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Review Article

Vaginal rejuvenation using energy-based devices

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ABSTRACT

Physiologic changes in a woman's life, such as childbirth, weight fluctuations, and hormonal changes due to aging and menopause, may alter the laxity of the vaginal canal, damage the pelvic floor, and devitalize the mucosal tone of the vaginal wall. These events often lead to the development of genitourinary conditions such as stress urinary incontinence; vaginal atrophy; dryness; and physiologic distress affecting a woman's quality of life, self-confidence, and sexuality. Various treatment modalities are currently available to manage these indications, varying from invasive vaginal surgery to more benign treatments like topical vaginal hormonal gels or hormone-replacement therapy. A new trend gaining momentum is the advent of energy-based devices for vaginal rejuvenation that apply thermal or nonthermal energy to the various layers of the vaginal tissue, stimulating collagen regeneration contracture of elastin fibers, neovascularization, and improved vaginal lubrication. This review aims to present the available technologies offering vaginal rejuvenation and the scientific evidence that underlines their safety and efficacy for this indication.

Introduction

Patient confidence and enthusiasm over the safety and documented efficacy of minimally invasive aesthetic procedures has spawned into seeking new indications and anatomical concerns to conquer. The aesthetics of the female genitalia have become an area of particular concern among women over the past decade, reinforced by the popularity of Brazilian waxing, fashion trends, and media promotion of nude images. Women in increasing numbers are choosing to alter their genital anatomy to gain greater self-esteem, diminish functional discomforts and difficulties, and improve sexual pleasure. Due to various causes ranging from childbirth and aging to genetics or even trauma, the female genital region becomes loose and lax over time, resulting in stress urinary incontinence, atrophic vaginitis, decreased sensation during coitus, and generalized dissatisfaction with the appearance of the area (Griffiths et al., 2006; Pauls et al., 2008a, 2008b, 2012). Thus, for both cosmetic and medical reasons, women seek to revitalize and strengthen the elasticity of the vaginal wall and hydration of the vaginal mucosa.

Vaginal rejuvenation, a marketing rather medical nomenclature, is an umbrella term used to describe a range of aesthetic and functional procedures that correct and restore the optimal structure of the vagina and surrounding tissues. On the one end of the spectrum lie noninvasive strategies that serve as a first-line approach to improving vaginal atrophy and dryness, such as lubricants and hormone replacement medications or rather ineffective Kegel exercises aiming to strengthen the pelvic floor muscles. On the other end, gynecologic or plastic surgeons perform invasive procedures such as labiaplasty to alter the labia minora and majora and the folds of skin surrounding the human vulva or vaginoplasty, which involves surgery to the pelvic floor (Benadiba, 2010; Dobbeleir et al., 2011; Goodman et al., 2016; Gowda et al., 2015; Griffiths et al., 2006; Hamori, 2014; Kent and Pelosi, 2012; Pauls et al., 2008a, 2008b, 2012).

Recently, however, surgical procedures and systemic and topical treatments have been supplemented with new, noninvasive, energy-based systems, which is a welcome development for the many women wary of surgery due to the risk, expense, and downtime involved. These devices have opened up a new market for nonsurgical vulvovaginal correction procedures that can be performed by a wider range of practitioners including dermatologists.

Among the new modalities being applied to feminine rejuvenation include CO2-based or erbium:yttrium-aluminum-garnet (Er:YAG) lasers and radiofrequency (RF)-based energy devices (Table 1). By harnessing laser or RF waves to heat the connective tissue of the vaginal wall to 40 °C to 42 °C, these energy-based devices aim to induce

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Table 1
Laser and Radiofrequency-Based Devices for Vaginal Rejuvenation.

Laser-based devices		Number of treatments
FemiLift Alma Lasers (Buffalo Grove, IL)	Fractional CO2 laser	3 Tx at 4–6 wk intervals
MonaLisa Touch, Cynosure (Westford, MA)	Fractional CO2 laser	3 Tx at 6 wk intervals
IntimaLase, Fotona (Dallax, TX)	2,940-nm nonablative Er:YAG	2 Tx at 8 wk intervals
Petit Lady, Lutronic (Burlington, MA)	2,940-nm Er:YAG	3 Tx at 2 wk intervals
Radiofrequency-based devices		
ThermiVa, ThermiAesthetics (Southlake,TX)	Temperature-controlled radiofrequency	3 Tx at 4–6 wk intervals
ReVive, Viora (Jersey City, NJ)	Bipolar radiofrequency	4-6 Tx at 2–3 wk intervals
Venus Fiore, VenusConcept (Toronto, CA)	Multipolar-radiofrequency with pulsed electromagnetic field	3 Tx at 1 wk intervals
Viveve System, Viveve Medical (Sunnyvale, CA)	Patented radiofrequency	1 Tx
Protégé Intima, BTL Aesthetics, (Framingham, MA)	Focused radiofrequency	2-4 Tx every 2–3 wks
Pelleve, Ellman International (Hicksville, NY)	Monopolar radiofrequency	3 Tx at 2–3 wk intervals

Tx = Treatment.

collagen contraction, neocollagenesis, vascularization, and growth factor infiltration that ultimately revitalize and restore the elasticity and moisture of the vaginal mucosa. Although numerous studies have demonstrated the therapeutic efficacy of energy-based devices in rejuvenation of the face, neck, and decollete, their application in the vaginal canal is a fairly new concept with a paucity of clinical studies currently available to validate their efficacy. Nevertheless, a plethora of devices are currently available, marketed, and developed with specific hand-pieces for this indication. The array of these devices, their underlying mechanism of action, and any available studies pertinent to their safety and efficacy will be described in this review.

RF-based devices for vaginal rejuvenation

RF devices that emit focused electromagnetic waves generating heat upon meeting tissue impedance have been widely applied for an array of aesthetic indications in facial and off-face sites, targeting cellulite, laxity, and noninvasive fat removal (Sadick et al., 2014a, 2014b). Since RF energy is unabsorbed by melanin, the technology is safe for all skin types and has a proven clinical history in terms of safety, efficacy, and patient satisfaction. Although transurethral monopolar RF has been used to treat stress urinary incontinence with minimal risk of adverse events, nonablative RF has only recently been explored as a noninvasive strategy to achieve tightening of the vaginal canal (Dillon and Dmochowski, 2009).

Several devices in the market currently offer RF-based vaginal rejuvenation. None of these technologies require anesthesia, and on average, the treatment duration spans 15 to 30 min. Patients report feeling a sensation of warmth, which is very tolerable, and due to the lack of downtime, they can resume their normal activities the same day.

The Protégé Intima from BTL Aesthetics, (Framingham, MA) exploits focused RF with built-in safety features that allow collagen remodeling treatments at high energy levels, without temperatures reaching the skin's surface or compromising patient comfort.

The Pelleve device from Ellman International (Hicksville, NY), which emits monopolar RF and is widely used for facial skin rejuvenation, has been used off-label for nonsurgical reduction of the labia majora. The device's thermal energy denatures the dermal collagen, inducing remodeling and tissue tightening and subsequent reduction of redundant skin in the area. Treatments at monthly intervals for three or four sessions have been recommended to achieve optimal clinical results (Hamori, 2014).

The ReVive from Viora (Jersey City, NJ) employs bipolar RF energy that utilizes three distinct RF frequency channels (0.8 MHz, 1.7 MHz, and 2.45 MHz) and an additional fourth multichannel mode, combining all three RF frequencies to improve labial skin laxity and texture using the unit's V-ST handpiece. This proprietary technology is designed to ensure accurate energy delivery for safe and painless treatments, broader dermal effect, and higher energy absorption for optimal clinical results. The V-ST handpiece emits RF energy fluency of up to 130 J/cm^3 with pulse duration of up to 200 ms and includes an integral cooling mechanism that cools the electrodes to 6 °C.

A single-center blinded study with 14 healthy female patients, mean age of 50 years, investigating the safety and efficacy of V-ST handpiece for labial skin laxity and texture demonstrated moderate improvement score according to the investigator ratings with 67% of the patients reporting great satisfaction with the treatment results. Patients underwent an average of 5.6 treatments with no anesthesia, which lasted 30 min, and sessions were at 2- to 3-week intervals. Treatments were well tolerated by all patients with no adverse events or side effects recorded (Steven et al., 2014).

The Viveve System from Viveve Medical, (Sunnyvale, CA) uses a proprietary form of RF-based energy to remodel collagen and restore the tissue in the vaginal introitus. The system's efficacy is bolstered by a strong safety profile and fast patient recovery. Two clinical reports have been published demonstrating the efficacy of the device for vaginal laxity following vaginal delivery.

Millheiser et al. (2010) conducted a pilot study in 24 women (aged 25–44 years) using reverse gradient RF energy (75–90 J/cm^2), delivered through the vaginal mucosa. Post-treatment assessments were at 10 days and 1, 3, and 6 months. Results from the study showed that after 1 month, post-treatment self-reported vaginal tightness significantly improved in 67% of subjects and in 87% at 6 months. Mean sexual function scores also improved, and no adverse events were reported. In another prospective single-arm study by Sekiguchi et al. (2013), 30 premenopausal women (aged 21–52 years) were treated with a single 30-min office treatment using Viveve at 90 J/cm^2. Results included significant improvement in sexual function at 6 months in all subjects and decreased in distress related to sexual activity. Subjects also reported decreased vaginal laxity within the first month after the procedure, and effectiveness was sustained through 12 months.

Another RF-based device, ThermiVa from ThermiAesthetics, (Southlake, TX) uses an S-shaped handpiece that tightens external and internal vulvovaginal tissue via a thermistor tip, which also controls heat delivered to the skin. Monitoring of tissue temperature is done via a minimally invasive treatment probe.

In a prospective study by Alinsod (2015), 23 subjects (age range 26–58 years, mean 43.6 years; median vaginal births = 2, mean parity 1.7; 5 menopausal, 6 perimenopausal) with mild to moderate vulvovaginal laxity, sexual dysfunction, and mild to moderate stress urinary incontinence were treated using the ThermiVa device for approximately 5 min per zone. The clinical endpoint was achievement of the target temperature range of 40 °C to 45 °C for approximately 3 to 5 min per zone (or longer, depending on heat tolerance). This was followed by treatment of the mucosal surface of the vaginal introitus starting at the hymenal ring and advancing to approximately 4 to 9 cm into the cavity for each zone of the vaginal wall. Total treatment

time was less than 30 min. A complete course of therapy consisted of three treatments with the device, at an interval of approximately 4–6 weeks. Assessment occurred at baseline, 10 days after first treatment, before second treatment, before third treatment, and 30 days after the third treatment session. Patients were able to resume all activity as normal, including sexual intercourse, immediately after each treatment. All patients experienced a tightening result immediately after the first treatment with a significant change in the vaginal laxity score by 3 points on a 7-point scale at the second treatment visit. Significant improvement in sexual satisfaction and decrease in urinary incontinence was also noted. Treatments were well tolerated, and no adverse effects were reported.

Laser-based devices for vaginal rejuvenation

Minimally ablative fractional laser therapy has gained acceptance as a safe, precise, and efficient method for skin resurfacing and restoration, especially in the field of plastic surgery and dermatology. The basis of fractional photothermolysis lies in using an array of small laser beams to create many microscopic areas of thermal necrosis within the skin, known as microscopic treatment zones. Epidermis and dermis within the microscopic treatment zones are destroyed inducing a wound-healing cascade with subsequent new collagen and elastin fiber formation that translates into healthier, firmer, and tighter skin (Ross et al., 1996; Sandel and Perkins, 2008). The CO2 (10,600 nm) and the Er:YAG laser, with its 2,940-nm wavelength that emits laser energy in the mid-infrared invisible light spectrum are the most widely used lasers in the skin rejuvenation field and have recently been applied to the vaginal tissues a for the treatment of symptomatic vulvar and vaginal atrophy (Gambacciani and Levancini, 2015; Gambacciani et al., 2015a, 2015b; Hutchinson-Colas and Segal, 2015).

Several fractional ablative lasers have been utilized for noninvasive rejuvenation of the vaginal canal and their safety profile, and efficacy has been underscored by peer-reviewed clinical studies. Typically, treatment sessions last 10 to 20 min, and no anesthetic is required. Most patients report almost no discomfort other than a warming sensation, but if a patient prefers, a topical anesthetic cream can be applied prior to treatment. No downtime is required, and regular activities can be resumed the same day.

MonaLisa Touch, which was developed in Europe by DEKA (Florence, Italy) and is now distributed in the United States by Cynosure, Inc. (Westford, MA), is a CO2 laser designed to stimulate and promote the regeneration of collagen fibers and to restore hydration and elasticity within the vaginal mucosa. The device is targeted for the treatment of atrophic vaginitis, vaginal laxity, mild urinary incontinence, or other sexual problems related to postpartum. It has also been utilized as an ancillary instrument in female genital surgery (labioplasty, vaginal reshaping, and clitoral unhooding), ensuring that surgery is effective and safe while also reducing postoperative discomfort. The MonaLisa fractional CO2 laser uses patented DOT Therapy to apply laser energy to the vaginal walls in a noncontinuous mode in small 200-micron dots, thus directly affecting only a small percentage of vaginal tissue. Different types of probes (360°, single-mirror, disposable, and vulvar applicator) accompany the device to adapt to the specific clinical and/or anatomic needs of individual patients.

Salvatore et al. analyzed ex vivo vaginal specimens from postmenopausal women and observed tissue remodeling without damage to surrounding tissue, after the application of fractional CO_2 laser technology (Salvatore et al., 2015a, 2015b). A subsequent study assessing the efficacy of microabalative fractional CO2 laser in treating sexually active menopausal patients who had dyspareunia related to vulvovaginal atrophy showed significant improvement reported at 12-week follow-up (Salvatore et al., 2014).

In an independent study by Zerbinati et al. (2015) on biopsies from vaginal mucosa samples extracted from 50 postmenopausal, nonestrogenized women treated with the MonaLisa, restoration of the vaginal thick squamous stratified epithelium with a significant storage of glycogen in the epithelial cells was observed together with fibroblast activation and neosynthesis of extracellular matrix. The laser settings used in this study were energy fluence above 100 mJ per pulse, with a pulse duration of 1,000 μs, and a single spot size of 200 μm.

Salvatore et al. conducted a prospective study in 77 postmenopausal women (mean age 60 years) treated for vulvovaginal atrophy with MonaLisa Touch to investigate the effect of treatment on sexual satisfaction. Sexual function and quality of life were evaluated with the Female Sexual Function Index and the Short Form 12, respectively, both at baseline and at 12-week follow-up. A 10-mm visual analog scale was used to measure the overall satisfaction with sexual life and the intensity of vulvovaginal symptoms (vaginal burning, vaginal itching, vaginal dryness, dyspareunia, and dysuria) before and after the study period. Results demonstrated a significant improvement in the total score and the scores in each specific domain of the Female Sexual Function Index at 12-week follow-up compared to baseline as well as significant overall satisfaction with sexual life. Seventeen out of 20 women, sexually inactive because of the severity of their condition, regained a normal sexual life at the 12-week follow-up (Salvatore et al., 2015a).

Gaspar et al. evaluated the effects of vaginal fractional CO2 laser combined with local application of platelet-rich plasma (PRP) and pelvic floor exercise for improving vaginal dryness, dyspareunia, and local irritation. The study group underwent PRP, CO2 laser, and pelvic exercise, whereas only PRP and pelvic exercise were applied to the control group. Results showed histological evidence of an increase in the fibrillar component of the extracellular matrix and vaginal epithelial thickness and a decrease of discomfort during sex in most patients in the study group compared with the control group (Gaspar et al., 2011). Perino et al. (2015) also confirmed safety, efficacy, and patient satisfaction following vaginal laser therapy for treating symptoms of vulvovaginal atrophy.

Similar to the MonaLisa, the FemiLift laser from Alma Lasers (Buffalo Grove, IL) is another device specifically designed to offer minimally invasive CO2 laser-based treatment that induces collagen deposition via concentrated thermal heating of the inner vaginal tissue layer.

The second type of ablative laser being utilized for vaginal rejuvenation is the Er:YAG laser with a 2,940-nm wavelength, which emits laser energy in the mid-infrared invisible light spectrum. This laser has 10 to 15 times the affinity for water absorption compared with the carbon dioxide wavelength (10,600 nm). In a comparative study using the ablative fractional lasers for vaginal tightening, in which one group received ablative CO2 laser therapy while the other group underwent treatment with a nonablative Er:YAG laser, improvement in vaginal tightening was observed in both groups; however, more complications were recorded in CO2-treated patients (Adrian, 2012).

IntimaLaser by Fotona (based in the United States and Europe) is a 2,940-nm, nonablative Er:YAG laser with proprietary "smooth-mode" technology that delivers energy to the vaginal mucosa tissue in a fast sequence of low-fluence laser pulses inside an overall super-long pulse of several hundred milliseconds, resulting in a nonablative heating to a depth of 100 microns that tightens the vaginal canal via neocollagenesis and remodeling. Another Er:YAG laser recently released in the market is the Action II Petit Lady from Lutronic, Inc. (Fremont, CA), which enables practitioners to effectively treat a wide range of vulvovaginal symptoms and conditions, including vulvovaginal atrophy and urinary incontinence. The Action II Petit Lady features a dual mode that automatically combines multiple micropulses with long-pulse modes. This new treatment approach enables a deeper secondary thermal effect and the controlled heating of the target mucous membrane of the vaginal wall.

Several clinical studies have utilized the Er:YAG for both improvement of vulvovaginal atrophy and stress urinary incontinence. In a

pilot prospective study, 45 postmenopausal women with genitourinary syndrome of menopause received three treatments at 30-day intervals with Er:YAG laser (spot size 7 mm, 1.6 Hz, 6.0 J/cm^2), and the results were compared with the effects of a standard treatment of hormonal vaginal gel therapy in a group of 25 postmenopausal women. Results demonstrated that compared to the vaginal gel, the Er:YAG treatment led to significant decrease in both vaginal dryness and dyspareunia as well as significant improvement of urinary incontinence. The effects were rapid and long lasting, up to the 24th week of the observation period, and treatments were well tolerated with less than 3% of patients discontinuing treatment due to adverse events (Gambacciani et al., 2015a, 2015b).

Ogrinc et al. (2015) evaluated the effects of Er:YAG laser in 175 women (mean age 49 years) suffering from stress urinary incontinence. The subjects were treated two times at a 2-month interval with the IntimaLase laser set in "smooth mode" (fluence 10.0 J/cm^2; four pulses per packet, packet pulse duration 250 ms; spot size 7 mm; repetition rate 1.6 Hz), and follow-ups were performed at 2, 6, and 12 months after the treatment. Results of the study showed that 77% of the subjects experienced a significant improvement after treatment, and only 34% of women exhibited mild urinary incontinence at the 1-year follow-up. No major adverse effects were noted, and treatments were well tolerated.

Finally, an international multicenter observational study is currently underway to evaluate the efficacy and safety of Er:YAG laser for the treatment of genitourinary syndrome and stress urinary incontinence called the Vaginal Erbium Laser Academy Study (VELAS). This study will evaluate the effects of three laser applications in mid-infrared 1,500 postmenopausal women. Subjective and objective symptoms will be evaluated at baseline with follow-up visits after 4 weeks from the last laser application, and subsequently every 3 months for 1 year. Findings from the VELAS have the potential to affect clinical care practice and health decisions for millions of women worldwide and substantiate the use of laser-based devices for the amelioration of genitourinary conditions (Gambacciani et al., 2015b).

Conclusion

New prevention, treatment, and management strategies are continuously explored to alleviate medical and aesthetic concerns in women regarding their genital area. The emergence of energy-based devices enables women and their physicians to have another treatment option in their armamentarium to consider, while weighing the associated risks and benefits. Although there is a lack of a robust, qualitative body of data on the therapeutic advantages of these technologies for vaginal rejuvenation, the research field is very active with large multicenter studies currently being conducted to facilitate the acquisition of knowledge and best practices (Digesu, 2015; Singh et al., 2015). Laser and RF technologies are widely and successfully used for treatments in dermatology and aesthetic medicine, stimulating the remodeling tissue properties and inducing the production of new collagen and elastic fibers. Thus, their application in the vaginal canal for feminine rejuvenation simply represents an expansion of therapeutic indications and hallmarks their versatility and the reactivity of biologic tissues to the beneficial effects of their mechanism of action. In the hands of well-trained physicians, energy-based devices are likely to benefit millions of women by aiding them in reclaiming, relishing, and reveling in their femininity at full capacity.

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