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Predicting estimates of oxygen transmissibility for scleral lenses

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ABSTRACT

Background/Purpose: Although scleral contact lenses are prescribed with increasing frequency, little is known about their long-term effects on ocular physiology. The main goal of this paper is to predict values of oxygen transmissibility of scleral lens systems by applying the concept of resistors in series to parameters characteristic of current scleral lenses. A second aim is to find the maximal lens and post-lens tear layer thickness combinations above which hypoxia-induced corneal swelling would be found.

Methods: Theoretical calculations were used to predict the oxygen transmissibility of scleral lens systems, considering several material permeabilities (*Dk*s 100–170), varying lens thicknesses (250–500 μm), the known tear permeability (*Dk* of 80) and expected post-lens tear layer thicknesses (100–400 μm). The Holden–Mertz *Dk*/*t* criteria of 24 Fatt units for the central cornea and the Harvitt–Bonanno criteria of 35 Fatt units for the limbal area were used as reference points.

Results: Our calculations of oxygen transmissibility, with varying tear layer and lens thicknesses, ranged from 10 to 36.7 at the scleral lens centers and from 17.4 to 62.6 at the peripheries. Our calculations of maximum central lens thicknesses show a practical range of 250–495 μm, in conjunction with a post-lens tear layer thickness of 100–250 μm.

Conclusion: Our computations show that most modern scleral lenses, with recommended fitting techniques, should lead to some level of hypoxia-induced corneal swelling. Recommendations are made to minimize hypoxia-induced corneal swelling: highest *Dk* available (>150) lens with a maximal central thickness of 250 μm and fitted with a clearance that does not exceed 200 μm.

1. Introduction

Over the past five years, there has been an increasing use of rigid, gas-permeable scleral lenses (15–24 mm in diameter) [1]. Not only are scleral lenses highly effective in correcting corneal irregularities [2], but they are also considered in the treatment of ocular dryness and other ocular surface diseases [3]. In addition, scleral lenses are useful to effectively address refractive issues such as high ametropia and moderate to severe astigmatism.

While scleral lenses may offer comfort and provide good visual acuity, little is known about long term effects of their wear on ocular health. The lack of knowledge regarding this impact is unfortunate, as many scleral lenses are being applied onto corneas that are already compromised. There is also a lack of consensus on the optimal amount of lens-cornea clearance. Some scleral lenses are fitted with low clearance (50–100 μm),[1] others with moderate (100–250 μm),[2] while larger lenses are fitted with higher one [4] (up to 400 μm),[3] depending on the fitting philosophy adopted. Other factors to consider are central and peripheral lens thicknesses which relate to the lens design and lens parameters (power, diameter, optic zone, etc.). All of these elements, in addition to the material oxygen permeability, affect oxygen transmissibility to the cornea and, hence, corneal physiology.

Reduced oxygenation of the cornea (hypoxia) triggers tissue swelling which may be seen clinically as corneal edema, becoming more visible with hypoxia severity and chronicity [5]. Hypoxia also promotes neovascularization, loss of transparency of the corneal tissue and may affect cell metabolism. Oxygen delivery under the lens periphery is particularly important for the limbal stem cells [6] because of limited lateral diffusion of oxygen within the cornea [7]. If limbal stem cell deficiency develops, which may be of particular concern for some compromised corneas that are fitted with scleral lenses, corneal re-epithelialization by the neighboring conjunctiva can lead to pain, poor vision, and non reversible opacification of

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[1] Ex: corneo-scleral lenses (SO$_2$Clear-Art Optical); Maxim Lens (Acculens).

[2] Ex: One Fit mini scleral (Blanchard Labs), mini-scleral Perimeter (Essilor), Valley 15 (Valley Contax).

[3] Ex: Jupiter 18.2 mm (Medlens, Chicago); ICD – Irregular Corneal Design lens (Pat Caroline).

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the corneal tissue [8]. Finally, hypoxia has been linked to contact lens intolerance and to an increased risk of developing infections and inflammatory reactions [9]. Such adverse effects were reported following the wear of scleral lenses made from materials with low to moderate oxygen transmissibility [10].

Tear fluid exchange under scleral lenses, contrary to that with smaller PMMA and rigid gas-permeable corneal contact lenses, can be limited and likely cannot compensate for any potential lack of oxygenation through the lens/tear layer series [11]. Ventilated scleral lenses can increase tear fluid exchange but even with this feature added, they can remain almost sealed by the way in which the scleral lens aligns with the conjunctiva [12,13]. Inhibition of regular tear exchange owing to a tight lens-to-sclera/conjunctiva relationship seems to be an increasing issue with larger lens size, as has been shown with >15-mm diameter non-toric scleral lenses resting on a highly toric sclero-conjunctival surface [14].

1.1. Oxygen permeability and transmissibility

The estimation of oxygen transmissibility through and availability under contact lens systems has been previously explored. The equivalent oxygen percentage (EOP) under a piggy-back system was measured by Giasson et al. [15] with a conclusion that selected combinations of soft and rigid gas permeable lenses do not induce corneal hypoxia. More recently, Weissman and Ye applied a theoretical model to existing single lens models in circumstances where two lenses offer resistance to oxygen in series [16]. According to their estimations, the use of moderate to high oxygen permeable materials in a two lens piggyback arrangement delivers sufficient oxygen to the cornea to alleviate significant negative impact on the tissue.

Current common practice is to describe oxygen permeability in terms of *Dk*, where (*D*) represents a diffusion coefficient and (*k*) oxygen solubility [17]. *Dk* is an intrinsic property of the material used to produce a contact lens and its value depends on the material oxygen-permeable moieties, such as polymer physico-chemical characteristics, water content and silicone composition.

The thickness (*t*) of a contact lens coupled with the lens material permeability determines the quantity of oxygen that is transmitted through the lens and delivered to the cornea. Consequently, the Dk/t ratio defines the oxygen transmissibility of a given material. In the literature, *Dk* is measured in units $\times\, 10^{-11}$ $(\mathrm{cm}^2/\mathrm{s})\,(\mathrm{ml\,O_2/ml} \times \mathrm{mmHg})$ and Dk/t in units $\times\, 10^{-9}$ $(\mathrm{cm/s})\,(\mathrm{ml\,O_2/ml} \times \mathrm{mmHg})$. For clarity, our consideration of *Dk* and Dk/t units and exponents throughout this paper refer to Fatt *Dk* units and Fatt Dk/t units, as suggested by Benjamin [18]. The published values of Fatt Dk/t units for a given material are based on an average lens thickness estimated over the entire lens area. It has been shown, however, that lens edge thicknesses can play a significant role on local permeability, especially on the superior cornea, more penalized by the presence of the upper lid [17].

It could be misleading to rely only on a manufacturer's published average lens thickness information for making appropriate clinical decisions [19]. This is why the concept of mean harmonic thickness (MHT) has been proposed [20]. This method of calculation averages the central radial thicknesses of several annular zones of equal area within the optic zone of a lens, for a range of powers (−8.00 to +6.00) defined as a series. This differs from average thickness (*t*) which implies the mean of 6 points taken from zones of equal width within the optic zone. For most materials, their transmissibility is reduced at the power extremes of the series because of the increased thickness [21]. Clinically, this implies that lenses made from a given material can transmit enough oxygen in low to moderate powers, but not for the entire range of the series. For example, the nominal permeability of lotrafilcon A is 140 Fatt *Dk* units but its MHT value is calculated at 113 Fatt *Dk* units considering these extremes.

It is also important to consider anterior and posterior boundary layer effects, in situ, because the contact lens will be surrounded by tears. Boundary layer is defined as a relatively stagnant layer of fluid next to the lens surface. This fluid acts as an additional barrier to the flow of oxygen through the contact lens surface, and, if not accounted for, will in turn lead to an overestimation of the true Fatt Dk/t or Fatt *Dk* unit values [22]. This effect can be corrected, however, by computing the oxygen transmissibility of a test sample using the least-squares method.

1.2. Theoretical concepts applied to scleral lenses

As Fatt [23] has suggested, contact lenses and the tear layer beneath or over them may be viewed as resistors in series. Considering the lens as the first part of the system (Dk/t_1) and the tear layer trapped under its surface as the second part (Dk/t_2), it is possible to use the following [16] to determine ultimate oxygen permeability of this scleral system (Dk/t_{scl}):

$$\frac{Dk}{t_{\mathrm{scl}}} = \frac{1}{(t_1/Dk_1) + (t_2/Dk_2)}$$

Computing the theoretical oxygen transmissibility for different combinations of scleral lens–tear layer (fluid) thicknesses is of clinical interest to determine lens–tear system characteristics that will alleviate corneal hypoxia throughout the entire corneal thickness. This may be done by considering the standard established by Holden and Mertz [24] ("H/M") (Dk/t units of 24, centrally, for daily wear), and revised by Harvitt and Bonanno [25] ("H/B") (Dk/t units of 35). More recently, Morgan et al. [26] have measured a Dk/t value of 20 as the central cornea threshold for alleviating hypoxia-induced swelling and of 33 for the peripheral cornea.

This paper aims to predict the oxygen transmissibility of scleral lens systems by applying the concept of resistors in series to parameters characteristic of current scleral lenses. A secondary goal is to estimate the possible combinations of scleral lens/clearance thicknesses that would meet the oxygen criteria for the avoidance of hypoxia-induced corneal edema, both centrally and peripherally. The results from this theoretical approach may influence the way scleral lenses are designed and fitted as well as the recommendation specifics of lens wear regimens.

2. Methods

For the purposes of this paper, we refer to the classic 24 (H/M criterion) and 35 (H/B criterion) Dk/t units as appropriate thresholds for alleviating hypoxia-induced corneal swelling, for the central cornea and peripheral area respectively.

2.1. Assumptions and estimates for metrics

Tear permeability was assumed to be close to that of water, which is equivalent to 80 *Dk* units [22]. For other parameters, we assumed that most of the mini-scleral lenses prescribed today, roughly defined as 15–18 mm lenses [12], are produced in central thickness ranges of 250–350 μm. An optimal fitting of a mini-scleral lens leads to a tear layer of 100–200 μm in the center [27] and of 10–50 μm in the periphery. Large scleral lenses, in the 18–25 mm range, are generally characterized by lens central thicknesses varying from 300 to 500 μm with a tear clearance of 250–500 μm [28,29]. All of these lenses are made of materials with published *Dk* values of 100, 150 or 170.

For peripheral corneal calculations we took average scleral lens thicknesses into account at a point associated 5.75–6 mm from the lens center (an 11.5–12 mm overall diameter lens that would rest

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Table 1
Predicted values of oxygen transmissibility (Fatt *Dk*/*t* units) under the center of scleral contact lenses with a *Dk* of 100.

Dk=100	Clearance (μm)	100	150	200	250	300	350	400
Lens thickness (μm)								
250		26.7	22.8	20.0	17.8	16.0	14.5	13.3
300		23.5	20.5	18.2	16.3	14.8	13.5	12.5
350		21.1	18.6	16.7	15.1	13.8	12.7	11.7
400		19.1	17.1	15.4	14.1	12.9	11.9	11.1
450		17.4	15.7	14.3	13.1	12.1	11.3	10.6
500		16.0	14.5	13.3	12.3	11.4	10.6	10.0

▭ : satisfies HM criteria

just above the limbal area) where the thicknesses vary from 250 to 450 μm.

Our first calculation allowed us to predict the oxygen transmissibility at the scleral lens center when manufactured in a material of 100, 150 and 170 Fatt *Dk* units. An example of this calculation follows, showing that a lens made of a 100 *Dk* material, with a central thickness of 250 μm, fitted on a 200 μm tear layer will lead to a *Dk*/*t* value of 20 for the scleral system.

$$\frac{Dk}{t_{\mathrm{scl}}} = \frac{1}{(t_1/Dk_1)+(t_2/Dk_2)} \Rightarrow \frac{1}{(2.5/100)+(2.0/80)} = 20.0$$

The same calculations were used to determine the predicted oxygen transmissibility under the periphery of scleral lenses.

To achieve our second aim we calculated the maximal thickness of a lens that would respect the H/M criterion for daily wear. For this purpose, we varied the *Dk* of the material from 100 to 300 Fatt units and estimated the tear layer thickness between 100 and 400 μm.

3. Results

Our calculations of oxygen transmissibility at the scleral lens center, with varying post-lens tear layer thickness and lens thicknesses, ranged from 10 to 26.7 for *Dk* of 100, from 12 to 34.3 for *Dk* of 150 and from 12.6 to 36.7 for *Dk* of 170 (Tables 1–3). The calculated transmissibility under the periphery of scleral lenses, again with varying tear layer and lens thicknesses, ranged from 17.4 to 62.6 (Table 4). Our calculations of maximum central lens thickness (μm) that would respect the H/M criterion and prevent hypoxia-induced corneal swelling in daily scleral lens wear ranged from −240 to +875 μm, with the practical range being 260–875 μm (Table 5).

4. Discussion and clinical implications

Hypoxia-related issues are seen occasionally in scleral lens practice but this occurrence is not considered as great a problem as the potential for lens suction to the eye [16]. However, practitioners should be mindful that the majority of scleral lenses prescribed today and the tear reservoirs that they create do not provide enough oxygen to avoid corneal edema, based on the standards established by Holden and Mertz for central cornea and by Harvitt and Bonanno for the limbal area. This is especially true if we consider the use of scleral lenses to correct high refractive powers, either hyperopia (increased central thickness) or high myopia (increased peripheral thickness). The thinnest lens that could be considered to meet the H/M criteria would need to be at least 250 μm thick (to avoid likelihood of breakage and flexure), made in a *Dk* 100 material and with a limited tear layer (100 μm centrally). Should the material *Dk* be increased up to 150 (one of the highest *Dk*, large-diameter lenses currently manufactured), eight lens combinations with a limited post-lens clearance meet the criteria, while all others failed to meet the criteria (Table 2). For a *Dk* of 170, eleven combinations can be prescribed, although most of these combinations rely on clearance of less than 200 μm to meet the criteria (Table 3). Since many larger lenses are prescribed with post-lens fluid layer higher than this, the implication is that these actual fits may not allow for a normal oxygen supply to the cornea, based on our calculations.

Lens thicknesses depend on the design, the power and other specific parameters (optic zone size, diameter, peripheries design, etc.). Our results should be interpreted accordingly, knowing that thicker lenses will lessen even more the oxygen supply to the cornea. For limbal clearance, depending on the way the lens was fitted on the eye, values ranged from 10 to 60 μm, on average. When larger

Table 2
Predicted values of oxygen transmissibility (Fatt *Dk*/*t* units) under the center of scleral contact lenses with a *Dk* of 150.

Dk=150	Clearance (μm)	100	150	200	250	300	350	400
Lens thickness (μm)								
250		34.3	28.2	24.0	20.9	18.6	16.6	15.0
300		30.8	25.8	22.2	19.5	17.4	15.7	14.3
350		27.9	23.7	20.7	18.3	16.4	14.9	13.6
400		25.5	22.0	19.3	17.2	15.6	14.2	13.1
450		23.5	20.5	18.2	16.2	14.8	13.5	12.5
500		21.8	19.2	17.1	15.5	14.1	13.0	12.0

▭ : satisfies HM criteria
🟩 : satisfies HM and HB criteria

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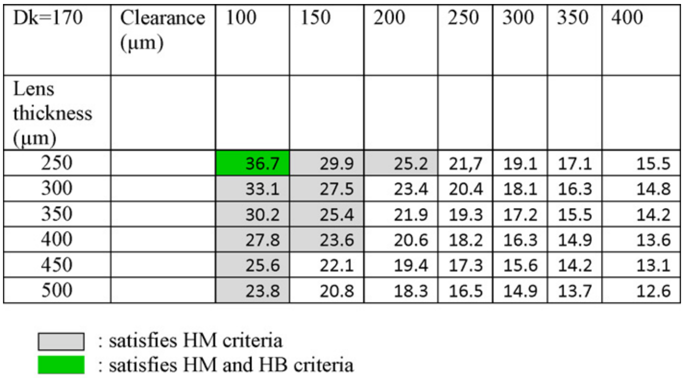
Table 3
Predicted values of oxygen transmissibility (Fatt *Dk*/*t* units) under the center of scleral contact lenses with a *Dk* of 170.



Dk=170	Clearance (μm)	100	150	200	250	300	350	400
Lens thickness (μm)								
250		36.7	29.9	25.2	21,7	19.1	17.1	15.5
300		33.1	27.5	23.4	20.4	18.1	16.3	14.8
350		30.2	25.4	21.9	19.3	17.2	15.5	14.2
400		27.8	23.6	20.6	18.2	16.3	14.9	13.6
450		25.6	22.1	19.4	17.3	15.6	14.2	13.1
500		23.8	20.8	18.3	16.5	14.9	13.7	12.6

▨ : satisfies HM criteria
🟩 : satisfies HM and HB criteria

lenses increase tear layer thickness over the limbal area the net *Dk*/*t* decreases proportionately for that area of the cornea/limbus.

As shown in Table 4, in order to avoid induced corneal swelling, lenses made of material with *Dk* 100 should not have a thickness (at 11–12 mm of diameter) that exceeds 250 μm when combined with a limbal tear fluid thickness >40 μm. For thicker lenses, or when relying on a larger volume of fluid at the limbus, lenses should be made in *Dk* of at least 150–170. Even when this is done, very few lenses (8 combinations) with peripheral thicknesses over 400 μm meet the H/B criteria for limbal oxygen transmissibility (*Dk*/*t* 35). Limiting the tear fluid thickness to 10–30 μm could meet the criteria in this case but such a low thickness value is not likely to be present with the larger lenses.

While our predictions are theoretical, they do address the topic area of hypoxic stress in scleral lens wear, as could be evidenced clinically by spectacle blur and neovascularization of the limbal area. There have been relatively few reports in this topic area, perhaps for a number of reasons. First, the individual response to various hypoxic stresses vary among human corneas [30]. Second, despite scleral lenses gaining in popularity, the numbers of patients fitted with this modality are still relatively small and adverse effects are not reported systematically. Often, therefore, adverse effects are simply offered anecdotally. Third, because many of the corneas fitted with scleral lenses are already challenged or compromised, any worsening may be attributed to disease progression instead of the presence of a scleral lens restricting oxygen supply to the cornea. Finally, a vast majority of these patients do not see well without their lenses and, without a reasonable vision correction alternative, some hypoxic signs may be deemed 'acceptable' under the circumstances. For example, spectacle blur, secondary to corneal swelling, may be difficult to perceive by patients with keratoconus, already known to be light sensitive and to have a reduced visual acuity in glasses, and therefore be deemed acceptable, in some cases, by the eye care practitioner.

More clinical research is required to determine the longer-term impact of scleral contact lenses on corneal physiology. Until the results of scleral lens clinical studies evaluate for the short and longer-term physiological responses predicted from our calculations, practitioners are urged to be mindful of our results and give careful attention to the material *Dk*, lens parameters and post-lens tear layer thicknesses (clearances) when designing and fitting scleral lenses. Following up patients after several hours of wear in order to evaluate for corneal edema is recommended, especially when patients are fitted with a large, thick lens and a high clearance.

While having calculated that many scleral lenses do not provide the cornea with the oxygen level criteria of H/M and H/B, we have determined that it is possible to design acceptable lens and fitting parameters for large-diameter scleral lenses, although we have found that less than half (27) of 56 combinations can be manufactured in ways that respect those criteria (Table 5).

Fig. 1 demonstrates that for *Dk* 100, central lens thickness should not exceed 220–260 μm and not have a tear layer thickness more

Table 4
Predicted values of oxygen transmissibility (Fatt *Dk*/*t* units) under the periphery of scleral gas-permeable contact lenses.

	Clearance	10 μm	20 μm	30 μm	40 μm	50 μm	60 μm
Lens thickness (μm)							
250	*Dk* 100	**38.1**	**36.4**	**34.8**	**33.3**	32	30.1
	Dk 150	**55.8**	**52.1**	**49.0**	**46.1**	**43.6**	**41.4**
	Dk 170	**62.6**	**58.1**	**54.2**	**50.8**	**47.7**	**45.1**
300	*Dk* 100	32.0	30.8	29.6	28.5	27.6	26.7
	Dk 150	**47.1**	**44.4**	**42.1**	**40.0**	**38.1**	**36.4**
	Dk 170	**52.9**	**49.6**	**46.7**	**44.1**	**41.2**	**39.8**
350	*Dk* 100	26.6	26.6	25.8	25.0	24.4	23.5
	Dk 150	**40.7**	**38.8**	**36.7**	**35.3**	33.8	32.4
	Dk 170	**45.7**	**43.3**	**41.1**	**39.1**	**37.2**	**35.6**
400	*Dk* 100	24.4	23.5	22.8	22.2	21.6	21.0
	Dk 150	**35.8**	**34.3**	**32.9**	31.6	30.4	29.3
	Dk 170	**40.3**	**38.4**	**36.6**	**35.1**	33.5	32.2
450	*Dk* 100	21.6	21.0	20.5	20.0	19.5	19.1
	Dk 150	32.0	30.8	29.6	28.5	27.6	26.7
	Dk 170	**36.1**	34.5	33.1	31.8	30.5	29.4
500	*Dk* 100	19.5	19.0	18.6	18.1	17.8	17.4
	Dk 150	28.9	27.9	26.9	26.1	25.3	24.4
	Dk 170	32.6	31.3	30.2	29.1	28.1	27.1

Values in bold satisfy the HB criteria (peripheral cornea).

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Table 5
Predicted maximal central lens thickness (µm) to prevent hypoxia-induced corneal swelling in daily scleral lens wear (HM criterion) considering determined clearance values.

	Clearance	100 µm	125 µm	150 µm	200 µm	250 µm	300 µm	350 µm	400 µm
Lens Dk									
100		291	260	229	167	104	42	-20	-80
125		364	325	286	208	130	52	-25	-100
150		437	391	343	250	156	62	-30	-120
170		495	443	389	283	177	70	-35	-136
200		583	521	458	333	208	83	-40	-160
250		729	651	575	417	260	104	-50	-200
300		875	781	687	500	312	125	-60	-240

■ : negative thickness indicates impossibility to manufacture such a lens
▨ : possible to manufacture the lens- but it is likely to flex/break because of a reduced thickness
□ : optimal lenses to manufacture

than 150 µm. A practical downside of such lens thickness (i.e., thinness) is lens flexure, which induces astigmatism, and susceptibility to breakage. For materials with higher *Dk*, the thicknesses of lens and tear layer may be increased, but fitting a lens supported by a tear layer of more than 250 µm remains only a theoretical possibility, as materials with a *Dk* of 250–300 (not available at present) would be needed in order to not induce corneal swelling (see Table 5).

4.1. Clinical considerations

Our calculated results indicate that the ways in which scleral lenses are designed and fitted in present-day practice can have, in theory, a significant impact on corneal physiology owing to deficiencies in oxygen transmissibility of the lens/post-lens tear layer system.

Based upon our calculations, we propose the following lens material, design and fitting guidance which practitioners should consider in order to minimize corneal hypoxia with today's scleral lenses.

1. Super-permeable materials should be used.We recommend prescribing scleral lenses with the highest *Dk* values available. This recommendation may be tempered, on occasion, by the susceptibility of today's higher *Dk* materials to induce residual astigmatism due to flexure, to warp during manual cleaning, and to be associated with difficulties during lens manufacture. In the future, perhaps we will be able to enjoy innovative new lens materials with *Dk* up to 300, having minimal to no flexure in thin designs and having improved optical qualities with low wetting angles. This should be the next goal for gas permeable manufacturers.
2. Smaller lenses are preferable.Smaller lenses (12–15 mm in diameter) have reduced central thicknesses and may be fitted with less clearance than larger scleral lenses (>15 mm). Therefore, whenever clinically reasonable, smaller diameter lenses should be preferred over larger scleral lenses because they are more likely to fulfill the oxygen requirements of the cornea. In addition, small lenses tend to not impinge as much on the high conjunctival toricity found further away from the limbus and this should favor tear exchange under the lens.
3. Central clearance should not exceed 200 µm.Central clearance should not exceed 200 µm for lenses made of the highest *Dk* material available in the market today. Peripheral clearance should not exceed 50 µm to avoid any impact on the oxygen delivery to the stem cells. This is particularly true if the corneal tissue is already compromised or affected by a pathological condition.

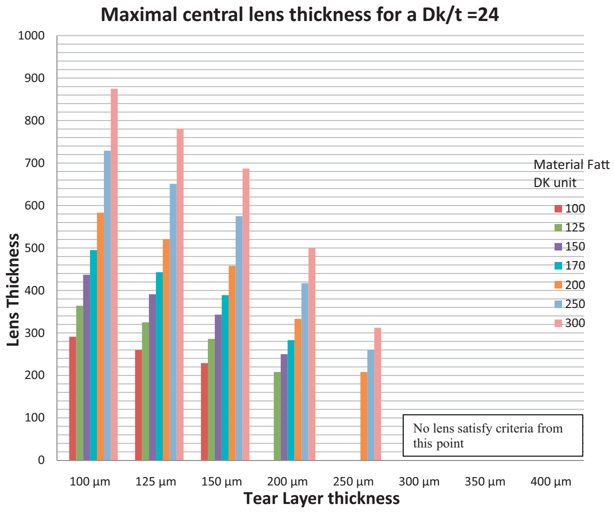

Fig. 1. Predicted maximal central scleral lens thickness for several Fatt *Dk* unit values to alleviate corneal induced swelling in the central cornea.

5. Conclusion

As for every type of lens, the oxygen transmissibility of a scleral lens is determined by the *Dk* of the material in relation to the thickness of the lens. Scleral lenses are typically substantially thicker than corneal lenses, decreasing their relative oxygen transmissibility. In addition, the tear layer reservoir behind the lens can be substantial, and this, based on theoretical considerations, should be viewed as an additional resistance for oxygen delivery (transmission) to the cornea. Our theoretical oxygen transmissibility computations, based on established corneal oxygen requirement criteria applied to different combinations of scleral lens/post-lens tear layer thicknesses, demonstrate that most of today's scleral fits should be associated with some level of hypoxia-induced corneal swelling. We conclude that 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 µm, and fitted in a manner to achieve a clearance that does not exceed 200 µm. For the corneal periphery, the lens thickness could range from 250 to 350 µm with clearance varying from 10 to 60 µm.

Disclosure

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