

ESCRS Study Halt: Prophylaxis Antibiotic Results Surpass Expectations

Study results examining the use of prophylaxis antibiotics in cataract surgery have turned out to be so conclusive that the study was terminated early. Results from the European Society of Cataract and Refractive Surgeons (ESCRS) study were published in the *Journal of Cataract and Refractive Surgery*.

ESCRS began the 2-year study in 2004 to determine if there was a beneficial effect of an intracameral injection of antibiotics at the end of surgery as a way of reducing postoperative endophthalmitis. By the end of 2005, close to 16,000 patients were recruited at 24 sites throughout Europe. A total of 14,000 recruited patients completed follow-up. The statistics, according to Study Chair Peter Barry, Consultant Ophthalmologist, were overwhelmingly in favor of the intracameral antibiotic injection.

In the group that did not receive the antibiotic, the rate of endophthalmitis was five times higher (23 of 6,862) compared with the group that received the antibiotic at the end of surgery (5 of 6,836). "This is confirmation that the potentially blinding complication of post-operative intraocular infection can be reduced," said Mr. Barry. "This should convince surgeons to adopt the use of intracameral [antibiotic] as a standard part of modern phacoemulsification cataract surgery."

While not all the patients enrolled in the study have finished follow-up, the ESCRS indicated that the results are not expected to substantially change. Full study results will be presented at the ESCRS annual meeting in London (September 9 to 13). The study was supported by a grant from Santen (Germering, Germany).

DORC Wins Blue Patent Battle

A battle over a patent for a dye used by surgeons in cataract surgery has been won by the Netherlands-based Dutch Ophthalmic Research Center (DORC, Zuidland, Netherlands). In a news release issued by the company, DORC said that the European Patent Office (EPO) has upheld the validity of its patent for Vision Blue, almost 3 years after the office initially issued the patent. The product — first introduced in 1999 — is used by cataract surgeons to improve visualization during cataract surgery. The US Food and Drug Administration (FDA) has also approved Vision Blue.

The EPO decision will enable DORC to fight the sale of knock-off versions of its products in Europe.

ESCRS Launches Refractive Data Collection Project

European refractive surgeons can now benchmark their results against colleagues at home and around the world, as a result of a new initiative by the ESCRS.

The ESCRS Refractive Surgery Outcomes Information System is a Web-based database that allows surgeons to record, audit and compare their results — confidentially. In announcing the project, the organization listed a number of benefits including

- confidential, self-auditing and benchmarking of results,
- contribution to a long-term study of refractive surgery results to raise the standards of care and
- using personal results for personal research projects.

The ESCRS will run the data collection program through its Web site (www.escrs.org), and each participating surgeon or clinic will receive a unique user ID and password once they join the project. Annual fees for ESCRS members will range from €500/year for a single user to €5,000 for 16+ users. Clinics will be responsible for adding patient records and keeping them updated over the follow-up period after surgery.

The ESCRS will own the aggregated data and will maintain the right to present or publish it, however, individual surgeons and clinics can use their individual data for practice marketing and presentations.

The organization said it believes that the data collec-

tion project will help to raise the standards of refractive surgery.

UK Panel Issues Refractive Surgery Guidelines

Refractive surgeons in the United Kingdom who are looking for government support on the safety and efficacy of laser procedures have received a somewhat lukewarm endorsement from a government panel.

Guidelines issued by the National Institute for Health and Clinical Excellence (NICE) have improved upon original guidelines that were issued in 2004. The original guidelines caused a strong negative reaction from British refractive surgeons.

In its new guidelines, NICE states, "Current evidence suggests that laser eye surgery is safe enough and works well enough for use in appropriately selected patients." The guidelines, however, further state that the public health system should not offer the procedure because most eye problems are easily corrected with spectacles or contact lenses. In reaching its conclusions, NICE conducted a review of all published evidence on PRK, LASIK and LASEK.

The guidelines urge refractive surgeons to ensure that prospective patients understand the benefits as well as the prospective risks of the procedures. In addition, it recommends that refractive surgeons collect and audit their clinical outcomes to ensure that patients are getting the best treatment.

Finally, the guidelines note that it remains difficult for consumers to identify properly trained surgeons. As a result, the Royal College of Ophthalmologists is currently working on a set of outcomes and assessments that will help consumers make an informed choice.

TASS, *Fusarium* outbreaks in United States

The American Society of Cataract and Refractive Surgery (ASCRS) and the American Academy of Ophthalmology (AAO) have issued an alert regarding numerous reports of toxic anterior segment syndrome (TASS) following cataract surgery. The reports have come from eye centers in North America. As of press time, the ESCRS had no reports of TASS in Europe.

According to the ASCRS/AAO alert, the recent increase in cases is very similar to the outbreak that occurred in late fall 2005, which was found to be related

to endotoxin contamination of balanced salt solution manufactured by Cytosol Ophthalmics (Lenoir, NC). Following a recall of Cytosol products, the outbreak seemed to have subsided by the beginning of this year. This new outbreak of TASS, however, appears to have started in March, is ongoing, and is unrelated to the product.

In other outbreak news, the FDA has sent out a preliminary public health advisory to practitioners regarding fungal keratitis infections related to soft contact lens use. There has been a recent increase in the number of reports in the United States of fungal keratitis caused by *Fusarium*. As with the TASS outbreak, no increase in the number of cases has been reported in Europe at this time.

Both the FDA and the Centers for Disease Control and Prevention are investigating this situation, the alert said. According to a Bausch & Lomb (Rochester, NY) news release, a majority of the cases investigated thus far are contact lens wearers who reported using the company's Renu Moistureloc product. At this time, Bausch & Lomb has agreed to stop shipping the brand of contact lens solution.

According to the Contact Lens Association of Ophthalmologists (CLAO), reports from practitioners and health officials in Singapore, Hong Kong and Malaysia were the first to have indicated an unusual occurrence of contact-lens-related *Fusarium*. In the United States, the city of New York and the New Jersey Department of Health and Senior Services are also investigating. Cornea specialists from Bascom Palmer Eye Institute of the University of Miami Miller School of Medicine have documented an increased incidence of an aggressive form of fungal corneal infection that appears to be related to soft contact lens use. This was confirmed by Eduardo C. Alfonso, MD, professor of ophthalmology and Edward WD Norton Chair in Ophthalmology.

Contact lens wearers should ensure that they are caring for their lenses properly and they should refer to the instructions given to them by their ophthalmologist, according to the CLAO statement.

ASCRS Presentation Highlights

Advanced-technology IOLs and wavefront-customized treatment were among the highlights presented at the ASCRS 2006 Symposium and Congress in San Francisco. Here are some selected summaries:

- The Tetraflex KH-3500 (LensteC, St. Petersburg, Fla) microincision presbyopic-correcting IOL has shown promising results when examined with a 3D refraction map and may enhance near vision better than most monofocal lenses.

During a Tetraflex User's Panel meeting, Deepak Chitkara, MD, from Manchester, UK, and five additional surgeons presented their latest results with the accommodative IOL. The Tetraflex KH3500 is tilted forward 5°, tilting it away from the posterior capsule. According to Dr. Chitkara's latest results — drawn from 60 patients — 60% of eyes reached 1.50 D to 2.00 D of accommodation, and 75% achieved 20/30 BCVA. Compared with the Acrysof IOL (Alcon Laboratories, Fort Worth, Texas), Tetraflex-implanted eyes reached $\geq 20/40$ distance-corrected night acuity in 91% of cases versus 7%, said Dr. Chitkara, who was first to use the Tetraflex and has the most worldwide experience with this IOL. An increased range of refraction was noted with the refraction maps.

Sunil Shah, MD, from Birmingham, UK, has implanted more than 300 Tetraflex IOLs in a 2-year period. The lens, he said, is straightforward to implant and is a viable choice for all patients. The lens does not create halos or glare and patients will not lose their distance vision, he added. There is a cost issue associated with the lens. Although it is approved for use in Europe, the FDA has not yet approved the lens. US clinical trials are under way.

- Combining an aspheric or multifocal IOL with wavefront-driven ablation may produce reliable results in up to 85% of patients with a cataract, according to Michael C. Knorz, MD, from Heidelberg, Germany.

Providing a refractive package (lenticular surgery plus LASIK or epi-LASIK, or wavefront-driven bioptics) may achieve the desired patient outcomes of spectacle independence and higher-order aberration correction, Dr. Knorz said during his presentation. Dr. Knorz highlighted that this process allows for the highest probability of these desired outcomes. He used the Restor (Alcon) and Rezoom (Advanced Medical Optics, Santa Ana, Calif) lenses, both of which produced similar results and worked in 80% of cases.

- Research undertaken by Ulrich Mester, MD, and Hakan Kaymak, MD, from Salzburg, Germany, was released during a presentation at ASCRS. Results from the prospective trial examining 70 cataract-presenting eyes showed that aspheric IOLs might reduce spherical aberration and improve visual function.

Dr. Kaymak presented the results; the investigators studied the effect of the Acrysof IQ Aspherical Natural IOL (Alcon) on higher-order aberrations including spheri-

cal aberration. Patients underwent standard phacoemulsification before lens implantation, and were then studied for high and low contrast visual acuity; ocular spherical aberration; contrast sensitivity; and depth of focus preoperatively and 2 months postoperatively.

Dr. Kaymak and his colleagues compared the function of the Acrysof IQ with the Acrysof SA60AT. They found that compared with the SA60AT, the IQ lens was better at decreasing spherical aberration (mean value, 0.04 μm on a 5-mm pupil). This lens also increased contrast vision. The IQ lens has a blue-light filter.

- José L. Rincon, MD, of the José L. Rincon Instituto Oftalmológico IUMO in Caracas, Venezuela, presented results of a retrospective trial that evaluated the efficacy and safety of bilateral implantation of the diffractive, pseudoaccommodative, apodized Restor IOL. From October 2004 through October 2005, a total of 302 eyes from 151 patients (121 female, 30 male) underwent phacoemulsification or coaxial microphacoemulsification. These procedures, which were all performed by Dr. Rincon, were followed by bilateral implantation of the Restor in each of the patients. A Snellen chart was used to measure the distance UCVA and distance BSCVA, and near UCVA was measured at 30 cm. The patients were examined preoperatively and up to 3 months following the surgery. According to the results, patients who received the Restor demonstrated both a high level of visual acuity and satisfaction. The distance UCVA of 92% of patients was 20/25 or better and 83% had a near UCVA of J1 or better. Approximately 95% of patients reported visual satisfaction, almost 80% of patients did not complain about halos, and 91% had spectacle freedom.

Winter ESCRS Presentation Highlights

Treatments for presbyopia, flap predictability and new phakic IOL options were among the highlights presented at the 10th Annual Winter ESCRS meeting in Monte Carlo. Here is a sampling of what was presented:

- Investigators of the LaserACE (anterior ciliary excision) study demonstrated that the technique helps to reverse presbyopia, with the added benefit of reducing IOP. The study of 26 patients (52 eyes) conducted in three countries showed an average increase in accommodation of 2.80 D. Investigators also reported on 2-year follow-up, showing that patients did not become more presbyopic over time. The procedure involves using an infrared laser to make scleral incisions in four

quadrants around the eye. Investigators reported no major complications in the study.

- Researchers in France are using the S4-Wavescan laser (Visx, Santa Clara, Calif) to perform customized presby-LASIK treatments. Surgeons from the University of Brest in France reported on the results of 16 eyes (12 patients) that were followed for 2 years. They reported that 90% of the eyes had achieved an additional gain of 0.63 D or more of vision and an improvement of J3 or more in uncorrected near vision. There were no losses in BSCVA. The investigators say their preliminary results show real promise for presby-LASIK treatments.

- Given the trend toward thinner LASIK flaps, several studies looked at the predictability of flap thickness using either mechanical microkeratomers or the femtosecond laser. One study, by Joseph Colin, MD, at the University of Bordeaux, compared 90 μm to 130 μm flaps created by the M2 Microkeratome (Moria, Antony, France), found there was no increase in flap-related complications in cutting the thinner flaps. The findings could benefit patients with thinner corneas who were previously ineligible for LASIK.

- A foldable version of the Verisyse phakic IOL (Ophtec, Groningen, Netherlands) offers surgeons the advantages of a smaller incision with the well-known safety and effectiveness of the original lens. That is the conclusion of Jose Güell, MD, and colleagues at the Instituto de Microcirugía Ocular in Barcelona. The 2-year study of the Artiflex/Veriflex iris-claw fixated lens involved 59 eyes — 30 implanted with the original IOL and 29 implanted with the foldable version. Mean spherical equivalent and astigmatism were ≤ 1.00 D in both groups. In addition, there was no significant loss of endothelial cell density in either group during the 2-year follow-up period.

- An American study that compared the results of customized refractive procedures with conventional treatments found that there is a real advantage to wavefront-guided treatments. The study conducted at the Naval Medical Center in San Diego by Steve Schallhorn, MD, compared the results of conventional, wavefront-optimized and wavefront-guided procedures. He used the various software options available on the Customvue Platform (Visx) and the Allegretto system (Wavelight Technologie AG, Erlangen, Germany) to make the comparisons. Dr. Schallhorn found that while wavefront-optimized procedures offer an improvement over conventional treatments, the results provided by wavefront-guided ablations clearly provide the best and safest outcomes.

New Method of Keratoconus Treatment Shows Promise

The use of riboflavin and UV light to strengthen the cornea appears to offer hope for keratoconus patients, according to a study presented at the Societa Oftalmologica Italiana (SOI) meeting in Milan. The study was conducted at the University of Sienna and presented by Aldo Caporossi, MD. The group based their work on animal eye research done at the University of Dresden.

The treatment involves using the riboflavin and UVA light to cross-link the collagen in the cornea to increase the rigidity of the stromal fibers. Doing so should make the cornea more resistant to ectasia, said Professor Caporossi. At SOI, he presented results from 15 eyes that the group had treated since 2004.

All of the patients had bilateral keratoconus at various stages of progression. The treatment involved use of a topical anesthetic followed by corneal marking and removal of the epithelium. Next, the surgeons instilled between two and four drops of a mixture of 0.1% riboflavin and Dextrane T500 (Pharmacia, Uppsala, Sweden) onto the cornea, which stayed on for 5 minutes. The UVA treatment was 5 minutes of exposure of UVA energy ($3 \text{ mW/cm}^2 = 5.4 \text{ J/cm}^2$) at a distance of 10 mm to 12 mm from the energy source. At the end of 5 minutes, surgeons added more solution and repeated 5 minutes of UVA exposure an additional four times (total UVA exposure time 25 minutes). Following irrigation with a balanced salt solution, an antibiotic and a cycloplegic was instilled into the eye and then a soft contact lens is kept in place until reepithelialization occurs.

At an average of 8 months postoperation, Professor Caporossi reported that the average corneal thickness, based on ultrasound pachymetry was 450 μm , compared with 431 μm preoperatively. The difference was not statistically significant. There is a definite difference when it comes to the postoperative vision of the patients in the study. Professor Caporossi found that there was an improvement in UCVA of 3.8 lines after the treatment, compared with the preoperative vision. The investigators also found a reduction in dioptric power of the center 3 mm of the cornea that stayed consistent at 9 months to 12 months of follow-up. Corneal topography of the treated eyes found improved symmetry of the treated surfaces, as well as a reduction in higher-order aberrations based on wavefront analysis.

The researchers concluded that this pilot study offers some encouraging results, with minimal side effects. ■