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FOR IMMEDIATE RELEASE

Clinical Investigation Elevates Safety for Cataract Patients

Eugene, Oregon doctor spearheads research into new lens designs

FDA finds driving safety and “low light” activities improved

“New Technology” designation from Medicare confirms advantages

Industry follow suit, develops new designs

Mark Packer, MD, Clinical Associate Professor at Oregon Health & Science University and practicing with Drs. Fine, Hoffman & Packer in Eugene, Oregon, has led clinical research that demonstrates the advantages of a new implant design for cataract implants. His research shows that the new design, called an aspheric lens, improves patients’ night driving performance.¹ In 2004 and 2005, the United States Food and Drug Administration (FDA) approved product labeling confirming these results, and the Center for Medicare and Medicaid Services (CMS) certified the new design as a New Technology Intraocular Lens (IOL), demonstrating that it provides significant patient benefits above and beyond standard implants. The implant is known as the Tecnis® IOL.

“Dr. Packer works closely with optical engineers in our research and development department to design the studies which have demonstrated the benefits of the Tecnis lens,” said James V. Mazzo, Chairman, President and CEO of Advanced Medical Optics, the manufacturer of the new implant. “His work has been published in multiple peer-reviewed scientific journals and recognized as a new standard in the industry.”

In fact, when Dr. Packer began his research five years ago not a single implant on the US market featured an aspheric design. Today, all of the major manufacturers of lens implants include an aspheric design in their portfolio. “What this says is that the benefits to patients have become widely recognized by eye surgeons,” said Dr. Packer.

Dr. Packer’s research involved a double-masked, prospective, randomized study, the highest level of scientific proof. Subjects with cataracts who enrolled in the study received the Tecnis® aspheric implant in one eye and a standard implant in the other eye. Neither the patients nor any of the technicians who examined them knew which implant was in which eye. A night driving simulation study formed a key part of the investigation.

“Subjects traveled to San Ramon, California, where they performed a night driving simulation test at Vision Sciences Research Corporation under the supervision of Arthur M. Ginsburg, PhD,” noted Dr. Packer. Results from that testing showed significantly better performance when using the eye with the new aspheric implant compared to the eye with the standard implant. This kind of performance test is called functional vision, because it demonstrates how well people actually function based on how well they see.

Another important aspect of Dr. Packer’s research with the Tecnis lens involved testing of contrast sensitivity. “Contrast sensitivity indicates how well a person can see faint objects in dim light, like an obstacle on the road at night,” Dr. Packer said. The results of contrast sensitivity testing have been linked to the incidence of car accidents and falls among the elderly. Dr. Packer’s research has shown that implanting aspheric Tecnis lens gives cataract patients a contrast sensitivity like people who are in their twenties.² “This surgery truly turns back the clock,” Dr. Packer said.

The FDA stated that the “These finding suggest that there is likely to be a meaningful safety benefit to elderly drivers with Tecnis lenses, and to the drivers and pedestrians with whom they share the road. The results of this performance/functional test demonstrate that the Tecnis lens improves functional vision, which in turn may improve patient safety for other life situation under low visibility conditions.” CMS Administrator Mark McClellan, MD, PhD stated that “for these lenses, there is clear evidence of improved functional vision and contrast acuity.”

The only drawback of these implants is that reading glasses are still required for near vision. “We are actively working on new designs to provide clear, sharp vision at all distances,” said Dr. Packer. “These are very exciting times for people approaching the age of cataract surgery.”

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About Mark Packer, MD, FACS

Dr. Packer grew up in Los Angeles near UCLA and graduated *cum laude* from Harvard University, receiving both an Honorary National Scholarship and a Harvard Scholarship. He received his medical degree from the University of California at Davis and completed his residency training in Ophthalmology at Boston University Medical Center; he achieved American Board of Ophthalmology Certification in 1997. He currently serves as Clinical Associate Professor of Ophthalmology at Oregon Health & Science University.

Dr. Packer focuses on refractive surgery and intraocular lens technology. He serves as Principal Investigator for the Carl Zeiss Meditec MEL-80 Excimer Laser, and was Coordinating Investigator for the US FDA monitored study of the aspheric Tecnis Intraocular Lens. He is Medical Monitor for the investigation of the AMO Tecnis Multifocal Intraocular Lens, and serves as Principal Investigator for the Visiogen Synchrony Dual Optic Accommodative Lens. He has also participated in FDA monitored studies of the Eyeonics accommodative Crystalens, VisionCare's Implantable Miniaturized Telescope and Rayner's C-flex IOL. Dr. Packer works extensively with leaders in the ophthalmic industry on the development of new technology for cataract and refractive surgery. He is a consultant to Advanced Medical Optics, Bausch & Lomb, Advanced Vision Science and WaveTec Vision Systems.

Dr. Packer's recent peer-reviewed publications include "Immersion A Scan Compared to Partial Coherence Interferometry," "The Physics of Phaco: A Review," and "Intraocular Lens Power Calculation Following Incisional or Thermal Keratorefractive Surgery," appearing in *The Journal of Cataract and Refractive Surgery*; "Initial Clinical Experience with an Anterior Surface Modified Prolate Intraocular Lens" appeared in the *Journal of Refractive Surgery*. He authored "Wavefront Technology in Cataract Surgery" in *Current Opinion in Ophthalmology* and edited the textbook *Refractive Lens Surgery* published by Springer. He also served as editor for the "Functional Vision" issue of *International Ophthalmology Clinics* and has edited the annual Cataract and IOL issue of *Current Opinion in Ophthalmology* since 2005.

Dr. Packer has delivered hundreds of presentations at scientific meetings around the world and demonstrated cataract surgery on four continents. He serves on the Cataract Clinical Committee of the American Society of Cataract and Refractive Surgery (ASCRS) and represents ASCRS on the Council of the American Academy of Ophthalmology. He also chairs the Cataract Subcommittee of the American Academy of Ophthalmology Annual Meeting Program Committee. In 2005 he was elected to membership in The International Intra-Ocular Implant Club and named one of 50 Top Opinion Leaders by *Cataract & Refractive Surgery Today*. He was named one of the Best Doctors in America in 2006.

Dr. Packer discloses the following financial relationships:

Consultant

- Advanced Medical Optics, Inc.
- Advanced Vision Science, Inc.
- Bausch & Lomb, Inc.
- Carl Zeiss Meditec, Inc.
- Carl Zeiss Surgical GmbH
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- Ethicon, Inc.
- Gerson Lehman Group, Inc.
- iScience Surgical Corporation
- I-Therapeutix, Inc.
- Johnson & Johnson Vision Care, Inc. (Vistakon Division)
- Leerink Swann & Company
- Visiogen, Inc*
- VisionCare, Inc.
- WaveTec Vision Systems*

Travel, Research & Honoraria

- Alcon Laboratories, Inc.
- Endo Optiks, Inc.
- eyeonics, inc.
- Staar Surgical, Inc.

*Stock Options

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¹http://www.tecnisiol.com/Support%20Files/TECNIS_Silicone_Pkg.Insert.pdf

² Packer M, Fine IH, Hoffman RS. “Functional Vision, Contrast Sensitivity, and Optical Aberrations,” in Packer M (editor), “Functional Vision.” International Ophthalmology Clinics Spring 2003; 43(2), 1-3.

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