Section: Ophthalmology

Original Research Article

TOPICAL RIPASUDIL VERSUS LOSARTAN FOR PERSISTENT STROMAL CORNEAL HAZE: A RANDOMIZED MULTICENTER TRIAL

Ali Afzal Bodla[1], Irfan Ahmed Sualeh[2], Ghulam Abbas[3], Razaullah Khan[4], Muhammad Awais Ashraf[5], Asim Mehmood[6]

[1]Associate Professor, Department of Ophthalmology, Multan Medical and Dental College, Multan.
[2]Consultant, Department of Ophthalmology, DHQ hospital Jhang.
[3]Associate Professor, Department of Ophthalmology, Multan Medical & Dental College, Multan.
[4]Assistant professor, Department of Ophthalmology, Sheikh Zayed Medical College, Rahim Yar Khan.
[5]Assistant Professor, Department of Ophthalmology, Multan Medical and dental college, Multan.
[6]Associate Professor, Department of Ophthalmology, Multan Medical and Dental College, Multan.

Received : 17/09/2026
Received in revised form : 12/10/2026
Accepted : 25/10/2026

Keywords:
Corneal haze, corneal fibrosis, ripasudil, losartan, visual acuity.

Corresponding Author:
Dr. Ghulam Abbas,
Email: drahanjum@yahoo.com

DOI: 10.47009/jamp.2026.8.6.1

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2026; 8 (6); 1-6

ABSTRACT

Background: Persistent corneal haze can limit visual recovery after infection, trauma or surgery, even when the original disease has been treated successfully. Ripasudil and losartan act on different parts of the wound-healing response, but they have not been compared directly in patients. **Objective:** To compare the efficacy and safety of topical ripasudil 0.4% and topical losartan 0.8 mg/mL in adults with persistent stromal corneal haze. **Materials and Methods:** In this randomized, open-label, assessor-masked study at three tertiary eye hospitals in Punjab, Pakistan. 132 adults were allocated equally to ripasudil 0.4% twice daily or losartan 0.8 mg/mL six times daily for 24 weeks. Recruitment ran from January to June 2025, and follow-up ended in December 2025. One eye per patient was analyzed. The primary outcome was improvement of at least one haze grade on masked photographic grading. Secondary outcomes were complete clearance, corrected visual acuity, intraocular pressure and ocular adverse events. **Results:** All 132 participants completed follow-up. Haze improved by at least one grade in 38/66 eyes (57.6%) treated with ripasudil and 48/66 (72.7%) treated with losartan, a difference of 15.2 percentage points in favor of losartan (95% confidence interval −1.1 to 30.3; p=0.100). Complete clearance occurred in 12 (18.2%) and 14 (21.2%) eyes, respectively. Mean visual improvement was similar (0.130±0.083 versus 0.134±0.091 logMAR; p=0.818), and 15 patients in each group gained at least 0.20 logMAR. Conjunctival hyperemia was more frequent with ripasudil (14 versus 6 patients; p=0.087). No persistent epithelial defect, corneal infection or treatment discontinuation was recorded. **Conclusion:** Haze and vision improved with both treatments. Losartan produced a numerically higher haze response rate and less hyperemia, but neither difference was statistically significant, and visual outcomes were almost identical. Larger controlled trials with objective densitometry are needed before either agent can be preferred.

INTRODUCTION

Persistent corneal haze remains a stubborn obstacle to visual rehabilitation, even after infection, trauma or surgery has otherwise been treated successfully. Its effect on vision goes beyond a visible white opacity: light scatter, disorganized stroma and an irregular surface can each degrade image quality. For this reason, the difference between transient wound-healing haze and established scarring fibrosis matters both when choosing treatment and when judging whether a patient has improved.[1] Whether the cornea regains transparency depends partly on regeneration of the epithelial basement membrane, which normally limits the passage of profibrotic growth factors into the underlying stroma.[2]

Corneal myofibroblasts are central to persistent opacity. They deposit disorganized extracellular matrix and alter the normal optical properties of the stroma.[3] Where the basement membrane fails to regenerate fully, continued exposure to transforming growth factor beta keeps this fibrotic response

ISSN (O): 2687-5365; ISSN (P): 2753-6556

active.[4] Injury to Descemet's membrane and the endothelium adds a further complication, because it disturbs stromal hydration and can produce edema that is easily confused with fibrosis.[5] The term corneal haze therefore needs a clear anatomical and clinical definition rather than serving as a label for any loss of corneal clarity.

Current management depends on the cause, depth and activity of the lesion. Corticosteroids are used to control inflammation, whereas established scars may need optical rehabilitation, phototherapeutic keratectomy or keratoplasty, and the behavior of haze after refractive surgery varies with the underlying healing process.[6] These limitations have prompted interest in drugs that act more directly on cellular repair and scar formation. In any comparison of such drugs, however, clearing of endothelial edema cannot be taken as evidence that stromal fibrosis has reversed.

Ripasudil, a Rho-associated protein kinase (ROCK) inhibitor, has drawn attention because experimental work shows that it promotes endothelial cell migration and proliferation and supports barrier function.[7] Clinical experience after Descemet stripping only suggests that it may also aid corneal clearance in selected patients with Fuchs endothelial dystrophy,[8] and more recent laboratory studies have further described its effects on endothelial migration and the surrounding microenvironment.[9] These findings give a biological reason to study ripasudil, but they do not show that it works against persistent anterior stromal scarring.

Losartan works through a different route, by dampening profibrotic signaling. In rabbits, topical losartan reduced scarring fibrosis and abnormal collagen deposition after Descemet's membrane–endothelial excision,[10] and further animal work showed an additive effect with corticosteroids after alkali injury, supporting its evaluation across different patterns of corneal damage.[11] Practical guidance for clinical studies has since stressed careful patient selection, a reliable formulation, appropriate dosing and adequate follow-up.[12]

The first human reports described improvement in haze after refractive surgery and after corneal cross-linking, although uncontrolled reports cannot separate a drug effect from natural remodeling.[13,14] Neither agent is yet an established treatment for stromal haze, and the two have not been compared directly. In tertiary eye services in Pakistan, a comparison built on visual acuity, slit-lamp grading and scheduled safety reviews offers a practical starting point. This study therefore compared topical ripasudil 0.4% with topical losartan 0.8 mg/mL over 24 weeks in adults with persistent stromal corneal haze. The primary question was whether either drug produced a clinically visible improvement in haze more often; visual recovery and tolerability were assessed as secondary outcomes. Eyes with primarily edematous disease were excluded so that the comparison addressed stromal opacity alone.

MATERIALS AND METHODS

This prospective, randomized, parallel-group, open-label study with masked outcome assessment was carried out in the ophthalmology departments between January and December 2025. Patients were recruited from January to June so that every participant could complete 24 weeks of follow-up by the end of the year. The sample size was based on an assumed haze response of 50% with ripasudil and 75% with losartan. With a two-sided alpha of 0.05 and 80% power, about 58 participants per group were needed; allowing for 10% attrition raised this to 65, which was rounded up to 66 per group (132 in total) to keep allocation balanced across hospitals. These response rates were planning assumptions rather than estimates from an earlier head-to-head trial, and the study was not powered to detect smaller differences or rare adverse events.

The study followed the tenets of the Declaration of Helsinki and was approved by the ethics review committee of each participating hospital. All participants gave written informed consent before enrollment, and were told that losartan eye drops are an off-label, pharmacy-prepared formulation.

Adults aged 18–65 years were eligible if they had central or paracentral stromal haze of grade 1–3 that had persisted for at least 12 weeks after healed non-herpetic keratitis, corneal surgery or mechanical trauma, with an intact epithelium. Exclusion criteria were active infection, recurrent herpetic disease, epithelial defects, endothelial decompensation, corneal dystrophy, severe ocular surface disease, glaucoma requiring medication, pregnancy, breastfeeding and known allergy to either study drug. Together, these criteria were intended to separate stromal scarring from primarily edematous opacity.

Only one eye per participant was included. When both eyes were eligible, the eye with the poorer corrected visual acuity was chosen; if acuity was equal, the right eye was used. A computer-generated randomization sequence, stratified by hospital, was concealed in sequentially numbered opaque envelopes that were opened only after the baseline examination. Because the two drugs differed in appearance and dosing schedule, neither participants nor treating clinicians were masked. Slit-lamp photographs were coded, and two reviewers unaware of treatment allocation graded them independently; disagreements were settled by consensus.

Ripasudil 0.4% was instilled as one drop twice daily and losartan 0.8 mg/mL (0.08%) as one drop six times daily, both for 24 weeks. Losartan was prepared by the hospital pharmacies under a common protocol covering sterile ophthalmic compounding, labeling, storage and bottle replacement. All participants also used preservative-free lubricants. Additional corticosteroids, immunomodulators and corneal procedures were not permitted except as rescue treatment, and any such use was recorded.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

The baseline examination included history, refraction, corrected distance visual acuity, slit-lamp biomicroscopy, fluorescein staining and Goldmann applanation tonometry. Follow-up visits took place at weeks 2, 6, 12 and 24. Photographic illumination and magnification were kept constant within each hospital so that images could be compared over time. Haze was graded on a predefined clinical scale: 0, clear; 1, faint haze with clear iris detail; 2, moderate haze with reduced iris detail; 3, dense haze with marked obscuration; and 4, complete obscuration. This is a clinical grading scale and is not a validated substitute for densitometry. Operational definitions of all outcomes and the assessment schedule are given in Table 1. Increasing pain, signs of infection, a persistent epithelial defect or a loss of two or more lines of acuity prompted urgent review.

All centers used identical case report forms. Adherence and any need for rescue treatment were reviewed at every visit. Agreement between graders was not quantified with a formal coefficient, and consensus grades were used in the efficacy analysis. The study was not designed to assess recurrence after treatment was stopped.

Analyses were performed in Python 3.12.14 using NumPy, pandas and SciPy. Continuous variables are reported as mean±standard deviation or median (interquartile range), and categorical variables as counts and percentages. The primary outcome was compared with Fisher's exact test, and the absolute difference was reported with a Newcombe hybrid score 95% confidence interval. Fisher's exact test was also used for secondary binary outcomes and adverse events, and Welch's t-test for visual improvement and intraocular pressure. Secondary analyses were exploratory, with no adjustment for multiplicity, and between-group comparisons were not adjusted for baseline covariates. A two-sided $p<0.05$ was considered statistically significant. Because every participant completed follow-up, no imputation was needed.

Table 1: Operational definitions and assessment of study outcomes

Outcome domain	Operational definition and measurement	Assessment time
Primary: haze response	Reduction ≥1 grade from baseline on the predefined 0–4 scale, assessed from coded slit-lamp photographs by masked reviewers.	Week 24 versus baseline
Secondary: complete clearance	Haze grade 0 on the same clinical scale.	Week 24
Secondary: visual recovery	Corrected distance acuity on a standardized logMAR chart; gain calculated as baseline minus follow-up. Clinically meaningful gain: ≥0.20 logMAR.	Baseline; weeks 6, 12 and 24
Secondary: ocular safety	Slit-lamp examination, fluorescein staining and symptom review for hyperemia, stinging, punctate staining, epithelial defects or infection.	Baseline; weeks 2, 6, 12 and 24
Secondary: intraocular pressure	Goldmann applanation tonometry; pressure recorded in mmHg.	Baseline; weeks 2, 6, 12 and 24
Treatment adherence	Patient interview and bottle checks; qualitative assessment without a numerical adherence score.	Weeks 2, 6, 12 and 24

RESULTS

Of 150 patients screened, 18 were excluded: eight had endothelial decompensation, four had active keratitis, three had epithelial defects, two required glaucoma medication, and one declined participation. The remaining 132 patients were randomized equally between the two treatment groups. No participant received rescue corticosteroids, additional immunomodulatory treatment or a corneal procedure during follow-up.

Baseline characteristics are shown in Table 2. Baseline visual acuity and haze duration were similar in the two groups. The losartan group was, on average, about three years older and included fewer men (40.9% versus 54.5%). Baseline haze was also slightly denser in the ripasudil group (median grade 2 in both groups, but interquartile range 2–3 versus 2–2; Table 3). Postinfectious, postsurgical and posttraumatic haze were represented in both arms. Because the comparisons were not adjusted, these imbalances should be kept in mind when interpreting the results.

Table 2: Baseline characteristics

Characteristic	Ripasudil (n=66)	Losartan (n=66)
Age, years	39.6±12.7	42.7±11.8
Male sex, n (%)	36 (54.5)	27 (40.9)
Haze duration, weeks	22 (17–29)	23 (17–30)
Postinfectious haze, n (%)	32 (48.5)	34 (51.5)
Postsurgical haze, n (%)	24 (36.4)	20 (30.3)
Posttraumatic haze, n (%)	10 (15.2)	12 (18.2)
Baseline acuity, logMAR	0.57±0.14	0.55±0.15

Values are mean±SD, median (IQR) or n (%).

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Haze grades during follow-up are summarized in Table 3. Both groups shifted toward lower grades over time, although some residual haze was common at week 24. The median final grade was the same in both groups even though the proportion of responders differed. This reflects the coarse resolution of an ordinal scale: two eyes can finish at the same grade after starting at different grades and improving by different amounts. Complete clearance was much less common than a one-grade improvement and is reported separately.

Table 3: Haze grades during follow-up

Measure	Ripasudil	Losartan
Week 0, median (IQR)	2 (2–3)	2 (2–2)
Week 6, median (IQR)	2 (1–2)	2 (1–2)
Week 12, median (IQR)	2 (1–2)	2 (1–2)
Week 24, median (IQR)	1 (1–2)	1 (1–2)
Final grade 0, n (%)	12 (18.2)	14 (21.2)
Final grade 1, n (%)	24 (36.4)	31 (47.0)
Final grade 2, n (%)	20 (30.3)	17 (25.8)
Final grade 3, n (%)	10 (15.2)	4 (6.1)

Each group included 66 eyes at every visit. Grade 0 indicates a clear cornea.

Corrected visual acuity improved in both groups (Table 4). The between-group difference in mean improvement was 0.003 logMAR (95% CI −0.026 to 0.033; p=0.818), and the same number of patients in each group gained at least 0.20 logMAR. The higher haze response rate with losartan was therefore not matched by any advantage in visual recovery, which underlines that corneal clarity and acuity are related but separate outcomes.

Table 4: Corrected visual acuity and change

Outcome	Ripasudil	Losartan
Week 0, logMAR	0.57±0.14	0.55±0.15
Week 6, logMAR	0.54±0.14	0.52±0.15
Week 12, logMAR	0.49±0.15	0.47±0.16
Week 24, logMAR	0.44±0.16	0.41±0.17
Improvement, logMAR	0.130±0.083	0.134±0.091

Values are mean±SD. Improvement was calculated as baseline minus week 24. Between-group comparison of improvement: p=0.818 (Welch's t-test).

The primary outcome was reached more often with losartan (Table 5). The absolute difference of 15.2 percentage points, however, had a 95% confidence interval of −1.1 to 30.3 (p=0.100). This interval is compatible with anything from no meaningful difference to a substantial benefit of losartan, so the study shows neither superiority nor equivalence.

Table 5: Clinical response at week 24

Endpoint	Ripasudil, n (%)	Losartan, n (%)	p-value
≥1-grade haze improvement	38 (57.6)	48 (72.7)	0.100
Complete clearance	12 (18.2)	14 (21.2)	0.827
≥0.20-logMAR improvement	15 (22.7)	15 (22.7)	1.000

p-values are from Fisher's exact test. Primary response difference (losartan minus ripasudil): 15.2 percentage points (95% CI −1.1 to 30.3).

Ocular adverse events and intraocular pressure are summarized in Table 6. Conjunctival hyperemia was more common with ripasudil (21.2% versus 9.1%; p=0.087), whereas stinging and punctate staining occurred at similar rates in both groups. Because a patient could have more than one event, individual counts were not added together; at least one listed event occurred in 24 and 16 patients, respectively (p=0.185). No persistent epithelial defect, corneal infection or treatment discontinuation was recorded. Mean intraocular pressure at week 24 was lower with ripasudil (13.7±2.1 versus 15.0±1.9 mmHg; p<0.001), which reflects the drug's ocular hypotensive action rather than any effect on stromal clarity. With 132 participants, the absence of uncommon complications does not establish comparative long-term safety.

Table 6: Ocular safety and intraocular pressure

Outcome	Ripasudil	Losartan
Hyperemia, n (%)	14 (21.2)	6 (9.1)
Stinging, n (%)	9 (13.6)	8 (12.1)
Punctate staining, n (%)	3 (4.5)	3 (4.5)
Any listed event, n (%)	24 (36.4)	16 (24.2)
Persistent epithelial defect	0	0

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Treatment discontinuation	0	0
Baseline pressure, mmHg	15.4±1.8	15.1±1.8
Week-24 pressure, mmHg	13.7±2.1	15.0±1.9

Events could overlap. Pressure values are mean±SD.

DISCUSSION

In this randomized comparison, haze improved by at least one grade more often with losartan than with ripasudil, but the difference was not statistically significant and the confidence interval was wide. Both groups improved, and visual outcomes were almost identical. An encouraging direction of effect is not enough to call one treatment more effective, particularly when visual acuity shows no separation. The slightly denser baseline haze in the ripasudil group may also have influenced the difference in response rates.

Local clinical experience is limited. A case report from Pakistan described improvement in a losartan-treated eye with persistent opacity related to nummular keratitis,[15] but a single-patient report cannot be compared with a parallel-group trial. Dutra and colleagues reported improvement in three patients with scarring after herpes simplex or varicella-zoster keratitis, extending clinical experience to another cause of opacity.[16] Those results do not provide expected response rates for the present population, which excluded recurrent herpetic disease.

Published experience with losartan has not been uniformly positive. In a small case series, Burgos-Blasco and Moloney found no statistically significant group-level improvement in visual acuity or densitometry, although several individual eyes improved.[17] Their findings argue against reading too much into favorable individual responses. In rabbits with established fibrosis, topical losartan reduced myofibroblast density and increased apoptosis,[18] which offers biological support but says little about comparative clinical effectiveness. A later prospective case series reported better vision and densitometry after losartan, although the absence of a control group limited causal interpretation.[19]

The link between cellular change and visible clearing also needs careful interpretation. Around acute incisions in rabbit corneas, losartan reduced myofibroblast generation without significantly changing opacity over the study period.[20] Suppressing fibrotic cells, in other words, does not guarantee a rapid return of optical quality. Dose matters as well: animal studies have shown epithelial toxicity at higher losartan concentrations, so surface monitoring remains necessary.[21] Ripasudil also needs surveillance, as honeycomb epithelial edema has been reported during treatment in a compromised cornea.[22] The more frequent hyperemia and lower intraocular pressure with ripasudil in the present study are consistent with its known pharmacological effects as a glaucoma medication.[23]

A two-phase model of losartan action separates the removal of myofibroblasts from the slower remodeling of disorganized extracellular matrix, which helps explain why improvement can take several months.[24] Recent laboratory work has shown that ROCK inhibition modulates extracellular matrix pathways in corneal endothelial dystrophies,[25] but this evidence concerns endothelial disease and does not establish a role for ripasudil in anterior stromal haze. A recent review similarly highlights the still-developing clinical evidence for topical losartan and the need for controlled evaluation.[26]

The multicenter design, randomized allocation, masked grading, one eye per participant and complete 24-week follow-up strengthened the study. Limitations included the moderate sample, open-label treatment, unadjusted baseline differences, subjective grading, qualitative adherence assessment and absence of a vehicle control. Larger controlled trials with objective measurements are needed.

CONCLUSION

Over 24 weeks, both topical ripasudil and topical losartan were followed by improvement in corneal clarity and corrected visual acuity in adults with persistent stromal haze. Losartan achieved a numerically higher haze response rate and caused less conjunctival hyperemia, but neither difference was statistically significant, and visual gains were essentially the same with both drugs. Losartan merits further study in larger controlled trials with objective measures of corneal clarity, but the present data do not show that it is superior to ripasudil.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556

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ISSN (O): 2687-5365; ISSN (P): 2753-6556