MonaLisa Touch is not cleared by FDA for the specific indication of Genitourinary Syndrome of Menopause

Use of a Novel Fractional CO_2 Laser for the Treatment of Genitourinary Syndrome of Menopause: 1-Year Outcomes

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Background

Genitourinary Syndrome of Menopause (GSM), previously called vulvovaginal atrophy (VVA), manifests as an involution of the mucous membranes and tissues of the vulva and vagina due to a drop in circulating estrogen that occurs during menopause[1]. This can result in significant thinning of the vaginal epithelium leading to vaginal dryness, dyspareunia and irritative symptoms of the lower urinary tract[2].

First-line therapies for GSM include vaginal moisturizers and lubricants. When first-line therapies fail to control symptoms, estrogen treatment should be considered in the absence of contraindications. The primary objective of this management is to alleviate symptoms and reverse atrophic anatomical changes[3]. Though local estrogen therapies are often effective[3,4], medication adherence among patients is variable (52-74%)[5], and contraindications may exist.

Fractional CO_2 lasers have been safely and effectively used in many area of the body including the skin of the face, neck and chest, with the effect of producing new collagen and elastic fibers[6-9]. Histological evaluation of vaginal tissue after fractional CO_2 laser treatment has demonstrated regeneration of connective tissue in the vaginal lamina propria without leading to tissue damage or side effects[10].

The SmartXide^2 V^2 LR (MonaLisa Touch Laser) is a fractional CO_2 laser system with a maximum power of 60 W, emitting laser energy at a 10,600 nm wavelength. The maximum depth of penetration of the laser energy into the vaginal tissue is 200 µm. Laser treatment of the vaginal wall has been shown to lead to formation of new collagen fibers, as well as elastic fibers and extracellular matrix (ECM). This restores cellular trophism, increases tissue permeability and re-establishes normal blood flow[11].

Objectives

PRIMARY OBJECTIVE

To assess the safety and the efficacy of the SmartXide^2 – V^{2}LR fractional CO2 laser for the treatment of Genitourinary Syndrome of Menopause (GSM).

SECONDARY OBJECTIVES

1. Assess the effect of treatment on female urogenital health using the “Vaginal Health Index” (VHI) score
2. Assess the effect of treatment on vaginal wall elasticity by tracking the maximum dilator size tolerable for the patient
3. Assess the effect of treatment on female sexual function using the “Female Sexual Function Index” (FSFI) specific questionnaire
4. Assess the effect of treatment on general quality of life using the “Short Form 12” (SF-12) questionnaire
5. Assess the degree of physician ease of treatment using a 5-point Likert scale
6. Assess patient satisfaction with treatment using the Patient Global Impression of Improvement (PGI)

Methods

This two-center study included 30 consecutive healthy, non-smoking post-menopausal women who presented with symptoms of GSM. Participants could not have menstruated for at least 12 months, had to have less than stage 2 prolapse on POP-Q and could not have had any procedures in the anatomical area for the previous 6 months. The use of vaginal creams, moisturizers, lubricants or homeopathic preparations was not permitted for at least 3 months prior to study commencement and throughout the entire study. The investigation was conducted according to Good Practice Guidelines (GCP) and was IRB approved. Informed consent was obtained from all patients.

A gynecological examination was performed for all patients to assess the conditions of the vaginal wall using the VHI (scores can range from 5-25 with 25 being the healthiest). The investigators performed a vaginal calibration and determined the largest dilator that the patient could comfortably tolerate. VVA symptoms were assessed using a Visual Analog Scale (VAS) which ranged from 0 (none) to 10 (worst). FSFI and SF-12 quality of life questionnaires were completed by each patient. The FSFI questionnaire had a minimum score of 2 and a maximum of 36. The SF-12 questionnaire had a minimum score of 0 and a maximum of 100 after being normalized. All assessments were performed before treatment and at the 12 month follow up.

Each patient received 3 treatments with the SmartXide^2 V^2 LR fractional CO_2 laser system at six week (+/-1 week) intervals. An external introducer ring was inserted into the vaginal canal, the markings on the probe were aligned with the edge of the ring to measure withdrawal of the probe after 1-3 series of pulses were delivered and the probe was rotated 60˚. Laser power could be adjusted before and during the treatment to assure patient comfort. The procedure was performed in the outpatient clinic, not requiring any specific preparation, analgesia, or anesthesia.

Fig. 1: Stacking Technology

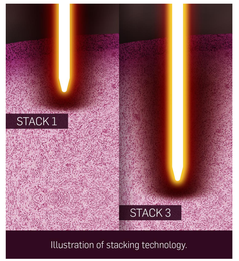


Illustration of stacking technology.

Participants were evaluated for side effects or complications, and asked to rate their level of discomfort during treatment (via VAS). Sexually active women were encouraged to avoid coitus for 3 days after treatment. Just prior to the second and third treatment participants completed the PGI. Follow-up at 3 months included reassessment of all pre-treatment evaluations, as well as an additional survey of overall satisfaction with the laser treatment using a 5-point Likert scale (1=very dissatisfied, 5=very satisfied). At one year after final treatment, follow-up evaluations included vaginal exam (including dilator measure of vaginal elasticity), VHI, VAS rating of all six VVA symptom categories, FSFI, SF-12, and a complete satisfaction survey assessing perception of results using a 5 point Likert Scale (1=very dissatisfied, 5=very satisfied).

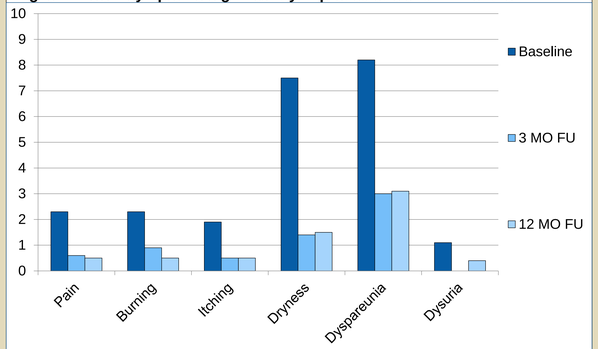
Results

30 patients were included in the study, all of whom were Caucasian. 6 patients were lost to follow up at 1 year.

Fig. 2: Patient demographics

AGE (years)	Onset of Menopause	Onset of VVA	At Screening
Minimum	27	30	34
Maximum	58	63	68
Average	48.9	51.2	58.6
Std. Dev	7.6	8.3	8.8

Fig. 3: All GSM symptoms significantly improved at 3 and 12 months



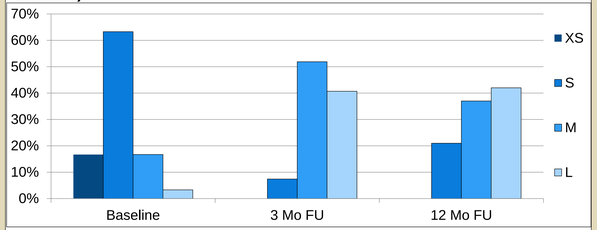
All patients had an improvement on the VHI scale. The average VHI score of patients before treatment was 14.4/25.0 (+/- 2.9). At 12 months, the average VHI score of patients was 21.7/25 (+/- 3.6), with an average improvement of 7.0 (+/- 3.7) points.

Fig. 4: FSFI scores significantly improved at 12 months

Female Sexual Function Index (FSFI)	Baseline	12 Month FU	Improvement
Minimum	2	3.3	-5.4
Maximum	25	33.8	31.5
Average	11.3	21.25	10.63
Std. Dev	7.3	11.47	10.01

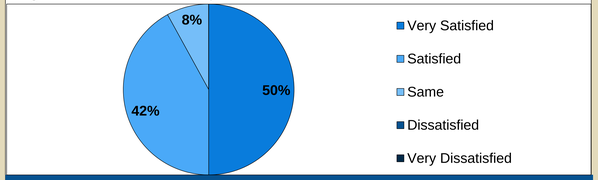
Results

Fig. 5: 79% comfortable with medium/large dilator at 12 months (vs. 20% at baseline)



SF-12 scores were found to have a non-significant change from baseline to 12 month follow up. Average physical health improvement was 1.0 (+/- 8.0), and average mental health improvement was 2.6 (+/- 4.7).

Fig. 6: 92% satisfied or very satisfied with their results at 12 months



Conclusion

The SmartXide^2 fractional CO_2 laser is a safe and efficacious method for the treatment of GSM with results that last up to 1 year.

References

1. Van der Laak JA, de Bie LM, de Leeuw H, de Wilde PC, Hanselaar AG. *The effect of Replens on vaginal cytology in the treatment of postmenopausal atrophy: cytomorphology versus computerised cytometry*. J Clin Pathol. 2002;55:446-51.
2. Bachmann GA, Cheng RJ, Rovner E. Vulvovaginal complaints. In: Lobo RA, ed. *Treatment of the Postmenopausal Woman: Basic and Clinical Aspects*, 3rd ed. Burlington, MA: Academic Press, 2007:263-270.
3. The North American Menopause Society. *Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society*. Menopause. 2013;20:888-902.
4. Suckling J, Lethaby A, Kennedy R. *Local oestrogen for vaginal atrophy in postmenopausal women*. Cochrane Database Syst Rev. 2006 Oct 18;(4):CD001500.
5. Shulman LP, Portman DJ, Lee WC, et al. A retrospective managed care claims data analysis of medication adherence to vaginal estrogen therapy: implications or clinical practice. Journal of Women's Health (Larchmt) 2008;17:569–78.
6. Ong MW, Bashir SJ. *Fractional laser resurfacing for acne scars: a review*. Br J Dermatol. 2012;166:1160-9.
7. Tierney EP, Hanke CW. *Fractionated carbon dioxide laser treatment of photoaging: prospective study in 45 patients and review of the literature*. Dermatol Surg. 2011;37:1279-90.
8. Tierney EP, Hanke CW. *Ablative fractionated CO2, laser resurfacing for the neck: prospective study and review of the literature*. J Drugs Dermatol. 2009;8:723-31.
9. Fistonić I, Fistonić-Gulbek S, Fistonić N. *Minimally invasive laser procedure for early stages of stress urinary incontinence (SUI)*. J Laser Health Acad, 2012; 1: 67-74.
10. Bachmann G. Urogenital ageing: an old problem newly recognized. Maturitas. 1995;22 Suppl:S1-S5.
11. S. Salvatore et al. *Histological study on the effects of microablative fraction CO_2 laser on atrophic vaginal tissue: an ex vivo study*. Menopause 2015 Jan 20. doi: 10.1097/GME.0000000000000401.
12. Sokol E. R., Karram M. Use of a novel fractional CO2 laser for the treatment of genitourinary syndrome of menopause. Poster session presented at: 26th Meeting of the North American Menopause Society; Sep 30 – Oct 3; Las Vegas, NV.