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Compendium of Clinical Studies

Fotona SMOOTH® Er:YAG
laser treatments in gynecology





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Foreword

Scientific Evidence Behind Fotona SMOOTH® Treatments in Gynecology

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 40 SCI (high Science Citation Index) publications.

The first research study introducing this novel non-ablative Er:YAG laser technology and its minimally-invasive effects in gynecology was written by Vizintin et al. and published in the *Journal of the Laser and Health Academy* in 2012. The authors for the first time demonstrated that Fotona SMOOTH® laser treatment exploits the photo-thermal effect of a laser beam on the mucosa tissue in order to cause its shrinkage without the removal of any tissue. The overall impact and burden on the patient's organism is thus minimal, as opposed to more invasive gynecological procedures.

In the same year two groundbreaking clinical studies were published. Dr. Fistonic et al. presented the first pilot clinical study showing exceptional efficacy of Fotona SMOOTH® Er:YAG for the treatment of stress urinary incontinence (SUI) - **IncontiLase®**. The results revealed for the first time that non-ablative Er:YAG laser therapy is an effective, safe and comfortable treatment option for patients with mild and moderate SUI. At the same time, Dr. Gaviria et al. tested the efficacy of the Fotona SMOOTH® therapy, but for a different application - treating vaginal relaxation syndrome - **IntimaLase®**. This resulted in the first ever study of the efficacy and safety of treating vaginal laxity with a non-ablative Er:YAG laser, which showed that an amazing 95% of treated patients reported significant improvement in vaginal tightness and enhanced sexual gratification. Four years later, Dr. Gaviria et al. published a 3-year follow-up study of patients with Vaginal Relaxation Syndrome participating in the IntimaLase® laser vaginal tightening study, which revealed a significant improvement in vaginal laxity after non-ablative Er:YAG laser treatment.

The unique non-invasive Fotona SMOOTH® photo-thermal effects on vaginal mucosa tissue were soon also applied to the treatment of other clinical gynecological indications. In 2013 Dr. Adrian Gaspar was the first to compare the efficacy and safety of two minimally invasive procedures for treating genitourinary syndrome of menopause (GSM): hormonal replacement therapy with estriol - and the new Fotona SMOOTH® mode therapy (today known as **RenovaLase®**). The study's results revealed that both groups showed improvement in GSM symptoms, but the laser therapy showed better and longer lasting effects. His pioneering findings were presented in 2014 at the IMS World Congress on Menopause in Cancun, Mexico with an abstract published in *Climacteric* (Gaspar A. Comparison of New Minimally Invasive Er:YAG Laser Treatment and Hormonal Replacement Therapy in the Treatment of Vaginal Atrophy, *Climacteric* 2014; 17 (Suppl 1): 48-108, P 124). A full study paper was published in *Lasers in Surgery and Medicine* two years later with results showing that a significant improvement in GSM symptoms and a decrease of pH in the laser group was detected up to 12 months after treatment. The improvement in all endpoints was more pronounced and longer lasting when compared to treatment with topical estriol. Furthermore, histological examination showed renewal of the epithelium and lamina propria in the laser group (*Lasers in Surgery and Medicine*, 2016).

Another important pilot study on RenovaLase® therapy was published in the *Journal of the North American Menopause Society* in 2017 by Dr. Gambacciani et al. Here expert laser practitioners evaluated the effects of the vaginal Er:YAG laser as a second-generation thermotherapy for GSM in breast cancer survivors. After applying the RenovaLase® therapy, patients showed significant reduction of GSM symptoms. This was groundbreaking research due to the fact that hormonal therapies are not an option for these patients, so non-ablative Er:YAG laser treatment presents a highly welcome alternative. In 2018 Dr. Gambacciani published another significant research study on the long-term effects of RenovaLase® treatment of GSM. His 2-year follow-up study showed that non-ablative Er:YAG laser treatment induced a statistically significant change in vaginal pH and improved dyspareunia and dryness (*Climacteric*, 2018).

Other noteworthy scientific articles on Fotona's gynecological laser treatments include a study by Dr. Bizjak-Ogrinc and Dr. Sencar in 2015, who together treated 175 women suffering from SUI and MUI. They found that 77% of patients with SUI significantly improved after Er:YAG IncontiLase® treatment. Impressed by the results, Dr. Bizjak-Ogrinc and Dr. Sencar also applied Fotona SMOOTH® for the treatment of pelvic organ prolapse - **ProlapLase®**. 61 patients with grade II-IV cystoceles were treated 2-5 times at 2-month intervals. In 2017 their results revealed that the grades of prolapse were reduced by at least one grade in 95% of patients, with 85% of patients reduced to grade 0 or 1 prolapses and the remaining 15% of patients with grade 2 prolapses (*Italian Journal of Gynaecology and Obstetrics*, 2017).

IncontiLase® therapy has also been examined by other respected medical practitioners over the past few years, with all revealing favorable treatment outcomes. Dr. Pardo et al. found that 79% of patients showed improvement of SUI symptoms and 82% of sexually active women also reported improvement in sexual gratification (*European Journal of Obstetrics Gynecology and Reproductive Biology*, 2016). Similarly, a study by Dr. Tien et al. revealed that non-ablative Er:YAG laser treatment improved symptoms of mild to moderate SUI in approximately 80% of the studied population (*International Urogynecology Journal*, 2016). Dr. Lapii et al. published a paper where histological findings showed that non-ablative Er:YAG technology leads to structural reorganization of the vaginal mucosa, improves its morphology and function and, consequently, improves SUI symptoms (*Bulletin of Experimental Biology and Medicine*, 2017). Just recently, Dr. Lukanovic et al. presented the first randomized control trial which evaluates the efficacy and safety of IncontiLase® non-ablative Er:YAG laser therapy. Here 114 premenopausal parous women with SUI were randomized in two groups: a laser intervention group and a placebo group. The results show that a single session of IncontiLase® treatment improves the impact of SUI symptoms on the quality of life and sexual function in premenopausal parous women significantly better than a placebo treatment (*European Journal of Obstetrics & Gynecology and Reproductive Biology*, 2018). The *World Journal of Urology* also recently published a study on IncontiLase® by Dr. Okui et al., which compares Er:YAG laser therapy and sling procedures in the treatment of stress and mixed urinary incontinence. Results of the 1-h pad test and ICIQ-SF showed that the TVT and TOT procedures and the laser therapy are comparable for SUI; however, laser therapy is superior in terms of MUI and complications. This study once again confirms the safety and efficacy of Fotona SMOOTH® laser therapy for urinary incontinence.

Important breakthroughs in researching the safety, efficacy and various treatment possibilities of the IncontiLase® laser therapy have also been made by Dr. Gaspar et al. In 2017 he published an article in *Lasers in Medical Science* on the effects of the Fotona SMOOTH® intraurethral therapy for the treatment of type III stress urinary incontinence (intrinsic sphincter deficiency). The results revealed that objective clinical improvement of SUI symptoms measured via 1-h pad test was achieved in 82% of patients 3 months post treatment. Another important pilot study by Dr. Gaspar et al. examines the effectiveness of the intraurethral Er:YAG Fotona laser for the management of urinary symptoms of GSM. Their findings reveal a nearly 60% improvement of urinary symptoms of GSM measured with 1-h pad test without any adverse events (*Lasers in Surgery and Medicine*, 2018).

Most recently, a mechanism of action of the Fotona SMOOTH® therapy was explored in more detail. It was proposed that a process of fast heat shocking of the epithelium, in addition to slow thermal injury of the connective tissue, is involved in non-ablative Fotona SMOOTH® mode treatment procedures. This dual tissue-regeneration mechanism (DTR) appears to contribute significantly to the reported safety and efficacy of the Fotona SMOOTH® thermotherapy.

In its 50-year history, Fotona has always based its promotion of effective laser use on stringent research and hard evidence. Lasers in gynecology are no exception. Fotona strongly encourages the exchange and dissemination of scientific knowledge among peers and promotes evidence-based laser medicine among practitioners and the general public. This *Compendium of Clinical Studies*, which includes abstracts from published scientific articles written by leading international expert gynecologists, provides the scientific evidence behind the effectiveness and safety of Fotona SMOOTH® technology.

Fotona Clinical Affairs Team





Abstracts of selected peer-reviewed publications

Er:YAG Fotona SMOOTH® Treatment for Stress Urinary Incontinence

Lin KL, Chou SH, Long CY., 2019. **Effect of Er:YAG Laser for Women with Stress Urinary Incontinence.** *Biomed Res Int.* Jan 15;2019:7915813.

AIM: The aim of our study is to assess efficacy of non-invasive erbium-doped yttrium aluminum garnet laser (Er:YAG laser) for female stress urinary incontinence (SUI).

METHODS: Forty-one women with SUI were included in the study and scheduled for vaginal Er:YAG laser treatment. The procedure was performed with a 2940 nm, Er:YAG laser (Fotona Smooth XS, Fotona, Ljubljana, Slovenia), designed to heat up the vaginal mucosa to around 60°C. All subjects had a baseline and 6 months' posttreatment assessment that included perineal sonography and lower urinary tract symptoms.

RESULTS: Significant improvements in both urinary frequency and incontinence were found 6 months after Er:YAG laser treatment when compared to the baseline results ($p < 0.001$). The battery of questionnaires administered to patients, including the UDI-6, IIQ-7, OABSS, and POPDI-6, all showed significant improvement posttreatment ($P < 0.001$). The treatment efficacy for the vaginal Er:YAG laser for SUI at 6 months posttreatment was 75.5% (31/41). Bladder neck mobility by perineal ultrasonography decreased significantly ($16.1 \pm 6.4\text{mm}$ to $10.5 \pm 4.6\text{mm}$) after treatment ($p = 0.039$). No permanent adverse events were found.

CONCLUSIONS: The Er:YAG vaginal laser seems to be a safe and efficacious treatment for women with mild to moderate SUI, this being partly related to the decrease of bladder neck mobility following laser treatment.

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 $\beta 3$ -adrenoceptor agonists.** *World J Urol.* Jan 28. doi: 10.1007/s00345-019-02644-7.

AIM: To examine the efficacy and safety of non-ablative vaginal Erbium:YAG laser (VEL) for the treatment of overactive bladder syndrome (OAB) compared with those of two other common pharmacotherapies, namely, anticholinergics and $\beta 3$ -adrenoceptor agonists.

METHODS: Female subjects aged 60-69 years who presented with symptoms of OAB from 2015 to 2017 were assigned to three groups ($n = 50$) receiving treatment with an anticholinergic agent (4 mg fesoterodine), a $\beta 3$ -adrenoceptor agonist (25 mg mirabegron), or VEL (20 min/session of VEL performed thrice). The OAB symptom score (OABSS), Vaginal Health Index Scale (VHIS), and occurrence of adverse effects were examined prior to and at 1 year following treatment initiation.

RESULTS: The three groups showed significant improvement ($p < 0.001$) for all items of the OABSS questionnaire. Improved VHIS scores were observed only in the VEL group. Furthermore, after VEL treatment, a negative correlation was observed between questions 3 (urinary urgency) and 4 (urgency urinary incontinence) of the OABSS and VHIS. Regarding safety, no adverse events were observed in the VEL group. However, subjects in the other two groups complained of constipation, as indicated by the Constipation Assessment Scale scores, and mouth dryness. The therapeutic effects were inadequate for one and two subjects in the VEL and $\beta 3$ -adrenoceptor agonist groups, respectively.

CONCLUSIONS: VEL safely and effectively improved OABSS through a different mechanism than that involved in pharmacotherapy. We propose the use of VEL as a novel surgical treatment option in the field of urology.

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 Journal of Urology*, 37(5):885-889.

AIM: Stress urinary incontinence (SUI) and mixed urinary incontinence (MUI) lead to poor quality of life. In Japan, urinary incontinence is treated with tension-free vaginal tape (TVT) or transobturator tape (TOT) sling procedures, which involves inserting a synthetic material; however, problems arise with artificial mesh in some instances, requiring new treatment methods. Hence, laser therapy, whereby an erbium-doped yttrium aluminum garnet laser is directed into the vagina and urethra, may be useful. The study aimed to compare the effects of these three treatments.

METHODS: Subjects included patients who received TVT, TOT, or laser therapy (n = 50 each). The 1-h pad test, International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), and overactive bladder symptom score were used to assess the patients before and 12 months after treatment. For laser therapy, a probe was inserted into the vagina after applying a local anesthetic to the vaginal wall, and irradiation was performed for 20 min at a wavelength of 2940 nm. This treatment was performed three times every alternate month.

RESULTS: As per the 1-h pad test and ICIQ-SF, the TVT, TOT, and laser therapy groups showed comparable improvements in SUI. For patients with MUI, some in the TVT and TOT groups showed exacerbation; however, all patients in the laser therapy group tended to improve.

CONCLUSIONS: The efficacy of laser therapy for urinary incontinence was confirmed. This is the first study to report on the effect of laser therapy on urinary incontinence in Japanese women.

Lin HY, Tsai HW, Tsui KH, An YF, Lo CC, Lin ZH, Liou WS, Wang PH., 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.* Dec;57(6):825-829.

AIM: Female pelvic floor disorders, including female stress urinary incontinence (SUI) or sexual dysfunction are notorious for affecting the quality of women's life. It is reported that laser therapy might result in collagen remodeling and improvement in tissue firmness. The study was conducted to evaluate the short-term outcome of female pelvic floor disorders treated by laser therapy.

METHODS: Women with self-reported symptoms of female pelvic floor disorders (limited to SUI and sexual dysfunction) were included in the study. The participants were treated with the Er:YAG laser or the fractional microablative carbon dioxide (CO2) laser system. The therapeutic effect was focused on SUI symptoms and sexual dysfunction.

RESULTS: There were 31 women underwent laser treatment, including 21 patients treated with Erbium:YAG laser and 10 treated with CO2 laser. In the Erbium:YAG laser group, International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ- SF) scores were dropped from 8.25 ± 5.66 to 5.00 ± 3.99 ($P = 0.007$); and in the CO2 laser group, scores were dropped from 11.11 ± 6.85 to 6.44 ± 4.25 ($P = 0.035$), contributing to the drop of ICIQ-SF scores from 9.14 ± 6.08 to 5.45 ± 4.05 for all enrolled patients ($P = 0.001$). However, objective measure using pad test did not show a statistically significant difference between before and after treatment (from 3.20 ± 5.84 g to 1.54 ± 3.18 g, $P = 0.224$). Sexual dysfunction was improved in 13 patients (44.83%), but Female Sexual Function Index (FSFI) scores were not different before and after laser treatment (44.22 ± 23.36 vs. 44.09 ± 24.51 , $P = 0.389$).

CONCLUSIONS: Laser therapy either by Erbium:YAG laser or CO2 laser seemed to be useful for female pelvic floor disorders, especially on improvement of SUI symptoms; however, the effectiveness needs further confirmation.

Gaspar, A. et al., 2018. **Intraurethral Erbium: YAG Laser for the Management of Urinary Symptoms of Genitourinary Syndrome of Menopause: A Pilot Study.** *Lasers in Surgery and Medicine*, 50(8):802-807.

AIM: Genitourinary syndrome of menopause (GSM) combines the conditions of vulvovaginal atrophy (VVA) and urinary tract dysfunction, which is a result of urethral atrophy. There are several treatment methods available for the management of vulvovaginal 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.

METHODS: Patients 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 intraurethral Er:YAG laser with a 3-week interval in- between the sessions. Laser energy was delivered in non- ablative way using Erbium SMOOTHM mode technology and a 4-mm thick cannula. Therapeutic efficacy was determined using ICIQ-SF, the 1-hour pad test and VAS scores. Occurrence of adverse effects was followed at every visit. Follow ups (FU) were at 3 and 6 months.

RESULTS: 29 female patients fulfilling the inclusion criteria were included in this pilot study and received two sessions of the intraurethral non-ablative Erbium SMOOTHM laser therapy. Significant improvement was observed in all measured parameters at both FU. ICIQ-SF improved by an average of 64% at 3 months FU and by 40% at 6 months. The 1-hour pad test showed a reduction of the quantity of leaked urine by 59% at 3 months FU and by 42% at 6 months FU. All urinary symptoms of GSM improved. Dysuria dropped to 13% and 31% of baseline values at three and 6 months respectively, urinary urgency dropped to 23% and 47% and frequency dropped to 22% and 43% after 3 and 6 months, respectively. Adverse effects were mild and transient.

CONCLUSIONS: Our findings suggest that intraurethral Er:YAG laser is an efficacious and safe modality for treatment of urinary symptoms of GSM, however, prospective, randomized, and controlled trials with larger number of patients are needed to better assess the long-term effect of this novel procedure.

Blaganje, M. et al., 2018. **Non-ablative Er:YAG laser therapy effect on SUI related quality of life and sexual function: a randomized controlled trial.** *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 224, pp.153–158.

AIM: Stress urinary incontinence (SUI) is a common complaint in women after childbirth. It affects their quality of life and sexual satisfaction and is one of the major reasons for gynaecological surgery. There is a need for effective non-invasive treatment alternatives. The aim of this study was to evaluate the efficacy and safety of non-ablative Er:YAG laser therapy in the treatment of SUI and improvement of sexual gratification in parous women.

METHODS: 114 premenopausal parous women with SUI were randomized in two groups of 57 women; a laser intervention group and sham group. Both groups were treated according to the IncontiLase1 clinical treatment protocol for SUI with non-ablative thermal-only Er:YAG laser, except that there was no energy output when treating the sham group. Patients were blinded to the allocation. 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 (PFM) function was assessed with perineometry. Validated International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) was used as the primary outcome measure. The Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire short form (PISQ-12) and The Female Sexual Function Index (FSFI) were used to assess the sexual function. Patients were monitored for discomfort and side-effects during treatment and follow-up period.

RESULTS: 3 months after treatment the ICIQ-UI SF ($p < 0.001$), PISQ-12 ($p = 0.014$) and FSFI ($p = 0.025$) scores were significantly more improved in the laser group than in the sham control group. All perineometry variables improved in the laser group after treatment; duration and maximum pressure had statistically significantly better improvement than the sham group, whereas average pressure did not. 21% of laser treated patients were dry (ICIQ-UI SF = 0) at follow up compared to only 4% of the sham control patients. No serious adverse effects were observed or reported. The treatment was well tolerated by patients.

CONCLUSIONS: The non-ablative Er:YAG laser therapy improves the impact of SUI symptoms on quality of life and sexual function in premenopausal parous women significantly better than placebo. It provides a promising minimally-invasive safe treatment alternative for SUI.

Fistonić, N. & Fistonić, I., 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 in Surgery and Medicine*, (Jan 23).

AIM: A growing body of evidence indicates that a non-invasive erbium yttrium-aluminum- garnet (Er:YAG) laser may be an effective and highly tolerable treatment for stress urinary incontinence (SUI) in women. The primary objective was to identify pre-intervention predictors of short-term Er:YAG outcomes. The secondary objective was to identify patient segments with the best Er:YAG laser treatment short-term outcomes.

METHODS: A prospective cohort study performed in 2016 at Ob/Gyn Clinic, Zagreb, Croatia, recruited 85 female patients who suffered from SUI. The intervention was performed with a 2940 nm wave length Er:YAG laser (XS Dynamis, Fotona, Slovenia). Outcomes were absolute change in the International Consultation on Incontinence Questionnaire—Short Form (ICIQ-UI SF) and a relative decrease in ICIQ-UI score of 30% 2–6 months after the intervention.

RESULTS: Age and pre-intervention ICIQ-UI values were independent significant predictors of laser treatment efficacy for SUI. A decrease in ICIQ-UI score (minimum important difference, MID) of 30% was independently significantly associated with body mass index and ICIQ-UI values before the intervention. All patients with four or five positive predictors saw a clinically relevant decrease in ICIQ-UI of 30%. The total accuracy of the predictive model defined by the area under the curve was 0.83 (95%CI 0.74–0.91). At the cut-off 3 positive predictors, C-index was 0.80 (95%CI 0.71–0.90), positive predictive value was 0.97 (95%CI 0.87–0.99), and negative predictive value was 0.53 (95%CI 0.45–0.55).

CONCLUSIONS: A relevant decrease in ICIQ-UI (MID) of 30% can be predicted based on age, body mass index, average birth weight, perineometer squeeze duration, and ICIQ-UI scores before the intervention. The association between Q-tip test and treatment outcome was moderated by age. Q-tip was a significant predictor for patients between 44 and 53 years of age. The best results should be expected in younger women with a body mass index of 23.3, average birth weight of >3.6 kg, ICIQ-UI at a baseline of 10, and perineometer squeeze duration at a baseline of 3.51 seconds. The critical age for Er:YAG laser effect is 47.5 years.

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. *Taiwanese Journal of Obstetrics & Gynecology*, 56(6), pp.815–820.

AIM: To investigate the effects of non-ablative laser treatment on overactive bladder (OAB) syndromes, stress urinary incontinence and sexual function in women with urodynamic stress incontinence (USI).

METHODS: Between April 2015 and June 2015, consecutive patients with USI with OAB syndromes underwent two sessions of Erbium:YAG laser treatment in a tertiary hospital. Patients received validated urological questionnaires, urodynamic studies, 1-h pad test and measurement of vaginal pressure before, one and three months after laser treatment. Questionnaires at 12 months were completed by telephone interview. Adverse effects and patients' satisfaction were also assessed.

RESULTS: We included 30 patients with a mean age of 52.6 ±8.8 years. Three months after therapy, mean 1-h pad test significantly decreased ($P = 0.039$). Significant improvement in OAB symptoms in four questionnaires were noted at three months post treatment, but not sustained for 12 months in two of them. Three months after therapy, mean vaginal pressure significantly improved ($P = 0.009$). Of 24 (82.7%) sexually active patients, 62.5% (15/24) and 54.2% (13/24) of their sexual partners reported improved sexual gratification three months later. No major adverse effects were noticed.

CONCLUSIONS: Erbium:YAG laser treatment can resolve USI and coexistent OAB symptoms three months after therapy. Sexual experience is also improved. However, repeated laser therapy may be necessary after six months.

Gaspar, A. & Brandi, H., 2017. **Non-ablative erbium YAG laser for the treatment of type III stress urinary incontinence (intrinsic sphincter deficiency).** *Lasers in Medical Science*, 32(3), pp.685–691.

AIM: The objective of this pilot study was to determine the safety and efficacy of a new non-ablative erbium YAG laser procedure for the treatment of type III stress urinary incontinence (intrinsic sphincter deficiency) in women.

METHODS: Twenty-two patients with a Valsalva leak point pressure less than 60 cm H₂O were recruited and treated with a non-ablative erbium laser delivering low fluence pulses inside the whole length of the urethra through a specially designed cannula. Treatment consisted of two treatment sessions with a 3-week interval in-between. Therapeutic efficacy, as assessed by a questionnaire addressing quality of life during urinary incontinence and the 1-h pad test, was measured at 3 and 6 months after the procedure.

RESULTS: Both methods of assessment showed similar levels of improvement in terms of incontinence severity and improvement in quality of life. All patients tolerated the therapy well and adverse effects were mild and transient. The results of this pilot study showed significant improvement of type III stress urinary incontinence.

CONCLUSIONS: Despite the limitations of this study, being small patient number and short follow-up, this non-ablative intraurethral erbium YAG laser procedure seems to be a safe and efficacious alternative for patients with type III stress urinary incontinence. More controlled studies should be performed to confirm this data and to evaluate the long-term effects.

Lapii, G.A., Yakovleva, A.Y. & Neimark, A.I., 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.

AIM: Structural characteristics of the vaginal mucosa in stress incontinence and its correction by IncontiLase technology were studied.

METHODS AND RESULTS: Studies of vaginal biopsy specimens before the exposure showed degenerative and atrophic changes in the stratified squamous epithelium, disorganization of fibrillary structures of the intercellular matrix, and microcirculatory disorders. Studies after Er:YAG laser exposure showed signs of neocollagenesis and elastogenesis, foci of neoangiogenesis, reduction of epithelial degeneration and atrophy, and an increase of the fibroblast population. Morphometry showed that the volume density of blood capillaries and the thickness of the epithelial layer increased by 61.1 and 64.5%, respectively.

CONCLUSION: The use of IncontiLase technology in stress incontinence led to structural reorganization of the vaginal mucosa, improving its morphology and function and alleviating the symptoms of incontinence.

Tien, Y.W. et al., 2017. Effects of laser procedure for female urodynamic stress incontinence on pad weight, urodynamics, and sexual function. *International Urogynecology Journal*, 28(3), pp.469–476.

AIM: The impact of the IncontiLase™ procedure on lower urinary tract symptoms (LUTS) remains unclear. Our aim was to evaluate the effects of the IncontiLase™ procedure for urodynamic stress incontinence (USI).

METHODS: All consecutive women with USI prospectively underwent the IncontiLase™ procedure. Urodynamic studies, pad testing, LUTS, and sexual function questionnaires were assessed before and after treatment.

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 %) improved. Among the 18 women with mild USI (i.e., baseline pad weight 1-10 g), nine (50 %) were cured and five (27.8 %) improved. Among ten women with baseline pad weight >10 g, two (20 %) were cured and six (60 %) improved. Among the 32 women with complete questionnaire data at 6 months, seven (21.9 %) were subjectively cured, and four (12.5 %) improved. Regarding LUTS, the majority of domains on the King's Health Questionnaire and female sexual desire and function exhibited significant improvements. Forty percent (12/30) of the partners of these patients felt their sexual function had improved at 6 months. Nonetheless, urodynamic values did not differ across the timeline.

CONCLUSIONS: The effect of the IncontiLase™ procedure for mild USI was moderate at 6-month follow-up but was not effective for pad weight >10 g. Moreover, it improved LUTS, quality of life, QoL, and sexual function of both partners. Further studies should be performed to assess long-term sustained efficacy.

Barber, M.A. 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.

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

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

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

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

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

Fistonić, N. et al., 2016. Minimally invasive , non-ablative Er:YAG laser treatment of stress urinary incontinence in women — a pilot study. pp.635–643.

AIM: The study presents an assessment of mechanism of action and a pilot clinical study of efficacy and safety of the Er:YAG laser for the treatment of stress urinary incontinence (SUI). The subject of this study is a treatment of SUI with a 2940 nm Er:YAG laser, operating in a special SMOOTH mode designed to increase temperature of the vaginal mucosa up to maximally 60–65 °C without ablating the epidermis.

METHODS: Numerical modelling of the temperature distribution within mucosa tissue following an irradiation with the SMOOTH mode Er:YAG laser was performed in order to determine the appropriate range of laser parameters. The laser treatment parameters were further confirmed by measuring in vivo temperatures of the vaginal mucosa using a thermal camera. To investigate the clinical efficacy and safety of the SMOOTH mode Er:YAG laser SUI treatment, a pilot clinical study was performed. The study recruited 31 female patients suffering from SUI. Follow-ups were scheduled at 1, 2, and 6 months post treatment. ICIQ-UI questionnaires were collected as a primary trial endpoint. Secondary endpoints included perineometry and residual urine volume measurements at baseline and all follow-ups. Thermal camera measurements have shown the optimal increase in temperature of the vaginal mucosa following treatment of SUI with a SMOOTH mode Er:YAG laser.

RESULTS: Primary endpoint, the change in ICIQ-UI score, showed clinically relevant and statistically significant improvement after all follow-ups compared to baseline scores. There was also improvement in the secondary endpoints. Only mild and transient adverse events and no serious adverse events were reported.

CONCLUSIONS: The results indicate that non-ablative Er:YAG laser therapy is a promising minimally invasive non-surgical option for treating women with SUI symptoms.

Pardo, J.I., Solà, V.R. & Morales, A.A., 2016. Treatment of female stress urinary incontinence with Erbium-YAG laser in non-ablative mode. *European Journal of Obstetrics Gynecology and Reproductive Biology*, 204, pp.1–4.

AIM: Objective To evaluate the efficacy of laser photothermal therapy in a group of Chilean women with SUI.

Methods: Longitudinal prospective study based on 42 women with mild-to-severe SUI, intervened with non-ablative Er:YAG laser, between July 2014 and October 2015, in Santiago, Chile. The therapy efficacy was evaluated through the difference between every patient's scores obtained, before and after treatment, with the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-SF), at a confidence level of 95%. Also, the patient satisfaction with treatment was reported through an ordinal scale.

RESULTS: ICIQ-SF median score was 11 before treatment and 3 after 6 months, with a significant difference per patient ($p < 0.001$). 78.6% ($n = 33$) reported improvement and 38.1% ($n = 16$), a complete healing of SUI at follow up. 66.7% ($n = 28$) reported high satisfaction and 81.8% ($n = 27$) of sexually active women, also reported improvement of sexual gratification. Only mild pain during the procedure was reported as adverse effect.

CONCLUSIONS: Based on this short-term pilot study, non-ablative Er:YAG laser procedure seems to be a safe and efficacious alternative for patients with SUI. Further controlled studies will help to validate the use of non-ablative Er:YAG for treatment of SUI.

Ogrinc, U.B., Senčar, S. & Lenasi, H., 2015. **Novel minimally invasive laser treatment of urinary incontinence in women.** *Lasers in Surgery and Medicine*, 47(9), pp.689–697.

AIM: Urinary incontinence (UI) is a common disorder that affects women of various ages and impacts all aspects of life. Our aim was to evaluate the non-invasive erbium:yttrium-aluminum-garnet (Er:YAG) laser that exploits its thermal effect and has been used in reconstructive and rejuvenation surgery as a potential treatment strategy for stress UI (SUI) and mixed UI (MUI).

METHODS: We included 175 women (aged 49.7 ± 10 years) with newly diagnosed SUI (66% of women) and MUI (34%), respectively. Patients were clinically examined and classified by incontinence types (SUI and MUI) and grades (mild, moderate, severe, and very severe) using International Consultation on Incontinence Modular Questionnaire (ICIQ) and assessing Incontinence Severity Index (ISI). Using Er:YAG laser, we performed on average 2.5 ± 0.5 procedures in each woman separated by a 2 month period. At each session, clinical examination was performed, ICIQ and ISI assessed and treatment discomfort measured with visual analog system (VAS) pain scale, and adverse effects and patients' satisfaction were followed. Follow-ups were performed at 2, 6, and 12 months after the treatment.

RESULTS: After the treatment, ISI decreased for 2.6 ± 1.0 points in patients diagnosed with mild UI before the treatment, for 3.6 ± 1.4 points in those with moderate UI, for 5.7 ± 1.8 points in those with severe UI and for 8.4 ± 2.6 in those with very severe UI ($P < 0.001$, paired samples t-test). Altogether, in 77% patients diagnosed with SUI, a significant improvement was found after treatment, while only 34% of women with MUI exhibited no UI at one year follow-up. Age did not affect the outcome. No major adverse effects were noticed in either group.

CONCLUSIONS: The results of our study, have shown that new non-invasive Er:YAG laser could be regarded as a promising additional treatment strategy for SUI with at least one year lasting positive effects. On the other hand, it does not seem appropriate for treating MUI.

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

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

METHODS: GSM was assessed in postmenopausal women before and after VEL (one treatment every 30 days, for 3 months; $n = 45$); 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; $n = 25$). GSM was evaluated with subjective (visual analog scale, VAS) and objective (Vaginal Health Index Score, VHIS) measures. In addition, in 19 of these postmenopausal women suffering from stress urinary incontinence (SUI), the degree of incontinence was evaluated with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) before and after VEL treatments.

RESULTS: VEL treatment induced a significant decrease of VAS of both vaginal dryness and dyspareunia ($p < 0.01$), with a significant ($p < 0.01$) increase of VHIS. In postmenopausal women suffering from mild to moderate SUI, VEL treatment was associated with a significant ($p < 0.01$) improvement of ICIQ-SF scores. The effects were rapid and long lasting, up to the 24th week of the observation period. VEL was well tolerated with less than 3% of patients discontinuing treatment due to adverse events.

CONCLUSIONS: This pilot study demonstrates that VEL induces a significant improvement of GSM, including vaginal dryness, dyspareunia and mild to moderate SUI. Further studies are needed to explore the role of laser treatments in the management of GSM.

Khalafalla, M.M. et al., 2015. **Minimal Invasive Laser Treatment for Female Stress Urinary Incontinence.** *Obstetrics & Gynecology International Journal*, 2(2).

AIM: Stress urinary incontinence (SUI) is common health problem and affects quality of life. This study was designed to evaluate minimal invasive laser as treatment option for female SUI.

METHODS: Fifty (50) women with SUI were included in this study which was conducted over one year. A specially designed laser speculum was introduced into women's vagina to serve as a guide for insertion of hand piece for irradiation of anterior vaginal wall. Second phase of the IncontiLase™ procedure was performed on the vestibule and introitus. Preoperative and 6 months post- operative urodynamic studies were done for all studied women.

RESULTS: Average flow rate was significantly improved from 3 ml/second before treatment to 11 ml/second after laser treatment and voiding time was also significantly improved from 9 seconds before treatment to 24 seconds after treatment. Residual urine volume was significantly increased from 17 ml before treatment to 38 ml after treatment, and first sensation was also significantly increased from 54 ml before treatment to 122 ml after treatment. First desire was significantly increased from 75 ml before treatment to 180 ml after treatment and strong desire was also significantly increased from 150 ml before treatment to 250 ml after treatment. Maximal urethral closure pressure was significantly increased from 16 cm H₂O before treatment to 34 cm H₂O after treatment.

CONCLUSIONS: Minimal invasive laser is outpatient procedure, has the advantage of improving of SUI symptoms without any possible complications as bladder perforation or hematoma. Also, it improves vaginal mucosa tone, regenerates collagen and collagen regains its power to contract with subsequent stabilization of bladder neck.

Fistonić, 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 1:37-42.

AIM: This is the first assessment of efficacy and safety of the Er:YAG laser in the treatment of stress urinary incontinence. The aim of this study was to assess the short-term outcome of a non-invasive laser treatment for mild-to-severe stages of this condition and to check its applicability in different body mass index, and age groups.

METHODS: A prospective cohort, single-center study at the Ob/Gyn Clinic, Zagreb, Croatia recruited a consecutive sample of 73 female patients suffering from stress urinary incontinence. The procedure was performed with a 2940-nm Er:YAG laser (XS Dynamis, Fotona, Slovenia) designed to achieve heating up of vaginal mucosa to around 60°C, 500–700 µm in depth.

RESULTS: The score in the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form was reduced to a median of 46% (95% confidence interval 33–67%; p 0.001). The reduction was significantly higher in women with normal body mass index (67%) than in overweight women (25%), as well as in women younger than 39 years (100%) compared with those older than 60 years (8%) (p 0.001). No serious adverse events were noticed.

CONCLUSIONS: This study of Er:YAG laser therapy in women has demonstrated a clinically relevant, short-term improvement of stress urinary incontinence, with minimal adverse events of a transient nature.

Fistonić, I., Štefica, F.G. & Fistonić, N., 2012. Minimally invasive laser procedure for early stages of stress urinary incontinence (SUI)., *Journal of the Laser & Health Academy*, 2012(1), pp.67-74.

AIM: The objective of this labeled, prospective, single-center pilot study was to assess the efficacy and safety of a novel minimally invasive, non-ablative laser treatment in the early stages of SUI.

METHODS: A total of 39 patients suffering from mild-to-moderate stress urinary incontinence underwent treatment with an Er:YAG (2940 nm) laser in non-ablative fractional mode. Assessment tools included the ICIQ-UI SF questionnaire for assessing the degree of incontinence and its impact on the quality of life, the Q-tip test for evaluating the mobility of the urethra and bladder neck, PISQ-12 for assessing quality of life in the area of sexuality, and perineometry for the measurement of muscle strength. Follow-ups were scheduled after 1 month for 39 patients, after 3 months for 22 patients and after 6 months for 6 patients.

RESULTS: Preliminary results of post-treatment evaluation showed significant improvement ($p < 0.05$) in all the domains tested: ICIQ-UI scores decreased by more than 3 points at all follow-ups. A mean duration of muscle contraction measured with perineometry at 1 month increased by 4.7 s, at 3 months by 11.8 s and at 6 months by 22.8 s. Q-tip angle decreased by 14.7° at 1 month follow-up, by 15.9° at 3 months and by 22.5° at 6 months. PISQ-12 scores increased after 1 month by 5.4 points, after 3 months by 5.9 points and after 6 months by 6.6 points.

CONCLUSION: The preliminary results confirm that a minimally invasive, non-ablative fractional laser treatment (IncontiLase™) is an effective, safe and comfortable treatment option for symptom relief in patients with mild and moderate SUI.

Zdenko Vizintin, Mario Rivera, Ivan Fistonić, Ferit Saraçoğlu, Paolo Guimares, Jorge Gaviria, Victor Garcia, Matjaz Lukac, Tadej Perhavec, L.M., 2012. Novel Minimally Invasive VSP Er:YAG Laser Treatments in Gynecology. *Journal of the Laser & Health Academy*, 2012(1), pp.46-58.

ABSTRACT: Some of the most common health problems among women that are caused by a deteriorating laxity, elasticity and tightness of mucous membranes are vaginal relaxation (and the associated loss of sexual gratification) and stress urinary incontinence. Recently, two novel minimally invasive, non-ablative Er:YAG laser techniques have been introduced, a vaginal tightening therapy IntimaLase™ and a stress urinary incontinence therapy IncontiLase™, which show the potential to become an optimal solution for many women suffering from these problems. Both treatment techniques exploit the photothermal effect of a laser beam on mucosa tissue in order to cause its shrinkage without any removal of tissue. The overall impact and burden on the patient's organism is thus minimal, as opposed to more invasive classical or laser surgical procedures.

Er:YAG Fotona SMOOTH® Treatment for Vaginal Laxity

Gaviria P, J.E. et al., 2016. Up to 3-year Follow-up of Patients with Vaginal Relaxation Syndrome Participating in Laser Vaginal Tightening. *Journal of the Laser & Health Academy*, 2016(1), pp.1-6.

ABSTRACT: Vaginal Relaxation Syndrome (VRS) is defined as a laxity of the vaginal wall due to changes in connective tissue, usually associated with the normal aging process. Laser vaginal tightening with non-ablative, minimally invasive Er:YAG laser using the IntimaLase® protocol has been performed in our practice since 2011, with over 1000 patients treated since then. After 3 years of performing laser treatments, a telephone follow up of 60 patients was performed to overview the results and to evaluate the long-term efficacy of laser vaginal tightening. Telephone interviews were obtained asking patients to answer the LVT questionnaire and self-assess the efficacy of the IntimaLase® laser vaginal tightening treatment, based on 6, 12, 18, 24 and 36-month follow ups. According to the patients' evaluation of the results, the average duration of effect after the therapy was 16 months, with significant improvement of stress urinary incontinence and prolapse. Adverse effects were limited to mild and transient edema and a tolerable heating sensation in a few cases. Further, results also showed that 83.33% of participants would be willing to repeat the therapy. From our observation we can suggest that two treatments are sufficient for obtaining a long-lasting improvement of vaginal relaxation syndrome, and a follow-up evaluation visit 8 months after the second treatment would be recommended, followed by a maintenance session if needed. The vast majority of patients find the concept of IntimaLase® therapy appealing, and the brief and painless ambulatory procedure motivates them to comply with a yearly maintenance.

Pardo, J.I. & Dalenz, V.S., 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.

BACKGROUND AND AIM: The main reason patients seek vaginal tightening surgery is because they feel loose or large and/or wish to increase friction and enhance sexual pleasure for themselves and their partner. In light of the possible side effects of surgery, there is a need for an effective minimally-invasive treatment. Non-ablative, thermal-only, minimally invasive Laser Vaginal Tightening (LVT) was evaluated in 50 consecutive patients in our practice.

METHODS: All patients were treated using 2940 nm Er:YAG laser according to the IntimaLase® protocol for LVT. Patient satisfaction after the procedure was evaluated by a questionnaire 1-8 months after the procedure. Patients were asked to rate their satisfaction with the LVT procedure and to rate the improvement of their sexual satisfaction after the procedure on a scale from 0 to 10. They were also asked whether they would be willing to repeat the procedure and whether they would recommend the procedure to others. 42 out of 50 patients (84%) responded to the questionnaire. The mean level of improvement in sexual satisfaction was 7 (SD=3.1) and the mean level of satisfaction with the LVT procedure was 7.5 (SD=3.1). 34 patients (81%) would be willing to repeat the procedure and recommend the procedure to others. There were no side effects.

CONCLUSIONS: Non-ablative LVT should be offered to patients who seek surgery because of a sensation of wide vagina. Most patients are likely to be satisfied with the results of LVT and thus avoid the risks and/or cost of surgery.

Gaviria P, J.E. et al., 2012. **Laser Vaginal Tightening (LVT) – evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome.**, *Journal of the Laser & Health Academy*, 2012(1), pp.59–66.

AIM: The objective of this study was to evaluate the safety and efficacy of a novel laser treatment for vaginal relaxation syndrome.

METHODS: A pilot study was conducted on 21 patients who received the novel laser treatment (IntimaLase) for vaginal tightening with a 2940 nm Er:YAG laser between June 2011 and January 2012. All patients received two treatment sessions with an interval between sessions of 15 to 30 days. In a non-ablative, thermal-only mode, laser energies of approx. 90 J per treated area in the vaginal canal and of approx. 10 J per treated area at the vestibule and introitus were delivered to the patient's vaginal mucosa. A special Laser Vaginal Tightening (LVT) questionnaire was designed for assessing the improvement of vaginal tightness via patient self-evaluation and by their sexual partner's assessment. POP-Q measurements were also performed prior to both treatment sessions in an attempt to objectively assess the change in vaginal tissue structure. Additionally, a PISQ-12 questionnaire was also used as a standard assessment tool for pelvic organ prolapse, urinary incontinence and sexual gratification. Patients were also asked about treatment discomfort, potential adverse effects, and their general satisfaction with the treatment.

RESULTS: Twenty of twenty one patients (95%) reported significant (moderate and strong) improvement of their vaginal tightness, and also all of their partners confirmed an improvement of vaginal tightness during sexual intercourse (85% reported significant improvement and 15% reported mild improvement). All patients but one (95%) reported better sex after the treatment. Five patients had prolapses (of stages 1-3) before receiving the treatment, which improved in all of these patients, leaving just two of them with prolapses (one with stage 1 and one with stage 2). Three patients suffering from SUI before the treatment reported significant improvement (2) and complete healing (1). There were no adverse effects and patient discomfort was assessed as minimal.

CONCLUSIONS: The novel laser vaginal tightening therapy (IntimaLase) is an effective and safe method for the treatment of vaginal relaxation syndrome.

Er:YAG Fotona SMOOTH® Treatment for Genitourinary Syndrome of Menopause

Gambacciani, M. et al., 2018. Long-term effects of vaginal erbium laser in the treatment of genitourinary syndrome of menopause. *Climacteric*, 21(2):148-152.

AIM: To evaluate the long-term efficacy of a second generation of vaginal laser treatment, the vaginal erbium laser, as a non-ablative photothermal therapy for the management of genitourinary syndrome of menopause.

METHODS: The study was performed using an erbium laser crystal yttrium-aluminum-garnet (XS FotonaSmooth™, Fotona, Ljubljana, Slovenia) with a wavelength of 2940nm. Postmenopausal women (n=205) were treated with three laser applications at 30-day intervals. Symptoms were assessed before and after treatment throughout 24 months, using the subjective visual analog scale (VAS) and the objective vaginal health index score (VHIS). In addition, postmenopausal women suffering from stress urinary incontinence were evaluated with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF).

RESULTS: Vaginal erbium laser treatment induced a significant ($p < 0.01$) decrease in VAS for both vaginal dryness and dyspareunia, as well an increase in VHIS ($p < 0.01$) up to the 12th month after the last laser treatment. The values returned to levels similar to the baseline after 18 and 24 months. In addition, vaginal erbium laser treatment improved mild-moderate stress urinary incontinence in 114 postmenopausal women. Less than 3% of patients discontinued treatment due to adverse events.

CONCLUSIONS: These results suggest that vaginal erbium laser may be effective and safe for the treatment of genitourinary syndrome of menopause.

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

AIM: The objective of this prospective comparative cohort study was to establish the effectiveness and safety of Erbium:YAG (Er:YAG) laser treatment for genitourinary syndrome of menopause and to compare it with an established topical estriol treatment.

METHODS: Fifty patients with genitourinary syndrome of menopause were divided into two groups. The estriol group received a treatment of 0.5 mg estriol ovules for 8 weeks and the laser group was first treated for 2 weeks with 0.5 mg estriol ovules 3 times per week to hydrate the mucosa and then received three sessions with 2,940 nm Er:YAG laser in non-ablative mode. Biopsies were taken before and at 1, 3, 6, and 12 months post-treatment. Maturation index, maturation value and pH were recorded up to 12-months post-treatment, while the VAS analysis of symptoms was recorded up to 18 months post-treatment.

RESULTS: Statistically significant ($P < 0.05$), reduction of all assessed symptoms was observed in the laser group at all follow-ups up to 18 months post-treatment. Significant improvement in maturation value and a decrease of pH in the laser group was detected up to 12 months after treatment. The improvement in all endpoints was more pronounced and longer lasting in the laser group. Histological examination showed changes in the tropism of the vaginal mucosa and also angiogenesis, congestion, and restructuring of the lamina propria in the laser group. Side effects were minimal and of transient nature in both groups, affecting 4% of patients in the laser group and 12% of patients in the estriol group.

CONCLUSIONS: Our results show that Er:YAG laser treatment successfully relieves symptoms of genitourinary syndrome of menopause and that the results are more pronounced and longer lasting compared to topical estriol treatment.

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. *The Journal of North American Menopause Society*, 24(3), pp.316–319.

AIM: The aim of this study was to evaluate the efficacy and acceptability of a second generation of vaginal laser treatment, the vaginal erbium laser, as a nonablative photothermal therapy for the management of genitourinary syndrome of menopause in postmenopausal breast cancer survivors.

METHODS: The study was performed using an erbium laser crystal yttrium-aluminum-garnet (XS FotonaSmooth™, Fotona, Ljubljana, Slovenia) with a wavelength of 2,940 nm. Forty-three postmenopausal breast cancer survivors were treated with three laser applications every 30 days. Symptoms were assessed 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). The procedures were performed on an outpatient basis without anesthesia or drug use before or after the intervention.

RESULTS: From baseline values of 8.5 1.0 cm, vaginal dryness VAS scores were 4.4 1.2 cm after the third treatment and 5.5 1.5 cm 12 months after the treatment ($P < 0.01$ vs basal values), whereas they were 7.5 1.8 cm after 18 months from the last laser application (NS vs basal values). From baseline values of 7.5 1.5 cm, dyspareunia VAS values decreased to 4.2 0.9 cm after the third treatment and 5.1 1.8 cm 12 months from the last laser application ($P < 0.01$ vs basal values), whereas they were 6.5 1.8 cm after 18 months from the last laser application (NS vs basal values). VHIS, from baseline values of 8.1 1.3, was 21.0 1.4 after the third treatment and 18.8 1.2 months from the last laser application ($P < 0.01$ vs basal values), whereas they were 14.8 1.5 cm after 18 months from the last laser application (NS vs basal values). No adverse events were recorded during the study.

CONCLUSIONS: This study suggests that the vaginal erbium laser is effective and safe for the treatment of genitourinary syndrome of menopause in breast cancer survivors.

Bojanini, J.F., 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 & Health Academy*, 2016(1), pp.35–40.

BACKGROUND AND AIM: Genitourinary syndrome of menopause (GSM) affects up to 50% of postmenopausal women. It can be especially severe in breast cancer survivors after therapy-induced menopause. The aim of this study was to collect data on the safety, efficacy and satisfaction of patients with Er:YAG laser vaginal treatment and to assess whether the result of the laser treatment for GSM is similar when performed either in women after menopause induced by treatment of breast cancer or in women after natural menopause.

METHODS: 40 patients with genitourinary syndrome of menopause were admitted in the study: 20 patients with no history of breast cancer (group A) and 20 patients with a history of breast cancer (group B). The patients in group A were randomly divided into two sub-group A1 and A2. Patients in group A1 received vaginal preparation with 0,5mg estriol topically 3 times per week for 2 weeks before laser treatment to hydrate the vaginal mucosa. Patients in group A2 and B received vaginal preparation with platelet rich plasma (PRP) injections two weeks before laser treatment. After vaginal preparation all three groups of patients were treated with 2 sessions of RenovaLase laser

treatment (2940 nm Er:YAG laser in non-ablative mode). Patients were followed for 12 months. The effects of laser on dyspareunia, dryness and frequency of intercourse avoidance were assessed. Patients were also asked about their satisfaction with the treatment.

RESULTS: Statistically significant reduction of vaginal dryness and dyspareunia was observed in all three groups at all follow-ups up to 12 months post-treatment. Also improvement in patients' sexual life measured by patient evaluation of intercourse avoidance was statistically significant in all three groups at all follow-ups. There were no serious side effects noted. Patients were highly satisfied with the treatment.

CONCLUSIONS: Laser treatment is successful in reducing GSM symptoms in women with natural menopause and also in women with therapy-induced menopause.

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

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

METHODS: GSM was assessed in postmenopausal women before and after VEL (one treatment every 30 days, for 3 months; n = 45); 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; n = 25). GSM was evaluated with subjective (visual analog scale, VAS) and objective (Vaginal Health Index Score, VHIS) measures. In addition, in 19 of these postmenopausal women suffering from stress urinary incontinence (SUI), the degree of incontinence was evaluated with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) before and after VEL treatments.

RESULTS: VEL treatment induced a significant decrease of VAS of both vaginal dryness and dyspareunia ($p < 0.01$), with a significant ($p < 0.01$) increase of VHIS. In postmenopausal women suffering from mild to moderate SUI, VEL treatment was associated with a significant ($p < 0.01$) improvement of ICIQ-SF scores. The effects were rapid and long lasting, up to the 24th week of the observation period. VEL was well tolerated with less than 3% of patients discontinuing treatment due to adverse events.

CONCLUSIONS: This pilot study demonstrates that VEL induces a significant improvement of GSM, including vaginal dryness, dyspareunia and mild to moderate SUI. Further studies are needed to explore the role of laser treatments in the management of GSM.

Bojanini, J.F. & Mejia C, A.M., 2014. **Laser Treatment of Vaginal Atrophy in Post-menopause and Post-gynecological Cancer Patients.**, *Journal of the Laser & Health Academy*, 2014(1), pp.65-71.

BACKGROUND: Between 4 and 6 of every 10 women undergoing menopause suffer from symptoms related to vaginal atrophy. Dyspareunia, in relation to vaginal dryness, can lead to sexual dysfunction. Vaginal hormone treatment has been regarded as the ideal treatment for vaginal atrophy management. Laser treatment is used to reduce the symptoms generated by vaginal atrophy, and to offer patients an alternative to traditional hormone replacement therapy that minimizes or eliminates the present risks.

AIM: The objective of this interventional, prospective study is to analyze data about laser treatment for vaginal atrophy in women with natural menopause in comparison to women with menopause induced by the treatment of cancer of gynecological origin. All patients were treated at the Ginestetica Laser Center. The study's procedures were always ambulatory. Periodic control was made up to 3 months after the laser treatment.

RESULTS: The vaginal atrophy laser treatment results are similar for all treatment groups, independent of whether or not the patient had gynecological cancer. Before treatment, all patients reported to have severe vaginal dryness and severe dyspareunia, and 97.5% of patients avoided having sex as a result of the symptoms. At 3 months post laser treatment, 70% of the patients reported not having vaginal dryness and 30% claimed to have only mild vaginal dryness; 90% of the patients said they did not have dyspareunia and no longer avoided sexual intercourse, while only 10% of the patients remained with mild dyspareunia and rare sex avoidance.

CONCLUSIONS: Laser treatment is an excellent alternative for vaginal atrophy symptoms management in menopausal women as well as in post-gynecological cancer patients.

Er:YAG Fotona SMOOTH® Treatment for Prolapse

Ogrinc, U.B. & Sencar, S., 2017. **Non-ablative vaginal erbium YAG laser for the treatment of cystocele.** *Italian Journal of Gynaecology and Obstetrics*, 29(1), pp.19–25.

AIM: the aim of the study was to evaluate the effects of Vaginal Erbium Laser (VEL), a non-ablative solid state erbium-doped yttrium-aluminum-garnet crystal (Er:YAG) laser treatment for reduction of prolapses.

METHODS: in this prospective cohort study, 61 patients with cystoceles of grades II–IV were submitted to 2–5 treatments with a non-ablative VEL laser at 2-month intervals. At baseline and 2, 6 and 12-month follow-ups, prolapses were photographed and graded using the Baden-Walker scale during a physical examination. Patients were interviewed at each follow-up about adverse effects and their satisfaction. Pain during treatment was measured on a 10-point visual analog scale (VAS).

RESULTS: at baseline 40 patients presented with grade II cystoceles, 15 with grade III and 6 with grade IV cystoceles. At the final follow-up, the grade of prolapse was reduced by at least one grade in 95% of patients, with 85% of patients presenting with grade 0 or I prolapses and the remaining 15% of patients with grade II prolapses. Most patients were either very satisfied (57%) or satisfied (33%) with the treatment. Treatment discomfort was low (0.5 VAS). No major adverse effects were reported.

CONCLUSIONS: the results of this pilot study show that the non-ablative VEL treatment may improve cystoceles with minimal patient discomfort and no adverse effects. If these preliminary results will be confirmed in a properly designed, controlled study, then VEL could be considered in selected cases as a minimally-invasive alternative to surgery.

Vizintin, Z. et al., 2015. **Erbium laser in gynecology.** *Climacteric*, 18(September), pp.4–8.

ABSTRACT: The aim of this paper is to present a novel laser technology utilizing the erbium YAG laser for various minimally invasive, non-surgical procedures in gynecology. Non-ablative, thermal-only SMOOTH-mode erbium pulses are used to produce vaginal collagen hyperthermia, followed by collagen remodelling and the synthesis of new collagen fibers, resulting in improved vaginal tissue tightness and elasticity. This erbium laser technology is used for treatments of vaginal laxity, stress urinary incontinence, pelvic organ prolapse and vaginal atrophy. In the period from 2010 to 2014, several clinical studies covering all four indications were conducted with the aim to prove the efficacy and safety of this novel technology. An overview is presented of the results of these studies where several objective as well as subjective assessment tools were used. The results have shown that SMOOTH-mode erbium laser seems to be an effective and safe method for treating vaginal laxity, stress urinary incontinence, pelvic organ prolapses and vaginal atrophy.

Other gynecological indications

Bizjak Ogrinc U, Senčar S, Luzar B, Lukanović A., 2019. **Efficacy of Non-ablative Laser Therapy for Lichen Sclerosus: A Randomized Controlled Trial.** *J Obstet Gynaecol Can.* Apr 11. pii: S1701-2163(19)30081-7. doi: 10.1016/j.jogc.2019.01.023.

AIM: The aim of this randomized controlled trial was to evaluate the safety and efficacy of neodymium: yttrium aluminum garnet laser treatment of lichen sclerosus (LS) by comparing it with topical corticosteroid treatment.

METHODS: A total of 40 female patients with vulvar LS were randomized 1:1 into a study (laser) group and a control (topical corticosteroids) group. The laser group received three laser treatments. Blinded evaluators evaluated biopsies and graded improvement on clinical photographs at baseline and at 3 months. Patients graded the intensity of symptoms on a 0 to 10 visual analogue scale at baseline and 1-, 3-, and 6-month follow-up. Patients also rated the tolerability of laser treatments, and side effects were monitored. (Canadian Task Force classification I)

RESULTS: Laser treatment discomfort was on average 1.5 of 10 on the visual analogue scale. At 1- and 3-month follow-up, patients in the laser group had significantly greater improvement in LS symptoms (burning, itching, pain, and dyspareunia), better patient satisfaction, and greater reduction of sclerosis than patients in the topical corticosteroid group. At 6-month follow-up, the improvement of symptoms in the laser group was still significant. The correct order of photographs (before and after treatment) was assigned significantly more often in the laser-treated patients compared with the control group.

CONCLUSIONS: Laser therapy for LS caused minimal patient discomfort during the treatment, with no adverse effects, and demonstrated better efficacy than in the control group, with significant improvement lasting up to 6 months. Laser therapy is a promising option for patients not responding to topical corticosteroid therapy or patients wishing to reduce long-term corticosteroid maintenance use.

Gómez-Frieiro M, Laynez-Herrero E., 2019. **Use of Er:YAG laser in the treatment of vulvar lichen sclerosus.** *Int J Womens Dermatol*, In press. Available online 4 June 2019.

AIMS: The aim of this research was to evaluate the efficacy and safety of Er:YAG laser for the improvement of signs and symptoms of vulvar lichen sclerosus.

METHODS: The study population was 28 women with symptomatic vulvar lichen sclerosus. Three non-ablative thermal-only Er:YAG laser treatment sessions (7 J/cm², 2 Hz, 7 mm spot) were performed at 4 weeks intervals. Each patient was asked about the presence of symptoms such as itching, pain and coital pain. Clinical diagnosis was established based on presence of lesions such as hypopigmentation, ecchymosis, hyperkeratosis, excoriations or fissures. Affected areas were divided by zones (clitoris, introitus, labia minora, labia majora, perineum, labial fusion, and effacement) and were visually evaluated. Based on the presence of symptoms, lesions and affected zones, a scale with a maximum of 14 scores was established for use before and after treatment. The impact of lichen sclerosus on patients' life before and after treatment was evaluated with 11-point VAS, and at each session treatment discomfort was assessed.

RESULTS: After analysis of each component of the scoring, individual statistically significant reductions were observed in itching, pain, ecchymosis, excoriations and hypopigmentation.

CONCLUSIONS: The Er:YAG laser is a safe, well tolerated and effective method for the adjuvant treatment of vulvar lichen sclerosus. Three sessions with monthly intervals using the indicated parameters are able to obtain a quantified

Erel TC., 2018. **Case report: Vulvodynia treated with Erbium:YAG laser.** *Eur J Obstet Gynecol Reprod Biol.* Dec;231:280-281.

AIM: The aim of this case report is to present a successful application of Fotona SMOOTH mode Er:YAG laser in treatment of vulvodynia.

In a 43 years old woman, the presenting symptom was pain just on the posterior commissure. She described the pain as something tearing during penile penetration. Her pain just started 6 months after her last delivery. But in the last 6 months the severity of the pain increased. Four years prior she had been treated by topical clotrimazole cream and vaginal tablet for several times. Then local 0.05% clobetasole cream was applied. Before the coital activity, she was said to use 5% lidocaine cream. Her psychiatrist prescribed her venlafaxine 150 mg, in order to relieve her depression and vulvodynia. Finally a gynecologist also offered her vestibulectomy as a treatment alternative.

METHODS: In the first step the fractional Fotona SMOOTH mode Er:YAG Laser beam was directed to the area where pain was provoked with the cotton tip. A PS03 handpiece was used with a fluence of 10 J/cm², 1.6 Hz, 7 mm with 4 shots in each spot. Four passes were performed during the two sessions performed at 4 weeks apart. Secondly, the Er:YAG laser beam was directed onto the episiotomy scar in order to improve the appearance of her perineum aesthetically. Three sessions at four weeks apart were performed. In each session, the PS03 handpiece was applied by using the short-pulse energy mode, 5 J/cm², 5 Hz, 5 mm with 4 shots in each spot, with 2 or 3 passes. In addition to that, the Er:YAG laser in Fotona SMOOTH mode with the PS03 handpiece was used with an energy of 10 J/cm², 1.6 Hz, 7 mm with 4 shots in each spot.

RESULTS: Eight months after the treatment, she was cured; her VAS score was 0 and her FSFI score was 25. Her perineum was found to be improved.

CONCLUSIONS: Although the treatment mechanism of the laser is not fully understood in vulvodynia, the temperature increase in the target tissue can trigger the production of HSP70 and inturn, of TGF-B, FGFs, EGF, PDGF, VEGF which induce the neocollagenogenesis and neoangiogenesis.





Short drafts of selected
scientific publications

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

Authors: *Urška 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 solution. 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.



Efficacy and safety of non-ablative vaginal erbium:YAG laser treatment as a novel surgical treatment for overactive bladder syndrome: comparison with anticholinergics and $\beta 3$ -adrenoceptor agonists.

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 $\beta 3$ -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.

Authors: Nobuo Peter Okui

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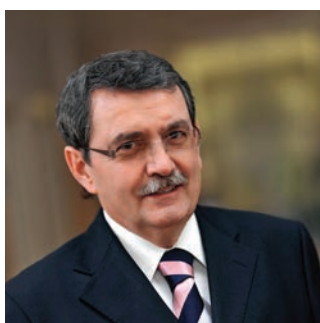
Published in: *World J Urol.*
2019 Jan 28.



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

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

Published in: *European Journal of Obstetrics & Gynecology and Reproductive Biology*.2018(224):153-158



OPEN  ACCESS

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.

Long-term Effects of Vaginal Erbium Laser in the Treatment of Genitourinary Syndrome of Menopause

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.

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

Published in
Climacteric.2018;1-5



IncontiLase® is an effective and durable non-invasive treatment for stress urinary incontinence – study in 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 in the use of lasers in medicine and biology.

2. LARGE GROUP OF TREATED PATIENTS

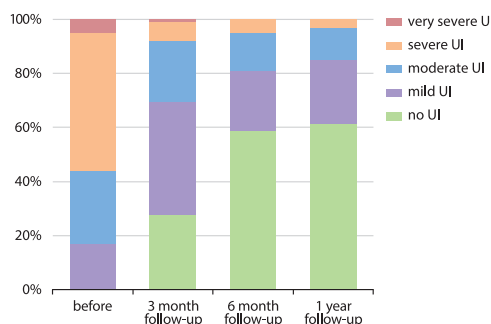
The prospective trial included 175 patients, who received 2-3 sessions of IncontiLase® treatment and were followed up to 12 months post-treatment. The study assessments included ICIQ questionnaire and ISI incontinence severity index determination, patient satisfaction questionnaire and VAS pain scale.

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.

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

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.

Authors: Urska B. Ogrinc and Sabina Sencar

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

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.

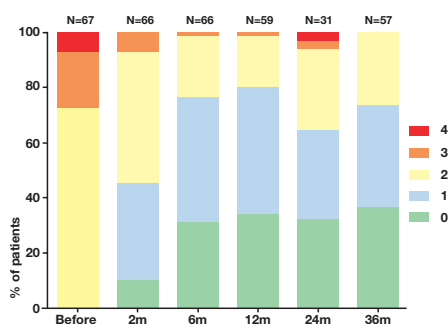


3. EXCELLENT RESULTS

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.



OPEN  ACCESS

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

Authors: Yi-Wen Tien, Sheng-Mou Hsiao, Chien-Nan Lee, and Ho-Hsiung Lin

Published in: *International Urogynecology Journal*. 2017;28(3):469-476

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

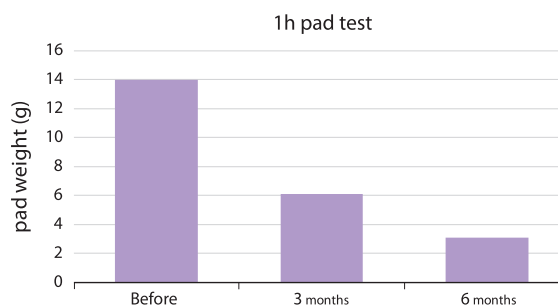
Thirty-two patients with mild, moderate, and severe SUI were treated once and followed for 3 and 6 months. Urodynamic studies, LUTS, and sexual function questionnaires (PBCC, USS, KHQ, and others) were assessed before and after the treatment.

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.



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

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)

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



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



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

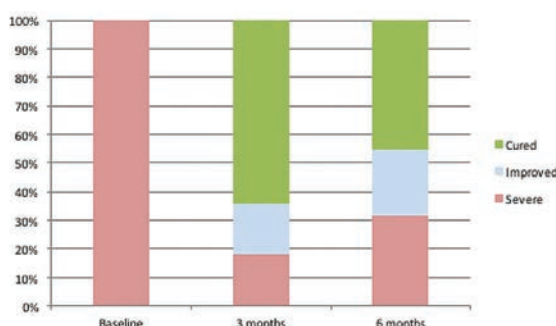
Twenty-two patients having diagnosed ISD participated in the study and were treated with the laser throughout the whole length of the urethra through a specially designed cannula. Treatment consisted of two laser sessions with a 3-week interval in-between. Therapeutic efficacy was assessed by the ICIQ-SF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

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

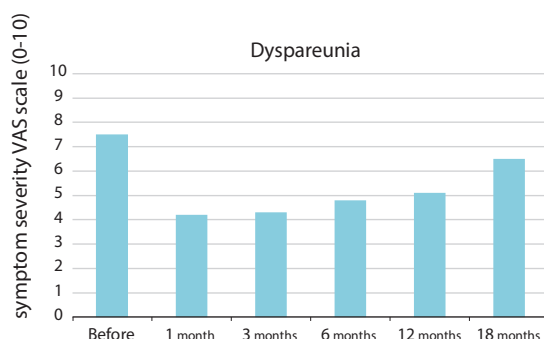
Forty-three postmenopausal breast cancer survivors received 3 RenovaLase® treatments with 30 days in-between the sessions. Symptoms were evaluated before the treatment and after 1, 3, 6, 12, and 18 months using two methods: subjective Visual Analog Scale (VAS) and objective Vaginal Health Index Score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



OPEN ACCESS

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



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.

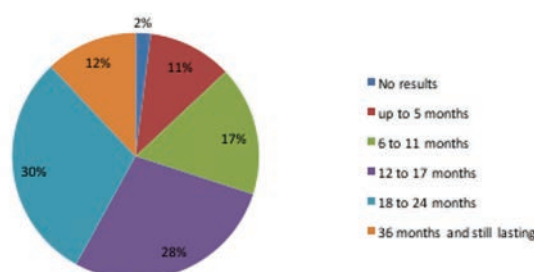
3. GREAT RESULTS

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



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 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



OPEN  ACCESS

IntimaLase® – an effective treatment for vaginal relaxation syndrome

Authors: Jorge E. Gaviria,
Jose A. Lanz

Published in: LAHA Journal
of Laser and Health Academy,
2012(1); 46-58.



1. PIONEERING STUDY OF NON-INVASIVE LASER VAGINAL TIGHTENING - INTIMALASE®

Published in LAHA (Journal of the Laser and Health Academy), an international peer reviewed journal that follows new trends in laser medicine.

2. TREATMENT OF VAGINAL RELAXATION SYNDROME WITH THE AIM OF IMPROVING SEXUAL LIFE

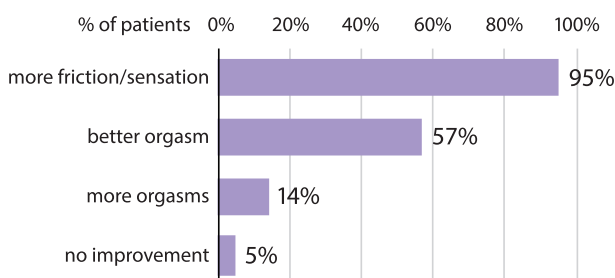
Vaginal Relaxation Syndrome is described as a loss of the optimal vaginal structure and is usually associated with vaginal child delivery and natural aging. Loss of vaginal tightness is directly related to reduction of friction during intercourse and thus to a decrease or loss of sexual gratification.

3. MATERIALS AND METHODS

21 patients suffering from vaginal looseness were treated with erbium gynecological laser (Fotona, Slovenia). Treatment consisted of two sessions with an interval between the sessions 15 to 30 days.

4. INTIMALASE® TREATMENT STRONGLY IMPROVES SEXUAL GRATIFICATION OF PATIENTS AND THEIR PARTNERS

95% of patients assessed their vaginal tightness and sexual gratification as strongly or moderately improved after laser vaginal tightening. All patients' sexual partners recognized the improvement in sensation, 85% assessing it as moderate or strong.



Patients' assessment of sexual gratification improvement after IntimaLase treatment.

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

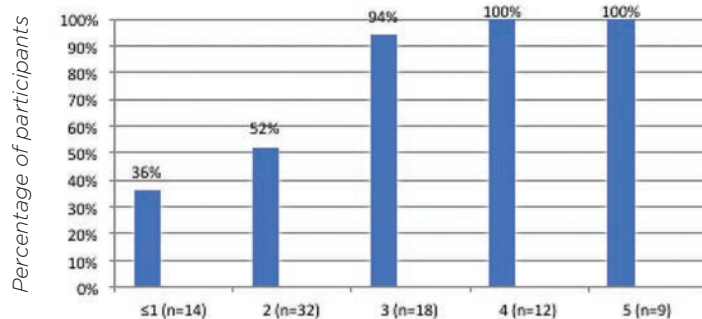
An analysis was performed on a sample of 84 female patients ranging in age from 30 to 70 who suffered from SUI. The patients were treated with a 2940 nm wavelength Er:YAG Fotona laser. In a three-step protocol (30 days in between), the laser irradiation was applied to the anterior vaginal wall, the entire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



Number of positive predictors

Authors: Ivan Fistonic and Nikola Fistonic

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Published in: *Lasers in Surgery and Medicine*.2018;50(1):1-7



RenovaLase® treatment induces significant improvement of genitourinary syndrome of menopause (GSM)

Authors: M. Gambacciani, M. Levancini and M. Cervigni
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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)

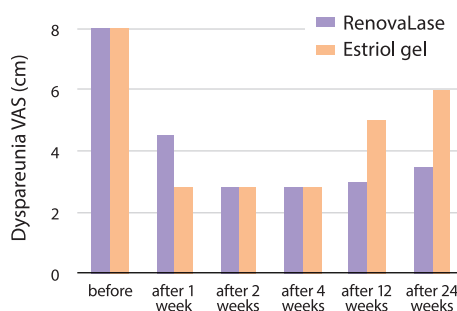
GSM (or vulvovaginal atrophy) is a chronic condition, which affects up to half of all postmenopausal women. Symptoms of GSM include dryness, burning, irritation, lack of lubrication and impaired sexual function. Traditional treatments have been limited to local or systemic estrogen therapy.

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 (1g of vaginal gel containing 50 Qg 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.

RenovaLase® treatment reduces the symptoms of Genitourinary Syndrome of Menopause (GSM) in Breast Cancer Survivors

1. IMPORTANT PILOT STUDY IN A SPECIFIC PATIENT POPULATION

The genitourinary syndrome of menopause (or vulvovaginal atrophy) affects almost half of all postmenopausal women. Because local hormone replacement therapy is contraindicated in women with a history of estrogen-dependent tumors, till now there was no single agent which could ameliorate the quality of life for this patients.

2. MATERIALS AND METHODS

13 postmenopausal women with the presence of GSM and a history of treated breast cancer were treated with Erbium gynecological laser (Fotona, Slovenia). Patients received 3 laser sessions, each 30 days apart. Subjective symptoms (vaginal dryness and dyspareunia) were assessed using a visual analogue scale (VAS) and Vaginal Health Index Score (VHIS) was calculated.

3. RENOVALASE® TREATMENT INDUCES SIGNIFICANT IMPROVEMENT OF GSM

Vaginal dryness and dyspareunia scores were progressively decreased following RenovaLase® treatment. The results were maintained at all follow-ups. Vaginal Health Index Score (VHIS) was significantly increased after treatment and the results were maintained at all follow-ups. There were no adverse events reported.

4. RENOVALASE® IS EFFECTIVE AND SAFE TREATMENT OF GSM IN POSTMENOPAUSAL BREAST CANCER SURVIVORS

Significant reduction of GSM symptoms in breast cancer survivors is a revolutionary step-up in improving the long-term quality of life of this group of women. More studies in specific post-cancer patients are needed to fully assess the potential of RenovaLase® in specific groups of cancer survivors.

Authors: M. Gambacciani,

M. Levancini

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Published in *Ital Journal*

Gynaecol Obstet.

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List of published clinical studies using the Fotona SMOOTH® Er:YAG laser treatment in gynecology

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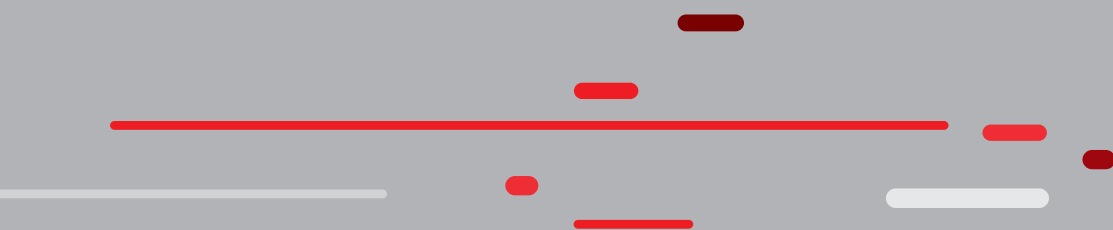
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