

# Customized Iris Prosthesis

Experience shows success with placing the device in the bag.

BY CONNI BERGMANN KOURY, EXECUTIVE EDITOR

Iris defects can be related to any number of congenital, traumatic, and pathologic causes. Often, the resulting constellation of symptoms associated with the condition includes glare, halos, arcs, photophobia, monocular multiple images, and reduced contrast sensitivity, according to Michael E. Snyder, MD, a member of the board of directors at Cincinnati Eye Institute and volunteer faculty at the University of Cincinnati. Although the magnitude and extent of symptoms vary from patient to patient, some individuals can be profoundly disabled. The management of high-risk iris defects depends on the origin, extent, and underlying pathophysiology. Dr. Snyder said some can be managed by suture repair, but when that is not possible or proves inadequate, iris prosthetic devices can be very useful. Different types of iris prostheses have been used, and each has its own appearance, design, outer diameter, and pseudopupillary aperture.



3.35 mm and is made with an outer diameter of 12.8 mm, which can be trephinated to the desired size.

During their first “in-the-bag” case, the surgeons learned that, even with a good red reflex, the capsulorhexis is very hard to see once the device is in the eye. Thereafter, they stained anterior capsules with trypan blue or, in congenital aniridia, with indocyanine green, because trypan blue reduces the elasticity of these already fragile capsules. An approximately 6-mm continuous curvilinear capsulorhexis is preferable. In some cases, Dr. Snyder said they re-stained the capsule after phacoemulsification if the original stain appeared to have faded. In the majority of cases they have performed, they placed a capsular tension ring (CTR), a capsular tension segment, a modified scleral suture, a Cionni CTR (Morcher, distributed in the United States by FCI Ophthalmics), or a combination thereof.

When implanting the device, Dr. Snyder and his colleagues have recently begun using an intraocular ruler to estimate the capsular bag’s size. They then manually trephinate the prosthesis against a flat block. Next, they fold the device in a trifold fashion with the colored side outward. In early cases, Dr. Snyder’s team implanted the prosthesis using forceps. Later, they placed the device in an injector cartridge with the pupillary aperture facing upward. The injector is then inserted through the 2.75-mm limbal wound. Next, they unfold the superior and inferior leaflets using one or

## THE SURGERY

Dr. Snyder and his colleagues at Cincinnati Eye Institute have experience using an investigational implant (HumanOptics) under the FDA’s compassionate use device exemption.<sup>1</sup> The investigational device has a pseudopupil of



Figure 1. The capsular margin can be seen overlying the device.

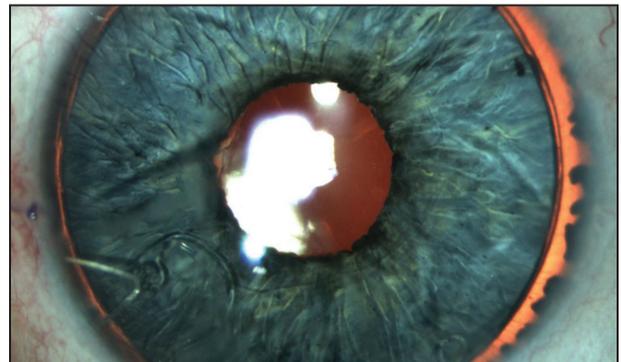


Figure 2. Customized iris device fully unfolded in the capsular bag with a Cionni CTR in place.

## IRIS PROSTHESIS CLINICAL TRIAL

The customized flexible iris device is the subject of an FDA investigational device exemption trial. Trial information is accessible at <http://clinicaltrials.gov/show/NCT01860612>. Michael E. Snyder, MD, is the medical monitor, and the contact person is Barbara Fant ([513] 961-8200; [bsfant@ccrregulatory.com](mailto:bsfant@ccrregulatory.com)).

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two Kuglen hooks, while taking care not to decenter the IOL (Figure 1).

Dr. Snyder said that passing a 9- or 10-mm device through a 6-mm capsulorhexis can be challenging. A few millimeters of the device will be under the nasal capsulorhexis margin in the bag (fornix), yet a few millimeters will remain overlying the proximal margin of the capsulorhexis. He and his colleagues use a 23- or 25-gauge microforceps placed transcamerally from a nasal paracentesis to grab the temporal pseudopupillary margin and to fold the temporal aspect of the iris device over itself. By thus reducing its outer diameter, the surgeon can tuck the device underneath the temporal capsulorhexis margin more easily. Such an overfolding maneuver will reduce the device's outer diameter, aiding placement of the trailing component as well. Greater degrees of overfolding further reduce the functional outer perimeter, according to Dr. Snyder, and the device can be placed through a smaller capsulorhexis margin, as in a case with a sutured CTR. Sometimes, other folds will spontaneously occur during the insertion process, he noted.

Any approach that reduces the perimeter will suffice to place the iris prosthesis into the bag, the team has found. They then unfold the device fully within the bag (Figure 2). In cases where the outer margin of the prosthesis entrapped

the IOL's haptic or CTR's eyelet, the surgeon gently lifts the periphery of the iris device to release the haptic to fall behind the pseudoiris diaphragm.

## CONCLUSION

In-the-bag placement permits excellent centration of a customized flexible iris device, maintains a small incision, and allows sequestration of the device within the capsular bag, Dr. Snyder said. Similar to the team's clinical experiences with IOLs, the iris device has been well tolerated in the ciliary sulcus in a large cohort of patients. Dr. Snyder said they still prefer to avoid any device-tissue contact whenever possible. A centered bag, when intact, provides the best mechanism for centering the iris device, leading to excellent functional and cosmetic results. ■

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1. Snyder M. Custom iris prostheses—it's in the bag! Presented at: The 2013 ASCRS/ASOA Annual Symposium & Congress; April 19-23, 2013; San Francisco, CA.