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Does Laser Make a Difference in SUI-Treatment? 2 Years Study and Longterm Experience Show Promising Results

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Abstract

Laser for treatment of female SUI symptoms is still part of a controversial discussion. Due to lack of longtime experiences this is reasonable. On the other side we can see a big potential in this therapy: With proper settings laser in SUI treatment is genuinely non-invasive and does not inhibit other therapies. With proper assessment of the patients (SUI I) laser can achieve very convincing and long lasting results.

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Introduction

Two roads diverged in a yellow wood. I took the one less traveled by. And that has made all the difference [1]. In this sense the difference is very obvious:

1) The Laser marks a new therapeutic device and allows a new approach for SUI treatment.

2) The laser is unknown device and therefore a potential risk especially in his longterm effects.

One side of this difference was marked by the FDA in July 2018: The treatment of these symptoms or conditions by applying energy-based therapies to the vagina may lead to serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain [2].

The other side is found in a community of gynecologists all over the world looking for this difference in their own practical work. And one outcome can be seen in the number of publications concerning laser and SUI therapy [3]: A nonsystematic review on PupMed database up to March 2019. Keywords laser, and urinary incontinenc, with exclusion for incontinence in male, laser use in surgery, non-laser techniques, and review articles, 24 papers met criteria regarding laser use in women with urinary incontinence. Laser effect in SUI patients was the primary goal in 21 studies [4].

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We had to answer this difference in 2014, coming in touch with non-ablative Er: YAG-laser for SUI treatment. The gynecological department of Lutherian hospital Hagen Haspe is a tertiary urogynecological centre. Our patients had all stages of SUI. And we offered all the bundle of well accepted standards: Pelciv floor training, pessary therapy, surgical interventions including revision of meshs and slings. And to improve ourselves we were strongly interested in this new technology, just coming up in the gynecological community. And for myself the laser device promised to be a non-invasive mean for a considerable part of my patients: Women with lighter SUI symptoms. Not yet ready for surgical intervention, but not willing or not successful in practicing pelvic floor and not accepting to try with pessary. For sure we had to communicate openly to the patients our lack of short- and longterm experience. Starting with the first treatments my doubts were dampen very soon. As a result of this experience and contribution to the discussion on laser and SUI we monitored SUI patients after laser treatment for two years [5].

The laser method

As we have been looking for the most minimal invasive way for treating our patients we decided for the non-ablative regime by Er: YAG. As alternative way the so-called Micro Ablative treatment, either with Er: YAG or CO_2 can be found. Our non-ablative approach does not create any open wound in the vaginal tissue. Most visible are small coagulation zones on the tissue - with typical light color. (Figure 1) The tissue itself will not be penetrated by the laser, the effect is superficial and pure thermal. We guessed - and in the meantime we know the guess was right - that this approach protects our patients from undesired side effects. For the treatment itself local Lidocaine gel anesthesia for introitus vaginae and periurethral area is sufficient. Patients describe their feeling like something happened but its not pain. After five years doing the procedure we have seen only slight side effects, lasting max for 2 days.

In our study we enrolled 59 patients in our urogynecological centre with SUI or MUI, no estrogen within three months before, minimum six month after delivery, BMI <35, no inflammation of urine tract and no prolapse > grade II.

Treatment regime (Figure 5)

As Laser source we used XS Smooth (Fotona, Slovenia) - Er: YAG-Laser. Laser energy is applied at introitus and intravaginal with two special applicators. First a speculum as guiding support is inserted into the vagina. (Figure 1) The 90° applicator (Figure 2) is inserted into the speculum and is moved step by step (distance 5 mm) from proximal to its entrance. At each step the laser is fired (4 smooth pulses 6J/cm^2, 1.4 Hz). (drawing 3) This step is repeated three more times, each with a different rotation of the applicator to cover the upper area of the vaginal canal in an angle of about 120°. After this four passes with 90° adapter, we do another pass with the 360° (Figure 3) adapter (4 smooth pulses 3J/cm^2, 1.4 Hz, distance 5 mm, starting from proximal). Procedure is finished by irradiation of whole vestibule and introitus in three passes (Figure 6).

The laser beam as spot is split in micro spots, creating a pattern of micro coagulation on the vaginal wall (Figure 6). There is always much more tissue not affected left than affected by the laser energy. The energy is delivered in a train of burst pulses, below the ablation threshold. The effect of laser energy is a pure thermal one. The laser energy is delivered in pulses to a depth of 500-700 µm and the tissue supporting the urethra is heated to temperatures up to 60°C [6].

Each patient was treated 5x in a fix interval of one month. By our daily practice we see that these intervals can be handled more flexible, without any loss of efficiency. The treatment is not stressful for our patients. One session is about 30 minutes, including 15 min for application of laser energy, and no need for aftercare. Patient comes and can continue daily routine immediately after. Our only recommendation is: Beware of sexual intercourse for a weeks time.

Normally we get first positive feedback already after first session within a weeks period. This is a good indication, that something is happening and facilitate a positive forecast. We tell the patient that this feeling is important, but that the intended reaction will be noticeable in five-six months. A more sustainable forecast is possible after second or third session.

In our study we measured the objective patient status by a 1 hour pad-test and the subjective one by ICIQ-UI SF and PISQ-12 at baseline and 2, 4, 10 and 28 months after baseline. Cured means <2 g urine at pad-test or ICQ-UI rating of ≤ 5. Improved means 50% reduction at pad-test, not-cured corresponds to a pad weight reduction ≤50% or an ICIQ-UI SF score >5.

Severity of SUI was graded by the Stamey's incontinence scoring system, i.e., SUI 0 = No incontinence, SUI I= Incontinence with coughing or straining, SUI II= Incontinence with change in position and walking, SUI III= Total incontinence at all times [7]. At baseline, 32 patients had SUI I (54%), 16 had SUI II (27%) and 11 had SUI III (19%). Patients only had prolapse stages I and II and presence of prolapse was not significantly different between incontinence groups. One hour pad weights, ICIQ-UI SF and PISQ-12 scores were significantly different between SUI groups. Only one patient with SUI III had a previous incontinence surgery with a sling [8].

Figure 1: Metal speculum as guiding support for laser applicator.

Figure 2: 90° applicator.

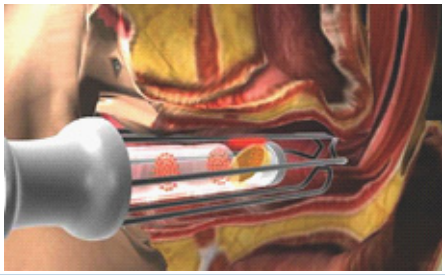

Figure 3: Applicators position inside the vagina.

Figure 4: 360° applicator.

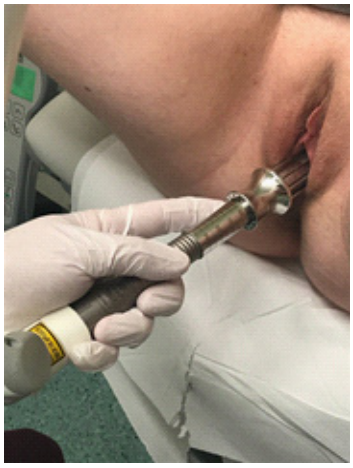

Figure 5: During procedure.

Figure 6: Typical pattern of non-ablative Laser on mucosal tissue (introitus. The therapeutic effect is caused on the tissue reaction on micro-hyperthermia by laser.

Result

Pad-test results (Table 1) for SUI I patients even two years after the 5th laser session showed 78% (25 of 32) as Cured or Improved. Statistic significance in urine loss was shown by reduction of the median from 7 g down to 3 g and reduction of interquartile from 6-8 g to 1-3 g.

These objective findings correlated nearly perfectly with subjective findings (Table 2) separately as follows. ICIQ-UI SF evaluates subjective incontinence symptoms and quality of life (sum scores: 0= No problems to 21= Severe problems) 66% (21 of 32) patients rated themselves in ICIQ-UI SF ≤ 5. Statistically significance was indicated by reduction of median from 10 down to 5 and the interquartile from 8-11 down to 4-6.

In contrast to the findings in the SUI I patient group the results for SUI II patient group were less convincing. According to the pad-test (Table 1) only 31% (5 of 16) could be rated as Cured or Improved. The same according to the ICIQ-Ui SF: Only 13% (2 of 16) rated themselves below the ≤ 5 value. Even worse the results in the SUI III group: Two years after the 5th none patient neither objective nor subjective could be rated as Cured or Improved. Similar can be seen in Table 2. For SUI II and SUI III patient group there is a general No Effect subjective assessment (ICQ-UI SF- Questionnaire).

Complications of laser therapy were minor. For most cases, topical anesthetic cream was not even necessary. Only six patients reported weak pain (11%, 6/57) during or after laser therapy. The pain was transient and restricted to the first few days after laser application. One patient (1/57; 2%) had a vaginal discharge [8].

Understanding by histology and molecular effects

Our study and our daily routine in SUI treatment by laser shows, that laser can be a successful treatment option. When we try to explain what is happening one idea is to understand the Pelvic Floor as a sort of connective tissue membrane. The bladder and urethra and the vagina and uterus are attached to the continued pelvic walls by a system of connective tissue that has been called the endopelvic fascia. Endopelvic fascia and ligaments are a mesh-like group of collagen fibers interlaced with elastin, smooth muscle cells, fibroblasts, and vascular structures [9].

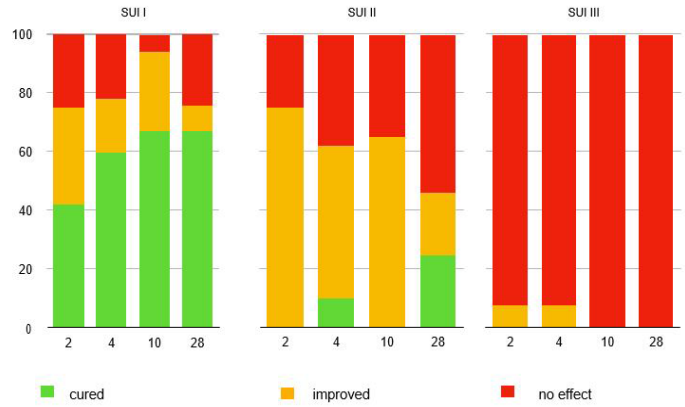

Table 1: Objective findings: Pad-Test results during timeline (months).

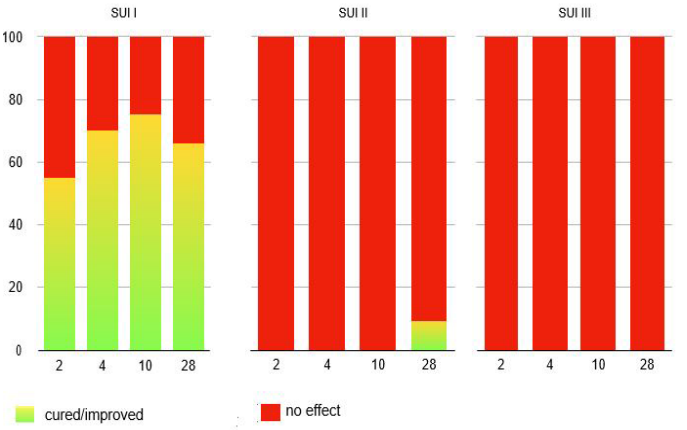

Table 2: Subjective findings: ICIQ-UI-SF results during timeline (months).

Studies on prolapse state a relation between disease and quality of the collagen [10]. Byung Ik Jeong found as well differences in collagen structure between SUI patients and a control [11].

What we are doing with non-ablative laser is nothing else than create a type of hyperthermia or better - due to the pattern of coagulation spots - a micro hyperthermia. And there is good evidence, that just this micro-hyperthermia is a cause for neo collagenesis and revascularization of pelvic floor tissue. Let's say it short: For SUI patients improved connective tissue is improved support of bladder and urethra and lesser probability of urine loss. Just recently Huth et al. published their study on molecular effects of non-ablative Er:YAG-laser in an in-vitro model of non-keratinized mucous membrane. The parameters and the laser system are the same as in our study.

Non-ablative Er:YAG-irradiation of 3-D mucous membrane model showed. Histologically no ablation of the epithelial equivalent, but coagulation of deeper tissue layers within the lamina propria equivalent immediately after laser treatment. Complete reconstitution of the lamina propria equivalent was detected on day 5 after laser treatment. The gene expression profiling showed an up-regulation of differentiation markers Loricrin (LOR) and Filaggrin (FLG). And - the authors compared non-ablative Er:YAG vs ablative Er: YAG/CO_2. All laser systems induced the expression of collagen-encoding genes (COL6A2, COL12A1) almost identically [12].

The above mentioned molecular effects are confirmed by real tissue histologies. Lapii et al. treated 98 SUI patients with non-ablative Er. YAG-mode, similar to our protocol. 18 of them where part of histological examination 6 to 8 month after two laser sessions. Comparing vaginal tissue before after Lapii found structural reorganization, reduced degenerative changes in the stratified squamous epithelium, increase of the epithelial layer thickness, signs of significant reorganization of the fibrillar structures of extracellular matrix and growth of fine bundles of collagen.

Microscopic studies showed obvious improvement of the morphology and function of the vaginal epithelium. Significant reorganization of the fibrillar structures of extracellular matrix was in progress. Growth of fine bundles of collagen fibers was detected in the majority of biopsy specimens. In the subepithelial zone this event was paralleled by enlargement of the stromal papillae, deeply embedded in the epithelium and pierced with capillaries with typical structure. The distribution of collagen fibers in deep layers of tissue was more orderly, foci of loose tissue were smaller and less in number, and a dense network of new fibers without signs of fibrosis was forming, all these events reflecting recovery of the collagen carcass microarchitecture and uniform fortification of the vaginal stroma [13]. And according to the statement in the 3-D-mucous-membran-study that as well ablative lasers cause the same effect we find nearly identical results using the thermoablative approach with CO2-laser [14].

What makes the difference

Regarding the FDA-statement concerning laser and SUI treatment, we can see at least a good probability to use a laser for SUI treatment without critical side effects. As more with the laser driven in a non-ablative mode [15]. Laser is ideal for a certain group of patients: Best results can be achieved at patients with lighter SUI symptoms (SUI degree I). Laser is as well ideal for younger patients, e.g.after delivery; for active women doing sports. A good indication for successful laser therapy is the situation of the skin. As more elasticity as better the prognosis.

However laser treatment can be helpful as well for patients with special requirement. I had one service bus driver as patient with SUI Grade III, she was single and mother. Due to her SUI symptoms our standard recommendation was the operative way (sling/mesh). With sling or mesh she is dry. But she did not want an operation. She had no one else to take care of her child. We treated her with the laser and her symptoms improved. Her standard ride was 2 hrs. Before she could not do this ride without using diapers. After the laser treatment, she was able just to do her ride. And it was a relief for her.

We meet a lot of patients where operation is not an option. Either SUI is not strong enough or not accepted. And a big part of them do not accept local estriol or accept pessary and become not happy with pelvic floor training. Up to now we had no or only unsatisfying therapeutic options for these type of patients. With a laser we have a possibility at least to improve the situation and in most cases patients are happy with. And even when we know that it is not the perfect solution according to our professional standards. Very often patients are happy with less, it depends on their very personal perception of their own life. And this we as professionals have to respect. Especially because the non-invasive laser-therapy does not hinder an operation afterwards at all. Therefore I would recommend, to apply laser therapy as one good different way to act in the benefit of our patients.

References

1. Robert Frost. The Road Not Taken [hyperlinked with https://www.robertfrost.org/the-road-not-taken.jsp]

2. FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication [hyperlinked with https://www.fda.gov/medical-devices/safety-communications/fda-warns-against-use-energy-based-devices-perform-vaginal-rejuvenation-or-vaginal-cosmetic]

3. Alka A, Bhide Vik, Khullar, Stephen Swift, Giuseppe A. Digesu. The use of laser in urogynaecology, International Urogynecology J. 2019; 30: 683–6920.1007/s00192-018-3844-7.

   Pergialiotis, Anastasia Prodromidou, Despina N. Perrea, Stergios K. Doumouchtsis. A systematic review on vaginal laser therapy for treating stress urinary incontinence: Do we have enough evidence? Int Urogynecol J (2017) 28: 1445–1451

4. Damir Franic, Ivan Fistonic. Laser Therapy in the Treatment of Female Urinary Incontinence and Genitourinary Syndrome of Menopause: An Update, p 6. Hindawi BioMed Research International. 2019.

5. Andrzej Kuszka, Marianne Gamper, Claudia Walser, Jacek Kociszewski.Volker Viereck. Erbium:YAG laser treatment of female stress urinary incontinence: midterm data; Int Urogynecol J. 2020; 31(9): 1859-1866.

6. Fistonic N, Fistonic I, Gustek SF, Turina IS, Marton I, Vizintin Z, et al. Minimally invasive, non-ablative Er: YAG laser treatment of stress urinary incontinence in women-a pilot study. Lasers Med Sci. 2016; 31: 635-643.

7. Kuzka et al. 2020

8. ibid

9. Sender Herschorn, Female Pelvic Floor Anatomy. The Pelvic Floor, Supporting Structures, and Pelvic Organs, Treatment of SUI S2. Reviews in Urology. 2004; 6: S5-S6.

10. Veronica F. LIM, John K. KHOO, Vivien WONG, Kate H. MOORE. Recent studies of genetic dysfunction in pelvic organ prolapse: The role of collagen defects; Australian and New Zealand Journal of Obstetrics and Gynaecology. 2014; 54: 198–205.

11. Byung Ik Jeong, Young Jun Seo, Bu Kyung Park, Jeong Ju Lee. Changes of Subtypes of Anterior Vaginal Wall Collagen in Female with Stress Urinary Incontinence, Journal of the Korean Continence Society 2004; 8: 134-139.

12. Laura Huth, Sebastian Huth, Yvonne Marquardt, Philipp Winterhalder, Timm Steiner et al. Deciphering the molecular effects of non-ablative Er:YAG laser treatment in an in vitro model of the non-keratinized mucous membrane, Lasers in Medical Science Springer. 2020.

13. G. A. Lapii, A. Yu. Yakovleva, A. I. Neimark. Structural Reorganization of the Vaginal Mucosa in Stress Urinary Incontinence under Conditions of Er:YAG Laser Treatment; Bulletin of Experimental Biology and Medicine, Morphology and Pathomorphology. 2017; 162; 513.

14. Pablo González Isaza, Kinga Jaguszewska, Jose Luis Cardona, Mariusz Lukaszuk. Long-term effect of thermoablative fractional CO2 laser treatment as a novel approach to urinary incontinence management in women with genitourinary syndrome of menopause; Int Urogynecol J. 2018; 29: 211–215.

15. Due to our experience with the non-ablative protocol we developed in our clinic a non-ablative protocol with CO2-laser. Since one year we use it and the results and side effects are practically the same as with Er: YAG.