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A clinical study on topical insulin in fungal keratitis with corneal epithelial defects

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Abstract:
Fungal keratitis remains an important cause of corneal morbidity, particularly in tropical regions. Therefore, it is of interest to evaluate the efficacy of topical insulin in fungal keratitis with corneal epithelial defects. Hence, eighty patients with fungal keratitis and corneal epithelial defects were included. Patients received either topical insulin 1 IU/mL four times daily in addition to conventional treatment or conventional treatment alone. Mean defect breadth decreased from 4.36 ± 2.37 to 1.97 ± 1.86 mm with insulin and from 4.31 ± 1.99 to 2.84 ± 1.37 mm with conventional treatment; the corresponding reductions were 2.39 ± 2.02 and 1.47 ± 1.14 mm, respectively. Topical insulin is a useful, inexpensive adjunct for promoting epithelial healing, while appropriate antifungal therapy remains essential.

Keywords: Fungal keratitis, topical insulin, corneal epithelial defect

Background:
Ocular trauma, particularly with vegetative matter, is a recognised risk factor and severe disease may result in persistent epithelial defects, stromal destruction and poor visual outcomes **[1]**. Appropriate antifungal therapy remains the cornerstone of treatment, with natamycin having demonstrated better outcomes than voriconazole in filamentous fungal keratitis **[2, 3]**. Clinical studies have subsequently reported encouraging results with topical insulin in persistent epithelial defects, postoperative epithelial defects and neurotrophic keratopathy **[4, 5]**. Recent review have also identified topical insulin as a promising, inexpensive adjunct for corneal epithelial healing, although heterogeneity in concentration, preparation **[6, 7]**. Therefore, it is of interest to evaluate whether adding topical insulin to conventional treatment was associated with greater reduction in epithelial defect dimensions than conventional treatment alone.

Materials and Methods:
This interventional study was conducted at the Department of Ophthalmology of a tertiary care teaching institution of central India, from December 2023 to October 2024. Patients diagnosed with fungal keratitis associated with a corneal epithelial defect were included in the present analysis. Patients with corneal perforation or other major ocular conditions that could independently affect epithelial healing were excluded. The intervention group received topical insulin 1 IU/mL four times daily (QID) in addition to conventional treatment. Insulin eye drops were prepared by diluting regular insulin (100 IU/mL) in a lubricating ophthalmic preparation. Conventional treatment consisted of standard management appropriate to the clinical diagnosis, including antifungal therapy for fungal keratitis. The thesis specifies the insulin preparation and QID administration. Topical insulin was used as an adjunctive epithelial-healing treatment and not as a substitute for antifungal therapy. Visual acuity was assessed using a Snellen chart. Corneal epithelial defects were examined after fluorescein staining using slit-lamp biomicroscopy and serial measurements were recorded during follow-up. The original protocol included serial photographic documentation of epithelial defects. The primary outcome was reduction in corneal epithelial defect length and breadth from baseline to the third follow-up. Secondary outcome was change in visual acuity during follow-up. Ethical clearance was obtained from the Institutional Ethics Committee of Shyam Shah Medical College and associated Gandhi Memorial Hospital, Madhya Pradesh vide letter number SSMC/IEC/2023/301077 dated 20/12/2023. Written informed consent was taken from all participants after explaining the study in their local language. Continuous variables were expressed as mean ± SD and categorical variables as n (%). Within-group changes were assessed using paired t-tests, while between-group differences in mean change were assessed using an independent-samples t-test. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. A two-sided $p<0.05$ was considered statistically significant.

Results:
A total of 80 patients with fungal keratitis were analysed; 44 (55.0%) received topical insulin and 36 (45.0%) received conventional treatment. Diabetes mellitus was present in 30 (68.2%) patients in the insulin group and 20 (55.6%) in the conventional group (p=0.353). Baseline epithelial defect dimensions were comparable between the groups (**Table 1**). Topical insulin was associated with a greater reduction in epithelial defect dimensions. Mean defect length decreased from 5.00 ± 2.78 to 2.33 ± 2.04 mm in the insulin group and from 5.33 ± 2.25 to 3.53 ± 1.71 mm in the conventional group. The mean reduction was significantly greater with insulin (2.67 ± 2.09 vs 1.79 ± 1.47 mm; p=0.032). Defect breadth similarly decreased by 2.39 ± 2.02 mm with insulin compared with 1.47 ± 1.14 mm with conventional treatment (p=0.012) (**Table 2**). Visual acuity improved progressively in both groups. By the third follow-up, 30 (68.2%) insulin-treated patients had BCVA (Best-Corrected Visual Acuity) of 6/6–6/18 compared with 16 (44.4%) in the conventional group. The proportion with BCVA <6/60 decreased from 18.2% to 9.1% in the insulin group, while it increased from 5.6% to 16.7% in the conventional group. The

difference in visual-acuity distribution at the third follow-up was not statistically significant (p=0.102) (**Table 3**).

Table 1: Baseline characteristics of study subjects

Variable	Topical insulin (n=44)	Conventional (n=36)	p value
Diabetes mellitus, n (%)	30 (68.2)	20 (55.6)	0.353
Defect length, mm, mean ± SD	5.00 ± 2.78	5.33 ± 2.25	0.561
Defect breadth, mm, mean ± SD	4.36 ± 2.37	4.31 ± 1.99	0.906

Table 2: Change in epithelial defect dimensions among study subjects

Outcome	Topical insulin (n=44)	Conventional (n=36)	p value
Length			
Baseline, mm	5.00 ± 2.78	5.33 ± 2.25	0.561
Third follow-up, mm	2.33 ± 2.04	3.53 ± 1.71	—
Mean reduction, mm	2.67 ± 2.09	1.79 ± 1.47	0.032
Within-group p	<0.001	<0.001	
Breadth			
Baseline, mm	4.36 ± 2.37	4.31 ± 1.99	0.906
Third follow-up, mm	1.97 ± 1.86	2.84 ± 1.37	—
Mean reduction, mm	2.39 ± 2.02	1.47 ± 1.14	0.012
Within-group p	<0.001	<0.001	

Table 3: Best-Corrected Visual Acuity during follow-up among study subjects

Best-Corrected Visual Acuity	First follow-up		Last follow-up	
	Insulin n (%)	Conventional n (%)	Insulin n (%)	Conventional n (%)
6/6–6/18	16 (36.4)	10 (27.8)	30 (68.2)	16 (44.4)
6/24–6/60	20 (45.5)	24 (66.7)	10 (22.7)	14 (38.9)
<6/60	8 (18.2)	2 (5.6)	4 (9.1)	6 (16.7)
Total	44 (100)	36 (100)	44 (100)	36 (100)
p value	0.101		0.102	

Discussion:

This study observed that adjunctive topical insulin was associated with a significantly greater reduction in corneal epithelial defect dimensions than conventional treatment alone in fungal keratitis. Both groups improved, but the reduction in defect length and breadth was greater in the insulin group. The findings support a potential role for topical insulin in enhancing epithelial repair rather than treating the fungal infection itself. The biological basis is plausible. Insulin promotes epithelial cell migration and proliferation and interacts with insulin/IGF signalling pathways involved in corneal wound repair **[8]**. Clinical evidence from other forms of epithelial disease is also supportive. In a study of diabetic patients with postoperative epithelial defects, topical insulin accelerated healing, with 0.5 IU/drop producing particularly favourable results **[9]**. Diaz-Valle *et al.* reported re-epithelialization in 81% of patients with refractory persistent epithelial defects treated with topical insulin **[10]**. More recent evidence remains encouraging. Reviews have reported generally favourable epithelial-healing outcomes with topical insulin and few treatment-related adverse effects **[11]**. A recent meta-analysis of controlled studies also found faster epithelialization and higher healing rates with topical insulin, although the certainty of evidence was low to very low **[12]**. These findings are broadly consistent with the greater reduction in epithelial defect dimensions observed in the present study **[13]**. The present study is clinically relevant because evidence specifically involving fungal keratitis is limited. Importantly, topical insulin should not replace established antifungal therapy. Its proposed role is to facilitate epithelial recovery after or alongside control of the underlying infection. This distinction is particularly important in fungal keratitis, where delayed treatment or inadequate antifungal therapy can result in stromal destruction and visual loss **[14, 15]**. Visual acuity improved in both groups, with a greater numerical improvement in the insulin group. However, the lack of a statistically significant between-group difference at the third follow-up means that the visual findings should be interpreted cautiously. Moreover, baseline visual-acuity distribution was not completely balanced between groups. Therefore, the more robust finding of this study is the significantly greater reduction in epithelial defect dimensions with topical insulin. The study has a few limitations as well. It was conducted at a single centre, the sample size was modest and follow-up was limited. Baseline visual acuity was not fully balanced between groups and the study did not compare different insulin concentrations. Another study from Iran evaluated the efficacy of topical insulin eye drops in patients with refractory persistent epithelial defects (PED) and noted that topical insulin reduces the PED area and accelerated the ocular surface epithelium wound healing **[16]**. Another study from Austria concluded that topical insulin may be considered as a treatment option in complicated cases refractory to conventional treatment, but outcomes may be less favorable than previously reported **[17]**. Future clinical trials need to be conducted to further evaluate optimal dosing, duration, and use of topical insulin for the restoration of the corneal surface **[18]**.

Conclusion:

Adjunctive topical insulin 1 IU/mL QID was associated with a significantly greater reduction in corneal epithelial defect length and breadth than conventional treatment alone in fungal keratitis. The findings suggest that topical insulin may be a useful, inexpensive adjunct for promoting epithelial healing, while appropriate antifungal therapy remains essential. Larger

randomized studies with standardized defect-area measurement and longer follow-up are needed to confirm its efficacy.

Conflicting interest: None

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