

Lasers and Energy-Based Devices for Women's Genitourinary Health: Scientific and Clinical Evidence and FDA Clearance

Macrene Alexiades MD PhD

Department of Dermatology, Yale University School of Medicine, New Haven, CT; Siggrou Hospital, University of Athens, EU; Dermatology and Laser Surgery Center of New York, New York, NY

Macrene Alexiades MD PhD

One year ago, in this journal, I predicted the FDA's concerns disseminated in recent months regarding a rapidly growing field of device-based treatment for women's genitourinary (GU) disorders. In that article entitled, "Devices in Women's Health" (JDD November 2017), I put forth the status of FDA clearance for devices in the women's GU health domain and warned of marketing preceding appropriate clearances.[1] Current FDA clearances are only for general use such as "incision, excision, vaporization, and coagulation of body soft tissues including gynecology and GU surgery," or "electrocoagulation and hemostasis and to create lesions in nervous tissue in dermatological and general surgical procedures."[1] On July 31, 2018, the FDA warned against the use of energy-based devices to perform vaginal "rejuvenation" or vaginal cosmetic procedures (https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm615013.htm) followed by a statement from FDA Commissioner Scott Gottlieb MD on efforts to safeguard women's health from deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation" (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615130.htm). As I forewarned a year ago, the proper testing and clearances for GU applications are imperative to ensuring these potential treatments are safe and effective for women's GU disorders; marketing of women's health technologies should not get ahead of clearances.

Lasers have a long over 40-year history of use in women's GU disorders among gynecologists, urologists, dermatologists, and plastic surgeons. Carbon dioxide (CO_2) laser has been used for incision and ablation of GU tissue, endometriosis, and genital warts, and defocused CO_2 for tissue contraction. Diode laser has been used for myomectomy. Photodynamic therapy has been performed with various lasers and light sources for lichen sclerosus, including those published in this journal.[2] Radiofrequency has been used in the lower genital tract for endometrial ablation. Over the past 15 years, fractional lasers and radiofrequency technologies have been increasingly reported for the treatment of atrophic vaginitis, stress urinary incontinence, and vulvovaginal laxity, a group of disorders also referred to as the genitourinary syndrome of menopause (GSM). In a recent consensus article co-authored with 34 colleagues, the basic science of device-vaginal interactions and the clinical data in the treatment of GU disorders was detailed.[3] In another consensus article authored by The North American Menopause Society and The International Society for the Study of Women's Sexual Health on treatment for breast cancer patients, the use of laser is supported as a potential treatment for GSM.[4]

The scientific basis for the application of laser and energy-based devices to GU tissue has thus been extensively studied. The vagina is lined by skin externally, directly relating to the transfer of dermatologic devices to external vaginal applications. The vaginal tract is lined by non-keratinized stratified squamous epithelium, which is estrogen-dependent, glycogen-rich, but which undergoes atrophy following menopause, ovarectomy, breast cancer, radiation, and breast feeding. It is estimated that 50% of post-menopausal women suffer from GSM. Treatment of atrophic post-menopausal vaginal epithelium with lasers and energy-based devices has been published in a number of histologic and clinical reports to restore vaginal epithelial thickness, glycogen levels, glycogen-rich shedding and pH, to stimulate fibroblasts and vascularity in the underlying lamina propria to pre-menopausal levels; and to improve the clinical signs and symtoms of GSM.[3]

An accumulating body of evidence, including randomized clinical trials comparing devices to topical estradiol, increasingly support the scientific and clinical basis for this therapeutic approach to a group of disorders for which there is a paucity of highly effective treatment options. From a safety perspective, while 14 adverse events (AE) from devices used on vaginal tissue were reported to the FDA to date, the rate of AE appears to be exceedingly small as the global sales for devices in this arena exceeded $100 million in 2016 and only immediate, short-term, mild, and the absence of severe AEs have been observed in clinical trials. An over-the-counter LED device has been determined by the FDA to constitute a general wellness product that is "low risk" to be used "to increase sexual pleasure and for personal wellness to improve confidence with sexual intercourse."[5] More randomized, controlled clinical trials comparing laser and energy-based devices to FDA-approved treatments are needed in order for FDA clearances to allow for any marketing of these technologies to treating women's health conditions.

References

1. Alexiades, M. Devices in women's health. *J Drugs Dermatol.* 2016;15(11):1299
2. Tadir, Y., Gaspar, A., Lev-Sagie, A., Alexiades, M., et al. Light and energy based therapeutics for genitourinary syndrome of menopause: Consensus and controversies. *Lasers Surg Med.* 2017;49(2):137-159.
3. Alexiades-Armenakas M. Laser-mediated photodynamic therapy of lichen sclerosus. *J Drugs Dermatol.* 2004;3(6 Suppl):S25-7.
4. Faubion SS, Larkin LC, Stuenkel CA, et al. Management of genitourinary syndrome of menopause in women with or at high risk for breast cancer: consensus recommendations from The North American Menopause Society and The International Society for the Study of Women's Sexual Health. *Menopause.* 2018;25(6):596-608.
5. De la Torre, S, Miller, L. Multimodal vaginal toning for bladder symptoms and quality of life in stress urinary incontinence. *Int Urogynecol J.* 2017;28:1201-7.