

Does CK Do OK After LASIK?

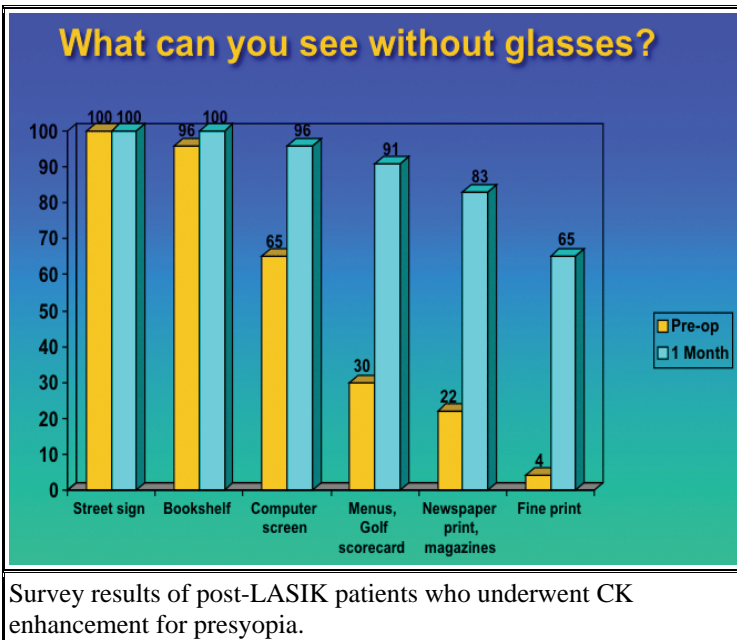
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Review of Optometry, April 2006

Preliminary study results show that conductive keratoplasty can improve near vision in postoperative LASIK patients as they become presbyopic.

The patient whose LASIK you comanaged five years ago, when he was 39 years old, now presents complaining that his once-successful LASIK is failing because he now has difficulty reading. This same patient was intolerant to contact lenses and did not want to wear spectacles. What options do you have?

You may find yourself asking this question more often. Consider: More than 1.7 million post-LASIK emmetropes in the United States currently find themselves in this situation, and 300,000 patients are being added to this number each year.¹ Although these patients have become presbyopic, they may still prefer not to wear glasses and contact lenses. Most were treated with LASIK between 1996 and 2000. Being early adopters of LASIK, they continue to want independence from spectacles. Also, given that many of these patients are contact lens intolerant, you are left looking at surgical treatment options.



Alternatives

There are several possible surgical options, but these have disadvantages for emerging presbyopes. The options include:

- ***A multifocal or accommodating IOL.***

However, many emerging presbyopes still have some accommodation remaining. Multifocal IOLs provide a pseudaccommodation approach. Also, the cost, invasiveness and potential

drop in contrast sensitivity under scotopic lighting conditions may make these IOLs a less desirable option for a patient at this stage of presbyopia.^{2,3}

• **A hyperopic LASIK enhancement.** In many of these presbyopic patients, however, the flap has not been lifted for five or more years, so there is some increased risk of complications, such as a flap tear.⁴ Also the hyperopic treatment pattern may involve a larger optic zone than the original flap diameter.

• **PRK on top of the flap.** The difficulty here is that patients will compare the longer recovery time of PRK to the original LASIK procedure. There is also the potential for corneal haze.⁵

Favored Treatment

Conductive keratoplasty (CK) is another treatment option for early post-LASIK presbyopia correction. NearVision CK uses radio waves to reshape the cornea and bring near vision back into focus. In April 2004, the FDA approved Refractec's ViewPoint CK System to perform the NearVision CK procedure on presbyopic patients.

A Phase III multicenter FDA clinical trial is currently under way to determine the safety and effectiveness of CK at improving near vision in post-LASIK emmetropes. The study involves 150 emmetropic eyes (150 patients) that had LASIK at least one year prior to the CK procedure, peripheral pachymetry of at least 560 μ m (the current requirement for CK) and central pachymetry of more than 400 μ m. Patients will receive eight spots of treatment in an 8mm optical zone.



NearVision CK applies radio waves through a cool-tip probe to reshape the cornea.

Early results on 23 patients (mean age of 51) showed that no patients lost more than two lines of best spectacle-corrected visual acuity, and 21 out of 23 showed no change in cylinder. The two patients with cylinder had uncorrected near vision of J1+. However, studies show that what we think is refractive cylinder is sometimes simply due to induced coma.⁶

The data also show that the accuracy and efficacy of CK on post-LASIK patients is higher than the original CK approval data. Uncorrected near vision of J1 or better was achieved in 87% of the patients, and 96% achieved uncorrected near vision of J3 or better at one month.

Binocularly, 100% of patients achieved visual acuity of 20/25 or better at distance, and 91% achieved J2 or better at near. Patients who had CK in one eye only also noted no change in depth perception and no change in their distance needs. Finally, 96% of patients stated they were "satisfied" or "very satisfied" with the results.

Several factors—namely the large optical zone and the ability to perform CK over LASIK—reduce the risk of dry eye. The other advantage is that no treatment takes place in the visual axis.

The results of this early FDA trial all point to CK as the potential optimal treatment for post-LASIK presbyopic patients.⁷ Enrollment in the clinical study is ongoing, and it will be interesting to see if the results continue to match the promising early success.

Dr. Karpecki is director of research at Moyes Eye Clinic in Kansas City, Mo. He is a paid consultant to Refractec but has no financial interest in any of the products mentioned here.

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