



Vaginal Rejuvenation with Radiofrequency Energy: Weighing the Evidence



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>> Aging occurs in the vaginal tissue just as it does elsewhere in the skin. The effects of vaginal aging can cause such symptoms as vulvovaginal laxity, vaginal atrophy, orgasmic dysfunction, and stress urinary incontinence (SUI). Until recently, treatment options were limited to topical ointments, hormonal therapy, and pelvic floor strengthening with exercise and surgery. There has been an increase in the marketing and use of energy-based devices to help alleviate vaginal concerns, as well as a corresponding uptick of interest in these procedures.

There are currently five radiofrequency (RF) devices used off-label for noninvasive vaginal rejuvenation (NVR). In this article, I will review the available evidence on the RF devices and identify areas where more research is needed.

No devices are currently FDA cleared for vaginal rejuvenation. In an attempt to crack down on “deceptive marketing,” the FDA sent warning letters to seven companies asking for evidence to support any claims that their device safely and effectively treats vaginal atrophy, urinary incontinence, or reduced sexual function.

In general, RF stimulates collagen fibril contraction, wound healing, neo-

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collagenesis and thus tissue tightening. The polarity of RF devices determines how energy passes through the tissue. Cooling mechanisms are often employed to avoid epidermal and/or neurovascular injury.¹⁻³

DATA TO DATE

Viveve. Viveve (Viveve Medical) is a cryogen-cooled, monopolar RF system. In 2010, Millheiser et al. performed a pilot study of 24 premenopausal, postpartum patients with self-reported vaginal laxity. The vaginal mucosa (excluding the urethra) was treated with one 30-minute session (energy ranging between 75-90 J/cm²). Patients were followed up at one, three, and six months. Vaginal laxity improved in 67 percent and 87 percent of patients at one and six months, respectively. Those

who reported diminished sexual satisfaction prior to the study said their sexual arousal, orgasm experience, and satisfaction improved and was maintained at six months, while increased lubrication was temporary and returned to baseline at the three month follow-up. There were no adverse events seen in this study.⁴

A similar study of 30 premenopausal patients showed that vulvovaginal laxity improved at one month and that these improvements were sustained through month 12. Sexual satisfaction and dyspareunia improved at months 1 through 6 months but diminished by month 12.^{3,5} In 2016, Krychman et al. completed the first placebo-controlled trial with Viveve. Fully 174 randomized patients completed a single active (90 J/cm²) or placebo treatment (1 J/cm²). At six-



TABLE 1. RADIOFREQUENCY DEVICES USED OFF-LABEL FOR NVR3-5

Device	RF System	Treatment protocol	FDA Clearance	Off-label published uses for NVR
Viveve (Viveve Medical, Sunnyvale, CA)	MRF, cryogen-cooled	1 treatment, 30-45 minute session	For use in general surgery for electrocoagulation and hemostasis in the United States.	VVL, sexual arousal/satisfaction, OD, dyspareunia, SUI
ThermiVA (ThermiAesthetics, Southlake, TX)	Unipolar RF, temperature-controlled, no cooling	3 treatments, 30 minutes each, at 4-6 week intervals	For use in dermatological and general surgical procedures for electrocoagulation and hemostasis	VVL, AV, OD, dyspareunia
Exilis Ultra 360 (BTL Aesthetics, Framingham, MA) Previously: Protégé Intima, or Ultra Femme 360	MRF and ultrasound (US), no cooling	2- 4 treatments, 15-30 minutes each, at 1-week intervals	For non-invasive dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids, to provide a temporary reduction in the appearance of cellulite, and to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain and increase in local circulation.	SUI
Revive (Viora, Jersey City, NJ)	Bipolar RF (BRF), no cooling	4-6 treatments, at 2-3 week intervals	No FDA clearance	Labial skin laxity and texture
Pelleve (Ellman International, Hicksville, NY)	MRF, no cooling	3-4 sessions, at monthly intervals	For full-face non-ablative treatment of mild to moderate facial wrinkles and rhytids for all skin phototypes.	Nonsurgical reduction of the labia majora

month follow-up, 43.5 percent of patients in the active group reported no vaginal laxity, versus 19.6 percent in the placebo group. Improvements in sexual function were greater in the treatment group. Adverse events were similar in both groups, with vaginal discharge being the most common.⁶

An SUI treatment protocol is currently being studied by Viveve Medical, in which additional energy is provided beyond the introitus for support of the urethra. A feasibility study (VI-ERP-007) of 10 patients, split evenly to receive one or two treatments with the SUI protocol, found subjective improvement in SUI in more than 90 percent of patients, with no adverse events. A follow-up study of 35 patients (VI-ERP-010; NCT03066180) with objective analysis using a pad weight test and a bladder-voiding diary is currently underway, with promising preliminary results showing an improvement of more than 75 percent in pad weight and daily episodes of incontinence.⁷

ThermiVa. ThermiVa (ThermiAesthetics) is a transcutaneous, temperature-controlled radiofrequency system that has been studied for vulvovaginal laxity, SUI, and sexual function. Initial studies report subjective improvement of vulvovaginal laxity in 23 patients undergoing one to three treatments at four to six week intervals, with follow up one month after final treatment. Researchers further studied orgasmic dysfunction in 25 patients and found an average 33 percent reduction in time to orgasm in 23 patients, as well as increased vaginal tightening, moisture, and sensation. Follow-up investigation in 16 patients with vaginal atrophy and dyspareunia showed increased moisture two weeks after treatment and continued improvement lasting nine to 12 months.⁸

Leibaschoff et al. treated 10 SUI patients with the ThermiVa device, and 70 percent had a negative cough test post-treatment with results lasting 12 weeks. Histologic examination of vaginal tissue showed improvement of vaginal atrophy.

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In 2018, our practice examined vaginal tissue histologically before and after three treatments with ThermiVa, showing increased collagen, elastin, vascularity, and nerves. Clinical results revealed statistically significant improvement in vulvovaginal laxity, vaginal atrophy, and sexual satisfaction, and a trend towards improvement in orgasmic dysfunction and SUI.⁹

Other devices. There are other RF devices used off-label for noninvasive vaginal rejuvenation, but limited data exist regarding their use, efficacy, and safety. In 2017, Lalji and Lozanova evaluated the use of a monopolar RF and ultrasound device (Exilis Ultra 360, BTL Aesthetics) for SUI and vulvovaginal laxity in 27 patients. Participants were treated three times at one-week intervals. At one-month follow-up, frequency of urine leakage and degree of vaginal laxity improved in all patients based on questionnaires.¹⁰

A bipolar RF device (Revive, Viora) was found to moderately improve labial skin laxity and texture in a single-center study of 14 patients. Fully 67 percent of patients reported great satisfaction. Lastly, another monopolar RF device (Pelleve, Ellman International) has been reported to improve vaginal laxity, but there are no formal studies.⁵

FURTHER STUDY NEEDED

Preliminary studies do support the use of non-invasive RF devices for vulvovaginal laxity, vaginal atrophy, orgasmic dysfunction, and SUI, however most of the literature is lacking objective measures for improvement, and follow-up has been limited. Ongoing research seeks to fill in these gaps so that dermatologists can feel confident and comfortable offering these treatments to our patients. ■

This article is based on a presentation given at Cosmetic Surgery Forum (CSF) 2018. CSF moves to Nashville, December 4-7, 2019. For more information: cosmeticsurgeryforum.com.

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