FemTouch™

Clinical Treatment Guide

Contributing Medical Expert:

Dr. Scott Evan Eder

Dr. Darush L. Mohyi

PB-2005717 Rev C

Lumenis®
Energy to Beauty

FemTouch™

Clinical Treatment Guide

Epidemiology of vulvo vaginal atrophy (VVA)

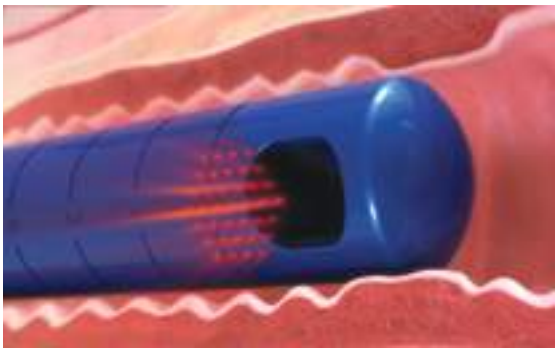
Vulvo vaginal atrophy (VVA) affects up to 80% of post-menopausal women. The symptoms primarily include vaginal dryness, irritation, itching, dysuria, and dyspareunia. These symptoms can adversely affect interpersonal relationships, quality of life and sexual function [1]. The main cause for VVA is a drop in estrogen levels during menopause. The change in estrogen level causes the vaginal lining to become thinner, dryer and less elastic. As the urinary tract is also estrogen dependent and since the urethral epithelium originates from the same embryologic tissue as the vaginal epithelium, women with VVA may also have symptoms such as urge incontinence (UI) or stress urinary incontinence (SUI) [1].

The efficacy of CO_2 laser in the treatment of VVA

Laser-based technologies and especially fractional CO_2 lasers, have been proven to be safe and effective for a range of indications involving tissue remodeling over the past few decades.
Recent scientific literature shows that treatment with fractional CO_2 lasers can be used also for treatment of vaginal health related conditions and specifically that it significantly improves symptoms of VVA in post-menopausal women [4-6].
In addition to symptoms improvement, histological data indicate that fractional CO_2 lasers cause a thickening and a restoration of the vaginal mucosa [7, 8].

The FemTouch™ Procedure

- FemTouch™ is a new procedure for treatment of vaginal health related conditions using a dedicated vaginal probe used in conjunction with the AcuPulse™ fractional CO_2 laser system
- FemTouch™ delivers low continuous wave CO_2 energy levels in a fractional pattern along the vaginal lining. Uniform delivery of the fractional pattern is achieved through a unique scanner designed to scan microbeams of 210µm each in a controlled and uniform manner
- Controlled small ablation/coagulation zones are created in the lamina propria using energy levels from 7.5 to 12.5mJ. The restriction of these parameters allow to provide effective vaginal remodelling process while limiting penetration depth up to 600µm to ensure fibromuscular layer safety. The fractional scanning pattern enables a quicker vaginal tissue healing
- To complement the intra-vaginal treatment, an optional external treatment of the introitus and vaginal vestibule is possible using the AcuScan120™ Microscanner
- In order to achieve optimal results, typically 2-4 treatment sessions are required at 4 weeks interval
- The FemTouch™ procedure is short and takes approximately 5 minutes to complete (full scan along the vaginal wall)



FemTouch™ intended use

The Lumenis AcuPulse system and the FemTouch™ is cleared by the United States Food and Drug Administration (FDA) 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.

Patient population*

Menopausal transition to post menopause

- Patients presenting one or more symptoms of vaginal atrophy:
  1. Itchiness
  2. Burning sensation
  3. Decreased vaginal lubrication
  4. Dyspareunia
  5. Vaginal bleeding during sexual intercourse
- Patients with discomfort related to vaginal laxity

***** Non exhaustive list. At the discretion of the Physician

Patient preparation*

- To exclude the presence of infections and any abnormality apart from atrophic vaginitis:
  - Pelvic exam must be performed
  - Papanicolaou test (PAP smear test) to meet national guidelines and standards
- For a better patient comfort, the patient will be preferably positioned as for a speculum exam with bended knees and feet in stirrups
- Patient with history of Herpes may be prescribed antiviral prophylaxis as per physician discretion
- Procedures are performed in ambulatory conditions and do not require analgesia nor anesthesia
- On patients with dryness of the vaginal canal, no extra preparation is required
- On patients with secretions left in the vaginal canal, wipe dry the canal with a sterile gauze

- Some discomfort might be associated at introitus level when inserting the HP tip on patients with introital stenosis
- As the treatment technique involves intravaginal handpiece motion, some patients may report a sensation of “vibration” which remains pain-free

*All recommended pre-treatment evaluations will meet local medical and regulatory requirements

Treatment session

The treatment may include two consecutive steps:

Intra-vaginal treatment using the FemTouch™ probe

Treatment parameters should be adjusted for each patient based on the atrophy level assessed by Vaginal Health Index Score (VHIS) (see table below).
Note: For severe atrophy, the use of low energy level in the first treatment is recommended. In sequential treatments, based on VHIS evaluation and physician discretion, energy and density level should be re adjusted.

External treatment (optional) using the AcuScan 120 Microscanner

Treatment parameters should be adjusted for each patient based on the atrophy level assessed by Vaginal Health Index Score (VHIS) (see table below).
Note: The use of low energy level in the first treatment is recommended. In sequential treatments, based on physician discretion, energy and density level should be re adjusted.

Treatment settings

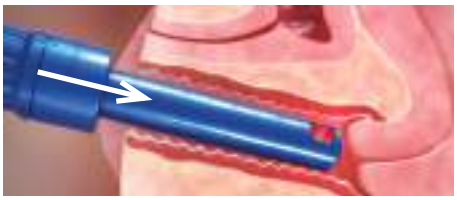
Treatment	Atrophy level	First treatment	Second treatment	Third treatment
Intra-vaginal (FemTouch™)	Severe (5< VHIS <15)	Energy: 7.5 / 10 mJ Density : 10%	Energy: 10 mJ Density : 10%	Energy: 10 mJ Density : 10%
	Moderate (15< VHIS <20)	Energy: 10 mJ Density : 10%	Energy: 10 / 12.5 mJ Density : 10% / 15%	Energy: 10 / 12.5 mJ Density : 10% / 15%
	Non atrophic (VHIS>20)	Energy: 10 mJ Density : 10%	Energy: 12.5 mJ Density : 10% / 15%	Energy: 12.5 mJ Density : 15%

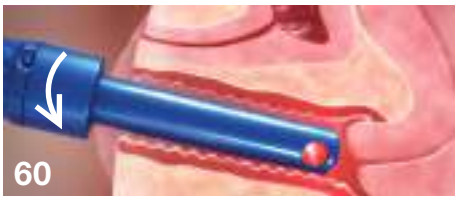
Treatment	Treatment area	Laser Type	First treatment	Second treatment	Third treatment
External (AcuScan 120 Microscanner, Deep mode)	Vaginal introitus	CW	Energy: 10 mJ Density : 5%	Energy: 10 mJ Density : 5% / 10%	Energy: 10 mJ Density : 5% / 10%
	Labia Minora	CW	Energy: 10 mJ Density : 5%	Energy: 10 mJ Density : 5%	Energy: 10 mJ Density : 5%
	Labia Majora	SuperPulse	Energy: 10 mJ Density : 5%-10%	Energy: 10 mJ Density : 5%-10%	Energy: 10 mJ Density : 5%-10%

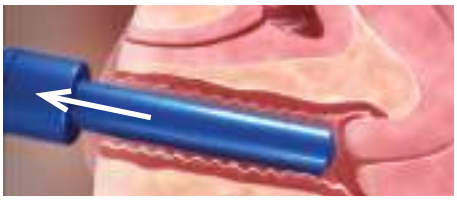
Treatment technique

1. Prepare the treatment screen with the settings (using the table above)
2. Keep the system on a Standby mode
3. Lubricate the FemTouch™ probe with baby oil
4. Gently insert the tip (with dimples facing up) into the vagina until you reach the cervix

5. Enter Ready mode and press the footswitch to deliver a scanned pulse to one side of the vaginal wall
6. Rotate the probe by 60° clock- or counterclockwise (double dots serve as indicators)
7. Following a rotation of the probe, deliver the next scanned pulse
8. Repeat the above to complete a treatment 6 times till you have covered the 360°
9. Retract the probe by one notch and deliver another set of scanned pulses
10. Keep rotating, pulsing and retracting, until you have covered the whole vaginal wall
11. The mirror of the probe should always remain in the canal during the lasing procedure







Post treatment instructions

- Vaginal hydrating gel* may be prescribed to soothe the vaginal lining and relieve the patient for up to 1 week
- Area should be kept moist using occlusive ointment
- The patient should be instructed to refrain from coital activity for 72 hours following the procedure
- The patient should avoid using hot water on the treated area until healing is complete

***** As per Physician's discretion

Clinical experience summary

This treatment guide summarizes the experience from clinical evaluations performed by leading gynecologists.

In clinical evaluations, an improvement in the symptoms of vaginal atrophy was noticed by the physicians as well as the patients. The improvement was observed in vaginal elasticity, fluid volume and epithelial integrity. In several patients who presented severe atrophy showed a great or total improvement after the treatment. In addition, an improvement in the vaginal tightening sensation was noticed following treatment. Vaginoscopy revealed that the color of the vaginal mucosa changed from a pale color, common in atrophy to a peachy color that characterizes normal vaginal mucosa.

In clinical evaluations, the patients reported being very satisfied with the results achieved and stated that they would be willing to recommend it to other patients. In addition, they reported that the procedure was very fast, painless and only in several cases, minimal discomfort was mentioned. No post-treatment adverse event was reported but two patients had a slightly burning sensation occurring 24 hours post treatment which resolved following in the application of vaginal moisturizing cream.

References

1. Simon JA. et al. Vaginal health in the United States: results from the vaginal health: insights, views & attitudes survey. Menopause (10) p. 1043-1048, 2013
2. Hussain M, et al. A prospective study of fractional scanned nonsequential carbon dioxide laser resurfacing: a clinical and histopathologic evaluation. Dermatol Surg 35(2): 222–228, 2009
3. Prignano F. et al. Fractional CO_2 laser: a novel therapeutic device upon photobiomodulation of tissue remodeling and cytokine pathway of tissue repair. Dermatol Ther S8-15, 2009
4. Gaspar, A., G. Addamo, and H. Brandi, Vaginal Fractional CO_2 Laser: A Minimally Invasive Option for Vaginal Rejuvenation. American Journal of Cosmetic Surgery, 2011. 28(3): p. 156-162
5. Salvatore, S., et al., A 12-week treatment with fractional CO_2 laser for vulvovaginal atrophy: a pilot study. Climacteric, 2014. 17(4): p. 363-9
6. 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
7. Salvatore S, Digesu G, Siesto G, et al. Vaginal collagen remodeling after fractional carbon dioxide laser surgery. Presented at Annual Meeting of the International Continence Society, Glasgow, United Kingdom, August – September 2011
8. Stefano Salvatore at al Histological study on the effects of microablative fractional CO_2 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

FemTouch™

Clinical Treatment Guide

Manufactured by Lumenis Ltd.
Industrial Park, Hakidma 6 Street
P.O.B. 240 Yokneam 2069204, Israel
T +972-4-959-9000

EC REP

Lumenis (Germany) GmbH
Heinrich-Hertz-Str 3 D-63303
Dreieich-Dreieichenhain GERMANY
T +49 (0) 6103 8335 0

PB-2005717 rev C

CE 0473

The information in this guide is based on clinical data available to Lumenis on the date this guide is first issued and is provided for convenience only. Lumenis does not have any obligation to update the information in this guide. All aspects of medical practice, including, without limitation, evaluating suitability of patients to undergo procedures with the device, examining medical history and the length, frequency and method of treatment, are under the sole discretion and responsibility of the healthcare practitioners treating patients and Lumenis hereby disclaims any and all liability with respect to the foregoing. For further clinical information, please refer to the user manual of the device.

AMERICAS
San Jose, CA, USA
T +1 408 764 3000
+1 877 586 3647
F +1 408 764 3999

EMEA
Dreieich, Germany
T +49 6103 8335 0
F +49 6103 8335 300

Rome (RM), Italy
T +39 06 90 75 230
F +39 06 90 75 269

Hertfordshire, UK
T +44 20 8736 4110
F +44 20 8736 4119

JAPAN
Tokyo, Japan
T +81 3 4431 8300
F +81 3 4431 8301

ASIA / PACIFIC
Beijing, China
T + 86 10 5737 6677

Gurgaon, India
T + 91 124 422 07 95

Kowloon, Hong Kong
T + 852 217 428 00
F + 852 272 251 51

Lumenis®
Energy to Beauty

WWW.LUMENIS.COM/AESTHETIC