

Dexamethasone Intravitreal Implant in Diabetic Patients Undergoing Cataract Surgery in King Saud Hospital, Unaizah

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ABSTRACT:

Background: Diabetic patients undergoing cataract surgery face an elevated risk of postoperative inflammation and macular edema, which can compromise visual outcomes. The dexamethasone intravitreal implant (Ozurdex®) provides sustained anti-inflammatory action and has shown promise in reducing these complications, although region-specific evidence from Saudi Arabia remains limited.

Objective: To evaluate the effectiveness and safety of the dexamethasone intravitreal implant on visual acuity and macular thickness in diabetic patients undergoing cataract surgery at King Saud Hospital, Unaizah.

Methods: A cross-sectional retrospective study reviewed the de-identified records of 80 diabetic patients who received a dexamethasone intravitreal implant following cataract surgery at the Eye Center, King Saud Hospital, Unaizah. Visual acuity (Snellen chart) and macular thickness (Topcon Maestro 2 optical coherence tomography) were assessed before and after treatment, and data were analyzed descriptively using SPSS.

Results: Mean visual acuity improved from 0.380 ± 0.1757 to 0.540 ± 0.2113 , while mean macular thickness decreased from $391.01 \pm 105.934 \mu\text{m}$ to $310.50 \pm 74.897 \mu\text{m}$ following implantation ($p < 0.05$), with consistent improvement observed across all measured percentiles.

Conclusion: Dexamethasone intravitreal implantation was associated with statistically significant improvements in visual acuity and reductions in macular thickness among diabetic patients undergoing cataract surgery, supporting its use as an effective and safe adjunct therapy in this population within the Saudi healthcare context.

Keywords: Diabetic Retinopathy, Visual Impairment, Cataract, Macular Edema, Diabetes

1. Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. It represents one of the most prevalent and challenging global health problems, affecting hundreds of millions of individuals worldwide. The condition is broadly classified into Type 1 diabetes, an autoimmune destruction of pancreatic β -cells leading to absolute insulin deficiency, and Type 2 diabetes, which results primarily from insulin resistance accompanied by a relative insulin deficiency. Long-term uncontrolled diabetes can lead to widespread microvascular and macrovascular complications that significantly reduce quality of life (1).

Diabetes mellitus has profound effects on the visual system, with the eye being one of the most affected organs. Chronic hyperglycemia leads to structural and functional changes in the ocular tissues, primarily through microvascular damage, oxidative stress, and inflammation. The most significant ocular manifestation is diabetic retinopathy (DR), a progressive disease of the retinal microvasculature that can culminate in vision loss. Early stages of DR are characterized by microaneurysms, hemorrhages, and vascular leakage, while advanced stages may involve neovascularization and vitreous hemorrhage. Another major vision-threatening condition associated with diabetes is diabetic macular edema (DME), resulting from the breakdown of the blood–retinal barrier and accumulation of fluid within the macula. In addition, diabetic patients are at increased risk of developing cataracts, glaucoma, and delayed wound healing after ocular surgery. These complications collectively make diabetes one of the leading causes of preventable blindness worldwide. Regular ophthalmic examinations and timely intervention are therefore essential to preserve vision and improve the quality of life in diabetic individuals (2,3).

Cataract is the clouding of the eye's natural lens, leading to blurred vision and, if untreated, potential vision loss. Cataract surgery in diabetic

patients is often complicated by heightened inflammation and delayed healing. Diabetes creates a pro-inflammatory ocular environment, increasing the risk of macular edema, progression of retinopathy, and corneal recovery delays after surgery. Surgical trauma can trigger the release of inflammatory mediators such as Interleukin-6 (IL-6) and Vascular Endothelial Growth Factor (VEGF), disrupting the blood–retinal barrier and worsening diabetic macular edema (DME). Careful retinal assessment, good glycemic control, and perioperative anti-inflammatory therapy — including topical steroids, non-steroidal anti-inflammatory drugs (NSAIDs), or intravitreal dexamethasone implants — are essential to minimize complications and achieve favorable visual outcomes (4).

The management of diabetic retinal diseases, particularly diabetic macular edema (DME), has evolved significantly with the introduction of sustained-release intravitreal corticosteroid therapy. The dexamethasone intravitreal implant (DEX implant; Ozurdex®; Allergan, Inc., Irvine, CA) is a biodegradable implant approved for the treatment of macular edema related to retinal vein occlusion and noninfectious posterior segment uveitis, releasing the potent corticosteroid dexamethasone into the vitreous over a period of up to six months (5). It plays a key role in reducing inflammation and vascular leakage in the diabetic retina by suppressing pro-inflammatory cytokines such as VEGF, IL-6, and tumor necrosis factor- α (TNF- α) (6), thereby stabilizing the blood–retinal barrier and decreasing macular thickness (7). The implant provides a sustained and controlled release of the drug over several months, offering a valuable option for patients who are resistant or non-responsive to anti-VEGF therapy, with studies demonstrating significant improvement in best-corrected visual acuity (BCVA) and reduction in central retinal thickness (CRT) following administration (8). However, potential adverse effects, including elevated intraocular pressure (IOP) and cataract progression, necessitate careful patient selection and regular monitoring.

2. Literature Review

The global burden of diabetes mellitus continues to expand rapidly, with the International Diabetes Federation projecting sustained increases in prevalence worldwide through 2045 (1). Within Saudi Arabia specifically, systematic reviews and meta-analyses have documented a substantial prevalence of diabetic retinopathy among adults with diabetes, identifying disease duration, glycemic control, and hypertension as key predictors of ocular involvement (10). These regional findings underscore the scale of diabetic eye disease as a public health priority, consistent with the broader objectives of the Vision 2030 Healthcare Transformation Initiative to strengthen non-communicable disease management across the Kingdom.

Cataract formation is recognized as one of the earliest and most common ocular complications of diabetes, with pathogenesis linked to osmotic and oxidative stress within the lens (2). A systematic review of cataract surgery outcomes in diabetic patients found a consistently elevated risk of postoperative inflammation, macular edema, and delayed visual recovery compared with non-diabetic patients, prompting calls for tailored perioperative management protocols in this population (4).

The sustained-release dexamethasone intravitreal implant was developed to maintain therapeutic corticosteroid concentrations within the vitreous over an extended period while minimizing the burden of repeated intravitreal injections (5). Mechanistically, dexamethasone suppresses key inflammatory mediators implicated in diabetic macular edema, including VEGF and IL-6, supporting restoration of the blood–retinal barrier (6,7). Large randomized controlled trials have demonstrated statistically significant gains in best-corrected visual acuity and reductions in central retinal thickness with implant therapy relative to sham treatment (9), while real-world cohort studies have generally reproduced these benefits outside the controlled trial setting, albeit with more heterogeneous outcomes (8).

Despite this accumulating evidence base, diabetic ocular complications — including DME and

cataract — remain major causes of visual impairment in Saudi Arabia (10), and data on the perioperative use of dexamethasone implants in diabetic patients undergoing cataract surgery within the Saudi population, particularly regarding timing, safety, and outcomes, remain limited. Most available evidence on implant efficacy originates from international cohorts (7,8,9), while regional epidemiological data describe the burden of diabetic eye disease without directly evaluating implant-assisted surgical pathways (10). Conducting this study at King Saud Hospital, Unaizah, helps address these knowledge gaps, provides region-specific evidence, and guides optimized, individualized management strategies for diabetic patients in Saudi Arabia.

3. Statement of the Problem

Diabetic patients undergoing cataract surgery are more likely to develop inflammation and macular edema following the procedure, which can have a poor impact on visual outcomes. Although traditional treatments are used to manage these complications, they may not always be effective. The dexamethasone intravitreal implant is thought to be a viable alternative for improving these outcomes. As a result, the purpose of this study is to determine its impact on visual acuity and macular thickness in diabetic individuals following cataract surgery.

4. Aim and Objectives

4.1 Aim of the Study

To assess the effectiveness and safety of the dexamethasone intravitreal implant in diabetic patients undergoing cataract surgery, especially its effect on visual acuity and macular thickness.

4.2 Objectives of the Study

- ◆ To evaluate changes in visual acuity before and after treatment.
- ◆ To measure changes in macular thickness before and after therapy.
- ◆ To assess the efficacy of a dexamethasone intravitreal implant in decreasing postoperative inflammation.

4.3 Research Hypothesis

Diabetic patients following cataract surgery benefit from a dexamethasone intravitreal implant, which improves visual acuity and lowers macular thickness ($p < 0.05$).

4.4 Research Questions

Does the dexamethasone intravitreal implant increase visual acuity and enhance macular thickness in diabetic individuals undergoing cataract surgery?

5. Research Design and Methods

5.1 Research Design

A cross-sectional retrospective study.

5.2 Study Population and Sampling

The study population comprised recorded cases of patients who received cataract surgery with a dexamethasone implant at the Eye Center, King Saud Hospital, Unaizah.

6. Criteria Of Selection

6.1 Inclusion Criteria

All ages of diabetic patients of all types with cataract.

6.2 Exclusion Criteria

Diabetic patients of all types without cataract, and non-diabetic patients.

7. Ethical Considerations

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and the research-governance standards adopted by the Saudi Commission for Health Specialties (SCFHS) and the Ministry of Health (MOH). As a retrospective, cross-sectional review of de-identified clinical records, the study posed minimal risk to participants, with data extracted exclusively from existing patient files maintained at the Eye Center, King Saud Hospital, Unaizah.

- ◆ Approval was obtained from the relevant institutional research and ethics committee prior to data collection.
- ◆ All patient identifiers were removed or coded to ensure confidentiality and

anonymity throughout data handling and analysis.

- ◆ Given the retrospective design, the requirement for individual informed consent was waived, consistent with standard ethical practice for de-identified record-based research.
- ◆ Data were stored and accessed in accordance with institutional data-governance and health-information-security protocols.
- ◆ The authors declare no conflict of interest associated with this research.

8. Data Analysis

Data analysis was completed using the Statistical Package for the Social Sciences (SPSS). The data were analyzed using descriptive statistics, including the mean and standard deviation, and percentiles, as appropriate.

9. Results

The study had 80 participants, which provides a sufficient sample size to evaluate the results and assess the reliability of the findings. The mean age of diabetic patients receiving a dexamethasone intravitreal implant was 53 years, with a variation of ± 13 years, with ages between 40 and 66 years old representing the typical age group affected by diabetic eye complications (Figure 1). Regarding gender distribution, 54% of the participants were males and 46% were females, suggesting that both groups were almost equally represented (Figure 2).

Pre-Treatment Assessment

In the pre-visual acuity (VA) group, tested using a Snellen chart in decimal acuity, the minimum recorded value was 0.1 and the maximum value was 0.8, indicating a wide range of measurements within the sample. The mean value of 0.380 ± 0.1757 reflects the data's central tendency and variability, pointing to a heterogeneous baseline state before treatment (Figure 3). In the pre-macular group, thickness was measured using Topcon Maestro 2 optical coherence tomography in micrometers, ranging from 177

μm to $640 \mu\text{m}$. The mean was $391.01 \pm 105.934 \mu\text{m}$, demonstrating the central tendency and degree of dispersion in the baseline macular status prior to therapy (Figure 4).

Post-Treatment Assessment

Results in the post-visual acuity (VA) treated group showed a variety of post-treatment outcomes, from a minimum of 0.1 to a maximum of 0.9, with a mean value of 0.540 ± 0.2113 . These results show generally satisfactory and consistent post-treatment performance, with the

standard deviation indicating little variation across participants (Figure 3). In the post-macular therapy group, findings ranged from $166 \mu\text{m}$ to $520 \mu\text{m}$, with a mean value of $310.50 \pm 74.897 \mu\text{m}$, reflecting a generally positive post-treatment outcome and a fairly uniform reaction among the analyzed instances (Figure 4). The median visual acuity (VA) increased from 0.4 prior to therapy to 0.6 following treatment, while the median macular thickness decreased from $383 \mu\text{m}$ before treatment to $290.5 \mu\text{m}$ after therapy (Table 1).

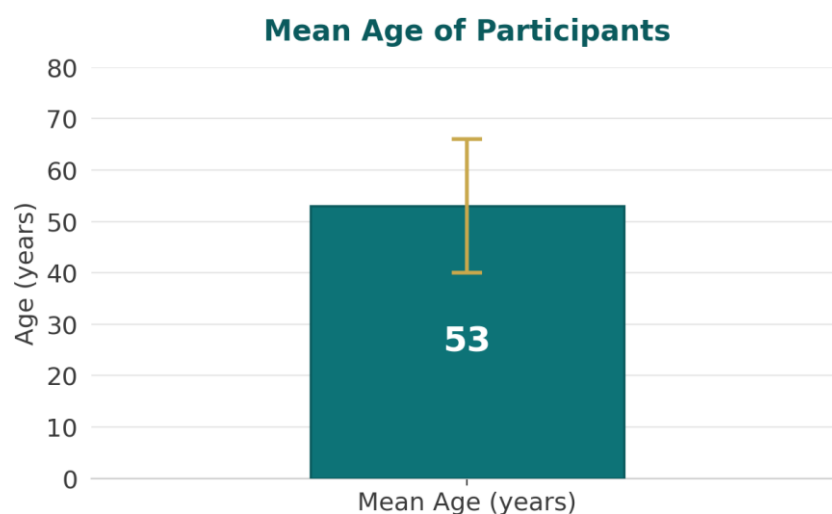


Figure 1: Mean Age of Participants



Figure 2: Gender Distribution

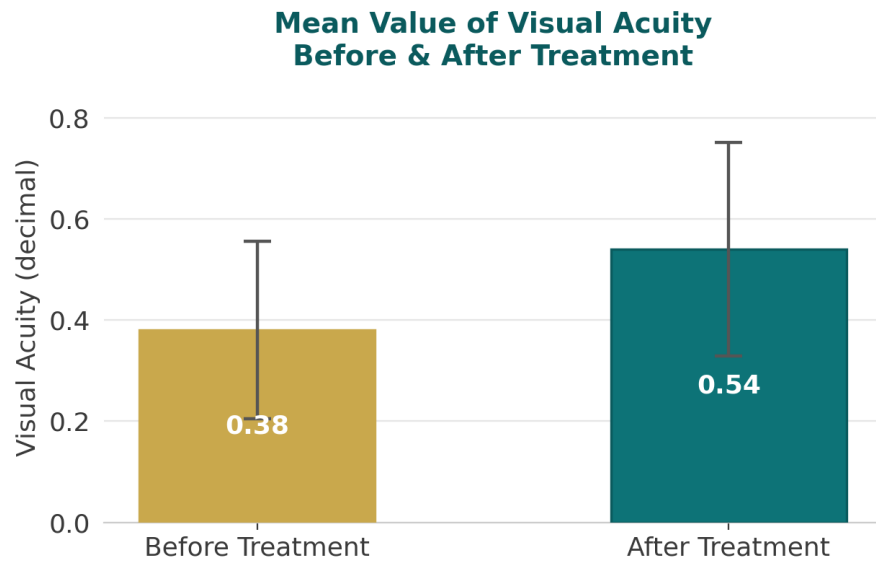


Figure 3: Mean Value of Visual Acuity Before & After Treatment

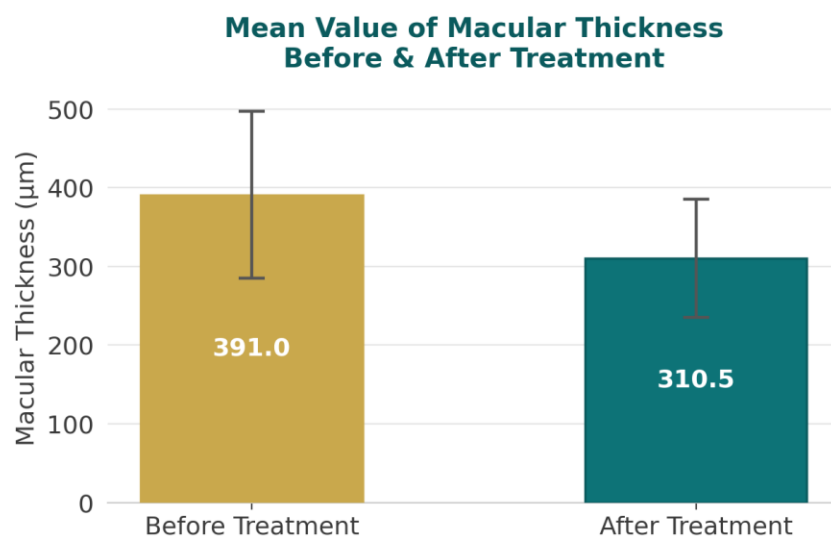


Figure 4: Mean Value of Macular Thickness Before & After Treatment

Table 1: Data Analysis

		VA Pre-Treatment	VA Post-Treatment	Macula Pre-Treatment (µm)	Macula Post-Treatment (µm)
N	Valid	80	80	80	80
	Missing	0	0	0	0
Median		0.400	0.600	383.00	290.50
Percentiles	25	0.300	0.400	315.50	253.75
	50	0.400	0.600	383.00	290.50
	75	0.500	0.700	454.75	352.75

Key Finding: Mean visual acuity improved from 0.38 to 0.54, and mean macular thickness decreased from 391.0 μm to 310.5 μm , following Ozurdex implantation ($p < 0.05$).

10. Discussion

Following therapy, the percentile analysis showed a decrease in macular thickness and an overall improvement in visual acuity (VA). VA showed consistent improvement across the patient distribution, with the 25th, 50th (median), and 75th percentiles rising from 0.30, 0.40, and 0.50 pre-treatment to 0.40, 0.60, and 0.70 post-treatment, respectively. Macular thickness decreased at all percentile levels following therapy, with the 25th percentile falling from 315.50 μm to 253.75 μm , the median from 383.00 μm to 290.50 μm , and the 75th percentile from 454.75 μm to 352.75 μm . These findings suggest that the treatment effect was not limited to a specific subgroup but was observed across patients with varying baseline measurements, reflecting a general improvement in visual function and anatomical outcomes (Table 1).

11. Limitations

As with any retrospective single-center investigation, several limitations should be considered when interpreting the present findings:

- ◆ The retrospective, cross-sectional design relies on existing medical records and is therefore susceptible to information and selection bias, limiting causal inference relative to a prospective trial.
- ◆ The study was conducted at a single center (King Saud Hospital, Unaizah), which may limit generalizability to other regions or healthcare settings within Saudi Arabia.
- ◆ The relatively modest sample size of 80 patients, while sufficient for descriptive analysis, may not capture the full variability of treatment response across diabetes subtypes and severities.
- ◆ The absence of a comparison group that did not receive the dexamethasone implant limits the ability to attribute observed

improvements solely to the intervention rather than to cataract surgery itself or spontaneous resolution.

- ◆ Glycemic control parameters, such as HbA1c, and diabetes duration were not consistently captured, despite their known influence on diabetic macular edema and treatment response.
- ◆ The follow-up period did not extend long enough to fully characterize the duration of therapeutic effect or to systematically capture delayed adverse events such as elevated intraocular pressure.

12. Recommendations

Building on the findings and limitations of this study, the following recommendations are proposed for future research and clinical practice:

- ◆ Future studies should adopt a prospective, multicenter design across Ministry of Health facilities to enhance generalizability and statistical power.
- ◆ Randomized controlled trials comparing dexamethasone implant therapy with standard perioperative anti-inflammatory regimens are recommended to more clearly establish causal benefit.
- ◆ Extended follow-up protocols, including routine intraocular pressure monitoring, should be incorporated to capture the full safety profile of the implant over time.
- ◆ Incorporating glycemic control indices, such as HbA1c, as covariates in future analyses would help clarify their interaction with treatment outcomes.
- ◆ Integration of outcome data into national digital health platforms, such as Nphies and Mumaris+, could support longitudinal, registry-based evaluation of implant use across Saudi healthcare facilities.
- ◆ Cost-effectiveness analyses are recommended to inform resource-allocation decisions consistent with the quality and value-based care objectives of

the Vision 2030 Healthcare Transformation Initiative.

13. Conclusion

A p-value less than 0.05 resulted in the rejection of the null hypothesis, indicating a statistically significant improvement. Ozurdex implantation resulted in significant improvements in visual acuity (VA) and reduced macular thickness ($p < 0.05$). The study determined that the administration of an intravitreal dexamethasone implant is both effective and safe for patients undergoing cataract surgery, with cataract

removal facilitating better visual and macular thickness improvement.

14. Acknowledgment

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