

Lasers Promising for Genitourinary Syndrome of Menopause

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SAN DIEGO — Vaginal dryness and dyspareunia, along with other symptoms of genitourinary syndrome of menopause, can be safely and effectively treated with laser therapy, preliminary results from a small study show.

Solid evidence for the laser treatment of genitourinary syndrome of menopause has been sparse, but it is increasing, said investigator Eric Sokol, MD, from the Stanford University School of Medicine in California.

About half the menopausal women in the United States report symptoms related to vulvovaginal atrophy that negatively affect their quality of life, Sokol said here at the North American Menopause Society 2018 Annual Meeting. Although menopause is the most common cause of vaginal atrophy, oophorectomy, antiestrogen medications, pelvic radiation for cancer, and breastfeeding can also all contribute to it.

The standard therapies — vaginal estrogens, ospemifene, moisturizers, and lubricants — work for most women and should remain the first-line option when possible, but some women need alternatives.

"We all have patients who have tried these and weren't satisfied, or we have cancer survivors with an estrogen-sensitive breast tumor or another cancer who can't or won't use estrogen," Sokol said. And then there are women who experience persistent symptoms or have difficulty with complying with treatment.

That's where laser therapy can play a role.

How Laser Therapy Works

During an office visit, clinicians can use either a CO₂ laser, most commonly used, or a YAG laser. The procedure does not require anesthesia, is usually painless, and can be performed in about 2 minutes. Women typically receive three treatments 6 weeks apart and are advised to abstain from intercourse for 3 days after each treatment.

The laser process increases growth factors that contribute to the restoration of vaginal health. Increased collagen offers better mechanical support, increased glycogen content and delivery leads to an increase in *Lactobacillus* activity, and more acidic mucopolysaccharides in the ground matrix lead to better mucosal hydration. And the epithelial tissue of the vaginal mucosa thickens considerably, to premenopausal levels.

"The increased permeability of the rehydrated extracellular matrix facilitates the diffusion of nutrients, mineral salts, ions, vitamins, antibodies, and hormones from the blood vessels to the tissue of the vaginal wall," Sokol reported.

Still, the US Food and Drug Administration (FDA) has not approved the use of lasers for the treatment of genitourinary syndrome of menopause or dyspareunia, and recently sent warning letters to seven companies that market laser devices, expressing concern about their use for vaginal rejuvenation, as [reported](#) by *Medscape Medical News*.

As a result, many of the companies marketing these devices "have had to change their approach, which I think is a positive step," said Sokol.

But the FDA "lumped all these technologies, which are very different, together, and they're used or being evaluated for different health conditions," he told the audience.

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In fact, several recent studies have supported the therapeutic value, safety, and effectiveness of lasers for vaginal pain

and dryness. But "everything I'm talking about here is off-label use and could be considered to be, to some extent, experimental," he emphasized.

Sokol and his colleagues assessed genitourinary syndrome of menopause symptoms — dyspareunia, dysuria, vaginal pain, burning, and itching — in 30 women who could not use lubricants or estrogens and who underwent fractional CO₂ laser treatment. The women rated their satisfaction with the procedure on 5-point Likert scales, and dilators were used to evaluate elasticity at baseline and 12-month follow-up.

Preliminary results show that there was significant improvement in symptoms for all women at 12 months, but the improvements were the greatest for vaginal dryness and dyspareunia.

Elasticity also improved. More women were able to tolerate the medium or large dilator at 12 months than at baseline (79% vs 20%). And there was a 10.6-point increase over the 12-month period in Female Sexual Function Index scores.

At follow-up, 92% of the women reported being satisfied or very satisfied with the procedure, and none of the women reported being dissatisfied.

And more studies are on the way.

Sokol said he will soon present findings from the VeLVET trial ([NCT02691936](#)) of 62 women in which vaginal laser treatment was compared with vaginal estrogen therapy at 6 months.

Data from a histology study comparing punch biopsies of the vaginal wall before and after CO₂ laser therapy are currently being analyzed.

And two other studies — a cost-effectiveness analysis and a multicenter randomized sham-controlled trial — are in the works.

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Sokol's presentation was well done and unbiased. "He talked about everything," said Uma Ananth, MD, NCMP, from Comprehensive Women's Care in Columbus, Ohio.

The presentation helped her feel more comfortable about the strength of the evidence backing laser treatments for patients with genitourinary syndrome of menopause, she added.

Three points in particular are important takeaways, she told *Medscape Medical News*.

"Number one: beware of all the sham treatments that are going around. Number two: don't treat what it is not useful for, like vestibulitis and other things. And number three: it is very reassuring to know that there is actually going to be a double-blind, sham-controlled study coming up. I was very impressed with that," Ananth said.

"There is evidence that laser treatment does, in fact, do what it is advertised to do," Rosemary Delgado, MD, an obstetrician-gynecologist in private practice in Walnut Creek, California, said after the presentation.

The talk validated the positive responses she has heard from her patients, Delgado explained, adding that it is "encouraging that there are studies that are ongoing that I think will end up supporting the positive results that we are seeing."

However, she said she was surprised that Sokol did not discuss potential complications and adverse events related to laser therapy.

Adverse Events?

Sokol reported that, so far, he has seen no serious adverse events in his patients or in the trials he is involved with. However, the trials to date have been small and adverse events will eventually emerge, he acknowledged.

"There's no way you can release a new technology that's going to take off like this seems to be doing — and hopefully that gets regulated — where you won't run into those," Sokol told *Medscape Medical News*. Common adverse events with CO₂ lasers are minor and typically result from not being able to use lubricant during insertion of the probe, he noted.

"Some patients we're treating have very small atrophic vaginal canals and haven't been sexually active in a decade," he explained. "People can have a little bit of vaginal bleeding, a little discomfort, particularly after an outside treatment, and a little discharge or a minor amount of spotting."

Sokol reports financial relationships with Cook MyoSite, ACell, Coloplast, Pelvalon, and Eximis Surgical. Ananth and Delgado, who both use vaginal laser treatments in their practices, have disclosed no relevant financial relationships.

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