Emerging Trends in Nonsurgical Female Genital Rejuvenation

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BACKGROUND Aging, childbearing, and hormonal changes can lead to vulvovaginal laxity and mucosal atrophy that negatively affect a woman's quality of life. As more minimally and noninvasive options for genital rejuvenation become available in the outpatient setting, it becomes increasingly important for the dermatologic surgeon to be familiar with these popular procedures.

OBJECTIVE To familiarize dermatologists with the nonsurgical options available for female genital rejuvenation, patient motivations for pursuing these procedures, relevant anatomy, and potential adverse events.

MATERIALS AND METHODS A MEDLINE search was performed on nonsurgical female genital rejuvenation from 1989 to 2015, and results are summarized.

RESULTS Reports of nonsurgical female genital rejuvenation procedures using fractional carbon dioxide lasers, nonablative lasers, monopolar radiofrequency devices, hyaluronic acid fillers, and fat transfer are concisely summarized for the practicing dermatologist.

CONCLUSION Review of the literature revealed expanding options for nonsurgical female genital rejuvenation.

The authors have indicated no significant interest with commercial supporters.

Dermatologists are very familiar with the aging process as it affects areas such as the face, neck, décolletage, abdomen, hands, and legs. These changes are addressed using a myriad of rejuvenation procedures daily but women have also long been interested in the appearance of their vulva, as is evidenced by the prevalence of pubic hair grooming and removal practices in the United States.[1] As with other parts of the body there is now an increasing demand for genital rejuvenation procedures; the American Society for Aesthetic Plastic Surgery reports that there was a 49% rise in the number of labiaplasty procedures performed from 2013 to 2014.[2] Although dermatologists are well trained to diagnose and treat genital skin pathologies, such as lichen sclerosus and extramammary Paget disease, they are often less familiar with the options available to patients seeking genital revitalization. As more minimally and noninvasive options for genital rejuvenation become available in the outpatient setting, it is increasingly important for the dermatologic surgeon to be familiar with these popular procedures.

Aging, menopause, childbirth, obesity, and many other factors contribute to vulvovaginal laxity (VVL) and vaginal atrophy. These changes can significantly impact quality of life, but women rarely discuss them, even with their physicians. In a survey of 421 women who have experienced at least 1 vaginal birth, 48% reported VVL. Of these women, 62% never discussed

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it with anyone despite 50% feeling that improving tightness would increase sexual satisfaction for both themselves and their partner.[3]

Although the term "genital rejuvenation" may imply that these procedures are only performed for cosmetic purposes, the reasons women seek female genital rejuvenation procedures are, in fact, varied and include but are not limited to painful intercourse, pain with athletic activity, urinary incontinence, orgasmic dysfunction, vulvar irritation, chafing, and discomfort with underwear/clothing.[4] A multicenter retrospective study found that of 258 women, 76% underwent surgery for functional reasons, 53% for cosmetic reasons, and 33% to enhance self-esteem; only 5% of patients were encouraged to have surgery by a romantic partner.[5]

In the past, therapies available to women with VVL have included a range of options from Kegel exercises, which are often minimally effective, to traditional invasive surgery. Surgical procedures, such as vaginoplasty, labiaplasty, and perineoplasty can be performed through a myriad of techniques by plastic surgeons and gynecologists but require significant recovery time and may result in complications such as dyspareunia. A survey of 563 members of the International Urogynecological Association (IUGA) showed that all respondents recommended physical therapy and Kegel exercises as treatment for vaginal laxity, whereas only 53% recommended surgery although they acknowledged that it is more effective. This may be related to the concern about postoperative dyspareunia reported by 83% of surgeons.[6]

In recent years, new technology is allowing for less invasive methods of treating VVL and atrophy without resorting to traditional surgery, and several studies have demonstrated that women are significantly interested in these procedures. A study performed with 50 focus group participants found that 50% of the women were interested in nonsurgical tightening, with 33% further classified as very interested. These women equated vaginal laxity with "feeling old or worn out, loss of sexuality, burdensome sexual performance, yearning for intimacy, and confidence experienced before having children."[7]

Although it is becoming less invasive, the issue of genital rejuvenation is fraught with controversy. There is no consensus on terminology, some physicians liken female genital cosmetic procedures to female genital mutilation, and long-term studies on safety and efficacy are largely lacking. This article is intended as a brief overview of genital rejuvenation options with an emphasis on those that are minimally and noninvasive and thus, more relevant to the practicing dermatologist.

Anatomy

An understanding of the anatomy of the external female genitalia is critical to successfully administering rejuvenation therapies in this area. Before initiating treatment, it is important to rule out pelvic organ prolapse by distinguishing between laxity of the vagina itself and the bulging of genitopelvic structures into the vaginal canal (Figure 1). Thus far, the data regarding the effectiveness of nonsurgical methods in improving prolapse are unclear.

Structures

The vulva comprises several major structures: the mons pubis, labia majora, labia minora, clitoris, vaginal introitus, and the urethral orifice (Figure 2).

The mons pubis is a hair-bearing triangular protuberance overlying the pubic bones and consisting of adipose tissue. The labia majora are symmetric skin folds that extend from the mons pubis to meet at the midline in front of the anus, at the perineum. The hair-bearing labia majora contain many eccrine, apocrine, and sebaceous glands.

Medial to the labia majora are paired labia minora that separate into 2 folds anteriorly. The anterior-most folds merge to form the clitoral hood, whereas the anterior and deeper folds attach to its inferior surface and form the clitoral frenulum. Posteriorly, the labia minora join to form the vaginal fourchette or frenulum of the pudendal labia. The labia minora consist of a fibroelastic stroma rich in neurovascular structures. The clitoris is a highly innervated erectile sex organ located at the fusion of the labia minora.

The vaginal opening, or introitus, is situated between the labia minora in a region called the vulvar vestibule.

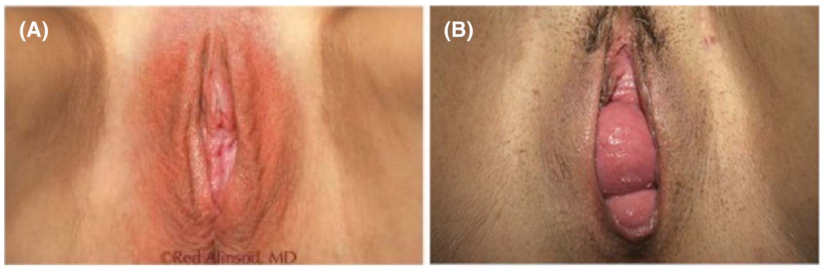

Figure 1. (A) Vulvovaginal laxity without pelvic organ prolapse. (B) Vulvovaginal laxity with severe cystocele, moderate-to-severe rectocele, and moderate uterovaginal vault prolapse. (Used with permission: Red M. Alinsod, MD).

It is surrounded by the hymen, a variable mucous membrane replaced by rounded caruncles after rupture. On either side of the introitus are the openings of the Bartholin glands.

The urethral orifice is immediately anterior to the vaginal introitus. On the posterior surface are paired Skene (paraurethral) glands.

The vaginal wall consists of 3 layers (Figure 3). The lining of the canal, or the most superficial layer of the mucosa, consists of nonkeratinized stratified squamous epithelium. Lubrication of the vagina occurs primarily through transudation, as well as secretions from Bartholin glands and the cervix. The surface of the vaginal canal is covered in ridges called rugae that allow for distention during intercourse and childbearing. Beneath the epithelium is the muscularis, which is composed of an inner circular and outer longitudinal layer of smooth muscle. The adventitia is the outermost fascial layer that is adherent to the muscularis.[8]

Vasculature/Innervation

Blood supply to the vulva is mainly from branches of the pudendal artery, although the mons pubis is supplied by the inferior epigastric artery, a branch of the external iliac artery (Figure 4). The blood supply to the

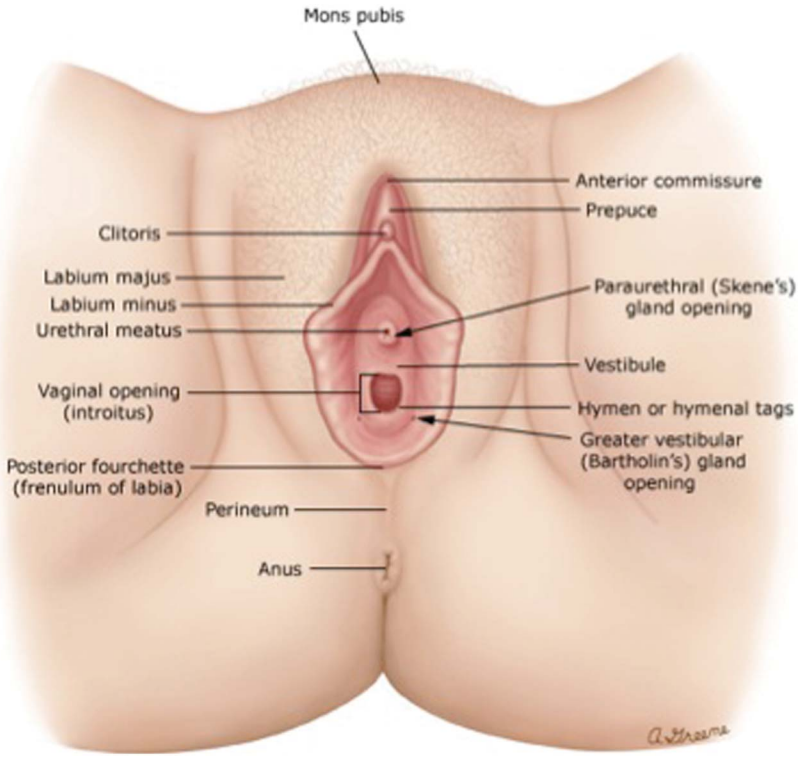

Figure 2. Illustration of vulvar anatomy. (Used with permission: UpToDate).

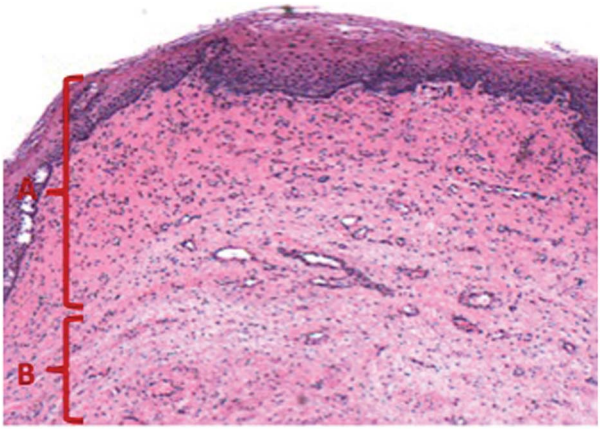

Figure 3. Histology of the normal vaginal wall demonstrating (A) mucosa and (B) muscularis layers. (Used with permission: Wenhua Liu, MD).

vagina is primarily derived from the vaginal artery, which is a branch of the anterior division of the internal iliac artery. The vagina also receives some of its vasculature from branches of the pudendal arteries.

The anterior vulva is innervated by the ilioinguinal nerve medially, over the mons pubis, and the genital branch of the genitofemoral nerve laterally. The posterior vulva receives its innervation from the pudendal nerve and the posterior cutaneous nerve of the thigh. Most of the innervation to the vagina is from the autonomic nervous system, although the distal vagina is innervated by the pudendal nerve.

Topicals

Vulvar Bleaching

Although there are no studies comparing the efficacy of the various vulvar skin lightening formulations available, there are many popular over-the-counter products that are specifically marketed for use in the anogenital area. A search of products available online demonstrates that the overwhelming majority are hydroquinone-free and use ingredients, such as niacinamide and kojic acid, which have been shown to be efficacious in lightening skin in other areas.[9,10]

Vaginal Tightening

There is also a myriad of over-the-counter creams, gels, suppositories, oils, wands, douches, and soaps that claim to improve vaginal laxity and blood flow for up to 24 hours, increasing the sexual satisfaction of the user and her partner.[11]

Topical vaginal "tightening" products rely primarily on astringents to achieve their effect. Numerous chemicals and herbs found in these products, such as woodfordia

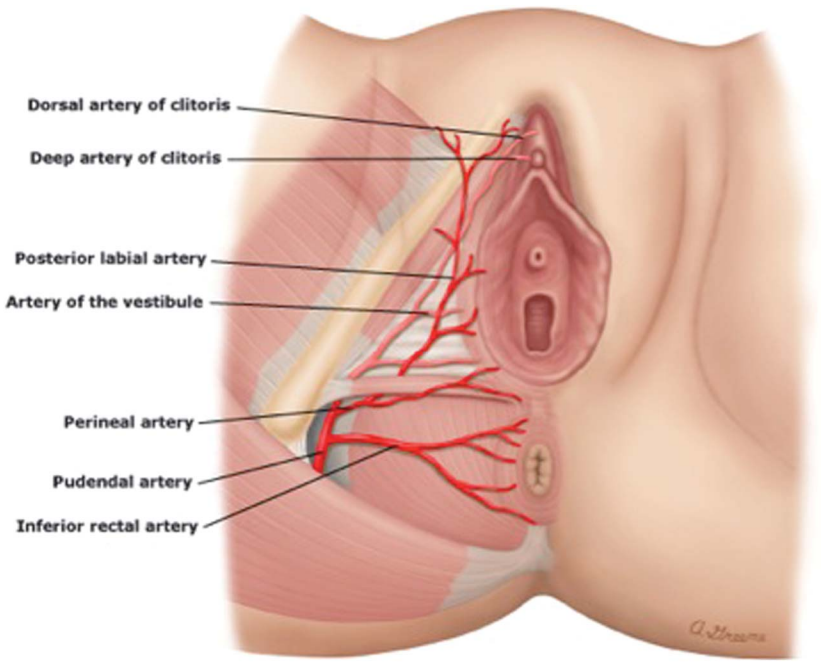

Figure 4. Illustration of vulvovaginal vasculature. (Used with permission: UpToDate).

floribunda, almond oil, and ficus glomerata, have astringent properties. Perhaps the most common astringent used for this purpose is alum (aluminum potassium sulfate hydrate), a salt that has been used throughout history for vaginal tightening and "revirginization."[12,13] Astringents dehydrate the epithelium through the induction of an osmotic gradient and by precipitation of cell surface proteins. Precipitation of these proteins creates a barrier that is mechanically stronger and less permeable to molecules.[14] This contraction of the superficial epithelium may create the impression of a "tightened" vagina, but the application of astringents does not influence the tone of the underlying muscularis or adventitia. Although astringents have mild antiseptic properties, repeated or prolonged exposure to astringents is irritating, and using these drying medications in the vagina may contribute to dyspareunia.

Other popular ingredients found in topical vaginal tightening products are *labisia pumila* (an herb with phytoestrogenic properties used in Southeast Asian communities for women's health), tea tree oil (antimicrobial), manjakani (antiinflammatory, antioxidant), vitamin E, aloe vera, and even gold.

Topical vaginal tightening products are not Food and Drug Administration (FDA)-approved, nor does any peer-reviewed literature exist to validate their efficacy and safety claims. Nonetheless, these products are widely available and popular among some patients.

Nonhormonal

Many of the symptoms of vaginal atrophy may be alleviated with topical products, such as moisturizers, lubricants, and estrogens. These products have not been demonstrated to improve laxity of vulvovaginal structures.

Despite a relative dearth of randomized clinical trials demonstrating efficacy, nonhormonal vaginal moisturizers, and lubricants, as well as regular sexual activity, are often recommended as first-line therapies for women with mild symptoms of atrophy.[15] Regular sexual activity maintains vaginal blood flow and induces lubrication, improving dyspareunia as well as the daily discomforts of atrophy. Habitual application of moisturizing agents can reduce vaginal pH, which is also associated with an improvement in atrophy symptoms. Although these moisturizers may not be as effective as hormonal agents, they can still significantly alleviate discomfort and improve quality of life.[16,17] In contrast to moisturizers that are intended to be used regularly, lubricants are used as needed to reduce dyspareunia during vaginal intercourse by decreasing friction.

Limited data regarding the safety of various moisturizers and lubricants are available. A 2012 study examining properties and relative safety of vaginal lubricants found that 60% of the water-based gels tested were hyperosmolar and contributed to epithelial sloughing and decreased tissue viability. In contrast, the iso-osmolar water- and silicone-based gels did not exhibit these properties.[18]

The use of lubricants may also impact vaginal flora and infection risk. For example, Brown and colleagues found that among 141 sexually active women aged 18 to 65 years, the intravaginal use of oils was associated with Candida species colonization (44.4% compared with 5%, $p < .01$), while women who reported the intravaginal use of petroleum jelly were 2.2 times more likely to test positive for bacterial vaginosis.[19]

Hormonal

If the symptoms of vulvovaginal atrophy are not adequately relieved by nonhormonal topical products, topical vaginal estrogen may be of benefit. Local delivery of estrogen through a topical product is preferred over systemic estrogen when vaginal symptoms are the only complaint. Topical estrogen minimizes systemic exposure and potential side effects, and is associated with greater symptomatic improvement.[15] Studies have shown that up to 90% of patients using local vaginal estrogen report improvement compared with 75% of those taking a systemic form.[20,21]

The local vaginal estrogen treatments currently available in the United States are 2 creams, 1 vaginal ring and 1 vaginal tablet.[22] A Cochrane review of 19 trials involving 4,162 women found that each of these products is equally efficacious in relieving the

symptoms of postmenopausal vulvovaginal atrophy, but that women seemed to find the vaginal ring easier to use and more comfortable.[23]

The 2 vaginal creams on the market are Premarin (Pfizer, Inc., New York, NY) and Estrace (Warner Chilcott, LLC, Rockaway, NY). In a 2009 randomized controlled study of Premarin, 423 postmenopausal women with moderate-to-severe vaginal atrophy were randomized to treatment or placebo once daily for 12 days on/7 days off or twice weekly for 12 weeks. Women in both of these groups demonstrated significant improvement in vaginal pH and symptoms, such as dyspareunia at 12-week follow-up with no reports of endometrial hyperplasia or carcinoma, and no significant increase in adverse events over the placebo group.[24] The literature does not currently contain any randomized controlled trials, or recent observational studies, using Estrace.[22]

Ablative Lasers

Vulvar and vaginal mucosal atrophy, resulting in a condition known as atrophic vaginitis, is one of the most characteristic consequences of menopause. The estrogen decline initiated by menstrual cycle arrest leads to changes in the vulvovaginal mucosa that manifest as clinical symptoms of itching, dryness, burning, dysuria, and dyspareunia.[25] As such symptoms tremendously detract from quality of life, significant research has been performed in the area of nonhormonal and long-lasting treatment of vulvovaginal atrophy.

Historical literature describes the use of carbon dioxide (CO_2) lasers in the area of the vulva and perineum to address cosmetic concerns, such as ridges, redundant skin, dyschromia, and skin tags, but this was often associated with significant patient discomfort.[26] Thus, more recently, fractional ablative CO_2 lasers are being used on the vulvovaginal mucosa to address atrophy.

A study of 50 postmenopausal patients who underwent a single treatment to the vaginal mucosa with a 10,600 nm fractional ablative CO_2 laser examined biopsies performed before treatment, and at 30 and 60 days after treatment. On microscopic and ultrastructural review, the investigators found treatment with fractional CO_2 laser restored vaginal mucosa to a premenopausal state by restoring epidermal thickness, increasing glycogen, and inducing a rich dermal vascular supply.[27]

Another study examined the effect of a series of 3 treatments over 12 weeks with fractional CO_2 in 50 women. Symptoms associated with vulvovaginal atrophy were significantly improved at 12-week follow-up. No significant adverse events were reported.[28] A study of 48 postmenopausal patients who underwent a series of 3 treatments to the vaginal mucosa found that 91.7% were satisfied or very satisfied with the procedure and reported a significant improvement in quality of life.[29]

Loss of vaginal rugae with aging and menopause is believed to possibly contribute to a decline in sexual satisfaction by decreasing friction during coitus. Fractional CO_2 has been used to restore rugae with reported improvement in sexual function. However, large studies establishing the safety and efficacy of this application are lacking.[30]

Nonablative Lasers

Vizintin and colleagues described the use of a nonablative 2,940 nm erbium-doped:yttrium-aluminum-garnet (Er:YAG) laser delivered through a collimated patterned handpiece that allows for consistent fluence delivery despite varying distances between the mucosal surface and the handpiece over irregularly shaped body surfaces such as the vagina. The laser pulses heat the tissue to a depth of 100 microns, leading to the contraction of the irradiated tissue and ultimately neocollagenesis. The authors report their clinical experience from 5 international clinical sites, demonstrating improvement in vaginal laxity with one adverse event of mild mucosal burns that healed without scarring among the 225 patients treated.[31]

Radiofrequency

Monopolar radiofrequency (RF) has been used in dermatology for rejuvenation of the skin on the face, limbs, abdomen, and buttocks since 2003.[32] It allows

for the safe delivery of thermal energy to the deep dermis to achieve lifting and tightening while avoiding epidermal and neurovascular damage.[33,34] Treatment with RF initially produces immediate collagen fibril contraction and resultant tissue tightening. This initiates a wound-healing response that produces long-term neocollagenesis, improving the appearance of rhytides, and producing further tissue contraction.[35]

In 2010, Millheiser and colleagues produced the first human study to demonstrate the efficacy of using monopolar RF to treat vaginal laxity after childbirth. The authors demonstrated that it could safely improve laxity and sexual function up to 6 months after treatment.[36] Since then, several studies have used various RF devices to improve VVL.

A study of 30 premenopausal women with self-reported vaginal laxity after childbirth underwent 1 RF treatment to the mucosal surface of the vaginal introitus with a device that does not require anesthesia and pairs RF submucosal heating with cryogen cooling of the mucosal surface. Subjects completed Female Sexual Function Indices (FSFI) and Female Sexual Distress Scales—Revised (FSDS-R), as well as questionnaires on vaginal laxity and sexual satisfaction at 1-, 3-, 6-, and 12-month follow-up. Treatment resulted in sustained significant improvements in laxity, sexual function, and sexual distress even at 12-month follow-up. Although there were no significant adverse events reported, one patient experienced mild vaginal leukorrhea and another reported mild abdominal discomfort. Both of these patients' symptoms resolved spontaneously within 10 days.[37]

A histologic study of the effects of this RF device on a sheep vagina after a single treatment found stromal remodeling and fibroblast reactivation between 1 and 4 weeks after treatment with variably increased submucosal and muscularis collagen over the 6 months after treatment, thus confirming that treatment induces neocollagenesis and connective tissue remodeling. The investigators also noted that the cryogen cooling did not produce necrosis or scarring of the epidermis.[38,39]

A transcutaneous temperature-controlled radiofrequency vulvovaginal rejuvenation device has recently demonstrated effectiveness in improving VVL (Figure 5). The treatment probe on this device contains thermistors and thermocouples that provide feedback to modulate the energy delivered to the tissues. Such feedback minimizes the risk of tissue injury and patient discomfort. This same technology is currently used for safe, effective skin tightening on other areas of the body.[40] A study examined 23 patients (5 menopausal, 6 perimenopausal) with self-described mild to moderate VVL who were treated up to 3 times at an interval of 4 to 6 weeks (Figure 6).

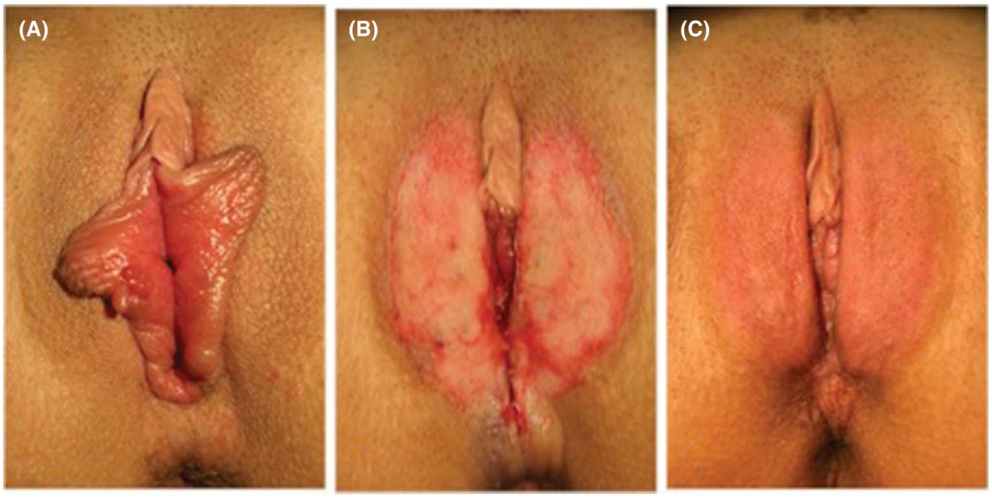

Figure 5. (A) Patient with significant VVL before treatment with ablative CO_2 laser. (B) Vulva immediately after treatment. (C) Eight weeks after treatment. (Used with permission: Red M. Alinsod, MD).

Figure 6. (A) Patient with significant VVL before treatment with transcutaneous temperature-controlled radiofrequency (TTCRF) (ThermiVa, ThermiAesthetics, Inc., Irving, TX). (B) Four weeks after third treatment with TTCRF. (Used with permission: Red M. Alinsod, MD).

The treatment protocol for this device includes application of RF to the labia majora, as well as the vaginal introitus and canal, to address laxity and to produce aesthetic improvement of the entire vulvovaginal unit. Subjects were able to resume normal activity, including intercourse, immediately after treatment. Subjects reported a statistically significant improvement in vaginal laxity and sexual satisfaction, with no significant adverse events reported.[41] The manufacturer states that current observations indicate results last for 9 to 12 months.[42] Clinical studies to validate the histopathologic changes induced by the device and to establish its efficacy for disorders such as mild to moderate stress urinary incontinence, atrophic vaginitis, and orgasmic dysfunction are ongoing.

Injectables

Although less common, the use of injectables, such as hyaluronic acid and autologous fat, are also described (and marketed) as minimally invasive methods of female genital rejuvenation.

G-Spot Amplification

The Grafenberg spot, or G-spot, is a term coined by Addiego et al in 1981 to credit Dr. Ernest Grafenberg who is believed to have first described an erogenous zone on the anterior vaginal wall located 1 to 2 cm from the urethra in 1950.[43] Despite its lore, there is significant debate in the medical literate as to whether the G-spot actually exists or plays a critical role in female sexual satisfaction.[44] Amplification of the G-spot with injection of hyaluronic acid fillers is a technique that aims to improve female sexual gratification during intercourse by increasing friction, which often declines in VVL and menopause. Other filler substances, such as collagen, autologous fat, silicone, and calcium hydroxylapatite, have been used for the same purpose with varying success.[45,46]

There are significant potential risks of this procedure, including bleeding, infection, and urinary complications. Perhaps the most serious adverse event is intravascular injection; a case of nonthrombotic pulmonary embolism has been reported after injection of 5 mL of hyaluronic acid to the vaginal wall. The patient recovered with supportive care and mechanical ventilation.[47] There exists in the literature a similar report of fatal pulmonary embolism after injection of polyacrylamide hydrogel in the vaginal wall to achieve a tightening effect.[48] Although the safety and efficacy of G-spot amplification has not been established, it remains popular among some patients.

O-Shot

The O-shot, or "orgasm shot," is a controversial rejuvenation procedure in which platelet-rich plasma (PRP) is injected into the clitoris and the upper vaginal wall. Platelet-rich plasma is usually derived from the fresh blood of a patient and is rich in chemokines, growth factors, and cytokines that have been implicated in tissue repair and inflammation. The use of PRP was initially popularized in maxillofacial and musculoskeletal disciplines, although several studies have failed to demonstrate efficacy in these applications.[49] Since then, PRP has been used to treat many dermatologic conditions, such as alopecia, chronic wounds, and photoaging, but studies have yet to show a consistent benefit.

The O-shot procedure is marketed as a minimally invasive means of improving sexual gratification and

urinary incontinence. The O-shot practitioners purport that using patient-derived PRP stimulates stem cells to grow healthy vaginal tissue, although peer-reviewed studies examining efficacy and safety are lacking in the literature.[50]

Fat Transfer

As with skin elsewhere, aging of the labia majora manifests as decreased volume, wrinkles, lost elasticity, and dyschromia. Volume loss in the labia majora may also expose the labia minora, leading to discomfort, dryness, and cosmetic distress. Surgical augmentation of the labia majora using both fat grafting and injection of autologous fat has been described as methods for addressing these concerns.[51,52] Palpable fatty cysts are a potential complication of this procedure, but in one study, they resolved in 5 of 6 patients within 6 months without treatment.[53] Other reported adverse outcomes include increased perspiration and the appearance of a "camel toe" or an exaggerated vulvar outline visible through clothing.[41,45]

Summary

Many studies have suggested that the scope and impact of VVL and vulvovaginal atrophy on women's quality of life is underestimated. Advances in medical technology now provide women with nonsurgical and minimally invasive options for genital rejuvenation to address cosmetic concerns, discomfort, and sexual dissatisfaction. In addition, both nonablative and RF techniques have even been found to be effective for treatment of stress urinary incontinence that can be associated with VVL.[31,54,55]

Although small studies of these procedures demonstrate effectiveness and relative safety, they do so by primarily relying on outcome and satisfaction questionnaires. The literature is lacking studies using objective measures of vaginal laxity and improvement because standardized measuring instruments for this purpose do not yet exist. Nonetheless, the number of techniques and devices marketed for nonsurgical female genital rejuvenation is increasing rapidly (Table 1).

TABLE 1. Devices Marketed for Female Genital Nonsurgical Rejuvenation

Fractional ablative CO_2
CO_2RE (Syneron, Inc., Irvine, CA)*
Femilift (Alma Lasers US, Buffalo Grove, IL)
FemTouch (Lumenis, Ltd., Yokneam, Israel)
MonaLisa Touch (DEKA, Florence, Italy)
Nonablative Er:YAG
IntimaLase (Fotona, San Clemente, CA)
Juliet (Asclepion Laser Technologies, Jena, Germany)†
Radiofrequency
ThermiVa (ThermiAesthetics, Inc., Irving, TX)
Viveve Vaginal Laxity RF Therapy System (Viveve, Inc., Sunnyvale, CA)†

*FDA-approved in 2015 for gynecological applications, including vaginal treatments.

†Not approved for use in the United States.

Dermatologists are very familiar with aging of the skin and the myriad of nonsurgical techniques available to address it. Dermatologists are often less familiar with how these principles are also being applied to the treatment of VVL and vaginal atrophy. The increasing demand for female genital rejuvenation requires that the dermatologic surgeon be familiar with office-based nonsurgical devices and procedures that can safely and effectively address these concerns.

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