

Cataract & Refractive Surgery TODAY

February 2007

BEST OF SOURCE



**Presentations from the
Symposium on Cataract, IOL, and Refractive Surgery
held at the 2006 AAO meeting in Las Vegas**

Transitioning From Cataract to Refractive IOL Surgery ERIC D. DONNENFELD, MD

Techniques for IFIS DAVID F. CHANG, MD

NSAIDs in Cataract Surgery MICHAEL B. RAIZMAN, MD

Phaco Myths and Reality RANDALL J. OLSON, MD

Mixing and Matching Multifocal IOLs FRANK A. BUCCI, JR, MD

Refractive Lens Exchange Techniques R. BRUCE WALLACE III, MD

A Study Comparing SBK to PRK STEPHEN G. SLADE, MD

Transitioning From Cataract to Refractive IOL Surgery

A primer on postoperative enhancements.

BY ERIC D. DONNENFELD, MD



I believe that refractive IOLs will take ophthalmology by storm in the coming years. Many surgeons are interested in adopting this technology but are also hesitant because of certain misconceptions they have about the procedure. I would like to debunk some of these “refractive legends” and also provide a brief primer on one of the most intimidating aspects of refractive IOL surgery: postoperative enhancements.

Refractive Legend No. 1: Presbyopic IOL patients tolerate small refractive errors.

Wrong. Presbyopic IOL patients are incredibly sensitive about their visual quality. One-half a diopter of mis-correction is sometimes too much. I perform refractive enhancements in approximately 10% of my multifocal IOL patients. I aim for +0.10 D of correction and use no adjustments. To perform refractive IOL surgery, you have to be willing and able to fix these errors.

Limbal-relaxing incisions (LRIs) are among the fastest, easiest, and most effective ways to correct residual refractive error. Several notable physicians have excellent LRI nomograms, some of which are available on the Internet. I use a simplified nomogram for easy application. For 0.50 D of cylinder, I make one incision of 1.5 clock hours. For 0.75 D, 1.50 D, or 3.00 D, I make two paired incisions of 1 clock hour, 2 clock hours, or 3 clock hours (Table 1). I lengthen the incisions slightly for against-the-rule cylinder and younger patients and shorten the incisions somewhat for older patients. This approach is effective and useful for an initial experience with LRIs, although it may not be as precise as other nomograms.

Surgeons should perform their first few LRIs in the OR during cataract surgery and under peribulbar anesthesia. I first mark the correct axis of keratometric astigmatism and then I insert the diamond blade and let it settle into the cornea for a second. I then fixate the eye and draw the knife toward myself.

Refractive Legend No. 2: Surgeons are not comfortable performing LRIs.

LRIs are easy to perform; the problem is that many ophthalmologists do not have access to an operating microscope in their offices. The solution is to perform LRIs at the slit lamp for small amounts of cylinder. I have been using

TABLE 1. LIMBAL-RELAXING INCISIONS FOR DUMMIES DONNENFELD NOMOGRAM: “DONO”

| | |
|----------------|-----------------------------------|
| 0.50 D: | 1 incision 1.5 clock hours |
| 0.75 D: | 2 incisions 1 clock hour |
| 1.50 D: | 2 incisions 2 clock hours |
| 3.00 D: | 2 incisions 3 clock hours |

- A little more for against-the-rule astigmatism and younger patients.
- A little less for older patients.

this technique for approximately 10 years because it is simple and effective. I use lidocaine gel and operate in the steep axis. When the patient is seated, I move the phoropter next to his head, and I dial in the plus-cylinder (steep) axis to determine where to place the incision.

First, I instill a drop of antibiotic 5 to 10 minutes before the surgery. I use Zymar (Allergan, Inc., Irvine, CA) with benzalkonium chloride (BAK) because it kills microorganisms rapidly. Because LRIs inoculate the deep cornea and an infection can be devastating, I feel more confident using an agent with BAK than without. I also treat these eyes with an NSAID preoperatively (Acular LS, Allergan, Inc.) to inhibit the production of prostaglandins from causing ocular discomfort, iritis, and photophobia.

Next, I position the 600- μ m preset diamond knife at the side of the cornea and make the incision 0.5 mm from the limbus. Postoperatively, I have the patient use Zymar q.i.d. for 5 days. I may also prescribe Acular (Allergan, Inc.) q.i.d. for 5 days to ease any ocular discomfort. I instruct the patient not to touch his eye, because the incision can throb a little. Usually, this procedure makes the difference between a patient's being 20/25 unhappy and 20/20 delighted.

Myth No. 3: If you offer multifocal IOLs, you have to be able to perform LASIK for refractive touch-ups.

Nothing could be farther from the truth. In fact, I think PRK is better than LASIK for postoperative touch-ups. If your refractive surgery volumes are not high but you want to get involved in multifocal IOLs, do PRK, because it is less



stressful and may produce better results than LASIK. Older patients may tolerate PRK better than LASIK because of having less-adherent epitheliums. Also, the vast majority of IOL patients do better with conventional rather than customized treatments. For conventional PRK, I position the patient under the VISX iris registration operating microscope (Advanced Medical Optics, Inc., Santa Ana, CA), mark the center of the cornea, and wipe off the epithelium, which usually comes off easily. I then perform photoablation and complete the operation. Making such small ablations, usually of 1.00 D or less, often takes no more than 30 seconds.

I firmly believe that all refractive surgical eyes should receive an NSAID postoperatively as soon as possible. A bandage contact lens soaked in Acular LS controls pain excellently. However, I would never soak a contact lens in any other NSAID, because other agents may be too toxic, and there is no literature to support their use in this manner. I am also confident using Acular LS with Restasis (Allergan, Inc.) postoperatively. I prescribe Pred Forte (Alcon Laboratories, Inc., Fort Worth, TX), Acular LS, and Zymar q.i.d. I have the patient stop using Acular LS at 3 days, I discontinue the antibiotics when the epithelium closes

(usually after 4 to 5 days), and I taper the Pred Forte over 3 to 4 weeks.

GETTING INVOLVED IN REFRACTIVE IOLS

Multifocal IOLs require expert cataract surgery. Pay attention to details and maximize outcomes with the appropriate pharmaceuticals. Be willing and able to treat small refractive errors. Learn how to perform LRIs and PRK or else partner with a refractive surgeon. Refractive IOL patients are among the most demanding and challenging ones we face, but they also represent an enormous opportunity. Giving a patient good near, far, and intermediate vision for the rest of his life is an incredibly satisfying feeling, and I am confident that we can now offer this procedure to the majority of patients. □

Eric D. Donnenfeld, MD, is a partner in Ophthalmic Consultants of Long Island and is Co-Chairman of Corneal and External Disease at the Manhattan Eye, Ear & Throat Hospital in New York. He is a consultant and performs research for Allergan, Inc., Alcon Laboratories, Inc., Advanced Medical Optics, Inc., and Bausch & Lomb. Dr. Donnenfeld may be reached at (516) 766-2519; eddoph@aol.com.

STUDY: ACULAR LS PLUS STEROID VERSUS STEROID ALONE

By John R. Wittpenn, Jr, MD

My colleagues and I recently completed a large-scale, double-blind, multisite study that evaluated the efficacy of Acular LS (Allergan, Inc., Irvine, CA) for preventing cystoid macular edema (CME) after cataract surgery. We randomized 546 patients who underwent uncomplicated cataract surgery. Group 1 received Acular LS pre- and postoperatively as well as Pred Forte (Alcon Laboratories, Inc., Fort Worth, TX) postoperatively q.i.d. for approximately 3 weeks. Group 2 received only Pred Forte postoperatively. None of the patients had risk factors for or a previous history of macular disease.

We obtained optical coherence tomography (OCT) scans of patients in both groups 43 to 50 days postoperatively and asked a masked retinal observer to determine if each eye had definite, probable, or possible CME based on the presence of macular thickening and cystic changes. This initial evaluation showed a statistically significant difference between the group that received the steroid alone and the group that received Acular LS plus the steroid. When we re-evaluated the reviewer's findings, this time looking at only the probable and definite categories, we found that none of the patients in the combination treatment group had definite-to-probable CME compared with 2.4% of the patients in the steroid-alone group.

We observed less overall macular thickening in the Acular LS group. Calvin Roberts, MD, reported similar results last year in a

head-to-head comparison of cataract patients treated with Acular LS or a steroid.¹ Our numbers agreed almost exactly with his. In fact, when we looked at increments of thickening, we saw a statistical significance at 10 μ m and beyond at all points measured. In terms of visual functioning, this means that visual acuity worsens as the macula gets thicker.

Furthermore, patients on steroid monotherapy were more likely to have suboptimal visual outcomes than those treated with a combination of the steroid and Acular LS. This is important, because every patient in the study was expected to achieve 20/20 vision. Thus, if a surgeon treats 1,000 low-risk/no-risk patients per year, 24 to 84 of them may develop some degree of CME (assuming they all have perfect maculas preoperatively and undergo perfect surgeries). Therefore, I think this study demonstrates that Acular LS should be the standard of care for all cataract patients.

John R. Wittpenn, Jr, MD, is Associate Professor of Ophthalmology at the State University of New York in Stony Brook and is a partner at Ophthalmic Consultants of Long Island in Rockville Centre, New York. He is a consultant to Allergan, Inc., and a member of the company's speakers bureau, but he acknowledged no financial interest in any company or product mentioned herein. Dr. Wittpenn may be reached at (631) 941-1400; jr Wittpenn@aol.com.

1. Roberts CW. Do we need a new definition of cystoid macular edema? *Refractive Eyecare*. 2005;7:1.

Techniques for IFIS

There is no single best approach to managing a floppy iris.

BY DAVID F. CHANG, MD



Benign prostate hyperplasia (BPH) causes poor urinary outflow due to an enlarged prostate. Flomax (Boehringer-Ingelheim Pharmaceuticals, Inc., Ridgefield, CT) is an alpha-blocker that improves urinary outflow by relaxing the smooth muscle in the prostate and the bladder's neck. There are three alpha-1-blocker receptor subtypes, alpha-1 A, B, and D. Flomax is specific to the alpha-blocker 1A, which is the predominant subtype in the prostate and the iris dilator muscle. The nonspecific blockers such as Hytrin (Abbott Laboratories Inc., North Chicago, IL), Cardura (Pfizer Inc., New York, NY), and Uroxatral (Sanofi-Aventis, Bridgewater, NJ) can also cause Intraoperative Floppy Iris Syndrome (IFIS), although much less severely. Because Flomax is more urospecific and causes less postural hypotension than most nonspecific agents, it is the most commonly prescribed drug for treating BPH symptoms. Unfortunately, cessation of this and other alpha-blocking drugs does not prevent IFIS.¹

MANAGING IFIS

Severity Scale

In order to manage IFIS, you must understand and recognize that there is a continuum of severity that varies between different patients and even between the two eyes of the same patient.² Mild IFIS is characterized by good pupillary dilation, slight billowing of the iris, and no significant miosis or prolapse. If there is also intraoperative miosis (eg, > 2-mm decrease in pupil diameter), I characterize this as moderate IFIS. Severe IFIS has billowing, miosis, and a strong tendency for iris prolapse (Figure 1). Because pupillary stretching is ineffective, there are three primary types of management strategies that can be used alone or in combination: pharmacologic; viscoadaptive; or mechanical restraining devices. For me, the choice of what techniques to use depends on the severity of the IFIS, and familiarity with all three methodologies is therefore beneficial.

Viscoadaptive Stretching

Popularized by Robert Osher, MD, and Douglas Koch, MD, the viscoadaptive ophthalmic viscosurgical device (OVD) Healon 5 (Advanced Medical Optics, Inc.,

Santa Ana, CA) is very effective for IFIS, because it can mechanically dilate the pupil and also forms an impenetrable barrier to iris prolapse. The caveat is that you must use low aspiration flow and vacuum settings so that the Healon 5 is not immediately withdrawn from the eye. I first try to chop the nucleus into multiple fragments within in the capsular bag. This allows me to delay the phaco-assisted aspiration of the mobilized pieces in the supracapsular plane, at which point the Healon 5 will also start to be aspirated. If the pupil begins to constrict during this step, you simply add more Healon 5. If the nucleus is soft, high vacuum is generally not needed. During cortical I/A, the principle is to keep the phaco tip in the peripheral fornices of the bag, where you can constantly reocclude it with more cortex to avoid removing the OVD.

If you have limited experience with Healon 5, do not try it in IFIS eyes until you have mastered the nuances of its use in routine cases. For example, Healon 5 changes the mechanical dynamics of flap manipulation during the capsulorhexis. It must also be aspirated from behind the IOL's optic to avoid a postoperative pressure spike.

Pharmacologic Strategies

Administering atropine preoperatively, as advocated by Samuel Masket, MD, may help hold a mild-to-moderate IFIS pupil open if it is well dilated to begin with. However, my preferred pharmacologic approach is to inject 1:1,000 bisulfite-free epinephrine diluted 1:3 with plain balanced salt solution (BSS Plus [Alcon Laboratories, Inc., Fort Worth, TX] works fine, also), as suggested by Joel Shugar, MD.³ Richard Packard, BSc, FRCOphth, and David Allen, BSc, FRCOphth, of the UK, have also published on the efficacy

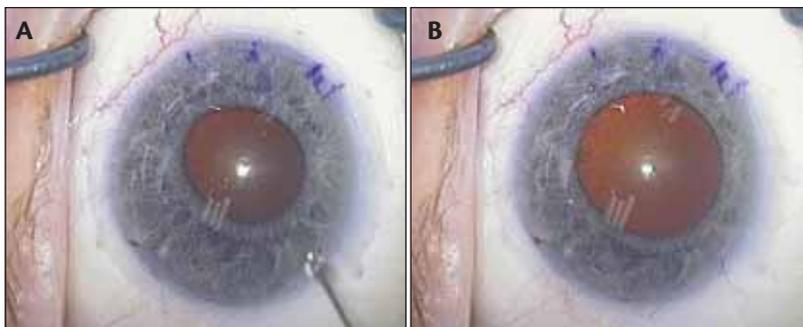


Figure 1. A Tamsulosin patient with IFIS both before (A) and after (B) the intracameral injection of epinephrine (1:1,000 bisulfite-free, mixed 1:3 with balanced salt solution).



TABLE 1. IFIS SEVERITY (FLOMAX)

Chang Multicenter Study (N=167)

| Severity | Percentage of cases |
|----------|---------------------|
| No IFIS | 10% |
| Mild | 17% |
| Moderate | 30% |
| Severe | 43% |

Chang DF, Osher RH, Wang L, Koch DD. A prospective multicenter evaluation of cataract surgery in patients taking tamsulosin (Flomax). *Ophthalmology*. 2007 (In press).

of using intracameral phenylephrine, which is not available in the US.⁴ These alpha agonists will further dilate the pupil in a mild-to-moderate IFIS case. More importantly, they increase the dilator's smooth muscle tone, which reduces or even eliminates the iris' floppiness and tendency to prolapse. Injecting epinephrine is a great rescue technique when IFIS is not recognized until after completion of the capsulorhexis and hydrodissection. Placing iris retractors is more difficult and risky at this point because of poor visibility of the capsulorhexis' edge, and I would therefore try intracameral epinephrine as a first step in this situation. I now use intracameral epinephrine with every potential IFIS case, unless I know that I will be using iris hooks.

The combination of Healon 5 and epinephrine works well if the pupil does not dilate enough after the intracameral injection of epinephrine. The epinephrine will increase the iris' rigidity, while Healon 5 viscomydriasis can facilitate the capsulorhexis.

Pupillary Expansion Devices

If the pupil hardly dilates in a Flomax patient, you should anticipate severe IFIS, because the dilator muscle is not responding at all. Another clue of greater IFIS severity is noticeable billowing of the iris as you first inject intracameral lidocaine. In these cases, you should consider using iris retractors.

I place the iris retractors in the diamond configuration.⁵ Through a separate paracentesis that I make immediately behind the clear corneal incision, I place a subincisional retractor that pulls the iris down and beneath the phaco tip. In contrast, the traditional square configuration of the hooks' placement tents the iris up in front of the incision. The nasal retractor also gives great exposure for placing the chopper. Fortunately, the IFIS pupil is usually very elastic and can be maximally stretched without damaging the iris sphincter. In contrast to eyes with pseudoexfoliation or on miotics, the IFIS pupil is not fibrotic, which is why it does not respond well to stretching.

Some surgeons prefer to use a pupil expansion ring as an alternative to iris hooks, although some experience is needed because they are difficult to position if the pupil is very small

or if the anterior chamber is shallow. I prefer reusable retractors that are made from 4-0 Prolene (Katena Products, Inc., Denville, NJ), and FCI Ophthalmics, Inc., Marshfield Hills, MA) instead of 6-0 nylon, because the former are easier to manipulate and also sturdy enough to be autoclaved and reused, which makes them very cost effective.

Because they guarantee a large pupil that will not constrict, I use iris retractors in IFIS eyes whenever I am concerned about visibility or other concomitant risk factors, such as a dense nucleus or pseudoexfoliation. If you are dealing with a one-eyed patient or plan to implant a presbyopia-correcting IOL, the security of a widely expanded pupil may well be worth the extra time needed to place retractors. With practice, using iris retractors will add a negligible amount of time to your procedure's overall duration.

STUDY

Because patient history obviously forewarns about IFIS, complication rates should be based on whether the syndrome was anticipated or unanticipated. Retrospective studies in which eye surgeons could not anticipate IFIS have reported higher rates of surgical complications in Flomax patients.¹ A prospective, multicenter study I conducted with nine colleagues evaluated the complication rate in 167 consecutive eyes in Flomax patients when the medication history was known in advance of the procedure.² Table 1 shows the severity of the IFIS. The surgeons used one of the three previously discussed categories of strategies, either alone or in combination, and the rate of vitreous loss and posterior capsular rupture was 0.6%. In short, the study showed that experienced surgeons who knew about their patients' history with Flomax preoperatively and were able to use these IFIS management strategies had very low complication rates. This was the basis for the joint AAO/ASCRS/AUA (American Urological Association) public press release in August 2006 that reported that these drugs were still safe to prescribe and take, as long as the ophthalmologist was informed. □

David F. Chang, MD, is Clinical Professor of Ophthalmology at the University of California, San Francisco. He is a consultant for Advanced Medical Optics, Inc., and Alcon Laboratories, Inc., but acknowledged no financial interest in the products or other companies mentioned herein. Dr. Chang may be reached at (650) 948-9123; dceye@earthlink.net.

1. Chang DF, Campbell JR. Intraoperative floppy iris syndrome associated with tamsulosin (Flomax). *J Cataract Refract Surg*. 2005;31:664-673.
2. Chang DF, Osher RH, Wang L, Koch DD. A prospective multicenter evaluation of cataract surgery in patients taking tamsulosin (Flomax). *Ophthalmology*. 2007 (In press).
3. Shugar, JK. Intracameral epinephrine for prophylaxis of IFIS [letter]. *J Cataract Refract Surg*. 2006;32:1074-1075.
4. Manvikar S, Allen D. Cataract surgery management in patients taking tamsulosin. *J Cataract Refract Surg*. 2006;32:1611-1614.
5. Oetting TA, Omphroy LC. Modified technique using flexible iris retractors in clear corneal surgery. *J Cataract Refract Surg*. 2002;28:596-598.

NSAIDs in Cataract Surgery

Routine use is no longer a question.

BY MICHAEL B. RAIZMAN, MD



It is my view that every cataract and refractive lensectomy patient should receive topical NSAID drops before and after surgery. Ensuring these patients' visual quality is critical, and they deserve the best protection against inflammation. For more than 10 years, I have advocated the routine use of NSAIDs in cataract surgery, and only recently have a majority of ophthalmologists accepted this strategy.

OCT REVEALED CYSTOID MACULAR EDEMA

When I started investigating cystoid macular edema (CME) in cataract surgery more than 10 years ago, I was satisfied if my patient saw 20/40 or better after surgery. These days, cataract and refractive IOL patients complain if their acuity is not 20/20, and some patients complain about 20/20 vision if they have symptoms. Many of the visual problems patients experience with 20/20 vision actually stem from changes in the macula, an association that has been documented with optical coherence tomography (OCT). Thickening of the macula may cause decreased contrast sensitivity or metamorphopsia even with 20/20 vision.

In the 1990s, a group of scientists from the Massachusetts Institute of Technology collaborated with ophthalmologists at Tufts University, where I have worked for the past 15 years, to create the first OCT unit. After using it for a short time, I was surprised by how many of my cataract patients had CME after what I thought was perfect surgery. Subsequently, I conducted a randomized trial¹ in which all patients received a topical NSAID for 2 days before surgery, and half the patients received an NSAID after surgery for 1 month. All patients received topical corticosteroids after surgery (Figure 1). None were diabetic or had any other risk factors for CME. The patients underwent uncomplicated clear corneal cataract surgery with no vitreous loss. None of the patients who received an NSAID and a corticosteroid drop developed CME, although 12% of those who received a corticosteroid alone had some. CME appeared in eyes with 20/25 to 20/30 postoperative vision as well as eyes with worse vision. One patient in the study did not respond to any postoperative therapy and permanently lost some visual acuity.

REASONS TO USE NSAIDS

Many surgeons used to think that they did not need to use NSAIDs if they used topical steroids. Steroids are incredibly potent for reducing ocular inflammation, but they are

relatively ineffective at inhibiting prostaglandin synthesis and the effects of arachidonic acid metabolites in the eye. During cataract surgery, prostaglandins are released from the iris and ciliary body. From there, they migrate to the retina and induce CME (Figure 2). The key to preventing CME is to block prostaglandin synthesis in the iris and ciliary body with a highly concentrated drug.

Several large studies have validated NSAIDs' ability to treat and prevent CME.²⁻⁴ Ketorolac (Acular; Allergan, Inc., Irvine, CA) is the most widely studied NSAID. Diclofenac (Voltaren; Novartis Ophthalmics, Inc., Duluth, GA) has also been studied for many years. Two newer agents (Xibrom [bromfenac 0.09%; Ista Pharmaceuticals, Inc., Irvine, CA] and Nevanac [nepafenac ophthalmic suspension 0.1%; Alcon Laboratories, Inc., Fort Worth, TX]) are now available, but their effectiveness in treating and preventing CME has not been confirmed in large trials.

All the agents available in the US are approved for and are effective in reducing postoperative inflammation (Figure 3). NSAIDs also prevent intraoperative miosis. Eric D. Donnenfeld, MD, recently presented an interesting study demonstrating that just small changes in the pupil's size make a difference in surgical outcomes and complications.⁴ Thus, any extra pupillary dilation we can get is valuable.

Finally, NSAIDs play a large role in comforting patients' eyes during surgery. They are excellent at reducing pain during topical anesthesia. NSAIDs effectively inhibit cyclooxygenase, which produces prostaglandins, whereas corticosteroids do not. Furthermore, corticosteroids have side effects. They are good at reducing inflammation, but they raise IOP, interfere with wound healing, and do not mitigate

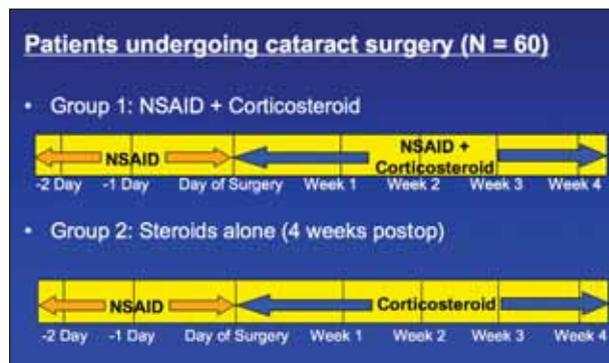


Figure 1. The study's efficacy comparison of topical NSAIDs and steroids in reducing the incidence of CME.¹

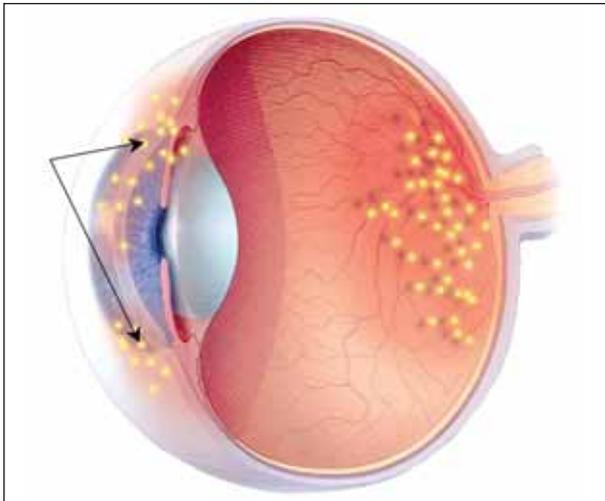


Figure 2. Prostaglandins are released in the anterior portion of the eye (yellow dots, indicated by arrows). They then diffuse to the posterior portion of the eye.

pain. Corticosteroids inhibit phospholipase A_2 , which is important in the production of arachidonic acid, but the effect is small. For this reason, we must block the cyclooxygenase with an NSAID as well.

USING NSAIDS APPROPRIATELY

A few years ago, there were problems of NSAIDs (primarily a generic formulation of diclofenac) causing corneal melting. Since that drug was pulled from the market, the incidence has of corneal melts has been negligible. I think NSAIDs are extremely safe. They have an excellent track record; millions of patients use these drops each year without difficulty. Of course, there are a few situations in which surgeons need to use them carefully. Cataract patients with severe dry eye, keratoconjunctivitis sicca, filamentary keratitis, or severe rheumatoid arthritis may not tolerate NSAIDs. If one of these patients were at high risk for developing CME, I would prescribe an NSAID but follow the patient more closely to monitor the cornea's reaction to the therapy. Also, NSAIDs must be used no more frequently than prescribed. In my view, dosing more than four times a day is inappropriate in any setting.

Some patients are at especially high risk for CME and therefore need more prolonged NSAID treatment before and after surgery. Patients with preexisting uveitis are at high risk, as are patients who developed CME in the opposite eye after undergoing previous surgery. Other high-risk patients include those with retinopathy (especially diabetics), retinal-vascular diseases, and retinitis pigmentosa (this last disease is quite uncommon, but these patients have an extremely high rate of CME with cataract surgery).

For cataract patients who are not at risk for CME, I start an NSAID 3 days before surgery. This approach provides the

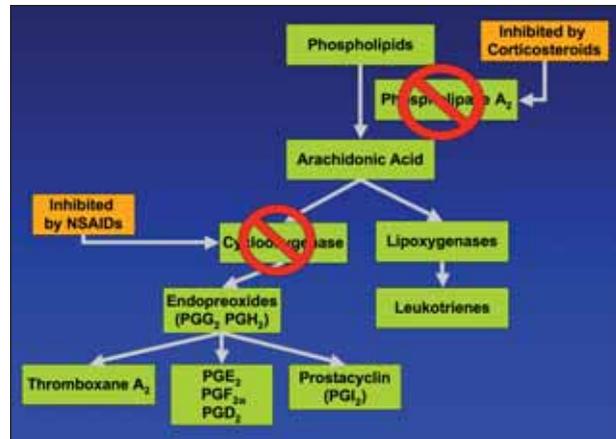


Figure 3. NSAIDs' mechanism of action.²

best reduction in postoperative inflammation, in my opinion. Postoperatively, I prescribe the NSAID for 4 weeks in combination with the corticosteroid. I start patients at high risk of developing CME on an NSAID 1 week before surgery and typically continue it for 6 to 8 weeks afterward.

Sometimes, surgeons think they can wait and see if CME develops and then treat the eye if it does. CME is not always treatable, however, and it can cause permanent vision loss. Furthermore, topical NSAIDs can improve the rapidity with which a patient's vision improves after cataract surgery. Using these agents therefore serves multiple purposes.

IN CLOSING

Ophthalmologists are more likely to see CME than endophthalmitis. CME is extremely common but effectively preventable with NSAIDs. The definition of this condition is evolving, especially with refractive patients who are more demanding. In my view, pre- and postoperative NSAID dosing is ideal, and postoperative dosing should be carried out for 4 weeks or longer in patients at high risk for CME. □

Michael B. Raizman, MD, is in private practice with Ophthalmic Consultants of Boston in Massachusetts. He is Associate Professor of Ophthalmology and Director of the Cornea and Cataract Service at Tufts University School of Medicine in Boston. Dr. Raizman has received research funds, consulting fees, and/or travel expenses from Alcon Laboratories, Inc., Allergan, Inc., and Ista Pharmaceuticals, Inc. Dr. Raizman may be reached at (617) 367-4800, mbraizman@eyeboston.com.

1. McColgin AZ, Raizman MB. Efficacy of topical diclofenac in reducing the incidence of postoperative cystoid macular edema. *Invest Ophthalmol Vis Sci.* 1999;40:S289.
2. Jampol LM. Pharmacologic therapy of aphakic cystoid macular edema. A review. *Ophthalmology.* 1982;89:891-897.
3. Flach AJ, Dolan BJ, Donahue MD, et al. Comparative effects of ketorolac 0.5% or diclofenac 0.1% ophthalmic solutions on inflammation after cataract surgery. *Ophthalmology.* 1998;105:1771-1779.
4. Donnenfeld ED, Perry HD, Wittmann JR, et al. Preoperative ketorolac tromethamine 0.4% in phacoemulsification outcomes: pharmacokinetic-response curve. *J Cataract Refract Surg.* 2006;32:1474-1482.

Phaco Myths and Reality

How your machine really works.

BY RANDALL J. OLSON, MD



Because phaco machines play an important role in refractive cataract surgery, it is incumbent upon us to understand the differences as well as the full spectrum of parameters between the available platforms. My group and I have published seven studies on phaco systems, and following is a review of the primary lessons I have learned from studying these machines.

Myth No. 1: Percent power is an appropriate way to compare different platforms.

Percent power is not equivalent across the phaco platforms, nor are one machine's parameters comparable to another's. A study that my colleagues and I published in the *Journal of Cataract & Refractive Surgery*¹ compared the percent power of four phaco machines: the Millennium Microsurgical System (Bausch & Lomb, Rochester, NY), the Infiniti Vision System (Alcon Laboratories, Inc., Fort Worth, TX), the Series 20000 Legacy Cataract System (Alcon Laboratories, Inc.), and the Sovereign System with WhiteStar technology (Advanced Medical Optics, Inc., Santa Ana, CA). We determined each system's percent power when working with its phaco tip in water alone versus with their tips working in water with a 200-gram weight placed on the end (to simulate a dense nuclear fragment). The purpose of the study was to see how the machines adjusted their power outputs in different environments.

We tested each phaco system at 20% to 100% linear power in 20% increments, but each one used more power when its tip was working with the load versus unweighted (Table 1). The Millennium has the lowest kilohertz but ran the hottest, which means it has the longest stroke length. Its percent power did not change much with the load, nor did the Sovereign's. The Legacy had the most change in percent power, and the Infiniti's change was moderate.

The Legacy's power system works like a car's cruise control, adjusting the amount of power to maintain its stroke length in different environments. So, if the phaco tip suddenly encounters a hard nuclear fragment, the Legacy will surge the

power without the surgeon's increasing pressure on the foot pedal. Indeed, we found a statistically significant difference in wound burn between the machines in another study.²

The Millennium had the least amount of wound burn, followed by the Sovereign (the two were statistically similar), and the Legacy had statistically significantly more than the other two. We did not have enough data on the Infiniti to include that system in this comparison.

Myth No. 2: Peristaltic systems create vacuum only after occlusion and vacuum are allowed to build.

I think this myth is the most pervasive and troublesome for surgeons. It is true that Venturi systems have active vacuum to produce flow, but we wanted to examine the belief that peristaltic systems have no vacuum in the unoccluded state. This is an important argument to understand, because many surgeons have concerns about active vacuum's not releasing an unintended object. Also, many physicians wonder whether active vacuum causes damage if it is set too high. Peristaltic systems offer a chance to pull the phaco tip free if necessary.

To determine each system's true flow rates, we compared the mL/min that the machines indicated versus what they really produced. We found errors in flow rates of up to 17% in general, and some of more than 20% when STAAR Cruise Control (STAAR Surgical Company, Monrovia, CA) was used. For example, the Sovereign machine set to 40 mL/min with Cruise Control produced a flow of only 32 mL/min. In fact, we found it difficult to achieve more than 35 mL/min in any phaco system we tested with Cruise Control.

When we tested the machines' actual vacuum power, we found errors of up to 23%. For instance, ABS, the bypass port at the phaco tip's end, decreased the actual vacuum by an average of 12.1%. Thus, on top of what

TABLE 1. COMPARISON OF PERCENT POWER

| Machine | Water Load | Water plus 200 gm | Ratio of the two |
|------------|-------------|-------------------|------------------|
| Millennium | 5.67+/-0.51 | 6.80+/-0.80 | 1.20 |
| Sovereign | 4.59+/-0.70 | 5.65+/-0.72 | 1.23 |
| Infiniti | 2.79+/-0.62 | 3.96+/-0.31 | 1.42 |
| Legacy | 1.99+/-0.49 | 4.27+/-0.76 | 2.15 |



TABLE 2. COMPARISON OF UNOCCLUDED VACUUM AT 32 ML/MIN

| Machine | Vacuum (unoccluded) |
|----------------|---------------------|
| Sovereign | 57.7+/-5.3 mm Hg |
| Sovereign - CC | 140.4+/-0.6 mm Hg |
| Infiniti | 66.4+/-0.5 mm Hg |
| Legacy | 70.1+/-1.5 mm Hg |
| Mill - P | 88.9+/-2.6 mm Hg |
| Mill - V | 104.7+/-0.0 mm Hg |

error may be in the system, ABS produces an additional error of 50 to 60 mm Hg at high vacuum levels.

Our findings on flow and vacuum rates were critical to determining each phaco system's true, unoccluded vacuum. At 32 mL/min actual flow, the Sovereign's unoccluded vacuum was 57.7 ±5.3 mm Hg, and 140 mm Hg with Cruise Control, which is more vacuum at this flow than the Millennium system using Venturi vacuum (Table 2)! Therefore, it is a myth that a peristaltic pump system provides no vacuum without occlusion, at least at most of the parameters we use today. In fact, a peristaltic device may have more active unoccluded vacuum than a Venturi device with a flow restrictor like Cruise Control. This is worth remembering when approaching the capsule and iris, because that amount of unoccluded vacuum can produce enough energy to damage the capsule or iris. The way each phaco system responds to different situations factors into how to control surge with each one.

Myth No. 3: Postocclusion surge is largely tame and nearly equivalent for all current phaco machines.

Postocclusion surge is one of ophthalmologists' biggest enemies to avoiding complications. A machine builds kinetic energy when its tip is occluded. Breaking occlusion creates a relatively rapid evacuation of fluid inside the eye, and that trampolining or loss of depth in the anterior chamber can cause an instantaneous break in the capsule. Therefore, controlling surge is a critical safety issue.

Having determined each system's true vacuum power, we could adjust them to equalize their power output. We also had to know each one's actual flow, because flow is related to surge. The higher the flow, the greater the surge.

These data appear in an article that is to be published in the *American Journal of Ophthalmology*. We used a bottle height of 75 cm, 20-gauge phaco tips, and a flow rate of 24 mL/min. We used 430 mm Hg/min vacuum power (the highest vacuum we could guarantee for all the machines in this testing). The Millennium peristaltic system surged the

least, at approximately 50 µm. The Sovereign was second, with 110 µm of surge, the Infiniti had 153 µm of surge, and the Legacy had 317 µm. These were highly statistically significant with tight standard deviations. The Millennium Venturi, however, almost completely collapsed the anterior chamber at that power. At over 2 mm, we could not quantify its surge, because the chamber collapsed so much that it pulled away from our measuring device.

Our next test produced results that I did not expect. Using the same parameters, we switched to using 19-gauge phaco tips. The Sovereign's surge increased by 140%, and the Infiniti's by 200%. In particular with the Millennium Venturi, Cruise Control was extremely powerful in decreasing the overall surge. The Millennium peristaltic system did not show a statistically or clinically significant change in surge: it went from 47 to 42 µm. The Sovereign went from 110 to 147 µm. The Millennium Venturi (tested at 400 mm Hg and 125cm bottle height, because the higher parameter was still not safe), however, went from more than 2 mm to 210 µm. Its surge went from a dangerous to a safe parameter. Also, at 400 mm Hg, the Millennium Venturi had a flow of approximately 90 mL/min. Remember that flow and vacuum are inseparable in a Venturi system, and the Cruise Control dropped the flow down to 60 mL/min—a great combination that makes this Venturi system much safer.

A FEW OTHER FINDINGS ABOUT SURGE

Adjusting ABS had no impact on the Infiniti system but improved the Legacy by 66%. Thus, it seems that ABS is not important if internal surge protecting systems are present. Increasing the bottle height to 125 cm improved surge on the Infiniti by only 37% and on the Legacy by 70%. Obviously, the machines use different tactics to control surge. Using 40 mL/min of flow increased surge in the Legacy by 60% but in the Infiniti by only 20%. These findings show that the Infiniti phaco system is much more forgiving in regard to surge than the Legacy, and that the other machines are as good or better than the Infiniti. Surge is the real barrier to better outcomes, particularly for refractive cataract patients. □

Randall J. Olson, MD, is the John A. Moran Presidential Professor, Chair of Ophthalmology, and Director of the John A. Moran Eye Center at University of Utah Health Sciences in Salt Lake City. He is a paid consultant for Advanced Medical Optics, Inc. Dr. Olson may be reached at (801) 585-6622 or (801) 581-8703; randall.olson@hsc.utah.edu.

1. Payne M, Georgescu D, Waite AN, Olson RJ. Phacoemulsification tip vacuum pressure: comparison of 4 devices. *J Cataract Refract Surg.* 2006;32:8:1374-1377.
2. Bradley MJ, Olson RJ. A survey about phacoemulsification incision thermal contraction incidence and causal relationships. *Am J Ophthalmol.* 2006;141:1:222-224.
3. Floyd MS, Valentine JR, Olson RJ. Abstract fluidics and heat generation of Alcon Infiniti and Legacy, Bausch & Lomb Millennium, and Advanced Medical Optics Sovereign phacoemulsification systems. *Am J Ophthalmol.* 2006;142:3:387-392.

Mixing and Matching Multifocal IOLs

The technologies of the Rezoom and Restor lenses are complementary, not antagonistic.

BY FRANK A. BUCCI, JR, MD



Since June 1, 2005, I have implanted 550 Rezoom refractive multifocal (Advanced Medical Optics, Inc., Santa Ana, CA) and Acrysof Restor diffractive multifocal (Alcon Laboratories, Inc., Fort Worth, TX) IOLs.

Following is what I have learned about achieving a high level of spectacle independence and patient satisfaction with these lenses.

FOUR CRITERIA FOR SUCCESS

I believe there are four essential elements to successfully treating presbyopic patients. They must receive (1) a high quality of distance visual acuity, (2) functional intermediate vision in order to read a computer screen at arm's length, (3) functional near vision in both bright and moderate light (they should be able to read a newspaper unaided after surgery), and (4) all this with an acceptable amount of light phenomena while driving at night.

None of the presbyopia-correcting IOLs currently available in the US consistently meets all these requirements when implanted bilaterally in a lensectomy patient. The Crystalens accommodating IOL (Eyeonics, Inc., Aliso Viejo, CA) provides excellent distance and intermediate vision when placed in the capsular bag correctly. It gives relatively poor near vision, with only 1.00 to 1.25 D of accommodation. It has minimal light phenomena at night because it lacks multifocal optics.

The Rezoom lens gives excellent distance and intermediate vision, especially in daylight when the pupil is smaller and the patient is looking through the central distance zone. Under these conditions, the quality of distance vision is similar to that of a monofocal IOL. The reading vision the Rezoom provides is fair in bright light and very good in moderate light (in the latter, the pupil expands and encompasses the second zone for near vision). In my experience, this lens has more light phenomena than the Crystalens and Restor IOLs but considerably less than the Array multifocal lens (Advanced Medical Optics, Inc.).

Distance vision with the Restor IOL has been problematic, in my experience. Patients can have waxy, shadowy, three-dimensional, and double vision, and they can also lose BCVA. However, the Restor optic's outer refractive component can minimize visual symptoms as the pupil dilates, because it does not hit any additional diffractive rings. The Restor's excellent reading power can drop off rather quickly

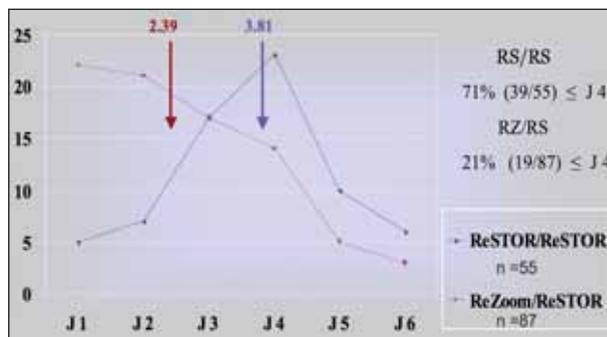


Figure 1. This frequency curve shows bilateral intermediate visual results for the study.

as the pupil dilates. Further, many patients perceive the lens' focal point as being somewhat too close. It delivers poor intermediate vision, in my experience, and trying to make the lens hyperopic to improve intermediate vision sacrifices distance visual acuity substantially.

I see less light phenomena with the Restor than with the Rezoom and Array lenses, but I do not hear strong complaints about halos from either Restor or Rezoom patients. I began using the Restor IOL in June 2005. My first cohort included 55 bilaterally implanted patients, two-thirds of whom underwent lensectomies. I observed poor intermediate vision in general, and 17 of the 55 patients had spontaneous, voluntary, severe complaints about their intermediate vision.

FIRST EXPERIENCE MIXING AND MATCHING

During this time, patients in whom I had unilaterally implanted an Array IOL were returning for their routine exams. They had been waiting for new multifocal technology that would give them stronger detailed reading vision. I placed a Restor IOL in their opposite eyes, and it improved their reading vision and induced no serious halos. They were some of the happiest people I had ever treated. Based on my success with these Array/Restor patients, I decided to test the efficacy of a Rezoom/Restor combination.

REZOOM/RESTOR DATA

I have since implanted 145 patients with a Rezoom IOL in one eye and a Restor lens in the other. My follow-up data are complete for 110 of the 145 patients. All the patients' astigmatism has been corrected and their posterior capsular

opacification treated when needed.

My 55 bilaterally implanted Restor patients (cohort I, mean follow-up = 16 months) were allowed to use their best focal near point to bring in an object as close to their face as they wanted. One hundred percent of these patients saw J1 at near. Cohort II includes my 110 Rezoom/Restor patients (mean follow-up = 9 months). Some might have expected the near vision in these patients to be weaker than the bilateral Restor group's, but there was no significant difference. The mean near vision was J1.07 bilaterally. Interestingly, some of these patients were happier with their near vision than some of the Restor/Restor patients, because their focal point was less close in their Rezoom eye, and they had a wider range of reading vision. The two groups were not equal with intermediate vision. Cohort I had intermediate vision of J3.81. Cohort II's intermediate vision was J2.39. These findings are both statistically and clinically significantly different ($P=.0001$).

A frequency curve (Figure 1) shows that 71% of the Restor/Restor patients' bilateral intermediate vision was J4, compared with only 21% of the Rezoom/Restor patients. The frequency table in Figure 2 includes yellow dots that represent the patients who had severe intermediate complaints (17 out of 55). Separating these complaints by procedure, 13 of the 17 patients with complaints underwent lensectomies versus cataract surgery. Eleven of those 13 lensectomy patients were under 60 years of age. Therefore, these results define a subgroup of patients who perform very poorly with bilaterally implanted Restor IOLs.

CORROBORATING STUDIES

Why are the Rezoom and Restor lenses synergistic and complementary instead of antagonistic, like many predicted? Each one's strengths overcome the other's weaknesses. The Rezoom covers the Restor by giving better distance vision during the day, excellent intermediate vision, and good reading in dim light. The Restor covers the Rezoom with better reading vision in bright light and fewer halos at

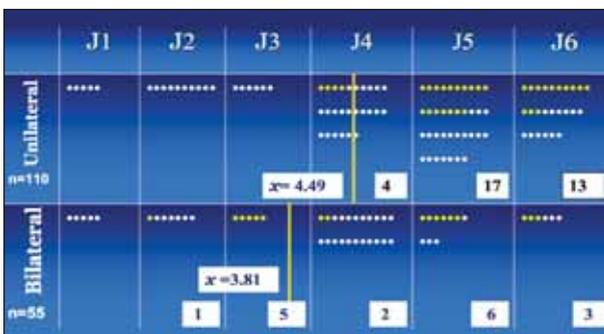


Figure 2. The yellow circles in this frequency table represent the 17 of 55 eyes that experienced severe intermediate visual complaints.

TABLE 1. RESTOR/RESTOR VERSUS REZOOM/RESTOR

| WORLD CORNEA CONGRESS ¹ | | |
|------------------------------------|---------------------------|---------------------------|
| | RS/RS (N=100) | RZ/RS (N=88) |
| Near | 1.40 (11.8") (Bucci 1.00) | 1.50 (15.4") (Bucci 1.07) |
| Intermed | 3.85 (Bucci 3.81) | 2.30 (Bucci 2.39) |
| Distance | 20/25 | 20/20 |
| Speed (Read) | 165 wpm | 155 wpm |
| Spec Indep | 89% | 100% |
| Halos/Glare | (1+) | (1+) |

night. At the 2006 World Cornea Congress in Brazil, Drs. Akaishi and Fabri presented their results from a similar comparative study that showed that a refractive/diffractive lens combination outperforms a diffractive/diffractive combination.¹ Of my 145 Rezoom/Restor patients, even those who had not yet received astigmatic correction, none has reported spontaneous intermediate visual complaints of the character and depth that I saw in the Restor/Restor group.

Unknowingly, the Brazilian study group was performing its comparison at the same time. Our bilateral results are remarkably similar and reinforce one another. Our bilateral intermediate visual results are almost identical (Table 1). The other group's near visual results are slightly different because they required patients to read at near at a specific focal length, and I did not. Note that in the Brazilian study, the investigators also observed some reduction of distance vision with the Restor/Restor combination. Its Rezoom/Restor group achieved 100% spectacle independence versus 89% in its Restor/Restor group.

SUMMARY

To date, the Rezoom/Restor combination appears to completely mitigate intermediate visual complaints. The relative risk of these complaints with bilaterally implanted Restor lenses increases with younger age and in lensectomy procedures. The unique optical characteristics of the two IOLs appear to be complementary, and this synergistic effect produces high levels of spectacle independence and patient satisfaction. □

Frank A. Bucci, Jr, MD, is Medical Director of Bucci Laser Vision Institute in Wilkes-Barre, Pennsylvania. He received a research grant from Advanced Medical Optics, Inc., in the form of a discount on Rezoom IOLs for the Rezoom/Restor investigation. He acknowledged no other financial interest in the products or companies mentioned herein. Dr. Bucci may be reached at (570) 825-5949; buccivision@aol.com.

1. Akaishi L, Fabri PP. PC IOLs mix and match technologies: Brazilian experience. Paper presented at: The World Ophthalmology Congress; Feb., 2006; São Paulo, Brazil.

Refractive Lens Exchange Techniques

The tricks I use to optimize my outcomes.

BY R. BRUCE WALLACE III, MD



I have been implanting multifocal IOLs for more than 18 years, and I am excited to see that the new generation of the technology is generating a higher degree of interest in refractive lens exchange for surgeons and their patients.

Because more ophthalmologists will want to offer this procedure to their presbyopic patients (Note: this is an off-label procedure for these FDA approved devices), following are the strategies that help me achieve consistent results with refractive lens exchange.

CENTERING THE CAPSULOTOMY

I use a 6-mm capsulotomy diameter mark (CDM) to make a template on the central cornea to center the capsulotomy and size it for capsular overlap after IOL implantation. If I stay just inside the mark, I can consistently perform a 5.0-mm central capsulorhexis.¹

STABILIZING THE GLOBE

I rely on frequent globe stabilization (Figure 1) when I use topical anesthesia. I use a blunt-tip cyclodialysis spatula while making the anterior capsulotomy, which I think helps stabilize the globe and is a very important part of the procedure. I use the cyclodialysis spatula again when inserting the nose cone of the IOL inserter, because I think it gives excellent control and minimizes the likelihood of breaking the capsule while I advance through Descemet's membrane.

EXPLAINING ASTIGMATIC CORRECTION TO PATIENTS

With multifocal IOLs gaining popularity, surgeons are hearing a lot about limbal relaxing incisions (LRIs) and the need to correct eyes that have more than 0.75 D of residual cylinder. Many patients do not fully understand the need for astigmatic correction (especially when paying extra for it), so my staff and I devised a low-tech way to demonstrate the value of an LRI procedure. We show them a picture of a doorknob to represent the normal cornea, and the back of a spoon to represent the astigmatic cornea.

Although corneal topography is not necessary to perform LRIs, it helps me to make surgical planning more reliable. I have a personalized nomogram for using a preset diamond

knife with a single foot plate (Duckworth & Kent Ltd., Hertfordshire, England). I also rely on a Mendez marker, which has numbers to keep the surgeon oriented when marking the axis' position before making the incision. I perform LRIs before phacoemulsification. I mark the axis and the incisional borders, and then I fixate the globe using the same forceps that I used to mark the cornea. Then, I advance the diamond knife toward fixation (Figure 2A and B).

CASE EXAMPLE

One particular case illustrates how these instruments help me improve outcomes. A male patient had approximately 1.75 D of with-the-rule cylinder. His corneal topographer showed the cylinder's location at 106°, where I decided to make the incision. It is helpful to irrigate the cornea well in order to reduce the amount of epithelial trauma. I pushed back the upper lid somewhat to see the 90° mark, and I adjusted the Mendez marker to place the handle at the lateral canthus (180°). I marked the axis at 106° and rotated the Mendez marker so I could put a hash mark on the mark that I just made. I then marked the cornea 30° on each side of the axis mark (I counted three slashes on each side, which comprised a 60° arc for the entire incision.). Placing single incisions in the periphery for low levels of astigmatism should avoid inducing much irregular astigmatism and will not interfere with the sideport or phaco inci-



Figure 1. The author stabilizes the globe with forceps and uses a blunt-tip cyclodialysis spatula to make the capsulotomy.

sions. Thus, my nomogram is biased toward single incisions for low levels of astigmatism.

CORTICAL CLEAVING HYDRODISSECTION

I think it is important to use an NSAID like Acular LS (Allergan, Inc., Santa Ana, CA) for refractive lens exchange patients. I prescribe an NSAID 3 days before and for 3 to 4 weeks after surgery. Intraoperatively, I also use a short-acting mydriatic like Mydracyl (Alcon Laboratories, Inc., Fort Worth, TX), because I like the pupil to be as normal as possible soon after surgery.

I use low-energy controlled phacoemulsification with a Sovereign phacoemulsification system (Advanced Medical Optics, Inc., Santa Ana, CA) with Whitestar technology (wherein micropulses generate less heat). I like to use the cortical cleaving hydrodissection technique that I. Howard Fine, MD, described many years ago, which involves injecting the balanced salt solution into the posterior surface of the anterior capsule to create a peripheral wave. This technique leaves very little cortex after the nucleus is extracted.

Good mydriasis is also important in refractive lens exchange, and medications other than intracameral epinephrine can be useful. Eric D. Donnenfeld, MD, conducted a study² that showed that Acular LS used preoperatively, before prostaglandin release, can both reduce CME and help maintain dilation during surgery.

THE BURST HEMIFLIP TECHNIQUE

I was looking for a refractive lens exchange technique that I could also utilize in standard cataract surgery for practice. Chopping and cracking do not apply to refractive lens exchange, so I worked with different phaco systems and ultimately developed the burst hemiflip technique. With micropulse parameters, I do not spend a lot of time in the eye. I prefer the hemiflip technique to full flip because I can use a 5-mm capsulotomy and perform phacoemulsification in the iris plane.

The idea is to split the nucleus in half before removing it, which is usually possible in patients 55 or older. I make a fairly wide groove in the nucleus, just like with a dense cataract, far enough away from the endothelium. I try to separate the hemispheres without a lot of chopping. Separating the hemispheres completely is the most challenging step. If the lens is still connected in the periphery, it will not flip up. The hemiflip technique is safe and controlled and minimizes phacoemulsification. Once I have split the nucleus, I lift one hemisphere and try to keep my other instrument beneath the phaco tip in order to avoid contact with the posterior capsule (Figure 3). As Dr. Olson's article points out, industry is developing new equipment and software to reduce surge. Thanks to the Sovereign's improved fluidics, I have been able to phacoemulsify some soft nuclei with no-power ultrasound, a mode I call *quiet phaco*.

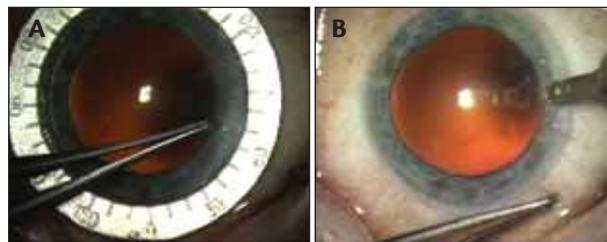


Figure 2. The surgeon marks the cornea with a Mendez marker (A) before advancing the diamond knife toward fixation (B).



Figure 3. The author uses his second instrument to lift the nuclear hemisphere up toward the phaco tip.

A RENAISSANCE IN LENTICULAR SURGERY

The range of surgical treatments for presbyopia is continuing to grow. The renaissance in lenticular surgery is particularly exciting, but many patients will not learn about multifocal IOLs until surgeons educate them. As the word spreads, we will see more people asking their ophthalmologists about multifocal and accommodative IOLs. I encourage surgeons interested in adopting refractive lens exchange to consider the surgical techniques outlined here in order to optimize their results. □

R. Bruce Wallace III, MD, FACS, is Clinical Professor of Ophthalmology at Louisiana State University Medical School in New Orleans, Assistant Clinical Professor of Ophthalmology at Tulane School of Medicine, and Medical Director of Wallace Eye Surgery in Alexandria, Louisiana. Dr. Wallace is a paid consultant for Advanced Medical Optics, Inc., and Allergan, Inc., but acknowledged no financial interest in any product mentioned herein. Dr. Wallace may be reached at (318) 448-4488; rbw123@aol.com.

1. Wallace RB. Capsulotomy diameter mark. *J Cataract Refract Surg.* 2003;29:1866-1868.
2. Donnenfeld ED, Kim T, Holland EJ, et al; American Society of Cataract and Refractive Surgery Cornea Clinical Committee. ASCRS White Paper: Management of infectious keratitis following laser in situ keratomileusis. *J Cataract Refract Surg.* 2005;31:10:2008-2011.

A Study Comparing SBK to PRK

Three-month results are better in the SBK eyes across the board.

BY STEPHEN G. SLADE, MD, FACS



Sub-Bowman's keratomileusis (SBK) may comprise the best of PRK and LASIK. The surgery involves making a customized, thin, smaller-diameter flap of no more than 100 μm . This thinner flap is believed to have the strength of PRK with no stress to the epithelium. Daniel S. Durrie, MD, and I are conducting an ongoing study to compare PRK versus LASIK with SBK. The following reports the study's 3-month results.

PARAMETERS

This study involves 100 eyes of 50 patients and is contralateral, prospective, and randomized to the dominant eye. We randomized one eye of each patient to PRK and the other eye to SBK. The patient demographics were normal for moderate myopes. The average age was 33.24 ± 6.97 (range, 22 to 48 years), and there were 21 males and 29 females.

All the eyes received Customcornea laser ablations (Alcon Laboratories, Inc., Fort Worth, TX), but half the eyes received an 8.5-mm, 100- μm SBK flap with the 60-Hz FS laser and the other half underwent 8.5-mm, ETOH-assisted PRK. The standard deviations for both groups in preoperative refractions were in the tenths of a diopter, thus showing the power of a contralateral eye study. There were no complications or aborted procedures in either group.

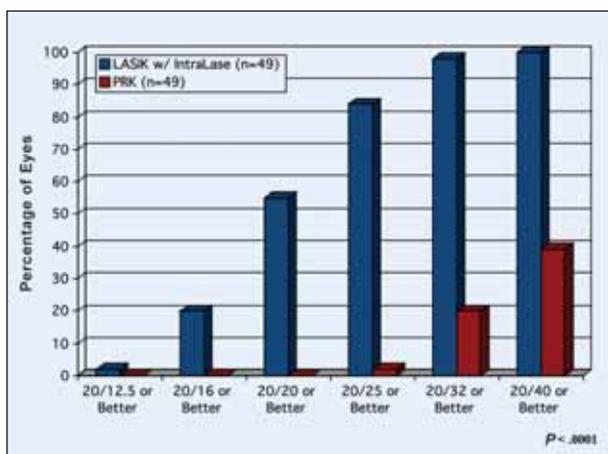


Figure 1. UCVA 3 days postoperatively.

UCVA RESULTS

On the first postoperative day, the SBK eyes had better UCVA than the PRK eyes across the board. Of the SBK eyes, 50% achieved 20/20 or better and 100% achieved 20/40 or better. Fewer than 10% of the PRK eyes saw 20/20 or better uncorrected, and only slightly more than 40% saw 20/40 on the first day.

At 3 days, the SBK eyes continued to improve (55% achieving 20/20 or better), but the PRK eyes actually worsened (only 20% achieving 20/32 or better) (Figure 1). The PRK eyes took 1 week to regain the level of vision they had at 1 day. Moreover, by 1 week, more than 30% of the PRK eyes still had not reached 20/40, the acuity at which patients can see well enough to drive without glasses. At 3 months, the two groups' UCVA began to equilibrate, although still twice as many SBK eyes as PRK eyes saw 20/12 (Figure 2).

We wondered whether the better results in the SBK eyes meant that those eyes were overcorrected and that these young patients were focusing through the error. We ruled out this possibility after looking at the refractions for the two groups, which were within 0.10 D.

BCVA

The SBK eyes also had better BCVA at 1 and 3 months than the PRK eyes (57% with gains in lines of vision versus 53% of the PRK eyes; $n=49$ in both groups). Improvements in MRSE were slightly better in the PRK eyes (-3.99 preoperatively and -0.08 postoperatively) versus the SBK eyes (-0.95 preoperatively and -0.11 postoperatively). Cylinder, however, had improved more in the SBK group (-0.63 to -0.24) versus the PRK group (-0.64 to 0.32). Patients' high and low contrast acuities remained better in their SBK eyes through 3 months (Figure 3).

CHANGES IN ABERRATIONS

At 3 months, the PRK eyes still had a significant amount (0.12 μm) of induced spherical aberration compared with the SBK eyes (0.04 μm). Tetrafoil, however, was slightly greater in the SBK eyes (-0.09 versus -0.04 in the PRK eyes) at 3 months (Figure 4).

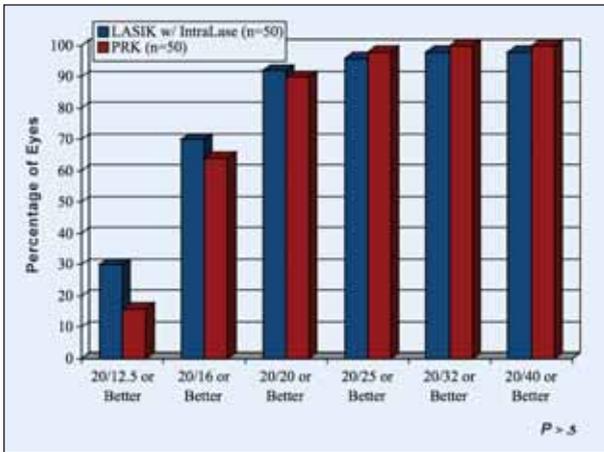


Figure 2. UCVA 3 months postoperatively.

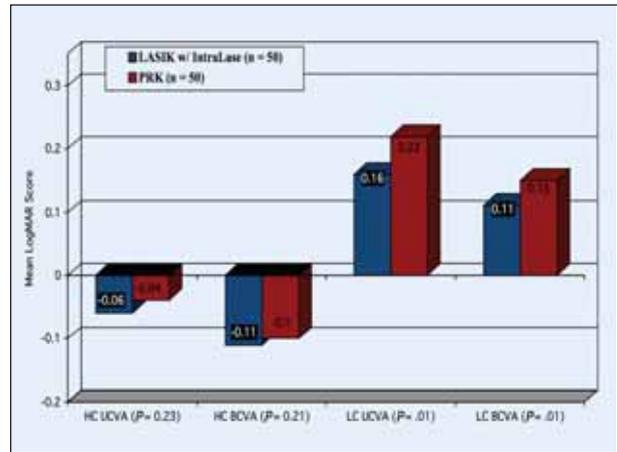


Figure 3. High and low contrast acuity, 3 months postoperatively.

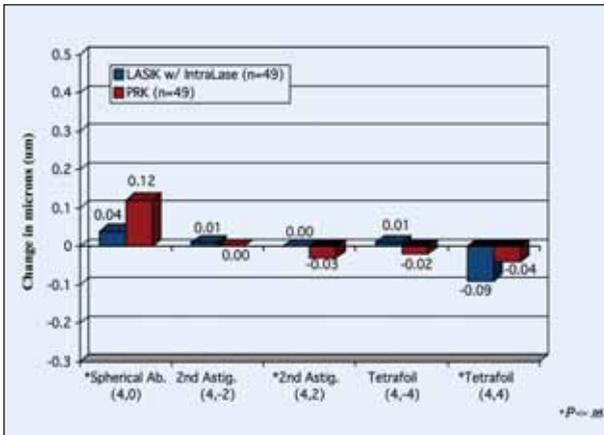


Figure 4. Changes in aberrations, 3 months postoperatively minus baseline.

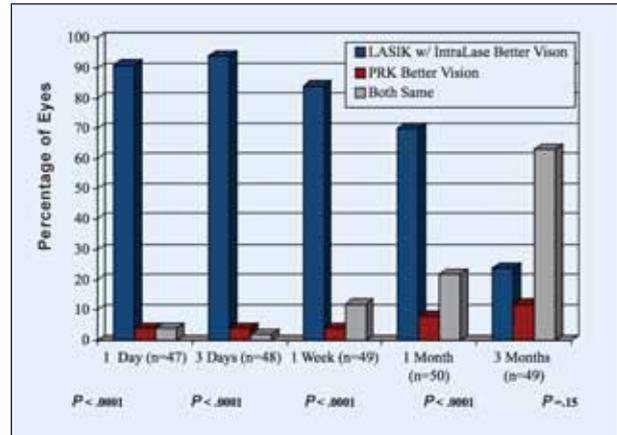


Figure 5. Which eye has better vision? Through 3 months postoperatively.

PATIENTS' SUBJECTIVE RESPONSES

Dr. Durrrie and I used independent observers to question our patients about their perceptions about their vision in each eye. A contralateral eye study is one of the best ways of determining which eye's vision patients prefer, because the eye is the only variable. All the patients in this study answered that the SBK eye saw better until 3 months, by which point both eyes saw about the same in most patients. (Figure 5). The answers remained consistent in bright, normal, and dim lighting, and for near vision and distance vision always favoring the SBK eye.

Furthermore, the PRK eyes felt more pain. Which eyes felt more dryness? Although LASIK and SBK do not cause dryness, they can make dry eyes worse for a while. However, these patients reported that their PRK eyes felt drier. Visual problems in terms of glare, halos, and difficulty driving were also worse in the PRK eyes, even at 3 months postoperatively.

CONCLUSIONS

All the traditional metrics were better with the SBK eyes. Compared with PRK, SBK gave a better quality of vision, was less painful, and was preferred by the patients. Based on these early results, I believe an SBK-thin flap has real utility for refractive practices. John Marshall, MD, has confirmed in studies that SBK is biomechanically indistinguishable from PRK.¹ Certainly, we need further studies to confirm our findings, but if SBK can offer the perceived safety of PRK and the "wow" factor of LASIK, it would seem worthwhile for both LASIK and PRK surgeons to help to develop it. □

Stephen G. Slade, MD, FACS, is in private practice at the Slade & Baker Vision Center in Houston. He is a consultant for IntraLase Corp. Dr. Slade may be reached at (713) 626-5544; sgs@visiontexas.com.

1. Marshall J. Wound healing and biomechanics of corneal flap creation. Paper presented at: The XXIV Congress of the ESCRS; Sunday, September 10, 2006; London, England.

