PEARL: A Novel Presbyopic Inlay

A NOVEL TREATMENT FOR PRESBYOPIA improves binocular uncorrected near visual acuity without seriously compromising distance acuity. Called PrEsbyopic Allogenic Refractive Lenticule (PEARL), the technique was developed by Soosan Jacob, MS, FRCS, DNB. She is director and chief of Dr. Agarwal’s Refractive and Cornea Foundation, at Dr. Agarwal’s Group of Eye Hospitals in Chennai, India, where about 20 PEARL procedures have been performed.

How it works. PEARL functions as a shape-changing corneal inlay, but it makes use of a lenticule of human corneal tissue rather than artificial material. The tissue is obtained from a patient undergoing a small incision lenticule extraction (SMILE) refractive procedure for correction of −2.5 to −3.5 D of myopia, and the lenticule is implanted in the recipient’s cornea. The PEARL procedure improves depth of focus by increasing the central radius of curvature and creating an area of hyperprolateness on the cornea, surrounded by normal topography.

PEARL. (A, B) Postop view of a PEARL lenticule; (C) Orbscan showing central area of prolateness; (D) anterior segment OCT showing the lenticule.

PEARLS for performing PEARL. “The ideal candidate for PEARL is a plano presbyope— with 20/20 uncorrected distance visual acuity—who is about 42 or 43 years old and unable to read small print (N6) on the near vision chart,” said Dr. Jacob.

The procedure involves using a femtosecond laser–dissected refractive lenticule with a diameter of 1 to 2 mm. “Over the central pupillary area of the nondominant eye, we then create a femtosecond intrastromal pocket into which we implant and center the PEARL lenticule under an inked mark,” said Dr. Jacob. “It’s important to center the lenticule on the coaxially sighted light reflex—which is the first Purkinje reflex, seen as the patient fixates coaxially.”

Benefits of PEARL. “The ease of lenticule implantation is a big plus,” said Dr. Jacob. And unlike corneal implants of synthetic materials, the lenticule is biocompatible, which allows passage of oxygen and nutrients through the cornea, prevents inflammation, and decreases the risk of corneal necrosis and melt.

A benefit of the inlay’s small size is that it allows peripheral rays to pass through the pupil. This preserves good uncorrected distance visual acuity with no loss of lines in the operated eye, while allowing the patient to perform near visual tasks.

Potential challenges and complications. Manual cutting and obtaining suitably sized lenticules are challenges of the procedure, said Dr. Jacob. “However, involving eye banks and automating steps should help overcome these problems.” Although intraoper-
ative difficulties can include incorrect centration or trouble with implantation, she said that the procedure has been completed with ease in all cases at her center.

Because PEARL makes use of donor corneal tissue, there is potential risk of stromal rejection. However, this has not been seen in any patient thus far.

To prevent postoperative problems, patients are kept on low-dose steroids and tear supplements for 3 to 4 months, said Dr. Jacob. “With experience, it is possible that this regimen will be modified.”

Propects for the future. Although initial results are encouraging, said Dr. Jacob, they need to be validated with a larger study and long-term follow-up.

“With automated production, widespread adoption is possible,” she said, “giving this the potential to become a game changer. And, in the future, PEARL could possibly be combined with LASIK or SMILE for correction of any refractive error as well as be implanted in pseudophakic patients.”

—Annie Stuart

Relevant financial disclosures—Dr. Jacob: None.

RETI NA disclosures—Dr. Jacob: None.

Assessing NPDR With OCT Angiography

Unlike conventional fluorescein angiography (FA), which mainly provides information about retinal circulation, a noninvasive, 3-D alternative is able to delineate the extent of capillary dysfunction in both superficial and deep vascular plexuses in nonproliferative diabetic retinopathy (NPDR), said K.V. Chalam, MD, PhD. He added that this technique, called split-spectrum amplitude-decorrelation angiography (SSADA)–assisted OCT angiography (OCT-A), uses a specialized processing algorithm to provide information about blood flow at 3 depths: superficial capillary, deep capillary, and choroidal.

Technical progress. Developed a few years ago at the Casey Eye Institute of Oregon Health & Science University, in Portland, SSADA-assisted OCT-A is based on detecting reflectance amplitude variation of blood flow over time. By decreasing the signal-to-noise ratio of flow detection, it enhances visualization of retinal vasculature using motion contrast. “Rather than using dye to highlight movement and create a 2-D image, it captures frame after frame, enhancing the moving particles in an image while suppressing the static particles,” said Dr. Chalam, at the University of Florida in Jacksonville.

Early use of OCT for angiography was clinically impractical, he said, because it required multiple and repeated scans at each location to build the angiogram. But the new algorithm speeds the process because only 2 scans are needed at each location to produce a high-quality angiogram.

Results with NPDR. For the study being presented at AAO 2016, OCT-A was obtained in 128 eyes of patients with NPDR using SSADA software to determine indices for 3 levels of flow in the perifoveal area. Compared with age-matched controls, patients with NPDR had severe compromise of the deep capillary macular vascular flow. Specifically, the mean deep perifoveal vessel density in NPDR was 13 ± 4.71% versus 48 ± 11.01% in controls. In addition, the mean macular deep vascular flow rate in NPDR was 0.009 versus 0.055 in controls.

Clinical use. “Because this technique allows you to see movement at different depths, it can detect diabetic changes sooner than with a typical angiogram,” said Dr. Chalam. “Being able to measure the amount and density of blood flow helps quantify changes within a particular radius, he said, with the level of compromise proportional to the degree of diabetic retinopathy. “Because of its ease and speed of use,” said Dr. Chalam, “this technology may be used more frequently, helping to identify the degree of damage in newly diagnosed patients and helping to monitor a patient’s disease progression—something that can’t be done using other technology.” On the downside, he said, it cannot evaluate vascular permeability, as can be done with a traditional angiogram.

Currently, Optovue’s Avanti with SSADA software is the only such system approved by the FDA; a similar system by Topcon is being investigated. Although the technology is not currently in widespread use, Dr. Chalam foresees its clinical utility for a range of other problems such as macular degeneration and vascular occlusion. —Annie Stuart

OCT ANGIOGRAPHY. (A, B) Mild NPDR. Vessel densities (VDs) in parafoveal and perifoveal areas, respectively, were 33% and 42% in superficial plexus (A) and 20% and 29% in deep plexus (B). (C, D) Severe NPDR. VDs were 18% and 21% in superficial plexus (C) and 7% and 9% in deep plexus (D) for the respective areas.

Related financial disclosures—Dr. Chalam: None.

OCT Angiography Reveals Severe Attenuation of Deep Capillary Macular Vascular Flow Index in Nonproliferative Diabetic Retinopathy. When: Sunday, Oct. 16, 3:00-3:07 p.m., during the first retina, vitreous original papers session (2:00-5:30 p.m.). Where: S405. Access: Free.
CATARACT PAPER

Reducing Waste in Cataract Surgery

BEING “GREEN” IN THE OR DOES NOT go hand-in-hand with poor outcomes. A recent comparison of materials, waste, and costs associated with phacoemulsification between India and the United States found that while cost and the carbon footprint differed dramatically, patient outcomes were similar.

**Striking differences in waste and carbon footprints.** Aravind Eye Hospital in India generated an average of 0.25 kg of waste per phacoemulsification procedure, two-thirds of which is recycled. In contrast, the 3 participating U.S. medical centers generated 2.3 to 3.9 kg of waste per case, all of it landfill or biohazardous material.

The study, conducted by Cassandra Thiel, PhD, assistant professor at New York University School of Medicine, uncovered other disparities as well. The cost of single-use surgical supplies was $380 per surgery in the United States, versus $7 in India. Moreover, the carbon footprint of surgery at Aravind was about 5% that of the same procedure in the U.S. institutions studied.

Although Dr. Thiel expected to find differences between the countries, the range of costs and materials used between U.S. locations (and even within the same health system) surprised her, “considering phaco is a fairly standardized procedure.”

**Emphasis on reuse.** The Aravind system minimizes single-use items: In contrast to U.S. practice, all gowns and drapes for cataract surgery are made of reusable materials, except for 1 disposable face drape. Most surgical instruments are also reusable, and pharmaceutical products are multiuse.

**Recommendations for physicians.** Dr. Thiel offers the following advice to physicians who want to reduce waste:
- Tell your surgical team that you want to minimize waste.
- Before opening surgical packs or supplies, confirm that the item is necessary.
- Ask your facility to switch to reusable instruments and supplies where appropriate.
- Encourage proper waste sorting or recycling and instrument reprocessing.
- Check out Health Care Without Harm (https://noharm.org) and/or Practice Greenhealth (https://practicegreenhealth.org) for more ideas.

Many factors contribute to the disparity between India and the United States, with litigious and regulatory issues topping the list, said Dr. Thiel. Although there is a justified concern about infection in the OR, she said, “Aravind demonstrates that properly treated reusable materials can be just as effective as disposable materials and far more frugal.” —Miriam Karmel

**Comparison of Cataract Surgical Wastes and Their Associated Costs in Both the United States and India.**

**OR IN INDIA.** In the Aravind Eye Hospital OR, the surgical gowns and drapes for cataract surgery are reusable, except for a single disposable face drape.

**GLAUCOMA PAPER**

MIGS Options Increase With FDA Approval of CyPass

**IN LATE JULY 2016, FOLLOWING release of results from the 2-year COMPASS trial,1 the FDA approved the CyPass Micro-Stent (Alcon). This minimally invasive glaucoma surgery (MIGS) device is designed to reduce intraocular pressure (IOP) in patients with mild to moderate glaucoma who are undergoing cataract surgery. It is placed through the phaco incision into the supraciliary space.

**Now there are 2.** Another MIGS device, the iStent (Glaukos), which is placed in the trabecular meshwork, was approved 4 years ago for the same indication. Although use of the iStent is increasing rapidly, it is being implanted in only a fraction of eligible patients, said Reay H. Brown, MD, a COMPASS investigator. He predicted that approval of CyPass should increase awareness among surgeons that MIGS devices are safe and effective, which may, in turn, lead to an increase in the number of MIGS implantations, he said.

**Trial results.** The multicenter COMPASS trial included 505 primary...
open-angle glaucoma patients who qualified for cataract surgery. Of those, 374 were randomized to receive phacoemulsification plus a microstent, while 131 controls underwent phaco only.

“CyPass patients achieved a reduction in IOP that was greater than in patients who had cataract surgery alone,” said Dr. Brown. “The COMPASS trial had 2 years of follow-up, and the IOP-lowering effect persisted for the full 2 years.”

The primary efficacy outcome measure was the proportion of eyes with unmedicated diurnal IOP reduction of 20% or more at 24 months after surgery compared with their unmedicated baseline IOP.

Baseline mean IOP was similar in the microstent and control groups: 24.4 mm Hg and 24.5 mm Hg, respectively. But mean IOP reduction was more robust in the stent group than in controls: 7.4 mm Hg versus 5.4 mm Hg, respectively. And a greater percentage of the stent group (72.5%) achieved IOP reduction of 20% or more compared with controls (58.0%).

Microstenting also reduced long-term glaucoma medication use to one-third of that required by control subjects, with a mean decrease of 1.2 medications at 24 months. At that point, 85% of microstent patients were medication free, versus 59% of controls.

**Looking ahead.** Dr. Brown said that CyPass approval should spur the market for MIGS devices. “There will definitely be competition between the iStent and CyPass, but both seem to be safe and effective.” —Miriam Karmel


Relevant financial disclosures: Dr. Brown—Alcon: C; Allergan: C; Glauskos: P; Rhein: P; Transcend: S.

---

Minimally Invasive Supraciliary Microstent for IOP Control in Combined Primary Open-Angle Glaucoma–Cataract Surgery: Two-Year COMPASS Randomized Controlled Trial Results. When: Monday, Oct. 17, 3:52-3:59 p.m., during the glaucoma original papers session (2:00-5:15 p.m.). Where: S405. Access: Free.