

Innovations in AMD Management

FROM THE EDITORS OF *RETINA TODAY*

Age-related macular degeneration (AMD) is noted to be the third leading cause of blindness worldwide behind cataract and glaucoma, and the top cause of blindness in industrialized nations.¹ Due to changing demographics in the United States, namely the aging baby boomer generation and an increase in the number of individuals living to older ages, there is every indication that the disease burden of age-related diseases, including AMD, will increase.

Where there is need, there is often innovation. The advent of anti-VEGF therapy and the introduction of optical coherence tomography have revolutionized the management of patients with AMD, but several gaps still exist. Below, we highlight a sampling of innovations—from the simple to the sophisticated—that may shape how patients with AMD are managed. Some are approved for use outside the United States, others may find their way into clinics tomorrow, and others are still in development. The common thread among these devices is that they offer a promise to improve the ability to help save patients' vision.

INTRAOCULAR INJECTION GUIDE

Vikas R. Maturi and Raj K. Maturi, MD, of Indianapolis, Indiana, have designed a single-use injection guide that allows physicians to administer drugs into the vitreous space efficiently and without the use of a speculum. The device is 35 mm long with tapered edges to help users grab the device. It is designed to align with the curvature of the cornea to ensure that needle entry takes place 3.5 to 4.5 mm from the limbus, which is “the optimal distance for injection,” according to Dr. Mutari. The lumen is constructed so that clinicians may use a variety of needle and syringe combinations with this device, thus avoiding the need to change guides for different medications.

There are several design considerations that make the device friendly for use in the clinic. The 2 × 2 mm opening at the bottom of the device allows for localized application of anesthetic and antiseptic (Figure 1), and the long, tubular construction directs the needle perpendicular to the eye,

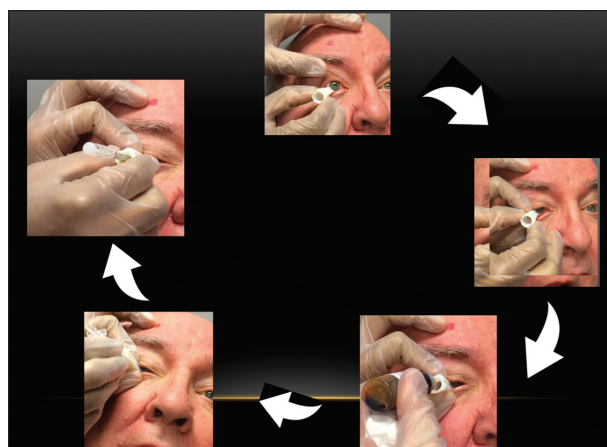


Figure 1. The injection guide is placed directly onto an anesthetized conjunctiva (top) and the medial curve of the device aligns along the limbus. Antiseptic is placed in the well, after which the needle containing the drug is introduced. After the injection, the syringe and device are withdrawn.

facilitating accurate delivery of medication (Figure 2). The bottom surface of the guide follows the curvature of the eye to deter eyelids from sliding under. The eyelids are instead directed over a flange, where they surround the device and allow for the maintenance of needle sterility.

VISION AIDS

Implantable Magnification Technology

Several devices have been proposed to restore the visual potential of patients with AMD. The concept was first introduced in the form of implantable telescopes in the mid-1990s,^{2,3} but applicability remained limited due to inherent compromises in visual function. In 2007, Orzalesi and authors described the first applications of implanted intraocular lenses designed to magnify images.⁴ Although it results in fewer visual compromises, the Intraocular Lens for Visually Impaired People (IOL VIP, distributed in the United Kingdom by Veni Vidi) does necessitate an 8.0-mm incision to implant the dual, nonfoldable lenses. In a more recent

iteration of the technology called the IOL VIP Revolution, both implants are placed in the capsular bag separated by a silicone ring. However, the surgery requires an 8.00-mm incision and capsulorhexis and it may be technically challenging to align the dual lenses while manipulating the silicone ring.

The Implantable Miniature Telescope (CentraSight) was recently introduced in the United States and elsewhere. It is a large device that protrudes through the cornea but offers between 2.2 and 2.7 $\times$ magnification as a unioocular implant. It has been greeted with some acclaim, as it is the first device to address an unmet need in delivering functional vision to patients going blind due to AMD. However, because it requires a tremendous visual compromise in the implanted eye, and the required complicated surgery, the device is limited to patients with end-stage disease.

Bobby Qureshi BSc, MBBS, FRCS (Ophth), a consultant ophthalmic surgeon and medical director at London Eye Hospital, has invented a device that he believes solves many of these issues associated with implants for patients with AMD. The iolAMD is a dual lens system, with 1 lens implanted to the sulcus and the other to the capsular bag to create a Galilean effect. The plate haptic design is inserted through a 3.00-mm incision and requires a 5.0-mm capsulorhexis. The current model offers about 1.3 $\times$ magnification with about 3° of prism to offset the image away from areas of pathology. Patients are selected via a lens simulator prior to surgery designed to test feasibility. "We have something that can be performed by any cataract surgeon, adding about a minute to a standard cataract surgery," Mr. Qureshi said in an interview with *Retina Today*.

The device has so far been implanted in about 100 patients with early and advanced AMD with about 4 months of follow up on 18 eyes of 12 patients. Overall, 67% of patients had gains in mean distance BCVA and 50% improved in near BCVA; side effects have been minimal (ie, no significant change in intraocular pressure and only a small, nonsignificant reduction in endothelial cell counts).⁵ According to Mr. Qureshi, important criteria for patient selection are phakic status with a minimal cataract and refraction of $\pm$ 4.00 D with less than 3.00 D of astigmatism. Patients who should be excluded include those who are pseudophakic or aphakic, or have advanced glaucoma, zonular instability, or pigment dispersion.

Retinal Prosthetics Study for Patients With AMD

At the Euretina 2014 meeting in London, Second Sight Medical Products, Inc., announced it is initiating a study of the Argus II retinal prosthetic in patients with dry AMD. The study, to be conducted at the Manchester Royal Eye Hospital, will enroll patients with complete central vision loss. The study is set to begin in November 2014, although the company did not specify when data might be available.

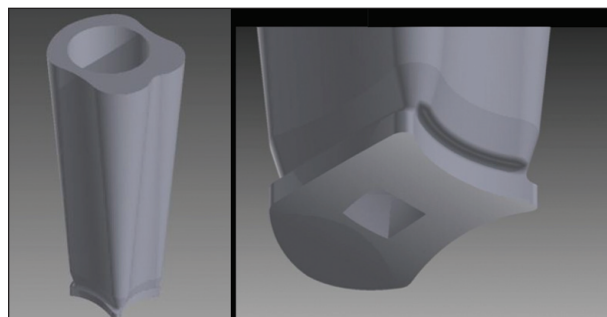


Figure 2. The long, tubular construction ensures the needle is being directed perpendicular to the globe and at the right distance from the limbus.

The Argus II was approved under a CE mark in 2011 in Europe and by the US Food and Drug Administration in 2013 for use in patients with retinitis pigmentosa.

DIAGNOSTICS

There has been much interest in earlier detection of AMD to give clinicians an opportunity to intervene sooner and affect better outcomes. Several studies have reported findings in the peripheral retina using ultra-widefield imaging that may indicate distinct AMD phenotypes, be an early index of the disease, and/or serve as biomarkers for disease progression. There are still issues to resolve before imaging the peripheral retina becomes regular clinical practice (see "Widefield Imaging in AMD: Unanswered Questions and Untapped Potential" in the May/June 2014 issue of *Retina Today*), yet ultra-widefield imaging remains a hot topic of research due to all the potential promise it holds.

Another potential approach to the early detection of AMD is testing patient's ability to adapt to low light conditions. Studies suggest that poor dark adaptation may be a harbinger of early, subclinical pathologic changes.⁶ MacuLogix has developed a testing protocol on its AdaptDx platform that the company says functions much like a perimetry device in that it tests patients' responses to visual stimuli on a handheld device. The device is not currently approved by the US Food and Drug Administration as a diagnostic device, although it is currently being used as a clinical endpoint in several drug treatment trials. ■

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