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Clinical comparison of optimum and large diameter soft contact lenses

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ABSTRACT

Purpose: To compare the clinical performance of large diameter lenses with optimally fit lenses in the same material and monocurve back surface design.
Method: In a four-visit, randomised, bilateral, crossover, study, 25 myopic subjects wore optimum diameter lenses (control) and large diameter lenses (test) in random succession for 1 week each. Both study lenses were made of methafilcon A and of an identical design. Trial fittings with Frequency 55 (Coopervision) lenses modified with a design algorithm were used to determine the appropriate custom-made study lenses.
Results: The least squares mean scores (± SE) for overall comfort and end-of-day comfort (0–10 scale) were 7.57 ± 0.33 vs. 7.42 ± 0.33 ($P = 0.59$) and 7.00 ± 0.31 vs. 7.27 ± 0.32 ($P > 0.05$) for the optimum and large diameter lenses, respectively. There were no significant differences in mean (± SE) gradings for limbal hyperaemia (1.23 ± 0.11 vs. 1.19 ± 0.11, 0–4 scale, $P = 0.60$) and corneal staining (1.79 ± 0.25 vs. 2.04 ± 0.25, $P = 0.39$). Conjunctival staining was greater for the optimum lens: 1.80 ± 0.28 vs. 0.93 ± 0.28 (0–4 scale, $P = 0.001$). With regard to lens fit, the large diameter lenses showed significantly less post-blink movement (0.22 ± 0.01 vs. 0.16 ± 0.01 mm, $P = 0.004$), and greater total decentration (0.15 ± 0.02 vs. 0.21 ± 0.02 mm, $P = 0.010$). However, there was no significant difference in the key fit variable of tightness on push-up (46 ± 0.69% vs. 48 ± 0.69%, 0–100 scale, $P = 0.12$).
Discussion: The findings suggest that larger than optimal soft lenses may be worn without detriment to either comfort or ocular physiology, provided an optimal fit is otherwise maintained.

1. Introduction

Corneal diameter (CD) varies widely in a typical population, for instance, horizontal CD has been measured by ocular coherence tomography (OCT) to range from 12.1 to 14.4 mm [1]. The importance of the relationship between lens and corneal diameter is clinically accepted and textbooks typically suggest that lenses should overlap the limbus by at least 1–2 mm [2,3].

Lenses that are too small for a given eye cause irritation due to the edge encroaching onto the cornea. However, the clinical effects of lenses which are too large are uncertain and there has been little previous work in this area [4]. Theoretical calculations suggest that relatively large lenses can cause excess peripheral pressure [5]. Since many soft lens types are only available in a single diameter, it is inevitable that a significant proportion of lenses dispensed are larger than optimum. It would therefore be useful to have a better understanding of the impact of large diameter lenses on comfort and ocular physiology. The purpose of this study was to evaluate the clinical effect of relatively large diameter soft lenses compared with the effects of optimally fit lenses.

2. Method

This was a randomised, bilateral, unmasked, crossover, study that compared the clinical performance of optimally fit methafilcon A lenses with larger diameter lenses of the same monocurve design and material for 1 week each. The study was undertaken at two investigational sites in the United Kingdom (Aston University, Birmingham; Visioncare Research, Farnham) between January and May 2015.

Twenty-five subjects, aged between 18 and 70 years, were enrolled and dispensed with lenses. Subjects were required to have a spherical contact lens requirement in the range −0.50 to −6.00D and astigmatism less than 1.50D in both eyes. Subjects were excluded if they demonstrated any signs of ocular infection, allergy, disease or corneal irregularity that could interfere with contact lens wear. Subjects were also excluded who had undergone corneal refractive surgery or any anterior segment surgery or had recently worn rigid contact lenses. Neophyte subjects were allowed, although most were existing soft contact lens wearers.

Both lens types were lathecut methafilcon A hydrogel lenses which

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Table 1
Lens Details.

	Trial Lenses	Controls	Test
Manufacturer	CooperVision	Ultravision	
Material	methafilcon A	methafilcon A	
Water content (%)	55	55	
Design	Frequency® 55	Custom manufactured, monocurve back surface, tricurve front surface	
Base curve (mm)	8.60	8.20 to 9.00 in 0.2 steps	
Diameter (mm)	14.2	13.5 to 16.0 in 0.1 steps	
Fitting	–	Optimal	Optimal diameter + 1.2 mm; optimal base curve + 0.6 mm
Sphere powers (D)	−0.50 to −6.00	−0.50 to −6.00	

Frequency® 55 lenses were used as trial lenses to determine the optimum diameter for a given subject by using photography to determine the limbal overlap.

were ordered following trial fitting with a cast moulded lens of the same material (Frequency® 55, CooperVision, Pleasanton, CA, USA). The lathecut lenses were custom manufactured to match the thickness and edge profile of the cast moulded lens (Ultravision CLPL, Leighton Buzzard, UK). The lens used for trial fitting was a single diameter and base curve design (Table 1) and, therefore, in order to select the optimum design for a given eye, an algorithm was used to: i) compensate for non-optimum tightness (i.e. tight or loose), ii) adjust for non-optimal lens diameters (Appendix A). For a lens fitting to be judged as optimum, it was required to cover the cornea in all directions of gaze, be central to the cornea with around 1.2 mm of conjunctival overlap, show sufficient post-blink movement with no edge stand-off, and to show optimal tightness by the push-up test [6,7]. The methods for assessing lens fit have previously been described [7].

Horizontal visible iris diameter was measured with a 0.1 mm increment graticule using a slit lamp biomicroscope and horizontal corneal diameter with an Anterior Segment Optical Coherence Tomographer (AS-OCT; Visante, Carl-Zeiss, Oberkochen Germany). Corneal topography was also conducted (E300, Medmont, Nunawading, VIC, Australia).

The large diameter lens was specified as being 1.2 mm larger in diameter than the optimal lens and 0.6 mm flatter in base curve so as to give a clinically equivalent fitting (e.g. Optimal lens = 8.6/14.2; Large diameter lens = 9.2/15.4) [5]. Since the lenses were custom made, the first pair was dispensed at a second visit at which the lens fit and visual performance were assessed and confirmed to be satisfactory.

Subjects were issued with the AOSept (Alcon, Fort Worth, TX, USA) hydrogen peroxide disinfection system. The use of saline for rinsing prior to insertion and rewetting drops was allowed, only if necessary.

A range of clinical variables was assessed at baseline and then re-assessed at the 1-week follow-up visit (Table 2) with the subjects having worn the lenses for at least 2 h on those visit days. Slit lamp findings were graded with reference to the CCLRU grading scales [8]. For assessment of corneal staining, a yellow filter was used to enhance the appearance of any staining and this was graded for each of five corneal sectors. Similarly, for conjunctival staining, this was graded for each of four segments.

Lens comfort (insertion, during day and end-of-day) was graded by subjects on a 0–10 scale. Symptoms were monitored with the CLDEQ-8 questionnaire [9]. The CLDEQ-8 results were consolidated to produce a total score on a 0–33 scale. Subjects reported their typical insertion time and, if there was a reduction in comfort, the time that this typically occurred so that their comfortable wearing time could be determined.

Between follow-up visits, subjective comfort was monitored by SMS text messaging. Subjects were contacted four times a day (08:00, 12:00, 16:00, 20:00) on Days 2 and 6 of each lens wear period and asked to grade current lens comfort, also on a 0–10 scale. The SMS messages were pre-scheduled to be sent and received via an internet-based messaging service, FASTSMS (Worcestershire, UK, http://www.fastsms.co.uk/).

Table 2
Summary of Clinical Assessments.

Comfort & Symptoms
- Comfort (0–10, where 10 = cannot be felt)
- CLDEQ-8 (0–33 scale, 0 = no problems)

Lens Fit
- Lens centration (mm, −ve value = inferior or temporal)
- Corneal coverage (Y/N)
- Post blink movement (mm)
- Primary-gaze lag (mm)
- Tightness on push-up (0–100, 50 = optimal, < 50 loose, > 50 tight)
- Overall fit acceptance (0–5, Grade 3–5 = acceptable)

Slit lamp Examination
- Limbal hyperaemia (0–4, 0.1 steps)
- Bulbar hyperaemia (0–4, 0.1 steps)
- Palpebral hyperaemia (0–4, 0.1 steps)
- Palpebral roughness (0–4, 0.1 steps)
- Corneal staining (0–4 in 5 sectors, i.e. 0–20)
- Conjunctival fluorescein staining (0–4 in 4 segments, i.e. 0–16)
- Conjunctival indentation (0–4)
- Other findings (0–4).

The study followed the tenets of the Declaration of Helsinki (2013). The protocol was reviewed by the Aston University Ethics Committee and a favourable opinion was received prior to undertaking the study. All subjects received detailed information about the study and signed an informed consent form before participation.

2.1. Statistical analysis

The statistical analysis was undertaken using SAS software Version 9.4 (SAS Institute, Cary, NC, USA). Four hypotheses were tested, specifically, that the following four variables would be significantly poorer with the large diameter lenses compared with the optimal lenses: overall comfort (at visit), end-of-day comfort, limbal hyperaemia, and conjunctival fluorescein staining. Each of these was tested using mixed linear models. The models included the following fixed effects: lens, order, visit, and site; and the random effect subject nested in site. Non-inferiority was concluded if the lower limit of the 95% confidence interval of the difference (test-control) was greater than X and superiority if the lower bound was greater than zero (X = −0.5, −1 and +0.5 for comfort, limbal hyperaemia and conjunctival staining, respectively). Due to the repeated measures study design, the recommended 15° of freedom could be achieved with at least 16 subjects completing the study [10]. Additional variables were tested for statistically significant differences using the mixed model analysis.