

Effect of the Fractional CO₂ Laser on the Quality of Life, General Health, and Genitourinary Symptoms in Postmenopausal Women With Vaginal Atrophy: A Prospective Cohort



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Abstract

Introduction: After menopause women experience vaginal atrophy related to hormonal changes and estrogen deficiency. The purpose of this paper was to evaluate the effect of the fractional CO₂ laser on the quality of life, vaginal atrophy symptoms, and urine incontinency in menopause women.

Methods: This prospective study was conducted among 140 women from 2017 to 2018 in Yas hospital, Tehran University of Medical Sciences. They encountered the fractional microablative CO₂ laser system three times at four-week intervals. The short form of the Health Questionnaire (SF-12) and the Female Sexual Functional Index (FSFI) questionnaire were utilized to assess the participants' quality of life. Also, the standard measuring tools including the vaginal health index (VHI) and International Consultation on Incontinence Questionnaire (ICIQ) Form were used to evaluate the vaginal atrophy symptoms.

Results: The quality of life improved significantly in somatic, social function, and mental health. In the sexual context, arousal and satisfaction status improved significantly. Also, the frequency of urinary incontinence, enuresis, urgency, and the leak improved significantly ($P < 0.05$). Among the scale variables for urinary function, it was seen that the urgency impact had no improvement. All vaginal indices improved ($P < 0.05$).

Conclusion: The fractional CO₂ laser can be effective in treating vaginal atrophy and urinary symptoms. Besides, it improved the quality of life and the sexual function of post-menopausal women.

Keywords: Vulvovaginal atrophy; Quality of life; laser therapy; Postmenopause.



Introduction

After menopause, the female body will be influenced by estrogen deficiency.^{1,2} Such a modification can lead to genital and urinary symptoms with negative effects on relations, the quality of life, activities, and sexual issues.³ Vulvovaginal atrophy (VVA) is thinning of the mucus and tissues of the vulva and vagina, caused by the estrogen deprivation that occurs in menopausal women.¹⁻³ These changes are commonly associated with low sexual activity and/or sexual dysfunction.^{4,5} Patients with VVA complain of vaginal irritation and discharges, itching, dryness, dysuria, and dyspareunia.⁶⁻⁸ In spite of the relevance of VVA to the quality of life, sexual function and relationships at menopause, it has remained a prohibited subject in routine menopausal consultation, especially in traditional countries, and health-care providers should have an active role in diagnosing and treating VVA symptoms properly.³

Treatment modalities are diverse according to their efficacy and safety, the severity of signs and symptoms, and women's choice.^{9,10} Lubricants are primarily applied to relieve vaginal dryness during sexual activity with no long-term effect.⁶ Nowadays hormonal replacement therapy (HRT) and topical estrogen are the most common approved methods for treating VVA. Topical estrogen is primarily prescribed to reduce symptoms and inverse atrophic anatomical erosion in the cases where VVA is the sole menopausal complaint.³ In addition, data on safety in a long period of time are not sufficient,¹⁰ especially in high-risk patients.^{6,11} Furthermore, women who suffer from breast cancer or other gynecological malignancies dependent on estrogen require special consideration and personal counseling before using any kind of topical estrogen therapy.⁶

Changes in aging skin have successfully been treated in

humans by applying the carbon dioxide (CO₂) fractional laser.¹⁰ The fractional CO₂ laser is safe and effective in remodeling tissues in many body organs, such as the skin of the face, neck and chest.^{10,11} Previous studies demonstrated microscopic and ultra-structural evidence of morphologic changes in the atrophic postmenopausal vaginal mucosa after applying the fractional CO₂ laser, though some controversies about the results of laser therapy still exist.^{12,13} The aim of this study was to determine the effect of the fractional CO₂ laser on vaginal atrophy, sexual activity, and urinary function.

Materials and Methods

Study Design

This prospective study was conducted from 2017 to 2018 in Yas hospital, an educational center related to Tehran University of Medical Sciences.

Study Population

Initially, 150 postmenopausal women with symptoms of VVA (vaginal dryness, irritation, soreness, or dyspareunia) were enrolled in this study. A total of 140 participants completed the study. The inclusion criteria were sexual activity at least once a month, cessation of menstruation for at least 12 months, and symptoms not alleviated by the previous local estrogen therapy. The exclusion criteria were any hormone replacement therapies (either systemic or topical) within 6 months, acute or recurrent urinary tract infections, active genital infections, prolapse stage \geq II according to the pelvic organ prolapse quantification (ICS-POP-Q) system, and smoking.

Study Protocol and Procedure

The study was conducted in an outpatient setting without any specific preparations including analgesia or anesthesia. The procedure was done every 4 weeks for three consequent months. Prior to each treatment, a thorough gynecological exam of the vulvar skin, vestibule, introitus, and vaginal canal was performed in order to find out any evidence of active infection, or signs of injury or bleeding, any color changes, and signs of atrophy. The participants were recommended to avoid sexual activity and the use of tampon for at least 3 days from each laser treatment session because the mild inflammatory reaction may last up to 48 hours.

In this study, the fractional microablative CO₂ laser system (Smaxel) was applied. Laser energy was transferred through a vaginal probe with a fractional density of 4% to 5% and an energy level of 50 to 60 mJ. The vaginal headpiece was placed into the vaginal canal (up to 12 cm). In order to provide a complete treatment of the vaginal wall, the vaginal probe was rotated 360° along the vaginal canal. The headpiece was planned towards a 45° oriented mirror placed at the tip of the probe so that it was only reflected on the vaginal walls but not on the uterine cervix.

Data Collection

Demographic data of the study population were gathered via the questionnaire before starting the first laser treatment. The evaluation of improvement in vaginal health on the first visit and three months after the last treatments was performed by means of the following tools: the vaginal health index (VHI) that is a quantitative measuring tool to assess the changes in vaginal elasticity, fluid volume, vaginal pH level, epithelial integrity, and moisture; the VHI scale which ranges from 5 (severe) to 25 (normal) across all five parameters; the International Consultation on Incontinence Questionnaire (ICIQ) which is a validated questionnaire on urinary incontinence to evaluate the impact of symptoms of incontinence on the quality of life; the Female Sexual Functional Index (FSFI) questionnaire which is used as a brief, multidimensional, self-reported instrument to evaluate the key dimensions of sexual function in women; and finally, the Iranian version of the Short Form 12 (SF-12) which assess the physical (PCS12) and mental (MCS12) component scores of the quality of life.

Data Analysis

The collected data were reported as the mean (standard deviation), the median and the percentage (%), and they were analyzed by SPSS software version 25.0 (SPSS Science, Chicago, IL, USA). The paired-samples t-test and the signed rank test were used to analyze continuous variables and the significance level was set at 0.05, corresponding to a 95% confidence interval.

Results

The mean (standard deviation) age was 56.8 (9.3), ranging from 40 to 84. The mean body mass index (BMI) was 29.3 (4.5), ranging from 21.4 to 46.2 kg/m². The mean duration from menopause were 8.6 (8.2) year, ranging from 1 to 30 year. The median gravity and parity were 3 and 2 respectively. The mode of previous deliveries was a cesarean section in 22 cases (15.7%).

Among the participants, 80.7% were housewives. The mean marital year was 34.7 (8.4), ranging from 20 to 60. The quality of life significantly improved in all somatic, social function, and mental health (Figure 1). Only 10% had a good quality of life before treatment, which finally increased to 54.3% ($P=0.0001$).

In the sexual questionnaire, only arousal and satisfaction status improved significantly (Figure 2). As shown in Figure 3, the frequency of urinary incontinence, enuresis, urgency, and the leak improved significantly ($P=0.0001$). As shown in Figure 4, all vaginal factors were improved ($P<0.05$). Significant improvement was observed in vaginal elasticity, fluid, epithelial integrity, and wetness ($P=0.0001$).

Discussion

Nearly half of women in postmenopausal age suffer from

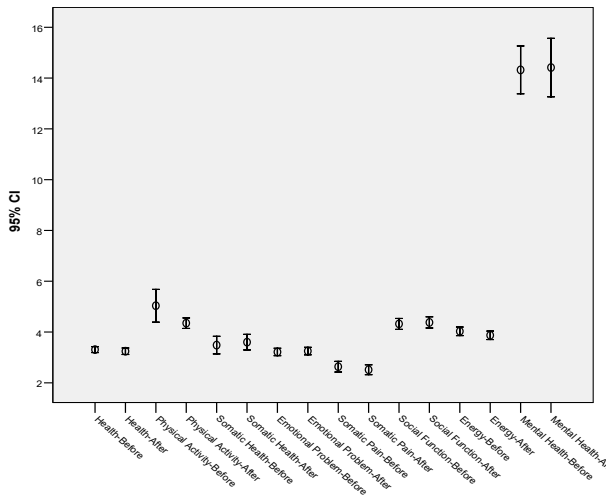


Figure 1. Health Status in the Participants.

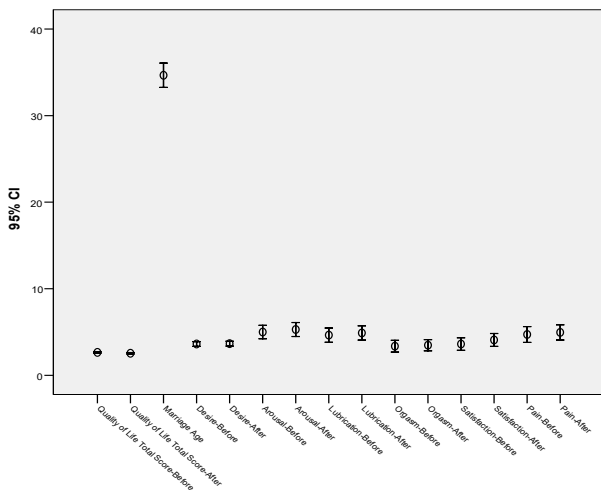


Figure 2. Sexual Function Status in the Participants.

at least one symptom of VVA.⁵ Vulvovaginal rejuvenation has been a matter of interest in recent years and along with this modern area of surgical interest, there has also been a rapid growth in the number of nonsurgical modalities for vulvovaginal rejuvenation.¹⁴ The important mechanism of the laser-effect is the induction of a local heat shock response followed by transient and rapid changes in cellular metabolism. Acute thermo-ablative damage induces proliferation due to the coordination and expression of growth factors and also the stimulation of new mature collagen synthesis in the treated site.¹² As reported by Enemchukwu, the CO₂ fractional laser application is an effective way for the relief of symptoms in vaginal atrophy.¹⁵

This study supports the recent findings for a one-year outcome in a postmenopausal population evaluated for long-term changes in vaginal health and subjective assessments of VVA symptoms following three fractional CO₂ laser treatments.

Perino et al studied the thermo-ablative fractional CO₂

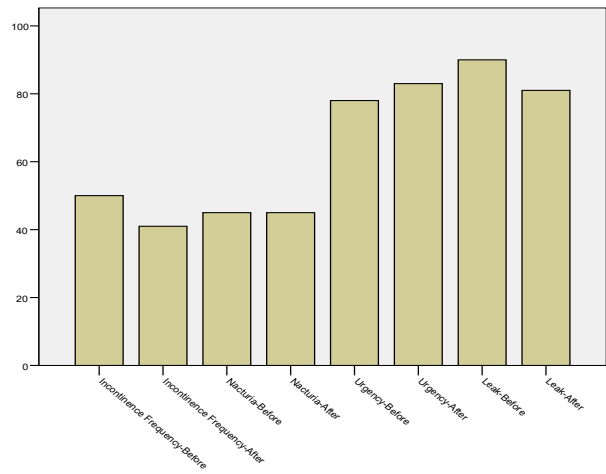


Figure 3. Urinary Status in the Participants.

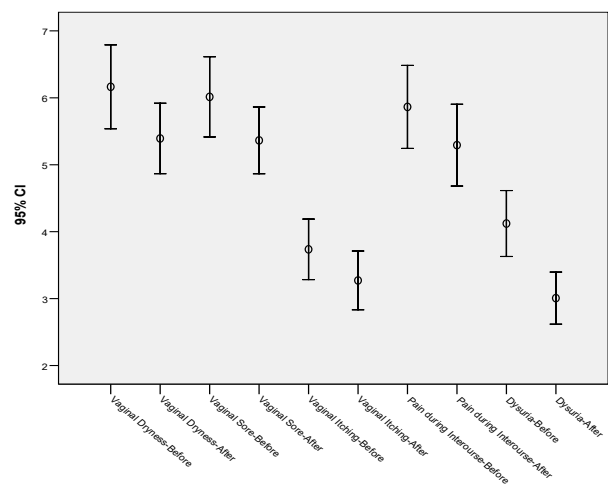


Figure 4. Vaginal Status Impact in the Participants.

laser for the treatment of symptoms related to VVA in 48 post-menopausal women. They indicated a significant improvement in VVA symptoms following 3 sessions of vaginal fractional CO₂ laser treatment, evaluated 30 days after the last laser application. They also reported a considerable improvement in the quality of life.¹²

We found significant improvements in all somatic, social function and mental health aspects of quality of life after fractional CO₂ laser therapy. In our study, we had longer time of follow-up to do the evaluations in three months after the last treatments.

Eder et al enrolled 28 healthy post-menopausal women in treatment with a fractional CO₂ laser 3 times at 4-week intervals. They evaluated the responses one month following each laser treatment and also in 3 and 6 months following all three laser treatments. They revealed an improvement in almost all VVA symptoms and an increase in the FSFI score at one month after the first treatment. A further significant improvement was indicated in 3 and 6 months following the last laser treatment.¹⁶ Arroyo¹⁷ indicated that VHI improvement remained significant

6–8 months after treatments.

Salvatore et al reported a significant improvement in the total score and in each single specific domain of the FSFI after 12-week follow-up compared with the baseline in postmenopausal women with VVA treated by the fractional microablative CO₂ laser.¹⁸ In contrast, in the sexual context, only arousal and satisfaction status improved significantly in our study.

Samuels et al in their study suggested that fractional CO₂ treatment may have a positive effect on urinary leakage. The results of their study showed a 72% reduction in the frequency of urinary leakage at a 6-month follow-up and after 12 months 64% of the patients continued to experience improvement and only 36% returned to the baseline frequency of urine leaking. The results of our study showed alleviation in the frequency of urinary incontinence, enuresis, urgency, and the leak.¹⁹

In recent years, there has been a greater requirement for safe and long-term modalities that can be effective in the deeper layers of the vaginal mucosa in addition to the epithelium. By applying the principles of regenerative and anti-aging modalities to the vaginal mucosa, the use of the fractional CO₂ laser may be extended to the patients with VVA.¹⁶

Non-surgical treatments are encouraged currently to improve therapeutic outcomes.¹⁴ As reported by Enemchukwu,¹⁵ the CO₂ fractional laser application is an effective way for the relief of symptoms in vaginal atrophy. Findings from a research study by Eder et al²⁰ indicated that the effect of fractional CO₂ laser treatment on 28 healthy post-menopausal women with vaginal atrophy may be both early and late. Hence studies with longer follow-up would develop more documented results.

Also, as proposed by Salvatore et al,¹⁸ the evaluation of outcome with concomitant clinical and histological assessments would be beneficial more evidently. However, such results are seen in laser therapy for other rejuvenation aims. In our study, all vaginal factors improved. We found significant improvement in vaginal elasticity, fluid, epithelial integrity, and wetness. In the sexual context, only arousal and satisfaction status improved significantly.

Some pilot studies have indicated that the thermoablative results of the CO₂ laser are effective in dyspareunia and dryness.^{12,13} The study by Arroyo¹⁷ assessed 21 patients and showed that 82 percent had an improvement in VHI with a 100% rate of patients' satisfaction, which is in congruence with our encouraging findings in the current study. The improvement in the VHI was also reported by Siliquini et al²¹ that also showed an improved visual analog scale. Furthermore, good efficacy and high safety were shown by Gambacciani et al.²² The study by Gaspar et al²³ reported the higher efficacy of the laser compared with medical treatment, but our study had no comparison group. The short-term and long-term efficacy of lasers in vaginal rejuvenation has been reported in two studies

by Sokol et al.^{24,25} Arroyo¹⁷ reported itching as the most common (20%) side effect, but we did not find any side effects in our patients.

Totally, regarding the obtained results, it may be concluded that the CO₂ laser would bring about good effects on atrophic postmenopausal vaginal status, which is accompanied by improved quality of life and sexual function besides the urinary continence status.

However, further studies about the long-term effects of laser therapy on post-menopausal symptoms would produce further evidence.

Conclusion

The CO₂ laser would have good effects on the atrophic postmenopausal vaginal status that is accompanied by the improved quality of life and sexual function besides the urinary continence status. The strong point of our study is that all the procedures for treatment and data collection have been done by 2 physicians with the least interpersonal bias. We have used the questionnaires which have been validated for the Iranian population. Follow-up duration can be considered as the limitation of our study and another limitation is that it is done in one center. It is recommended to design a study in a multicentric format with longer follow-up duration.

Ethical Considerations

The study protocol was approved by the Ethics Review Committee of Tehran University of Medical Sciences by this number: IR.TUMS.MEDICINE.REC.1398.010. All participants signed the written informed consent. The study was conducted according to the guidelines recommended by the Declaration of Helsinki.

Conflict of Interests

The authors declare no conflict of interest.

Acknowledgments

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