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Full length article

European Board and College of Obstetrics and Gynaecology (EBCOG) position statement on the use of laser vaginal devices for treatment of genitourinary syndrome of menopause, vaginal laxity, pelvic organ prolapse and stress urinary incontinence

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ABSTRACT

One in three women will experience pelvic floor disorders in her lifetime and nearly 60 percent of post-menopausal women are affected by vaginal dryness. Conservative management is recommended as first line treatment for pelvic organ prolapse and stress urinary incontinence. Also, vaginal estrogens are often prescribed for symptomatic vaginal atrophy. Lasers have been used in cosmetic industry for connective tissue remodeling and repair of skin. Their use in the last decade for treating genitourinary symptoms of menopause, pelvic organ prolapse and stress urinary incontinence has gained popularity but there is lack of robust evidence to support its use in routine practice. The European Board and College of Obstetrics and Gynaecology calls for high quality evidence with patient related outcome measures before adopting to routine clinical practice.

Energy-based devices (EBDs) have been used for connective tissue remodeling in dermatology for many decades. Vaginal lasers aiming to achieve collagen remodeling of the vaginal subepithelial connective tissue have been introduced over the last decade and promoted as innovative, non-invasive, safe and effective treatments for a number of gynaecological conditions such as genitourinary syndrome of menopause, stress urinary incontinence, vaginal laxity and pelvic organ prolapse. The most commonly used devices in gynaecology are the carbon dioxide (CO_2) ablative laser and the erbium YAG (Er:YAG) non-ablative laser.

In 2018, the United States Food and Drug Administration (FDA) issued a warning against the use of EBDs, including lasers, to perform "vaginal rejuvenation" [1]. There is a lack of robust evidence on effectiveness and safety of vaginal lasers.

Laser treatment for genitourinary syndrome of menopause (GSM)

GSM is a chronic condition affecting approximately 40 %–60 % of postmenopausal women [2]. The first line treatment is low dose vaginal estrogens while vaginal moisturisers or oral ospemifene are the alternative options. Non-hormonal options such as intravaginal laser have potential when vaginal estrogens are contraindicated or ineffective and for women who decline hormones [3]. The safety of vaginal fractional CO_2 laser therapy has been shown in several randomised controlled trials (RCTs). The efficacy of the CO_2 laser was found to be similar to vaginal estrogens for GSM symptoms [4]. However, RCTs comparing the microablative CO_2 laser with sham have reported conflicting results. Salvatore et al. [5] and Ruanphoo et al. [6] demonstrated the superiority of the laser while Li et al. [7] and Page et al. [8] showed that the treatment response after laser application was comparable to that of sham application (Table 1).

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Table 1
Laser treatment for GSM.

Study	Design	Primary outcome	Results
Salvatore, 2021 [5]	RCT	Dryness/dyspareunia as VAS at 4 months	Laser group (n = 30) vs sham group (n = 30). 58 were followed-up. Laser group vs sham group: mean [SD] −5.6 [2.8] vs −1.9 [2] for dryness (p < 0.001), −6 [2.6] vs −1.1 [1.8] for dyspareunia (p < 0.001).
Ruanphoo, 2020 [6]	RCT	VHI[1] score at 12 weels – intention-to-treat analysis	Laser group (n = 44) vs sham group (n = 44). 79 were followed-up. The mean difference between laser versus sham group was 1.37 (95 % CI: 0.12–2.63) (p < 0.001)
Li, 2021 [7]	RCT	VAS[2] and VSQ[3] at 12 months	Laser group (n = 43) vs sham group (n = 42). 78 were followed-up. No significant difference between groups. VAS score for overall vaginal symptoms: −17.2 vs −26.6; difference, 9.4 [95 % CI, −28.6 to 47.5]. VAS score for the most severe symptom: −24.5 vs −20.4; difference, −4.1 [95 % CI, −32.5 to 24.3]. VSQ score: −3.1 vs −1.6; difference, −1.5 [95 % CI, −5.9 to 3.0].
Page, 2022 [8]	RCT	MBS[4] at 3 months	Laser group (n = 30) vs sham group (n = 30). 57 were followed-up. The decrease of the MBS severity score was 23.6 % (95 % CI −36.1 % to −11.1 %) in the laser group and 13.2 % (95 % CI –22.7 % to −3.73 %) in the sham group. There was no difference in drop of MBS score (p = 0.13).

1. VHI = vaginal health index; 2. VAS = visual analog scale; 3. VSQ = vulvo-vaginal symptom questionnaire; 4. MSB = most bothersome symptom.

Laser for vaginal laxity and pelvic organ prolapse (POP)

Vaginal laxity is a poorly understood but common symptom of pelvic floor dysfunction that currently lacks a standardised definition. It may be considered a symptom of prolapse and it is a manifestation of levator ani hyperdistensibility [9]. The use of laser therapy for vaginal laxity and POP is still a relatively new approach, with limited available evidence for its efficacy and safety [10]. Supervised pelvic floor muscle training and use of pessaries are established non-surgical options for treatment of POP. Ogrinc et al. [11] evaluated the effects of non-ablative Er:Yag in 61 women with a stage 2 to 4 cystocele. Follow-up visits were performed at 2, 6 and 12 months. The authors report a consistently significant anatomical improvement throughout the study period. Of note, a control group was not evaluated. Athanasiou et al. [12] enrolled 30 postmenopausal women, who were awaiting surgery for a symptomatic stage 2/3 cystocele and/or rectocele. These were randomised to either non-ablative Er:YAG laser treatment or watchful waiting. A stage 0 or 1 POP ("objective cure") at 4 months following laser treatment was primarily evaluated. However, none of the patients were cured. In the laser group, the POP stage remained unchanged in 11/15 (74 %) of participants and decreased by one stage in 2/15 (13 %). There are no good quality studies to evaluate the use of laser for women with vaginal laxity.

Laser treatment for stress urinary incontinence (SUI)

The first line treatment for SUI is supervised pelvic floor muscle training. Due to the concerns about the use of synthetic midurethral slings, vaginal lasers have been promoted as a potential treatment option for SUI. Recently, four RCTs have been published that have shown conflicting results. Regarding the Er:YAG laser, O'Reilly et al. [13] conducted a multicentre sham-controlled trial including 110 women with urodynamic SUI. A standardised 1-h pad weight test was performed at baseline and at 6-month follow-up. A greater than 50 % reduction in the pad weight was considered as primary outcome. Of 89 women followed-up, treatment success was observed in 33/56 (59 %) in the active arm and 12/33 (36 %) in the sham arm. The authors conclude that women treated with Er:YAG laser had a three-fold higher chance of success, with an odds ratio of 3.6 (95 % CI: 1.3 – 11.2, p-value = 0.02). Interestingly, women with mild to moderate SUI appeared to have benefitted from the laser treatment to a greater degree compared to women with severe SUI. These findings contrast with the results reported by a single site RCT from Canada [14], which enrolled 134 women with a clinical diagnosis of SUI. Over 90 % of participants from either Er:YAG laser (67/73) and sham (58/61) treatment were followed-up at 6 months. A self-reported symptom of no urinary incontinence with the International Consultation on Incontinence Questionnaire-Urinary Incontinence (ICIQ-UI) Short Form (SF) was evaluated as primary outcome. "Cure" was reported by one patient only in each group. Both laser and sham groups showed an improvement in ICIQ-SF total scores at 6-months, but there was no significant difference in the changes from baseline between groups. There are also conflicting reports for the CO_2 laser. A single centre RCT from Seki et al. [15] evaluated the subjective impression of improvement in SUI (Likert scale) and objective cure as primary outcomes. At 12-month follow-up, both outcomes were significantly better in the laser (n = 38) when compared to the sham (n = 38) group. However, the effect of CO_2 laser was also evaluated by Alexander et al. [16]. This multicentre Australian RCT included 52 women in the active treatment arm and 49 in the sham arm. At 3 months, there was no difference between the groups in subjective (ICIQ-UI SF questionnaire) and objective SUI.

EBCOG position

Laser treatments appear to be safe when performed by clinicians with appropriate training both in the use of laser but also in the condition they treat. There is heterogeneous and conflicting evidence as regards the efficacy of laser treatment. Vaginal laser is expensive, and it is unlikely to be cost-effective compared to alternative treatments. It may have a value in specific cohort of patients, not responding or not suitable for other treatments, such as women with GSM undergoing treatment for breast cancer. EBCOG recommends that laser device manufacturers should provide evidence about long-term data on safety and effectiveness of their own devices. We would recommend further good quality research targeting specific cohort of patients, standardising treatment regimens and using appropriate patient reported outcome measures.

This paper was approved at the Council meeting of EBCOG in May 2024.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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