

Improvement of Near Vision after LASIK: Early Results from the Multicenter Clinical Trial

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INTRODUCTION

Many myopes who had LASIK in earlier years to improve their distance vision are dismayed by the loss of near vision after the onset of presbyopia. However, many of these patients would not welcome a return to spectacles or contact lenses. Surgical options to correct their near vision loss would include hyperopic LASIK, a procedure that has requires a large flap and has the risks of flap complications and epithelial ingrowth. Also, dry eye post-LASIK is not infrequent and is especially undesirable in older patients who have decreased tear production.

Conductive keratoplasty (CK) is a non-ablative, radiofrequency-based treatment; this minimally-invasive treatment does not involve use of a laser. The treatment is performed using the ViewPoint[®] CK System, and is based on the delivery of a precise amount of radiofrequency energy through a probe tip inserted into the peripheral corneal stroma in a ring pattern outside of the visual axis. The peripheral application of the CK treat-

ment creates a band of circumferential tightening, resulting in a steepening of the central cornea to achieve the desired refractive effect.

In April, 2002, the United States Food and Drug Administration granted approval of the ViewPoint CK System (Refractec, Inc., Irvine, CA) for the treatment of mild to moderate (0.75 D to 3.00 D) previously untreated, spherical hyperopia in persons 40 years old or older.¹⁻³ This was followed by the approval in March 2004 of using CK to improve near vision for presbyopic hyperopes or emmetropes through induction of a mild myopia in the non-dominant eye.⁴

Other potential uses of the CK treatment that some CK surgeons have explored include treatment of over- or undercorrections following LASIK or other excimer laser procedures, and the enhancement of outcomes following cataract surgery and implantation of monofocal, multifocal, or accommodating IOLs. CK has been very well received by surgeons, and more than 125,000 CK

treatments have been performed to date. This paper will describe the early clinical trial results of CK used in patients who have undergone a LASIK procedure for the treatment of myopia in the past and now need improvement of near vision because of the onset of presbyopia.

PATIENTS AND METHODS

Patients enrolled in this FDA approval study are emmetropic presbyopes who had LASIK treatment for 1.00 to 6.00 D of myopia at least 1 year earlier. Post-LASIK, these patients must also have a manifest refractive spherical equivalent (MRSE) of +0.50 D to -0.50 D, ≤ 0.75 D of cylinder, residual central pachymetry of ≥ 400 μm , and peripheral pachymetry of ≥ 560 μm . They will all be treated with 1 ring of CK treatment (or 8 CK treatment spots) in the non-dominant eye for a 1.25 D add. A total of 150 post-LASIK presbyopic patients will be enrolled in the study and followed for 1 year.

CLINICAL STUDY RESULTS

Objective Results: One month results are available on a total of 23 patients. The mean age of this group was 51.5 years and they had a mean pre-LASIK MRSE of -3.23 D. In the CK treated eye at 1 month, 91% have uncorrected visual acuity (UCVA) at near of J2 or better and 96% have J3 or better, 78%

are at ± 0.50 D of target, and 91% have no clinically significant change in cylinder. One patient had 1.00 D, and another one had >1.00 D of induced cylinder post-CK. However, both of these patients had J1+ uncorrected near VA. Uncorrected distance VA in the treated eye was 20/40 or better in 48% and 20/63 or better in 87%. The mean refractive effect was $1.22 \text{ D} \pm 0.35$. A

total of 83% had binocular UCVA-distance of 20/20. No patient lost 2 or more lines of best spectacle corrected distance vision.

No adverse events, or LASIK flap complications occurred. A summary of key results appears in Table 1.

TABLE 1: KEY RESULTS 1 MONTH AFTER CK

	1 Month
Uncorrected Near VA	
J1 or Better	87%
J2 or Better	91%
J3 or Better	96%
Binocular Uncorrected Distance VA	
20/20 or Better	83%
20/25 or Better	100%
Predictability	
± 0.50 D of Intended	78%
± 1.00 D of Intended	96%
Induced Cylinder	
No Change	91%
1.00 D Change	4% (J1+)
> 1.00 D Change	4% (J1+)

SUBJECTIVE RESULTS

Patients rated their near vision and depth perception as good to excellent and reported little or no dependence on glasses for distance, near, and intermediate vision. Ninety-six percent (22 out of 23) of patients reported being satisfied or very satisfied with their vision post-CK. On a scale of +3 (significant improvement) to -3 (significant worsening), the patients mean score for level of visual improvement after NearVision CK was +2.7.

After the NearVision CK treatment, patients on average reported a slight decline from preoperative in their uncorrected distance vision, a marked increase in uncorrected near vision, and no change in depth perception.

CK Post-LASIK – One Month Results How do you rate your current uncorrected vision?



CK Post-LASIK – One Month Results How dependent are you on glasses for:



After the NearVision CK treatment, patients on average reported no change in their dependence on glasses for distance vision (same as preoperatively), and a marked decrease in dependence on glasses for near and intermediate vision.

After the NearVision CK treatment, 83% of the patients reported being able to read newspaper-size print, compared with 22% who reported being able to do so before the treatment. Sixty-five percent were able to read small print after NearVision CK, compared with 4% before treatment. Yet the patients still retained their distance vision, with no change from pre-CK to post-CK in ability to see street signs.

CK Post-LASIK – One Month Results What can you see without glasses?



CONCLUSION

Post LASIK presbyopic patients treated with 1 ring of CK treatment at the 8 mm optical zone showed a mean refractive effect of 1.22 D and improvement in uncorrected near and intermediate vision. An excellent safety profile was seen in those patients treated with NearVision CK who have previously had LASIK surgery: there was no significant loss of best

spectacle corrected visual acuity, no adverse events or LASIK flap complications, further supporting CK's exceptional safety profile. High subjective patient satisfaction ratings and assessment of improvement in near, intermediate and distance vision were reported by patients in the study. These interim results of this ongoing trial are encouraging. Previous studies have shown some loss of effect after the 1 month visit so the expanded

clinical trial will use a slightly smaller 7.5 mm optical zone to increase the effect. Longer term data on a larger number of patients is needed to definitively determine the safety and efficacy of NearVision CK performed on emmetropic presbyopes who have previously had a LASIK procedure.

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