An Assessment of the Safety and Efficacy of the SmartXide² – V²LR CO² Laser for the Treatment of Vulvovaginal Atrophy

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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) 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.

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 (cont.)

Each patient received 3 treatments with the SmartXide² – V²LR fractional CO² laser system. The average energy used for each treatment was 150 J/cm². The VHI score of patients before treatment was 14.4/25.0 (+/- 2.9) and the average age of patients treated was 58.6 years.

Results

Fig. 5: The average age of patients treated was 58.6 years.

Fig. 9: 96% of patients were either satisfied or very satisfied with their treatment, while no patients were dissatisfied.

Dilator Size Distribution at all Visits

Fig. 10: SF-12 scores were found to have a non-significant change from baseline to follow up. Average physical health improvement was 1.6 (+/- 1.1), and average mental health improvement was -2.6 (+/- 0.6).

Conclusion

Use of the SmartXide² – V²LR fractional CO² laser (Monalisa Touch) is an effective and safe method for the treatment of symptoms related to Genitourinary Syndrome of Menopause (GSM).

References


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

Fig. 11: 60% of patients were either satisfied or very satisfied with their treatment, while no patients were dissatisfied.

Satisfied

Not Satisfied

Fig. 7: All VVA symptoms significantly improved after 3 treatments. Average Scores of VVA Symptoms

Baseline

3 Month FU

Vaginal Dryness

None, mucosa not inflamed

Not friable, moderate to much vaginal dryness

Slight vaginal dryness

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

Fig. 3: VAGINAL HEALTH INDEX (VHI)

Score below and indicate pH score:

Elasticity.Fluid Secretion Type and Consistency.

pH.

Epithelial.

Mucosa.

Moisture.

None.

Fluffy

None.

Punched, noted before contact

None.

Mucosa, not inflamed

1 Very

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) scores that could range from 5-25. The investigators performed a vaginal calibration and determined the largest dilator that the patient could comfortably tolerate.