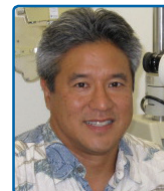


horizons



GROUNDBREAKING TECHNOLOGY

By Randall Sakamoto, OD, PhD



Miru: Not Just a Pretty Package

Menicon introduces innovative new contact lens.

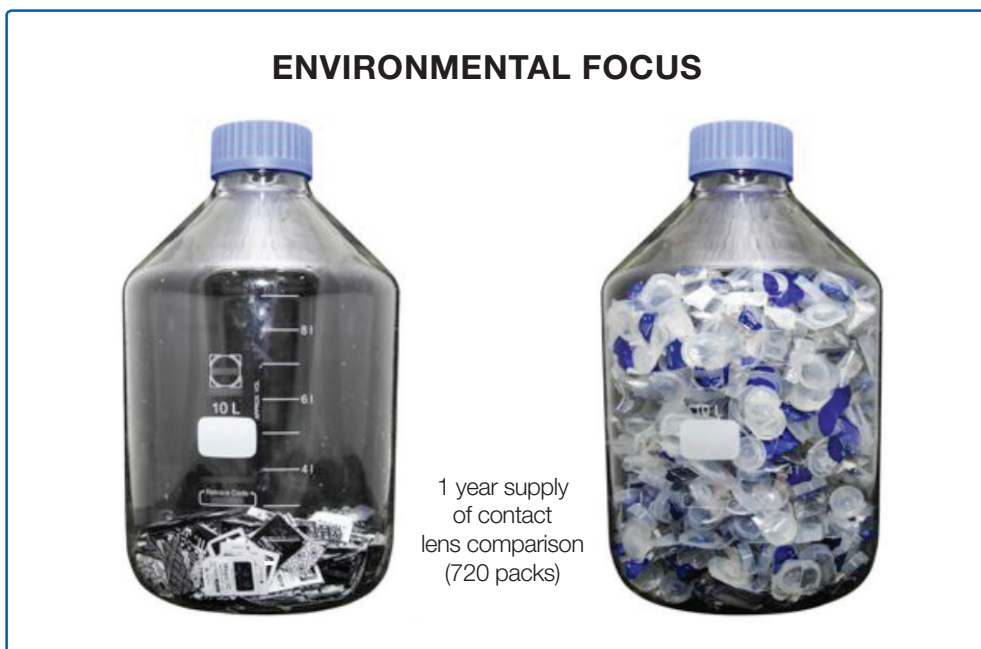
By now, many practitioners have heard of, or actually tried Menicon's new daily disposable lens, Miru 1 day Menicon Flat Pack. This lens is yet another example of a product developed in accordance with Menicon's corporate philosophy: "To strive to produce innovative and safer contact lenses." Every aspect of 1 day Miru is unique, but its novel packaging is truly eye-catching, so let's start there.

NOVEL FLAT PACK Environmentally Friendly

1 day Miru's 1-mm thick Flat Pack is the most environmentally friendly packaging in the contact lens industry. The entire Flat Pack is recyclable, and 1 year's worth of open Flat Packs generates only about 20% of the usual packaging bulk when compared with traditional blister packs (Figure 1).

Easy to Open

A major complaint of patients is that blister packs are difficult to open. 1 day Miru was designed to provide superior ease of opening. Whereas most blister packs require an initial peel force of 15N to 20N to open, the Miru 1 day Menicon Flat Pack requires only 5N of initial peel force. This is one-third to one-fourth of the peel force of traditional contact lens blister packaging. In addition, the Flat Pack was designed to provide an easy-to-open



► **Figure 1:** 1 day Miru's unique Flat Pack generates approximately 20% of the usual bulk of a year's supply of traditional blister packs. It is the most ecological packaging to date in the contact lens industry.

peel force that increases at the end to prevent the two halves of the package from separating (Figure 2).

Hygienic

The Miru 1 day Menicon Flat Pack is also the hygienic way for contact lenses to be applied. When the Flat Pack is opened, the lens is always base curve side down (Figure 3). When patients handle the

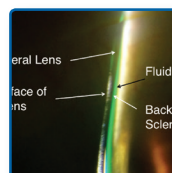
lenses correctly, they do not touch the base curve surface as they remove the lenses and apply them to their eyes. An added benefit of this feature is that the lens can never be inside out for ease of handling and application. Studies have shown that corneal contamination can be far less with the 1 day Miru lens when compared with lenses in traditional blister packs (Figure 4).¹

Inside...

PROGENT:
Integral to Today's
GP Lens Care
p. 5



Insights on Oxygen
Transmissibility for
Scleral Lenses
p. 6



California OD Helps
Establish Keratoco-
nus Clinic in Kenya
p. 8



INNOVATIVE LENS Precise Manufacturing Technology

The molding technology used to produce 1 day Miru lenses is another first for the contact lens industry. The CENTRAFORM™ process is a precisely controlled combination of spin casting and injection molding. As the polymer is injected into the mold, it is also spun in a calculated manner. This technique produces a smooth, junction-free, aspheric surface and thinner, precise edges compared with any other molded lenses

Residuals and Other By-products

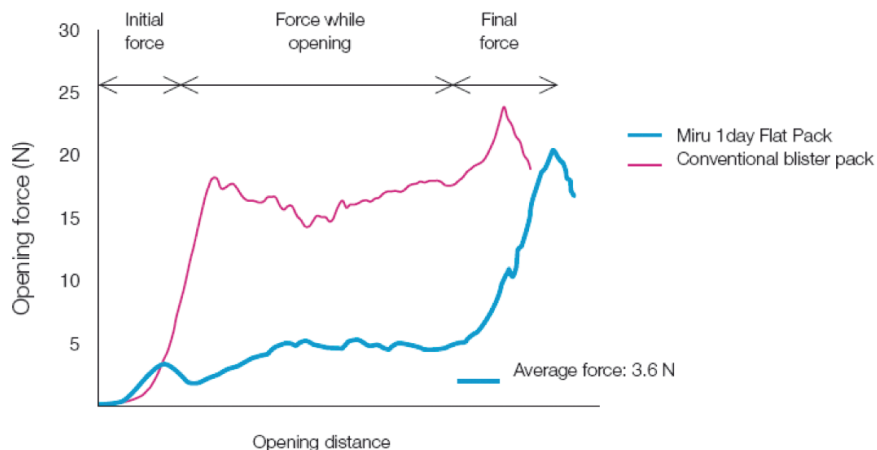
Many practitioners are not aware that residual polymers and other by-products of the contact lens manufacturing process can remain in the lens matrix or reside in the saline solution of contact lens blister packs. These are termed “residuals” in manufacturing vernacular.

The ISO standard for residuals in contact lens blister packs requires a series of preapproval studies to establish lack of toxicity and to ensure that the lens material will not induce a sensitivity reaction in patients. These are well-defined and understood studies, but they are based upon short-term evaluation periods. They do not evaluate the possible long-term effects of residuals on the ocular environment.

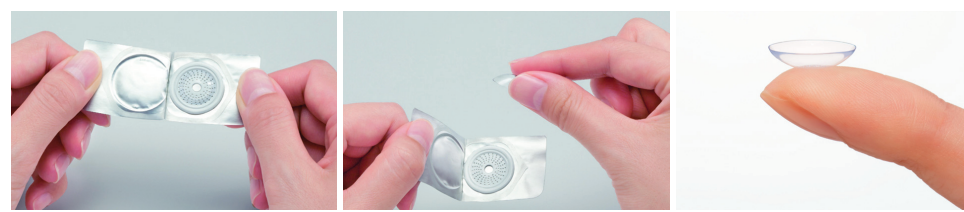
In the case of monthly or 2-week lenses, the potential exposure to the patient is relatively minor because the lenses are replaced infrequently, and they are stored in a multipurpose solution not the original blister pack saline. With daily disposable lenses, however, the patient is exposed to a new pair of lenses every day. Consequently, the purity of the lens and the saline must be as high as possible.

True to its corporate philosophy, Menicon took the issue of residuals to heart, spending time and resources in the development of Miru to arrive at the lowest possible residuals in the industry. Residuals in the Miru 1day Menicon Flat Pack are below detectable limits when measured with high-performance liquid chromatography. That means less than 0.15 parts per million. As a result, Menicon uses total organic carbon counting as a reliable means to gauge residual levels prior to any lot being released to the market.

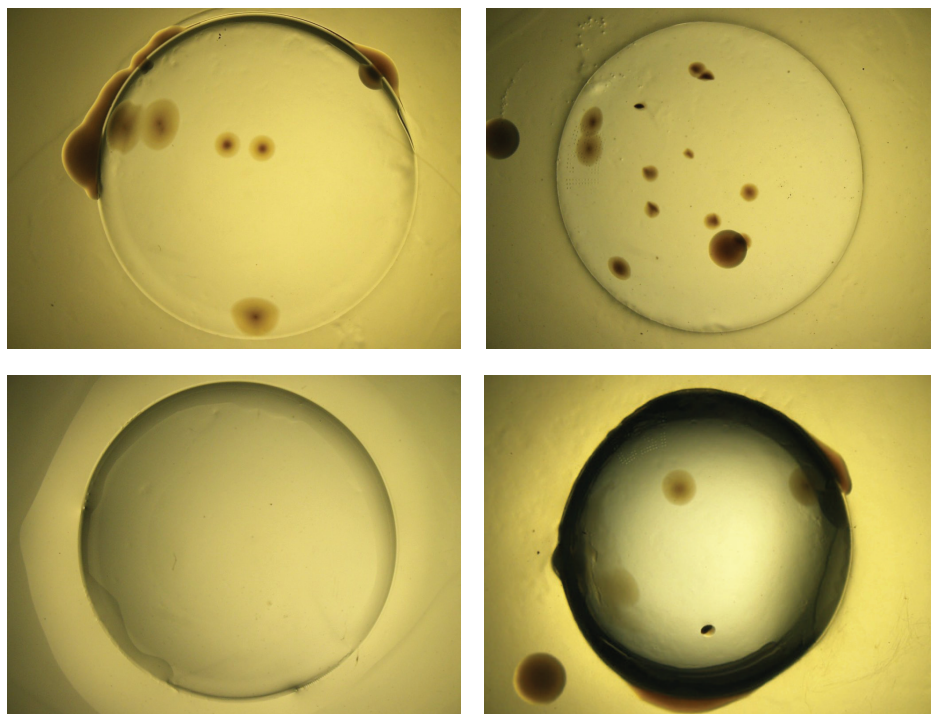
This is all the more amazing because the Miru 1day Menicon Flat Pack contains only 0.2 mL of saline compared with 0.8 mL of saline contained in standard blister packs. That is 25% of the volume of saline, yet Miru's residuals are significantly lower than expected by industry standards.



► **Figure 2:** The low peel force of the Miru 1day Menicon Flat Pack increases at the end to prevent the two foils from separating. There is virtually no spillage or expelling of the saline upon opening because of the low peel force and the small amount (0.2 mL) of saline contained in the package.



► **Figure 3:** The 1 day Miru lens is always base curve side down upon opening the Flat Pack. The lens can be picked up without touching the base curve side of the lens. This reduces the potential for contamination and further enhances the safety of this unique modality.



► **Figure 4:** In an *in vitro* study, gloved hands dipped in *Staphylococcus* bacteria opened and handled lenses from traditional blister packs and the Miru 1day Menicon Flat Pack. Upon culturing the lens surfaces, the researchers found the traditional blister pack lenses showed contamination on both front and back surfaces of the lens, whereas the Flat Pack showed contamination only on the front surface of the lens.

(Figure 5). Researchers have demonstrated that 1 day Miru produces significantly less conjunctival staining in comparison to patients' habitual daily disposable lenses.² Conjunctival staining has been identified as one factor in the perception of dryness.³

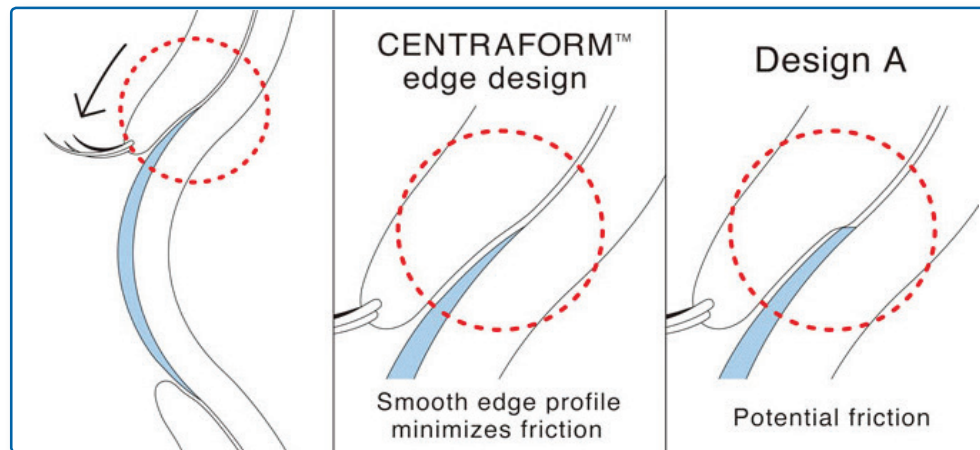
Wettable Material

1 day Miru lenses are made from HEMA GMA (hioxifilcon A) material, a time-proven soft lens material that is known for its wettability. The GMA portion of the polymer is structurally similar to oligo-saccharide, which is a major component of mucin found at the base of the tear layer (Figure 6). It binds naturally with water, providing a wettable lens surface

for long periods of lens wear. This feature in combination with refined lens edges and minimal conjunctival staining work together to provide excellent wettability.

Accurate Aspheric Optics

The CENTRAFORM™ process also allows for accurate aspheric optics, which can reduce unwanted spherical aberration for clearer vision (Figure 7). This is characterized by constantly changing aspheric optics over the power range, gradually changing surface from center to edge (varying radius of curvature). This effectively provides *in vivo* high-order aberration control, which is also helpful in mesopic lighting conditions.



► **Figure 5:** The CENTRAFORM™ process, a proprietary combination of molding and spin casting, produces smooth edges to enhance comfort and reduce the sensation of dryness.

Foil on Foil

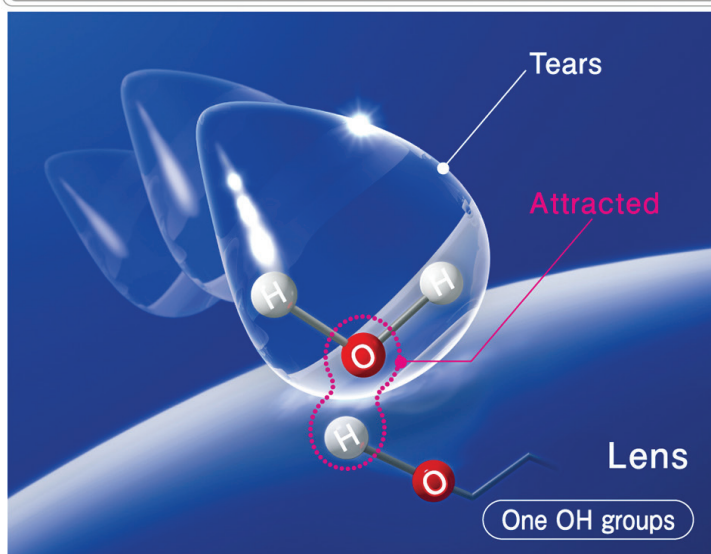
Miru 1day Menicon Flat Pack is a “foil on foil” package as opposed to a standard blister pack, which is foil over polypropylene plastic. Another fact that many practitioners may not be aware of is that standard blister packs lose water vapor via gradual evaporation through the polypropylene lens bowl. Manufacturers must allow for an evaporation rate that is based upon various factors relating to the blister pack material and construction. If the wall of the polypropylene pack is too thin, the vapor transfer rate increases. Manufacturers must also include sufficient saline to allow for this evaporation to ensure that the desired tonicity and pH properties will be maintained throughout the shelf life of the lens.

1 day Miru's “foil on foil” Flat Pack has a zero evaporation rate. The saline is always the proper concentration.

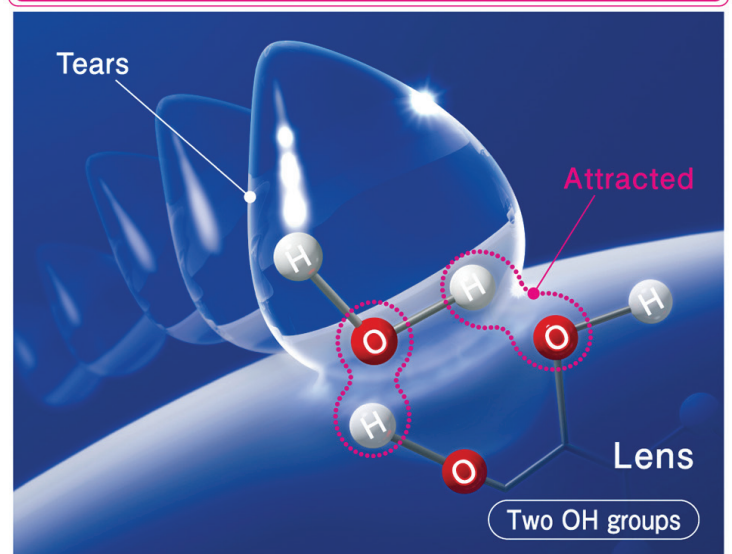
From the environmental aspect, ease of opening and handling, lack of contamination, unique edge technology and wettability, the Miru 1day Menicon Flat Pack is one of the most innovative developments in soft contact lens technology in the last 30 years. This technology deserves a place in every practitioner's office.

Currently, Miru 1day Menicon Flat Pack lenses are available in powers from

HEMA: Standard lens component



GMA: Part of the material used in Miru



Long-lasting moisture with two OH groups in Miru line material to attract more tears!

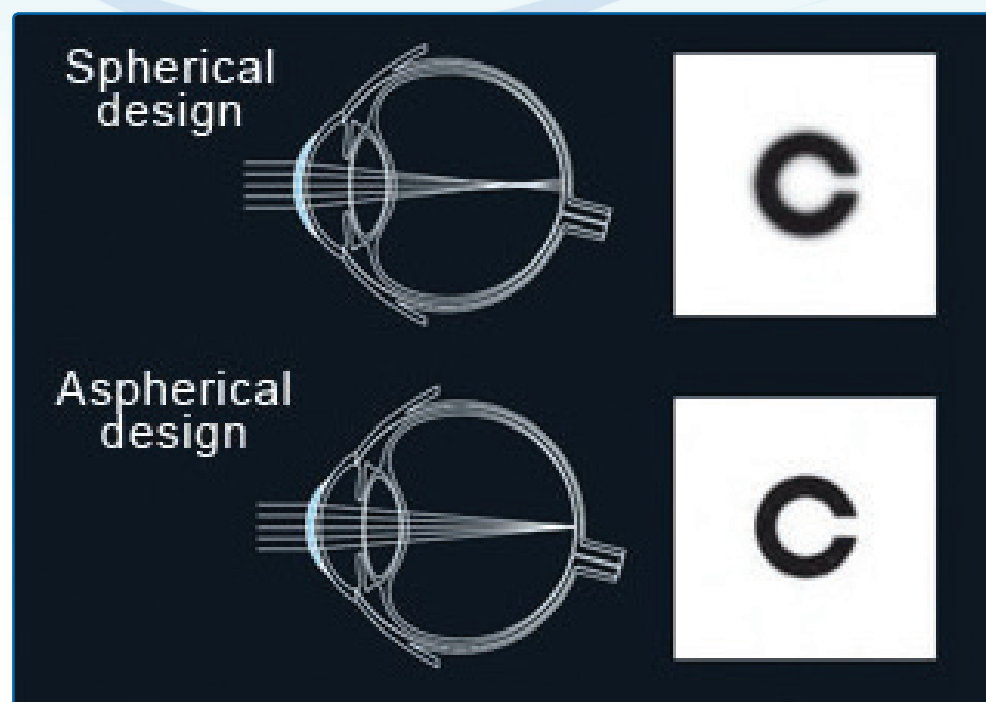
► **Figure 6:** HEMA-GMA (FDA Group II, high water content, nonionic) works naturally with the tears for extra moisture and all-day comfort. It possesses a unique ability to double-bond with water and improve *in vivo* wettability over time, mimicking the oligosaccharides of the mucin layer. It binds 5 times more water than HEMA while maintaining good polydispersity throughout the contact lens and helps to stabilize the tear film over the lens.

−0.50D to −10D. The plus spheres will be available in the near future.

The more I understand the depth of

innovation and technology behind Miru 1day Menicon Flat Pack lenses, the more convinced I am that these lenses

will quickly become an industry standard. I invite everyone to become familiar with this new technology. It is here to stay. ■



► **Figure 7:** Aspheric optics control longitudinal spherical aberration.

Special thanks to Steve Newman, Chief Technical Officer, Menicon Co., Ltd., and inventor of Miru 1day Menicon Flat Pack technology, for his technical advice and contributions to this article.

References

1. Nomachi M, Sakanishi K, Ichijima H, Cavanagh HD. Evaluation of diminished microbial contamination in handling of a novel daily disposable flat pack contact lens. *Eye Contact Lens*. 2013;39:234-238.
2. Namiki I. Clinical evaluation of a Menicon 1 Day Flat Pack. *J Jap Soc CL*. In press.
3. Lakkis C, Brennan NA. Bulbar conjunctival fluorescein staining in hydrogel contact lens wearers. *CLAO J*. 1996;22:189-194.

GLOBAL EXPANSION

Menicon Appoints Executive Manager for Latin America

Juan Céspedes to lead new market expansion.

Menicon Co., Ltd., appointed Juan Céspedes as Executive Manager for Latin America. He will be responsible for business development in Latin America as part of a new department encompassing new markets.

Mr. Céspedes, who will be based in the Menicon America office in Boston, USA, joined Menicon in 2000, working at the company's European headquarters in Paris. He subsequently cofounded Menicon Espana, which he directed for 10 years, positioning the company as a leader in specialty contact lenses.

In 2010, Mr. Céspedes relocated to Menicon's headquarters in Japan, where he developed various global activities along with the Latin America project, which will launch soon with the company's debut in Colombia.

The Latin America expansion will continue to Guatemala, Peru, Chile, Mexico, Brazil, and Argentina, where Menicon aims to provide high quality contact lenses to eye care professionals. To do this, the company will seek strategic partnerships with industry leaders in each country. The main pillar of the implementation strategy will be Menicon's training programs, which offer the latest and most innovative educational tools to eye care professionals.

"I am grateful for the trust Menicon has placed in me, and I am excited to lead this project," Mr. Céspedes said. "We are committed to eye care professionals and to providing them with our products, which are recognized for their high quality."

Mr. Hiroshi Murakami, Executive Officer of the Overseas Sales Division of



► Menicon's Chairman Kyoichi Tanaka presents Juan Céspedes with a woodblock carving of Daruma on the occasion of the opening of the South American markets. Mr. Tanaka is not only the founder and inventor of the first contact lens in Japan but also an accomplished artist.

Menicon Co., Ltd., said, "Mr. Céspedes is very knowledgeable about the Latin American markets as well as understanding Menicon's commitment to safety and customer satisfaction. We are looking forward to working closely with him to enter Latin America for the first time with our products and to meet the vision care needs of each market." ■



PROGENT: An Integral Part of Today's GP Lens Care Regimen

Scanning electron microscopy validates Menicon PROGENT's efficacy.

Menicon PROGENT is rapidly becoming a standard of care for deep-cleaning GP lenses in many practices. How well does it work? Anecdotally, many practitioners have observed the seemingly miraculous removal of heavy protein deposits from GP lenses, and their patients have reported improved lens-wearing comfort after a PROGENT cleaning. But what is

really going on across the surface of a GP lens following a PROGENT cleaning? To answer this question, we used a scanning electron microscopy (SEM) to examine a lens before and after cleaning with PROGENT.

Study Method and Results

We used a finished GP lens that was worn for several months and maintained with a daily cleaner and disinfecting solution. One half of the lens was left untreated, and the other half was treated with PROGENT. As expected, the "PROGENTED" side appears clean with no visible protein (Figure 1).

Further analysis with the SEM demonstrated the microscopic changes that occurred after the lens was treated with PROGENT (Figure 2). Before treatment, the SEM revealed rough surface protein covering the entire lens, which

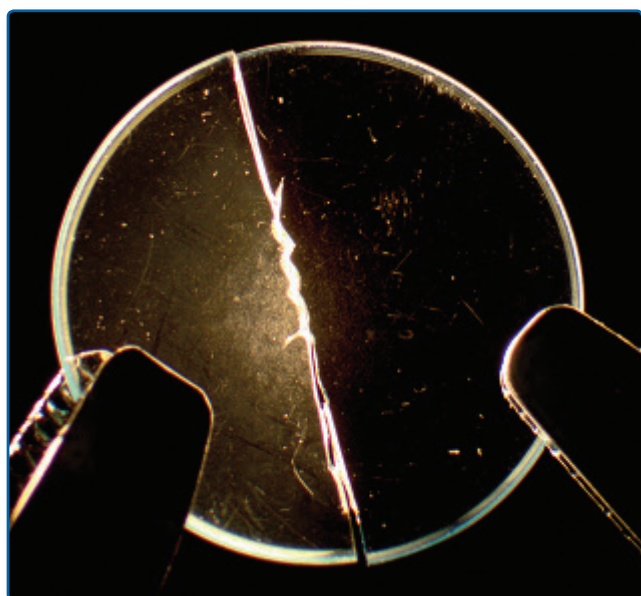
would likely irritate the delicate conjunctiva and corneal epithelium. After a 30-minute treatment with PROGENT, the SEM showed the lens surface is clean and smooth, devoid of irritating protein deposits.

This SEM analysis clearly demonstrates how thoroughly PROGENT removes protein deposits. PROGENT has also been tested and found to be compatible with a wide variety of GP lens materials. No damage to the lens surface or change of parameters occurred.

Most-wanted Benefits

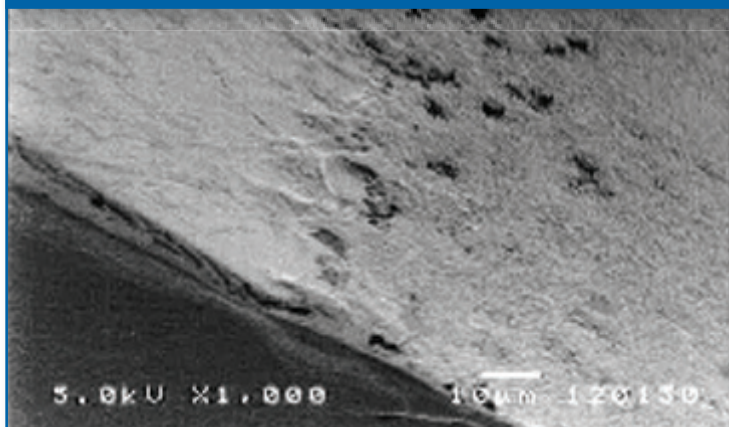
In the United States, PROGENT is approved for home use under the direction of an eye care professional. It is available for resale from your practice, or you may invite patients to join the Menicon Solutions WebStore for convenient online ordering.

PROGENT enables eye care practitioners to provide healthy, protein-free lenses for comfortable, sharp vision in just 30 minutes, benefits that all patients who wear GP lenses will appreciate. ■

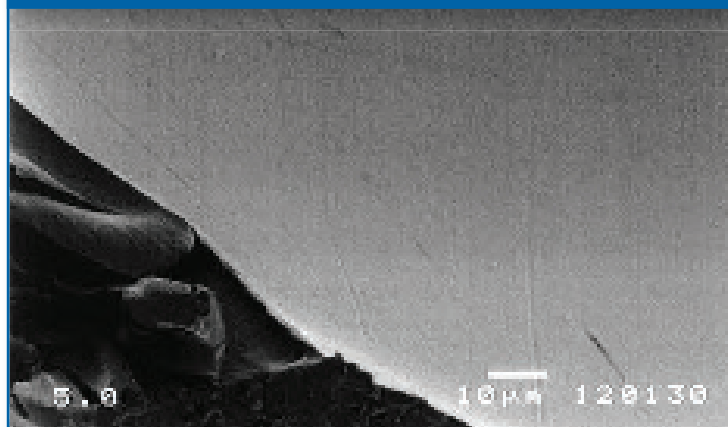


► **Figure 1:** The right side of this GP lens, which was worn for several months and maintained with daily cleaning and disinfecting, was treated with PROGENT.

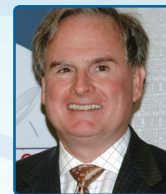
Before PROGENT



After PROGENT



► **Figure 2:** A view of a lens through a scanning electronic microscope before treatment with PROGENT (left) shows the rough surface protein covering the entire lens. Following a 30-minute soak with PROGENT treatment (right), the surface is smooth and devoid of any irregularities.



Insights on Oxygen Transmissibility for Scleral Lenses

Factors to consider for healthy lens wear..

Scleral lenses offer patients superior optics as well as comfort that equals or exceeds that of custom soft lens designs. As we gain experience fitting scleral lenses, our understanding of their unique designs and available parameters continues to evolve. For example, not all high-Dk materials are available in buttons large enough for scleral lens manufacture. The latest to enter this market is Menicon Z, which captures the highest Dk spot at Dk 163 and is available in a 16.5 mm blank.

Calculating Dk

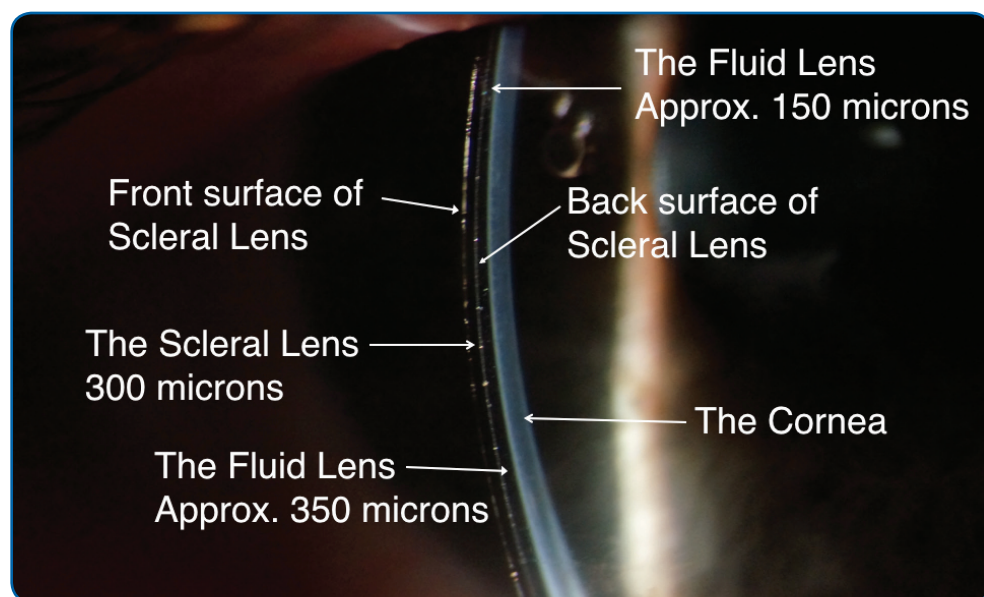
The percentage of oxygen that reaches the cornea is an important factor in determining if a contact lens will be physiologically successful, and this can vary, depending on where you are in the world. In Boston, at sea level, the amount of oxygen in the air is 20.9%. In Aspen, Colo., with an elevation of 8,000 feet, the oxygen in the air is 15.4%; on Mount Kilimanjaro, at 19,000 feet, the oxygen in the air is 10.1%.

Both soft and gas permeable (GP) contact lenses reduce the amount of oxygen that reaches the corneal surface. Unlike soft lenses, however, GP lenses can create a substantial fluid lens between the cornea and the GP lens. This fluid also reduces oxygen transmission to the cornea.

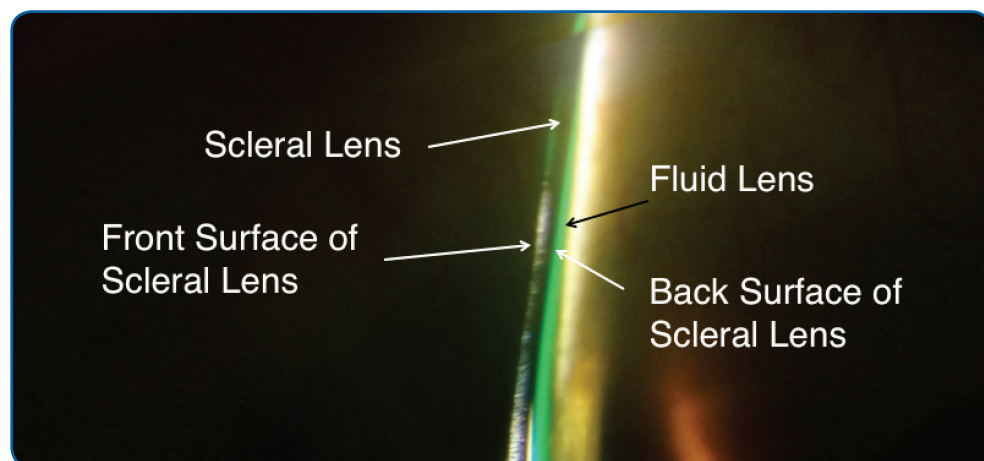
In designing and fitting scleral lenses, we must consider the Dk of the lens material, the Dk of the fluid lens, the thickness of the scleral lens and the thickness of the fluid lens spanning the cornea and the limbus.

Michaud and colleagues theoretically calculate oxygen transmission through GP lens materials (Dk 100, 150 and 170) and through the fluid lens (Dk 80), treating the combined GP and fluid lenses as a series of resistors. They vary the GP lens thickness and the fluid lens thickness at the center and the periphery, determining the theoretical oxygen available. As reference points, they use the Holden–Mertz Dk/t criteria of 24 Fatt units for alleviating hypoxia-induced swelling in the central cornea and the Harvitt–Bonanno criteria of 35 Fatt units for alleviating hypoxia-induced swelling in the limbal area.

As expected, the higher the Dk of the GP lens, the better the result, and the thinner the scleral lens and the fluid lens, the better. According to Michaud and colleagues, “To avoid swelling of the central cornea, the ideal combination of scleral lens/tear clearance should be as follows: a lens made of the highest Dk available, designed with a maximal central thickness of 250 microns, and fitted in a manner to achieve a clearance that does not exceed 200 microns. For the corneal periphery, the lens thickness could range from 250 microns to 350 microns, with clearance varying from 10 microns to 60 microns.”



► **Figure 1:** Optic section through a scleral lens, depicting a consistent scleral lens thickness and a varying fluid lens thickness.



► **Figure 2:** Optic section through a scleral lens periphery, demonstrating scleral lens thickness and fluid lens thickness at the limbus.

This is not always what we see clinically as depicted in Figures 1 and 2.

Conform to standards

How can we successfully fit our patients with scleral lenses and remain within these standards? Scleral lenses can be made with a center thickness of 250 microns, but scleral toricity can result in significant lens flexure with resulting residual astigmatism. Using keratometry, we can easily determine lens flexure, and over-refraction determines the residual refractive astigmatism. Comparing the refractive astigmatism to the corneal flexure, we can determine if the refractive astigmatism is caused by internal astigmatism or by

the induced surface toricity. Increasing center thickness will decrease lens flexure, but this decreases the oxygen transmissibility of the lens.

Lens flexure can also be reduced or eliminated by using toric peripheral fitting curves. Peripheral lens thickness can be increased to accommodate toric peripheral curves and easily stay within the 250-micron to 350-micron limit. When toric peripheral fitting curves are used, the toric curves lock the lens on the eye, stopping lens rotation; this allows the addition of front toric optics to correct for any residual astigmatism.

With the availability of higher-Dk lens materials and better understanding of lens design limitations and lens fitting requirements, fitting specialty lenses has never been more exciting or more rewarding. ■

Reference

1. Michaud L, van der Worp E, Brazeau D, Warde R, Giasson CJ. Predicting estimates of oxygen transmissibility for scleral lenses. *Cont Lens Anterior Eye*. 2012;35:266-271.

GREEN SOLUTIONS

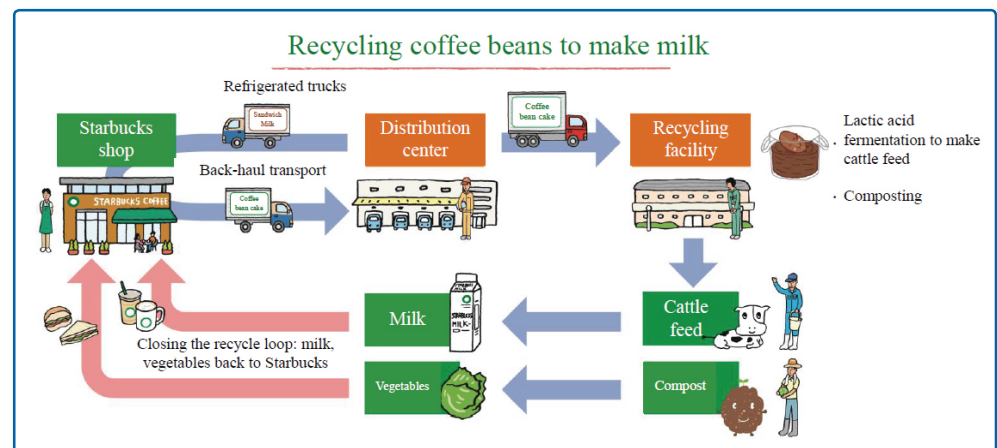
Turning Coffee Grounds Into Cattle Feed

A process developed by Menicon's materials scientists enables Starbucks to capture nutritional content previously left in the compost pile.

Menicon Co., Ltd., has helped Starbucks Coffee to pioneer fermentation technology that allows the coffee grounds from Starbucks stores in the Tokyo area to be converted into feed for dairy cows.

Starbucks was seeking a better use than plant compost for the coffee grounds produced in its stores across Japan. Although composting coffee grounds (known as "bean cake") is an acceptable green solution for this waste, it leaves significant nutritional value unused. How much more elegant to turn it into feed for the cows that make the milk that go in Starbucks coffee? Unfortunately, the technology to accomplish this did not exist.

This is where Menicon stepped in. As an offshoot of their work with contact lens materials, Menicon's researchers had been experimenting with fermentation techniques to find new uses for rice straw. They found that one lactic acid fermentation technique they had developed could be used for bean cake. In a joint effort with the Veterinary Medicine Department of Azabu University, Men-



icon developed a cattle feed that results in milk with a lower somatic cell count, which is a key quality indicator in dairy products.

Starbucks next faced the logistical challenges of regularly collecting bean cake from 1,000 stores nationwide in a hygienic and economical fashion and delivering it to a dedicated production facility. The intense concentration of Starbucks stores in the Tokyo area was critical to the solution. Special storage areas were added to the refrigerated trucks that deliver chilled products to each store. These trucks, which usually

return empty to Starbucks distribution centers, now back-haul bean cake and accumulate it at several locations from where the recycler economically trucks it to a plant in the Tokyo suburbs.

Menicon and Starbucks, along with Sanyu Plant Service Co., Ltd., have jointly applied for a patent on the process used to produce this lactic acid-fermented feed.

For Menicon, this is an important step toward realizing a corporate vision: to become a world enterprise friendly to people, animals and the environment. ■

On a Mission

California OD helps establish keratoconus clinic in Kenya with help from Menicon and Blanchard Contact Lens.

When people who live in rural Western Kenya are diagnosed with keratoconus, they have only two treatment options: spectacles or corneal transplantation. Now, however, these patients as well as patients with high myopia or traumatic irregular corneas have a contact lens option, thanks to the work of Yin-Yin Aung, OD, FAAO, and support from Menicon.

Dr. Aung is an attending optometrist at Goodman Eye Center and a clinical instructor at the University of California, Berkeley, School of Optometry. She recently spent a week at Friends Church Sabatia Eye Hospital in Vihiga, Kenya, helping to set up a keratoconus clinic and teaching staff optometrist Justus Kimaiyo how to fit Rose K specialty lenses. "Now, the hospital is capable of treating irregular cornea cases with contact lenses, which decreases the need to perform expensive and complicated corneal transplantation surgeries," she says. "None of this would be possible without the generous donation of lenses." Blanchard Contact Lens Inc., an authorized manufacturer of Menicon's Rose K family of lenses,

donated the diagnostic sets used by Dr. Aung during her visit to Vihiga.

This was not Dr. Aung's first mission trip, but it was her first trip to Kenya, and it was memorable for two reasons. "Of all of the other mission trips I've taken, this was probably the most rewarding for me personally," she says. "Not only is this my field of specialization, but the Sabatia Eye Hospital is a sustainable clinic with a staff optometrist who can now take care of these patients. I know the patients I treated can return to the hospital and receive appropriate follow-up care from Dr. Kimaiyo."

Dr. Aung saw 30 to 40 patients during her week at Sabatia Eye Hospital, most of whom had never had contact lenses on their eyes. "The vast majority of the patients I saw had no history of contact lens wear," she says. "I saw patients as young as 8 years old with some of the worst keratoconus I've ever seen. Many patients were school-age children who wanted the opportunity to receive higher education. To be able to help a young person see well enough

to read and perform optimally is a remarkable experience."

Dr. Aung plans to continue to work remotely with Dr. Kimaiyo to ensure the keratoconus clinic endures. She is prepared to offer her support via video e-mail to help with complicated lens fitting and trouble-shooting. "We could work together similarly to a satellite clinic," she says, "with Dr. Kimaiyo sending me something as simple as an iPhone video taken through the microscope of a lens on a patient's eye. We haven't set that up yet, mostly because we must secure funding. We are also trying to obtain a grant to help subsidize the cost of the lenses for patients."

Sabatia Eye Hospital is the only independent nonprofit referral center for eye care services for adults and children in Western Kenya. It serves approximately 15 million people in 17 counties and is a training center for ophthalmologists, cataract surgeons, optometrists, ophthalmic nurses and other health care workers. The hospital reported almost 43,000 patient visits in 2012. ■



► **Figure 1:** Dr. Yin-Yin Aung, Berkeley, Calif., and Dr. Justus Kimaiyo, staff optometrist at Sabatia Eye Hospital in Kenya, received Rose K lenses from Menicon to assist in their efforts to establish a keratoconus clinic at the hospital.



► **Figure 2:** Friends Church Sabatia Eye Hospital serves approximately 15 million people in western Kenya.