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Refractive

A surgical solution

CK helps near vision in presbyopic, post-surgical eyes

Procedure fills void in practices with presbyopic patients who previously had no other surgical options

By Lynda Charters

Reviewed by Bradley C. Black, MD, and Stephen E. Pascucci, MD

Conductive keratoplasty (CK) (NearVision, Refractec Inc.) improves near vision in presbyopic eyes and in presbyopic eyes that had undergone an excimer laser procedure.

Two experts in the technique discuss how the procedure has been incorporated into their practices.

"CK is a non-ablative, collagen-shrinking procedure that changes the corneal curvature. It is the first corneal-based procedure approved by the FDA specifically to improve near vision in patients with presbyopia," Stephen E. Pascucci, MD, said. He noted that use of CK after an excimer laser procedure is an off-label application.

"Patients who have undergone LASIK, PRK, or LASEK may be dissatisfied with their near vision after the onset of presbyopia. These patients usually dislike wearing readers and are interested in a surgical solution to improve their near vision," he said.

CK treatment to improve near vision involves inducing slight to moderate myopia, –1 to –1.5 D, in the patient's nondominant eye. Patients who have undergone the procedure show improved near vision without experiencing significant, compromised functional distance vision, as occurs with excimer laser monovision procedures, he explained.

CK works, Dr. Pascucci explained, like a belt tightening the cornea in the mid-periphery when a full circle of treatment spots is applied. The central cornea steepens, and the corneal asphericity increases. This happens because the resistance of the stromal tissue creates even heating along the path of the keratoplasty tip. When the corneal tissue is heated from the bottom to the top, there is deep stromal collagen contraction in the treatment spot. This produces a cylindrical footprint about 80% deep.

Nomogram adjustment

Typically, when using the 16-spot nomogram, the treatment is applied at the 6- and 7-mm optical zones to achieve 1 to 1.625 D of correction. With the 24-spot nomogram, the spots are applied at the 6-, 7-, and 8-mm optical zones for 1.75 to 2.25 D of correction. When performing CK after LASIK, the nomogram must be modified because collagen shrinkage under this circumstance is quite robust. Usually an eight-spot treatment will suffice after LASIK.

Dr. Pascucci and Daniel S. Durrie, MD, conducted a study in which they evaluated whether CK can provide functional near vision in patients with presbyopia who had undergone LASIK, LASEK, or PRK. Forty-two patients (42 eyes) were treated with CK after undergoing LASIK, LASEK, or PRK and followed for 3 months. The mean patient age was 52 ± 4 years (range, 44 to 60).

Before CK, the mean sphere was 0.20 ± 0.49 D (range, 0.75 to –1.25 D), the mean cylinder was –0.23 ± 0.26 D (range, 0.0 to –0.75 D), and the mean spherical equivalent was –0.31 ± 0.50 D (range, –0.75 to –1.25 D). Thirty-eight patients had undergone LASIK, one underwent LASEK, and three underwent PRK. The patients underwent the procedures a mean of 48 ± 27 months before CK (range, 6 to 143). All eyes were treated with eight spots at a 7.5-mm optical zone. The mean corneal pachymetry value was 493 ± 103 µm (range, 226 to 651 µm). The near add before CK was 1.70 ± 0.68 D (range, 0.0 to 3.00).

Dr. Pascucci reported that the near vision values increased with time after CK.

"At 1 and 2 months postoperatively, 71% of eyes saw newspaper size print (J3) or better. The distance vision in the eyes treated for near decreased from the preoperative level. At 3 months postoperatively, 48% had an uncorrected distance visual acuity of 20/40 or better," he said.

Patient questionnaire

Thirteen patients completed a questionnaire after undergoing CK. The results indicated that 100% of the patients did not wear their corrective lenses for distance vision, and 92% did not do so for near vision.

Regarding glare, haze, and halos, the questionnaire results showed similar responses from preoperatively to postoperatively. When the patients rated the three disturbances on a scale of 1 to 5 with 1 indicating no glare, haze, or halos, and 5 indicating disabling visual disturbances, the preoperative values were 1.62, 1.37, and 1.22, respectively, and the postoperative values were 1.48, 1.37, and 1.35, respectively.

Postoperatively, patients reported major improvements in near vision compared with preoperatively when reading small print, menus, and street signs, with small print showing the greatest improvement. For example, on a scale of 1 to 10, with 1 indicating no problem and 10 indicating a severe problem, patients rated reading small print as 8 preoperatively compared with 3.8 after CK. Conversely, distance vision scored a 1.5 preoperatively and 2.8 postoperatively. Interestingly, patients reported higher scores for fluctuating vision (2.2 preoperatively and 3.4 postoperatively) and diplopia (1.2 preoperatively and 1.9 postoperatively).

When asked to rate their postoperative vision using a scale of 1 to 10 with 1 indicating excellent and 10 indicating very poor, patients rated their overall visual quality as 2.8 and their visual effectiveness in daily activities as 2.3.

The questionnaire results also showed a high patient satisfaction with the procedure and willingness to recommend CK to others. When rated on a scale of 1 to 10, with 1 indicating highly recommended and 10 strong no, CK scored an average 1.8 (range, 1 to 5). Regarding recovery postoperatively, with 1 indicating very easy and 10 very dif-

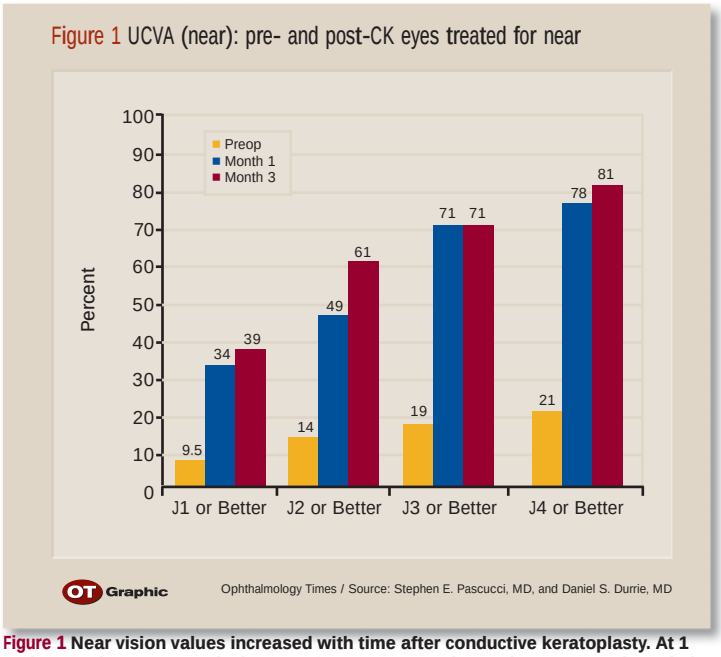

Figure 1 Near vision values increased with time after conductive keratoplasty. At 1 and 2 months postoperatively, 71% of eyes saw J3 or better (newspaper-size print).

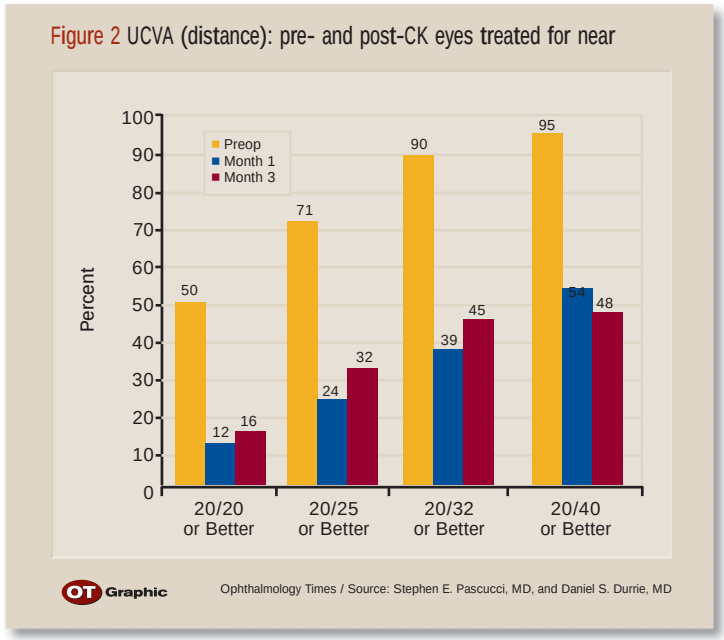

Figure 2 Distance vision in the eyes treated with conductive keratoplasty for near decreased from preoperative baseline. At 3 months postoperatively, 48% achieved uncorrected visual acuity for distance of 20/40 or better.

ficult, CK scored 2.6 (range, 1 to 8). Patients rated their postoperative pain as 2.2 (range, 1 to 5) on the scale of 1 to 10 with 1 indicating none/very little and 10 very much.

Positive outcomes

After evaluating these results, Dr. Pascucci said, "CK effectively improved near vision in presbyopic eyes that had undergone an excimer laser procedure. The near vision increased with time postoperatively. At 1 and 2 months postoperatively, 71% of eyes saw J3 (newspaper size print) or better. The mean spherical equivalent appeared stable at 3 months. Subjective responses showed improvement for all near-vision activities. There was a high rate of patient satisfaction for effectiveness of the procedure for daily activities. The treatment with only eight CK spots at the 7.5-mm optical zone is recommended for eyes after excimer laser procedures."

Bradley C. Black, MD, associate clinical professor of ophthalmology, University of Louisville, Louisville, KY, has been performing CK for about 2 years. He described CK as fitting nicely into his practice, in which cataract surgery accounts for about 75% of the surgeries performed and refractive surgery makes up the balance.

"CK has filled a void in our practice. Many of our patients are baby boomers, who are 45 to 60 years old. Before CK, we did not have much to offer this group to help with presbyopia. CK gave us an option for these patients. We now have a new subset of patients in the practice that we were not seeing before. These patients, who have good vision except for their near vision, typically do not have routine eye examinations and have been getting by wearing readers," Dr. Black said.

Like Dr. Pascucci, Dr. Black also performs CK in patients who underwent a previous refractive procedure and did not achieve the desired result or underwent a previous refractive procedure and later developed mild hyperopia. A third group is composed of patients who achieved excellent distance vision following a refractive procedure but needed CK to read.

"Many patients who have had PRK or LASIK are in their 40s and now do not need contacts and glasses to drive, but are disconcerted by the fact that they can't see up close without wearing readers," he said.

Other patients who are interested in CK are those who have undergone cataract surgery, achieved good distance vision with implantation of IOLs, but still need glasses for reading, he explained.

An important point, Dr. Black stated, is that CK is not indicated for those patients who have undergone incisional refractive surgery, such as RK or astigmatic keratotomy (AK).

"If patients have undergone RK or AK, CK is contraindicated," he emphasized.

Another noteworthy point is that many patients who have had PRK or LASIK have an overresponse to CK.

"Surgeons who want to perform CK on patients who have undergone PRK or LASIK have to adjust their nomograms to avoid an overresponse," he said.

Regarding outcomes following CK, Dr. Black reported that overall the results he and his colleagues have achieved match the FDA study, i.e., 80% to 90% of patients are satisfied with the results.

"Those percentages may not sound that high. However, when we consider the patient population, they generally are very difficult to please. In light of that, this is a high rate of satisfaction," he said.

The visual data from preoperatively to postoperatively are also similar to the FDA findings.

Ninety-two percent to 95% of patients regain the ability to read at the J3 level and see 20/20 at distance with binocular vision, Dr. Black explained. For patients who have had CK and then require cataract surgery, he has not adjusted the IOL calculations but believes that that might be necessary because CK probably affects the IOL power. OT

FYI

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Dr. Pascucci reported a proprietary interest in this technology.