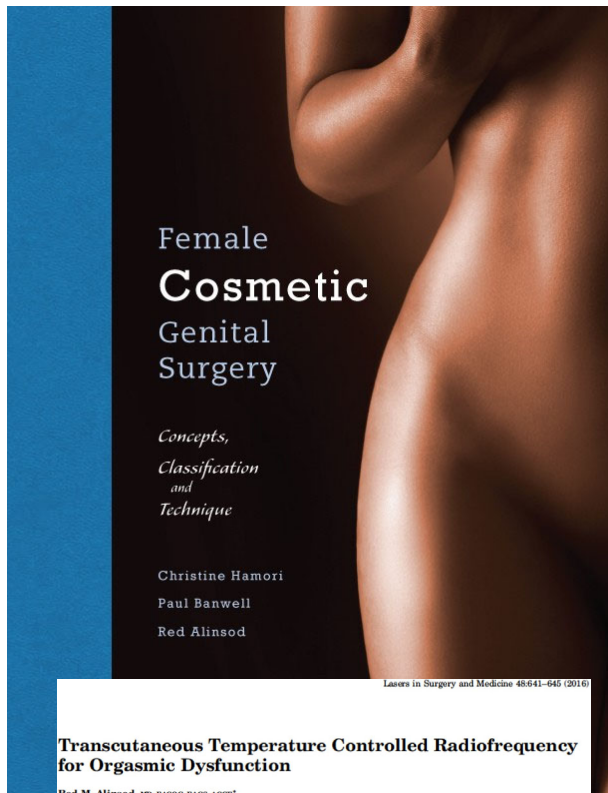


## Publications



### 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 (TTCRF) on vulvovaginal tissue for orgasmic dysfunction.

**Study Design/Methods:** Subjects included 25 sexually active women, ages 21–65, with self-reported difficulty in achieving orgasms 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 stamped 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:** TTCRF 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 38% 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 (TTCRF) 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

PEER-REVIEW | RADIOFREQUENCY | FFSM

## 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 (TTCRF) for vulvovaginal rejuvenation and document any beneficial effects of treatment.

**Patients and methods:** subjects (n=23; age range 20–58 years, mean 43.6; 5% menopausal, 6% perimenopausal) presented with mild to moderate primary or secondary vulvovaginal laxity. Associated conditions (orgasmic

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 Papapanicolaou 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 (VQLQ)

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=excellent, as well as observations of associated conditions such as incontinence, atrophic vaginitis, and orgasmic dysfunction.

**Results:** median improvement of 5 points on the VQLQ 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:** TTCRF is safe, tolerable, and effective for vulvovaginal rejuvenation. Evidence suggests applications in the treatment of atrophic vaginitis, orgasmic 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



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vulvovaginal laxity<sup>2</sup> 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 uterus, rather than laxity of the intravaginal 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. Orgasmic dysfunction, reduced

sexual satisfaction, and stress incontinence

are also associated with vulvovaginal laxity.

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: TTCRF is safe, tolerable, and effective for vulvovaginal rejuvenation.

Evidence suggests applications in the treatment of atrophic vaginitis, orgasmic dysfunction, and stress incontinence

## Transcutaneous Temperature Controlled Radiofrequency (TTCRF) 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 (TTCRF) 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 TTCRF (1 treatment every 10 days, for 1 month; 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

## 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), organic 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, neovascularity, and the first reported finding of TTCRF-related neurogenesis.

Supported by ThermoGen LLC.

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 organic 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, neovascularization, 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.

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

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Red Alinsod MD<sup>8</sup> | Elizabeth Shane French<sup>9</sup> | Nathan Guerette MD<sup>10</sup> | Yegor Kolodchenko MD<sup>11</sup> | Michael Krychman MD<sup>12</sup> | Susan Murrmann MD<sup>13</sup> | Julene Samuels<sup>14</sup>

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**Summary**

**Introduction:** The use of energy-based devices for the treatment of vaginal laxity, organic 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 organic 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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**Conflict of Interest**

Dr. Red Alinsod, Dr. Elizabeth Shane French, Dr. Nathan Guerette, Dr. Yegor Kolodchenko, Dr. Michael Krychman, Dr. Susan Murrmann, Dr. Julene Samuels, and Dr. Michael Gold have received honoraria from the following companies: Sciton, Candela, Syntex, Futura, Luminus, Venus, BTL, and Thermo.

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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 touch-up 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, neuromodulation, 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 5-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

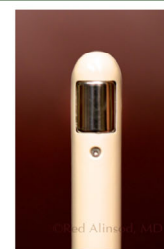
- 68/75 (90.6%) patients overactive bladder without incontinence reported a reduction of OAB symptoms by at least one third, 33%.
- 43/75 (57%) patients with overactive bladder without incontinence reported a 50%+ reduction in OAB symptoms.
- Of these patients 24/75 (32%) completely resolved their OAB 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 5-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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# ADVANCES IN AESTHETIC VULVOVAGINAL SURGERY

Dr Red M. Alinsod, specialist in aesthetic vaginal surgery, discusses his experience of using Ellman's Pelleve system, and the increased precision it offers for vulvovaginal surgery



RED M. ALINSOD, MD, FACS, FACS, ACCE, specialist in Urogynecology and Reconstructive Pelvic Surgery and Aesthetic Vaginal Surgery at South Coast Urogynecology, Inc. and Laguna Institute for Aesthetic Vaginal Surgery in Laguna Beach, CA, US

"Ellman's Pelleve Generator is the device of choice for any labial and revision surgery"

**D**UE TO THE EFFECTS of childbirth, ageing, trauma, and/or genetics, the vaginal tissue and surrounding muscles can become stretched and lose their strength and tone. Labial enlargement, unevenness, or traumatic tears from childbirth also affect the appearance of the labia which may result in discomfort with intimate contact, chronic rubbing, pulling sensation, vulva pain, and discomfort when wearing certain types of clothing, such as jeans or swimsuits.

Aesthetic vulvovaginal surgery (AVS), also called female genital cosmetic surgery (FGCS), cosmetic vaginal surgery, or cosmetic gynaecologic surgery, is an umbrella term for various surgical procedures performed to improve the appearance or function of the vulvovaginal region. Aesthetic and functional techniques include traditional vaginal prolapse procedures, as well as cosmetic vulva and labial procedures. These consist of elective minimally invasive surgeries, such as vaginoplasty (vaginal tightening techniques), perineoplasty for vaginal tightening, labia minora plecty for hypertrophic or irregularly shaped labia minora, clitoral hood reduction for an excessively large clitoral hood, labia majora plecty for enlarged or lax labia majora, or labia majora augmentation for hypotrophic labia majora.

The line between cosmetic and medically indicated procedures has become blurred, and many operations are performed for both purposes. Women seeking FGCS need to be educated about the range and variation of 'normal' labia widths and genital appearance, and should be evaluated for true pelvic support disorders such as pelvic organ prolapse and stress urinary incontinence.

Most patients want their prolapse repaired, and their genital area to be tighter and more attractive. The typical age of women seeking labial surgery is 20s to 30s. We also see teens who are athletic and self-conscious about the way their genital area appears in a bathing suit or shorts. There may be a genetic component and some girls will present with a predisposition to larger labia.

Women post childbirth and those who are back on the dating scene after divorce may seek vaginal tightening or require deep pelvic surgery to correct a prolapsed uterus or rectum. Being able to address the functional as well as aesthetic issues in one stage offers significant advantages in terms of recovery, convenience, and costs.

## Ellman's Pelleve offers versatility

The Pelleve® S5 System (Ellman International, Inc.) is a versatile radiofrequency (RF) device that can be used for both surgical and non-invasive vaginal tightening. Our

practice was the first to perform and develop protocols for non-surgical labia majora laxity. Formerly, only surgery could help a patient suffering from the unsightly drop of their labia majora and loss of skin tone. Patients who had the 'camel toe' appearance or had personal discomfort issues with their labia majora are able to avoid labia majora plecty surgery with the 30-minute non-invasive labial skin tightening technique.

My philosophy is to do the most minimal surgery to get maximum results.

Therefore, we can achieve minimal damage to the tissues, with good precision, which is important especially when you are working around tender genital areas. By using the minimally invasive technique, I can perform 98% of the cosmetic work with the patient awake, without IVs, and not experiencing pain. I was the first to use the technique of dermo-electroporation (DEP) for anaesthesia. This transdermal delivery technique utilizes the skin's water-based channels to allow macromolecules of the anaesthetic agent to penetrate safely into the tissue so patients are totally comfortable during the procedure. We have perfected a protocol for vaginoplasty using a monodermiscent local anesthetic, without the need for invasive tubes, lines, and spinal needles. The typical labiaplasty uses only 4-7cc of local anesthetic. My development of the pudendo-levator block in conjunction to the Lone Star APS Vaginal

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Lasers in Surgery and Medicine

## Safety and Efficacy of a Non-Invasive High-Intensity Focused Electromagnetic Field (HIFEM) Device for Treatment of Urinary Incontinence and Enhancement of Quality of Life

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**Background and Objectives:** Urinary incontinence is a common and distressing condition which interferes with everyday life. Patients frequently experience discomfort related to urine leakage and the subsequent need to use absorbent pads. Since the continence mechanism is primarily maintained by a proper function of pelvic floor muscles (PFM), many treatment methods focused on strengthening of the PFM have been introduced in the past. The aim of this study was to evaluate the safety and efficacy of a high-intensity focused electromagnetic technology (HIFEM) for treatment of urinary incontinence with emphasis on effects on prospective patients' quality of life.

**Study Design/Materials and Methods:** The study followed an institutional review board approved protocol. A total of 75 women (55.45 ± 12.80 years, 1.85 ± 1.28 deliveries) who showed symptoms of stress, urge, or mixed urinary incontinence were enrolled. They received six HIFEM treatments (2 per week) in duration of 28 minutes. Outcomes were evaluated after the sixth treatment and at the 3-month follow-up. The primary outcome was to assess changes in urinary incontinence by the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and changes in the number of absorbent pads used per day. The secondary outcome was subjective evaluation of the therapy and self-reported changes in quality of life. The statistical analysis was conducted by paired *T*-test and Pearson correlation coefficient ( $\alpha = 0.05$ ). **Results:** After the sixth session, 61 out of 75 patients (81.33%) reported significant reduction of their symptoms. The average improvement of 49.93% in ICIQ-SF score was observed after the sixth treatment, which further increased to 61.42% at the follow-up (both  $P < 0.001$ ). Individually, the highest level of improvement was reached in patients suffering from mixed urinary incontinence (69.90%). The reduction of absorbent pads averaged 43.80% after the sixth treatment and 53.68% at 3 months (both  $P < 0.001$ ), while almost 70% of patients (30 out of 43) reported decreased number of used pads. At the follow-up, a highly significant

medium correlation ( $r = 0.53$ ,  $P < 0.001$ ) was found between the ICIQ-SF score improvement and the reduction in pad usage. A substantial decrease in the frequency of urine leakage triggers was documented. Patients reported no pain, downtime or adverse events, and also reported additional beneficial effects of the therapy such as increased sexual desire and better urination control.

**Conclusions:** This study demonstrated that HIFEM technology is able to safely and effectively treat a wide range of patients suffering from urinary incontinence. After six treatments, an improvement in ICIQ-SF score and reduction in absorbent pads usage was observed. Based on subjective evaluation, these changes positively influenced quality of life. *Lasers Surg. Med.*

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**Key words:** HIFEM; pelvic floor muscles; urinary incontinence

## INTRODUCTION

Urinary incontinence (UI), defined as involuntary loss of urine [1], is a chronic condition which may negatively affect quality of life (QOL). On the basis of its etiology and

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**Conflict of Interest Disclosure:** All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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