TREATMENT OF THE VAGINAL INTROITUS TO EVALUATE EFFECTIVENESS: RESULTS FROM A RANDOMIZED, PLACEBO-CONTROLLED STUDY

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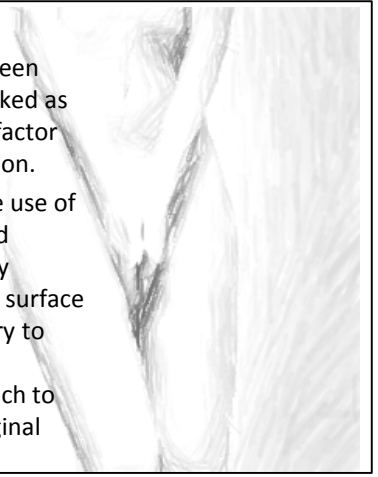
Introduction:



Vaginal tissue laxity has been understudied and overlooked as a contributing etiological factor to female sexual dysfunction.

This study investigates the use of a patented cryogen-cooled monopolar radiofrequency (CCMRF) system that uses surface cooling and energy delivery to provide a non-ablative, minimally-invasive approach to create heat deep w/in vaginal tissue.

Treatment:

- **Monopolar RF energy with surface cooling** (3-5 mm)
  - Fibroblast activation-> new collagen
  - Initiation of collagen remodeling (~ 30-90 days after tx)
  - Improves tissue integrity proximal to clitoral body,
- Procedure consists of 110 pulses (~8 seconds/pulse)
- Procedure lasts only 30 minutes, no anesthesia

Study Design:

Subjects: Pre-menopausal women, ≥ 1 FT vaginal delivery

Study Sites: 9 sites in 4 countries (Canada, Italy, Spain, Japan)

Objective: Validate safety and efficacy

2:1 Randomization: [Active (90 J/cm^2): Sham (1 J/cm^2)

Efficacy: Measured at 1, 3 and 6 months post-treatment
- Vaginal Laxity Questionnaire (VLQ)
- Validated Female Sexual Function Index (FSFI)

Safety: Adverse event reporting

Subject Disposition:

	Active (n)	Sham (n)	Total (n)
Randomized & Treated Subjects	**117**	**57**	**174**
Month 6 Follow-Up:			
Randomized & Treated	**108**	**56**	**164**
Per Protocol w/ Vaginal Laxity (VSQ)	***103***	***52***	***155***
Per Protocol w/ Sexual Dysfunction (FSFI)	***71***	***32***	***103***

Methods:

VLQ: Vaginal Laxity Questionnaire

How would you rate your current level of vaginal laxity/looseness during intercourse?

LAXITY	1	Very Loose
	2	Moderately Loose
	3	Slightly Loose
	4	Neither Loose Nor Tight
NO LAXITY	5	Slightly Tight
	6	Moderately Tight
	7	Very Tight

FSFI: Female Sexual Function Index

Areas of Focus	No. Questions
Sexual Desire/Interest	2
Sexual Arousal	4
Lubrication	4
Orgasm	3
Satisfaction	3
Pain	3
Total	19

VIVEVE IS EFFECTIVE FOR LAXITY: Statistically Significant Improvement in Laxity (VLQ)

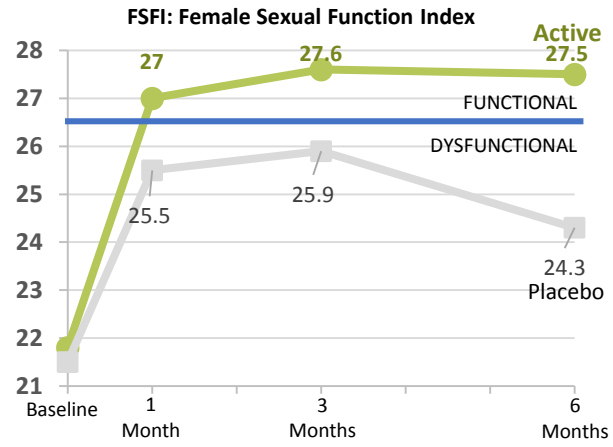
Month 6 Results

Treatment Group	N	No Laxity n	χ^2 p-value	Logistic Regression Odds Ratio	95% CI	p-value
Active	103	43	**0.005**	**3.05**	**(1.37, 6.79)**	**0.006**
Placebo	52	10				

Likelihood of "no vaginal laxity" > 3x greater for Active vs Placebo

Acknowledgements: Viveve would like to thank all of the 9 investigational sites and study subjects for their participation in this study.

VIVEVE IS EFFECTIVE FOR SEXUAL FUNCTION: Statistically Significant Improvement in Sexual Function



Significant and sustained improvement after a SINGLE treatment.

Placebo effect diminished at 6 months.

Adjusted Mean Difference of 3.2 at 6 Months

p-value = 0.009

Analysis conducted on 103 per protocol subjects with baseline FSFI score ≤26.5.

2 FSFI domains showed significant results w/respect to placebo: Arousal (p=0.007) & Orgasm (p=0.007)

93% of women in the active group showed a positive (+) change in arousal and/or orgasm.

VIVEVE IS SAFE: Treatment Emergent Adverse Events (TEAEs), N=174

	Active	Sham
Subjects with TEAE	38 (32.5%)	20 (35.1%)
Subjects with Related TEAE	13 (11.1%)	7 (12.3%)
Subjects with Serious TEAE	0 (0.0%)	1 (1.8%)

AE = untoward medical occurrence, whether or not related; **Related** = 'Possibly Related', 'Related', 'Unknown/ Undetermined,' or relationship missing; **TEAE** = an AE that began or worsened after treatment

Conclusions:

- Achieved primary endpoint: **NO** laxity at 6 months (active vs placebo), statistically significant at 95% confidence level
- Achieved statistically significant difference at 95% confidence level for change from baseline to 6 months (active vs placebo):
  - Sexual function (FSFI)
  - Vaginal laxity (VLQ)
- The Viveve system is a **safe** and **effective** treatment for vaginal laxity.

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