Opinion

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Does Laser make a Difference in SUI-treatment? 2 years study and long-term experience show promising results

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ABSTRACT

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Opinion

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 long-term 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 incontinence. 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]. For us we had to answer this difference in 2014, coming in touch with non-ablative Er:YAG-laser for SUI treatment. At this time in gynecological department of Lutherian hospital Hagen Haspe, we where a tertiary urogynecological centre. Patients with visited us in all stages of SUI. And we offered all the bundle of well accepted standards: pelvic 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 me the laser device promised to get a non-invasive mean for just the women, not yet ready for surgical intervention, but not willing, not able, not successful in practicing pelvic floor and not willing to try with pessary. And for sure we had to communicate openly to the patients a lack of short- and long-term experience, and discuss pros and cons. But with the first experience my doubts were dampen very soon. And as a contribution to the discussion on laser and SUI we see our study, published in dec 2019 [5]. Here we monitored SUI patients after laser treatment patients for two years.

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 CO2 can be found. Our method does never create any open wound in the vaginal tissue; most visible are small coagulation zones on the tissue - with its typical light color. The tissue itself will not be penetrated by the laser, the effect is superficial 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 Lidocain gel anesthesia for introitus vaginae and perurethral area is sufficient. Patients describe their feeling like something happened but it's

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 noprrolaps > grade II.

Treatment Regime

Laser energy is applied at introit us and intravaginally with special applicators. The beam as spot is spitted in micro spots, creating a pattern of micro coagulation on the vaginal wall. In this way it is guaranteed that there stays always much more tissue not affected than affected by the laser energy. The energy is delivered in a train of burst pulses, below the ablation threshold. In this way the tissue is burdened only thermally by the laser energy. The laser energy is delivered in pulses to a depth of 500-700 m 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 it seems that these intervals can be handled more flexible without any loss of efficiency. Most important for our daily work is that 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 goes home immediately after, or only recommendation is to beware of sexual intercourse for a week's time. Normally we get first positive feedback after first treatment within a week's period. For us it is an indication, that something is happening and the first forecast is positive. We tell the patient that this feeling is important, but that the intended reaction will be noticeable in five-six months. A realistic forecast is possible after about two or three settings.

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 <2g urin 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. At baseline, 32 patients had SUI I (54%), 16 had SUI II (27%) and 11 had SUI III (19%). Patients only had prolapsed 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 [7].

Result

Pad-test results for SUI I patients even two years after the 5th laser session showed 78% (25 of 32) as cured or improved. Statistic significance in urin loss was shown by reduction of the median from 7g down to 3g and reduction of interquartile from 6-8g to 1-3g. These objective findings correlated nearly perfectly with subjective findings 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. 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]. In contrast to the findings in the SUI I patient group the results for SUI II where less convincing. According to the pad-test 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 nonpatient neither objective nor subjective could be rated as cured or improved. (Table 1) shows the timeline of the results of the pad-test for each SUI group separately. Similar appearance in (Table 2) with the results of ICQ-Ui SF- questionnaire.

Table 1: Timeline results Pad-Tast.

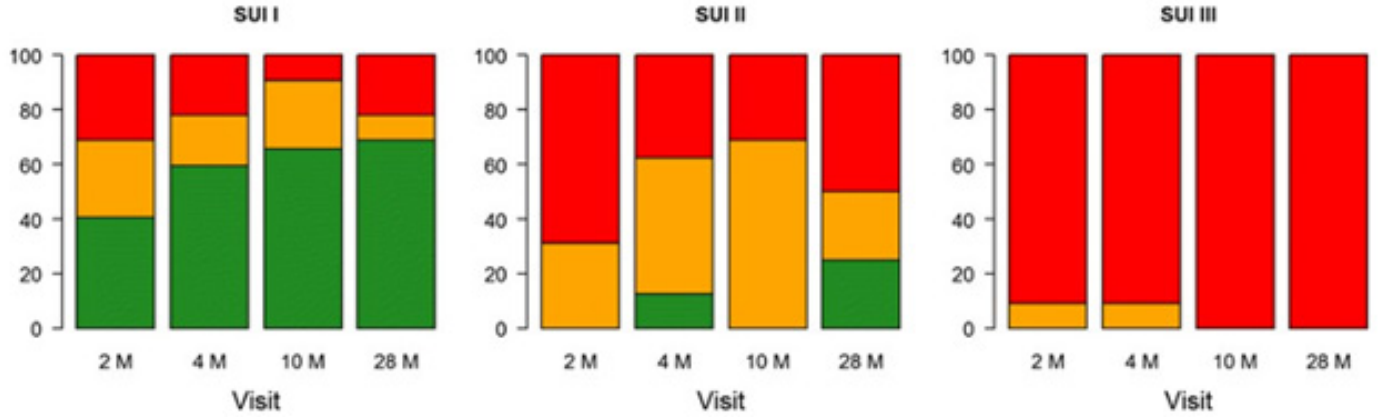
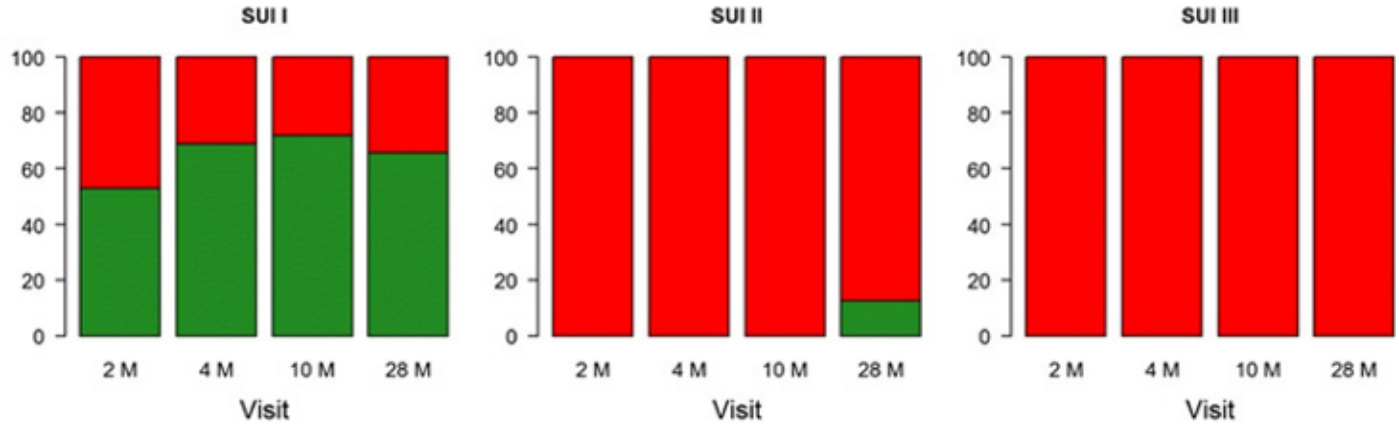


Table 2: Timeline results ICQ-US SF.



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 elastic, smooth muscle cells, fibroblasts, and vascular structures [9]. Studies on prolaps 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 mikro hyperthermia. And there is good evidence, that just this mikro-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 prbability of urin 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 moucos membrane. The parameters and the laser system are the same as in our study.

Non-ablative Er:YAG-irradiation of 3-D moucos 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/CO2 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 eptihelium, 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 febrile structures of extracellular matrix was in progress. Growth of fine bundles of collagen fibers was detected in the majority of biopsy specimens. In the sub epithelial 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 micro architecture and uniform fortification of the vaginal stroma [13]. And according to the statement in the 3-D-moucose-membran-study that as well ablative lasers because the same effect we find nearly identical results using the thermo ablative approach with CO_2-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 [15-17]. But, to stay realistic, we must say, laser is ideal for younger patients, e.g. after delivery; laser is ideal for active women doing sports all with SUI Grade I. As a good indication fur successful laser therapy is the situation of the skin, as more elasticity as better the prognosis. And laser treatment can be helpful for special patient requirement. I had one service

bus driver as patient with SUI Grade III, she was single and mother. As she had no one else to take care of her child, she did not want an operation. We treated her with the laser and SUI 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. Due to her SUI grade our normal recommendation is the operative way (sling/mesh). After this she is dry. But very often our patients are happy with less.

It depends on their very personal perception of their situation and the way they want to deal with it. And non-invasive laser-therapy does not hinder an operation afterwards at all. Therefore I would recommend, keeping laser therapy at least as one good different way to act in the benefit of our patients.

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17. 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.

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