



REGULATORY/LEGISLATIVE

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FDA panel says CK is approvable for temporary reduction of hyperopia

Twelve-month analysis of 171 eyes showed that the procedure easily beat the FDA guidelines by showing that 91% of patients were corrected to 20/40 or better.

WASHINGTON — The Food and Drug Administration's Ophthalmic Devices Panel voted 9-1 Nov. 30 to make Refractec's PMA requests for conductive keratoplasty, using the ViewPoint CK System, approvable with conditions. Among those conditions was that the labeling include "for the temporary reduction of hyperopia."

The ViewPoint CK system uses radio-frequency for the treatment of spherical hyperopia between 0.75 and 3 D.

The panel expressed concern with the device's stability. The 12-month data Refractec provided the ophthalmic panel did not convince panel members that the ViewPoint CK System could maintain a refractive change in hyperopes for more than a year. It was the impression of the panel that the ViewPoint CK System induced an initial overcorrection at the start of the procedure that patients had to wait for regression to occur.

But the panel said that the 12-month analysis of 171 eyes using the final nomogram showed that the procedure easily beat the FDA guidelines by showing that 91% of patients were corrected to 20/40 or better, 58% had a mean refractive spherical equivalent (MRSE) of ≤ 0.50 D or better, and 91% had an MRSE of ≤ 1 D or better.

Refractec did not provide any 24-month data as to whether the regression stopped in later months. The company said 24-month data were not available because patients had not reached their 24-month follow-up period.

In the end, the panel voted to make the device approvable with conditions because it had met the FDA conditions for safety and effectiveness.

CK for hyperopia

CK is performed using a controlled release of radio-frequency energy delivered intrastromally via a probe tip. The thermal profile is homogeneous to approximately 80% the depth of the cornea with an average width of 450 μm and an average depth of 500 μm . The CK places 8 to 32 probe treatment application spots around the peripheral cornea outside the visual axis. The number of treatment spots is determined by the required refraction.

Refractec submitted the PMA for CK for the reduction of spherical hyperopia in the range of +0.75 to +3.25 D of cycloplegic spherical hyperopia; -0.75 D or less of refractive astigmatism; +0.75 to +3 D cycloplegic spherical equivalent; in patients with a difference equal to 0.5 D between preoperative manifest and cycloplegic refractions; and in patients 40 years of age or older. Refractec officials also asked the FDA to include that the magnitude of correction diminishes over time with an average loss of approximately 7% of the intended correction at 1 year.

The 1-year study, led by chief investigator Marguerite B. McDonald, MD, studied 401 eyes of 233 patients with hyperopia.

The stability charts noted there was a mean change of 0.03 D to 0.04 D per month from months 6 through 12, which the FDA stated could be cause for concern in terms of regression. While the 1-month results showed only 79% of the patients achieved uncorrected visual acuity of 20/40 or better, by month 3 that number had climbed to 86% and 91% by month 12.

FDA concerns

The FDA chief investigator of Refractec's PMA, Sheryl Berman, MD, pointed out that the CK procedure produced an induced absolute axis shift in a large number of patients. At 12 months 58% of patients had a shift of greater than 15°, 37% had a shift of greater than 45° and 11% had a shift greater than 75°.

Michael R. Grimmer, MD, pointed out that the induced axis shift could be related to the procedure's inaccurate spot placement, non-perpendicular needle track and non-uniform needle depth, which all meant poor predictability. He said that without 24-month data, the procedure could not be called temporary or stable.

With regard to regression — a major sticking point of the panel — Peter Hersh, MD, a CK investigator for Refractec, said that regression has been found in all the corneal refractive procedures and is likely due to wound healing.

Panel member Andrew J. Huang, MD, asked Refractec's presenters if they had any data that proved the regression stopped. Refractec's regulatory consultant Judy Gordon said they did not have any formal results from the 12- to 24-month data, but she said what the company had seen so far indicated there was a small change. Panel member A. Ralph Rosenthal, MD, did not allow Refractec to speak regarding the company's 24-month data.

Daniel S. Durrie, MD, one of Refractec's investigators, said he expects the ViewPoint CK system to be one of the major devices of 2002. "It had the highest safety and efficacy ratings presented for a hyperopia procedure."

He continued, "The 24-month data looks good to date, but it's only on 54 eyes. And Refractec did not want to present partial data, which [FDA ophthalmic division director] Ralph Rosenthal said would not be acceptable to the FDA anyway. [The procedure] is still more stable than LTK, and I've done trials for both," Dr. Durrie told *Ocular Surgery News*.

For Your Information:

- Marguerite B. McDonald, MD, can be reached at 2626 Napoleon Ave., New Orleans, LA, 70115; (504) 896-1250; fax: (504) 896-1251; e-mail: mbm2626@aol.com.
- Peter S. Hersh, MD, can be reached at Glenpointe Centre East, 300 Frank W. Burr Blvd., Teaneck, NJ 07666; (201) 883-0505; fax: (201) 692-9646; e-mail: phersh@vision-institute.com; Web site: www.vision-institute.com.
- Daniel S. Durrie, MD, can be reached at 5520 College Blvd., Suite 200, Overland Park, KS 66211; (913) 491-3737; fax: (913) 491-9650; e-mail: ddurrie@novamed.com. Dr. Durrie does not have a direct financial interest in any of the products mentioned in this article. He is a clinical investigator for Refractec.

References:

- Refractec Inc., manufacturers of the ViewPoint CK system, can be reached at 3 Jenner, Suite 140, Irvine, CA 92618; (949) 784-2600; fax: (949) 784-2601. Web site: www.refractec.com.