Refractive options
Correcting presbyopia: Monovision or corneal inlays?

by Michelle Dalton EyeWorld Contributing Writer

Surgical correction of presbyopia remains one of the “Holy Grails” of ophthalmology. Monovision—correcting 1 eye for distance and the other for near—is a fairly well understood concept. Today, the corneal inlay is fast approaching regulatory approval in the U.S., and understanding the advantages and disadvantages is integral to providing better patient outcomes, experts say. The “best way” to differentiate between the 2 approaches is to think of corneal inlays as “modified monovision” and standard monovision as just “monovision,” said Richard L. Lindstrom, MD, founder of Minnesota Eye Centers, Minneapolis.

"Whether you’re doing monovision or modified monovision with an inlay, you take the usually dominant eye and target it for distance—20/12 if you can,” he said. In standard monovision, the fellow eye is corrected for near, so the patient is likely to have “very blurry” distance vision, with some loss of binocularity and stereopsis, he said. But as long as surgeons do not correct above −2 (and preferably closer to −1.5 D) in the near eye, patients can use spectacles to regain distance vision and stereopsis. In modified monovision, good distance vision is retained in the near eye, with less loss of binocular summation for distance and stereopsis.

To date, patient satisfaction has been “pretty good” with the 2 inlays furthest along in the studies, said Jeffrey Whitman, MD, in practice at the Key-Whitman Eye Center, Dallas. Those two inlays—the KAMRA (AcuFocus, Irvine, Calif.) and the Raindrop (ReVision Optics, Lake Forest, Calif.)—have shown impressive results in the clinical studies, and are commercially available outside the U.S.

“In general, visual side effects are low and very rare,” Dr. Whitman said. “The rate of dryness, haze, and glare are very low, in accordance with making a LASIK flap. But there will be a percentage of people that don’t react well to an inlay. They’ll denote a foreign body reaction or inflammatory reaction, which usually can be treated with steroids, but there are going to be some people in whom the inlay will have to be removed.”

Method of action

Both monovision and inlays typically treat the non-dominant eye, said Vance Thompson, MD, director of refractive surgery, Vance Thompson Vision, Sioux Falls, S.D.

The KAMRA uses a pinhole effect to create a 1.6 mm pupil, while the Raindrop increases depth of focus, Dr. Whitman said.

“There is more loss of distance with the Raindrop than there is with the KAMRA, but some would argue—and the data suggests it may be true—that the near may be a little better with the Raindrop and intermediate better with KAMRA,” Dr. Lindstrom said. “The Raindrop creates a multifocal cornea so it hits far and near.”

Another inlay, the Flexivue (Presbia, Irvine, Calif.), changes the refractive index rather than the shape of the cornea, he added, but does result in about a line of distance vision lost.
One advantage to the KAMRA is it offers good intermediate vision and a continuous range of vision, but because it creates a pinhole effect, night vision is slightly reduced, Dr. Lindstrom said. Similarly, the Raindrop boasts all the advantages of multifocal lenses, "but it has the potential for all the negatives, too, including loss of quality, loss of contrast, and halos at night.”

The Raindrop is steeper in the center than in its intermediate areas, Dr. Whitman said, but patients may lose up to a line of distance vision. "They tend to regain a lot of it back over a year’s time," he said. While some complain about the KAMRA's visibility, Dr. Whitman said the 2 mm diameter, 30 μm thick Raindrop is imperceptible in a patient’s eye. Simply put, the inlays are trying to create a surgical alternative to monovision and multifocal contact lenses, Dr. Lindstrom said.

There is also the VisAbility Implant and VisAbility Implant System (VIS) from the Refocus Group (Dallas). It is made up of 4 small, clear plastic implants that are inserted below the surface of the sclera. The implants work through the vaulting of the sclera, according to the company’s website.

"This vaulting of the sclera also lifts the underlying ciliary muscles surrounding the crystalline lens,” material from the company said. "Lifting of the ciliary muscles increases the [circumventricular space], thus tightening the zonules that hold the lens in place. With proper tension on the zonules, the ciliary muscles can once again manipulate and change the shape of the lens to focus on near objects.”

Pros and cons

For John Doane, MD, FACS, in private practice at Discover Vision Centers, Kansas City, Mo., however, there are no attributes of the inlays that make him prefer them over monovision.

"A pinhole will create increased depth of focus. Certain levels of asphericity and spherical aberration can also increase the range of usable vision. With the latter 2 there can and will always be a trade-off in the quality of the image," he said. "Quality of vision and contrast sensitivity will be negatively affected. Conversely, one can maintain quality of vision by utilizing monovision or setting one eye for near focus, i.e., a -2 D residual refractive error.”

With monovision, the trade-off is that for some patients, fusion is disrupted and some brains will not tolerate this, he said. "Probably close to 30% of patients cannot accept monovision,” he said.

"For the 70% that do, best distance vision will be reduced [to] a certain degree.”

Finally, there may be scotopic, unwanted imagery so bothersome that spectacles may be necessary—thereby depleting the advantages of surgery in the first place, he said. Dr. Thompson said he rarely has a patient who wants to have the inlay removed, certainly fewer than those with monovision who want the effect reversed.

"The main reason is because inlays give not only good near and intermediate effect, but they preserve distance better. You're not dealing with such distance blur, so there's high patient satisfaction,” he said.

The "whole basis of corneal inlays is to be able to have 20/20 distance vision, but still have a reading eye,” Dr. Thompson said. "Like a multifocal implant after surgery, that gives you 20/20 distance and good near.”

Monovision in a 55-year-old often means targeting -1.5 D to -2 D, Dr. Thompson said. Inlays do not require blurring distance nearly as much as this level of monovision does. Inlays provide good binocular distance vision, as they do not interfere with distance, and "very good reading vision,” Dr. Whitman said. For him, the biggest drawback is that any of the known potential complications with making LASIK flaps exist for the inlays, as the KAMRA is placed in a pocket under a flap, and the Raindrop is placed directly under the LASIK flap.

The Flexivue comes in different powers, which Dr. Whitman thinks may be a disadvantage. "As people age, our power needs change," he said. "So what happens 5 years after the Flexivue is implanted? A lens exchange? I don’t think that’s the best platform. The KAMRA and the Raindrop do not depend on a power to work.”

Dr. Doane said the ease of removal, exchange, and repositioning are all welcome features in an inlay, but unacceptable vision or actual biologic incompatibility "may not be noticed in the first 6 months. It is important to assess biological compatibility 12–24 months after implantation,” he said.

Some patients are simply going to develop an inflammatory reaction, Dr. Whitman said. "We can try to treat that with steroids, but for some patients, inflammation will persist.” Dr. Doane said: “These products run a 24/7/365 risk of acute intervention. Corneal
surgeons need to become corneal internists—always ready with medicines to calm down the eye.” Not every patient will have such a dire reaction, “but it is a certain percentage, and every doctor will, in time, find his or her number.”

Surgeons need to remember that “the inlay is still an implant,” Dr. Thompson said. “Watch the patient for any dry eye symptoms because inlays do their best when tear film is healthy,” he said.

Even with all the potential negatives, Dr. Whitman said “there’s no comparison in terms of binocular vision improvement. It’s a dramatic leap forward versus monovision.”

Anterior segment specialists have had “the exact same argument at every meeting. What’s better: multifocal vision or monovision or modified monovision? It turns out that all 3 can work well. There isn’t a right answer. You just need to understand the differences,” Dr. Lindstrom said.

Editors’ note: Drs. Lindstrom and Thompson have financial interests with AcuFocus. Dr. Doane has no financial interests related to his comments. Dr. Whitman has financial interests with ReVision Optics.

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