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ORIGINAL ARTICLE

Corneal oedema during open-eye fenestrated scleral lens wear

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Abstract

Introduction: Studies examining the effect of fenestrating soft and corneal rigid contact lenses upon corneal oedema have yielded conflicting results. Although often utilised in clinical practice, no studies have quantified the effect of fenestrating a scleral contact lens upon corneal oedema. Therefore, the aim of this experiment was to examine the effect of incorporating a single peripheral fenestration on central corneal oedema during short-term open-eye scleral lens wear, while controlling for potential confounding variables.

Methods: Nine participants (mean age 30 years) with normal corneas wore a fenestrated (1 × 0.3 mm limbal fenestration) and non-fenestrated scleral lens (both lenses manufactured using a material Dk of 141×10^{-11} cm^3 O_2(cm)/[(sec.)(cm^2)(mmHg)]) under open-eye conditions on separate days. Scleral lens thickness profiles were measured using a high-resolution optical coherence tomographer (OCT). Epithelial, stromal and total central corneal oedema were also measured using the OCT immediately after lens application and following 90 min of wear, prior to lens removal.

Results: After adjusting for differences in initial central fluid reservoir thickness and scleral lens thickness between the two lens conditions, the mean (standard error) total corrected central corneal oedema was 0.50 (0.36)% for the fenestrated lens and 0.62 (0.16)% for the non-fenestrated lens. This small difference was not statistically significant ($t_8 = 2.31$, $p = 0.81$) and represents a 19% relative reduction in central corneal oedema. Similarly, epithelial ($t_8 = 2.31$, $p = 0.82$) and stromal ($t_8 = 2.31$, $p = 0.92$) corneal oedema were not significantly different following the fenestrated and non-fenestrated wearing conditions.

Conclusion: Central corneal oedema in healthy corneas was comparable between fenestrated and non-fenestrated high Dk scleral lenses under short-term open-eye conditions when controlling for lens oxygen transmissibility and initial central fluid reservoir thickness.

KEYWORDS
corneal oedema, fluid reservoir, lens fenestration, scleral lens, tear exchange

INTRODUCTION

Numerous studies have investigated the effect of central and peripheral fenestrations on the corneal response during corneal rigid and soft contact lens wear, with conflicting results. For example, Hill et al.[1] reported that fenestrations only provide a local oxygenation effect at the fenestration site during corneal rigid lens wear, while Harris et al.[2] observed a gradual reduction in central oedema as the number of fenestrations increased. Similarly, some studies examining fenestrated soft lenses reported no reduction in central corneal oedema compared to non-fenestrated lenses,[3] while others[4] suggested that soft lens fenestrations may enhance tear exchange due to increased lens movement and altered post-lens tear layer dynamics.

During the 1930s and 1940s, Dallos[5] and Bier[6] independently observed that the onset of Sattler's veil (a visual symptom associated with corneal oedema) was delayed if patients wore a loose (flat) fitting scleral lens, or if a freely moving air bubble was introduced into the fluid reservoir. This led to the development of 'ventilated' or fenestrated scleral lenses. Dallos[7] theorised that Sattler's veil was a result of an osmotic imbalance between the fluid reservoir and the corneal epithelium, which resulted in an uptake of fluid into the cornea. Fenestrations were thought to allow the release of trapped metabolites from the fluid reservoir, resulting in a reduction in corneal oedema. Bier[8] suggested that the delay of onset, or the reduction in severity of Sattler's veil, was due to the constant turnover of tears resulting in the introduction of atmospheric oxygen and egress of carbon dioxide from the fluid reservoir.

While studies have examined the effect of scleral lens oxygen permeability,[9–11] lens thickness[12,13] and fluid reservoir thickness[14–16] upon corneal oedema, none have quantified the effect of incorporating a fenestration. Ko et al.[17] investigated tear exchange during fenestrated scleral lens wear (a single 1- to 1.5-mm-diameter fenestration located at the limbus) in four participants by adding sodium fluorescein within the scleral bowl prior to lens application and quantifying its decay. Two participants developed misty vision ('superficial corneal oedema') after 4 h of lens wear, while one achieved 16 h of lens wear without visual symptoms. The authors concluded that fenestrating a scleral lens may not improve tear exchange or corneal oxygenation significantly, but did not measure corneal oedema.

While there is anecdotal clinical evidence that incorporating a fenestration can reduce the signs and symptoms of contact lens-induced corneal oedema, no studies have quantified the magnitude of corneal oedema induced by a fenestrated scleral lens. Consequently, the aim of this study was to examine the effect of a single peripheral fenestration on corneal oedema during short-term open-eye scleral lens wear compared to a non-fenestrated scleral lens control condition.

Key points

- This is the first study to demonstrate that a single limbal fenestration does not reduce central corneal oedema after 90 min when controlling for fluid reservoir thickness and lens oxygen transmissibility.
- Fenestrations may have other clinical benefits, such as decreased fluid reservoir debris and midday fogging, easier lens application and removal and less conjunctival compression and limbal redness.
- Minimising the central fluid reservoir thickness provides a greater reduction in corneal oedema than the addition of a single limbal fenestration in highly oxygen-permeable scleral lenses.

MATERIALS AND METHODS

Participants

Nine young, healthy adults (mean age [standard error] 30 [1] years, three female and six male) were recruited. All participants had healthy corneas and visual acuity ≤0.00 logMAR in each eye. The study was approved by the Queensland University of Technology Human Ethics Research Committee and was conducted in accordance with the tenets of the Declaration of Helsinki. Informed consent was provided by each participant following an explanation of the nature of the experiment. Participants underwent an initial screening assessment to exclude participants with any ocular or vision abnormalities, contraindications to contact lens wear, history of ocular injury or surgery or current use of topical medications. Soft contact lens wearers ($n = 5$) ceased lens wear for 24 h prior to any experimental session, and none of the participants were rigid lens wearers.

Scleral lens fitting

The scleral lenses used in this experiment were Irregular Corneal Design™ (Capricornia, capcl.com.au/), manufactured in hexafocon B material (Dk 141×10^{-11} cm^3 O_2(cm)/[(sec.)(cm^2)(mmHg)), with a back vertex power of −1.00 D, total diameter of 16.5 mm, back optic zone radius of 7.46 mm and nominal centre thickness of 300 µm. A spherical landing zone was used for all lenses, and the overall sagittal height of each lens was varied through modifications to the limbal tangent angles, with no modifications to the landing zone. This approach was used to minimise any potential variation in landing zone alignment with the underlying conjunctiva (and therefore variations in potential tear exchange via the landing zone). The

fenestrated and non-fenestrated lenses used for each participant had these same lens specifications, except for the lens fenestration (one 0.3-mm-diameter fenestration located 2 mm from the lens edge, or 6.25 mm from the centre of the optic zone positioned to approximately overlie the limbus). The fenestrated lens used for each participant was selected to achieve an initial central fluid reservoir thickness of 150 μm to ensure any air bubbles that entered the fluid reservoir remained towards the peripheral cornea.[18] The target initial fluid reservoir thickness for the non-fenestrated lenses was also 150 μm. The lens thickness profile across the central 12.5 mm of each lens was measured using an optical coherence tomographer (OCT) as described previously,[19] and these data were used to calculate the average Dk/t for each lens.

Measurement sessions

Following the initial screening assessment, participants attended the laboratory on two separate days (fenestrated or non-fenestrated lens wear days), with measurements collected at the same time on each day to minimise the potential confounding influence of natural diurnal variations in corneal thickness. After inserting the appropriate scleral lens with preservative-free saline, the central corneal thickness (averaged across the central 5 mm) and central fluid reservoir thickness (measured at the location of the corneal apex) were measured using an OCT (Spectralis, Heidelberg Engineering, heidelbergengineering.com) and again after 90 min of lens wear before lens removal. This is a highly reliable technique for measurement of corneal thickness using customised software with a mean (standard deviation) intraobserver repeatability of 0.3 (± 1.6) μm and intrasession repeatability of −0.7 (± 1.9) μm for a single observer.[20] This duration of lens wear was chosen since central corneal oedema peaks after approximately 90 min of high Dk open-eye scleral lens wear. Since the introduction of a rigid contact lens results in an underestimation of thickness measurements due to the higher refractive index of the lens material compared with the cornea, both the initial and final OCT measurements were captured with the scleral lens on the eye to control this factor.

Corrections for variations in initial fluid reservoir thickness

Due to small differences in the initial fluid reservoir thickness and the lens thickness between the fenestrated and non-fenestrated lens conditions, a series of corrections were applied to each participant's total corneal oedema data, based on measurements obtained in previous experiments, which examined the magnitude of central corneal oedema during open-eye non-fenestrated scleral lens wear as a function of initial fluid reservoir thickness[16] and lens thickness.[13] Table 1 outlines this correction process for one participant as an example.

Statistical analyses

The normality of the data was confirmed using the Kolmogorov–Smirnov test. Two-tailed paired t-tests were

TABLE 1 Example of the process to correct the magnitude of corneal oedema to account for variations in initial fluid reservoir thickness and the average scleral lens thickness across the central 12.5 mm for participant 9

STEP 1: Extract polynomials	Open-eye fluid reservoir thickness effect	$y = -5x10^{-6}x^2 + 0.0078x - 0.40$ *y* denotes central corneal oedema (%); *x* denotes initial central fluid reservoir thickness (μm)
	Open-eye scleral lens thickness effect	$y = -4 \times 10^{-6}x^2 - 0.0037x + 2.41$ *y* denotes central corneal oedema (%); *x* denotes the average scleral lens thickness across the central 12.5 mm (μm)

	Lens condition	Non-fenestrated	Fenestrated
STEP 2: Initial central fluid reservoir correction	Initial fluid reservoir thickness (μm)	155	152
	Measured central total corneal oedema (%)	0.68	2.72
	Estimated oedema due to fluid reservoir difference (from fluid reservoir polynomial) (%)	+0.02	
	Oedema corrected for difference in initial fluid reservoir thickness (%)	0.66	2.72
STEP 3: Scleral lens thickness correction	Scleral lens thickness (central 12.5 mm) (μm)	299	314
	Oedema corrected for difference in initial fluid reservoir thickness (%)	0.66	2.72
	Estimated oedema due to scleral lens thickness difference (from lens thickness polynomial) (%)		+0.09
	Oedema corrected for difference in initial fluid reservoir and central scleral lens thickness (%)	0.66	2.63

used to examine the difference in fluid reservoir metrics and the raw and corrected total central corneal oedema between the sealed and fenestrated lens conditions. Data are presented as the mean or mean difference and the standard error. The required sample size was determined using G*Power (Version 3.1.9.2; Heinrich Heine Universität Dusseldorf, psychologie.hhu.de), assuming an effect size of 1.17 based on the open-eye central corneal oedema data from a corneal rigid lens study (material Dk 100) comparing non-fenestrated and fenestrated lenses (one 0.25 mm fenestration).[21] For a two-tailed, matched-pairs t-test, assuming a 0.5 correlation between groups, with a type I error probability of 0.05, a sample size of eight participants would provide a power of 0.8 (actual power of 0.81 was achieved based on the experimental results with a sample size of nine).

RESULTS

The average scleral lens thickness across the central 12.5 mm and the Dk/t calculated from this average thickness for the fenestrated and non-fenestrated lenses are listed in Table 2. The fluid reservoir thickness metrics for the fenestrated and non-fenestrated lens conditions are summarised in Table 3, along with the central corneal oedema for the epithelium, stroma and total cornea following 90 min of fenestrated and non-fenestrated lens wear. Figure 1 displays the raw and corrected total central corneal oedema data for the two lens conditions, and Figure 2 highlights the individual variation in corneal oedema between the two conditions. One participant displayed an increase in corrected oedema for fenestrated lens wear compared to non-fenestrated lens wear (a 2.0% increase), three participants showed minimal change (a mean decrease of 0.01%), and five participants demonstrated a decrease in oedema (mean decrease of 0.53%). Overall, the mean (standard error) total corrected central corneal oedema was 0.50 (±0.36) % for the fenestrated lens and 0.62 (±0.16) % for the non-fenestrated lens; this small difference was not statistically significant ($t_8 = 2.31$, $p = 0.81$).

DISCUSSION

On average, a single 0.3-mm-diameter peripheral lens fenestration did not alter central corneal oedema compared to a non-fenestrated highly oxygen-permeable lens after correcting for variations in the initial central fluid reservoir thickness and lens thickness between the two conditions. This could potentially be attributed to the significantly lower oxygen permeability of the fluid reservoir (Dk 80) compared to that of the lens material (Dk 141), since previous work[13] has demonstrated that large variations in scleral lens thickness have substantially less impact upon corneal oedema than variations in central fluid reservoir thickness. No significant difference was observed between the fenestrated and non-fenestrated lens for total (both raw ($t_8 = 2.31$, $p = 0.86$) and corrected ($t_8 = 2.31$, $p = 0.81$)), epithelial ($t_8 = 2.31$, $p = 0.82$) or stromal ($t_8 = 2.31$, $p = 0.92$) corneal oedema. Fenestrated lens wear resulted in a wider range of oedema values (Figure 1) and greater between participant variation (Figure 2) compared to the non-fenestrated lens condition.

TABLE 2 Mean (standard error) nominal (manufacturer provided thickness) and average (measured across the central 12.5 mm) centre lens thickness and corresponding Dk/t values

Metric	Fenestrated lens	Non-fenestrated lens
Nominal centre lens thickness	300 (0)	300 (0)
Dk/t (based on nominal centre lens thickness)	47 (0)	47 (0)
Average lens thickness (central 12.5 mm)	319 (2)	308 (4)
Average Dk/t (central 12.5 mm)	44 (0)	46 (1)

TABLE 3 Mean (standard error) initial and final central fluid reservoir (FR) thickness metrics and central corneal oedema after 90 min of lens wear

Metric	Fenestrated lens	Non-fenestrated lens	*p*-value ($t_8 = 2.31$)
Initial central FR thickness (μm)	151 (14)	146 (8)	0.78
Final central FR thickness (μm)	112 (17)	98 (4)	0.42
Reduction in central FR thickness (μm)	−39 (7)	−48 (8)	0.21
Epithelial oedema (%)	0.12 (0.73)	0.40 (0.72)	0.82
Stromal oedema (%)	0.70 (0.35)	0.73 (0.20)	0.92
Total corneal oedema (raw) (%)	0.65 (0.33)	0.70 (0.17)	0.86
Total corneal oedema (corrected) (%)	0.50 (0.36)	0.62 (0.16)	0.81

Note: *p*-value for a two-tailed paired t-test ($n = 9$, degrees of freedom = 8).

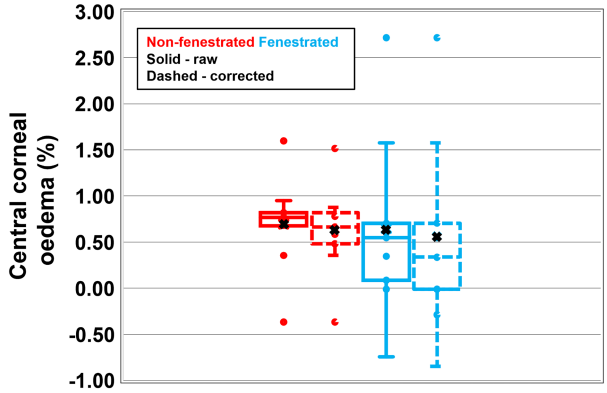

FIGURE 1 Box-and-whisker plots of the raw (solid lines) and corrected (dashed lines) total central oedema for the non-fenestrated (red) and fenestrated (blue) lens wear conditions. The x indicates the mean, the central horizontal line indicates the median, the upper and lower box limits are the 75th and 25th percentile, and the whiskers indicate 1.5 × the interquartile range. Data points outside the whiskers indicate outliers.

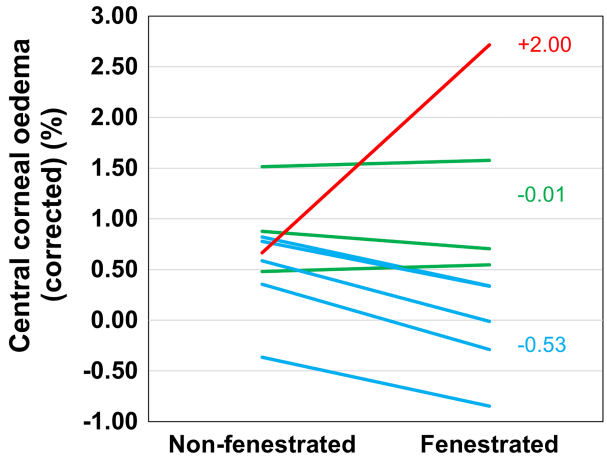

FIGURE 2 Corrected central corneal oedema for each participant across the two lens wear conditions. Relative to non-fenestrated lens wear, one participant displayed an increase in oedema (red, 2.0% increase), three participants showed minimal change (green, mean change 0.01% decrease), and five participants demonstrated a reduction in oedema (blue, mean change 0.53% decrease).

Early qualitative studies of fenestrated scleral lenses mention the presence of an air bubble within the fluid reservoir.[18] However, the presence of a bubble can be detrimental to vision if located centrally, and is typically managed by fitting the lens with minimal central fluid reservoir thickness to ensure any bubbles remain peripherally. Fadel and Ezekiel[18] stated that while a bubble is common, scleral lenses with fenestrations can be fitted without a bubble and suggested a maximum initial central fluid reservoir thickness of 150 µm. The lenses used in this study were fitted without a bubble, most likely due to the size of the fenestration and the initial reservoir thickness.

While the average magnitude of reduction in central corneal oedema by introducing a single peripheral lens fenestration was statistically insignificant (a 0.12% reduction in corrected total oedema), there was a 19% relative reduction in oedema compared to the non-fenestrated condition (i.e., a 0.12% reduction from 0.62% oedema). This could potentially be of clinical benefit to patients with compromised corneas (e.g., following a corneal transplant), consistent with reports of fenestrating hybrid lenses in such cases.[22]

In comparison with other lens fitting modifications, minimising the central fluid reservoir thickness provides a substantially greater reduction in corneal oedema under open-eye conditions (e.g., a 62% relative reduction when decreasing the central reservoir thickness from ~500 to 150 µm).[16] Future studies should quantify the reduction in corneal oedema achieved with fenestrated lenses in such clinical populations (e.g., keratoconus or post-graft eyes) using a larger sample size with longer wearing times. The incorporation of a fenestration may also have other benefits such as decreased fluid reservoir debris and midday fogging, easier lens application and removal and less conjunctival compression and limbal redness.[18] It should also be noted that the addition of fenestrations may yield different clinical outcomes for different scleral lens designs, materials or fitting philosophies.

Future studies could also examine the clinical effect of altering the number of scleral lens fenestrations. Mountford et al.[23] utilised three equally spaced peripheral fenestrations separated by 120 degrees throughout the limbal zone to ensure at least one opening remained within the palpebral aperture. However, others have utilised a single limbal fenestration[17] or added additional fenestrations if the lens rotated and the fenestration located under the eyelid.[24] Increasing the number of fenestrations from 0 to 3, 5, 10 and 20 in corneal polymethyl methacrylate lenses reduced oedema on average during short-term open-eye lens wear,[2] but in some individuals, more fenestrations yielded greater oedema. Conversely, for hydroxyethyl methacrylate soft contact lenses, doubling the number of mid-peripheral fenestrations from 4 to 8 resulted in no change to equivalent oxygen percentage at the corneal epithelium during open-eye wear.[25]

The optimal fenestration size to minimise corneal oedema also remains to be determined for scleral lenses, with previous clinicians using fenestrations ranging from 0.25[23] to 1.5 mm[17] in diameter. Harris et al.[26] observed that increasing the fenestration diameter for polymethyl methacrylate corneal lenses did not significantly reduce the magnitude of central corneal clouding, while doubling the diameter of soft lens fenestrations (increasing four mid-peripheral fenestrations from 0.8 to 1.8 mm) resulted in a 1.4x increase in oxygen availability during open-eye conditions; however, the lens design was impractical due to discomfort.[25]

CONCLUSION

On average, the incorporation of a single 0.3-mm diameter peripheral lens fenestration into a highly oxygen-permeable scleral lens did not reduce the magnitude

of corneal oedema in healthy eyes compared to a non-fenestrated scleral lens, when controlling for initial central fluid reservoir thickness and scleral lens thickness, during 90 min of open-eye lens wear. While a 0.12% reduction in corrected total corneal oedema would be considered clinically insignificant in a young healthy adult, this was equivalent to a 19% reduction in oedema relative to the non-fenestrated control condition, which may be of benefit when fitting a compromised cornea. Further work is needed to examine the effect of scleral lens fenestrations (including optimal number and size) within these population groups, using a large sample size and the potential mechanisms that may contribute to a reduction in corneal oedema that has been observed in clinical practice.

AUTHOR CONTRIBUTIONS

Damien Fisher: Conceptualization (equal); data curation (lead); formal analysis (lead); funding acquisition (equal); investigation (equal); methodology (equal); software (equal); validation (lead); writing – original draft (equal); writing – review and editing (equal). **Michael J Collins:** Conceptualization (equal); project administration (equal); resources (equal); supervision (equal); writing – review and editing (equal). **Stephen J Vincent:** Conceptualization (equal); formal analysis (equal); methodology (equal); project administration (equal); software (equal); supervision (lead); validation (supporting); writing – review and editing (equal).

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CONFLICT OF INTEREST

The authors report no conflict of interest.

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