Menicon PremiO MeniSilk & NanoGloss Technology

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The Company's pursuit of perfection

Spanning more than 60 years of history. Menicon's goal is to develop safe and effective contact lenses. For this purpose, the company's R&D departments have focused for decades on developing hyper-oxygen transmissible contact-lens materials, as it is well known that this is one of the most important features for safe contact-lens wear. In 1979, the founder of Menicon, Mr. Kyoichi Tanaka, patented the first silicone hydrogel (SiH) material in the world for use in the manufacture of contact lenses.¹In 2001, Menicon successfully launched the Menicon Z lens, which has the highest oxygen permeability of all gas-permeable lenses available worldwide and is the only one approved by the FDA for up to 30 days of continuous wear.

Menicon PremiO with MeniSilk and NanoGloss technologies. Menicon joins the few manufacturers in the world that distribute contact lenses made of this innovative material. The purpose of this article is to explain the unique features of the unrivalled Menicon PremiO silicone hydrogel contact lens.



Development of silicone hydrogel contact lenses

The wearing of hydrogel soft contact-lens has been associated with a number of changes to the ocular surface, many of which are related to hypoxia.² The introduction of silicone hydrogel contact lenses has

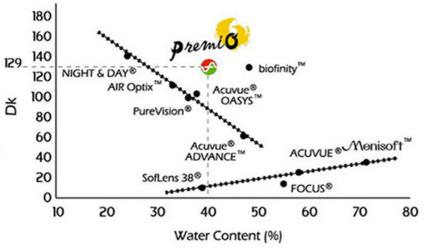
eliminated most hypoxia-related complications; ³⁻⁵ however, early generations of these lenses have not solved other complications. Adverse events associated with mechanical trauma, such as superior epithelial arcuate lesions, localized papillary conjunctivitis, and conjunctival epithelial flaps, occur at higher rates of incidence than those reported with hydrogel contact lenses; this may be a result of the lens' modulus of rigidity as well as inadequate lens-fitting characteristics.^{6,7} Early generations of these lenses were developed to meet the minimum levels of oxygen transmissibility required to avoid hypoxia during continuous wear of contact lenses.^{8,9} However, this has been pursued at the expense of increased modulus of rigidity and reduced wettability, water content, and lubricity. 10-12 Furthermore, seven years after the launch of these lenses, it is well know that continuous wear of silicone hydrogel lenses have shown better comfort rates, lower incidences of mechanically-related adverse events, decreased lens surface deposition, and increased lens wettability compared to first generations of SiH contact lenses.^{6,7} Hypoxia being virtually eliminated with SiH contact lenses, the other issue of special relevance for contact lens users is comfort. In 72% of cases, discontinuation of contact-lens wear occurs as a result of poor comfort,¹⁴ with dryness being the most commonly reported symptom.¹⁵⁻¹⁷ Symptoms of discomfort and dryness have been related to lens movement and edge profiles; ^{7,18} lens dehydration; ¹⁹ protein and lipid deposition;²⁰ high modulus of rigidity; poor wettability and lubricity; ^{21,22} and solution toxicity.^{23,24} Furthermore, initial contact-lens comfort during trial fitting has been shown to greatly influence patients' perception of contact lenses, and this might have an effect on the ultimate success of contact-lens wear. ^{25,26} The relatively stiff nature of SiH contact lenses compared to conventional hydrogel lenses suggests that the lens-to-cornea curvature relationship may be more critical when fitting the former lens than with the latter.²⁷

Menicon's requirements for the development of Menicon PremiO

The Menicon PremiO with MeniSilk and NanoGloss technologies was developed by taking into account the problems found with early generations of SiH contact lenses. The properties of this advanced lens are possibly the most balanced of all SiH contact lenses currently available on the market.

OXYGEN PERMEABILITY

In material science, the gas permeability of a membrane is defined as the product of the material diffusivity of the gas (D) and the solubility (S) of the gas within the membrane material. In the contact-lens field, solubility is normally represented as "k," so permeability is known as "Dk." However, the amount of oxygen that reaches the cornea through a manufactured contact lens does not only depend on the material, but also on the lens thickness. For example, if two lenses are manufactured with the same material, but one is two times thicker than the other, the amount of oxygen that reaches the cornea through the thicker lens would be half of that which passes through the thinner lens. This is known as oxygen transmissibility and is represented by the product of diffusivity of the material divided by the lens thickness (Dk/t).¹² Holden and Mertz and Harvitt and Bonanno estimated that contact lenses must be manufactured with oxygen transmissibility values of 87 and 125 units, 33,34 respectively, to prevent hypoxia during closed-eye conditions. Although extended wear of contact lenses still represents a small amount of the contact-lens wearing population, it is believed that a substantial number of wearers take naps while wearing their lenses.¹³ Furthermore, the oxygen transmissibility of contact lenses is normally measured through the centre of a -3.00D lens. However, the thickness profile of a contact lens changes from the centre to the periphery of the lens. Negative-powered lenses are thinner in the centre than in the periphery, whereas the opposite occurs with positive-powered lenses. Menicon PremiO, with an extraordinarily high oxygen transmissibility of 161 units, prevents hypoxia across all parts of the lens and for all lens powers, regardless of whether lenses are worn under open- or closed-eye conditions (Figures 1 and 2).



 $10^{-9}(\text{cm/sec}) \cdot (\text{mLO}_2/(\text{mL} \times \text{mmHg}))$

Figure 1 Relationship between oxygen permeability and water content for different hydrogel and silicone hydrogel contact lenses.

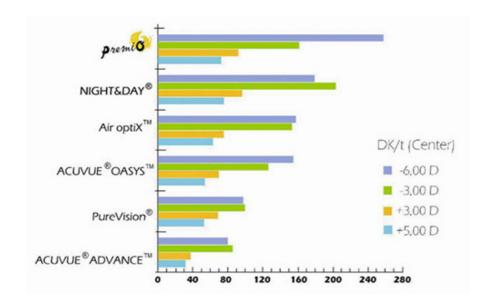


Figure 2

 $\mathsf{Oxygen}\xspace$ transmissibility (Dk/t) of different silicone hydrogel contact lenses for different lens powers.

WATER CONTENT

The transport of fluid and ions through contact lenses is crucial for the provision of essential nutrients and the removal of waste products and debris. The flow of water through the lens is also necessary for on-eye lens movement, comfort, and wettability. With hydrogel lenses, as the oxygen permeability increases, water content also increases. However, the opposite occurs with SiH contact lenses. The Menicon PremiO lens has been developed with high water content, while also maintaining a well-balanced modulus of rigidity and oxygen permeability (Figure 1).

SURFACE PROPERTIES

The surface characteristics of a contact lens govern the interaction of the lens with the tear film and ocular structures. Therefore, the nature of the material surface can have a vital effect on comfort, wearing time, and clarity of vision. In order to achieve this, the NanoGloss technology of the Menicon PremiO lens provides a highly controlled, smooth surface reproducibility that delivers unmatched levels of comfort throughout the entire day.^{28,29} Atomic Force Microscopy images support the production of a smooth surface in the Menicon PremiO lens compared to early generations of plasma-treated or – coated SiH lenses (Figure 3).

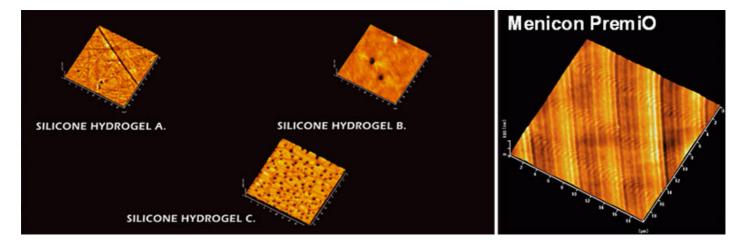
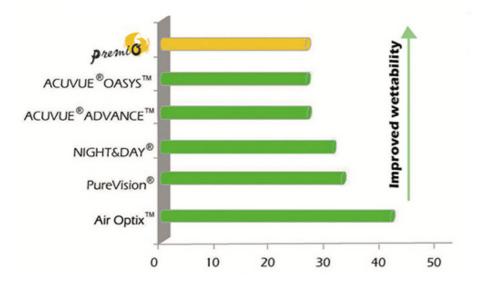


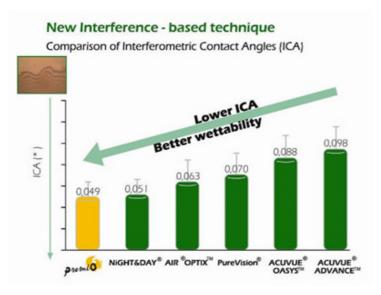
Figure 3

Atomic Force Microscopy images ($20x20 \ \mu$ m) of different silicone hydrogel contact lenses showing the smoothness of the Menicon PremiO vs. other silicone hydrogel lenses.

IMPROVED WETTABILITY

The surface wettability of a contact lens is of key importance in regard to maintaining stable vision, comfort, and the biocompatibility of the lens with the ocular structures. Furthermore, contact-lens surfaces with poor wettability also have a greater tendency to attract deposits. Traditional methods of measuring wettability in-vitro involve the measurement of contact angles. ³⁰ Recently, advanced interference-based techniques of measuring wettability have been proposed.³¹ During the polymerization process, the MeniSilk technology provides Menicon PremiO lenses with an advanced hydrophilic molecule that provides wettability levels never seen before with any other SiH contact lens (Figures 4 and 5).







MODULUS OF RIGIDITY

With the introduction of SiH lenses, the rigidity modulus of the material has received increasing attention in the contact-lens field. This describes how well a material resists deformation and it is defined by measuring the force-per-unit required to compress the material by a given amount.³² First-generation silicone hydrogel contact lenses are associated with higher incidence rates of mechanical-related adverse events, and this might be partly related to their high modulus of rigidity.^{6,7} Although contact lenses with a low modulus of rigidity are associated with a lower incidence of mechanically-related adverse events, the challenge for the contact lens manufacturer concerns the development of contact lenses with an intermediate modulus of rigidity that not only prevent mechanical-related adverse events, but also provide adequate lens-handling and -fitting characteristics. Menicon PremiO with MeniSilk and NanoGloss has a well-balanced modulus of rigidity that minimizes mechanical-related adverse events while maintaining excellent handling and fitting characteristics.

CLINICAL PERFORMANCE

Clinical studies on the Menicon PremiO lens have detected remarkable clinical performance and comfort levels.^{28,29} Additionally, the availability of this lens in two different base curves (8.3 and 8.6 mm) allows for better lens-fitting than SiH contact lenses available in just one single base curve do. The latter is of special relevance, taking into account the intimate lens-to-cornea curvature relationship observed with SiH lenses manufactured with a relatively high modulus of rigidity. A previous study found that when two base curves are available for a silicone hydrogel lens, approximately 74% of subjects enjoy better performance with the flatter base curve, whereas 24% enjoy better performance with the steeper base curve.²⁷

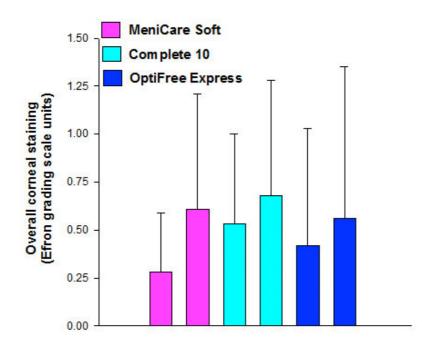
The Menicon PremiO lens, available in two different base curves, affords contact-lens practitioners a wider choice in their search for a better lens fit for a broader range of patients. Additionally, the

biweekly replacement of the lens provides a safer modality of lens wear than those lenses with longer replacement cycles do.

SOLUTION COMPATIBILITY

Multipurpose solution contact lenses should provide a broad spectrum of disinfection against pathogenic microorganisms without inducing toxic effects in the ocular structures. Several toxic reactions on ocular structures have been identified when certain SiH contact lenses are used with specific contact-lens solutions.³⁵ These toxic reactions might occur when antimicrobial agents come in contact with the ocular structures.₃₆ Typically, toxic effects induced by contact-lens care regimens include signs of corneal staining, limbal and conjunctival hyperaemia, as well as a variety of other symptoms. Additionally, it has been found that the higher the toxicity of the SiH lens/multipurpose solutions combination, the higher the incidence of corneal infiltrative events.³⁷

A compromised corneal epithelium is more prone to pathogenic microorganism adherence³⁸ and, thus, to incidences of severe adverse ocular events such as microbial keratitis, which in severe cases could induce a permanent reduction of visual acuity.³⁹ Based on all of the above, the use of a SiH lens compatible with the different multipurpose solutions currently available on the market is of key importance. The Menicon PremiO lens has shown excellent levels of compatibility with multipurpose solutions formulated with both polyhexamethylene biguanide (PHMB) and polyquad as disinfecting agents.⁴⁰





Conclusions

The Menicon PremiO with MeniSilk and NanoGloss technologies is the latest and most advanced SiH contact lens on the market. This lens has been developed taking into account the problems found in early generations of SiH contact lenses. Its well-balanced combination of material and surface properties, as well as its remarkable compatibility with different contact-lens care regimens, provide excellent clinical performance and extraordinary levels of comfort.

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