

# CLINICAL UPDATE

## Protecting Vision During Radiation Treatment

Researchers at UCLA's Jules Stein Eye Institute (JSEI) have discovered that silicone oil, a substance commonly used in retinal surgery, may protect ocular melanoma patients from a side effect of radiation treatment, vision loss.

Ocular melanoma, which forms in the pigmented layers of the choroid under the retina, is the most common eye cancer in adults, with approximately 2,000 new diagnoses each year, according to the National Eye Institute. It is treated by stitching a gold plaque containing radioactive seeds to the white of the eye and removing it a few days later. While effective at killing cancer cells, radiation may harm the optic nerve and central vision, or macula, of the eye, leading to vision loss.

"We have known for years that radiation works very well — it kills the tumor in the eye, and if the tumor is small enough we are able to save the eye," says Tara A. McCannel, M.D., Ph.D., assistant professor of ophthalmology and

director of JSEI's UCLA Ophthalmic Oncology Center. "Unfortunately, though, there may be extraneous radiation that affects the healthy tissues of the eye, and if the tumor is close to the central vision or the macula, there is a higher risk for deterioration of vision beginning anywhere from six months to several years after the treatment."

Various approaches have been attempted to stave off the vision loss, from laser surgery to drug injections into the eye, but long-term effectiveness is disappointing, says Dr. McCannel. She has taken a different tact, applying silicone oil as a protective shield at the time the tumor is treated. Dr. McCannel removes the vitreous gel inside the eye, then replaces the gel with the silicone oil. After removing the radiation plaque from the treated eye, Dr. McCannel removes the oil, replacing it with fluid that is eventually replaced by the patient's aqueous fluid.

*continued on back cover*



▲ Dr. Tara McCannel, director of the UCLA Ophthalmic Oncology Center, applies silicone oil as a protective shield to stave off vision loss that may result from radiation treatment.

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### In This Issue

Radiation Treatment	Cover
Custom Artificial Iris	Cover
Corneal Transplant	p. 2

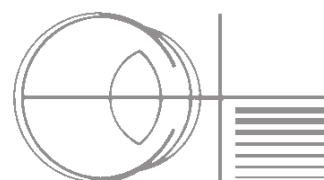
## Clinical Trial Launched for First Custom Artificial Iris

The Jules Stein Eye Institute (JSEI) is enrolling patients for a clinical trial of the first custom-made artificial iris. The multi-center trial is being headed at UCLA by Kevin M. Miller, M.D., professor of clinical ophthalmology at JSEI who was the second surgeon in the United States to implant the device, created by the Germany-based company HumanOptics

AG. Dr. Miller has implanted the device in several patients under a "compassionate use" exemption from the Food and Drug Administration (FDA).

Unlike previous iris implants, which were flat in color and mask-like, the custom implant creates a rollable and foldable

*continued on page 3*



JULES STEIN EYE INSTITUTE

# Milestone Artificial Corneal Transplant Performed

Corneal transplantation — replacing a patient's damaged cornea with donor corneal tissue — is an increasingly common and successful procedure, with more than 40,000 procedures performed in the United States each year. But many ophthalmologists are unaware of a similarly steep recent increase in the number of artificial corneal transplants — a boon for patients who can't benefit from donor tissue.

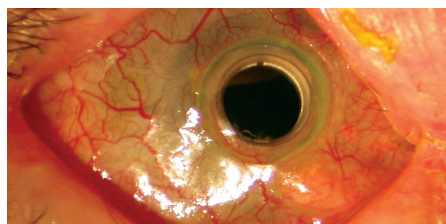
“The artificial cornea has gone from being considered experimental when I did my first one more than six years ago to being an accepted treatment modality for a variety of indications,



Dr. Anthony Aldave demonstrates the assembly of the Boston keratoprosthesis during a surgical training course in Mumbai, India.

◀ Fifty-eight-year-old man with a history of a severe alkali burn to each eye, limiting his vision to light perception in each eye (left).

Four years after the performance of a Boston type I keratoprosthesis implantation, cataract extraction and Ahmed tube shunt implantation in his right eye, the patient maintains 20/50 uncorrected visual acuity (right).



based on the results published by those of us who have been performing this surgery,” says Anthony J. Aldave, M.D., associate professor of ophthalmology at UCLA's Jules Stein Eye Institute (JSEI). “Surgeons are finding that for patients who previously had no hope of seeing after experiencing repeat corneal transplant failure, they now have a viable alternative for reestablishing vision for a meaningful period of time.”

The Boston type I keratoprosthesis (artificial corneal transplant) was first approved for use in the United States by the Food and Drug Administration in 1992, but it was performed only sparingly over the next 10 years. In 2002, there were fewer than 100 of the Boston type I keratoprosthesis procedures performed worldwide. That number has grown significantly each year, and is expected to exceed 1,200 in 2010.

Two developments in the last decade have significantly improved outcomes and led to the

growing popularity of the procedure, Dr. Aldave explains. The first was modifications in the design of the device — specifically, the placement of holes in the back plate of the keratoprosthesis to address the unacceptably high rate of melting of the donor cornea by enabling the fluid inside of the eye (aqueous humor) to gain access to and provide nourishment to the donor cornea. That development was followed by improved medical therapy after the surgery: the use of vancomycin and the advent of newer antibiotics, both of which have dramatically reduced the rate of bacterial infections.

Dr. Aldave recently reached a milestone when he performed his 100th artificial corneal transplant; he believes that only two other surgeons in the world have performed as many. His results have been dramatic: Prior to the surgery, 92 percent of the patients had vision of counting-fingers or worse. One year after surgery, 63 percent of patients have vision between 20/20 and 20/100, and that percentage has remained steady at three-

year follow-up and beyond. “These are patients who had previously been told there was nothing that could be done for them,” Dr. Aldave notes.

In an effort to bring the artificial corneal transplant's advantages — which include elimination of the risk of corneal transplant rejection and the need for healthy donor corneal tissue — to more patients, Dr. Aldave has trained many other surgeons in the United States and throughout the world to perform the procedure. In 2008 he founded a nonprofit foundation, Visionaries International ([www.visionaries-international.org](http://www.visionaries-international.org)), whose aim is to train surgeons around the world to perform the most advanced forms of corneal transplant surgery, including artificial corneal transplantation. In 2010, Dr. Aldave traveled to India, Saudi Arabia, Indonesia, the Philippines and Russia, lecturing

*continued on page 3*



and operating with local corneal surgeons to enable them to develop their own programs.

Although ophthalmologists have typically viewed the artificial corneal transplant as a last resort to be offered only after repeated failures of donor corneal transplants, Dr. Aldave says indications are expanding. “Traditionally this was for patients who had two or more failed corneal transplants and those who had poor vision in both eyes,” he explains. “Now, more

than half of the patients for whom I perform this procedure have never had a corneal transplant or only had one previously. For patients with multiple risk factors for corneal transplant failure, many surgeons are looking to an artificial corneal transplant sooner.”

Among the patients in this group are those with corneal limbal stem cell failure, who benefit from the fact that artificial corneal transplant recipients don’t require immune-suppression

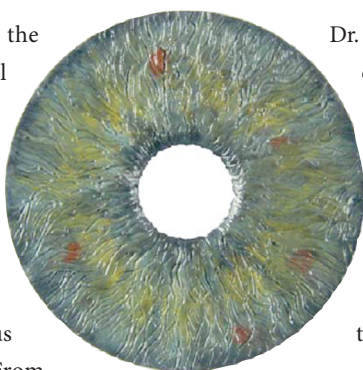
therapy, unlike recipients of donor limbal stem cell transplants. In addition, Dr. Aldave and colleagues at JSEI have recently published a paper showing that even in patients with good vision in their other eye, an artificial cornea is beneficial because more than 90 percent of such patients regain the ability of their eyes to work together.



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### *Clinical Trial Launched for First Custom Artificial Iris continued from cover*

silicone device that matches the color of the patient’s normal eye by taking a high-quality photograph of that eye and sending it to the manufacturer to fabricate a match. “From a cosmetic perspective, this looks much less artificial than the previous devices,” says Dr. Miller. “From conversational distance, it’s difficult to tell which is the normal eye.”



Dr. Miller explains. In the absence of clinical trials, and with none of the devices having been approved by the FDA, ophthalmologists wishing to implant the devices had to obtain compassionate-use exemptions — a costly and time-consuming process.

But beyond the cosmetic improvements, the artificial iris implant addresses a major quality-of-life issue for patients with congenital or acquired aniridia by giving them a functional pupil. “For people lacking iris tissue, light tends to stream into the eye, and these patients have a lot of light and glare sensitivity, as well as not being able to see as well,” Dr. Miller says. “They might be willing to accept the poor-quality vision but it’s hard to ignore the bright sunlight pouring in.” Although the custom implant doesn’t open and close like a natural iris, it limits the light coming into the eye, he explains.

The first artificial iris implant was introduced in the 1980s by Morcher GmbH, specifically for patients with a cataract and an intact capsule. Since then, other devices have been manufactured. But because aniridia is a rare condition — affecting fewer than 4,000 new patients per year in the United States — there has been little money invested in research and product development,

In an effort to bring artificial iris implants to more patients, Dr. Miller in 2002 worked with Morcher and the FDA and organized the first U.S. clinical trial of Morcher’s black implants, which are placed within the capsular bag. The same year, he began working with a Dutch company, Ophtec BV, to study colored iris reconstruction lenses. Both clinical trials are ongoing; between the two, Dr. Miller has implanted artificial iris devices in approximately 90 patients, giving him more experience with the procedure than nearly every other ophthalmologist in the country.

To be eligible for the HumanOptics trial, patients must have a cataract or be pseudophakic; patients with a clear lens who want an artificial device would have to undergo simultaneous refractive lens exchange. The handcrafted silicone wafers have a 12.8-mm diameter and a 3.35-mm pupil that is implanted with forceps or an injector. “This device blocks out all light coming in through the cornea except what goes through the pupil,” Dr. Miller says. “It looks great, and we expect it to produce a significant functional and cosmetic benefit for patients.”



Charles Haverstick, the grateful recipient of a custom artificial iris (pre-surgery photo above)

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AARP The Magazine ranks  
Jules Stein Eye Institute as  
No. 3 in the country for  
complex eye-care referrals.



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### *Ocular Melanoma Treatment* continued from cover

In the July 2010 issue of *Archives of Ophthalmology*, Dr. McCannel and colleagues reported that the silicone oil absorbs approximately 50 percent of the extraneous radiation, reducing radiation exposure to the back and sides of the eye. "By eliminating half of that side-scatter of radiation, we hope to be able to reduce vision loss in these patients," she explains.

Dr. McCannel has performed the procedure in more than a dozen patients since her paper was accepted for publication in February 2010. She says patients most likely to benefit are those whose tumors are located in the posterior equatorial region of the eye; those whose tumors are located in the central vision area of the macula are unlikely to benefit since the radiation must be aimed there, she explains.

Dr. McCannel is hopeful that a significant number of patients may benefit from a visual standpoint. "We need longer-term follow-up and results before we know for sure," Dr. McCannel says. To facilitate

study of the procedure, Dr. McCannel is measuring patients' vision before the procedure and at follow-up appointments, and will be comparing it to results for patients who haven't had the silicone oil treatment. Early results are promising, but Dr. McCannel says it will be at least two years before long-term effects on vision are clear.

"We already know that patients tolerate the silicone oil surgery well and that the tumors respond to radiation just as they do without silicone oil," Dr. McCannel notes. "We're adding a tried-and-true procedure that we've been doing for many years in retinal surgery, and we are optimistic that it will prevent the vision deterioration that has been an unfortunate side effect of ocular tumor treatment. We feel there's a lot more that can be done to help these patients, and this would be a major step forward."

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