# S H EUROPE L S 2 VOL. 11, NO. 7

# GREATER SATISFACTION REPORTED WITH LASIK THAN CONTACT LENSES

Compared with contact lens wear, LASIK did not significantly increase dry eye symptoms and it improved ease of night driving and resulted in higher levels of satisfaction at 1, 2, and 3 years' follow-up, according to a study in Ophthalmology.1

Marianne O. Price, PhD, of the Cornea Research Foundation of America in Indiana, and colleagues conducted a prospective, longitudinal, parallel-group, multicenter survey of 1,800 patients, aged 18 to 60 years, who had LASIK or continued using contact lenses. Twenty sites across the United States enrolled patients who completed a study-specific baseline survey during a contact lens fitting or while being evaluated as a candidate for LASIK. Links to follow-up surveys were emailed annually for 3 years. Between-group differences were assessed by analysis of variance, and associations were assessed by logistic multivariate regression.

Of the 1,800 patients, 694 (39%) comprised the control group who continued contact lens wear, 819 (45%) wore contacts at baseline and had LASIK, and 287 (16%) wore glasses at baseline and had LASIK. Most contact lens users had worn them successfully for 5 years or longer.

The proportion of patients expressing strong satisfaction with their current vision correction method decreased from 63% at baseline to 54% at year 3 in the contact lens control group, whereas 88% of former contact lens wearers and 77% of former glasses wearers were strongly satisfied with LASIK at year 3. Patients who were 40 years of age or younger when they had LASIK were somewhat more likely to be strongly satisfied than older patients.

LASIK significantly reduced difficulties with night driving and nighttime visual disturbances among former contact lens users and former glasses wearers. The proportion of patients with dry eye symptoms at 1, 2, or 3 years after LASIK was not significantly increased relative to baseline contact lens wear but was significantly increased relative to baseline glasses use; this was consistent with many glasses users having tried and abandoned contact lenses because of latent dry eye problems. Compared with continued contact lens wear, LASIK significantly reduced self-reported rates of eye infections, ulcers, and abrasions each year.

1. Price MO, Price DA, Bucci FA Jr, Durrie DS, Bond WI, Price FW Jr. Three-year longitudinal survey comparing visual satisfaction with LASIK and contact lenses [published online ahead of print May 18, 2016]. Ophthalmology. doi:10.1016/i.ophtha.2016.04.003.

### **Raindrop Near Vision Inlay Receives FDA Approval**

ReVision Optics has received US FDA approval for the Raindrop Near Vision Inlay for the surgical correction of presbyopia, according to a company news release. The inlay is indicated to improve near vision by reshaping the anterior curvature of the cornea in presbyopia patients who have emmetropic refractions (1.00 to -0.50 D).

The Raindrop is the second FDA-approved implantable corneal device for the correction of near vision in patients who have not undergone cataract surgery, joining the Kamra inlay (AcuFocus), which received FDA approval in April 2015. The Raindrop is the first FDA-approved implantable device that changes the shape of the cornea to achieve improved vision, the news release said.

The approval was based on a study of 373 patients treated at 11 investigational sites in the United States. Results from the study, which were submitted to the FDA in ReVision Optics' premarket approval application, showed clinically significant improvement in near visual performance. Average UNVA improved by 5 lines in treated eyes, and there was no loss of binocular distance vision. Ninetyeight percent of patients achieved a UNVA of 20/40 or better, and 88% of patients achieved a UNVA of 20/25 or better in the treated eye at 24 months. Mean UCVA for both eyes exceeded 20/20 at all distances. Refractive stability was achieved at 6 months.

Information provided in the premarket approval submission confirmed that the Raindrop is removable and that patients return to their baseline visual acuities if the device is removed.

### **Pixium Vision Gains UK Approval** for Trial of Bionic Vision System

Pixium Vision has received approval from the UK Medicines & Healthcare products Regulatory Agency to initiate a clinical trial of the Intelligent Retinal Implant System (IRIS) II bionic vision system in patients who have lost sight due to retinitis pigmentosa, according to a company news release.

The IRIS II epiretinal system incorporates innovative features being evaluated, including a bio-inspired camera that is intended to mimic the functioning of the eye; an epiretinal implant with 150 electrodes; and an explantable design, minimizing the risk of retinal damage and permitting potential upgrade to newer therapy options, the news release said.

Participation of Moorfields Eye Hospital NHS Foundation trust broadens the clinical study centers of excellence, adding to sites across France, Germany, and Austria.

Pixium Vision initiated the CE Mark approval process this past December on the basis of IRIS clinical experience. Commercialization is expected to start in the second half of 2016.

## Oculus Introduces Corvis ST Tonometer

Oculus introduced the Oculus Corvis ST, which combines tonometry and pachymetry with measurement of the biomechanical response of the cornea, a company news release said. According to Oculus, the Corvis ST is the first device that provides the ability to perform fast and comprehensive screenings for biomechanically weak corneas. The integration of Pentacam data allows the combination of biomechanical and tomographic data in patient screening prior to refractive surgery.

By measuring both biomechanical response and corneal thickness, the Corvis ST is able to correct for both factors at the same time and return a biomechanically corrected IOP. In addition to biomechanical screening, the Corvis ST software allows comprehensive keratoconus detection; the Corvis Biomechanical Index enables ophthalmologists to perform keratoconus screenings based on the biomechanical response of the cornea.

It is the first available screening software that combines biomechanical information with pachymetric progression data, the news release said.

Combining tomographic data from the Pentacam with biomechanical data from the Corvis ST provides improved sensitivity and specificity in the detection of patients at significant risk for developing ectasia after refractive surgery, according to Oculus. Based on these data, a tomographic biomechanical index is created, which, together with the comprehensive display, helps surgeons avoid risks and care for more patients safely, the news release said.

# Positive EU Regulatory Opinion for Once-Daily Nevanac Eye Drops

The EU's Committee for Medicinal Products for Human Use recommended the approval of once-daily Nevanac 3mg/mL (nepafenac; Novartis) eye drop suspension in Europe for the reduction in risk of postoperative macular edema associated with cataract surgery in diabetic patients, according to a company news release.

Nevanac 3mg/mL is a once-daily nonsteroidal antiinflammatory ophthalmic suspension. It is approved in Europe for prevention and treatment of pain and inflammation associated with cataract surgery. A lower concentration of nepafenac (Nevanac 1 mg/mL eye drops, suspension) is approved for both of the above indications but is administered three times daily.

# Nicox to Transfer Commercial Operations

Nicox has reached an agreement with GHO Capital, a European specialist investor in health care, to transfer its European and international commercial operations to a newly founded private company focused on the commercialization of a portfolio of ophthalmic products in Europe, according to a company news release. The transaction is valued at €26 million.

The new company will combine Nicox's existing European and international commercial infrastructure and portfolio, including some products in late-stage development for Europe only, with the financial resources and capabilities of GHO capital. All rights to Nicox's unencumbered research and development pipeline programs, including AC-170 and rights under the latanoprostene bunod agreement with Bausch + Lomb, remain entirely with Nicox, the news release said.

# MicroSurgical Technology Names Jeff Castillo President

MicroSurgical Technology has appointed Jeff Castillo President, according to a company news release.

Mr. Castillo began his career at Procter & Gamble and then spent 21 years in a variety of roles and positions at Johnson & Johnson, including Sales and Marketing Manager for the infection control business; International Business Director Latin America; Regional Director, Ethicon; and Director, US Sales and Marketing for Advanced Sterilization Products.

More recently, Mr. Castillo was the Vice President of Commercial Operations, Americas, for Abbott Medical Optics,

where he was responsible for revenues in the United States, Canada, and Latin America operations. Immediately before joining MST, Mr. Castillo was President of the performance division at Alphaeon Corporation.

Former President and MST Founder Larry Laks will remain on the board of directors, the news release said.

### Harman and HelpMeSee Partner to Reduce Global Blindness

Harman International will participate in developing an enterprise software solution for simulation-based training management with HelpMeSee, the global campaign to end cataract blindness, according to a company news release.

HelpMeSee has employed Harman's software services to develop a simulation-based training management system for delivering standardized cataract surgery training. The system includes an application that allows development of a library of preconfigured training scenarios that are presented to trainee specialists. Using these scenarios, trainees can learn and practice performing surgical tasks in manual smallincision cataract surgery. HelpMeSee plans to offer the training program at selected training centers around the world.

### **Moorfields Eye Hospital Partners** With Google's DeepMind Health

Moorfields Eye Hospital has entered a medical research partnership with Google's DeepMind Health that could revolutionize the way professionals perform eye tests and lead to earlier detection of common eye diseases, according to a news release.

DeepMind Health specializes in using artificial intelligence to address some of society's toughest challenges, according to Google. Together with Moorfields, the company will explore how cutting-edge technologies can help medical research into eye diseases such as age-related macular degeneration and sight loss due to diabetes. As part of the research project, machine learning will be applied to 1 million anonymous eye scans to detect early signs of eye conditions that humans might miss.

"Our research with DeepMind has the potential to revolutionize the way professionals carry out eye tests and could lead to earlier detection and treatment of common eye diseases such as age-related macular degeneration," Peng Tee Khaw, Director of the National Institute for Health Research Biomedical Research Centre in Ophthalmology at Moorfields Eye Hospital, said in the news release. "With sight loss predicted to double by the year 2050, it is vital we explore the use of cutting-edge technology to prevent eye disease."

> - Compiled by Steve Daily, Executive Editor, News; and Callan Navitsky, Senior Editor



 Air Pollution Now Major Contributor to Stroke

> Findings of a recent global study show that harm caused by air pollution to the lungs, heart, and brain has been underestimated.



https://www.theguardian.com/science/2016/jun/09/air-pollution-now-major-contributor-to-stroke

Abortion Demand Soars Amid Zika Fear

> Fears over the Zika virus have contributed to a large increase in the number of women in Latin America wanting abortions, researchers say.

http://www.bbc.com/news/health-36595448

**Donated Blood Will Not** Transmit Alzheimer or Parkinson Disease

> A study of nearly 1.5 million patients found no evidence that degenerative brain disorders can be transmitted via donated blood.



https://consumer.healthday.com/circulatory-system-information-7/blood-disorder-news-68/donated-blood-won-t-transmitalzheimer-s-parkinson-s-disease-study-712166.html

Scientists Launch Proposal to Create Synthetic Human Genome

> A US\$100 million global consortium has been proposed to devise ways to assemble human DNA in the



laboratory to better understand how it works and to look for new ways of treating disease.

https://www.theguardian.com/science/2016/jun/02/scientistslaunch-proposal-to-create-synthetic-human-genome-dna

Fifteen Minutes of Exercise May Boost Lifespan

> Just 15 minutes of exercise per day may lower older adults' risks of early death by one-fifth, a study suggests.



http://www.webmd.com/healthy-aging/news/20160614/got-aspare-15-minutes-a-little-exercise-may-boost-life-span