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Original Article

SAFETY AND EFFICACY OF STEM CELL FORTIFIED EYE DROPS IN CORNEAL ULCER TREATMENT

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Abstract

Purpose: *To evaluate the therapeutic efficacy of stem cell-derived Fortified Drops (ACE Orbit™) in managing persistent and regular corneal ulcers unresponsive to conventional treatment.* ***Methods:*** *This prospective, interventional study included 33 eyes—10 with persistent ulcers (>2 weeks) and 23 with regular ulcers (<2 weeks)—treated with bioactive peptide-based Fortified Drops thrice daily for 30 days. Clinical assessments included epithelial closure, visual acuity, corneal clarity via OCT, pachymetry, and levels of inflammatory biomarkers (MMP-9 and IL-1β).* ***Results:*** *Complete epithelial healing occurred in 80% of persistent ulcers and 100% of regular ulcers (p= 0.009). Group 2 exhibited significantly better outcomes in corneal clarity (p<0.001), faster healing (15.2 ± 3.2 vs. 22.5 ± 4.5 days, p<0.001), and greater reductions in MMP-9 and IL-1β levels (p= 0.045 and p=0.027, respectively). Visual acuity and central corneal thickness improved in both groups, though not statistically significantly between them. Mild irritation was the only common adverse effect; one case of perforation occurred in Group 1.* ***Conclusion:*** *Fortified Drops significantly enhanced corneal healing, reduced inflammation, and improved corneal clarity, particularly in regular ulcers. Although persistent ulcers showed slower and less complete healing, the drops demonstrated promising regenerative potential and a favorable safety profile. These findings support the use of Fortified Drops as a non-invasive, adjunctive treatment for challenging corneal ulcer cases.*

Keywords: *Corneal ulcers, Stem cell, Fortified eye*

1. Introduction

Corneal ulcers are a major significant cause of ocular morbidity and visual impairment worldwide. These lesions, which arise from various etiologies, including trauma, infection, or underlying systemic conditions, can lead to complications, such as scarring, neovascularization, and even corneal perforation if not properly managed [1, 2]. In cases where standard therapeutic options, including topical antibiotics, antiv-

irals, or anti-inflammatory—fail to produce adequate healing, the ulcers are categorized as persistent, indicating a need for advanced intervention [3,4]. Persistent epithelial defects are particularly challenging because of disrupted cellular signaling, inflammation, and impaired regeneration mechanisms. These chronic ulcers often resist conventional treatments, placing patients at an increased risk of severe outcomes [5]. Therefore, novel biologically active therapies are being explored to enhance corneal repair and prevent long-term visual sequelae [6]. Stem cells Fortified Drops represent an innovative approach in this domain, potentially transforming corneal ulcers management. Formulated with bioactive peptides derived from corneal stromal cells and placental trophoblasts, these drops are designed to modulate inflammation, stimulate cellular proliferation, and accelerate epithelial closure. By leveraging the regenerative properties of these peptides, Fortified Drops aim to restore corneal integrity in cases where traditional therapies fall short. Early evidence suggests that these drops may offer an effective, non-invasive solution for patients with impaired corneal healing capacity [7,8], comparable to advancements made in other regenerative therapies. This study aimed to evaluate the therapeutic safety and efficacy of Stem cells Fortified Drops in the treatment of persistent corneal ulcers in adult patients, especially those unresponsive to conventional treatments. This study specifically investigated the effects of drops on corneal epithelial healing, clarity, stromal hydration, and visual acuity. In addition, it assesses molecular biomarkers associated with inflammation and tissue remodeling, such as MMP-9 and IL-1β, to elucidate the biological mechanisms underlying treatment outcomes. Through this evaluation, the study aims to establish Fortified Drops as a viable regenerative treatment option for refractory corneal ulcers, offering a potential non-surgical alternative for improving ocular surface health in challenging clinical cases, similar to how other regenerative therapies have been employed in various medical fields.

2. Subjects and Methods

2.1. *Study design*

This prospective, interventional study aimed to evaluate the therapeutic effects of topical Fortified Drops in two distinct patient groups: Group 1 consisted of 10 eyes diagnosed with persistent corneal ulcers (non-healing epithelial defects lasting >2 weeks). Group 2: 23 eyes with regular corneal ulcers (epithelial defect healing within two weeks of conventional treatment). All patients provided written informed consent prior to enrollment.

2.2. *Inclusion criteria*

***)** Age between 18 and 50 years. ***)** Presence of a corneal epithelial defect (persistent >2 weeks for Group 1; <2 weeks for Group 2). ***)** No active bacterial, fungal, or Acanthamoeba infection at enrollment. ***)** No prior ocular surgeries involving the cornea (e.g., keratoplasty). ***)** Ability to comply with treatment and scheduled follow-up visits.

2.3. *Exclusion criteria*

***)** Confirmed active infectious keratitis. ***)** Autoimmune-related corneal ulcers (e.g., Mooren's ulcer, ocular pemphigoid). ***)** History of limbal stem cell deficiency. ***)** Pregnancy or lactation. ***)** Known hypersensitivity to components of Fortified Drops.

2.4. *Treatment protocol*

All eyes received the same standardized topical therapy, a regimen designed to deliver consistent therapeutic dosing across both groups for accurate comp-

arative analysis: of Stem cells Fortified Drops (ACE ORBIT [tm]. ACE Cells Lab Limited, Wirral, UK). Compose of Bioactive peptides derived from placental trophoblasts, and corneal stromal cells (2–5 kDa molecular weight). Two drops dosage (approximately 50 µL) instilled topically three times daily (8:00 AM, 2:00 PM, 8:00 PM) for 30 days for all patients. *Compliance monitoring*: Patients were instructed to record daily drop administration using a mobile health app; weekly in-person reviews ensured >90% compliance.

2.5. *Clinical evaluations*

Clinical examinations were performed at baseline and after 30 days of treatment: ***)** Visual Acuity Testing: using Snellen charts. ***)** Slit-Lamp Biomicroscopy: Assessment of epithelial closure, stromal haze, neovascularization, and any adverse effects. ***)** Anterior Segment OCT: Imaging corneal epithelial thickness and stromal reflectivity. ***)** Pachymetry: Central corneal thickness measurements using ultrasonic pachymeter. ***)** Tear Film Analysis: Quantification of inflammatory markers, specifically MMP-9 and IL-1β levels, was conducted via ELISA at baseline and again at day 30, allowing for a robust assessment of the treatment's impact on inflammatory responses.

2.6. *Outcome measures*

Primary outcome: Safety and Rate of complete epithelial closure at 30 days in each group. *Secondary outcomes*: ***)** Improvement in corneal clarity (OCT opacity scoring). ***)** Decrease in central corneal thickness (edema resolution). ***)** Enhancement of uncorrected visual acuity (UCVA). ***)** Reduction in tear inflammatory biomarkers (MMP-9, IL-1β). ***)** Safety and Tolerability: Incidence of adverse reactions during the treatment period. Comparative Analysis: Outcomes between the persistent ulcer group (Group 1) and the regular ulcer group (Group 2) were statistically compared to assessing differential healing responses to topical Fortified Drops therapy.

2.7. *Ethics approval*

The study was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Ethical approval was obtained from the Faculty of Medicine, Beni-Suef Univ. Research Ethics Committee (Approval No. FMBSUREC/03122024). Written informed consent (participation and publish) was obtained from all participants after a full explanation of the study procedures, risks, and benefits.

3. Results

A total of 33 eyes were enrolled in this rigorous study, comprising 10 eyes in Group 1 (persistent ulcers) and 23 eyes in Group 2 (regular ulcers), enabling a nuanced comparison of treatment effects across varied clinical presentations. The mean age across groups was 29.4 ± 5.7 years, with no statistically significant difference in age or gender distribution, ensuring the validity of demographic factors in the outcomes assessed, tab. (1).

3.1. ***Primary outcome***, tab. (2).

Complete epithelial closure at 30 days: ***)** Group 1: 8 out of 10 eyes (80%) achieved complete epithelial closure. ***)** Group 2: 23 out of 23 eyes (100%) achieved complete epithelial closure. ***)** P-value: 0.009 (statistically significant).

3.2. ***Secondary outcomes***, tab. (2).

Visual Acuity: ***)** Group 1 improved from 0.2 ± 0.15 to 0.35 ± 0.2. ***)** Group 2 improved from 0.3 ± 0.18 to 0.55 ± 0.12. ***)** P-value: 0.092 (not statistically significant).

3.3. *Corneal clarity (OCT scoring)*

***)** In OCT scoring it could be seen that Group 1: 2.0 ± 0.5. ***)**, Group 2: 3.6 ± 0.3. ***)** and P-value: <0.001 (statistically significant).

3.4. *Central corneal thickness*

***)** Regarding central corneal thickness, it could be noted that Group 1 reduced from 540 ± 40 µm to 520 ± 35 µm. ***)**, Group 2 reduced from 530 ± 35 µm to 500 ± 30 µm. and ***)** P-value: 0.090.

3.5. *Reduction in tear biomarkers*

MMP-9: ***)** Group 1: 42.0 ± 10.3 pg/mL. ***)** Group 2: 34.0 ± 8.2 pg/mL. ***)** P-value: 0.045. *IL-1β:* ***)** Group 1: 30.0 ± 8.5 pg/mL. ***)** Group 2: 23.5 ± 6.9 pg/mL. ***)** P-value: 0.027.

3.6. *Adverse events*

***)** Group 1: 1 mild irritation, 1 corneal perforation. ***)** Group 2: 2 mild irritation cases. ***)** No statistically significant difference in adverse events (P=0.752). After 30 days of treatment with Fortified Drops: **-)** Group 2 showed superior outcomes in epithelial healing, corneal clarity, and inflammation control. **-)** Group 1 had a higher incidence of complications including one case of perforation. **-)** Both groups exhibited biomarker reduction, suggesting anti-inflammatory effects of Fortified Drops.

3.7. *Interpretation of results (1-month follow-up)*

Visual acuity: At 1 month, Group 2 demonstrated significantly better uncorrected visual acuity (UCVA) compared to Group 1 ($p<0.001$). Both groups showed improvement in visual acuity, but Group 2 had better outcomes overall. The difference in corrected visual acuity was not statistically significant ($p=0.092$). *Rate of complete epithelial closure*: Group 1 showed an 80% rate of complete epithelial closure at 1 month, while Group 2 achieved 100% closure ($p=0.009$), indicating that Group 2 healed faster and more completely. *Corneal perforation*: One case of corneal perforation occurred in Group 1 (10%) after 1 month, which was not observed in Group 2. This indicates a more complicated healing process in Group 1, and the difference between the groups was marginally significant ($p=0.053$), suggesting that persistent ulcers might be at higher risk for complications. *Corneal clarity (OCT score):* The improvement in corneal clarity was significantly better in Group 2 compared to Group 1 ($p<0.001$), indicating better recovery in terms of corneal opacity. *Central corneal thickness*: Both groups showed a reduction in central corneal thickness at 1 month, but the difference between the groups was not statistically significant ($p= 0.090$). This suggests that both groups experienced some resolution of corneal edema, although Group 2 had a slightly better outcome. *Reduction in inflammatory bomarkers (MMP-9 and IL-1β)*: Both groups showed a reduction in MMP-9 and IL-1β levels, indicating a decrease in inflammation. Group 2 had a significantly greater reduction in both biomarkers compared to Group 1 ($p=0.045$ for MMP-9 and $p=0.027$ for IL-1β), suggesting a more effective inflammatory response in Group 2. *Adverse events*: Adverse events were minimal in both groups, with mild irritation reported in 1 case from Group 1 and 2 cases from Group 2. Group 1 also experienced a single case of corneal perforation. There was no significant difference in the incidence of adverse events ($p=0.752$). Finally, after 1 month of treatment, Group 2 (regular ulcers) demonstrated significantly better healing compared to Group 1 (persistent ulcers). The occurrence of corneal perforation in Group 1 indicates a more complicated and slower healing process, with Group 2 showing better outcomes across various measures, including epithelial closure and reduction in inflammation. This

critical outcome measure provides insight into the efficacy of Fortified Drops, highlighting the comparative healing timelines of the two patient groups, tab. (3).

3.8. *Interpretation*

The observed disparity in healing timelines significantly contributes to the understanding of persistent versus regular ulcers, indicating a pressing need for innovations such as Fortified Drops in managing chronic corneal conditions. *Time to complete epithelial healing*: Group 1 (persistent ulcers) took significantly longer to achieve complete epithelial healing, with an average healing time of 22.5 ± 4.5 days. In contrast, Group 2 (regular ulcers) achieved complete epithelial healing much faster, with an average of 15.2 ± 3.2 days ($p < 0.001$). This difference reflects the expected slower healing process for persistent ulcers, which may require more time and intensive management to resolve, fig. (1).

3.9. *Interpretation of complications*, tab. (4)

Corneal perforation: One case of corneal perforation occurred in Group 1 (10%), which was not observed in Group 2. This was a significant complication, suggesting a more severe and complicated healing process in the persistent ulcer group ($p = 0.053$). *Mild Irritation*: Mild irritation occurred in 1 case (10%) of Group 1 and 2 cases (8.7%) of Group 2. The incidence of mild irritation did not differ significantly between the groups ($p=0.752$), suggesting that this was a minor and common side effect. *Corneal Scarring*: Two cases of corneal scarring were observed in Group 1 (20%), while no cases occurred in Group 2. The difference was approaching statistical significance ($p=0.067$), indicating that persistent ulcers have a higher risk of scarring. *Neovascularization*: One case of neovascularization was observed in Group 1 (10%), which did not occur in Group 2. The difference between the groups was marginally significant ($p=0.053$), suggesting that persistent ulcers may have a higher risk of developing neovascularization. *Increased Inflammation* (Grade 2-3): One case of increased inflammation (Grade 2-3) occurred in Group 1 (10%), while there were no such cases in Group 2. This difference was also marginally significant ($p=0.053$), further indicating that persistent ulcers may be more prone to complications involving inflammation. Finally, Group 1 (persistent ulcers) experienced more complications, including corneal perforation, scarring, neovascularization, and increased inflammation, compared to Group 2 (regular ulcers). These findings suggest that persistent ulcers may require more intensive management and monitoring due to their increased risk of complications.

Table 1: demographic data and baseline data

	Group 1 (Persistent Ulcers)	Group 2 (Regular Ulcers)	Total
Demographic Variable			
▪ ***Total eyes enrolled***	10 eyes (1 with PRK history)	23 eyes	33 eyes
▪ ***Mean age (± SD)***	29.1 ± 6.3 years	29.6 ± 5.5 years	29.4 ± 5.7 years
▪ ***Age range***	20–45 years	18–50 years	18–50 years
Gender Distribution			
▪ ***Male (%)***	60%	60%	60%
▪ ***Female (%)***	40%	40%	40%
Baseline visual acuity			
▪ ***Range of visual acuity (snellen)***	<0.1 to 0.6	<0.1 to 0.6	<0.1 to 0.6
▪ ***Mean baseline visual acuity (± SD)***	0.2 ± 0.15	0.3 ± 0.18	0.25 ± 0.17
Corneal ulcer characteristics			
▪ ***Duration of ulcer (days)***	>14 days (persistent)	≤14 days (regular)	
▪ ***Prior Ocular Surgery History***	PRK (1 case)	None	1 case
Comorbidities	None	None	None

Table 2: Results of both groups with statistical comparison (Follow-Up Period: 1 Month)

Outcome Measure	Group 1: Persistent Ulcers (n=10)	Group 2: Regular Ulcers (n=23)	P-Value
Range of Visual Acuity (Snellen)	**<0.1 to 0.6**	**<0.1 to 0.6**	**<0.1 to 0.6**
Baseline Visual Acuity (Mean ± SD)	0.2 ± 0.15	0.3 ± 0.18	0.312
Visual Acuity at 1 Month (Mean ± SD)	0.35 ± 0.2	0.55 ± 0.12	0.092
Rate of Complete Epithelial Closure (%)	80% (8/10)	100% (23/23)	0.009*
Corneal Perforation (n)	1 case (10%)	0 cases	0.053
Improvement in Corneal Clarity (OCT Score)	2.0 ± 0.5	3.6 ± 0.3	<0.001*
Central Corneal Thickness at Baseline (µm)	540 ± 40	530 ± 35	0.457
Central Corneal Thickness at 1 Month (µm)	520 ± 35	500 ± 30	0.090
Uncorrected Visual Acuity (Mean ± SD)	0.3 ± 0.12	0.55 ± 0.15	<0.001*
Reduction in MMP-9 Levels (pg/mL)	42.0 ± 10.3	34.0 ± 8.2	0.045*
Reduction in IL-1β Levels (pg/mL)	30.0 ± 8.5	23.5 ± 6.9	0.027*
Adverse Events	1 mild irritation, 1 corneal perforation	2 mild irritations	0.752

Table: 3 Time taken for complete epithelial Healing:

Outcome Measure	Group 1: Persistent Ulcers (n=10)	Group 2: Regular Ulcers (n=23)	P-Value
Time to complete epithelial healing (days)	22.5 ± 4.5 days	15.2 ± 3.2 days	<0.001*

Figure 1: a case with resistant ulcer that heals after using the fortified drops

Table: 4 Complications observed in both groups

Complication	Group 1: Persistent Ulcers (n=10)	Group 2: Regular Ulcers (n=23)	P-Value
Corneal Perforation	1 case (10%)	0 cases	0.053
Mild Irritation	1 case (10%)	2 cases (8.7%)	0.752
Corneal Scarring	2 cases (20%)	0 cases	0.067
Neovascularization	1 case (10%)	0 cases	0.053
Increased Inflammation (Grade 2-3)	1 case (10%)	0 cases	0.053

4. Discussion

This study evaluated the clinical efficacy and safety of Fortified Drops in promoting corneal healing in patients with persistent and regular corneal ulcers over a 30-day period. The results demonstrated that Fortified Drops significantly enhance epithelial healing, reduce inflammation, and improve corneal clarity, particularly in regular ulcers. These findings align with and add to the body of literature supporting bioactive peptide-based therapies for corneal epithelial defects. The epithelial closure rate of 100% in regular ulcers (Group 2) is consistent with prior data on acute ulcers managed with supportive topical treatments. Studies such as Kaufman et al. and Bassetto et al [10] have shown rapid healing in non-chronic ulcers when managed appropriately, with minimal complications and faster restoration of visual acuity. The 80% closure rate in persistent ulcers (Group 1), while lower, still represents a significant improvement over standard therapies, which often report closure rates between 50%–70% for similar chronic cases [11,12]. Tian et al. [8] demonstrated that bioactive peptides derived from corneal stromal cells significantly enhance epithelial regeneration, particularly through modulating matrix metalloproteinase (MMP) activity and supporting cellular migration. Fortified Drops, which contain RPE-derived peptides and trophoblastic factors, appear to replicate and expand upon these effects by targeting

multiple pathways involved in corneal repair. This may explain the observed improvement in both structural (corneal clarity) and biochemical (MMP-9, IL-1β) markers. The improvement in corneal clarity observed in Group 2 aligns with findings by Mak et al. [13], who found that stromal remodeling and reduced fibrosis were facilitated by peptide-based formulations. In contrast, persistent ulcers often involve deeper stromal injury and greater inflammatory burden, contributing to less pronounced improvements in transparency. Chaurasia et al [14] and Lopes et al [15] similarly reported reduced optical outcomes in chronic corneal ulcers due to increased scarring and delayed epithelial repair. Visual acuity improvements further reflect the differing disease courses of regular versus persistent ulcers. In our study, regular ulcers demonstrated a larger gain in UCVA over 30 days, which mirrors the outcomes seen in studies of early intervention biopeptide therapies [16]. Chronic ulcers, such as those in Group 1, may experience only modest improvements unless the underlying pathological mechanisms—particularly inflammation and epithelial-stromal dysregulation—are aggressively targeted [3,7]. The biomarker reductions observed in both groups, particularly for MMP-9 and IL-1β, indicate that Fortified Drops exert potent anti-inflammatory effects. This aligns with the findings of Al-Dhibi et al. [7] and Tian et al [8], who emphasized the role of inflammation suppression in promoting epithelial closure and preventing tissue breakdown. MMP-9 is known to degrade the extracellular matrix and basement membrane, prolonging epithelial defects; its downregulation has been associated with faster healing and fewer complications [14]. When compared to other advanced topical therapies, such as autologous serum eye drops or amniotic membrane extracts, Fortified Drops offer comparable efficacy without the logistical and ethical challenges of harvesting biological material [5,17]. Autologous serum drops, while rich in growth factors, require repeated blood draws and may carry risks of contamination or variability in composition. Similarly, amniotic membrane transplantation, although effective in recalcitrant ulcers, is more invasive and cost prohibitive. [18] Notably, the complication profile in Group 1 included one case of corneal perforation and two cases of stromal scarring—outcomes well-documented in the literature as risks in persistent ulcers [6,19,20]. These complications highlight the need for early intervention with regenerative agents like Fortified Drops to minimize structural damage and preserve vision.

5. Conclusion

The current findings support the use of Fortified Drops as an effective, non-invasive therapy for both persistent and regular corneal ulcers. By targeting inflammation, stimulating epithelial proliferation, and promoting stromal remodeling, Fortified Drops offer a multifaceted approach to corneal repair. Comparative analysis with other studies underscores their potential as first-line or adjunctive treatment in managing a spectrum of corneal ulcer presentations.

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