



MonaLisa Touch

International Scientific Community Recognition

Collection of Peer-Reviewed Scientific Papers

June 2026

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SCIENTIFIC DATA ANALYSIS



Scientific Evidence

- Supported by over 137 positive scientific publications
- Published data from more than 7,300 treated patients
- In-depth analyses: clinical, histological, microscopic, and ultrastructural
- Up to 24-36 months follow-up



Global Research

- Studies and collaborations across more than 30 countries
- Strong market penetration in Europe, the USA, South America, Asia, and Australia



Technology Maturity

- First publication: 2014
- More than 10 years of clinical use
- Innovative, well-established, and validated technology



Safety and Efficacy

- High rate of clinical success
- No significant adverse events
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A 12-week treatment with fractional CO₂ laser for vulvovaginal atrophy: A pilot study

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ABSTRACT

Objective

This pilot study aimed to assess the efficacy and feasibility of fractional CO₂ laser in the treatment of vulvovaginal atrophy (VVA) in postmenopausal women.

Methods

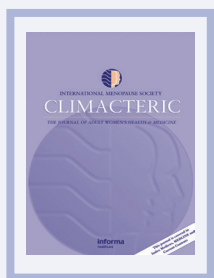
VVA symptoms were assessed before and after three applications of laser over 12 weeks in 50 women (age 59.6 ± 5.8 years) dissatisfied with previous local estrogen therapies. Subjective (visual analog scale) and objective (Vaginal Health Index Score, VHIS) measures were used during the study period to assess VVA. Quality of life was measured by using the SF-12. A subjective scale to evaluate the degree of pain related to the laser application and the degree of difficulty to perform the laser procedure was used.

Results

Fractional CO₂ laser treatment was effective to improve VVA symptoms (vaginal dryness, vaginal burning, vaginal itching, dyspareunia, dysuria; $p < 0.001$) at 12-week follow-up, as well as the VHIS (13.1 ± 2.5 at baseline vs. 23.1 ± 1.9 ; $p < 0.001$). Both physical and mental scores of quality of life were significantly improved in comparison with baseline ($p < 0.001$). Satisfaction with the laser procedure was reported by 42 women (84%) and a minimal discomfort was experienced at the first laser application, mainly because of the insertion and the movements of the probe. Finally, the technique was very easy to perform in all women starting from the second application at week 4 and no adverse events were recorded during the study period.

Conclusions

A 12-week treatment with the fractional CO₂ laser was feasible and induced a significant improvement of VVA symptoms by ameliorating vaginal health in postmenopausal women. Further controlled studies should be performed to confirm the present data and to assess the long-term effects of the laser procedure on vaginal tissues.



Microablative fractional CO₂ laser improves dyspareunia related to vulvovaginal atrophy: A pilot study

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TAG

VVA

Menopause

Sexual function

ABSTRACT

This pilot study aimed to assess the efficacy in treating sexually active menopausal patients who had dyspareunia related to vulvovaginal atrophy (VVA).

The intensity of VVA symptoms was recorded for each patient. Patients were administered the Short Form 12 (SF-12) and the female sexual function index (FSFI) to assess quality of life and sexual function, respectively. An objective evaluation of female urogenital health was performed using the Gloria Bachman Vaginal Health Index (VHI).

At 12-week follow-up, the laser treatment was efficacious in improving dyspareunia in 100% of patients included in the study (n = 15). The intensity of dyspareunia significantly decreased from baseline (8.7 ± 1.0) to 12-week follow-up (2.2 ± 1.0 ; $p < 0.001$). In addition, all other VVA symptoms significantly ameliorated at the same follow-up. Furthermore, after the treatment, a significant improvement in quality of life (QoL) and sexual function were shown.

This pilot study demonstrated that treatment with the microablative fractional CO₂ laser of patients with dyspareunia related to VVA was efficacious at 12-week follow-up.



Histological study on the effects of microablative fractional CO₂ laser on atrophic vaginal tissue: an ex vivo study

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ABSTRACT

Objective

Microablative fractional CO₂ laser has been proven to determine tissue remodeling with neoformation of collagen and elastic fibers on atrophic skin. The aim of our study is to evaluate the effects of microablative fractional CO₂ laser on postmenopausal women with vulvovaginal atrophy using an ex vivo model.

Methods

This is a prospective ex vivo cohort trial. Consecutive postmenopausal women with vulvovaginal atrophy managed with pelvic organ prolapse surgical operation were enrolled. After fascial plication, the redundant vaginal edge on one side was treated with CO₂ laser (SmartXide²; DEKA Laser, Florence, Italy). Five different CO₂ laser setup protocols were tested. The contralateral part of the vaginal wall was always used as control. Excessive vagina was trimmed and sent for histological evaluation to compare treated and nontreated tissues. Microscopic and ultrastructural aspects of the collagenic and elastic components of the matrix were studied, and a specific image analysis with computerized morphometry was performed. We also considered the fine cytological aspects of connective tissue proper cells, particularly fibroblasts.

Results

During the study period, five women were enrolled, and 10 vaginal specimens were finally retrieved. Four different settings of CO₂ laser were compared. Protocols were tested twice each to confirm histological findings. Treatment protocols were compared according to histological findings, particularly in maximal depth and connective changes achieved. All procedures were uneventful for participants.

Conclusions

This study shows that microablative fractional CO₂ laser can produce a remodeling of vaginal connective tissue without causing damage to surrounding tissue.



Microscopic and ultrastructural modifications of postmenopausal atrophic vaginal mucosa after fractional carbon dioxide laser treatment

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TAG

Vaginal Atrophy

Menopause

Histological examination

ABSTRACT

Vaginal atrophy occurring during menopause is closely related to the dramatic decrease in ovarian estrogens due to the loss of follicular activity.

Particularly, significant changes occur in the structure of the vaginal mucosa, with consequent impairment of many physiological functions. In this study, carried out on bioptic vaginal mucosa samples from postmenopausal, nonestrogenized women, we present microscopic and ultrastructural modifications of vaginal mucosa following fractional carbon dioxide (CO₂) laser treatment. We observed the restoration of the vaginal thick squamous stratified epithelium with a significant storage of glycogen in the epithelial cells and a high degree of glycogen-rich shedding cells at the epithelial surface.

Moreover, in the connective tissue constituting the lamina propria, active fibroblasts synthesized new components of the extracellular matrix including collagen and ground substance (extrafibrillar matrix) molecules.

Differently from atrophic mucosa, newly-formed papillae of connective tissue indented in the epithelium and typical blood capillaries penetrating inside the papillae, were also observed. Our morphological findings support the effectiveness of fractional CO₂ laser application for the restoration of vaginal mucosa structure and related physiological trophism. These findings clearly coupled with striking clinical relief from symptoms suffered by the patients before treatment remodeling of vaginal connective tissue without causing damage to surrounding tissue.



Sexual function after fractional microablative CO₂ laser in women with vulvovaginal atrophy

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ABSTRACT

Objective

To investigate the effects of fractional microablative CO₂ laser on sexual function and overall satisfaction with sexual life in postmenopausal women with vulvovaginal atrophy (VVA).

Method

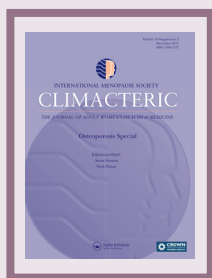
This prospective study included 77 postmenopausal women (mean age 60.6 ± 6.2 years) treated for VVA symptoms with the fractional microablative CO₂ laser system (SmartXide² V²LR, MonaLisa Touch[®], DEKA, Florence, Italy). Sexual function and quality of life were evaluated with the Female Sexual Function Index (FSFI) and the Short Form 12 (SF-12), respectively, both at baseline and at 12-week follow-up. A 10-mm visual analog scale was used to measure the overall satisfaction with sexual life and the intensity of VVA symptoms (vaginal burning, vaginal itching, vaginal dryness, dyspareunia and dysuria) before and after the study period.

Results

We observed a significant improvement in the total score and the scores in each specific domain of the FSFI at 12-week follow-up compared to baseline ($p < 0.001$). After concluding the laser treatment, the overall satisfaction with sexual life significantly improved ($p < 0.001$). Seventeen (85%) out of 20 (26%) women, not sexually active because of VVA severity at baseline, regained a normal sexual life at the 12-week follow-up. Finally, we also found a significant improvement in each VVA symptom ($p < 0.001$) and in quality-of-life evaluation, both for the scores in the physical ($p = 0.013$) and mental ($p = 0.002$) domains.

Conclusions

Fractional microablative CO₂ laser treatment is associated with a significant improvement of sexual function and satisfaction with sexual life in postmenopausal women with VVA symptoms.



Vulvovaginal atrophy: A new treatment modality using thermo-ablative fractional CO₂ laser

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TAG

VVA
Menopause

ABSTRACT

Objective

To evaluate the efficacy and feasibility of thermo-ablative fractional CO₂ laser for the treatment of symptoms related to vulvo-vaginal atrophy (VVA) in post-menopausal women.

Methods

From April 2013 to December 2013, post-menopausal patients who complained of one or more VVA-related symptoms and who underwent vaginal treatment with fractional CO₂ laser were enrolled in the study. At baseline (T0) and 30 days post-treatment (T1), vaginal status of the women was evaluated using the Vaginal Health Index (VHI), and subjective intensity of VVA symptoms was evaluated using a visual analog scale (VAS). At T1, treatment satisfaction was evaluated using a 5-point Likert scale.

Results

During the study period, a total of 48 patients were enrolled. Data indicated a significant improvement in VVA symptoms (vaginal dryness, burning, itching and dyspareunia) ($P < 0.0001$) in patients who had undergone 3 sessions of vaginal fractional CO₂ laser treatment. Moreover, VHI scores were significantly higher at T1 ($P < 0.0001$). Overall, 91.7% of patients were satisfied or very satisfied with the procedure and experienced considerable improvement in quality of life (QoL). No adverse events due to fractional CO₂ laser treatment occurred.

Conclusions

Thermo-ablative fractional CO₂ laser could be a safe, effective and feasible option for the treatment of VVA symptoms in post-menopausal women.



The use of pulsed CO₂ lasers for the treatment of vulvovaginal atrophy

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ABSTRACT

Purpose of Review

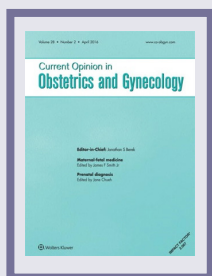
This article reviews the literature regarding the safety and efficacy of the use of a pulsed CO₂ laser for the treatment of vulvovaginal atrophy (VVA).

Recent Findings

Prospective observational studies have demonstrated histological changes after the use of pulsed CO₂ laser vaginally in atrophic conditions. Increased collagen and extracellular matrix production has been reported together with an increase in the thickness of the vaginal epithelium with the formation of new papilla. Three different observational studies reported a significant improvement of VVA assessed subjectively (with a 10-point visual analogue scale) and objectively (using the Vaginal Health Index) after a cycle of three treatments of pulsed CO₂ laser. Also sexual function (assessed with the Female Sexual Function Index) and quality of life (evaluated with the SF12 questionnaire) significantly improved. No complications or sideeffects were reported during or after the laser procedure that was performed in an outpatient setting.

Summary

Increasing evidence with histological and clinical data supports the use of pulsed CO₂ lasers in the treatment of VVA; however, no randomized control trial (sham versus treatment) has yet been produced and no data on the duration of therapy are currently available.



Fractional microablative CO₂ laser for vulvovaginal atrophy in women treated with chemotherapy and/or hormonal therapy for breast cancer: A retrospective study

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TAG

VVA

**Oncological menopause
Breast cancer survivors**

ABSTRACT

Objectives

Breast cancer is one of the most common malignancies in women. Hormonal treatment and chemotherapy induce a transient or permanent menopause status. Vulvovaginal atrophy (VVA) is a frequent debilitating symptom of menopause that is best treated with local or systemic estrogen formulations. Because estrogens drive the growth of the majority of breast cancers, most effective VVA therapies are precluded. The aim of this study was to evaluate the effects of fractional microablative CO₂ laser on sexual function and in relieving symptoms in women with breast cancer and VVA induced or exacerbated by iatrogenic menopause.

Methods

This retrospective study included 26 women affected by hormone-receptor positive breast tumors and treated for VVA symptoms with the fractional microablative CO₂ laser system. Every 30 to 40 days, women underwent a cycle of treatment for a total of three cycles. During each cycle, women underwent a gynecological examination and completed visual analog scale questionnaires designed to assess (1) the degree of symptoms and (2) procedure-related discomfort.

Results

Treatment resulted in a significant regression of VVA symptoms and procedure-related discomfort versus baseline ($P < 0.001$ in almost all cases). No adverse reactions were observed nor reported by women.

Conclusions

Fractional microablative CO₂ laser treatment is associated with a significant improvement of VVA symptoms in women affected by hormone-driven breast cancer. This procedure has the advantage of relieving iatrogenic/physiological VVA symptoms without resorting to contraindicated estrogen preparations, which have been the most effective therapy thus far.



An assessment of the safety and efficacy of a fractional CO₂ laser system for the treatment of vulvovaginal atrophy

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ABSTRACT

Objective

The aim of the study was to assess the safety and efficacy of a novel fractional CO₂ laser for the treatment of genitourinary syndrome of menopause (GSM).

Patients and Methods

Women presenting with GSM and meeting study criteria were enrolled. Examinations at baseline and follow-up (3 mo after final treatment) evaluated dilator tolerance and vaginal pH. Visual analog scales were used to assess pain, vaginal burning, vaginal itching, vaginal dryness, dyspareunia, and dysuria; Vaginal Health Index scores were completed before each treatment and at follow-up; Female Sexual Function Index and Short Form 12 questionnaires were also completed. Participant satisfaction was measured on a 5-point Likert scale (1=very dissatisfied, 5=very satisfied). Women received three laser treatments, 6 weeks apart.

Results

Thirty women participated (mean age 58.6±8.8 y). None withdrew or were discontinued due to an adverse event; three were lost to follow-up. Average improvement in visual analog scale scoring was 1.7±3.2 for pain, 1.4±2.9 for burning, 1.4±1.9 for itching, 6.1±2.7 for dryness, 5.1±3.0 for dyspareunia, and 1.0±2.4 for dysuria; improvement in average Vaginal Health Index and Female Sexual Function Index scores were statistically significant ($P<0.001$). Twenty-five of 30 participants (83%) showed increase in comfortable dilator size at 3-month follow up. Before the second and third treatments, 86.6% (26 of 30) of women reported they were better or much better than at the previous treatment; 26 of 27 women (96%) were reportedly satisfied or extremely satisfied at follow-up.

Conclusions

In this sample, the data suggest that the fractional CO₂ laser is effective and safe for treatment of the symptoms associated with GSM.



Fractional CO₂ laser for vulvovaginal atrophy (VVA) dyspareunia relief in breast cancer survivors

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TAG

VVA

Dyspareunia

Oncological menopause

Breast cancer survivors

ABSTRACT

Purpose

The aim of this study was to evaluate the efficacy of fractional CO₂ laser therapy in breast cancer survivors as a therapeutic method for vulvovaginal atrophy (VVA) dyspareunia.

Methods

50 patients (mean age 53.3 years) underwent fractional microablative CO₂ laser treatment for dyspareunia in oncological menopause (mean time of menopause 6.6 years). The Gloria Bachmann's Vaginal Health Index (VHI) score was chosen as system to evaluate the presence of VVA and its improvement after the treatment. Intensity of dyspareunia was evaluated using a visual analog scale (VAS).

Results

Data indicated a significant improvement in VVA dyspareunia ($p < 1.86 \times 10^{-22}$) in breast cancer survivors who had undergone 3 sessions of vaginal fractional CO₂ laser treatment. Moreover, VHI scores were significantly higher 30 days post-treatment (T4) ($p < 0.0001$). 76 % of patients were satisfied or very satisfied with the treatment results. The majority (52 %) of patients were satisfied after a long-term follow-up (mean time 11 months). No adverse events due to fractional CO₂ laser treatment occurred.

Conclusions

The treatment with fractionated CO₂ laser appeared to be a feasible and effective treatment for VVA dyspareunia in breast cancer survivors with contraindications to hormonal treatments.



Is vaginal fractional CO₂ laser treatment effective in improving overactive bladder symptoms in post-menopausal patients? preliminary results

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5: University of Ferrara, Ferrara - Italy.

ABSTRACT

Objective

To evaluate the role of vaginal fractional CO₂ laser treatment in the relief of Overactive Bladder (OAB) symptoms in post-menopausal women.

Patients and Methods

Post-menopausal women who complained of one or more symptoms related to vulvo-vaginal atrophy (VVA), who experienced symptoms of OAB and who underwent vaginal treatment with fractional CO₂ laser were enrolled in the study. At baseline (T0) and 30 days post-treatment T1), vaginal status (using Vaginal Health Index - VHI), subjective intensity of VVA symptoms (using a visual analog scale - VAS) and micturition diary were evaluated. OAB symptoms were also assessed using a validated questionnaire.

Results

Thirty patients were enrolled. A statistically significant improvement in VVA symptoms was observed and in VHI at T1 ($p < 0.0001$). A significant improvement was also identified in the micturition diary, in number of urge episodes and OAB-q ($p < 0.0001$). Nine of the 30 patients suffered from incontinence episodes and had improved at T1.

Conclusions

We showed that fractionated CO₂ laser vaginal treatment has proved to be effective in improving OAB symptoms in post-menopausal women. Moreover, it is a safe and efficacious measure for the relief of VVA related conditions. Further long-term studies are needed to confirm these preliminary results.



Fractional CO₂ laser for vulvovaginal atrophy

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Thammasat University, Rangsit Campus, Pathum Thani - Thailand.

TAG

**VVA
Menopause**

ABSTRACT

Purpose

To evaluate the short term efficacy and safety of Fractional CO₂ laser for the treatment of vulvovaginal atrophy.

Methods

112 menopausal women were recruited. All women with VVA were treated by using Fractional CO₂ laser; power 30 W 1-3 stacks with 360° vaginal probe for 3 consecutive times, 4 weeks apart. Before laser treatment, the subjective measurement of VVA symptoms was evaluated by using a questionnaire and the objective measurements were evaluated by using pH paper and VMI. Visual analog pain-score was used to scaling their discomfort during and immediately after each treatment. At 3 months after the last procedure, the subjective and objective measurements were re-assessed. Any short-term and long-term adverse event recorded. Statistical analysis was performed by using SPSS program with p-value <0.05.

Results

There was a significant reduction of the VVA symptom score after laser treatment. The average percentage of pretreatment VMI was 34.7+16.1% and at one and three months after complete laser course, it was significantly increased with the mean change of 25.0+12.2% and 34.8+15.5%, respectively. For the vaginal pH, the average pH before treatment was 7.5+1.0 and the average decrement after 3 months was 0.9+1.3 with statistical significance, p-value <0.01. There were no serious complications and all were satisfied with the treatment.

Conclusions

Fractional CO₂ laser could ameliorate the VVA symptoms with at least 3 months of long lasting improvement of vaginal health with safety.



The curative effect and feasibility analysis of fractional CO₂ laser in the treatment of vulvovaginal in postmenopausal women

Miao Y¹, Li J¹, Wang J¹¹: Peking University People's Hospital, Beijing - China.

ABSTRACT

Objective

This prospective study aimed to assess the curative efficacy and feasibility of fractional CO₂ laser in the treatment of vulvo-vaginal atrophy (VVA) in postmenopausal women.

Methods

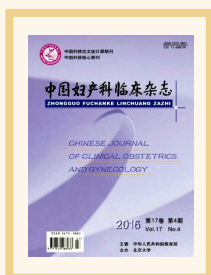
30 patients with VVA recruited in this study, fractional CO₂ laser treatment was applied, visual analogue scale (VAS) and vaginal health index score (VHIS) measures were used to assess VVA, and degree of pain before and after the treatment, additionally, satisfaction survey was done post treatment.

Results

Fractional CO₂ laser treatment was significant improved VVA symptoms (vaginal itching, 6.00±2.60 vs. 1.38±0.97, P<0.001; vaginal dryness 7.04±2.26 vs. 1.88±1.03, P<0.001; vaginal burning, 6.25±2.13 vs. 1.50±0.88, P<0.001; dyspareunia, 7.54±2.54 vs. 2.04±1.15, P<0.001), as well as the VHIS (9.79±2.76 vs. 16.33±2.06, P<0.001). Satisfaction with the laser procedure was reported by 28 women (93.33%) and a minimal discomfort was experienced at the laser application. No adverse events were recorded.

Conclusions

The fractional CO₂ laser treatment can improve the VVA symptoms in postmenopausal patients with vulvo-vaginal atrophy and was proved to be a simple, outpatient therapy for VVA patients.



The application of fractional CO₂ laser in the treatment of vulvar lichen sclerosis

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TAG

Lichen sclerosis

ABSTRACT

Objectives

To investigate the efficacy and side effects for fractional CO₂ laser in the treatment of vulvar lichen sclerosis (VLS).

Methods

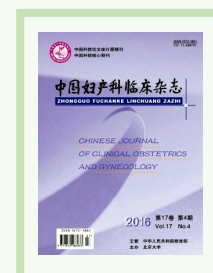
31 patients with VLS symptoms were enrolled prospectively from July 2015 to April 2016 in Peking University People's Hospital. The fractional CO₂ laser was used for VLS lesions, a total of 3-5 times, each time per-month. Visual analogue scale (VAS) was assessed the degree of vulvar pruritus, skin chapping, dyspareunia before and after treatment. After the treatment, satisfaction survey was done.

Results

The rate improvement of VLS symptoms was 90.32% (28/31) with fractional CO₂ laser ($P < 0.001$). Compare with before treatment, there were significant difference in pruritus score at the first and the third after treatment one month (8.07 ± 1.97 vs. 3.43 ± 0.94 and 1.93 ± 0.62 , $P < 0.001$), vulvar skin chapping score (3.5 ± 1.79 vs. 1.36 ± 1.22 and 0.64 ± 0.84 , $P < 0.005$), respectively. The dyspareunia score (4.29 ± 2.70 vs. 1.14 ± 0.95 , $P < 0.05$) were improved significantly at the third after treatment one month. After treatment 48h, there were 2 cases with mild pain, 6 cases with local mils hyperemia, 4 cases with mild swelling. No adverse events due to fractional CO₂ laser treatment occurred. During 3-7 months follow-up, 4 cases (12.9%) with the skin color from white to gray, 2 cases recovered sex from 6 cases. The overall satisfaction rate was 96.77% (30/31).

Conclusions

The fractional CO₂ laser is effective, minimal injury and acceptable side effects for vulvar lichen sclerosis, and may be a new treatment for it.



The effect of microablative fractional CO₂ laser on vaginal flora of postmenopausal women

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4: San Raffaele Hospital, Milan - Italy. 5: IASO General Hospital, Athens - Greece.
6: Tufts University School of Medicine, Boston, MA - USA.
7 : Alexandra Hospital", Athens - Greece.

ABSTRACT

Objectives

To assess the effect of microablative fractional CO₂ laser (MFCO₂-Laser) therapy on the vaginal microenvironment of postmenopausal women.

Methods

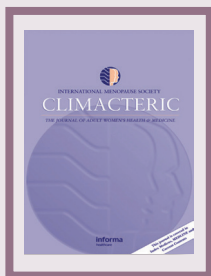
Three laser therapies at monthly intervals were applied in postmenopausal women with moderate to severe symptoms of genitourinary syndrome of menopause, pH of vaginal fluid >4.5 and superficial epithelial cells on vaginal smear <5%. Vaginal fluid pH values, fresh wet mount microscopy, Gram stain and aerobic and anaerobic cultures were evaluated at baseline and 1 month after each subsequent therapy. Nugent score and Hay-Ison criteria were used to evaluate vaginal flora.

Results

Fifty-three women (mean age 57.2±5.4 years) participated and completed this study. MFCO₂-Laser therapy increased Lactobacillus (p<0.001) and normal flora (p<0.001) after the completion of the therapeutic protocol, which decreased vaginal pH from a mean of 5.5±0.8 (initial value) to 4.7±0.5 (p<0.001). The prevalence of Lactobacillus changed from 30% initially to 79% after the last treatment. Clinical signs and symptoms of bacterial vaginosis, aerobic vaginitis or candidiasis did not appear in any participant.

Conclusions

MFCO₂-Laser therapy is a promising treatment for improving the vaginal health of postmenopausal women by helping repopulate the vagina with normally existing Lactobacillus species and reconstituting the normal flora to premenopausal status.



Microablative fractional CO₂-laser therapy and the genitourinary syndrome of menopause: An observational study

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TAG

GSM

ABSTRACT

Objective

This study aimed to assess the effect of the Microablative Fractional CO₂ Laser (CO₂-laser) therapy on vaginal pathophysiology and the symptoms of the Genitourinary Syndrome of Menopause (GSM).

Methods

Postmenopausal women with moderate to severe symptoms of GSM underwent three sessions of CO₂-laser therapy at monthly intervals. Participants were evaluated at baseline and 4 weeks after the last treatment.

Main Outcome Measures

The primary outcomes were Vaginal Maturation Value (VMV) and Vaginal Health Index Score (VHIS). Secondary outcomes included symptoms of GSM, Female Sexual Function Index (FSFI), International Consultation on Incontinence Questionnaire of Female Urinary Tract Symptoms (ICIQ-FLUTS) and Urinary Incontinence Short Form (ICIQ-UI SF), Urogenital Distress Inventory (UDI-6) and King's Health Questionnaire (KHQ).

Results

Fifty-three postmenopausal women completed this study. VMV, VHIS and FSFI increased significantly. Dyspareunia, dryness, burning, itching, dysuria, frequency, urgency, urgency incontinence, stress incontinence and scores on the ICIQ-FLUTS, ICIQ-UI SF, UDI-6 and KHQ decreased significantly. Factors predicting for which women the CO₂-laser therapy was more effective were not identified.

Conclusion

This study suggests that intravaginal CO₂-laser therapy for postmenopausal women with clinical signs and symptoms of GSM may be effective in improving both vaginal pathophysiology and reported symptoms.



Fractional CO₂ laser treatment: A novel approach for stress urinary incontinence management in post-menopausal women

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ABSTRACT

Objective

To describe the results of the fractional CO₂ laser as an alternative treatment for stress urinary incontinence in post-menopausal women, and to demonstrate an improvement in quality of life after the treatment.

Materials and Methods

A prospective, single centre descriptive study was conducted on 10 post-menopausal patients with diagnosis of stress urinary incontinence. Recruited patients were evaluated with Stress Cough test and urethral Mobility Q-Tip Test, which confirmed the diagnosis. They then began a 3 session treatment protocol; 1 every 3 weeks using the SmartXide² V²LR fractional microablative CO₂ laser system for the MonaLisa TouchTM procedure in the urethrovesical junction. The Urogenital Distress Inventory UDI-6 was performed to evaluate severity and quality of life impact related to stress urinary incontinence in the patients included in the study, before and after treatment. Patients were monitored from July to December 2013.

Results

Analysis of the UDI-6 Scores before and at the end of treatment showed an improvement in the score in comparison to the baseline condition, indicating a subjective improvement in all the symptoms related to SUI included in the score.

Conclusions

The MonaLisa TouchTM procedure performed with SmartXide² V²LR laser system is a complementary alternative to traditional surgical techniques, providing a safe and effective treatment for urinary incontinence in post-menopausal women.



Fractional CO₂ laser treatment of the vestibule for patients with vestibulodynia and genitourinary syndrome of menopause: A pilot study

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TAG

**Vestibulodynia
GSM**

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 CO₂ 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 CO₂ 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 CO₂ 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 CO₂ 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 CO₂ laser treatment of the vestibule in women with vestibulodynia and genitourinary syndrome of menopause.



Fractional CO₂ laser treatment for vaginal atrophy and vulvar lichen sclerosis

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University of California, San Francisco, CA - USA.

ABSTRACT

Objectives

The aim of this research was to assess the efficacy of fractional CO₂ laser energy for treating vaginal atrophy and lichen sclerosis.

Materials and Methods

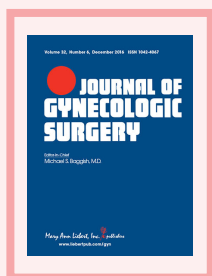
The first study population was 23 postmenopausal women diagnosed with vaginal atrophy via microscopic evaluation and who were symptomatic. The second study population was 27 postmenopausal women diagnosed with lichen sclerosis by biopsy and who were symptomatic. Patients with vaginal atrophy had 3 treatment sessions spaced at 4–6 weeks between each session. Laser settings for this group were: power: Watts, 30; time, 1000 microseconds; and spacing, 1000 micrometers. For the lichen sclerosis group, the power was set at 20 Watts and 3–4 treatments were given at 4–6-week intervals.

Results

In the vaginal atrophy cohort, 22/23 women who previously complained of dryness and discomfort had these symptoms alleviated and vaginal microscopic exam showed significant changes in color, elasticity, and wetness following 3 courses of CO₂ laser fractional treatment; additionally 20/23 women had elimination of urinary frequency and urgency, 18/21 women had alleviation of dyspareunia. In the lichen sclerosis cohort 24/27 patients who had laser treatment reported cessation of itching and pain/discomfort; and 26/27 women demonstrated visible improvement of skin color, elasticity, vascularity following 3–4 laser treatments. All examinations were performed with the operating microscope.

Conclusions

The fractional CO₂ laser beam is useful for treating vaginal atrophy and lichen sclerosis. This new technique represents a significant divergence from estrogenic-, steroid- and corticosteroid-bulwark dependence. All treatments were performed in an office setting and were associated with either no pain or, at the most, minimal and temporary discomfort. This new use of the CO₂ laser is an excellent alternative for managing these two troublesome problems, particularly in postmenopausal women.



Fractional CO₂ laser: From skin rejuvenation to vulvo-vaginal reshaping

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TAG

VVA

ABSTRACT

Background

The CO₂ laser has become the gold standard treatment in dermatologic surgery for the treatment of a large number of skin and mucosal lesions. The introduction of the fractional micro-ablative technology represented an integration to the ablative resurfacing technique, reducing the healing time and the side effects.

Objective

Vaginal rejuvenation performed with this technique is a minimally invasive procedure that stimulates internal tissues of the female lower genital tract to regenerate the mucosa, improving tissue trophism and restoring the correct functionality.

Methods

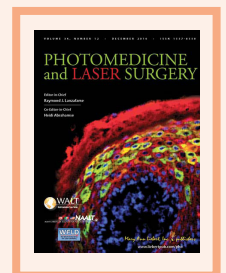
In our experience, 386 menopausal women affected with vulvo-vaginal atrophy (VVA) were treated with three section of fractional micro-ablative CO₂ laser.

Results

After three treatments, patients reported a complete improvement of the symptoms (59.94% dryness, 56.26% burn, sensation, 48.75% dyspareunia, 56.37% itch, 73.15% soreness, and 48.79% vaginal introitus pain).

Conclusions

Fractional micro-ablative CO₂ laser seems to reduce symptoms related to vaginal atrophy. The beneficial effects were reported just after the first session and confirmed 12 months after the last session.



Use of a novel fractional CO₂ laser for the treatment of genitourinary syndrome of menopause: 1-year outcomes

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ABSTRACT

Objectives

To assess safety and efficacy of a fractional CO₂ laser therapy for the treatment of genitourinary syndrome of menopause (GSM) with follow-up to 1 year posttreatment.

Methods

Women presenting with GSM and meeting inclusion criterion were enrolled. Visual Analog Scales were used to grade vaginal pain, burning, itching, dryness, dyspareunia, and dysuria. Dilators were used to rate vaginal elasticity at baseline and at each follow-up visit. Before each treatment and at follow-up, Vaginal Health Index scoring and Female Sexual Function Index questionnaires were completed. Women received three vaginal laser treatments spaced 6 weeks apart. Participant satisfaction was measured on 5-point Likert scales (1=very dissatisfied, 5=very satisfied).

Results

Of 30 women (mean age 58.6±8.8 years), three were lost to follow-up at 3 months and six at 1 year. None were discontinued or withdrew due to an adverse event. Average improvement in Visual Analog Scale scores for all symptom categories was statistically significant at 3 months and remained so through 1 year, except dysuria. Differences between data at 3 months and 1 year were not statistically significant, indicating persistence of positive outcomes. Average overall improvement in pain was 1.9 (±3.4), burning 1.9 (±3.1), itching 1.4 (±1.9), dryness 5.9 (±2.8), dyspareunia 4.9 (±3.3), and dysuria 0.9 (±3.1). Improvement in average Vaginal Health Index and Female Sexual Function Index scores was also statistically significant ($P<0.0001$). Of 19 women undergoing dilator examination at 1 year, 18 (94.8%) were comfortable with the same or larger dilator size. Twenty-two of 24 women (92%) were satisfied or extremely satisfied with the treatment at 1 year.

Conclusions

Based on study data up to 1 year, the fractional CO₂ laser may be an effective and safe treatment for women suffering from symptoms of GSM, although additional studies with larger populations and placebo control is needed to confirm these results.



Safety and long-term efficacy of fractional CO₂ laser treatment in women suffering from genitourinary syndrome of menopause

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4: The University of Adelaide - Australia. 5: Robinson Research Institute - Australia.

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TAG

GSM

Long-term follow-up

ABSTRACT

Objective

To evaluate the safety and long-term efficacy of fractional CO₂ laser treatment in reducing the severity of symptoms of genitourinary syndrome of menopause (GSM) in menopausal women.

Study Design

102 women presenting with symptomatic GSM were treated with the fractional CO₂ laser (MonaLisa Touch, DEKA) system across a series of treatments delivered at intervals of six or more weeks. The Australian Pelvic Floor Questionnaire was used to gather data on sexual function and side-effects at three time-points across the study period (prospective panel design study). Wilcoxon signed-rank tests were used to detect statistically and clinically significant changes in sexual function and side-effects occurring from pre- to post-treatment. The primary outcome of this study was an improvement of the symptoms of GSM. The secondary outcome included bladder function and prolapse symptoms.

Results

A total of 102 women suffering from moderate to severe GSM were recruited. Eighty-four percent experienced significant improvement in their symptoms after CO₂ laser treatment. Scores on measures of sexual function, dyspareunia, and bothersomeness of sexual issues were improved from pre-treatment to long-term (12–24 month) follow-up. Furthermore, there were improvements on measures of bladder function ($P = 0.001$), prolapse ($P = 0.001$), vaginal sensation ($P = 0.001$), vaginal lubrication ($P < 0.001$) and urge incontinence ($P = 0.003$) from the pre-treatment assessment to the second assessment (i.e. after the third treatment).

Conclusions

In this study, fractional microablative CO₂ laser treatment was associated with an improvement in symptoms of GSM and sexual function.



Fractional CO₂ laser therapy: A new challenge for vulvovaginal atrophy in postmenopausal women

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ABSTRACT

Objectives

To evaluate the effects of CO₂ laser in the treatment of vulvovaginal atrophy (VVA) in postmenopausal women.

Methods

VVA was assessed in 87 postmenopausal women (mean age 58.6 ± 6.9 years) before and after the treatment. The protocol consisted of three monthly treatments and included the treatment of vulva. Subjective measures included VAS (Visual Analog Scale) both for vaginal dryness and dyspareunia; DIVA (Day-by-day Impact of Vaginal Aging); a questionnaire on treatment satisfaction and one about the degree of pain during the procedure. Objective measures included VHI (Vaginal Health Index) and VVHI (Vulvo-Vaginal Health Index). Time points of the study were at the screening visit (T0), at baseline (T1), at week 4 (T2), at week 8 (T3), after 3 months since the last laser application (T4), after 6 months (T5), after 9 months (T6), after 12 months (T7) and after 15 months (T8).

Results

Treatment induced significant improvement in the VAS score. After treatment, VHI and VVHI indicated no VVA and this improvement was long lasting. Multivariate analysis showed that the time of follow-up was correlated with better VHI and VVHI ($p < 0.001$). DIVA improved over time ($p < 0.001$).

Conclusions

This study shows that CO₂ laser treatment induces a significant and long-lasting improvement of symptoms.



Long-term effect of thermoablative fractional CO₂ laser treatment as a novel approach to urinary incontinence management in women with genitourinary syndrome of menopause

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3: Medical Centre Nowe Orłowo, Gdynia - Poland. 4: Technological University of Pereira, Pereira - Colombia.

TAG

SUI

Menopause

Long-term follow-up

Histological examination

ABSTRACT

Introduction and Hypothesis

The aim of this study was to evaluate the long-term effect of thermoablative fractional CO₂ laser (TACO2L) as an alternative treatment for early stages of stress urinary incontinence (SUI) in postmenopausal women with genitourinary syndrome of menopause.

Methods

A total of 161 postmenopausal patients (age 53.38 ± 5.1 years, range 45-65 years) with a clinical diagnosis of mild SUI were prospectively enrolled in the study. Patients received one treatment with TACO2L every 30-45 days, each treatment comprising four sessions, followed in all patients by a yearly treatment session at 12, 24 and 36 months. SUI was evaluated using the International Continence Society 1-h pad test and the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) before and after TACO2L treatment.

Results

TACO2L treatment was associated with a significant improvement in ICIQ-UI SF scores and 1-h pad weight test at 12 months (both p < 0.001), 24 months (both p < 0.001) and 36 months (both p < 0.001). Improvements were maintained for up to 36 months without the need for any further intervention. The results were confirmed by significant histological changes related to trophic restoration of the vagina, responsible for extrinsic and intrinsic mechanisms involved in urinary continence.

Conclusions

Our results suggest that TACO2L is an efficient and safe novel treatment strategy in patients with mild SUI. Further investigation to confirm the long-term results presented here is still warranted.



Laser therapy for the genitourinary syndrome of menopause. A systematic review and meta-analysis

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2: Alfa Institute of Biomedical Sciences (AIBS), Athens - Greece. Henry-Dunant Hospital Center, Athens - Greece.
3: Tufts University School of Medicine, Boston, MA - USA. 4: San Raffaele Hospital, Milan - Italy.

ABSTRACT

This study aimed to identify and then synthesize all available data regarding the efficacy of laser therapy for postmenopausal women with genitourinary syndrome of menopause (GSM) with/without urinary incontinence (UI). PubMed, Scopus, Web of Science, Cochrane Library and ClinicalTrials.gov were searched in October 2016. The keywords were "laser genitourinary syndrome of menopause", "laser vulvovaginal atrophy", "laser vaginal atrophy" and "laser women incontinence".

Quality of reporting and risk of bias of the included studies were assessed according to STROBE and MINORs checklists, respectively. Quality of the body of evidence was evaluated with the GRADE approach.

Fourteen studies involving 542 participants were included in this systematic review and meta-analysis. All GSM symptoms (dryness/dyspareunia/itching/burning/dysuria/urgency/frequency) and UI decreased significantly and consistently in all available publications. The pooled mean differences for the various symptoms were: dryness $-5.5(95\%CI:-6.7,-4.4;7\text{studies};I^2:0\%)$, dyspareunia $-5.6(95\%CI:-6.8,-4.5;7\text{studies};I^2:0\%)$, itching $-4(95\%CI:-5.7,-2.2;6\text{studies};I^2:79\%)$, burning $-3.9(95\%CI:-5.9,-2;6\text{studies};I^2:87\%)$, dysuria $-2.9(95\%CI:-5.1,-0.7;4\text{studies};I^2:90\%)$ and UI $-4.9(95\%CI:-6.4,-3.4;2\text{studies};I^2:0\%)$. Because urgency/frequency was assessed by different methodologies the data could not be meta-analyzed. Furthermore, KHQ, UDI-6, MCS12/PCS12, FSFI, overall sexual satisfaction and measurements of the effect of laser therapy on the local pathophysiology improved significantly.

In conclusion, laser therapy for postmenopausal women with GSM appears promising. It may reduce symptom severity, improve quality of life of postmenopausal women and restore the vaginal mucosa to premenopausal status. However, the quality of the body of evidence is "low" or "very low" and, thus, evidence-based modification of current clinical practice cannot be suggested.



CO₂-laser for the genitourinary syndrome of menopause. How many laser sessions?

TAG

GSM

Athanasίου S¹, Pitsouni E¹, Falagas ME^{2,3},
Salvatore S⁴, Grigoriadis T¹

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ABSTRACT

Objectives

The aim of this prospective study was to assess the efficacy of 3, 4 or 5 CO₂-laser sessions for the management of the genitourinary syndrome of menopause (GSM).

Methods

Postmenopausal women with moderate to severe symptoms of dyspareunia, wanting to resume/retain sexual activity, were treated with 3–5 laser sessions depending on symptom severity/presence, sexual function, clinical findings and women's preference following the third laser application.

Main Outcomes

Severity of dyspareunia, dryness, sexual function, sexual satisfaction and frequency of sexual intercourse defined the primary outcomes. Vaginal Maturation Value (VMV) and Vaginal Health Index Score (VHIS) defined the secondary ones.

Results

Fifty-five women received three sessions, 53 an extra fourth and 22 an extra fifth. Following the third, fourth and fifth laser sessions, respectively: dyspareunia completely regressed in 15/55 (27%), 32/55 (58%) and 38/47 (81%) of participants; dryness completely regressed in 20/55 (36%), 36/55 (66%) and 44/51 (86%); normal sexual function resumed in 23/55 (41%), 37/54 (69%) and 41/49 (84%); VMV regained non-atrophic values in 29/55 (53%), 38/55 (69%) and 42/50 (84%); and VHIS regained non-atrophic values in 44/55 (80%), 53/55 (96%) and 55/55 (100%) of participants.

Conclusion

Results of this study indicate that CO₂-laser therapy may contribute to complete regression of dyspareunia and dryness and reestablishment of normal sexual function in postmenopausal women, in a dose-response manner. An extra fourth or fifth session may further increase the GSM symptom-free rate.



Re: "Safety and long-term efficacy of fractional CO₂ laser treatment in women suffering from genitourinary syndrome of menopause"

Louis-Vahdat C¹, Gaucher S²

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2 : Université Paris Descartes; Hôpital Cochin, Paris - France.

EXCERPT

In Reply

[...] The results of this single-centre study are very encouraging, especially in view of the scarcity of the literature about GSM treatment by vaginal laser. We would like to share our experience and difficulties and discuss some points raised by this study. [...] Our patients are very motivated; none has been lost to follow-up. However, the use of laser treatment is still limited, perhaps because it is not yet widely known by women, but probably more because laser treatments are not currently covered in France by the national health insurance fund. Further research is needed to assess safety and effectiveness of this innovative treatment in correctly selected patients. [...]



Randomized, double-blind, placebo-controlled clinical trial for evaluating the efficacy of fractional CO₂ laser compared with topical estriol in the treatment of vaginal atrophy in postmenopausal women

Cruz VL, Steiner ML, Pompei LM, Strufaldi R, Fonseca FLA, Santiago LHS, Wajsfeld T, Fernandes CE

ABC School of Medicine, São Bernardo do Campo, São Paulo - Brazil.

TAG

Vaginal atrophy

Menopause

**Randomized, double-blind,
placebo-controlled clinical trial**

Topical estriol

ABSTRACT

Objective

The aim of the study was to evaluate efficacy of fractional CO₂ vaginal laser treatment (Laser, L) and compare it to local estrogen therapy (Estriol, E) and the combination of both treatments (Laser + Estriol, LE) in the treatment of vulvovaginal atrophy (VVA).

Methods

A total of 45 postmenopausal women meeting inclusion criteria were randomized in L, E, or LE groups. Assessments at baseline, 8 and 20 weeks, were conducted using Vaginal Health Index (VHI), Visual Analog Scale for VVA symptoms (dyspareunia, dryness, and burning), Female Sexual Function Index, and maturation value (MV) of Meisels.

Results

Forty-five women were included and 3 women were lost to follow-up. VHI average score was significantly higher at weeks 8 and 20 in all study arms. At week 20, the LE arm also showed incremental improvement of VHI score ($P=0.01$). L and LE groups showed a significant improvement of dyspareunia, burning, and dryness, and the E arm only of dryness ($P<0.001$). LE group presented significant improvement of total Female Sex Function Index (FSFI) score ($P=0.02$) and individual domains of pain, desire, and lubrication. In contrast, the L group showed significant worsening of pain domain in FSFI ($P=0.04$), but FSFI total scores were comparable in all treatment arms at week 20.

Conclusions

CO₂ vaginal laser alone or in combination with topical estriol is a good treatment option for VVA symptoms. Sexual-related pain with vaginal laser treatment might be of concern.



Microablative fractional CO₂ laser for the genitourinary syndrome of menopause: Power of 30 or 40 W?

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ABSTRACT

This retrospective case-control study aimed to compare 30 versus 40 W power of CO₂ laser for the therapy of genitourinary syndrome of menopause (GSM). Postmenopausal women with severe intensity of dyspareunia and dryness were eligible to be included in this study. Primary outcomes were dyspareunia and dryness. Secondary outcomes were itching/burning, dysuria, frequency and urgency, Female Sexual Function Index (FSFI), vaginal maturation value (VMV), and Vaginal Health Index Score (VHIS).

One laser therapy was applied every month for 3 months. Outcomes were evaluated at baseline and 1 month following the 3rd therapy. Fifty (25 per group) women were included in this study. In the 30-W group, mean improvement of dyspareunia, dryness, itching/burning, FSFI, VMV, and VHIS was 6.1 ± 1.7 , 6.0 ± 1.9 , 5.9 ± 2.0 , 16.6 ± 6.7 , 29.9 ± 13.0 , and 11.0 ± 2.9 , respectively (within group comparisons all $p < 0.001$). In the 40-W group, mean improvement of dyspareunia, dryness, itching/burning, FSFI, VMV, and VHIS was 6.1 ± 1.7 , 6.5 ± 2.0 , 5.2 ± 2.5 , 14.8 ± 7.1 , 25.0 ± 13.4 , and 10.5 ± 4.1 , respectively (within-group comparisons, all $p \leq 0.001$).

Comparison between 30 and 40 W revealed that mean improvement or presence of all GSM symptoms and clinical signs was not statistically significant different. CO₂ laser therapy may improve GSM symptoms and clinical signs. This improvement did not seem to associate to power of 30 or 40 W.



Sexual function in women suffering from genitourinary syndrome of menopause treated with fractionated CO₂ laser

TAG

GSM

**Sexual function
Review**

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ABSTRACT

Introduction

Genitourinary syndrome of menopause (GSM) has a significant impact on the trophism of the genital and lower urinary tracts and can considerably impair sexual function. Fractional CO₂ laser has a regenerative effect on vulvovaginal tissue trophism after menopause.

Aim

To review the available literature on the effect of fractional CO₂ laser on the sexual function of postmenopausal women affected by GSM.

Methods

A database search was carried out using the terms CO₂ laser, vaginal atrophy, sexual function, dyspareunia, and genitourinary syndrome of menopause and excluding studies using other types of laser or including breast cancer survivors with vulvovaginal atrophy. For statistical analysis, the estimated overall laser effect was computed (when at least two studies were involved) and data type of generic inverse variance was computed using inverse variance as the statistical method, a random-effects model, and the difference in means as an effect measurement.

Main Outcome Measures

Different methods of evaluating sexual function were reported and studies were grouped and analyzed accordingly. Subjective assessment for dyspareunia was evaluated with a 10-point visual analog scale. Patient-reported outcome for an overall perception of sexual function was evaluated with a Likert scale. The Female Sexual Function Index was used as a condition-specific questionnaire.

Results

Six articles were considered for this review. A total of 273 women (mean age = 57.8 years) were treated with the same protocol in all studies. Compared with baseline, at the end of the treatment, dyspareunia significantly decreased in severity ($P < .001$), and the patient's perception of overall sexual function showed a statistically significant improvement ($P < .001$). At the last follow-up visit, the Female Sexual Function Index score for each single domain and overall score was significantly better than at entry ($P < .001$).

Conclusion

Fractional CO₂ laser can improve sexual function in postmenopausal women affected by GSM by restoring a better trophism in the lower genitourinary tract



Long-term reliability of fractioned CO₂ laser as a treatment for vulvovaginal atrophy (VVA) symptoms

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ABSTRACT

Purpose

The aim of this study was to evaluate long-term effects of the fractional CO₂ laser for the treatment of vulvovaginal atrophy (VVA) symptoms.

Methods

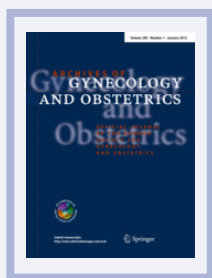
Women presenting with VVA symptoms and meeting inclusion criterion were enrolled to fractioned CO₂ laser therapy. Patient's satisfaction was measured on five-point Likert scale at 4 weeks and 6, 12, 18, 24 months after treatment by interview and clinical examination for vaginal livability.

Results

184 patients constituted the final study group: 128 women were spontaneous menopause and 56 were oncological menopause. 117 women were nulliparous and 36 had previous hysterectomy. 95.4% (172/184) of the patients declared that they were satisfied or very satisfied with the procedure at 4 weeks after treatment. At 6 months 92% (170/184) patients were satisfied; at 12 months 72% (118/162) were satisfied; at 18 months 63% (60/94) were satisfied; at 24 months 25% (4/16) of patients answered they were still satisfied. We observed a decline in patient's satisfaction between 18 and 24 months after laser therapy. Data showed that the time interval from onset of menopause was a statistically significant factor ($p < 0.05$) for treatment satisfaction in oncological group.

Conclusions

Long-term data showed that the improvement of vaginal health may continue up to 24 months after fractional CO₂ laser treatment although between 18 and 24 months benefits decline, and approximately 80% of women decide to start a new treatment cycle of laser applications.



Fractional CO₂ laser of the vagina for genitourinary syndrome of menopause: Is the out-of-pocket cost worth the outcome of treatment?

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TAG

GSM

ABSTRACT

Objectives

The purpose of this study is to assess patient's satisfaction treatment outcomes and out-of-pocket expense for the fractional CO₂ laser (SmartXide) in the treatment of genitourinary symptoms of menopause (GSM).

Materials and Methods

A multicenter retrospective cohort study of patients who completed a course of three vaginal treatments with the SmartXide Fractional CO₂ laser. Patients contacted via telephone and asked to participate in questionnaires to evaluate for adverse outcomes since last treatment, symptom severity before and after treatment, patient satisfaction with treatment, patient satisfaction with out-of-pocket expense, and sexual function.

Results

Of the 368 patients contacted, 122 agreed to be interviewed. No patients reported seeking emergent medical treatment. Patient reported vaginal dryness significantly improved following treatment ($P < 0.05$). The frequency of intercourse increased from "once a month" to "few times a month" ($P < 0.001$). The vast majority of patients reported being satisfied with their treatment results (86%) and with the cost of treatment (78%). Satisfaction with the out-of-pocket expense did not correlate with household income ($P = 0.07$).

Conclusions

The SmartXide Fractional CO₂ laser is a safe and efficacious treatment for GSM. This treatment is associated with a high level of patient satisfaction with both treatment results and out-of-pocket expense.



Fractional microablative CO₂ laser in breast cancer survivors affected by iatrogenic vulvovaginal atrophy after failure of nonestrogenic local treatments: A retrospective study

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ABSTRACT

Objective

Vulvovaginal atrophy (VVA) is a condition frequently observed in menopause. Its symptoms can significantly affect the quality of life of patients. Since VVA is related to estrogen deficiency, chemotherapy and hormone therapy for breast cancer (BC) might cause VVA by inducing menopause. Given the lack of effective treatment for VVA in BC survivors, we retrospectively evaluated the efficacy and tolerability of fractional microablative CO₂ laser therapy in these patients.

Methods

We treated 82 BC survivors with three cycles of CO₂ laser after failure of topical nonestrogenic therapy. The severity of symptoms was assessed with a visual analog scale (VAS) at baseline and after completion of laser therapy. Differences in mean VAS scores of each symptom before and after treatment were assessed with multiple t tests for pairwise comparisons. Multivariate analyses were used to adjust the final mean scores for the main confounding factors.

Results

Pre versus post-treatment differences in mean VAS scores were significant for sensitivity during sexual intercourse, vaginal dryness, itching/stinging, dyspareunia and dysuria ($P < 0.001$ for all), bleeding ($P = 0.001$), probe insertion ($P = 0.001$), and movement-related pain ($P = 0.011$). Multivariate analyses confirmed that results were significant, irrespective of patients' age and type of adjuvant therapy.

Conclusions

This study shows that CO₂ laser treatment is effective and safe in BC patients with iatrogenic menopause. However, the optimal number of cycles to administer and the need for retreatment remain to be defined. Prospective trials are needed to compare CO₂ laser therapy with therapeutic alternatives.



Response to letter to editor

Sokol ER

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TAG

GSM

Response

EXCERPT

In Reply:

[...] Although a full discussion of the mechanism of action, safety, and efficacy of FCL for the treatment of GSM is beyond the scope of this response, the authors of this letter rightly raise some important issues surrounding this emerging therapy. I agree that FCL is being heavily marketed and patients often do not have accurate information with which to base a decision regarding proceeding with treatment. Unfortunately, FCL is not covered by insurance, so patients have to pay out of pocket. I hope this changes in the future. I agree that many physicians and health practitioners are beginning to offer this treatment, with minimal experience regarding the technical aspects of the therapy as well as a lack of understanding of mechanism of action and scientific validity of effectiveness. We are indeed in the hype cycle and quickly approaching the “peak of inflated expectation” (https://en.wikipedia.org/wiki/Hype_cycle), with numerous other energy sources now being marketed with minimal to no data. As the proverbial saying goes, the only way to go is down from here.

So what is the best way forward? We will get to that. But first, a brief response to the three reported cases highlighting possible “severe” adverse side effects to FCL in this article:

Case 1: A 53-year-old woman reported intense itching after a second FCL treatment for vaginal atrophy, but was found to have a vaginal infection, which was treated with antibiotics. She carries a diagnosis of interstitial cystitis and had undergone chemotherapy for breast cancer.

Although it is very possible that her itching is related to the FCL treatment, she has some confounding factors that may have contributed to her symptomatology including progressive atrophy, possible adverse reaction to a medication she may have been taking, and a vaginal infection. This case highlights the importance of proper patient selection for FCL therapy. In our studies, we did not see any major adverse events (including itching), but patients were carefully screened to ensure they were appropriate candidates and did not have confounding health conditions. [...]



Early regenerative modifications of human postmenopausal atrophic vaginal mucosa following fractional CO₂ laser treatment

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ABSTRACT

Background

Postmenopausal women experience undesired symptoms that adversely affect their quality of life. In the recent years, a specific 12 - week fractional CO₂ laser treatment has been introduced, with highly significant relief of symptoms.

Aim

The aim of this paper is the identification of the early modifications of structural components of atrophic vaginal mucosa induced by laser irradiation, which is responsible for the restorative processes.

Materia and Methods

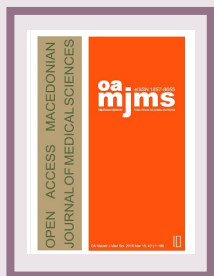
We investigated by microscopical, ultrastructural and biochemical methods the modifications of the structural components of postmenopausal atrophic vaginal mucosa tissues after 1 hour following a single fractional laser CO₂ application.

Results

In one hour, the mucosal epithelium thickens, with the maturation of epithelial cells and desquamation at the epithelial surface. In the connective tissue, new papillae indenting the epithelium with newly formed vessels penetrating them, new thin fibrils of collagen III are also formed in a renewed turnover of components due to the increase of metalloproteinase - 2. Specific features of fibroblasts support stimulation of their activity responsible of the renewal of the extracellular matrix, with an increase of mechanical support as connective tissue and stimulation of growth and maturation to epithelium thanks to new vessels and related factors delivered.

Conclusion

We found the activation of regenerative mechanisms expressed both in the connective tissue - with the formation of new vessels, new papillae, and new collagen - and in the epithelium with the associated thickening and desquamation of cells at the mucosal surface.



Fractional CO₂ laser for genitourinary syndrome of menopause in breast cancer survivors: Clinical, immunological, and microbiological aspects

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TAG

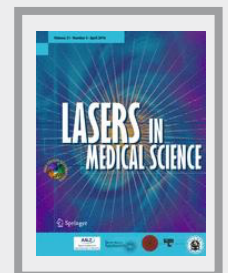
GSM

Oncological menopause

Breast cancer survivors

ABSTRACT

The composition of vaginal microbiome in menopause and cancer survivor women changes dramatically leading to genitourinary syndrome of menopause (GSM) in up to 7% of patients. Recent reports suggest that laser therapy may be valuable as a not hormonal therapeutic modality. The aim of the present study was to evaluate the effects of fractional CO₂ laser treatment on the vaginal secretory pathway of a large panel of immune mediators, usually implicated in tissue remodeling and inflammation, and on microbiome composition in postmenopausal breast cancer survivors. The Ion Torrent PGM platform and the Luminex Bio-Plex platform were used for microbiome and immune factor analysis. The significant reduction of clinical symptoms and the non-significant changes in vaginal microbiome support the efficacy and safety of laser treatment. Moreover, the high remodeling status in vaginal epithelium is demonstrated by the significant changes in inflammatory and modulatory cytokine patterns. Laser therapy can be used for the treatment of GSM symptoms and does not show any adverse effects. However, further studies will be needed to clarify its long-term efficacy and other effects.



Sexual function

Oncological menopause

Breast cancer survivors

Natural Menopause

The effects of fractional microablative CO₂ laser therapy on sexual function in postmenopausal women and women with a history of breast cancer treated with endocrine therapy

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ABSTRACT

Purpose

To examine the outcomes of sexual function in postmenopausal women and women with a history of breast cancer treated with endocrine therapy who were experiencing the symptoms of GSM for which they were treated with fractional microablative CO₂ laser.

Methods

From July 2015 to October 2016, a retrospective chart review of women who underwent fractional microablative CO₂ laser therapy (MonaLisa Touch, DEKA) for GSM was conducted. Several validated questionnaires were used to assess changes in symptoms and sexual function including the Female Sexual Function Index (FSFI), the Wong-Baker Faces Scale (WBFS), and the Female Sexual Distress Scale-Revised (FSDSR). Comparisons of mean symptom scores were described at baseline and six weeks after each treatment.

Results

There was a statistically significant improvement in every domain of FSFI, WBFS, and FSDS-R when comparing baseline symptom scores to after treatment three symptom scores for all patients. The secondary outcome was to evaluate the differences, if any, in outcomes of sexual function between postmenopausal women and women with a history of breast cancer treated with endocrine therapy. Both groups had statistically significant improvements in many domains studied.

Conclusions

Fractional microablative CO₂ laser therapy (MonaLisa Touch, DEKA) is an effective modality in treating the symptoms of GSM in postmenopausal women and women with a history of breast cancer treated with endocrine therapy.



CO₂ laser for the treatment of vaginal symptoms of genitourinary syndrome of menopause

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TAG

**GSM
Review**

ABSTRACT

Genitourinary syndrome of menopause (GSM) brings together a collection of signs including vaginal dryness, burning sensation and itching discomfort as well as deterioration of sexual health, dysuria, urgenturia and repeated urinary infections and may be responsible for a significant impairment of quality of life in symptomatic postmenopausal women. The management of GSM therefore represents a public health issue. Systemic or local hormonal treatments are frequently offered, as well as non-hormonal treatments. The existence of contraindications to hormonal treatments and the constraints of using local treatments lead us to propose other therapeutic options. CO₂ LASER is now part of the therapeutic arsenal for the treatment of vaginal dryness in the context of GSM. There is a growing interest in this technique, especially for women who have a contraindication to hormonal therapy, as it is a globally effective, long-acting alternative with very little adverse effect. Current evidence suggests that this tool could provide a quality of life benefit to many patients with minimal side effect exposure, if used in the respect of its indications and implementation protocols. However, clinical data based on high-level therapeutic trials remain absolutely essential for this treatment to be validated and recommended by health professionals.



Microablative fractional CO₂ laser for the genitourinary syndrome of menopause: Up to 12-month results

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ABSTRACT

Objectives

The aim of this study is to assess the efficacy of microablative fractional CO₂ laser therapy for genitourinary syndrome of menopause (GSM) management, when three, four, or five laser therapies were applied in a follow-up period of 12 months.

Methods

Retrospective study evaluating GSM symptoms at baseline, and 1, 3, 6, and 12 months after last laser therapy. Visual analog scale, International Consultation on Incontinence Questionnaires- Female Urinary Tract Symptoms, International Consultation on Incontinence Questionnaires-Urinary Incontinence Short Form, Urogenital Distress Inventory-6, and Female Sexual Function Index were used for assessment of GSM symptoms' intensity or bothering and parameters of sexual function.

Results

Overall, 94 women were included (35, 35, and 24 received three, four, and five therapies, respectively). All GSM symptoms improved statistically significantly. Intensity of dyspareunia and dryness decreased from 9 (5-10) (median [minimum-maximum]) and 8 (0-10) at baseline to 0 (0-6) and 0 (0-8), 1 month after last laser therapy (all $P < 0.001$), respectively. FSFI and frequency of sexual intercourse increased from 10.8 (2-26.9) and 1 (0-8) at baseline to 27.8 (15.2-35.4) and 4 (2-8) 1 month after last laser therapy (all $P < 0.001$), respectively. The positive laser effect remained unchanged throughout the 12 months of follow-up. The same pattern was followed for symptom-free rates. Four or five laser therapies may be superior in lowering the intensity of GSM symptoms in comparison to three laser therapies, in short and long-term follow-up. Differences between four and five laser therapies were not found.

Conclusions

Laser therapy may provide significant improvement and/or absence of GSM symptoms up to 12 months follow-up, irrespectively to the number of laser therapies applied. Symptoms intensity 1 month after last laser therapy may be indicative of GSM symptoms intensity at 12 months. One month after third laser therapy is the critical time to decide whether treatment extension should be offered.



How i do? a treatment with fractional CO₂ laser for vulvovaginal atrophy symptoms in menopausal women

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1: Hôpital Universitaire Pitié-Salpêtrière-Charles-Foix, Paris - France. 2: Private Office, Paris - France.

TAG

GSM

ABSTRACT

Objectives

The objective of this article is to describe the physical principles and technical methods of using a CO₂ fractional LASER. The parameters discussed are those available on the DEKA Mona Lisa Touch device of which we have experience.

Methods

Materials used are : protective eyewear ; LASER source ; probes: different probes are available depending on the area to be treated, the extent of vaginal atrophy, the caliber of the probe and the type of treatment. the area to be treated, the extent of vaginal atrophy, the calibre of the vagina. of the vagina. The practitioner, his assistants and the patient must systematically wear the protective goggles before turning on the device. The LASER device is locked annually with a security key. The vaginal probe or handpiece is then connected to the LASER source and to a ventilation system. The different operating parameters of the vaginal LASER are selected manually on the device.

Conclusions

Provided that it is used under rigorous conditions and in accordance with its indications, fractional vaginal LASER with CO₂ seems to constitute an effective treatment modality, well tolerated, and without major complications. This strategy has been developed over the last few months and seems to bring an improvement in symptoms, in particular for women with a contraindication to hormonal treatments.



Fractional CO₂ laser for treatment of stress urinary incontinence

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ABSTRACT

Objectives

To evaluate the impact of trans-vaginal fractional CO₂ laser treatment on symptoms of stress urinary incontinence (SUI) in women.

Study Design

Women clinically diagnosed with SUI preferring non-surgical treatment were recruited to the study. Fractional CO₂ laser system (MonaLisa T, DEKA) treatments were administered trans-vaginally every 4-6 weeks for a total of three treatments. Response to treatment was assessed at baseline (T1), at 3 months after treatment completion (T2) and at 12-24-month follow-up (T3) using the Australian Pelvic Floor Questionnaire (APFQ). The primary outcome was changes in reported symptoms of SUI. Secondary outcomes assessed included bladder function, urgency, urge urinary incontinence (UUI), pad usage, impact of urinary incontinence on quality of life (QOL) and degree of bothersome bladder.

Results

Fifty-eight women were recruited and received the study treatment protocol. Eighty-two percent of participants reported an improvement in symptoms of SUI at completion of treatment (mild to no SUI) ($p = <0.01$). Treatment effect waned slightly when assessed at follow-up. Nevertheless, 71% of participants reported ongoing improvement in SUI symptoms at 12-24 months ($p < 0.01$). All secondary outcome measures were improved after treatment compared to baseline.

Conclusions

This study suggests that fractional CO₂ laser is a safe, feasible, and beneficial treatment for SUI and may have a role as a minimally-invasive alternative to surgical management.



Fractional CO₂ laser versus promestriene and lubricant in genitourinary syndrome of menopause: A randomized clinical trial

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TAG

GSM

**Randomized clinical trial
CO₂ laser vs. promestriene
CO₂ laser vs. lubricant**

ABSTRACT

Objectives

The aim of this study was to compare the effects of fractional CO₂ laser therapy, promestriene, and vaginal lubricants on genitourinary syndrome treatment and sexual function in postmenopausal women.

Methods

We performed a randomized clinical trial including 72 postmenopausal women over the age of 50 years. The women were randomized into three intervention groups to receive one of the following treatments: three sessions of intravaginal fractional CO₂ laser therapy; 10mg of intravaginal promestriene cream 3 times a week; and vaginal lubricant application alone. Vaginal maturation, Vaginal Health Index (VHI) score, and Female Sexual Function Index (FSFI) were evaluated at baseline and after 14 weeks of therapy.

Results

We observed an improvement in the vaginal elasticity, volume, moisture, and pH in the CO₂ laser and promestriene groups. The VHI score at 14 weeks was higher in the CO₂ laser group (mean score 18.68) than in the promestriene (15.11) and lubricant (10.44) groups (P < 0.001). Regarding vaginal maturation, basal cells were reduced and superficial cells were increased after treatment. This improvement was more significant in the CO₂ laser group (P < 0.001). The FSFI score only showed improvement in the desire and lubrication domains in the CO₂ laser group. There were no differences in total FSFI score among the three treatment groups. There were no adverse effects associated with any of the treatments.

Conclusions

The use of fractional CO₂ laser therapy to treat genitourinary syndrome resulted in better short-term effects than those of promestriene or lubricant with respect to improving the vaginal health in postmenopausal women.



Efficacy of fractional CO₂ laser in the treatment of genitourinary syndrome of menopause in Latin-American population: First Peruvian experience

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ABSTRACT

Objectives

This PUBA study aimed to assess the efficacy of fractional CO₂ laser in the treatment of genitourinary syndrome of menopause (GSM).

Methods

GSM symptoms were assessed before, 1 month after the first session and 1 month after the third session of laser (3 sessions with a 30 days interval between them) in 60 women (median, interquartile range: 55, 49-69). Subjective (visual analog scale) and objective (Vaginal Health Index, VHIS; Vaginal Maturity Index/Frost Index; Spanish Overactive Bladder Questionnaire-Short Form, USMEX Spanish OAB-qSF and Female Sexual Function Index, FSFI) measures were used during the study period to assess CO₂ fractionated laser treatment outcomes compared to baseline.

Results

Fractional CO₂ laser treatment was effective to improve GSM symptoms (vaginal dryness, vaginal itching, vaginal burning, dyspareunia, dysuria, urinary urgency; $P < 0.001$) after three sessions, as well as VHIS (median, interquartile range: 13, 10-15 at baseline vs. 21, 20-23 at the fourth month follow up; $P < 0.001$), Frost Index (median, interquartile range: 28, 24-31 at baseline vs. 8, 6-10 at the fourth month follow up; $P < 0.001$), USMEX (median, interquartile range: 56, 46-68 at baseline vs 14, 13-16 at the fourth month follow up: $P < 0.001$) and FSFI (median, interquartile range: 5, 2-14 at baseline vs 30, 28-32).

Conclusions

In this sample, the data suggests that fractionated CO₂ laser is an effective alternative for GSM treatment with positive outcomes that persists over time.



In response to the FDA warning about the use of photomedicine in gynecology

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3: Complejo Hospitalario Metropolitano Caja Seguro Social, Panamá, Panama.

4: Alexandra Hospital, National and Kapodistrian University of Athens, Athens - Greece.

5: University of Insubria, Varese - Italy.

6: General Secretary of the World Society of Cosmetic Gynecology, Dallas, TX - USA.

7: San Raffaele Hospital, Milan - Italy. 8: Diatros Medical Centre, Barcelona - Spain.

ABSTRACT

To alert patients and health care providers about the use of energy-based devices to perform a vaginal "rejuvenation," cosmetic vaginal procedures, or nonsurgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function, the US Food and Drug Administration (FDA) has issued a warning about the effectiveness and safety of such devices. We agree with the FDA that certain devices (laser, radiofrequency, etc.) have been marketed inappropriately for uses that are outside of their cleared or approved intended uses. We want to position ourselves in the strict training of professionals so that the indications and techniques are used in the best possible way, knowing that, similar to any medical or surgical technique, the side effects can appear in the short and long term, and should be recognized and remedied.



Effects of vulvovaginal laser therapy on postmenopausal vaginal atrophy: A prospective study

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ABSTRACT

Objectives

About 45% of healthy postmenopausal women have symptoms related to vaginal atrophy that can affect quality of life, including self-esteem and relationships. Initial studies on laser therapy for postmenopausal vaginal atrophy have shown promising results, with reduction of signs of atrophy and improved quality of sexual life. The study was designed to evaluate the viability and efficacy of laser treatment for genitourinary syndrome during menopause.

Materials and Methods

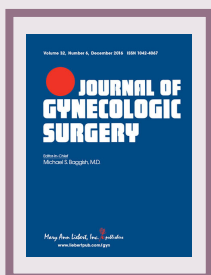
For this prospective cohort study, women with signs and symptoms of overt urogenital atrophy were enrolled between November 2014 and June 2016, after giving informed consent. A cycle of five treatments of the vagina, at 0, 1, 2, 3, and 6 months was performed using a CO₂ laser (Mona Lisa Touch® Smart Xide DOT, DEKA Laser, Florence, Italy) through a 360°-calibrated probe. Patients were evaluated for reduction of signs and symptoms, and the Gloria Bachman Vaginal Health Index was used to reassess the patients at 3- and 6-month follow ups after the last session of laser therapy. When possible, patients completed the Short Form-12 (SF-2) and Female Sexual Function Index (FSFI) questionnaires at the 6-month follow up, and satisfaction with the therapy was scored on a 5-point Likert scale.

Results

Forty-five women were recruited, of which 41 (91.1%) were postmenopausal. The average age of the patients was 59.7 years. The average time since menopause was 10.9 years. Twenty-five (55.5%) women were sexually active, and 26 (57.8%) had previous hysterectomies. Thirty-eight patients (84.4%) completed the 6-month follow-up after the fifth laser session. Twenty-seven of 30 patients (90%) with dryness who completed follow-up reported reduction of dryness, and 17 (89.5%) of the 19 patients with dyspareunia who completed follow-up reported reduction of dyspareunia. A visual analogue scale for scoring severity of symptoms and the FSFI and SF-12 questionnaires could not be used for all patients, as many of them were not well-educated and had difficulty answering the questions. There were no side-effects or complications reported, except for a few patients reporting discomfort during probe insertion and some reporting vaginal soreness.

Conclusions

Vulvovaginal laser therapy appears to be a promising option for managing genitourinary symptoms of menopause. Further randomized controlled trials with long-term follow-up data are needed before routine use of the therapy for this indication.



Letters to the editor

TAG

Letter

**Gonzalez P¹, Salvatore S², Athanasiou S³, Borrego RS⁴, Leibaschoff G⁵,
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3: National and Kapodistrian University of Athens, Athens – Greece.

4: Diatros Barcelona, Barcelona – Spain. **5:** Universidad de Buenos Aires, Buenos Aires – Argentina.

6: Complejo Hospitalario Metropolitano Caja Seguro Social Panama – Panama.

7: Nidad de Ginecoestitica Laser, Madrid – Spain. **8:** University of Insubria, Varese - Italy.

9: Academia Nacional de Medicina Colombia, Bogota - Colombia.

EXCERPT

We have read with interest the article by Gordon et al, in which four complications are reported after a vaginal procedure with CO₂ laser for the genitourinary syndrome of menopause (GSM). We have always recommended reporting any complications that occur when using any energy-based device for gynecological procedures. Although the authors admit that "...this technology shows wide utilization and excellent promise for the treatment of VVA and other conditions. ..." they also rightly say that "... providers must critically examine the evidence of efficacy, safety and adverse events." [...]



Karram M, Stachowicz A

The Christ Hospital, Cincinnati, OH - USA.

EXCERPT

We read with interest the article, "Rethinking the techno vagina: a case series of patient complications following vaginal laser treatment for atrophy," by Gordon et al, published in Volume 26, Number 4 of Menopause. We agree that laser treatment for genitourinary syndrome of menopause (GSM) is a relatively new use of this technology and should be scrutinized in regards to potential efficacy and complications and that more long-term data on this technology would be welcome. We have, however, concerns regarding how the authors define a complication. The cases described patients who presented with symptoms of GSM, had a series of laser treatments, and then continued to experience the same or perceived worsening of the same symptoms. To brand these outcomes as complications of the laser treatments is arguably an incorrect usage of the term, complication. As GSM is a clinical diagnosis where treatments have patient-derived outcomes, a lack of objective data exists to support their assumption that persistent symptoms were a direct result of the laser. We do not consider persistent urinary incontinence a complication of midurethral sling, rather it is a potential outcome. Likewise, persistent dyspareunia after vaginal laser treatment should be classified as the latter and the patients who experience persistent symptoms are either nonresponders or were not appropriate candidates to begin with. The authors had no information regarding pretreatment examinations or how the laser treatments were delivered. Since 2014, our center has utilized a fractional CO₂ laser (SmartXide Touch; DEKA, Florence, Italy) on hundreds of patients with GSM, and has published results on treatment of approximately 200 patients on research protocols. Our experience indicates that in appropriately selected patients the treatment is very safe and produces subjective success rates in the 85% range, defining success as the patient stating she was happy with the outcome and felt the out-of-pocket costs were worth the results she achieved. Furthermore, persistence of positive outcomes at 1 year has been reported. To date, there are 37 peer-reviewed publications noting favorable outcomes with minimal adverse events. [...]



Short-term efficacy of vaginal CO₂ laser therapy as a treatment modality for genitourinary syndrome of menopause

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TAG

GSM

ABSTRACT

Introduction

Genitourinary syndrome of menopause (GSM) affects up to 40-57% of postmenopausal women. Intravaginal microablative fractional CO₂ laser is a new proposal for the management of GSM, although the evidence of safety and efficacy of the procedure appears to be insufficient. Aim: The aim of the study was to assess the efficacy of fractional CO₂ laser for the treatment of GSM at the Department of Obstetrics and Gynecology of the University of Debrecen.

Method

Postmenopausal women with symptoms of GSM underwent three sessions of microablative fractional rejuvenation CO₂ laser therapy at 4-6 weeks intervals. Vaginal health index (VHI) scores were completed before each treatment and at 6 weeks follow-up as an objective measurement and visual analog scale was used to assess subjective complaints. Statistical analysis included Student's paired two-sampling t-test for the measure of statistical significance using the standard cutoff for significance $p < 0.05$.

Results

51 women participated (mean age 57.0 ± 9.9 y). Average VHI score was 14.0 ± 4.9 before treatment, 15.0 ± 4.7 after the first session, 18.2 ± 4.6 after the second treatment and 19.5 ± 4.9 at follow-up. The improvement of VHI score was statistically significant between all sessions. Average VAS score was 15.6 ± 14.1 before treatment, 9.0 ± 10.8 after the first session, 5.9 ± 9.2 after the second treatment and 3.4 ± 7.5 at follow-up. The improvement of VAS score was statistically also significant between all sessions.

Conclusions

Our study suggests that the fractional CO₂ laser is an effective and safe treatment of symptoms associated with GSM.



Case report: Treatment for rectovaginal fistula in crohn's disease using fractionate CO₂ vaginal laser with anti-TNF therapy

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Pannain GD¹, Esperança SD¹, Condé CMS³

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2: Federal University of São Paulo, Sao Paulo - Brazil. 3 : Ultrimagem, Juiz de Fora - Brazil.

ABSTRACT

Background

Rectovaginal fistulas (RVFs) are defined as any connection between the anorectum and the vagina. They can have several causes, being Crohn's disease, the second leading cause of RVFs, responsible for ~10% of the RVFs. Despite the advances in surgical and clinical treatment, there is no consensus regarding the best line of treatment.

Objective

To report another therapeutic option, we describe the case of a patient with Crohn's disease and RVF refractory to anti-tumor necrosis factor (TNF) therapy, submitted to intravaginal CO₂ fractional laser treatment.

Materials and Methods

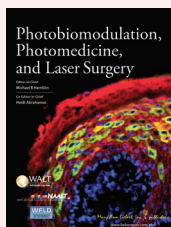
Three laser sessions with monthly interval and analysis by clinical examination, sexual evaluation questionnaire, and magnetic resonance of the pelvis were performed.

Results

We obtained an important improvement of the symptoms and of the dimension of the fistulous path.

Conclusions

We believe this method to be a complementary, promising, and safe therapeutic alternative for the management of vaginal fistula. Future studies using this therapeutic strategy are needed to confirm the efficacy of this method in this clinical setting.



Postpartum perineal pain: May the vaginal treatment with CO₂ laser play a key-role in this challenging issue?

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TAG

Postpartum perineal pain

ABSTRACT

Purpose

Pregnancy and childbirth, despite being physiological events, represent a very delicate period in a woman's life, because they expose to important vulvo-perineal traumas. The pelvic pain that follows each delivery, whether spontaneous or surgical (caesarean section), does not end in the first days after birth but, depending on the studies, becomes persistent in a very variable percentage of cases. Therefore, in the present pilot study, we aimed, for the first time in literature, to assess the efficacy of CO₂ laser in women affected by perineal postpartum symptoms.

Materials and Methods

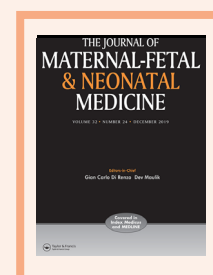
Between February 2013 and June 2018, all women with late postpartum pelvic pain referred to the Department of Obstetrics and Gynecology of San Marino Hospital, were recruited and treated using the CO₂ laser for three applications every 4-6 weeks.

Results

Between February 2013 and June 2018, according to the inclusion and exclusion criteria, 32 women with late postpartum pelvic pain were recruited in our protocol study. Mean age of patients was 34.1 years. At latest follow-up, our data demonstrated an improvement in symptoms (dyspareunia, pain at introitus, vaginal dryness, itching and vaginal burning) with a mean reduction of this symptom of 70% from baseline.

Conclusions

This study has shown the effectiveness of CO₂ laser treatment in postpartum perineal pain. Nevertheless, our results should be considered promising but preliminary. In fact, they need to be tested in larger cohort of patients to confirm its application in clinical practice and to evaluate the long-term duration of this treatment.



The effect of fractional CO₂ laser treatment on the symptoms of pelvic floor dysfunctions: Pelvic floor distress inventory-20 questionnaire

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2: Eastern Virginia Medical School, Norfolk, VA - USA.

ABSTRACT

Background and Objectives

To assess the improvement on pelvic floor distress (PFD)-related urogenital symptoms using validated questionnaires after intravaginal CO₂ laser treatment.

Study Design/Materials and Methods

Forty postmenopausal women with genitourinary symptoms of menopause (GSM) were enrolled into this prospective cohort study and underwent vaginal laser treatment using MonaLisa Touch® fractional CO₂ laser system. Patients received three vaginal laser treatments with 360° probe 4 weeks apart. A three-component Pelvic Floor Distress Inventory (PFDI-20) validated questionnaire was filled out by each patient before each session and 4 weeks after the final treatment. Wilcoxon rank sum test was used to compare the before and after treatment scores.

Results

Pelvic Organ Prolapse Distress Inventory (POPDI-6) scores were not significantly different after the first treatment compared with baseline (mean ± standard deviation [SD], 21 ± 18 vs. 17 ± 15, P = 0.44). However, each subsequent treatment resulted in further, statistically significant improvement in symptom scores (14 ± 15, P = 0.03 and 13 ± 13, P = 0.01, after the second and third treatments, respectively). Similarly, Urinary Distress Inventory (UDI-6) scores were not significantly different after the first laser treatment (mean ± SD, 36 ± 25 vs. 29 ± 23, P = 0.36). After the second and third treatments there were significant improvement in the standardized scores (24 ± 20, P = 0.03 and 22 ± 21, P = 0.01). Colorectal-Anal Distress Inventory (CRADI-8) scores did not change significantly after three laser treatments.

Conclusions

Three sessions of microablative fractional CO₂ vaginal laser treatment significantly improves patient reported urinary and pelvic organ prolapse symptoms.



Vaginal CO₂ laser for the treatment of vulvovaginal atrophy in women with breast cancer: LAAVA pilot study

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TAG

VVA

Oncological menopause

Breast cancer survivors

ABSTRACT

Purpose

Vulvovaginal atrophy (VVA) is a commonly reported issue among breast cancer patients, and its aetiology is multifactorial. Treatment is difficult in these women, particularly because the use of oestrogens has traditionally been discouraged. Vaginal laser treatment has been reported to improve symptoms. We aimed to assess the impact on symptoms and sexual function of vaginal laser in women with early breast cancer (EBC).

Methods

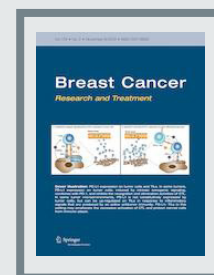
We performed a single-arm investigator initiated pilot study of female EBC patients with symptomatic VVA. A total of 3 vaginal laser treatments were administered 4 weeks apart. Questionnaires were completed at baseline, 4, 8 and 12 weeks. Our primary endpoint was symptomatic improvement of VVA at 12 weeks on 10 cm visual analogue scales. Our secondary endpoints were improvement in sexual function using the Female Sexual Function Index (FSFI) and patient-reported improvements in symptoms, sexual function and quality of life. Statistical analysis was performed with a Wilcoxon Signed Rank test.

Results

26 patients were enrolled between February 2016 and August 2017. All patients were post-menopausal, 25 of whom had received anti-oestrogen therapy for their breast cancer. Questionnaire compliance was high (98%) and all patients received the three pre-planned treatments. There was significant improvement in each of the VVA symptoms: dryness ($p < 0.001$), itch ($p < 0.001$), burning ($p = 0.003$), dysuria ($p < 0.001$) and dyspareunia ($p < 0.001$). Patients also reported improvement in sexual function on the FSFI ($p \leq 0.001$).

Conclusions

Patients receiving vaginal laser had improvement in VVA symptoms and sexual function. Further randomised sham-controlled trials are needed to further assess this treatment.



Sexual function

Oncological menopause

Breast cancer survivors

Gynecological cancer survivors

Review and meta-analysis

Intravaginal energy-based devices and sexual health of female cancer survivors: A systematic review and meta-analysis

Athanasίου S¹, Pitsouni E¹, Douskos A¹, Salvatore S²,
Loutradis D¹, Grigoriadis T¹

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ABSTRACT

A systematic review and meta-analysis was undertaken to assess the efficacy and safety of intravaginal energy-based therapies (laser and radiofrequency) on sexual health of cancer survivors (CS) (breast cancer (BCS) and/or gynecological cancer (GCS)). PubMed, Scopus, Web of Science, and Cochrane Library were searched until 21/02/2019. Quality of reporting, methodology, and body of evidence were assessed using STROBE, MINORS, and GRADE. Primary outcomes were dyspareunia, dryness, and sexual health (FSFI, FSDS-R). Secondary outcomes were burning, itching, dysuria, incontinence, Vaginal Health Index Score (VHIS), microbiome-cytokine evaluation, and adverse events. Main analyses, subgroup analyses, and sensitivity analyses were performed. Eight observational studies (n=274) were eligible for inclusion. None of the studies evaluated radiofrequency. BCS and BCS-GCS were included in 87% and 13% of studies, respectively. All primary outcomes improved significantly with the exception of FSDS-R (dyspareuniaudies (n=233), standardized mean difference (StdMD) (-1.17), 95%CI [-1.59, -0.75]; p<0.001; I² =55%), vaginal dryness (4 studies (n=183), StdMD (-1.98), 95%CI [-3.31, -0.65]; p=0.003; I² =91%), FSFI (2 studies, n=28, MD (12.79), 95%CI [7.69, 17.89]; p<0.001; I² =0%). Itching, dysuria, and VHIS increased significantly, while burning was not improved. Serious adverse events were not observed by any of the studies. Intravaginal laser therapies appear to have a positive effect on dyspareunia, vaginal dryness, and FSFI of CS. However, the quality of evidence is “very low,” with no data on intravaginal radiofrequency therapy. Further research with high-quality RCTs and long-term follow-up is needed to evaluate the value of energy-based devices as a therapeutic option for CS with sexual problems.



Laser users' expert opinion in response to "The clinical role of laser for vulvar and vaginal treatments in gynecology and female urology: An ICS/ISSVD best practice consensus document"

Salvatore S¹, Athanasious S², Yuen HTH², Karram M³

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3: The Christ Hospital, Cincinnati, OH - USA.

TAG

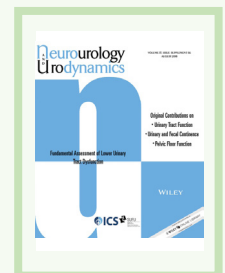
Response

EXCERPT

Letter to the editor:

We read with interest "The clinical role of LASER for vulvar and vaginal treatments in gynecology and female urology: An ICS/ISSVD best practice consensus document" by Preti et al.¹ While we welcome efforts to improve research quality in any field of our discipline, we were disappointed by the methodological confusion and incorrect statements presented. It is inappropriate to incorporate different clinical and cosmetic indications treated with LASER technology in a consensus document. The data is not presented in an impartial fashion as one would expect for a consensus document representing two prestigious societies. Examples of inappropriate and inaccurate statements regarding LASER therapy for women with Genitourinary Syndrome of Menopause (GSM) are listed as follows:

1. It is unacceptable to include GSM and "vaginal rejuvenation" in the same category, as GSM is a true disease state, while "vaginal rejuvenation" is a poorly defined term that implies an aesthetic or cosmetic treatment. [...]



A randomized clinical trial comparing vaginal laser therapy to vaginal estrogen therapy in women with genitourinary syndrome of menopause: The VELVET Trial

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3: Women and Infants Hospital, Brown University Medical Center, Providence, RI - USA.
4: Wake Forest Baptist Health, Winston Salem, NC - USA. 5: The Christ Hospital, Cincinnati, OH - USA.
6: Medstar Washington Hospital Center/Georgetown University School of Medicine, Washington, DC - USA.

ABSTRACT

Objective

The aim of the study was to compare 6-month efficacy and safety for treatment of vaginal dryness/genitourinary syndrome of menopause in women undergoing fractionated CO₂ vaginal laser therapy to women using estrogen vaginal cream.

Methods

This multicenter, randomized trial compared fractionated CO₂ laser to estrogen cream at 6 institutions. We included menopausal women with significant vaginal atrophy symptoms and we excluded women with prolapse below stage 2, recent pelvic surgery, prior mesh surgery, active genital infection, history of estrogen sensitive malignancy, and other autoimmune conditions. The primary outcome was the visual analog scale vaginal dryness score. Secondary outcomes included evaluation of vaginal atrophy, quality of life symptoms, assessment of sexual function, and urinary symptoms. Adverse events (AEs) and patient global impression of improvement (PGI-I) and satisfaction were also assessed.

Results

Sixty-nine women were enrolled in this trial before enrollment was closed due to the Federal Drug Administration requiring the sponsor to obtain and maintain an Investigational Device Exemption. Of the 69 participants enrolled, 62 completed the 6-month protocol; 30 women were randomized to the laser and 32 to estrogen cream from June 2016 to September 2017. Demographics did not differ between groups except the laser group was less parous (0 [range 0-4] vs 2 [0-6], $P = 0.04$). On patient global impression, 85.8% of laser participants rated their improvement as "better or much better" and 78.5% reported being either "satisfied or very satisfied" compared to 70% and 73.3% in the estrogen group; this was not statistically different between groups. On linear regression, mean difference in female sexual function index scores was no longer statistically significant; and, vaginal maturation index scores remained higher in the estrogen group (adj P value 0.02); although, baseline and 6-month follow-up vaginal maturation index data were only available for 34 participants (16 laser, 18 estrogen).

Conclusions

At 6 months, fractionated CO₂ vaginal laser and vaginal estrogen treatment resulted in similar improvement in genitourinary syndrome of menopause symptoms as well as urinary and sexual function. Overall, 70% to 80% of participants were satisfied or very satisfied with either treatment and there were no serious adverse events.



Ospemifene plus fractional CO₂ laser: A powerful strategy to treat postmenopausal vulvar pain

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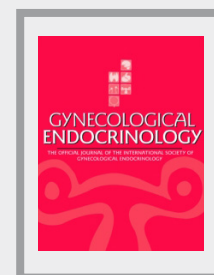
TAG

Vulvar pain
CO₂ Laser + ospemifene

ABSTRACT

Objective

This study is a single-center, retrospective analysis of postmenopausal women presenting with dyspareunia and vulvar pain, aiming to evaluate relative effectiveness of vestibular CO₂ laser therapy as a treatment. Three monthly sessions of laser were performed to each patient and thereafter a three-months follow-up was established. A total number of 72 patients undergoing vestibular laser treatment were recruited from patient files in the period between 2016 and 2018. Among these, 39 women also received a concomitant treatment with ospemifene (60 mg/day) during the study period. There was a statistically significant reduction of all the symptoms in both groups up to the three month follow-up. Regarding dryness and dyspareunia, the relief tended to be more prominent in the ospemifene + laser group at all follow-ups and remained statistically significant at three-month follow-up. Specifically, vestibular dryness was significantly lower in the ospemifene + laser group compared with the laser treatment group (-87% vs -34%, respectively), and the vestibular health score started declining faster in the ospemifene + laser group. Although, additional research is needed to understand the mechanism of action, our data shows that a combination regimen of laser and ospemifene may improve clinical effectiveness for long-term treatment of symptoms associated with the under-recognized genitourinary syndrome of menopause.



Promising impact of platelet rich plasma and carbon dioxide laser for stress urinary incontinence

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3: FBW Gynaecology Plus, Adelaide - Australia. 4: IRCCS San Raffaele University, Milan - Italy.
5: Centre for Advanced Reproductive Endosurgery, Sydney - Australia.

ABSTRACT

Objectives

To evaluate the safety, feasibility and efficacy of trans-vaginal fractional micro-ablative CO₂ laser therapy in combination with platelet rich plasma (PRP) for the treatment of stress urinary incontinence (SUI) in women.

Study Design

Participants with SUI underwent three sessions of transvaginal CO₂ laser and PRP treatment, administered at 4-6-week intervals. Outcomes were assessed using the bladder function section of the Australian Pelvic Floor Questionnaire (APFQ). The primary outcome was changes in the participants' symptoms of SUI. Secondary outcomes were related to general bladder function. Outcome differences from baseline (T1) to 3 months (T2) and 12 months (T3) were analysed using Wilcoxon signed-rank tests. Subjective verbal scales were used to assess the degree of pain associated with PRP injections and laser treatment.

Results

Sixty-two women with SUI were enrolled into this study. There were 66% (41/62) of participants who reported improved SUI symptoms from T1 to T2 ($p < 0.001$) and at T3, 62% (23/37) of patients reported improved SUI symptoms ($p < 0.001$). From T1 to T2, all bladder function variables were improved significantly ($p < 0.002$). At T3, significant improvements ($p < 0.03$) were maintained for all bladder function variables, except pad usage ($p = 0.073$).

Conclusions

Combining transvaginal fractional CO₂ laser with PRP might be a beneficial treatment for SUI. It may have the potential to be a minimally-invasive and low-risk alternative to surgery, with reduced recovery time.



Efficacy of fractional CO₂ laser treatment in postmenopausal women with genitourinary syndrome: A multicenter study

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Montera R², Plotti F², Candiani M³, Angioli R²

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2: Campus Bio-Medico University, Rome - Italy. 3: IRCCS San Raffaele Hospital, Milan - Italy.

4: Careggi University Hospital, Florence - Italy.

TAG

GSM

ABSTRACT

Objective

Genitourinary syndrome of menopause (GSM), especially vulvovaginal atrophy (VVA), is one of the most common conditions among women in either natural (4%-47%) or medically induced (23.4%-61.5%) menopause. The aims of this study are to assess the efficacy and effectiveness of CO₂ laser in postmenopausal women with clinical signs and symptoms of GSM, in particular VVA, and to evaluate both possible early and late side effects related to this kind of treatment.

Method

This retrospective, multicenter study was conducted after collecting data from a pre-existing database. We performed three to four CO₂ laser treatments on all the women enrolled in this protocol. We used a fractional CO₂ laser system (SmartXide2 V2LR, Deka m.e.l.a., Florence, Italy) with a VulvoVaginal Laser Reshaping (V2LR) scanning system and appropriate handpieces for the vaginal area. All women before and after the treatment were assessed. The pre- and post-treatment averages of the symptoms, the standard deviation, and the P values were calculated.

Results

Six hundred forty-five women who met the inclusion criteria were considered. In all the parameters examined (dyspareunia, vaginal orifice pain, dryness/atrophy, itching, burning, pH) statistically significant data were found between the pretreatment and the post-treatment (dryness: before=8.30, after=2.97 [P<0.0001], dyspareunia: before=8.70, after=3.51 [P<0.0001]; burning: before=6.12, after=1.78 [P<0.0001]; vaginal orifice pain: before=8.07, after=2.94 [P<0.0001]; itching: before=6.09, after=1.32 [P<0.0001]).

Conclusions

Our results show the effectiveness and a good degree of tolerance of treatment with the CO₂ laser system in postmenopausal women with GSM.



Fractional CO₂ laser therapy for genitourinary syndrome of menopause for breast cancer survivors

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2: The Ohio State University Center for Biostatistics, Columbus, OH - USA.

3: Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD - USA. 5: Mayo Clinic, Rochester, MN - USA.

ABSTRACT

Purpose

Fractional CO₂ laser therapy is an emerging treatment for genitourinary syndrome of menopause (GSM). The objective of this study was to determine the feasibility and preliminary efficacy of fractional CO₂ laser therapy in breast cancer survivors.

Method

This was a single arm feasibility study of breast cancer survivors with dyspareunia and/or vaginal dryness. Participants received three treatments of fractional CO₂ laser therapy at 30-day intervals and returned for a 1-month follow-up. Feasibility was defined as treatment completion without serious adverse events (SAE) in 80% of patients. We collected data on the Vaginal Assessment Scale (VAS), the Female Sexual Function Index (FSFI), the Urinary Distress Index (UDI), and SAE.

Results

A total of 64 patients participated in the study. The majority of women had Estrogen receptor/Progesterone receptor (ER/PR) positive/Her2neu negative (n=37; 63%), stage I (n=32, 54%) or II (n=19, 32%) breast cancer. Most were receiving endocrine therapy (n=54, 92%), most commonly aromatase inhibitors (AI; n=40, 68%). Fifty-nine (88.1%) of those enrolled completed all treatments according to protocol with no reported SAE. No patient withdrew due to SAE. The scores of the VAS (mean Δ -0.99; 95% CI [-1.19, -0.79], $p < 0.001$), FSFI (mean Δ 9.67; 95% CI [7.27, 12.1], $p < 0.001$), and UDI (mean Δ -8.85; 95% CI [-12.75, -4.75], $p < 0.001$) improved from baseline to follow-up.

Conclusions

Fractional CO₂ laser treatment for breast cancer survivors is feasible and appears to reduce GSM symptoms across treatment and follow-up.



Treatment for vaginal atrophy using microablative fractional CO₂ laser: A randomized double-blinded sham-controlled trial

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Chulalongkorn University, Bangkok - Thailand.

TAG

**Vaginal atrophy
Menopause**

**Randomized, double-blind,
placebo-controlled clinical trial**

ABSTRACT

Objective

The aim of this study was to evaluate the efficacy of vaginal CO₂ laser for the treatment of vaginal atrophy compared to the sham procedure.

Methods

Between June 2016 and May 2017, postmenopausal women with moderate to severe intensity of any vaginal atrophy symptoms (VAS) were invited to participate in the study. A total of 88 women were randomized to receive treatment with either vaginal CO₂ laser or sham procedures every 4 weeks for three sessions. Both the participants and the evaluators were blinded to the treatment. Vaginal Health Index (VHI) score (primary outcome), VAS score, and the item for vaginal dryness from the International Consultation on Incontinence Modular Questionnaire-Vaginal Symptoms questionnaire were compared between the two groups by intention-to-treat analysis at 12 weeks after treatment.

Results

Eighty-eight women were enrolled into the study and nine women were lost to follow-up. After 12 weeks of laser treatment, the VHI, VAS, and International Consultation on Incontinence Modular Questionnaire-Vaginal Symptoms (item for vaginal dryness) scores were significantly improved. For VHI and VAS scores the mean difference between the laser group versus the sham group was 1.37 (95% CI: 0.12-2.63), $P < 0.001$ and -1.52 (95% CI: -2.21 to -0.82), $P = 0.03$, respectively.

Conclusion

This study demonstrated that the application of microablative fractional CO₂ laser was effective in treating vaginal atrophy. It could be a promising alternative treatment for postmenopausal women with vaginal atrophy.



The effect of vaginal microablative fractional CO₂ laser treatment on vaginal cytology

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ABSTRACT

Background and Objectives

Most recently vaginal laser treatment was introduced as a new option for women with genitourinary syndrome of menopause, vaginal dryness. Our objective was to assess the effects of intravaginal CO₂ laser treatment on vaginal cytology.

Study Design/Materials and Methods

Fifty-two women with symptoms of vaginal dryness were enrolled and underwent vaginal laser treatment using a fractional CO₂ laser. Patients received three vaginal laser treatments 4 weeks apart. Vaginal cytology was obtained before the first treatment and 4 weeks after each additional treatment. Vaginal dryness was assessed by using a Visual Analog Scale (VAS).

Results

Out of the 52 women enrolled, 34 were in menopause. Postmenopausal women had significantly lower vaginal maturation values (VMV) compared with premenopausal women at the baseline visit (mean±standard deviation [SD], 42±23 vs. 68±13, P<0.01). The vaginal dryness VAS was higher (worse) in postmenopausal women compared with premenopausal cases (mean±SD, 5.7±4 vs. 2.4±3, P<0.01). The VMV did not change significantly over time after vaginal laser treatment. However vaginal dryness VAS improved significantly after each treatment. Both in the premenopausal and postmenopausal groups, vaginal dryness scores improved significantly from baseline after the three treatments (postmenopausal 5.7±4 vs. 1.6±2.5, P<0.01 and premenopausal 2.4±3 vs. 0.2±0.5, P<0.01). Those patients who had improvement in VMV had significantly better (lower) dryness VAS compared with those women without an improvement in VMV after the three treatments (mean±SD, 0.3±0.8 vs. 1.6±2.6, P=0.04).

Conclusions

Vaginal dryness VAS improved significantly in a cohort of premenopausal and postmenopausal women undergoing vaginal CO₂ laser treatment despite no significant change in vaginal cytology.



Effect of rescue fractional microablative CO₂ laser on symptoms and sexual dysfunction in women affected by vulvar lichen sclerosis resistant to long-term use of topic corticosteroid: A prospective longitudinal study

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TAG

Lichen sclerosis

ABSTRACT

Objective

The objective of this study was to evaluate the efficacy of rescue fractional microablative CO₂ laser treatment in women with severe symptoms and sexual dysfunction related to lichen sclerosis not responsive to long-term ultra-potent topical corticosteroid treatment.

Method

Consecutive eligible women with lichen sclerosis referred to our unit who received fractional microablative CO₂ laser treatment after failure of ultra-potent topical corticosteroid treatment were enrolled in the study. The diagnosis was confirmed by histological assessment in all cases. Patients underwent two cycles of CO₂ laser every 30 to 40 days. The severity of lichen sclerosis-related symptoms, sexual function, and procedure discomfort were evaluated with a visual analog scale in the same individual at baseline, after completion of each treatment cycle. Follow-up visits were scheduled during each treatment cycle and at least 1 month after completion of the treatment. The Friedman ANOVA test was used to evaluate differences in the visual analog scale scores of each symptom during treatment.

Results

A total of 100 patients with vulvar lichen sclerosis were screened, 40 of whom fulfilled the eligibility criteria. We found a significant improvement in vulvar itching ($\chi^2 [2]=31,182$, $P<0.001$), vulvar dryness ($\chi^2 [2]=40,364$, $P<0.001$), superficial dyspareunia ($\chi^2 [2]=37,488$, $P<0.001$), and sensitivity during intercourse ($\chi^2 [2]=22,143$, $P<0.001$) after two CO₂ laser cycles. Pain related to probe movement and laser application was low and did not change significantly consequent to treatment. No systemic or local adverse effects occurred during or after laser treatment.

Conclusions

Fractional microablative CO₂ laser treatment is safe and might represent an effective rescue procedure for patients suffering from lichen sclerosis who fail to respond to long-term ultra-potent topical corticosteroid treatment. These preliminary findings require further study with adequately powered randomized controlled trials.



Efficacy of fractional CO₂ laser, promestriene, and vaginal lubricant in the treatment of urinary symptoms in postmenopausal women: A randomized clinical trial

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ABSTRACT

Background and Objectives

Evaluating the efficacy of the fractional CO₂ laser, promestriene, and vaginal lubricant to treat urinary symptoms in women with genitourinary syndrome of menopause.

Study Design/Materials and Methods

We conducted a randomized clinical trial with 72 postmenopausal women aged 50 years or older. The participants were randomized to one intervention each in three treatment groups fractional CO₂ laser, promestriene, and vaginal lubricant. Urinary symptoms were assessed prior to treatment and 2 weeks after treatment completion using validated questionnaires, the International Consultation on Incontinence Questionnaire (ICIQ-UI SF), and the International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB).

Results

There was a significant reduction in the total ICIQ-UI SF score in the intragroup comparison (baseline vs. week 14) of the CO₂ laser group ($P=0.004$). This group also showed a statistically significant reduction in nocturia (1.33 ± 0.87 vs. 1.00 ± 0.76 , respectively; $P=0.031$). In the intergroup comparison after treatment, nocturia in the lubricant group had worsened compared with that of the other two groups ($P=0.002$). Regarding the total ICIQ-OAB score, the results of the CO₂ laser group were superior to those of the lubricant group in the intergroup comparison (7.76 ± 3.36 , $P=0.020$; analysis of variance $P=0.038$).

Conclusions

The results were significantly different between the intravaginal fractional CO₂ laser and topical estrogen groups for treating urinary symptoms related to the genitourinary syndrome of menopause. Further controlled and randomized studies are needed.



Fractionated CO₂ laser as therapy in recalcitrant lichen sclerosis

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TAG

Lichen sclerosis

EXCERPT

Objectives

The aim of this study was to evaluate the efficacy of the fractionated CO₂ laser in treating recalcitrant lichen sclerosis (LS).

Study Design

The study population was 40 women diagnosed with LS who were symptomatic despite medical treatment. Patients had at least 2 or more laser sessions with a 2-month follow-up visit at the Drexel Vaginitis Center. A fractionated CO₂ laser was used on affected areas at mild or standard power settings. Analyses were performed of changes in symptom rating scales, verbal reports, and physical examination findings.

Results

In the LS cohort of 40 patients, 22 women (55%) experienced symptoms that had persisted longer than 5 years before treatment. After the appropriate laser sessions, 72.5% of women described their improvement as significant or more than 66% improvement. In addition, there was a statistically significant reduction in vaginal pain, itching, dyspareunia, and dysuria. The presence of white epithelium decreased 20% after treatment. Furthermore, the mean corticosteroid use declined from 4.28 times per week to 2.04 times per week, indicating a resolution of many symptoms.

Conclusions

The fractionated CO₂ laser may be a helpful approach for managing LS that is unresponsive to traditional treatment options.



Response letter to comments related to “The effect of microablative fractional CO₂ laser on vaginal flora of postmenopausal women”

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ABSTRACT

Objectives

To assess the effect of microablative fractional CO₂ laser (MFCO2-Laser) therapy on the vaginal microenvironment of postmenopausal women.

Methods

Three laser therapies at monthly intervals were applied in postmenopausal women with moderate to severe symptoms of genitourinary syndrome of menopause, pH of vaginal fluid >4.5 and superficial epithelial cells on vaginal smear <5%. Vaginal fluid pH values, fresh wet mount microscopy, Gram stain and aerobic and anaerobic cultures were evaluated at baseline and 1 month after each subsequent therapy. Nugent score and Hay-Ison criteria were used to evaluate vaginal flora.

Results

Fifty-three women (mean age 57.2 ± 5.4 years) participated and completed this study. MFCO2-Laser therapy increased Lactobacillus (p < 0.001) and normal flora (p < 0.001) after the completion of the therapeutic protocol, which decreased vaginal pH from a mean of 5.5 ± 0.8 (initial value) to 4.7 ± 0.5 (p < 0.001). The prevalence of Lactobacillus changed from 30% initially to 79% after the last treatment. Clinical signs and symptoms of bacterial vaginosis, aerobic vaginitis or candidiasis did not appear in any participant.

Conclusion

MFCO₂-Laser therapy is a promising treatment for improving the vaginal health of postmenopausal women by helping repopulate the vagina with normally existing Lactobacillus species and reconstituting the normal flora to premenopausal status.

Keywords

UTIs; Vaginal atrophy; dyspareunia; intravaginal therapy; menopause; urinary tract infections; urogenital infections; vaginitis.



Effectiveness of CO₂ laser on urogenital syndrome in women with a previous gynecological neoplasia: A multicentric study

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TAG

Urogenital syndrome
Oncological menopause
Gynecological cancer survivors

ABSTRACT

Background

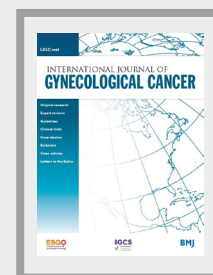
Many women diagnosed with gynecological cancers undergo adjuvant therapy, which may lead to transient or permanent menopause that ultimately leads to urogenital syndrome and vulvovaginal atrophy. Studies advise against the use of estrogen in women with a history of hormone-dependent cancer. One alternative is vaginal microablative fractional CO₂ laser, which promotes tissue regeneration through the production of collagen and elastic fibers.

Objective

To evaluate the effectiveness of CO₂ laser in the treatment of urogenital syndrome-in particular, symptomatic vulvovaginal atrophy in women who have survived gynecological cancers.

Methods

A retrospective study was carried out, including all patients with a history of gynecological cancers and vulvovaginal atrophy who underwent CO₂ laser treatment between November 2012 and February 2018 in four Italian centers. The study was approved by the local ethics committee of each participating institution. The inclusion criteria were women aged between 18 and 75; Eastern Cooperative Oncology Group performance status <2; and history of breast, ovarian, cervical, or uterus cancer. Patients had to have vulvovaginal atrophy and at least one of the following symptoms of urogenital syndrome: vaginal dryness, dyspareunia, vaginal introitus pain, burning, or itching. Three applications were administered at baseline, 30 days, and 60 days. All patients were evaluated before the first laser session, at each session, and 4 weeks after the last session. In particular, patients were asked to indicate the intensity of symptoms before the first session and 4 weeks after the last session, using Visual Analog Scale (VAS) scoring from 0 ('no discomfort') to 10 ('maximum discomfort').



Results

A total of 1213 patients underwent CO₂ laser treatment and of these, 1048 were excluded because they did not meet the inclusion criteria in the analysis. Finally, a total of 165 patients were included in the study. The mean age at the time of treatment was 53 years (range 31-73). Dryness improved by 66%, dyspareunia improved by 59%, burning improved by 66%, pain at introitus improved by 54%, and itching improved by 54%. The side effects were evaluated as pain greater than VAS score 6 during and after the treatment period. No side effects were seen in any sessions.

Conclusions

Fractional microablative CO₂ laser therapy offers an effective strategy in the management of the symptoms of genitourinary syndrome in post-menopausal women and in survivors of gynecological cancer.

Results

A total of 1213 patients underwent CO₂ laser treatment and of these, 1048 were excluded because they did not meet the inclusion criteria in the analysis. Finally, a total of 165 patients were included in the study. The mean age at the time of treatment was 53 years (range 31-73). Dryness improved by 66%, dyspareunia improved by 59%, burning improved by 66%, pain at introitus improved by 54%, and itching improved by 54%. The side effects were evaluated as pain greater than VAS score 6 during and after the treatment period. No side effects were seen in any sessions.

Conclusions

Fractional microablative CO₂ laser therapy offers an effective strategy in the management of the symptoms of genitourinary syndrome in post-menopausal women and in survivors of gynecological cancer.

Fractional CO₂ laser for treatment of vulvovaginal atrophy: A short time follow-up

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TAG

VVA
Menopause

ABSTRACT

Objectives

The aim of this study was to evaluate the safety and efficacy of fractional CO₂ laser for treatment of vulvovaginal atrophy.

Materials and Methods

Evaluated the laser effect on vulvovaginal atrophy in 47 women aged 43-80 years. Each woman was treated with fractional CO₂ laser, SmartXide2 V²LR, DEKA, Monalisa Touch, vaginal 360° probe and cosmetic probe. The severity of vulvovaginal atrophy symptoms was evaluated before first session of laser and every 4 weeks after laser treatment until 12 weeks. Adverse effects including pain and itching were assessed at all visits. The statistical analysis was performed using SPSS version 23.

Results

The response to laser therapy for vaginal dryness was significantly ($p < 0.001$) improved. Also, the response to laser therapy for each symptom include dyspareunia, vaginal discharge, itching and urge urinary incontinence was statistically significant ($p < 0.001$) based on visual analogue scale (VAS).

Conclusions

It seems vaginal fractional CO₂ laser can be applied as an effective and safe treatment method in genitourinary syndrome of menopause (GSM). It is necessary to conduct studies with long-term follow-up.



A cost-effectiveness analysis of vaginal carbon dioxide laser therapy compared with standard medical therapies for genitourinary syndrome of menopause-associated dyspareunia

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ABSTRACT

Background

Topical vaginal estrogen therapy is considered the gold standard treatment for genitourinary syndrome of menopause-associated dyspareunia, but early investigations of energy-based devices show promise for patients with contraindications or those who are refractory to vaginal estrogen cream therapy. Although evaluating safety, efficacy, and long-term outcomes for novel technologies is critically important when new technologies become available to treat unmet healthcare needs, evaluation of the costs of these new technologies compared with existing therapies is also critically important but often understudied.

Objective

We sought to perform a cost-effectiveness analysis of 3 therapies for genitourinary syndrome of menopause, including vaginal estrogen therapy, oral ospemifene therapy, and vaginal CO₂ laser therapy and determine if vaginal laser therapy is a cost-effective treatment strategy for dyspareunia associated with genitourinary syndrome of menopause.

Study Design

An institutional review board-exempt cost-effectiveness analysis was performed by constructing a decision tree using decision analysis software (TreeAge Pro; TreeAge Software, Inc, Williamstown, MA) using integrated empirical data from the published literature. Tornado plots and 1-way and 2-way sensitivity analyses were performed to assess how changes in the model's input parameters altered the overall outcome of the cost-effectiveness analysis model.



Results

All 3 treatment methods were found to be cost-effective below the willingness-to-pay threshold of \$50,000.00 per quality-adjusted life year for moderate dyspareunia. The incremental cost-effectiveness ratio for vaginal CO₂ laser therapy was \$16,372.01 and the incremental cost-effectiveness ratio for ospemifene therapy was \$5711.14. Although all 3 treatment strategies were on the efficient frontier, vaginal CO₂ laser therapy was the optimal treatment strategy with the highest effectiveness. In a 1-way sensitivity analysis of treatment adherence, vaginal CO₂ laser therapy was no longer cost-effective when the adherence fell below 38.8%. Vaginal estrogen cream and ospemifene therapies remained cost-effective treatment strategies at all ranges of adherence. When varying the adherence to 100% for all strategies, oral ospemifene therapy was “dominated” by both vaginal CO₂ laser therapy and vaginal estrogen cream therapy. In a 2-way sensitivity analysis of vaginal CO₂ laser therapy adherence and vaginal CO₂ laser therapy cost, vaginal CO₂ laser therapy still remained the optimal treatment strategy at 200% of its current cost (\$5554.00) when the adherence was >55%. When the cost fell to 20% of its current cost (\$555.40), it was the optimal treatment strategy at all adherence values above 29%.

Conclusions

This study showed that vaginal fractional CO₂ laser therapy is a cost-effective treatment strategy for dyspareunia associated with GSM, as are both vaginal estrogen and oral ospemifene therapies. In our model, vaginal CO₂ laser therapy is the optimal cost-effective treatment strategy, and insurance coverage should be considered for this treatment option if it is proven to be safe and effective in FDA trials.

Sexual function

Menopause

Randomized clinical trial

CO₂ laser vs. premarin

The effect of the co₂ fractional laser or premarin vaginal cream on improving sexual function in menopausal women: A randomized controlled trial

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ABSTRACT

Introduction

Sexual dysfunction is a complex problem in postmenopausal women with a prevalence rate of 68%-86%. This study aimed to evaluate the effect of a fractional CO₂ laser or vaginal cream on the improvement of sexual function in menopausal women.

Methods

This is a two-group clinical trial study. Postmenopausal women with the inclusion criterion were enrolled and randomly divided into 2 groups of intervention (n=25) and control group (n=25). In the intervention group, CO₂ laser therapy was performed every month for three months, and in the control group, Premarin vaginal cream was applied (0.625 mg, 3 nights a week for 3 months). Vaginal health index (VHI) scoring and Female Sexual Function Index (FSFI) questionnaires were completed before and three months after the treatment.

Results

The effects of the laser treatment were greater than the Premarin group with respect to improvement in sexual desire, orgasms, sexual satisfaction, less pain during sexual relations, and overall sexual function (P <0.05).

Conclusion

It seems that the fractional CO₂ laser may be more effective than hormonal therapy in improving sexual function in postmenopausal women.



A rare case of Mayer-Rokitansky-Kuster-Hauser (MRKH) Syndrome: Relief of symptoms with fractional CO₂ laser therapy

Mayer-Rokitansky-Kuster-Hauser syndrome
Case Report

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ABSTRACT

We report the case of a 27-year-old woman with Mayer-Rokitansky-Kuster-Hauser (MRKH) syndrome suffering from vaginal dryness, dyspareunia and recurrent vaginal infections, unresponsive to non-hormonal local treatment (lubricants and moisturizers) and to antibiotics drugs, who underwent CO₂ laser therapy. She underwent a series of three laser treatments (one every four weeks), and a further treatment 18 months later. Objective (Vaginal Health Index, VHI score) and subjective (Visual Analogue Scale, VAS, scores for dyspareunia and vaginal dryness) evaluations were employed. After the three laser treatments, there was an improvement in all the scores employed until the eighteen-month follow-up, when the patient again complained of vaginal dryness (VAS score 4). She underwent another laser application and felt well again. Vaginal CO₂ laser therapy was effective in treating vaginal dryness in this patient. This treatment can be used not only in post-menopausal patients, but also in other women who suffer from vaginal dryness and dyspareunia due to particular pathological conditions.

Fractional microablative CO₂ laser-related histological changes on vulvar tissue in patients with genitourinary syndrome of menopause

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ABSTRACT

Background and objectives

Fractional CO₂ laser has been proposed as an effective treatment for the genitourinary syndrome of menopause (GSM). However, the effects of laser treatment on vulvar tissue have never been assessed. We aimed to assess histological changes related to fractional CO₂ laser in vulvar tissue from GSM patients.

Study Design/Materials and Methods

A single-center observational prospective cohort study was performed enrolling all GSM patients from July 2017 to October 2018. Patients underwent three outpatient vulvovaginal applications of fractional CO₂ laser and vulvar biopsy before and after treatment. Rates of histological changes in vulvar tissue, the difference in means of Vulva Health Index (VuHI), Vaginal Health Index (VHI), Visual Analogue Scale scores for GSM symptoms, and procedure-related pain, and rate of patient's overall satisfaction with treatment were assessed. Univariate comparisons between continuous variables were performed by using the paired t-test (α error = 0.05).

Results

Of 20 enrolled patients, 18 underwent all laser applications, and 15 underwent both vulvar biopsies. 93.3% of patients showed remodeling of vulvar connective tissue; 80% showed improvement in vulvar epithelium trophism and 86.7% showed neovascularization. Differences in means between before and after treatment were significant for VuHI, VHI, and all GSM symptoms. Means $\pm$ standard deviation of the degree of pain at each laser application were 4.4 ± 0.9 , 3.7 ± 1.6 , and 2.9 ± 1.9 . The rate of overall satisfaction with the treatment was 72.2%.

Conclusion

Fractional CO₂ laser leads to a restoration of the normal architecture of vulvar tissue, with significant improvement in GSM-related signs and symptoms, and overall satisfaction with the treatment in most GSM patients.



CO₂ laser and the genitourinary syndrome of menopause: A randomized sham-controlled trial

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TAG

GSM

**Randomized placebo-
controlled trial**

ABSTRACT

Purpose

This study aimed to clarify the efficacy of intravaginal CO₂-laser treatment in postmenopausal women with genitourinary syndrome of menopause (GSM).

Materials and Methods

This double-blind, randomized, sham-controlled trial included postmenopausal women diagnosed with GSM and bothersome dryness and dyspareunia. Treatment consisted of three sessions. Active CO₂-laser treatments (active group) were compared to sham treatments (sham group) with the primary endpoints being changes in dryness and dyspareunia intensity, as assessed by the 10-cm visual analog scale. Secondary endpoints were as follows: changes in Female Sexual Function Index (FSFI; total score and all domains), itching, burning, dysuria, and Urogenital Distress Inventory (UDI-6); incidence of symptoms; and presence of adverse events. All outcomes were evaluated at baseline and 4 months post baseline.

Results

Fifty-eight women (28 in the active group and 30 in the sham group) were eligible for inclusion. In the active group, dryness, dyspareunia, FSFI (total score), itching, burning, dysuria, and UDI-6 were significantly improved (mean [standard deviation] -5.6 [2.8], -6 [2.6], 12.3 [8.9], -2.9 [2.8], -2.3 [2.8], -0.9 [2.1], and -8.0 [15.3], respectively). In the sham group, dryness, itching, and burning were significantly improved (-1.9 [2], -1.4 [1.9], and -1 [1.9], respectively). All changes were in favor of the active group. After completion of the protocol, the proportion of participants with dryness, dyspareunia, and sexual dysfunction was significantly lower in the active group compared to those in the sham group (all $p < 0.005$).

Conclusion

CO₂ laser could be proposed as an effective alternative treatment for the management of GSM as it is superior to sham treatments



Evaluation of the efficacy of fractional CO₂ laser in the treatment of vulvar and vaginal menopausal symptoms

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ABSTRACT

Purpose

The objective of this study was to evaluate the efficacy of fractional CO₂ laser to manage vulvar and vaginal symptoms of Genitourinary Syndrome of Menopause (GSM) in postmenopausal women.

Methods

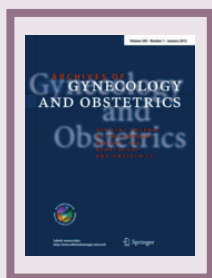
All postmenopausal women with symptoms of GSM undergoing fractional CO₂ laser treatment in our centers were asked to fill out a validated quality of life questionnaire (Global Quality of Life Questionnaire), Visual Analog Scale (VAS) for symptoms, a questionnaire on overall discomfort related to pelvic floor symptoms, and the Female Sexual Function Index (FSFI) at several points: before each session (three sessions at monthly intervals) and one 3 months after treatment completion. Statistical analysis compared pre-therapy data and data at 3 months of treatment.

Results

Forty-six women were included with a mean age of 57.3 years ($\pm$ 11.1 years). A significant improvement was demonstrated in vaginal dryness ($p = 6.34 \times 10^{-6}$) and for symptoms of stress urinary incontinence ($p = 0.043$). Among sexually active patients, there was a significant improvement in the degree of symptom discomfort affecting their satisfaction ($p = 0.007$), dyspareunia ($p = 0.001$) and sensitivity during sexual intercourse ($p = 0.001$). Significantly, more women were able to achieve ($p = 0.026$) and maintain ($p = 0.018$) lubrication during intercourse.

Conclusion

CO₂ laser treatment seems to improve the quality of life and sexual health of patients as well as GSM symptoms at 3 months of treatment; long-term reevaluation is necessary to demonstrate that improvement persists over time.



The fractional CO₂ laser for the treatment of genitourinary syndrome of menopause: A prospective multicenter cohort study

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5: West China Second University Hospital, Chengdu - China. 6: The Third Affiliated Hospital of Zhengzhou University, Zhengzhou - China.

7: Puyang Oilfield General Hospital, Puyang - China. 8: Maternity and Child Healthcare Hospital, Liuzhou - China.

TAG

GSM

CO₂ laser vs. topical estrogen

ABSTRACT

Background and objectives

This prospective multicenter cohort study aimed to compare the efficacy and safety of the fractional carbon dioxide (CO₂) laser with that of topical estrogen for vaginal treatment and relieving symptoms of genitourinary syndrome of menopause (GSM).

Materials and Methods

This study included 162 postmenopausal patients who received vaginal laser or topical Estriol cream therapy between January 2017 and May 2019 at eight study centers in China. The degree of GSM-related symptoms (vaginal burning, dryness, and dyspareunia) was evaluated using the Vaginal Health Index score (VHIS) and Visual Analog Scale (VAS) at baseline, 1, 3, 6, and 12 months posttreatment. The primary endpoint was the improvement in vaginal burning, dryness, and dyspareunia at 6 months after treatment. Multivariate logistic regression was used to compare the rate of improvement in the two groups.

Results

In the laser group, compared with baseline, significant differences were seen in the VHIS after the first or second treatment session and at 1, 3, 6, and 12 months posttreatment ($P < 0.01$). At 6 months after treatment, both laser and control group showed improvement in vaginal burning, vaginal dryness, and dyspareunia ($P > 0.05$). The VAS findings at 6 months posttreatment were significantly different when compared with the pretreatment findings ($P < 0.001$). There were no significant adverse effects in the two groups.

Conclusion

Fractional CO₂ laser vaginal treatment could be a safe and effective option for treating symptoms of GSM, including vaginal burning, dryness, and dyspareunia. The improvement in symptoms was comparable with that seen with topical estrogen therapy and lasted for at least 6–12 months posttreatment.



Vaginal atrophy

Perineal changes

Lactation

Puerperium

CO₂ laser vs. lubricant or vaginal hormone tablets or cream

The beneficial effects of fractional CO₂ laser treatment on perineal changes during puerperium and breastfeeding period: A multicentric study

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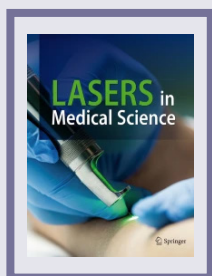
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ABSTRACT

Childbirth is a great change in woman life because of hormonal, physical and psychological alterations that are associated with this process. Dyspareunia and perineal pain are commonly reported symptoms in the postpartum period, mainly due to perineal trauma, lacerations, episiotomy, and forceps or vacuum use at delivery. Among non-pharmacological treatment, a new trend is gaining popularity, which is the energy-based therapy, including fractional micro-ablative CO₂ laser. We conducted a multicentric retrospective study to assess the efficacy and the possible side effects of CO₂ laser treatment on transient vulvovaginal atrophy and perineal postpartum pain related to puerperium and breastfeeding period. All patients were submitted to 3 or 4 sessions of CO₂ laser treatment. As per protocol, an initial, intermediate (after 2 sessions) and final (3 months after the last cycle) evaluation of the symptoms were made, using a VAS (Visual Analogue Scale 0-10). We also compared this group of patients with a control group with no treatment. At the final evaluation, patients showed a significant improvement for dyspareunia (VAS from 7.95 to 3.14, $p < 0.0001$). A significant improvement was also registered in pain at the vaginal orifice (VAS from 6.94 to 2.05, $p = 0.0001$), dryness (VAS from 6.6 to 2.9, $p = 0.0022$), itching (VAS from 4.5 to 1.16, $p = 0.0053$), heat (VAS from 3 to 0, $p = 0.0119$) and burning (VAS from 5.5 to 1.6, $p = 0.0013$) if compared with the control group. Quality of life for the women during the breastfeeding and puerperium is important and training is mandatory to avoid side effects in order to improve the CO₂ laser performance.



The short-term efficacy and safety of fractional CO₂ laser therapy for vulvovaginal symptoms in menopause, breast cancer, and lichen sclerosis

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TAG

VVA

Sexual function

Oncological menopause

Breast cancer survivors

Natural menopause

Lichen sclerosis

ABSTRACT

Objectives

To review the short-term effects and safety of vulvovaginal fractional microablative CO₂ laser therapy on atrophy symptoms using validated questionnaires pre- and posttreatment.

Materials and Methods

Retrospective chart review 139 women with vulvovaginal atrophy symptoms, who completed three treatments about 6 weeks apart. All were >18 years old and non-pregnant. As is the practice in our clinic for all women receiving treatment, they were surveyed prior to the 1st and 3rd treatments with validated questionnaires, Female Sexual Function Index (FSFI) and Vulvovaginal Symptoms Questionnaire (VSQ), as well as a visual analog scale (VAS). Paired t test was completed on the pre- and post FSFI and VAS scores. Pre- and postproportions of the VSQ were evaluated by the Fisher's exact test. Means were presented for each study variable. Multivariable regression analysis was completed on continuous and binomial variables for scores predictors.

Results

Mean age was 62 years with a mean follow-up of 13.8 weeks. Concomitant topical estrogen was reported in 53% (n = 74). Breast cancer diagnosis was documented in 27% (n = 38), and lichen sclerosis in 22% (n = 31). All FSFI scores improved (pre: 12.7, post: 19.0, P < 0.001). The VSQ showed 18 of 21 questions significantly improved (P < 0.05). The VAS showed significant improvement in painful intercourse (pre: 6.6, post: 2.4, P < 0.001), and vulvar dryness (pre: 4.6, post: 1.5, P < 0.001). Posttreatments, 17 additional women became sexually active. No major adverse events were reported.

Conclusion

Fractional CO₂ laser may be effective and safe for the treatment vulvovaginal atrophy.



Does the time of onset of urinary symptoms affect microablative fractional CO₂ laser efficacy in postmenopausal women?

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ABSTRACT

Background and objective

To evaluate the safety and efficacy of transvaginal fractional microablative CO₂ laser therapy (MLT) on urinary symptoms in postmenopausal women with genitourinary syndrome of menopause (GSM) in relation to the timing of their onset; if prior to or after menopause. Secondary, the efficacy of MLT on vulvovaginal atrophy (VVA)-related symptoms.

Study design/materials and methods

This is a retrospective analysis of prospectively collected data. Postmenopausal women affected by at least one urinary symptom (urinary frequency, urgency incontinence, stress urinary incontinence) and VVA symptom each (dryness, dyspareunia, itching, burning) were enrolled. Our population was divided into two groups in relation to the onset of urinary symptoms, prior to or after menopause. Women were treated with three CO₂ MLT laser sessions, administered at a 4-week interval. For urinary symptoms evaluation, we used the following disease-specific questionnaires previously validated in Italy: the Urogenital Distress Inventory score (UDI-6) and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF). For each single VVA symptom, we assessed patient's severity perception with a 10-point visual analog scale. Time points of the study were at entry (T0) and at 16 weeks since the first treatment (T1). Collected data were analyzed with the Pearson χ^2 test for categorical variables and the Wilcoxon rank-sum test (for non-normally distributed data), and statistical significance was defined with a P-value <0.05.



Patient-reported sexual function of breast cancer survivors with genitourinary syndrome of menopause after fractional CO₂ laser therapy

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TAG

Sexual function
Oncological menopause
Breast cancer survivors
Long-term follow-up

ABSTRACT

Objectives

The objective of this pilot study was to evaluate the change in sexual function following treatment with fractional CO₂ laser therapy in breast cancer (BC) survivors with genitourinary syndrome of menopause (GSM).

Materials and Methods

A single-arm feasibility study of BC survivors with symptoms of GSM, including dyspareunia and/or vaginal dryness, was conducted. Participants who received three treatments with fractional CO₂ laser and 4-week follow-up were contacted for patient-reported outcomes and adverse events at 12 months. Sexual function was measured using the Female Sexual Function Index (FSFI) and Female Sexual Distress Scale Revised (FSDS-R). Descriptive statistics were calculated for patient demographics and disease characteristics for the set of participants who agreed to long-term follow-up and those who were lost to follow-up. FSFI and FSDS-R scores were summarized at baseline, 4 weeks and 12 months, as well as the change from baseline, and were compared using a Wilcoxon signed rank test.

Results

A total of 67 BC survivors enrolled, 59 completed treatments and 4-week follow-up; 39 participated in the 12 month follow-up. The overall FSFI score improved from baseline to 4-week follow-up (median Δ 8.8 [Q1, Q3] (QS) (2.2, 16.7)), $P < 0.001$). There were improvements at 4 weeks in all domains of the FSFI ($P < 0.001$ for each) including desire (median Δ 1.2; QS [0.6, 1.8]), arousal (median Δ 1.2; QS [0.3, 2.7]), lubrication (median Δ 1.8 (0, 3.3)), orgasm (median Δ 1.2; QS [0, 3.6]), satisfaction (median Δ 1.6 (0.4, 3.2)), and pain (median Δ 1.6 (0, 3.6)). The FSDS-R score also improved from baseline to 4-week follow-up (median Δ -10.0; QS [-16, -5] $P < 0.001$) indicating less sexually related distress. The scores of the FSFI and FSDS-R remained improved at 12 months and there were no serious adverse events reported.

Conclusion

In BC survivors with GSM, the total and individual domain scores of the FSFI and the FSDS-R improved after fractional CO₂ laser therapy.



Microablative fractional CO₂ laser for vulvovaginal atrophy in women with a history of breast cancer: A pilot study at 4-week follow-up

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ABSTRACT

Background

Breast cancer (BC) is the most common female cancer worldwide. Menopausal symptoms are a well-known side effect in women with BC and have a significant negative impact on quality of life (QoL) and sexuality. Nowadays, hormonal replacement therapy and local estrogens are the most common prescriptions to treat vulvovaginal (VVA) symptoms. However, in women with a history of BC, proper therapy for such conditions remains an often inadequately addressed clinical problem. A treatment with microablative fractional CO₂ laser (MLT) can produce a remodeling of the vaginal connective tissue without causing damage to the surrounding tissue. The aim of this pilot study is to assess the efficacy and safety of MLT for treating VVA symptoms in women with a history of BC at 20-week follow-up since the first laser treatment.

Patients and methods

Women with BC and VVA symptoms were enrolled in the study and treated with 5 laser applications (one every 4 weeks). The rate of satisfied patients at 20 weeks of follow-up was evaluated with a 5-point Likert scale. Changes of the Vaginal Health Index (VHI) after treatment was compared with baseline. Effects of the laser treatment on VVA symptoms was measured using a 10-cm visual analog scale (VAS). Changes in overall QoL were assessed with a generic QoL questionnaire: the Short Form 12 (SF-12) that we analyzed considering its physical (PCS12) and mental (MCS12) domains. Sexual function was evaluated by the Female Sexual Function Index (FSFI).



Results

In this prospective cohort study, we enrolled 40 women with a history of BC and who currently were or (Group 2) who had been (Group 1) on treatment with endocrine therapy for their condition. Six (15.0%) women were very satisfied, 25 (62.5%) were satisfied, 6 (15.0%) were uncertain, and 3 (7.5%) were dissatisfied with the MLT. VVA symptoms and VHI improved significantly at 20 weeks from baseline ($P < .05$) with no differences between the 2 groups ($P > .05$). In terms of QoL measured by the SF-12, the PCS12 and the MCS12 significantly improved at the 20-week follow-up. A significant improvement in total FSFI and in all domains was reported in both study groups ($P < .05$) with no differences between groups ($P > .05$).

Conclusion

MLT was safe and effective in treating VVA symptoms in women with a history of BC, irrespective of being previously or currently on endocrine therapies.

Fractional CO₂ vaginal laser for the genitourinary syndrome of menopause in breast cancer survivors

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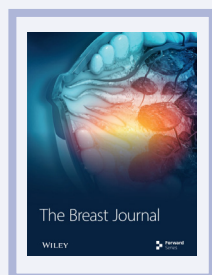
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ABSTRACT

Adjuvant chemotherapy and endocrine therapy can induce early iatrogenic menopause or worsen pre-existing menopausal symptoms in breast cancer survivors (BCS). The second most frequent menopausal symptom after hot flushes is the genitourinary syndrome (GSM). Since hormone replacement therapy is contraindicated in BCS, vaginal laser might represent a new nonhormonal option for GSM. This study aims at evaluating the effectiveness of the fractional CO₂ vaginal laser for GSM in BCS compared with healthy women. This is a retrospective study on 135 postmenopausal women (45 BCS and 90 healthy women) who underwent fractional CO₂ laser for GSM. Objective (VHI and WHI) and subjective outcomes (VAS for dyspareunia and vaginal dryness and a pain questionnaire) were evaluated at baseline visit and at every follow-up visit. Subjective and objective parameters improved significantly in both groups after laser therapy. The improvement was progressive and long-lasting up to 12 months after the end of the treatment. No severe adverse events were observed during the treatment. Fractional CO₂ vaginal laser induces a significant and long-lasting improvement on GSM symptoms in BCS. However, this improvement is slower than in healthy women undergoing the same treatment. Laser therapy turns out to be safe and well-tolerated.

Keywords

breast cancer survivors; vaginal atrophy; vaginal laser.



Effects of local laser treatment on vulvovaginal atrophy among women with breast cancer: A prospective study with long-term follow-up

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TAG

VVA

Oncological menopause

Breast cancer survivors

Long-term follow-up

ABSTRACT

Purpose

Women with breast cancer (BC) often suffer from severe vulvovaginal atrophy (VVA) which ultimately leads to poor sexual and urinary quality of life. We conducted a prospective study among women with BC and VVA, in order to evaluate the long-term effect of laser therapy on VVA.

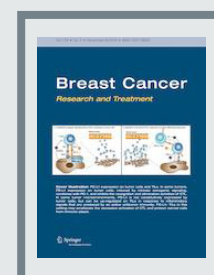
Methods

Women with BC and VVA were proposed to have fractional microablative CO₂ laser therapy (MonaLisaTouch®, DEKA) once per month for 3 months. Efficacy of laser therapy was assessed at baseline, 6 months and 18 months after treatment, using Female Sexual Function Index (FSFI) score, Ditrovie score and vaginal pH. A pap smear was also performed and the epithelial maturation pattern was noted. Paired statistical tests were used to compare results between baseline, 6 months and 18 months. Results: 46 women with BC (median age [interquartile range] 56.5 years [47.0 - 59.4]) were included between May and October 2018. PH level slightly decreased over time (mean Δ at 18 months -0.3, SD = 0.7, $p = 0.02$) whereas maturation pattern on pap smear did not change. Sexual quality of life was significantly improved at 6 months and 18 months (mean Δ at 6 months 8.3, SD = 6.2 ($p < 0.0001$) and mean Δ at 18 months 4.3, SD = 8.4 ($p = 0.01$)). Ditrovie total score improved at 6 months (mean Δ -1.2, SD = 2.7, $p = 0.01$) but returned to baseline afterwards. Side effects were very mild. Three women developed low (2)- and high (1)-grade HPV-linked cervical lesions during follow-up.

Conclusion

Among women with BC, fractional microablative CO₂ laser is effective on the long term on VVA symptoms and gynaecological quality of life.

Trial registration number: ID-RCB 2018-A01500-55.



Comparison of topical fractional CO₂ laser and vaginal estrogen for the treatment of genitourinary syndrome in postmenopausal women: A randomized controlled trial

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ABSTRACT

Objectives

To compare the efficacy of fractional CO₂ laser therapy with topical estrogen therapy for the treatment of postmenopausal genitourinary syndrome of menopause.

Materials and Methods

We conducted a randomized controlled clinical trial involving 25 postmenopausal women. Participants were aged between 50 and 65 years with at least 1 year of amenorrhea and follicle-stimulating hormone levels of >40 IU/L. The women were randomized into two groups: the laser therapy group (n = 13) and the vaginal topical estrogen therapy group (n = 12). Changes in the vaginal epithelium thickness, Frost index, and cell maturation were analyzed in both the groups. The female sexual quotient of each woman was also evaluated. Subjective evaluation was performed through a physical examination.

Results

Histological analysis showed a significant increase in the vaginal epithelium thickness at the end of treatment in females in both the laser therapy (P < 0.001) and topical estrogen therapy (P = 0.001) groups. The topical estrogen therapy group tended to present a higher maturation index at the end of treatment when compared with that of the other group. Sexual function increased significantly over time in both the topical estrogen therapy (P < 0.001) and laser therapy (P < 0.001) groups. Subjective evaluation through physical examination showed a significant improvement in atrophy in both the groups.

Conclusion

Despite the nonequivalence with topical estrogen therapy, our data suggest that laser therapy is an effective method for the treatment of vulvovaginal atrophy.



Clobetasol compared with fractionated carbon dioxide laser for lichen sclerosus: A randomized controlled trial

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TAG

Lichen sclerosus
Randomized clinical trial
CO₂ laser vs. clobetasol

ABSTRACT

Objectives

To compare 6-month safety and efficacy outcomes of fractionated CO₂ laser (laser) with topical clobetasol propionate (steroid) for treatment of symptomatic vulvar lichen sclerosus.

Materials and Methods

We conducted a single-center randomized controlled trial that compared fractionated CO₂ laser with steroid treatment for patients with biopsy-proven lichen sclerosus. Randomization was stratified by prior clobetasol propionate use. The primary outcome was mean change in Skindex-29 score at 6 months. A total sample size of 52 participants were recruited to detect a mean difference of 16 points on the Skindex-29 (SD±22) with 80% power, based on a one-sided two-sample t test with $\alpha=0.05$, accounting for 10% attrition. Secondary outcomes included validated subjective and objective measures. Intention-to-treat, per protocol, and regression analysis based on prior steroid exposure were performed.

Results

202 women were screened, 52 were randomized, and 51 completed a 6-month follow-up. No significant difference was found in baseline demographics, symptoms, and physician assessment scores. There was greater improvement in the Skindex-29 score in the laser arm at 6-months (10.9 point effect size, 95% CI 3.42-18.41; $P=.007$). Overall, 89% (23/27) of patients in the laser group rated symptoms as being “better or much better” compared with 62% (13/24) of patients in the steroid group, $P=.07$. More patients (81%, 21/27) were “satisfied or very satisfied” with laser treatment compared with steroid treatment (41%, 9/24); $P=.01$. After stratification for previous steroid use, the significant change of Skindex-29 score was only seen in the previously exposed group. There was one adverse event in each group: minor burning and blistering at the laser site and reactivation of genital herpes 1 week after starting steroid.

Conclusion

Fractionated CO₂ laser treatment showed significant improvement in subjective symptoms and objective measures compared with clobetasol propionate, without serious safety or adverse events at 6 months.



Vaginal dryness

Menopause

Cervicovaginal lavage zinc
and copper levels

Fractional CO₂ laser treatment effect on cervicovaginal lavage zinc and copper levels: A prospective cohort study

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ABSTRACT

Objectives

To compare the efficacy of fractional CO₂ laser therapy with topical estrogen therapy for the treatment of postmenopausal genitourinary syndrome of menopause.

Materials and Methods

We conducted a randomized controlled clinical trial involving 25 postmenopausal women. Participants were aged between 50 and 65 years with at least 1 year of amenorrhea and follicle-stimulating hormone levels of >40 IU/L. The women were randomized into two groups: the laser therapy group (n = 13) and the vaginal topical estrogen therapy group (n = 12). Changes in the vaginal epithelium thickness, Frost index, and cell maturation were analyzed in both the groups. The female sexual quotient of each woman was also evaluated. Subjective evaluation was performed through a physical examination.

Results

Histological analysis showed a significant increase in the vaginal epithelium thickness at the end of treatment in females in both the laser therapy (P < 0.001) and topical estrogen therapy (P = 0.001) groups. The topical estrogen therapy group tended to present a higher maturation index at the end of treatment when compared with that of the other group. Sexual function increased significantly over time in both the topical estrogen therapy (P < 0.001) and laser therapy (P < 0.001) groups. Subjective evaluation through physical examination showed a significant improvement in atrophy in both the groups.

Conclusion

Despite the nonequivalence with topical estrogen therapy, our data suggest that laser therapy is an effective method for the treatment of vulvovaginal atrophy.



Vaginal CO₂ laser therapy versus sham for genitourinary syndrome of menopause management: A systematic review and meta-analysis of randomized controlled trials

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TAG

GSM

**Review and meta-analysis
Randomized placebo-
controlled trial**

ABSTRACT

Importance

The research of new therapeutic modalities, especially with energy-based devices, has been increasing nowadays for genitourinary syndrome of menopause (GSM) management. Microablative fractional CO₂ laser has been used for pelvic floor dysfunction management.

Objective

To conduct a systematic review and meta-analysis of randomized controlled trials to compare fractional CO₂ laser therapy versus sham therapy for GSM management.

Evidence Review

We searched for the available randomized clinical trials in Cochrane Library, PubMed, ISI web of science, and Scopus during March 2021. We included randomized clinical trials that compared CO₂ laser to sham among postmenopausal women with GSM diagnosis. We extracted the available data from included studies and pooled them in a meta-analysis model using RevMan software. Our main outcomes were total vaginal score assessment using the Vaginal Assessment Scale, sexual function using the Female Sexual Function Index, urinary symptoms using the Urogenital Distress Inventory-6, and satisfaction.

Findings

Three studies met our inclusion criteria with a total number of 164 women. The CO₂ laser was linked to a significant reduction in Vaginal Assessment Scale score when compared with the sham group (mean difference [MD] = -0.49, 95% CI [-0.75 to -0.22], P = 0.004). The CO₂ laser was associated with a significant improvement in Female Sexual Function Index score in comparison with sham group (MD = 9.37, 95% CI [6.59-12.14], P < 0.001). In addition, a significant reduction in Urogenital Distress Inventory-6 score was reported among the CO₂ laser group (MD = -6.95, 95% CI [-13.24 to -0.67], P = 0.03). More women were significantly satisfied among the CO₂ laser group (risk ratio = 1.98, 95% CI [1.36-2.89], P = 0.004).

Conclusions and relevance

CO₂ laser therapy is a promising alternative for GSM management. Further randomized trials with larger sample sizes are required to confirm our findings.



Conservative management of urinary stress incontinence in selected post menopause patients with fractional CO₂ laser

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ABSTRACT

Objectives

This PUBA study aims to evaluate the effectiveness of the Fractional CO₂ Laser in the conservative treatment of Urinary Stress Incontinence in pre-selected Post-Menopausal Patients, with urine loss to Valsalva maneuvers.

Materials and Methods

Symptoms of Urinary Stress Incontinence were evaluated before, and 1 month after the last session (3 sessions with a 30-day interval between them) in 50 post-menopausal women (Middle Age - Menopause, Interquartile Range Parity - BMI). Subjective measures (ICIQ SF, VAS) and objective measures such as PAD TEST were used (a dry diaper was previously weighed, and she was instructed to take 500 cc for 15 minutes at rest, and then for 45 minutes to perform Valsalva maneuvers, go up and down stairs, sit, stand up, etc. and then reweigh the diaper) during the study period in order to evaluate the results of the fractional CO₂ laser treatment compared to the baseline.

Results

Of the 50 patients enrolled, 12 patients in total who presented minimal Urinary symptoms of incontinence (USI) according to the ICIQ questionnaire, all were cured, defining this, as the no loss of urine. Of the 18 patients who presented moderate USI, 10 were cured (55%), that is, they did not present urine loss, and the other 8 patients (45%) had partial recovery, but continued losing urine. Of the 20 patients who presented severe USI, none were cured, 9 (45%) of them remained in severity, and 11 (55%) patients had partial recovery, migrating to the degree of moderate USI. An objective assessment was also performed using the PAD TEST, of the 12 patients with minimal USI, all were cured, of the 18 patients who presented moderate USI, what was found in the ICIQ was confirmed, with 10 patients cured, and 8 with partial recovery. Likewise, of the 20 patients with severe USI, none were cured.

Conclusion

In the present study, the data suggest that Fractional CO₂ Laser is an effective alternative for the treatment of Minimal-Moderate Urinary Stress Incontinence in well-selected post-menopausal patients, with positive results that persist over time.



The CO₂ ablative laser treatment in perimenopausal patients with vulvovaginal atrophy

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TAG

**VVA
Menopause**

ABSTRACT

Objectives

The aim of the study was to evaluate the effectiveness of CO₂ fractional laser therapy on perimenopausal urogenital symptoms.

Material and methods

This prospective, open-label study included 205 patients who received three CO₂ laser treatments. Clinical assessment was checked at baseline as well as at six weeks and 12 months post-treatment. The following scores were measured Vaginal Health Index Score (VHIS), International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) and assessment of the severity of selected urogenital symptoms.

Results

Significant improvements in dryness, dyspareunia, burning, vaginal laxity, urinary incontinence, as were the results on the VHIS and ICIQ-UI SF at six weeks post-treatment ($p < 0.05$ for all scores), which were maintained through the follow-up visit at 12 months. No complications were observed either during or after laser therapy.

Conclusions

CO₂ ablative laser treatment can be effective in reducing vulvovaginal atrophy symptoms such as vaginal laxity, dryness, painful sexual intercourse, burning, and decreases the severity of stress urinary incontinence and urge incontinence symptoms. Positive results were maintained at 12 months after the laser treatment. .



Treatment of rectovaginal fistula using fractionate CO₂ vaginal laser: A case series

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ABSTRACT

Objectives

To report five cases of patients with RVF submitted to intravaginal CO₂ fractional laser treatment, as a complementary and additional therapeutic option in this scenery.

Materials and Methods

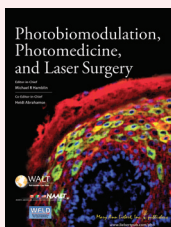
Five laser sessions with monthly intervals followed by complete evaluation through clinical examination and magnetic resonance imaging of the pelvis were performed for all patients.

Results

Three patients had complete resolution of symptoms after the end of planned vaginal laser sessions, whereas two patients reported significant improvement in symptoms. Four patients who had stopped having sex due to their condition admitted to resuming regular sexual activity. In addition, all five patients had closure of the fistulous track confirmed by pelvic MRI. No adverse events from vaginal laser therapy were reported by any of the patients.

Conclusion

We believe this method to be a complementary, promising, and safe therapeutic alternative for the management of RVF. It may potentially enable return to regular sexual activity. Future studies using this therapeutic strategy are needed to confirm the efficacy and safety of this method in this clinical setting.



Efficacy of CO₂ laser treatment in postmenopausal women with vulvovaginal atrophy: a meta-analysis

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Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing - China.

TAG

VVA

Menopause

Review and meta-analysis

ABSTRACT

Objectives

To explore the efficacy of CO₂ laser treatment in postmenopausal women with vulvovaginal atrophy.

Method

PubMed, Embase, Cochrane Library and Web of Science were searched to June 9, 2020. Prospective studies on the efficacy of CO₂ laser treatment were included. Two researchers independently reviewed articles and extracted data. Heterogeneity test was conducted for each outcome indicator. Sensitivity analysis was performed in all models.

Results

Twelve articles including 459 participants were enrolled. Compared with baseline, vaginal health indeices (VHIs) were significantly higher at the 1-, 3-, 6-, and 12-month follow ups ($P < 0.001$). For VVA severity, the visual analog scale scores for vaginal dryness at 1-, 3-, 6-, and 12-month follow-ups ($P < 0.050$), vaginal burning, itching, and dysuria at 1-month follow up ($P < 0.001$), and dyspareunia at 1-, 3-, 6-, and 12-month follow-ups ($P < 0.001$) were all significantly lower. For FSFI, total scores at 1-, 3-, 6-, and 12-month follow ups ($P < 0.001$), and the scores in desire, arousal, lubrication, orgasm, satisfaction, and pain at 1-month follow up ($P < 0.050$) were all significantly higher. For quality of life, the PCS12 and MCS12 scores were all significantly higher ($P < 0.050$) at the 1-month follow up.

Conclusion

CO₂ laser treatment may be effective for postmenopausal women with VVA symptoms in improving quality of life and sexual function.



Treatment of vulvovaginal atrophy with fractional CO₂ laser: Evaluating real-world data

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ABSTRACT

Objectives

To evaluate real-world data for the use of fractional CO₂ laser therapy for treating symptoms of vulvovaginal atrophy (VVA).

Materials and Methods

Thirty-six patients were treated in a single medical center. They consisted of pre- and postmenopausal women and received three fractional CO₂ laser therapy treatments with 3-6 weeks between each treatment. Each patient financed the treatment privately. The symptoms pain, pruritus, dyspareunia, burning, dryness, and dysuria were recorded with a visual analog scale (1-10) before the first, second, and third laser treatment. The data were examined retrospectively.

Results

Pain was reduced from a mean of 2.5 points (minimum 0, maximum 9 points) to 1.1 (minimum 0, maximum 8 points) before the third laser treatment. Pruritus showed a mean score of 3.8 (minimum 0, maximum 10 points). This decreased to 1.4 (minimum 0, maximum 8 points). Dyspareunia scored a mean of 6.8 (minimum 0, maximum 10 points). After two laser therapies, the score was 3.3 (minimum 0, maximum 8 points). Burning showed 4.2 points (minimum 0, maximum 10 points). Having experienced two laser therapy sessions, the patients scored 1.5 (minimum 0, maximum 9 points) points. The severity of dryness dropped from 6.5 (minimum 0, maximum 10 points) to 3.3 (minimum 0, maximum 9 points). Dysuria was stated with 1.8 points (minimum 0, maximum 10 points) before the first and 0.5 points (minimum 0, maximum 6 points) before the third laser therapy. All changes showed statistical significance ($p < 0.002$).

Conclusion

This real-world data propose fractional CO₂ laser to reduce VVA-associated genital discomfort, thus being a valuable therapy option for pre- and postmenopausal women.

Fractional CO₂ laser treatment after transvaginal polypropylene mesh for urinary incontinence and pelvic organ prolapse treatment as an alternative to improve mesh erosion rates

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TAG

Vaginal mesh-related complications
Histological examination

ABSTRACT

The support advantages of synthetic mesh in vaginal reconstructive surgery and stress urinary incontinence are significant. However, erosion of the mesh may occur as a complication, Four sessions of fractional CO₂ Laser treatment protocol (Mona Lisa Touch Deka M.E.L.A Florence Italy protocol, were performed in the study group to 96 patients, beginning at 30 days, after mesh insertion, important improvement regarding erosion rates was found inside our study group, thanks to the trophic effects of fractional CO₂ laser protocol. The use of alternative technologies that provide bio -stimulation of vaginal epithelium by increasing its thickness, and trophic changes that may be related to the very low erosion rate was found in our group of patients.



Effects of fractional CO₂ laser treatment on patients affected by vulvar lichen sclerosis: a prospective study

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ABSTRACT

Objectives

This is a prospective, single-center study aimed at evaluating the effect of fractional microablative CO₂ laser treatment on women affected by VLS.

Materials and Methods

Patients with histologically confirmed VLS underwent three fractional microablative CO₂ laser treatments, 4 weeks apart, on the genital affected areas. Clinical and VLS-related symptoms, side effects, and patient satisfaction index were assessed and recorded for all the patients using the visual analog scale (VAS).

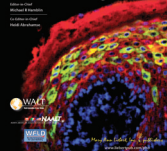
Results

Data from a total of 70 patients were included, paired at different time points and analyzed. VLS-related symptoms and other relevant parameters (pH, vaginal introitus discomfort, dyspareunia, vaginal dryness, itching, and burning) showed a statistically significant improvement ($p < 0.001$) after the first laser treatment and kept improving after second and third sessions. According to VAS, the two most common symptoms, vaginal introitus discomfort and dyspareunia, went from (mean $\pm$ standard deviation) 8.2 ± 2.3 and 8.3 ± 2.2 , respectively, at baseline, to 3.6 ± 2.6 and 3.8 ± 2.6 , respectively, 1 month after the last treatment. Vaginal dryness, itching, and burning were significantly improved as well. Most patients declared to be very satisfied with the results of the treatment. A total of 62.8% of the women expressed a satisfaction score ≥ 8 on a scale from 0 to 10.

Conclusion

Fractional microablative CO₂ laser treatment seems to be safe and effective to treat VLS and improve VLS-related symptoms.

Photobiomodulation,
Photomedicine,
and Laser Surgery



CO₂-laser therapy and genitourinary syndrome of menopause: A systematic review and meta-analysis

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TAG

GSM

Review and meta-analysis

ABSTRACT

Objectives

Review of the current literature on CO₂-Laser therapy efficacy for the treatment of GSM.

Materials and Methods

MEDLINE and Embase databases were systematically queried in December 2020. Studies included women with a diagnosis of Vulvo-Vaginal Atrophy (VVA) or GSM without an history of gynaecological and/or breast cancer, pelvic organ prolapse staged higher than 2, pelvic radiotherapy or Sjogren's Syndrome. The quality of the evidence was assessed with the Cochrane risk of bias tool. This study is registered on PROSPERO, number CRD42021238121.

Results

All studies showed a significant reduction in VVA and/or GSM symptoms (dryness, dyspareunia, itching, burning, dysuria). The pooled mean differences for the symptoms were: dryness -5.15 (95% CI:-5.72,-4.58; P < .001; I²:62%; n = 296), dyspareunia -5.27 (95% CI:-5.93,-4.62; P < .001; I²:68%; n = 296), itching -2.75 (95% CI:-4.0,-1.51; P < .001; I²:93%; n = 281), burning -2.66 (95% CI:-3.75, -1.57; P < .001; I²:86%; n = 296) and dysuria -2.14 (95% CI:-3.41,-0.87; P < .001; I²:95%; n = 281). FSFI, WHIS and VMV scores also improved significantly. The pooled mean differences for these scores were: FSFI 10.8 (95% CI:8.41,13.37; P < .001; I²:84%; n = 273), WHIS 8.29 (95% CI:6.16,10.42; P < .001; I²:95%; n = 262) and VMV 30.4 (95% CI:22.38,38.55; P < .001; I²:24%; n = 68). CO₂-Laser application showed a beneficial safety profile and no major adverse events were reported.

Conclusion

The data suggest that CO₂-Laser is a safe energy-based therapeutic option for the management of VVA and/or GSM symptoms in postmenopausal women.



Long-term follow-up of fractional CO₂ laser therapy for genitourinary syndrome of menopause in breast cancer survivors

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ABSTRACT

Objectives

The objective of this study was to determine the long-term efficacy of fractional CO₂ laser therapy in breast cancer survivors.

Materials and Methods

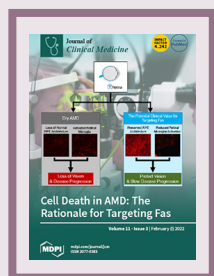
This was a single-arm study of breast cancer survivors. Participants received three treatments of fractional CO₂ laser therapy and returned for a 4 week follow-up. Participants were contacted for follow-up at annual intervals. The Vaginal Assessment Scale (VAS), the Female Sexual Function Index (FSFI), the Female Sexual Distress Scare Revised (FSDS-R), the Urinary Distress Inventory (UDI), and adverse events were collected and reported for the two-year follow-up. The changes in scores were compared between the four-week and two-year and the one-year and two-year follow-ups using paired t-tests.

Results

In total, 67 BC survivors were enrolled, 59 completed treatments and the four week follow-up, 39 participated in the one-year follow-up, and 33 participated in the two-year follow-up. After initial improvement in the VAS from baseline to the four week follow-up, there was no statistically significant difference in the VAS score (mean Δ 0.23; 95% CI [-0.05, 0.51], $p = 0.150$) between the four week follow-up and the two-year follow-up. At the two-year follow-up, the FSFI and FSDS-R scores remained improved from baseline and there was no statistically significant change in the FSFI score (mean Δ -0.83; 95% CI [-3.07, 2.38] $p = 0.794$) or the FSDS-R score (mean Δ -2.85; 95% CI [-1.88, 7.59] $p = 0.227$) from the one to two-year follow-up. The UDI scores approached baseline at the two-year follow-up; however, the change between the one- and two-year follow-ups was not statistically significant (mean Δ 4.76; 95% CI [-1.89, 11.41], $p = 0.15$).

Conclusion

Breast cancer survivors treated with fractional CO₂ laser therapy have sustained improvement in sexual function two years after treatment completion, suggesting potential long-term benefit.



Vaginal laser therapy for female stress urinary incontinence: New solutions for a well-known issue-a concise review

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TAG

SUI

Both menopausal and non-menopausal patients

Review

ABSTRACT

Background and Objectives

Insufficient connective urethra and bladder support related to childbirth and menopausal estrogen decrease leads to stress urinary incontinence (SUI). The aim of this review is to narratively report the efficacy and safety of new mini-invasive solutions for SUI treatment as laser energy devices, in particular, the microablative fractional carbon dioxide laser and the non-ablative Erbium-YAG laser.

Materials and Methods

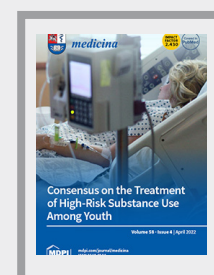
For this narrative review, a search of literature from PubMed and EMBASE was performed to evaluate the relevant studies and was limited to English language articles, published from January 2015 to February 2022.

Results

A significant subjective improvement, assessed by the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI-SF) was reported at the 6-month follow up, with a cure rate ranged from 21% to 38%. A reduction of effect was evidenced between 6 and 24-36 months. Additionally, the 1-h pad weight test evidence a significant objective improvement at the 2-6-month follow up.

Conclusion

SUI after vaginal laser therapy resulted statistically improved in almost all studies at short-term follow up, resulting a safe and feasible option in mild SUI. However, cure rates were low, longer-term data actually lacks and the high heterogeneity of methods limits the general recommendations. Larger RCTs evaluating long-term effects are required.



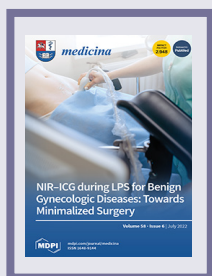
New innovations for the treatment of vulvovaginal atrophy: an up-to-date review

Benini V¹, Ruffolo AF¹, Casiraghi A¹, Degliuomini RS¹, Frigerio M², Braga A³, Serati M⁴, Torella M⁵, Candiani M², Salvatore S¹

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ABSTRACT

Vulvovaginal atrophy (VVA) is a chronic progressive disease involving the female genital apparatus and lower urinary tract. This condition is related to hypoestrogenism consequent to menopause onset but is also due to the hormonal decrease after adjuvant therapy for patients affected by breast cancer. Considering the high prevalence of VVA and the expected growth of this condition due to the increase in the average age of the female population, it is easy to understand its significant social impact. VVA causes uncomfortable disorders, such as vaginal dryness, itching, burning, and dyspareunia, and requires constant treatment, on cessation of which symptoms tend to reappear. The currently available therapies include vaginal lubricants and moisturizers, vaginal estrogens and dehydroepiandrosterone (DHEA), systemic hormone therapy, and Ospemifene. Considering, however, that such therapies have some problems that include contraindications, ineffectiveness, and low compliance, finding an innovative, effective, and safe treatment is crucial. The present data suggest great efficacy and safety of a vaginal laser in the treatment of genital symptoms and improvement in sexual function in patients affected by VVA. The beneficial effect tends to be sustained over the long-term, and no serious adverse events have been identified. The aim of this review is to report up-to-date efficacy and safety data of laser energy devices, in particular the microablative fractional carbon dioxide laser and the non-ablative photothermal Erbium-YAG laser.



Fractional CO₂ laser for vulvo-vaginal atrophy in gynecologic cancer patients: A valid therapeutic choice? a systematic review

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TAG

VVA

**Oncological menopause
Gynecologic cancer survivors
Review**

ABSTRACT

Introduction

One of the most common adverse events reported by gynecological cancer survivors with spontaneous or iatrogenic menopause is vulvo-vaginal atrophy (VVA). An increasing number of women have this kind of discomfort related to the menopause induced by different cancer therapies. In this regard, fractional CO₂ laser may be a valid therapeutic choice for these patients.

Methods

We performed a literature search of PubMed, EMBASE, SCOPUS and Web of Science databases with search terms of laser CO₂ treatment of vulvovaginal atrophy and gynecologic cancer survivors and reviewed major US Society Guidelines to create this narrative review of this topic. Breast, ovarian endometrial and cervical cancers were included.

Results

Nine studies were included. Fractional CO₂ laser improves clinical symptoms and sexual function, in terms of VHI (vaginal health index) and FSFI (female sexual function index). Non severe adverse event occurred.

Conclusions

According to the best evidence available, fractional CO₂ laser treatment for VVA is an effective and safe therapeutic option for gynecological cancer survivors, improving sexual life and quality of life (QoL).

Keywords

CO₂ laser; Cancer survivors; Menopause; Quality of life; Vulvo-vaginal atrophy.



Comparison of severity of genitourinary syndrome of menopause symptoms after carbon dioxide laser vs vaginal estrogen therapy: A systematic review and meta-analysis

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ABSTRACT

Importance

Vaginal estrogen for genitourinary syndrome of menopause (GSM) should be used with caution in women with contraindications, highlighting the need for effective treatment alternatives.

Objective

To compare the severity of GSM after vaginal laser vs estrogen therapy.

Data Sources

The PubMed, Embase, and Cochrane Library databases were searched for articles published from database inception to April 8, 2022, with no language restrictions. Reference lists were also searched.

Study Selection

Randomized clinical trials (RCTs) that compared the use of lasers with vaginal estrogen in adults were selected.

Data Extraction and Synthesis

Two investigators independently extracted data from included studies. The Cochrane risk of bias tool for RCTs was used to assess risk of bias of each study. A random-effects model was used to pool mean differences (MDs) with 95% CIs.



Main Outcomes and Measures

Primary outcomes were Vaginal Analog Scale (VAS; higher scores indicate severer symptoms), Vaginal Health Index (VHI; higher scores indicate better vaginal health), Vaginal Maturation Index (VMI; higher scores indicate higher estrogen effect on the vaginal epithelium), Female Sexual Function Index (FSFI; higher scores indicate better female sexual function), and Sexual Quotient–Female (SQ-F; higher scores indicate better female sexual function) questionnaire scores. Urinary symptoms were assessed as an additional outcome. Data analyses were performed from April 9 to 12, 2022.

Results

A total of 6 RCTs with 270 women with GSM were included (135 were randomized to laser therapy and 135 to estrogen therapy; mean age ranged from 54.6 to 61.0 years). No significant differences were found between carbon dioxide laser and vaginal estrogen from baseline to the end of follow-up in overall VAS scores (MD, -0.16 ; 95% CI, -0.67 to 0.36 ; I², 33.31%), VHI (MD, 0.20 ; 95% CI, -0.56 to 0.97 ; I², 83.25%), VMI (MD, -0.56 ; 95% CI, -1.14 to 0.02 ; I², 35.07%), FSFI (MD, -0.04 ; 95% CI, -0.45 to 0.36 ; I², 41.60%), and SQ-F ($P = .37$ based on 1 study). Other questionnaire-based outcome measures demonstrated no difference between groups from baseline to the end of follow-up for changes in urinary symptoms.

Conclusions and Relevance

This systematic review and meta-analysis of RCTs found that vaginal laser treatment is associated with similar improvement in genitourinary symptoms as vaginal estrogen therapy. Further research is needed to test whether vaginal laser therapy could be a potential treatment option for women with contraindications to vaginal estrogen.

Efficacy of thermoablative fractional CO₂ laser (MonaLisa Touch) in stress urinary incontinence

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Nardone CC, Guzzo F, Plotti F, Luvero D

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ABSTRACT

Purpose

Usually, in stress urinary incontinence (SUI), nonsurgical therapy such as pelvic floor muscle training (PFMT) and lifestyle changes are proposed before surgical treatment. Laser therapy has recently been recommended for the treatment of SUI, helping to reconstruct the collagen that supports the vagina and the pelvic floor. The aim of the study was to evaluate the efficacy of SUI treatment with a CO₂ intravaginal laser in patients waiting for anti-incontinence surgery (TVT-O).

Methods

This is a prospective, case-control study. Fifty-two patients have been included in our study and we divided them into two groups: atrophy and no atrophy. We also adopted a control group retrospectively identified from our database of patients undergoing PFMT. The subjective estimation of SUI symptoms before and after treatment was evaluated using the Visual Analog Scale before and after 1, 6, and 12 months of treatment. The objective evaluation with the urodynamic study with the stress test and a 3-day voiding diary to count the number of episodes of incontinence, before and after treatment.

Results

The intravaginal CO₂ laser improved all the parameters considered for SUI in both groups. Its results were more relevant in the atrophy group, in comparison to the no atrophy group, even if they were both statistically significant. There were no statistically significant differences for all the parameters evaluated for SUI between laser treatment and PFMT in the control group.

Conclusion

The CO₂ laser is well-tolerated, minimally invasive, safe, and showing efficacy for SUI. More studies are needed to consider it as first-instance therapy, like PFMT, or at least, as a bridge therapy to surgery.



Randomized clinical trial with fractional CO₂ laser and clobetasol in the treatment of vulvar lichen sclerosis: A clinic study of feasibility

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TAG

Lichen sclerosis
Randomized clinical trial
CO₂ laser vs. clobetasol
Long-term follow-up

ABSTRACT

Objectives

The main objective of the study was to describe and compare the feasibility of using fractional CO₂ laser to the usual treatment with Clobetasol. Randomized clinical trials brought together 20 women from a Brazilian university hospital, 9 of them were submitted to Clobetasol treatment and 11 to laser therapy. Sociodemographic data were obtained and quality of life parameters, vulvar anatomy, self-perception and histopathological analysis of vulvar biopsies were evaluated. Evaluations were made before the beginning of the treatment, during its implementation, right after its completion (3 months), and 12 months after. The SPSS 14.0 software was used, obtaining descriptive measurements. The level of significance adopted was 5%.

Results

The clinical/anatomical characteristics of the vulva did not differ between the treatment groups, as much before as after its performance. There was no statistically significant difference between the treatments performed regarding the impact on the life quality of the patients. A higher satisfaction degree with the treatment was obtained with the patients in the Laser group in the third month of evaluation. Laser therapy also revealed higher occurrence of telangiectasia after treatment completion. Fractional CO₂ laser has proven to be well accepted and is a promising therapeutic option. Registration number and name of trial registry The institutional review board status was approved by the Research Ethics Committee of HU/ UFJF under advisory number 2881073 and registered in the Brazilian Clinical Trials, with consent under registration RBR-4p9s5y. Access link: <https://ensaiosclinicos.gov.br/rg/RBR-4p9s5y>. continence symptoms. Positive results were maintained at 12 months after the laser treatment.



Efficacy of fractional CO₂ laser treatment for genitourinary syndrome of menopause in short-term evaluation-preliminary study

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ABSTRACT

The postmenopausal state covers 40% of modern women's lives and 50-70% of postmenopausal women report GSM symptoms such as vaginal dryness, itching, frequent inflammations, lack of elasticity, or dyspareunia. Consequently, a safe and effective method of treatment is crucial. In a group of 125 patients, a prospective observational study was performed. The aim was to evaluate the clinical effectiveness of fractional CO₂ laser in the treatment of GSM symptoms using a protocol of three procedures in 6-week intervals. The vaginal pH, VHIS, VMI, FSFI, and treatment satisfaction questionnaire were used. The fractional CO₂ laser treatment was effective in improving all the objective forms of evaluation: vaginal pH (from 5.61 ± 0.50 at the baseline up to 4.69 ± 0.21 in the 6-week follow-up after the third procedure); VHIS (12.02 ± 1.89 at the baseline vs. 21.50 ± 1.76); VMI (21.5 ± 5.66 vs. 48.4 ± 4.46). Similar results were obtained for FSFI: 12.79 ± 5.351 vs. 24.39 ± 2.733 , where 79.77% of patients were highly satisfied. Fractional CO₂ laser therapy increases the quality of life by having a beneficial effect on the sexual function of women with GSM symptoms. This effect is obtained by restoring the correct structure and proportions of the cellular composition of the vaginal epithelium. This positive effect was confirmed by both objective and subjective forms of evaluating GSM symptom severity.



The efficacy and feasibility of fractional CO₂ laser therapy for the treatment of urinary incontinence: A multicentric case-control study

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TAG

SUI

MUI

**Both menopausal and
non-menopausal patients**

ABSTRACT

Background

Female urinary incontinence is a significant public health problem. Conservative treatments require high patient compliance, while surgery often leads to more complications and recovery time. Our aim is to evaluate the efficacy of microablative fractional CO₂ laser therapy in women with urinary incontinence (UI).

Methods

This is a retrospective analysis of prospectively collected data on women with stress urinary incontinence (SUI) and mixed urinary incontinence (MUI) with predominant SUI subjected to four sessions of CO₂ laser therapy performed once a month, between February 2017 and October 2017, with a 12-month follow-up. The subjective Visual Analogue Scale (VAS) 0-10 was used to score and variables were evaluated at baseline and at one, six and 12 months after initiation of therapy. Finally, results were compared to a control group.

Results

The cohort consisted of 42 women. The proportion of patients with vaginal atrophy among those younger than 55 years was substantially lower (3/23; 13%) than among those older than 55 years (15/19; 78.9%). CO₂ laser treatment was associated with a significant improvement in VAS scores recorded one-month, six-months, and one-year, after conclusion of therapy ($P < 0.001$). VAS scores improved significantly in patients with either SUI (26/42; 61.9%) or mixed UI (16/42; 38.1%). No major post treatment complications were registered. Women with vaginal atrophy demonstrated significantly better results ($P < 0.001$).

Conclusion

Results confirm the efficacy and a good safety profile, for CO₂ laser treatment in SUI, mostly in women with postmenopausal vaginal atrophy and should be considered as a treatment option for female patients with concomitant SUI and vaginal atrophy.



Efficacy of laser remodeling treatment in genitourinary syndrome of menopause

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4: DEKA Medical Multidisciplinary Medical Center.

ABSTRACT

Objective

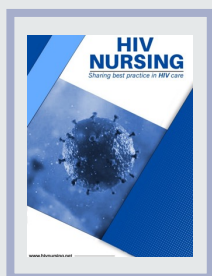
To evaluate the efficacy of laser remodeling in genitourinary syndrome of menopause using fractional microablative CO₂ laser remodeling treatment (SmartXide2 V2LR Monalisa Touch; DEKA (Florence, Italy).

Materials and Methods

This prospective, observational study included 105 patients (n=105) aged 52.0 ± 1.3 years with a verified diagnosis of postmenopausal atrophic vaginitis (ICD N.95.2) who provided voluntary informed consent to participate in this study. Based on the regimens of fractional microablative CO₂ laser remodeling treatment using the SmartXide2 V2LR Monalisa Touch laser system (DEKA, Florence, Italy) patients in the study cohort were assigned to either group I (n= 50; 40/1000/1000/1 ST/DP) or group II (n=55; 40/1400/1000/1 ST/DP). The control group for clinical and morphological comparison (n=30) included women of the similar age who did not have a verified diagnosis of postmenopausal atrophic vaginitis, N95.2. For objectification, the clinical manifestations of GSM in patients of the study cohort were scored using a 5-point D. Barlow scale and the vaginal health index was calculated (G. Bachmann, 1995).

Results

Following the laser remodeling procedure, patients in groups I and II demonstrated a significant increase in the vaginal health index, i.e., 1.25-fold (3.0 ± 0.81 versus 3.74 ± 0.69 ; $p < 0.001$) and 1.3-fold (3.15 ± 0.65 versus 4.11 ± 0.57 ; $p < 0.001$) after 3 months and 1.55-fold (3.0 ± 0.81 versus 4.66 ± 0.48 ; $p < 0.001$) and 1.5-fold (3.15 ± 0.65 versus 4.71 ± 0.46 ; $p < 0.001$) after 12 months, respectively. However, there were no statistically significant differences between the study groups ($p = 0.310$, $p = 0.003$, $p = 0.593$, respectively). In patients in the study cohort the baseline scores of the clinical manifestations of GSM using the D. Barlow scale were 2.74 ± 1.23 and 2.92 ± 1.14 in groups I and II, respectively. Following the laser remodeling procedure, patients in groups I and II experienced a significant decrease in these scores of 1.49-fold (2.74 ± 1.23 versus 1.84 ± 0.93 ; $p < 0.001$) and 1.45-fold (2.92 ± 1.14 versus 2.02 ± 0.87 ; $p < 0.001$) after 3 months and 3.8-fold (2.74 ± 1.23 versus 0.72 ± 0.7 ; $p < 0.001$) and 4.11-fold (2.92 ± 1.14 versus 0.71 ± 0.66 ; $p < 0.001$) after 12 months, respectively. However, there were no



statistically significant differences between the study groups ($p=0.418$, $p=0.314$, $p=0.935$, respectively). In this study, two regimens (40/1000/1000/1 ST/DP and 40/1400/1000/1 ST/DP) of the microablative laser remodeling treatment using the SmartXide² V²LR Monalisa Touch fractional CO₂ laser (DEKA, Florence, Italy) were found to be similar in clinical efficacy and safety and had no adverse effects associated with burns and/or adhesions to the vaginal mucosa..

Conclusions

Therefore, it can be concluded that the use of the SmartXide² V²LR Monalisa Touch fractional CO₂ laser (DEKA, Florence, Italy) in treatment of GSM is pathogenetically justified and is an effective and safe treatment option in postmenopausal patients with vulvovaginal atrophy.

Quality of life and sexual function in patients with genitourinary syndrome of menopause: Focus on laser remodeling therapy

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ABSTRACT

Objective

To evaluate the quality of life and sexual function in patients with genitourinary syndrome of menopause prior to and following laser remodeling using the fractional microablative CO₂ laser remodeling therapy (SmartXide² V²LR Monalisa Touch; DEKA (Florence, Italy).

Study Design

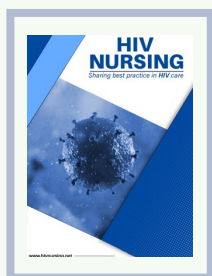
An open, multicentre, comparative, independent, prospective study.

Materials and Methods

This prospective, observational study included 105 patients (n = 105) aged 52.0 ± 1.3 years with a verified diagnosis of postmenopausal atrophic vaginitis (ICD N.95.2) who provided voluntary informed consent to participate in this study. Based on the regimens of fractional microablative CO₂ laser remodeling treatment using the SmartXide² V²LR Monalisa Touch laser system (DEKA, Florence, Italy) patients in the study cohort were assigned to either group I (n = 50; 40/1000/1000/1 ST/DP) or group II (n = 55; 40/1400/1000/1 ST/DP). The control group (n = 30) included women of similar age who did not have a verified diagnosis of postmenopausal atrophic vaginitis. For objectification, the clinical manifestations of GSM in study patients were scored using a 5-point D. Barlow scale and the vaginal health index was calculated (G. Bachmann, 1995). The quality of life and sexual function in the study cohort were evaluated using the following tools: Female Sexuality Index (SSI), 5-point Likert scale, and SF-36 quality of life questionnaire. The pain intensity in patients suffering from GSM-related dyspareunia was measured using a Visual Analogue Scale (VAS). The efficacy of therapy was evaluated 3 and 12 months after laser remodeling procedures. For statistical analysis, the results were processed using IBM SPSS v.23.0 and StatTech software.

Results

The mean age of patients in the study cohort (n=105) was 52 ± 1.3 years. The mean postmenopausal period was 2.38 ± 0.9 years and 2.26 ± 0.84 years in the first and the second study groups, respectively. Two study groups practically did not differ



in the mean duration of clinical GSM which was 2.26 ± 0.88 years in the first group and 2.26 ± 0.84 in the second group. Following the laser remodeling procedure, patients in groups I and II experienced a significant decrease in GSM symptom intensity of 1.49-fold (2.74 ± 1.23 versus 1.84 ± 0.93 ; $p < 0.001$) and 1.45-fold (2.92 ± 1.14 versus 2.02 ± 0.87 ; $p < 0.001$) after 3 months and 3.8-fold (2.74 ± 1.23 versus 0.72 ± 0.7 ; $p < 0.001$) and 4.11-fold (2.92 ± 1.14 versus 0.71 ± 0.66 ; $p < 0.001$) after 12 months, respectively. A similar positive trend was observed in scores obtained using the D. Barlow scale: 3.8-fold (2.74 ± 1.23 versus 0.72 ± 0.7 ; $p < 0.001$) and 4.11-fold (2.92 ± 1.14 vs. 0.71 ± 0.66 ; $p < 0.001$) 3 and 12 months after the treatment, respectively. Following the laser remodeling procedure, there was a significant improvement in quality of sexual life of 1.33-fold (Female Sexuality Index (SSI), 19.58 ± 6.88 versus 26.02 ± 4.81 ; $p < 0.001$) and 1.25-fold (21.4 ± 6.76 versus 26.76 ± 4.9 ; $p < 0.001$) after 3 months and 1.58-fold (19.58 ± 6.88 versus 30.98 ± 3.12 ; $p < 0.001$) and 1.46-fold (21.4 ± 6.76 versus 31.16 ± 3.3 ; $p < 0.001$) after 12 months, respectively. Following the laser remodeling procedure, patients demonstrated a significant decrease in intensity of GSM-related dyspareunia of 1.6-fold (4.44 ± 2.18 versus 2.76 ± 1.4 ; $p < 0.001$) and 1.75-fold (4.24 ± 2.08 versus 2.42 ± 1.26 ; $p < 0.001$) after 3 months and 4.83-fold (4.44 ± 2.18 versus 0.92 ± 0.75 ; $p < 0.001$) and 5.44-fold (4.24 ± 2.08 versus 0.78 ± 0.69 ; $p < 0.001$) after 12 months, respectively. The quality of life measured using SF-36 was also found to improve significantly, i.e., 1.35-fold (48.18 ± 20.06 versus 65.02 ± 16.45 ; $p < 0.001$) and 1.31-fold (53.2 ± 21.1 versus 69.64 ± 15.96 ; $p < 0.001$) after 3 months and 1.59-fold (53.2 ± 21.1 versus 84.64 ± 9.78 ; $p < 0.001$) after 12 months, respectively. The analysis of quality of life measured using the Likert scale demonstrated a significant decrease in the scores of 1.66-fold (2.82 ± 0.98 versus 1.7 ± 0.97 ; $p < 0.001$) and 1.76-fold (2.62 ± 0.87 versus 1.49 ± 0.84 ; $p < 0.001$) 3 months after and 4.03-fold (2.82 ± 0.98 versus 0.7 ± 0.54 ; $p < 0.001$) and 3.82-fold (2.62 ± 0.87 versus 0.685 ± 0.58 ; $p < 0.001$) 12 months after the laser remodeling procedure, respectively.

Conclusions

In summary, it can be concluded that the use of the SmartXide² V²LR Monalisa Touch fractional CO₂ laser (DEKA, Florence, Italy), regardless of the parameters of the selected ablation regimen in the treatment of GSM symptoms, has a beneficial effect on the quality of life and sexual function in patients with genitourinary syndrome of menopause.

Comparative efficacy of treatments for genitourinary syndrome of menopause

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ABSTRACT

Study Objective

To evaluate the comparative efficacy of the treatments for genitourinary syndrome of menopause.

Study Design

An open-label, multicentre, prospective, comparative study.

Materials and Methods

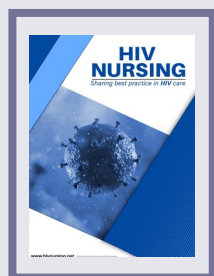
This study included 114 patients aged 52.04 ± 1.48 years with a verified diagnosis of postmenopausal atrophic vaginitis (ICD N.95.2) who provided voluntary informed consent to participate in this study. Patients were divided into two study groups. To treat vulvovaginal atrophy, patients in group I ($n = 59$) administered intravaginal suppositories containing 0.5 mg of estriol, 1 suppository per day for the first 4 weeks and then 1 suppository 2 times a week for 8 weeks. Thus, the total course of topical hormone therapy was 3 months. In group II ($n = 55$) all patients underwent laser remodeling of the vulvovaginal area using the SmartXide² V²LR Monalisa Touch laser system (DEKA, Florence, Italy) in the mode of 40/1400/1000/1 ST/DP for 3 sessions in total with a 1-month interval. Thus, the total laser remodeling treatment course was 3 months. The control group ($n = 30$) included women of similar age who did not have a verified diagnosis of postmenopausal atrophic vaginitis, N95.2. For objectification, the clinical manifestations of GSM in study patients were scored using a 5-point D. Barlow scale and the vaginal health index was calculated (G. Bachmann, 1995).

Results

The mean age of patients in groups I and II was 51.85 ± 1.37 and 52.1 ± 1.26 years with the mean postmenopausal period of 2.44 ± 0.86 years and 2.26 ± 0.84 years, respectively. Thus, the mean time from the onset of clinical manifestations of vulvovaginal atrophy was 2.32 ± 0.84 years in group I and 2.26 ± 0.84 years in group II. In this study, two treatment options, i.e., the topical hormone therapy and the microablative laser remodeling treatment using the SmartXide² V²LR Monalisa Touch fractional CO₂ laser (DEKA, Florence, Italy) in the mode of 40/1400/1000/1 ST/DP, demonstrated similar clinical efficacy in management of GSM symptoms and restoration of vaginal health in studied patients and had no adverse effects associated with burns and/or adhesions to the vaginal mucosa.

Conclusions

The use of the SmartXide² V²LR Monalisa Touch fractional CO₂ laser (DEKA, Florence, Italy) in treatment of GSM is pathogenetically justified and is an effective treatment option in postmenopausal patients with contraindications to topical hormone therapy.



Clinical and morphological efficacy and safety of laser remodeling therapy in patients with GSM

TAG

GSM

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ABSTRACT

Study Objective

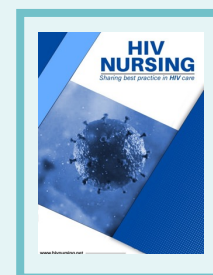
To evaluate the clinical and morphological efficacy and safety of laser remodeling therapy in patients with genitourinary syndrome of menopause.

Study Design

An open, multicentre, comparative, independent, prospective clinical and morphological study.

Materials and Methods

This study included 114 patients aged 52.04 ± 1.48 years with a verified diagnosis of postmenopausal atrophic vaginitis who provided voluntary informed consent to participate in this study. Patients were divided into two study groups. To treat vulvovaginal atrophy, patients in group I ($n = 59$) administered intravaginal suppositories containing 0.5 mg of estriol, 1 suppository per day for the first 4 weeks and then 1 suppository 2 times a week for 8 weeks. The total course of topical hormone therapy was 3 months. In group II ($n = 55$) all patients underwent laser remodeling of the vulvovaginal region using the SmartXide2 V2LR Monalisa Touch laser system (DEKA, Florence, Italy) in the mode of 40/1400/1000/1 ST/DP for 3 sessions in total with a 1-month interval. The control group ($n = 30$) included women of similar age who did not have a verified diagnosis of postmenopausal atrophic vaginitis, N95.2. In all patients, tissue specimens (up to 3 mm in diameter) were obtained by punch biopsy at baseline and 3 months after the treatment. Morphological examination was carried out using the light microscopy, which was preceded by standard preparation of biopsy specimens (fixation in neutral formalin, histological processing, staining with hematoxylin and eosin, embedding). Two tissue samples, namely from the anterior and posterior vaginal walls, were obtained in each patient at two time points, i.e., prior to and 3 months after the treatment for GSM. A total of 516 vaginal wall histopathological examinations ($114 \text{ patients} * 2 \text{ biopsy specimens} * 2 \text{ time points} + 30 * 2 \text{ biopsy specimens in the morphological control group}$) were performed using light microscopy (hematoxylin and eosin staining) and immunohistochemistry. The results of the IHC with anti-type IV collagen, anti-VEGF-A, and anti-CD-31 antibodies were scored based on the percentage of stained cells and the staining intensity. For objectification, the clinical manifestations of GSM in study patients were rated using a 5-point D. Barlow scale and the vaginal health index was calculated (G. Bachmann, 1995).



Fractional CO₂ laser treatment is safe and effective for the management of genitourinary syndrome of menopause in korean women

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ABSTRACT

This study evaluates the efficacy and safety of fractional CO₂ lasers for treating genitourinary syndrome of menopause (GSM) in Korean women. The patients received three laser applications at an interval of 4 weeks each. The severity of GSM symptoms was assessed using a visual analog scale (VAS) at baseline and at every visit. The objective scale was measured using the vaginal health index score (VHIS) and Vaginal Maturation Index (VMI) after completion of the laser procedure. During each procedure, the patients' pain in the VAS score was recorded. In the last visit, patients evaluated their satisfaction with the laser therapy using a 5-point Likert scale. Thirty women completed all the study protocols. After two sessions of laser therapy, some GSM symptoms (vaginal dryness and urgency) and VHIS improved significantly. After completion of the treatment, all GSM symptoms improved ($p < 0.05$), and the VHIS further increased significantly (VHIS at baseline, 8.86 ± 3.2 vs. V3, 16.83 ± 3.15 , $p < 0.001$). The average satisfaction was 4.3. This study shows that fractional CO₂ laser treatment is effective and safe for Korean women with GSM. Further studies are needed to confirm these results and assess the long-term effects of laser therapy.



Safety and efficacy of fractional CO₂ laser treatment to the vestibule: A randomized, double-blind, sham-controlled, prospective 3-site clinical study in women with vestibular pain

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TAG

Vestibulodynia

**Randomized, double-blind,
placebo-controlled trial**

ABSTRACT

Background

Data are limited regarding fractional CO₂ laser as a nonhormonal treatment for vestibular pain.

Aim

We sought to perform what is, to our knowledge, the first multisite prospective randomized, double-blind, sham-controlled clinical trial to assess the safety and efficacy of fractional CO₂ laser treatment to the vestibule in women with vestibular pain.

Methods

Subjects (n = 70) meeting inclusion/exclusion criteria at each of 3 sites were randomized 2:1 to active or sham (zero energy) fractional CO₂ laser treatment using the vestibular probe (SmartXide² V²LR - MonaLisa Touch, DEKA, Florence, Italy). Subjects in each treatment arm received 3 treatments 4 weeks apart. At the initial follow-up (week 12), subjects were unblinded and those initially assigned to sham started active treatment.

Outcomes

Outcome measures included changes from baseline in sexual activity diaries and scores for the Vulvoscopic Genital Tissue Appearance Scale (VGTA), vestibular cotton-tipped swab testing, McGill Pain Questionnaire, Female Sexual Function Index (FSFI), Female Sexual Distress Scale-Revised (FSDS-R), and the O'Leary-Sant voiding and pain indices, the Interstitial Cystitis Symptom Index (ICSI) and Interstitial Cystitis Problem Index (ICPI).



Vaginal laser therapy for GSM/VVA: Where we stand now - A review by the EUGA working group on laser

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ABSTRACT

Vulvovaginal atrophy (VVA) is a chronic progressive condition that involves the genital and lower urinary tracts, related to the decrease of serum estrogenic levels when menopause occurs. The definition of genitourinary syndrome of menopause (GSM) is a medically more accurate, all-encompassing and publicly acceptable term than VVA. Due to the chronic progressive trend of GSM, symptoms tend to reappear after the cessation of therapy, and frequently long-term treatment is required. First-line therapies include vulvar and vaginal lubricant or moisturizers, and, in the case of failure, low-dose vaginal estrogens are the preferred pharmacological therapy. Populations of patients, such as breast cancer (BC) survivors, are affected by iatrogenic GSM symptoms with concerns about the use of hormonal therapies. The non-ablative erbium:YAG laser and the fractional microablative CO₂ vaginal laser are the two main lasers evaluated for GSM treatment. The aim of this comprehensive review is to report the efficacy and safety of Er:YAG and CO₂ vaginal lasers for GSM treatment. Vaginal laser therapy has been demonstrated to be effective in restoring vaginal health, improving VVA symptoms and sexual function. The data suggest that both Er:YAG and CO₂ vaginal lasers are safe energy-based therapeutic options for management of VVA and/or GSM symptoms in postmenopausal women and BC survivors. .



Comparison between laser and transobturator tape therapy in the treatment of stress urinary incontinence and role of overweight in treatment: A prospective observational study

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TAG

SUI

Both menopausal and non-menopausal patients
CO₂ laser vs. transobturator tape
Long-term follow-up

ABSTRACT

Introduction and hypothesis

Stress urinary incontinence (SUI) is treated with transobturator tape (TOT) sling procedures, but problems arise with artificial mesh in certain instances. Hence, non-invasive laser therapy may be useful under such circumstances. The current study was aimed at comparing the effects of these two treatments and at checking their applicability in various body mass index (BMI) groups.

Methods

Seventy-nine patients, who were clinically diagnosed with SUI, were divided into two groups, those who preferred TOT and those who preferred the transvaginal fractional micro-ablative CO₂ laser system. The SUI symptoms and International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) scores of the patients were determined before and at the 12th month after the treatment. General linear model, Stuart-Maxwell, and Bonferroni correction for pairwise comparison analyses were performed to compare the efficacy of the treatment type.

Results

The ICIQ-SF score decreased by 56.8% for laser therapy and 43.5% for TOT therapy (mean $\pm$ SE = 5.97 $\pm$ 0.16 and 5.09 $\pm$ 0.14 respectively). Laser therapy had a better effect on ICIQ-SF than TOT therapy (η^2p : 0.176, $p_{\text{time} \times \text{group}}$ < 0.001). Regardless of the types of treatment, the ICIQ-SF scores of healthy-weight participants decreased more than those of overweight participants (η^2p : 0.050, $p_{\text{time} \times \text{group}}$ = 0.045). In the TOT group, healthy-weight participants were more than twice as likely to recover fully from SUI symptoms as overweight participants, 1 year after the treatment. In the laser group, the majority of healthy-weight participants (88.8%) did not report any SUI symptoms after the treatment.

Conclusions

The efficacy of laser therapy for urinary incontinence was confirmed. Furthermore, it was observed that being overweight may be a risk factor for the failure of laser therapy.



Long-term clinical and histological safety and efficacy of the CO₂ laser for treatment of genitourinary syndrome of menopause: An original study

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3: University of Insubria, Varese - Italy. 4: IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy.

ABSTRACT

Objective

This study aimed to evaluate histological modifications of the vaginal mucosa after repeated microablative fractional CO₂ laser treatments. As secondary objectives we evaluated the clinical effects associated with repeated microablative fractional CO₂ laser treatments using validated questionnaires.

Methods

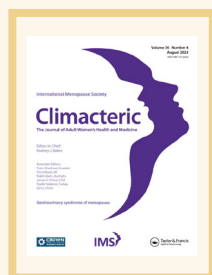
A prospective intervention study was performed in the Division of Gynecology and Obstetrics, Urogynecology Unit, IRCCS San Raffaele Scientific Institute with 15 postmenopausal women complaining of genitourinary syndrome of menopause symptoms. The cohort of patients was submitted to at least two previous laser treatment cycles in the past years. The Vaginal Health Index (VHI), visual analog scale (VAS), Female Sexual Function Index (FSFI), Urinary Distress Inventory-6 (UDI-6), International Consultation on Incontinence Questionnaire - Urinary Incontinence (ICIQ-UI) and 5-point Likert scale were used. Moreover, histological examinations were carried out on all samples.

Results

At 4 weeks after the last treatment, the VHI score and all FSFI items were significantly increased compared with baseline. We observed a statistically significant decrease in both frequency and severity for all urinary symptoms after the follow-up. We observed a statistically significant increase in the number of epithelial cell layers with a consequent increase in epithelial thickness, in the number of glycogen-filled cells and in the number of papillae after the laser treatment. No signs of fibrosis were observed as neovascularization was observed in each woman.

Conclusions

This is the first study demonstrating the histological persistency of efficacy in repeated annually laser treatment cycles, with tissue changes always leading to regenerative results without any sign of fibrosis.



Vaginal laser therapy for urogenital symptoms in postmenopausal women and breast cancer survivors

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TAG

GSM

Oncological menopause

Breast cancer survivors

Natural menopause

Long-term follow-up

ABSTRACT

Introduction

Genitourinary syndrome of menopause (GSM) is common after natural menopause as well as in women with induced menopause due to endocrine therapy and/or oophorectomy following breast cancer. Vaginal laser therapy is a nonhormonal treatment option that appears to alleviate GSM symptoms in natural menopause; however, women with induced menopause may respond differently. The aim of this study was thus to evaluate the efficacy and safety of laser treatment on GSM in postmenopausal women and breast cancer survivors.

Methods

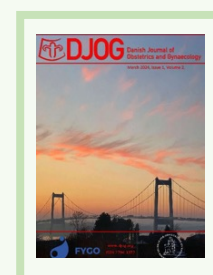
A total of 34 women were enrolled in the study, each completing three treatments at monthly intervals. After each treatment, sexual function was assessed with PISQ-12, urinary incontinence and overactive bladder symptoms were measured using ICIQ-UI SF and ICIQ-OAB, and the improvement of urinary incontinence was measured using PGI-I and PGI-S.

Results

At the time of follow-up, one year after the start of treatment the total PISQ-12 score had significantly increased in both groups compared to baseline (33 to 35.5, difference 2.5, 95% CI: 0.9-4.3). As assessed by ICIQ-UI SF scores, vaginal laser therapy also improved urinary incontinence from 5.3 at baseline to 3.4 at one-year follow-up (difference 1.9, 95% CI:0.4-3.1) for the total group. Improved urgency score from 3.1 at baseline to 2.5 at one-year follow-up (difference 0.7, 95% CI:0.02-1.5) and less leakage after urgency 3.1 at baseline to 2.8 at one-year follow-up (difference 0.8, 95% CI:0.05-1.5) were also reported. No complications were observed.

Conclusion

Vaginal laser therapy appears to be safe and may reduce GSM symptoms in postmenopausal women and breast cancer survivors. Separate randomized controlled studies are needed.



Results

The mean age of patients in groups I and II was 51.85 ± 1.37 and 52.1 ± 1.26 years, respectively. The mean postmenopausal period was 2.44 ± 0.86 years and 2.26 ± 0.84 years in group I and group II, respectively. The mean time from the onset of clinical manifestations of vulvovaginal atrophy was 2.32 ± 0.84 years in group I and 2.26 ± 0.84 years in group II. This study demonstrated similar clinical and morphological efficacy of the two treatments: 3 months after the therapy the expression of this marker significantly increased by 1.19 (2.19 ± 0.57 versus 2.61 ± 0.5 ; $p < 0.001$) and 1.14 times (2.29 ± 0.63 versus 2.6 ± 0.49 ; $p < 0.001$) in groups I and II, respectively; as well there were 1.17-fold (13.6 ± 3.8 versus 15.97 ± 4 , $p < 0.001$) and 1.3-fold (12.75 ± 4.26 versus 16.69 ± 4.3 , $p < 0.001$) increases in the expression of the above marker of angiogenesis and 1.25-fold (14.63 ± 9.01 versus 18.33 ± 10.83 , $p < 0.001$) and 1.22-fold ($16.78 \pm 10, 13$ versus 20.51 ± 11.50 , $p < 0.001$ respectively) increases in the expression of type IV collagen. In groups I and II the vaginal health scores using the G. Bachmann scale significantly increased 1.27-fold (2.98 ± 0.75 vs. 3.78 ± 1.15 ; $p = 0.006$) and 1.17-fold (3.14 ± 0.65 vs. 3.66 ± 1.58 ; $p = 0.006$), respectively, 3 months after the treatment for GSM.

Conclusions

In summary, in this study the laser remodeling treatment for symptoms of vulvovaginal atrophy using the SmartXide² V²LR Monalisa Touch fractional CO₂ laser (DEKA, Florence, Italy) was shown to have similar clinical and morphological efficacy to topical hormone therapy in improving the parameters of angio- and collagenogenesis in postmenopausal patients: following the treatment the expression of the VEGF-A marker significantly increased 1.19- and 1.14-fold along with increases in the expression level of CD-31 of 1.17- and 1.3-fold, in the expression of type IV collagen of 1.25- and 1.22-fold and in the vaginal health scores using the G. Bachmann scale of 1.27- and 1.17-fold ($p < 0.05$).

CO₂ laser versus sham control for the management of genitourinary syndrome of menopause: A systematic review and meta-analysis of randomized controlled trials

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TAG

GSM

Randomized, placebo-controlled trial

Review and meta-analysis

ABSTRACT

Purpose

In the context of the menopausal transition, genitourinary syndrome of menopause (GSM) refers to a range of genitourinary symptoms, from vaginal dryness to dysuria and urinary urgency. While hormonal treatments are standard, their associated side effects have driven the exploration of alternatives like vaginal CO₂ laser. We aimed to evaluate the randomized controlled trials (RCTs) comparing vaginal CO₂ laser treatment for GSM to sham controls. This systematic review sourced four electronic databases until June 2023. The analysis incorporated seven RCTs with 407 women. The CO₂ laser and sham control were comparable for most parameters, including the female sexual function index (FSFI) and visual analogue scale (VAS) for dyspareunia, vaginal health index, pH, and patient satisfaction. However, the CO₂ laser group showed significant improvement in the vaginal assessment scale for GSM symptoms. Sensitivity analyses revealed that parameters like FSFI showed significant differences in favor of CO₂ laser group upon the exclusion of specific studies. In conclusion, vaginal CO₂ laser therapy emerges as a promising alternative for GSM management, especially for most bothersome GSM symptoms; however, the need for further well-designed RCTs remains to validate its broad safety and efficacy.



Results

Sixty-one women were enrolled in this study. Overall, at T1 MLT brought to a significant improvement in urinary symptoms ($P < 0.05$) in women with urinary symptoms started after the menopause (Group B), contrary to the ones with urinary symptoms started before the menopause (Group A). Specifically, urinary frequency significantly improved only in Group B ($P < 0.05$), while urgency incontinence, significantly reduced in both groups ($P < 0.05$). Stress urinary incontinence did not significantly improve in both groups ($P > 0.05$). Secondary, all VVA symptoms showed a statistically significant improvement ($P < 0.05$) at 16 weeks from baseline; no differences were registered between groups. No adverse events were recorded.

Conclusions

This study confirms the safety and efficacy of CO₂ MLT for GSM symptoms. When urinary symptoms are considered, it seems that MLT might have a higher efficacy when symptoms started after menopause, in particular when they are part of the OAB syndrome.

Combined clinical and radiological remission of rectovaginal fistulas using fractional CO₂ vaginal laser: A case series and medium-term follow-up

**Rectovaginal fistula
Medium-term follow-up**

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ABSTRACT

Introduction

Despite the advances in surgical and clinical approaches, there is no consensus regarding the best line of treatment from rectovaginal fistula (RVF). Faced with a challenging scenario in the approach of RVF, the fractional CO₂ laser receives attention as a possible form of treatment.

Objectives

A single-center, prospective, open-label study evaluating the effectiveness and safety of laser therapy for RVF treatment.

Subjects and methods

The total of 15 patients was recruited at the Juiz de Fora University Hospital between August 2018 and July 2022. Inclusion criteria were presence of clinically suspects RVF of any etiology confirmed by pelvic magnetic resonance image (MRI) and gynecological examination. Five fractional CO₂ laser sessions with monthly interval followed by complete evaluation through clinical examination and pelvic MRI were performed for all patients after the completion of treatment. Analysis of sexual function before and after the treatment was performed using Female Sexual Quotient (FSQ).

Results

The evaluation through physical examination showed no persistent inflammatory signs in the vagina for all patients. Additionally, 10 of out 15 (67.7%) patients achieved clinical remission of RVF symptoms, while 33.3% patients reported significant improvement. Of note, five patients who did not have previous sexual activity returned to regular sexual activity while seven patients who have baseline sexual activity had improvement in their sexual function as assessed by the FSQ. Three out of four ostomized patients had their ostomy reversed and remained without complains. All six patients with RVF secondary to Crohn's disease reported a marked improvement in symptoms and sexual function. In seven (47%) patients radiological remission was confirmed by pelvic MRI.

Conclusions

CO₂ fractional laser can be considered a promising and safe therapeutic alternative for the management of RVF.



The utility of CO₂ laser treatment of pelvic symptoms in women with previous perineal trauma during delivery

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ABSTRACT

This study aimed to examine the impact of fractional CO₂ laser treatment of pelvic symptoms in women who have undergone perineal trauma from vaginal delivery. It was a retrospective, monocentric analysis that encompassed all women assessed for pelvic discomfort or signs of vulvovaginal atrophy following vaginal delivery between 2013 and 2018. The severity of symptoms was assessed using the Visual Analogue Scale (VAS). Twenty-seven patients met the inclusion criteria and were sorted into two groups: (1) women who had undergone episiotomies during labor (n = 11); and (2) women who had experienced spontaneous tears during vaginal delivery (n = 16). For women with episiotomies, each treatment and subsequent evaluation consistently showed a significant reduction in dyspareunia intensity. A similar positive trend was observed regarding pain at the introitus (7.5 vs. 6.5 after the first treatment, p = 0.03; 6.5 vs. 3 after the second treatment, p = 0.01; 3 vs. 1 after the third treatment, p = 0.01). Among women experiencing spontaneous perineal tears during delivery, there was a notable decrease in dyspareunia following all treatments (8 vs. 7 after the first treatment, p = 0.01; 8 vs. 4 after the second treatment, p = 0.02; 3 vs. 1 after the third treatment, p = 0.03). The impact of laser treatment did not exhibit significant differences between women who underwent episiotomies and those who experienced spontaneous perineal tears. In conclusion, fractional CO₂ laser can be regarded as a non-pharmacological option for managing pelvic floor symptoms in women who encountered perineal trauma during delivery, independently from the nature, spontaneity, or iatrogenesis of the perineal laceration.



Results

After active treatment, VGTA scores significantly improved in 5 parameters. Pain associated with cotton-tipped swab testing was significantly reduced at weeks 4 through 16 (mean change from baseline -0.64 [95% CI, -0.79 to -0.50] and -1.31 [95% CI, -1.46 to -1.16], respectively). FSFI pain domain scores improved significantly at weeks 12 and 16 (mean change from baseline 0.925 [95% CI, 0.10-1.75] and 1.22 [95% CI, 0.40-2.05], respectively). FSFI total scores increased significantly at weeks 12 and 16 (mean change from baseline 6.24 [95% CI, 2.64-9.85] and 4.96 [95% CI, 1.36-8.57], respectively). FSDS-R scores decreased significantly at weeks 12 and 16 (mean change from baseline -5.84 [95% CI, -8.80 to -2.87] and -9.15 [95% CI, -12.11 to -6.18], respectively). ICSI scores decreased significantly at weeks 12 and 16 (mean change from baseline -0.91 [95% CI, -1.65 to -0.18] and -0.754 [95% CI, -1.49 to -0.02], respectively). ICPI scores decreased significantly at week 16 (mean change from baseline -0.99 [95% CI, -1.63 to -0.34]). In contrast, there were no significant changes in outcomes in the sham arm. No serious adverse events occurred.

Clinical implications

Fractional CO₂ laser treatment in women with vestibular pain resulted in improvement from baseline in multiple key outcome measures of vestibular health.

Strengths and limitations

Strengths of the study were that it was a multisite prospective randomized double-blind, sham-controlled clinical trial that included multiple measures related to vestibular pain and sexual function. Limitations were the nonvalidated primary outcome measure and limited study cohort.

Conclusion

Fractional CO₂ laser therapy is a safe and effective nonhormonal treatment for vestibular pain.

SUI

Both menopausal and
non-menopausal patients

Randomized clinical trial

CO₂ laser and pelvic floor
muscle training

Urogynecology (Philadelphia, Pa.) - Epub 2024 Apr 25

Laser and pelvic floor muscle training for urinary incontinence: A randomized clinical trial

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ABSTRACT

Importance

Pelvic floor muscle training (PFMT) is considered the first option as a conservative treatment for female stress urinary incontinence (SUI). However, there is still debate whether energy-based devices are effective for treating SUI.

Objective

The objective of this study was to assess whether PFMT and fractional CO₂ laser therapy may improve symptoms in women with SUI.

Study Design

A parallel, randomized, nonblinded, noninferiority trial included 94 of 144 women 18 years or older with SUI randomized into 2 groups. The CO₂ laser group (n = 47) received 3 vaginal applications at monthly intervals. The PFMT group (n = 47) underwent 2 weekly sessions. Primary outcome was the mean difference of International Consultation on Incontinence Questionnaire-Urinary Incontinence Short-Form (ICIQ-UI-SF) total scores between groups after 3 and 6 months. Main secondary outcomes were questionnaires for assessment of pelvic floor symptoms (Pelvic Floor Impact Questionnaire-Short Form 7 [PFIQ-7]), sexual function (Female Sexual Function Index [FSFI]), and improvement after treatment (Patient Global Impression of Improvement [PGI-I]).

Results

A reduction in the ICIQ-UI-SF total score, PFIQ total score, and the Urinary Impact Questionnaire score was perceived between baseline and 3-6 months in both groups. CO₂ laser did not reach the noninferiority margin when compared with PFMT in both follow-up periods and analyses. Pelvic floor muscle training has improved the FSFI desire domain between baseline and 3-6 months, whereas CO₂ laser improved the FSFI orgasm, pain, and total score after 3 months and FSFI orgasm and total score after 6 months. PGI-I assessment has shown an improvement in both groups.

Conclusions

Fractional CO₂ laser therapy was noninferior to PFMT after 3-6 months of treatment. Both groups presented a reduction in the ICIQ-UI-SF scores, and both methods could be considered for women with SUI.



Understanding the benefits of CO₂ laser treatment for vulvovaginal atrophy

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TAG

VVA

Menopause

Sexual function

ABSTRACT

Background and Objectives

Postmenopausal vaginal discomfort is often attributed to vulvovaginal atrophy (VVA). Women with VVA experience symptoms such as vaginal dryness, itching, burning, irritation, and dyspareunia.

Materials and Methods

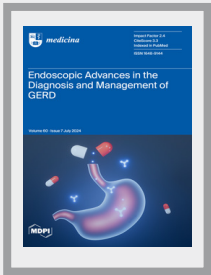
This pilot study was conducted to assess the effects of a micro-ablative fractional CO₂ laser on the clinical symptoms of VVA, as well as concordant sexual function. The severity of VVA symptoms was evaluated by a visual analogue scale (VAS), while the condition of the vaginal mucosa was evaluated using the Vaginal Health Index Score (VHSI). Sexual function was evaluated using the Female Sexual Function Index (FSFI) Questionnaire.

Results

Our cohort included 84 sexually active postmenopausal women with bothersome VVA, leading to sexual health complaints. The mean age of the participants in our study was 55.2 ± 5.4 years, with an average postmenopausal period of 6 ± 4.8 years. The age of our patients and the length of their postmenopausal period exhibited a significant negative correlation with VHSI scores, while a longer postmenopausal period was associated with increased severity of vaginal dryness and dyspareunia. Baseline VHSI values showed that 65% of patients had atrophic vaginitis with pronounced VVA symptoms (70.2% experienced vaginal itching, 73.8% reported vaginal burning, 95.3% had vaginal dryness, and 86.1% suffered from dyspareunia). Lower VHSI values significantly correlated with lower FSFI scores, while more severe VVA symptoms scores correlated with lower FSFI scores. VVA symptoms were significantly less severe after treatment. VHSI regained high non-atrophic values in 98.8% of patients post-treatment ($p < 0.001$). FSFI total and domain scores were significantly higher after treatment ($p < 0.001$).

Conclusions

Our study revealed that fractional CO₂ laser is a useful treatment option to alleviate VVA symptoms and improve vaginal health and sexual functioning in postmenopausal women.



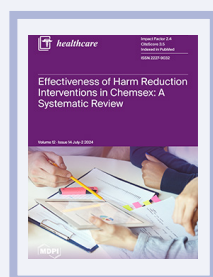
Multifaceted impact of CO₂ laser therapy on genitourinary syndrome of menopause, vulvovaginal atrophy and sexual function

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ABSTRACT

Genitourinary syndrome of menopause (GSM) encompasses a range of distressing symptoms in the vulvovaginal and/or bladder-urethral regions related to menopause changes, negatively influencing woman's quality of life and sexual activity. Fractional micro-ablative CO₂ laser therapy has shown the potential to reinstate the vaginal epithelium to a condition akin to the premenopausal state, thereby ameliorating the subjective symptoms associated with GSM. We conducted a prospective, pilot study in 73 sexually active postmenopausal women treated with CO₂ laser for their GSM symptoms, while assessing Vaginal Health Index Score (VHIS) and sexual function through the Female Sexual Function Index (FSFI) Questionnaire. The laser treatment resulted in a decrease in VHIS and patient-reported vulvovaginal atrophy (VVA) symptoms, with a significantly lower prevalence of vaginal itching, dryness, and burning ($p < 0.001$), as well as dyspareunia ($p = 0.002$). The occurrence of urinary incontinence, urgency, and vaginal heaviness significantly reduced, with an improvement in the staging of cystocele, either to Stage 1 or complete resolution ($p < 0.001$). FSFI total and domain scores were significantly higher after the treatment, indicating better sexual function, with a post-treatment score median of 25 ($p < 0.001$). Therefore, using a three-cycle fractional CO₂ laser was an effective choice for reducing urogenital discomfort related to GSM in postmenopausal women.



The efficacy of CO₂ vaginal laser in the treatment of recurrent, post-coital and interstitial cystitis: A multicentric prospective study

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TAG

Cystitis

Long-term follow-up

ABSTRACT

Background

This multicentric prospective study was carried out at Fondazione Policlinico Universitario Campus Bio Medico and Ospedale di Stato of St. Marino Republic. Between 1 January 2019, and 31 December 2022, all pre- and post-menopausal women diagnosed with recurrent, post-coital, and interstitial cystitis at both centers were included in the study. The main aim of the study was to assess the effectiveness of vaginal CO₂ laser treatment, alone or combined with intravesical hyaluronic acid instillations, in managing cystitis symptoms, such as dysuria, pollakiuria, and urgency, across the entire patient cohort. The secondary objective was to investigate the reduction in number of annual cystitis episodes post-treatment.

Methods

Each woman underwent three to four sessions of micro-ablative CO₂ vaginal laser treatment. A follow-up examination was conducted 12 months after the final laser session (up to December 2023), during which a post-treatment VAS assessment evaluated dysuria, daily pollakiuria, and urgency. The enrolled patients recorded the number of cystitis episodes experienced during the 12-month pre- and post-treatment period.

Results

Results indicated the laser's efficacy in reducing the total number of cystitis episodes per year and an improvement in symptoms up to one year post-treatment. Greater efficacy of the CO₂ laser treatment, particularly when combined with intravesical hyaluronic acid instillation, was observed in both pre- and post-menopausal women.

Conclusions

Fractional CO₂ laser therapy represents a safe and efficacious, non-hormonal approach for pre- and post-menopausal women diagnosed with recurrent, post-coital, and interstitial cystitis.



Predictors of the efficacy of CO₂ laser therapy for female stress urinary incontinence

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ABSTRACT

Background

Predictors of the efficacy of a single session of CO₂ laser therapy for female stress urinary incontinence are important for pretreatment consultation. Therefore, this study aimed to evaluate these predictors.

Methods

All consecutive women who underwent vaginal CO₂ laser therapy for stress urinary incontinence were prospectively enrolled in the obstetrics and gynecology department of a medical center from October 2018 to December 2021. Women with a global response assessment (GRA) ≤0 during follow-up were considered to have subjective failure. A multivariable backward stepwise Cox proportional hazard model was used to identify factors influencing subjective failure.

Results

A total of 75 women who underwent single-session vaginal CO₂ laser therapy were evaluated. The median duration of subjective improvement (defined as ≥1 on the GRA) was 18.3 (95% CI, 12.1-18.3 months) months. Multivariable analysis revealed that low voided volume (dL, hazard ratio [HR] = 0.707; area under the curve [AUC] = 0.66, cutoff value of voided volume ≤4.0 dL), high postvoid residual volume (dL, HR = 2.714; AUC = 0.60, cutoff value of postvoid residual volume ≥1.0 dL), and low functional profile length (HR = 0.956; AUC = 0.58, cutoff value of functional profile length ≤2.8 cm) were predictors of subjective failure. Logit(p) was found to predict failure (HR = 1.775; AUC = 0.71, cutoff value of logit(p) ≥0.0). Pad weights decreased at 3- and 6-month follow-up visits (e.g., pad weights: 46.9 ± 62.8 g at baseline, 13.1 ± 29.5 g at 3 months, and 21.0 ± 38.2 g at 6 months, p = 0.006). At 6 months, 8 (21%) women were cured (<1 g pad weight), and 16 (42%) women showed improvement (>50% decrease in pad weight). Overactive bladder symptom improved at 3 and 6 months (ie, Overactive Bladder Symptom Score: 3.2 ± 2.7 at baseline, 2.1 ± 2.2 at 3 months, and 2.0 ± 1.2 at 6 months, p < 0.001). However, no significant change in female sexual function was observed from baseline.

Conclusions

Low voided volume and high postvoid residual volume are significant predictors of subjective failure following a single session of transvaginal CO₂ laser therapy. However, the subjective therapeutic effects appear to diminish over a median duration of 18 months.



Impact of a single session of hybrid carbon dioxide 10600 nanometer and 1540 nanometer laser with platelet-rich plasma treatment in the genital area to treat female sexual dysfunction: A pilot study

**Sexual dysfunction
CO₂ laser + 1540 nm laser**

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ABSTRACT

Background

Female sexual dysfunction (FSD) affects a significant portion of the female population, negatively impacting quality of life. New therapeutic approaches, such as the combination of laser therapy and platelet-rich plasma (PRP), are being explored as potential treatments to enhance sexual function in affected women.

Methods

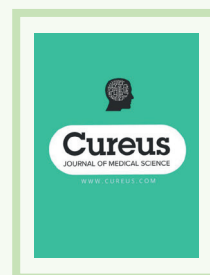
This original study involved 23 women aged 37 to 72, all diagnosed with varying degrees of FSD (mild, moderate, severe). The participants underwent a pre-treatment evaluation using a custom-designed Likert scale (Female Sexual Health Questionnaire) designed by the authors to evaluate the symptoms of the patients. The treatment involved a single session combining hybrid carbon dioxide 10600 nm and 1540 nm laser therapy with PRP applied to the genital area. One month post-treatment, participants were reassessed using the same questionnaire.

Results

Of the 23 patients studied, 65.2% (15 patients) exhibited hypoactive sexual desire, and 73.33% of them (11 out of 15) demonstrated improvement post-treatment ($P = 0.00048$). Overall sexual satisfaction increased by 28.2% ($P = 0.0032$), and lubrication improved in 54.5% of patients ($P = 0.0027$). Significant reductions in dyspareunia were observed, with 80% of patients experiencing pain relief ($P = 0.0035$). Patients with moderate dysfunction showed the highest response, with 100% (6 out of 6) demonstrating improvement across domains ($P = 0.0009$). Postmenopausal women experienced a 30.9% improvement in sexual function ($P = 0.007$), while premenopausal women exhibited a 7.5% improvement ($P = 0.04$). Statistically significant changes were also noted in the frequency of orgasm ($P = 0.0058$) and genital sensitivity in patients with moderate dysfunction.

Conclusions

Our data indicated significant improvements in FSD, particularly in moderate to severe dysfunction, with positive changes in key aspects of sexual function such as lubrication, desire, and ease of orgasm. However, the limited number of participants and short follow-up in this pilot study highlight the need for further investigation into hybrid CO₂/1540 nm laser therapy combined with PRP as a therapeutic option for female sexual dysfunction.



Assessing the long-term effectiveness of fractional CO₂ laser treatment in perimenopausal women with genitourinary syndrome of menopause-single center preliminary study

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ABSTRACT

Background

Genitourinary Syndrome of Menopause (GSM) is a prevalent condition in postmenopausal women characterized by symptoms such as vaginal dryness, itching, and urinary tract issues due to declining estrogen levels. Despite its widespread impact on quality of life, GSM often remains underdiagnosed and without effective treatment.

Methods

This study assessed the long-term efficacy of fractional CO₂ laser treatment in alleviating GSM symptoms in perimenopausal women. The study involved 125 participants, with clinical evaluations conducted using vaginal pH, the Vaginal Health Index Score (VHIS), the Vaginal Maturation Index (VMI), and the Female Sexual Function Index (FSFI).

Results

Results indicated significant improvements in these parameters, with pH levels decreasing, VHIS scores rising, and notable gains in VMI and FSFI observed up to 12 months post-treatment. This improvement has been validated through both subjective and objective assessments of GSM.

Conclusions

The findings indicate that this method is effective and safe, with no significant side effects reported. However, conducting a long-term observational study on eventual longer protocol for maintaining the positive effect of this therapy should be conducted.



Study on the efficacy of fractional CO₂ laser treatment for vaginal relaxation syndrome combined with recurrent bacterial vaginitis

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TAG

**Vaginal relaxation syndrome /
Vaginal laxity**

Recurrent bacterial vaginitis

Randomized clinical trial

ABSTRACT

To investigate the efficacy and mechanisms of fractional CO₂ laser treatment for Vaginal Relaxation Syndrome (VRS) combined with recurrent bacterial vaginitis. Patients with VRS and recurrent bacterial vaginitis were randomly assigned to an intervention group (n=60) receiving fractional CO₂ laser therapy in addition to metronidazole, or a control group (n=60) receiving metronidazole alone. Post-treatment assessments included vaginal relaxation, vaginal health index (VHI) scores, lactobacilli distribution, vaginal pH, recurrence rates, and the correlation between lactobacilli distribution and VHI. (1) Vaginal relaxation improved significantly in the intervention group compared to both pre-treatment and the control group (P=0.000). (2) VHI scores and lactobacilli distribution improved in both groups post-treatment, with significantly higher scores in the intervention group (P=0.000). (3) The intervention group exhibited a significantly lower vaginal pH compared to pre-treatment and the control group (P=0.001). (4) Recurrence rates were significantly lower in the intervention group (8.33%) compared to the control group (36.67%) (P=0.000). A strong positive correlation was found between lactobacilli distribution and VHI in the intervention group (r=0.79, P<0.001). Fractional CO₂ laser combined with conventional therapy improves VRS and recurrent bacterial vaginitis outcomes, reduces recurrence, and enhances vaginal microecology.

Trial registration

Chinese Clinical Trial Registry, Registration number ChiCTR2400094125.



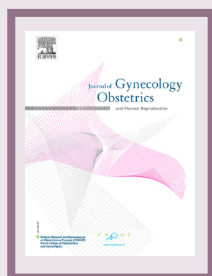
Long-term efficacy of CO₂ fractional laser in the treatment of genitourinary syndrome of menopause

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Uzan C^{1,2,3}, Canlorbe G^{1,2,3}

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ABSTRACT

The aim of this study was to evaluate the long-term efficacy and adverse effects of fractionated CO₂ laser in the treatment of GSM (Genitourinary Syndrome of menopause). This was a retrospective, monocentric, study conducted between January 2017 and July 2023. Forty-six patients receiving 3 sessions of fractional CO₂ laser at 4-6 weeks apart were included. The primary endpoint was the satisfaction of the patient (unsatisfied, neutral or satisfied) 24 months after the treatment. Secondary endpoints were improvement of their GSM, with the use of a sexual health and quality of life scores (FSFI and SF-12), changes in the use of local treatments and adverse events. A sub-group analysis evaluated patients with a history of breast cancer and patient ongoing antihormone therapy. Twenty-four months after treatment, 41 % (n = 19) patients were satisfied, 21 % (n = 10) patients were neutral, and 38 % (n = 17) patients were unsatisfied. There was a significant reduction in hypoesthesia during intercourse (p = 0.007), vaginal discharge (p = 0.009) and vaginal dryness (p = 0.0003). There was no significant improvement in SF-12, FSFI scores or reduction in the use of local treatments. No serious short- or long-term adverse events were reported. Among patients with a history of breast cancer (n = 26), there was a significant reduction in hypoesthesia during intercourse (p = 0.016), vaginal discharge (p = 0.041) and vaginal dryness (p = 0.0004). The CO₂ fractional laser showed an improvement in GSM 24 months after treatment. In the population of patients followed for breast cancer, results were also promising over the long term of treatment.



Thermo-ablative fractional CO₂ lasers combined with 1540 nm wavelengths is a promising treatment option in stress urinary incontinence

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2: El.En. Group, Florence - Italy. 3: Centro Médico Teknon, Barcelona - Spain.

TAG

SUI

CO₂ laser + 1540 nm laser

Both menopausal and non-menopausal patients

ABSTRACT

Background/Objectives

Stress urinary incontinence (SUI) is a common and often under-reported condition that significantly impacts quality of life. SUI is more than just a physical issue; it can also affect social interactions, mental health, and emotional well-being due to the embarrassment and limitations it can cause. SUI is often acquired during pregnancy and childbirth as a result of pelvic floor muscle weakness. The aim of this study was to evaluate the effectiveness of an innovative dual-wavelength laser system (CO₂ + 1540 nm) in SUI management.

Methods

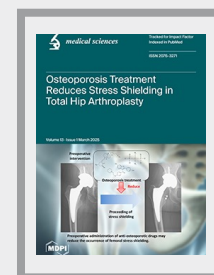
Each woman underwent three to four sessions of micro-ablative CO₂ vaginal laser treatment. A follow-up A total of 56 women affected by SUI were enrolled in this study. Half of the patients were treated with CO₂ alone, while the other half were treated with the combination of CO₂ + 1540 nm wavelengths. The patients were split into four groups based on the type of treatment they received and their menopausal status. Data were acquired at baseline and at various follow-ups (T1, T2, and T3, respectively, after the first, second, and third treatment). The Visual Analog Scale (VAS) (score 0-10) was used. Cystoscopic images were acquired before and at the end of the laser treatment cycle.

Results

At the end of the treatment, the patients in each group were very satisfied, on average. In each group, the treatment led to a statistically significant improvement in the SUI VAS score between baseline and follow-up after the first treatment; in both groups 3 and 4, the treatment led to a significant change in the dryness score, both from baseline to T1 ($p < 0.05$) and also for T2 and T3 compared to baseline. Finally, cystoscopic photos showed an evident increase in mucosa epithelial thickness after the laser treatment cycle.

Conclusions

The use of a dual-wavelength laser system (CO₂ + 1540 nm) was proven to be well tolerated and safe, with promising outcomes in reducing SUI symptoms, especially in non-menopausal patients..



Platelet-rich plasma and fractional CO₂ laser therapy to reduce surgical intervention for symptomatic vaginal mesh-related complications

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4: Mayo Clinic, Phoenix, Arizona - USA. 5: University of Melbourne, Melbourne, Victoria - Australia.

ABSTRACT

Background/Objectives

Stress urinary incontinence (SUI) is a common and often under-reported condition that significantly impacts quality of life. SUI is more than just a physical issue; it can also affect social interactions, mental health, and emotional well-being due to the embarrassment and limitations it can cause. SUI is often acquired during pregnancy and childbirth as a result of pelvic floor muscle weakness. The aim of this study was to evaluate the effectiveness of an innovative dual-wavelength laser system (CO₂ + 1540 nm) in SUI management.

Methods

Each woman underwent three to four sessions of micro-ablative CO₂ vaginal laser treatment. A follow-up A total of 56 women affected by SUI were enrolled in this study. Half of the patients were treated with CO₂ alone, while the other half were treated with the combination of CO₂ + 1540 nm wavelengths. The patients were split into four groups based on the type of treatment they received and their menopausal status. Data were acquired at baseline and at various follow-ups (T1, T2, and T3, respectively, after the first, second, and third treatment). The Visual Analog Scale (VAS) (score 0-10) was used. Cystoscopic images were acquired before and at the end of the laser treatment cycle.

Results

At the end of the treatment, the patients in each group were very satisfied, on average. In each group, the treatment led to a statistically significant improvement in the SUI VAS score between baseline and follow-up after the first treatment; in both groups 3 and 4, the treatment led to a significant change in the dryness score, both from baseline to T1 ($p < 0.05$) and also for T2 and T3 compared to baseline. Finally, cystoscopic photos showed an evident increase in mucosa epithelial thickness after the laser treatment cycle.

Conclusions

The use of a dual-wavelength laser system (CO₂ + 1540 nm) was proven to be well tolerated and safe, with promising outcomes in reducing SUI symptoms, especially in non-menopausal patients.



A randomized controlled trial of platelet-rich plasma combined with fractional CO₂ laser therapy for mild and moderate stress urinary incontinence in women

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TAG

SUI

Both menopausal and non-menopausal patients

Randomized clinical trial

CO₂ laser alone vs. CO₂ laser + PRP

ABSTRACT

Introduction and Hypothesis

This study aimed to evaluate the effectiveness of platelet-rich plasma (PRP) combined with fractional CO₂ laser therapy in women diagnosed with mild or moderate stress urinary incontinence (SUI).

Methods

In this single-center, single-blinded, randomized controlled trial, 69 women diagnosed with mild or moderate SUI were randomly assigned to receive fractional CO₂ laser therapy, PRP injections, or a combination of both treatments (n=23 per group). Each participant underwent three treatment sessions at 30-day intervals. Outcomes were assessed using the International Consultation on Incontinence Questionnaire–Short Form (ICI-Q-SF), the Incontinence Quality of Life (I-QOL) questionnaire, and a 1-h pad test at baseline and at 1, 3, and 6 months post-treatment. Generalized estimating equations (GEE) were used to analyze repeated measures across groups.

Results

No statistically significant differences in baseline characteristics were observed among the groups ($P > 0.05$). All groups demonstrated significant post-treatment improvements in ICI-Q-SF scores, I-QOL scores, and 1-h pad weights ($P < 0.05$). Compared to the fractional CO₂ laser group, the PRP group showed no significant advantage, whereas the combined group exhibited significantly greater improvements at all time points: greater reductions in ICI-Q-SF scores ($\beta = -1.09, -1.30, -1.39$; all $P < 0.001$), higher I-QOL scores ($\beta = 4.39, 4.61, 5.04$; all $P < 0.001$), and greater decreases in pad weights ($\beta = -1.22, -1.48, -1.78$; all $P < 0.05$).

Conclusions

Combined PRP and fractional CO₂ laser therapy significantly improves urinary incontinence symptoms and quality of life compared to either treatment alone, offering a potentially more effective therapeutic option for women diagnosed with mild or moderate SUI.



Vaginal lactobacillus alteration and vaginal symptom relief after carbon dioxide vaginal laser therapy in postmenopausal women

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ABSTRACT

Background

To assess changes in the prevalence and abundance of vaginal *Lactobacillus* after fractional micro-ablative carbon dioxide (CO₂) therapy in postmenopausal women with vulvovaginal atrophy (VVA).

Methods

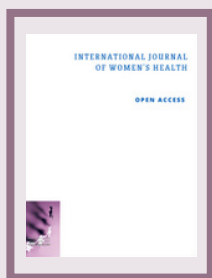
This prospective, single-arm clinical study was conducted in postmenopausal women who underwent treatment with CO₂ laser therapy. Eligible participants were enrolled before the first session of therapy and evaluated at weeks 0, 8, 20, and 32. Vaginal fluid samples were collected using a standardized protocol and processed for Gram staining and expanded quantitative urine culture (EQUC). The level of *Lactobacillus* was assessed using the Nugent scoring system. The secondary outcomes included the prevalence of *Lactobacillus*, VVA symptoms, and vaginal pH. The results were analyzed using multilevel mixed-effects linear regression and paired t-tests.

Results

Forty-three postmenopausal women with at least one symptom of VVA, with a mean age of 67.3 ± 8.7 years, were recruited. The mean Nugent scores for *Lactobacillus* morphotypes gradually decreased from 2.84 (95% CI: 2.38-3.29) at baseline to 2.28 (95% CI: 1.79-2.77) at week 8, 2.09 (95% CI: 1.60-2.58) at week 20, and further to 1.84 (95% CI: 1.31-2.35) at week 32 ($p < 0.05$). The prevalence of *Lactobacillus* increased from 27.9% (12/43) at baseline to 48.8% (21/43) at week 8, 55.8% (24/43) at week 20, and 58.1% (25/43) at week 32 ($p < 0.05$). VVA symptom severity and vaginal pH consistently declined from baseline to week 32 ($p < 0.05$).

Conclusion

Fractional CO₂ laser treatment improved the prevalence and level of *Lactobacillus* after treatment and sustained improvements were observed at 3- and 6-month follow-ups. These positive effects were correlated with improvements in VVA symptoms.



Impact of vaginal carbon dioxide laser therapy alone versus its combination with oral bioactive collagen peptides, ultra-low molecular weight hyaluronic acid, and other functional components on the genitourinary syndrome of menopause: A cohort pilot study in Italy

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TAG

GSM

CO₂ laser alone vs. CO₂ laser + oral food supplementation

ABSTRACT

Background

Genitourinary syndrome of menopause (GSM) includes clinical manifestations attributed to estrogen deficiency affecting the genitourinary tract of postmenopausal women. Treatment may require a multifaceted approach, including patient education, lifestyle modifications, physical, as well as hormonal and non-hormonal therapies.

Aims

To evaluate the efficacy and tolerability of vaginal CO₂ laser therapy (MonaLisa Touch) combined with an oral food supplement containing bioactive collagen peptides (BCP) and other functional components for GSM treatment. We hypothesized that this combination would enhance GSM symptom relief.

Patients/methods

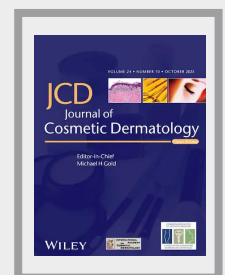
Twenty postmenopausal women with GSM were divided into two groups. Group 1 (n = 10) underwent three sessions of vaginal CO₂ laser treatment alone, while Group 2 (n = 10) received the same laser treatment in addition to oral food supplementation. Improvements in vaginal health (Vaginal Health Index-VHI), vaginal pain (Visual Analogue Scale-VAS), and sexual function (Female Sexual Function Index-FSFI), along with patient satisfaction and tolerability, were evaluated.

Results

Both groups showed improvements in VHI, pain scores, and FSFI, with Group 2 displaying more significant gains. Compared to Group 1, Group 2 had greater median differences in VHI ($\Delta = 11.00$ vs. $\Delta = 8.50$, $p = 0.005$) and VAS ($\Delta = -7.00$ vs. $\Delta = -5.50$, $p = 0.017$). Similarly, FSFI scores increased meaningfully in both groups, more so in Group 2 (from 53.50 to 67.50, $p = 0.005$ vs. from 51.50 to 60.50, $p = 0.014$ in Group 1). Treatment satisfaction was also higher in Group 2 ($p = 0.047$).

Conclusions

The addition of oral supplementation with BCP and other functional components to vaginal CO₂ laser treatment for GSM offered significant benefits over laser treatment alone, improving vaginal health, reducing pain, and ameliorating sexual function. This combination therapy presents a promising non-hormonal option for GSM management, warranting further investigation in larger, long-term studies to confirm these preliminary findings.



Retrospective study on CO₂ laser for second-line treatment of vulvar lichen sclerosis

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ABSTRACT

Background

Vulvar Lichen Sclerosus (VLS) represents a persistent inflammatory disease of the skin that particularly affects the genital area.

Aim

The study purpose was to investigate the effectiveness of CO₂ laser as a treatment of recalcitrant VLS. The parameters examined included treatment tolerance, patient satisfaction, symptoms, and VLS clinical markers.

Methods

This retrospective study enrolled 85 adult women affected by Vulvar Lichen Sclerosus (VLS), refractory to local corticosteroids. Patients were treated with three sessions of fractional CO₂ laser treatment at 4-week intervals. For vulvovaginal treatment, a device with a scanning handpiece and dedicated probes was used. The effectiveness of the treatment was evaluated at 1 month follow up (T1) and at 6 months follow up (T2) from the last treatment session. The Vulvar Health Index (VuHI) and the Vaginal Health Index score (VHI) were used. Patients assessed the severity of their symptoms (dyspareunia and dryness specifically) using the Visual Analogue Scale (VAS), a 10-point scale going from 0 (no symptoms) to 10 (maximum symptoms).

Results

VuHI showed significant improvement after completion of treatment compared to baseline ($p < 0.001$). VHI showed significant improvement after completion of treatment compared to baseline ($p < 0.001$). There was clear improvement, compared to baseline values, in the VAS score for superficial dyspareunia and for vulvar dryness.

Conclusion

Overall, the results of this study demonstrated that treatment of recalcitrant VLS with fractional CO₂ laser improved both clinical assessment and symptoms.



Effect of vaginal laser therapy for gynecologic patients on vaginal microbiota: A prospective cohort study

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TAG

**GSM
SUI**

Vaginal flora / Microbiota

ABSTRACT

Purpose

We aimed to evaluate vaginal microbiota distribution before and after laser therapy for gynecologic patients with stress urinary incontinence (SUI) and genitourinary syndrome of menopause (GSM).

Methods

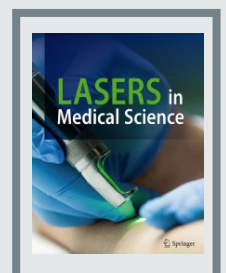
Fifty patients undergoing CO₂ vaginal laser treatment were enrolled. The primary outcomes included UDI-6, IIQ-7, OABSS, and VSQ-21 scores before and at 1, 2, and 3 months after laser treatment, as well as vaginal microbiota diversity before and 1 month after laser treatment.

Results

UDI-6, IIQ-7, OABSS, and VSQ-21 scores for patients who received CO₂ laser therapy all showed significant improvement at 1, 2, and 3 months post-treatment. Vaginal pH showed no significant change after laser treatment. Overall, 91 samples were successfully sequenced. Alpha diversity showed significant differences in the menopause ($p = 0.034$) and GSM ($p = 0.004$) groups, but not between pre- and post-laser treatment samples. PERMANOVA revealed differences in microbiota composition associated with menopause ($p = 0.009$) and SUI ($p = 0.026$). Beta diversity analysis showed no significant treatment effect due to high inter-individual variability. The six most abundant vaginal bacterial genera included Lactobacillus (40.4%), Gardnerella (8.4%), Prevotella (7.4%), Escherichia-Shigella (6.0%), Streptococcus (5.6%), and Bifidobacterium (3.2%), with changes in Lactobacillus dominance observed in some patients post-treatment. Network analysis revealed that Gardnerella disappeared post-laser treatment, as Lactobacillus increased in abundance.

Conclusions

CO₂ laser treatment may improve SUI and GSM, and be associated with shifts in microbiota.



Efficacy and safety of CO₂ laser therapy combined with collagen cream in managing vulvo-vaginal atrophy: A randomized, controlled study on symptom relief and microbiome modulation

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ABSTRACT

Background and Objectives

Vulvo-vaginal atrophy (VVA), a prevalent condition among postmenopausal women, significantly impairs quality of life through symptoms like vaginal dryness, dyspareunia, and burning. Non-hormonal treatments, such as CO₂ laser therapy, have shown promise in managing VVA symptoms with minimal side effects. The addition of adjunctive treatments may enhance efficacy and mitigate possible adverse effects. To evaluate the combined efficacy and safety of CO₂ laser therapy and a collagen-based cream in treating VVA and to explore their potential impact on the vaginal microbiome.

Materials and Methods

This was a single-center, randomized, interventional. Sixty postmenopausal women diagnosed with VVA were randomized into two groups: a control group receiving laser-only treatment and a treatment group receiving laser therapy with daily collagen-based cream application. Primary outcome measures included symptom improvement on the Visual Analog Scale (VAS) for VVA-associated symptoms. Secondary outcomes involved microbiome composition analysis.

Results

Both groups showed significant symptom improvement, with the combination therapy group demonstrating superior reductions in burning, dyspareunia, and vaginal dryness ($p < 0.05$). Microbiome analysis revealed increased levels of beneficial species (*Lactobacillus iners* and *Lactobacillus crispatus*) and decreased pathogenic bacteria (*Gardnerella vaginalis* and *Atopobium vaginae*) in the treatment group, though these changes were not statistically significant. Mild side effects, such as burning and swelling in the first days following the treatment, were less frequent in the combination therapy group, likely due to the anti-inflammatory effects of the collagen-based cream.

Conclusion

This study provides evidence supporting the use of CO₂ laser therapy with collagen-based cream as an effective and well-tolerated treatment for VVA in postmenopausal women, achieving significant symptom relief. The combined therapy approach holds potential for enhanced efficacy and reduced side effects compared to laser-only treatment, offering a promising alternative for women ineligible for hormone-based therapies.



Impact of fractional CO₂ laser therapy on vaginal wall histology in breast cancer survivors

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TAG

GSM

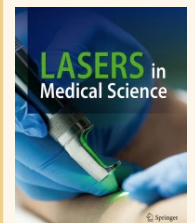
Oncological menopause

Breast cancer survivors

Histological examination

ABSTRACT

To investigate histological changes in the vaginal wall of breast cancer survivors (BCSs) with genitourinary syndrome of menopause (GSM) treated with five sessions of fractional CO₂ vaginal laser therapy, focusing on epithelial morphology and stromal extracellular matrix composition. In this prospective single-center study, 26 BCSs underwent five sessions of fractional CO₂ vaginal laser therapy. Vaginal punch biopsies were collected at baseline and four to six weeks after completing the final session. Mucosal morphology was classified (Type 1, 2, or 3) independently by two pathologists, blinded to baseline and follow-up status. Stromal elastin, total collagen, and collagen types I and III were quantified by digital image analysis of Verhoeff-Van Gieson, Masson's trichrome, and immunohistochemistry. Paired tests and the Stuart-Maxwell test evaluated changes over time. At baseline, 42.3% of participants were classified as Type 1, 19.2% as Type 2, and 38.5% as Type 3 mucosal morphology. Elastin index increased from 33.1% to 56.8% ($p < 0.01$), and collagen type III index from 44.5% to 58.4% ($p = 0.03$), while total collagen and collagen type I showed no significant change. No significant differences in epithelial microscopic features were observed (Stuart-Maxwell $p = 0.16$). Fractional vaginal CO₂ laser therapy was associated with selective stromal remodelling in BCSs - higher elastin and collagen type III indices, but without detectable improvement in epithelial morphology. Given the absence of a control group, the short follow-up, and limited epithelial morphometry due to section orientation, these findings should be interpreted as preliminary histological evidence of a stromal response rather than a confirmation of functional or regenerative benefit.



Archivio Italiano di Urologia e Andrologia - Epub 2026 March 6

Effectiveness of CO₂ micro-ablative vaginal laser therapy in the treatment of recurrent cystitis

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ABSTRACT

Background

Cystitis is the most common clinical manifestation of urinary tract infection (UTI) in women.

Aim

The current study intends to assess the effectiveness of CO₂ micro-ablative vaginal laser therapy in the treatment of recurrent cystitis RC.

Methods

A total of 75 women were divided into 2 Groups: Group 1 included 34 women (22 were menopausal women and 12 were non-menopausal women) with bacterial cystitis who were positive to urine culture analysis. The Group 2 included 41 women (34 were menopausal women and 7 were nonmenopausal women) with interstitial cystitis who were negative for urine culture analysis. Patients received three treatment sessions with a dual-wavelength (10600 nm/1540 nm) laser system. A visual analog scale (VAS) evaluation, ranging from 0 to 10, was administered to assess baseline and post-laser treatment urinary symptoms associated with cystitis. Concerning IUS (stress urinary incontinence) and Urgency score measurements, a VAS ranging from 0 to 5 was used. The O'Leary-Sant Interstitial Cystitis Symptom Index (ICSI) was used as treatment outcome measures.

Results

In both groups, a significant reduction in the average number of cystitis episodes after treatment was observed and the VAS scale showed a significant reduction in pre- and post-treatment symptoms. VAS results for patients' satisfaction and expectations showed positive outcomes revealing that more than 90% of patients were satisfied following the treatment.

Conclusions

CO₂ vaginal laser may represent an advantageous therapeutic approach to treating recurrent cystitis.



The long-term effectiveness of fractional CO₂ laser in stress urinary incontinence: A two-year follow-up study

TAG

SUI

Long-term follow-up

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ABSTRACT

Introduction and hypothesis

To evaluate the long-term effectiveness of fractional CO₂ laser in the treatment of stress urinary incontinence (SUI), the permanence of symptom control, and additional session requirements over a 2-year follow-up period.

Methods

This retrospective cohort study included 215 women with clinically diagnosed SUI who underwent a standardized course of fractional CO₂ laser therapy. Assessments were conducted at baseline, 4-6 weeks, 1 year, and 2 years. Primary outcome measures included patient-reported satisfaction and Michigan Incontinence Symptom Index (MISI) scores. Secondary outcomes were changes in sexual function determined using the Female Sexual Function Index (FSFI), vaginal symptom severity using the Vaginal Symptom Questionnaire (VSQ), and genital self-image using the Female Genital Self-Image Scale (FGSIS). Data distribution was evaluated using the Shapiro-Wilk test. Repeated measures were analyzed using Friedman or repeated-measures ANOVA, followed by the Dunn or Newman-Keuls post hoc tests. Statistical significance was set at $p < 0.05$.

Results

Significant improvement was observed throughout follow-up in all primary and secondary outcomes ($p = 0.0001$). Satisfaction scores increased significantly at 4-6 weeks compared to baseline and still exhibited a high level at 1 year. Although a partial decrease occurred in the second year, values still remained significantly above baseline (from median 2 to 4; $p = 0.0001$). MISI decreased from 19.51 ± 4.41 at baseline to 1.96 ± 1.38 at 4-6 weeks. Although values rose to 6.31 ± 4.01 in the second year, significant improvement compared to baseline was maintained ($p = 0.0001$). Significant improvement was observed in all FSFI subdomains (including desire, arousal, lubrication, orgasm, satisfaction, pain, and total score) in the early period ($p = 0.0001$), and despite a slight decrease in the second year, the gains were largely maintained. Similar marked improvements were also observed in VSQ and FGSIS scores, with no return to baseline values despite a partial decline in the second year ($p = 0.0001$). Supportive additional session requirements were determined in association with subjective worsening in symptoms in the second year in approximately 20% of the participants.

Conclusions

Fractional CO₂ laser therapy produces significant and clinically important improvement in SUI symptoms, sexual function, vaginal symptoms, sexual function, vaginal comfort, and genital self-image. All effects peak at 4-6 weeks, are largely preserved at 1 year, and despite a partial decline in the second year, remain markedly superior to baseline. These findings show that fractional CO₂ laser is an effective, minimally invasive, nonsurgical option in the management of SUI.



Two-year outcomes of fractional CO₂ laser for vaginal laxity: Effectiveness, retreatment need

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7: Samsun Women's Health Clinic, Samsun - Turkey.

ABSTRACT

Objective

The purpose of this study was to evaluate the long-term efficacy of fractional CO₂ laser in the treatment of vaginal laxity (VL) and to determine additional treatment requirements during two-year follow-up.

Methods

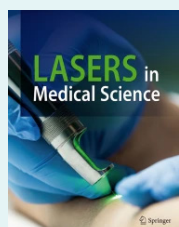
A total of 176 women who underwent fractional CO₂ laser therapy for vaginal laxity between January 2020 and January 2023 were retrospectively evaluated. Three sessions of laser therapy were applied at 4–6 week intervals in all cases. Primary outcome measures were additional laser therapy requirements, patient satisfaction with primary and secondary treatments, and the general clinical effect of laser therapy on VL. Secondary outcomes included the evaluation of genital self-image, sexual function, urinary symptoms, and vulvovaginal complaints assessed using the following five validated measurement tools: the Patient Global Impression of Improvement (PGI-I), Michigan Incontinence Symptom Index (MISI), Female Sexual Function Index (FSFI), Vulvovaginal Symptoms Questionnaire (VSQ), and Female Genital Self-Image Scale (FGSIS).

Results

Additional laser therapy requirements occurred in 33.5% of patients at the end of two-year follow-up. Significant levels of improvement were determined in all FSFI, FGSIS, PGI-I, MISI, and VSQ scores following completion of the first treatment series ($p < 0.001$). A marked increase was observed in FSFI total scores and the arousal subdomain, while orgasm decreased significantly at the end of the second application compared to the first ($p < 0.05$). The increase in FGSIS scores showed that genital self-image improved consistently following both the first and second applications. PGI-I data revealed high post-treatment patient satisfaction ($p < 0.001$). In addition, the MISI and VSQ scores showed that urinary symptoms and vulvovaginal discomfort decreased significantly following both the initial treatment and second application. However, the marked initial clinical benefit tended to decrease over time, and additional intervention requirements increased one year after the first treatment.

Conclusion

Fractional CO₂ laser therapy provides significant and clinically important improvement in the management of VL. The positive effects recorded in post-treatment sexual function, genital self-image, and vaginal symptoms are significantly preserved during the first year. However, due to the gradual decrease in the effects, we recommend the application of a second laser session approximately one year following the first treatment series in order to enhance the continuity of the therapeutic benefit.



Clinical and vaginal microbiota effects of oral *Lactobacillus crispatus* M247 combined with vaginal laser therapy in menopausal women with atrophic vulvovaginitis: a prospective, randomized and controlled study

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ABSTRACT

Vaginal atrophy is a common condition in postmenopausal women, frequently associated with vaginal symptoms and alterations of the vaginal microbiota. This randomized study evaluated the clinical and microbiological effects of vaginal CO₂ laser therapy administered alone or in combination with an oral probiotic containing *L. crispatus* M247 in postmenopausal women with vulvovaginal atrophy. Women were randomized (2:1) to receive vaginal laser therapy alone (laser-only group) or laser therapy plus oral probiotic for 90 days (probiotic plus laser group). Clinical efficacy was assessed through a prespecified panel of outcomes, including vaginal pH and symptom severity assessed by Visual Analogue Scale (VAS), at baseline and during follow-up up to 90 days, with Day 90 representing the main efficacy timepoint. Vaginal microbiota composition was analyzed in a subset of participants. Both groups showed improvement over time in vaginal pH and VAS scores for vaginal dryness, dyspareunia, burning, itching, and introital pain. Compared with laser alone, the probiotic plus laser group showed lower symptom scores at Day 90 in selected clinical domains, with effect estimates generally favoring the probiotic plus laser group, although confidence intervals were relatively wide for some endpoints. P-values for individual outcomes should be interpreted as nominal in the absence of prespecified multiplicity adjustment across clinical domains. For vaginal pH, both groups showed a decrease over time, but the group × time interaction was not statistically significant, indicating no clear differential temporal response. Microbiota analysis showed an increase in the relative abundance of *L. crispatus* and a concomitant decrease in *L. iners* only in the probiotic plus laser group, suggesting a shift toward a more favorable vaginal microbial profile. Overall, vaginal CO₂ laser therapy was associated with clinical improvement, and adjunctive treatment with *L. crispatus* M247 was associated with additional benefits across selected clinical and microbiological outcomes; however, confidence intervals for several clinical estimates were relatively wide, supporting cautious interpretation and confirmation in larger blinded studies.

TAG

VVA

Menopause

Vaginal flora / Microbiota





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