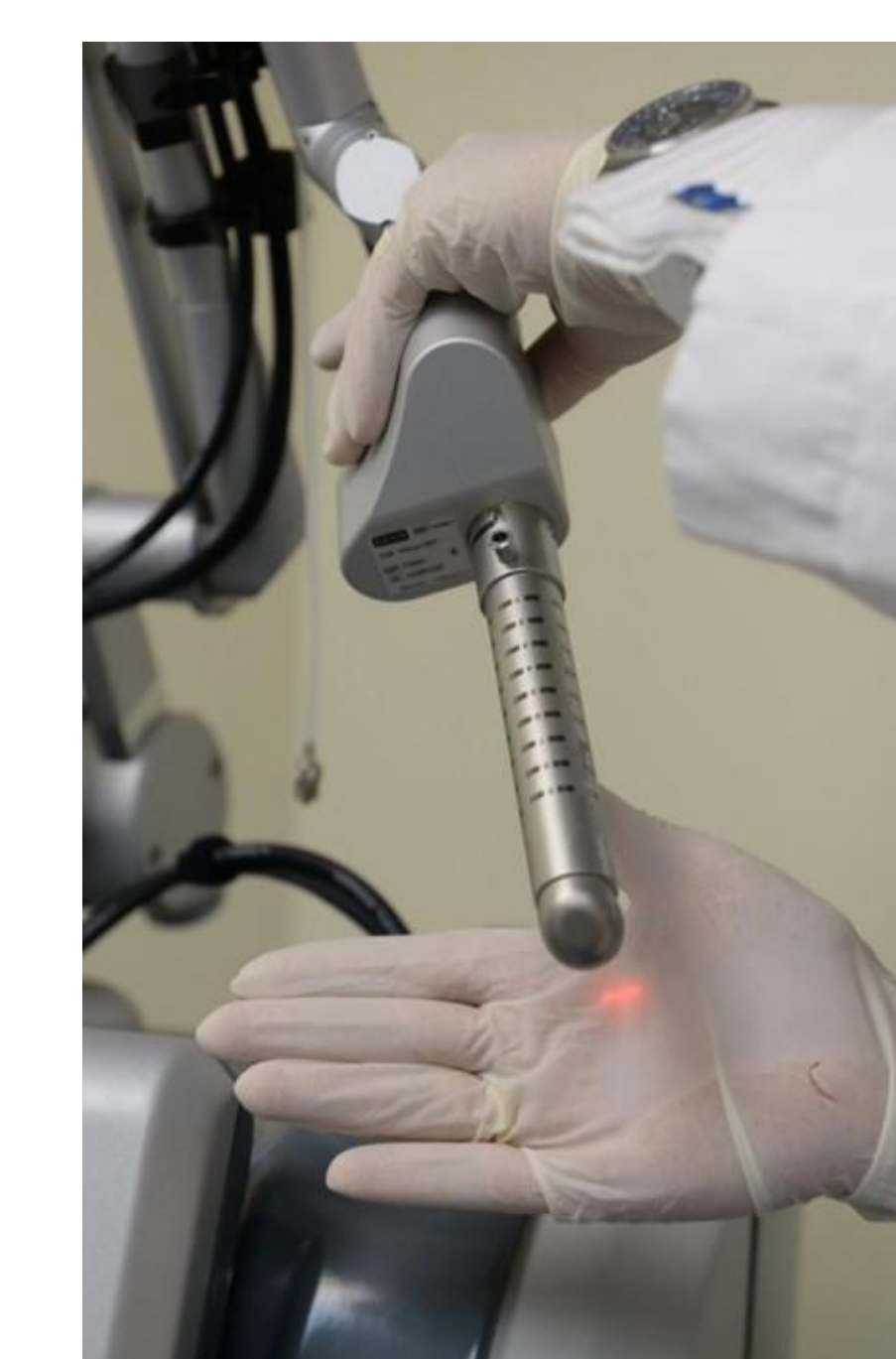


# Efficacy of Vaginal Laser Treatment for Symptomatic Relief of Vulvovaginal Atrophy in Postmenopausal Women

Kathleen Parker, MMS (c)

Faculty Advisor: Kimberly Erikson, MSPAS, PA-C

Department of Medical Science



## Abstract

As women age and go through menopause, the decrease in estrogen that occurs with this process causes many changes in the body, one being atrophy of the vaginal skin. The thinning and drying of the vaginal canal as well as the external vulvar skin due to this lack of estrogen can cause burning, dyspareunia, dysuria, and even contribute to vaginal infections, incontinence and urinary tract infections<sup>1</sup>. This review aims to determine if laser therapy can be used vaginally to treat vulvovaginal atrophy in postmenopausal women with equal or better results than the current standard of care, estrogen cream.

## Introduction

### Vulvovaginal Atrophy (VVA)

- The North American Menopause Society estimates symptoms related to vulvovaginal atrophy (VVA) affect 20-45% of perimenopausal and post-menopausal women in North America<sup>2</sup>
- Affect women's quality of life and cause intimacy issues

### Symptoms

- Burning, itching, dyspareunia, dysuria

### Treatment

- Current gold standard of treatment for moderate to severe atrophic vaginitis is vaginal estrogen therapy, most commonly in cream form, 0.5g to 1.0g applied vaginally 2-3x/wk for long term use → compliance issues
- Ablative CO2 lasers, are FDA approved for dermatologic facial treatments, now being explored for VVA treatment – not FDA approved, patients pay out of pocket for off label use



## Methods

Literature search performed in November 2019 using:

- PubMed & Google Scholar

### Search terms:

- "CO2 laser vulvovaginal atrophy OR laser genitourinary syndrome of menopause OR laser vaginal atrophy NOT rejuvenation NOT incontinence NOT cancer".

### Search Criteria:

- Articles published in scholarly journals within last 5 years
- Filtered for title of articles only and English language
- Excluded: Systematic reviews, meta-analyses, commentary or critical appraisals, studies not including a clinical trial
- Excluded: Studies only comparing types of lasers or number of treatments, only trialing women of a specific race, studies with "short term effects" or "early effects" in the title, indications for women with vestibulodynia or the laser treatment was done intraurethrally

## Results

1. Cruz, V.L., Steiner, M.L., Pompei, L.D., Strufaldi, R., Fonseca, F.L., Santiago, L.H., Wajsfeld, T., & Fernandes, C.E. 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. *Menopause*. 2017; 25(1): 21-28.

- **RCT w/ 45 participants (15 laser, 15 estrogen, 15 both); Vaginal Health Index higher in all 3 groups with significant improvement in the laser group of dyspareunia, dryness and burning symptoms**

2. Politano, C., Costa-Paiva, L., Aguiar, L., Machado, H., Baccaro, L. Fractional CO2 laser versus promestriene and lubricant in genitourinary syndrome of menopause: a randomized clinical trial. *Menopause*. 2019; 26(8): 833-840.

- **RCT w/ 72 participants (24 laser, 24 estrogen, 24 OTC lube); Vaginal Health index higher in laser group at the end than the estrogen or lubrication group**

3. Paraiso, M.F., Ferrando, C., Sokol, E., Rardin, C., Karram, M., Iglesia, C. A randomized clinical trial comparing vaginal laser therapy to vaginal estrogen therapy in women with genitourinary syndrome of menopause: The VeLVET Trial. *Menopause*. 2020; 27(1):50-56.

- **RCT w/ 62 participants (30 laser, 32 estrogen); 85% laser group rated improvement "better/much better" compared to 70% in estrogen group**

4. Pieralli, A., Bianchi, C., Longinotti, M. et al. Long-term Reliability of Fractioned CO2 Laser as a Treatment for Vulvovaginal Atrophy (VVA) Symptoms. *Archives of Gynecology and Obstetrics*. 2017; 296(5): 973-978.

- **Prospective Cohort study w/ 184 participants; 6 months after last treatment 92% of patients reported being satisfied**

5. Behnia-Willison, F. et al. Safety and long-term efficacy of fractional CO2 laser treatment in women suffering from genitourinary syndrome of menopause. *European Journal of Obstetrics and Gynecology and Reproductive Biology*. 2017; 213: 39 – 44.

- **Prospective cohort study w/ 102 participants; 84% experienced significant improvement in their symptoms including sexual function, dyspareunia and vaginal lubrication**

6. Lekskulchai, O., Mairaing, K., Vinayanuvattikhun, N. Fractional CO2 Laser for Vulvovaginal Atrophy. *Journal of the Medical Association of Thailand*. 2016; 4: S54-S55

- **Prospective cohort study w/ 112 participants; VVA symptom score significantly decreased, pre-treatment 58% noted "vulvar irritation", after treatment 0%**

7. Gaspar, A. et al. Efficacy of Erbium:YAG laser treatment compared to topical estriol treatment for symptoms of genitourinary syndrome of menopause. *Lasers in Surgery and Medicine*. 2017; 49(2): 160-168.

- **RCT w/ 50 participants (25 laser, 25 estrogen); Statistically significant (P<0.05) reduction of all assessed symptoms in the laser group up to 18mo**

Study	Total N	Type of treatment	Control	Duration of intervention & follow up	Outcome measurements
1	45	CO2 vaginal laser therapy vs vaginal estriol cream vs combination	Vaginal estriol cream	Two laser treatment at wks 0, 4 1mg vaginal cream used 3x/wk for 20 wks Assessment at weeks 0, 8, 20	VHI, VAS for VVA symptoms, FSFI, MV of Meisels
2	72	CO2 vaginal laser vs. Promestriene vaginal cream vs. KY water based gel	Promestriene vaginal cream & water base gel	3 laser treatments performed 30 days apart Estrogen cream used 3x week for 12 weeks Lubricant applied w/ sexual activity Assessments at weeks 0 and 14	VHI, FSFI, VM
3	62	CO2 vaginal laser therapy vs. Vaginal estrogen cream (Premarin)	Vaginal estrogen cream (Premarin)	3 laser treatments at least 6 weeks apart 0.5g daily x14 days, then 2x wk for 24 wks Assessments at weeks 0, 12, 24	Vaginal dilator size assessment & 5-point Likert scale, VAS for GSM symptoms, FSFI, DIVA questionnaire, UDI-6, PGII scale
4	184	CO2 vaginal laser therapy	None	3 laser treatments 4 weeks apart Assessments at 16 wks, 6mo, 1, 1.5 & 2yrs	Patient satisfaction w/ 5pt Likert scale
5	102	CO2 vaginal laser therapy	None	3 treatments, 6 weeks apart Follow up 1 year after initial treatment	Australian Pelvic Floor Questionnaire
6	112	CO2 vaginal laser therapy	None	3 treatments, 4 weeks apart Assessments at baseline, 1 week after last treatment, and 3 months after last treatment	VVA symptom score, vaginal pH, VMI, VAS
7	50	Erbium:YAG vaginal laser therapy vs 0.5mg estriol ovules	0.5mg vaginal estriol ovules	Laser therapy group pretreated w/ 0.5mg estriol ovules 3x wk for 2 wks, then 3 laser treatments 3 wks apart Control group: Estriol ovules vaginally once daily for 2 wks, then 3x wk for 2 wks, then 2x wk for 4 wks Assessments at baseline, 1, 3, 6, 12, 18 mo	MI/MV, vaginal pH, VAS, Biopsies taken from 6 patients per group at baseline and 1-, 3-, 6-, and 12-months post treatment

## Discussion

- All seven studies included showed a **statistically significant improvement in the patients' vulvovaginal atrophy with the use of laser therapy based on the measured outcomes** or improvement with the laser therapy that was equal or **not statistically significantly different from the control of vaginal estrogen cream**.
- Of the seven studies, three were cohort studies, and four were RCTs with three using blinding
- Studies similar in timing and number of treatments, 2-3 treatments
- Follow up assessments varied in timing, shortest stopping at 14 weeks and longest 24 months after
- **Most studies admit further studies needed with longer term follow up and larger sample size**
- Studies varied in design with the presence or absence of a control, collectively they are valuable in accumulating data for this new treatment strategy and evaluating its safety profile.

## Conclusion

- Vaginal lasers show promise as a treatment for VVA, especially when compared to the current standard of care, but more evidence is needed for FDA approval
- The benefits of using laser therapy as a treatment for GSM/VVA outweighs the risks and adverse events
- Patients have to be aware this is still considered an off label option based on FDA approval.
- Recommendations can be made for use of laser therapy but significant patient education has to be done concurrently to make them aware of the reason for the lack of FDA approval at this time.



## References

1. American College of Obstetricians and Gynecologists Committee on Practice Bulletins—Gynecology: ACOG practice bulletin no. 141: management of menopausal symptoms. *Obstet Gynecol.* 2014;123(1):202-16.
2. Gass, M.L. Management of symptomatic vulvovaginal atrophy: 2013 position statement of The North American Menopause Society. *Menopause: The Journal of The North American Menopause Society.* 2013; 20(9): 888–902.
3. Gianfaldoni S, Tchernev G, Wollina U, et al. An Overview of Laser in Dermatology: The Past, the Present and the Future (?). *Open Access Maced J Med Sci.* 2017;5(4):526–530.
4. American College of Obstetricians and Gynecologists Position Statement. Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance. <https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/fractional-laser-treatment-of-vulvovaginal-atrophy-and-us-food-and-drug-administration-clearance#3>. July 2018. Accessed April 8, 2020.
5. Sturdee, D.W., Panay, N. Recommendations for the management of postmenopausal vaginal atrophy. *Climacteric.* 2010; 13(6): 509-22.
6. Portman, D., Shulman, L., Yeaw, J., Zeng, S., Uzoigwe, C., Maamari, R., Iyer, N. One-year treatment persistence with local estrogen therapy in postmenopausal women diagnosed as having vaginal atrophy. *Menopause.* 2015; 22(11): 1197-203
7. Archer, D.F. et al. A Randomized, Multicenter, Double-Blind, Study to Evaluate the Safety and Efficacy of Estradiol Vaginal Cream 0.003% in Postmenopausal Women with Vaginal Dryness as the Most Bothersome Symptom. *Journal of Women's Health.* 2018; 27(3): 231-237.