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An innovative dual-phase protocol for pulsed ablative vaginal Erbium: YAG laser treatment of urogynecological symptoms

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ABSTRACT

Objectives: To evaluate a dual-phase protocol for vaginal ablative Erbium:YAG laser treatment in pelvic floor medicine.
Study design: Data from consecutive patients undergoing vaginal Erbium:YAG laser for first-degree pelvic floor complaints at a certified university urogynecological unit were analyzed. Fractional ablative and thermal treatment with adjustable pulse duration, fluence, and pulse interval was performed in single ten-minute treatment course. Followed up interval was 6 weeks including interviews on expectations, goal setting, goal achievement, and satisfaction (EGGS), vaginal pH, and determination of the Gloria-Bachmann-Index (VHI). Post-procedural complications were classified according to definition and classification of the Clavien-Dindo system.
Results: Of 84 patients treated, 71 (21% pre-, 79% post-menopausal) were evaluated. 27% had single urogynecological symptoms, 35% had three or more combined symptoms. Minor post-procedural complications occurred in three patients (CD I, $n = 1$; CD II, $n = 3$). The ranges of fluence, determined according to the atrophy state, in the first and second phases were 15–35 and 3–12 J/cm^2, respectively. In patients with genitourinary syndrome of menopause, pre- and post-treatment VHI and pH differed significantly [15.3 ± 4.5 vs. 19.9 ± 2.8 ($p < 0.001$, Student's t test) and 5.2 ± 0.6 vs. 4.8 ± 0.4 ($p = 0.024$, respectively]. Overall, 82% ($n = 58$; mean age, 58 ± 12 years) of patients were satisfied with the treatment, 84% (47/56) post-menopausal patients were satisfied.
Conclusions: Vaginal ablative Erbium:YAG laser dual-phase protocol for early urogynecological symptoms was successful and safe, with high patient satisfaction and few, minor complications. Prospective studies are needed to confirm our first data.

Introduction

In urogynecological units in Germany, patients with mild pelvic floor symptoms seek advice regarding non-surgical treatment approaches to increase quality of life (QoL) and to avoid or delay surgery for progressing pelvic organ prolapse (POP). Special attention should be given to patients with an increased risk of POP [1]. With the aging of western populations, health care systems will face enormous increases in the number of patients with age-related diseases, such as pelvic floor disorders and QoL impairment [1,2]. This development, and consideration of the costs entailed [3,4], has led some western governments to support and strengthen preventive medicine, mirrored by medical prevention laws [5].

Our group has examined risk constellations eventually leading to the indication for pelvic floor surgery [1], revealing key roles of difficult obstetric history, aging processes, long-term postmenopausal hormone deficiencies, obesity, and familial signs of connective tissue weakness [1,6]. Many affected patients do not have diagnoses necessitating surgery, but they should do everything possible to strengthen the connective tissue and pelvic floor. The importance of conservative treatment options for the tissue laxity underlying many urogynecological complaints, which can result from aging or inherited connective tissue weakness, is obvious. According to epidemiological data from the United States, one in three women between the ages of 50 and 59 years and one in two women aged 80 years or older suffers from one or more pelvic floor problems [2].

Abbreviations: CD, Clavien-Dindo; EGGS, expectations, goal setting, goal achievement, and satisfaction; Er:YAG, erbium: yttrium aluminum garnet; GSM, genitourinary syndrome of menopause; POP, pelvic organ prolapse; QoL, quality of life; SUI, stress urinary incontinence; VHI, vaginal health index.

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Aside from non-surgical treatment options to address early risks related to pelvic floor conditions, such as pelvic floor exercises and the use of topical estrogens, biofeedback, and pessaries, thermal tissue remodeling (hyperthermia) with laser technologies was introduced recently. Although various laser techniques and protocols have been developed for use in urogynecology [7–14], few data are available on their indications, and few studies have compared these technologies or sought to define an ideal laser protocol.

In laser techniques employing erbium: yttrium aluminum garnet (Er:YAG) crystals, the laser has a defined wavelength of 2940 nm at the peak of water absorption, which avoids coagulation and tissue necrosis. This paper presents a dual-phase Er:YAG laser protocol for vaginal application to address early urogynecological symptoms. The innovative dual Er:YAG laser protocol using a fractional ablative mode and a thermal mode right after another was evaluated. By combining the two modes in an Er:YAG laser protocol the advantages of an Erbium laser with its low complication rates and painlessness due to the absence of coagulation are combined with fractional ablation. Pilot data were gathered from patients during interviews using the expectation, goal setting, goal achievement, and satisfaction (EGGS) approach [15], and procedural complications were registered according to the validated classification system of Clavien and Dindo (CD) [16–18].

Materials and methods

This study utilized data from consecutive patients who underwent vaginal Er:YAG laser therapy as a conservative treatment option for first-degree pelvic floor complaints and were evaluated at a certified university urogynecological unit between 2016 and 2017. Laser treatment was offered to patients with low grade stress urinary incontinence (SUI) [19], urgency with no anatomic cause for residual volume (cystocele), grade I prolapse/vaginal laxity, symptoms of vaginal atrophy (e.g., itching, dryness, burning, discomfort, sexual impairment), and/or genitourinary syndrome of menopause (GSM) [11,20–22]. Exclusion criteria were abnormal Papanicolaou test or gynecological examination finding, vaginal wound or infection, urinary tract infection, pregnancy, menstruation, current use of photosensitive drugs or topical estrogens, and previous history of malignant pelvic or systemic disease. Patients with previous histories of genital herpes infection were asked to take oral Aciclovir (Aciclovir-ratiopharm™, ratiopharm GmbH, Ulm, Germany) for preventive purposes. Patients underwent guideline-based counselling by a certified pelvic floor expert at the urogynaecological unit of the university. Depending on findings and symptoms a variety of non-surgical treatment options were offered individually like anticholinergic drugs, local hormones, pessaries, pelvic floor exercises, biofeedback, conus treatment. All patients gave informed consent in the context of other established treatment alternatives and were counselled not to have sexual intercourse for 72 h after treatment.

The two-phase treatment approach used a pulsed Er:YAG laser (MCL 31 Dermablate; Asclepion Laser Technologies, Jena, Germany) with a defined wavelength of 2940 nm. A single ten-minute treatment course was applied. All treatments were performed as outpatient procedures. The first phase utilized the physical parameters of the laser's Gyn C pre-set: 300-μs pulse duration, 15–35 J/cm^2 fluence (depending on individual tissue thickness), 0.5–2-s pulse interval, and 45° rotation. The fractional mode was realized by a fractional handpiece containing a squared 9 x 9 mm microspot optic (MicroSpot, Asclepion Laser Technologies, Jena, Germany) with stable and precise micro lens array technology, consisting of 169 spots (Fig. 1). The purpose of this ablative phase was to create small

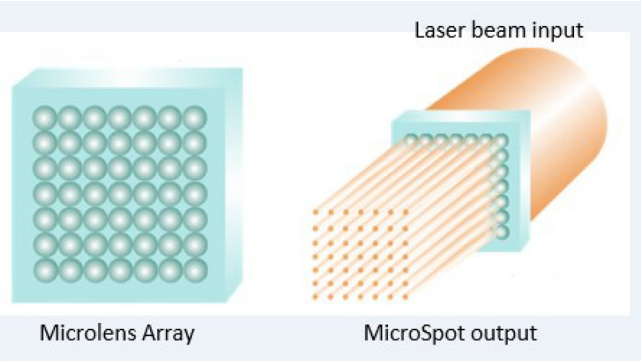

Fig. 1. Microlens Array technology (Copyright Asclepion Laser Technologies GmbH 2017).

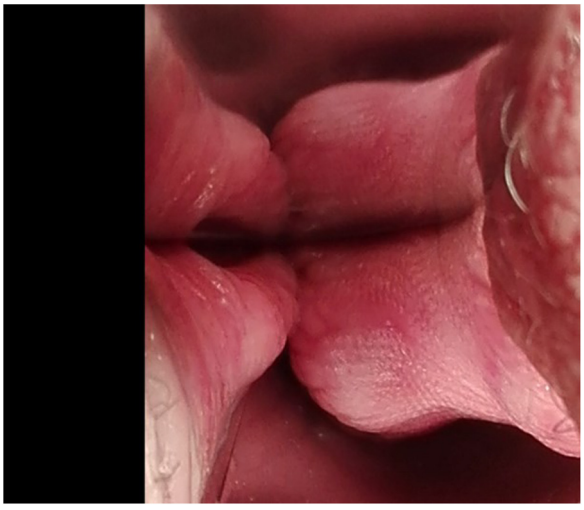

Fig. 2. Vaginal epithelium after first phase of fractional ablation.

canals in the superficial layer of the vaginal epithelium with the laser (Fig. 2). This phase was followed immediately by the second phase, performed in thermal mode using the laser's Gyn W pre-set parameters: 1000-μs pulse duration, 3–12 J/cm^2 fluence (depending on individual tissue thickness), 0.5–2-s pulse interval, and 22.5° rotation. The same fractional microspot handpiece used in the first phase was used in this phase. The goal of the second phase utilizing higher pulse duration is to induce thermal effects (hyperthermia, Fig. 3) reaching the lamina propria of the vaginal epithelium, thereby stimulating neocollagenesis. The laser parameters were adjusted according to each patient's condition, symptoms, and history with regard to the vaginal epithelium. Inspection of the vaginal epithelium by speculum examination before selection of the pulse length and fluence of the Er:YAG laser is thus important.

Patients were followed at the urogynecological unit, including the performance of interviews with focus on expectations, goal setting, goal achievement, and satisfaction (EGGS) [15,23], pH measurement, and determination of the vaginal health index (VHI) [24] by speculum examination at 6-week intervals. Second treatment courses were scheduled on demand. Post-procedural complications were classified according to definition and the CD system [16–18]. Student's *t* tests were used for statistical analysis. Data are reported as mean ± standard deviation or *n* (%).