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Review

Vaginal rejuvenation: From scalpel to wands☆

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Women's Health Highlight

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ABSTRACT

Vaginal rejuvenation procedures are increasing in popularity in terms of types of treatment offered, number of patients undergoing them, clinical studies, and in the controversy surrounding them. Both non-invasive and invasive solutions are being developed by pharmaceutical and technological companies. Radiofrequency devices and lasers are spearheading the energy-based device space, and fillers and platelet-rich plasma are used to address several concerns surrounding vaginal health. In this review, an overview of the growing field of vaginal rejuvenation is presented, as well as the authors' personal view and analysis of this clinical space.

Introduction

Vaginal rejuvenation refers to procedures that primarily reduce the width of the vagina for reasons of function and well-being (Barbara et al., 2017). The concept is more than a thousand years old and was first described by Trotula in 1050 AD in *Treatments for Women*, wherein she sutured vaginal lacerations postdelivery. Since then, fueled by increased technological innovation, surgical and nonsurgical treatments have been developed.

Global awareness and changing trends

Today, with increasing life expectancy and women living longer, >20 million women are affected by uterine prolapse, birthing injuries, and incontinence. Causes for conditions such as vaginal relaxation syndrome or vulvovaginal laxity include vaginal delivery, natural aging, and atrophy. Aside from functional consequences, these conditions also have an effect on women's sexuality and sense of well-being. Until recently, it was a taboo topic to discuss these topics, even with a women's health care provider. This fact is highlighted by a survey conducted by the International Urogynaecological Association in 2012, which showed that 84% of physicians believed that vaginal laxity was underreported, and 95% believed that laxity affected sexual function (Pauls et al., 2012).

Moreover, 40% of women have psychological distress from female sexual dysfunction, but only 14% consult a physician about sex during their lifetime (American College of Obstetricians and Gynecologists, Committee on Practice Bulletins-Gynecology, 2011). Today, through public awareness programs, physician education, and media sources, the barriers of communication on issues with regard to female sexual dysfunction and incontinence have been broken. Information on these conditions and treatments options are more readily available, and, as a result, the demand for such interventions is growing.

Aside from surgery, the advent of nonsurgical methods and energy sources for these indications is receiving tremendous response and patient acceptance (Karcher and Sadick, 2016). The American Society of Plastic Surgeons reported a 30% increase in the rate of vaginal rejuvenation procedures between 2005 and 2006 (Lowenstein et al., 2014), and an Indian study also showed growing trends in the demand of esthetic vaginal procedures from 3.9% in 2012 to 28.97% in 2015 (Desai and Dixit, 2018).

Clarity

Female cosmetic genital surgery (FCGS) refers to a subset of treatments that address the vaginal appearance, and the term vaginal

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rejuvenation has evolved into an umbrella term that covers procedures that enhance vaginal esthetics, sexuality, and functionality. Common procedures include surgical (e.g., vaginal tightening, labia minoraplasty, labia majoraplasty, clitoral hood reduction, clitoral unhooding, lipofilling, and hymen reconstruction) or nonsurgical (e.g., energy-based treatments, platelet-rich plasma [PRP], and fillers) interventions (Barbara et al., 2017).

Results interpretation

The clinical results of procedures for these indications have been assessed in terms of safety and efficacy in several peer-reviewed studies. Although objective, validated measurements and scales are still lacking, indices commonly referred to include the Female Sexual Functional Index (FSFI; Rosen et al., 2000), Millheiser Vaginal Laxity Scale (Millheiser et al., 2010), Millheiser Sexual Satisfaction Scale (Davis et al., 2006), visual analogue scale (Lukaez et al., 2004), International Consultation on Incontinence Questionnaire (Avery et al., 2004), Satisfaction Scores (Likert scale; Sullivan and Artino, 2013), and Vaginal Health Index (Bachmann, 1995).

Surgical vaginoplasty

Surgical vaginoplasty involves surgical vaginal tightening and the correction of vaginal damage or deformity. The procedure may be done under local or regional anesthesia in an office-based surgical facility and involves a full-length tightening of the vagina (i.e., not just of the introitus) whereby dissection occurs all the way up to the levators and laterally to the ischial spines. A depth of 7 to 8 cm is recommended for full-length tightening. The vagina can be resized to the exact dimension the patient desires. This procedure usually also includes perineoplasty because this requires remodeling and strengthening of the perineum. Complication rates of surgical vaginoplasty range from 2% to 3.77% and include dyspareunia, lack of lubrication, constipation, wound infection, hemorrhage, suture breakdown (mostly in the perineum), buttock pain for weeks, and rectal mucosa perforation (Pardo et al., 2006).

Various studies have addressed different aspects of surgical vaginal tightening. In a study of 53 women undergoing surgical colporrhaphy, where the vaginal diameter is decreased by two-thirds, 66% of women showed a great improvement in their sex lives, 24% a significant improvement, and 10% slight or no improvement. There were two cases of wound dehiscence (Pardo et al., 2006). Goodman et al. conducted a large multicenter study of 258 women with FCGS, including 47 cases of vaginoplasty. The researchers concluded that surgical vaginoplasty/perineoplasty showed a high rate of enhancement of sexual functioning in both women and their partners (Goodman et al., 2010).

Another study showed that the Female Sexual Function score was globally improved after colpoperineoplasty in 79 women (Abedi et al., 2014). Dyspareunia and low lubrication were reported as side effects. A recent study of 39 patients undergoing surgical vaginal tightening showed improvements in FSFI from 19.5 to 27 (Desai and Dixit, 2018). This study also showed that 81.6% of patients were very satisfied, 14.5% satisfied, and 3.9% not satisfied with the FCGS procedures.

Noninvasive modalities

Noninvasive procedures for ameliorating symptoms of genitourinary syndrome of menopause (GSM) are increasingly emerging in the form of energy-based devices and injectable agents, such as fillers and PRP (Qureshi et al., 2018).

Energy-based devices for vaginal rejuvenation harness power from radiofrequency (RF) or laser sources, such as carbon dioxide (CO_2; 10,600 nm; Table 1) and erbium-YAG (2940 nm; Table 2), to induce thermal-dependent matrix remodeling (Gambacciani et al., 2015a, 2015b). Energy-based devices stimulate type 1 collagen production in the extracellular matrix via the stimulation of fibroblasts. This process results in the contracture of elastin fibers, neovascularization, and improved vaginal lubrication. A study by Ostrzenski on CO_2 laser treatment for vaginal rejuvenation included 10 patients who were treated with a continuous-mode CO_2 laser with defocus, where vaporization was stopped at the endopelvic fascia. The study showed a great clinical improvement after only one treatment (Ostrzenski, 2012).

Recent RF studies showed an increase in the small nerve fiber density in the papillary dermis (Gold et al., 2018; Table 3). Posttreatment biopsy tests have demonstrated neocollagenesis and neoelastogenesis in the submucosa after RF (Leibaschoff et al., 2016; Figure). The creation of new elastin, which is relatively unique to RF, may contribute to treating vaginal laxity (Tadir et al., 2017). Several types of RF devices exist, and some have been developed with specific hand pieces for the vaginal canal (Sadick et al., 2014). Transurethral monopolar RF has also been used to treat stress urinary incontinence (SUI). Nonablative RF was used to achieve tightening of the vaginal canal (Dillon and Dmochowski, 2009; Sadick et al., 2014).

Additional clinical effects of energy-based devices include the increase of glycogen content, as documented by histopathology (Tadir et al., 2017). Energy-based vaginal rejuvenation procedures are appealing because they are noninvasive lunchtime procedures, with an average treatment time of 8 to 30 minutes depending on the indications and the method used (Table 4). The procedure is usually painless, and no anesthesia is required. Two or three sittings are advocated, spaced approximately 1 month apart. A touch-up sitting or repeat single session is done after 12 to 18 months.

Energy-based procedures are well tolerated by most patients because they are either totally pain-free or cause slight discomfort. There is no downtime, and usual daily activities can be immediately resumed (except for sexual activity in laser treatments, after which

Table 1
Clinical studies using CO_2 lasers for vaginal rejuvenation

Study	Results
Salvatore et al., Climacteric 2015 77 patients, menopausal	Significant improvement in FSFI scores (14.8–27.2) 17 patients inactive; normal sex life
Gaspar et al., Am J Cosmet Surg 2011 CO2 + PRP + PFE	Significant reduction in sexual discomfort
Filippini et al., Photomed Laser Surg 2017 386 patients, postmenopausal	Effective in treating vaginal epithelium and dyspareunia due to atrophy
Perino et al., Maturitas 2015 48 patients, postmenopausal	Confirmed safety, efficacy, satisfaction in reducing VVA symptoms
Pieralli et al., Arch Gynecol Obstet 2016 50 patients (41–66 years)	VHI score: 8.9–21.6 (<15 VVA) VAS: statistics improvement in dyspareunia 52% satisfied at 11 months

CO_2, carbon dioxide; FSFI, Female Sexual Functional Index; VAS, visual analog scale; VHI, vaginal health index; VVA, vulvovaginal atrophy

Table 2
Clinical studies using Er:YAG lasers for vaginal rejuvenation

Study	Results
Adrian, J Lasers Health Acad 2012	Improved tightening
Gambacciani et al., Climacteric 2015a, b 45 patients (postmenopausal)	Significant decrease in vaginal dryness and dyspareunia
Vizintin et al., Climacteric 2015	Effective and safe to treat vaginal laxity

Table 3
Clinical studies on the use of radiofrequency devices for vaginal rejuvenation

Device	Study	No. of patients	Results	Adverse effects
TTCRF	Leibaschoff et al., Surg Technol Int 2016 GSM; prospective RCT	20	VHI, ICIQ-UI, UDI6, IIQ7, VAS, punch biopsies Marked improvement	None
	Alinsod, Prime 2015 Prospective for laxity, UI	23	Statistically significant: Vaginal laxity, sexual satisfaction. Improved SUI, atrophy, orgasms	None
	Alinsod, Lasers Surg Med 2016 Prospective for orgasms	25	Average reduced time to orgasm 50% Improved tightening, moisture, sensitivity Co-relates with histopathology	None
CMRF	Millheiser et al., J Sex Med 2010 Prospective for laxity	24	87% improved in 6 months Sexual scores: 27.6–32 Sustained improvement on SSQ at 6 months	None
	Sekiguchi et al., J Womens Health 2013 Prospective for laxity	30	Significant FSFI: 22.4–26	None
	Kryhman et al., J Sex Med 2017 Randomized, placebo sham controlled multicenter study	174	Significant change in laxity 43.5% active gp v/s 19.6%	None
BIPOLAR RF	Women in 50s	14	64% satisfied with results	None
MONOPOLAR RF	Clark, J Cosm Laser Ther 2018 Prospective for aesthetic appearance	19	Improvement in vulvar appearance and sexual function	None
	Lalji and Lozanova, J Cosmet Dermatol 2017 Mild/moderate SUI & vaginal laxity	27	Improvement in all evaluated areas of SUI and vaginal laxity	None

CMRF, cryogen-cooled monopolar radiofrequency; FSFI, Female Sexual Function Index; GSM, genitourinary symptoms of menopause; ICIQ, International Consultation on Incontinence Questionnaire; RCT, randomized control trial; RF, radiofrequency; SSQ, Sexual Satisfaction Questionnaire; SUI, stress urinary incontinence; TTCRF, transcutaneous temperature controlled radiofrequency; UI, urinary incontinence; VAS, visual analogue scale; VHI, vaginal health index

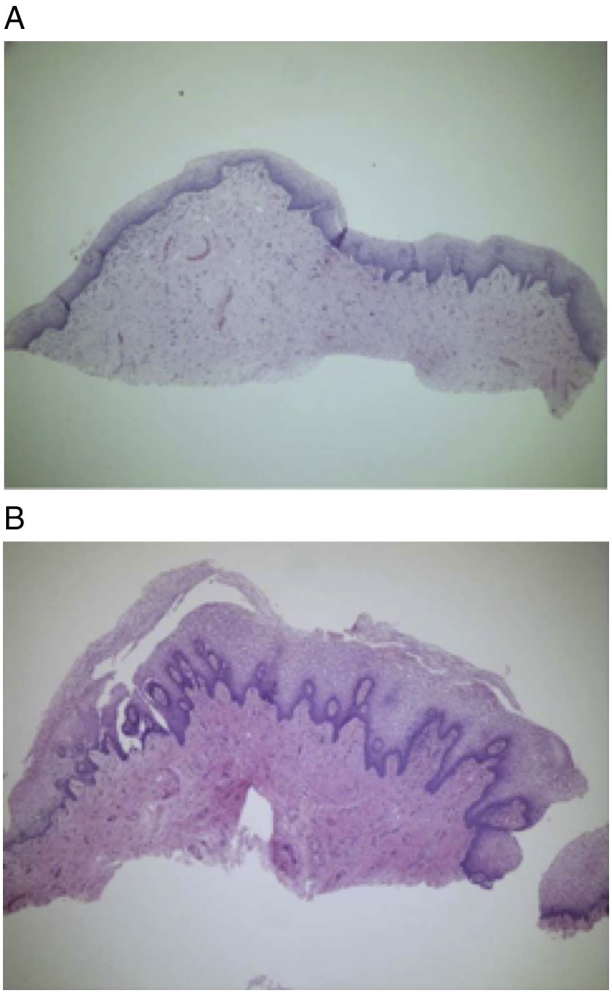

Fig. Vaginal mucosa (A) before and (B) 6 months after one treatment with the radiofrequency device ThermiVA (Thermiaesthetics, Irving, TX)

3 days of abstinence is recommended). Patients who benefit the most from energy-based procedures are those who have symptoms of mild-to-moderate SUI, overactive bladder, vaginal dryness, decreased lubrication, orgasmic dysfunction, grade 1 prolapse, and vaginal laxity. The indications are ever increasing, but more studies are required to evaluate the true breadth of the efficacy of energy-based devices.

In 2013, the North American Menopause Society validated energy-based devices; the society passed a position statement acknowledging that the use of lasers appeared to be an emerging therapy and may provide clinicians with other options to treat common and distressing problems of GSM (Alinsod, 2016; Gaspar et al., 2017; Leibaschoff et al., 2016; Tadir et al., 2017).

Other noninvasive modalities for vaginal rejuvenation involve the use of injectable volumizers, such as hyaluronic acid, PRP, and physical devices (e.g., Gore-Mycromesh and silicone threads). Aside from addressing laxity in the canal and dryness, some of these techniques specifically enhance the female sexuality center (e.g., amplify the G-spot).

Lipo-filling

A minimally invasive technique of vulvovaginal lipo-filling of the posterior vaginal wall was performed by Aguilar et al. in 2016. They also injected hyaluronic acid and PRP subcutaneously in the perineum (Aguilar et al., 2016).

Gore-mycromesh

In 2015, Park et al. did a study using a biocompatible compound (expanded poly-tetrafluoroethylene) as a Gore-Mycromesh on 50 women. They inserted, under local anesthesia, a 2×4 cm^2 mesh under the posterior wall submucosa. The results showed a substantial improvement in sexual function in a year, especially for FSFI rates of satisfaction (Park and Whang, 2015).

Silicone threads

Park et al. performed a study among 180 women by inserting silicone threads under the vaginal submucosa (Park et al., 2015). They made incisions at the 3 and 9 o'clock positions and found that the FSFI

Table 4
Comparison of energy-based devices

	RF devices		Lasers	
	Monopolar	Bipolar and other RFs	CO_2	Erb:YAG
Size and portability	Large and nonportable	Portable	Usually nonportable	Large and nonportable
Hand pieces	Disposable, small ergonomic wand	Barrel-shaped hand pieces for vagina, or small introital hand pieces	Larger, barrel-shaped hand pieces with disposable sleeves that are attached to an articular arm	Larger, barrel-shaped hand pieces with disposable sleeves that are attached to an articular arm
Depth of penetration	0.2–0.5 mm	4 mm	0.5 mm	0.6 mm
Procedure room	Outpatient room	Designated procedure room	Special room with laser-specific regulation required	Special room with laser-specific regulation required
Safety	No special safety gear required	No special safety gear required	User-laser protection glasses, etc	User-laser protection glasses, etc
Frequency of sittings	3–4 sittings at monthly intervals	4–6 sittings at 2–3 week intervals (bipolar), 3 sittings, each a week apart (multipolar), single Rx (patented), 2–4 times every 2–4 weeks (focused)	3–4 sittings @ 4–6 week intervals	Protocols are different for different machines: 2 Rx at 8 weeks (Intimalaser) 3 Rx at 2 weeks (Petit Lady)
Anesthesia	No anesthesia	No	No	No
Time taken	15–30 minutes	10–20 minutes	8–20 minutes	8–20 minutes
Downtime	None	None	Sexual intimacy after 3 days	Sexual intimacy after 3 days
Pain	No pain	Introital area may be painful with pre-heated rings	Pain near introitus; hence, need to decrease energy in that area	Pain near introitus; hence, need to decrease energy in that area
Effects last for	12 months	12 months	12 months	12 months
Functional probe	Same probe can be used on vulva, in anal canal, or on the penile shaft	Separate probes for vagina and vulva	Separate probe used on vulva	Separate probe used on vulva
Skin lightening	Separate probe for skin lightening	—		Separate probe for skin lightening
Upgrade the machines	Newer machines with higher voltage; hence, quicker action	—	Automated laser dispensers (robotic) arms make the procedure user independent and faster. Some machines are now adding an RF probe to work on the introital area	Robotic arms make the procedure user independent and faster. Some machines are now adding an RF probe to work on the introital area

CO_2, carbon dioxide; RF, radiofrequency; Rx, prescription

significantly improved, especially for orgasms. Of their patients, 92.8% were satisfied with the vaginal width correction. Complications included implant exposure (5%), capsule contracture (3.9%), and infection (1.7%).

G-spot amplification

This procedure, which was empirically developed, makes the G spot more prominent and, hence, increases friction, which leads to better chances of vaginal orgasm. Bulking the sensitive area forward toward the vaginal lumen for greater frictional contact may lead to easier, longer, more frequent and intense orgasms. The G-spot was first described by Gräfenberg (Gräfenberg, 1950) and named by Perry and Whipple (Perry and Whipple, 1981). It is located below or inferior to the urethra, midway between the pubic bone and cervix, and is believed to be responsible for vaginal-mediated orgasms. Methods of amplification include nonpermanent fillers (e.g., hyaluronic acid) as patented by Dr. David Matlock (called the G-shot), PRP, and collagen injections. The results of the G-shot may last 3 to 5 months, but the procedure is limited by a lack of randomized controlled data.

Combination treatments

Combination treatments have increasingly been adopted for the comprehensive care of patients with esthetic and medical concerns. For vaginal rejuvenation, commonly proposed combination treatments include energy-based devices with PRP, energy-based devices after surgery, energy-based devices and fillers, and a combination of energy-based devices.

Energy-based devices with platelet-rich plasma

PRP is the most common rejuvenating injectable used in various parts of the body. Patients' venous blood is collected in special tubes and centrifuged to obtain a supernatant of PRP. PRP acts by being very rich in and promoting growth factors with a fibrin scaffolding. PRP has been combined with energy-based devices as follows: 1) PRP is applied after microablative lasers as a rejuvenating liquid in the vagina; and 2) PRP is injected in the clitoro-urethro-vaginal space for better orgasms and better urinary control for stress urinary incontinence after use of energy-based devices (e.g., the O Shot, as patented by Runnels [Runels et al., 2014]).

Energy-based devices after surgery

With surgical vaginal tightening, the tissues are cut and resutured in layers with support that leads to structural and physical tightening. However, because energy-based devices improve the functionality of tissues, they can be offered to patients after a surgical vaginoplasty to improve elasticity and vaginal mucosa. Energy-based devices help improve symptoms of dyspareunia and lack of lubrication that are noted after surgery.

Energy-based devices and fillers

G-spot amplification can be done in combination with the third treatment of energy-based devices for vaginal orgasms.

Combination of energy-based devices

Some clinicians combine a laser device with RF and use laser in the vaginal canal and RF for the introital area and the vulva. This has prompted certain laser companies to add a separate RF device for use on the introital area.

Position of leading medical bodies

There is no federal or state legislation that currently prohibits or limits FCGS in the United States (Clinch et al., 2011). Despite the excitement of the medical and patient community about procedures to improve vaginal conditions and appearance and/or sexual health, several organizations have expressed concerns about the efficacy and safety of these procedures. Coupled with the paucity of peer-reviewed clinical trials, health care providers must tread the waters lightly so as not to run into medicolegal issues. We outlined the positions of the leading medical bodies.

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists Committee Opinion (2007, reaffirmed in 2017), indicated that FCGS is not medically indicated, and the safety and effectiveness of such procedures have not been documented. Women who ask for such procedures should be informed about the lack of data supporting their efficacy and about their potential complications, including infections, altered sensations, dyspareunia, scarring, and adhesions (American College of Obstetricians and Gynecologists, 2007).

Royal College of Obstetricians and Gynecologists

The Royal College of Obstetricians and Gynecologists stated in 2013 that "Presenting FCGS procedures as an unproblematic lifestyle choice is inappropriate" (Royal College of Obstetricians and Gynecologists, 2013).

Royal Australian and New Zealand College of Obstetricians and Gynecologists, and Society of Obstetricians and Gynecologists of Canada

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists Society of Obstetricians and Gynaecologists of Canada holds a public stand against FCGS (College Statement C-Gyn 24, 2015; Shaw et al., 2013).

U.S. Food and Drug Administration

The U.S. Food and Drug Administration recently issued a stern warning (US Food and Drug Administration, 2018) about procedures that destroy or reshape vaginal tissue using lasers or other energy-based devices, such as RF. The warning elaborates that "the full extent of the risks is unknown. But these reports indicate these procedures can cause serious harm." The U.S. Food and Drug Administration warning does not include sufficient data to address safety or efficacy, but it underscores the need for more thorough and long-term studies to be conducted.

Ongoing clinical trials

Large, blinded, randomized control trials are required to establish appropriate indications, effects, and complications for energy-based devices. Several ongoing multicenter trials use fractional CO_2 lasers in GSM, often comparing their efficacy with that of a topical estrogen preparation (Cruz et al., 2018). The Vaginal Erbium Laser Academy Study for GSM and SUI is an international, multicenter trial, and the ThermiVa in Genital Hiatus Treatment trial is a multicenter Australian trial that investigates whether transcutaneous, temperature-controlled RF is an effective treatment for vaginal laxity (Dilgir, 2017).

Conclusions

Energy-based devices undoubtedly show great promise for the functional and esthetic issues of women's intimate areas, especially vaginal rejuvenation. Larger, double-blinded, randomized control trials are required to draw definitive conclusions, including accepting these devices as standard, preventive, or first-line treatments.

Appendix A. Supplementary data

For patient information on skin cancer in women, please click on Supplemental Material to bring you to the Patient Page. Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijwd.2019.02.003.

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