

FemTouch™ Treatment for Improving Vulvovaginal Health

Dr. M. Marziali MD
PhD in Gynecology and Obstetric



Introduction

Vulvovaginal atrophy (VVA) accompanies the natural aging of the vagina and affects up to 80% of women after menopause, and imparts a substantially negative impact on quality of life⁽¹⁾. Clinical signs include vaginal walls thinning and reduced vaginal secretions, ascribed to the reduced estrogen levels following menopause, and result in vaginal dryness, itching, dyspareunia or/and bleeding during sexual intercourse. In addition, women with VVA often suffer from urinary symptoms such as urge incontinence (UI), urinary tract infections (UTI) and stress urinary incontinence (SUI). Available treatment options include application of vaginal lubricants and administration of systemic or local vaginal estrogen, which act upon the vaginal epithelium only. However, there are cases in which estrogen treatments may not be a treatment option. For instance, in female patients suffering from VVA symptoms following chemotherapy or in patients that are nonresponsive to estrogen.

CO₂ lasers have recently been deployed to address VVA symptoms in postmenopausal women, and have been shown, in both objective and subjective assessments, to significantly relieve symptoms such as vaginal dryness, irritation and burning sensations⁽²⁻⁴⁾. These findings have been further confirmed by histological evidence that showed that microablative fractional CO₂ laser treatment of the vaginal mucosa induced tissue remodeling, activation of fibroblasts and neocollagenesis⁽⁵⁾. One month after fractional CO₂ laser treatment, the lamina propria formed connective tissue with vessel-rich papillae, a thick stratified squamous epithelium and normal superficial cells⁽³⁾.

The FemTouch™ device (Lumenis) is a new fractional CO₂ laser solution that, in conjunction with the AcuPulse CO₂ laser system, provides safe and effective treatments to improve vaginal health. The minimally invasive FemTouch™ fractional scanning procedure, delivers continuous wave (CW) fractional energy that provides uniform coverage along the vaginal wall. The microbeam penetration into the lamina propria is controlled using the available settings, which range from 7.5-12.5 mJ.

FemTouch™ is intended for a wide range of indications including, but not limited to, ablation, coagulation, incision, excision, and vaporization of soft tissue in medical specialties such as gynecology.

In this paper we present preliminary treatment results of three patients treated with FemTouch™ device.

FemTouch™ Treatment

Three women presenting at least one VVA symptom, were treated with FemTouch™ device. Prior to treatment, a vaginal examination was performed to ensure patient eligibility for treatment and to determine the Vaginal Health Index Score (MHIS), Subjective evaluation of VVA symptoms was provided using the visual analog scale (VAS) and the Vaginal tightening and patient satisfaction was assessed⁽⁶⁾. The treatment regimen included three⁽³⁾ sessions, with a

4-week interval between sessions. Treatment parameters were individually tailored to address patient atrophy level. In general, energy level varied between 7.5 -12.5mJ and density level varied between 5-15%.

Vaginal Health Index Score (VHIS) consists of five vaginal parameters:

1. Elasticity
2. Secretion/fluid volume
3. Vaginal pH
4. Integrity of the epithelium
5. Lubrication/moisture of the vaginal wall.

Each parameter was graded from 1 to 5 (1 abnormal to 5 normal - maximal score 25=normal; minimal score 5=abnormal) according to the table below . If VHIS<15, the vagina is considered atrophic.

Table 1: VHIS by Bachmann

Score	1	2	3	4	5
Elasticity	None	Poor	Fair	Good	Excellent
Fluid volume (pooling of secretion)	None	Scant amount, vault not entirely covered	Superficial amount, vault entirely covered	Moderate amount of dryness (small areas of dryness on cotton tip applicator)	Normal amount (fully saturated on cotton tip applicator)
pH	6.1 or above	5.6-6.0	5.1-5.5	4.7-5.0	4.6 or below
Epithelial integrity	Petechiae noted before contact	Bleeds with light contact	Bleeds with scraping	Not friable - thin epithelium	Normal
Moisture (coating)	None, surface inflamed	None, surface not inflamed	Minimal	moderate	normal

Subjective evaluation of VVA symptoms was provided using the visual analog scale (VAS).

The evaluation included 5 symptoms:

1. Vaginal itching
2. Vaginal burning
3. Vaginal dryness
4. Dyspareunia
5. Dysuria.

The intensity of each symptom was evaluated by the patient on a 10 cm VAS where extreme left indicated “absence of the symptom” and extreme right indicated “symptom as bad as it could be”. Results were converted and presented as % of improvement from baseline.

Vaginal tightening and patient satisfaction with treatment results were assessed one month following the second treatment using validated questionnaires.

Results

Case No. 1:

- Patient age: 38
- Indication for laser treatment: vaginal atrophy following treatment with gonadotropin-releasing hormone (GnRH).

Vaginal-related medical history: Endometriosis grade IV and a surgical treatment (bilateral salpingectomy, resection of utero sacral ligaments, ablation of peritoneal endometriosis, removing of bilateral ovarian cysts).

- Alternative treatment used: One year of hormonal replacement therapy

VHIS Results:

Treatment	Elasticity	Fluid	pH	Integrity	Moisture	Total score
Baseline	2	3	3	5	5	18
Before 2 nd treatment	3	5	5	5	5	23

- VHIS parameters: Improvement in VHIS parameters was already evident one month after a single treatment session. Elasticity improved from poor to fair, the vaginal fluid volume increased from superficial amount to normal and pH levels improved from 5.1-5.5 at baseline to below 4.6.
- Patient satisfaction following the second session was very high. The third treatment session was not conducted, as per patient request, as she felt much better and saw no need for last treatment.

Subject Assessment of Improvement of VVA Symptoms (VAS)

Itching	Burning	Dryness	Dyspareunia/ Dysuria
62%	50%	38%	60%

Vaginal Tightening and Satisfaction Questionnaire

Vaginal tightening sensation	Partner: vaginal tightening sensation	Willing to recommend this treatment to friends?	Is this worth treatment?
Moderate improvement	Major improvement	yes	yes

Case No. 2:

- Patient age: 55
- Indication for laser treatment: menopause for 4 years, VVA symptoms such as vaginal dryness and dyspareunia
- Vagina-related medical history: 2 vaginal deliveries

VHIS Results:

Treatment	Elasticity	Fluid	pH	Integrity	Moisture	Total score
Baseline	2	2	3	3	2	12
Before 2 nd treatment	4	4	4	4	3	19
Before 3 rd treatment	5	5	4	5	5	24

- **VHIS parameters:** VHIS parameters improved throughout the course of treatment, with an enhancement in elasticity from poor to excellent, vaginal fluid volume from scant to normal amounts and pH levels from 5.1-5.5 at baseline to below 4.7-5.0.
- **Total VHIS score:** Over the course of treatment sessions, the total VHIS score improved from atrophic to normal.

Subject Assessment of Improvement of VVA Symptoms (VAS)

Itching	Burning	Dryness	Dyspareunia/ Dysuria
75%	88%	75%	88%

Vaginal Tightening and Satisfaction Questionnaire

Vaginal tightening sensation	Partner: vaginal tightening sensation	Willing to recommend this treatment to friends?	Is this worth treatment?
Major improvement	Major improvement	yes	yes

Case No. 3:

- Patient age: 68
- Indication for laser treatment: menopause for 18 years, VVA symptoms such as dyspareunia and burning sensation
- Vaginal-related medical history: 2 vaginal deliveries.
- Medication used for this indication: no hormonal replacement therapy provided

VHIS Results:

Treatment	Elasticity	Fluid	PH	Integrity	Moisture	Total score
Baseline	1	1	2	3	2	9
Before 2nd treatment	3	3	3	4	3	16
Before 3rd treatment	5	5	4	5	5	24

- **VHIS parameters:** Improvements in all VHIS parameters was evident following the first and second treatment sessions. Elasticity improved from none to excellent, and vaginal fluid volume increased from none to normal amounts. PH levels improved from 5.6-6.0 at baseline to below 4.7-5.0. In addition, epithelial integrity improved from “Bleeds with scraping” to “normal” and vaginal moisture improved from “none, surface not inflamed” to “normal”.
- **Total VHIS score:** Over the course of treatment sessions, the total VHIS score improved from atrophic to normal.

Subject Assessment of Improvement of VVA Symptoms (VAS)

Itching	Burning	Dryness	Dyspareunia/ Dysuria
88%	88%	87%	88%

Vaginal Tightening and Satisfaction Questionnaire

Vaginal tightening sensation	Partner: vaginal tightening sensation	Willing to recommend this treatment to friends?	Is this worth treatment?
Major improvement	Major improvement	yes	yes

Safety and comfort aspect:

- Patients described the treatment regimen as fast, painless and relatively comfortable.
- No downtime was reported.
- No complications were noted.

Summary:

We present 3 case reports of patients with WA symptoms. Significant improvement from baseline in WA-related symptoms: itching, burning, dryness Dyspareunia/Dysuria were reported by all three patients one month following the second treatment. Moreover, moderate to major improvement in vaginal tightening was reported by both the patients and their partners.

Tight correlation between clinical observations and subjective patient assessments of vaginal atrophy symptoms following FemTouch™ therapy was observed. VHIS scores for each parameter such as vaginal elasticity, fluid volume and epithelial integrity, had improved over the course of treatment. Overall, vaginal health improved from a severely atrophic to a non-atrophic state at one month after the second treatment session.

Notably, all patients were willing to recommend the treatment to a friend and declared the treatment as worthwhile. Patients described the treatment regimen as fast, painless and relatively comfortable.

References:

1. Simon JA. et al. Vaginal health in the United States: results from the vaginal health: insights, views & attitudes survey. *Menopause* (10) p1043-1048, 2013.
2. Gaspar, A., G. Addamo, and H. Brandi, Vaginal Fractional CO₂ Laser: A Minimally Invasive Option for Vaginal Rejuvenation. *American Journal of Cosmetic Surgery*, 2011. 28(3): p. 156-162.
3. Salvatore, S., et al., A 12-week treatment with fractional CO₂ laser for vulvovaginal atrophy: a pilot study. *Climacteric*, 2014. 17(4): p. 363-9.
4. Nicola Zerbinati et al. Microscopic and ultrastructural modifications of postmenopausal atrophic vaginal mucosa after fractional carbon dioxide laser treatment. *Lasers Med Sci* (2015) 30:429–436
5. Stefano Salvatore et al Histological study on the effects of microablative fractional CO₂ laser on atrophic vaginal tissue: an ex vivo study. *The Journal of The North American Menopause Society* Vol. 22, No. 8, pp. 845/849 2015.
6. Bachmann GA et al. A new option for managing urogenital atrophy in postmenopausal women. *Contemporary Obstetrics and Gynecology* 1997. (42) 13–28.