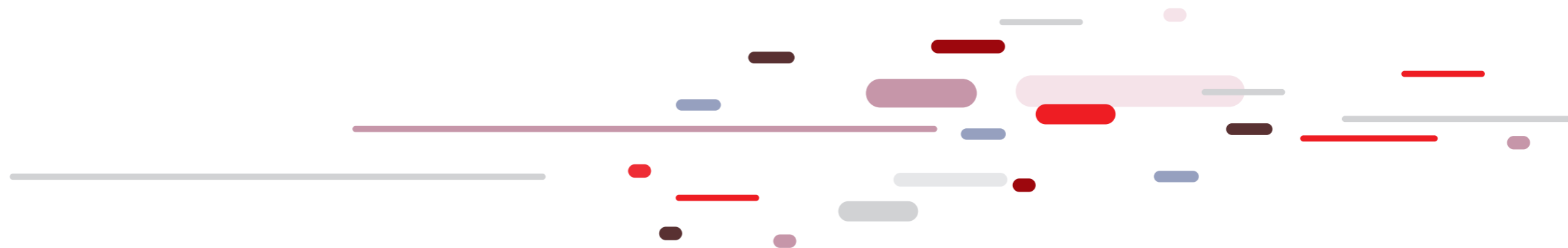


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Compendium of Clinical Studies

Fotona Technology in Gynecology



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- 45 List of Published Clinical Studies of Fotona's Gynecological Treatments

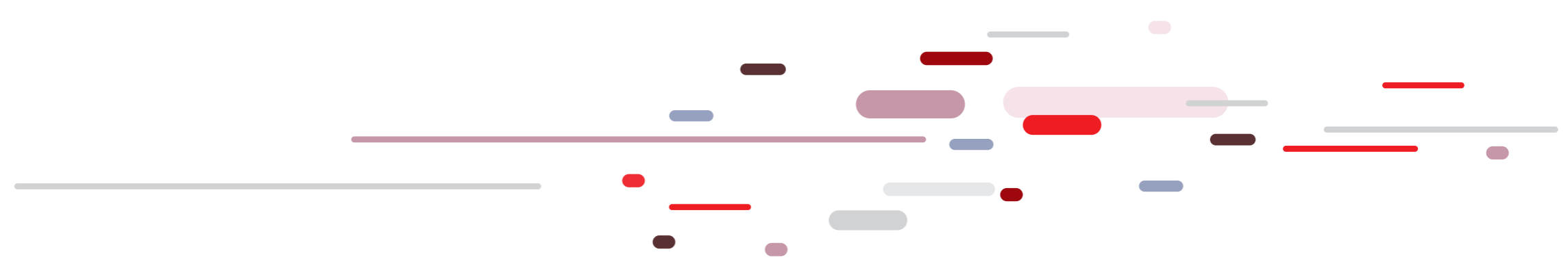
Scientific Evidence Behind Fotona's Gynecological Treatments

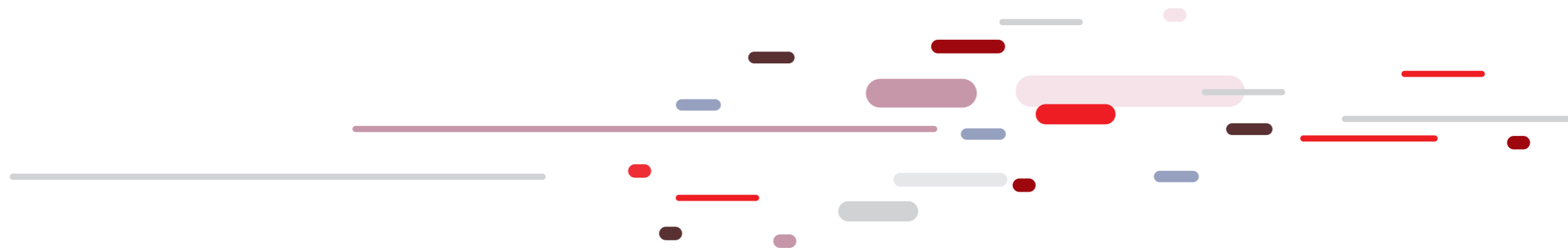
Since the introduction of the unique **Fotona SMOOTH**® laser therapy in gynecology in 2012, a number of independent gynecological studies examining its safety and effectiveness have been published in the most highly respected, peer-reviewed international journals. To date, clinically proven results have been published in more than 65 SCI (high Science Citation Index) publications.

This new compendium contains summaries of published clinical studies conducted by leading international gynecologists, providing the scientific evidence behind the effectiveness and safety of Fotona's gynecological treatments. In the first part you will find short drafts from selected publications where we have highlighted some of the key findings of each study. In the second part we present all of the published studies with QR codes added for easier access to the official online sources.

We believe this compendium will bring critical scientific evidence closer to users. In its 50-year history, Fotona has always based its promotion of effective laser technology on stringent research and hard evidence. Lasers in gynecology are no exception. Fotona highly encourages the exchange and dissemination of scientific knowledge among peers and actively promotes wider adoption of evidence-based laser medicine among practitioners and the general public.

The Fotona Clinical Affairs Team





Short Drafts of Selected Scientific Publications

Vaginal Erbium Laser for SUI – A Prospective Multicentre Randomized Placebo-controlled Trial to Evaluate Efficacy and Safety of Non-ablative Er:YAG Laser for Treatment of Stress Urinary Incontinence (SUI)

Authors: O'Reilly B, Phillips C, Toozs-Hobson P, Kuhn A, Vierek V, Athanasiou S, Lukanovic A, Lukanovic D, Palmer B, Dahly D, Koron N, Cardozo L

Submitted:



1. COMPARING THE RESULTS OF ER:YAG LASER WITH SHAM TREATMENT FOR SUI

This multicentric randomized controlled trial (RCT) evaluated the efficacy and safety of Fotona's IncontiLase® treatment for stress urinary incontinence (SUI) using both objective and patient-reported outcomes.

2. FIRST MULTICENTRIC TRIAL OF INCONTILASE®, CONDUCTED IN 5 EUROPEAN COUNTRIES

Between October 2015 and October 2019, 110 eligible patients with diagnosed urodynamic stress incontinence (USI) were enrolled in the trial from eight specialist centres: three from UK, two from Switzerland, and one from Ireland, Greece and Slovenia, respectively. This was a single blind clinical trial with the participants being blinded to allocation. Patients were randomised 2:1 to receive either two active treatments of laser therapy, a month apart, or a sham treatment in which the laser light was physically blocked from contacting the tissue. The primary outcome measure was the standardized 1h pad weight test at 6-month follow up, where a treatment success was defined as a change in pad weight at 6 months follow-up that represented a > 50% reduction in the used pad weight recorded at baseline.

3. RESULTS SHOW SIGNIFICANTLY BETTER IMPROVEMENT WITH INCONTILASE®

A treatment success (> 50 % reduction in pad weight from baseline to 6 months) was observed in 36% of patients from the sham group (n=12), and in 58% of patients in the active group (n=33). Analysis of the primary outcome (Table 1) concluded that the odds of treatment success was approximately three times greater in the active group compared to the sham group (OR 3.11, 95% CI 1.15-9.06, p-value = 0.03).

4. INCONTILASE® IS A BENEFICIAL, NON-SURGICAL SOLUTION FOR TREATING SUI

The study concluded that IncontiLase® performs significantly better than sham treatment in reducing the symptoms of stress urinary incontinence and should therefore be offered as a non-surgical treatment option for patients suffering from SUI.

Summary of study results.

Outcome Measure	Timepoint	Observations (n)		Active				Sham				Active vs. Sham	p
		Active	Sham	Median	Min	Max	IQR	Median	Min	Max	IQR		
Pad weight (g)	Baseline	72	37	6.5	0	203	16.6	6.0	0.06	174	13.0	OR = 3.11 [1.15-9.06]	0.030
	6 month follow-up	57	33	1	0	222	4.4	5	0	65.1	10.4		
	12 month follow-up	41	NA	1	0	174	13.3	NA	NA	NA	NA		
3-day bladder diary	Baseline	66	34	1.67	0	9	2	1.84	0	7.33	1.58	IRR = 0.70 [0.45-1.11]	0.125
	6 month follow-up	44	22	0.5	0	6.3	2	1.16	0	9.3	1.34		
ICIQ-UI SF	Baseline	68	34	11	5	21	8	12	4	20	5	OR = 0.50 [0.22-1.10]	0.084
	6 month follow-up	56	33	9	0	20	6	10	0	18	6		
KHQ Part I	Baseline	70	34	91.6	0	200	33.4	95.8	25	150	43.8	OR = 0.32 [0.13-0.77]	0.012
	6 month follow-up	56	30	58.3	0	150	58.3	79.2	0	125	39.6		
KHQ Part II	Baseline	69	34	208	52.7	658	253	266	16.6	566	230	OR = 0.41 [0.17-0.99]	0.048
	6 month follow-up	55	29	133	0	672	153	216	0	500	208		
PISQ-12	Baseline	66	35	36	7	46	7	36	9	45	9.5	OR = 2.5 [1.04-6.01]	0.040
	6 month follow-up	45	28	39	22	44	6	36.5	22	46	9.25		
PGI-I	Baseline	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	OR = 0.27 [0.11-0.65]	0.030
	6 month follow-up	50	33	3	2	6	2	4	2	5	0		

ICIQ-UI SF International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form, KHQ King's Health Questionnaire, PISQ-12 Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire short form, PGI-I Patient Global Impression of Improvement, IQR interquartile range

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

Authors: M. Gambacciani, M. Cervigni, A. Gaspar, A. Novakov Mikic, J. Gaviria, N. Koron and Z. Vizintin

Published in: *Climacteric*. 2020;23(sup1): S28-S32. doi: 10.1080/13697137.2020.1813098.



OPEN ACCESS



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 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 effects (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	Overall frequency (%) ^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

^aBCa, 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); ^bcalculated 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

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.

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

Published in: *Int Urogynecol J*. 2020 Dec;31(12):2473-2484. doi: 10.1007/s00192-020-04452-9.



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

Authors: N. Okui & H. Miyazaki & W. Takahashi & T. Miyauchi & C. Ito & M. Okui & K. Shigemori & Y. Miyazaki & Z. Vizintin & M. Lukac

Published in: *Lasers Med Sci.* 2021 Apr 22. doi: 10.1007/s10103-021-03317-x



OPEN ACCESS



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

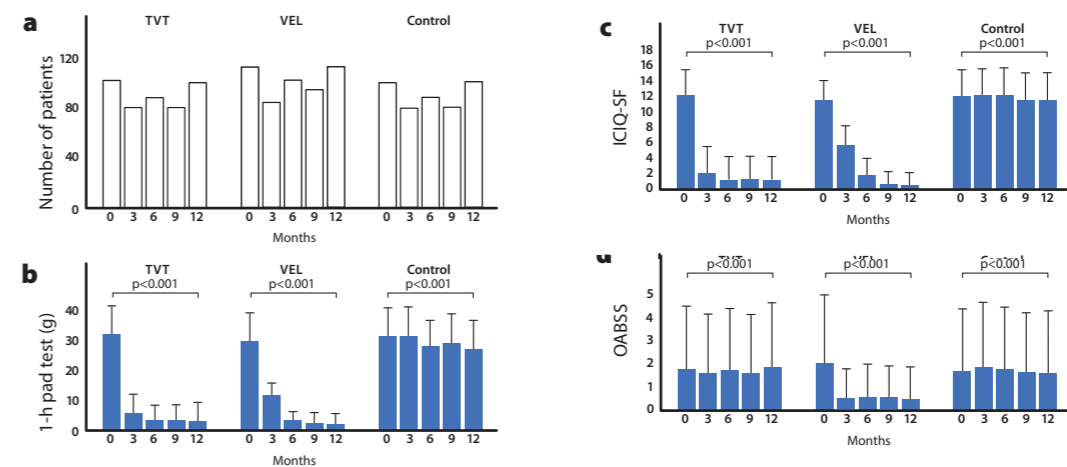
The study analyzed 102, 113, and 112 patients in the TVT, VEL, and control groups, respectively. The subjects were patients between 35 and 50 years of age at the time of treatment who (1) underwent TVT surgery, (2) received VEL treatment, or (3) were placed under observation with no treatment (control) 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. **e-g** Comparison between TVT and VEL with respect to changes in outcomes from pretreatment (0 months) to post-treatment (1 year). Only OABSS was significantly different between the two groups. The Mann-Whitney U test was used to compare the three groups at 1 and 12 months post-treatment.

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

Authors: C.T. Erel, L.D. Carazo Fernandez, D. Inan, M. Makul

Published in: *Eur J Obstet Gynecol Reprod Biol.* 2020 Sep;252:399-403. doi: 10.1016/j.ejogrb.2020.07.010.



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.

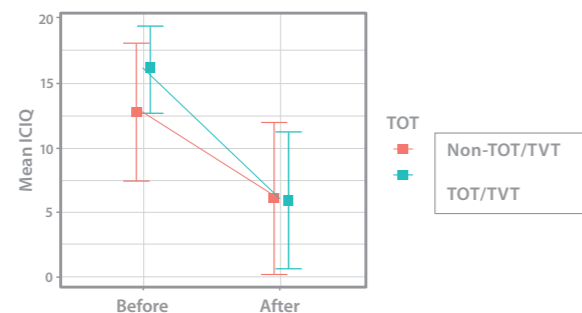
2940 nm Er:YAG laser was used in the treatment procedure for SUI. The patients were evaluated on the basis of ICIQ-SF before and after the procedure. According to the differences in the ICIQ-SF before and after, the percentage of improvement was graded as "good responders" ($\geq 50\%$) or "poor responders" ($< 50\%$). 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-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: C.T. Erel, D. Inan, A. Mut

Published in: *Maturitas.* 2020 Feb;132:1-6. doi: 10.1016/j.maturitas.2019.11.003.



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 in this cohort study. The patients were evaluated by ICIQ-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-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 ($p < 0.01$). 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: C. T. Erel, I. Fistonic, M. Gambacciani, Y. Oner and N. Fistonic
 Published in: *Climacteric*. 2020;23(sup1):S18-S23.
 doi: 10.1080/13697137.2020.1814728.



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

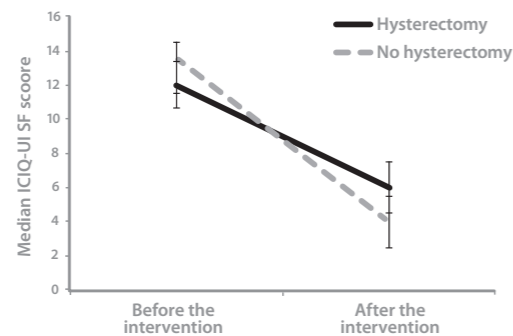
In this real-world, retrospective cohort study performed in Turkey, Croatia and Italy, a consecutive sample of 35 hysterectomized and 34 non-hysterectomized patients with SUI were treated with Er:YAG SMOOTH® laser. All three centers are members of VELA (Vaginal Er:YAG SMOOTH® Laser Academy), which defined 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. ICIQ-SF, International Consultation on Incontinence Questionnaire—Urinary Incontinence Short-Form.

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

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

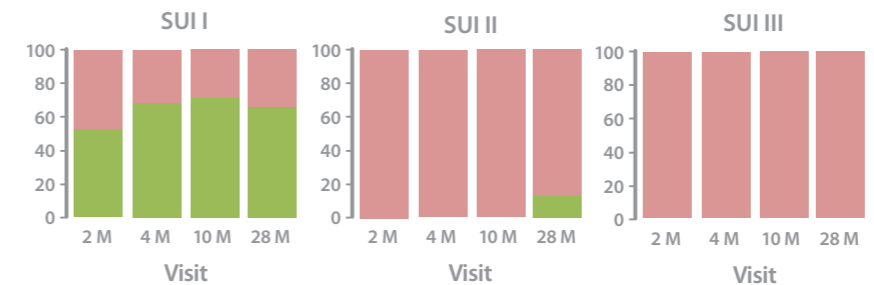
Fifty-nine women, 32 with SUI I, 16 with SUI II, and 11 with SUI III were treated using an erbium-doped yttrium aluminium garnet (Er:YAG) laser following the IncontiLase® protocol. Therapy included five laser sessions with a 1-month interval between sessions. Objective (1-h pad test) and subjective data (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 SUI 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.



International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form (ICIQ-UI SF) score. Subjective cure rates [%] are shown for patients with initial 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). M month, green cured (ICIQ-UI SF < 5), red not cured (ICIQ-UI SF > 5).

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

Published in: *Int Urogynecol J*. 2020 Sep;31(9):1859-1866. doi: 10.1007/s00192-019-04148-9.



Efficacy and Safety of Non-ablative Vaginal Erbium:YAG Laser Treatment as a Novel Surgical Treatment for Overactive Bladder Syndrome: Comparison with Anticholinergics and β 3-adrenoceptor Agonists

Authors: Nobuo Peter Okui
 -
 Published in: World J Urol.
 2019 Jan 28.



1. IMPROVEMENT OF OAB SYMPTOMS

According to this large study with 150 patients, Er:YAG laser treatment demonstrated comparable efficacy to anticholinergics (fesoterodine, 4 mg) or β 3-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.



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

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.

Authors: M. Blaganje,
 D. Scepanovic, L. Zgur, I.
 Verdenik, F. Pajk and
 A. Lukanovic
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 Published in: European
 Journal of Obstetrics &
 Gynecology and Reproductive
 Biology.2018(224):153-158



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

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

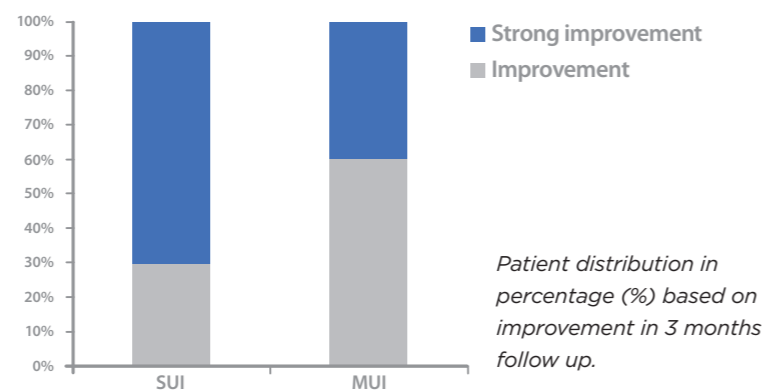
A total of 20 patients were included (10 patients with SUI and 10 patients with MUI) who underwent treatment using a 2940 nm Er:YAG laser with a special SMOOTH mode in an outpatient office without anesthesia or postoperative medications. All patients completed two sessions of treatment with an interval 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.



Baseline ICIQ-UI Score, Body Mass Index, Age, Average Birth Weight, and Perineometry Duration as Promising Predictors of the Short-Term Efficacy of Er:YAG Laser Treatment in Stress Urinary Incontinent Women: A Prospective Cohort Study

1. NEW PREDICTIVE MODEL FOR ASSESSING EXPECTED RESULTS OF SUI LASER TREATMENT

Dr. Ivan Fistonic et al. developed a new predictive model which will help practitioners assess the expected result of SUI laser treatment. The model identifies four key pre-intervention predictors which effect short-term Er:YAG outcomes.

2. METHOD

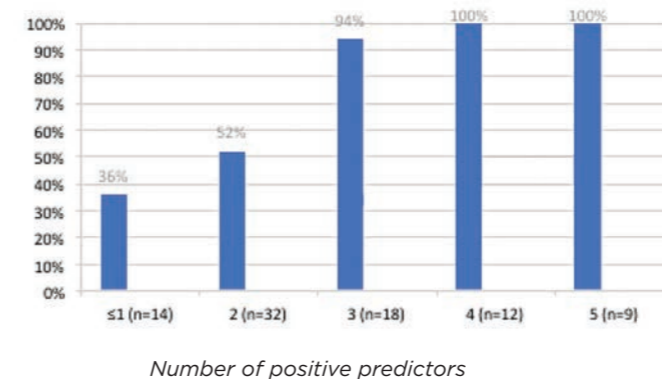
An analysis was performed on a sample of 84 female patients ranging in age from 30 to 70 who suffered from SUI. The patients were treated with a 2940 nm wavelength Er:YAG Fotona laser. In a three-step protocol (30 days in between), the laser irradiation was applied to the anterior vaginal wall, the entire circumference of the vaginal canal, and the vestibule area.

The analyzed predictors were: patient age, body mass index, number of births, average birth weight, last delivery weight, menopausal status, pelvic floor muscle strength (PFMS) of the pelvic diaphragm, adequacy of anatomic support to the bladder neck and urethro-vesical angle measured by Q-tip elevation, and ICIQ-UI baseline, pre-intervention value.

3. RESULTS IDENTIFY FOUR KEY PREDICTORS EFFECTING OUTCOME

The study reveals that age, body mass index, Q-tip elevation, and ICIQ-UI values prior to treatment are the four predictors that can be used to assess the outcome of laser treatment for SUI in female patients.

The effects of laser treatment were evident by an absolute change in the ICIQ-UI SF score and a relative decrease of 30% in the ICIQ-UI score 2-6 months after the treatment. The association between the Q-tip test and treatment outcomes was moderated by age. Q-tip was a significant predictor for patients between 44 and 53 years of age.



Authors: Ivan Fistonic and Nikola Fistonic
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 Published in: Lasers in Surgery and Medicine.2018;50(1):1-7



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IncontiLase® is an Effective and Durable Non-invasive Treatment for Stress Urinary Incontinence – Study of 175 Women with a 12-month Follow-up

Authors: Urska B. Ogrinc, Sabina Sencar and Helena Lenasi
Published in: Lasers Surg Med. 47(9):689-697

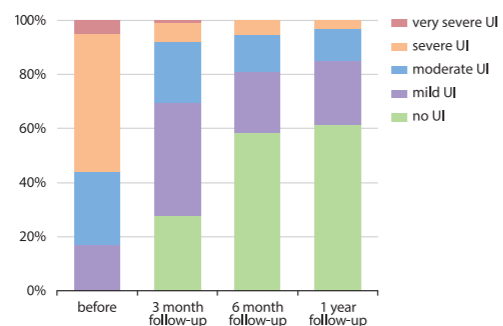


1. PUBLISHED IN HIGH-IMPACT PEER-REVIEWED LASER MEDICINE JOURNAL
Lasers in Surgery and Medicine is the official journal of the American Society for Laser Medicine and Surgery (ASMLS) – it publishes the highest quality research and clinical manuscripts on the use of lasers in medicine and biology.

2. LARGE GROUP OF TREATED PATIENTS
The prospective trial included 175 patients, who received 2-3 sessions of IncontiLase® treatment and were followed up to 12 months post-treatment. The study assessments included ICIQ questionnaire and ISI incontinence severity index determination, patient satisfaction questionnaire and VAS pain scale.

3. EXCELLENT RESULTS
One year after the IncontiLase® treatment, 62% of patients were free of symptoms of urinary incontinence. Results were even better in patients with pure stress urinary incontinence - 77% of these patients were dry 1 year after treatment.

4. INCONTILASE® IS A HIGHLY EFFICIENT AND SAFE METHOD FOR PATIENTS SUFFERING FROM STRESS URINARY INCONTINENCE
Patients with mixed urinary incontinence also get relief in stress symptoms, so it could be used in conjunction with overactive bladder therapy.



The effect of IncontiLase® therapy on the improvement of the grade of urinary incontinence (UI). Figure shows the distribution of patients (in %) with regard to the grade of incontinence (mild, moderate, severe, very severe) before treatment, at 2 months, six months and one year after the procedure.



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Effects of Laser Treatment for Female Urodynamic Stress Incontinence on Pad Weight, Urodynamics, and Sexual Function

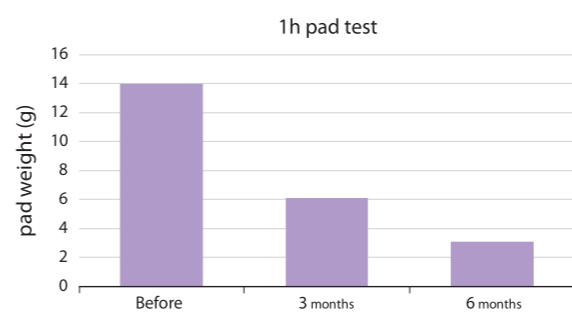
1. PUBLISHED IN HIGH IMPACT PEER-REVIEWED UROGYNECOLOGY JOURNAL
The International Urogynecology Journal is the official journal of the International Urogynecological Association (IUGA). It covers active topics on urogynecology and pelvic floor disorders and presents interdisciplinary coverage of all aspects of the field.

2. METHODOLOGY
Thirty-two patients with mild, moderate, and severe SUI were treated once and followed for 3 and 6 months. Urodynamic studies, LUTS, and sexual function questionnaires (PBCC, USS, KHQ, and others) were assessed before and after the treatment.

3. OUTSTANDING RESULTS
Thirty-five women underwent the IncontiLase® procedure. Among the 28 women with baseline pad weights >1 g, 11 (39.3%) were objectively cured and 11 (39.3%) had improved. Among the 18 women with mild SUI, nine (50%) were cured and five (27.8%) had improved. Among the ten women with baseline pad weight >10 g, two (20%) were cured and six (60%) had improved. Data gained from different questionnaires also shows significant improvements. 40% of the partners of these patients reported improved sexual function.

4. CLINICALLY MEANINGFUL IMPROVEMENT IN SUI SYMPTOMS
Compared to surgical procedures, the IntimaLase® procedure seems to be very effective in the treatment of SUI and is not associated with any severe adverse effects. Further studies should be performed to assess the long-term sustained efficacy of this minimally invasive therapy.

Authors: Yi-Wen Tien, Sheng-Mou Hsiao, Chien-Nan Lee, and Ho-Hsiung Lin
Published in: International Urogynecology Journal.2017;28(3):469-476



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

Authors: Adrian Gaspar and Hugo Brandi
Published in: Lasers in Medical Science.2017; 32(3):685-691



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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

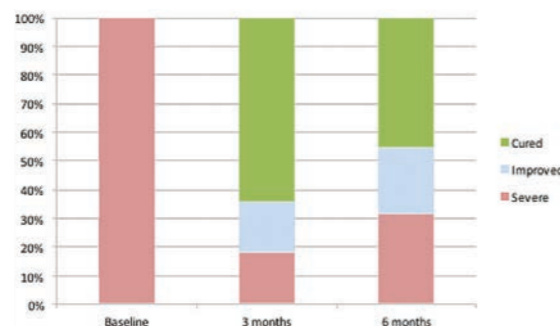
Twenty-two patients having diagnosed ISD participated in the study and were treated with the laser throughout the whole length of the urethra through a specially designed cannula. Treatment consisted of two laser sessions with a 3-week interval in-between. Therapeutic efficacy was assessed by the ICIQ-SF 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-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

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, 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.

Authors: Fistonc et. al.,
Published in: Lasers Med Sci, Feb 9, 2016, DOI: 10.1007/s10103-016-1884-0



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Sexual Function After Vaginal Erbium Laser: the Results of a Large, Multicentric, Prospective Study

Authors: M. Gambacciani, E. Albertin, M. G. Torelli, G. L. Bracco, A. C. Casagrande, L. Martella, G. Baiocchi, S. Alfieri, N. Russo, M. Cervigni

Published in: *Climacteric*. 2020;23(sup1):S24-S27. doi:10.1080/13697137.2020.1804544.



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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

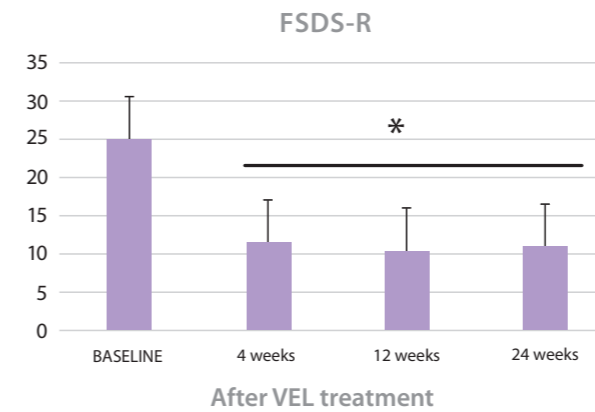
The study was performed on an outpatient basis without anesthesia or drug use before or after the intervention, using an erbium laser (XS Fotona Smooth®) in 1081 postmenopausal women (age 54.3 ±3.9 years) treated with up to three laser applications every 30 days. Patients were assessed using the Female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



FSFI domain	Before treatment	After treatment		
		4 weeks	12 weeks	24 weeks
Desire	3.0 ± 0.5	4.0 ± 1.5	4.5 ± 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 554 Female Sexual Distress Scale-Revised (FSDS-R) tests in baseline conditions and after treatment with vaginal erbium laser (VEL), irrespective of number of laser treatments (see text for details). Data are presented as mean ± standard error. *The values were significantly ($p < 0.01$) different vs. basal values.

The values of 569 Female Sexual Function Index (FSFI) tests in baseline conditions and after treatment with vaginal erbium laser, irrespective of number of laser treatments (see text for details). Data are presented as mean ± standard error. 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: A. Gaspar, J. Silva, A. Calderon, V. Di Placido & Z. Vizintin

Published in: *Climacteric*. 2020;23(sup1):S11-S13. doi: 10.1080/13697137.2020.1764525. PMID: 33124455.

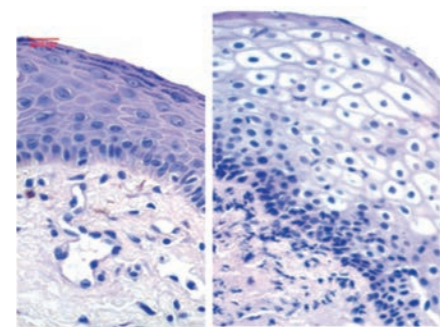


1. EVALUATING THE USE OF ER:YAG LASER FOR SEVERE VAGINAL ATROPHY
The aim of this study was to evaluate the effect of non-ablative erbium vaginal laser treatment on vaginal mucosa tissue affected by severe atrophy.

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 non-ablative erbium-doped yttrium aluminium garnet laser (Er:YAG laser) 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 of patient No.2 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 Erbium Laser in the Treatment of Genitourinary Syndrome of Menopause

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

Published in *Climacteric*. 2018;1-5



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®.

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

Authors: Adrian Gaspar, Sandra Maestri, Joaquin Silva, Hugo Brandi, Daniel Luque, Neza Koron, and Zdenko Vizintin
 Published in: Lasers in Surgery and Medicine. 2018 Oct;50(8):802-807



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 Erbium SMOOTH™ mode laser therapy, 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

	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)

Results are presented as mean (SD)

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

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

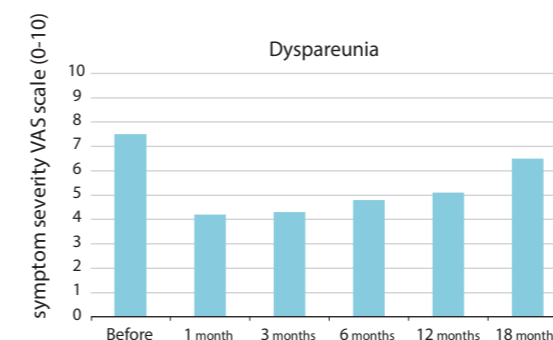
Forty-three postmenopausal breast cancer survivors received 3 RenovaLase® treatments with 30 days in-between the sessions. Symptoms were evaluated before the treatment and after 1, 3, 6, 12, and 18 months using two methods: subjective Visual Analog Scale (VAS) and objective Vaginal Health Index Score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



Authors: Marco Gambacciani and Marco Levancini

Published in: The Journal of The North American Menopause Society. 2017;24(3):316-319



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

Authors: M. Gambacciani, M. Levancini and M. Cervigni
 -
 Published in *Climacteric*.
 2015;18(5):757-763.



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)

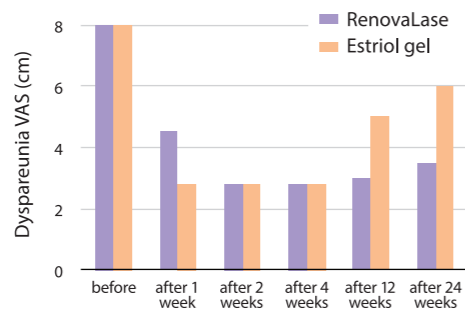
GSM (or vulvovaginal atrophy) is a chronic condition, which affects up to half of all postmenopausal women. Symptoms of GSM include dryness, burning, irritation, lack of lubrication and impaired sexual function. Traditional treatments have been limited to local or systemic estrogen therapy.

3. MATERIALS AND METHODS

45 postmenopausal women with symptoms of GSM were treated with a non-ablative vaginal erbium laser (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.

Vaginal erbium laser: the second-generation thermotherapy for the genitourinary syndrome of menopause

M. Gambacciani, M. Levancini, and M. Cervigni

Department of Obstetrics and Gynecology, The Veneto Medical School, Italy; Department of Obstetrics and Gynecology, The Veneto Medical School, Padua, Italy; Department of Obstetrics and Gynecology, The Veneto Medical School, Treviso, Italy; Department of Obstetrics and Gynecology, The Veneto Medical School, Udine, Italy

ABSTRACT

AIM: To evaluate the effects of the vaginal erbium laser (VEL) in the treatment of postmenopausal women with genitourinary syndrome of menopause (GSM).

METHODS: GSM was treated in postmenopausal women before and after VEL laser treatment every 10 days, for 3 months. The results were compared with the effects of a standard treatment for GSM (1 g of vaginal gel containing 50 µg of estriol twice weekly, for 3 months). GSM was evaluated using validated visual analog scale (VAS) and objective (vaginal health index score, VHIS) measures. In addition, a 10-point patient satisfaction questionnaire (IntimaLase®) was used. The degree of improvement was evaluated with the International Committee on Women's Questionnaire (ICWQ) Symptom Score.

RESULTS: GSM treatment resulted in a significant decrease of VAS in both vaginal dryness and dyspareunia (p < 0.05), with a significant (p < 0.05) increase of VHIS. In parallel, both patient satisfaction and ICWQ Symptom Score improved significantly (p < 0.05). Significant (p < 0.05) improvement of GSM was observed in both VAS and VHIS scores. The effects were rapid and long-lasting, up to the 24th week of the observation period. VHIS was significantly higher than that of the estriol group throughout the entire study.

CONCLUSIONS: This pilot study demonstrates that VEL induces a significant improvement of GSM, including vaginal dryness, dyspareunia and patient satisfaction. Further studies are needed to confirm the role of laser treatment in the management of GSM.

INTRODUCTION

Genitourinary syndrome of menopause (GSM) is the new addition to the variety of menopausal symptoms associated with the decline of the levels of estrogen and progesterone. It is characterized by vaginal dryness, burning, irritation, lack of lubrication and impaired sexual function. It affects up to 50% of postmenopausal women. The symptoms are often associated with a significant decrease in the quality of life. The management of GSM is often challenging, but also unsatisfactory. The use of local or systemic estrogen therapy is the mainstay of treatment, but also associated with a risk of adverse effects, such as increased risk of breast cancer, thromboembolic events, and osteoporosis. The use of non-hormonal treatments is an alternative option. The aim of this study was to evaluate the effects of the vaginal erbium laser (VEL) in the treatment of GSM.

OPEN ACCESS



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

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®) 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.

Authors: M. Mitsuyuki, U. Stok, I. Hreljac, K. Yoda, Z. Vizintin
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 Published in: *Sex Med*. 2020 Jun;8(2):265-273. doi: 10.1016/j.esxm.2020.01.001.



SEXUAL MEDICINE

ORIGINAL RESEARCH ARTICLE

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

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

ABSTRACT

AIM: To evaluate the effectiveness and safety of a nonablative Er:YAG laser procedure (IntimaLase®) for vaginal laxity in patients treated in a clinical practice during a 2.5-year period.

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

RESULTS: 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.

CONCLUSIONS: 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.

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The Efficacy of Erbium-doped Yttrium Aluminum Garnet (Er:YAG) Laser in the Treatment of Decreased Sexual Sensation: A Randomized, Placebo-controlled Trial

Authors: A. Sathaworawong,
W. Manuskiatti, C.
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Ungaksornpairote & J.N. Ng
-
Lasers Med Sci. 2021 Apr 1.
doi: 10.1007/s10103-021-03305-1.



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 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 Laser on Pelvic Floor Strength and Sexual Satisfaction in Women Complaining of Vaginal Looseness: a Randomized Controlled Trial

Authors: S.M. Ahmed, H.G. Kotb, A.M. Yousef, H.A.H. Ahmed

Published in: Fizjoterapia Pol [Internet]. 2019;19(2):88-93.



OPEN ACCESS



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

The study aimed to determine the effect of erbium:yttrium-aluminum-garnet (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 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

Erbium:yttrium-aluminum-garnet (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 ^{NS}	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: Jorge E. Gaviria P, Branka Korosec, Jessica Fernandez, Geramel Montero
 Published in: *Journal of the Laser and Health Academy*.2016; 2016(1):1-6



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® 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.

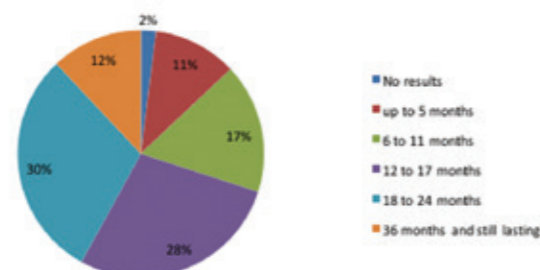
3. GREAT RESULTS

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



Non-ablative Vaginal Erbium YAG Laser for the Treatment of Cystocele

Authors: Urska B. Ogrinc and Sabina Sencar

Published in: *Italian Journal of Gynaecology and Obstetrics*.2017;29(1):19-25



OPEN ACCESS



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

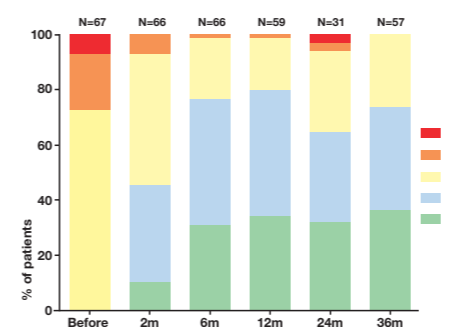
61 patients with grade II-IV cystoceles were treated 2-5 times at 2-month intervals. Prolapses were photographed and graded using the Barden-Walker scale.

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.

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

Authors: N. Okui, M. Okui and Z. Vizintin

Published in: *Climacteric*. 2020;23(sup1):S14-S17. doi: 10.1080/13697137.2019.1703940.



OPEN ACCESS



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

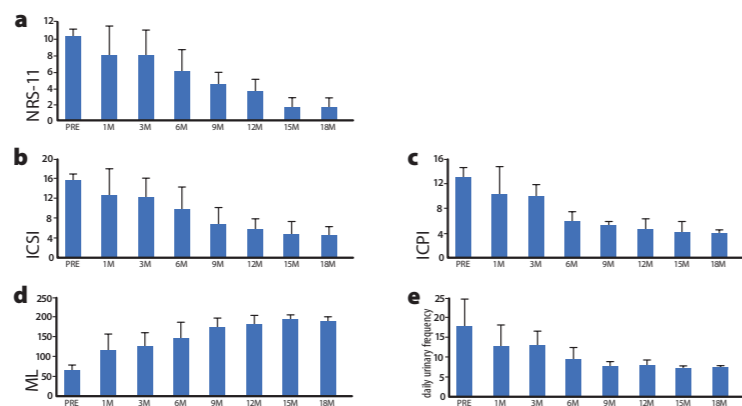
A total of 12 patients without improvement after several treatments underwent nonablative vaginal Er:YAG laser treatment once a month for 12 months. The numeric rating scale-11 (NRS-11), O'Leary-Sant interstitial cystitis symptom and problem indexes (ICSI and ICPI), functional bladder capacity, and daily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

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

Authors: Urska B. Ogrinc, Sabina Sencar, Bostjan Luzar, Adolf Lukanovic.

Published in: *J Obstet Gynaecol Can*. 2019 Apr 11. pii: S1701-2163(19)30081-7.



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 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.



OPEN ACCESS



Sutureless Laser Labiaplasty of Labia Minora

Authors: U. Bizjak Ogrinc, S. Senčar

Published in: Sex Med. 2021 Oct;9(5):100406. doi: 10.1016/j.esxm.2021.100406.



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 2 before and 3 weeks after procedure.

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

Authors: U. Bizjak Ogrinc, S. Senčar

Published in: ZdravVestnik [Internet]. 31Aug.2020. Available from: <https://vestnik.szd.si/index.php/ZdravVest/article/view/3050>



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 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

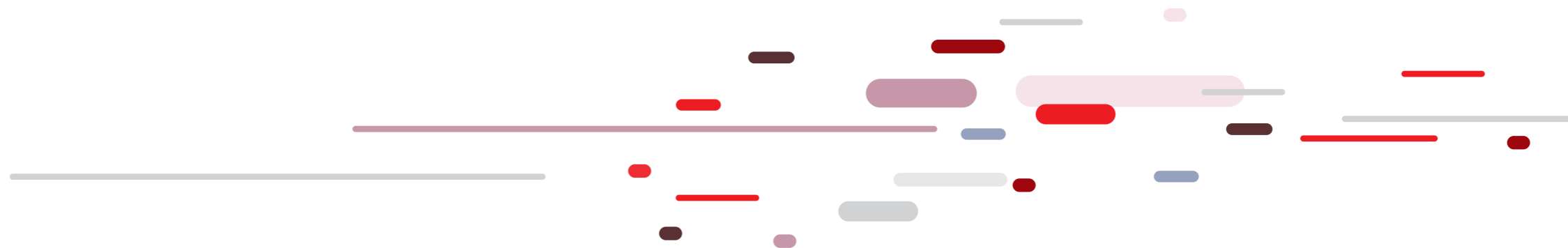
The majority of the 116 patients who completed therapy (74 patients) received only one treatment and 82 of the patients (n = 95) showed complete clearance of the lesions, without recurrence observed to date of analysis. Complete clearance was achieved after an average of 1.33 treatment sessions. Recurrence 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 ^a (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.



List of Published Clinical Studies of Fotona's Gynecological Treatments

Literature

STRESS URINARY INCONTINENCE (SUI)

1. Okui N et al., 2021. Comparison of urethral sling surgery and non-ablative vaginal Erbium:YAG laser treatment in 327 patients with stress urinary incontinence: a case-matching analysis. *Lasers Med Sci.* 2021 Apr 22. doi: 10.1007/s10103-021-03317-x. Epub ahead of print. PMID: 33886071.



2. Erel CT et al., 2020. Er:YAG laser in hysterectomized women with stress urinary incontinence: a VELA retrospective cohort, non-inferiority study. *Climacteric.* 2020;23(sup1):S18-S23. doi: 10.1080/13697137.2020.1814728. PMID: 33124456.



3. Erel CT et al., 2020. Er:YAG laser treatment of urinary incontinence after failed TOT/TVT procedures. *Eur J Obstet Gynecol Reprod Biol.* 2020 Sep;252:399-403. doi: 10.1016/j.ejogrb.2020.07.010. Epub 2020 Jul 9. PMID: 32711294.



4. Su CF et al., 2019. Preliminary outcome of non-ablative vaginal Erbium laser treatment for female stress and mixed urinary incontinence. *Taiwan J Obstet Gynecol.* 2019 Sep;58(5):610-613. doi: 10.1016/j.tjog.2019.07.006. PMID: 31542080.



5. Okui N, 2020. A two-year study of a non-ablative erbium YAG laser procedure for stress urinary incontinence with a focus on the sexual function - A comparison with the tension-free vaginal tape procedure. *The Japanese Journal of Medicine*, 34, 205-214, 2020

6. Kuszka A et al., 2020. Erbium:YAG laser treatment of female stress urinary incontinence: midterm data. *Int Urogynecol J.* 2020 Sep;31(9):1859-1866. doi: 10.1007/s00192-019-04148-9. Epub 2019 Dec 11. PMID: 31828400.



7. LV J et al.. Non-ablative transurethral Erbium YAG laser in treatment of female stress urinary incontinence, *Journal of Modern Urology*, ISSN:1009-8291, <http://kns.cnki.net/kcms/detail/61.1374.R.20181207.1403.002.html> , 2018



8. Erel CT et al., 2020. Predictive factors for the efficacy of Er:YAG laser treatment of urinary incontinence. *Maturitas.* 2020 Feb;132:1-6. doi: 10.1016/j.maturitas.2019.11.003. Epub 2019 Nov 9. PMID: 31883657.



9. Okui N, 2019. Efficacy and safety of non-ablative vaginal erbium:YAG laser treatment as a novel surgical treatment for overactive bladder syndrome: comparison with anticholinergics and β 3-adrenoceptor agonists. *World J Urol.* 2019;37(11):2459-2466. doi:10.1007/s00345-019-02644-7



10. Lin KL et al., 2019. Effect of Er:YAG laser for women with stress urinary incontinence. *Biomed Res Int.* 2019 Jan 15;2019:7915813.



11. Lin HY et al., 2018. The short-term outcome of laser in the management of female pelvic floor disorders: Focus on stress urine incontinence and sexual dysfunction. *Taiwan J Obstet Gynecol.* 2018 Dec;57(6):825-829.



12. Okui N, 2019. Comparison between erbium-doped yttrium aluminum garnet laser therapy and sling procedures in the treatment of stress and mixed urinary incontinence. *World J Urol.* 2019 May;37(5):885-889. doi: 10.1007/s00345-018-2445-x. Epub 2018 Aug 16. PMID: 30116962; PMCID: PMC6505485.



13. Okui N, 2018. The first evaluation of erbium laser for treatment of female overactive bladder syndrome in comparison to standard medication therapies with 12 months follow-up, 12 months follow-up. *Progress in Medicine*, Vol.38, No.4.

14. Gaspar A et al., 2018. Intraurethral Erbium:YAG laser for the management of urinary symptoms of genitourinary syndrome of menopause: A pilot study. *Lasers Surg Med.* 2018 Oct;50(8):802-807. doi: 10.1002/lsm.22826. Epub 2018 Apr 18. PMID: 29667744; PMCID: PMC6175161.



15. Blaganje M et al., 2018. Non-ablative Er:YAG laser therapy effect on stress urinary incontinence related to quality of life and sexual function: A randomized controlled trial. *Eur J Obstet Gynecol Reprod Biol.* 2018 May;224:153-158. doi: 10.1016/j.ejogrb.2018.03.038. Epub 2018 Mar 22. PMID: 29604548.



16. Fistončić I & Fistončić N, 2018. Baseline ICIQ-UI score, body mass index, age, average birth weight, and perineometry duration as promising predictors of the short-term efficacy of Er:YAG laser treatment in stress urinary incontinent women: A prospective cohort study. *Lasers Surg Med.* 2018 Jan 23. doi: 10.1002/lsm.22789. Epub ahead of print. PMID: 29360142.



17. Lin Y et al., 2017. Effect of non-ablative laser treatment on overactive bladder symptoms, urinary incontinence and sexual function in women with urodynamic stress incontinence. *Taiwan J Obstet Gynecol*, 56(6), pp.815-820.



18. Gaspar A & Brandi H. Non-ablative erbium YAG laser for the treatment of type III stress urinary incontinence (intrinsic sphincter deficiency). *Lasers Med Sci.* 2017 Apr;32(3):685-691. doi: 10.1007/s10103-017-2170-5. Epub 2017 Feb 16. PMID: 28210823.



19. Lapii GA et al., 2017. Structural reorganization of the vaginal mucosa in stress urinary incontinence under conditions of Er:YAG laser treatment. *Bulletin of Experimental Biology and Medicine*, 162(4), pp.510-514.



20. Tien YW et al., 2017. Effects of laser procedure for female urodynamic stress incontinence on pad weight, urodynamics, and sexual function. *Int Urogynecol J.*, 28(3), pp.469-476.



21. Tadir Y et al., 2017. Light and energy based therapeutics for genitourinary syndrome of Menopause: Consensus and Controversies. *Lasers Surg Med.*, Volume 49, Issue 2 (February): pp.137-159.



22. Kulikov IA et al., 2017. A method for photothermal tissue reconstruction using ErYAG laser Fotona in modern gynecology. *Akusherstvo i Ginekologiya / Obstetrics and Gynecology*, 2017 (11): pp.160-167.



23. Barber MA et al., 2016. Patient satisfaction with vaginal erbium laser treatment of stress urinary incontinence, vaginal relaxation syndrome and genitourinary syndrome of menopause. *Journal of the Laser and Health Academy*, 2016(1), pp.18-23.



24. Fistončić N et al., 2016. Minimally invasive, non-ablative Er:YAG laser treatment of stress urinary incontinence in women — a pilot study. *Lasers Med Sci* Science, 2016(31), pp.635-643.



25. Pardo JI et al., 2016. Treatment of female stress urinary incontinence with Erbium-YAG laser in non-ablative mode. *Eur J Obstet Gynecol Reprod Biol.*, 204, pp.1-4.



26. Bizjak Ogrinc U et al., 2015. Novel minimally invasive laser treatment of urinary incontinence in women. *Lasers Surg Med*, 47(9), pp.689-697.



27. Gambacciani M et al., 2015. Vaginal erbium laser: The second-generation thermotherapy for the genitourinary syndrome of menopause. *Climacteric*, 18(5), pp.757-763.



28. Khalafalla MM et al., 2015. Minimal invasive laser treatment for female stress urinary incontinence. *Obstetrics & Gynecology International Journal*, 2(2), pp.1-5.



29. Fistončić N et al., 2015. First assessment of short-term efficacy of Er:YAG laser treatment on stress urinary incontinence in women: prospective cohort study. *Climacteric*, 18(Suppl. 1), pp.37-42.



30. Bezmenko AA et al., 2014. Treatment of stress urinary incontinence with Er:YAG laser: some biochemical parameters of connective tissue metabolism. *Journal of Experimental and Clinical Urology*.

31. Bezmenko AA et al., 2014. Conservative ways of urinary stress incontinence treatment. *Journal of Russian Military Medical Academy*.

32. Bezmenko AA et al., 2014. Morphological substantiation of applying the Er:YAG laser for the treatment of stress urinary incontinence in women. *Journal of Obstetrics and Women Diseases*, No.3.



33. Fistončić I et al., 2012. Minimally invasive laser procedure for early stages of stress urinary incontinence (SUI). *Journal of the Laser and Health Academy*, 2012(1), pp.67-74.



34. Vizintin Z et al., 2012. Novel minimally invasive VSP Er:YAG laser treatments in gynecology. *Journal of the Laser and Health Academy*, 1(1), pp.46-58.



GENITOURINARY SYNDROME OF MENOPAUSE (GSM)

35. Gambacciani M et al., 2020. Sexual function after vaginal erbium laser: the results of a large, multicentric, prospective study. *Climacteric*. 2020;23(sup1):S24-S27. doi: 10.1080/13697137.2020.1804544. PMID: 33124454.



36. Gambacciani M et al., 2020. Safety of vaginal erbium laser: A review of 113,000 patients treated in the past 8 years. *Climacteric*. 2020;23(sup1):S28-S32. doi: 10.1080/13697137.2020.1813098. PMID: 33124457.



37. Hympanova L et al., 2020. Effects of non-ablative Er:YAG laser on the skin and the vaginal wall: systematic review of the clinical and experimental literature. *Int Urogynecol J*. 2020 Dec;31(12):2473-2484. doi: 10.1007/s00192-020-04452-9. Epub 2020 Aug 11. PMID: 32780174.



38. Gaspar A et al., 2020. Histological findings after non-ablative Er:YAG laser therapy in women with severe vaginal atrophy. *Climacteric*. 2020;23(sup1):S11-S13. doi: 10.1080/13697137.2020.1764525. PMID: 33124455.



39. Gambacciani M et al., 2018. Long-term effects of vaginal erbium laser in the treatment of genitourinary syndrome of menopause. *Climacteric*. pp.1-5.



40. Gambacciani M & Palacios S, 2017. Laser therapy for the restoration of vaginal function. *Maturitas*, 99, pp.10-15.



41. Gambacciani M et al., 2017. Vaginal erbium laser as second-generation thermotherapy for the genitourinary syndrome of menopause: a pilot study in breast cancer survivors.



42. Dobrokhotova E et al., 2017. Er:YAG Laser treatment for genitourinary disorders. *Akusherstvo i Ginekologiya / Obstetrics and Gynecology*, 2017 (10): pp.84-91.



43. Gaspar A et al., 2016. Efficacy of Erbium:YAG laser treatment compared to topical estriol treatment for symptoms of genitourinary syndrome of menopause. *Lasers Surg Med*, 49(2), pp.160-168.



44. Bojanini JF, 2016. Treatment of Genitourinary syndrome of menopause with Erbium:YAG laser: a prospective study of efficacy and safety of the treatment for women after menopause of natural origin and therapy-induced menopause in breast cancer survivors. *Journal of the Laser and Health Academy*, 2016(1), pp.35-40.



45. Gambacciani M et al., 2015. Vaginal erbium laser: The second-generation thermotherapy for the genitourinary syndrome of menopause. *Climacteric*, 18(5), pp.757-763.



46. Gambacciani M et al., 2015. Rationale and design for the Vaginal Erbium Laser Academy Study (VELAS): an international multicenter observational study on genitourinary syndrome of menopause and stress urinary incontinence. *Climacteric*, 18: sup1, pp.43-48.



47. Bojanini JF & Mejia CAM, 2014. Laser treatment of vaginal atrophy in post-menopause and post-gynecological cancer patients. *Journal of the Laser and Health Academy*, 2014(1), pp.65-71.



VAGINAL LAXITY

48. Sathaworawong A et al., 2021. The efficacy of erbium-doped yttrium aluminum garnet (Er:YAG) laser in the treatment of decreased sexual sensation: a randomized, placebo-controlled trial. *Lasers Med Sci.* 2021 Apr 1. doi: 10.1007/s10103-021-03305-1. Epub ahead of print. PMID: 33791888.
49. Mitsuyuki M et al., 2020. Treating vaginal laxity using nonablative Er:YAG laser: A retrospective case series of patients from 2.5 years of clinical practice. *Sex Med.* 2020 Jun;8(2):265-273. doi: 10.1016/j.esxm.2020.01.001. Epub 2020 Feb 7. PMID: 32044277; PMCID: PMC7261675.
50. Lukac M et al., 2021. Characteristics of non-ablative resurfacing of soft tissues by repetitive Er:YAG laser pulse irradiation. *Lasers Surg Med.* 2021 Nov;53(9):1266-1278. doi: 10.1002/lsm.23402. Epub 2021 Apr 1. PMID: 33792949.
51. Lukač M et al., 2019. Variable heat shock response model for medical laser procedures. *Lasers Med Sci.* 2019 Aug;34(6):1147-1158. doi: 10.1007/s10103-018-02704-1. Epub 2019 Jan 3. PMID: 30607720.
52. Ahmed SM et al., 2019. Effect of laser on pelvic floor strength and sexual satisfaction in women complaining of vaginal looseness: A randomized controlled trial. *Fizjoterapia Polska*, 19(2), pp.88-93.
53. Gaviria PJE et al., 2016. Up to 3-year follow-up of patients with vaginal relaxation syndrome participating in laser vaginal tightening. *Journal of the Laser and Health Academy*, 2016(May), pp.1-6.
54. Pardo JI & Dalenz VS, 2016. Laser vaginal tightening with non-ablative Er:YAG for vaginal relaxation syndrome evaluation of patient satisfaction. *Journal of the Laser and Health Academy*, 2016(1), pp.12-17.
55. Gaviria PJE et al., 2012. Laser Vaginal Tightening (LVT) – evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome. *Journal of the Laser and Health Academy*, 2012(1), pp.59-66.



PELVIC ORGAN PROLAPSE (POP)

56. Bizjak Ogrinc U & Senčar S, 2017. Non-ablative vaginal erbium YAG laser for the treatment of cystocele. *Italian Journal of Gynaecology and Obstetrics*, 29(1), pp.19-25.
57. Bizjak Ogrinc U & Senčar S, 2013. Laser treatment of higher grade cystocele. *Journal of the Laser and Health Academy*, 2013(1), p.S22.
58. Vizintin Z et al., 2015. Erbium laser in gynecology. *Climacteric*, 18(September), pp.4-8.



OTHER GYNECOLOGICAL INDICATIONS

59. Bizjak Ogrinc U & Senčar S. Sutureless laser labiaplasty of labia minora. *Sex Med.* 2021;9(5):100406.
60. Ghelardi A et al., 2021. Surgical treatment of vulvar HSIL: Adjuvant HPV vaccine reduces recurrent disease. *Vaccines*, 9(2).
61. Okui N et al., 2020. Effects of non-ablative vaginal erbium:YAG laser treatment for interstitial cystitis/bladder pain syndrome: a case series (UNICORN-2 study), *Climacteric*, 23:sup1, S14-S17, DOI: 10.1080/13697137.2019.1703940
62. Bizjak Ogrinc U & Senčar S. Effectiveness and safety of ablative Er:YAG laser treatment for external genital warts, *Zdravstveni Vestnik*, July-August 2020, Vol.89: 357-364
63. Gómez-Frieiro M et al., 2019. Use of Er:YAG laser in the treatment of vulvar lichen sclerosus, *International Journal of Women's Dermatology*, available online 4 June 2019, <https://www.sciencedirect.com/science/article/pii/S2352647519300486>
64. Bizjak Ogrinc U et al., 2019. Efficacy of non-ablative laser therapy for lichen sclerosus: A randomized controlled trial. *J Obstet Gynaecol Can.* 2019 Apr 11. pii: S1701-2163(19)30081-7.
65. Erel TC. Case report: Vulvodinia treated with Erbium:YAG laser. *Eur J Obstet Gynecol Reprod Biol.* 2018 Dec;231:280-281.



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