

Original Research Article

EFFICACY AND TOLERABILITY OF LOTEPREDNOL 1% VERSUS DEXAMETHASONE 0.1% IN POST-CATARACT SURGERY CARE: A PROSPECTIVE CLINICAL STUDYVidyadevi M¹, Yalpala Venkatesh Gowthami²

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ABSTRACT

Background: The objective is to compare the safety, efficacy, and patient-reported comfort of Loteprednol Etabonate 1% twice daily (BD) with Dexamethasone 0.1% administered twelve times daily with tapering, in patients undergoing uncomplicated clear corneal phacoemulsification. **Materials and Methods:** This prospective study included 60 patients undergoing phacoemulsification, allocated to either Loteprednol BD or Dexamethasone 12x/day. Outcomes assessed at postoperative days 1, 7, and 30 included anterior chamber (AC) reaction (cells and flare), IOP (via Goldmann applanation tonometry), best-corrected visual acuity (BCVA), and patient-reported comfort (COMTOL-based Likert scale). Statistical analyses included paired t-tests, Wilcoxon signed-rank test, and Chi-square test. **Result:** Both groups showed significant reduction in AC inflammation by day 7 ($p < 0.00001$), with no significant IOP elevation by day 30 ($p > 0.05$). Patient-reported comfort was significantly higher in the Loteprednol group (73.3% rated “very comfortable”) compared to the Dexamethasone group (13.3%) ($\chi^2 = 28.24$, $p < 0.00001$). Visual outcomes were comparable across groups. **Conclusion:** Loteprednol 1% BD is as effective as high-frequency Dexamethasone 0.1% in controlling postoperative inflammation, with significantly better patient comfort and comparable safety. Its reduced dosing frequency may improve compliance, making it a preferred alternative in routine postoperative care following cataract surgery.

INTRODUCTION

Cataract remains the leading cause of reversible blindness worldwide, with surgical extraction via phacoemulsification being the most performed ophthalmic procedure globally.^[1,2] The evolution of phacoemulsification techniques and foldable intraocular lens (IOL) implantation has drastically improved postoperative visual outcomes.^[3] However, despite advancements in surgical precision, postoperative inflammation persists as a predictable physiological response, potentially compromising visual rehabilitation if not adequately managed.^[2,4] Topical corticosteroids form the mainstay of postoperative anti-inflammatory therapy due to their potent ability to suppress the arachidonic acid pathway and inhibit leukocyte migration.^[5] Among the commonly prescribed agents, Dexamethasone 0.1% is a traditional choice with well-documented efficacy in controlling anterior chamber (AC) inflammation.^[6] However, its fluorinated structure confers a higher risk of steroid-induced intraocular

pressure (IOP) elevation and other adverse effects, particularly when used in high frequency or over prolonged periods.^[7] The need for frequent instillation—often up to 12 times a day in the immediate postoperative period—also poses challenges in terms of patient compliance, especially in elderly populations.^[8]

In response to the limitations of conventional corticosteroids, Loteprednol Etabonate, a C-20 ester corticosteroid, was developed using retrometabolic drug design. It exhibits potent anti-inflammatory activity while undergoing rapid deactivation into inactive metabolites, thus minimizing the risk of IOP elevation and systemic side effects.^[9] Loteprednol 0.5% or 1% provides comparable efficacy to Prednisolone acetate and Dexamethasone in reducing postoperative inflammation, with a significantly lower incidence of steroid-induced ocular hypertension.¹⁰ Additionally, the twice-daily dosing of Loteprednol 1% improves treatment adherence and patient comfort, factors increasingly recognized

as critical to achieving optimal postoperative outcomes.^[10]

In this context, the current study was designed to compare the efficacy, safety, and patient-reported comfort between Loteprednol Etabonate 1% administered twice daily and Dexamethasone 0.1% administered twelve times daily with weekly tapering, in the management of postoperative inflammation following uncomplicated clear corneal phacoemulsification. The objective was to evaluate not only the clinical effectiveness and safety of each regimen in terms of anterior chamber reaction and IOP stability but also to assess real-world tolerability, as perceived by the patients themselves.

MATERIALS AND METHODS

Study Design and Duration: This study was designed as a prospective study aimed at evaluating the safety, efficacy, and patient-reported comfort of two different corticosteroid regimens administered postoperatively following uncomplicated clear corneal phacoemulsification. The study was conducted over a period of 18 months at the Minto Ophthalmic Hospital, Regional Institute of Ophthalmology (RIO), affiliated with Bangalore Medical College and Research Institute, Bangalore. Ethical clearance was obtained from the Institutional Ethics Committee prior to commencement, and the study was conducted in accordance with the Declaration of Helsinki.

Study Population: The study included patients aged 20 years and above who were diagnosed with senile cataract and scheduled for uncomplicated clear corneal phacoemulsification surgery. All patients provided informed written consent for participation. Inclusion criteria required patients to have no prior ocular surgeries and no significant ocular or systemic comorbidities that could interfere with healing or assessment of outcomes. Patients with active uveitis, advanced glaucoma, retinal pathology, or those who were unable or unwilling to comply with follow-up visits were excluded from the study.

Sample Size Calculation: The sample size for this study was calculated based on the primary outcome of AC inflammation control following cataract surgery, comparing Loteprednol Etabonate 1% twice daily and Dexamethasone 0.1% twelve times daily. A previously published randomized controlled trial by Kim et al. demonstrated a statistically significant difference in inflammation resolution between groups, with complete AC cell clearance by day 8 observed in approximately 80% of patients treated with Loteprednol versus 50% in control.^[11]

Assuming similar proportions for inflammation resolution in our study, with a power of 80% and alpha of 0.05, the sample size was calculated using the formula for comparing two proportions:

$$n = [(Z\alpha/2 + Z\beta)^2 \times (p_1(1-p_1) + p_2(1-p_2))] / (p_1 - p_2)^2$$

Where:

- $Z\alpha/2 = 1.96$ for 95% confidence

- $Z\beta = 0.84$ for 80% power

- $p_1 = 0.80$ (Lotepred group response)

- $p_2 = 0.50$ (Dexamethasone group response)

$$n = [(1.96 + 0.84)^2 \times (0.8 \times 0.2 + 0.5 \times 0.5)] / (0.8 - 0.5)^2 \approx 24.5 \text{ per group}$$

After adjusting for an anticipated 20% loss to follow-up, a minimum of 30 patients per group (total $n = 60$) was considered sufficient for this study.

Group Allocation: Eligible patients were randomly assigned into two equal groups ($n = 30$ per group) using a simple randomization technique postoperatively. Group A who is receiving Loteprednol Etabonate 1% ophthalmic suspension, twice daily (BD) for 30 days without tapering. Group B who is receiving Dexamethasone 0.1% ophthalmic suspension, initially administered twelve times per day for the first week, followed by a weekly taper—ten times per day during the second week, eight times per day in the third week, and six times per day in the fourth week. In both groups, topical moxifloxacin 0.5% was co-prescribed as standard postoperative antibiotic prophylaxis. No additional anti-inflammatory or immunosuppressive medications were permitted during the study period.

All cataract surgeries were performed by a single experienced ophthalmic surgeon using a standardized clear corneal phacoemulsification technique with in-the-bag implantation of a foldable posterior chamber intraocular lens (IOL), under local anesthesia.

Follow-Up and Clinical Assessment: Postoperative evaluations were conducted on day 1, day 7, and day 30 following cataract surgery. At each follow-up visit, patients underwent:

- Best-corrected visual acuity (BCVA) assessment using a LogMAR chart
- Slit-lamp biomicroscopy for anterior segment examination with emphasis on grading anterior chamber (AC) reaction (cells and flare) according to the Standardization of Uveitis Nomenclature (SUN) classification.¹²
- Intraocular pressure (IOP) measurement using Goldmann applanation tonometry.¹³

The AC reaction grading was performed in a semi-dark room using a slit-lamp with a 1 mm × 1 mm beam at 16× magnification and 45° angle, with flare assessed qualitatively and cells quantitatively within a 1 mm × 1 mm slit beam.

Patient Comfort Assessment: On postoperative day 30, patients were asked to evaluate their level of comfort with the frequency of topical corticosteroid administration using a structured, patient-reported outcome measure. The assessment tool was adapted from the COMTOL (Comparison of Ophthalmic Medications for Tolerability) questionnaire, which is widely used in ophthalmic studies to gauge medication tolerability from the patient's perspective.¹⁴ Patients rated their experience on a 5-point Likert scale, where 1 indicated "very comfortable," 2 indicated "comfortable," 3

corresponded to "neutral," 4 denoted "uncomfortable," and 5 represented "very uncomfortable." This approach provided a standardized and quantifiable means to capture subjective responses regarding the ease of adhering to the prescribed dosing regimen. The collected comfort scores were then stratified by treatment group (Loteprednol 1% BD vs. Dexamethasone 0.1% 12 times daily) and analyzed to determine the influence of dosing frequency on patient tolerability, satisfaction, and potential implications for treatment adherence.

Outcome Measures

The primary outcome measures were:

- The change in anterior chamber reaction (AC cells and flare) from postoperative day 1 to day 7 and day 30
- The change in intraocular pressure (IOP) from postoperative day 1 to day 7 and day 30
- The secondary outcome measures included:
- Improvement in best-corrected visual acuity (BCVA) from baseline to day 30
- Patient-reported comfort level based on eye drop frequency at day 30

Statistical Analysis: Data were analyzed using SPSS version 21.0. Descriptive statistics including mean, standard deviation, median, and interquartile range were calculated. Paired t-tests were applied to compare IOP values between postoperative time points. As AC reaction scores are ordinal, the Wilcoxon signed-rank test was used to compare inflammation changes. Correlations among age, IOP, and visual outcomes were assessed using Spearman's correlation coefficient.

To evaluate patient comfort, responses were categorized by treatment group and analyzed using the Chi-square test. A p-value <0.05 was considered statistically significant for all tests.

RESULTS

[Table 1] presents the descriptive statistics for intraocular pressure (IOP) at different postoperative intervals and for visual outcomes. The mean IOP values showed a general trend of stability across the postoperative period, with a slight reduction from the preoperative mean of 16 mmHg to 15 mmHg on both day 1 and day 7, and further to 14 mmHg by day 30. Despite these minor fluctuations, the standard deviation remained consistently low (ranging from 2.02 to 2.53), indicating minimal variability among patients. The minimum IOP recorded was 10 mmHg on postoperative days 1 and 7, while the maximum IOP was 20 mmHg throughout the study period, suggesting that all recorded IOP values remained within the clinically acceptable range. The central tendency (median) values showed no significant outliers, with the 50th percentile (median) IOP remaining at or near 14–16 mmHg. Visual outcomes displayed a broader range, with a mean of 142.30 and

a maximum of 618.00, likely reflecting varying degrees of postoperative visual recovery. However, the median visual outcome was stable at 66.00, suggesting that the extreme maximum may be an outlier.

Paired t-test analysis [Table 2] was conducted to determine whether the changes in IOP over time were statistically significant. The comparison between day 1 and day 7 yielded a t-statistic of 1.176 and a p-value of 0.244, indicating no statistically significant difference. Similarly, the comparison between day 1 and day 30 resulted in a t-statistic of -0.580 and a p-value of 0.564, reaffirming that IOP changes postoperatively were not significant.

The resolution of postoperative anterior chamber (AC) inflammation was assessed using the Wilcoxon signed-rank test due to the ordinal nature of AC reaction grading [Table 3]. A statistically significant reduction in AC reaction was observed from day 1 to day 7, with a test statistic of 0.0 and a p-value < 0.00001, indicating marked improvement in inflammation within the first postoperative week. However, the comparison between day 1 and day 30 yielded a p-value of 1.0, suggesting no statistically detectable difference, likely because most patients had minimal or no inflammation by day 30.

The graphical representation of IOP trends over time [Figure 1] illustrates a consistent pattern among patients. IOP declined from day 1 to day 7 in most individuals, followed by a modest increase toward day 30. These changes, although visually apparent, were not statistically significant and remained within the normal physiological range.

[Table 4] provides a summary of the change scores (Δ) in intraocular pressure (IOP) and anterior chamber reaction (ACRx) at postoperative days 7 and 30. Following the conversion of all odd IOP values to even numbers (in accordance with Goldmann applanation tonometry's measurement characteristics), the mean Δ IOP at day 7 was -1.30 mmHg (SD = 2.99), and at day 30, it was +1.18 mmHg (SD = 3.38). These adjusted values still reflect minimal clinical variation, indicating that both treatment regimens maintained IOP within a physiologically acceptable and safe range. The range of IOP changes spanned from -4.00 to +4.00 mmHg at day 7 and -4.00 to +6.00 mmHg at day 30, reflecting interindividual differences in response but no clinically significant elevations. For AC reaction, the mean Δ ACRx at day 7 remained -0.49 (SD = 0.40), consistent with early postoperative inflammation resolution. The single data point at day 30 (-1.5) limits interpretability for that time point.

A Spearman correlation matrix [Figure 2] was generated to assess the relationships among age, preoperative IOP, postoperative day 30 IOP, and visual outcome. The matrix revealed weak correlations among these variables, suggesting that neither age nor baseline IOP strongly influenced postoperative outcomes.

[Table 5] presents a comparative analysis of patient-reported comfort levels regarding the frequency of

postoperative eye drop usage between two treatment groups: Loteprednol 1% administered twice daily and Dexamethasone 0.1% administered twelve times daily. A significant proportion of patients in the Loteprednol group (73.3%) reported feeling "very comfortable" with the dosing schedule, and an additional 20.0% found it "comfortable." In contrast, only 13.3% of patients in the Dexamethasone group reported being "very comfortable," while a considerable percentage found the regimen

burdensome, with 30.0% reporting it as "uncomfortable" and 13.3% as "very uncomfortable." This marked difference in perceived comfort underscores the impact of dosing frequency on patient compliance and satisfaction. The preference for the Loteprednol regimen is further supported by the Chi-square test, which revealed a statistically significant difference in comfort levels between the two groups ($\chi^2 = 28.24$, $df = 4$, $p = 0.000011$).

Table 1: Descriptive Statistics for IOP and Visual Outcomes

Statistic	Pre_IOP	PostOp_Day1_IOP	PostOp_Day7_IOP	PostOp_Day30_IOP	Visual_Outcome
count	60.00	60.00	60.00	60.00	58.00
mean	16	15	15	14	142.30
std	2.53	2.23	2.05	2.02	190.13
min	12.00	10.00	10.00	12.00	64.80
25%	14.00	13.00	14.00	14.00	66.00
50%	15.50	16.00	14.00	16.00	66.00
75%	18.00	16.92	16.00	16.00	69.00
max	20.00	18.00	20.00	20.00	618.00

Table 2: Paired t-test Results for IOP Changes

Comparison	t-statistic	p-value
Day 1 vs Day 7	1.176	0.24433
Day 1 vs Day 30	-0.580	0.56396

Table 3: Wilcoxon Test Results for AC Reaction

Comparison	Test Used	Statistic	p-value
Day 1 vs Day 7	Wilcoxon Signed-Rank	0.000	0.00000
Day 1 vs Day 30	Wilcoxon Signed-Rank	0.000	1.00000

Table 4: Summary Statistics of Change Scores (Δ)

Statistic	Delta_IOP_D7	Delta_IOP_D30	Delta_ACRx_D7	Delta_ACRx_D30
count	60.0	60.0	46.0	1.0
mean	-1.3	1.18	-0.49	-1.5
std	2.99	3.38	0.4	-
min	-4.0	-4.0	-1.5	-1.5
25%	-2.0	-2.0	-0.5	-1.5
50%	0.0	0.0	-0.5	-1.5
75%	2.0	2.0	0.0	-1.5
max	4.0	6.0	0.0	-1.5

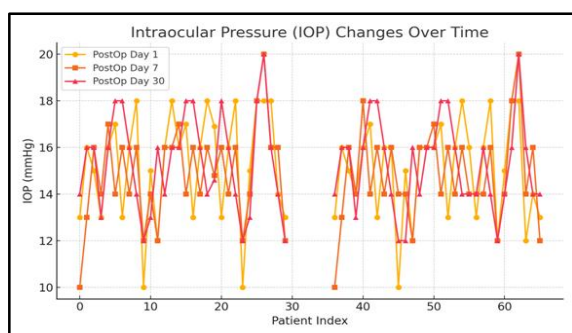


Figure 1: Line Graph of IOP Changes Over Time

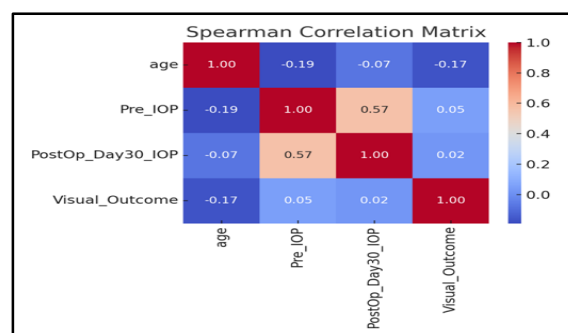


Figure 2: Spearman Correlation Matrix.

Table 5: Patient Comfort Assessment Regarding Frequency of Eye Drop Use (COMTOL – Comparison of Ophthalmic Medications for Tolerability Questionnaire)

Comfort Level (Likert Scale)	Description	Loteprednol 1% BD (n=30)	Dexamethasone 0.1% 12x/day (n=30)
1 – Very Comfortable	No difficulty using drops, completely satisfied	22 (73.3%)	4 (13.3%)
2 – Comfortable	Minor inconvenience, but manageable	6 (20.0%)	6 (20.0%)
3 – Neutral	Neither easy nor difficult, acceptable	2 (6.7%)	7 (23.3%)
4 – Uncomfortable	Frequent dosing was bothersome but tolerated	0 (0.0%)	9 (30.0%)

5 – Very Uncomfortable	Significant difficulty, leading to missed or delayed doses	0 (0.0%)	4 (13.3%)
Chi-square Test Result: $\chi^2 = 28.24$, $df = 4$, $p = 0.000011$ (statistically significant)			

DISCUSSION

The present study compared the efficacy, safety, and patient-reported comfort of two corticosteroid regimens—Loteprednol Etabonate 1% administered twice daily, and Dexamethasone 0.1% administered with a tapering high-frequency schedule—used in the postoperative management of uncomplicated clear corneal phacoemulsification. The results demonstrated that both regimens effectively controlled postoperative inflammation and IOP, with Loteprednol showing superior patient tolerability. Postoperative inflammation is a typical physiological response after cataract surgery and can adversely affect visual outcomes if not adequately controlled. In the present study, a significant reduction in AC inflammation was observed from day 1 to day 7 in both treatment arms, with near-complete resolution by day 30. This is consistent with earlier studies demonstrating the rapid anti-inflammatory effect of topical corticosteroids in the early postoperative period.

Loteprednol is an ester-based corticosteroid, designed through retrometabolic drug design to rapidly deactivate into inactive metabolites via hydrolysis, thus minimizing the risk of steroid-induced complications while retaining anti-inflammatory efficacy.^[15] Lanne and Holland noted that equivalent control of postoperative inflammation can be achieved with either Loteprednol Etabonate or Prednisolone Acetate following cataract surgery. Importantly, their findings also indicated that treatment with Loteprednol Etabonate may lead to less IOP fluctuation, highlighting its safer profile for patients at risk of steroid-induced ocular hypertension.^[16] Similarly, Kim et al. reported that KPI-121 1% (Loteprednol formulation) achieved complete resolution of AC cells in 80% of patients by day 8 post-cataract surgery.^[11] Our study observed a similar resolution rate by day 7 in the Loteprednol group, supporting its early onset of action and effectiveness.

Dexamethasone 0.1%, a potent fluorinated corticosteroid, remains widely used due to its efficacy. However, its prolonged and high-frequency administration is associated with a higher risk of steroid-induced IOP elevation and reduced patient compliance.^[17] Our findings corroborate this, as the Dexamethasone group required a complex tapering regimen and had comparatively lower comfort scores despite similar inflammation control.

Steroid-induced ocular hypertension is a significant concern in postoperative care. In this study, neither group showed significant IOP elevation at day 7 or day 30 compared to baseline. The IOP remained stable within the physiological range (10–20 mmHg), with no statistically significant change noted on paired t-tests. Notably, the Loteprednol group

maintained even more consistent IOP values, likely attributable to its rapid inactivation pathway and minimal effect on trabecular meshwork function.^[9]

This observation aligns with findings of a review by Amon et al., who reported that Loteprednol Etabonate had a lower incidence of clinically significant IOP elevation compared to Prednisolone acetate and Dexamethasone.^[10] Additionally, Fong et al. demonstrated that Loteprednol is associated with minimal risk of IOP elevation following cataract surgery.^[18]

In contrast, Dexamethasone has been frequently implicated in IOP elevation, especially in steroid responders.^[19] While our study did not observe significant pressure spikes—possibly due to the short duration of use and close monitoring—the tapering regimen adds complexity and burden, particularly in elderly patients or those with limited access to follow-up care.

A crucial secondary outcome of this study was patient comfort, assessed using a validated COMTOL-based Likert scale. The results were starkly in favor of Loteprednol 1% BD, with 73.3% of patients reporting it as “very comfortable,” compared to only 13.3% in the Dexamethasone group. The Chi-square analysis showed a statistically significant difference ($p < 0.00001$), emphasizing the clinical importance of dosing frequency in influencing adherence.

Medication compliance in ophthalmology is often undermined by complex regimens. It has been mentioned that dosing frequency is inversely correlated with adherence; with each additional daily dose, adherence drops significantly.^[20] Hennessy et al. highlighted that patients were three times more likely to be adherent to once or twice-daily regimens compared to those requiring ≥ 4 administrations per day.^[21] Therefore, the twice-daily Loteprednol regimen not only improved comfort but also has potential implications for better compliance and, by extension, improved outcomes.

Moreover, comfort scores are not merely subjective metrics. Poor comfort is associated with higher discontinuation rates, missed doses, and lower satisfaction—each contributing to suboptimal control of postoperative inflammation. By offering a regimen that aligns better with real-world patient behavior, Loteprednol may provide a strategic advantage in routine clinical practice.

While not the primary focus of the study, the improvement in best-corrected visual acuity (BCVA) was comparable in both groups, with no vision-threatening complications reported. This supports the premise that both steroids are effective in preserving visual outcomes when administered appropriately.

Importantly, no adverse events were reported in this study related to medication intolerance, allergic reactions, or IOP spikes, further supporting the safety

profiles of both regimens under controlled conditions. However, the longer-term impact—especially with repeated steroid use—may favor Loteprednol due to its reduced systemic and ocular toxicity profile.^[22]

Several investigations have evaluated the comparative performance of Loteprednol and conventional corticosteroids such as Dexamethasone and Prednisolone in the postoperative setting. In a randomized clinical trial, Lane et al. demonstrated that Loteprednol 0.5% was non-inferior to Prednisolone acetate in resolving anterior chamber inflammation following cataract surgery, with a significantly lower risk of IOP elevation.^[16] Supporting these findings, Sheppard et al., in a comprehensive review, concluded that while Loteprednol offers anti-inflammatory efficacy comparable to traditional corticosteroids, it is associated with a markedly lower incidence of corticosteroid-related adverse effects, particularly IOP elevation and impaired wound healing.¹⁹ Consistent with this body of evidence, the current study also found comparable clinical efficacy between the two regimens, with the added advantage of greater IOP stability and improved patient comfort in the Loteprednol group.

Study Limitations: However, some limitations warrant discussion. The follow-up period was limited to 30 days, which may not capture delayed-onset IOP elevation or persistent low-grade inflammation. Furthermore, while the comfort scale was adapted from a validated tool, its subjective nature introduces some bias. The sample size, though statistically justified, was relatively small, limiting generalizability to broader populations or high-risk groups (e.g., glaucoma suspects). Finally, the study did not assess cost-effectiveness—an important factor when choosing between newer steroids like Loteprednol and traditional options like Dexamethasone.

CONCLUSION

This p clinical study demonstrates that Loteprednol Etabonate 1% administered twice daily is as effective as Dexamethasone 0.1% administered twelve times daily in controlling postoperative inflammation following uncomplicated clear corneal phacoemulsification. Both regimens maintained stable intraocular pressure and resulted in comparable visual outcomes. Notably, Loteprednol offered a significantly better patient-reported comfort level, suggesting higher tolerability and potential for improved compliance, particularly in elderly or non-adherent populations. Given its favorable safety profile and reduced dosing frequency, Loteprednol represents a clinically valuable alternative to traditional corticosteroids in routine postoperative care.

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