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Dr. Red Alinsod completed medical training at Loma Linda University Medical Center in 1990. He served a 12-year Air Force career with 4 active duty years at George and Nellis Air Force Bases. He has practiced in Southern California.

Red has built a thriving urogynecology and aesthetic vulvovaginal surgery following. He is the Director and founder of South Coast Urogynecology and The Alinsod Institute for Aesthetic Vulvovaginal Surgery, an educational institute.

His International teaching program is the first of its kind to combine both pelvic reconstructive and aesthetic principles together. He has trained many of the world's leading doctors and instructors in cosmetic gynecology and has presented his techniques worldwide for over 20 years.

He is co-editor of *Female Cosmetic Genital Surgery, Concepts, Classification and Technique*, the seminal textbook for plastic surgeons and gynecologists in this rapidly growing field. He is the Founder and Chairman of CAVS (Congress on Aesthetic Vulvovaginal Surgery), the oldest and longest running Congress dedicated to Female Cosmetic Genital Surgery. It is now incorporated into The International Society for Cosmetogynecology, the Grand Daddy of the field.

He is the inventor of the "Barbie Look" and "Hybrid Look" Labiaplasty, Medial Curvilinear Labia Majoraplasty, Central and Lateral Clitoral Hood Reduction, In-office No-IV Labiaplasty, Perineoplasty, Vaginoplasty, Pudendo-Levator Block. He is the inventor and patent owner of the Lone Star APS Vaginal Retractor, APS Surgical Table, Alinsod Scissors, and various pelvic reconstructive devices and techniques such as *Sling with Bladder Support* and *Implants and Procedures for Treatment of Pelvic Floor Disorders*.

Dr. Alinsod is the inventor and patent owner of ThermiVa. He is the inventor of amniotic fluid use for overactive bladder with AmDrop and co-developer of O2Vasc for improvement in genital bloodflow.

Dr. Alinsod specializes in non-surgical labial and vaginal tightening, treatment of stress incontinence, non-drug treatment of overactive bladder, atrophic vulvovaginitis, orgasmic dysfunction, vulvar dystrophy, and modern management of menopausal symptoms. These disruptive and safer methodologies of treatments, developed by Dr. Alinsod, are changing the face of gynecology for the benefit of women worldwide. Dr. Alinsod welcomes your calls, emails, and inquiries.

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	9/94 – 12/04	<b>Facey Medical Group, Partner</b> Department of OB/GYN Risk Management Chairman Litigation Committee, Pension Trustee Board Member 1999 – 2000, 2002 Clinical Instructor: NH FP Residency Clinical Instructor: UCLA Urogynecology
	9/91 – 8/94	<b>Chief of Gynecologic Services</b> 554 Med Group, Nellis AFB Las Vegas, NV
	7/90 – 8/91	<b>Chief of Gynecologic Services</b> 35 <sup>th</sup> Medical Group, George AFB Victorville, CA
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	7/82 – 6/86	<b>Loma Linda University Medical School</b> Loma Linda, CA MD, BS Human Biology Scholarship: USAF Health Professions Activities: Chief Photographer
	09/78 – 6/82	<b>Pacific Union College, Angwin, CA</b> BS, Biochemistry

**CERTIFICATION STATUS**

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ACOG, ACS, AUGS, IUGS, ICS, ISPP  
AAGL, AAOCG, AACS  
Felix Rutledge Fellow

**PERSONAL**

Married, 3 children  
Skiing, Dobermans, Golden Retrievers  
Photography

**SPECIALIZED SURGICAL SKILLS**

**Aesthetic Vaginal Surgery (AVS)**  
Labia Minora and Majora Plasty  
Clitoral Hood Reduction  
Vaginoplasty/Perineoplasty  
Hymenoplasty  
Non-Invasive Labial tightening  
ThermiVa Feminine Restoration  
Pelvic Floor Reconstruction  
Single Incision Slings  
Advanced Laparoscopy/Hysteroscopy  
Aesthetic Lasers, Fillers, Botox  
O-Shot, Vampire Lift  
Awake/In-Office Aesthetic Gyn Surgery

**CLINICAL & INDUSTRY**

ARMS Medical, Consultant  
Thermi: ThermiVa Inventor  
Cooper Surgical: LoneStar Inventor  
Monarch Medical: Alinsod Scissors/Table  
Haupt Lab/D-Moore Consultant  
Amnion LLC/Tula Medical Consultant  
Intigen, Lumisque, and Joylux Consultant  
Caldera Medical Consultant

**PATENTS & INVENTIONS**

ThermiVa RF for Non-Surgical Labial and  
Full Depth Vaginal Therapy

Lone Star APS Vaginal Retractor

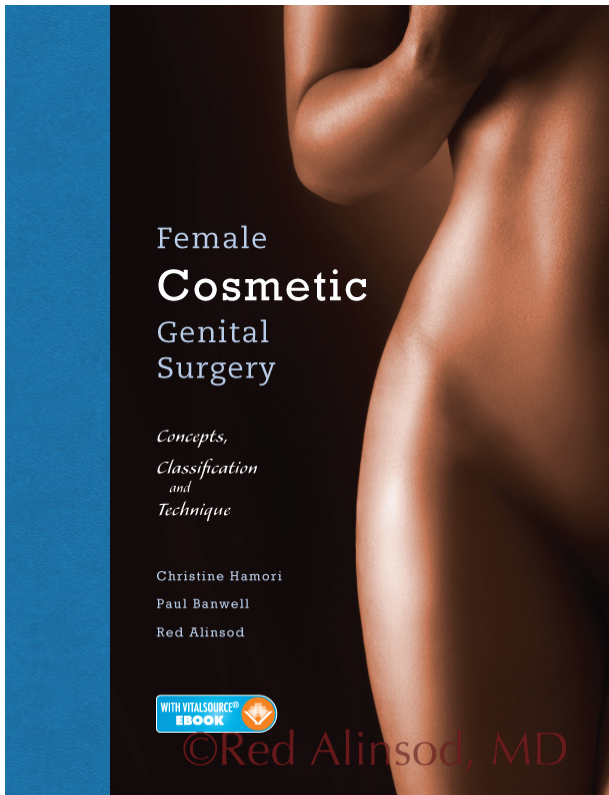
Sling with Bladder Support  
Implants and Procedures for the Treatment  
of Pelvic Floor Disorders

Alinsod Surgical Table and Stand  
Alinsod Scissors, Pickups, and Clamp

Surgical Techniques for Labial and Vaginal  
Surgery (RF Barbie Look Labiaplasty,  
Curved Medial Labia Majoraplasty, Vertical  
Clitoral Hood Reduction, Lateral Hood  
Reduction, RF Hemorrhoidectomy  
Pudendo-Levator Block, Clitoral Block  
Predictive Permeation for Gynecology  
O2Vasc for genital bloodflow

**LECTURES, PRESENTATIONS, PUBLICATIONS**

Upon Requests



**Female  
Cosmetic  
Genital  
Surgery**

*Concepts,  
Classification  
and  
Technique*

Christine Hamori  
Paul Banwell  
Red Alinsod

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## Transcutaneous Temperature Controlled Radiofrequency for Orgasmic Dysfunction

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**Background and Objectives:** To evaluate the safety, tolerability, and clinical efficacy of transcutaneous temperature controlled radiofrequency (TCRF) on vulvovaginal tissue for orgasmic dysfunction.

**Study Design/Materials and Methods:** Subjects included 25 sexually active women, ages 21-65, with self-reported difficulty in achieving orgasm during sex (anorgasmic or slow-to-orgasm). Each patient received three sessions at intervals of about 1 month. Treatment was performed using a slim S-shaped probe with a stamp-sized metal radiofrequency emitter on one surface of the tip (25 minutes total time on average). External treatments covered the labia majora and minora, lower mons pubis, perineal body, clitoral hood, and clitoris. Full length treatment of the vagina with concentration on the anterior wall was performed. Tissue temperature during therapy was elevated to and maintained between 40°C and 45°C. No anesthesia was required. After treatment, patients immediately resumed normal activities, including sex.

**Results:** Twenty-three of 25 patients reported an average reduction in time to orgasm of 50%. Patients also noted significant vaginal tightening effects, increased vaginal moisture, and improved vulvar and clitoral sensitivity. All anorgasmic patients reported the ability to achieve orgasm. Two patients had minimal response.

**Conclusion:** TCRF is an effective non-hormonal, non-surgical option for women having difficulty achieving orgasm. Treatment also has visible tightening effects on feminine tissues and appears to increase local blood flow, resulting in increased vaginal tightness and moisture. Improved appearance and friction resulted in improved confidence and reduced performance anxiety. *Lasers Surg. Med.* 48:641-645, 2016. © 2016 The Authors. *Lasers in Surgery and Medicine* Published by Wiley Periodicals, Inc.

**Key words:** temperature-controlled radiofrequency; vulvovaginal rejuvenation; orgasmic dysfunction; vaginal rejuvenation; vaginal laxity

### INTRODUCTION

The use energy-based therapies for rejuvenation of the skin in aesthetic medicine is common, and among them non-invasive or minimally invasive radiofrequency (RF) energy is a well-studied and popular alternative [1]. By creating heat via impedance as electric current is conducted through tissue, stimulation of fibroblasts

occurs, and the therapeutic outcome is achieved; the target tissue temperature range lies between 40°C and 45°C [2]. Recently, this skin rejuvenation modality has been harnessed for rejuvenation of vaginal tissue to treat vulvovaginal laxity resulting from age- or childbirth-related causes. Orgasmic dysfunction, manifesting as anorgasmia or increased time to orgasm, rests among the associated symptom suite [3]. As many as 35% of women may experience orgasmic dysfunction and its resultant effect on quality of life [4], and research suggests a strong need for treatment alternatives when surgical correction is not indicated [5]. Other than psychological, behavioral, and hormonal therapies, recent alternatives include injectable autologous platelet-rich plasma, which is safe and without the potential side effects noted with other injectable treatments, but results were relatively modest.

Transcutaneous temperature controlled radiofrequency (TCRF) is the combination of RF, an established technology proven safe and effective for skin laxity, with feedback controls for the monitoring and maintenance of tissue temperature via thermocouples and thermistors in the treatment probe [6]. Power is modulated in relation to tissue impedance to elevate tissue temperature near the electrode stimulating neocollagenesis plus contraction and denaturation of collagen, triggering the healing cascade to produce healthier new tissue. With the goal of raising and maintaining tissue temperature to a therapeutic target of between 40°C and 45°C, temperature feedback controls power, and thus adjusts energy delivery to maximize non-invasive delivery of RF energy while minimizing patient discomfort. There is no downtime.

The character of vaginal wall tissue, similar to that of skin, makes it an obvious candidate for such treatment. RF is particularly effective on naturally moist, well hydrated

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Conflict of Interest Disclosure: The author is a paid research consultant for Thermo, An Alinsod Company, manufacturer of the TCRF technology used during the investigation.  
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PEER-REVIEW | RADIOFREQUENCY | FFS

# TEMPERATURE CONTROLLED RADIOFREQUENCY FOR VULVOVAGINAL LAXITY

Red M. Alinsod evaluates the results of his study on the effectiveness of non-invasive transcutaneous temperature controlled radiofrequency for vulvovaginal rejuvenation

**ABSTRACT**  
Objective: To evaluate the safety, tolerability, and clinical efficacy of non-invasive transcutaneous temperature controlled radiofrequency (TCRF) for vulvovaginal rejuvenation and document ancillary beneficial effects of treatment.

Patients and methods: subjects (n=23) age range 26-68 years, mean 43.6, 5 menopausal, 6 perimenopausal presented with mild to moderate primary or secondary vulvovaginal laxity. Associated conditions: organic

dysfunction, stress incontinence, atrophic vaginitis were present in most subjects. Exclusion criteria included pelvic surgery within 5 years, pregnancy or planned pregnancy within the study period, recent abnormal Papanicolaou test result, and presence of vulvar lesions or any condition that may potentially interfere with the safe treatment. Informed consent was obtained from all subjects. Patients were treated up to three times at an interval of 4 to 6 weeks.

Outcome measures: subject assessment via vaginal laxity questionnaire (VCLQ)

rating on a 7 point scale where 1=very loose and 7=very tight, and sexual satisfaction questionnaire (SSQ) rating on a six point scale where 1=none and 6=satisfied, as well as observations of associated conditions such as incontinence, atrophic vaginitis, and organic dysfunction.

Results: median improvement of 5 points on the VCLQ scale and 2.5 points on the SSQ scale were noted; results were statistically significant (p<0.05). The most pronounced outcomes manifested after initial treatment with

additional improvement after each of the second and third treatments. Patients with organic dysfunction, stress incontinence, and/or atrophic vaginitis noted substantial improvement regardless of number of treatments. Menopausal subjects were able to cease usage of vaginal estrogens.

Conclusion: TCRF is safe, tolerable, and effective for vulvovaginal rejuvenation. Evidence suggests applications in the treatment of atrophic vaginitis, organic dysfunction, and stress incontinence.

**T**HE VAGINAL WALL, PREDOMINANTLY consists of dense connective tissue that is heavily vascularized and through which many nerves pass, lined by a slightly keratinized, stratified squamous epithelium. The vulva, particularly the labia majora, is even more skin like although generally more heavily vascularized and innervated than skin in most bodily regions. During vaginal delivery, stretching causes damage to the connective tissue that heals in a varying state of laxity that increases with each successive birth; the vulva is similarly affected. In addition, reductions in the quality of connective tissue due to neuroendocrine changes and age serve as contributing factors. This condition is rarely discussed in a clinical setting.<sup>1</sup> Other conditions such as stress incontinence and atrophic vaginitis arise in conjunction with vulvovaginal laxity, as well as natural results of delivery trauma and advancing age. An additional consequence to vulvovaginal laxity is reduced sensation during coitus, with a potential negative effect on sexual satisfaction and quality of life.<sup>2</sup>

The term vulvovaginal laxity encompasses laxity of both the vaginal introitus and labia majora. Given that most people refer to the entire compound structure as "the vagina" it stands to reason that "vaginal laxity" and



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**KEYWORDS**  
Vulvovaginal laxity, temperature-controlled radiofrequency, non-surgical vaginal rejuvenation

"vulvovaginal laxity" will be used synonymously by some but it is important to note that, technically, vaginal laxity does not involve the vulva specifically. Laxity of the vagina, specifically, is often referred to as pelvic organ prolapse but that term is also inaccurate because it refers to a more severe condition possibly involving vaginal and other genitopelvic structures bulging into the vaginal canal and introitus, rather than laxity of the introitus itself.<sup>3</sup>

To the patient, there are other notable characteristics of vulvovaginal laxity and the aesthetic appearance of the vagina may be perceived as significantly compromised, leading to self-consciousness. Laxity of the labia majora may be associated with discomfort and irritation when tight clothing is worn, as well as discomfort during intercourse. Organic dysfunction, reduced friction during sex due to looseness, and other aspects of laxity-related changes are perceived to negatively impact the sexual experience in a variety of ways. So vaginal laxity or looseness as a medical or aesthetic concern is not new. It is, however, only recently becoming socially acceptable as a topic of consideration. References to the vagina—structure, function, and associated problems—are now less taboo. Gynecological and urological issues that women may have been reluctant to address directly with physicians or even friends in the past

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## Transcutaneous Temperature Controlled Radiofrequency (TCRF) for the Treatment of Menopausal Vaginal/Genitourinary Symptoms

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### ABSTRACT

**Objective:** The aim of this study was to evaluate the effects of non-ablative, monopolar transcutaneous temperature controlled radiofrequency (TCRF) technology in the treatment of postmenopausal women suffering from genuine stress urinary incontinence (SUI) related to menopause and to evaluate histological changes vaginally associated with the treatment.

**Materials and Methods:** Subjective and objective symptoms of SUI were assessed in study subjects before and after TCRF, (1 treatment every 30 days, for 3 months; n=10) and compared with the effects of a placebo treatment on a control group of demographically similar women (n=10). SUI was subjectively evaluated with subjective Urogenital Distress Inventory (UDI-6) and with the International Consultation on Incontinence

- 1 -



# Histologic and Clinical Changes in Vulvovaginal Tissue After Treatment With a Transcutaneous Temperature-Controlled Radiofrequency Device

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**BACKGROUND** Although transcutaneous temperature-controlled radiofrequency (TTCRF) may effectively treat vulvovaginal laxity (VVL), atrophic vaginitis (AV), orgasmic dysfunction (OD), and stress urinary incontinence (SUI), there is a lack of histopathologic evidence to validate its use.

**OBJECTIVE** Evaluate clinical and histological changes induced by vulvovaginal TTCRF.

**MATERIALS AND METHODS** This was a prospective, nonrandomized trial. Ten female subjects with mild-to-moderate VVL, with or without AV, OD, and/or SUI underwent 3 TTCRFs at 4-week intervals. Five subjects underwent pre- and post-treatment biopsies of the labia majora and vaginal canal for histology. Assessments were performed at baseline and Days 10, 30, 60, and 120.

**RESULTS** Investigator-rated VVL improved significantly from baseline to Day 10, with improvement maintained through Day 120 ( $p = .001$  and  $.001$ , respectively). Sexual satisfaction improved significantly by Day 60 ( $p = .001$ ). Improvement in AV reached significance at Day 120 ( $p = .048$ ). Although OD and SUI improved steadily, the difference in improvement did not reach statistical significance. Histology revealed that post-treatment increases in collagen, elastin, vascularity, and small nerve fibers.

**CONCLUSION** Transcutaneous temperature-controlled RF resulted in significant improvements in AV, VVL, and sexual satisfaction with milder improvements in OD and SUI. Post-treatment histology demonstrated neocollagenesis, neolastogenesis, neoangiogenesis, and the first reported finding of TTCRF-related neurogenesis.

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Vulvovaginal rejuvenation is an increasingly popular procedure. Aging, menopause, weight fluctuations, and childbirth create mechanical forces on the vulva and vagina, and reduce the quality of connective tissue in the area, leading to symptoms of vulvovaginal laxity (VVL), atrophic vaginitis (AV), stress urinary incontinence (SUI), and orgasmic dysfunction (OD). Although women rarely discuss these issues, they can significantly detract from quality of life. In the past, options for addressing these concerns were limited to hormonal therapies,

lubricants, Kegel exercises, and traditional surgical intervention. Now, there are several laser and energy devices that can provide minimally and noninvasive vulvovaginal rejuvenation.<sup>1</sup>

Monopolar radiofrequency (RF) is an established modality for tissue tightening both on and off the face.<sup>2</sup> Radiofrequency induces collagen denaturation with subsequent contraction of fibrils, neocollagenesis, and activation of the healing cascade.<sup>3,4</sup> In 2010, Millheiser and colleagues<sup>5</sup> demonstrated the efficacy of monopolar

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## Light and Energy Based Therapeutics for Genitourinary Syndrome of Menopause: Consensus and Controversies

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Gynecologist and plastic surgeons pioneered the application of lasers in medicine and surgery almost 5 decades ago, initially used to treat cervical and vaginal pathologies. Ever since, energy-based devices have been deployed to treat pelvic pathologies and improve fertility. Recent technological developments triggered an unprecedented wave of publications, assessing the efficacy of fractional laser, and radiofrequency on the vaginal wall in reversing natural aging processes. Studies have shown that a certain degree of thermal energy deposited on the vaginal wall stimulates proliferation of the glycogen-enriched epithelium, neo-vascularization, and collagen formation in the lamina propria, and improves natural lubrication and control of urination. This review aimed to review such data and to guide future research. A unique assembly of experts from around the globe, compiled and edited this manuscript based on a thorough literature review and personal experience. *Lasers Surg Med*. 49:137–159, 2017.

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**Key words:** laser; radiofrequency; energy based device; genitourinary syndrome of menopause (GSM); vagina; vulva; rejuvenation; stress urinary incontinence (SUI); lichen sclerosus; vulvodynia

### LASERS IN GYNECOLOGY: HISTORIC OVERVIEW

Almost 5 decades ago, gynecologist and plastic surgeons pioneered the integration of lasers for the ablation of

diseased tissue [1]. Energy of the focused CO<sub>2</sub> laser beam was exploited to create incisions by tissue vaporization, while the defocused beam, featuring a lower energy density, elicited tissue contraction, and was applied to treat various cervical and vaginal pathologies [2]. In the 1970s, various lesions such as genital warts on the uterine cervix, were treated with the CO<sub>2</sub> laser which has since become a common treatment approach for genital warts with micromanipulators connected to colposcopes.

**Conflict of Interest Disclosure:** All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and have disclosed the following: Yona Tadir is a scientific consultant for Alma Lasers. Red Alinsod is a consultant for Thermo, receive royalty for ThermoVa, Cooper Surgical, Lase Star Retractor, and Coloplast. Consultant, Calligaris Medical. Stock owner, Manarich Medical Products. Consultant, Royalty for Alinsod Surgical Equipment. Selih-Martinez is an invited speaker by Alma Lasers. Alberto Calligaris, Stefano Salvatore, and Nicola Zerbinati are scientific consultants for DEKA laser. All other co-authors: nothing to disclose. No commercial source supported the collaboration and preparation of this manuscript.

[Correction added on 24 February 2017, after first online publication: The spelling of Jorge E. Gaviria's name and affiliation number were corrected.]

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### ORIGINAL CONTRIBUTION

WILEY  
Journal of Clinical Dermatology

## Review and clinical experience exploring evidence, clinical efficacy, and safety regarding nonsurgical treatment of feminine rejuvenation

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### Summary

**Introduction:** The use of energy-based devices for the treatment of vaginal laxity, orgasmic dysfunction, and stress incontinence, such as minimally ablative fractional laser and radiofrequency, is gaining momentum. This review aims to answer clinical questions on the application of energy-based devices for feminine genital rejuvenation.

**Methods:** The target group includes physicians involved in esthetic medicine and feminine genital rejuvenation. A literature review was conducted on technologies in use for feminine rejuvenation to explore their safety, efficacy, tolerability, patient satisfaction, and clinical usability. A panel of physicians with clinical experience conducting these types of treatment reviewed and discussed the results of the literature search and gave clinical evidence-based recommendations.

**Results:** Energy-based devices may induce wound healing, stimulating new collagen, and elastin fiber formation. Radiofrequency treatment may also increase small nerve fiber density in the papillary dermis, improving nerve sensitivity, sexual function, including arousal and orgasmic dysfunction. Both minimally ablative fractional laser and radiofrequency have been shown to be effective when treating mild to moderate primary or secondary vulvovaginal laxity and associated secondary conditions. These treatments are reported to be safe, effective, and well tolerated with a rapid return to activities of daily living.

**Conclusions:** As this is an evolving medical field, clinical evidence often lacks robustness. Studies and clinical experience suggest that feminine genital rejuvenation using energy-based devices seems an attractive option for patients with mild-to-moderate medical conditions. The treatment can be safely and effectively delivered by trained staff as part of the comprehensive care, that is, currently available to women.

### KEYWORDS

CO<sub>2</sub>-based lasers, erbium:yttrium-aluminum-garnet lasers, feminine rejuvenation, radiofrequency devices

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### INSTRUMENT REVIEW

## ThermiVa: The Revolutionary Technology for Vulvovaginal Rejuvenation and Noninvasive Management of Female SUI

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**About the Reviewer**  
Dr. Naymet Magon currently works with Indian Armed Forces, and is presently posted to the busiest hospital of Armed Forces Medical Services. Actively involved with academics, Dr. Magon has over 60 peer-reviewed publications to his credit, which includes publications in *Shank's* CPOG, and has contributed chapters to various postgraduate books. Dr. Magon is a peer-reviewer for many national and international journals and is on the roll of honor of the World Association of Medical Editors (WAME). He is the National Corresponding Editor for the Journal of Obstetrics and Gynecology of India, the official journal of FOGSI. Awarded with the prestigious FOGSI Dr. Kamini Rao Oration for year 2014 and AFOGOS Dr. S.S. Rahaman Young Gynecologist Award 2015, he is presently the National Coordinator for FOGSI Endoscopy Committee (2015–2019) as well as FOGSI Urogynecology Committee (2014–2017). An ace pelvic reconstructive and endoscopic surgeon, Dr. Magon is also the President of Urogynecology and Pelvic Health Association of India.

**Abstract** Addressing vaginal laxity, atrophic vaginitis, stress urinary incontinence (SUI), and different manifestations of sexual dysfunction has always been problematic due to women's traditional difficulty discussing these issues with doctors as well as the societal attitude of resignation toward these conditions. The recent rise of non-invasive feminine rejuvenation using energy-based

modalities to vaginal tissue has its origins in aesthetic medicine. Transcutaneous temperature-controlled radiofrequency therapy at the vulvovaginal region has shown promising results in giving a more youthful appearing vulva, restoration of vaginal elasticity and 'tightness', considerable improvement in SUI, reduction in overactive bladder symptoms, and reduction in sexual dysfunction. It is also emerging as the non-invasive treatment modality for mild to moderate SUI. It seems that the time has come, when women shall ever be grateful to their gynecologist for management of SUI with ThermiVa without an incision.

**Keywords:** Female sexual dysfunction • Stress urinary incontinence • Vaginal Rejuvenation • ThermiVa • Laser

Between childbirth and menopause, vagina and nearby tissues undergo numerous changes leading to a well-

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## Transcutaneous Temperature Controlled Radiofrequency for Atrophic Vulvovaginitis and Dyspareunia

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### OBJECTIVE

To evaluate the safety, tolerability, and clinical efficacy of non-surgical transcutaneous temperature controlled radiofrequency (TTCRF) for atrophic vulvovaginitis and dyspareunia.

### BACKGROUND

TTCRF brings with it numerous advantages for the treatment of skin disorders.<sup>1</sup> RF is an established modality for tissue tightening via stimulation of neo-collagenesis, tissue contraction, and activation of the healing cascade. This was shown in a histological study of RF in animal studies.<sup>2</sup> Improvement of blood flow also appears to be a key mechanism of action that results in increased neuropeptide release, vasodilation of arterioles, and increased transudate into the vaginal canal. The specific temperatures (40-45 C) to achieve these tissue endpoints is modulated by controlling the power, in relation to tissue impedance, which raises tissue temperature in the proximity of the RF electrode.

Thermistors and thermocouples within the treatment probe provide feedback to the device, which controls power to modulate energy deposition and maximize therapeutic relevancy without causing damage and minimizing the potential for patient discomfort. Unlike laser-based treatments, skin type (color of pigmentation) is not an issue with RF energy; and while it is proven effective on surface skin of the face and other body regions, RF is even more effective in tissue that is naturally moist and well hydrated, as in the vaginal and vulvar structures.

### PATIENTS

- 25 patients (age range 35-69 years, mean 54) who complained of significant atrophic vaginitis and dyspareunia
- 5 Patients had severe introital stenosis allowing only small fingertip entry
- 8 patients were being treated with hormone replacement therapy including vaginal estrogens but with unsatisfactory responses
- Exclusions: Pregnancy, chronic steroid and anti-inflammatory medication use, undiagnosed vulvar lesions, prior pelvic mesh surgery
- Methods: 3 Monthly 20 minute sessions using TTCRF handpiece both on vulva (10 min) and vagina (10 min), No anesthesia
  - Treatment Endpoints: 40-45 Celcius on tissues lasting 3-5 minutes per site of treatment
- Evaluation:
  - Patient report of symptoms resolution, Evaluation of moisture production, comfort during intercourse
  - Validated questionnaires (Vaginal Laxity Questionnaire, Sexual Satisfaction Questionnaire, FSFI)
  - Photographic evaluation Before and After each treatment at each visit
  - No serious adverse complications. No blisters or burns.



Figure 1. Before and after pictures of multiparous woman, age 59 years, complaining of severe atrophic vulvovaginitis with poor response to long term vaginal estrogens; outcome after three treatments with TTCRF included visible aesthetic improvement and complete resolution of atrophic vulvovaginitis. Dyspareunia was resolved and the patient felt significant tightening effects and increased sensitivity.

### OUTCOME

- All 25 patients reported resolution of their symptoms of vulvovaginal dryness and dyspareunia.
- All showed improvement in the Sexual Satisfaction Scale (Average of 2.5 points)
- All reported elimination of lubricant use or only an occasional need for lubricants.
- Effects of treatment are lasting 9-12 months before the need for single touchup treatments.
- Of the 25 patients in the atrophic vaginitis study group, there were 12 with SUI and/or OAB symptoms. Those 12 had resolution of both symptoms without the need for pelvic floor physical therapy or Kegels exercises. Tissue tightening effects were seen externally and internally. Ongoing studies are being performed on this subset of SUI and OAB patients as well as laxity patients.
- Severe vaginal introital stenosis resolved with TTCRF treatments in 5 patients resulting in improved post treatment pliability, softness, and thickness of vaginal tissues.



## Transcutaneous Temperature Controlled Radiofrequency for Overactive Bladder

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### INTRODUCTION

Overactive bladder with and without incontinence is rising with the aging population. Most treatments involve lifestyle change, medications, neuromodulations, and more recently paralytic agents. Anticholinergic medications often have undesirable side effects. Other treatments have procedural and surgical risks. Transvaginal radio frequency treatments for vaginal tightening and atrophy have recently been introduced that have shown shrinkage of the vaginal mucosa with increased vaginal moisture. Radio frequency effects on bladder and urethral tissue at 40-45 Celcius has been shown to be safe and well tolerated.

### AIM

To evaluate the safety, tolerability, and clinical efficacy of transcutaneous temperature controlled radiofrequency (TTCRF) on anterior vaginal tissue for overactive bladder.

### METHOD

- 75 women, ages 21-85, with overactive bladder included in the study
- Each patient received 3 sessions at intervals of about 1 month.
- Treatment was performed using a slim S-shaped probe with a stamp-sized metal radiofrequency emitter on one surface of the tip (10 minutes total time on average).
- Full length treatment of the anterior vagina with concentration on the pubocervical fascia was performed.
- Tissue temperature during therapy was elevated to and maintained between 40 degrees C and 45 degrees C.
- No anesthesia was required.
- After treatment patients immediately resumed normal routines, including exercise and sexual activities.

### RESULTS

- 68/75 (90.6%) patients overactive bladder without incontinence reported a reduction of OAB symptoms by at least one third, 33%.
- 43/75 (57%) patients with overactive bladder without incontinence reported a 50%+ reduction in OAB symptoms.
- Of these patients 24/75 (32%) completely resolved their OAB symptoms.
- Seven patient with s (9%) had more moderate symptoms reduction of 25% and less. All seven of these patients had overactive bladder with incontinence.
- All patients noticed some reduction in OAB symptoms over baseline.
- Results for nocturia were similar.

### CONCLUSIONS

TTCRF is an effective non-pharmacologic, non-surgical option for women with overactive bladder symptoms. Treatment have a visible tightening effects on vaginal mucosa and also appears to increase local blood flow, resulting in increased vaginal tightness and moisture. Improvement of symptoms in overactive bladder without incontinence is more dramatic than with overactive bladder with incontinence.



A slim finger sized S-shaped wand with a stamp sized metal radiofrequency emitter on the back side can be used on the external vulvar structures and deep inside the vagina all the way to the apex. The entire anterior compartment is treated with emphasis on the pubocervical fascia to 40-45 degrees Celcius for approximately ten minutes to shrink tissues, increase collagen production, and increase local blood flow.



Radiofrequency emitting tip.

### ACKNOWLEDGEMENTS

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Honorary Founder of Aesthetic Gyn Societies in Brazil, Paris, Germany, Poland

### **Patents/Patent Pending and Equipment Developed**

1. ThermiVa
2. Lone Star APS Retractor
3. Implantable Sling with Bladder Support
4. Implants and Procedures for Treatment of Pelvic Floor Disorders
5. Desara Incontinence Sling System
6. Ascend A and Ascend P Pelvic Reconstruction System
7. Brought first Ultra Lightweight Mesh to USA in 2005 (POP Mesh/Restorelle)
8. Alinsod Urogyn Table
9. Alinsod Scissors, Pickups, Clamps
10. Predictive Permeation/DEP Vulvovaginal Wand

### **Procedures Developed**

1. Radiofrequency Surgical Techniques for Aesthetic Gynecologic Surgery In-Office
  - a. First to treat vulvovaginal tissues with non-surgical RF energy
  - b. Feathering Technique for Resurfacing Revision surgery
  - c. Pudendal-Levator Block
2. In-Office RF Labiaplasty
  - a. Barbie Look
  - b. Hybrid Look
  - c. Vertical and Lateral Clitoral Hood Reduction and Hoodoplasty
  - d. Lateral Curvilinear Clitoral Hood Reduction
3. In-Office Vaginoplasty and Perineoplasty
4. Medial Curvilinear Labia Majoroplasty
5. Thermi-O (ThermiVa + O-Shot) and O-Shot with AmDrop Amniotic Fluid
6. ThermiVa Research on
  - a. Tightening of vulva and vagina
  - b. GSM
  - c. Urinary and Fecal Incontinence
  - d. OAB
  - e. Orgasmic Dysfunction
  - f. Stack Therapy with Fractional Laser combination
  - g. Vulvar Dystrophy, Vulvar Vestibulitis, Lichen Sclerosis, Pelvic Pain



7. Gynecologic Predictive Permeation for local anesthesia, vulvar lightening and plumping, platelet rich plasma and amniotic fluid placement, treatment of vulvar dystrophy/LS/Dermatitis.
8. O2Vasc development, research, production: Topical serum to increase genital bloodflow

## Recent Awards

1. July 2015: Best Feminine Rejuvenation, The Aesthetic Show, Las Vegas, NV



2. April 2016: Award of Innovations in Cosmetic Gynecology, European Society of Aesthetic Gynecology, Rome, IT



3. Feb 2017: Outstanding Contributions to Cosmetic Surgery 2017, International Society of Cosmetogynecology, San Diego, CA



4. May 2017: Award of Lifetime Contribution in Cosmetic Gynecology, European Society of Aesthetic Gynecology, Madrid, Spain.





5. July 2017: Best Feminine Rejuvenation Enhancement, The Aesthetic Show, Las Vegas, NV



6. April 2018: Outstanding Contribution in Cosmetic Gynecology, European Society of Aesthetic Gynecology, London, UK.



7. June 2019: ESAG Master's Course Faculty, Edinburg, Scotland. With Marco Pelosi II, Alexander Bader, Marco Pelosi III, John Miklos.



8. March 2020: Award for Best Results in Cosmetic Genital Surgery and for Teaching Excellence, The International Society of Cosmetogynecology, Ft. Lauderdale, FL.





9. March 2021: Award for Best Results in Cosmetic Genital Surgery, The International Society of Cosmetogynecology, Ft. Lauderdale, FL

