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12-month results

CK for presbyopia helps improve near vision

Procedure able to preserve contrast sensitivity, depth perception

By Lynda Charters

Reviewed by Marguerite B. McDonald, MD, FACS

Editor's Note: *This study started in May 2001 and conductive keratoplasty was approved for the treatment of presbyopia in March 2004. Dr. McDonald presented the data that led to the procedure's FDA approval for the treatment of presbyopia during the annual meeting of the American Society of Cataract and Refractive Surgery.*

San Diego—The 12-month results of the FDA trial of conductive keratoplasty (CK) using the ViewPoint CK System (Refractec Inc., Irvine, CA) indicate that the procedure is safe and effective for treating presbyopia.

Dr. McDonald

Conductive keratoplasty, which delivers radiofrequency energy to shrink the collagen in the peripheral cornea, thereby steepening the central cornea, improves near vision and preserves contrast sensitivity and depth perception, according to Marguerite B. McDonald, MD, FACS.

"We know that the average amplitude of accommodation decreases rapidly from up to 16 D at age 8 down to an average of 1.5 D at age 60," explained Dr. McDonald, clinical professor of ophthalmology, Tulane University School of Medicine, and director, Southern Vision Institute, New Orleans. "Presbyopia is defined as the inability to maintain 3 D of accommodation for any length of time."

This trial included 188 eyes of 150 patients (mean age, 53 years), 38 of whom underwent bilateral correction. The mean intended correction was 2.03 D and ranged up to 3 D.

Distance, near vision improve

The visual acuity results of the procedure were impressive.

"The binocular uncorrected distance vision increased from 92% with 20/20 or better vision to 97% with 20/20 or better at 1 year after the procedure," Dr. McDonald said. "Binocular uncorrected near vision increased from 15% with J3 preoperatively to 89% with that visual acuity level 1 year postoperatively; 98% had J5 vision or better at the same time point. Eighty-seven percent of patients had binocular uncorrected 20/20 distance and near vision (J3 or better) at 1 year after surgery."

The investigators looked at the following safety parameters: loss of more than 2 lines of vision, best-corrected visual acuity (BCVA) less than 20/40, preoperative BCVA better than 20/20 now worse than 20/25 postoperatively, and an increase of more than 2 D of cylinder. At the 1-year follow-up, no patients had experienced any safety problems, and there were no serious device-related adverse effects of the treatment. Very few patients reported significantly worse glare, halos, or blurred vision after treatment.

There was no change in mesopic contrast sensitivity over time when preoperative values were compared with those after conductive keratoplasty.

The evaluation of depth perception also showed good results, with 93% of patients grading it as excellent, very good, or good, and 7% grading it as fair.

"At 1 year after the procedure, 98% of patients said that their quality of vision was improved, 84% were satisfied or very satisfied with the results of their procedure, and 100% rated the quality of their depth perception as fair to excellent," Dr. McDonald said.

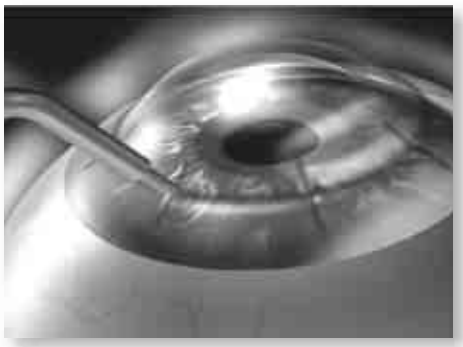

Figure 1 Conductive keratoplasty uses radiofrequency energy to heat and reshape the cornea. (Figure courtesy of Refractec Inc.)

"Based on these results, conductive keratoplasty using the ViewPoint CK System is safe and effective for improving near vision in patients with presbyopia. Approximately, nine of 10 patients could see both 20/20 at distance and near and J3 or better at near without glasses. These patients retained good mesopic contrast sensitivity, quality of vision, and subjective quality of depth perception, yielding high patient satisfaction," she concluded. **OT**

FYI

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Dr. McDonald reported a proprietary interest in this technology.