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ORIGINAL PAPER

# Treatment of vaginal relaxation syndrome with an Erbium:YAG laser 360° scanning scope via automatic dual mode technique

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## Abstract

**Background** Vaginal relaxation syndrome (VRS) is a common phenomenon affecting women and their partners which may lead to decreased sexual satisfaction. Recently, the use of 2940-nm Erbium:YAG laser (Er:YAG) has been extended to cosmetic gynecology to treat VRS. This study evaluated the efficacy of this non-surgical laser procedure.

**Methods** From October 2014 till January 2017, 39 females with vaginal relaxation syndrome (VRS) were treated with the 2940-nm Er:YAG. Their ages ranged from 27 to 47. Those 39 patients received one to four treatment sessions at 2–3-week intervals. The sessions were performed with a 360° scope via automatic dual step technique. The first step consisted of three passes of multiple pulses ranging from 1.7 to 2.2 J per pulse. The second step consisted of two passes of long-pulsed wave of 3.7 J and a pulse width of 1 s. The improvement in sexual satisfaction was assessed subjectively by patients' questionnaire.

**Results** Improvement in sexual satisfaction was reported by 78% of the patients. A few minor side effects were reported such as vaginal ecchymosis and mild burning sensation.

**Conclusions** In patients suffering from VRS, the use of automatic dual pass technique Er:YAG is a convenient non-surgical method to obtain reasonable tightening of vaginal wall and improve sexual satisfaction.

Level of Evidence: Level IV, case series study.

**Keywords** Automatic dual mode · Vaginal tightening · 360° scanning scope · Sexual satisfaction · Tissue remodeling

## Introduction

As women age, they may suffer from vaginal relaxation syndrome (VRS) due to laxity of the vaginal walls [1]. This is particularly noted with multiple parity and repeated vaginal deliveries [2]. It is also associated with menopause-related hormonal changes. VRS can lead to a number of problems; a major one of which is decreasing of sexual satisfaction for both the female and her partner [3, 4], which often referred to loss of vaginal wall tightness. Urinary incontinence (UI) is also a problem associated with VRS. Many social problems are face by women affected by involuntary loss of urinary control [5].

Many options exist for the treatment ranging from invasive to non-invasive approaches. For the non-invasive approaches, exercise such as Kegel exercises can tighten relaxed musculature in the pelvic floor and to some extent in the vaginal wall. "Tightening creams," hormonal creams, sprays, and other pharmacological medications are available but of limited value. Invasive approaches include surgical procedures where vaginal and surrounding tissues are incised and rearranged [6–8], giving better and long-lasting results but with high risks of scar formation or nerve damage leading to dysthesia [9–12]. Surgical strategies regain the tone of the vaginal muscle by tightening the supportive structures of the vulvovaginal complex [13, 14].

Recently, the laser has been used because of its ability to limit the surgical damage. The laser with high water

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affinity is used. Both the micro-ablative fractional $CO_2$ laser and the non-ablative vaginal Erbium:YAG laser (Er: YAG) induce morphological changes in the vaginal tissues. The laser-assisted vaginoplasty is based on the ablation of mucosal tissue aiming to stimulate collagenesis of the mucous layer of the vagina [15, 16]. The fractionated mode of laser delivery is currently available. The bulk laser beam is split into multiple micro-beams with the ability to control the depth of the micro-ablative columns (MACs).

Fractional Er:YAG systems with gynecological delivery system recently became available as a non-surgical approach in vaginal tightening [17, 18]. Evidence from non-randomized clinical trials suggest that Er:YAG laser can be used as a safe, efficacious alternative to hormone replacement therapy for genitourinary syndrome of menopause. It will improve vaginal prolapse, vaginal dryness, and dyspareunia. It can also be used as first-line treatment for stress urinary incontinence before resorting to surgical procedures [19].

Animal studies also show that laser treatment for a vaginal laxity produces remodeling of the vaginal connective tissue.

Histologically, it was confirmed that there is an increase in collagen and elastic fibers due to neocollagenesis and angiogenesis, and the vaginal walls became firmer and tighter because of increased capillary and vessel formation [20].

In this study, we used special 360° scanning scope that was designed to deliver the laser beam in 360° with controlled coagulative effect without any ablation of the full thickness of the vaginal wall. Anterior wall of the vaginal canal can also be treated to improve urinary incontinence [21–23]. This study was designed to assess the patient satisfaction with the automatic dual pass mode of Er:YAG laser using 360° scope.

## Subjects and methods

### Subjects

The study was conducted between October 2014 and January 2017. It consisted of a survey of 58 parous females with vaginal relaxation syndrome (VRS). The ages ranged from 27 to 47 (mean 39). Out of 58 patients, 39 patients responded to the survey while the remaining 19 were excluded from the survey. All patients were treated using 2940-nm ACTION II™ Er:YAG (Lutronic, Goyang, South Korea) in automatic dual mode technique. The sessions were performed using the recommended parameters by the manufacturer. The sessions were performed with a 360° scope via automatic dual step. The first step consisted of three passes of multiple pulses ranging from 1.7 to 2.2 J per pulse. The second step consisted of two passes of long-pulsed wave of 3.7 J and a pulse width of 1 s. The improvement in sexual satisfaction was assessed subjectively by patients' questionnaire.

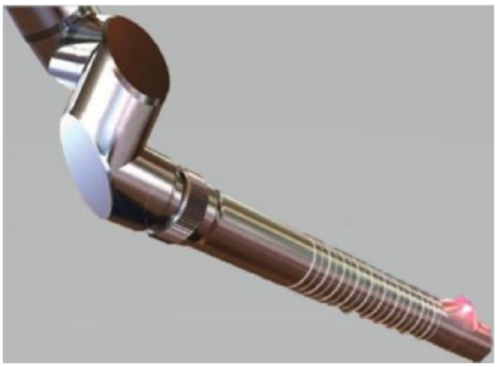

**Fig. 1** The 90° scanning scope (copyright permission from International Journal of Aesthetic and Anti-Ageing Medicine, PetitLady, September 2014 edition)

The scope is supported in the vagina by a specially designed guide (Figs. 1 and 2). In general, the supporting guide is initially inserted, and then the 360° scope is fully inserted into the guide. The body of the scope is marked with 2.5-mm gradations, the laser is fired, and then the probe is withdrawn by 1 gradation (2.5 mm), and the process was repeated for the entire length of the vaginal canal. Multiple passes may be necessary. The procedure was performed with routine antiseptic but no regional or general anesthesia; topical anesthesia (Emla ® [Lidocaine or Prilocaine 1%]) was applied on a vaginal gauze and inserted 20 min prior to the procedure. The procedure can be accomplished in under 10 min. The session number ranged from one to four sessions with 2–3-week interval between sessions, with follow-up evaluation at 2 months followed by a maintenance session if needed [17, 24]. Post-procedure instructions include avoiding sexual

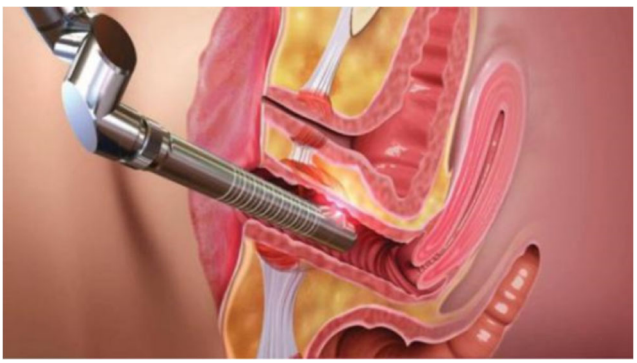

**Fig. 2** Illustration showing the special support for the scanning scopes inserted in the vagina (copyright permission from International Journal of Aesthetic and Anti-Ageing Medicine, PetitLady, September 2014 edition)

**Table 1** Patient characteristics

| Pat. no | Age | Parous | Delivery type | | Pre/post-menopausal | Patients | No. of sessions |
|---|---|---|---|---|---|---|---|
| | | | C-sec | NSVD | | | |
| P-1 | 45 | 5 | 2 | 3 | Post | 1 | 4 |
| P-2 | 36 | 3 | 1 | 2 | Pre | 2 | 2 |
| P-3 | 37 | 4 | 1 | 3 | Pre | 2 | 4 |
| P-4 | 33 | 2 | | 2 | Pre | 2 | 1 |
| P-5 | 30 | 2 | | 2 | Pre | 0 | 2 |
| P-6 | 40 | 4 | | 4 | Pre | 2 | 1 |
| P-7 | 38 | 2 | | 2 | Pre | 0 | 2 |
| P-8 | 46 | 7 | 1 | 6 | Post | 1 | 3 |
| P-9 | 38 | 7 | 2 | 5 | Pre | 1 | 1 |
| P-10 | 41 | 4 | 1 | 3 | Pre | 3 | 4 |
| P-11 | 37 | 4 | | 4 | Pre | 1 | 1 |
| P-12 | 42 | 3 | | 3 | Pre | 3 | 2 |
| P-13 | 38 | 4 | | 4 | Pre | 0 | 1 |
| P-14 | 36 | 1 | | 1 | Pre | 1 | 1 |
| P-15 | 32 | 2 | | 2 | Pre | 1 | 3 |
| P-16 | 43 | 5 | | 5 | Pre | 0 | 2 |
| P-17 | 46 | 4 | | 4 | Post | 1 | 1 |
| P-18 | 37 | 3 | 1 | 2 | Pre | 3 | 4 |
| P-19 | 27 | 2 | | 2 | Pre | 0 | 2 |
| P-20 | 34 | 1 | 1 | | Pre | 0 | 1 |
| P-21 | 41 | 7 | 1 | 6 | Pre | 2 | 2 |
| P-22 | 40 | 4 | 1 | 3 | Pre | 1 | 2 |
| P-23 | 36 | 1 | 1 | | Pre | 0 | 2 |
| P-24 | 42 | 6 | 1 | 5 | Pre | 2 | 2 |
| P-25 | 40 | 4 | 1 | 3 | Pre | 2 | 2 |
| P-26 | 34 | 5 | 1 | 4 | Pre | 2 | 2 |
| P-27 | 37 | 7 | 1 | 6 | Pre | 2 | 4 |
| P-28 | 45 | 6 | | 6 | Post | 0 | 4 |
| P-29 | 37 | 4 | | 4 | Pre | 2 | 1 |
| P-30 | 47 | 2 | 2 | | Post | 3 | 2 |
| P-31 | 39 | 5 | | 5 | Pre | 3 | 1 |
| P-32 | 35 | 4 | | 4 | Pre | 3 | 3 |
| P-33 | 45 | 5 | | 5 | Pre | 0 | 2 |
| P-34 | 37 | 3 | | 3 | Pre | 2 | 4 |
| P-35 | 38 | 5 | | 5 | Pre | 3 | 3 |
| P-36 | 38 | 4 | | 4 | Pre | 3 | 4 |
| P-37 | 40 | 5 | 1 | 4 | Pre | 2 | 3 |
| P-38 | 41 | 3 | | 3 | Pre | 2 | 1 |
| P-39 | 34 | 4 | 1 | 3 | Pre | 2 | 1 |

Patient sexual satisfaction was self-rated using the following scale: dissatisfied, 0; somewhat satisfied, 1; satisfied, 2; and extremely satisfied, 3. *Pat. no.*, patient reference No; *NSVD*, normal spontaneous vaginal delivery, *C-sec*, cesarean section

intercourse for 2 days. The subjects were discharged immediately after procedure. The post-menopausal females were not receiving any hormonal therapy or suffering from urinary incontinence.

## Results

The collected data included demographics and relevant histories, age, parous status, delivery type, and

**Table 2** Patient sexual satisfaction

| Score | Patient satisfaction | No. of patients | Percentage (%) |
|---|---|---|---|
| 0 | Dissatisfied | 9 | 23 |
| 1 | Somewhat satisfied | 8 | 21 |
| 2 | Satisfied | 14 | 36 |
| 3 | Extremely satisfied | 8 | 21 |
| | Total | 39 | 100 |

menstrual status. Patient satisfaction assessed through a questionnaire was obtained 1–2 months within and after laser sessions (Table 1).

Age ranges from 27–47 years (mean 39 years); median 38 years and parity status range from 1–7 (mean 4).

Data regarding the parity level is shown in Table 3. The average parity was more than 4.

The subject's satisfaction with the degree of improvement in sexual satisfaction was determined through a patient-answered subjective scoring on a 4-point scale (Table 2) where they asked to self-rate their satisfaction using the following scale.

The data on menopausal status was also charted (Table 4).

### Regarding side effects

Out of 58 patients treated, 39 (67%) completed the treatment and the 2-month assessment. All patients felt some heating in the vagina during treatment, vaginal ecchymosis with a mild burning sensation which lasted 24–48 h and resolved spontaneously. No subject reported any major or lasting adverse side effects after any of the treatments. The improvement was seen in the subjects' own assessment of improved sexual satisfaction (78%).

The parity status range was from 1 to 7 with mean of 4; patient with low satisfaction (0 and 1) were 14 with a parity average of 3.7. The delivery type: cesarean section is 21 times (14%) and normal vaginal delivery is 132 times (86%) due to the fact that multiparous patients may have had C-section and NSVD; it is not possible to conclude if the type of delivery had any impact on their satisfaction. Menopausal status: pre-menopausal 34 patients (87%) and post-menopausal five patients (13%) (Table 3). Improvement in sexual satisfaction was reported more in pre-menopausal patients with overall improvement (78%) than in post-menopausal women although limited number (5), but four of them reported a low satisfaction (Table 4).

**Table 3** Satisfaction by parity level

| Satisfaction score | No. of patients | Total parity | Average parity |
|---|---|---|---|
| 0 | 9 | 28 | 3.11 |
| 1 | 8 | 34 | 4.25 |
| 2 | 14 | 61 | 4.35 |
| 3 | 8 | 30 | 3.75 |

## Discussion

Dual mode laser Mectron M+ consisting of superficial ablation using its initial high power peak and deep penetration with its low-power longer duration pulse is a known technique in vaginal relaxation syndrome (VRS). Its efficiency in the treatment of menopause-related vaginal atrophy was also described [15, 23].

A small study on 21 patients showed promising results of the use of Er:YAG in the treatment of vaginal relaxation syndrome with 85% significant improvement [25].

A recent study published in 2018 included 84 patients with of urogynecologic symptoms. The objective was to evaluate a dual-phase protocol for vaginal Erbium YAG laser treatment in pelvic floor medicine. Eighty-two percent of patients were satisfied with the treatment, and it concluded that this treatment was successful and safe for early urogynecologic symptoms, with high patient satisfaction and few minor complications [26].

A prospective comparative cohort study on 50 patients with genitourinary syndrome of menopause was performed to evaluate the effectiveness and safety of Er:Yag laser treatment and compare it to topical estriol treatment.

There was statistically significant reduction of all assessed symptoms in the laser group up to 18 months post treatment. In conclusion, Er:YAg laser treatment successfully improve genitourinary symptoms of menopause, and its effect is more pronounced and longer lasting than that of topical estriol treatment [27].

Another study comparing the effect of vaginal Er:Yag laser treatment for genitourinary syndrome of menopause (one session every month for 3 months) to a standard treatment with topical estriol twice weekly for 3 months, 45 patients versus 25 patients, respectively. Laser treatment resulted in significant improvement in vaginal dryness, dyspareunia, and mild-to-moderate stress urinary incontinence. The effects were tolerated, rapid, and lasting up to the 24th week of the follow-up period [28].

**Table 4** Menopausal status

| Menopausal status | Number of patients | Percentage (%) | |
|---|---|---|---|
| Post-menopausal | 5 | 13 | |
| Pre-menopausal | 34 | 87 | |
| Total | 39 | 100 | |
| Satisfaction score | | | |
| | No. of patients | Satisfaction score | Average satisfaction score |
| Post-menopausal | 5 | 6 | 1.2 |
| Pre-menopausal | 34 | 55 | 1.6 |

Similarly, 65 patients with genitourinary syndrome of menopause were treated with vaginal erbium laser (one session every month for 3 months). Twenty one of them had mild-to-moderate stress urinary incontinence. There were significant improvement in vaginal dryness, dyspareunia, vaginal health index score, and stress urinary incontinence. The procedure was well tolerated with less than 2% of patients discontinuing treatment due to adverse events [29].

This study was conducted on 39 patients who have received one to four sessions of treatment using the Er:YAG laser with a follow-up assessment of 1–2 months. The primary target of Er:YAG is the significant amount of water in the vaginal mucosa. It causes controlled ablation and secondary thermal damage on the wall. The wavelength of 2940 nm is optimum for water absorption. In contrast, the $CO_2$ laser could potentially cause unwanted damage to the tissues of the vaginal canal due to the deeper penetration and more aggressive nature of action of the $CO_2$ laser [30, 31]. In our series, the technique used is unique as dual mode ablation action. The first shot of 250-μs multi-pulse creates a window in the epidermal tissue, allowing the thermal effect of the subsequent shots to penetrate to the lamina propria layer of the vaginal wall mucosa. In the second stage of the dual mode technique, a sub-ablative single shot in a long-pulsed mode penetrates through the created epidermal window and into the lamina propria causing the desired wound healing and vaginal tightening effect (Fig. 3) [32].

This technique allows to balance the degree of necessary effect with as short as downtime as possible and minimal side effects. Comparatively, a study of 30 patients with vaginal relaxation syndrome was conducted to evaluate the clinical efficacy of ER:Yag vaginal laser treatment. Their results were similar to our study with significant improvement in vaginal wall relaxation in all patients based on perineometer values, 76.6% improvement on the partners' input for vaginal tightening and 70% improvement in sexual satisfaction as assessed by the patients themselves. Additionally, histological findings also suggested improved elasticity, tightening, and firming of the vaginal wall [16].

In our study, the average age was 39 years (ranged 27–47), and a high mean parity of 4 (range 1–7) (Table 1). Definitely satisfied patients were 57%, but those who expressed improvement were 78%. Based on the study, no conclusions can be made regarding

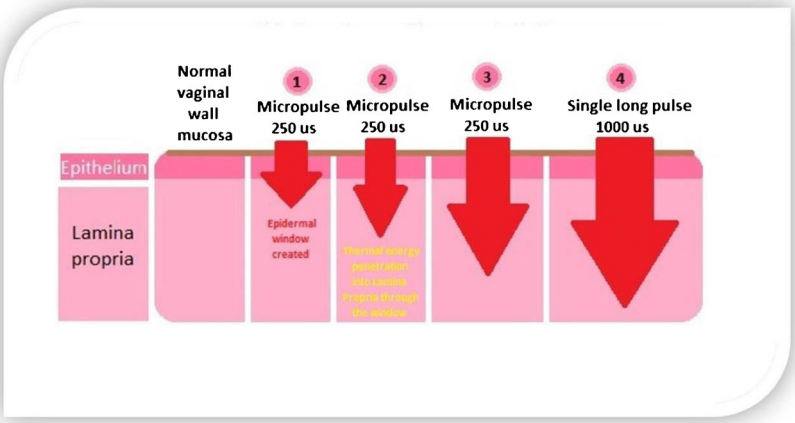


**Fig. 3** Illustration showing the different levels of penetration depending through the vaginal wall layers

parity level and the satisfaction rate. Both menopausal and pre-menopausal women expressed improvement, but the pre-menopausal were more satisfied.

The main advantages of Er:YAG seen in this case series are:

1. No definitive contraindication for early coitus (1 week post session)
2. No antibiotic or pain killer
3. Easily repeated
4. Short procedure time
5. Ambulatory procedure
6. No risk of anesthesia
7. No patients reported dryness or dyspareunia which is quite an improvement if compared to the surgical patients who may suffer from prolonged healing, pain, localized infection, vaginal bleeding, dyspareunia, and decreased of vaginal lubrication [11, 12, 33, 34].

There are many conflicting opinions and controversy regarding esthetic vaginal surgery. Recently, this has been a hot topic in medical and public media. Some publications of negative articles regarding cosmetic gynecology have been unfair to the cosmetic gynecologist [35, 36].

The problem with statements of important medical organization like ACOG and FDA is that they group all cosmetic surgical procedures together. ACOG committee opinion included vaginal rejuvenation, design vaginoplasty, revirgination, and G-spot amplification all together stating that there is lack of data supporting the efficacy and safety of the procedures [37].

The recent FDA statement that the safety and effectiveness of laser and energy-based devices have not been evaluated or confirmed for vaginal rejuvenation and that these procedures have serious risks like vaginal burns, scarring, pain during intercourse, and chronic pain [38].

Unfortunately, this is a strong blanket statement including all devices without differentiation or specific evidence. We are here talking about vaginal laser treatment for vaginal laxity, genitourinary symptoms of menopause, and stress urinary incontinence. So in this context, the issue of safety and complications does not apply because we have enough evidence from many non-randomized clinical trials that vaginal treatment with $CO_2$ or Er:Yag laser for genitourinary symptoms of menopause, vaginal tightening, and stress urinary incontinence is very safe with minimal side effects. There have been no reported cases of scarring, adhesions, dyspareunia, infections, or altered sensation [1, 4, 15–18, 24–29, 39].

Probably, the confusion comes from combining surgical procedure (that involves cutting the vagina tissue using laser for the aim of doing vaginal repair) with the use of Er:Yag or $CO_2$ laser for vaginal tightening or genitourinary syndrome of menopause under one heading "vaginal rejuvenation procedures" which is not correct because the use of Er:Yag laser does not involve any cutting or scarring, and it has minimal side effects.

Arguments that these procedures are not medically indicated may be true for women who simply want tighter vaginas without any symptoms. However, we as physicians have been always taught to respect the patient's autonomy which means her right to make decisions about her medical care without the health care provider trying to influence the decision, but does allow to educate the patient.

Our job as health care providers is to explain to the patient the pros and cons of the procedure and let her decide if she wants to do it. So in the case of Er:Yag laser vaginal tightening, we are explaining that the response to treatment is variable, and we do not promise that it will improve sexual function. Also, the patient is informed that there is some evidence from clinical trials that up to 70% of patients are satisfied with the treatment.

On the other hand, patients with genitourinary syndrome of menopause and those with stress urinary incontinence have real medical indication requiring intervention. Few cohort and pilot studies have shown that laser vaginal treatment is successful in relieving these symptoms, and even when compared to topical hormonal treatment, the results were more pronounced and longer lasting for those who received the laser therapy. Also, patients with stress urinary incontinence show improvement with vaginal laser treatment [28, 29, 39].

## Conclusions

Er:YAG laser treatment for VRS, the dual mode (multiple micro-pulse mode followed by a long-pulsed mode), can be of a beneficial effect in vaginal relaxation and consequentially may improve sexual satisfaction. In our parent population, this non-surgical treatment was safe, easily tolerated, pain- and side-effect free, and can be an effective treatment to improve the quality of life for females of all ages suffering from VRS.

Further studies with longer follow-up are needed to evaluate laser and other energy-based treatment, to compare it to other modalities of therapies and to assess the duration of the therapeutic effects as well as the sexual satisfaction of the sexual partners after the treatment.

## Compliance with ethical standards

**Conflict of interest** Jamal Jomah, Abdullah Wael Bahi, Khaled Prince Mousa, Alaa El-Saharty, and Salwa Mohammed Neyazi declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this retrospective study formal consent from a local ethics committee is not required.

**Informed consent** Informed consent was obtained from all individual participants in the study.

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