The authors identified in vitro or ex vivo studies on human cells or tissues, studies in rats, and clinical studies. Most studies were on the skin (n = 11), while the rest were on the vagina (n = 4). Owing to the lack of methodological uniformity, no meta-analysis could be performed and therefore results were presented as a narrative review.

3. RESULTS SHOW A POSITIVE RESPONSE IN MULTIPLE OBJECTIVELY MEASURED EFFECTS

Although the methods used were not comparable, there were demonstrable effects in all studies. Immediately after application, an increase in superficial temperature, partial preservation of epithelium and subepithelial extracellular matrix coagulation were documented. Later, an increase in epithelial thickness, inflammatory response, fibroblast proliferation, an increase in the amount of collagen, and vascularization were described.

4. ER:YAG LASER PRODUCES POSITIVE EFFECTS WITHOUT EPITHELIAL ABLATION

Er:YAG laser energy may induce changes in the deeper skin or vaginal wall, without causing unwanted epithelial ablation. Laser energy initiates a process of cell activation, production of extracellular matrix, and tissue remodeling.



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Laser and Health Academy
Stegne 3
1000 Ljubljana
Slovenia, EU

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