

CLINICAL UPDATE

Custom-Molded Lens Brings Hope to Patients with Irregular Eye Surfaces



Dr. Shibayama takes a custom mold of the patient's eye. The entire procedure lasts for approximately 5 minutes.

Patients who cannot benefit from standard visual correction due to eye surface irregularities can now achieve better vision thanks to a technology that allows for custom lens fabrication, according to the specialty lens expert at the UCLA Stein Eye Institute, Vivian Shibayama, OD.

Scleral contact lenses, which are designed to vault over the corneal surface and land on the sclera, have long been the go-to solution for patients with hard-to-fit eyes in need of correction. Made of gas-permeable materials similar to regular contact lenses but larger in diameter, scleral lenses are commonly used in patients with irregular corneas, as well as to treat high refractive errors and presbyopia. They are also prescribed to provide relief for patients with severe dry eyes by holding fluid against the cornea.

“The scleral lens that is available on the market right now fits about 90% of the population that needs it,” says Dr. Shibayama. “However, there are some patients, those with irregular scleras, those with surgical tubes and blebs, who can’t wear this lens because the lens needs to land on a smooth surface to fit properly.”

Dr. Shibayama works primarily with patients with irregular corneas due to keratoconus, corneal transplants, or ocular surface disease, such as severe dry eye, most of whom are referred to Dr. Shibayama for ocular treatment and specialty lenses.

Fitting patients with basic scleral lenses involves using a standard fitting set, which includes about 20 prefabricated lenses of different shapes. Doctors adjust the standardized curvatures on the lenses to estimate the fit that each patient needs. But the spherical design of the curvatures makes fitting challenging for patients with an irregular eye surface, according to Dr. Shibayama.

“Whatever change I make, it is reflected 360-degrees,” Dr. Shibayama explains. “For

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Biodegradable Implant May Help Preserve Vision for Glaucoma Patients

A new way of delivering medicine to decrease intraocular pressure, currently in clinical trials at the UCLA Stein Eye Institute and other centers around the world, could revolutionize the treatment of patients with open-angle glaucoma, according to Joseph Caprioli, MD, David May II Endowed Chair in Ophthalmology and chief of the Stein Eye Institute’s Glaucoma Division.

“Vision loss from glaucoma is still a big problem even with treatment, and a large

reason why, is that patients don’t use their medicine properly,” says Dr. Caprioli, who is leading a Phase III clinical trial at the Stein Eye Institute to study the safety and efficacy of bimatoprost sustained-release (SR).

Standard treatment of patients with open-angle glaucoma includes ocular antihypertensive therapy, delivered daily or several times a day in the form of self-administered eye drops. Patients’ lack

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The tray is in the patient's eye for 1 minute. The procedure is painless, and no anesthetic is necessary.



Image of the mold that is sent to the lab for scanning.



Two dots are marked at 6 o'clock to help the patient orient the lens.



Each lens is designed to be unique for each patient.

example, a patient who had glaucoma surgery, who might have a bleb at 2 o'clock, will not have that elevation at 6 o'clock. It's really difficult to fit these patients because they are not spherical."

Unlike prefabricated basic scleral lenses, the EyePrintPRO™ lens is designed based on impressions of the patient's ocular surface, allowing it to match the contour of any eye. The resulting lens is made from a high-oxygen permeable material and improves vision much like standard correction, by creating a smooth refractive surface for the affected eye.

"The EyePrint lens offers a custom mold of the eye," says Dr. Shibayama. "Just like a dentist takes a mold of your teeth, I take an impression of the eye, which is then sent to the EyePrint Prosthetics lab. The lab scans it and builds a custom lens for the patient based on the scan, so it's a perfect fit for every patient."

Dr. Shibayama says EyePrint works well for most patients with an irregular sclera, including those who have had multiple eye surgeries, such as corneal transplants and LASIK. "Not only does this lens provide therapeutic relief in eye pain and discomfort associated with ocular surface disease, but these patients typically have irregular astigmatism that cannot be fully corrected by glasses," she explains. "Assuming the poor vision is due to the irregular cornea, and not another factor like a detached retina or severe glaucoma, the EyePrint lens will mask this corneal irregularity and give the patient better vision."

The custom-fabricated lens also makes vision correction possible for patients who cannot wear regular contact lenses or scleral lenses due to eye irregularities resulting from scarring, chemical burns, or any type of ocular trauma that has altered the sclera. "Traditionally, it has been very hard to fit these

patients because their scleras are irregularly shaped," Dr. Shibayama notes.

Impressions for the EyePrint lens are taken during a simple office procedure, which lasts up to five minutes. A tray containing impression material is inserted into the eye and allowed to set for one minute to copy the irregularities of the cornea and sclera surface. Patients, who are instructed not to wear any type of lens for 48 hours prior to the procedure, usually do not experience side effects.

"Anesthetic of any type is not necessary," says Dr. Shibayama, who received her training from the creator of the lens. "The impression material feels a little cold and bulky in the eye, but it's painless."

EyePrint lenses last about a year, but may last longer with proper care, provided no changes occur in the eyes. Patients may wear them daily and remove them every night.

The Stein Eye Institute's Contact Lens Center is one of 26 centers in the United States working with this technology, and it is the only center that offers EyePrint lenses within a 100-mile radius of Los Angeles. In addition to Stein Eye, patients in California can receive EyePrint lenses at clinics in Blythe and San Diego.

The lens has no contraindications, but is recommended mostly for patients who cannot benefit from standard visual correction. "I always try to fit patients with the standard scleral lens first, but there are certain patients who have very sick eyes, and you just can't risk a poor fit," Dr. Shibayama adds. "These lenses are almost always a perfect fit. If a second lens order is needed, the shape of the lens is not usually adjusted, just the refractive power of the lens."

Biodegradable Implant May Help Preserve Vision for Glaucoma Patients continued from cover

of compliance or inconsistency in using the drops complicates the regimen, making treatment less effective in preventing further vision loss, explains Dr. Caprioli.

Improperly administered treatment is a widespread challenge among elderly patients, who typically suffer from primary open-angle glaucoma, the most common form of the disease. “A new way to deliver medicine would be very welcome,” Dr. Caprioli notes. “Patients notoriously don’t use drops very well, and many studies show they don’t use the eye drops as directed.”

Glaucoma affects more than 2.7 million individuals over age 40 in the United States and 60.5 million people globally, according to the American Academy of Ophthalmology. About two-thirds of patients with open-angle glaucoma, the form with the highest incidence, have elevated intraocular pressure. Although the risk of vision loss due to glaucoma has decreased by nearly half since 1980, the disease still leads to blindness in a significant number of patients, according to a study published last year in the journal *Ophthalmology*.

The sustained-release formulation of bimatoprost, an alternate ocular antihypertensive therapy that does not require patient self-administration, is “a major new and exciting way to deliver glaucoma treatment, which clearly has many advantages,” according to Dr. Caprioli.

The new form of drug delivery involves injecting a microscopic, biodegradable pellet inside the anterior chamber of the eye during a simple office procedure. The implant slowly dissolves over a period of several months, releasing preservative-free bimatoprost SR to decrease intraocular pressure. “This would theoretically relieve the patient from having to use any drops during that period of time,” Dr. Caprioli notes.

Stein Eye, which joined the trial in July and is expecting to enroll at least 10 patients, is one of 72 sites participating in the Phase III clinical trial that will enroll approximately 600 patients worldwide. The study is investigating the safety and efficacy of two different dose strengths (10 µg or 15 µg) of bimatoprost SR compared to treatment with timolol 0.5% eye drops in lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

To qualify for the study, participants must be diagnosed with either open-angle glaucoma or ocular hypertension in each eye and require intraocular pressure-lowering treatment in both eyes. The trial—the last step before the

The bimatoprost implant helps to mitigate compliance issues, as it theoretically relieves the patient from having to self-administer eye drops.

treatment is approved for the U.S. market—includes a 12-month treatment period with an 8-month extended follow-up. The medicine is injected every 3 or 4 months, but may last up to 6 months.

“The preliminary data is very encouraging,” says Dr. Caprioli. “Bimatoprost is a drug that is also used as a drop, once a day, usually at night. It’s the same drug now implanted with this pellet. The preliminary studies with the pellet show that it is safe and well tolerated. We need more information, though, about how long it lasts and how well it works in different kinds of patients with glaucoma. There is not enough data to give us those last pieces of information, but safety has been pretty well demonstrated.”

Previous studies found bimatoprost eye drops to be clinically and statistically superior to 0.5% timolol eye drops in lowering intraocular pressure in patients with glaucoma or ocular hypertension. Timolol works by decreasing aqueous humor production, whereas

bimatoprost increases aqueous humor outflow to reduce intraocular pressure.

“Bimatoprost is the single most effective FDA-approved drop that’s on the market to date,” explains Dr. Caprioli. The challenge, he says, is having patients adhere to this medication regimen, especially when eye drop application may cause adverse reactions. Bimatoprost eye drops have been associated with side effects, such as eye redness, swelling, itching, and increased sensitivity to light. Redness, a particularly bothersome side effect of topical application, was considerably reduced in the preliminary studies with the injectable SR, says Dr. Caprioli. “That’s another advantage,

in addition to avoiding compliance issues and having a long-term duration of action,” he adds. “The only disadvantage is you have to inject it.”

Timolol, which is used alone or in combination with other ocular antihypertensive agents, has long been the standard against which the Food and Drug Administration tests other intraocular pressure-lowering medicines, Dr. Caprioli notes. But the bimatoprost implant may eliminate the need for any self-administered drops.

“My own feeling and hope is that it’s going to be very effective as a single medicine,” says Dr. Caprioli. “And the advantage is that patients don’t have to use drops. Older patients don’t remember to use the drops or physically have a difficult time putting the drops in their eye, and that’s a considerable problem.” He says the older demographic could benefit the most from this new way of delivering ocular antihypertensive treatment. ○

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