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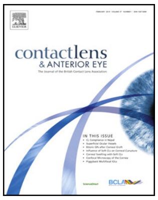

Acute and short-term changes in visual function with multifocal soft contact lens wear in young adults

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ABSTRACT

Purpose: To characterise the effects on accommodation and binocular vision in young adults of 2 distance centre multifocal soft contact lenses (MFSCLs), differing in add power.
Methods: Twenty-four young adult myopes (18–28 years; 20 females, 4 males) had baseline visual acuity, accommodation, near phoria, fixation disparity and stereopsis data collected with single vision (SV) SCLs. The same set of measurements was repeated immediately after subjects were fitted with each of two MFSCLs (with either +1.50 or +3.00 D add), and after 2 weeks of daily wear in each case. The order of testing was randomised and a one-week washout period was allowed between the first and second MFSCL trials.
Results: Differences in distance and near acuities with MFSCLs compared to SVSCLs were small and clinically insignificant. Compared to responses with SVSCLs, MFSCLs increased accommodative lags with this change reaching statistical significance for the +1.50 D add lens. Furthermore, both MFSCLs induced significant shifts in near phorias in the exo direction. Finally, there were no significant differences in stereopsis and fixation disparity with MFSCLs compared to SVSCLs.
Conclusion: Differences in acuities, accommodation accuracy and binocular posture with MFSCLs compared to SVSCLs were clinically small and mostly not significant. These results predict good tolerance of MFSCLs in young patients fitted with them for myopia control.

1. Introduction

The prevalence of myopia has increased dramatically worldwide [1–3], with associated ocular health risks resulting in myopia becoming a leading cause of visual impairment and blindness [4–6]. In the interest of trying to prevent myopia or slow its progression, various optical modalities are either being trialled clinically, or currently under development, including novel spectacle lens designs [7,8], multifocal soft contact lenses (MFSCLs) [9–11], and orthokeratology [12–16].

Myopia is likely a multifactorial condition, and it is possible that different factors come into play for different individuals and/or under different conditions. However, landmark animal model studies have drawn attention to the important influence of retinal defocus on ocular growth. Consistent with results from animal studies showing that imposed hyperopic retinal defocus enhances axial length elongation, it has been suggested that lags of accommodation may act as a myopiogenic factor [17–20]. Furthermore, a number of studies have reported poorer accommodation, i.e., increased lags, in myopes compared to emmetropes and hyperopes [21–23]. Thus it is plausible that correction of such lags [23–26] contribute to the reported myopia control effects of multifocal (MF) spectacles and contact lenses [26–28]. As subjects with near esophorias or fixation disparities tend to exhibit increased accommodative lags, the larger myopia control effects of MF optical corrections in such patients are also as predicted [26,28–30]. Improvements in accommodation performance, i.e., reduced lags, have also been reported with orthokeratology [31], lending further support to the notion that reduction or elimination of accommodative lags contributes to the myopia control effects of such treatments.

The notion that the peripheral retina plays a critical role in refractive error development and thus in myopia progression also has its origins in animal model studies [32–36] and is driving the development of some novel designs of spectacles [7,8] and soft contact lenses (SCLs) [9–11] for myopia control. The underlying premise is that by manipulating the defocus experience of the peripheral retina, one can either neutralise the optical defocus

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stimulus for excessive axial length elongation, i.e., by correcting peripheral (off-axis) hyperopia, or reverse it by imposing myopic defocus, thereby inhibiting eye growth. Thus peripheral myopic defocus is believed to contribute to the reduced myopia progression reported with orthokeratology [12,37–39], and also that of MFSCLs designed with a distance centre and near add periphery [9–11,27,29,30].

The aim of the study reported here was to characterise the acute and short-term effects on accommodation and other visual functions of distance centre MFSCLs with two different near additions, to obtain insight into whether such lenses are likely to sufficiently impair vision as to result in noncompliance and/or intolerance. The data collected also offered an opportunity to gain further insight into the possible mechanism underlying the myopia control effect of this lens design.

2. Methods

2.1. Subjects

Twenty-four young adult subjects were enrolled (age range 18–28 years; 20 females, 4 males). Exclusion criteria included rigid gas permeable wear. SCL wearers were instructed to cease lens wear at least 24 h prior to experimental sessions. Spherical equivalent central (on-axis) refractions (M) ranged between −1.00 and −6.50 D, with astigmatism being ≤−0.75 D.

2.2. Study design

2.2.1. Study protocol

The study made use of Proclear® sphere (single vision, SVSCLs), as well as two distance centre design Proclear® multifocal lenses, differing only in their near add powers (+1.50 and +3.00 D). This MFSCL design has a progressive power profile, with a central 2.3 mm distance correction zone, a treatment zone diameter of 8.5 mm, and a gradual increase in positive power to the full near addition. A battery of functional vision measurements was applied, initially with the SVSCLs in place (baseline, BL), and then at the beginning and end of two study periods of 2 weeks duration (study visit 1 [V1] & study visit 2 [V2]), over which each of the MFSCLs were worn in turn on a daily wearing schedule. The order of testing of the two MFSCL designs was randomised across subjects to prevent learning/practice effects and biases related to residual adaptation effects, and a week-long “washout period” was allowed between the two study phases during which subjects wore their habitual distance correction (i.e., no MFSCL wear). With each MFSCL, subjects were first fitted, the lenses allowed to settle for approximately 5 min and then the first set of data collected.

2.2.2. Lenses & fitting

Both SVSCLs and MFSCLs were made of omafilcon A material (62% water content, CooperVision; USA). During the first visit, both eyes of each subject were initially fitted and tested with SVSCLs to obtain their vertex-adjusted subjective central refractive errors and other baseline data. Subsequent study visits involved measurements with the two MFSCLs, which will be referred to here after as MF-P1.5-SCL (+1.50 D add), and MF-P3-SCL (+3.00 D add).

Centration, corneal coverage, and movement (tightness) of each lens were assessed to confirm clinically acceptable fits before measurements were taken. Lenses showing centration with complete corneal coverage, up to 1 mm movement on blink and 50 ± 15% lens tightness were considered clinically acceptable [40].

2.3. Measurements

2.3.1. Central (on-axis) refractive errors

Both subjective and objective noncycloplegic central refractions were measured. Subjective refractions made use of the technique of maximum plus for best visual acuity (VA) to determine monocular subjective sphere endpoints [41] while the power and axis of astigmatism were determined by the Jackson Cross Cylinder method [42]. Subjective refraction data were used to select the appropriate SV and MFSCLs to fully correct manifest central distance spherical equivalent refractive errors.

Objective refractions were recorded with a Shin-Nippon NVision-K 5001 autorefractor (Tokyo, Japan). Five measurements were taken and averaged. The output of this instrument is in conventional sphero-cylindrical format ($S/C \times \theta$). These data were converted into power vectors M (spherical equivalent), J_{180} (90° to 180° astigmatic component) and J_{45} (45° to 135° astigmatic component) for statistical analysis, using the method reported by Thibos et al. [43].

2.3.2. Ocular biometry

Anterior chamber depths and axial lengths of both eyes were measured with a Zeiss IOLMaster. Five measurements were averaged in each case.

2.3.3. Visual acuity (VA)

High and low (50%) contrast distance VAs were measured with a computer-generated VA chart (M&S Technologies, USA), presented at 6 m. Near VA was measured using a high contrast reading chart (Precision Vision, USA) only, presented at 40 cm.

2.3.4. Accommodation measurements

Accommodation responses were measured with a Complete Ophthalmic Analysis System (COAS) wavefront analyser (Abbott Medical Optics, Albuquerque, NM), with the open field adaptor in place. Measurements were taken under binocular conditions at 4 m and 33 cm (near target vergence of 3 D) from right eyes. For distance measurements, subjects were asked to look at a blank wall 4 m away. The near target consisted of 5 high contrast, 6/24 letters positioned on the subject’s midline. Subjects were instructed to look at the central letter. The COAS wavefront analyser measures ocular aberrations based on the Shack–Hartmann principle, with output in Zernike coefficients. Refractive errors and related accommodation data were derived using the Seidel method, which makes use of both defocus (Z_2^0) and spherical aberration (Z_4^0) terms. Refractive errors thus derived have been shown to most closely match subjective refractive error data [44]. Natural pupil sizes were used in these calculations, so as to best reflect the visual experience of our subjects. Further arguments supporting our choice of the COAS instrument and Seidal method combined with natural pupil sizes for deriving refractive error data relate to first, the age of the subjects, who were all young adults, with relatively larger pupils, and second, the designs of the MFSCLs, which would have substantially altered the ocular spherical aberration profiles [45]. Sphero-cylindrical outputs were converted to power vectors for statistical analysis and the derived spherical equivalent data are reported.

A minimum of 5 measurements was recorded for each of the 4 m and 33 cm distance settings. Accommodative responses were calculated as differences in the spherical equivalent recordings for 4 m and 33 cm distances. Accommodative errors were calculated as the differences between the accommodative demand at 33 cm and recorded responses.

Because the MFSCL design used in this study had a progressive profile, with maximum add power in its periphery, projecting onto more peripheral retinal regions, we undertook additional