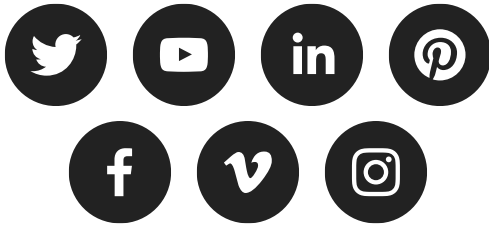




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VAGINAL TISSUE REJUVENATION TO TREAT PELVIC ORGAN PROLAPSE SYMPTOMS: FDA MEDIA BLITZ, FEAR VS FACT

August 7, 2018

I wouldn't see an aesthetician or dermatologist to provide a vaginal treatment, and I wouldn't see a gynecologist to fix wrinkles on my face. Call me crazy. I prefer my parts remain fully optimized and relatively functional. Walking the walk of a pelvic organ prolapse (POP) patient advocate, I get to see, touch, and explore a multitude of

**HEALTHCARE DOES NOT
EVOLVE BY CHANCE
~IT EVOLVES BY CHANGE~**



treatments and tools utilized to treat this condition, and that includes some that have made me wonder what...were....they....thinking? But I've also seen a couple over the years that have made me sit right up in my chair and immediately go down the Google rabbit hole to capture more data. Energy based vaginal tissue regeneration (VTR) is a nonsurgical treatment I've had my eyes on for years.

Pelvic organ prolapse is an incredibly diverse condition. POP may occur at any time between mid-teens through end of life. While most often the result of childbirth or menopause, a multitude of lifestyle, behavioral, and comorbid conditions and experiences compound risk for every woman. Currently no accurate prevalence data exists (and won't until screening becomes a standardized aspect of routine pelvic exams, cue the Medicare policy architects), but there is zero doubt the pandemic occurrence. The 50% prevalence figure is bandied around relatively freely in research and articles these days, and I believe in my heart it is relatively accurate.

As a global nonprofit patient advocacy agency, Association for Pelvic Organ Prolapse Support (APOPS) makes every effort to address the various needs of women navigating pelvic organ prolapse, and that includes sharing the good, the bad, and the ugly of treatments to address POP. APOPS is definitively pro-choice, whether we are talking about surgical or nonsurgical treatment options. Over the years, there have been a multitude of tools and studies sent APOPS' way, both significant and insignificant. The options now available for pelvic floor/core fitness programs are considerable. Surgical procedural preferences have shifted over the years. While mesh is considered a viable option here in the states, it is currently embedded in controversy overseas. New treatments and devices float to the surface on a relatively regular basis, a good thing, considering women's needs are extremely variable to address a condition that encompasses 5 types, 4 degrees of severity, and 8 decades-long risk factors. At the end of the day however, what is key to every woman's optimized treatment is a qualified clinician with evolved skill-set to provide care, whether we are talking surgical or nonsurgical treatments.

Every now and then, treatment issues float to the surface. Generally, I'm not surprised when they do; our patient following provide plenty

of feedback in our secure space regarding tooling they are testing to address POP symptoms. However, the FDA press release on July 30, 2018 indicating concerns about off-label laser and radio frequency energy-based treatments caught me by surprise. I've been chasing down research and networking with researchers, clinicians, and industry regarding these treatments since I was first exposed at the MIPS medical conference in Slovenia in 2015. I mistakenly assumed all the energy-based treatments were FDA approved for treatment of incontinence and vaginal atrophy and discovered via the FDA press release that they are not. That being said however, and it's a big however, I feel these treatments are and will continue to be a valuable tool to address POP symptoms. I've heard considerable positive feedback from women who have utilized these procedures. I jumped on the bandwagon myself to experiment with radio frequency in 2017 (I've had transvaginal mesh surgery and will not risk experimenting with lasers until research validates it's safe with mesh). And I was both shocked and delighted at how amazing my pelvic and vaginal spaces felt post treatment.

Upon reviewing the FDA vaginal rejuvenation press release, I reached out to many patient, white coat, and white-collar contacts in the POP arena, as well as the Food and Drug Administration. The FDA responded with a blanket statement:

"The FDA is aware that certain device manufacturers may be marketing their energy-based medical device for vaginal "rejuvenation" and/or cosmetic vaginal procedures. The safety and effectiveness of energy-based medical devices to perform these procedures has not been established. Vaginal "rejuvenation" is an ill-defined term; however, it is sometimes used to describe non-surgical procedures intended to treat vaginal symptoms and/or conditions including, but not limited to the following: vaginal laxity; vaginal atrophy, dryness, or itching; pain during sexual intercourse; pain during urination; decreased sexual sensation.

To date, the FDA has not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function. The treatment of these symptoms or conditions by applying

energy-based therapies to the vagina may lead to serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain.

For further information, please refer to the FDA's Safety Communication, FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication, dated July 30, 2018."

<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm615013.htm>

But patient voice must always play a pivotal role in the evolution of healthcare. Patient feedback as well as studies clarify that these treatments, although results are temporary, provide relief to women experiencing pelvic organ prolapse symptoms. So where do we go from here?

Media-generated healthcare fear factor is running rampant these days. A quality health article should share objective information from both sides of the fence, but seldom does. Off-label use of procedures and medications is not new to healthcare, it has likely gone on since the beginning of healthcare practice, and in the hands of qualified clinicians, is a good thing. Physicians should continually research current, real-world experiences as well as tooling that affects healthcare treatment results. The majority of specialists assess and interpret clinical data as well as research study data appropriately, which results in measurable benefit to patients to improve outcomes. While the FDA must continue to play a pivotal role in guiding medical tooling safety and efficacy, we must remain mindful that patient feedback plays a significant role in validation of researched medical procedures such as energy based vaginal tissue regeneration.

Patient feedback:

"The best way I can explain the profound shift I experienced with vaginal tissue regeneration, is it felt like a magical reboot of internal tissue support. My guts hadn't felt this great since I was in my early 30's prior to my pregnancy. I was amazed at the impact the ratio

frequency treatments had to address overactive bladder (OAB), stress urinary incontinence (SUI), urinary urge, pelvic pressure, atrophy, and weak urine stream, which were non-issues after my successful transvaginal mesh surgery in 2008, but appeared as markers of the aging process years later. These amazing changes began to diminish at 3 months, and by 4 months were gone, but I still feel there is considerable value. With VTR, I literally experienced how great my pelvic floor and pelvic contents could feel again. I'm hopeful if I utilize RF semi-annually, I'll optimize long term benefit."

Sherrie P (US), APOPS Founder/CEO

"I've had the vaginal laser. I had no issues. The biggest risk is going to a non-medical professional, like an aesthetician, to have it done. I don't think vaginal rejuvenation is cosmetic. I think atrophied vaginal tissue causes multiple quality of life issues for women, even those who don't have POP, and shame on those within the medical community and the gatekeeper insurance companies who trivialize treating atrophy down to a 'cosmetic' procedure."

Melissa F (US), APOPS Support Forum Member

"I had laser treatment at the end of 2017 into the beginning of 2018. I think it was helpful in terms of my tissues and would have it again even though I didn't see a massive difference in POP symptoms. Although I didn't experience any big benefits, I feel that any increase in collagen is a good idea for my vagina and my bladder wall issues as well, which was a reason I had this done. I plan to have my yearly laser treatment both vaginally as well as vulvally. Whatever I can do to keep my tissues as healthy as possible I will do!"

Bethany S (UK), APOPS Support Forum Member

"I have vaginal atrophy and Lichen Sclerosus. I've undergone 3 Mona Lisa Touch laser treatments with great success. I'm 64 years old and I'm able to be intimate again! I'm thankful for this technology since I'm unable to use estrogen creams due to breast cancer. I highly recommend!"

Patricia R (US), APOPS Support Forum Member

Practitioner feedback:

"I have been involved as both a user and a consultant to the industry on these devices since their FDA approval. I have extensive training, education, and experience in the treatment of vaginal atrophy, urinary incontinence, vaginal laxity, and lasers. I am consulted when physicians have problems with these technologies and the problems have never been related to adverse events. I have witnessed the explosion of marketing for these indications by the industry and I am very well aware of the paucity of data to support the use of these technologies for these indications. However, in my experience, these technologies work well in carefully selected patients. I haven't seen the serious adverse events listed in the Safety Communication.

In my opinion, the main risk of these technologies to patients, is the lack of an expected treatment effect. Expectations should be based on both personal and published experience, patient counseling, and intimate knowledge of the conditions being treated and of the techniques and technologies being considered. This is the essence of solid clinical judgement.

Credible, yes. Limited, yes. Short-term, yes. Similar to laparoscopy when it first emerged and was denigrated as a gimmick, it is a new technology that has gained its initial traction in the world of private practice outside of academia. There is no question that it has been over-marketed based on limited preliminary data. In five to ten years, it will be another mainstream tool in the gynecologic armamentarium."

**Marco A. Pelosi, III, MD, FACOG, FACS, FICS, FAACS
Cosmetic Gynecologist, ISCG Founder, International Lecturer**

"The Mona Lisa fractional CO2 laser has now been used to treat over 150,000 women worldwide with symptoms of vaginal atrophy. There are now 35 peer reviewed scientific publications in the medical literature documenting excellent outcomes with minimal to no adverse events. This treatment is an excellent procedure for women who either do not or can not take local estrogen"

**Mickey Karram, M.D. Director of Urogynecology at The Christ Hospital
Professor of Obstetrics & Gynecology at University of Cincinnati**

"After nearly 5 years of using energy-based devices for a multitude of vaginal conditions, I have yet to see the adverse events in question. The biggest risk of these devices is a less than desired result that a patient may expect. This can best be minimized by appropriate patient selection which is best achieved by specialists with a deep understanding of urogynecology, menopausal medicine and sexual health.

It is our duty as physicians and surgeons to perform thorough/thoughtful evaluations and offer patients both surgical and non-surgical treatment options for them to choose from."

**Oscar A. Aguirre, MD, FPMRS, FACOG, FAACS
Medical Director Aguirre Specialty Care - Pelvic Surgery & Intimate Aesthetics®
The Center for Female Pelvic Medicine & Cosmetic Surgery**

"Radio frequency, while shown to increase collagen, elastin, and small nerve fiber density, is not a laser, it is a non-ablative and non-destructive device, without need for topical anesthetics. ThermiVa has provided over 100,000 treatments to more than 30,000 women worldwide, with no serious or reportable adverse events. Patient quality of life has been validated to be tremendously improved with radio frequency treatments by the Female Sexual Function Index Questionnaire, Vaginal Laxity Questionnaire, and Global Health Index."

**Red M. Alinsod, M.D., FACOG, FACS, ACGE
Urogynecology & Pelvic Reconstructive Surgery
Alinsod Institute**

"I appreciate and applaud the FDA for continuing to make sure patients are not misled, misinformed or deceived. I would, however, like to clarify some information that has been reported in the media. In order to fully understand the FDA's recent letter, it is critical to understand the intent and purpose of their communication. The FDA's letters were not WARNING letters, but rather letters addressing the

concerns about marketing "vaginal rejuvenation" procedures.

As a board certified Urogynecologist, I specialize in treating female patients with many different conditions that massively affect their quality of life. For example, I have treated women for years who suffer from Genitourinary Syndrome of Menopause. This is a horrible condition that leads to very painful, dry, cracked, irritated vaginas, as well as, urinary symptoms, recurrent urinary tract infections, persistent vaginal infections and in most cases, the inability to have normal relations. The treatments that have been available for many years are options such as vaginal moisturizers, vaginal hormones, or systemic hormones. These treatment options are of course always offered, and some patients do well with them, however, what happens when they don't do well with them? Or what happens when they have been told that they cannot take hormones because of cancer risks? What do we do with these patients?

I started researching lasers, specifically vaginal lasers. This laser technology is the same technology that has been used safely and effectively for many years to improve the health of body tissue and has been FDA approved for use in Gynecology. The vagina is no different, it is a body tissue that often times, when not optimal, will cause severe symptoms and a significant strain on one's life. In my practice, the diVa vaginal therapy has given my patients hope and in many, many cases restored their lives."

Michael J. Coyle DO, FACOOG, FPMRS

President and CEO

Coyle Institute for Female Pelvic Medicine and Reconstructive Surgery

Research:

In the interest of providing resources for those who would like to dig deeper, here are several paths. The following studies explore the use of energy-based treatments to address stress urinary incontinence (SUI), genitourinary syndrome of menopause (GSM), vaginal pain, burning, itching, dryness, dyspareunia, dysuria, vaginal prolapse, decreased sensation during coitus, vaginal laxity, labial appearance, and cellular interpretation. In no particular order:

Vaginal Rejuvenation Using Energy-based Devices (United States)[1]

Microablative fractional CO2-laser therapy and the genitourinary syndrome of menopause: An observational study (Italy, Greece)[2]

Laser Therapy for the Restoration of Vaginal Function (Italy)[3]

Histological study on the effects of microablative fractional CO2 laser on atrophic vaginal tissue: an ex vivo study (Italy, Greece)[4]

Lasers for Pelvic Floor Dysfunctions: Is There Evidence? (United States)[5]

Safety and Long-term Efficacy of Fractional CO2 Laser Treatment in Women Suffering from Genitourinary Syndrome of Menopause (Italy, Australia, US, Iran)[6]

Use of a Novel Fractional CO2 Laser for the Treatment of Genitourinary Syndrome of Menopause: 1-year Outcomes (United States)[7]

Sexual Function in Women Suffering From Genitourinary Syndrome of Menopause Treated With Fractionated CO2 Laser (Italy, Greece)[8]

Microscopic and Ultrastructural Modifications of Postmenopausal Atrophic Vaginal Mucosa after Fractional Carbon Dioxide Laser Treatment (Italy)[9]

Laser Technologies in Treatment of Pelvic Floor Dysfunctions in Women (Moscow)[10]

Laser Thermotherapy in Pelvic Floor Dysfunction - a Randomized Placebo-Controlled Study (Slovenia)[11]

The following studies are to on-going at ClinicalTrials.gov (United States):

Radiofrequency and Hybrid Fractional Laser for Vaginal Rejuvenation (United States)[12]

Hybrid Fractional Laser Treatment for Symptoms of Urinary Incontinence (United States)[13]

All medical procedures come with risks. It is imperative patients do their homework, and research both medical procedures and the clinicians providing them. Clearly VTR does not help all women, no procedure does. When considering a new procedure, patients should expect to be fully informed of both benefits and risks by the providing clinicians. In this day and age, it is a red flag when a clinician providing a procedure does not comply with full disclosure policies. Even when all indications point to treatment benefit and quality care, patients have choices - they can choose to move forward, continue to dig for additional info, or walk away.

Women are hungry for hope regarding POP treatment, and media generated fear does nothing to appropriately educate patients about pelvic organ prolapse treatment options. Regarding Dr. Google, recognize that quality healthcare cannot be quantified by a fancy website; It pivots upon clinician skillset, empathy, honesty, competence, and commitment. Anything less is simply not enough.

Every Voice Matters

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SHERRIE PALM BIO

Sherrie Palm is the Founder/CEO of Association for Pelvic Organ Prolapse Support (APOPS), a pelvic organ prolapse (POP) Key Opinion Leader, a global women's pelvic health advocate, author of 3 editions of the award winning book Pelvic Organ Prolapse: The Silent Epidemic, and has been a national and international speaker on multiple aspects of pelvic organ prolapse quality of life impact since 2011.

Sherrie's points of focus are generating global POP awareness, developing guidance and support structures for women navigating POP, and bridge building within POP healthcare, research, academic, industry, and policy sectors toward the evolution of POP directives.

Additional information about APOPS, pelvic organ prolapse, or Ms. Palm's book or speaking presentations is available on the APOPS website.

<http://www.pelvicorganprolapsesupport.org/sherrie-palm/>

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