Accepted: 13 February 2018

DOI: 10.1111/jocd.12524

ORIGINAL CONTRIBUTION

WILEY JCD Journal of Cosmetic Dermatology

Review and clinical experience exploring evidence, clinical efficacy, and safety regarding nonsurgical treatment of feminine rejuvenation

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Funding information
Fotona Dynamis, Syneron-Candela, Sciton, Luminus, ThermiAesthics, Viveve Medical, VenusConcept and BTL Aesthetics supported research for the manuscript with a grant

Summary

Introduction: The use of energy-based devices for the treatment of vaginal laxity, orgasmic dysfunction, and stress incontinence, such as minimally ablative fractional laser and radiofrequency, is gaining momentum. This review aims to answer clinical questions on the application of energy-based devices for feminine genital rejuvenation.

Methods: The target group includes physicians involved in esthetic medicine and feminine genital rejuvenation. A literature review was conducted on technologies in use for feminine rejuvenation to explore their safety, efficacy, tolerability, patient satisfaction, and clinical usability. A panel of physicians with clinical experience conducting these types of treatment reviewed and discussed the results of the literature search and gave clinical evidence-based recommendations.

Results: Energy-based devices may induce wound healing, stimulating new collagen, and elastin fiber formation. Radiofrequency treatment may also increase small nerve fiber density in the papillary dermis, improving nerve sensitivity, sexual function, including arousal and orgasmic dysfunction. Both minimally ablative fractional laser and radiofrequency has been shown to be effective when treating mild to moderate primary or secondary vulvovaginal laxity and associated secondary conditions. These treatments are reported to be safe, effective, and well tolerated with a rapid return to activities of daily living.

Conclusions: As this is an evolving medical field, clinical evidence often lacks robustness. Studies and clinical experience suggest that feminine genital rejuvenation using energy-based devices seems an attractive option for patients with mild-to-moderate medical conditions. The treatment can be safely and effectively delivered by trained staff as part of the comprehensive care, that is, currently available to women.

KEYWORDS
CO2-based lasers, erbium:yttrium-aluminum-garnet lasers, feminine rejuvenation, radiofrequency devices

1 | INTRODUCTION

Women are actively seeking treatment options to improve both the appearance and function of their genitalia. Improving vaginal health or feminine genital rejuvenation describes a diverse range of esthetic and functional outpatient procedures to correct and restore the form and functionality of the vagina and its surrounding tissues.[1] The treatment may be aimed at improving sensitivity, hydration and elasticity in the vulvar, introital, and vaginal tissue.[1] Surgical procedures may be supplemented with noninvasive, energy-based systems, suitable for women wary of surgery due to the risk, adverse effect/complications rates, expense, and impact on recovery. The current review presents technologies in use for feminine genital rejuvenation and summarizes the clinical evidence to support their, safety, and efficacy in clinical medicine.

2 | MATERIALS AND METHODS

The target group included healthcare professionals and physicians involved in esthetic medicine and feminine genital rejuvenation. A literature review was conducted exploring the current status on feminine rejuvenation using energy-based devices. In addition, a panel of physician experts, who have experience with the use of energy-based devices for feminine genital rejuvenation discussed the results of the literature review and their clinical experience; henceforth, they presented clinical recommendations. The expert panel was composed of 5 obstetrician-gynecologists, one dermatologist and 3 plastic/esthetic surgeons, who practice in North America and Europe. The panel explored new learnings on the etiology of labial and vulvar laxity and the effect of nonsurgical procedures using energy-based devices.

The following clinical questions on the application of nonsurgical procedures using energy-based devices for feminine genital rejuvenation were addressed:

- Clinical positioning of the various treatments (ideal patient profile)
- Clinical efficacy, optimal dose, frequency of application, and need/evidence for maintenance treatment
- Safety of the procedures, contraindications to implementation, risks/benefits, and adverse events when applying these treatments
- Patient comfort and postprocedure impact (downtime) when applying these noninvasive treatments
- Patient satisfaction, and tools to manage patient expectations when implementing these treatments
- Strengths and weaknesses of these treatments from a health care professional/physician and patient perspective

Explorative literature searches took place February, 2017 of PubMed, Medline, Embase, CINAHL, and the Cochrane Library databases. The literature searches were prospectively limited to publications in English and publication dates were between January 2005 and February 2017.

Medical subject headings terms used in various combinations were: Genitourinary syndrome of menopause; vaginal atrophy; dryness; laxity; atrophic vaginitis; decreased sensation during coitus; dissatisfaction with the appearance of the area; strengthen elasticity of the vaginal wall; hydration of the vaginal mucosa; vaginal laxity, vulvovaginal laxity, labia majora laxity, orgasmic dysfunction vaginal, feminine rejuvenation; energy-based devices; fractional CO2-based or erbium:yttrium-aluminum-garnet (Er:YAG) lasers; radiofrequency (RF)-based energy devices; temperature-controlled, bipolar, monopolar, multipolar-radiofrequency; safety, efficacy, and patient satisfaction.

2.1 | Vulvovaginal atrophy and laxity

The labial and vulvar regions may, over time, become loose and lax.[2,3] Although the etiology is unclear, possible causes range from congenital disease and/or trauma, obstetrical/childbirth trauma, to genetics, and weight fluctuations.[2,3] Chronic constipation and excess weight bearing may also be considered contributory, as the pelvis is funnel shaped and weight may be projected and forced through the vaginal hiatus. The damage to the pelvic floor and devitalized mucosal tone of the vaginal wall may be associated with pelvic prolapse, such as cystocele, rectocele, apical prolapse, uterine prolapse, enterocele, stress urinary incontinence, vaginal/vulvar atrophy, dryness, and/or physiologic distress affecting a woman's quality of life, self-esteem/confidence, and overall sexuality.[1-3] The panel could not agree if dryness results from these mechanisms and were interested in changes in the pelvic floor after childbirth. The panel noted that answers to these questions may trigger interest to expand treatment with nonsurgical procedures using energy-based devices to younger women.

Genitourinary syndrome of menopause, a newer terminology to encompass vulvovaginal atrophy and other genito-pelvic regions affected by hypoestrogenic state, is a common condition that may impair quality of life and sexual function and cause sexual pain as well as pain with penetration.[2-4] The panel agreed that currently conclusive data on this phenomenon is scarce.[2-4] Depending on age, symptoms of sexual dysfunction—including decreased libido, dyspareunia, changes in orgasmic intensity or latency, as well as arousal or lubrication concerns),—are common medical complaints affecting approximately 40% of all women.[2] Women with the sensation of a wide/loose, or lax, vagina may complain of decreased introital friction during coitus, leading to a diminished arousal, decreased orgasmic intensity, and prolonged orgasmic latency which all are influential in overall sexual satisfaction, for both the woman and her partners.

Traditionally, treatment has been performed primarily by gynecologic surgeons and occasionally by plastic surgeons. These invasive surgical procedures include reduction labiaplasty and clitoral hood reduction to alter the labia minora and majora and the folds of skin surrounding the vulva, or vaginoplasty and perineoplasty, which

involves surgery to the pelvic floor. Gynecological and urogynecological surgeons frequently perform vaginoplasty, perineoplasty and anterior and/or posterior repairs to improve sensation of a wide vagina. There are no established or uniform surgical methods for performing these procedures. Guidelines on patient selection criteria are currently lacking.[5-9] There are few studies which focus on the sensation of a wide vagina, and it is commonly known that an objective detailed measure to assess vaginal laxity is lacking. Frequently, patient-reported outcomes and validated sexual questionnaires such as the Female Sexual Function Index (FSFI) are used in clinical and research studies as objective criteria are lacking. In some clinical studies, improved patient satisfaction rates (assessed by patient reported improved sensation of a tighter vagina) at 6 months postoperative visit have been reported. In addition, the prevalence of dyspareunia has also been noted to be increased in some studies yet demonstrate a significant decrease in vaginal lubrication.[7,10]

2.2 | Clinical experience with nonsurgical energy-based treatment options

Of the energy-based devices available for feminine genital rejuvenation, fractional laser, and radiofrequency devices will be discussed. Both laser and RF treatments aim to induce neocollagenesis and vascularization to restore elasticity and moisture of the vaginal mucosa. The mechanism is believed to be by activation of heat shock proteins. The modalities in use for this purpose include Er:YAG, carbon dioxide (CO2) based lasers, and RF based energy devices, which may also improve sensitivity of vulvovaginal tissues (Table 1).

2.2.1 | Er:YAG devices

Laser vaginal tightening technologies may utilize fractional laser techniques, modified for vaginal use, that deliver pixels of energy to the vaginal canal.[11,12] Typically a series of 2-3 sessions spaced 4-6 weeks apart are required to achieve an optimal effect. Fractional lasers used for feminine rejuvenation use less energy than those used on the face, hence there is minimal, or no pain sensation and no subsequent peeling of the vaginal mucosa.[11,12] Experience using Er:YAG fractional laser (Table 2) for improvement of vaginal health has been reported in a case series of women undergoing treatment for postmenopausal vaginal atrophy.[11-14] Two nonablative, thermal-only erbium pulse devices (eg, IntimaLase and IncontiLase, Er:YAG laser system and Fotona Dynamis) were used to improve vaginal tightness and stress incontinence in mainly small studies conducted in 7 different countries.[12] Treatment was performed using the laser device with collimated hand-pieces and 2 adaptors. In the first treatment, phase irradiation of the full circumference of the vagina was applied. The device was set in the nonablative mode, delivering energy onto the vaginal mucosa in a fast sequence of low-fluence laser pulses, reaching effective temperatures (up to 42°C) in the deeper mucous layer.[12] The device used a patterned or fractional laser spot to enable a fast immune response and to stimulate healing.[12] Upon completion of the first phase the hand-piece was replaced with a straight adapter using a pixilated nonablative mode. Treatment was delivered in several passes to the mucosa of the vestibule and introitus.[12]

The Er:YAG laser device for stress urinary incontinence treatment was also used in 2 treatment phases. In a series of ten small studies, the 2 devices were shown to achieve improvements in vaginal tightening and sexual function as well as in improving symptoms of urinary stress incontinence.[12,15,16]

A novel innovation to the typical Er:YAG laser, called Hybrid Fractional Laser (HFL), adds an additional coincident and consecutive nonablative pulse of 1470 nm diode laser. Unlike the other available Er:YAG or CO_2 lasers, HFL fires a primary pulse of Er:YAG for precise ablation of a microchannel for immediate contraction of tissue followed by a secondary coagulative diode pulse to stimulate the heat shock proteins (HSP) that result in collagenesis and remodeling in the weeks post the inflammatory response. The use of 2 independent lasers may provide a greater range of customization and specificity for targeted therapy to tissues of all thicknesses.

2.2.2 | CO_2 devices

Carbon dioxide (CO_2) fractional lasers may be used to coagulate and to stimulate remodeling of the vaginal mucosa (Table 3).[17-23] Compared to erbium lasers, which are proposed to cause tissue contraction as a normal part of the wound healing response, CO_2 lasers may stimulate underlying collagen via heat-induced collagen contraction.[22] Thinning of the epithelial layer of the vagina may demonstrate improvement after treatment with CO_2 laser.[17,20,21] A case series including 50 postmenopausal women evaluated treatment for vulvovaginal atrophy with 3 fractional CO_2 laser (CO2RE Intima Syneron Candela) treatments over a 12-week course.[17] The visual analog scale (VAS), vaginal health index score (VHIS) and SF-12 quality of life tool were used for, before and after treatment evaluations. At week 12, a significant improvement ($P < .001$) in both vulvovaginal atrophy symptoms and vaginal health index score was reported.[17]

In a study by Perino[20] and colleagues, 48 patients with vulvovaginal atrophy received fractional CO_2 laser during 3 treatment sessions. At 30 days follow-up, significant improvements in self-reported vaginal dryness, burning, itching, and dyspareunia ($P < .0001$) were demonstrated coupled with considerably improving patient-reported quality of life.[20] In an ex-vivo study, Zerbinati, et al.[21] evaluated biopsies from vaginal mucosa samples extracted from 50 postmenopausal, nonestrogenized women treated with a CO_2 laser. Restoration of the vaginal epithelium was noted with storage of glycogen in the epithelial cells. Fibroblast activation and neo synthesis of extracellular matrix was also noted. Moreover, there was restoration of the vaginal mucosa pH after CO_2 laser treatment, and an improvement in symptoms of dryness, itching, dysuria, and recurrent infections.[21]

Stress urinary incontinence symptoms may also be improved following treatment with this device, which is reported to improve the tissue structure of the anterior vaginal wall under the mid-portion of

TABLE 1 Energy-based devices used for improvement of vaginal health

Type of device	Type of technology	Mechanism	Number of treatments (Tx)
Laser-based devices	2.940-nm Erbium Er:YAG laser system[a]	Collagen contracture from wound-healing response and pigmentation improvement.	10-20 min 1 Tx Maintenance unknown
	CO_2RE digital pulsed fractional laser[b]	Heat-induced ablation and coagulation leading to collagen contraction and elastin generation. Improves pigmentation and mucosa texture.	10-15 min 3 Tx at 4-6 wk intervals Maintenance unknown
	diVa® motorized Er: YAG & Diode hybrid fractional laser[c]	Fractional laser emits infrared light for ablation (2940 nm wavelength) and coagulation (1470 nm wavelength). Wavelengths are tunable for hybrid or independent use.	3-5 min 3 Tx at 4-6 wk intervals Maintenance unknown
	FemTouch CO_2 laser system[d]		
Radiofrequency (RF)-based devices	Temperature-controlled radiofrequency[e]	Transmucosal heating of the tissue to 40-47°C, promotes tightening of vaginal mucosa. At 460 kHz radiofrequency.	Up to 30 min per area 3 Tx at 4-6 wk intervals. Maintenance every 6 mo
	Cryogen-cooled monopolar radiofrequency[f]	Reverse thermal gradient cools surface mucosa allowing for the application of high-energy RF at 6 MHz radiofrequency to promote submucosal neocollagenesis. Heats target tissue to above 50°C at a depth of 3-5 mm.	20-30 min 1 Tx Maintenance annually.
	Multipolar radio frequency and pulsed electromagnetic fields[g]	Non-thermal device releases tissue growth factors (FGF2) to trigger new collagen synthesis, new fibroblasts, and angiogenesis.	1 Tx Maintenance unknown
	Focused radiofrequency device[h]	Results after 4 wk of treatment.	20-30 min 2-4 TX at 2-3 wk apart. Maintenance annually.

[a]IntimaLase and IncontiLase both Fotona Dynamis, Dallas, TX, USA.
[b]Intima laser Syneron-Candela, Wayland, MA, USA.
[c]diVa, Sciton, Inc, Paulo Alto, CA, USA.
[d]FemTouch CO2 laser system (Luminus).
[e]ThermiVa, ThermiAesthics (Southlake, TX, USA).
[f]Viveve System, Viveve Medical, Inc (Sunnyvale, CA, USA).
[g]Venus Fiore, VenusConcept, Sunrize, FL, USA.
[h]BTL Protégé Intima (Is now called Ultra Femme and similar to Intima uses the Exilis Ultra platform), BTL Aesthetics, Framingham, MA, USA.

the urethra.[23] In a comparative study,[24] one group of patients were treated with Er:YAG laser at 2.940-nm and a second group was treated with CO_2 laser at 10.600 nm. Both groups demonstrated vaginal tissue and symptomatic improvement. Mild adverse events were noted to occur more in the CO_2 laser treated group.

2.2.3 | Radiofrequency-based devices

Radiofrequency devices that emit focused electromagnetic waves are used in clinical medicine to generate heat to the underlying connective tissue of the vaginal wall (Table 4). These energy-based devices induce immediate contraction of collagen, induce new collagen and elastin formation/production, increase in growth factor infiltration, neocollagenesis, vascularization, increased vaginal transudate, and increased small nerve fiber density.[25-27]

ThermiVa, Thermi Aesthetics, Southlake, TX, was evaluated in 3 prospective uncontrolled small studies.[25,26] Typically 3 treatments with a 4-6 week interval were applied. The clinical endpoint temperature had a range of 40-45°C, which was maintained for 3-5 minutes per treated zone during a total of 30 minutes of treatment. Marked subjective improvements were shown in vaginal atrophy symptoms, patient-reported sexual function, incontinence, overactive bladder reduction, and vulvovaginal tightening effects.[25,26]

A cryogen-cooled monopolar radiofrequency (CMRF) device, the Viveve System (Viveve Medical, Inc., Sunnyvale, CA, USA) was evaluated in 3, prospective studies; a large, multi-centered randomized, sham-controlled, blinded, prospective trial, and 2 smaller pilot studies.[27,28] Both small studies showed significant improvement in overall sexual function at 6 months. One of the smaller studies

TABLE 2 Clinical studies using an Er:YAG laser system

Type of study	Results	Adverse events
Two clinical evaluations (a) N = 135 and (b) N = 27.[12]	(a) At 1 mo after treatment, 90.4% (n = 122/135) scored improved and 9.6% wanted a second session. At 3 and 6 mo all scored improved. (b) MFSQ average improvement of 8.5 points (36 point scale), tightening ranging from 3% to 28% and an average shrinkage of 17% (12 mm).	No
Pilot study on N = 17)[12]	Before and after treatment PISQ-12 was scored. Follow-up at 1 and 3 mo showed an average in PISQ-12 of 2.4 points. After 1 mo perineometric measurements were significantly higher ($P < .028$).	Mild I burns (n = 1)
N = 73[14]	Single treatment evaluated (ICIQ) at 1 and 2-6 mo. Significant improvement at 2-6 mo (12 (6-16) vs 7 (0-13); $P = <.001$).	Mild vulvar edema
Clinical evaluation on N = 32[12]	Interviews of both patient and partner at 1, 2, and 4 mo after treatment. At 4 mo, 96% of partners reported an excellent/good improvement.	No
Pilot study on N = 21[11,12]	Two treatments with an interval of 15-30 d. Before and after PISQ-12 and POP-Q scores at 3 mo. Patients and partners completed LVT questionnaire. 95% of patients and 85% of partners noted a strong/moderate improvement. POP-Q measurements: 5/21 had prolapses (stage 1-3). All had improved after 1 session.	No
Pilot N = 29[12]	FSFI prior to treatment and after 21 d post-treatment. 16/21 Patients received 2 treatments. Subjective improvement was noted in 96.6% of cases. IFSF total scores were significant ($P < .05$).	No
Prospective study (a) N = 45 and (b) N = 19[13]	Both studies used once per month treatments for 3 mo. (a) Comparing laser with standard treatment for GSM a significant decrease in vaginal dryness and dyspareunia ($P < .01$) was observed and a significant ($P < .01$) increase in VHIS. (b) Significant ($P < .01$) improvement of ICIQ-SF scores.	No
Comparative study in GSM[14]	After treatment significant decrease in vaginal dryness and dyspareunia was observed.	No
Clinical evaluation N = 115 patients with SUI (n = 77 mild, n = 37 moderate and 1 severe)[12]	After 1 session, n = 62 (89.6%) had mild SUI and N = 29 (76.3%) of patients with moderate SUI were healed. At 1 mo after the 2nd session, 6/8 patients with mild SUI and 5/9 with moderate SUI were healed.	No
Pilot N = 39 had SUI[12,16] treatment.	ICQI-UI questionnaire before treatment and at 1 and 3 mo after treatment. Significant ($P < .002$) ICQI-UI scores.	No
Clinical evaluation on N = 28[12]	At 1 mo after treatment, 87% had improved and 17% reported no changes. At 3 mo, 6% reported no change, all others had improved.	No
Pilot in N = 9 with SUI and 4 requesting tightening.[12]	Before and after POP-Q, PISQ-12, and ICIQ-UI. The SUI patients all improved after treatment as well as the patients who were treated for tightening.	No
Clinical evaluation[15] N = 175	2Tx at 2-months intervals. Evaluations at 2, 6, and 12 mo. Of the patients, 77% had a significant improvement and 34% exhibited mild urinary incontinence at the 1-year follow-up.	No

FSFI, Female Sexual Function Index; GSM, genitourinary syndrome of menopause; ICIQ-UI, International Consultation on Incontinence-Urinary Incontinence Questionnaire; LVT, Laser vaginal tightening Questionnaire; MSFQ, McCoy Female Sexuality Questionnaire; PISQ-12, pelvic organ prolapse/urinary incontinence sexual questionnaire; SUI, stress urinary incontinence; VHIS, vaginal health index score.

demonstrated sustained improvement at 12 months post-treatment.[28] This treatment differs from other radiofrequency procedures as it systematically cools and protects the surface tissue while heating the underlying tissues. The Geneveve treatment consists of a single 30 minute, outpatient procedure delivering 90 Joule/cm^2 of radiofrequency energy and targeting the vaginal introitus; no anesthesia is necessary. The CMRF trial is the only published, large-scale, randomized, placebo (sham)-controlled, blinded study on a radiofrequency-based treatment for vaginal tissue.[24] This multi-centered international study demonstrated statistically significant results in the arousal and orgasm domains of the FSFI in the active group as compared to the sham group. There were also statistically significant differences in the FSFI and Female Sexual Distress Scale-Revised (FSDS-R) total scores in favor of the active treatment arm. In addition, patients in the active treatment arm reported statistically significant improvement in overall sexual satisfaction coupled with lowered overall sexual distress. These data are particularly provocative, as the treatment with the CMRF device demonstrated superior efficacy comparatively to the sham control, and published evidence demonstrates that medical device trials employing a sham arm often demonstrate particularly large placebo/sham effects.[15]

Focused external monopolar radio frequency (Intima, BTL Industries Inc., Boston, MA) delivered in 4 consecutive treatments at 1-week intervals for labia tissue tightening was safe and demonstrated a positive short time effect.[30] Post-treatment, this small study (n = 17) showed a significant improvement in overall sexual satisfaction. The BTL Ultra Femme, an external and internal monopolar radio frequency device, was evaluated in 27 woman with mild/moderate

TABLE 3 Clinical studies using a CO_2RE laser system

Observational study (N = 50) on vulvovaginal atrophy[17]	After 3 Tx over 12 wk a significant ($P < .001$) improvement of vulvovaginal atrophy symptoms and VHIS scores was noted.	Mild events
Prospective study N = 77 postmenopausal women.[22]	3 Tx at 12 wk vulvovaginal atrophy symptoms and sexual function had significantly improved.	Mild events
Clinical evaluation included 48 patients with vulvovaginal atrophy[20]	At 30 d follow-up, significant improvements in vaginal dryness, burning, itching, and dyspareunia ($P < .0001$) were demonstrated	No
Clinical evaluation[23]	Stress urinary incontinence symptoms improved together with tissue structure of the anterior vaginal wall under the mid-portion of the urethra.	No
Clinical research study (N = 50)[21]	Vaginal biopsies on n = 50 with VVA changes and symptoms at baseline and at 2 mo showing signs of remodeling after treatment.	No
Controlled comparative study.[18] N = 40	Fractional laser with local administration of platelets rich plasma and pelvic floor exercise. The study group underwent PRP, CO2 laser, and pelvic exercise, whereas only PRP and pelvic exercise were applied to the control group. In the study group, histological evidence of vaginal mucus improvement and sexual function was shown.	No
Comparative study.[24]	One group was treated with Er:YAG laser at 2.940-nm and the results were compared to a group treated with CO_2 laser at 10.600 nm. Improvement in vaginal tightening was observed in both groups.	More mild events in the CO_2group.

FSFI, Female Sexual Function Index; GSM, genitourinary syndrome of menopause; ICIQ-UI, International Consultation on Incontinence-Urinary Incontinence Questionnaire; LVT, Laser vaginal tightening Questionnaire; MSFQ, McCoy Female Sexuality Questionnaire; PISQ-12, pelvic organ prolapse/urinary incontinence sexual questionnaire; SUI, stress urinary incontinence; VHIS, vaginal health index score.

TABLE 4 Clinical studies using radiofrequency-based devices

Device	Type of study	Results	Adverse events
Transmucosal controlled radiofrequency heating device	Prospective randomized controlled trial (N = 20): vaginal function (n = 10) and urethral muscle tone (n = 10)[25]	1 Tx every 30 d for 3 mo used for both arms. Evaluations using VHI, ICIQ-UI SF, UDI-6, IIQ-7, VAS. Punch Biopsies taken at the urethra- vesical junction in the anterior compartment, before and at the end of the treatment protocol. Basic and histochemical staining was used for analysis. Marked improvements in the treatment groups for all parameters.	No
	Prospective study N = 23 with mild-moderate vaginal laxity and SUI[26]	3 TX with a 4-6 wk interval. Endpoint temperature range of 40-45°C for 3-5 min per zone during a total of 30 min treatment. Statistically significant improvements based on Vaginal Laxity Questionnaire and Sexual Satisfaction Questionnaire outcomes were shown. Improvements in stress incontinence, atrophic vaginitis, and orgasmic dysfunction were also observed.	No
	Single center, prospective study (N = 25)[32]	The transcutaneous temperature-controlled radiofrequency device was used for treating orgasmic dysfunction. Twenty-three of 25 patients reported an average reduction in time to orgasm of 50% as well as tightening effects, vaginal moisture improvements, and improved sensitivity of the vulva and clitoris. The clinical data correlates with histopathology data.	No
Cryogen-cooled monopolar radiofrequency	Pilot study N = 24[27]	1 Tx with reverse thermal gradient RF energy (60-90 J/cm^2). Self-reported vaginal tightness improved in 87% at 6 mo. Mean sexual function scores improved from 27.6 +/− 8.7 to 32.0 =/− 3.0 at 6 mo. All reported sustained improvements on SSQ at 6 mo after treatment ($P = .002$)	None reported
	Prospective single-arm study N = 30[28]	1 TX at 90 J/cm^2 during 30-min. Significant improvement in sexual function at 6 mo (mean FSFI scores improved from 22.4 +/− 6.7 to 26.0 +/− 5.8 [$P = .002$]) was observed and was sustained through 12 mo	No
	Randomized, placebo-sham-controlled, blinded, multi-center study N = 174[24]	1 TX at 90 J/cm^2 during 30-min. Vaginal laxity was improved by 43.5% and 19.6% ($P = .002$) in the active and sham groups, respectively. Differences in favor of active treatment vs sham were shown in FSFI and FSDS-R total scores of 1.8 ($P = .031$) and −2.42 ($P = .056$), respectively	Similar levels reported in both active and sham tx groups

FSFI, Female Sexual Function Index; GSM, genitourinary syndrome of menopause; ICIQ-UI, International Consultation on Incontinence-Urinary Incontinence Questionnaire; LVT, Laser vaginal tightening Questionnaire; MSFQ, McCoy Female Sexuality Questionnaire; PISQ-12, pelvic organ prolapse/urinary incontinence sexual questionnaire; SUI, stress urinary incontinence; VHIS, vaginal health index score.

stress urinary incontinence and vulvovaginal laxity who received 3 once-a-week sessions.[31] At 1-month follow-up, the device was shown to be safe and demonstrated improvements both in stress urinary incontinence and vulvovaginal laxity symptoms.[31]

3 | DISCUSSION

The use of energy-based devices for vaginal laxity treatment, such as minimally ablative fractional laser and radiofrequency, is currently gaining popularity in the community and momentum in the medical field. The idea that nonsurgical treatment using energy devices can increase moisture is difficult to accept according to the panel without understanding the cause and a plausible mechanism of action of treatment to support it.

Treatments using minimally ablative fractional laser are based on photothermolysis, creating many microscopic areas of necrosis within the treated tissue, inducing wound-healing with subsequent new collagen and elastin fiber formation.[13,18] Treatment using radiofrequency devices also aims to induce neocollagenesis, by fibroblastic activation and also induces vascularization, which restores elasticity and moisture levels at the vaginal mucosa.[25]

Positioning of these energy-based devices for the treatment of vaginal laxity, defining the ideal patient profile, requires further research.[3] Studies on both minimally ablative fractional laser[17,20-22] and radiofrequency,[24,25,27,28,30-32] have mostly included patients with mild to moderate primary or secondary vulvovaginal laxity and associated secondary medical or sexual conditions (orgasmic dysfunction, stress incontinence, atrophic vaginitis). The panel agreed that they select a similar population for female genital treatment with energy-based devices. Regarding preference of one treatment type over the other there was no agreement as according to the panel feminine rejuvenation using energy-based devices is still in its initial stages.

Minimally ablative fractional laser may also be used as an ancillary instrument in female genital surgery (labiaplasty, vaginal reshaping, and clitoral unhooding), enabling reduction of postoperative recovery and discomfort.

Regarding clinical efficacy, minimally ablative fractional laser has been shown in multiple case series, to improve the condition of vaginal tissues and symptoms of vulvar and vaginal atrophy as well as urinary incontinence.[17,18,20-23] Following radiofrequency treatment, an increase in collagen production as well as improvement of maturation index, deepening of rete pegs and thickening of stroma was shown together with clinical benefits such as a 70% improvement rate in stress incontinence symptoms.[25]

Clinical studies[15,31] evaluating RF for orgasmic dysfunction have demonstrated an increase in small nerve fiber density in the papillary dermis postradiofrequency treatment.[28,32]

The optimal dose, frequency of application, and maintenance treatment depends on the type of device used and the patients' condition (Table 1). For minimally ablative fractional laser 1-3 treatments of 10-20 minutes at 4-6 weeks intervals are reported.[11,13,18,22,29,33,34] There is no information given on maintenance treatment or the interval whereby repeat treatments are indicated. All radiofrequency devices and procedures are not similar. For ThermiVa radiofrequency treatment 2-4 treatments of 20-30 minutes at 4-6 weeks intervals are typically performed.[2,25-28,32] For Ultra Femme/Intima, 4 treatments with 1 week intervals are usually performed.[30,31] Maintenance treatment with radiofrequency is reported at 6-12 months. Viveve/Geneveve Treatment, which involves cooling of the vaginal mucosa, is a single 20-30 minute outpatient procedure, which has sustained efficacy out to 12 months duration.

A literature review included, hyaluronic acid fillers, and fat transfer together with laser and radiofrequency for feminine genital rejuvenation.[35] The authors concluded that these nonsurgical interventions were options of interest.[35]

The panel discussed the possibility to combine certain types of treatment and/or to use energy-based devices for maintenance after surgical intervention. They agreed that it is too early to give recommendations.

Both laser and radiofrequency treatment for feminine genital rejuvenation are reported to be safe and well tolerated with only minor adverse events. There are few case reports of mild burns, which typically resolve within a week.

Patient satisfaction with the treatment result is typically reported as high, especially in the mild-to-moderate cases. It is important to select the correct patient who may benefit from these treatments. It is also important to manage patient expectations, by setting realistic expectations, when applying these treatments. Physicians delivering medical esthetic treatment may consider adding these special procedures to their acumen of treatments they currently offer to their patients.

3.1 | Limitations

Although the number and quality of the studies using minimally ablative fractional laser and radiofrequency devices is growing, clinical randomized, sham-controlled evidence is sparse; with only one large, randomized, sham-controlled, multi-center study using the CMRF therapy. Further data are forthcoming, such as an ongoing trial comparing laser treatments to minimally absorbed local vaginal estrogen. Ongoing research should involve standardized validated instruments to assess patient's complaints and outcomes.

4 | CONCLUSION

Energy-based devices are increasingly applied to improve function and esthetic vaginal health. Although the clinical evidence base is increasing, the use of energy-based devices for feminine genital rejuvenation of mild and moderate conditions seems an attractive, effective and safe option which can be add to the toolkit of many health care professionals who are currently delivering medical esthetic/functional treatments.

DISCLOSURE AND CONFLICT OF INTEREST

Michael H. Gold, MD: Consultant and advisory boards: Aerolase, Allergan, Alma Lasers, Almirall, Anacor Pharmaceuticals, Aquavit

Pharm, Bayer Health Care, Celgene, Clarisonic, SkinCeuticals, L'Oreal, Croma, DefanAge, DUSA Pharmaceuticals, EndyMed, Erchonia, Exeltis, Galderma, Intra Derm, Invasix, Johnson & Johnson, Lumenis, Merz, Neothetics, Novartis, Pierre Fabre, Prollenium, Promius, Senté, Sinclair Pharma, Smith & Nephew, Syneron-Candela, Suneva, Thermi Aesthetics, Valeant, Viviscal, Zimmer. Anneke Andriessen, PhD: Investigator Prollenium, Stiefel GSK and Valeant Pharmaceuticals. Bader Alexandros, MD: International Key opinion Leader KOL: Alma Lasers, RegenLabs, Consultant: Alma Lasers, IBSA Pharamaceuteci ITALIA, Researcher: IBSA Pharmaceuteci ITALIA. Inventor and owner of Register Marggrks: Single Thread Vaginal Tightening STVT®, Femi -O®, Vampire Vaginal Rejuvenation VVR®. Scientific Society: Founder of The European Society of Aesthetic Gynecology ESAG. Alinsod Red, MD: Consultant: Thermi, Cooper Surgical, Coloplast, Monarch Medical, D-More, ALMI, TouchMD, Canfield Scientific, Royalties: Thermi, Cooper Surgical, Monarch Medical, Stock: Caldera Medical, Inventor: ThermiVa, Lone Star APS Retractor, Alinsod Scissors/Pick-ups/Clamps, Advisory Board: Thermi, D-More, ALMI. French Shane: No conflict of interest. Nathan L. Guerette, FPMRS, FACOG: Investigator, consultant and advisory board of Sciton, Inc., consultant CL Medical, consultant Boston Scientific. Kolodchenko Yegor, MD: Consultant and KOL: VenusConcept, Scientific Society: Founder and President of Association of Laser Medicine & Cosmetology (Ukraine). Michael Krychman, MDCM, MPH, is a consultant for Viveve Medical, Shionogi Inc., Sermonix, TherapeuticsMD, Palatin Technologies, and Valeant Pharmaceuticals. He is a speaker for Shionogi and Valeant Pharmaceuticals. Murrmann Susan, MD. Samuels Julene, GYN: Consultant and/or advisory board member for: BTL, Syneron-Candela, InMode. Investigator for: Allergan, Mentor, InMode, Syneron-Candela.

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How to cite this article: Gold M, Andriessen A, Bader A, et al. Review and clinical experience exploring evidence, clinical efficacy, and safety regarding nonsurgical treatment of feminine rejuvenation. *J Cosmet Dermatol*. 2018;00:1–9. https://doi.org/10.1111/jocd.12524