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Effectiveness of 0.4% Ripasudil Eye Drops in Reducing Postoperative Corneal Edema and Improving Visual Recovery Following Cataract Surgery: A Prospective Observational Study.

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ABSTRACT

To assess the therapeutic efficacy of 0.4% Ripasudil eye drops in resolving postoperative corneal edema and enhancing visual recovery following cataract surgery. This prospective observational study included 15 eyes from 15 patients presenting with corneal edema after uneventful cataract surgery at a tertiary care centre in South India. Patients were administered 0.4% Ripasudil hydrochloride eye drops twice daily. Clinical outcomes were evaluated using best-corrected visual acuity (BCVA), central corneal thickness (CCT), slit-lamp biomicroscopy, and anterior segment optical coherence tomography at baseline, week 1, and week 3. Treatment duration ranged from one to three weeks. Statistically significant improvements were observed in BCVA, improving from 6/60–6/36 to 6/12–6/9 ($P < 0.0001$). CCT decreased from 597 ± 25 μm to 540 ± 22 μm ($P < 0.0001$), with 86.7% of patients achieving complete anatomical resolution. Notably, 54.9% of total visual improvement occurred within the first week, indicating a rapid therapeutic onset. No adverse events were reported. Ripasudil 0.4% demonstrated robust efficacy in reducing corneal edema and accelerating visual rehabilitation in the early postoperative period. These findings support its potential role as a targeted adjunct therapy for endothelial dysfunction following cataract surgery, warranting further validation through larger controlled trials.

Keywords: *Ripasudil, Corneal Edema, Cataract Surgery, Visual Acuity, Central Corneal Thickness.*

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INTRODUCTION

Cataract surgery, though widely performed, can compromise the corneal endothelium, disturbing fluid balance and leading to postoperative edema. Long-term studies have shown that endothelial cell density (ECD) may decline by nearly 8–9% within a year, underscoring the susceptibility of this non-regenerative layer [1]. Corneal transparency hinges on the endothelial layer's ability to regulate hydration via active pump and barrier mechanisms. These hexagonal cells form a delicate monolayer, typically numbering around 2500 cells/mm^2 in healthy adults [2]. Surgical trauma may trigger endothelial cell migration and attrition. When cell density dips below 500 cells/mm^2, the cornea loses its ability to maintain hydration resulting in stromal haze and clinically evident edema. The Rho-associated kinase (ROCK) pathway regulates cytoskeletal dynamics. Its dysregulation amplifies cellular contractility, impairs migration, and suppresses proliferation, culminating in endothelial dysfunction [3–5]. By modulating ROCK signaling, inhibitors promote endothelial regeneration, enhancing cell adhesion, reducing apoptosis, and ultimately mitigating corneal edema [5]. Ripasudil, a selective ROCK inhibitor developed by Kowa Company, is approved in Japan for glaucoma and ocular hypertension. Its emerging role in corneal therapeutics has sparked interest due to its regenerative effects on endothelial cells. Administered twice daily, Ripasudil is generally well tolerated, though mild adverse effects such as conjunctival hyperemia, blepharitis, and transient epithelial changes have been reported [6,7].

Aim

To evaluate the therapeutic effect of 0.4% Ripasudil eye drops in reducing corneal edema and improving visual recovery after cataract surgery.

Objectives

In post-cataract surgery patients,

- To Assess reduction in central corneal thickness (CCT) before and after treatment with 0.4% Ripasudil eye drops.
- To Assess improvement in visual acuity before and after treatment with 0.4% Ripasudil eye drops.

MATERIALS AND METHODS

Study Design and Setting

A prospective observational study was conducted in the Department of Ophthalmology at Aarupadai Veedu Medical College & Hospital, Puducherry, over 9 months (July 2024 – March 2025).

Participants

Fifteen eyes from fifteen post-cataract surgery patients with corneal edema and BCVA (Best Corrected Visual Acuity) <6/36 were enrolled. Inclusion criteria: postoperative corneal edema with reduced visual acuity. Exclusion criteria: pre-existing corneal decompensation or dystrophy. Ethical approval and informed consent were obtained.

Treatment Protocol

Patients received 0.4% Ripasudil hydrochloride eye drops twice daily. Baseline assessments included Snellen visual acuity, slit-lamp biomicroscopy, and central corneal thickness (CCT). Follow-up evaluations were performed at week 1 and week 3.

Data Collection and Bias Minimization

According to standard proformas, Demographic and Clinical data were recorded. Investigators followed uniform protocols to minimize selection and observer bias. No missing data were reported.

Sample Size Justification

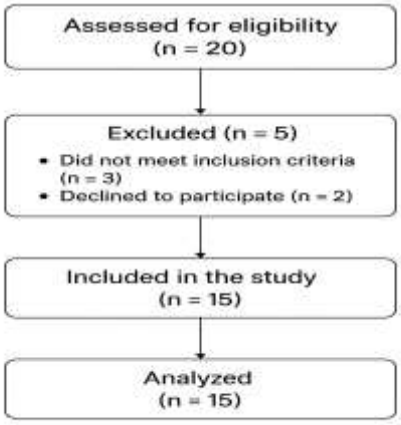
A sample size of 15 was chosen based on feasibility and prior studies showing significant CCT changes with similar interventions [8].

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS. Descriptive statistics included mean ± SD, percentages, and confidence intervals. Inferential tests included paired t-tests, Pearson correlation, Cohen's d, and post-hoc power analysis. Visualizations were generated using Vizly AI (Artificial Intelligence) tools; interpretation was manual.

RESULTS

Study Enrolment: Fig.1.Flow diagram representing participant enrolment.



Out of 20 screened patients, 15 eyes from 15 patients were enrolled. All completed follow-up at week 1 and week 3 (100% compliance). (Fig.1.)

Baseline Demographic Characteristics

Age & Gender Distribution

- Mean Age: 68.5±3.4 years.
- Females: 9/15(60%).
- Males: 6/15(40%).

Visual Acuity (VA) Results

Visual acuity, converted to logMAR for analysis.

Baseline VA

- Mean±SD*:* 0.852±0.169 logMAR units.

Week 1 VA

- Mean±SD*:* 0.467±0.189 logMAR units.

Week 3 VA

- Mean±SD*:* 0.151±0.150 logMAR units.

Baseline to Week 1 VA Improvement

- Mean Difference: 0.385 logMAR units (0.852 - 0.467).
- 95% CI: [0.280, 0.490].
- Interpretation: We are 95% confident that the true improvement in visual acuity after 1 week lies between 0.280 and 0.490 logMAR units.

Baseline to Week 3 VA Improvement

- Mean Difference: 0.701 logMAR units (0.852 - 0.151).
- 95% CI: [0.617, 0.785].
- Interpretation: We are 95% confident that the true improvement in visual acuity after 3 weeks lies between 0.617 and 0.785 logMAR units.

Clinical Significance Thresholds

- Minimally Important Difference: 0.1 logMAR (0.5 lines).
- Clinically Significant: 0.2 logMAR (1 line).
- Substantial Benefit: 0.3 logMAR (1.5 lines).

Study Results vs Thresholds

- Week 1: 0.385 logMAR (>substantial benefit).
- Week 3: 0.701 logMAR (>substantial benefit).

Clinical Response

Table.1. Visual Acuity Improvement Categories (week 3)

Improvement Level	logMAR Threshold	n (%)	95% CI
Minimal (0-0.2 logMAR)	<1 line improvement	1 (6.7%)	[0.2%, 31.9%]
Moderate (0.2-0.5 logMAR)	1-2.5 lines	3 (20.0%)	[4.3%, 48.1%]
Substantial (>0.5 logMAR)	>2.5 lines	11 (73.3%)	[44.9%, 92.2%]

Foot Note: logMAR = logarithm of the minimum angle of resolution; n = Number of patients; CI = Confidence Interval. The 95% confidence intervals confirm that even the lower bounds represent clinically meaningful improvements as depicted in Table.1.

Central Corneal Thickness (CCT) Results

Baseline CCT (μm)

- Mean±SD: 597±25; 95% CI [583, 611].

Post-treatment CCT (μm)

- Mean±SD: 540±22; 95% CI [528, 552].

CCT Change (Pre- to Post-treatment)

- Mean Reduction: -57 μm (597 - 540).
- 95% CI for reduction: [-68.4, -45.6] μm.
- Interpretation: We are 95% confident that Ripasudil reduces CCT by between 45.6 and 68.4 μm.
- Clinical Significance Thresholds:
- *Normal Range:* 540-560 μm.

- *Study Achievement:* Mean post-treatment CCT = 540 µm (within normal range).

Clinical Response

Table 2: CCT Response Categories (week 3)

Response Level	Threshold	n (%)	95% CI
Complete Resolution	CCT ≤560 µm	13 (86.7%)	[59.5%, 98.3%]
Partial Resolution	CCT 561-580 µm	2 (13.3%)	[1.7%, 40.5%]
No Response	CCT >580 µm	0 (0%)	[0%, 21.8%]

Foot Note: n = Number of patients; CI = Confidence Interval; CCT = Central Corneal Thickness. The 95% confidence interval represents majority of the study population had substantial edema resolution, with the entire interval indicating clinically significant improvement as shown in table.2.

Effect Size Calculations

Table 3: Cohen's d (Standardized Effect Sizes)

Comparison	Cohen's d	95% CI	Effect Size
Baseline vs Week 1 (VA)	2.15	[1.34, 2.96]	Very Large
Baseline vs Week 3 (VA)	4.37	[3.17, 5.57]	Very Large
CCT Pre vs Post	2.51	[1.64, 3.38]	Very Large

*Foot Note: **Effect Size Interpretation: 0.2 = small, 0.5 = medium, 0.8 = large, >1.2 = very large.** CI = Confidence Interval; VA = Visual Acuity; CCT = Central Corneal Thickness. **VA - Baseline vs Week 1**: Cohen's d = 2.15 which is **2.7 times larger** than Cohen's "large" threshold (0.8). **VA - Baseline vs Week 3**: Cohen's d = 4.37 which is **5.5 times larger** than the "large" threshold. **CCT Reduction:** Cohen's d = 2.51 which is **3.1 times larger** than "large" effect threshold.*

Statistical Power Analysis

Table 4: Post-hoc Power Calculations

Outcome	Observed Effect	Statistical Power	Minimum Detectable Effect
Visual Acuity (Week 3)	Cohen's d = 4.37	>99%	0.3 logMAR units
CCT Reduction	Cohen's d = 2.51	>99%	25 µm reduction

*Foot Note: High statistical power achieved despite small sample size due to very large effect sizes. Actual Visual Acuity effect (0.701 logMAR) is **2.3 times larger** than this minimum. logMAR = logarithm of the minimum angle of resolution; Actual CCT reduction (57 µm) is **2.3 times larger** than detectable minimum. CCT = Central Corneal Thickness.*

Age vs Treatment Response

Visual Acuity Improvement vs Pearson correlation coefficient (r)

r = -0.226:

- Interpretation: There is a weak negative linear relationship between visual acuity improvement and the other variable being examined. As one increases, the other tends to decrease slightly, but the association is weak.

95% CI [-0.635, 0.275]:

- Interpretation: We are 95% confident that the true correlation lies somewhere in this interval. Because the interval includes 0, the observed association is not statistically distinguishable from no correlation.

p = 0.415:

- Interpretation: There is no statistically significant evidence of a linear relationship at common alpha levels (e.g., 0.05).

R^2 = 0.05 (5% variance explained):

- Interpretation: About 5% of the variance in visual acuity improvement is explained by the other variable (the one correlated with it). The remaining 95% is due to other factors or random variation.

CCT Reduction vs Pearson correlation coefficient (r)

r = -0.145:

- Interpretation: There is a very weak negative linear relationship between CCT reduction and the other variable.

95% CI [-0.588, 0.365]:

- Interpretation: The true correlation could be moderately negative or modestly positive; the interval includes 0, indicating uncertainty about any real association.

p = 0.606:

- Interpretation: There is no statistically significant correlation.

R^2 = 0.02 (2% variance explained):

- Interpretation: Only about 2% of the variance in CCT reduction is explained by the related variable. Most of the variability is due to other factors.

Gender Comparison (Independent t-tests) vs Treatment Response

Visual Acuity Improvement (Week 3)

Males:

- Mean±SD improvement: 0.683±0.187 logMAR units.

Females:

- Mean±SD improvement: 0.712±0.139 logMAR units.

Inferential statistics:

- t(13): Independent samples t-test with 13 degrees of freedom.
- t = -0.347 indicates very little difference between sex relative to within-group variability.
- p = 0.734: Not statistically significant (conventional threshold $p < 0.05$).
- Cohen's d = 0.18: Small effect size (difference between groups is small).

Interpretation

The reported means are close (0.683 vs 0.712 logMAR); the small effect size ($d \approx 0.18$) aligns with the non-significant p-value. A higher logMAR value indicates *worse* visual acuity, so the direction of "improvement" would depend on the baseline; this line alone does not indicate improvement magnitude without baseline values or post-treatment vs baseline comparison.

CCT Reduction (Week 3)

Males

- Mean±SD reduction: 54.2±28.5 μm.

Females

- Mean±SD reduction: 58.7±21.3 μm.

Inferential statistics

- t = -0.385: Little difference between sexes.
- p = 0.706: Not statistically significant.
- Cohen's d = 0.18: Small effect size.

Interpretation

The average thickness reduction is similar between sexes (roughly 54–59 μm). Small effect size and non-significant p-value suggest no substantial sex difference in CCT reduction at Week 3.

Time-to-Response Analysis

Week 1 vs Week 3 Improvement Rates

Percentage of Total Improvement Achieved by Week 1: Mean±SD: 54.9%±18.2%; 95%CI: [45.1%, 64.7%]; Range: 25.3%-89.1%.

Interpretation: Most patients achieve >50% of their total improvement by Week 1.

Safety Analysis

- No serious adverse events reported.
- Minor side effects include Conjunctival hyperemia noted in 2 patients (13.3%) and Eye irritation in 1 patient (6.7%).
- Discontinuation rate: 0/15 (0%).

Results Summary

A summary of results describing the demographics and clinical outcomes of this study were presented in the table (5) and figures (2,3,4,5,6) below.

Table 5: Summary of Demographics and Clinical Outcomes

Parameter	Value / Result	Statistical Test	Confidence Interval	t-value	p-value
Sample characteristics	15 eyes; age: 68.5 ± 3.4 (62–75); 9F/6M	—	—	—	—
Visual acuity (logMAR) – Baseline	0.852 ± 0.169	—	[0.759, 0.945]	—	—
Visual acuity (logMAR) – Week 1	0.467 ± 0.189 (vs baseline)	Paired t-test	[0.364, 0.570]	8.32	<0.0001
Visual acuity (logMAR) – Week 3	0.151 ± 0.150 (vs baseline)	Paired t-test	[0.069, 0.233]	16.90	<0.0001
Central corneal thickness (CCT, μm) – Baseline	597 ± 25	—	[583, 611]	—	—
Central corneal thickness (CCT, μm) – Post-treatment	540 ± 22 (Δ = −57 μm)	Paired t-test	[528, 552]	10.43	<0.0001
Correlation: age vs visual improvement	$R^2 \approx 0.05$ (no meaningful correlation)	Scatter-plot regression	[-0.635, 0.275]	—	0.415
Correlation: age vs CCT reduction	$R^2 \approx 0.02$ (no meaningful correlation)	Scatter-plot regression	[-0.588, 0.365]	—	0.606

Footnote: logMAR = logarithm of the minimum angle of resolution; CCT = central corneal thickness; F = female; M = male; SD = standard deviation; Δ = mean change from baseline; R^2 = coefficient of determination;

CI = confidence interval. Visual acuity measurements converted to logMAR for statistical analysis (lower logMAR values indicate better visual acuity). Paired t-tests were used to compare pre- and post-treatment outcomes. Pearson correlation analysis was performed to assess relationships between age and treatment response. Statistical significance was set at $p < 0.05$. All confidence intervals are reported at the 95% level.

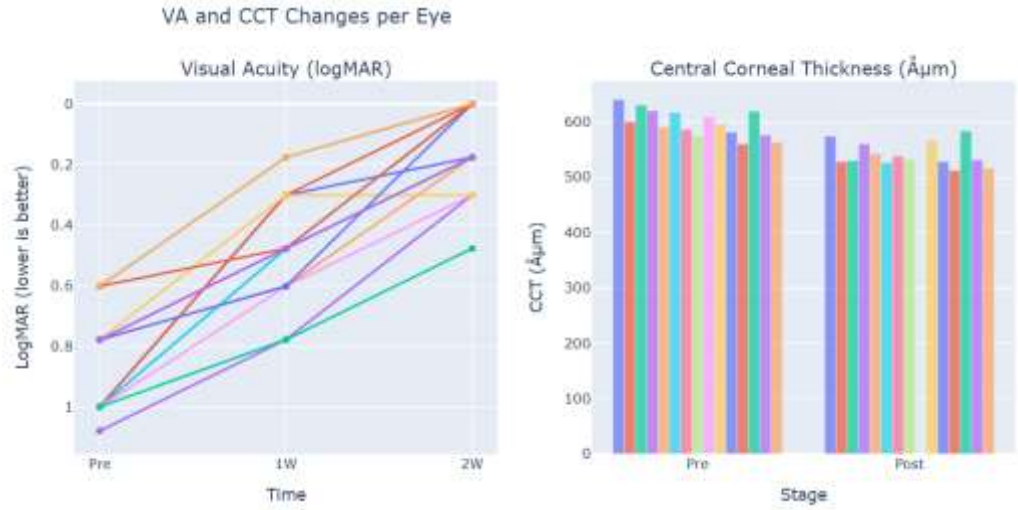


Figure 2: Visual Acuity and Central Corneal Thickness changes: Pre-Treatment vs Post-Treatment.

*# Left-hand panel – **Visual Acuity (logMAR):** Each coloured line represents one operated eye. Points show the individual VA measurements at Pre-op, 1 week, and 2 weeks. The y-axis is reversed so that lower logMAR (better vision) sits higher on the plot. Right-hand panel – **Central Corneal Thickness (µm):** Grouped bars show the paired Pre- and Post-operative CCT for the same eye, in the same colour as its VA trace. (Images created by AI tool – Vizly.) # = Foot Note.*

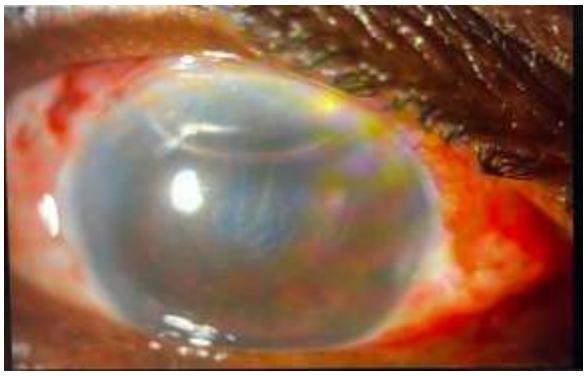


Figure 3: Pre-treatment - Corneal Edema.

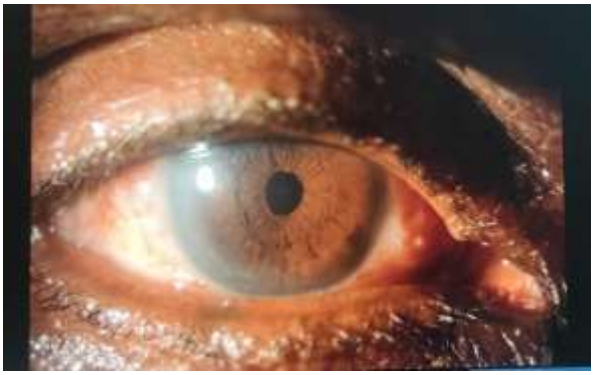


Figure 4: Post-treatment - No Corneal Edema.

 # Fig.3. and Fig.4. shows one of the patient's eye underwent cataract surgery following which there is a presence of corneal edema which responds to the treatment with Risapudil eye drops. Corneal edema before treatment and resolution of corneal edema after treatment seen in Fig.3. and Fig.4. respectively (Original Photos). # = Foot Note.

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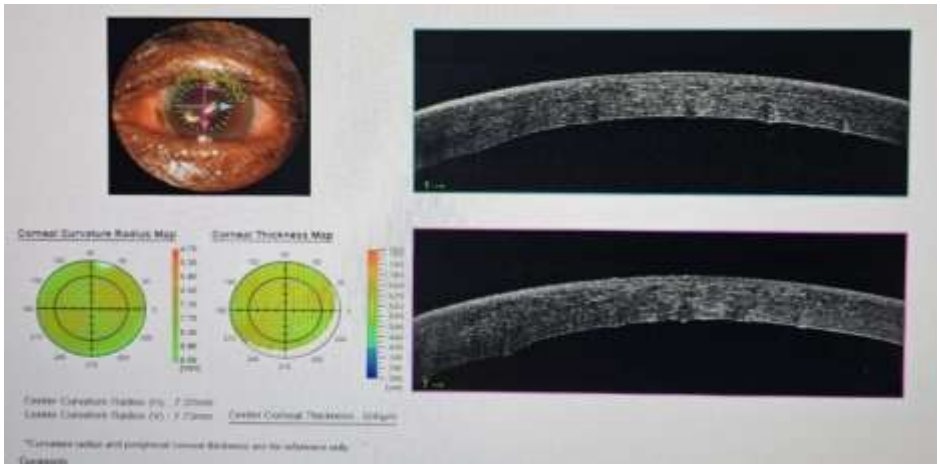

Figure 5: CCT Pre-treatment (606 µm).

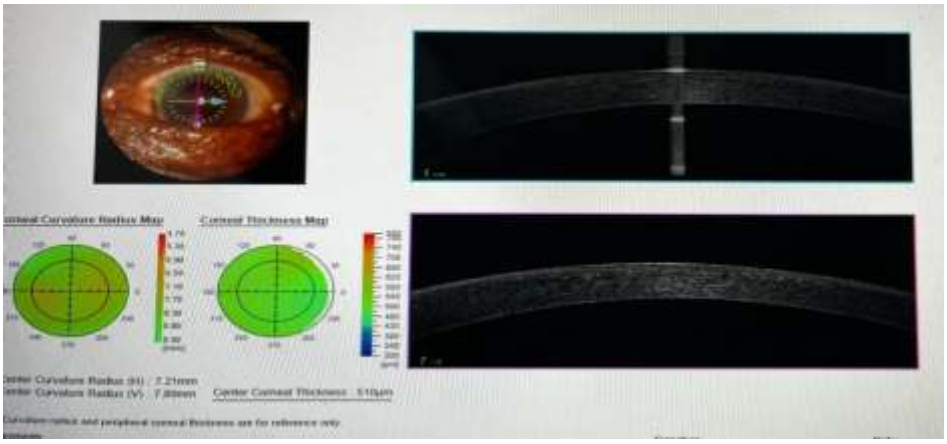

Figure 6: CCT Post-treatment (510 µm).

 # Picture of one of the patient's eye Central Corneal Thickness (CCT) shown before and after treatment with Risapudil eye drops in Fig.5. and Fig.6. respectively. It was noted that there is a reduction in the CCT after treatment (Original Photos). # = Foot Note.

DISCUSSION

Our observational study demonstrates the clinical benefit of Ripasudil 0.4% in accelerating recovery of vision and resolving corneal edema following cataract surgery. The findings reinforce the broader therapeutic relevance of ROCK inhibitors in promoting endothelial recovery.

Demographic Characteristics and Study Population

Our study population mirrored previously reported cataract demographics, with an average age of ~68 years and a slight female predominance. This is comparable to the cohort described by Lavy et al. (2019), who also evaluated Ripasudil in post-cataract endothelial outcomes [9]. The frequency of postoperative corneal edema observed in our tertiary care center was consistent with published incidence rates of 0.2%–2.4% [12].

Visual Acuity Outcomes: Comparison With Existing Evidence

Patients in our cohort experienced clinically meaningful and rapid gains in visual acuity. By the first postoperative week, vision had improved by nearly two lines, with over three lines gained by week 3. These findings exceed minimal thresholds for clinical significance and correspond to the restoration of corneal

clarity. Although direct comparison with previous Ripasudil trials is difficult due to differences in endpoints, the trend of improved corneal transparency aligns with earlier observations [9, 4].

Time Course of Recovery

In our study, more than half of the total visual improvement occurred within the first week, reflecting Ripasudil's swift pharmacologic action. This trajectory aligns with experimental models showing early endothelial healing and pump function restoration following ROCK inhibition. Okumura et al. (2015) demonstrated that ROCK inhibitor Y-27632 promotes endothelial wound healing within days through enhanced cell migration and reduced apoptosis [5]. Our clinical observations align with these experimental findings, suggesting that the therapeutic effects of Ripasudil manifest quickly once endothelial pump function begins to recover.

Corneal Thickness Outcomes: Mechanistic Validation

Quantitative CCT Reduction

The reduction in central corneal thickness (CCT) by 57 μm confirms anatomical resolution of edema, complementing functional improvements in visual acuity. More than 85% of patients achieved full normalization (≤560 μm), supporting the hypothesis that Ripasudil enhances endothelial pump activity through ROCK pathway modulation [4,5].

Comparison with Alternative Treatments

Traditional management strategies for corneal edema, such as hyperosmotic agents, provide only symptomatic relief and do not restore endothelial health [10]. In contrast, Ripasudil offers a mechanistically targeted approach, addressing the underlying dysfunction. The dual improvement in CCT and visual acuity highlights this therapeutic advantage.

Mechanistic Considerations and Biological Plausibility

ROCK Pathway Modulation

large effect sizes observed reinforce the centrality of ROCK signaling in endothelial integrity. By modulating this pathway, Ripasudil appears to restore pump and barrier functions disrupted by surgical trauma. As established by Bourne (2003), the corneal endothelium maintains transparency through active pump and barrier functions [1]. Our results support the hypothesis that ROCK inhibition effectively restores these critical functions following surgical trauma.

The biological plausibility of our findings is strengthened by the established mechanism of endothelial cell loss during cataract surgery. Bourne (2003) documented an 8.5% reduction in endothelial cell density one-year post-surgery [1], while Miyata et al. (2001) and Lass et al. (2011) confirmed that surgical trauma leads to immediate endothelial dysfunction [14,15]. Ripasudil's ability to inhibit apoptosis and promote cell migration, as demonstrated by Okumura et al. (2015) [5], directly addresses these pathophysiological processes.

Dose-Response Relationship

Administering Ripasudil at 0.4% twice daily aligns with its validated dosing for glaucoma, and our findings suggest this regimen is equally effective for corneal edema without notable adverse effects, as validated by Kinoshita et al. (2015) in their safety and efficacy analysis [16].

Clinical Significance and Therapeutic Implications

Comparative Effectiveness

The 73.3% rate of substantial visual improvement (>2.5 lines) in our study compares favorably with reported outcomes for alternative interventions. While direct comparative data are limited, traditional

treatments for corneal edema typically require weeks to months for significant improvement, whereas our patients demonstrated meaningful recovery within one week of Ripasudil initiation.

The universal response rate for CCT improvement (100% of patients showing some reduction) suggests that Ripasudil may be effective across a broad range of corneal edema severity, although our study was limited to patients with visual acuity ≤6/36, representing moderate to severe dysfunction.

Safety Profile Considerations

No serious adverse events were reported, and minor side effects such as transient hyperemia and irritation were infrequent. This aligns with the established safety profile of Ripasudil from glaucoma studies [7,16].

Study Limitations And Methodological Considerations

Despite the small sample size (n=15), the large effect sizes (Cohen's d > 2.0) yielded high statistical power (>99%). However, the limited cohort restricts subgroup analysis and generalizability.

The absence of a control group prevents definitive causal inference. Although spontaneous recovery from corneal edema is possible, the rapid improvement observed suggests a treatment effect. A randomized controlled trial would provide stronger evidence.

Being a single-center study, results may not extrapolate to other populations or surgical settings. Variations in patient demographics and techniques could influence outcomes.

Although standardized protocols were used, lack of masked assessments may introduce measurement bias. Future studies should incorporate blinding to enhance objectivity.

The short follow-up period (3 weeks) limits evaluation of long-term efficacy and safety. Extended monitoring is needed to assess durability and delayed adverse effects.

Recommendations

The promising results of this study warrant larger randomized controlled trials comparing Ripasudil with standard care or placebo.

Future research should include extended follow-up, formal safety monitoring, and cost-effectiveness analysis to establish its long-term role in managing post-cataract corneal edema.

Clinical Practice Implications

Ripasudil shows promise as a therapeutic option for postoperative corneal edema, offering rapid onset and substantial anatomical and visual recovery. Its favorable safety profile and ease of administration make it a practical adjunct in cases of endothelial dysfunction after cataract surgery.

While encouraging, these findings stem from a small observational study. Ripasudil should be considered investigational until validated by larger trials with long-term safety data.

CONCLUSION

Ripasudil 0.4% eye drops significantly reduced postoperative corneal edema and improved visual acuity within one week of treatment. These findings support its potential as a targeted adjunct therapy for endothelial dysfunction after cataract surgery. Larger controlled trials are needed to confirm efficacy and safety.

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