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Corneal swelling caused by conventional and new-design low-Dk soft contact lenses following a 10-day daily wear trial regime

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ABSTRACT

Purpose: To investigate the efficacy and safety of a fenestrated and channelled soft contact lens (F-SCL) compared to a standard and non-fenestrated soft contact lens (S-SCL) in experienced soft contact lens (SCL) wearers.
Methods: This was a randomised, crossover, single-blinded (subject), and multicentre clinical trial. Sixteen experienced SCL wearers were randomly divided into two groups (FS and SF). The FS group first wore F-SCLs followed by S-SCLs, each for 10 days, separated by a 1-week washout period, whereas the SF group wore the S-SCLs first and crossed over to F-SCLs in the same manner. The F-SCLs were designed with three equally spaced, symmetrical fenestrations and a partial-thickness, connecting, circumferential channel on the back surface of the mid-periphery of the lens. Measurement of central corneal thickness using ultrasonic pachymetry was performed on the day of screening, after the 1-week washout period, and after 10 days of wearing each kind of lens, based on which central corneal swelling was calculated and compared. One eye in each subject was chosen at random for analysis.
Results: Central corneal swelling was $1.92 \pm 1.73\%$ vs. $5.26 \pm 2.14\%$ in F-SCLs vs. S-SCLs wearers, which was statistically significant ($P < 0.001$). There was no significant difference between the groups in terms of SCL-corrected visual acuity or SCL-related adverse events.
Conclusion: The use of F-SCLs led to reduced corneal swelling compared to S-SCLs. The newly incorporated features appear to improve tear mixing and thereby the oxygen supply to the cornea, which results in reduced corneal oedema.

1. Introduction

Since the main breakthrough in soft contact lens (SCL) development by the Czech chemists Wichterle and Lim in 1959 [1], followed by U.S. FDA approval in 1971, considerable improvements have been achieved in SCLs, with the ultimate goal of improving oxygen permeability and lens wettability, and minimising adverse effects. The major adverse effect of extended SCL wear is corneal oedema, which arises from contact lens (CL)-induced corneal hypoxia with corresponding hypercapnia [2,3]. The cascade of events from corneal hypoxia to corneal oedema is as follows [3]: an oxygen concentration below the critical level [4] in corneal tissue induces switching from aerobic to anaerobic glycolysis by the Embden–Meyerhof pathway. This leads to the accumulation of lactate, the end product of anaerobic glycolysis. Lactate together with the accompanying hypercapnia results in stromal acidosis. Low ATP production and acidic pH dampens the pumping action of the corneal endothelium, inducing corneal oedema. Therefore, to avoid corneal oedema, hypoxia should be minimised. Two strategies can be applied to achieve this for a SCL: first, by increasing oxygen transmissibility, which is limited by the fragility of the lens, and second by enhancing the tear exchange rate in the post-lens tear film (PoLTF) [5–7]. The second strategy removes metabolic by-products and cell-debris accumulated in the PoLTF and adds oxygen-rich tears to the PoLTF. The efficiency of the tear exchange rate is affected by vertical (up-down) and transverse (in-out) motions of the contact lens [5,8]. These motions lead to dispersive mixing from the

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PoLTF [8]. Vertical motion may be increased by a smaller-diameter contact lens with a flatter base curve radius; however, these lens designs are less comfortable for the wearer [8]. Increasing transverse motion solves this problem because the considerably reduced transverse-motion amplitude results in more effective mixing [8,9] and less discomfort.

It has been demonstrated theoretically that incorporation of fenestrations or channels in SCLs is one of the most effective ways to improve mixing in the PoLTF [5]. Enhancement of the transverse motion using fenestrations/channels leads to increased dispersive tear mixing [5,9]. Clinical data on fenestrated SCLs with various designs have been published [10–13]. In our study, a newly designed SCL with three equally spaced, symmetrical fenestrations and a connecting partial thickness, circumferential channel at the mid-peripheral region was evaluated.

Quantitative measurement of contact lens-induced corneal swelling demonstrates the impact of contact lens-induced hypoxia on corneal health [2]. This measurement is normally carried out immediately after CL removal [14–16]. The central cornea is the most important region for clear vision, and central corneal thickness (CCT) is a sensitive indicator of overall corneal health [17]. We determined CCT using ultrasonic pachymetry [17], from which the central corneal swelling ratio was calculated.

We compared the corneal swelling response of a new fenestrated and channelled SCL (F-SCL) to a standard and non-fenestrated SCL (S-SCL). Other efficacy and safety parameters, including contact lens-corrected visual acuity, foreign body sensation, conjunctival injection, and superficial punctate keratitis, of the two types SCLs were evaluated and compared.

2. Methods

2.1. Study design

This was a prospective, randomised, crossover, single-blinded (subject), and multicentre clinical trial.

2.2. Subjects

We enrolled 16 experienced SCL wearers (12 females and 4 males), with a mean age of 33.3 ± 6.4 years. Inclusion criteria were: existing SCL wearers willing to sign a written informed consent and having astigmatism of ≤2.00 D in both eyes, which was correctable to a visual acuity of 16/20 or better in each eye. Exclusion criteria were: clinically significant (grade 3 or 4) corneal oedema, corneal vascularisation, tarsal abnormalities, bulbar infection, clinically significant corneal staining (grade 3 in more than one region), keratoconus or other corneal irregularities, refractive surgery, or any other abnormality of the cornea that would contraindicate CL wear. Informed consent was obtained from each subject after approval was granted by the Institutional Review Board of the hospital. All subjects underwent treatment in accordance with the tenets of the Declaration of Helsinki.

2.3. Instrumentation and lenses

The CCT of each eye was measured using an ultrasound pachymeter (Ultrasonic Pachymeter SP-3000, Tomey, Japan). The cornea was anaesthetised using one drop of 0.5% proparacaine hydrochloride (0.5%) (Alcaine Eye Drops, Alcon Inc., Fort Worth, TX, USA). The probe was applied perpendicular to the apex of the corneal surface, using the pupil centre as a reference point. All measurements were performed by the same person with a masked operator. Three readings were obtained for each cornea each time and the mean was considered to be the final value. Except for the washout period, all measurements were obtained immediately after SCL removal.

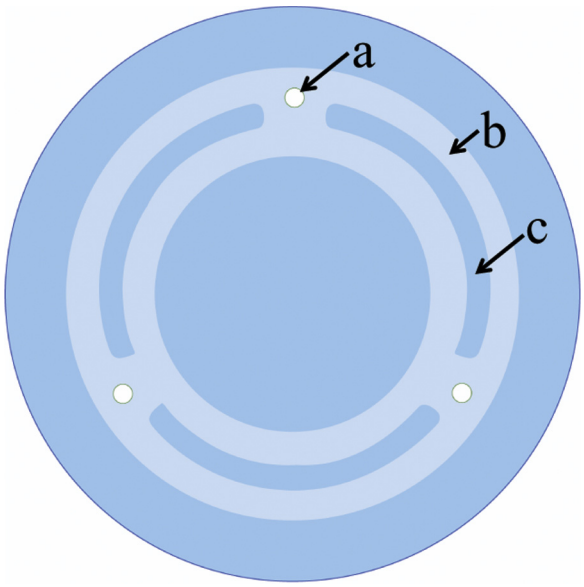

Fig. 1. Diagrammatic representation of a fenestrated and channelled soft contact lens. (a) Fenestration, (b) connecting circumferential channel, and (c) ridge in contact with the corneal surface.

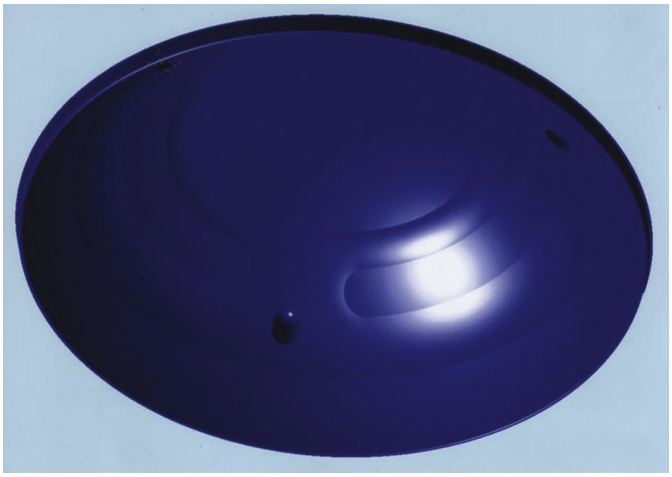

Fig. 2. Inner aspect of a fenestrated and channelled soft contact lens. Fenestrations, a channel, and intervening ridges are shown.

The basic design of the new F-SCL incorporated fenestrations (0.3 mm) and a channel. These fenestrations were arranged symmetrically and their centres were 5.5 mm from the lens centre, the mid-peripheral region. The fenestrations were connected with a partial thickness, circumferential channel. This channel had three arced ridges, which rested on the corneal surface, while the remainder of the channel was above the corneal surface. A geometric representation of the F-SCL is shown in Figs. 1 and 2. The remaining details of the F-SCL were identical to those of the S-SCL (14.5-mm diameter, 90-μm central thickness, and 8.40-mm base curve for a −3.0 D sphere power, Dk = 11)

2.4. Procedures

The study duration was 5 weeks, with seven visits, including the screening day. First, an initial screening examination was performed. Subjects who met the inclusion criteria were enrolled in the study. The study procedure, as well as lens care, maintenance,