

SYMPOSIUM

Cataract Surgery Outcomes Optimizing With Innovative Drugs and Technologies

September 15, 2014 (1-2 PM)

Venue: Boulevard F

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Disclosures Sponsorships/Consultant

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Post Cataract Macular Edema in Diabetic Patients



Objectives

➤ Understand the development and impact of macular oedema – Irvine-Gass Syndrome Post Cataract Surgery

➤ Explore the increase in cost of cataract care if patients develop CME

➤ Explore the increased risk for macular edema development in diabetic patients

Postoperative Complications Associated With Modern Cataract Surgery

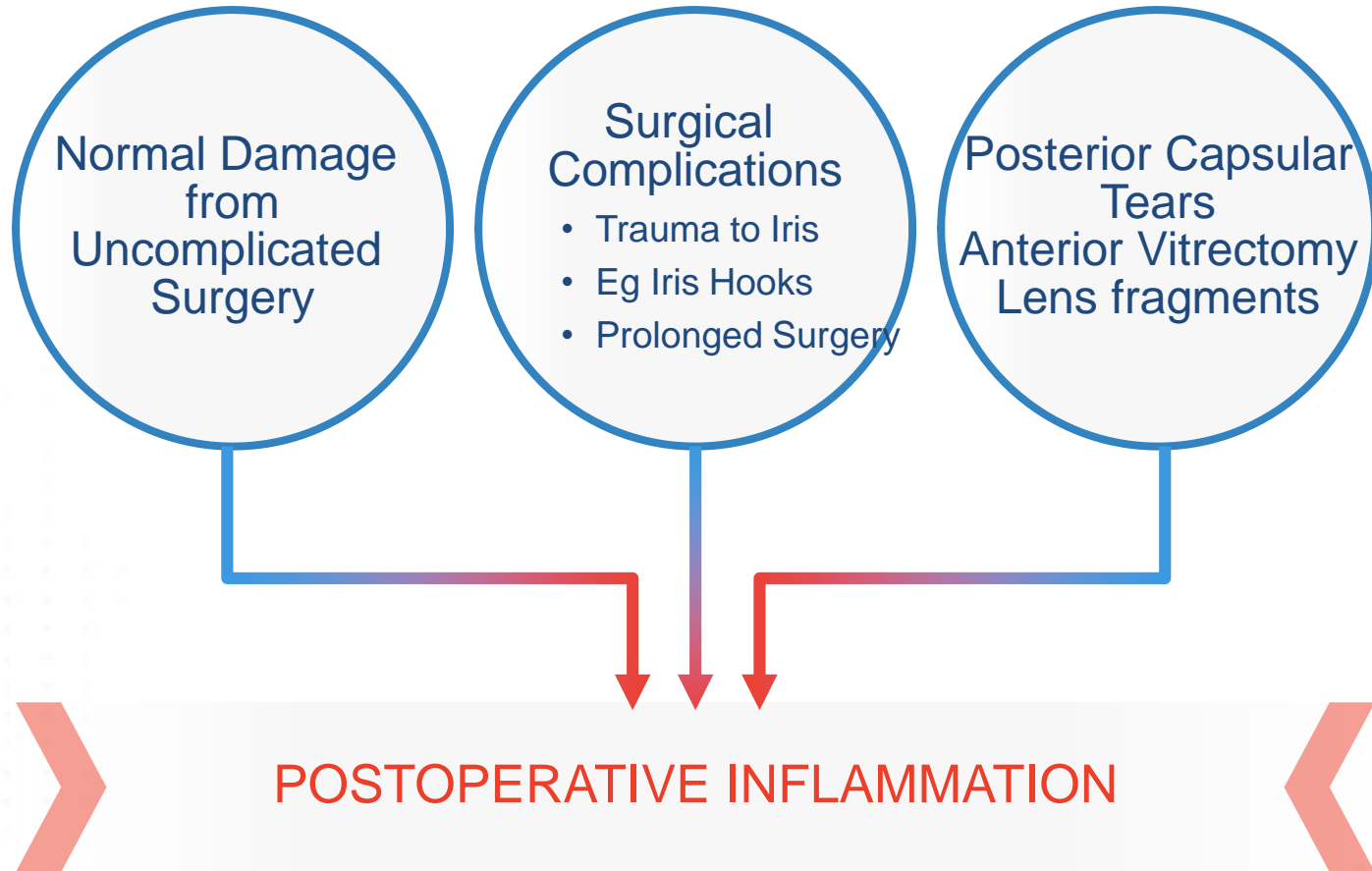
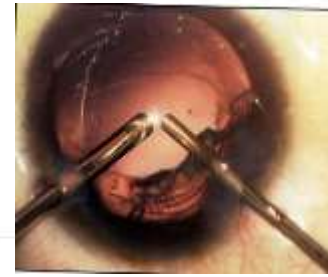
Complication	Range of Estimated Incidences (%)
Intraoperative	
Posterior capsular or zonular rupture	1.5 – 3.5
Vitreous loss/anterior vitrectomy or aspiration	0.8 – 1.39
Iris/ciliary body injury	0 – 1.2
Loss of nuclear material into vitreous	0.1 – 0.28
Suprachoroidal hemorrhage	0 – 0.14
Retrobulbar hemorrhage	0 – 0.1
Postoperative	
Cystoid macular edema	1.2 – 3.5
Corneal edema	0.03 – 5.18
IOL dislocation, removal, or exchange	0.19 – 1.1
Endophthalmitis	0.03
Retinal tear, break, or detachment	0.14 – 0.9
Persistent iritis	1.1

Related to inflammation

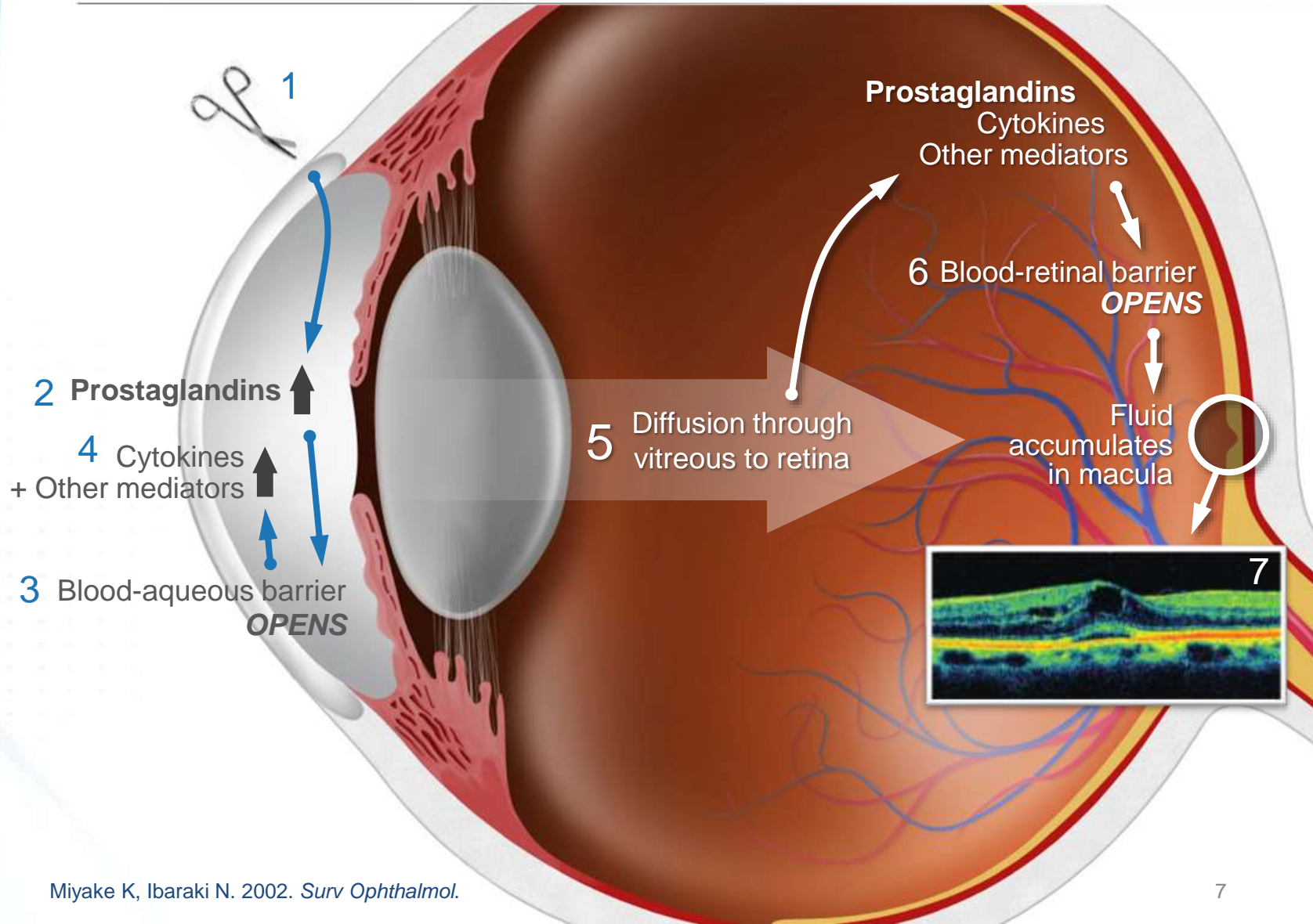


Note: NEVANAC is indicated in adults for the reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.

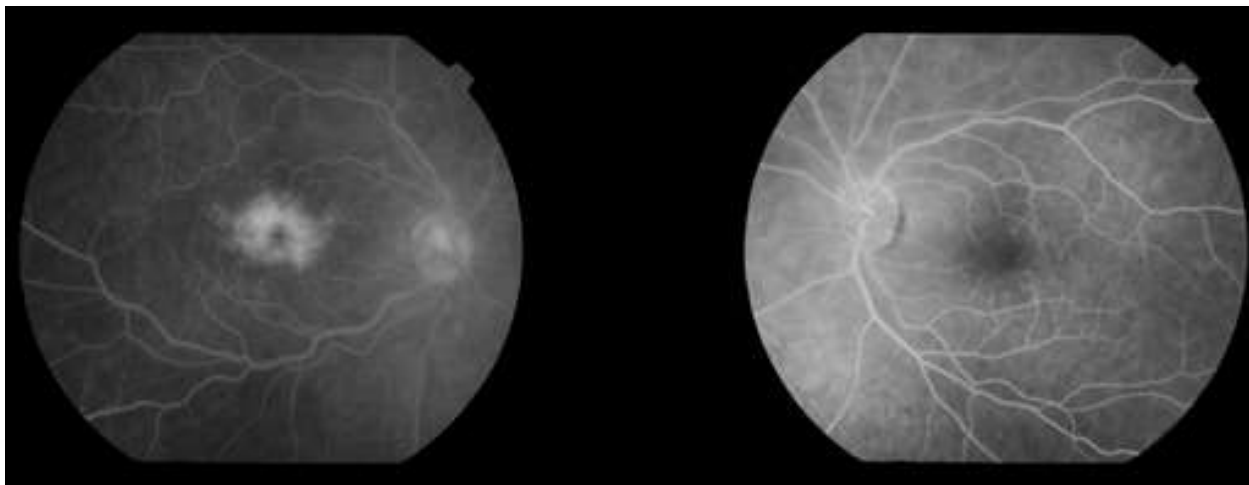
Surgery Causes Tissue Damage That Induces Inflammation



Inflammation May Lead to Macular Edema by Relaxing the Ocular-Blood Barriers



What Is Macular Edema?



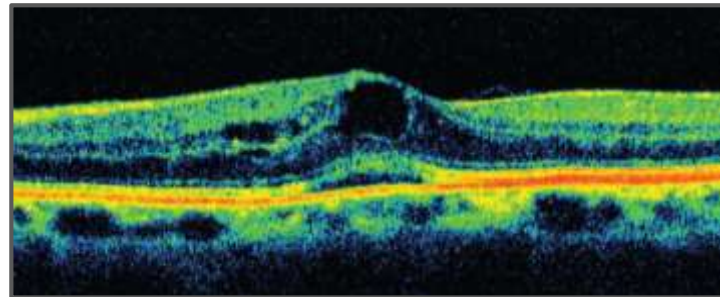
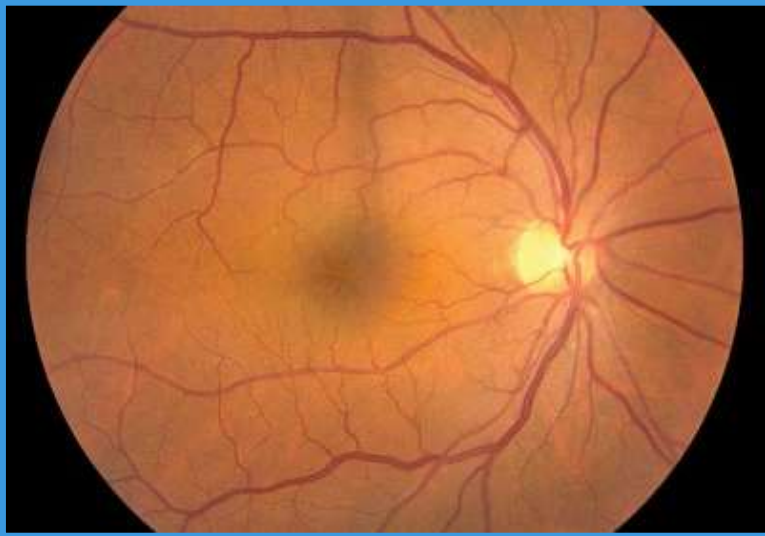
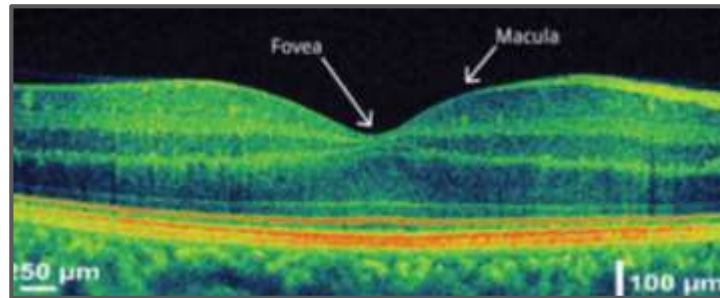
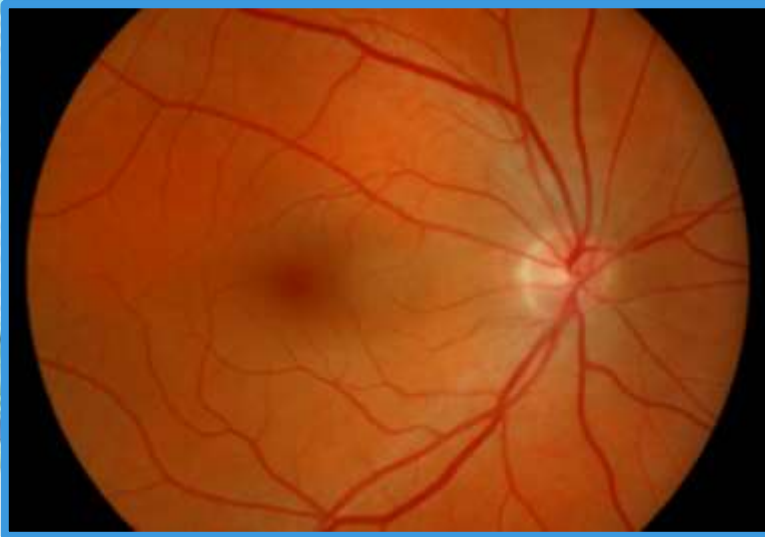
Macular edema is a painless disorder that affects the central retina, or macula.

Macular edema is caused by the breakdown of the blood-retina barrier, which increases vascular leakage.

Increased vascular leakage causes fluid to accumulate in the macula, which leads to edema and increased macular thickness.

Difficult to differentiate vs **DIABETIC MACULAR OEDEMA**. Post op Hyperfluorescence of Optic disc on Fundus fluorescein angiography. Treat **DME** Prior to surgery On table Anti-VEGF/Steroids

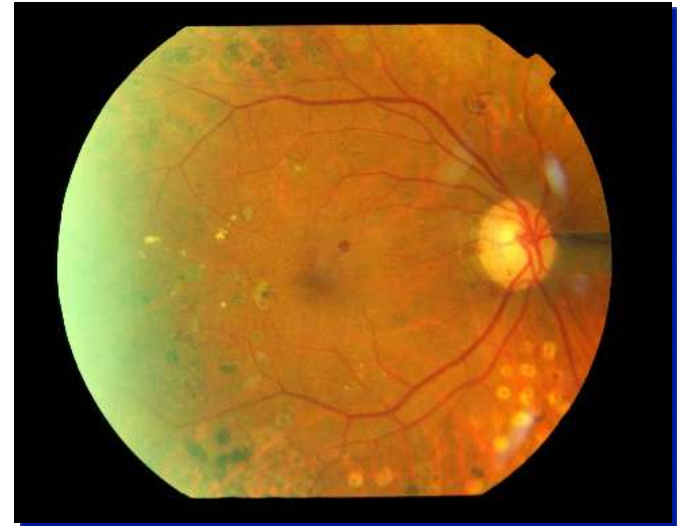
Healthy Vs Macular Oedema Retina Fundus Photograph and SD-OCT



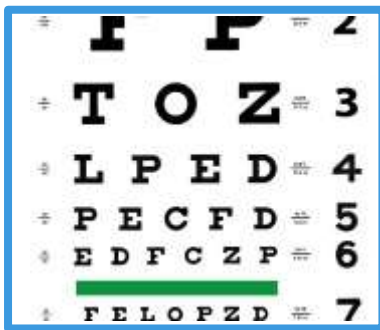
Irvine-Gass Syndrome

- Angiographic CME – Normal Vision
 - Normal OCT
- Clinically Significant CME
 - Reduced vision, CME on OCT
 - Within 4 months of surgery-Usually 4-6 Weeks

- Late CME > 4 months
- Chronic CME Lasts > 6 Months
- Diabetic macular oedema VS Irvine-Gass – Co-exist



Frequency of Macular Edema Development After Cataract Surgery

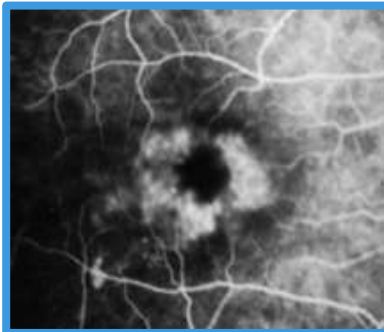


Clinically Significant Macular Edema

Associated with decreased visual acuity

Estimated Incidence

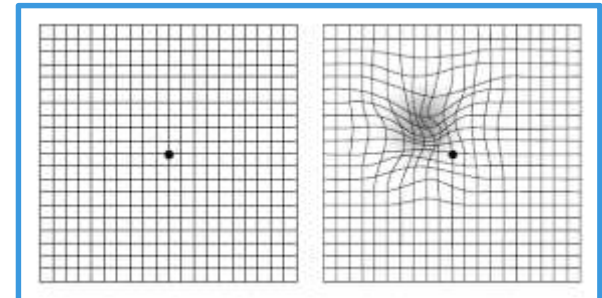
≤5.8%



Cystoid Macular Edema

Detected by ocular imaging

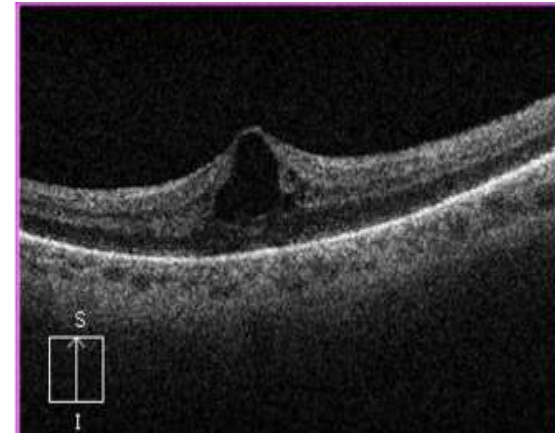
4%-20%



Macular Edema Is Associated With Reduced Quality of Vision

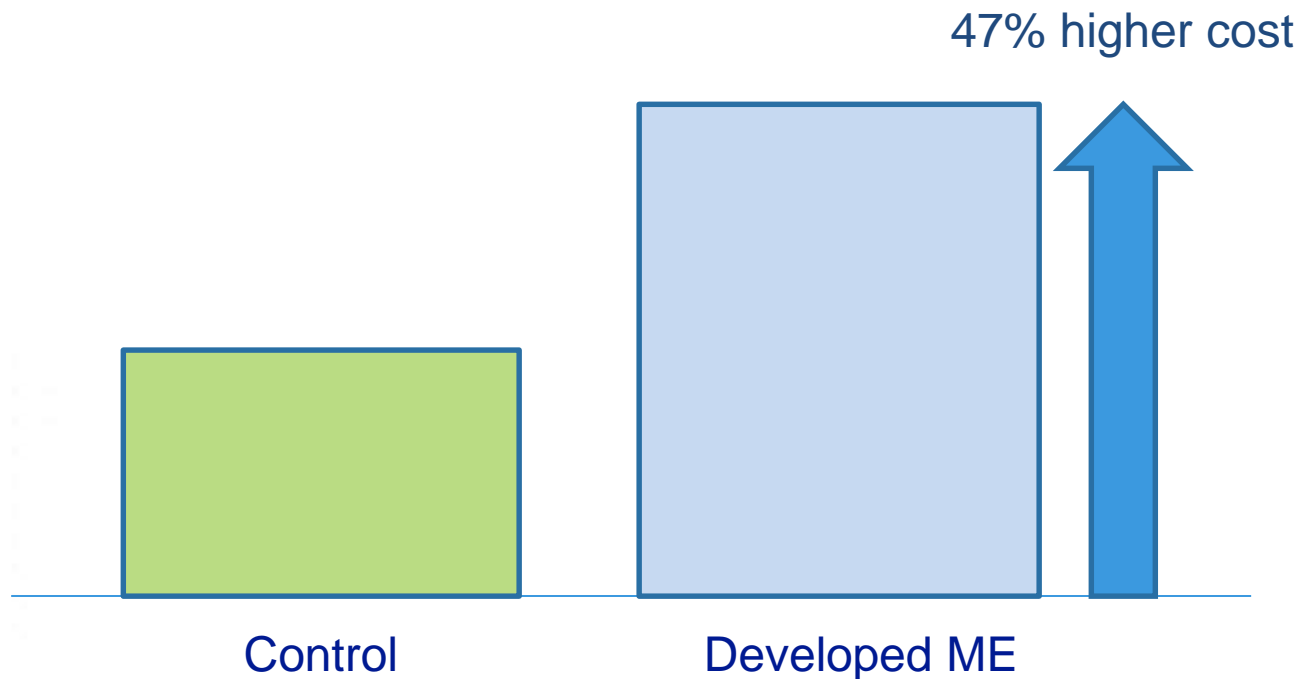
Quality of Vision

- Cystoid macular edema is **a common cause of decreased vision** after cataract surgery.
- Cystoid macular edema can develop even if cataract surgery was successful and uncomplicated.
- Patients may experience vision that is **reduced in quality without being reduced in acuity.**



Cost of Managing Macular Edema Post Cataract Surgery

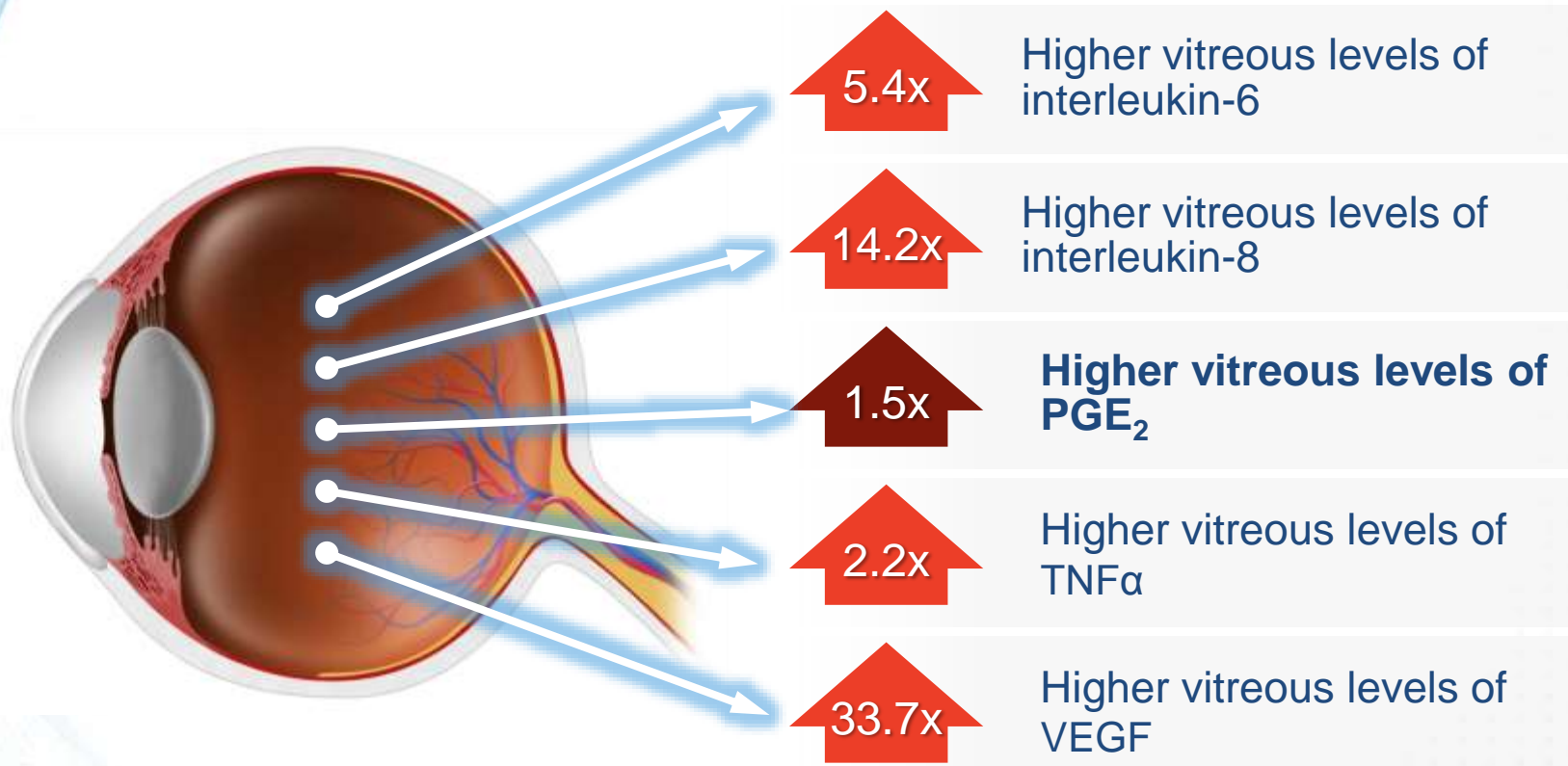
Preventing macular edema is likely to result in cost savings in both normal and diabetic patients.



Note: NEVANAC is indicated in adults for the reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.

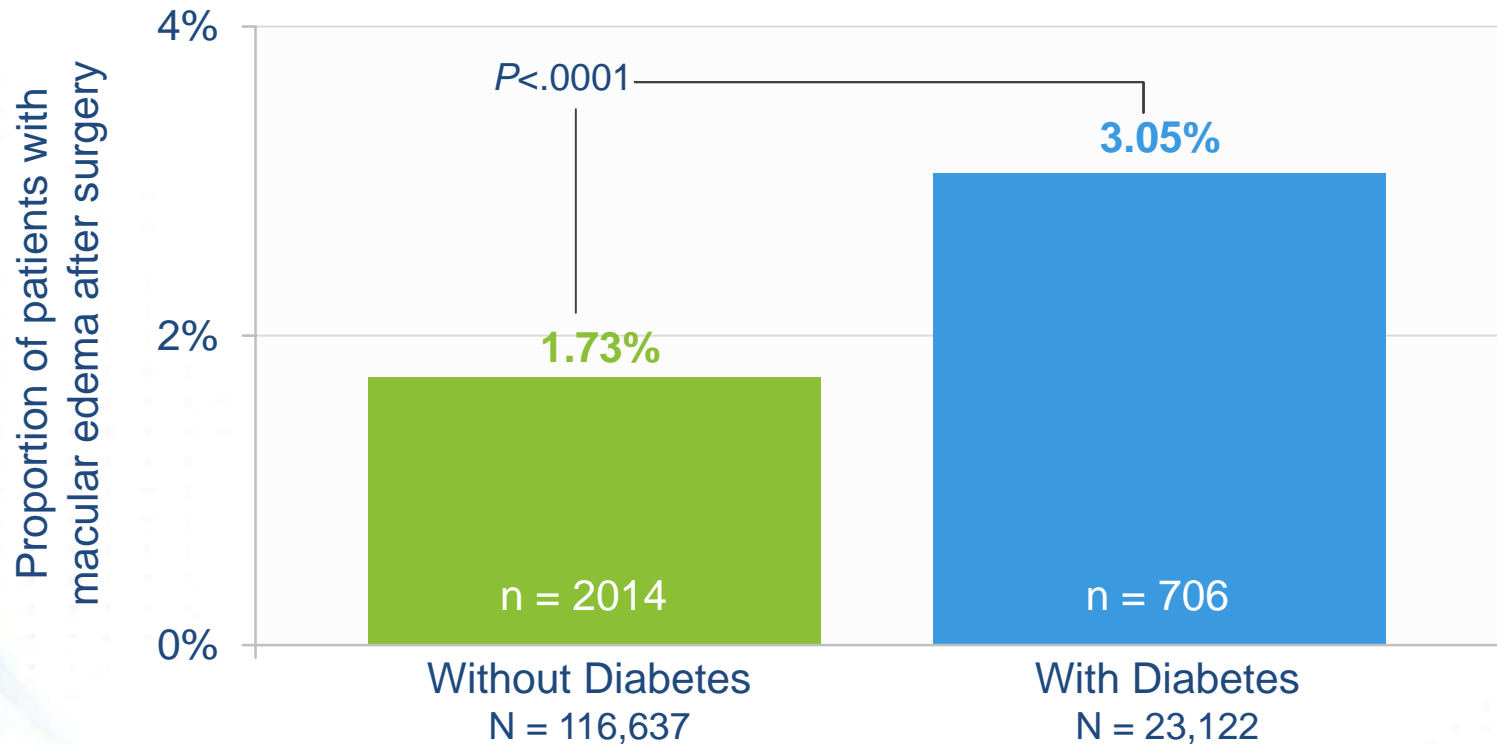
Vitreous Prostaglandin Levels Are Higher in Eyes With Proliferative Diabetic Retinopathy

Compared to patients without any diabetic retinopathy, patients with proliferative diabetic retinopathy have:



Higher Incidence of Postoperative Macular Edema With Diabetes

- Among patients filing Medicare claims for cataract surgery.
- Includes mix of cases with and without diabetic retinopathy.

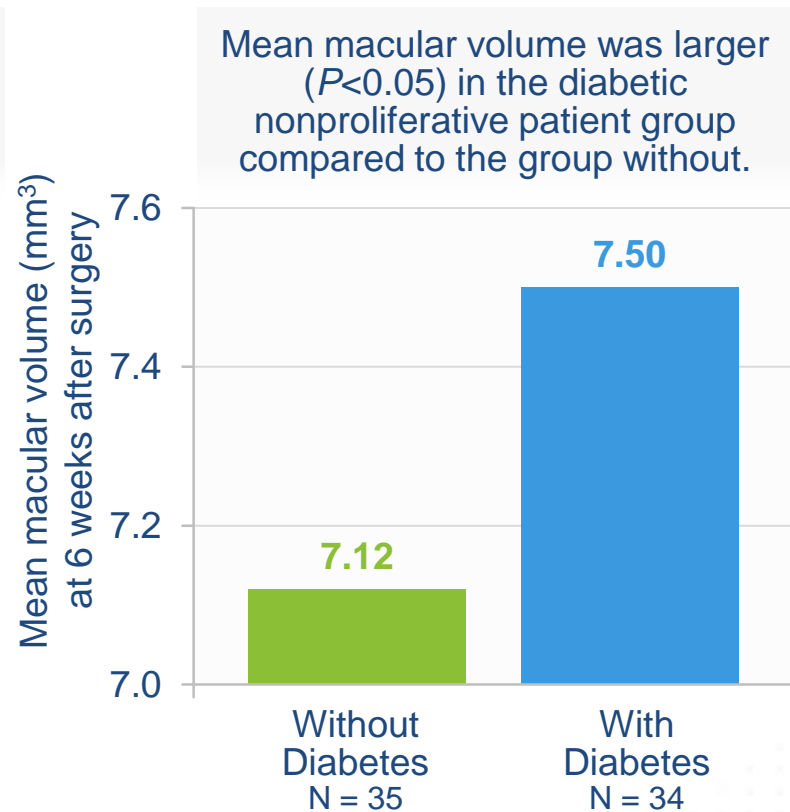
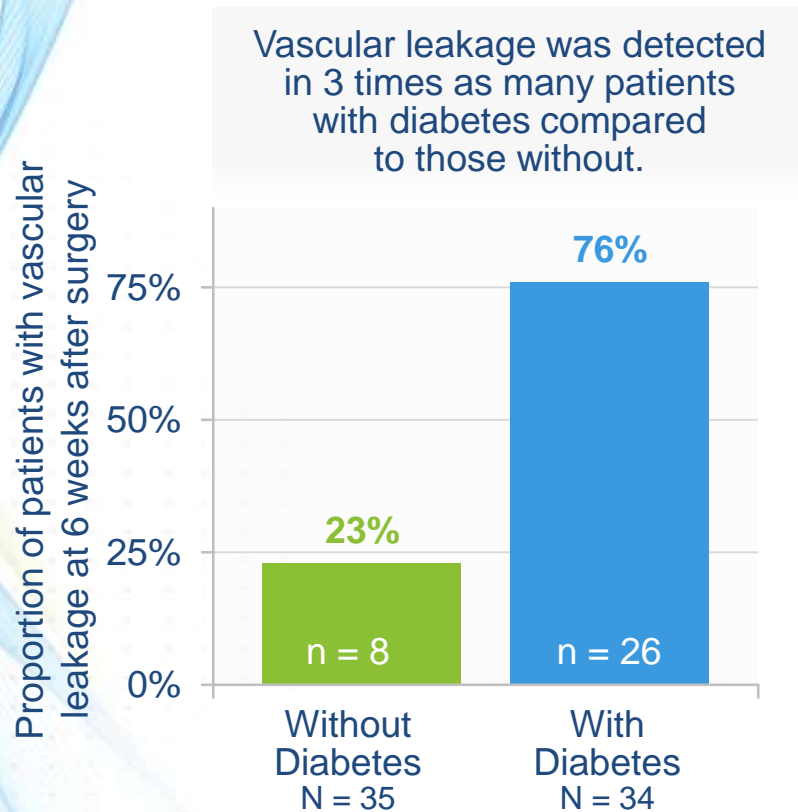


NOTE: Based on patients with 1 or more cataract claims from the 1997–2001 Medicare 5% Beneficiary Encrypted Files; patients were analyzed by diagnosis of cystoid macular edema in the same quarter as or within the following 3 quarters after surgery. Schmier JK, et al. 2007. *Retina*.

Note: NEVANAC is indicated in adults for the reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.

Higher Incidence of Postoperative Macular Edema With Diabetic Retinopathy

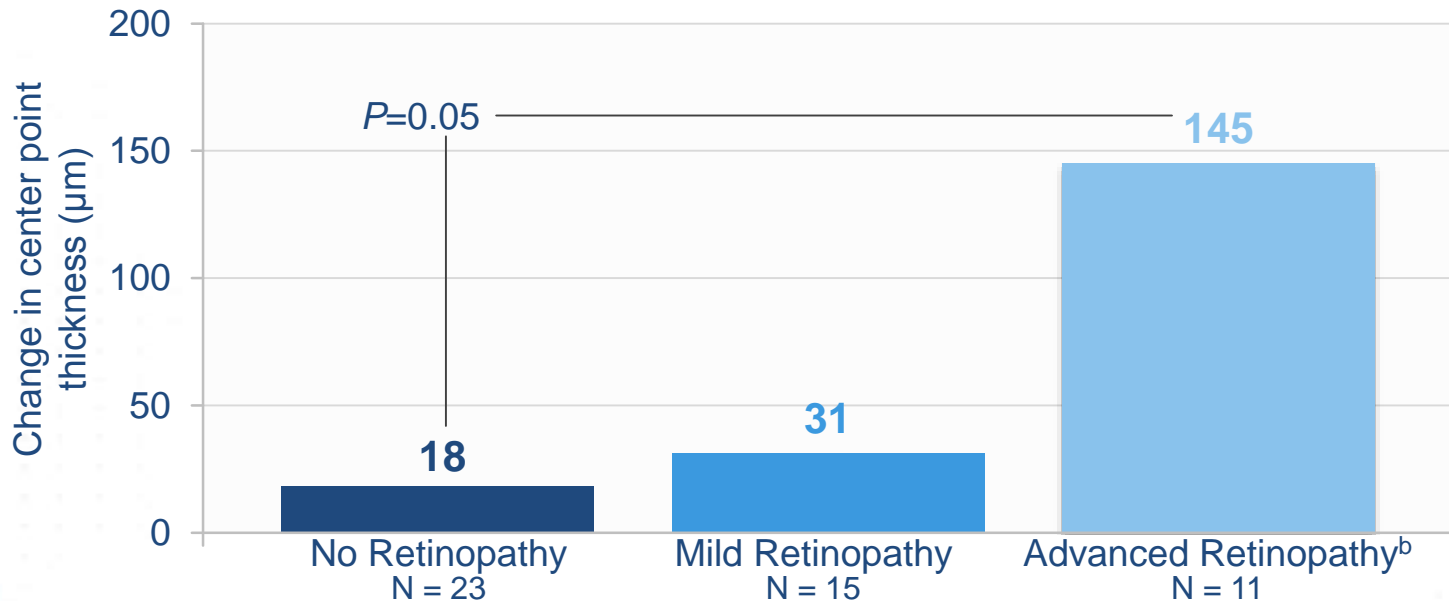
- All diabetic patients in the study had mild or moderate diabetic retinopathy.



Note: NEVANAC is indicated in adults for the reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.

Thicker Macular Edema in Patients With Advanced Diabetic Retinopathy

- Diabetic patients with varying severity of diabetic retinopathy.
- All patients had normal center point thicknessa ≤4 weeks.
- All phacoemulsification procedures were performed without complication.



a Center point thickness was measured on OCT as retinal thickness at the center point of the fovea.

b Advanced diabetic retinopathy included moderate and severe nonproliferative diabetic retinopathy, and proliferative diabetic retinopathy.

Kim SJ, et al. 2007. *Ophthalmology*.

Reasons for Increased Incidence of Macular Edema After Cataract Surgery in Patients With Diabetes

Higher levels of prostaglandins and other proinflammatory cytokines in the vitreous

Proliferative diabetic retinopathy vs without diabetic retinopathy

Higher incidence of vascular leakage after cataract surgery

Mild or moderate diabetic retinopathy vs without diabetes

Larger mean macular volume after cataract surgery

Mild or moderate diabetic retinopathy vs without diabetes

Higher incidence of macular edema diagnosis after cataract surgery

Diabetes vs without diabetes

Wrap-Up and Questions



NEVANAC Prescribing Information

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 1 ml of Nevanac suspension contains 1 mg nepafenac, benzalkonium chloride 0.05 mg. Indication(s): Prevention and treatment of postoperative pain and inflammation associated with cataract surgery. Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. Posology and method of administration: Adults, including the elderly: For the prevention and treatment of pain and inflammation, 1 drop in the affected eye(s) 3 times daily beginning 1 day prior to cataract surgery, continued on the day of surgery and up to 21 days of the postoperative period, as directed by the clinician. An additional drop should be administered 30 to 120 minutes prior to surgery. For the reduction in the risk of macular oedema associated with cataract surgery in diabetic patients, 1 drop in the affected eye(s) 3 times daily beginning 1 day prior to cataract surgery, continued on the day of surgery and up to 60 days of the postoperative period, as directed by the clinician. An additional drop should be administered 30 to 120 minutes prior to surgery. Children and adolescents: Not recommended. Hepatic and renal impairment: No dose adjustment warranted. Contra-indications: Hypersensitivity to nepafenac, any of the excipients, or to other nonsteroidal anti-inflammatory drugs (NSAIDs); and in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs. Warnings and precautions: Do not inject, or swallow. Instruct patients to avoid sunlight during treatment. Use of topical NSAIDs may result in keratitis, in some susceptible patients, continued use may be sight threatening. Topical NSAIDs may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. Topical NSAIDs should be used with caution in patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases, rheumatoid arthritis or repeat ocular surgeries within a short period of time. These patients may be at increased risk for corneal adverse reactions which may become sight threatening. Prolonged use of topical NSAIDs may increase patient risk for occurrence and severity of corneal adverse reactions. Ophthalmic NSAIDs may cause increased bleeding of ocular tissues (including hyphaemas) in conjunction with ocular surgery. Use NEVANAC with caution in patients with known bleeding tendencies or who are receiving other medicinal products which may prolong bleeding time. Concomitant use of prostaglandin analogues and NEVANAC is not recommended. Benzalkonium chloride may cause keratopathy and irritation and is known to discolour soft contact lenses. Contact lens wear is not recommended during the postoperative period following cataract surgery. Patients should be advised not to wear contact lenses during treatment with NEVANAC. Close monitoring is required with frequent or prolonged use. An acute ocular infection may be masked by the topical use of anti-inflammatory medicines. NSAIDs do not have any antimicrobial properties. In case of ocular infection, their use with anti-infectives should be undertaken with care. Cross-sensitivity: Potential exists for cross-sensitivity of nepafenac to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs. Interactions: In vitro studies have demonstrated a very low potential for interaction with other medicinal products and protein binding interactions. Pregnancy and lactation: Pregnancy: not recommended during pregnancy and in women of childbearing potential not using contraception. Lactation: Can be used during lactation. Effects on ability to drive and use machines: If blurred vision occurs wait until the vision clears before driving or using machinery. Undesirable effects: Common: Punctate keratitis. Frequency not known: Dizziness, impaired corneal healing, corneal scar, reduced visual acuity, eye irritation, eye swelling, blood pressure increased. Serious: Keratitis, choroidal effusion, corneal epithelium defect, corneal opacity. Prescribers should consult the SmPC in relation to other side effects. Overdose: No experience of overdose with ocular use. Application of >1 drop/eye is unlikely to lead to unwanted sideeffects. Practically no risk of adverse effects due to accidental oral ingestion. Incompatibilities: Not applicable. Special Precautions for Storage: Do not store above 30°C. Legal Category: POM. Package Quantities and Basic NHS Costs: 5ml £14.92. MA Number(s): EU/1/07/433/001. Further information available from the MA Holder: Alcon Laboratories (UK) Ltd, Frimley Business Park, Frimley Camberley, Surrey, GU16 7SR United Kingdom. Date of preparation: 20 May 2013 (V9). Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Alcon Medical Information. Tel: 0871 376 1402. Email: GB.ADR@alcon.com