

Second LASIK Visits Were Cut Drastically With New Formula

Ophthalmologists have developed a formula that reduces by nearly two-thirds the likelihood patients will need to adjust their vision after LASIK.

The new results, presented at the XXIV European Society of Cataract and Refractive Surgery (ESCRS) meeting in London, are the result of a complex computer formula compiled by doctors and scientists at the University of Rochester Medical Center, (Rochester, New York), that takes into account myriad imperfections within the eye.

Eye surgeon Scott MacRae, MD, of the University of Rochester Eye Institute, presented the results, which showed a dramatic drop in farsightedness among LASIK patients after Dr. MacRae and colleagues used the formula during surgery. Known as the University of Rochester Nomogram, just six of 445 eyes (1.3%) were slightly farsighted after LASIK procedures that used the formula. In a previous study of

LASIK without the formula, of the 340 eyes treated, 21.8% were slightly farsighted.

"Though those results were among the best anyone had gotten to date, we thought we could do better," said Dr. MacRae, who worked with Manoj Venkiteshwar, PhD, for 2 years to develop the University of Rochester Nomogram.

The software, developed by Drs. Venkiteshwar and MacRae, controls how the laser beam hits the surface of the cornea during the LASIK procedure by taking into account unique anomalies in the eye. The formula predicts what patients are most likely to be slightly farsighted after LASIK and adjusts the laser accordingly.

Dr. MacRae believes that the new formula, part of a procedure he calls second-generation customized ablation, lessens the need for repeat treatments in patients from approximately 8% to 3%.

IOL Implantation Safe in Infants

A study released by researchers from the Bristol Eye Hospital, (Bristol, UK) showed that IOL implantation in infants aged more than 1 year is generally a safe procedure, but final acuities can be disappointing.

The researchers reviewed 18 infants who underwent the procedure, with eight patients receiving unilateral and 10 receiving bilateral implants. The average age for the surgery was 15 weeks, with a mean follow-up at 95 months (range, 60 months to 139 months).

Researchers found the best outcomes for IOL implantation were in the bilateral group, where 50% of eyes achieved 6/18 or better, with a best acuity of 6/9. Acuities were poor in the unilateral group, where only 38% achieved 6/60 or better. There was a mean refractive shift between first refraction after surgery and refractive at 36 months after surgery of -3.44 D (range, 2.00 D to -15.50 D). There was a significantly greater myopic shift in the unilateral cases. Main complications were amblyopia, especially in unilateral cataracts and posterior capsular opacification, P. Gouws, MD, and colleagues from Bristol Eye Hospital, wrote. "Amblyopia, was most probably related to a combination of early onset of dense cataract

in this young age group, late presentation for initial surgery, delay in capsulotomies and imperfect compliance with rigorous occlusion regimen."

German Doctors Protest Reimbursements

"Doctors at public clinics throughout Germany and parts of Europe have been on strike, protesting low wages, poor reimbursement, and their working conditions. The protest, which affects mainly noncritical surgeries, has reduced ophthalmologic and other procedures at public clinics by about 20%," said Reinhard Pichl, of Advanced Medical Optics (Santa Ana, California), in a telephone interview with *Cataract & Refractive Surgery Today Europe*.

Surgeons employed by the state at public hospitals have been protesting their employment conditions, including their long work hours, with only partial or no reimbursement, and below average salaries.

Independent of public hospital strikes, some ophthalmic surgeons in Germany are protesting again reimbursement rates from insurance companies, said Manfred Tetz, MD, in an e-mail to *CRST Europe*. "There have been actions taken by doctors in some states and

regions against the severe cuts in reimbursement for cataract surgery services. In addition, in some areas, there are also new contracts limiting the total number of cataract procedures that will be reimbursed. This may have affected sales for many IOL companies, especially during the first half of 2006."

The strikes have lasted several days and have cut total procedures by about 20% in certain German districts. Currently, the German ministry of health is looking at the pressure on the total financial health care system, and is beginning a restructuring of that system.

Laser Surgery Safer Than Contacts, Doctors Said

Several peer-reviewed studies have found that contact lens users may have a greater chance for vision loss than patients who undergo refractive surgery. The findings of one study by William Mathers, MD, of Oregon Health & Science University Casey Eye Institute, Portland, Oregon, were published as a letter in *Archives of Ophthalmology*.

According to data extrapolated from other studies, the authors wrote that lifetime risk of contracting bacterial keratitis was 1 in 100 for daily contact users—a risk that has decreased little over the years. Authors also wrote that vision loss of one line for people who underwent refractive surgery was 1 in 1,250.

The authors stated that the risks of refractive surgery versus contact lenses cannot be directly compared, and the risks of vision loss from contact lenses and laser surgery are subject to change. Highly oxygen-permeable contact lenses and advances in laser surgery should make both safer, the authors wrote.

Wavelight Receives US Approval for Allegretto Wave

The US Food and Drug Administration (FDA) approved Wavelight's wavefront-guided procedure, a LASIK treatment approach that combines the Allegro Analyzer with the 200 Hz Allegretto Wave excimer laser (Wavelight AG, Erlangen, Germany). The Allegretto Wave was approved for the reduction or elimination of less than or equal to -7.00 D of spherical equivalent myopia or myopia with astigmatism, with less than or equal to 7.00 D of spherical component and less than or equal to 3.00 D of astigmatic component with the spectacle plane.

A randomized clinical study of 374 eyes treated at five US centers validated that patients enrolled in either the

wavefront-guided treatment group or the wavefront-optimized group achieved similar visual results for UCVA, manifest refractive spheroequivalent and postoperative UCVA versus preoperative best spectacle visual acuity.

The Allegretto Wave was the first refractive laser to receive concurrent approvals for the treatment of myopia less than or equal to -12.00 D to -6.00 D and hyperopia less than or equal to 6.00 D with astigmatism of less than or equal to 5.00 D, not exceeding a mean spherical equivalent of 6.00 D.

Viewpoint CK Approved in Brazil, Russia, and Taiwan

Refractec (Irvine, California) has received approvals from the governments of Brazil, Russia, and Taiwan to market its Viewpoint CK System. The system is used to perform the Nearvision CK treatment, which improves near vision in patients with presbyopia or hyperopia.

Nearvision CK is a 3-minute treatment that uses radio waves instead of a laser or scalpel to bring near vision back into focus without cutting or removing any tissue. In addition to Nearvision CK's use in treating presbyopia and hyperopia, Refractec is seeking expanded approval in the United States for its use to improve near vision patients with a history of LASIK surgery. "These markets are critical expansion opportunities for our global operations," said Keith Burgess, Refractec's director of worldwide sales, in a news release. "These approvals mark the continued international adoption and growth of the Nearvision CK treatment as a benefit to patients worldwide." The Nearvision CK treatment is approved in more than 65 countries in North America, Europe, Asia, and Latin America.

Schering AG license SEGRA Compound

Bausch & Lomb (Rochester, New York) and Schering AG, (Berlin) announced that Bausch & Lomb obtained an exclusive worldwide license from Schering to develop and market a selective glucocorticoid receptor agonist (SEGRA) for the nonsystemic treatment of eye disorders.

Bausch & Lomb will evaluate the compound's potential as a novel antiinflammatory medication with an improved safety profile for ophthalmic indications. Glucocorticoids are the most potent and frequently used antiinflammatory compounds, but their value is limited by side effects including glaucoma induction. SEGRAs, using a distinct molecular mechanism after binding to a glucocorticoid receptor, may demonstrate a superior effect/side-effect

profile when compared with standard glucocorticoids. The project is in the initial preclinical stage of evaluation.

“Our agreement with Schering ... is yet another example of how we at Bausch & Lomb are actively pursuing unique compounds and creative therapeutic approaches in order to expand our pipeline of new products to help people with vision-threatening ophthalmic conditions,” said Praveen Tyle, PhD, Bausch & Lomb chief scientific officer and senior vice president, in a news release.

Under the terms of the agreement, Bausch & Lomb is responsible for development of the SEGRA compound for nonsystemic use in ophthalmology. Bausch & Lomb will make upfront and milestone payments based on the development and registration progress, and pay ongoing royalties based on product sales.

Epi-K Achieves Visual Outcomes Superior to Wavefront Procedures

H. L. Milne, MD, presented his experience in using the Moria Epi-K epithelial separator (Antony, France) to perform advanced surface treatment, at the 5th International Congress on Epi-LASIK, LASEK and Advanced Surface Ablation in London.

In a study of 100 eyes treated with the Epi-K, visual recovery was significantly faster than cited by Intralase (Irvine, California) consultants in their clinical assessment of wavefront-guided PRK. Dr. Milne noted that his results were a “huge improvement” over his previous experience with PRK. Patients’ vision was checked at 5 minutes postop, with most patients BCVA at 20/40 and many at 20/20. After 1 month follow-up, patients visual acuities were virtually identical to those cited by surgeons using wavefront-guided Intra-LASIK, Dr. Milne reported. The shift in laser surgery from 95% LASIK to 95% advanced surface treatment with the Epi-K is based on the fact that patients are willing to trade off immediate gratification for the longer-term safety and biomechanical stability of advanced surface treatment, he said in a news release.

NEWS FROM ESCRS

Device Determines Tissue Water Content and RI

Surgeons at the Visum Institute of Ophthalmology, in Alicante, Spain, developed a system to determine tissue

water content during refractive surgery procedures. The Visum Corneal Hydrator is a digital surgical hydrometer based on the principles of Abbe refractometry. Sudhir Patel, MD, presented results of a study at the European Society of Cataract and Refractive Surgeons (ESCRS) meeting, comparing the performance of the new hydrometer with a traditional device.

According to published studies in animal eyes, the level of corneal hydration affects the ablation rate of laser surgery; the greater the hydration, the less the ablation for a given laser pulse. By measuring the stromal hydration or refractive index before and immediately after an application of the excimer laser, the true extent of any dehydration directly caused by the photoablative treatment is better understood, explained Dr. Patel. Hydration of the stromal bed was determined after lifting the flap prior to, and immediately after photoablation. Hydration and the refractive index (RI) were measured with either the Visum Corneal Hydrator or the traditional device. The patient’s age and duration of photoablative treatment was also recorded, and water content was calculated using the Fatt-Harris refractive index equation.

Results revealed that for each 10 seconds of treatment, there was 7% to 10% stromal dehydration. Stromal RI increases with age, suggesting a 1.5% to 2.6% fall in water content per decade. Undercorrection appeared to be associated with relatively increased stromal hydration and lowered RI and overcorrection with relatively decreased stromal hydration and elevated RI. In theory, it should be possible to reduce the incidence of both under- and overcorrections by measuring the RI of the stromal surface before photoablation and using this information to fine-tune the laser delivery algorithm.

New Developments May Improve Presbyopia Treatment

Research presented at the ESCRS annual congress focused on developments to improve eyesight as people age, reducing dependence on reading glasses.

More than 25 million people in the United Kingdom have presbyopia. One solution presented at ESCRS to address deterioration of eyesight with age is IOLs, corneal lasers, implants into the wall of the eye, and conductive keratoplasty.

“Presbyopia is an inevitable and disabling condition that unfortunately affects nearly everyone as they age. I am very excited to see such a large number of new devel-

opments in refractive and laser eye surgery offering patients more opportunities to improve their eyesight as they age," said Paul Rosen, consultant ophthalmic surgeon at Oxford Eye Hospital, in a news release.

With refractive eye surgery fast becoming a routine procedure, prospective refractive eye surgery patients are seeking additional reassurance on the procedure. The ESCRS Refractive Surgery Outcomes Information System (RSOIS), launching at the ESCRS congress, is the first Web-based database that enables ophthalmologists to record and compare refractive surgery outcomes across Europe and the world. The ESCRS will now be able to publish data from around the world about outcomes and safety for patients considering refractive eye surgery.

Julian D. Stevens, FRCS, FRCOphth, consultant ophthalmologist at Moorfields Eye Hospital in London, said: "With regulation of refractive surgery looking to be introduced to the UK in the next year, refractive surgeons will be required to produce an audit of their results. The ESCRS RSOIS allows benchmarking of outcomes and measure the incidence of complications in refractive surgery. Through participation in the RSOIS, refractive surgeons can demonstrate to prospective patients the high level of responsibility of the surgeon and the clinic."

Intracorneal Ring Segments for Keratoconus

Keraring (Mediphacos, Belo, Brazil) implants for keratoconus improved visual acuity and refraction, reported Marta Sartori, MD, from the Federal University of Sao Paulo,

Brazil, at the ESCRS. Dr. Sartori and colleagues conducted a prospective study of 84 eyes with keratoconus and found that the implants produced a reduction in dioptrically power values and achieved a central island shaped cornea.

Dr. Sartori presented 48-month follow-up. The study team evaluated pre- and postoperative UCVA, BCVA, manifest refraction, and full corneal topography. Results showed that BCVA improved in 92.3% of eyes. Significant improvements were also seen in UCVA values as well as topographical regularity.

Hasan Razmjoo, MD, of Isfahan University of Medical Sciences and Health Services, in Iran, also presented results from a study of the Ferrara intracorneal ring (Mediphacos) in the treatment of keratoconus. This was a prospective study of 57 eyes (44 patients) with mild or moderate keratoconus. Pre- and postoperative objective and subjective refraction was recorded, and topography was recorded using the Orbscan II corneal topography system (Bausch & Lomb). Ferrara intracorneal ring segments were inserted following the manufacturers instructions. The mean follow-up time was 8 months (range, 3 months to 15 months).

The results showed a mean improvement in spherical equivalent refractory error of $5.49 \text{ D} \pm 3.65 \text{ D}$ ($P < .001$). The mean change in the magnitude of cylindrical error was 1.89 ± 2.55 ($P < .001$). Improvement of uncorrected logMAR after surgery was 0.61 ± 0.46 ($P < .001$); and best corrected logMAR was 0.18 ± 0.36 ($P = .002$). In five patients, rings were removed due to complications. The Ferrara intracorneal ring segments, concluded Dr. Razmjoo, effectively improved vision and refractive status of keratoconic patients. Although, he warned, complications are likely. ■

Letters

THE FIRST PHACOEMULSIFICATION

Dear Editors,

I am writing in reference to the article, "The History (and Future) of Cataract Surgery in Italy," by Lucio Buratto, MD (Vol. 1, No. 5, pages 47 to 48). It is a very prestigious article on the history of cataract surgery in Italy, but I beg to call your kind attention to a small historical mistake that is very important for the history of phacoemulsification in Italy.

The first phacoemulsification in



Figure 1. A flyer for the first congress of phacoemulsification.

Italy was performed on May 15, 1976 (by me) and not in 1978, as the article stated. Franco Verzella, MD, one of my best and most sincere friends who I hold in a high esteem, performed his first phaco 15 days after me. I absolutely do not want to diminish Dr. Verzella, however, as this was an article on the history of cataract surgery, I believe it is important to right the inaccuracy.

I would like to remind the readers that Dr. Verzella organized the first congress of phacoemulsification in Italy (Figure 1). It was held in Rimini in June 1977, with the participation of many surgeons.

I do hope you can modify and publish this exact information in your next issue. Thank you for your cooperation.

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