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Monovision LASIK Wins FDA Approval

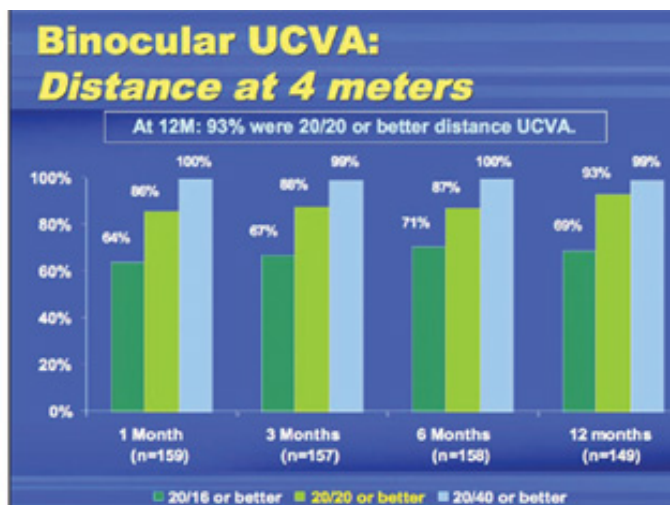
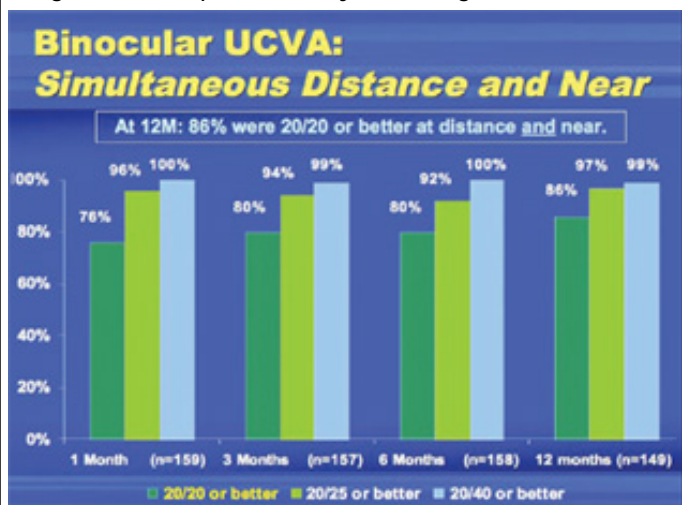
Surgeons: New AMO technology improves the procedure.

BY JERRY HELZNER, SENIOR EDITOR

The new technology used in Advanced CustomVue Monovision LASIK from Advanced Medical Optics (AMO, Santa Ana, Calif.) has greatly improved a procedure that was previously performed off-label and that had involved some less-than-precise calculations on the part of the surgeon. Surgeons who participated in the clinical trial for CustomVue Monovision interviewed for this article report that the combination of the Star S4 IR excimer laser and the complementary WaveScan Wavefront and Iris Registration technologies now enable accurate and precise vision correction for many myopic presbyopic patients with and without astigmatism.

Choosing Candidates

The procedure involves the custom correction of low-to-moderate myopia in the dominant eye and the partial correction of nearsightedness in the non-dominant eye. The approved range of correction is myopia to -6 D and up to 3 D of astigmatism for patients 40 years of age and older.



Figures 1 (left) and 2. The vast majority of the 149 patients involved in the clinical trial for Advanced CustomVue LASIK Monovision saw 20/20 or better at both near and distance after 1 year.

"Patients with otherwise healthy eyes who can report being 'very satisfied' after a 1-week trial wearing monovision contact lenses — or who have already been wearing monovision contact lenses — are excellent candidates for CustomVue Monovision," says Colman Kraff, M.D., of Kraff Eye Institute in Chicago. "We see the procedure as an excellent functional alternative to reading glasses, resulting in good vision and high patient satisfaction."

"The overall clinical trial results from 149 CustomVue Monovision patients are that after 12 months 86% see 20/20 or better at both distance and near (**Figure 1**), 93% are seeing 20/20 or better at distance (**Figure 2**), 87% see 20/20 or better

at intermediate range and 92% see 20/20 or better at near," says Mitchell Weikert, M.D., of BaylorVision in Houston.

Though the FDA approval is for a LASIK procedure, it can also be performed as either PRK or epi-LASIK depending on surgeon preference and evaluation of what is best for the patient. But the surgeons emphasize that monovision is not for every myopic presbyope and that considerable time must be spent in patient education.

"I think if the patient is highly selective in regard to his or her visual expectations, such as a competitive golfer, an engineer or someone who does a lot of night driving, then monovision may not be the best choice," says Dr. Weikert. "That's why it's important to spend a lot of time explaining the procedure and what the patient should expect from it. In our practice, the preop process involves the surgeon, the refractive coordinator and educational materials about monovision that we provide to the patient."

Dr. Weikert says that patients who are comfortable with monovision will have the visual function to participate in almost any type of activity. He prefers the CustomVue Monovision procedure to refractive lens exchange, which he says is more invasive, more expensive and involves a slight risk of retinal detachment.

Performing the Procedure

In performing the procedure, surgeons first use Iris Registration to properly align the corneas. They then perform a standard custom correction on the dominant eye, while adjusting the custom correction to preserve a small amount of myopia in the non-dominant eye. Surgeons say they perform an undercorrection of 1.25 D to 2.00 D in the non-dominant eye.

"You have to decide how much to undercorrect between 1.25 D and 2.00 D," says Dr. Weikert. "Typically, the younger the patient the less undercorrection and the older the patient, the more toward the 2 D upper end of the range." Dr. Weikert says he has successfully performed CustomVue Monovision on patients up to 60 years of age.

Both Dr. Weikert and Dr. Kraff agree that a major benefit of Advanced CustomVue Monovision over conventional monovision ablation is that CustomVue is a highly automated procedure that enables more precise correction, particularly in the non-dominant eye. The benefits also include elimination of aberrations and more accurate centration.

"Before CustomVue Monovision was approved, the procedure necessarily involved considerable guesswork in correcting the non-dominant eye," says Dr. Kraff.

"What sets wavefront-guided ablation apart from conventional monovision ablation is the clarity and accuracy of the near vision correction," says Douglas D. Koch, M.D., professor and the Allen, Mosbacher and Law Chair in Ophthalmology, Cullen Eye Institute, Baylor College of Medicine. "I feel more confident of hitting the target, whether it be -1.25 D or -1.75 D and the clarity of the near vision is so good that the need for supplemental reading glasses is reduced. I think that it will increase our use of monovision as a primary mode of correction in presbyopic patients."

In regard to pricing the procedure, all three surgeons say that despite the extra time involved in patient counseling they do not charge extra for the procedure.

"We have a premium-priced practice, so we are not charging anything additional," says Dr. Kraff. "The chair time is definitely much greater than it would be for the average 29-year-old LASIK patient and some practices might want to consider higher pricing for this procedure."

Offering Pearls

As many refractive surgeons will be shifting from performing off-label laser monovision to the new CustomVue Monovision,

Dr. Kraff and Dr. Weikert are able to offer some helpful pearls based on their extensive experience with this procedure.

"If the patient hasn't already been wearing monovision contact lenses, you may want to do the monovision contact lens trial to determine if he or she is a good candidate for this procedure," says Dr. Weikert. "Do not do a monovision trial with eyeglasses.

"Don't overshoot on the undercorrection of the non-dominant eye," he adds. "It is usually better to move more toward the 1.25 D undercorrection than toward 2.00 D."

Finally, he emphasizes the amount of preoperative education that CustomVue Monovision requires.

"You've got to spend a lot of chair time with the patient. Make sure that your refractive coordinator, and even your staff, are trained to participate in the counseling process."

Dr. Kraff emphasizes the importance of choosing myopic presbyopes who otherwise have normal, healthy eyes and who can successfully complete at least a 1-week trial in monovision contact lenses.

"In performing the procedure, the Iris Registration software can orient the eye in a cyclotorsional manner, which is very helpful in dealing with any astigmatism."

Both Dr. Kraff and Dr. Weikert are avid proponents of CustomVue Monovision, offering it to patients between 40 and 60 years of age who fit the candidate profile.

"I think when you explain the difference between CustomVue Monovision and an alternative procedure for presbyopic myopes such as refractive lens exchange, nine out of 10 patients will choose CustomVue Monovision," concludes Dr. Kraff. **OM**

Colman Kraff, M.D., Mitchell Weikert, M.D., and Douglas D. Koch, M.D., have consulting relationships with AMO/VISX and served as investigators in the clinical trial for Advanced CustomVue Monovision LASIK.

Contact Lens
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BUSINESS

Retinal
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