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# A Randomized Trial on the Efficacy of Topical Estrogen vs. Vaginal Laser Therapy for Postmenopausal Vaginal Atrophy and Urinary Incontinence

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## Abstract

A randomized controlled trial evaluated the efficacy of topical estrogen (TE) versus fractional $CO_2$ vaginal laser therapy (VLT) in treating postmenopausal vaginal atrophy (PVA) and urinary incontinence (UI). One hundred twenty postmenopausal women with moderate-to-severe PVA and stress or mixed UI were randomized to receive either daily TE (0.5 mg estradiol cream, n=60) or three monthly sessions of VLT (n=60). Primary outcomes were vaginal maturation index (VMI), Vaginal Health Index (VHI), and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) at baseline, three, and six months. At six months, TE and VLT both significantly improved VMI (mean increase: 32% vs. 28%; p=0.12) and VHI (mean increase: 6.8 vs. 6.4; p=0.18), with no significant intergroup differences. Both groups demonstrated significant UI symptom reduction (ICIQ-SF decrease: TE −8.3 ± 2.4 vs. VLT −7.9 ± 2.6; p=0.28). Treatment satisfaction was high (>85%) in both arms, with no serious adverse events. These findings suggest that VLT offers non-hormonal efficacy comparable to TE in improving vaginal atrophy and UI, supporting its use as an alternative treatment option.

**Keywords:** vaginal atrophy; estrogen cream; vaginal laser; urinary incontinence.

## Introduction

Postmenopausal estrogen deficiency commonly leads to vaginal atrophy, characterized by thinning epithelium, dryness, and decreased elasticity. These changes are often accompanied by urinary incontinence (UI), significantly impairing quality of life[1]. Topical estrogen (TE) therapy has long served as the first-line treatment, restoring mucosal integrity and alleviating urinary symptoms[2]. However, TE is contraindicated in women with estrogen-sensitive pathologies and carries concerns about systemic absorption[3]. Vaginal non-ablative laser therapy (VLT), specifically microablative fractional $CO_2$ laser, has emerged as a promising, non-hormonal treatment for genitourinary syndrome of menopause (GSM) and UI[4].
Initial pilot studies (2022–2023) demonstrated improvements in VHI and UI scores after three $CO_2$ laser sessions, with effects lasting six to twelve months[5][6]. A randomized trial by Pérez et al. showed VLT efficacy matching TE in epithelial biomarkers after six months[7].
Despite growing interest, high-quality RCTs with both morphological and urinary symptom endpoints are limited. Furthermore, comparative studies assessing durability and patient satisfaction between TE and VLT remain scarce but essential for informed treatment choices[8]. This RCT aims to compare TE versus VLT over six months in postmenopausal women with PVA and mild-to-moderate UI, hypothesizing that VLT will achieve non-inferior improvements in VMI, VHI, and UI symptoms, with high patient satisfaction and minimal adverse effects.

## Methodology

This single-center, randomized controlled trial was conducted from January to December 2024 at Aziz Fatima Medical and Dental College. Postmenopausal women aged 50–70 with symptomatic vaginal atrophy (VHI ≤12) and stress or mixed UI (ICIQ-SF score ≥6) were recruited. Exclusion criteria included estrogen-dependent neoplasia, active genital infection, pelvic organ prolapse ≥ stage II, prior vaginal surgery, systemic hormone therapy within six months, or contraindications to laser. After informed consent, 120 participants were randomized 1:1 using computer-generated blocks into TE (n=60) or VLT (n=60). Sample size, calculated via Epi Info® (power=80%, $\alpha$=0.05), targeted a 4-point VHI difference.
TE arm used 0.5 mg estradiol cream nightly for two weeks, then twice weekly. VLT received three monthly sessions of 30 W fractional $CO_2$ laser with 1.0–1.5 J/cm² fluence. Follow-ups at baseline, 3 months, and 6 months included VMI (cytology), VHI, ICIQ-SF, patient satisfaction survey (5-

point Likert), and safety assessment (adverse events, endometrial thickness via transvaginal ultrasound).

Between-group comparisons used t-tests and chi-square tests; repeated measures ANOVA evaluated longitudinal changes; non-inferiority margins were set. Analyses were performed per protocol with SPSS v26; significance at $p<0.05$.

**Results**

**Table 1. Baseline Characteristics (n = 120)**

| **Characteristic** | **TE (n=60)** | **VLT (n=60)** | **p-value** |
|---|---|---|---|
| Age (years) | 62.5 ± 5.4 | 63.1 ± 5.2 | 0.52 |
| Years since menopause | 12.1 ± 6.3 | 11.8 ± 6.0 | 0.78 |
| Vaginal Health Index (VHI) | 9.5 ± 1.4 | 9.4 ± 1.3 | 0.65 |
| Vaginal Maturation Index (VMI%) | 35 ± 12 | 36 ± 11 | 0.72 |
| ICIQ-SF score | 14.3 ± 3.5 | 14.5 ± 3.4 | 0.82 |

Baseline parameters were well-balanced.

**Table 2. Primary Outcomes at 6 Months**

| **Outcome** | **TE** | **VLT** | **p-value** |
|---|---|---|---|
| VHI mean increase | +6.8 ± 1.9 | +6.4 ± 2.0 | 0.18 |
| VMI increase (percentage) | +32 ± 14 | +28 ± 15 | 0.12 |
| ICIQ-SF reduction | −8.3 ± 2.4 | −7.9 ± 2.6 | 0.28 |

Both treatments led to clinically significant and comparable improvements.

**Table 3. Secondary and Safety Outcomes**

| **Measure** | **TE** | **VLT** | **p-value** |
|---|---|---|---|
| Patient satisfaction ≥4/5 | 55 (92%) | 52 (87%) | 0.42 |
| Endometrial thickness change | 0.2 ± 0.5 mm | Not applicable | – |
| Adverse events (vaginal spotting) | 6.7% (n=4) | 5.0% (n=3) | 0.69 |
| Endometrial hyperplasia | 0 | – | – |

Treatments were well-tolerated; no serious adverse events occurred.

## Discussion

This RCT demonstrates that VLT is non-inferior to TE for treating vaginal atrophy and UI in postmenopausal women. Both arms significantly improved VHI and VMI at six months, with statistically similar outcomes ($p>0.05$), echoing earlier RCTs showing morphological equivalence. Symptom relief was comparable, with both groups achieving clinically meaningful ICIQ-SF reductions (~8 points). These improvements align with prior trials indicating ≥4-point changes as clinically,significant.

High satisfaction rates (>85%) support the acceptability of both interventions. The absence of estrogen-related endometrial changes in the TE group confirms low systemic absorption with low-dose topical regimens[10-12]. Adverse events were minimal and similar, consistent with earlier clinical,reports[10-15].

VLT offers a hormone-free alternative, beneficial for women contraindicated for estrogen use. However, limitations include costs, device availability, and uncertain long-term durability beyond six months. While TE is well-established, VLT's effects may require periodic re-treatment. Study strengths include randomized design, objective indices, and safety monitoring. Limitations include absence of sham laser control and lack of longer-term follow-up. Future studies should investigate 12-month outcomes, cost-effectiveness, and the long-term prevention of UTIs and GSM-related complications.

In summary, VLT offers a safe, effective non-hormonal option matching TE in improving PVA and UI symptoms. Personalized treatment decisions can consider patient preferences, contraindications, and resource availability.

## Conclusion

Fractional $CO_2$ vaginal laser provides efficacy comparable to topical estrogen in improving vaginal atrophy and urinary incontinence symptoms, with high patient satisfaction and favorable safety profiles. It represents a suitable non-hormonal alternative, particularly for women with contraindications to estrogen therapy.

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