

Defining the Boundary Between Phakic IOLs and LASIK

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What parameters do you follow when considering a patient for LASIK or a phakic IOL?

JAY BANSAL, MD

I am significantly more inclined to discuss phakic IOLs with patients who have more than -10.00 D of myopia, thin corneas, irregular topography, and large pupils. In these cases, I spend considerably more time discussing the risks, benefits, and costs of refractive procedures, as I am not as comfortable with the currently available technology for this group of patients. However, if a patient simply is not a good candidate for LASIK, then my recommendation is refractive lens exchange, phakic IOL implantation, or to wait for future technology.

WILLIAM I. BOND, MD

I have had very good results with LASIK for the treatment of up to 14.00 D of ametropia. I will still treat as much as 14.00 D with LASIK, provided the patient has acceptable ocular parameters (corneal thickness, no questionable topography, etc.). LASIK's safety and ease for my patients and me is unsurpassed. I believe this is due to current methods for safely creating thin, consistent flaps with Nidek's MK-2000 keratome system (Gamagori, Japan). My patients—even highly myopic ones—have achieved great subjective quality-of-vision results with both the 200- and 400-Hz models of the Allegretto Wave Eye-Q laser (Alcon Laboratories, Inc., Fort Worth, TX).

Phakic IOLs are for patients who are not good candidates for LASIK. It is generally accepted that there is a potential for more severe, inside-the-eye risks with phakic IOLs than LASIK, particularly endophthalmitis. Also, IOLs

are more costly to me and to my patients. Finally, I have been told IOLs are completely reversible. If you stick an ice pick into someone's head, and the entry point seals itself after you pull out the tool, was that reversible?

“There is a potential for more severe, inside-the-eye risks with phakic IOLs than LASIK, particularly endophthalmitis.”

- William I. Bond, MD

PARAG A. MAJMUDAR, MD

Many factors would play into my decision to offer a patient a phakic IOL rather than LASIK. If I had to follow a general rule, I would use -10.00 D as the arbitrary cutoff. Many patients with a refractive error of less than -10.00 D may have thin corneas or “funny” topographies, but they would also qualify for a phakic IOL. The risk-reward ratio for implanting a phakic IOL must be discussed with the patient, who must take into consideration the many variables that we evaluate on a daily basis. One additional issue is cost. In most cases, the phakic IOL procedure is performed at an ambulatory surgical center. Consequently, fees (anesthesia, facility) are charged in addition to the actual price of the IOL. These costs usually are not a factor in LASIK. Nonetheless, we should not use cost as the sole criterion for selecting a procedure. Rather, we should, as usual, keep the best interests of the patient in mind.

NANCY A. TANCHEL, MD

LASIK has greatly improved over the years, as our understanding has grown regarding how to deliver the optimal corneal profile with the excimer laser and how

to create thin, consistent, safe flaps. Even very high myopes can achieve excellent results safely. Currently, I believe phakic IOLs are best suited to patients with -12.00 D of refractive error or more (although most higher myopes are still great LASIK candidates). Patients with lower myopia are also candidates if they have very thin corneas or topographic abnormalities. Phakic IOLs are as reversible as walking in the snow and then backing out and claiming you were never there, so it is not a benign procedure. Opening the eye has a very different risk profile than corneal surgery. ■

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Nevanac® (nepafenac ophthalmic suspension) 0.1%

INDICATIONS AND USAGE

NEVANAC® ophthalmic suspension is indicated for the treatment of pain and inflammation associated with cataract surgery.

CONTRAINDICATIONS

NEVANAC® ophthalmic suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation or to other NSAIDs.

WARNINGS

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

With some nonsteroidal anti-inflammatory drugs including NEVANAC®, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

PRECAUTIONS

General: Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including NEVANAC®, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including NEVANAC® and should be closely monitored for corneal health.

Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post surgery may increase patient risk for occurrence and severity of corneal adverse events.

It is recommended that NEVANAC® ophthalmic suspension be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Information for Patients: NEVANAC® ophthalmic suspension should not be administered while wearing contact lenses.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Nepafenac has not been evaluated in long-term carcinogenicity studies. Increased chromosomal aberrations were observed in Chinese hamster ovary cells exposed *in vitro* to nepafenac suspension. Nepafenac was not mutagenic in the Ames assay or in the mouse lymphoma forward mutation assay. Oral doses up to 5,000 mg/kg did not result in an increase in the formation of micronucleated polychromatic erythrocytes *in vivo* in the mouse micronucleus assay in the bone marrow of mice. Nepafenac did not impair fertility when administered orally to male and female rats at 3 mg/kg (approximately 90 and 380 times the plasma exposure to the parent drug, nepafenac, and the active metabolite, amfenac, respectively, at the recommended human topical ophthalmic dose).

Pregnancy: Teratogenic Effects.

Pregnancy Category C: Reproduction studies performed with nepafenac in rabbits and rats at oral doses up to 10 mg/kg/day have revealed no evidence of teratogenicity due to nepafenac, despite the induction of maternal toxicity. At this dose, the animal plasma exposure to nepafenac and amfenac was approximately 260 and 2400 times human plasma exposure at the recommended human topical ophthalmic dose for rats and 80 and 680 times human plasma exposure for rabbits, respectively. In rats, maternally toxic doses ≥ 10 mg/kg were associated with dystocia, increased postimplantation loss, reduced fetal weights and growth, and reduced fetal survival.

Nepafenac has been shown to cross the placental barrier in rats. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, NEVANAC® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Non-teratogenic Effects: Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of NEVANAC® ophthalmic suspension during late pregnancy should be avoided.

Nursing Mothers: NEVANAC® ophthalmic suspension is excreted in the milk of pregnant rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NEVANAC® ophthalmic suspension is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of NEVANAC® in pediatric patients below the age of 10 years have not been established.

Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

In controlled clinical studies, the most frequently reported ocular adverse events following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation. These events occurred in approximately 5 to 10% of patients.

Other ocular adverse events occurring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment.

Some of these events may be the consequence of the cataract surgical procedure.

Nonocular adverse events reported at an incidence of 1 to 4% included headache, hypertension, nausea/vomiting, and sinusitis.

DOSAGE AND ADMINISTRATION

Shake well before use. One drop of NEVANAC® ophthalmic suspension should be applied to the affected eye(s) three-times-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period.

NEVANAC® ophthalmic suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics.

Rx ONLY

Manufactured by:
Alcon Laboratories, Inc.
Fort Worth, TX 76134 USA
U.S. Patent No: 5,475,034

References:

1. Data on file, Alcon Laboratories, Inc. 2005. 2. Ke T-L, Graff G, Spellman JM, Yanni JM. Nepafenac, a unique nonsteroidal prodrug with potential utility in the treatment of trauma-induced ocular inflammation. *It in vitro* bioactivation and permeation of external ocular barriers. *Inflammation*. 2000;24:371-384. 3. Lane SS, Modi SS, Holland EJ, et al. Nepafenac ophthalmic suspension 0.1% before and after surgery for postoperative anterior segment inflammation. Paper presented at: American Society of Cataract and Refractive Surgery; April 19, 2005; Washington, DC. 4. NEVANAC® suspension prescribing information.

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