

PAIN

Fractional CO<sub>2</sub> Laser Treatment of the Vestibule for Patients with Vestibulodynia and Genitourinary Syndrome of Menopause: A Pilot Study



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ABSTRACT

**Introduction:** Chronic vulvar pain and burning remains one of the most perplexing problems faced by practicing gynecologists.

**Aim:** To evaluate the effectiveness and safety of the application of micro-ablative fractional CO<sub>2</sub> laser to the vulvar vestibule in the management of patients with vulvar pain from vestibulodynia or genitourinary syndrome of menopause.

**Methods:** Patients (N = 70) underwent fractional micro-ablative CO<sub>2</sub> laser treatment for vestibular pain plus vestibulodynia (n = 37) or genitourinary syndrome of menopause (n = 33). Inclusion criteria were the existence of vestibular atrophic changes and the absence of moderate or severe pelvic floor hypertonic dysfunction.

**Main Outcome Measures:** A visual analog scale of pain and the Marinoff score of dyspareunia were chosen to evaluate improvement. Grading of vestibular health also was quantified using a four-point scoring system (0 = no atrophy, 3 = severe atrophy). Data were collected at baseline, at weeks 4, 8, and 12, and 4 months after the final treatment.

**Results:** For visual analog scale and dyspareunia scoring and for the overall vestibular health index scoring, statistically significant improvement was noted after three sessions of vestibular fractional CO<sub>2</sub> laser treatment. Improvement gradually increased throughout the study period and was maintained through the 4-month follow-up visit. There was no statistically significant difference in outcomes between the two study groups. No adverse events from fractional CO<sub>2</sub> laser treatment were noted. Overall, 67.6% of patients stated significant improvement from the laser procedure.

**Conclusion:** This preliminary case series showed encouraging results using fractional CO<sub>2</sub> laser treatment of the vestibule in women with vestibulodynia and genitourinary syndrome of menopause.

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**Key Words:** Vestibulodynia; Genitourinary Syndrome of Menopause; Fractional CO<sub>2</sub> Laser

INTRODUCTION

Chronic vulvar pain and burning remains one of the most perplexing problems faced by practicing gynecologists. The condition can affect up to 16% of women in all age groups.<sup>1</sup> A recent consensus statement revised the current terminology of vulvar pain based on the significant increase in high-quality research.<sup>2</sup> The current classification distinguishes two

subgroups of vulvar pain: pain caused by a specific disorder (infectious, inflammatory, neoplastic, trauma-induced, iatrogenic, or hormone deficiency) and vulvar pain (vulvodynia) with no clear-cut etiology. The vulvar vestibule, a thin band of tissue demarcating the entrance to the vagina, exhibits a high concentration of sensory free ends with a dense and shallow ramification, rendering this skin very sensitive.<sup>3</sup>

Vestibulodynia (VBD) describes pain that is localized to the vestibule. Because loss of estrogen is associated with an increased density of sensory nerve fibers in the vulva and vagina,<sup>4</sup> the most recent consensus statement includes genitourinary syndrome of menopause (GSM) as a cause of vulvar pain.

Micro-ablative fractional CO<sub>2</sub> has been used as an effective method for skin resurfacing and restoration. This technique has recently been applied to the vaginal and vulvar skin for symptomatic vulvovaginal atrophy or GSM.<sup>5</sup>

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The aim of this study was to evaluate the effectiveness and safety of the application of micro-ablative fractional CO<sub>2</sub> laser to the vulvar vestibule in the management of patients presenting with vulvar pain that was idiopathic (VBD) or from GSM.

## METHODS

This study was approved by the institutional review board and conducted in accordance with Good Practice Guidelines. Subjects (N = 70; age range 30.1 ± 7.7 years) included women presenting with vulvar pain and/or burning plus dyspareunia and/or vestibular atrophy (thinned, dry, fragile, or pale mucosa) in whom previous therapeutic intervention (medical, hormonal, and behavioral) was unsuccessful or produced unsatisfactory outcomes. Exclusion criteria included presence of active genital infection, moderate to severe hypertonic pelvic floor dysfunction or overactivity (as determined by physician digital examination),<sup>6</sup> or any other circumstance or condition deemed to potentially interfere with study participation or data collection. Subjects using systemic or local hormone replacement (estriol cream 0.05%) were required to undergo a 3-month washout period before enrollment.

Informed consent was obtained and subjects were placed into two groups. Group 1 (n = 37) included patients with VBD (defined as vulvar pain localized at the vestibule) of at least 3 months' duration, without clear identifiable cause, who exhibited focal allodynia (by positive cotton-tipped swab test result) on physical examination.<sup>1</sup> Group 2 (n = 33) included menopausal patients (age > 50 years, absence of menstruation ≥ 12 months) who presented with vulvar pain secondary to vulvovaginal atrophy or GSM.

Procedures were performed using a fractional CO<sub>2</sub> laser system (SmartXide<sup>2</sup>, DEKA M.E.L.A., Calenzano, Italy) equipped with a Vulvo-Vaginal Laser Reshaping (V2LR) scanning system and appropriate probes for the vulva; the probe has two parallel arms positioned at a distance of approximately 2 cm. Settings were 30-W power, a dwell time of 1,000 μs, DOT spacing of 700 μm, and SmartStack 2 using DP pulse mode. All patients underwent three treatment sessions that were spaced over a period of at least 30 days. No anesthesia or analgesia was required at any time. Patients were advised to abstain from sexual activity for at least 3 weeks after the first treatment and for 2 weeks after each subsequent laser application. Figure 1 shows the vestibular surface immediately after treatment.

Data were collected at baseline and at weeks 4, 8, and 12 after treatment and at final follow-up at 4 months. Vulvar pain and burning was assessed on a 10-point visual analog scale (0 = no pain, 10 = worst pain). Dyspareunia was evaluated using the grading system of Marinoff and Turner (1 = pain occasionally prevents penetration, 2 = pain most often prevents penetration, 3 = pain completely prevents intercourse).<sup>7</sup> A decrease of at least one grade was considered improvement. Vaginal pain was assessed by Q-tip testing at various points, with pain rated by the patient on a scale of



**Figure 1.** View of vestibular surface immediately after a session of fractional CO<sub>2</sub> laser therapy. The macroscopic ablation zones are demarcated by the Hart line. Figure 1 is available in color at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

0 to 3 (0 = no pain, 3 = severe pain). Vestibular health (epithelial integrity, surface thickness, and color observed by examination with vulvoscopy) was quantified using a four-point scale (0 = no atrophy, 3 = severe atrophy). Efficacy was rated at the 4-month follow-up using a four-point Likert scale (1 = worsened, 2 = unchanged, 3 = improved, 4 = very improved).

Statistical differences in pain were evaluated using analysis of covariance, with change of a single parameter (final value minus baseline value) as the dependent variable, treatment group as the cofactor, and baseline value as the covariate. The number and proportion of patients reporting improvement after treatment were compared with the Y<sup>2</sup> test (using the standard cutoff of  $P < .05$  for statistical significance).

## RESULTS

All subjects completed the study through follow-up. Mean time for each treatment session was 7 ± 3 minutes. No major adverse events were reported; three patients (one in the VBD group and two in the GSM group) reported a transient burning sensation after treatment, which resolved within 5 to 6 days.

Statistically significant ( $P < .05$ ) improvement was noted in dyspareunia and pain scores, with gradual improvement over each time point persisting through 4-month follow-up. Average overall vestibular health index score improved significantly in the two groups after each of the three individual treatments. There was no statistically significant difference in outcomes between the two study groups.

For overall satisfaction at follow-up, 13 of 37 patients (35.2%) in the VDB group reported “very improved” and 12 (32.4%) reported “improved,” with 12 (32.4%) reporting no change.

## DISCUSSION

This is the first report of fractional CO<sub>2</sub> laser therapy of the vestibule in patients with VBD.

This pilot study showed a significant improvement in pain and dyspareunia and a significant increase in vestibular health score in women who underwent three sessions of vestibular fractional CO<sub>2</sub> laser treatment. Overall, 67.6% of patients reported significant improvement or that their condition had significantly improved with the laser procedure.

Recent studies have demonstrated the efficacy of micro-ablative fractional CO<sub>2</sub> laser in the treatment of GSM, with significant improvement in vaginal dryness, vaginal burning, vaginal itching, dyspareunia, and dysuria.<sup>5</sup> This pilot study also confirms that many menopausal women with complaints of dyspareunia have significant vestibular tenderness, adding to the body of literature supporting this therapy for women with GSM and stressing the need to treat the vestibule separately and distinctly from the vaginal canal. According to the literature, additional improvement sometimes can be obtained with the application of estrogen on the vulvar vestibule.<sup>8</sup>

Weaknesses of the study are the absence of a placebo or sham treatment arm, the subjective rating of all outcome parameters, and only a 4-month follow-up after treatment.

## CONCLUSION

This preliminary case series showed very encouraging results using simple fractional CO<sub>2</sub> laser treatment of the vestibule in women with VBD and GSM. Placebo-controlled studies with longer follow-up are needed to further support these data.

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## REFERENCES

1. Pukall CF, Goldstein AT, Bergeron S, et al. Vulvodynia: definition, prevalence, impact, and pathophysiological factors. *J Sex Med* 2016;13:291-304.
2. Bornstein J, Goldstein AT, Stockdale CK, et al; Consensus Vulvar Pain Terminology Committee of the International Society for the Study of Vulvovaginal Disease (ISSVD). 2015 ISSVD, ISSWSH, and IPPS consensus terminology and classification of persistent vulvar pain and vulvodynia. *Obstet Gynecol* 2016;127:745-751.
3. Goldstein I, Meston C, Davis S, et al. Women's sexual function and dysfunction: study, diagnosis and treatment. Abington, UK: CRC Press; 2016.
4. Straub R. The complex role of estrogens in inflammation. *Endocr Rev* 2007;28:521e74.
5. Salvatore S, Athanasiou S, Candiani M. The use of pulsed CO<sub>2</sub> lasers for the treatment of vulvovaginal atrophy. *Curr Opin Obstet Gynecol* 2015;27:504-508.
6. Graziottin A, Murina F. Vulvodynia tips and tricks. Philadelphia, PA: Springer; 2011.
7. Marinoff SC, Turner ML. Vulvar Vestibulitis Syndrome: An overview. *Am J Obstet Gynecol* 1991;165:1228-1233.
8. Burrows LJ, Goldstein AT. The treatment of vestibulodynia with topical estradiol and testosterone. *Sex Med* 2013;1:30-33.