Lasers for pelvic floor dysfunctions: is there evidence?

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Purpose of review
The purpose of this review is to discuss the available energy sources used in the vaginal canal that are currently being promoted for certain pelvic floor conditions and explore the body of peer-reviewed literature supporting their use.

Recent findings
The majority of research has focused on the use of fractional CO_2 laser treatment for genitourinary syndrome of menopause (GSM). Most of these studies are nonrandomized prospective studies, but their data consistently shows an improvement in symptoms without significant side effects.

Summary
Vaginal laser treatment for GSM is of particular interest to gynecologists as it provides patients with a history of estrogen receptor positive breast cancer, thromboembolic event, or other contraindication to hormone therapy, an effective treatment option. Currently, we are in the early stages of scientific investigation into the use of lasers in the treatment of pelvic floor dysfunction, but the emerging data is encouraging. The existing data is limited to mostly observational studies with additional quality randomized controlled trials and sham studies needed to ensure that physicians are providing the optimum evidence-based treatments to their patients. At the present time there is insufficient data to promote these therapies for stress incontinence, vaginal tightening, or other pelvic floor abnormalities.

Keywords
pelvic floor dysfunction, radio frequency ablation, vaginal laser

INTRODUCTION

The term 'pelvic floor dysfunction' (PFD) encompasses bladder, bowel, and sexual symptoms and issues with pelvic support and certain pain disorders [1]. The incidence of PFDs increases with age and with life expectancy rising, the burden of PFDs will only increase over time [2]. Consequently, PFD-related healthcare costs are expected to rise by 50% over the next 30 years [3].

PFD is often complex and multifactorial in origin. The wide range of conditions, which commonly result in multiple symptoms, can create significant challenges in the management of these patients. In general, these symptoms reflect quality of life issues whose outcomes assessment from various treatments should be patient derived, utilizing validated questionnaires.

Treatment options for PFD range from minimally invasive options (i.e. physical therapy) to medications and finally to invasive options such as surgery. Each treatment modality carries a unique set of risks and benefits. The use of lasers to treat gynecologic conditions dates back to the 1970s with the treatment of conditions such as genital warts, cervical dysplasia, and endometriosis [4]. Lasers have also been used to treat premalignant conditions of the vagina and vulva. However, more recently vaginal laser treatment have been offered in gynecology as a noninvasive treatment for a variety of pelvic floor issues such as vaginal atrophy, dyspareunia, vaginal laxity, and stress urinary incontinence (SUI). However, vague terminology, lack of formal definitions of success, and financially driven motives has led to confusion and skepticism. The objectives of this study are to discuss the available energy sources currently being promoted for certain

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KEY POINTS

- The quality of data supporting the use of vaginal lasers varies depending on the condition being treated; with the largest body of data surrounding its use for the treatment of GSM.
- The use of fractional CO_2 laser appears to be a viable treatment option for genitourinary syndrome of menopause.
- At the present time there is insufficient data to support the promotion of these therapies for treatment of PFDs such as SUI and vaginal tightening.

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CURRENT STATUS OF LASER USE FOR TREATMENT OF PELVIC FLOOR DYSFUNCTION

As previously mentioned, the role of lasers in gynecology has evolved from their initial use in the destruction and vaporization of lesions, to more recently promoting revitalization or what is sometimes termed 'rejuvenation' of vaginal and vulvar tissue in the hope of improving symptoms of vaginal atrophy, vaginal laxity, SUI, sexual dysfunction, and vulvar lesions. The quality of data supporting the use of vaginal lasers varies, with the largest body of data surrounding its use being in the treatment of GSM.

Up to 50% of postmenopausal patients will suffer from symptoms of GSM [5]. Unlike other menopausal symptoms, GSM symptoms are unlikely to resolve without treatment. Many patients will try several treatment modalities because of side effects or marginal improvement. Symptoms of GSM can also affect women who have undergone premature menopause while being treated for medical conditions such as breast cancer or endometriosis. In these conditions, estrogen treatment may be contraindicated, further limiting their treatment options. Several studies have shown that fractional CO_2 lasers can be an effective nonhormonal treatment option for GSM in breast cancer survivors [6–8] and the general population [9,10▪].

The majority of the studies investigating the use of laser treatment in gynecology have focused on its use in the treatment of GSM. As practitioners have gained experience with the treatment modality, some have extended its use to the treatment of other conditions of the pelvis (i.e. vaginal laxity, stress urinary incontinence) based on anecdotal experience or weak scientific evidence. These expanded indications may be premature and we should proceed with caution until adequately powered studies are performed.

TECHNIQUE FOR PERFORMING FRACTIONAL CO_2 LASER TREATMENT OF THE VAGINA

Fractional CO_2 laser treatment is an office-based procedure requiring less than 10 min to perform. The patient is placed into dorsal lithotomy position and the vulva can be prepped with topical lidocaine if severe introital discomfort is present. The vaginal probe is inserted to the vaginal apex and treatment is administered at designated intervals as the probe is withdrawn (Fig. 1). The procedure is generally well tolerated with patients able to return to normal activity the same day.

MECHANISM OF ACTION FOR LASER TREATMENT OF PELVIC FLOOR DYSFUNCTION

Lasers use beams of light to cause microscopic columns of thermal injury in a grid-like pattern, leaving intervening tissue intact. These small areas of damage heal quickly and result in less epidermal injury, fewer side effects (i.e. irritation or discharge) while still providing thermal damage into the middermis [11,12]. Histology studies have shown both immediate and delayed effects following fractional CO_2 laser treatment. Immediate effects include collagen denaturation and contractions resulting in tightening of the skin while fibroblast recruitment with new collagen and elastin formation occurs later [13,14]. Fractional CO_2 lasers have been used in dermatology for over 40 years to treat pigmented lesions, tattoos, scars and unwanted hair [15]. The main fractional CO_2 laser system that has been utilized in the majority of the peer-reviewed publications is the Smart MonaLisa Touch

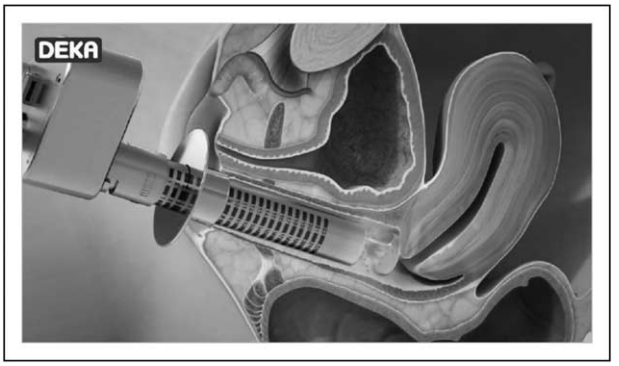

FIGURE 1. Technique for vaginal CO_2 laser. Printed with permission from DEKA.

(Cynosure, Westford, Massachusetts, USA). Other currently available systems in the U.S. include the FemiLift (Alma, Buffalo Grove, Illinois, USA) and Luminex (Medical Laser Systems, Branford, Connecticut, USA).

A 2015 ex-vivo cohort study by Salvatore evaluated the effects of the fractional CO_2 laser on postmenopausal women with vulvovaginal atrophy who were undergoing surgical correction of pelvic organ prolapse. Following tissue plication, redundant tissue on one side was treated with fractional CO_2 laser, excised and sent for microscopic evaluation. They reviewed 10 vaginal specimens collected from five patients with the contralateral vaginal specimen serving as control for each patient. They found morphological features related to vaginal connective tissue remodeling present immediately following treatment without signs of damage to the surrounding tissue [16▪▪].

Another study from that same year by Zerbinati evaluated vaginal mucosal samples taken from postmenopausal, nonestrogenized women following fractional CO_2 laser treatment of the vagina. They found rebuilding of thick stratified squamous epithelium and significant increase in glycogen storage in epithelial cells. They also noted fibroblasts actively synthesizing new collagen and newly formed papillae and blood capillaries piercing the papillae (Fig. 2). The authors concluded that these morphological changes provide evidence for the use of fractional CO_2 lasers for the restoration of vaginal mucosa [17].

Two prospective studies have evaluated the use of fractional CO_2 lasers for the treatment of lower urinary tract symptoms. A 2016 study by Perino *et al.* evaluated 30 postmenopausal patients with overactive bladder (OAB) who had previously failed vaginal estrogen therapy. Patients were evaluated at baseline and following a cycle of three treatments. They found significant improvement in number of voids per day, number of urge episodes per day, and

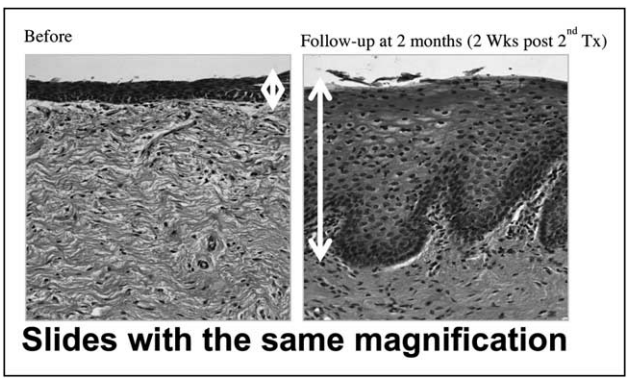

FIGURE 2. Vaginal histology before and after vaginal CO_2 laser treatment. Reproduced with permission [17].

OAB quality of life indicator scores (all $P < 0.0001$) [18]. Similarly, a 2016 observational study of 53 postmenopausal women with GSM undergoing fractional CO_2 vaginal laser therapy showed significant improvement from baseline in all validated quality of life questionnaires used (all $P < 0.001$) [9].

Similar to fractionated CO_2 lasers, Erb:YAG lasers use pixilated beams of light to induce a microscopic column of thermal injury that leads to both collagen contraction and fibroblast recruitment to the area.

Recently, several studies have evaluated the use of Erb:YAG lasers in the treatment of varying causes of PFD. Overall these studies have shown positive changes to tissue histology and improvement in patient assessments of GSM and SUI. These preliminary studies are promising, but further high-quality studies will be needed before Erb:YAG laser therapy can be fully endorsed as a treatment for PFD.

Erb:YAG laser for genitourinary syndrome of menopause

A 2016 single-site nonrandomized prospective study by Gaspar evaluated GSM symptoms in 50 postmenopausal women who received either vaginal Erb:YAG laser therapy with two weeks of pretreatment with vaginal estriol ($n = 25$) or 8 weeks of vaginal estriol. They found a significant decrease in vaginal pH at 12-month follow-up for the laser group ($P < 0.001$). Unlike the laser group, patients receiving estriol alone were noted to have an initial decrease in vaginal pH, but by 12 months, the pH had returned to baseline. Finally, vaginal biopsies of patients in the laser therapy group at baseline and 1, 3, 6, and 12 months after treatment completion showed increased fibroblasts, fibrillary components, and vascularity in the lamina propria and in thickness of epithelial layers and dermal papillae supporting both physiologic and histologic responses to vaginal Erb:YAG laser treatment [19].

Two single-site, nonrandomized, nonblinded comparative studies compared vaginal Erb:YAG laser therapy to local vaginal estrogen therapy for the treatment of GSM. Both studies found significant improvements in visual analog scores and the Gloria Bachmann Vaginal Health Index for both laser and estrogen therapy groups, but noted that the improvement in symptoms was greater and lasted longer in the laser therapy group after treatment completion ($P < 0.05$) [8,19].

Erg:YAG laser for stress urinary incontinence

Four single-site, prospective studies evaluated Erb:YAG laser therapy for treatment of SUI using

the Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF). All four studies found significant decreases in scores from baseline to approximately 2–6 months after treatment completion ($P \leq 0.001$–0.01), although results may be confounded by the inclusion of women with mixed urinary incontinence and multiple other potential confounding variables [8,20–22].

RADIOFREQUENCY ABLATION FOR TREATMENT OF PELVIC FLOOR DYSFUNCTION

Radiofrequency ablation is an energy-based therapy that allows for noninvasive treatment of PFD. Radiofrequency energy creates heat via impedance as electric current is passed though tissue. The isolated increase tissue temperature results in local fibroblast activation [23]. While several radiofrequency ablation devices are available, this review of the literature only evaluates the Geneveve (Viveve) and ThermiVa (Almirall) systems. The majority of research surrounding the use of radiofrequency ablation for PFD is focused on 'vaginal tightening'.

A 2016 study evaluated the Viveve radiofrequency ablation device in women with subjective complaints of vaginal laxity. They found patients undergoing active treatment were more likely to report 'no vaginal laxity' and had improved Female Sexual Function Index (FSFI) and Female Sexual Distress Scale-Revised (FSDS-R; $P = 0.031$ and 0.056, respectively) [24]. Another 2016 prospective study found an improvement in SUI amount menopausal women with GSM undergoing vaginal radiofrequency therapy [25]. Overall these studies demonstrate positive results for the treatment of SUI and vaginal laxity, but are limited by study design and small sample size. In addition, questions regarding the durability of treatment effects remain to be answered.

CONCLUSION

The use of energy sources (laser and radiofrequency) has seen a rapid rise in popularity for the treatment of PFDs due to its noninvasive nature, short recovery time and minimal side effects. This widespread adoption has outpaced the production of quality scientific data to support their use for certain conditions. The American College of Obstetricians and Gynecologists (ACOG) published a position statement in 2016 regarding the use of fractional CO_2 laser therapy for vulvovaginal atrophy. The college cautions providers adopting technology based upon marketing while urging physicians to provide thorough counseling to patients involving device safety, efficacy, and alternative treatment modalities [26].

Currently, we are in the early stages of scientific investigation into the use of lasers in the treatment of PFD, but the emerging data are encouraging. The largest number of studies focuses on the use of fractional CO_2 laser therapy for GSM. The use of vaginal laser for GSM is an exciting addition to the gynecologist armamentarium to treat a condition that affects a large percentage of the population. A search of ClincalTrials.org finds one such study currently enrolling patients is the multicenter, randomized single blinded clinical trial, Comparison of Vaginal Laser Therapy to Vaginal Estrogen Therapy (VeLVET). At the present time there are insufficient data to support the promotion of these therapies for treatment of PFDs such as SUI and vaginal tightening.

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Conflicts of interest

M.K. is a consultant and speaker for Cynosure.

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- ■ of special interest
- ■■ of outstanding interest

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