

Ophthalmology Times

All the Clinical News in Sight

SEPTEMBER 1, 2005
www.ophtalmologytimes.com

Innovation

Scleral lens an important tool in many 'last resort' scenarios

Patients with severe ocular surface disease and other corneal disorders may benefit from lens

By Cheryl Guttman

Reviewed by Ernest W. Kornmehl, MD, and Perry Rosenthal, MD

Needham, MA—Outcomes achieved with the fluid-ventilated, gas-permeable Boston Scleral Lens (Boston Foundation for Sight) in approximately 1,000 eyes underscore its role as a valuable option for eyes with severe ocular surface disease and many other corneal disorders that would otherwise be candidates for penetrating keratoplasty, said Perry Rosenthal, MD.

Dr. Rosenthal invented the technology and is founder and president of the Boston Foundation for Sight, a 501(c)3 nonprofit organization dedicated to developing sight-restoring contact lenses for persons disabled by corneal diseases.

By avoiding all corneal contact while masking irregular astigmatism, the Boston Scleral Lens can rehabilitate vision in eyes with a variety of corneal disorders that are unable to tolerate traditional rigid gas-permeable (RGP) contact lenses or for which these devices are contraindicated, according to Dr. Rosenthal, assistant clinical professor of ophthalmology, Harvard Medical School, Boston. They include corneal ectasia such as keratoglobus, keratoconus, pellucid marginal degeneration, Terrien's marginal degeneration, or eyes that suffer from irregular astigmatism following radial keratotomy, LASIK, penetrating keratoplasty, or trauma.

Moreover, the oxygenated fluid reservoir contained by this device functions as a unique "corneal liquid bandage" that has proven to have palliative and therapeutic value superior to soft bandage lens in the management of severe ocular surface disease associated with corneal stem cell deficiencies (Stevens-Johnson syndrome, ocular pemphigoid, aniridia, chemical and thermal injuries), severe dry eye, neurotrophic corneas, and exposure keratopathy, he said.

Patients in whom management of severe ocular surface disease is the primary indication have experienced dramatic relief from pain and photophobia and also benefit from the effectiveness of its corneal liquid bandage in promoting the healing of corneal erosions, persistent full-thickness epithelial defects, and filaments when all other measures have failed. According to Dr. Rosenthal, it has been more effective than extensive tarsorrhaphy in many cases. Its ability to mask irregular astigmatism and improve vision is an additional benefit for these eyes.

With rigorous screening, involving careful patient evaluation and trial lens fitting, together with an advanced computer-aided method of lens design, success—which is measured by continued lens wear—exceeds 90% for both vision enhancement and ocular surface disease indications, according to Dr. Rosenthal.

"Wearing these lenses is a burden because insertion and removal can be awkward and frustrating, the care regimen is time-consuming, and many patients with severe dry eye are required to remove and clean them periodically when accumulated surface debris interferes with vision," Dr. Rosenthal said. "Therefore, continued use of this device is a broad and important marker of success because one can conclude that their benefits far outweigh these disadvantages."

Patients benefit from technology

The Boston Scleral Lens is a welcome addition to the ophthalmologist's armamentar-

ium, according to Ernest W. Kornmehl, MD, medical director, Kornmehl Laser Eye Associates, Boston.

"The lens can offer benefit when there seems to be little hope for a select group of patients. This device is significant considering the numbers affected nationwide," Dr. Kornmehl said. "Ophthalmologists need to be aware of this valuable technology and it is deserving of our support."

One of the most dramatic illustrations of



Perry Rosenthal, MD

The lens can rehabilitate vision in eyes with a variety of corneal disorders that are unable to tolerate traditional rigid gas-permeable contact lenses or for which these devices are contraindicated.

the value of the lens is provided by the experience of patients with severe dry eye secondary to chronic graft-versus-host disease.

"They have been incredibly disabled by constant, severe pain and photophobia, sometimes for years, and must be examined in dim ambient light," Dr. Rosenthal said. "Yet, they are able to open their eyes without pain in a fully lit room within minutes after the initial trial lens insertion. It is an amazing phenomenon."

Dr. Rosenthal was motivated to dedicate his career to promoting the unique optical benefits of hard contact lenses for patients with corneal disorders ever since he was a resident and asked to establish the first contact lens clinic at the Massachusetts Eye and Ear Infirmary, Boston.

"My first contact lens patient was a student with keratoconus, and I was amazed at his ability to read the lower lines of the Snellen chart after I inserted a hard contact lens," he said. "So you can imagine my disappointment when he rejected the lenses, as did most subsequent patients."

In his quest to overcome the obstacle of corneal hypoxia associated with existing hard contact lens materials, Dr. Rosenthal co-founded Polymer Technology Corp. to develop gas-permeable rigid polymers (Boston Lens). Despite this advance, the distorted topography and fragile surfaces of diseased corneas continued to pose a mechanical impediment to successful corneal RGP contact lens wear for those who could benefit most from this modality.

Because scleral contact lenses avoid this limitation, Dr. Rosenthal became intrigued by the work of Australian optometrist Don Ezekiel, OD, the first to report the use of gas-permeable scleral lens.

"A major limitation of scleral lenses is that they can generate suction as they decompress after minute quantities of fluid are squeezed out of the fluid reservoir during blinking," Dr. Rosenthal said. "To avoid that complication, a hole was drilled in the lens that allowed air to be aspirated into the fluid compartment.

"However, large air bubbles often cause corneal epithelial desiccation, which is a contraindication to its use in eyes with severe ocular surface disease," he added.

Channeling tears

Dr. Rosenthal's concept was to design a fluid-ventilated lens constructed of a high oxygen-permeable polymer (Boston XO, Polymer Technology Corp.) that would prevent suction by aspirating external tears into the reservoir instead of air. In the Boston Scleral Lens, tears are channeled into the fluid reservoir through a series of radial trenches created between the lens haptic and sclera.

Nevertheless, maintaining patency of the trenches and preventing intrusion of air bubbles into the fluid compartment requires a precise fitting relationship between the bearing surface of the haptic and the underlying sclera.

To meet this need, Dr. Rosenthal and his collaborators began work in 1992 to develop a lens design software program based on mathematical spline functions, a relatively new branch of mathematics for defining and creating junctionless surface shapes. That software, which they have continued to refine over the years, allows each lens to be cus-

tom-designed on a desktop computer. The data are then transmitted to the operating system of a high-precision digital lathe for lens fabrication.

Screening candidates

All patients are seen by referral and only those with significantly disabling diseases that are not adequately addressed by other low-risk treatment strategies and who can be potentially helped by this technology are accepted for evaluation. Patients with frank corneal edema or marginal endothelial function are excluded because the scleral lens can exacerbate corneal swelling. Patients thought to have a reasonable chance of success with the Boston Scleral Lens after the initial evaluation are fitted with a trial device selected from a library of more than 300 lenses. Only if the ocular response is favorable and the patient and Dr. Rosenthal concur that the lens can fulfill a mutually agreed upon goal(s) does the process move onto the final step of custom lens fitting.

On average, the skill-intensive, time-consuming trial-and-error fitting process involves the fabrication of 3.5 lenses per eye and requires 5 to 7 days.

However, in more challenging cases where the bulbar conjunctiva is severely distorted by scarring, the custom fitting process can take up to 3 weeks and require the fabrication of numerous lenses, Dr. Rosenthal said.

The most serious complication that has been encountered with the fluid-ventilated, gas-permeable scleral lens is the development of microbial keratitis in four eyes. All

of those events occurred in eyes with persistent epithelial defects (PED) that followed penetrating keratoplasty and were on an extended lens-wear schedule.

However, after adding a drop of the non-preserved, fourth-generation fluoroquinolone moxifloxacin (Vigamox, Alcon Laboratories) to the fluid reservoir for prophylaxis, there have been no cases of bacterial keratitis in about 20 eyes that wore the lens on an overnight schedule until the PED had resurfaced, according to Dr. Rosenthal.

Currently, Blue Cross/Blue Shield of Massachusetts reimburses the full fee for fitting the Boston Scleral Lens, and Dr. Rosenthal is hopeful that this will set a precedent for other health insurance carriers. However, Boston Foundation for Sight provides free or subsidized care to qualified patients.

Getting the word out

Considering that it is a "last resort" option for many patients, the demonstrated value of the device, and efforts made to raise professional and public awareness through lectures and publications, Dr. Rosenthal is surprised that this technology has not gained more widespread interest.

"You would think patients would be lined up at our door, but for many years I felt as if we were offering a pay-what-you-can feast for starving people and nobody came," he said.

Disseminating information about the Boston Scleral Lens has recently taken on added importance as plans are being made to broaden patient access to this technology. Until now, the Boston Scleral Lens has been available in the United States only through the Boston Foundation for Sight's clinic in Needham, MA.

However, a \$240,000 Gift of Sight grant from Johnson & Johnson will be used to expand training of practitioners who will staff a network of satellite clinics across the country and abroad in tertiary ophthalmology centers that serve major geographic catchment areas.

In addition, the support of Bausch & Lomb since the founding of the foundation has enabled it to expand its onsite manufacturing facilities, according to Dr. Rosenthal. He said the expansion will include a custom-designed, state-of-the-art, computer-driven lathe/milling machine that will serve the needs of the satellites while advancing the design of the device to simplify its fitting process. ○ T

Take-Home Message

The fluid-ventilated Boston Scleral Lens is an important tool in the management of severe ocular surface disease unresponsive to traditional treatment strategies and is a superior alternative to tarsorrhaphy. It also expands the non-surgical options for eyes with corneal disorders that are intolerant of corneal rigid gas permeable contact lenses. Perry Rosenthal, MD, inventor and founder/president of the Boston Foundation for Sight, is hopeful that health insurance carriers will cover the device after Blue Cross/Blue Shield of Massachusetts agreed to reimburse the full fee for fitting the lens. His nonprofit foundation provides free or subsidized care to qualified patients.