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CrossRef DOI of original article:

1	Fractional CO2 Laser in the Treatment of Post-Menopausal
2	Vaginal Atrophy
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4	Received: 1 January 1970 Accepted: 1 January 1970 Published: 1 January 1970

Abstract

Introduction: Similarly to other parts of the body, the vagina changes over time, and vaginal 7 atrophy is a common condition in women between 45 and 55 years of age. It causes discomfort 8 and psychological suffering, in addition to being the main cause of pain during sexual 9 intercourse. Objective: This study aimed to evaluate the use of intravaginal fractional CO2 10 laser in the treatment of atrophy of the vaginal mucosa, as well as its effect on symptoms such 11 as itching, irritation, pain, dyspareunia, urinary incontinence, dryness, and loss of mucosal 12 elasticity. Methods: This is a prospective cohort of 14 menopausal women with vulvoyaginal 13 symptoms who were evaluated pre-and post-procedure with CO2 laser treatment using the 14 Monalisa Touch[®] technique. Cytological examination and validated questionnaires were used 15

- in the assessment. 16
- 17

Index terms—vaginal atrophy, vaginal rejuvenation, fractional CO2 laser. 18

Introduction 1 19

ot long ago, the decline in sexual interest among women started before menopause, a period when estrogen 20 production decreases gradually until the loss of libido and the appearance of uncomfortable symptoms in the 21 perineal region. In a study published in 2014, Filippini stated that this painful and debilitating condition is often 22 23 associated with psychological suffering and has a negative impact on women's lives. In addition to pain in the 24 region, many women suffer from symptoms related to vaginal atrophy. These begin to appear between the ages of 45 and 55 and usually persist or even worsen over time. "This condition may cause dryness, irritation, burning, 25 or pain during intercourse, affecting 40% of postmenopausal women" 1. 26

Salvatore, a pioneer in the application of Monalisa Touch® fractional CO2 laser, has published several studies 27 assessing the effectiveness of this treatment in improving the symptoms of vaginal atrophy, and these have shown 28 significant improvement in the physical and mental quality of life of the evaluated women 2. 29

According to Filippini 1 (2017), a clinical and histological study on the effectiveness of the Monalisa Touch® 30 CO2 laser treatment in the restoration of the vaginal mucosa and lower urinary tract was presented at the 20 th 31 World Congress of the International Federation of Gynecology and Obstetrics (FIGO) held in Rome. Based on 32

this study, the author has published several works confirming how promising the use of the Monalisa Touch® 3 33 34 has been.

35 In a study on a 12-week treatment with the Monalisa Touch® fractional CO2 laser, Salvatore et al. evaluated 36 50 women aged between 59.6 and 65.4 years who were dissatisfied with their previous local estrogen therapies.

After three laser applications throughout the treatment, 42 women (84%) reported being satisfied with the 37 procedure and experiencing minimal discomfort due to the insertion and movements of the probe during the first 38

application. Data concerning the patients' physical and mental quality of life showed significant improvement 2. 39 After analyzing such positive data regarding the Monalisa Touch® treatment in women in Europe, the present 40

study was designed to confirm those data and evaluate objectively (by histological examination) and subjectively 41

the effects of the procedure on the vaginal mucosa. 42

43 **2** II.

44 **3** Methodology

This is a prospective cohort study of 14 menopausal women with vulvovaginal symptoms (vaginal dryness, irritation, soreness, or dyspareunia). The patient enrollment required sexual activity at least once a month, no menstrual cycle for at least 12 months, and symptoms not alleviated by previous local estrogen therapy. Systemic or topical hormone replacement therapies within the past 6 months, acute or recurrent urinary tract infections, active genital infections, prolapse stage ? II according to the pelvic organ prolapse quantification (ICS-POP-Q) system, and smoking constitute exclusion criteria.

⁵¹ 4 a) Study Protocol and Procedure

The study was a prospective, outpatient setting. Prior to treatment, a complete gynecological exam was performed. The patients were recommended to avoid sexual activity for 3 days from each laser treatment session (mild inflammatory reaction may occur up to 48 hours).

55 In this study, a fractional microablative CO2 laser system (Rentall Medical Brazil, SmartXide2, Monalisa

⁵⁶ Touch[®], DEKA Laser, Florence, Italy) was applied twice time using dot spacing1,000, dwell time 1,000, dot

power 30 W, and 360° tip. Laser energy was transmitted through an intravaginal probe inserted into the vaginal canal (up to 12 cm).

59 5 b) Data Collection

Demographic data of the study population were gathered using a questionnaire applied before the first laser
 treatment.

Patients were evaluated before and after intravaginal CO2 laser treatment (Monalisa Touch®, SmartXide2, DEKA Laser, Florence, Italy). Two questionnaires were administered to assess vulvovaginal atrophy (VVA)

symptoms using a visual analog scale (VAS) and the Bachmann vaginal health index (VHI). These were applied pre-treatment and 30 to 40 days after the second and third laser applications. The VAS scores were classified

66 into three groups: mild (0-2), moderate (3-7), and severe (8-9).

Bachmann's VHI measures elasticity, secretion volume, vaginal pH, and epithelial integrity. The scale was used to assess vaginal itching, vaginal burning, pain during intercourse, vaginal dryness, and difficulty urinating or dysuria and categorize these symptoms into mild (0-2), moderate (3-7), and severe (8-9).

In order to observe vaginal cellularity, cytopathology samples were collected pre-treatment and 30 to 40 days after the last laser application.

⁷² 6 c) Data Analysis

73 The collected data were reported as mean (standard deviation), median, and percentage (%). Analyzes were 74 performed using the SPSS software version 25.0 (SPSS Science, Chicago, IL, USA). The paired-samples t-test 75 and the signed-rank test were used to analyze continuous variables at a significance level of 0.05, corresponding 76 to a 95% confidence interval.

77 **7 III.**

78 8 Results

79 The mean (standard deviation) age was 58.1 (8.5), ranging from 46 to 78 years.

The analysis of the Bachmann vaginal health index (VHI), which measures elasticity, secretion volume, vaginal pH, epithelial integrity, and lubrication, showed a statistically significant difference (p < 0.005) between pre-and post-procedure, suggesting a substantial improvement in vaginal health.

The data from the VAS regarding VVA symptoms showed overall improvement. When considering vaginal itching, nine patients (64.29%) reported that the condition improved, and five (35.71%), that it remained the same (without pruritus). The seven patients (50%) who had vaginal burning indicated improvement, while the rest of them did not have it. Pain during sexual intercourse improved for nine patients (64.28) but did not improve

for one (7.14%); three (21.42%) remained abstinent and one (7.14%) did not feel pain. Regarding vaginal dryness,

- 11 patients (78.57%) reported improvement, two (14.28%) did not have this symptom, and one (7.14%) did not
- 89 mention improvement. Difficulty urinating or dysuria affected seven (50%) patients; for six (42.86%) of them, it 90 improved, and for one (7.14%), it remained the same. The mean time between applications was 116 days SD=66
- 91 (59-265).

There was a significant increase in vaginal epithelial cells (p < 0.05). Figures 1 and 3 show pre-procedure images of vaginal epithelial cells with severe atrophy and low cellularity. Figures 2 and 4 show smears demonstrating

94 post-procedure recovery of vaginal cellularity and normal epithelium.

IV. 9 95

Discussion 10 96

In recent years, there has been a greater demand for safe, effective, and long-term treatments of the deeper layers 97 of the vaginal mucosa and the epithelium. 98

Non-invasive treatments for vulvovaginal atrophy VVA 4 symptoms are being researched, such as carboxyther-99 apy and radiofrequency, in addition we also have fractional CO2 laser as a recent treatment option. 100

Relief of symptoms of vaginal atrophy can be achieved by non-surgical therapies, including fractional CO2 laser 101 5. This type of laser produces rapid transient changes in cellular metabolism. The local production of collagen 102 synthesis, induction, coordination and expression of growth factors are induced by the acute thermos-ablative 103 damage produced by the laser 6. 104

As reported by Enemchukwu, the CO2 fractional laser application is an effective way for the relief of symptoms 105 in vaginal atrophy, even one year after the procedure 5. Significant improvement in VVA symptoms after three 106 sessions of fractional CO2 laser and improvement in quality of life were reported by Perino et al. 6 30 days 107 after the last laser application. These finding could be corroborated by the present study, even after only two 108 applications of fractional CO2 laser. Our study showed significant improvement in VVA symptoms after a month 109 110 of follow-up fractional CO2 laser therapy.

111 VVA symptoms in 28 healthy post-menopausal women undergoing treatment with 3 sessions of intravaginal fractional CO2 laser was evaluated one, 3 and 6 months post-laser; in this study Eder et al (2018) 7 showed 112 improvement in VVA symptoms and an increase in the Female Sexual Functioning Index (FSFI) from one month 113 after the first treatment. This same finding had already been reported by Salvatore et al 8, in 2015, where the 114 FSFI improved in the first 12 weeks after intravaginal CO2 laser application. 115

The VHI, studied by Arroyo (2017) showed improvement up to the eighth month after CO2 laser treatment 9 116 117

According to Filippini & Farinelli, the Monalisa Touch® is an innovative CO2 laser treatment developed by 118 DEKA which gently acts on the vaginal tissues to stimulate collagen production, improve the functionality of the 119 treated area, and restore the propermucosal trophic balance. In another study, the author used the same method 120 to treat postpartum dyspareunia. A significant improvement in symptoms could be observed in 5 to 6 patients, 121 especially regarding dryness, dyspareunia, and pain in the vulval-perineal region. It is also noteworthy that most 122 123 of these patients tried, without success, alternative therapies such as physical therapy, perineal massage, and tranquilizers 1. 124

Arroyo 9 performed a clinical and histopathological evaluation, as suggested by Salvatore et al 8, and 125 found improvement in elasticity, secretion, epithelial integrity, lubrication and histopathological aspects, without 126 reporting side effects. 127

Tahereh et al. (2020) compared intravaginal CO2 laser and the application of hormone therapy with Premarin 128 vaginal cream. They demonstrated how the laser was betterat improving sexual desire, orgasms, and sexual 129 satisfaction, and at decreasing pain during intercourse and overall sexual function in menopausal women. In the 130 present study, no comparison was made with another treatment 10. 131

In a recent study, Macrene et al. (2021) demonstrated persistent positive effects in vulvovaginal treatment 132 after one year of postmenopausal fractional CO2 laser treatment 11 . The limitation of their study was the use 133 of a small sample; however, the statistical significance found indicates that it did not affect the results. 134

Our study has the particularity of evaluating the cellular changes of the vaginal mucosa, objectively proving its 135 improvement and recovery after the application of fractional CO2 laser. Furthermore, a significant improvement 136 in objective signs and symptoms of genital function could also be seen. 137 V.

Conclusion 11 139

138

In addition to objectively demonstrating the improvement of vaginal cellularity, the results of the present 140 study corroborate the physical, psychological, and social benefits of the Monalisa Touch® fractional CO2 laser 141 technology for menopausal women in terms of quality of life. 142

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Figure 1: Figure 1 :



Figure 2: Figure 2 :



Figure 3: Figure 3 :



Figure 4: Figure 4 :

11 CONCLUSION

143 .1 Acknowledgment

144 We thank Augusta Ketzer Menezes for the English assistance.

¹⁴⁵.2 Ethical Considerations

This study was approved by the Research Ethics Committee of the Moinhos de Vento Hospital under protocol number 81915417.0.0000.5330.All participants signed a written informed consent form. The study was conducted according to the guidelines of the Declaration of Helsinki.

¹⁴⁹.3 Conflict of Interests

- 150 The authors declare no conflict of interest.
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