

Results of United Kingdom Anesthesia Survey Released

The British Ophthalmic Surveillance Unit (BOSU) recently released data from a 13-month prospective observational study on the potential complications of local anesthesia (LA) for cataract surgery. The study was based on information gathered from an estimated 375,000 cataract surgeries performed during 2002 to 2003, in the United Kingdom.

According to the report, "potentially sight-threatening complications" were most reported in association with retrobulbar and peribulbar anesthesia techniques, with 26 cases of penetration or perforation, 16 of which had poor visual outcome ($P < .0001$). Eight neurological complications, consistent with brainstem anesthesia, were reported. Seven occurred with peribulbar or retrobulbar LA ($P < .030$), the

authors wrote. The survey found a lower rate of serious complications with sub-Tenon's, topical, and topical-intracamerar LA techniques.

Overall, authors found that cataract surgery performed under the National Health Service comprised of 4.1% using general anesthesia, 92.1% using LA without sedation, and 3.9% using LA with sedation. Usage for the LA techniques was broken down into 30.5% peribulbar, 3.5% retrobulbar, 42.6% sub-Tenon's, 1.7% subconjunctival, 9.9% topical, and 11.0% topical-intracamerar LA.

Details for this study were obtained by sending questionnaires to ophthalmologists in the BOSU database each month for the duration of the survey.

AMO to Offer All-Laser LASIK

Advanced Medical Optics, Inc. (Santa Ana, California) announced the expansion of its laser vision correction capabilities through the acquisition of IntraLase Corp. (Irvine, California) for \$808 million.

Combining the technology from the two companies will uniquely position Advanced Medical Optics, Inc. as the eye care professional's "complete refractive solution," according to Jim Mazzo, Advanced Medical Optics, Inc. Chairman, President and CEO.

"As the leader in LASIK surgery, we will now combine our Advanced CustomVue excimer laser and the premium IntraLase femtosecond laser to provide the highest level of technology as the standard of care in all-laser LASIK surgery," Mr. Mazzo said in a telephone interview with *Cataract and Refractive Surgery Today Europe*. "IntraLase is has clearly defined femtosecond lasers, as we have defined LASIK surgery—together we will now be able to surround the practitioners with the best technologies."

The acquisition, set to finalize in the second quarter of 2007, will combine both company's research and development expertise in excimer lasers, femtosecond lasers, diagnostics, and optics and has been well received among surgeons, Mr. Mazzo said.

"As a customer of both AMO and IntraLase, and as a sur-

geon performing 98% of LASIK surgeries with the IntraLase laser, I think it was a great idea for them to combine forces," said Michael C. Knorz, MD, professor of ophthalmology at the University of Heidelberg Medical Faculty, in Mannheim Germany. "Femtosecond laser flap creation is certainly the way to perform LASIK in the future. Plus, femtosecond laser technology also holds great promise for intrastromal corrections and corneal transplants," Dr. Knorz added in an email to *CRST Europe*.

The transaction is subject to IntraLase stockholder approval, as well as regulatory approvals and other conditions.

Deutsche Bank to Launch Fund Supporting Eye Hospitals

The Deutsche Bank will create a \$20 million investment fund to finance the expansion of eye care hospitals in developing countries. The Eye Fund will provide loans and guarantees to support the development of affordable, sustainable, and accessible eye care for the world's poor while providing a near-market return for investors.

The Eye Fund is modeled after a proven planning and business model that has enabled approximately 400 hospitals in the last 5 years become financially sustainable. The Fund seeks to replicate this success on a large scale, ultimately assisting 4,000 hospitals over the next 5 years to become self-financing from user fees while at the same time

serving the poor. A complimentary grant fund will also be established to provide technical assistance, business planning, and training.

Of an estimated 37 million blind people worldwide, 90% live in the poorest parts of the developing world. Each year an additional 1 to 2 million people lose their sight. An estimated 75% of these incidences of blindness are treatable and/or preventable. Without proper interventions, the number of blind people will increase by 75 million by 2020.

Vista Optics Acquires Contact Lens Materials Business

Vista Optics (Cheshire, UK) has acquired the contact lens materials and consumables business of Lamda Polytech (Northants, UK). Vista Optics will absorb the entire Lamda Polytech range into its portfolio of products, but will not acquire any of the business relating to the Lamda Polytech engineering division, which manufactures the lathes and ancillary equipment for manufacturing contact lenses.

The entire operation will be relocated to pharmaceutical standard facilities at the Vista Optics headquarters in the Cheshire Science Center (Widnes, UK).

Vista Optics is a specialist supplier of medical grade plastics, predominantly for intraocular and contact lenses. The company exports its products to more than 50 countries worldwide. The company was instrumental in the development of foldable IOLs, being the first to produce a commercial hydrophilic acrylic in conjunction with its research partners, according to a news release. Its present IOL research is focused on hydrophobic materials.

CCK-8 May Prove Therapeutic Against Diabetic Cataracts

New research from the People's Republic of China shows that cholecystinin octapeptide-8 (CCK-8) may be a useful therapeutic agent against diabetic cataracts. Authors of the report, published in the *Chinese Medical Journal*, wrote: "Cataracts is considered to be formed because of an abnormal glucose metabolic pathway or oxidative stress. We explored the damaging role of ONOO—an antagonism of CCK-8 in diabetic cataractal rats lenses."

Researchers believe an antagonizing mechanism in CCK-8 may be related to direct antagonism of ONOO as well as its inhibition of the production of nitric oxide (NO), which therefore decreases the formation of ONOO.

Researchers at Hebei Medical University wrote, "A diabetic cataractal animal model was established by peritoneal

injection of streptozotocine (STZ). Thirty-six normal rats were taken as a control group; 72 were given STZ (45 mg/kg) and then divided into STZ group and CCK-8 group (peritoneal injection CCK-8).

"STZ induced diabetic rats were treated with CCK-8 for 60 days. Lenses were examined with slit-lamp at 20, 40, and 60 days. Immunofluorescent staining and Western blot analysis were used for determining nitrotyrosine (NT, a marker for ONOO)."

Data showed that the STZ group developed lens opacity by 20 days and reached a high level by 60 days after STZ injection. CCK-8 group rats, however, delayed the cataract formation... and showed a weak expression of NT and down regulation of inducible nitric oxide synthetase mRNA.

Intrastromal Corneal Rings Effective for Myopia Correction

In a 10-year follow-up of 10 eyes, intrastromal corneal rings were found as an effective and stable method of correcting mild myopia, according to a study published in the *Journal of Refractive Surgery*.

Andrew P. Schwartz, MD, and colleagues at Mount Sinai School of Medicine, in New York, evaluated myopic eyes, that were treated with the placement of 360° complete intrastromal corneal rings with sutured ends. There was no statistically significant difference noted between UCVA and manifest refraction spherical equivalent at 1 year and 10 years, authors wrote. At the 10-year examination, 90% of patients had BSCVA of greater than 20/25 and 100% of patients had a BSCVA of greater than 20/30. At the 10-year follow-up, induced manifest refractive cylinder was more than 1.00 D in no eyes, and less than 0.25 D in 60% of the eyes. Additionally, there was no statistically significant difference between mean central keratometric power at the 1-year follow-up. Authors also found that there was no significant difference noted in central corneal thickness.

Intacs Inserts Stabilized Ectasia in Post-LASIK Corneas

Corneas that developed ectasia after LASIK were stabilized for at least 5 years with the use of intrastromal corneal ring implants, according to a retrospective study in *Ophthalmology*.

George D. Kymionis, MD, PhD, and colleagues at the University of Crete, in Greece, examined the long-term

refractive and mechanical stability of eight post-LASIK ectatic eyes that were implanted with Intac ring segments (Addition Technology, Des Plaines, Illinois).

No intraoperative or late postoperative complications occurred in the five patients with post-LASIK corneal ectasia. At 5 years, the mean spherical equivalent error had decreased from -5.47 to -2.56 ($P=.010$) (range, -9.50 D to 1.5 D). At the end of postoperative year 1, refractive stability was obtained and remained stable during follow-up, the authors wrote. Before the Intacs were implanted, UCVA was 20/100 or worse in all eyes, whereas at the last follow-up examination, 75% ($n=6$) of eight eyes had UCVA of 20/40 or better. Two eyes maintained the pre-Intacs BCVA, while the rest of the eyes ($n=6$) experienced a gain of one or two lines.

The authors concluded that there was no evidence of progressive time-dependent corneal ectasia, late regression, or sight-threatening complications during the study.

New Cleanser Yielded Significant Results

Cynacon/OcuSoft (Richmond, Texas) announced the findings of two independent studies focusing on the efficacy of eyelid cleansers as a means of reducing the presence of harmful bacteria. In the three studies, reviewed by Paul Koch, MD, OcuSoft's newest eyelid cleanser (OcuSoft Lid Scrub Plus Extra Strength) killed more bacteria and was less irritating than its competitor. According to study results from Care Biopharma (Mundelein, Illinois), the OcuSoft cleanser showed a 5.5 log reduction of *Staphylococcus epidermidis* compared with the 3.5 log reduction of the competitor SteriLid (TheraTears, Woburn, Massachusetts).

A separate study focusing on eye irritation, conducted by Tox Monitor Laboratories (Oak Park, Illinois), found that OcuSoft lid scrub plus extra strength to be 1.67/110, placing it in a practically no-irritation category. OcuSoft Lid Scrub Plus was categorized as an entire ratings category milder than SteriLid—a rating approximately 300% lower.

NearVision CK to Benefit Post-LASIK Baby Boomers

Refractec, Inc. (Irvine, California) announced its interim results for evaluating the effectiveness of NearVision CK (conductive keratoplasty) for post-LASIK patients.

Clinical study data presented during the American Academy of Ophthalmology in Las Vegas, showed positive 3 month postoperative results on a cohort of 60 patients aged 41 years to 63 years, who underwent NearVision CK including:

- 95% of patients with a UCVA of J3;
- 83% of patients achieving 20/32 or better intermediate vision;
- More than 90% of patients reporting satisfaction with quality of vision and depth perception.

Additionally, the study found that NearVision CK was safe and effective, with no adverse events or flap complications. The study fulfilled all US Food and Drug Administration safety limits and targets for outcome predictability.

"Post-LASIK patients who had NearVision CK showed improvements in both their near and intermediate UCVA, and patient's subjective satisfaction ratings exceeded 85%," said Michael Gordon, MD, of the Gordon, Binder & Weiss Vision Institute in San Diego, in a news release. "The NearVision CK procedure is exceptionally safe, and could be very promising for the millions of post-LASIK patients who do not wish to rely upon corrective lenses as they age."

LASIK, LASEK Compared

The study of the safety, efficacy, and reliability of LASIK and LASEK found no significant differences between the two types of laser eye surgery, according to a study led by the University of Illinois, Chicago. The study was published in the *American Journal of Ophthalmology*.

"Although there have been many studies of the safety and efficacy of both types of laser surgery, there has not been a large study directly comparing the outcomes of the two procedures," said Dimitri Azar, MD, field chair of ophthalmologic research and professor and head of ophthalmology and visual sciences at University of Illinois, Chicago.

In the retrospective case-matched study, eyes that had undergone laser eye surgery were matched for visual acuity and astigmatism; 122 LASIK and LASEK treated eyes were matched from a review chart of 2,257 surgeries performed by Dr. Azar. Follow-up was performed at more than 6 months.

"We found that although there were some difference in the visual and refractive results that favor the LASEK procedure, the differences were not clinically significant," said Dr. Azar. "These results are in line with previous smaller studies that we reviewed comparing the procedures. Both procedures seem safe, effective and predictable for the treatment of low to moderate myopia."

Update on Toric ICL Application

STAAR Surgical (Monrovia, California) has provided an update on the status of the company's submission

to the FDA for approval of its Visian toric implantable Collamer lens (TICL), designed to treat both myopia and astigmatism. The FDA's Office of Device Evaluation had recently requested that STAAR amend its submission to provide additional information and analyses of clinical data to permit the agency to complete its review of the TICL. The FDA indicated that evaluation of the amendment could extend the review period by up to 180 days after submission of the amendment.

STAAR's submission for TICL approval was initially delayed to allow for an astigmatism analysis based on a scientific paper of the American National Standards Institute Subcommittee on Astigmatism authored by FDA staff, prominent ophthalmologists and industry representatives.

"The FDA's careful groundwork for the entire field of toric phakic implants has led to a request to analyses on the Visian TICL that go beyond the general experience of the industry in this area. This request is in addition to more routine types of follow-up questions the agency has regarding the Visian TICL. As a result of the scope of the information requested, any potential approval of the product will take longer than anticipated," said David Bailey, CEO of STAAR, in a company news release. "While it was possible that the timeline would have been shorter, the FDA's request is not unusual, given that it is considering the submission for a first-of-its kind product.

"We are pleased with this data point along with other longer term follow-up from the US clinical trial where the cohort of 526 eyes now includes follow-up on 73% at 4 years or later and 59% at 5 years or later. ... Clinically significant anterior subcapsular cataracts were observed in a cumulative total of only 1.3% cases, and no other types of cataract were observed since the premarket approval was submitted. Cumulative endothelial cell loss at 5 years post-operatively was 12.5%, and cell morphology was most consistent with corneal endothelial remodeling with early stabilization and not chronic endothelial cell loss," said Mr. Bailey in a company news release.

Nidek Gained Approval for Excimer Laser

The US FDA has approved the EC-5000 Excimer Laser (Nidek Inc., Gamagori, Japan) for the treatment of hyperopia and hyperopic astigmatism for use in LASIK.

With this approval, US ophthalmic surgeons may treat hyperopia and hyperopic astigmatism, in addition to the current approved range for myopia and myopic astigmatism with the laser.

Mr. Motoki Ozawa, Nidek vice president, said the approval is a historic event for the company. "The excellent and outstanding results from 291 eyes demonstrate Nidek's commitment to providing an innovative, technologically superior excimer platform for laser vision correction surgery. Furthermore, Nidek is actively developing its own custom ablation and wavefront technology platform. The EC-5000 excimer laser system is the perfect pairing to Nidek's strong, world-class product portfolio."

Posterior Chamber PRL Implantation Improved Visual Acuity

Clinical results with the medennium phakic refractive lens (PRL) for the correction of high myopia, are detailed in a study published in the *Journal of Refractive Surgery*. Researchers from Prasat Neurological Institute, in Bangkok, Thailand examined 50 eyes of 31 patients who underwent posterior chamber PRL implantation.

"At 6 months, 1 and 2 years, PRL implantation yielded encouraging visual and refractive results with excellent biocompatibility. The efficacy, stability, and short-term safety of this lens was established," researchers wrote.

According to the study, 3 months after surgery, mean spherical equivalent refraction was $-0.21 \text{ D} \pm 0.42 \text{ D}$. At 6 and 12 months, mean spherical equivalent refraction was $-0.23 \text{ D} \pm 0.38 \text{ D}$. At the last examination, UCVA was greater or equal to 20/20 in 41 (82%) eyes and equal or equal to 20/20 in 22 (44%) of eyes. BSCVA was greater or equal to 20/40 in 42 (84%) and greater or equal to 20/20 in 27 (54%) eyes. Comparison of preoperative and postoperative BSCVA at 12 months showed that 12 (36.4%) of 33 eyes gained one or more lines of BSCVA and seven (21.2%) of 33 eyes gained two or more lines.

Although a majority of patients saw improvements in UCVA and BSCVA, more study is needed to determine serious complications long-term, including cataracts, and acute angle closure glaucoma.

Correction

In the November/December issue of CRST Europe, a cataract complications case response written by Alberto Villarrubia, MD, on zonular weakness, was mistakenly placed in the refractive surgery complications case on "Managing a Buttonhole After LASIK."

We apologize for the error and regret any confusion it may have caused. ■