First 100 CustomCornea Commercial Eyes

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ABSTRACT

PURPOSE: With the advent of wavefront-guided custom ablation we not only try to reach a target of 20/20 vision, but strive for improvement in what has always been most important—the quality of this vision.

METHODS AND RESULTS: Insights are presented based on clinical experience at Durrie Vision with our first 100 commercial CustomCornea eyes. We highlight key points for preparing a clinical practice for this new technology, such as staff training, marketing, and pricing. We discuss technical aspects such as patient selection and target adjustment as they relate to the Alcon LADARWave system.

CONCLUSION: In our practice we have thus far had clinical success with CustomCornea; patient acceptance has been high, and by closely monitoring our first few patients we were able to reduce the number of future enhancements. [J Refract Surg 2003;19:S687-S690]

I first became involved with refractive surgery in 1978 after finishing my residency. At that point there were only two procedures available, keratomileusis and radial keratotomy with steel blades. Over the last 25 years, amazing progress has been made. Originally, the goal was to give people with thick glasses thinner ones. In the 1980s, we tried to facilitate people passing a driver's test without their glasses, and it wasn't until the 1990s that we first started using 20/20 as our target. Now, with the advent of wavefront-guided customized ablation, some patients see better than they were able to see with their glasses and contact lenses (O'Brien TP. Refractive outcomes with wavefront ablations. Cataract & Refractive Surgery Today 2002;2:44-45.)

The introduction of wavefront-guided custom surgery is a major event for ophthalmology and refractive surgeons. Since the introduction of excimer lasers in 1998, our main focus has been on safety. We have made tremendous progress in making refractive surgery one of the safest surgical procedures performed today; advancements in surgical techniques, lasers, microkeratomes, and pharmaceuticals have made this possible. We have also addressed the issues of convenience (eg, outpatient surgery), faster recovery of vision, and continue to refine business models and pricing.

With the introduction of wavefront-guided custom ablation, we now focus on what has always been important to patients—their quality of vision. An important component is diagnostic equipment. In refractive surgery, we use not only manifest and cycloplegic refraction, but also now rely on corneal topography, pupil size, and pachymetry. With the available wavefront devices, we can now find defects in the visual system that in the past we did not know existed. Adding treatment of coma, spherical aberration, and other higher order aberrations is a natural thing for us to do, just as we added astigmatism correction to spherical myopia treatment when it became available. Clinical trials on custom ablation have occurred over the last several years; we introduced custom ablation to our patients in December of 2002. This paper presents results of approximately the first 100 eyes.

PATIENTS AND METHODS

Staff Training

As with any new technology, it is important to educate staff before introducing the new technology to patients. Physicians who are interested in this technology will be taking training courses provided by the manufacturers and should take every opportunity to use this expertise to educate themselves and their staff. In most cases, one needs to set aside at least 2 days for staff training; we have also found this knowledge base very helpful in the practice. Even though we have been using the lasers in clinical studies, hands-on education in both the aberrometer and the laser is needed and is beneficial. Visiting someone who has already efficiently
incorporated wavefront procedures into their practice can be exceedingly useful to the physician and the refractive surgery coordinator.

Pricing

One of the questions that needs to be addressed before marketing this procedure is how it will affect the pricing for refractive surgery. Since we have known custom ablation was coming for the last 2 years, 6 months before introduction, we re-established our pricing model. By doing an in-depth business analysis of our fixed and variable costs, and potential volume changes, we were able to establish a base price for non-custom treatment. In our practice, we have an Intralase, but we also have microkeratomes and offer surface ablation, so we have established a single price for these three non-custom procedures. After evaluating the capital investment, staff training, and extra time required, our practice decided to charge a premium of $500 per eye for custom ablation. Therefore, we have two pricing tiers, custom, and non-custom for those patients who do not qualify. We have found that 90% of all patients who are within the approved range and are candidates for custom ablation decide to pay the premium and we have had no resistance on pricing of the procedure.

Marketing

Once the staff is well-trained and able to handle patient questions, it is then important to use both internal and external marketing to let patients know this technology is available in your practice. We have always found seminars to be a helpful tool anytime a new technology is introduced, and this has been tremendously important with customized ablation. Taking the opportunity to educate a group of patients on the basics of wavefront diagnostics and the associated advantage works well in a seminar atmosphere. It is essential to inform patients about alternatives for treatment, potential risks, as well as advantages of wavefront-guided custom ablation. Patients who are interested in refractive surgery have certainly heard that laser treatment is available, but have usually held off because of fears of the risks or obsolescence of the procedure. Now that something new is available, we are finding these same people are quite eager to hear how it may be adaptable to their vision conditions.9 Our external marketing has focused primarily on patient education and announcement of seminars; we have found print and radio advertising to work quite well.

Patient Selection

We began with conservative patient selection. Our clinical trial experience was important, but I have always found I learn more during the first 6 months of introduction into the commercial market. In a clinical trial, a protocol is written to standardize the procedure, which is followed carefully to make sure that data are valid and can be pooled. After approval, more clinical judgement is available about what is best for an individual patient, along with some variations that become important. With the Alcon CustomCornea (Alcon, Orlando, FL) procedure, myopia is treated up to -7.00 diopters (D) and astigmatism up to 0.49 D. The FDA approval allowed a 1.00-D variation between manifest and wavefront refraction, so wavefront refractive errors up to -7.99 D and up to 1.49 D of astigmatism were acceptable for treatment. In our practice, we used laser in situ keratomileusis (LASIK), IntralASIK, and photorefractive keratectomy (PRK), and have taken a very conservative approach to retreatment.

During the first 14 weeks starting December 2002, a total of 111 eyes underwent CustomCornea treatment. This included 78 LASIK eyes, 21 PRK eyes, 6 lift-flap retreatments, and 6 PRK retreatments. Figure 1 shows the gradual increase in procedures from the first 2 weeks, when we performed only 4 eyes per week, to 18 eyes per week at the end of the series. This gradual introduction was valuable before we increased our volume. Retreatments were not attempted until the 11th week (Fig 1) to make sure that these more complicated cases were done after we had more experience.

Target Adjustment

In the past, we referenced a patient’s old spectacles, their manifest and cycloplegic refractions, keratometric power, and corneal topography to select the attempted correction. The physician had leeway.
to select the correction to be programmed into the laser, could adjust the nomogram, and consider other environmental factors. With the advent of wavefront-guided ablation, the aberrometer talks directly to the laser, and the physician’s role in deciding the treatment plan is limited. However, the physician can make spherical power adjustment, which is known as the target adjustment. This means that the surgeon has the ability to either increase or decrease sphere from the wavefront calculated focus term. In the Alcon CustomCornea system, when one inputs a plus target adjustment, it decreases attempted myopia; with a minus target adjustment, it increases attempted myopia. It is important that this target adjustment be put in the LADARVision 4000 laser prior to loading the disc from the LADARWave. This adjustment is then applied to the shot file as it is calculated. When initially approved, the target adjustment was only 0.50 D; it has since been expanded by the FDA to 0.75 D, either plus or minus.

RESULTS

After considering our results in the clinical trial as well as evaluation of other clinical data, a +0.50-D target adjustment was selected for the first 10 patients (group A in Table 1). After following these patients over the first 3 months, the average spherical equivalent refraction at 1 month after surgery was -0.29 D and at 3 months, -0.49 D. Since the +0.50-D target adjustment decreased the attempted sphere by 0.50 D, it was easy to note that in my clinic no target adjustment was required. After the first 10 patients, a 0.00-D target adjustment was introduced into the laser and at 1-month follow-up, the average spherical equivalent refraction for this second group of 68 eyes with LASIK was -0.12 D. This was also reflected in the uncorrected visual acuity for group A (first 10 patients). With the +0.50-D target adjustment, 1-month uncorrected visual acuity was 20/20 in 50% of eyes; at 3 months after custom ablation, 70% achieved 20/20. No eyes had 20/15 visual acuity at 1 month, but 20% of eyes had 20/15 visual acuity at 3 months. After changing to no target adjustment, group B eyes improved significantly at 1 month after surgery; 21% had 20/15 and 88% had 20/20 visual acuity. My experience during clinical trials has been that there should be continued improvement in uncorrected visual acuity, and I would expect that over 90% of eyes would achieve 20/20 visual acuity by the 3-month follow-up (3 month follow-up in all eyes was not available at the time of this writing).

Regarding predictability in group B (68 eyes without target adjustment, Table 2), 71% of eyes were within ±0.25 D, 87% were within ±0.50 D, and 99% were within ±0.75 D. As noted in Figure 2, all but three eyes were either ±0.25 D or slightly undercorrected. Since hyperopic custom ablation has not yet been approved, I was pleased to note that if there was a residual refractive error, it was on the slightly myopic side. Based on these early
outcomes, no adjustments have been made in the target. When surgeons begin to use custom ablation, they should do a similar evaluation in a small group of eyes, examining the results before a permanent decision on target adjustment is made (Hakim O. Customized LASIK correction. Cataract and Refractive Surgery Today 2002;2:47). However, with PRK custom ablation, because of the results in the clinical trials, a 0.50-D target adjustment should be done on all eyes with an attempted correction greater than -3.00 D.4

Patient Acceptance

Patient acceptance in our practice has been excellent. Not only have patients signed up for the procedure, those who had been waiting for the next technological advancement are excited with the promise of custom ablation. Overall, patients have been pleased with the results. We will report 3-month follow-up and wavefront data, as well as results from patient questionnaires administered before and after surgery. Experience has indicated that wavefront data at the 1-month postoperative examination usually is not as accurate due to continued wound healing.

Future Plans

Clinical trials continue in CustomCornea PRK and treatment of higher amounts of astigmatism and hyperopia are ongoing with US clinical trials. As these expanded approvals are obtained, we will introduce them to our patient population. Although many surgeons have been worried that custom ablation would not live up to its expectations, it certainly has in our practice. The two major improvements seen with custom ablation are patient comments about quality of night vision, and in group B (no target adjustment) there have been no enhancements. Refractive changes associated with wound healing will occur over time, and additional follow-up is necessary.

REFERENCES