



PRESBIA ANNOUNCES 12-MONTH RESULTS FOR FLEXIVUE MICROLENS[®]

Almost 80% of Patients No Longer Need Reading Glasses

AMSTERDAM—(November 14, 2011)—Presbia, a medical device company and leader in near vision restoration, announced today its preliminary 12-month post market surveillance study of patients implanted with the Flexivue Microlens[®], a corneal inlay treatment for presbyopia. The results showed significant improvement in near visual acuity in all patients, with 78 percent no longer using reading glasses to see objects up close.

The randomized study of 40 emmetropic patients between the ages of 45 and 60 was conducted at two European post market surveillance sites—with 27 patients at the University of Crete in Greece under the direction of Prof. Ioannis Pallikaris, M.D., and 13 patients at Prato Hospital in Italy under the direction of Dr. Marco Fantozzi. The Flexivue Microlens[®] procedure involves implanting, in the patient's non-dominant eye, a 3-mm diameter lens in a corneal pocket created using a 150 kHz femtosecond laser (commonly used in LASIK surgery, a technique pioneered by Prof. Pallikaris).

Patients achieved dramatic improvements in their near vision after just one week, from pre-operative vision of 20/100 to 20/25⁻¹. The 12-month results show that the Flexivue Microlens[®] continues to improve near vision over time and produces stable near vision after a full year of implantation without any medical complications.

Over a period of 12 months, the average uncorrected near visual acuity of the patients' operated eye improved from 20/100 pre-operatively to 20/25 after surgery. In addition, the study also showed that patients experienced no change in their distance visual acuity using both eyes, although the distance vision in only the operated eye did show declines of about two lines on the Snellen chart. All patients recorded a binocular distance vision of 20/25 or better within one-month of the surgery, with continued improvement over time.

"This study demonstrates that the Flexivue Microlens[®] provides a clinically useful and very satisfactory treatment for emmetropic presbyopia," said Dr. Michael Gordon, founder of the Gordon Binder Vision Institute in San Diego, CA and a member of Presbia's Medical Advisory Board. "I think this solution provides another tool in presbyopia treatments that is exchangeable and removable, and provides patients with very satisfactory and useful near vision in a safe and stable manner."



Drs. Pallikaris and Fantozzi reported that during the 12-month time period after implantation, none of their patients experienced any degradation to the optical system and no major adverse events were reported with the Flexivue Microlens[®].

“Today’s results verify the long-term benefit of the Flexivue Microlens[®] solution, both empirically as well as in terms of quality of life,” said Prof. Pallikaris, Chairman of Presbia’s Medical Advisory Board. “The fact that all respondents either don’t use reading glasses at all or less than 50 percent of the time shows that the Flexivue is a superior treatment for this common eye ailment that affects more than one billion people globally.”

In addition, patients in this study reported very high satisfaction rates one year after implantation with 98 percent of patients reporting that uncorrected near vision in the implanted eye was either good or excellent, and 100 percent of patients reporting that their uncorrected binocular distance visual acuity was either good or excellent.

The Flexivue Microlens[®] is commercially available in 42 countries, including Brazil and Israel where the device recently received registration approvals. The lens received the CE mark in 2009.

About Presbia’s Flexivue Microlens[®]

Presbia’s Flexivue Microlens[®] solution involves implanting a 3-mm lens, approximately 15 microns in edge thickness, in the corneal stroma of the patient’s non-dominant eye. Using Presbia’s proprietary insertion tool, the lens is placed in a pocket created in the cornea by a femtosecond laser. The lens may stay in place permanently, or can be easily removed and/or replaced if the patient’s presbyopia advances and a stronger prescription is required. The less than 10-minute procedure requires no general anesthesia, and the patient’s visual recovery takes only a couple of days. Since the Flexivue Microlens[®] solution utilizes standard equipment and requires minimal additional training, the procedure requires no significant capital investment by the surgeon’s practice.

An animated video of the procedure is available at www.presbia.com.

ABOUT PRESBIA

Presbia is a leading ophthalmic-device company focused on the development of solutions for presbyopia, the age-related loss of the ability to read or focus on near objects. Chief among these approaches is the Presbia Flexivue Microlens[®], a 3mm-diameter lens implanted using femtosecond laser technology. Further information is available at www.presbia.com.



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Note: The Presbia Flexivue Microlens® and related medical procedures are not available in the United States and have not been evaluated or approved by the U.S. Food and Drug Administration.