

Life-Changing Advance for Iris Repair

There is no FDA-approved iris prosthesis to date.

BY BRANDON D. AYRES, MD

When I was asked recently to comment on a game-changing technology, my mind first went to fancy new technology like femtosecond lasers, three-dimensional imaging, intraoperative aberrometry, and the like. The more I thought about it, the more it appeared to me that these technologies may have advanced cataract surgery, but cataract surgery is still cataract surgery, just better. In my opinion, the single game-changing device is the iris prosthesis.



Figure 1. A patient with aniridia and aphakia prior to surgery.

IRIS REPAIR AND REPLACEMENT

Iris repair and replacement have been a passion of mine for as long as I can remember having an interest in ophthalmology. Iris repair can be a tedious surgery with mixed results. Some pupils may end up too big, too small, or misshapen. If enough of the iris has been damaged or lost, repair may not be an option at all. In cases where there is not enough iris to repair, replacement is a better option. The problem with replacement is that there is no FDA-approved iris prosthesis. With a lot of paperwork to gain FDA and investigational review board approval, compassionate use of a variety of devices may be possible, but it can be a long and frustrating process. Many of the prosthetic devices have a limited color range, making it difficult to match the contralateral iris, or the colors may look very artificial in ambient light.

During the past year, I have had the privilege of being a part of the HumanOptics Artificial Iris-001 (HO AI-001)

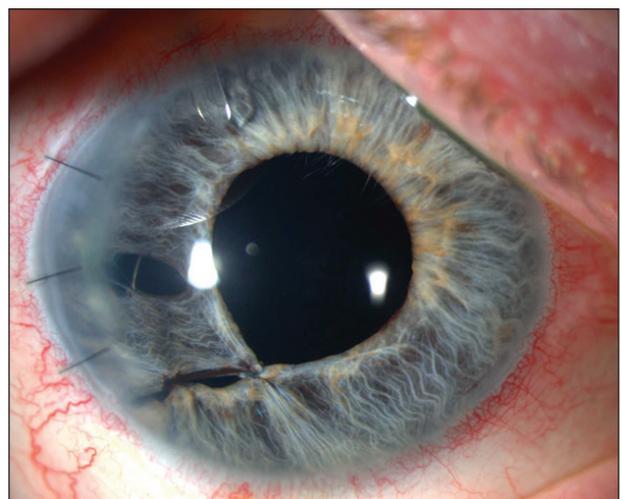


Figure 2. A patient after surgical repair of the iris and secondary sutured IOL placement.

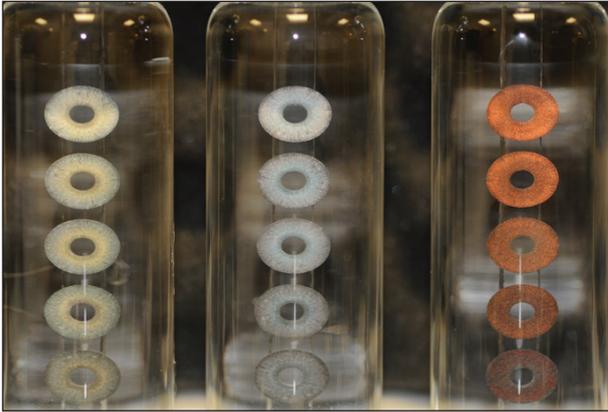


Figure 3. Morcher iris prosthesis color match system. PMMA IOLs are compared with the patient’s iris color. Once the correct color is selected, the IOL can be ordered with the correct dioptric power. This is a large (10 mm) nonfoldable IOL.



Figure 4. Postoperative appearance of a patient with a Morcher color-matched IOL. The right eye has a reflector-like quality, and the color match is poor.

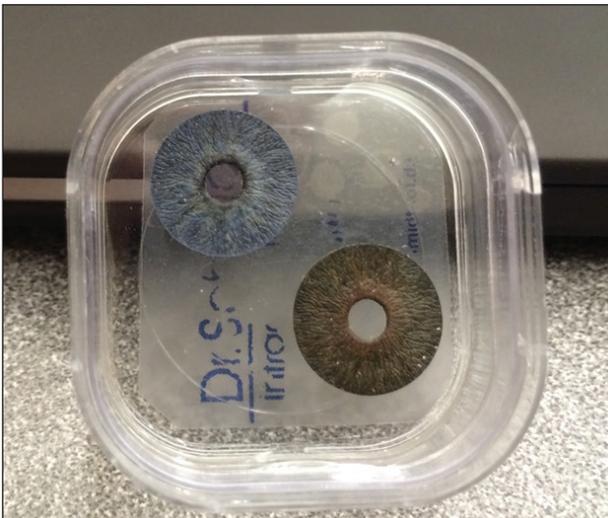


Figure 5. Dr. Schmidt HumanOptics silicone iris prosthesis. The silicone iris has the color and the texture of a natural iris.



Figure 6. A patient about 3 months after secondary IOL and iris prosthesis surgery on the right eye.

FDA trial. In this trial, we are examining the effectiveness and safety of a silicone color-matched iris prosthesis for partial and complete aniridia (Figures 1-6). The device is a silicone iris that has the look and feel of an actual iris. Pictures of the unaffected iris (sometimes there is not one in aniridia) are taken, and painstaking efforts are made to try to match the color and texture. The implant can be placed in the capsular bag or sulcus or sutured to the scleral wall. The ability to use this iris prosthesis is definitely a game changer for me.

CONCLUSION

Not only is the artificial iris a major advance for the surgeon, it is a game changer for the patient and, in some cases, even a life changer. It is not often I see

patients shed tears of joy after surgery. Their tears are not a result of their improvement in vision; they reflect that the patients finally feel whole again. They are no longer self-conscious or worried about people’s asking questions. They now have what many doctors told them they could never have: a new iris and a new outlook on life. ■

The HumanOptics CustomFlex Artificial Iris device is investigational and not yet approved by the FDA.

Brandon D. Ayres, MD, is a surgeon in the Cornea Service at Wills Eye Hospital in Philadelphia. He was a clinical investigator in the HO AI-001 FDA trial. Dr. Ayres may be reached at (484) 434-2700; bayres@willseye.org.

