

Vaginal Rejuvenation: FDA Cautions About Elective Procedures

By Deborah Jeanne Sergeant

Childbirth, menopause and the passage of time can affect both the appearance and function of women's vaginal tissues. For some, dryness and lax tissue make intercourse less pleasurable and even painful.

Some health care providers, including gynecologists, dermatologists and plastic surgeons, now offer non-surgical treatments to restore both vaginal moisture and tightness.

In July, the FDA issued a cautionary statement about providers using energy-based devices for elective vaginal procedures. The FDA statement read that "the safety and effectiveness of energy-based devices for treatment of these conditions has not been established" and that "non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events."

The FDA has approved energy-based devices — radiofrequency or laser — for dermatological and general purposes, including removal of genital warts, growths or pre-cancerous tissue. The FDA has not specifically approved some of these devices for vaginal procedures. It states that using the devices for cosmetic reasons may cause "vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain."

Robert A. Jason, board-certified gynecologist and cosmetic gynecologist, believes that the FDA statement has caused a great deal of confusion, though there's merit in warning women to approach vaginal rejuvenation carefully.

"They should go to a gynecologist who understands the benefits and pros and cons of non-invasive vaginal rejuvenation equipment," Jason said. Jason serves as medical director and owns the Laser Vaginal Rejuvenation Institute of New York, in New York City and Lake Success on Long Island.

He said that vaginal rejuvenation should be overseen by a gynecologist or cosmetic gynecologist physician in charge.

Patients should also maintain realistic expectations. Women seeking tighter tissue, for example, should understand that non-invasive procedures may not offer the tightness they want.

Jason said that he and other gynecologists use certain lasers or radiofrequency devices as a scalpel or knife. He added that there are also other lasers and radiofrequency devices on the market that are used as non-invasive, non-surgical devices that gynecologic and non-gynecologic physicians use for non-invasive

vaginal rejuvenation.

"That is the confusing part," Jason said. "After careful examination, if the right candidate uses non-invasive procedures, myself as well as many colleagues across the country have had excellent results, over 90 percent success rates.

"The problem is that when women need more involved surgical repairs, their expectations were not met and that non-invasive procedures done by offices not well-versed in vaginal health can have less than desired or harmful results."

He said that many women had procedures that were not appropriate for them and were hurt, prompting the FDA's warning.

"To truly put this in perspective, laser hair removal in the wrong person's hands can cause burns and harmful results also," Jason added.

David Gandell, clinical professor of OB-GYN practicing at Rochester Gynecologic & Obstetric Association, PC, uses MonaLisa Touch for what he likes to call "vagina revitalization, which is restoring some of the qualities which have changed from chemotherapy, radiation or menopause," he said.

The MonaLisa Touch website describes the treatment as "a vaginal probe is inserted into the patient's vagina, and delivers gentle laser energy to the vaginal wall, stimulating a healing response."

Gandell said revitalization stimulates blood supply to the tissue to improve moisture and improve the quality of the tissue without damaging it. Patients may return to normal activities immediately and sex within two or three days.

Gandell views MonaLisa Touch as an option for women who can't or won't use hormone replacement or medication to resolve these issues.

The protocol is three treatments, scheduled six weeks apart. Each treatment takes five minutes. Gandell said that the effect is similar to that of vaginal estrogen for post-menopausal women.

The effects last on average a year to 18 months. Re-treatment should last another year.

The procedure is contraindicated for women with undiagnosed vaginal bleeding, presence of a mesh in the vaginal wall, complete prolapse, or any active infection. He also wants women to realize that not all genital conditions may be fixed by surgery, laser treatment or hormonal therapy.

Gandell said that women may experience mild irritation that lasts a few hours to a few days and a little spotting.

"I've had patients who'd been unable to have intercourse 10 years who are now are satisfyingly sexually active again," Gandell said. "I've seen it work beautifully for couples."

Robert A. Jason, board-certified gynecologist and cosmetic gynecologist,




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