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Adjunctive Biocompatible Film and Laser Therapy for Oral Mucosal Trophic Ulcers: A Comparative Clinical Study

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Abstract

Background: Persistent oral mucosal ulcers require etiologic assessment and treatment of local and systemic contributing factors. Biocompatible films and low intensity laser therapy may offer complementary approaches to wound management, but comparative clinical evidence for lesions classified as trophic ulcers is limited.

Objective: To compare ulcer epithelialization time after conventional comprehensive treatment with that after comprehensive treatment supplemented by a biocompatible film and laser irradiation.

Methods: A single center comparative clinical study was conducted in Tashkent, Uzbekistan, during 2022–2025. Fifty-five patients were treated with adjunctive Novacel Ziyo film followed by laser irradiation (n = 28) or conventional comprehensive therapy (n = 27). Twenty healthy participants provided laboratory reference measurements. Epithelialization time was the principal outcome of this manuscript. Salivary immune and blood endothelial markers were examined as exploratory outcomes. The present draft uses aggregate results; allocation procedures, uncertainty estimates, and several laboratory entries require confirmation from original records.

Results: Reported epithelialization time was 6.8 ± 0.3 days in the adjunctive group and 11.2 ± 0.4 days in the conventional group, with ranges of 5–10 and 8–16 days, respectively. The descriptive mean difference was −4.4 days, corresponding to a 39.3% shorter mean duration relative to conventional therapy. No new significance test was performed. Laboratory tables suggested recovery of selected salivary defense markers and decreases in endothelial injury markers, although inconsistencies prevented definitive comparative inference.

Conclusions: Adjunctive film and laser therapy was associated with shorter reported epithelialization time in this cohort. The findings are preliminary and do not establish causality or the independent contribution of either component. Verification of the treatment protocol and original data is necessary before submission and further controlled evaluation.

Keywords: Oral mucosal ulcer; trophic ulcer; epithelialization; biocompatible film; low intensity laser therapy; mucosal immunity.

1. Introduction

Persistent ulceration of the oral mucosa presents a diagnostic and therapeutic challenge. Oral ulcers can arise from trauma, infection, immune mediated disease, medication exposure, or malignancy. A detailed history and clinical examination are therefore essential, and biopsy or additional investigations may be necessary when the diagnosis is uncertain or a lesion does not respond as expected [1]. The term trophic ulcer, used in the present study, describes the investigators' clinical classification; it should not be taken to establish a single histopathologic diagnosis.

The rationale for this study was to combine a local protective film with laser irradiation as an adjunct to comprehensive care. The supplied study describes Novacel Ziyo as a film based on sodium carboxymethylcellulose and methylene blue. Such a formulation provides a basis for investigating a wound covering approach, but product specific clinical effects must be demonstrated rather than assumed.

Randomized studies in recurrent aphthous stomatitis have investigated photobiomodulation for pain and lesion healing [2,3]. These studies provide indirect context because aphthous ulcers differ from chronic lesions classified as trophic ulcers. A position paper on photobiomodulation in cancer supportive care also underscores the role of treatment parameters in defining a reproducible intervention [4]. Neither evidence base establishes efficacy for the intervention or population examined here.

We aimed to compare the reported time to epithelialization in patients receiving conventional comprehensive therapy and those receiving additional biocompatible film application followed by laser irradiation. Laboratory observations were considered exploratory because the available abstract does not provide a fully reconciled dataset.

2. Methods

Study setting and participants

The study was conducted in the Department of Therapeutic Dentistry at Tashkent State Dental Institute during 2022–2025. The clinical cohort comprised 55 patients with oral mucosal lesions classified as trophic ulcers, including 28 men and 27 women. The intervention group comprised 28 patients and the comparison group 27 patients. An additional 20 healthy participants without oral mucosal lesions constituted a laboratory reference group; they were not a treatment comparator.

The supplied abstract reports conflicting patient age ranges. The verified age distribution, eligibility criteria, recruitment method, diagnostic criteria, and procedures for excluding malignant, infectious, and immune mediated ulceration must be inserted from the study records [author confirmation required]. Random sequence generation, allocation concealment, and blinding are not documented in the available source. Accordingly, this manuscript does not describe the study as randomized.

Interventions

Patients in the adjunctive group received comprehensive treatment supplemented by application of Novacel Ziyo film, described as containing sodium carboxymethylcellulose and methylene blue, followed by irradiation using the AVLT device (Trima, Russian Federation). The methods section describes a scanning technique and a course of 5–10 daily sessions. The film concentration, dimensions, application frequency, retention time, and replacement procedure were not provided [author confirmation required].

The source methods section reports a wavelength of 650 nm, output power of at least 1.5 mW, and modulation frequencies ranging from 1 to 10 Hz during the course. Other sections describe 890–940 nm infrared irradiation. The actual wavelength, calibrated power, beam area, exposure duration, energy density, pulse characteristics, and timing relative to film application therefore require verification. No claim of a specific photobiomodulatory or photodynamic mechanism is made on the basis of the available information.

The comparison group received conventional comprehensive therapy. The constituent medications, doses, duration, local trauma management, oral hygiene measures, and management of systemic conditions were not detailed in the abstract. These components and any differences in concurrent care must be documented to permit replication and interpretation of the treatment comparison [author confirmation required].

Clinical and laboratory assessments

Clinical evaluation included history taking, inspection and palpation of lesions, and assessment of dental and periodontal status. The principal outcome reported here was time to ulcer epithelialization. The abstract provides group means and minimum and maximum times. A reproducible definition of complete epithelialization, the observation schedule, the assessor, and whether all patients healed require confirmation.

Exploratory assessments included salivary immune markers, microbiological examination of material obtained from lesions, and blood markers associated with endothelial injury. Unstimulated saliva was collected after mouth rinsing, stored at −20 °C, thawed, and centrifuged before analysis. The source describes radial immunodiffusion and an IgA secretory ELISA BEST assay but does not clearly map each assay to each reported outcome. Sampling times relative to treatment completion and assay details for several additional markers remain unspecified.

Blood testing included endothelin 1, von Willebrand factor, and circulating desquamated endothelial cells. The source identifies a Mindray MR 96A analyzer and the Hladovec counting method for endothelial cells. The specimen matrix, assay identifiers, units, and analytic procedures must be confirmed. Microbiological methods were insufficiently detailed to support a reproducible quantitative analysis of treatment related changes.

Data presentation and statistical approach

This draft was prepared from aggregate data in the dissertation abstract; patient level records were not available. Values are reproduced using the source notation M ± m. Whether m denotes the standard error or another measure has not been verified. Descriptive differences and percentage changes were calculated directly from reported means. No new p values, confidence intervals, adjusted analyses, or subgroup comparisons were generated.

The source uses $p < 0.05$ as a significance threshold but does not adequately identify the statistical test and comparator for each result. Definitive statistical reporting requires the original dataset, the meaning of the dispersion estimates, missing data information, and the analysis plan. Laboratory observations are therefore presented as descriptive and provisional.

Ethics

The abstract reports permission from the Pharmaceutical Committee of Uzbekistan for a one time investigation of the film. It does not provide an institutional ethics committee name, approval number, approval date, or informed consent statement. These details must be supplied before submission. Product investigation permission must not be represented as documented ethics committee approval.

3. Results

Ulcer epithelialization

The reported mean epithelialization time was lower in the adjunctive group than in the conventional treatment group (Table 1). The absolute descriptive difference was 4.4 days. Relative to the conventional group mean, this represents a 39.3% shorter mean epithelialization duration. The ratio of conventional to adjunctive mean duration was 1.65; this calculation differs from the 1.3 fold comparison stated in the source narrative. The tabulated means were retained without importing the inconsistent narrative ratio.

Table 1. Reported time to ulcer epithelialization

Treatment group	n	Minimum days	Maximum days	Mean days M ± m
Film plus laser adjunct	28	5	10	6.8 ± 0.3
Conventional therapy	27	8	16	11.2 ± 0.4

Values are transcribed from source Table 4.1. The meaning of m and the definition and ascertainment of epithelialization require verification. The −4.4 day mean difference is descriptive, without a newly calculated confidence interval or significance test.

Exploratory laboratory observations

Source Table 4.3 reports posttreatment salivary sIgA concentrations of 165.1 ± 7.1 mg/L in the adjunctive group and 152.3 ± 7.0 mg/L in the comparison group. The corresponding reported IL 1β values were 22.3 ± 1.9 and 25.1 ± 2.0 pg/mL. However, the surrounding narrative supplies different concentrations and significance claims, and another table labels several of the same posttreatment values as belonging to all 55 patients. Consequently, these observations cannot establish a group specific immune effect until the sample labels and measurements are reconciled.

Source Table 4.4 reports decreases in circulating desquamated endothelial cells from 6.67 ± 0.47 to 2.75 ± 0.13 × 10^4/L in the adjunctive group and from 6.71 ± 0.47 to 3.22 ± 0.15 × 10^4/L in the comparison group. Von Willebrand factor values decreased from 112.10 ± 9.34% to 77.38 ± 3.21% and from 110.50 ± 9.14% to 79.54 ± 3.76%, respectively. These entries are provisional because other sections give conflicting endothelial cell values and an unexplained laboratory denominator of 52 patients.

Endothelin 1 findings were not used for comparative inference because the source contains conflicting posttreatment values and units requiring laboratory verification. Quantitative microbiological treatment effects were also not estimated: the source narrative describes reduced microbial burden, but the necessary group specific numeric results, denominators, and analytic methods were not adequately available. Adverse events, treatment discontinuations, and ulcer recurrence were not sufficiently reported to characterize safety or durability.

4. Discussion

The main finding was a shorter reported mean epithelialization time with adjunctive film and laser therapy. A 4.4 day descriptive difference could be clinically relevant if confirmed with a consistent endpoint and comparable baseline groups. However, the available aggregate results cannot distinguish an intervention effect from differences in ulcer size, duration, etiology, comorbidities, concurrent care, or outcome assessment.

The combination has a plausible clinical rationale: a film may cover an ulcerated surface, while appropriately dosed light treatment may support repair. These are hypotheses rather than mechanisms demonstrated by this study. Because both components were introduced together, the comparison cannot identify their independent effects or establish synergy. The inclusion of methylene blue also makes the sequence of film application and irradiation relevant; antimicrobial photodynamic activity cannot be inferred without the necessary formulation and dosimetry information.

Randomized trials by AlHerafi and colleagues and Bardellini and colleagues found benefits of photobiomodulation for selected outcomes in aphthous ulcer populations [2,3]. Their findings support further investigation of light based adjuncts but do not directly validate treatment of the chronic trophic lesions in this cohort. Differences in diagnosis, patient age, wavelength, treatment schedule, and comparator limit transfer of those results.

The exploratory laboratory patterns could be consistent with changes accompanying wound resolution. They do not establish that immune recovery or improved endothelial function caused the shorter epithelialization time. Posttreatment between group comparisons require baseline group specific values and consistent sampling times. In particular, a healthy laboratory reference group cannot substitute for an adequately characterized clinical comparator.

The conflicting laser wavelengths are a material limitation. Visible red and near infrared irradiation cannot be treated as interchangeable protocols. The WALT position paper illustrates the specificity of photobiomodulation dosing and clinical context [4]. Reproducible reporting here requires confirmation of wavelength, calibrated output, exposure time, spot size, energy delivered, and whether the film was present during irradiation.

Diagnostic verification is equally important. Persistent ulcers may reflect disorders that require etiologic treatment or biopsy [1]. The present data do not justify attributing all lesions to microcirculatory impairment or prior SARS CoV 2 infection. The final manuscript should document diagnostic criteria and any relevant infection history rather than infer these features from the discussion in the abstract.

5. Limitations and Future Research

This study involved a small clinical cohort at one center. Allocation procedures and blinding were not documented, and group specific baseline characteristics were unavailable. The source contains conflicting age ranges, laboratory denominators, laser parameters, and immune and endothelial measurements. Outcome definitions, treatment details, follow up timing, safety assessment, and handling of missing observations were incompletely described. These limitations preclude a robust causal or safety conclusion.

A subsequent controlled study should use verified eligibility criteria, a standardized conventional treatment regimen, reproducible film and laser protocols, and masked assessment of complete epithelialization. Baseline ulcer size and duration, systemic disease, and concurrent medication should be recorded. Separate film only and laser only groups would help evaluate component effects. Follow up should assess recurrence and adverse events as well as healing.

6. Conclusions

In the supplied comparative cohort, adjunctive Novacel Ziyo film followed by laser irradiation was associated with a reported mean epithelialization time of 6.8 days, compared with 11.2 days under conventional comprehensive therapy. The descriptive difference supports further investigation but does not establish definitive efficacy. The original clinical records and treatment parameters must be reconciled before submission, and confirmatory controlled research is required.

Declarations

Ethics approval and consent to participate: [Insert verified committee, approval number and date, and consent procedure].

Consent for publication: [Confirm requirements and consent for any identifiable clinical images; no patient images are included in this draft].

Funding: [Author to disclose actual funding and any product support].

Competing interests: [All authors to disclose relationships with the film or device manufacturer and other relevant interests].

Data availability: [State actual availability and access conditions after confirming ownership and participant privacy requirements].

Author contributions: [Confirm the complete author list and actual contributions; additional authors have not been inferred from the dissertation publications].

Acknowledgments: [Add only verified contributions with permission].

Prior dissemination: Based on Saparov A B, Optimization of complex treatment of oral trophic ulcers, PhD dissertation abstract, Tashkent, 2026. Related publications listed in the abstract must be reviewed for overlapping participants, data, tables, and text before submission.

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