# First-ever Data on Vaginal Regeneration for ThermiVa

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Thermi's ThermiVa® device has been shown to deliver significant improvements in common vaginal disorders and improve sexual satisfaction, according to a study published in Dermatologic Surgery. Since it was cleared by the FDA in 2013, ThermiVa has been used in more than 85,000 procedures worldwide. It is part of the ThermiRF system.

The study demonstrated that treatment with ThermiVa resulted in significant improvements in atrophic vaginitis, vulvovaginal laxity and sexual satisfaction, as reported in physician and patient assessment questionnaires. Milder improvements in orgasmic dysfunction and stress urinary incontinence also were reported, but did not achieve statistical significance. By the end of the four-month study, 78 percent of patients said they were satisfied or very satisfied with treatment results.

Importantly, the results also showed the first-ever improvements in intimate tissue biopsied from patients participating in the study. Tissue samples taken after treatment were found to have produced new collagen, nerves and blood vessels and to have improved elasticity.

Thermi President Vlad Paul-Blanc said, "The data presented in this study set a new, exciting, and unprecedented standard for both the clinical and histopathologic changes observed in vulvovaginal tissue after treatment with ThermiVa. We are pleased the data support clinical experience as well as previous studies on the significant impact of ThermiVa treatments. We look forward to continuing our data-driven approach through research and educating clinicians and patients globally about the impact of true temperature-controlled energy delivery and future clinical findings."

The single center, prospective, open label study enrolled 10 women with mild-to-moderate vulvovaginal laxity, with or without atrophic vaginitis, organismic dysfunction and/or stress urinary incontinence. All women underwent three treatments with ThermiVa at four-week intervals. Five women had pre- and post-treatment biopsies of the labia majora and vaginal canal.

Physicians made clinical visual assessments of laxity using the five-point Vulvovaginal Laxity Questionnaire, and patients completed self-assessments using the Millheiser Vaginal Laxity Scale, the Millheiser Sexual Satisfaction Questionnaire and the Female Sexual Function Index.

*Vulvovaginal laxity.* Physicians reported a significant improvement in vulvovaginal laxity by day 10, and this improvement was sustained through study conclusion at day 120. Patients also reported significant improvement from baseline at day 120.

*Atrophic vaginitis*. Both physicians and patients reported improvement in atrophic vaginitis symptoms over the course of the study.

*Sexual satisfaction*. Patients reported significant improvement in sexual satisfaction at day 60, and this improvement was maintained through day 120. These improvements were seen in various aspects of sexual function including sexual interest, arousal during intercourse or sexual activity, and improved lubrication. Patients reported significant improvement in satisfaction with their ability to achieve orgasm following treatment.

*Stress urinary incontinence*. By day 120, five of nine patients had at least a 50 percent improvement in stress urinary incontinence, and three patients experienced even greater improvement.

*Tissue changes*. Tissue biopsied from five patients following treatment showed significant changes, including improved epidermal maturation, thickened mucosa, and evidence of new collagen and increased density of elastic fibers when compared to pre-treatment biopsies.

The histological photos shown here show before and afters of vaginal mucosa following treatment in the study. More before and after photos can be seen in the article.

Treatment was well tolerated, and there were no unanticipated adverse side effects.