Summit-Autonomous CustomCornea Laser in situ Keratomileusis Outcomes

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The U.S. Food and Drug Administration (FDA) feasibility trial includes 20 patients who underwent bilateral laser in situ keratomileusis (LASIK) and 20 patients who underwent bilateral photorefractive keratectomy (PRK). One eye was randomly selected for CustomCornea (Summit-Autonmous Technologies, Orlando, FL), and the other eye was selected for treatment with conventional LADARVision (Summit-Autonmous Technologies, Orlando, FL) surgery. Myopic, hyperopic, and astigmatic corrections have all been included. We used the negative cylinder convention throughout our study, and hyperopia means positive sphere (ie, some hyperopes have negative spherical equivalent refractions preoperatively).

The right and left eyes must agree preoperatively to within 1.00 diopter (D) in the spherical and cylindrical components, and the wavefront/phoropter must agree preoperatively. The "match" parameter must have a value of greater than or equal to 0.5 (this indicates goodness of fit).

The conventional LADARVision correction is always based on manifest phoropter refraction for myopic patients, and cycloplegic refraction for hyperopic patients. The LADARVision cylinder is corrected if it is greater than or equal to 0.50 D. The ablation zone for all eyes is 6.5 mm in diameter (wavefront data is available on greater than or equal to 7 mm in all eyes). A blend zone of 1.25 mm is utilized in all CustomCornea patients as well as LADARVision patients receiving hyperopic and/or cylindrical correction.

Of the 20 LASIK patients treated, we have greater than or equal to 1-month follow-up data on 13 patients, with 1-week data available on 7 patients. The first 3 PRK patients were treated for myopia during the week prior to the presentation of this data, therefore no data are reported here.

The initial myopic LASIK patients treated on October 12, 1999 (5 patients) had between -2.00 and -3.75 D of myopia and up to -1.25 D of cylinder preoperatively. At 1 month postoperative, the uncorrected visual acuities ranged between 20/16 and 20/25 in the CustomCornea eyes, and 20/12.5 to 20/25 in the conventional LADARVision eyes. Three of five patients saw better in their conventional LADARVision eye than they did in their CustomCornea eye. One month postoperative best corrected visual acuities improved in both eyes of two patients.

Visual acuity was always tested with a back-lit EDTRS chart in a 4 meter exam lane, with room illumination at the patient's eye set at 12 to 15 cd/m^2.

The assessment of myopia group Number 1 was that the CustomCornea eyes appeared to be slightly overcorrected. An algorithm modification was made prior to treating myopia group Number 2 to account for this.

The remaining myopic LASIK patients were treated in November 1999 and January 2000 for a total of five additional patients, treated for up to -4.00 D of myopia and -1.75 D of astigmatism. This time, all five patients saw better in their CustomCornea eye then their conventional LADARVision eye (CustomCornea uncorrected visual acuities ranged from 20/12.5 to 20/20, and the LADARVision uncorrected visual acuities ranged from 20/16 to 20/25).

Four out of five CustomCornea eyes had better best corrected visual acuity postoperatively than they had preoperatively, versus three out of five conventional LADARVision eyes at 1 month postoperative. This group of patients included one patient who had a postoperative decrease in her higher order aberrations when compared to the preoperative value (0.15 µm root mean square postoperative

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compared to 0.22 µm preoperative) in her CustomCornea eye; her conventional LADARVision eye had a near doubling of the higher order aberrations (0.25 µm root mean square postoperatively compared to 0.14 µm preoperatively). This was the first time in the U.S. that a LASIK patient received an intentional and successful decrease in higher order aberrations postoperatively when compared to preoperative values.

At one month postoperative, myopia group Number 2 was assessed to have significantly improved outcomes in the CustomCornea eyes as the result of algorithm modification that had been made, with all five CustomCornea eyes having better uncorrected visual acuity than the five conventional LADARVision eyes, and with best corrected visual acuity improved over preoperative values in four of the five CustomCornea eyes (versus three out of five conventional LADARVision eyes).

The initial three hyperopic LASIK patients were treated in December 1999 for between +2.00 and +3.00 D of hyperopia and up to -1.75 D of astigmatism. At 1 month postoperative, all three conventional LADARVision eyes had better uncorrected visual acuity than the CustomCornea eyes (though one eye had occult trauma just prior to the 1-month examination, resulting in a displaced flap with the presence of fresh blood noted at the slit lamp; visual acuity measurements were taken prior to refloating of the flap; this patient had an uncorrected visual acuity of 20/25 one month after the refloat).

The 1-month postoperative spectacle-corrected visual acuity of these three patients indicated that only one of the six eyes had better best corrected visual acuity postoperatively compared to preoperatively, and this was a conventional LADARVision eye.

The assessment of hyperopia group Number 1 was that there was a general undercorrection of the sphere in the CustomCornea eyes. It has been our conventional LADARVision surgical experience that hyperopic patients require a 50% increase in the sphere term; an algorithm adjustment had been made for the conventional LADARVision eyes but not for the CustomCornea eyes. The CustomCornea algorithm was therefore modified to include this correction prior to the treatment of hyperopia groups Number 2 and Number 3.

The remaining hyperopic patients were treated in January 2000, for a total of seven additional patients. They were treated for up to +4.25 D of hyperopia and up to -3.25 D of astigmatism. At 1 month postoperative, four of the seven patients saw better with their CustomCornea eye, versus three out of the seven who saw better with their conventional LADARVision eye. This postoperative data actually represents only 1 week of follow-up for six out of the seven patients. Postoperative best corrected visual acuity was better than preoperative for three of the seven CustomCornea eyes, as compared to one of the seven conventional LADARVision eyes.

Hyperopia groups Number 2 and Number 3 were assessed to have improved clinical outcomes for the CustomCornea eyes based on the algorithm modification, with the CustomCornea uncorrected visual acuities better than those for the conventional LADARVision eyes in four of seven cases (based on 1 week data for six of the seven patients), and best corrected visual acuity was improved over preoperative in three of seven CustomCornea eyes (versus one of seven conventional LADARVision eyes). Though encouraged, the investigators think there is still room for significant improvement.

When high order aberrations are considered for the 12 patients with 1 month data, 8 of the 12 patients (myopes and hyperopes) had smaller postoperative higher order wavefront errors in the CustomCornea eye than in the conventional LADARVision eye. One patient out of twelve (a CustomCornea myope) had smaller higher order wavefront errors after surgery than before treatment; no conventional LADARVision eyes showed this improvement.

The average higher order root mean square error for the CustomCornea eyes was 0.28 ± 0.70 µm, and was 0.35 ± 0.09 µm for the conventional LADARVision eyes. No eye lost more than 1 line of best corrected visual acuity in either group.

This staged feasibility trial has allowed us to treat patients, learn from them, and improve. Standardized testing conditions are essential to evaluate treatment efficacy, and the randomization of treatment for both eyes of each patient (ie, one eye CustomCornea, one eye conventional LADARVision) is an ideal study design. Algorithm modifications have been identified and implemented at each stage, resulting in improved visual outcomes for the CustomCornea patients (particularly for the myopes). Additional work is needed to realize the full potential of the wavefront approach.