Research Square

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Single-operator learning curve analysis of transvaginal fractional CO_2 laser treatment for female stress urinary incontinence: a subgroup study based on vaginal mucosal stratification

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Abstract

Purpose: Stress urinary incontinence (SUI) is a prevalent condition that significantly impairs quality of life, and transvaginal fractional CO_2 laser has emerged as a minimally invasive treatment; however, its learning curve remains poorly characterized. This study aimed to investigate the learning curve of a single operator performing transvaginal fractional CO_2 laser for SUI, to conduct subgroup analysis stratified by vaginal mucosal status, and to introduce withdrawal precision and rotation precision as objective, quantifiable hand-stability metrics for assessing operator proficiency.

Methods: This retrospective study included 80 female patients with SUI who underwent transvaginal fractional CO_2 laser therapy (wavelength 10600 nm) at a single center between January and June 2026. All treatments were performed by one operator (deputy chief nurse, 29 years of experience). Patients were stratified into Subgroup A (normal mucosa, n = 43) and Subgroup B (atrophic mucosa, n= 37) based on intraoperative mucosal assessment. Cumulative sum (CUSUM) control charts were used to analyze learning curves, with 5-case rolling average cure rates for cross-validation. Multivariate logistic regression identified independent predictors of cure. Pearson correlation analysis evaluated relationships between hand-stability metrics and case sequence. Clinical trial number: not applicable.

Results: CUSUM inflection points occurred at case 30 (Subgroup A) and case 33 (Subgroup B). Cure rates improved significantly from the learning to proficiency phases (53.3% vs. 92.3%, Subgroup A; 51.5% vs. 100.0%, Subgroup B; both $P < 0.01$). Case sequence, power setting, and treatment endpoint achievement were independent predictors of cure ($P < 0.05$). Withdrawal deviation and rotation deviation showed strong negative correlations with case sequence ($r = -0.906$ to -0.807, all $P < 0.001$), while hand-stability scores showed strong positive correlations ($r = 0.926–0.942$, $P < 0.001$). All 7 adverse events (8.8%) occurred during the learning phase and were mild.

Conclusion: Transvaginal fractional CO_2 laser for SUI demonstrates a quantifiable learning curve, with longer training required for patients with atrophic mucosa due to altered laser–tissue interactions. Withdrawal precision and rotation precision serve as promising prototype metrics for objective proficiency assessment. The identified thresholds (withdrawal deviation < 0.1 cm, rotation deviation < 2°) are proposed as competency-based entry criteria for future clinical trials.

1. Introduction

Stress urinary incontinence (SUI), defined as the involuntary leakage of urine upon exertion, sneezing, or coughing, affects approximately 30–50% of middle-aged and older women and significantly impairs quality of life.[1,2] The pathophysiology of SUI centers on the weakening of urethral support structures, particularly the collagen fiber network (predominantly type I and type III collagen) within the periurethral connective tissue that constitutes the “hammock” support, as well as the pubourethral ligaments and anterior vaginal wall that suspend the urethra.[3,4] When pelvic floor support tissues are damaged or

degenerated, the urethra cannot maintain adequate closure pressure during increased intra-abdominal pressure, resulting in urine leakage.[4]

Fractional CO_2 laser (wavelength 10,600 nm) has emerged as a minimally invasive treatment option for SUI. Through the creation of microscopic thermal treatment zones (MTZs) in the vaginal mucosal sublayer, the laser stimulates fibroblast proliferation, collagen remodeling (primarily neoformation and cross-linking of type I and type III collagen), angiogenesis, and epithelial repair.[2,5–7] Multiple randomized controlled trials have demonstrated the efficacy of fractional CO_2 laser for SUI, with cure rates ranging from 45% to 75%.[8–11]

However, the efficacy and safety of laser treatment are highly operator-dependent. Unlike pharmacotherapy, laser treatment requires the operator to manually control the delivery handpiece—advancing it along the vaginal wall in 1-cm increments and rotating it at 45° intervals to achieve 360° circumferential coverage with 8 laser spots per station. This manual operation introduces variability in energy delivery that depends on the operator's skill and experience. While learning curves have been extensively studied for surgical procedures,[12–14] no study has specifically examined the learning curve for transvaginal CO_2 laser treatment of SUI, nor has any study stratified the learning process by vaginal mucosal status—a factor that fundamentally alters laser–tissue interactions.

The present study aimed to: (1) investigate the learning curve of a single operator performing transvaginal fractional CO_2 laser treatment for SUI using CUSUM analysis; (2) stratify the analysis by vaginal mucosal status to identify subgroup-specific learning requirements; and (3) introduce and validate two objective hand-stability metrics—withdrawal precision and rotation precision—as quantitative tools for assessing operator proficiency.

2. Materials and Methods

2.1. Study Design and Participants

This retrospective study included 80 female patients with SUI who underwent transvaginal fractional CO_2 laser treatment at a single tertiary hospital in China between January 2026 and June 2026. All treatments were performed by a single operator (deputy chief nurse with 29 years of clinical experience).

Inclusion criteria: (1) Female, age 40–75 years; (2) SUI diagnosed according to International Continence Society criteria; (3) ICIQ-SF score ≥ 3; (4) Positive 1-hour pad test (leakage ≥ 1 g); (5) Completion of 4 treatment sessions and 3-month follow-up.

Exclusion criteria: (1) Urgency or mixed urinary incontinence; (2) Previous pelvic surgery; (3) Severe cardiopulmonary disease or coagulopathy; (4) Pregnancy or lactation; (5) Active vaginal inflammation or infection.

The study was approved by the hospital's Institutional Review Board (Approval No. 2025037), and all patients provided written informed consent.

2.2. Subgroup Stratification

Based on the manufacturer's treatment parameter guidelines (Fuhao Laser System) and intraoperative mucosal assessment, patients were stratified into two subgroups: Subgroup A (vaginal laxity with normal mucosa, n = 43): Age < 57 years or age 55–56 years with good mucosal status, corresponding to energy density 80–110 mJ/pixel; Subgroup B (thin vaginal mucosa, n = 37): Age ≥ 57 years with atrophic/thin mucosa, corresponding to energy density 50–80 mJ/pixel. Patients aged 55–56 years (peri-menopausal transition) were assigned based on intraoperative visual assessment of mucosal color, moisture, and elasticity.

2.3. Treatment Equipment and Parameters

Treatment was performed using a fractional CO_2 laser system (Ligenesis-MC30, MF multi-focus technology, Wuhan LaserGen Sci-Tech Co., Ltd.; NMPA registration No. 20163012515), wavelength 10,600 nm. Parameters were differentiated by subgroup: Subgroup A: Laser power 22–25 W, energy density 80–110 mJ/pixel; Subgroup B: Laser power 18–21 W, energy density 50–80 mJ/pixel. The handpiece was withdrawn along the vaginal wall in 1-cm increments (number determined by vaginal length). At each station, 360° rotation was performed at 45° intervals (8 emissions per station). Treatment was administered monthly for 4 sessions per course.

During each session, withdrawal deviation (|actual withdrawal distance − 1.00 cm|) and rotation deviation (|actual rotation angle − 45°|) were recorded. A composite hand-stability score (0–100) was calculated as: 100 − weighted deviation (50% withdrawal deviation + 50% rotation deviation, normalized).

2.4. Learning Curve Analysis

CUSUM control charts were independently calculated for each subgroup. The baseline success rate was set at $p_0 = 0.72$. A continuously rising CUSUM indicated the learning phase; the case number at which the CUSUM began to decline and stabilize was defined as the inflection point. Five-case rolling average cure rates were calculated to cross-validate CUSUM inflection points.[18,19] Pearson correlation analysis was performed to evaluate linear trends between hand-stability metrics and within-subgroup case sequence.

2.5. Efficacy Assessment

The primary outcome was cure rate. Cure was defined as ≥ 50% improvement in both ICIQ-SF score and 1-hour pad test leakage. Secondary outcomes included ICIQ-SF score, 1-hour pad test leakage, UDI-6, IIQ-7, patient satisfaction VAS, and PGI-I.

2.6. Statistical Analysis

Statistical analyses were performed using SPSS 26.0 and R 4.5.0. All continuous variables were first assessed for normality using the Shapiro–Wilk test (preferred for $n < 50$) and for homogeneity of variance using Levene's test. Normally distributed continuous variables were expressed as mean ± standard deviation and compared using independent samples t-tests (or paired t-tests for within-group comparisons); non-normally distributed variables were expressed as median (interquartile range) [M (P_{25}, P_{75})] and compared using the Mann–Whitney U test (or Wilcoxon signed-rank test for paired comparisons). Categorical variables were expressed as frequency (percentage) [n (%)] and compared using the chi-square test or Fisher's exact test. Multivariate logistic regression was performed separately for each subgroup, with "cure" as the dependent variable, to calculate odds ratios (OR) and 95% confidence intervals (CI). All tests were two-sided, with $P < 0.05$ considered statistically significant.

3. Results

3.1. Baseline Characteristics

The two subgroups were comparable in BMI, disease duration, baseline ICIQ-SF, 1-hour pad test leakage, UDI-6, and IIQ-7 scores (all $P > 0.05$). Subgroup B patients were significantly older than Subgroup A patients ($P < 0.001$), consistent with the subgroup design. Detailed baseline characteristics are presented in Table 1.

Table 1
Comparison of baseline characteristics between the two subgroups

Variable	Subgroup A (n = 43)	Subgroup B (n = 37)	Statistic	P value
Age (years)*	50.0 (44.0, 53.0)	61.0 (59.0, 63.0)	Z = − 5.82	< 0.001
BMI (kg/m²)†	25.7 ± 3.2	25.7 ± 3.1	t = 0.03	0.976
Disease duration (years)*	14.9 (7.9, 18.8)	13.3 ± 7.4	Z = − 0.51	0.610
ICIQ-SF†	11.5 ± 3.4	11.8 ± 4.4	t = − 0.34	0.737
1-h pad test (g)*	9.8 (6.3, 13.5)	10.4 (6.4, 14.8)	Z = − 0.44	0.659
UDI-6†	45.5 ± 13.5	46.5 ± 18.2	t = − 0.28	0.778
IIQ-7†	34.6 ± 10.8	35.4 ± 13.6	t = − 0.29	0.770
SUI mild [n (%)]	7 (16.3)	9 (24.3)	χ^2 = 2.89	0.236
SUI moderate [n (%)]	30 (69.8)	19 (51.4)		
SUI severe [n (%)]	6 (14.0)	9 (24.3)		

*Non-normally distributed data expressed as median (P_{25}, P_{75}); Mann–Whitney U test.

†Normally distributed data expressed as mean ± SD; independent samples t-test.

3.2. CUSUM Learning Curves

Subgroup A: The CUSUM curve rose continuously from case 1 to case 30, peaking at CUSUM = 22.00, then declined and stabilized, indicating an inflection point at case 30 (Fig. 1). Learning-phase cure rate was 53.3% (16/30) vs. 92.3% (12/13) in the proficiency phase ($P < 0.01$).

Subgroup B: The CUSUM curve rose continuously from case 1 to case 33, peaking at CUSUM = 25.57, then declined and stabilized, indicating an inflection point at case 33 (Fig. 2). Learning-phase cure rate was 51.5% (17/33) vs. 100.0% (4/4) in the proficiency phase. The Subgroup B learning curve was 3 cases longer than Subgroup A (33 vs. 30), and its peak CUSUM value was higher (25.57 vs. 22.00), with a slower decline phase (Fig. 3). Given the small sample size of the Subgroup B proficiency phase ($n = 4$), the 100% cure rate should be interpreted with caution; the 95% confidence interval for this estimate (Wilson score interval) ranges from 51% to 100%.

3.3. Comparison of Learning and Proficiency Phases

Both subgroups showed significant improvements from the learning to proficiency phases in cure rate, treatment endpoint achievement rate, treatment time, and all hand-stability metrics (all $P < 0.05$; Table 2).

Table 2
Comparison of efficacy and operative metrics between learning and proficiency phases

Metric	Subgroup A Learning (1–30)	Subgroup A Proficiency (31–43)	Subgroup B Learning (1–33)	Subgroup B Proficiency (34–37)	P value
Laser power (W)*	22.0 (22.0, 23.0)	25.0 (24.3, 25.0)	20.0 (20.0, 20.0)	20.3 ± 0.3	< 0.001
Treatment time (min)†	8.0 ± 1.0	6.6 ± 0.6	6.9 (6.5, 8.3)	6.4 ± 0.7	< 0.001
Pulse width (ms)*	369.5 (350.0, 400.0)	407.0 (400.0, 421.0)	334.0 (300.0, 357.0)	343.0 ± 12.0	< 0.001
Energy density (mJ/pixel)*	8.1 (7.7, 9.2)	10.2 ± 0.5	6.7 (6.0, 7.2)	7.0 ± 0.1	< 0.001
Endpoint achievement (%)	43.3	76.9	63.6	75.0	< 0.01
Cure rate (%)	53.3 (16/30)	92.3 (12/13)	51.5 (17/33)	100.0 (4/4)	< 0.001
Satisfaction VAS	75.7 ± 12.4	88.0 ± 6.9	82.0 (68.0, 89.0)	89.5 ± 6.9	< 0.05
PGI-I	2.0 (1.0, 4.0)	2.0 (2.0, 2.0)	2.0 (2.0, 4.0)	1.0 (1.0, 1.2)	< 0.05
Withdrawal deviation (cm)†	0.27 ± 0.11	0.06 ± 0.02	0.24 ± 0.10	0.06 ± 0.03	< 0.001
Rotation deviation (°)†	5.26 ± 1.65	1.41 ± 0.66	5.14 ± 1.82	0.80 (0.67, 1.27)	< 0.001
Hand-stability score†	55.86 ± 15.07	89.15 ± 3.38	58.93 ± 13.95	90.17 ± 5.33	< 0.001

*Non-normally distributed data expressed as median (P_{25}, P_{75}).

†Normally distributed data expressed as mean ± SD. P values: comparison between learning and proficiency phases within each subgroup.

3.4. Multivariate Logistic Regression

Subgroup A: Within-subgroup case sequence (OR = 1.08, 95% CI: 1.02–1.15, P < 0.01), power setting (OR = 1.20, 95% CI: 1.03–1.40, P < 0.05), and treatment endpoint achievement (OR = 2.86, 95% CI: 1.53–5.35, P < 0.01) were independent predictors of cure. Subgroup B: Within-subgroup case sequence (OR = 1.09, P < 0.05) and treatment endpoint achievement (OR = 2.59, P < 0.01) were independent positive predictors; age (OR = 0.91, P < 0.05) and severe SUI (OR = 0.32, P < 0.05) were independent negative predictors (Table 3).

Table 3
Multivariate logistic regression analysis results

Variable	β	SE	Wald χ^2	P value	OR	95% CI
Subgroup A (n = 43)						
Within-subgroup case sequence	0.08	0.03	7.11	< 0.01	1.08	1.02–1.15
Age (per 5 years)	−0.05	0.04	1.56	0.21	0.95	0.88–1.03
BMI	−0.02	0.05	0.16	0.69	0.98	0.89–1.08
Power setting (per W)	0.18	0.08	5.06	< 0.05	1.20	1.03–1.40
Endpoint achievement	1.05	0.32	10.76	< 0.01	2.86	1.53–5.35
SUI moderate vs. mild	−0.35	0.40	0.77	0.38	0.70	0.32–1.54
SUI severe vs. mild	−0.95	0.50	3.61	0.057	0.39	0.15–1.03
Subgroup B (n = 37)						
Within-subgroup case sequence	0.09	0.04	5.06	< 0.05	1.09	1.02–1.17
Age (per 5 years)	−0.10	0.05	4.00	< 0.05	0.91	0.83–0.99
BMI	−0.03	0.06	0.25	0.62	0.97	0.87–1.09
Power setting (per W)	0.12	0.09	1.78	0.18	1.13	0.94–1.35
Endpoint achievement	0.95	0.35	7.36	< 0.01	2.59	1.30–5.14
SUI moderate vs. mild	−0.45	0.45	1.00	0.32	0.64	0.27–1.53
SUI severe vs. mild	−1.15	0.55	4.37	< 0.05	0.32	0.11–0.93

Dependent variable: cure (cured = 1, not cured = 0).

3.5. Hand-Stability Analysis

Hand-stability metrics demonstrated a characteristic rapid-improvement-then-plateau pattern, with withdrawal and rotation deviations declining with increasing case volume (Fig. 4); these improvements are summarized in the key metrics comparison (Fig. 5). Pearson correlation analysis (Table 4, Fig. 6) revealed strong negative correlations between withdrawal deviation and case sequence (Subgroup A: r = − 0.906; Subgroup B: r = − 0.914; both P < 0.001), and between rotation deviation and case sequence (Subgroup A: r = − 0.855; Subgroup B: r = − 0.807; both P < 0.001). Hand-stability scores showed strong positive correlations with case sequence (Subgroup A: r = 0.926; Subgroup B: r = 0.942; both P < 0.001). Hand-stability scores also positively correlated with cure rate (r = 0.315, P < 0.05) and satisfaction VAS (r = 0.387, P = 0.010) in Subgroup A.

Table 4
Pearson correlation analysis of hand-stability metrics

Correlation	Subgroup A r	Subgroup A P	Subgroup B r	Subgroup B P
Withdrawal dev. vs. case sequence	−0.906	< 0.001	−0.914	< 0.001
Withdrawal dev. vs. cure	−0.290	0.060	−0.160	0.343
Withdrawal dev. vs. satisfaction VAS	−0.318	0.038	0.110	0.517
Rotation dev. vs. case sequence	−0.855	< 0.001	−0.807	< 0.001
Rotation dev. vs. cure	−0.323	0.035	−0.142	0.401
Rotation dev. vs. satisfaction VAS	−0.463	0.002	−0.078	0.645
Hand-stability score vs. case seq.	0.926	< 0.001	0.942	< 0.001
Hand-stability score vs. cure	0.315	0.040	0.165	0.329
Hand-stability score vs. satisfaction VAS	0.387	0.010	−0.037	0.826

Pearson correlation coefficient r; |r| < 0.3: weak; 0.3 ≤ |r| < 0.5: moderate; |r| ≥ 0.5: strong.

3.6. Safety

Seven adverse events occurred (8.8%), all mild in severity: vaginal discharge increase (n = 4), vaginal burning sensation (n = 2), and transient urgency (n = 1). Notably, all 7 adverse events occurred during the learning phase (Subgroup A: 4/43 = 9.3%; Subgroup B: 3/37 = 8.1%; P > 0.05 between subgroups). No adverse events occurred during the proficiency phase (Table 5).

Table 5
Adverse events by subgroup and phase

Phase	Subgroup A (n = 43)	Subgroup B (n = 37)	Total (n = 80)
Learning phase	4 (9.3%)	3 (8.1%)	7 (8.8%)
Proficiency phase	0 (0%)	0 (0%)	0 (0%)
Vaginal burning sensation	1	0	1
Vaginal discharge increase	3	2	5

All adverse events were mild and resolved spontaneously without intervention. No serious adverse events occurred. Chi-square test between subgroups: P = 0.866.

4. Discussion

4.1. SUI Pathophysiology and CO_2 Laser Treatment Principles

The pathophysiology of SUI centers on the weakening of periurethral support structures. Female urethral closure depends on the collagen fiber network (predominantly type I and type III collagen) within the periurethral connective tissue that forms the “hammock” structure.[3,12,13] Fractional CO_2 laser creates microscopic thermal treatment zones (MTZs) in the vaginal mucosal sublayer, stimulating fibroblast proliferation and collagen remodeling (primarily neoformation and cross-linking of type I and type III collagen), while promoting angiogenesis and epithelial repair.[2,5,8,15–17] Gao et al.[2] confirmed that CO_2 laser treatment significantly increased vaginal wall collagen content and improved pelvic floor support structures. A recent systematic review by Sikora et al.[27] comparing various energy-based SUI treatments confirmed the clinical viability of laser therapy, while Yilmaz et al.[28] provided comparative data between laser and transobturator tape approaches with attention to learning curve implications.

4.2. Mechanistic Basis for Subgroup Differences: Laser–Tissue Interactions in Atrophic Mucosa

This study is the first to perform subgroup analysis of a single operator’s CO_2 laser learning curve based on vaginal mucosal status. Both subgroups demonstrated clear, quantifiable learning curves, but with different inflection points: Subgroup A (normal mucosa) at case 30 and Subgroup B (atrophic mucosa) at case 33. This 3-case difference can be explained at the laser–tissue interaction level.

The 10,600 nm CO_2 laser wavelength is strongly absorbed by water, the primary chromophore in soft tissue. The optical absorption coefficient of water at 10,600 nm is approximately 814 cm^{-1}, meaning that > 90% of incident laser energy is absorbed within the first 100–200 μm of tissue.[5,8] In normal vaginal mucosa (Subgroup A), the epithelial layer is thick and well-hydrated, and the submucosal collagen network is dense and well-vascularized. This tissue composition enables predictable and efficient photothermal conversion: laser energy is absorbed at the mucosal surface, generating controlled thermal denaturation of submucosal collagen (60–70°C) while maintaining surface temperatures below the carbonization threshold (200°C). The resulting MTZs are uniform in depth and diameter, yielding consistent collagen remodeling across treatment zones.

In atrophic vaginal mucosa (Subgroup B), however, several histological changes fundamentally alter the photothermal interaction: (1) Collagen depletion and architectural disorganization: Atrophic mucosa exhibits a marked reduction in total collagen content (particularly type I collagen), decreased collagen fiber density, and disorganized fiber orientation.[22,23] This reduction in the primary thermal target tissue means that the same energy dose produces less collagen denaturation and remodeling per unit area. (2) Reduced tissue water content: Atrophic mucosa has significantly lower tissue hydration due to decreased mucosal gland activity.[22] Since water is the primary chromophore at 10,600 nm, reduced water content decreases the optical absorption coefficient, causing laser energy to penetrate deeper and

spread more widely through thermal diffusion. (3) Impaired microcirculation: Atrophic tissue exhibits reduced microvascular density and decreased blood flow.[22,23] Blood perfusion normally serves as a critical heat sink, dissipating excess thermal energy. In poorly perfused atrophic tissue, this protective mechanism is compromised, increasing the risk of focal thermal accumulation. (4) Thinner tissue layers: The total mucosal thickness in atrophic tissue may be reduced by 30–50% compared to normal mucosa,[22] narrowing the therapeutic window. These combined factors create a fundamentally more challenging operating environment in Subgroup B: the thermal response is less predictable, visual endpoint cues are less reliable, the safety margin is narrower, and the risk of adverse events is elevated. The higher CUSUM peak in Subgroup B (25.57 vs. 22.00) reflects not only the longer learning period but also a greater cumulative deficit in performance before achieving consistent proficiency. A recent study by Yang et al.[25] also identified a clear learning curve for CO_2 laser treatment of atrophic vaginitis using CUSUM analysis, corroborating our finding that atrophic tissue conditions present greater operational challenges.

4.3. Impact of Vaginal Mucosal Status on Energy Parameter Selection

The manufacturer's guidelines recommend differentiated energy density settings based on patient age and mucosal status: 50–80 mJ/pixel for patients > 55 years or postmenopausal, and 80–110 mJ/pixel for patients ≤ 55 years. This study validated this recommendation through subgroup design. Logistic regression further showed that power setting was an independent predictor of cure in Subgroup A (OR = 1.20, $P < 0.05$), suggesting that appropriately higher power in normal mucosa improves outcomes; whereas in Subgroup B, power setting did not enter the regression model ($P = 0.18$), possibly due to the narrower power variation range in this group.

4.4. Hand-Stability Metrics as Prototype Gold Standards for Proficiency Assessment

This study innovatively introduced withdrawal precision and rotation precision as objective hand-stability metrics. While previous learning curve studies have relied on outcomes-based measures, these metrics provide a direct, real-time assessment of the operator's manual skill—a dimension that is critical for laser procedures but has not been previously quantified.

The physical basis for these metrics lies in the fundamental requirement for uniform energy delivery in fractional CO_2 laser treatment. The treatment protocol mandates that the handpiece be advanced along the vaginal wall in 1-cm increments, with 8 laser emissions at 45° intervals per station. Withdrawal deviation directly alters the laser spot overlap ratio (SOR): excessive withdrawal (> 1.0 cm) creates gaps between treatment rings, leaving zones of untreated tissue with SOR below the therapeutic threshold; insufficient withdrawal (< 1.0 cm) causes excessive overlap, leading to energy stacking where cumulative energy density may reach 1.5–2.0 times the intended dose—explaining the higher rate of adverse events during the learning phase when withdrawal deviations were 0.27 ± 0.11 cm (Subgroup A) and 0.24 ± 0.10

cm (Subgroup B), compared to 0.06 ± 0.02 cm and 0.06 ± 0.03 cm in the proficiency phase. Rotation deviation directly affects the angular distribution of energy: a systematic rotation deviation of just 5° per step accumulates to 40° over 8 steps, potentially leaving entire sectors of the vaginal wall untreated.

Together, withdrawal precision and rotation precision capture the two fundamental dimensions of manual laser operation: linear positioning accuracy and angular positioning accuracy. They determine the energy density uniformity coefficient (EDUC)—a theoretical metric describing the consistency of energy delivery across the entire treatment surface. An operator with withdrawal deviation < 0.1 cm and rotation deviation < 2° achieves an EDUC of > 95%, meaning that > 95% of the treated surface receives energy within ± 10% of the target dose. We therefore propose that these metrics represent a prototype objective proficiency standard for vaginal laser procedures—one that could be refined through future development of real-time monitoring devices.

4.5. Clinical Implications for Training

The subgroup learning curve data provide the following training recommendations: (1) Phased training strategy: Novice operators should begin with normal-mucosa patients (Subgroup A), where tissue response is more predictable. We recommend 30 cases as the basic training threshold. (2) Advanced training: After completing basic training, operators may progress to atrophic-mucosa patients (Subgroup B), requiring an additional 33 cases to achieve proficiency. (3) Real-time hand-stability monitoring: When deviations fall below proficiency-phase thresholds (withdrawal deviation < 0.1 cm, rotation deviation < 2°), the operator has entered the proficiency phase. These training recommendations align with the principles described by Guerette et al.,[26] who emphasized the critical role of standardized operator training in ensuring treatment safety and consistent outcomes with energy-based vaginal therapies.

4.6. Advantages of CUSUM in Subgroup Analysis

Using CUSUM control charts independently for each subgroup offers several advantages: subgroup-specific CUSUM more precisely reflects the learning process under different mucosal conditions, avoiding the masking effect of combined analysis;[18,19] direct comparison of learning curve length and difficulty between subgroups; and cross-validation with rolling average curves improves inflection point reliability.[20,21] The CUSUM methodology has been validated across multiple procedural specialties, including urological laser surgery as demonstrated by Kondo et al.,[24] further supporting its applicability to our study context.

4.7. Limitations and Future Directions

This study has several limitations that must be acknowledged. (1) Single-center, retrospective design: This study was conducted at a single center with a single operator, which limits generalizability. However, the methodological framework—particularly the hand-stability metrics and subgroup stratification strategy—provides a replicable template for multi-center validation. (2) Small sample size in the Subgroup B proficiency phase (n = 4): The 100% cure rate observed in this subgroup must be interpreted with considerable caution. The 95% confidence interval for a 100% cure rate with n = 4 (Wilson score

interval) ranges from 51% to 100%, indicating substantial uncertainty. We explicitly acknowledge that this finding should be considered hypothesis-generating rather than confirmatory. Nevertheless, the clear downward trend in the CUSUM curve after the inflection point, combined with the significant improvement in hand-stability metrics (withdrawal deviation: 0.24 ± 0.10 → 0.06 ± 0.03 cm; rotation deviation: 5.14 ± 1.82° → 0.80° [IQR: 0.67–1.27]; both $P < 0.01$), supports the conclusion that genuine proficiency was achieved. (3) Retrospective nature: Treatment parameters were not standardized by protocol but were adjusted at the operator's discretion. The hand-stability metrics were measured using simulated models rather than real-time intraoperative monitoring devices. (4) Subjective subgroup assignment: Future studies should incorporate objective mucosal assessment tools, such as the Vaginal Health Index Score (VHIS) or optical coherence tomography (OCT). (5) Short follow-up duration: The 3-month follow-up is insufficient to assess long-term efficacy; extended follow-up of 12–24 months is needed.

Future research directions: The findings of this study lay the methodological foundation for future prospective, multi-center randomized controlled trials. Specifically, we propose that "withdrawal deviation < 0.1 cm" and "rotation deviation < 2°" be adopted as operator competency-based entry criteria for future clinical trials—analogous to the credentialing standards required in surgical trials. This would ensure that only operators who have demonstrated objective manual proficiency participate in efficacy studies, thereby reducing operator-related variability and improving the quality of evidence. Furthermore, the development of real-time hand-stability monitoring devices incorporating optical position tracking or electromagnetic sensing technology would enable objective, continuous assessment of operator performance during actual clinical procedures.

5. Conclusion

Transvaginal fractional CO_2 laser treatment for SUI demonstrates a clear learning curve, with different learning periods required for different vaginal mucosal conditions. The atrophic mucosa's altered photothermal response characteristics require operators to develop refined parameter adjustment and endpoint determination skills over a longer training period. Withdrawal precision and rotation precision serve as effective objective metrics for assessing operator proficiency, with the identified thresholds (withdrawal deviation < 0.1 cm, rotation deviation < 2°) proposed as competency-based entry criteria for future clinical trials.

Declarations

Author Contribution

Y.L. and C.X. contributed equally to this work. Y.L. collected the data, designed the study, and wrote the original draft. C.X. collected the data. J.L. designed the study. A.W. supervised the project, reviewed and edited the manuscript. All authors reviewed and approved the final manuscript.

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Data Availability

Yes. I have used or generated research data in this study.

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Figures

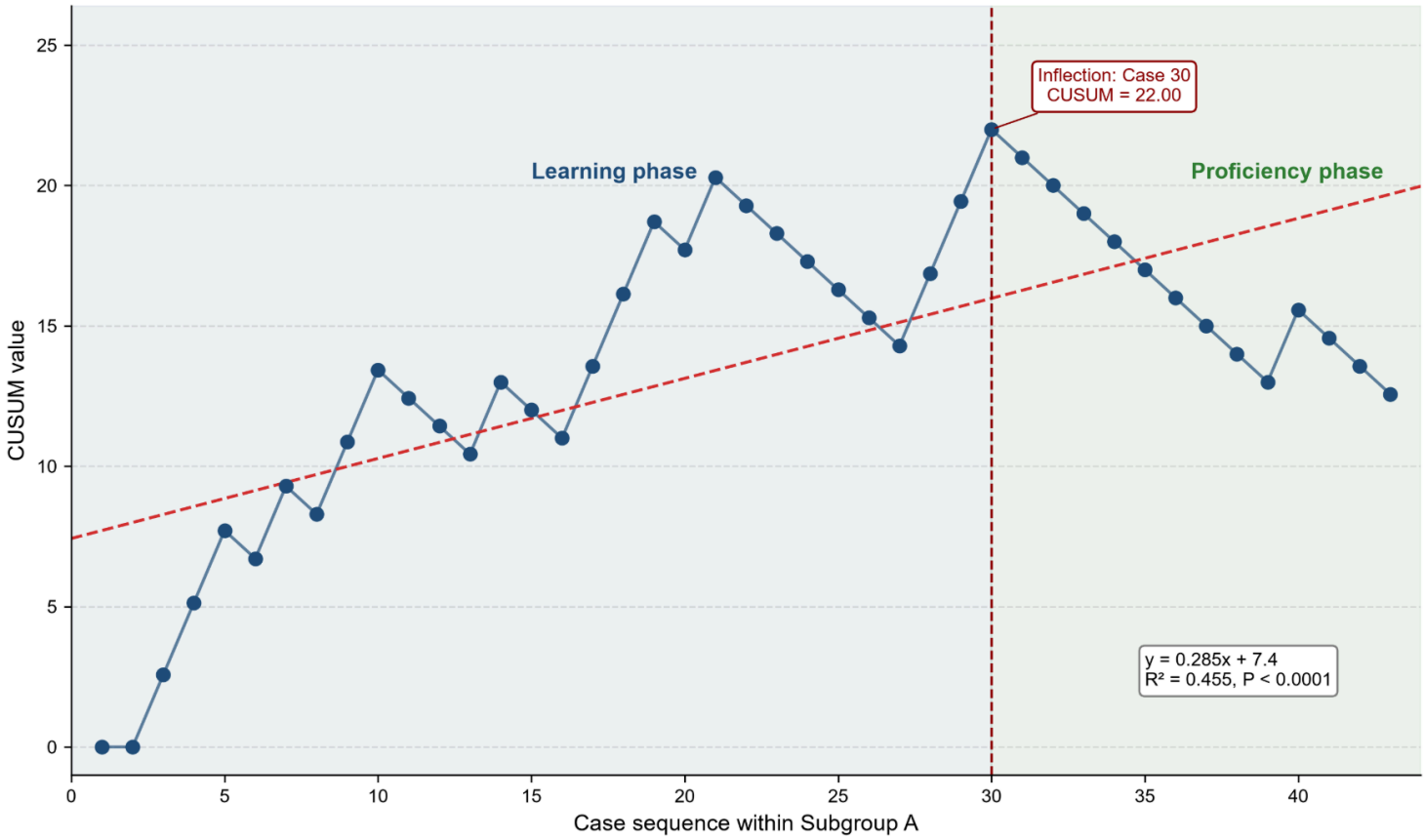


Figure 1

CUSUM learning curve for Subgroup A (vaginal laxity + normal mucosa, n = 43). The CUSUM value peaked at case 30 (CUSUM = 22.00), marking the inflection point from the learning phase to the proficiency phase.

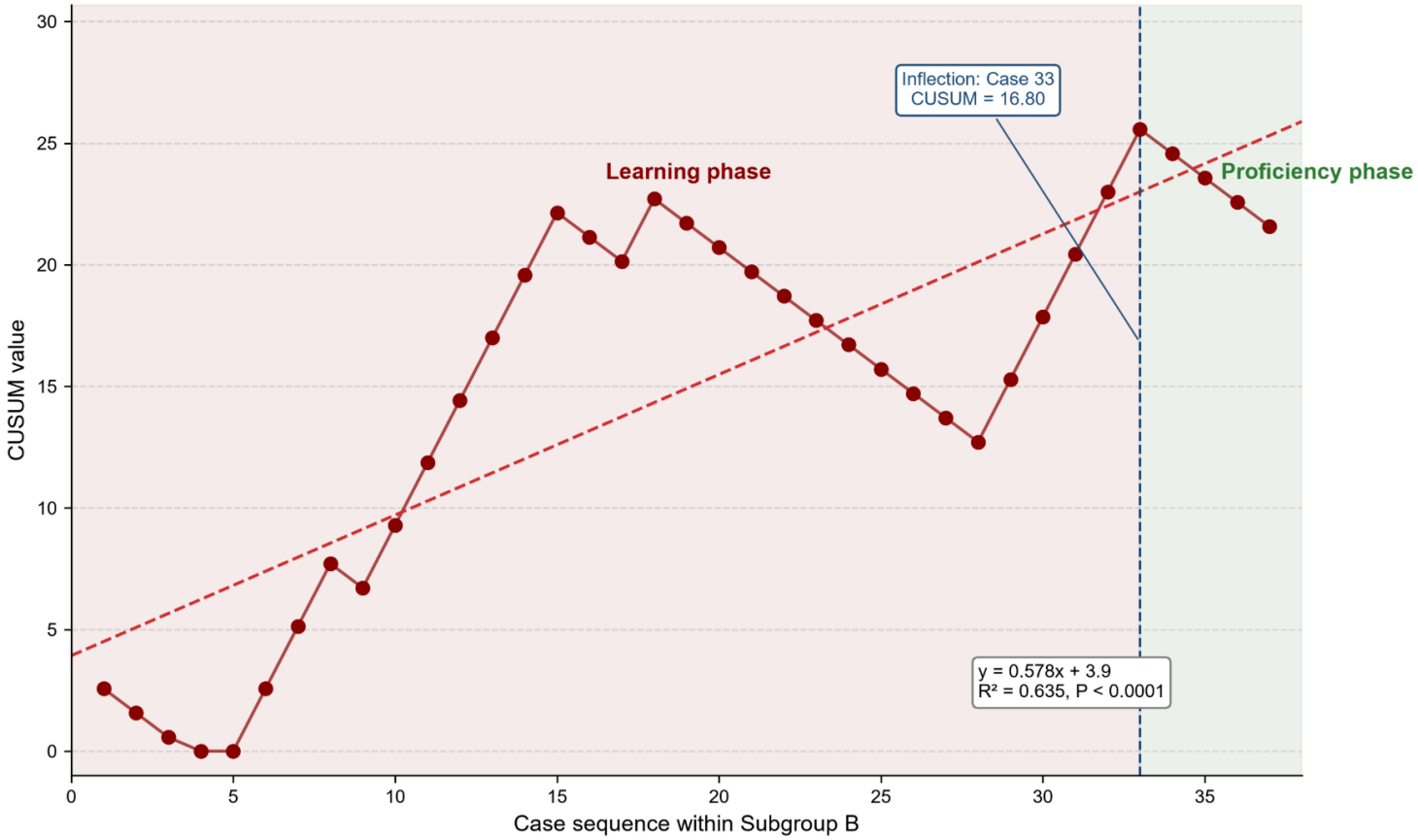


Figure 2

CUSUM learning curve for Subgroup B (atrophic vaginal mucosa, n = 37). The CUSUM value peaked at case 33 (CUSUM = 25.57), marking the inflection point.

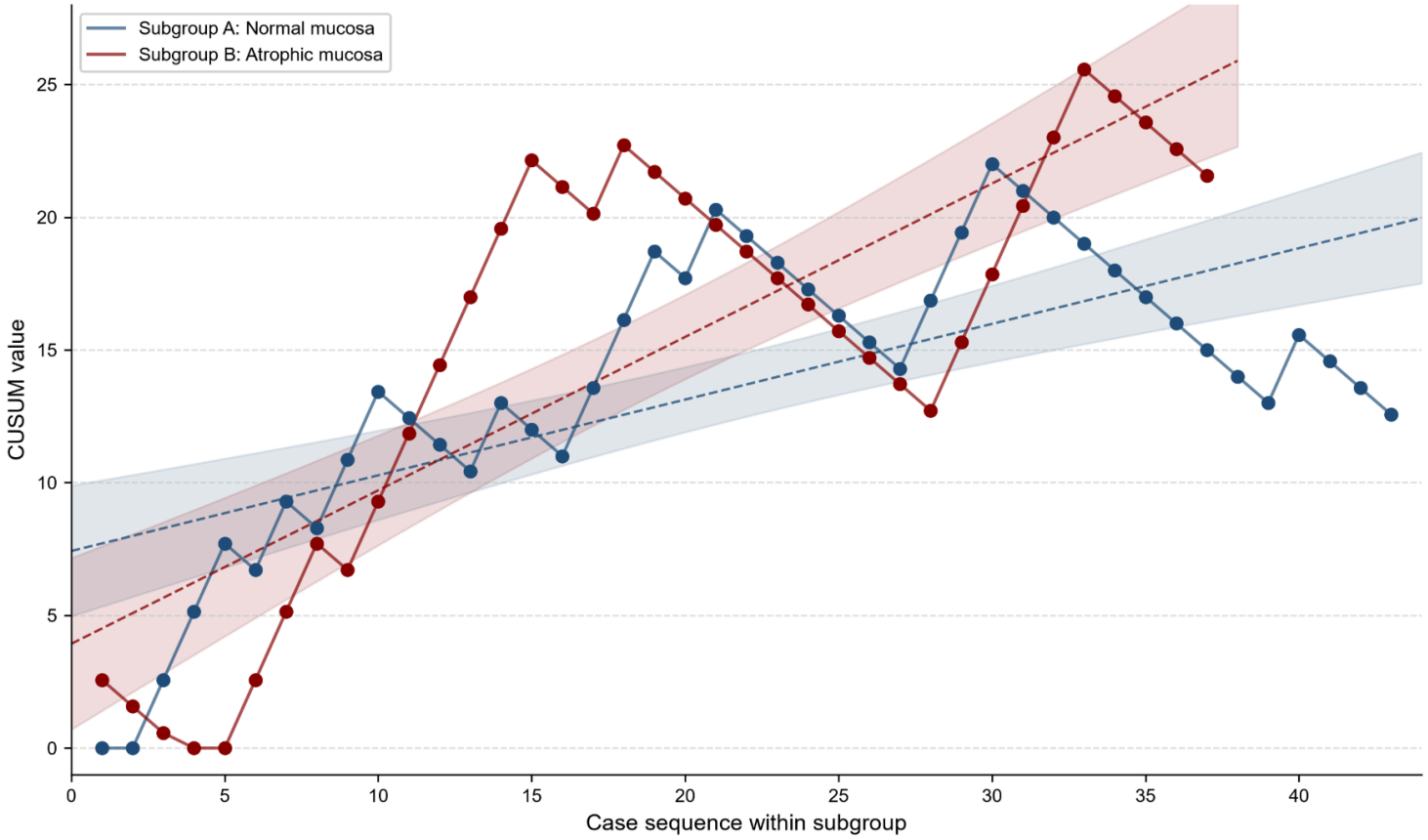


Figure 3

Comparison of CUSUM learning curves between the two subgroups. Subgroup B showed a higher peak (25.57 vs. 22.00), a later inflection point (33 vs. 30), and a slower decline phase, reflecting greater operational difficulty in atrophic mucosa.

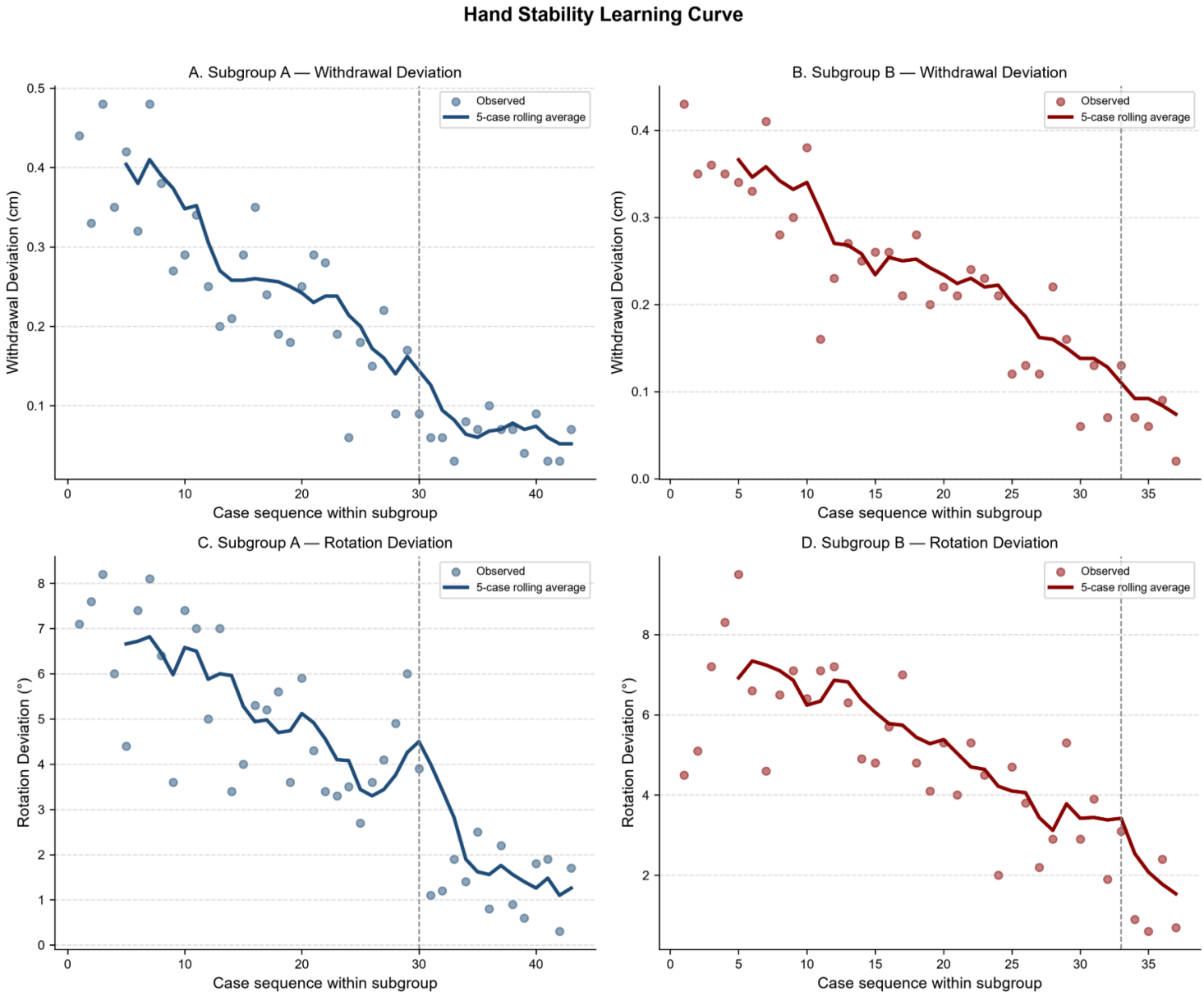


Figure 4

Hand stability learning curve. Upper panels: 5-case rolling average of withdrawal deviation (cm) for Subgroup A (left) and Subgroup B (right). Lower panels: 5-case rolling average of rotation deviation (degrees). Vertical dashed lines indicate CUSUM-derived inflection points (case 30 for Subgroup A, case 33 for Subgroup B). Both metrics declined with increasing case volume and stabilized at low values in the proficiency phase.

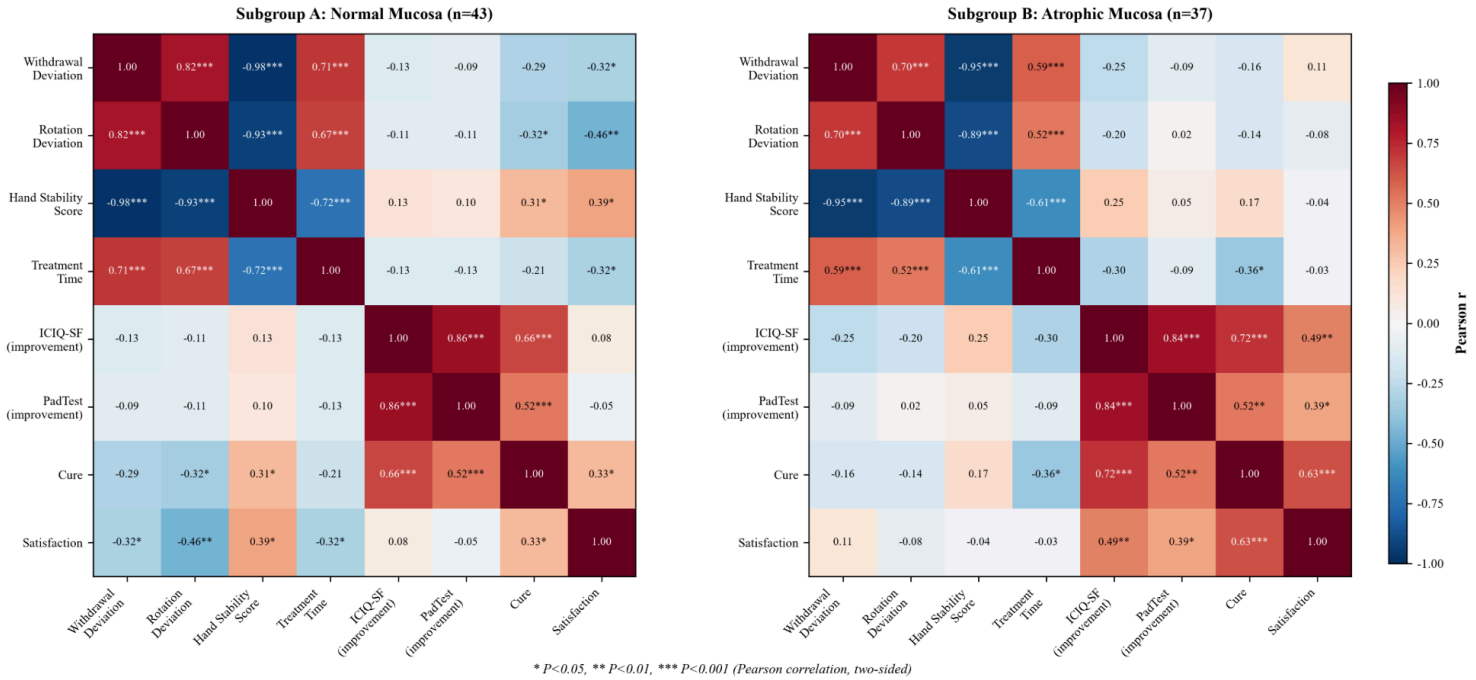


Figure 5

Pearson correlation heatmaps of hand-stability metrics and clinical outcomes. Left: Subgroup A (normal mucosa, n = 43). Right: Subgroup B (atrophic mucosa, n = 37). Color intensity indicates correlation direction and magnitude (red = positive; blue = negative).

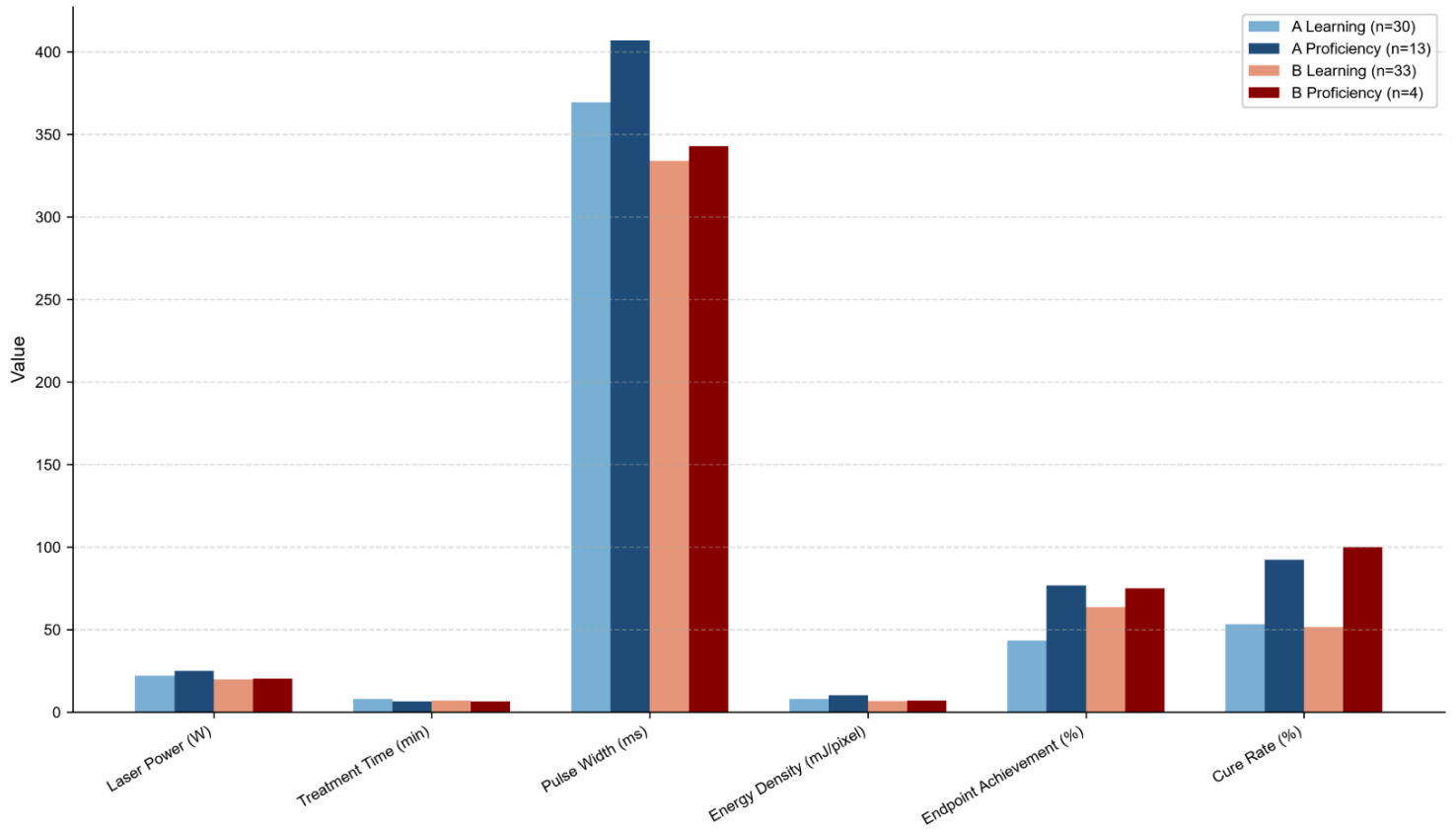


Figure 6

Comparison of key efficacy and operative metrics between the learning and proficiency phases. Bars represent the mean or median values for each metric: laser power (W), treatment time (min), pulse width (ms), energy density (mJ/pixel), treatment endpoint achievement (%), and cure rate (%).