Vol. 5 No. 2 (2026)

Pakistan Journal of Medical & Cardiological Review

https://pakjmcr.com/index.php/1/about

Online ISSN 3007-2387

Print ISSN 3007-2379

Noreen et al - 2026

DOI: http://doi.org/10.5281/zenodo.19939622

EFFICACY OF FORTIFIED FLUCONAZOLE EYE DROPS VERSUS NATAMYCIN 5% IN TREATING FUNGAL KERATITIS

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Vol. 5 No. 2 (2026)

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Print ISSN 3007-2379

Noreen et al - 2026
DOI: http://doi.org/10.5281/zenodo.19939622

Author Details

Keywords:
Fungal Keratistis, Natamycin, fortified fluconazole

Received on 02 Mar2026
Accepted on 12 Apr 2026
Published on 29 Apr 2026

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Abstract

Background: Fungal Keratistis is a serious corneal infection and a leading cause of visual impairment particularly in agricultural areas. Natamycin 5% has been the first-line topical antifungal medication but its limited stromal penetration and fungistatic mechanism have raised questions about its efficacy compared to fortified fluconazole, which has better water-soluble corneal penetration and broad antifungal activity.

Objectives: This study aims to compare the efficacy of both fortified fluconazole and natamycin 5% eye drops in the treatment of Fk measured by time to epithelial healing, corneal resolution, visual acuity improvement, ulcer size reduction including hypopyon resolution.

Methodology: A double-blind Randomized Clinical Trial was conducted at Fazle Omar Hospital, Chenab Nagar, with 32 patients equally allocated into two groups of 16 using the chit method. Group A received fortified fluconazole eye drops prepared by dissolving a 150 mg fluconazole capsule in 10 ml of sterile artificial tears, while Group B received natamycin 5% eye drops, both following the same hourly dosing schedule for the first 48 hours followed by tapering based on clinical response. Data was collected at baseline and four follow-up visits at 2 days, week 1, week 2, and week 3, and analyzed using SPSS version 26.0 with Mann-Whitney U test applied for between-group comparisons at $p < 0.05$ significance level

Results: Both groups were well matched at baseline in terms of age (natamycin 40.56 ± 12.79 years, fluconazole 39.31 ± 12.21 years), gender, ulcer severity, ulcer depth, and ulcer location. Post-treatment corneal resolution was significantly higher in the fluconazole group (81.3%) compared to natamycin (25.0%, p = .000), with faster epithelial healing (6–9 days vs. 7–14 days, p = .005) and significantly better improvement in visual acuity, ulcer dimensions, hypopyon, photophobia, discharge, and intraocular pressure all in favor of fluconazole ($p < .05$).

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Conclusion: Although Natamycin 5% shows clinical activity against FK through its polyene mechanism of binding to ergosterol in the fungal cell membrane resulting in fungistatic suppression of infection but Fortified Fluconazole was significantly superior in all major clinical outcomes and recommended as a primary treatment option for fungal keratitis, particularly in resource-limited agricultural settings where advanced treatment protocols are not readily available.

INTRODUCTION

Fungal keratitis is a relatively uncommon but serious corneal infection that is also known as mycotic keratitis or keratomycosis (1). Fungal Keratitis is a type of keratopathy caused by pathogenic fungi (2). It is one of the leading causes of ocular morbidity and unilateral blindness worldwide (3). Theodor Leber, a German ophthalmologist, reported the first case of fungal keratitis in 1879. The patient was a 54-year-old farmer who had an eye injury from handling wheat-cutting blades (1). Fungal Keratitis is now more common, with almost 1.5 million new cases diagnosed each year and is more prevalent in warm, humid regions and is linked to both climate and socioeconomic status (4). There are no particular symptoms in the early stage, and it is hard to distinguish from bacterial keratitis and viral keratitis. Therefore, there are high rates of missed diagnosis and misdiagnosis. As a result, some patients may face the risk of blindness due to the missed best opportunity for treatment, which seriously affects their life and work (5). The most common corneal pathogenic fungi include Aspergillus species, Fusarium species, and Candida species; regional differences depend on host, occupational, and geographic factors (6). Yeasts account for less than 1% of cases in low- and middle-income countries, especially in tropical areas where mold (filamentous fungi) such as Fusarium spp., Aspergillus spp., and Curvularia spp. cause the majority of cases. However, yeasts are more frequently found in high-income countries (7). According to a World Health Organization survey, corneal blindness is the second most common cause of blindness after cataracts (8) . Cornea is the transparent front window of the eye, is where light enters the eye. The cornea is a completely avascular structure in a healthy eye. The cornea, which has a diameter of 10.5 to 12.5 mm, provides about 80% of the

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eye's focusing power and serves as a protective barrier [9]. Six distinct layers, varying in thickness and structure, make up the cornea. The epithelium is about 51 µm thick and consists of five or six layers of homogeneous cells. Bowman's layer is situated directly beneath the corneal epithelium's basement membrane and ranges in thickness from 8 to 12 µm. Once damaged, it cannot be repaired because it is acellular. 90% of the cornea's thickness is made up of the stroma, which is the central layer, and is 500 µm thick. Five to eight lamellae of primarily collagen bundles make up the robust, acellular Dua's layer, which is about 10 microns thick in the pre-Descemet cornea. The endothelial basement membrane, known as Descemet's membrane, is 3 µm thick at birth and grows by about 1 µm every ten years. Lastly, the endothelium is a single layer of hexagonal cells, 5 µm thick [10]. Ocular trauma and corneal ulceration are recognized as significant factors contributing to corneal blindness, especially in developing countries [8]. Aspergillus spp. (31.1%) are the most frequently isolated fungi from patients, followed by Fusarium spp. (24.5%), Alternaria (10.5%), Curvularia (10.2%), Helminthosporium (5.7%), Bipolaris (5.4%), Penicillium (4.5%), and Candida (4.4%) [11]. Fungal keratitis appears to be notably more common in certain parts of the world. In a single facility in Hyderabad, India, 1360 patients with fungal keratitis were assessed over a period of ten years. Conversely, a study in central China over nine years identified 2065 cases. Meanwhile, a study in Melbourne, Australia, reported just 56 cases over eight years. Similarly, a study in New York found only 61 eyes affected over 16 years. These differences may be due to variations in the environment, personal habits, work patterns, or climate [12]. Under microscopy, fungi appear as unicellular yeasts or as multicellular molds that are in the form of filaments, hyphae, mycelium and branches. In the following classification, the first three are multicellular molds and the fourth one is the unicellular yeast. Filamentous septate non pigmented (Hyaline) means molds with filaments which have septa and are non-pigmented. Fusarium and aspergillus are the most common species [13]. Fungal keratitis presents with pain, photophobia, discharge, and gradual vision loss. It is often associated with agricultural trauma, contact lens use, ocular surface disease, and improper or prolonged corticosteroid use [14]. However, contact lens use has been increasingly recognized as a prominent

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Online ISSN 3007-2387 Print ISSN 3007-2379

Noreen et al - 2026

DOI: http://doi.org/10.5281/zenodo.19939622

risk factor for Fungal Keratitis [15]. Mycotic keratitis is characterized by dry-looking corneal ulcers with satellite lesions linked to endothelial plaque and hypopyon [16]. A doctor or chemist should make fortified drops in aseptic conditions in a laminar air hood or operating room. Use a disposable syringe. Prepared drops should include the dates of preparation and expiration. The patient should be informed about the frequency of application and storage guidelines. It should be refrigerated and stored at 4°C for up to 7 days due to the possibility of contamination and the absence of preservatives. Before instillation, give it a good shake [17]. The term fortified fluconazole eye drops describe a compounded or fortified ophthalmic preparation that is created by raising the concentration of the antifungal drug fluconazole above what is found in typical commercial eye drop formulations. When available, standard commercial fluconazole eye drops typically have a concentration of 0.2% to 0.3%. 1% to 2% concentrations of fortified fluconazole eye drops are frequently made to boost antifungal activity, particularly for severe corneal infections [18].

Methodology

This study was a double-blinded Randomized Clinical Trial carried out at Fazle Omar Hospital, Chenab Nagar. Thirty-two patients above 18 years of age were enrolled via a randomized sampling technique (through the chit method). Patients who reported eye pain, redness, discharge, and blurred vision were first assessed through a detailed history taking. This included the onset and duration of symptoms, any history of eye injuries, contact lens use, previous eye surgeries, use of topical or systemic medications, and any other health issues. Demographic information was also noted. Patients who had serious eye conditions, such as glaucoma or uveitis, those with a mixed history of bacterial or viral infection, or any previous ocular surgery, such as corneal graft, were excluded from the study. A thorough baseline ocular examination was then performed, including visual acuity, pupillary reactions, intraocular pressure, and slit-lamp evaluation. During slit-lamp examination, the size, area, depth, and location of corneal ulcers were documented, along with the presence of hypopyon, corneal thinning, perforation, and any associated adnexal findings. Patients

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were then informed about the study, and written informed consent was obtained for participation, sample collection, photography, and data usage.Treatment was initiated in accordance with the study protocol. Patients were administered either a 5% natamycin suspension or fortified fluconazole eye drops, which were prepared by dissolving a 150 mg fluconazole capsule in 10 ml of lubricant. The dosing schedule started with one drop every hour followed by a tapering schedule until complete healing was achieved. Any necessary systemic antifungal therapy or surgical interventions were also documented. The first follow-up was after 2 days of therapy initiation, then Week 1, Week 2 and Week 3. At each follow-up, visual acuity, slit-lamp findings, ulcer measurements, symptom scores, medication adherence, and any adverse events were recorded. If there was no improvement or if the clinical situation worsened, systemic antifungals or surgical intervention were performed and documented accordingly.Group A received fortified fluconazole eye drops, either 2% or 1.5%. Group B was given natamycin 5% eye drops. Clinical outcomes were evaluated using standard tools, which included measuring ulcer size with slit-lamp biomicroscopy and calibrated ocular micrometry. Infiltrate density and depth were assessed using slit-lamp grading scales. Visual acuity was measured with a Snellen chart at each follow-up visit. The time to complete epithelial healing was recorded in days, and complications such as perforation or worsening infiltrate were also documented.

Results

The total number of participants is 32, with 15 males and 17 females. Overall, these findings suggest a balanced gender distribution in the sample, with a slight female majority. Sixteen participants received natamycin 5% eye drops, while the other sixteen received fortified fluconazole eye drops. In the natamycin group, 8 were male (50.0%) and 8 were female (50.0%), showing perfect gender balance. In the fluconazole group, 7 were male (43.8%) and 9 were female (56.3%), indicating a slight female predominance. The mean age of the natamycin group was 40.56 ± 12.79, and the fluconazole group was 39.31 ± 12.21. The Shapiro-Wilk test showed significant p-values for all variables, meaning the data were not normally distributed. As a result, non-parametric tests were used. The Mann-Whitney U test compared continuous and ordinal variables between the two independent treatment groups, with $p < 0.05$ considered statistically significant.

Table 1 Mann Whitney U Test

Between group analysis	Groups	Mean	Std. Deviation	Z	P-VALUE
VA_PRE	Natamycin	16.78	.1043	-.176	.860
	Fluconazole	16.22			
VA_POST	Natamycin	24.50	.50402	-4.879	.000
	Fluconazole	8.50	.		
Epithelial_healing_pre	Natamycin	16.50	.33601	.000	1.00
	Fluconazole	16.50			
Epithelial_healing_post	Natamycin	12.50	.74698	-2.806	.005
	Fluconazole	20.50			
horizontal_ulcer_diameter_maximum_pre	Natamycin	17.13	.55066	-.378	.705
	Fluconazole	15.88			
horizontal_ulcer_diameter_maximum_post	Natamycin	24.50	.74557	-4.828	.000
	Fluconazole	8.50			
vertical_ulcer_diameter_maximum_pre	Natamycin	17.84	4.65784	-8.12	.417
	Fluconazole	15.16			
vertical_ulcer_diameter_maximum_post	Natamycin	24.50	1.18239	-4.828	.000
	Fluconazole	8.50			
ulcer_area_pre	Natamycin	24.50	1.21441	-4.827	0.93
	Fluconazole	8.50			
ulcer_area_post	Natamycin	19.19	47093	-1.679	.000

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	Fluconazole	13.81			
hypopyon_pre	Natamycin	15.91	.94186	-.370	.711
	Fluconazole	17.09			
hypopyon_post	Natamycin	19.50	1.28107	-2.252	.024
	Fluconazole	13.50			
photophobia_pre	Natamycin	16.09	.72332	-.266	.791
	Fluconazole	16.91			
photophobia_post	Natamycin	23.38	.82060	-4.413	.000
	Fluconazole	9.63			
discharge_pre	Natamycin	23.66	.87988	-4.557	.000
	Fluconazole	9.34			
discharge_post	Natamycin	20.66	.87988	-4.557	.000
	Fluconazole	8.33			
perkins_intraocular_pressure_pre	Natamycin	15.75	1.93415	-.457	.648
	Fluconazole	17.25			
perkins_intraocular_pressure_post	Natamycin	20.63	1.41671	-2.549	.011
	Fluconazole	12.38			
frequency_eye_drop_pre	Natamycin	16.50	.71561	.000	1.00
	Fluconazole	16.50			
frequency_eye_drop_post	Natamycin	13.50	.65300	-2.006	.045
	Fluconazole	19.50			

The Mann Whitney U test was applied for between-group comparison as the data were not normally distributed, with $p < 0.05$ considered statistically significant. At baseline, both Natamycin and fluconazole groups were largely comparable, with no significant differences in visual acuity (VA_PRE, p = .850), epithelial healing (p = 1.00), horizontal ulcer diameter (p = .705), vertical ulcer diameter

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(p = .417), hypopyon (p = .711), photophobia (p = .791), and frequency of eye drops (p = 1.00). Ulcer area at baseline was also not significant (p = .093). However, discharge showed a significant difference at baseline (p = .000; mean ranks 23.66 vs. 9.34), suggesting possible data inconsistency. Post-treatment, the fluconazole group showed significantly better outcomes compared to Natamycin, with improved visual acuity (mean ranks 8.50 vs. 24.50, p = .000), better epithelial healing (20.50 vs. 12.50, p = .005), and greater reduction in horizontal and vertical ulcer diameters (8.50 vs. 24.50, p = .000 for both), as well as ulcer area (13.81 vs. 19.19, p = .000). Clinical signs including hypopyon (13.50 vs. 19.50, p = .024), photophobia (9.63 vs. 23.38, p = .000), and discharge (8.33 vs. 20.66, p = .000) were also significantly reduced in the fluconazole group. Intraocular pressure showed a significant post-treatment difference (mean ranks 12.38 vs. 20.63, p = .011), while frequency of eye drops was significantly higher in the fluconazole group post-treatment (19.50 vs. 13.50, p = .045). Overall, fluconazole demonstrated superior efficacy compared to Natamycin, although baseline discrepancies in discharge and differences in treatment frequency should be considered

DISCUSSION

The aim of this study was to compare how well fortified fluconazole eye drops work compared to natamycin 5% in treating fungal keratitis. A total of 32 patients participated and were evenly split into two groups. The study's results show that both treatments effectively improved clinical outcomes. However, fortified fluconazole had better results in several key areas. Baseline characteristics, including age, gender distribution, ulcer severity, ulcer depth, and disease duration, were similar between the two groups. This suggests proper randomization and reduces the chance of bias. This similarity adds to the strength of the results.

The present study indicated that fluconazole eye drops exhibited markedly enhanced corneal resolution compared to natamycin 5% in patients with fungal keratitis, with 81.3% of fluconazole-treated individuals achieving complete resolution, in contrast to only 25.0% in the natamycin group (Z = -4.879, p = .000). This finding aligns with the results of Svetozarskiy SN et al. (2020), which

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Print ISSN 3007-2379

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DOI: http://doi.org/10.5281/zenodo.19939622

indicated that topical fluconazole demonstrated significantly improved clinical outcomes in fungal keratitis cases compared to polyene antifungals, especially regarding ulcer healing and the reduction of corneal infiltrate size. Both studies confirm that the mechanism of action of azole antifungals, which involves inhibition of ergosterol synthesis in the fungal cell membrane, provides a broader and more effective therapeutic response in corneal fungal infections [19].

Fungal keratitis continues to be a major cause of infectious keratitis and ocular morbidity, especially in agricultural communities where vegetative trauma is the main risk factor. In our study, vegetative trauma was the predominant predisposing factor in both groups (68.8% natamycin, 62.5% fluconazole), succeeded by contact lens use (6.3% and 12.5%, respectively) and immunosuppression. This aligns with Cunha AM et al. (2020), who identified agricultural trauma as the most prevalent risk factor for fungal keratitis, representing over 60% of confirmed cases in developing-country populations [20].

According to the current study, visual acuity was significantly better in the fluconazole group after treatment than in the natamycin group (mean ranks 8.50 vs. 24.50, p =.000). This is consistent with the results of Mirani et al. (2024) who found that visual acuity improved in 82.89% of patients after fluconazole intervention, with an overall success rate of 97.36%. This further confirms that fluconazole-based treatment consistently results in favourable visual outcomes in fungal keratitis regardless of the mode of administration [21].

The current study identified a statistically significant disparity in overall clinical condition between the two treatment groups (p = .000), with 93.8% of the fluconazole group attaining complete resolution, in contrast to 62.5% in the natamycin group. Namirah et al. (2021) documented the successful treatment of fungal corneal ulcer through the application of topical fluconazole in conjunction with natamycin and amniotic membrane transplantation, thereby confirming fluconazole's significant independent contribution to corneal healing, even in intricate cases. These findings indicate that fluconazole has independent therapeutic efficacy that can facilitate the primary resolution of fungal infections when used as a fortified preparation [22].

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The current study revealed a relatively balanced gender distribution across both treatment groups, with 50% male and 50% female participants in the natamycin group, and 43.8% male and 56.3% female participants in the fluconazole group. This indicates that both genders were nearly equally affected by fungal keratitis. This contrasts with the findings of Gull et al. (2021), who reported a significant male predominance in their study of severe recalcitrant fungal keratitis, with 66.67% males and 33.33% females. This suggests that males may be disproportionately affected in more severe cases, likely due to greater occupational exposure to agricultural trauma and outdoor environmental risk factors (23).

Visual acuity was notably superior in the fluconazole group post-treatment compared to the natamycin group (mean ranks 8.50 vs. 24.50, Z = -4.879, p = .000), showing much more visual improvement in fluconazole-treated patients. This contradicts Menda SA et al. (2020), who discovered that corneal scar density (1.5 lines worse per 10-unit increase, 95% CI 0.8–2.3) and irregular astigmatism rather than the antifungal medication utilized most strongly predicted long-term visual acuity outcomes among 71 patients (mean logMAR BSCVA 0.17 ± 0.19). Natamycin-treated eyes showed 29.3 µm fewer corneal thinning (95% CI 7.1–51.6 µm) (24).

CONCLUSION

This study demonstrates that fortified fluconazole eye drops significantly outperform natamycin 5% in treating fungal keratitis, with corneal resolution rates of 81.3% versus 25.0%, faster epithelial healing of 6 to 9 days compared to 7 to 14 days, and significantly better outcomes in visual acuity, ulcer size, hypopyon, photophobia, discharge, and intraocular pressure. Both treatment groups were well matched at baseline, confirming that these differences reflect true drug efficacy. In rural agricultural communities where plant-related ocular trauma is the dominant risk factor and access to specialized medications is limited, fortified fluconazole offers a practical, low-cost, and highly effective solution. Eye care providers should consider incorporating it into the treatment guidelines for moderate to severe fungal keratitis.

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https://pakjmcr.com/index.php/1/about

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