Noninvasive Vaginal Rejuvenation

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PRACTICE **POINTS**

- Noninvasive vaginal rejuvenation represents a growing area of cosmetic dermatology.
- Radiofrequency and ablative laser devices have demonstrated promising results in treating vaginal laxity and genitourinary syndrome of menopause, but US Food and Drug Administration approval has yet to be obtained.

Vaginal rejuvenation procedures are designed to improve the aesthetic appearance and/or function of the female genitalia. The popularity of these techniques continues to increase as more patients seek to reverse the effects of aging, childbearing, and/or hormonal changes. Newer strategies focus on laser and radiofrequency (RF) devices, which have provided noninvasive options for treatment. In this article, we review the safety and efficacy data behind these modalities.

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Vaginal rejuvenation encompasses a group of procedures that alter the vaginal anatomy to improve cosmesis or achieve more pleasurable sexual intercourse. External vaginal procedures are defined as those performed on the female genitalia outside of the vaginal introitus, with major structures including the labia majora, mons pubis, labia minora, clitoral hood, clitoral glans, and vaginal vestibule. Internal vaginal procedures are defined as those performed within the vagina, extending from the vaginal introitus to the cervix.

The prevalence of elective vaginal rejuvenation procedures has increased in recent years, a trend that may be attributed to greater exposure through the media, including reality television and pornography. In a survey of 482 women undergoing labiaplasty, nearly all had heard about rejuvenation procedures within the last 2.2 years, and 78% had received their information through the media.[1] Additionally, genital self-image can have a considerable effect on a woman's sexual behavior and relationships. Genital dissatisfaction has been associated with decreased sexual activity, whereas positive genital self-image correlates with increased sexual desire and less sexual distress or depression.[2,3]

Currently, the 2 primary applications of noninvasive vaginal rejuvenation are vaginal laxity and genitourinary syndrome of menopause (GSM). Vaginal laxity occurs in premenopausal or postmenopausal women and is caused by aging, childbearing, or hormonal imbalances. These factors can lead to decreased friction within the vagina during intercourse, which in turn can decrease sexual pleasure. Genitourinary syndrome of menopause, previously known as vulvovaginal atrophy, encompasses genital (eg, dryness, burning, irritation), sexual (eg, lack of lubrication, discomfort or pain, impaired function), and urinary (eg, urgency, dysuria, recurrent urinary tract infections) symptoms of menopause.[4]

Noninvasive procedures are designed to apply ablative or nonablative energy to the vaginal mucosa to tighten a lax upper vagina, also known as a wide vagina.[5] A wide vagina has been defined as a widened vaginal diameter that interferes with sexual function and sensation.[6] Decreased sexual sensation also may result from fibrosis or scarring of the vaginal mucosa after prior vaginal surgery, episiotomy, or tears during childbirth.[7] The objective of rejuvenation procedures to treat the vaginal mucosa is to create increased frictional forces that may lead to increased sexual sensation.[8] Although there are numerous reports of heightened sexual satisfaction after reduction of the vaginal diameter, a formal link between sexual pleasure and vaginal laxity has yet to be established.[8,9] At present, there are no US Food and Drug Administration (FDA)–approved energy-based devices to treat urinary incontinence or sexual function, and the FDA recently issued an alert cautioning patients on the current lack of safety and efficacy regulations.[10]

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In this article we review the safety and efficacy data behind lasers and radiofrequency (RF) devices used in noninvasive vaginal rejuvenation procedures.

Lasers

CO_2 Laser—The infrared CO_2 laser utilizes 10,600-nm energy to target and vaporize water molecules within the target tissue. This thermal heating extends to the dermal collagen, which stimulates inflammatory pathways and neocollagenesis.[11] The depth of penetration ranges from 20 to 125 μm.[12] Zerbinati et al[13] demonstrated the histologic and ultrastructural effects of a fractional CO_2 laser on atrophic vaginal mucosa. Comparing pretreatment and posttreatment mucosal biopsies in 5 postmenopausal women, the investigators found that fractional CO_2 laser treatment caused increased epithelial thickness, vascularity, and fibroblast activity, which led to augmented synthesis of collagen and ground substance proteins.[13]

New devices seek to translate these histologic improvements to the aesthetic appearance and function of female genitalia. The MonaLisa Touch (Cynosure), a new fractional CO_2 laser specifically designed for treatment of the vaginal mucosa, uses dermal optical thermolysis (DOT) therapy to apply energy in a noncontinuous mode at 200-μm dots. Salvatore et al[14] examined the use of this device in a noncontrolled study of 50 patients with GSM, with each patient undergoing 3 treatment sessions at monthly intervals. Intravaginal treatments were performed at the following settings: DOT (microablative zone) power of 30 W, dwell time of 1000 μs, DOT spacing of 1000 μm, and SmartStack parameter of 1 to 3. The investigators used the Vaginal Health Index (VHI) to objectively assess vaginal elasticity, secretions, pH, mucosa integrity, and moisture. Total VHI scores significantly improved between baseline and 1 month following the final treatment (mean score [SD], 13.1 [2.5] vs 23.1 [1.9]; $P<.0001$). There were no significant adverse events, and 84% of patients reported being satisfied with their outcome; however, the study lacked a comparison or control group, raising the possibility of placebo effect.[14]

Other noncontrolled series have corroborated the benefits of CO_2 laser in GSM patients.[15,16] In one of the largest studies to date, Filippini et al[17] reviewed the outcomes of 386 menopausal women treated for GSM. Patients underwent 3 intravaginal laser sessions with the MonaLisa Touch. Intravaginal treatments were performed at a DOT power of 40 W, dwell time of 1000 μs, DOT spacing of 1000 μm, and SmartStack of 2. For the vulva, the DOT power was reduced to 30 W, dwell time of 1000 μs, DOT spacing of 1000 μm, and SmartStack of 1. Two months after the final treatment session, patients completed a nonvalidated questionnaire about their symptoms, with improved dryness reported in 60% of patients, improved burning in 56%, improved dyspareunia in 49%, improved itch in 56%, improved soreness in 73%, and improved vaginal introitus pain in 49%. Although most patients did not experience discomfort with the procedure, a minority noted a burning sensation (11%), bother with handpiece movement (6%), or vulvar pain (5%).[17]

Recently, Cruz et al[18] performed one of the first randomized, double-blind, placebo-controlled trials comparing fractional CO_2 laser therapy, topical estrogen therapy, and the combination of both treatments in patients with GSM. Forty-five women were included in the study, and validated assessments were performed at baseline and weeks 8 and 20. Intravaginal treatments were performed at a DOT power of 30 W, dwell time of 1000 μs, DOT spacing of 1000 μm, and SmartStack of 2. Importantly, the study incorporated placebo laser treatments (with the power adjusted to 0.0 W) in the topical estrogen group, thereby decreasing result bias. There was a significant increase in VHI scores from baseline to week 8 ($P<.05$) and week 20 ($P<.01$) in all study arms. At week 20, the laser group and laser plus estrogen group showed significant improvements in reported dyspareunia, burning, and dryness, whereas the estrogen arm only reported improvements in dryness (all values $P<.05$).[18]

Erbium-Doped YAG Laser—The erbium-doped YAG (Er:YAG) laser is an ablative laser emitting light at 2940 nm. This wavelength provides an absorption coefficient for water 16 times greater than the CO_2 laser, leading to decreased penetration depth of 1 to 3 μm and reduced damage to the surrounding tissues.[19,20] As such, the Er:YAG laser results in milder postoperative discomfort and faster overall healing times.[21]

In a noncontrolled study of vaginal relaxation syndrome, Lee[22] used an Er:YAG laser fitted with Petit Lady (Lutronic) 90° and 360° vaginal scanning scopes. Thirty patients were divided into 2 groups and were treated with 4 sessions at weekly intervals. In group A, the first 2 sessions were performed with the 360° scope, and the last 2 sessions with the 90° scope in multiple micropulse mode (3 multishots; pulse width of 250 μs; 1.7 J delivered per shot). Group B was treated with the 90° scope in all 4 sessions in multiple micropulse mode (same parameters as group A), and during the last 2 sessions patients were additionally treated with 2 passes per session with the 360° scope (long-pulsed mode; pulse width of 1000 μs; 3.7 J delivered per shot). Perineometer measurements taken 2 months after the final treatment showed that the combined patient population experienced significant increases in both maximal vaginal pressure ($P<.01$) and average vaginal pressure ($P<.05$). Roughly 76% of patients' partners noted improved vaginal tightening, and 70% of patients reported being satisfied with their treatment outcome. Histologic specimens taken at baseline and 2 months postprocedure showed evidence of thicker and more cellular epithelia along with more compact lamina propria with denser connective tissue. The sessions were well tolerated, with patients reporting a nonpainful heating sensation in the vagina during treatment. Three patients from the combined patient population experienced a mild burning sensation and

vaginal ecchymoses, which lasted 24 to 48 hours following treatment and resolved spontaneously. There was no control group and no reports of major or long-term adverse events.[22]

Investigations also have shown the benefit of Er:YAG in the treatment of GSM.[23,24] In a study by Gambacciani et al,[24] patients treated with the Er:YAG laser FotonaSmooth (Fotona) every 30 days for 3 months reported significant improvements in vaginal dryness and dyspareunia ($P<.01$), which lasted up to 6 months posttreatment, though there was no placebo group comparator. Similar results were seen by Gaspar et al[23] using 3 treatments at 3-week intervals, with results sustained up to 18 months after the final session.

Radiofrequency Devices

Radiofrequency devices emit focused electromagnetic waves that heat underlying tissues without targeting melanin. The release of thermal energy induces collagen contraction, neocollagenesis, and neovascularization, all of which aid in restoring the elasticity and moisture of the vaginal mucosa.[25] Devices also may be equipped with cooling probes and reverse-heating gradients to protect the surface mucosa while deeper tissues are heated.

Millheiser et al[26] performed a noncontrolled pilot study in 24 women with vaginal laxity using the Viveve System (Viveve), a cryogen-cooled monopolar RF device. Participants underwent a single 30-minute session (energy ranging from 75–90 J/cm^2) during which the mucosal surface of the vaginal introitus (excluding the urethra) was treated with pulses at 0.5-cm overlapping intervals. Follow-up assessments were completed at 1, 3, and 6 months posttreatment. Self-reported vaginal tightness improved in 67% of participants at 1-month posttreatment and in 87% of participants at 6 months posttreatment ($P<.001$). There were no adverse events reported.[26] Sekiguchi et al[27] reported similar benefits lasting up to 12 months after a single 26-minute session at 90 J/cm^2.

A prospective, randomized, placebo-controlled clinical trial using the Viveve system was recently completed by Krychman et al.[28] Participants (N=186) were randomized to receive a single session of active treatment (90 J/cm^2) or placebo treatment (1 J/cm^2). In both groups, the vaginal introitus was treated with pulses at 0.5 cm in overlapping intervals, with the entire area (excluding the urethra) treated 5 times up to a total of 110 pulses. The primary end point was the proportion of randomized participants reporting no vaginal laxity at 6 months postintervention, which was assessed using the Vaginal Laxity Questionnaire. A grade of no vaginal laxity was achieved by 43.5% of participants in the active treatment group and 19.6% of participants in the sham group ($P=.002$). Overall numbers of treatment-emergent adverse events were comparable between the 2 groups, with the most commonly reported being vaginal discharge (2.6% in the active treatment group vs 3.5% in the sham group). There were no serious adverse events reported in the active treatment group.[28]

ThermiVa (ThermiGen, LLC), a unipolar RF device, was evaluated by Alinsod[29] in the treatment of orgasmic dysfunction. The noncontrolled study included 25 women with self-reported difficulty achieving orgasm during intercourse, each of whom underwent 3 treatment sessions at 1-month intervals. Of the 25 enrolled women, 19 (76%) reported an average reduction in time to orgasm of at least 50%. All anorgasmic patients (n=10) at baseline reported renewed ability to achieve orgasms. Two (8%) patients failed to achieve a significant benefit from the treatments. Of note, the study did not include a control group, and specific data on the durability of beneficial effects was lacking.[29]

The Ultra Femme 360 (BLT Industries Inc), a monopolar RF device, was evaluated by Lalji and Lozanova[30] in a noncontrolled study of 27 women with mild to moderate vaginal laxity and urinary incontinence. Participants underwent 3 treatment sessions at weekly intervals. Vaginal laxity was assessed by a subjective vulvovaginal laxity questionnaire, and data were collected before the first treatment and at 1-month follow-up. All 27 participants reported improvements in vaginal laxity, with the average grade (SD) increasing from very loose (2.19 [1.08]) to moderately tight (5.74 [0.76]; $P<.05$) on the questionnaire's 7-point scale. The trial did not include a control group.[30]

Conclusion

With growing patient interest in vaginal rejuvenation, clinicians are increasingly incorporating a variety of procedures into their practice. Although long-term data on the safety and efficacy of these treatments has yet to be established, current evidence indicates that fractional ablative lasers and RF devices can improve vaginal laxity, sexual sensation, and symptoms of GSM.

To date, major complications have not been reported, but the FDA has advocated caution until regulatory approval is achieved.[10] Concerns exist over the limited number of robust clinical trials as well as the prevalence of advertising campaigns that promise wide-ranging improvements without sufficient evidence. Definitive statements on medical or cosmetic indications will undoubtedly require more thorough investigation. At this time, the safety profile of these devices appears to be favorable, and high rates of patient satisfaction have been reported. As such, noninvasive vaginal rejuvenation procedures may represent a valuable addition to the cosmetic landscape.

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