FDA warning on vaginal laser procedures should emphasize informed choices, not fear

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On July 30th, the FDA sent out a stern warning against the use of energy devices (laser therapy) to perform "vaginal rejuvenation," and for procedures to treat symptoms related to sexual function, because of worries about adverse events. I agree with the FDA that these devices need more study, clear indications, informed patients, and skilled and ethical physicians to be used safely.

However, I have concerns that the FDA, in an overabundance of caution, may limit availability of innovative therapies, which when used correctly may benefit women's reproductive health. In addition, press coverage is causing confusion about the different procedures.

Genitourinary syndrome of menopause (GSM)

The North American Menopause Society and International Society for the Study of Women's Sexual Health recently introduced the term *genitourinary syndrome of menopause* (GSM) to describe the constellation of signs and symptoms associated with decreased estrogen and other hormones at the time of menopause. This syndrome affects approximately 50% of menopausal women and can cause vaginal dryness, itching, irritation, discharge, and painful sex. Vulvovaginal atrophy often worsens over time when it is not treated, unlike hot flashes that usually go away within a few years. Over 90% of women do not seek treatment for vaginal dryness and painful intercourse because of stigma, embarrassment, or doubt that there are safe therapies to help.

Standard treatments for GSM fall short for some

Standard treatment options for vulvovaginal atrophy include nonhormonal vaginal moisturizers and low-dose vaginal estrogen. In addition, maintaining regular intercourse can enhance vaginal health by increasing blood flow. Estrogen helps alleviate symptoms through enhanced lubrication, and improved pelvic muscle tone and elasticity of the vagina. However, many women do not want to use estrogen or can't (even topically), because while absorption of vaginal estrogen is limited, some hormone exposure can pose a risk. For these women and their doctors, the limited options for effective treatment are frustrating. Vaginal laser therapy appeared to offer a promising nonhormonal option.

Vaginal laser therapy for GSM is not the same as vaginal rejuvenation

Preliminary data suggest that laser technology may offer benefits in treating vulvovaginal atrophy, but we need more data to assess its true safety and effectiveness, particularly over the long term. The FDA's goal to protect women seeking treatment for vulvovaginal atrophy is best served by giving women accurate information about their options. Generally speaking, standard treatments should be tried first until we know more about the long-term risks and benefits of laser procedures. That said, I worry about misunderstanding of the FDA statement shutting down studies (and minds). For some women, laser-based therapies may prove to be a reasonable way to relieve GSM symptoms and improve quality of life.

So what is vaginal rejuvenation, anyway?

Typically, the term "vaginal rejuvenation" applies to procedures that alter the size or shape of the vagina or labia or recreate the hymeneal ring. The goals of these procedures are primarily cosmetic changes, or to enhance sexual satisfaction. Unfortunately, the procedures are not clearly defined. The American College of Obstetricians and Gynecologists defines vaginal rejuvenation and cosmetic procedures as "designer

vaginoplasty," "revirgination," other cosmetic vaginal procedures, and "G-spot amplification" (injection of collagen into front wall of the vagina). These are elective procedures without a clearly defined medical purpose.

Taking the FDA warning in context

We must not forget that advances in women's health care have been hindered by lack of rigorous studies in women, and by hesitance to openly address women's reproductive and sexual health concerns. (Concerns about erectile dysfunction drugs causing dangerously low blood pressure did not result in warnings against using those drugs altogether.) With this history in mind, the FDA could have crafted this warning more carefully to delineate between the types of procedures, and to encourage further research on how women's bodies respond to such innovations. In addition, off-label use of medications and procedures has often led to FDA approval of new therapies (including, interestingly, the most popular class of erectile dysfunction drugs, which were initially studied as a treatment for high blood pressure and chest pain).

Physicians must provide accurate and current information to patients, who should be fully engaged in the informed decision-making process for *all* medications and procedures. We should not inflame women's fear of estrogen, and we should give them all options to consider. The FDA should not conflate cosmetic procedures with innovative treatments that may improve quality of life, and it should not engage in fearmongering with regard to women's health and relevant technology.

I welcome the dialogue and hope the FDA will work to allow this technology to continue to be studied by gynecologists, just like it was for dermatologists treating skin conditions.

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POSTED AUGUST 15TH, 2018 AT 9:46 AM

Alexander Bader

Great article. From my side and as one of the first Physicians ever since 2010 who used these technologies and with an experience more over more than 2000 cases, I have never ever came across any of these so called adverse results for patients. Case selection is the key in every medical praxis and it sounds like a dum discussion to consider the FDA statement in a serious way. Plenty of clinical studies have showed what CO2 and other technologies could achieve for better tissue quality and function. We all need to realise that we are living in a historical moments on women health. Women health deserves more than a statement which is coming to acuse all this project for no data of evidence but they also come with this acuse without any data of evedince from their side!!!

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POSTED AUGUST 6TH, 2018 AT 10:21 AM

Shah Zarak

I would add further comments on Dr Hope kind explanation.Frankly, the issue on the fda to those related companies are basicly on the laser outcome.CO2 are ablative.However, CO2 works better than Erbium lasers and RF for treatments of vagina as mentioned.The buggust issue is that, we have those manufacturers developing poor quality of laser tech which were more for cosmetics and surgeries applications.They were nit fully design for gyne applications.Many of these companies are repackages where they get the basic tech else where and rebrand them as their products for cost savings benefits.Therefore mild side effects tend to occur.Thise machine are used by Spa centers and are not guided by Gynecologist.Its like getting a rehab nurse to administer a treatment.Some of the manufacturers uses disposable to act as psychology approach to better sterile outcome but neglect the danger of silicone toxic vapours left behind.I must stress that fimilift laser from Alma do have mild side effects on patients outcome and patients do encounter post bleeding.In Summary, not all lasers are the same.You may have develop a CO2 laser or Erbium laser or RF, the quality of outcome differs and i have experience that those names which was mentioned by fda do have quality issues.Some are over claimed.I have also experienced that pkasma lasers that were approved for lipolises were used in spine surgeries which is not recommended as it produces high temp withinn the disc.Again i applaud good quality lasers but we need to ensure that those manufacturers who are seeking for fortune by playing ALL FITS ONE should be storaged.

▶ Reply

POSTED AUGUST 5TH, 2018 AT 2:03 PM

Marco A. Pelosi, III, MD, FACOG, FACS, FICS, FAACS

Rejuvenation is poorly chosen marketing word plucked from the world of aesthetics. Nonetheless, fractional laser ablation of atrophic vaginal epithelium reverses vaginal atrophy histologically. This has been published repeatedly in the peer reviewed medical literature for the past 8 years. The effect is consistent and the duration of the effect is temporary. I treat patients and they respond well consistently. Some are physicians like you and I. The title of the FDA warning would lead the reader to believe that we are in the midst of a laser vaginal trauma epidemic. However, they make no statement of any morbidity spike nor any data or references to suggest as much. Hence, the FDA statement does not either confirm or refute any reservations that anyone has on using these devices from a safety perspective. From an effectiveness perspective, it's correct that there are few studies available and long term studies need to be conducted. As with anything, you need to be knowledgeable in both the indications and technologies to deliver treatments with reasonable expectations.

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POSTED AUGUST 4TH, 2018 AT 11:37 AM

Maria Jasmine Freeman

As a physician, I never accepted that those laser-and the like- procedures could rejuvenate a vagina of a woman at menopause! Function stems from structure and hormone receptors, and given at that stage vaginal epithelial cells are changed, and have turned devoid of estrogen, it turns difficult to believe any durability of effect of those procedures, let alone efficacy to start with. Worse, serious risks, as referred to, are v likely, and turn more troublesome than the problem for which they were resorted to.

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POSTED AUGUST 3RD, 2018 AT 9:43 PM

Molly Black

Are you speaking about the Mona Lisa Touch laser?

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