Twenty-five years ago, the word among contact lens fitters was, "Silicone lenses are the lenses of the future and always will be." Silicone held a great deal of promise, especially in terms of oxygen transmissibility and the potential for safe overnight wear, but early attempts to fabricate lenses concentrated on silicone elastomer materials (which had the elastic properties of natural rubber), rather than the silicone hydrogels that we are using today. The early lenses were fraught with problems, since they were hydrophobic and did not allow fluid transport through the material. Their high degree of elasticity compromised the cornea by both its mechanical effects and the trapping of debris due to lens adherence, thus limiting their usefulness in clinical practice.

Conventional hydrogel HEMA-based soft lens materials reached their limits in terms of oxygen transmissibility long ago. These materials, which have been in use for over 35 years, transmit oxygen as a function of their percentage of water (which has a limited ability to dissolve and transport oxygen), and lens thickness. In order to increase oxygen permeability, water content must be increased. Since the Dk of water is approximately 80, a HEMA-based soft lens would have to be 100% water in order to achieve a Dk value of 80. Current conventional hydrogels have a maximum water content under 80% and a Dk value of less than 40.

The cornea is the only body tissue that receives oxygen directly from the atmosphere. Clinical signs of oxygen deficiency with HEMA-based hydrogel materials include conjunctival injection, limbal redness, neovascularization, corneal staining, corneal edema, increased corneal thickness, myopic creep, corneal distortion, and endothelial changes, including polymegathism, pleomorphism, and a decrease in cell density. Patients experiencing hypoxia may complain of reduced wearing time, increased lens awareness, soreness, irritation, end-of-day burning, sensitivity to light, halos around lights after many hours of lens wear, and spectacle blur.

Industry statistics indicate that 84% of soft lens wearers tend to unintentionally fall asleep or nap with their lenses and 28% of patients who sleep with their lenses for more than 7 nights continuously are wearing lenses that are not approved for such use. Additionally, 94% of all HEMA-based hydrogel contact lens wearers report experiencing one or more symptoms potentially related to corneal hypoxia such as developing red eyes, blurred or hazy vision, and end-of-day discomfort and dryness.

The Dk value, or permeability of a contact lens material refers to the rate of flow of oxygen through the material. Its actual transmissibility of oxygen, however, is also dependent on the thickness of the lens. This ratio is designated as Dk/t.
The criteria for creating a material that is safe for overnight wear include high oxygen transmissibility, good fluid transport through the lens, good surface wettability, resistance to dehydration, resistance to surface deposits, and good comfort. Proper movement is critical to facilitate tear flow, flush out debris, and move oxygen and nutrients to the corneal surface. The lens must displace slightly with each blink.

The challenge faced by the contact lens industry was to create a material with the high Dk of silicone elastomers and the on-eye movement of conventional hydrogels. It was believed that if the structural elements of silicone rubber could be incorporated into hydrogels, many of the adverse effects of hypoxia that occur with conventional hydrogels could be eliminated. Oxygen transmissibility could be enhanced significantly without increasing water content, since oxygen is more soluble in silicone rubber than it is in water (oxygen transmissibility through silicone hydrogel materials actually increases as water content decreases). Early attempts to create a viable material yielded results that were described as “like mixing oil and water.” The silicone, which was hydrophobic, and the hydrogel, which was hydrophilic, separated into distinct layers, resulting in materials that were translucent or opaque.

Eventually, the obstacles to developing a silicone-based lens that fulfilled these criteria were overcome. Silicone lenses are no longer the lenses of the future. The best qualities of silicone and hydrogel materials have been successfully combined. Today’s silicone hydrogel lenses have high oxygen permeability and a highly biocompatible hydrophilic surface, which provide unparalleled comfort. The materials’ efficient fluid transport and good resistance to dehydration help to prevent lens adhesion and promote the removal of waste products and debris. Silicone hydrogel lenses are now able to eliminate many of the signs and symptoms of hypoxia experienced by both daily wear patients and those who wish to sleep with or unintentionally fall asleep while wearing their contacts.

Studies have determined that a minimum Dk/t value of 125 is required in order to minimize corneal swelling in overnight contact lens wear so that it will be equivalent to the swelling that occurs when no lens at all is worn during sleep. Today there are three silicone hydrogel lenses that fulfill this criterion: NIGHT & DAY®, ACUVUE® OASYS™, and O₂OPTIX™. A Dk/t value of 125 has also been determined to be needed to avoid limbal hyperemia in daily wear patients, since lens edge thickness in the limbal area limits oxygen transmission peripherally and may have an adverse effect on limbal stem cells that are so critical in maintaining corneal integrity.

**Characteristics of Silicone Hydrogel Lenses**

**Modulus**

When we speak about the characteristics of silicone hydrogel materials, the term, “modulus” is often used. Modulus refers to the ratio of applied stress to the degree of change in the shape of an elastic body. In other words, it describes how well a material resists deformation. The higher the modulus, the less easily it is deformed. The actual stiffness of a contact lens is determined not only by its modulus but also by its geometry and its thickness. Most silicone hydrogel lenses have a relatively high modulus compared with HEMA-based hydrogels. Since they do not drape as well as conventional hydrogels, fitting must be more precise. Selection of a base curve/diameter combination that fits well in a hydrogel material may not demonstrate the same fitting characteristics when a silicone hydrogel material is chosen, since the corneal eccentricity, limbal contour, and scleral geometry have a much greater effect on the lens/cornea relationship with the stiffer material.

Inferior edge fluting, which is rarely seen with conventional hydrogels, is more often seen with silicone hydrogels, and often requires the use of a steeper-than-anticipated base curve or a more-forgiving material with a lower modulus to provide an optimum fit. CIBA Vision’s NIGHT & DAY® (lotrafilcon A) and Bausch & Lomb’s PureVision®.
(balafilcon A) lenses have a high modulus and are relatively stiff compared with conventional hydrogels. CIBA Vision's O2OPTIX™ (lotrafilcon B) is somewhat softer and more flexible. Vistakon's ACUVUE® OASYS™ (senofilcon A) and the soon-to-be-available CooperVision Biofinity™ (comfilcon A) are softer still, and Vistakon's ACUVUE® ADVANCE™ (galafilcon A) has the lowest modulus of all current silicone hydrogels and is closer to HEMA-based hydrogels in its handling characteristics.

**Oxygen Permeability**

As previously noted, current HEMA-based hydrogels have a maximum Dk value under 40; current silicone hydrogels range from 60 (Dk/t 86) for Vistakon's ACUVUE® ADVANCE™ to 140 (Dk/t 175) for CIBA Vision's NIGHT & DAY®. Since the Dk/t of a lens depends on its center thickness, this will vary by power and will always be lower for plus lenses than for minus lenses. The Dk/t value given by each manufacturer generally represents that of a 3.00 diopter lens. It also does not reflect differences in oxygen distribution caused by the differences in lens thickness from center to periphery (see figure 1).

The passage of oxygen through a lens material is also related to the "driving force," or partial pressure difference across the lens. All current silicone hydrogel lenses except the ACUVUE® ADVANCE™ have Dk/t values of at least 100 and are FDA-approved for extended wear. The ACUVUE® ADVANCE™ lens, with a Dk/t value of 86, is approved for daily wear only.

**Wettability**

The third characteristic of silicone hydrogel materials that must be considered is the innate hydrophobic nature of their surfaces, which can result in significant lipid attraction and poor wettability and usually necessitates the use of surface treatments. Bausch & Lomb's PureVision® (balafilcon A) utilizes a plasma oxidation surface treatment; CIBA Vision's NIGHT & DAY® (lotrafilcon A) and O2OPTIX™ (lotrafilcon B) materials incorporate gas plasma surface treatments that enhance both wettability and biocompatibility; Vistakon's ACUVUE® ADVANCE™ (galafilcon A) contains HYDRACLEAR™, an internal wetting agent; and its newer ACUVUE® OASYS™ (senofilcon A) material contains HYDRACLEAR™ PLUS, which has an added amount of the wetting agent to offset the higher silicone content.

**Patient Selection**

The growth of the silicone hydrogel sector has been extraordinary. It has been predicted that within five years, conventional hydrogels will rarely be used. The high oxygen transmissibility of silicone hydrogels should significantly reduce the incidence of hypoxic complications, including chronic conjunctival injection, corneal neovascularization, microcysts, and endothelial cell changes such as polymegathism and pleomorphism. Although parameters are somewhat limited currently for astigmats and presbyopes, practitioners are fitting silicone hydrogels whenever possible in order to improve or maintain corneal metabolism and physiology, especially in patients with signs and symptoms of hypoxic stress, young wearers, diabetes, patients on immuno-suppressive therapy, patients with corneal dystrophies, patients who are part-time or occasional lens wearers, patients who wear their lenses for long hours or tend to nap with their lenses, and, above all, patients who want to wear their lenses on a continuous/extended wear basis.

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**Figure 3A**: Right eye endothelial cells of daily wear, standard HEMA contact lens wearer. Photo courtesy of Chuck Edmonds, OD, FAAO.

**Figure 3B**: Same eye after one year of 30-night continuous wear with NIGHT & DAY® contact lenses. Photo courtesy of Chuck Edmonds, OD, FAAO.
The ease-of-handling and excellent durability imparted by the higher modulus of silicone hydrogels make them a good choice for patients who have had difficulty inserting conventional hydrogels or who frequently damage their lenses. Their super permeable qualities also make them ideal for therapeutic use. At the present time, only NIGHT & DAY® and PureVision® lenses have received FDA approval for use as bandage lenses. The fundamental goals of a therapeutic contact lens are to aid in healing and to relieve pain. Silicone hydrogels can be used as bandage lenses for conditions such as trichiasis, recurrent corneal erosions, bullous keratopathy, corneal perforations, corneal burns, corneal dystrophies, filamentary keratitis, indolent ulcers, neurotrophic keratopathy, post-refractive surgery, postcorneal transplant surgery, and trauma that prevents lid closure. Silicone hydrogel lenses are preferred over HEMA-based bandage lenses in these situations because they reduce hypoxic stress and seem to have less impact on corneal physiology. It is precisely because of these qualities that they have become the lenses of choice for many practitioners for use in piggyback systems for keratoconus patients.

While silicone hydrogels are becoming the lenses-of-first-choice for both routine daily and extended wear, extended wear candidates should meet certain criteria before they are permitted to wear their lenses on a flexible or continuous wear basis. First and foremost, they must be hygienic and compliant with the lens wear and care regimens. A red flag should go up when patients request extended wear lenses because they are lazy or afraid to touch their eyes. They must also be willing and able to return for regular follow-up. Extended wear candidates should not have GPC, blepharitis, or a previous history of corneal ulcers, and should have good tear quality and quantity. Patients who have a history of arthritis, thyroid disease, allergies, eczema, asthma, or atopic dermatitis should be monitored closely. Caution should be used for patients taking any medication that causes a reduction in tear output, since these patients tend to have dry or sensitive eyes, may react to preservatives in solutions, and can have a high rate of failure. Their work environment should be free of dust, debris, and chemicals, and they should not spend a lot of time in hot, dry, or windy environments that might cause lenses to shrink and tighten on their eyes.

Caring for Silicone Hydrogels

Recently, the interaction between silicone hydrogel contact lenses and lens care solutions has been a hot topic. All silicone hydrogels except PureVision® lenses are in FDA Group 1, low-water-content non-ionic lenses, the least likely group to be involved in solution reactions. PureVision® lenses are low-water-content ionic lenses and thus in FDA Group 3. However, silicone hydrogel materials may produce different corneal staining than that observed with HEMA-based materials. Various reports have noted differences in rates of toxic corneal staining with certain silicone hydrogel lenses and solution combinations, which has led some to recommend that a new FDA lens material group be established that would address the uniqueness of silicone hydrogel materials.

When silicone hydrogel lenses are used as an extended wear modality, few solution problems are seen, since the lenses are inserted in the eye directly from their blister packs and there is no need for nightly disinfecion. However, when silicone hydrogels are used for daily wear, problems with significant corneal staining and epithelial disruption have been observed with some lens/solution combinations. As with all solution-related staining, the highest level of staining is noted two to four hours after lens insertion and slowly diminishes as the day progresses. Most patients are asymptomatic and, since most daily wear follow-up visits are usually scheduled later in the day, the punctate staining may not be apparent by then. Instillation of high molecular weight fluorescein and use of cobalt blue slit lamp illumination with a Wratten #12 filter will make the staining easier to observe.

The reaction reaches its peak after two to four hours because the contact lenses selectively absorb and release preservatives from solutions. Once released, some agents, especially some formulations of solutions that contain PAPB (polyaminopropyl biguanide), PHMB (polyhexamethylene biguanide) can alter the corneal epithelium. A higher incidence of toxic corneal staining has been observed when PureVision® lenses are disinfected with Bausch & Lomb's ReNu® Multiplus and ReNu Multiplus® solutions or their generic equivalents. Toxic corneal staining is not seen when silicone hydrogels are disinfected with hydrogen peroxide systems and seldom seen when lenses are disinfected with Alcon's OPTI-FREE® EXPRESS® and OPTI-FREE® RepleniSH®, or CIBA Vision's AQuavit® MPS. According to Bausch & Lomb, the use of AMO's Ultrace® is contraindicated with PureVision® lenses since it may cause changes in the sagittal depth of the lenses. Clearly, it is prudent for wearers of silicone hydrogels to avoid products that are incompatible with their lenses and especially important for them to stay away from private label products, whose formulations are unknown or may change from time-to-time when a contract runs out and the retail chain chooses another supplier to manufacture its solutions.
Silicone hydrogel materials may also promote the formation of mucin balls, which appear as small, discrete spherical, translucent entities that vary in size and cause depressions in the ocular surface that resolve after lens removal. They are formed by the gradual movement of the lens across the tear film, which creates a shearing effect and causes small balls of tear film mucin, protein, and lipid to be rolled up as the patient blinks, trapping them against the corneal surface. Also, unlike HEMA-based lenses which can cause GPC or general CLPC (Contact Lens Papillary Conjunctivitis), silicone hydrogels are more likely to cause more of a local CLPC that is confined to a smaller area of the upper palpebral conjunctiva and resolves quickly by discontinuing extended wear, steepening the base curve, or changing the lens material.

Recently, a new clinical observation, conjunctival epithelial flaps (CEF), has been reported in wearers of silicone hydrogel lenses, again predominantly in those lenses with a high modulus. These flaps, which involve the splitting of conjunctival epithelium from its underlying tissue, have a jagged edge and are usually found in the inferior and/or superior quadrants about 0.5 mm away from the lens edge, marking the limits of its vertical movement. An incidence of about 3% in daily wearers and 37% in extended wearers has been reported, with most patients being asymptomatic. The condition is thought to be benign and resolves if lens wear is discontinued.

There have also been reports of refractive changes in wearers of high modulus silicone hydrogel lenses. The changes involve a hyperopic shift and can result in a reduction of as much as 2.00 diopters of myopia in some patients. It has been suggested that this may represent a reversal of myopic creep caused by corneal hypoxia from prior low Dk/t lens wear.

Most wearers of silicone hydrogel lenses will never experience any of these complications and will enjoy excellent visual acuity, good comfort, and the benefits of maximum oxygen transmissibility. Patients who do experience an adverse reaction related to high modulus materials can still remain in silicone hydrogels and be refit with lenses that have a lower modulus. Frequent use of rewetting drops may also help to limit the occurrence of some of these complications.

The future has finally arrived. It's now time to revisit the motto, "If it ain't broke, don't fix it," and upgrade patients to materials that will help to maintain ocular health over many years of contact lens wear.