An Assessment of the Safety and Efficacy of the SmartXide² – V²LR CO_2 Laser for the Treatment of Vulvovaginal Atrophy

Eric R. Sokol MD[1], Mickey M. Karram MD[2]

[1] Urogynecology and Pelvic Reconstructive Surgery, Stanford University, Stanford, California

[2] Advanced Urogynecology and Pelvic Surgery, The Christ Hospital, Cincinnati, Ohio

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 SmartXide² V² 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

The primary objective was to assess the safety and the efficacy of the SmartXide² – V²LR 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 pliability by tracking the maximum dilator size tolerable for the patient
3. Assess the change in vaginal pH before and after each treatment session
4. Assess the effect of treatment on female sexual function using the "Female Sexual Function Index" (FSFI) specific questionnaire
5. Assess the effect of treatment on general quality of life using the "Short Form 12" (SF-12) questionnaire
6. Assess the degree of physician ease of treatment using a 5-point Likert scale
7. Assess the rate of patient satisfaction with treatment using the Patient Global Impression of Improvement (PGI)

Method

This study was IRB-approved. Patients were assessed for their eligibility and willingness to participate in the study.

A gynecological examination was performed for all patients to assess the conditions of the vaginal wall (VHI) with scores that could range from 5-25. 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) (Fig. 1) and VHI (Fig. 2) scores were obtained. 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 3 month follow up.

Fig. 1

VISUAL ANALOG SCALE (VAS) Please indicate below the discomfort you are experiencing:					
0	2	4	6	8	10
Very happy, no hurt	Hurts just a little bit	Hurts a little more	Hurts even more	Hurts a whole lot	Hurts as much as you can imagine

Fig. 2

VAGINAL HEALTH INDEX (VHI) Score below and indicate pH score:					
Score	Overall Elasticity	Fluid Secretion Type and Consistency	pH	Epithelial Mucosa	Moisture
1	None	None	6.1	Petechiae noted before contact	None, mucosa inflamed
2	Poor	Scant thin yellow	5.6-6.0	Bleeds with light contact	None, mucosa not inflamed
3	Fair	Superficial, thin white	5.1-5.5	Bleeds with scraping	Minimal
4	Good	Moderate, thin white	4.7-5.0	Not friable, thin mucosa	Moderate
5	Excellent	Normal (white flocculent)	≤4.6	Not friable, normal mucosa	Normal

Fig. 3

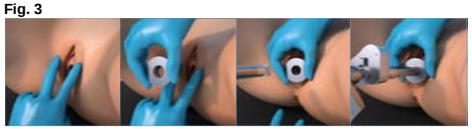
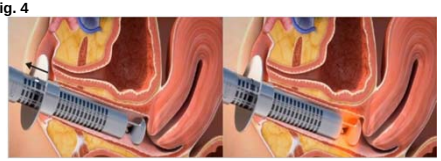


Fig. 4



Method (cont.)

Each patient received 3 treatments with the SmartXide² V² LR fractional CO_2 laser system (Fig. 5) 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 a series of pulses were delivered (Fig. 3), and the probe was rotated 60°(Fig. 4). 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.

To determine patient satisfaction with the treatment, PGI scores were collected from patients at the 3 month follow up.

Fig. 5

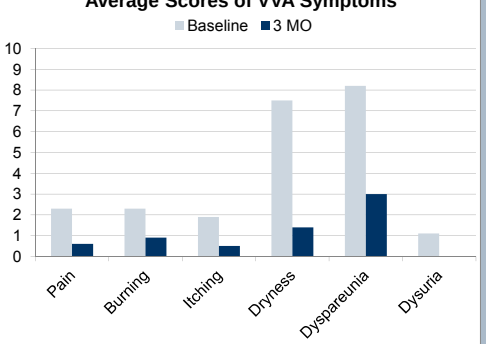
Results

30 patients were included in the study, all of which were Caucasian. 3/30 patients were lost to follow up and didn't complete the study.

Fig. 6: The average age of patients treated was 58.6 years

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. 7: All VVA symptoms significantly improved after 3 treatments



Ease of treatment scores were 4.8/5, 4.8/5, and 5/5 for the first, second, and third treatment respectively. The lowest score for any treatment performed was a 4/5. This implies the treatment is easy for physicians to perform.

All patients had an improvement on the VHI scale. The average VHI score of patients before treatment was 14.4/25.0 (+/- 2.9). After three treatments, the average VHI score of patients was 21.4/25 (+/- 2.9), indicating an average improvement of 7.0 points.

Results

Fig. 8: Patient's FSFI Scores indicated an 8.8 point improvement

Female Sexual Function Index (FSFI)		
	Baseline	3 Month FU
Minimum	2	2
Maximum	25	33.9
Average	11.3	20.1
Std. Dev	7.3	11.0

Fig. 9: Patients had increased vaginal wall elasticity and were able to comfortably handle a larger dilator after treatment.

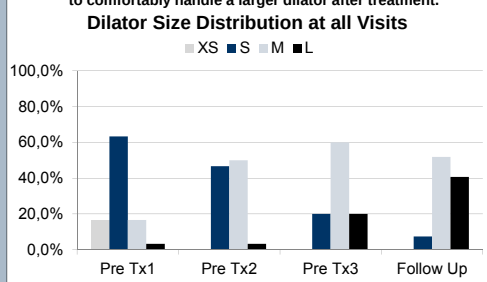
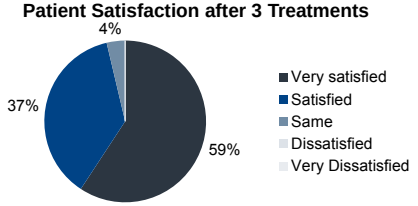


Fig. 10: 96% of patients were either satisfied or very satisfied with their treatment, while no patients were dissatisfied.



SF-12 scores were found to have a non-significant change from baseline to follow up. Average physical health improvement was 1.6 (+/- 8.1), and average mental health improvement was -2.6 (+/- 10.6).

Conclusion

Use of the SmartXide² V² LR fractional CO2 laser (MonaLisa Touch) is an effective and safe method for the treatment of symptoms related to Genitourinary Syndrome of Menopause (GSM).

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, Findri-Guštek Š, 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.