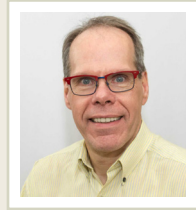


Contact Lens Update

CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Management of ocular allergy itch with an antihistamine-releasing contact lens

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It is difficult to predict the future for contact lenses. However, about a decade ago, Nathan Efron attempted this feat by proclaiming the end of the gas permeable (GP) lens era in the years to follow.¹ This statement was never realized, and to the contrary, there has actually been growth of the rigid contact lens market, mostly driven by scleral lenses. Today, GP lenses are far from extinct, accounting for a small, but growing proportion of the market, recently boosted even more by the use of orthokeratology (OK) lenses for myopia management.^{2, 3}

There is a growing number of eyecare practitioners (ECPs) who are embracing specialty lenses. The prevalence of corneal ectasias like keratoconus has increased significantly,⁴ as its detection has become easier with the increased use of corneal topography. Dry eye disease affects large numbers of people, with more than 16 million estimated to be diagnosed in the US alone.⁵ A significant portion of this dry eye group are also soft contact lens wearers seeking better options for their chronic vision and lens tolerance issues.⁶ The use of scleral lenses in these situations can provide ECPs with a valid, safe and clinically proven treatment option to help their patients.⁷ Furthermore, the current concern about myopia, its prevalence and the risk factors associated with this disease⁸ has resulted in ECPs recognizing the problem and endorsing myopia management,⁹ one option of which is OK.¹⁰ Considering the fact that 50% of the world's population is estimated to be myopic by the year 2050,¹¹ the use of OK lenses is likely to increase significantly in the years to come, due to its clinically proven efficacy in controlling myopia progression.¹² For these reasons, the future of the GP lens market seems to be brighter than ever.

Both scleral and OK lenses are made from the same types of GP materials, which in all cases should offer a high amount of oxygen permeability to alleviate any adverse physiological effects on the eye. However, how high should the material Dk be? Do we have the right tools available to optimize lens outcomes with our patients?

Scleral lens induced hypoxic stress

Current research establishes that scleral lenses generate chronic hypoxic stress during all wearing hours, if they are fitted with a relatively thick profile compared with corneal GP lenses (>250 μm) and with a high fluid reservoir behind the lens (>200 μm).¹³ This hypoxic stress appears rapidly after lens application (45-60 minutes) and remains at the same level (2-3% swelling) until the lens is removed from the ocular surface.¹⁴ In cases of hypoxia, all of the corneal layers are affected. Epithelial cells are deprived 30% of their normal oxygen consumption when lenses are fitted with higher tear reservoir thicknesses.¹⁵ The stroma is more affected than other layers and swells proportionally to the level of hypoxic stress generated.¹⁴ Finally, endothelial blebs were recently identified in scleral lens wearers as a consequence of early hypoxia and hypercapnia.¹⁶

The hypoxic stress comes from the fact that scleral lenses and their fluid reservoir act like reservoirs in a series. Oxygen from the atmosphere, having passed through the lens material, then has to dissolve in the tear reservoir to reach the cornea. The permeability (Dk) of the lens material varies from 100 to 200 Dk, and the

fluid Dk is estimated at around 80, which further limits oxygen delivery to the cornea. The Harvitt-Bonnano¹⁷ criteria is established on the basis of this permeability but divided by the surface thickness, t , of the lens (Dk/t). Consequently, oxygen transmissibility, Dk/t , of the lens is influenced by the lens permeability (Dk) and lens thickness (t). Dk/t of the fluid reservoir is not influenced by the nature of the fluid instilled in the reservoir (saline or artificial tears, drops or gel) but its thickness.

Three parameters can, in theory, be manipulated to influence the system overall Dk/t : the lens thickness, the reservoir thickness, and lens material's permeability.

Playing with lens thickness

Lens thickness is determined by the power of the lens and the manufacturing process. In general, if the power of the lens cannot be modified, the lens thickness, which is dictated by the manufacturing process, may be modifiable. Manufacturers recommend producing scleral lenses from 300 to 400 μm thick on average. Excluding certain exceptional cases, they are reluctant to go thinner, assuming that the lens will break or warp during blinking, which is actually not true.¹⁸ For example, a -3.00D lens, made 350 μm thick, can certainly be improved and manufactured at a thickness of 225 μm , providing the lens remains aligned with the conjunctiva in all quadrants. On the other hand, sometime the required prescription of the lens dictates the thickness, for example it is difficult diminish the thickness of a +10.00D lens thinner than 450 μm .

Looking at lens material permeability

Next comes lens permeability. In the last year, two new GP materials were launched that may be useful in the fitting of scleral lenses. These two new materials (Acuity 200, Acuity Polymers and Infinite 200, Contamac) aim to provide a better environment for the cornea by providing more oxygen. Looking at many other typical fitting guides, manufacturers often recommend DK 100 for their material of choice. Using the following equation¹⁹:

$$\frac{Dk}{t_{scl}} = \frac{1}{t_1/Dk_1 + t_2/D}$$

it is easy to demonstrate that migrating from a 100 to 200 Dk material will improve the system oxygen permeability by 60 to 100%. In some cases, especially for fragile ocular surfaces such as a post-graft cornea, this may represent the difference between a successful fit and a failure that could lead to graft rejection or neovascularization.²⁰

In order to test the clinical difference between Dk 200 vs Dk 100 lenses, a pilot study was conducted at the University of Montreal. The results, published at the recent GSLS 2020 meeting,²¹ indicate a significant difference in the clinical responses between materials. The Dk 200 lens generated trace amounts of edema, whereas 3-4 % edema was observed in the central cornea when using the Dk 100 material.

What about the reservoir?

The nature of the fluid in the reservoir does not influence oxygen permeability. Saline solution or artificial tears, in gel form or not, does not influence oxygen permeability, all of them being around 80 Dk. Reservoir thickness is thought to have a higher influence. Thicker reservoirs are associated with deprived oxygen delivery and, consequently, higher rates of hypoxic stress.²²

Authors recommend limiting reservoir thickness to around 250 to 300 μm at most, assuming that the reservoir thickness will be further reduced during lens wear as the lens settles back against the cornea.^{23, 24} This goal leaves 150 to 200 μm after lens stabilization on the ocular surface, which represents the optimal thickness to alleviate hypoxia. Some practitioners may argue that a limited reservoir may favor lens warpage or induce astigmatism. This is not true if the lens fit is well aligned with the conjunctiva in every quadrant.

In summary, increasing material Dk to 200 and lowering the initial tear reservoir thickness are the most achievable ways to increase oxygen delivery to the cornea and to limit hypoxic stress.

Extended-wear needs oxygen too

More than 700 children are seen on a regular basis for myopia management at the Clinique Universitaire de la Vision of the Université de Montréal. Of this group, 75% are equipped with GP OK lenses to manage their refractive error. OK lenses are designed to be worn overnight. Consequently, we must consider them as extended-wear lenses. The oxygen requirement to keep the cornea healthy with this kind of wearing modality is higher compared to daily wear, with the Harvitt-Bonanno criteria increasing to 120 Dk/t for extended-wear modalities.¹⁷ This means that lenses should be manufactured with a Dk of at least 150, considering the thickness of a typical GP OK lens varies from 15 to 25 μm . In the case of a small GP lens, some oxygen can also come from the tear exchange, a phenomena which does not exist in scleral lenses. However, OK lenses are worn under closed eye conditions with no blinking and very limited tear exchange. This puts even more importance on the appropriate Dk material to alleviate hypoxic stress to the cornea.

Another important factor to consider is the corneal response to OK lens wear, which is possibly influenced by the levels of available oxygen and potential hypoxia.²⁵ A swollen corneal epithelium seems to be less 'moldable' and it is expected that the same lens, with the same design, will generate less corneal power modification (mid-peripheral thickening) if the corneal epithelium is under hypoxic stress compared to a normal tissue. To test this hypothesis, another pilot study is actually conducted at the University of Montreal. A customized lens design was manufactured from a regular Dk 120 material, and a second pair was produced with a 200 Dk material. The preliminary results indicate that the same lens design applied to the same cornea generates more corneal power modification with the higher Dk lens. On average, the lens with a Dk of 200 led to an overcorrection of +0.50D after 1 month of wear. This may indicate that higher Dk materials, which do not generate hypoxic stress, provide better outcomes compared to regular lower Dk lenses. This result also indicates that the algorithm to design OK lenses should be modified whenever higher Dk materials are used, in order to avoid over-correction. At the time of writing, analysis of the full results is not completed and must be confirmed.

Impacts of higher Dk on vision and comfort

In the past, the use of higher Dk GP materials has been linked to improved visual acuity and lens wettability, as well as superior patient comfort.²⁶ In the aforementioned studies and based on the clinical experience we have with these new 200 Dk materials, there was no compromise in visual acuity, and the wetting angle of both materials remained very low, which, it felt, helps to enhance the patient's comfort. In fact, the property of low wetting angles makes these materials potentially suitable for use in patients with marginal or confirmed dry eyes.

Conclusion

Oxygen delivery to the cornea is crucial in order to keep this fragile tissue healthy. In the world of soft lenses, the silicone hydrogel revolution was driven by the need to preserve healthy corneal physiology. The same approach should be applied to scleral and OK lenses. Practitioners should aim for the highest Dk material whenever considering scleral or OK lenses for their patients. So do we have the right tools to hand? The answer is most likely yes, at least for newer materials, which offer high permeability and low wetting angles.

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