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SIHY DAILY DISPOSABLES

The Benefits of Silicone Hydrogel Daily Disposable Lenses

A look at why silicone hydrogel daily disposable lenses are our preferred option for daily wear.

BY DESMOND FONN, MOPTOM, & DEBORAH SWEENEY, PHD

This article is written as a tribute to Professor Brien Holden for the contribution that he made toward improving the physiological response of contact lens-wearing eyes through the development of silicone hydrogel contact lenses. The realization that hydrogel lenses limited oxygen transmission—resulting in unacceptable levels of corneal swelling if the lenses were worn overnight and, in some cases, producing noticeable corneal edema even when worn during the day—came from the Holden and Mertz (1984) paper on critical oxygen transmission to avoid corneal swelling.

Silicone hydrogel (SiHy) contact lenses were introduced almost two decades ago. At that time, it was estimated that there were approximately 70 million contact lens wearers worldwide. Since then, the number of wearers has doubled, and a sizeable majority now wear SiHy lenses, resulting in a steady and noticeable decline in the number of hydrogel wearers. A survey conducted in 2014 by the International Consortium (Morgan et al, 2015) illustrates that point. Although, according to this survey, SiHy lens usage varies considerably around the world. In the United States, Canada, Australia, and the United Kingdom, four to six times as many patients were fitted with SiHy lenses compared to hydrogels in 2014, and in each of those countries, SiHy daily disposable (DD) lenses were also prescribed in greater frequency compared to hydrogel DD lenses.

SiHy materials were developed primarily for continuous wear, with the hope that their high oxygen permeability would minimize or eliminate corneal infections. Although this expectation did not eventuate, the high oxygen transmission of the materials has essentially eliminated hypoxia-related consequences seen with hydrogels when used for either extended wear or daily wear. Today, up to 90% of SiHy contact lenses are prescribed for daily wear (Morgan et al, 2015), and 87% of two-week and monthly replacement reusable lens fits in the United States are with SiHy contact lenses (GfK Q4 2014 data).

When the first SiHy DD lens was introduced in 2008, it was heralded as a breakthrough in technology. Since that launch, new SiHy DD lenses have been introduced in sphere, toric, and multifocal designs, resulting in a considerable increase in the use/prescribing of DD lenses made from SiHy materials.

The Cornea's Oxygen Needs

Shortly after hydrogel lenses were developed, it became obvious that these lenses caused hypoxic sequelae (Polse et al, 1975; Harris et al, 1975). Attempts to alleviate these reactions by increasing the water content and/or decreasing the thickness of hydrogel lenses did not increase oxygen transmission enough to eliminate hypoxia. The seminal study by Holden and Mertz in 1984 determined the critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses: values of 87 x 10^{-9} oxygen transmissibility (Dk/t) for overnight wear and 24 x 10^{-9} for daily wear. This study was limited by the lenses that were available at that time; only one high-Dk lens (silicone elastomer) and one ultra-thin, low-water-content hydrogel lens (20µm) were included in the study.

With the development of SiHy materials, a much greater range of Dk/t lens values became available, resulting in a considerably higher estimate of the Dk/t (average) required to produce the same level of overnight

corneal swelling as that occurring in a non-lens-wearing eye (Holden et al, 2012).

These studies only address the needs of corneal oxygen to avoid corneal swelling for an average eye. While the Holden and Mertz daily wear benchmark has not been challenged, the criterion does not address the potential chronic effects of exposing corneas to a lower level of oxygen, nor does it address individuals' corneal needs for oxygen. We may assume that some patients who exhibit high levels of corneal swelling (Moezzi et al, 2006) will develop signs and symptoms of hypoxia when wearing contact lenses with the 24 x 10^{-9} level of Dk/t even though this Dk/t meets the criteria for daily wear.

Consequences of Oxygen Deficiency

The clinical effects of wearing contact lenses that limit oxygen supply have been extensively reported. Most corneal structures and functions are affected. The following is a list of clinically observable hypoxia-related responses that typically occur with low-Dk/t hydrogel contact lenses:

• ***Corneal Swelling*** This invariably occurs after overnight lens wear, but it can also occur after approximately four hours of daily wear; it is an acute response. The current DD hydrogel lenses meet the Holden and Mertz criteria of 24 x 10^{-9} Dk/t, so it is unlikely that more than 5% to 10% of a sample will exhibit corneal swelling with these lenses simply based on the tail of a normal distribution curve. The clinical manifestation of corneal edema will be vertical striae at the posterior central stroma if the swelling is 5% or more. However, chronic edema below clinically detectable levels may cause other long-term changes.

• ***Epithelial Microcysts*** Microcysts usually develop due to chronic hypoxia and are more noticeable and frequent with extended wear (Holden and Sweeney, 1991; Keay et al, 2001). In addition, epithelial thinning also occurs as a chronic response and is more prevalent with extended wear (Holden et al, 1985).

• ***Refractive Error Changes and Corneal Distortion*** Chronic hypoxia from hydrogel lenses has also been associated with increasing myopia and, to a lesser extent, with corneal curvature changes (Dumbleton et al, 1999; Jalbert et al, 2004). Both of these chronic effects are generally associated with extended wear due to the level of hypoxic stress. In daily wear, these phenomena were reported to occur with thick, low-water-content hydrogel lenses (Grosvenor, 1975), but there is a risk of some patients developing these changes with current reusable and DD hydrogels after 10 to 15 years of wear, and the risk increases with higher-power (thicker) lenses. In a recent study of retrospective chart reviews, Kinoshita et al (2015) found that the rate of increase in minus power (myopia) was significantly greater with reusable and DD hydrogel lenses compared to with SiHy lenses.

• ***Limbal Hyperemia*** Increased limbal hyperemia is probably the most easily recognized change from soft lens daily wear, with overwhelming evidence that it is more severe in response to hydrogel lenses (Papas et al, 1997; Maldonado-Codina et al, 2004; Dumbleton et al, 2006). This reaction is undoubtedly due to the reduced oxygen transmission of hydrogel lenses. Not only is it observed by clinicians, but patients also sometimes self-report this observation. While this is a clinically unappealing sign of contact lens wear, the greater concern is that it is a precursor to corneal vascularization (Cogan, 1948; Collin, 1973) and an indicator of chronic hypoxic stress. Sweeney et al's study (1992) is an excellent example of comparing long-term wearers of hydrogel and GP lenses to a control group of spectacle wearers. The hydrogel wearers were correctly identified in 85% of the cases based on their levels of limbal hyperemia.

• ***Corneal Vascularization*** This is a grave concern because of its permanence. Vessels may empty when the hypoxic stimulus (i.e., a low-Dk/t hydrogel lens) is removed, but the vessels refill with return of lens wear (McMonnies, 1983; McMonnies et al, 1982). This is a response to chronic hypoxia induced by a low-Dk/t lens. However, this is of less concern in patients who wear hydrogel contact lenses on a part-time basis for less than all-day wear. The risk of vascularization is much greater with higher prescriptions (greater thickness), all-day wear, and long-term wear. However, in one study, researchers found that 30% of patients wearing low-Dk frequent replacement hydrogel lenses developed corneal neovascularization (Nomura et al, 2004). There is compelling evidence that SiHy lenses do not induce and, in fact, minimize corneal vascularization (Dumbleton et al, 2001; Fonn et al, 2002; Bergenske et al, 2007).

In addition, other hypoxia-related corneal changes may occur with wearing low-Dk/t hydrogel lenses: endothelial polymegethism and pleomorphism, corneal exhaustion, stromal thinning, increased epithelial fragility, decreased corneal sensitivity, and reduced epithelial adhesion. While there is low risk of all of these complications with current hydrogel DD lenses, they can be avoided with the use of SiHy lenses. Despite these rare occurrences, the risk is high for both limbal hyperemia and eventual vascularization, especially for patients who may be physiologically vulnerable. That includes those who exhibit higher levels of corneal swelling in provocative testing. Horton et al (1989) found that older people exhibit greater corneal swelling compared to younger people after three hours of eye closure with or without a contact lens, and Polse et al (1989) demonstrated that corneal hydration control decreases with age. Greater corneal swelling also occurs in those who have more demanding prescriptions such as high refractive errors, astigmatism, and some types of presbyopic corrections that result in thicker lens designs, which have an effect on transmissibility (Lira et al, 2015).

Oxygen Transmission Similarities Between DD and Reusable Hydrogel Lenses

Morgan and Efron (1998) published the Dk/t (average) of a series of hydrogel contact lenses. The higher-water-content lenses (~60%) had Dk/t values that ranged from 19.6 to 28.7. Manufacturers' listed values of current DD –3.00D hydrogel lenses include only central Dk/t (25.5 to 28); these values would be marginally lower if average thickness is included in the calculation, but they are essentially the same as the reusable hydrogel equivalents. All of these DD hydrogel lenses meet the Holden and Mertz daily wear criterion of 24 x 10^{-9} for zero lens-induced corneal swelling during open-eye conditions; but even at that level, it is anticipated that some patients will be subjected to hypoxia, which may result in chronic ocular changes. The message is clear—the vast majority of reusable lenses prescribed are SiHy lenses primarily because of high oxygen transmission, and the tendency appears to be the same for DD lenses, as it should be.

Oxygen Transmission and Eye Appearance

Some classic studies were conducted to determine whether oxygen transmission had any influence on the appearance of the eyes. As mentioned previously, clinicians were able to correctly identify long-term hydrogel lens wearers 85% of the time based on the limbal hyperemia appearance (Sweeney et al, 1992). Covey and colleagues (2001) conducted a similar study to determine whether subjects wearing SiHy lenses could be differentiated from non-contact-lens-wearing subjects. The results revealed that there were no observable hypoxia-associated effects in SiHy lens-wearing eyes.

Morgan and colleagues (2013) reported on a study comparing neophytes who wore DD SiHy lenses to non-wearing controls. After one year, bulbar and limbal hyperemia were clinically equivalent between the SiHy DD wearers and the non-wearing controls.

DD Lenses and Compliance

DD lens wearers are more compliant with their lens replacement frequency compared to those who are supposed to replace their contact lenses at two weeks or one month (Dumbleton et al, 2010; Dumbleton et al, 2009). Despite this, some DD lens wearers are noncompliant in other ways: 9% of DD lens wearers reused their lenses, 75% napped in their lenses, and 28% wore their lenses during sleep (Dumbleton et al, 2013). Chalmers and colleagues (2012) reported similar results.

Dumbleton and colleagues (2013) reported in their multi-country survey that more than half of the respondents wear their lenses every day and approximately 15 hours per day. These patients would benefit in the long term from wearing SiHy DD lenses by eliminating the consequences of chronic hypoxia from low-Dk hydrogels.

The Relative Merits of Hydrogel and SiHy Materials for Use in DD Lenses

The modulus of hydrogel materials is lower compared to that of some SiHy lenses (Young et al, 2011), and therefore hydrogels should be more comfortable. However, there is no scientific evidence for general support of hydrogel lens comfort being better than that of SiHy lenses. Some studies have claimed an improvement in comfort with SiHy reusable lenses compared to patients' previous hydrogel experience (Dumbleton et al, 2006; Dillehay and Miller, 2007; Riley et al, 2006). However, these study designs did not include experimental controls.

The most comprehensive review of contact lens discomfort has been undertaken by the Tear Film and Ocular Surface Society's International Workshop on Contact Lens Discomfort. In essence, the review was inconclusive about the etiology of contact lens discomfort; it stated that patient-reported overall comfort was essentially similar among lens materials (hydrogels and silicone hydrogels) (Jones et al, 2013). Guillon's (2013) review of the subject came to the conclusion that there is no difference in comfort between SiHy and hydrogel lenses worn on a daily-wear basis. However, one study has shown that MyDay (CooperVision) SiHy DD lenses had significantly higher overall comfort and less dryness compared to 1-Day Acuvue Moist (Johnson & Johnson Vision Care, Inc.) hydrogel DD lenses (Shah et al, 2013). The supposition is that lens wettability may be indirectly related to comfort through the association with coefficient of friction. While these factors apply to both hydrogel and SiHy lenses, it appears that in-vivo wettability of SiHy and hydrogel lenses is similar (Keir and Jones, 2013).

The incidence of corneal infiltrative events is reported to be approximately two times greater with daily wear of reusable SiHy lenses than with hydrogels (Chalmers et al, 2012; Radford et al, 2009). There is only one report that has studied the rates of adverse events with hydrogel and SiHy DD lenses: Chalmers and colleagues (2015) reported that there was no significant difference in the rate of adverse events for the two lens types when used on a DD basis (0.4% per year for SiHy lenses and 0% per year for hydrogels). These rates are significantly lower compared to the rates reported for reusable lenses.

The tear protein lysozyme, which has beneficial anti-bacterial properties (Selinger et al, 1979), appears to be taken up in greater amounts on Group IV (high water, ionic) hydrogel lenses (Jones et al, 2015). It has been hypothesized that lysozyme in its natural form may have a protective effect. However, an association of lysozyme and decreased adverse events has not been demonstrated.

Conclusions

Numerous studies have provided evidence that all hydrogel contact lenses cause hypoxia that results in some unacceptable and sometimes irreversible corneal and ocular changes. The risk of occurrence is extremely high with hydrogel extended (overnight) wear, but with current reusable and DD hydrogel lenses, the risk is considerably less and only likely with chronic use. This risk can be avoided by prescribing SiHy DD contact lenses.

Sentiment has been expressed that SiHy lens materials should be routinely prescribed over traditional hydrogel lenses for daily wear use to avoid clinical sequelae due to corneal hypoxia (Morgan et al, 2010; Brennan and Morgan, 2005; Holden et al, 2006; Brennan and Morgan, 2009). Given the availability of SiHy DD lenses on the market today, this is especially sensible for patients who have greater oxygen demands and who have to wear thicker lenses because of higher and more complex prescriptions.

Practitioners will always select the “best” lens for each patient. Based on current fitting trends, it will most likely be a DD lens dependent on prescription. Irrespective of prescription, as SiHy DD lenses can meet all of the other requirements of a “best” lens including comfort, vision, and ease of handling, we believe that it should be the material/lens of choice in preference to a hydrogel. **CLS**

For references, please visit ***www.clspectrum.com/references*** *and click on document #241.*

Dr. Fonn is distinguished professor emeritus, School of Optometry and Vision Science, University of Waterloo, Ontario, Canada. He is also a consultant/advisor to CooperVision.

Professor Sweeney is Pro vice-chancellor Research and Innovation at the Western Sydney University. Her major research interests include corneal physiology, effects of contact lens wear and refractive surgery on the cornea, and alternate forms of vision correction.

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