

In Pursuit of a Better Quality of Life:

How Feminine Rejuvenation Can Help?

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Disclosures

Consultant:

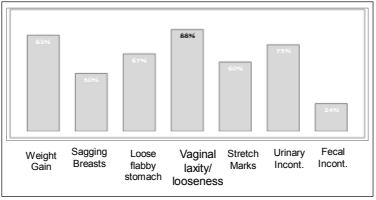
- Medimetriks Pharmaceuticals, Inc.

What is Vaginal Rejuvenation?

<p>Surgical Options</p> <ul style="list-style-type: none"> • Labiaplasty • Vaginoplasty 	<p>Non-Surgical Options</p> <ul style="list-style-type: none"> • O-Shot • Lasers • Radio Frequency
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Vaginal Laxity: Most Prevalent Physical Change Discussed or Observed by OB/GYNs

Change in vaginal laxity more prevalent than weight gain or urinary incontinence!



OB/GYN Alliance survey October 2009, n = 502
 Of those patients with physical changes related to delivery, what specific changes do they discuss or do you find on exam?

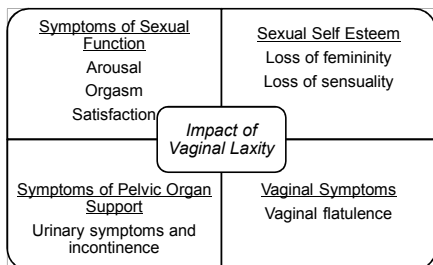
Significant Unmet Need

Vaginal Laxity - a significant concern for millions of women

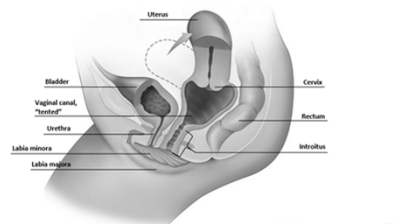
<p>#1 Reported Change Post-Partum</p> <ul style="list-style-type: none"> • Vaginal childbirth overstretching the vaginal introitus (opening) ✓ Feeling of "Looseness" ✓ Diminished sensation during intercourse ✓ Reduction in sexual function and quality of life 	<p>Impacts 50% of Women Post-Partum</p> <ul style="list-style-type: none"> • UroGYNs recognize it is underreported, yet bothersome, medical condition that impacts personal happiness and sexual function • Vaginal laxity causes include: pregnancy, childbirth, aging, genetic predisposition, lifestyle, and/or trauma
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Data sources - available upon request.

The Impact of Vaginal Laxity

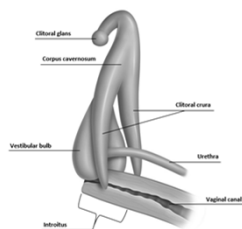


Treating Internal Vaginal Laxity

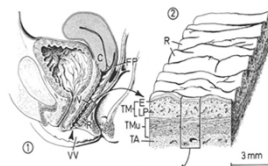


Why only the Introitus?

- Primary region for sexual pleasure for women
- Clitoral tissue wraps around this region and provides majority of sexual sensation
 - Coupling and friction is key for women's physical sensation
- Dense fibrous tissue
- Canal laser treatments are being marketed primarily for mucosal indications, post menopausal – dryness, itchiness, painful intercourse and very mild incontinence. Little supporting data available has been published
- Any tightening of the upper 2/3 of the canal achieved by surgery or energy delivery is likely diminished during intercourse due to the expansion of the canal that occurs during stimulation

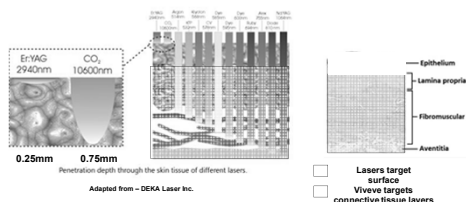


Vaginal Histology



- Epithelium (E) is a layer of non-keratinized, stratified squamous cells and is about 200 microns thick
- Lamina Propria (LP) is a moderately dense layer of connective tissue containing an abundance of elastic fibers and an extensive venous plexus
- Tunica Muscularis (TMu) is a layer comprised of circular and longitudinal smooth muscle and is often called the fibromuscular layer
- Tunica Adventitia (TA) is a thick layer of loose connective tissue

Ablative lasers directly impact the mucosa but not the deeper connective tissues

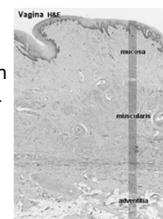


Ablative and non-ablative lasers have been shown to improve the appearance of the vulva and the integrity and function of the vaginal mucosa.

Tissue tightening requires sustained heating of connective tissue layers. CO₂ and Er:YAG laser & heat penetration is limited.

Choosing a Radiofrequency Feminine Rejuvenation Modality

- When determining which energy sources are optimally suited to treating the vagina it is important to identify the areas and the depth the treatment effect should reach.
- Radiofrequency systems in monopolar, bipolar or unipolar configurations can deliver energy externally to the vulva as well as to the vaginal mucosa.



Radiofrequency – Depth of heating varies with the polar configuration

Increasing depth of heating →

Unipolar Bipolar Monopolar

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Comparison of Depth of Penetration

Vagina Topical RF CO₂ Erbium

Epithelium
Lamina Propria
Muscularis

Cryo-Cooled Monopolar RF is the only clinically proven single treatment approach for tightening vaginal introital tissue

Safety Comparison: Radio Frequency to CO2 Lasers

<p>Lasers</p> <ul style="list-style-type: none"> • 3-5 days downtime • May experience watery discharge and/or spotting • Potential for burns and necrosis if tissue is over-treated • Smoke evacuator-possible HPV spread airborne 	<p>Radio Frequency</p> <ul style="list-style-type: none"> • No downtime • No serious adverse reactions reported • Cryogen-cooling makes the treatment safe and comfortable
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Evolution of Vaginal Energy-based Treatments in my Practice

Why Monopolar Cryogen Cooled Radiofrequency in my Practice?

- ✓ In Office, 30 Minute treatment
- ✓ Single Session Treatment
- ✓ No anesthesia & Non-surgical
- ✓ Little or no downtime / recovery
- ✓ Safe & Clinically proven
- ✓ Improved vaginal tightness & sexual satisfaction
- ✓ Complimentary to CO2 lasers

The Science Behind It All...

Dual-modal monopolar radiofrequency with controlled cooling (Lower Energy Device):

- Volumetric heat (90 J/cm²) 3-5 mm deep
 - Stimulates fibroblasts
 - Subtly modifies collagen
- Maintains functional tissue architecture

Higher Energy Device:

- Thermal injury
- Reparative healing

- Reverse thermal gradient – cools and protects the surface mucosa while enabling significant healing of deep tissue
- Capacitive coupling – distributes energy evenly across tip for uniform heating
- Reproducible delivery – parameters and algorithms are preset for controlled heating and cooling
- Monopolar energy – penetrates deep into connective tissue

References:
Vos et al. Proc of SPIE, 2011 Feb, 7901: 790104.
Coad et al. J Sex Med 2012; 9(suppl 3):131-2.
Coad et al. J Sex Med 2013; 10(suppl 2):175.

Mechanism of Action

1. Monopolar RF energy creates an electric field under the RF tip (electrode) that changes tissue polarity 6 million times per second. This creates heat at 3-5mm deep
2. Activation of fibroblasts and neocollagenesis, which produce new collagen fibers in the vaginal tissue
3. Collagen restoration process takes within 30-90 days after the RF treatments
4. Collagen remodeling improves the tissue integrity proximal to the clitoral body improving sexual function

The treatment tip delivers pulses of heat to the collagen fibers, while also cooling the surface.

References:
Vos et al. Proc of SPIE, 2011 Feb, 7901: 790104.
Coad et al. J Sex Med 2012; 9(suppl 3):131-2.
Coad et al. J Sex Med 2013; 10(suppl 2):175.

Simple Treatment Delivery Platform

- Treatment tip delivers 3-phased pulses to the tissue:
 - Phase 1: Cools and protects the surface
 - Phase 2: Delivers controlled low-level heat below the tissue surface
 - Phase 3: Cools and protects until heat dissipates
- Treatment is complete after five full passes or rounds have been performed.
- It takes approximately 30 minutes to complete the 5 passes of 21 pulses per pass.

Treatment Tip placed in vaginal opening at the 1 o'clock position. Insert just behind the hymenal ring, about 1-2 centimeter into the vagina. Use the markers on the shaft of the Treatment Tip shaft to maintain consistent placement and depth in the vagina.

The Clinical Data

Successful Clinical Study Results

Animal Studies ⁽¹⁾	US Study ⁽²⁾	Japan Study ⁽³⁾	VIVEVE I Study
<ul style="list-style-type: none"> • Subjects: 38 sheep • Objective: Use RF therapy to stimulate tissue response, titrate dosing levels and confirm safety • Treatments: treatment passes using 60 J/cm² – 200 J/cm² energy levels • Results: Positive biopsy results revealing fibroblast activation and collagen remodeling with no cellular or tissue damage 	<ul style="list-style-type: none"> • Subjects: 24 women • Objective: Determine the safety and efficacy of the Viveve treatment – single arm • Treatments: 3 subjects treated at 60 J/cm², 3 subjects at 75 J/cm² and 18 subjects at 90 J/cm² 	<ul style="list-style-type: none"> • Subjects: 30 women • Objective: Determine the safety and efficacy of the Viveve treatment – single arm • Treatments: 30 subjects treated at 90 J/cm² 	<ul style="list-style-type: none"> • Subjects: 155 women • Objective: Determine safety and efficacy of Viveve treatment in randomized, sham-controlled, blinded study • Treatments: 103 subjects treated at 90 J/cm², 52 subjects sham control (per-protocol) • Results: 6 months <ul style="list-style-type: none"> • Treated women 3 times more likely to experience NO vaginal laxity • On average returned to sexual function after treatment
<p>Results: 12 months</p> <ul style="list-style-type: none"> ✓ 88% of women reported increased vaginal tightness ✓ Women experienced a 68% mean improvement in their vaginal laxity scores ✓ NO serious adverse events reported 			

(1) Laxity: Miller, MB, Anderson, RA, et al. 2007. (2) US Study: Kychman et al. 2017. (3) Japan Study: Kychman et al. 2017. VIVEVE I Study: Kychman et al. 2017.

The first randomized, sham-controlled study of the effect of an energy-based device on vaginal laxity

Reference: Kychman et al. J Sex Med. 2017 Feb;14(2):215-225.

The only multi-center, randomized, blinded, sham-controlled study results to date

Objective: Validate safety & efficacy of the Viveve® System in treating vaginal tissue

- Study Sites: 9 sites in 4 countries (Canada, Italy, Spain, Japan)
- Subjects:
 - Pre-menopausal women, ≥ 1 full-term vaginal delivery
 - 155 subjects who met protocol criteria
 - ACTIVE GROUP (90 J/cm², 5 tx passes): 103 subjects
 - SHAM GROUP (1 J/cm², 5 tx passes): 52 subjects
- Methodology: Patient reported outcomes at 1, 3 and 6 months
 - Proprietary Vaginal Laxity Questionnaire (VSQ)
 - Validated Sexual Function Questionnaire (FSFI)
- Safety: Adverse event reporting

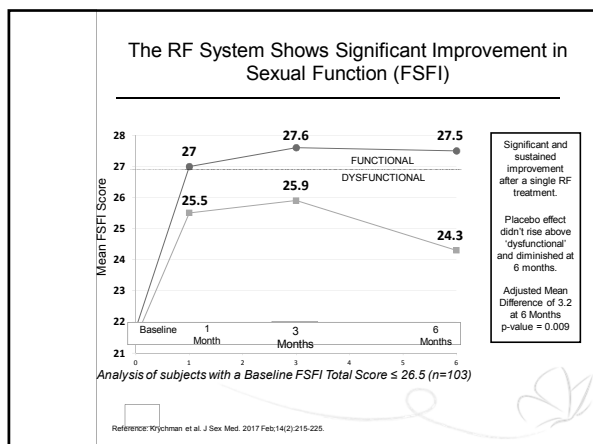
Reference: Kychman et al. J Sex Med. 2017 Feb;14(2):215-225.

The RF System Shows Statistically Significant Improvement in Laxity

- Subjects had to have a score of ≤3 to participate on VSQ
 - On a 7-point scale (from very loose to very tight)
- Likelihood of “no vaginal laxity” at 6 months is more than 3x greater for subjects in the active vs the sham group (p < 0.006)
- More than half of all subjects in the active group moved at least 2 points on the VSQ scale towards a “tighter” vagina
 - Just 1 point can denote a substantial change in how a woman feels

Vaginal Laxity Questionnaire (VSQ)	
How would you rate your current level of vaginal laxity/looseness during intercourse?	
1	Very Loose
2	Moderately Loose
3	Slightly Loose
4	Neither Loose Nor Tight
5	Slightly Tight
6	Moderately Tight
7	Very Tight

Reference: Kychman et al. J Sex Med. 2017 Feb;14(2):215-225.



The RF System was safe, well-tolerated and comparable to sham

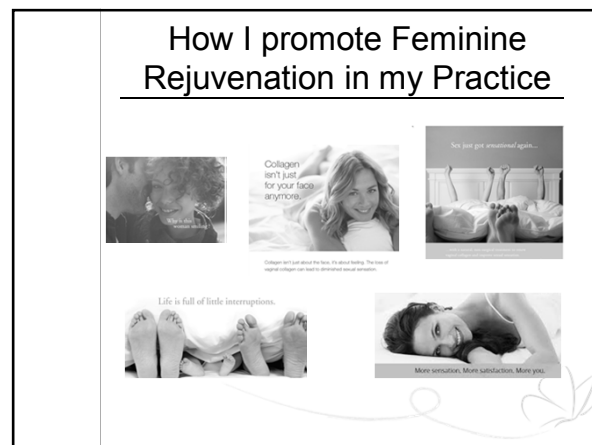
Overview of Treatment Emergent Adverse Events (TEAEs) N=174

	Active Treatment	Sham Treatment
Subjects with Related TEAE	11.1%	12.3%
Subjects with Serious TEAE	0.0%	1.8%

Related = "Possibly Related," "Related," "Unknown/Undetermined," or relationship missing. Examples of "related" TEAEs included: yeast infections, mild uterine cramping and sensitivity, feeling of heat, constipation, decrease in vaginal discharge, less lubrication, changes in vaginal discharge, slight irritation, and mild vaginal discomfort.

Reference: Kiyochman et al. J Sex Med. 2017 Feb;14(2):215-225.

- ### Summary of Clinical Results
- First ever study of its kind in the vaginal rejuvenation field raises the bar
 - Large (short-term) placebo effect seen with a benign treatment
 - Improvement in laxity AND sexual function was statistically significant with the Viveve® System compared to sham
 - Significant and sustained improvement with the Viveve System at six months
 - No serious adverse events
- Reference: Kiyochman et al. J Sex Med. 2017 Feb;14(2):215-225.



- ### Monopolar RF with Cryogen Cooling is my choice to Improve Vaginal Laxity
- Vaginal laxity is one of the fastest growing categories
 - The need is HUGE
 - Look for Science & Clinical Studies when choosing a technology
 - Temperature, Depth & Cooling matter
 - Single Session Treatments
 - Safe, Effective & Comfortable

Patient Testimonial 2 Week Post Geneveve Treatment

After I delivered my first child in 2013, I suffered from **spontaneous incontinence** when doing high-intensity exercise. I tried physical therapy, but was uncomfortable with the invasive nature and length of the sessions, so stopped addressing the issue.

I delivered my second child in February 2017, and the problem persisted and increased in intensity. Exactly **3 months post-partum**, I saw Dr. Rita Linkner at Skinfluence for a Viveve Geneveve treatment. Dr. Linkner and I discussed my issues + concerns and the best course of action.

After a thoughtful discussion, we moved forward with the Geneveve treatment. The entire process took 25-minutes and was **completely painless**. After a single treatment, I noticed a significant and sustained improvement in incontinence within 24 hours (read: no more peeing while doing jumping jacks), and I also benefited from the decrease in vaginal laxity that the treatment provides.

Highly recommend for new moms!

- Lindsey H.

