

# Would You Undergo Lens-Based Surgery for Presbyopia?

BY GEORGE BEIKO, BM, BCH, FRCSC; ALAN M. BERG, MD;  
RICHARD J. MACKOOL, MD; AND MARK PACKER, MD

*Would you yourself choose to receive a presbyopia-correcting IOL for either refractive or cataract surgery purposes? Why or why not, and what type of lens would you choose if you elected to have this surgery?*

## GEORGE BEIKO, BM, BCH, FRCSC

Yes, especially as I have reached the age where I begin to encounter presbyopic symptoms, I would consider presbyopic lens implantation. Recognizing that I am an obsessive ophthalmologist with some engineering tendencies, who has been spectacle independent up until recently, and who is very particular about the quality of vision I desire, I would choose mini monovision. I have been impressed with the high quality and range of visual outcomes and relatively low incidence of dysphotopsia with this approach. My lens of choice is the Tecnis (Abbott Medical Optics Inc., Santa Ana, CA), and I would target -0.25 D in one eye and -0.75 D in the other.

## ALAN M. BERG, MD

I believe that, when choosing the appropriate implant for any patient undergoing refractive lens exchange or cataract surgery, his or her needs and occupation are the most important factors to consider. Because I am an eye surgeon, if I were to undergo either of these procedures, I would select the Crystalens (Bausch + Lomb, Rochester, NY), because it would offer me excel-

"When choosing the right implant for any patient . . . his or her needs and occupation are the most important factors to consider."

—Alan M. Berg, MD

lent distance and midrange vision. I would have my nondominant eye undercorrected for a mild degree of monovision, as my vision has been this way for years. Although I have implanted multifocal lenses with great success, in my case, I would choose the Crystalens.

## RICHARD J. MACKOOL, MD

If I required cataract surgery, I would first undergo implantation of the AcrySof IQ Restor IOL +3.0 D (Alcon Laboratories, Inc., Fort Worth, TX) in my nondominant eye. Assuming that I did not develop significant glare or halo problems, I would have the same IOL implanted in my dominant eye. If I did develop symptoms, I would have an aspheric monofocal IOL implanted in my dominant eye. This arrangement would permit night driving because the dominant eye with the aspheric monofocal IOL would be glare free.

## MARK PACKER, MD

I would choose a presbyopia-correcting IOL if I had deteriorating visual function due to cataracts. I currently have a little bit of myopic astigmatism, and I only have to wear glasses for night driving. I consider myself relatively spectacle independent for a 52-year-old, and I am not considering refractive surgery. However, if I needed cataract surgery now, I would travel outside the

## RESTASIS®

(cyclosporine ophthalmic emulsion) 0.05%  
Sterile, Preservative-Free

### INDICATIONS AND USAGE

RESTASIS® ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

### CONTRAINDICATIONS

RESTASIS® is contraindicated in patients with active ocular infections and in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

### WARNING

RESTASIS® ophthalmic emulsion has not been studied in patients with a history of herpes keratitis.

### PRECAUTIONS

General: For ophthalmic use only.

### Information for Patients

The emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

Do not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion.

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

### Carcinogenesis, Mutagenesis, and Impairment of Fertility

Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low doses in mice and rats are approximately 1000 and 500 times greater, respectively, than the daily human dose of one drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Cyclosporine has not been found mutagenic/genotoxic in the Ames Test, the V79-HGPRT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes *in vitro* gave indication of a positive effect (i.e., induction of SCE).

No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 15,000 times the human daily dose of 0.001 mg/kg/day) for 9 weeks (male) and 2 weeks (female) prior to mating.

### Pregnancy-Teratogenic Effects

Pregnancy category C.

**Teratogenic Effects:** No evidence of teratogenicity was observed in rats or rabbits receiving oral doses of cyclosporine up to 300 mg/kg/day during organogenesis. These doses in rats and rabbits are approximately 300,000 times greater than the daily human dose of one drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

**Non-Teratogenic Effects:** Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP, was embryo- and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 30,000 and 100,000 times greater, respectively, than the daily human dose of one-drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryofetal toxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 17,000 and 30,000 times greater, respectively, than the daily human dose.

Offspring of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 post partum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 45,000 times greater than the daily human topical dose, 0.001 mg/kg/day, assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (15,000 times greater than the daily human dose).

There are no adequate and well-controlled studies of RESTASIS® in pregnant women. RESTASIS® should be administered to a pregnant woman only if clearly needed.

### Nursing Mothers

Cyclosporine is known to be excreted in human milk following systemic administration but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of RESTASIS® ophthalmic emulsion, caution should be exercised when RESTASIS® is administered to a nursing woman.

### Pediatric Use

The safety and efficacy of RESTASIS® ophthalmic emulsion have not been established in pediatric patients below the age of 16.

### Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

### ADVERSE REACTIONS

The most common adverse event following the use of RESTASIS® was ocular burning (17%).

Other events reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

### Rx Only



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U.S. Patent 5,474,979

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## TODAY'S TOPICS

**"If I needed cataract surgery now, I would travel outside the United States to receive the Synchrony in both eyes."**

*—Mark Packer, MD*

United States to receive the Synchrony (Abbott Medical Optics Inc.) in both eyes. I like how the design of this IOL approximates the physiology of the crystalline lens, maintains an open capsule, and moves in response to ciliary contraction and relaxation. ■

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