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Objective analysis of contact lens fit

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ABSTRACT

Purpose: To assess the validity and repeatability of objective compared to subjective contact lens fit analysis.
Methods: Thirty-five subjects (aged 22.0 ± 3.0 years) wore two different soft contact lens designs. Four lens fit variables: centration, horizontal lag, post-blink movement in up-gaze and push-up recovery speed were assessed subjectively (four observers) and objectively from slit-lamp biomicroscopy captured images and video. The analysis was repeated a week later.
Results: The average of the four experienced observers was compared to objective measures, but centration, movement on blink, lag and push-up recovery speed all varied significantly between them ($p < 0.001$). Horizontal lens centration was on average close to central as assessed both objectively and subjectively ($p > 0.05$). The 95% confidence interval of subjective repeatability was better than objective assessment (±0.128 mm versus ±0.168 mm, $p = 0.417$), but utilised only 78% of the objective range. Vertical centration assessed objectively showed a slight inferior decentration (0.371 ± 0.381 mm) with good inter- and intrasession repeatability ($p > 0.05$). Movement-on-blink was lower estimated subjectively than measured objectively (0.269 ± 0.179 mm versus 0.352 ± 0.355 mm; $p = 0.035$), but had better repeatability (±0.124 mm versus ±0.314 mm 95% confidence interval) unless correcting for the smaller range (47%). Horizontal lag was lower estimated subjectively (0.562 ± 0.259 mm) than measured objectively (0.708 ± 0.374 mm, $p < 0.001$), had poorer repeatability (±0.132 mm versus ±0.089 mm 95% confidence interval) and had a smaller range (63%). Subjective categorisation of push-up speed of recovery showed reasonable differentiation relative to objective measurement ($p < 0.001$).
Conclusions: The objective image analysis allows an accurate, reliable and repeatable assessment of soft contact lens fit characteristics, being a useful tool for research and optimisation of lens fit in clinical practice.

1. Introduction

There is a growing body of evidence to support the long-held clinical view that the assessment of lens fit is critical to contact lens practice. For soft contact lenses, this is limited to lens centration and corneal coverage, movement, surface wettability and subjective comfort. However, these characteristics in clinical practice are often recorded as acceptable ("good" fit) or unacceptable ("poor" fit) and may vary greatly between individual practitioners [1]. It is acknowledged that there are fewer lens parameters to consider when fitting soft lenses than with rigid lenses. Changes in lens fit cannot be predicted reliably by lens base-curve or material properties and vary between individuals [1,2]. Nevertheless, attention to lens selection which includes lens material, dimensions and wearing modality, and accurate recording fit characteristics should not be ignored in order to ensure successful lens wear, avoiding future lens complications and to assist in overcoming contact lens discontinuations [3].

Studies have shown that poor fitting soft contact lenses are commonly associated with discomfort [4], poor vision [4] and drop out from wear [5] and have a more negative impact on ocular physiology, as assessed by bulbar and limbal hyperaemia and corneal staining, compared to well-fitting lenses [6]. It is generally believed that lens mobility is correlated with the tear interchange, which is required to remove trapped debris, inflammatory cells and other tear components that would otherwise accumulate under the lens, as well as to being necessary to provide sufficient oxygen levels at

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the tear-lens interface [7]. In the same way, the tear layer between the contact lens and cornea is also likely to reduce the friction between the surfaces, avoiding significant mechanical interaction, whereas the tear layer between the contact lens front surface and eye lid prevents tissue damage [8].

Previous studies attempting to evaluate the relative importance of contact lens fit metrics have generally been subjective in nature, assessing features such as lens centration, movement on blink, lag and push-up, although the method employed was not always clearly articulated [4,9,10]. A recent study assessing the impact of central and peripheral ocular surface shape on lens fit identified that the inherent variability of subjective lens fit was likely to have influenced the limited variability (24%) that could be explained [11]. Moreover, it has also been demonstrated that the grading ability of even experienced eye-care practitioners is more variable and less sensitive than objective assessment [12], although this has not yet been evaluated with lens fit metrics.

To overcome clinical bias and lack of precision, several studies have attempted to assess lens movement on blink objectively from video, but not all define the direction of gaze (primary or up-gaze), and other lens movements such as lag and push-up recovery speed have not been objectively evaluated [13–16]. Pritchard and Fonn [13] and Schwallie and Bauman [14] video recorded lens movement through a slit lamp and assessed centration and blink movement with a ruler used to make measurements off a monitor. A similar technique was used by Maldonado-Codina and Efron [15] after superimposing a projected gauge over the videos. Tranoudis and Efron [2] also used the same apparatus, but they adjusted the image to match an overlaid circle of known size to take measurements which additionally included up-gaze lag. However, the study by Wolffsohn and colleagues [1] was the first to make a comprehensive objective evaluation of lens fit in primary and multiple other positions of gaze, showing that movement on blink in up-gaze, horizontal lag and push-up recovery speed were the key metrics to independently characterise soft contact lens mobility.

Despite the increasing availability of digital capture through slit-lamp biomicroscopes, the validity and repeatability of objective lens fit analysis has never been determined. The aim of this study was to assess objectively soft contact lens fit characteristics and to determinate how objective analysis can provide the same key parameters as subjective evaluation, but with the advantages of being more repeatable, as well as having a higher resolution.

2. Method

Thirty-five habitual contact wearing subjects (average 22.0 ± 3.0 years: 61% female) took part in the present study. The study was approved by the Human Sciences Ethical Committee and followed the tenets of the Declaration of Helsinki. Written informed consent was obtained from all subjects after receiving a full explanation of the nature and possible consequences of the study. All contact lenses used were commercially available and CE marked. Each subject was only included in the study if there was no evidence or history of binocular vision anomalies, or ocular disease including dry eye, or any pathology that would normally contraindicate contact lens wear. None of the subjects were on ocular medication.

The subjects, with a range of different corneal curvatures (horizontal meridian: 7.85 ± 0.36 mm; vertical meridian: 7.63 ± 0.36 mm; difference: 0.20 ± 0.10 mm), each wore two different soft contact lenses of power −2.50 diopters (D); a conventional hydrogel design (Vistakon Acuvue® 2, etafilcon A material, modulus 0.30 MPa) in one randomly assigned eye and a silicone-hydrogel design (Vistakon Acuvue® Advance®, galyfilcon A material, modulus 0.43 MPa) in the other (i.e. contralaterally). These lenses were chosen for their similar geometries and identical base curve (8.3 mm) and diameter (14.0 mm) parameters. The steepest available base curve (8.30 mm) was selected for dispensing in each case. The assessment of two contact lenses of different moduli allowed for a range of contact lens fit parameters that are commonly seen in clinical practice to be observed.

The study was designed as a randomised, double-blind, repeated measures study. Lens blister packs were re-labelled by a clinical assistant in order to ensure both investigator and subject were masked to lens type. After insertion by the masked investigator, at least thirty minutes to settle the contact lenses were given before assessment, a representative time of that of a lens settled after several hours of wear [13,16]. The subject was asked to look straight ahead, then blink twice in primary gaze, look up and blink a further two times, look down while the upper lid was raised by the examiner to expose the superior lens edge and to look to the left and right. The lens was then pushed upwards digitally while the patient viewed in primary gaze so that the lower lens edge was raised to the middle of the cornea, before being released. The same experienced contact practitioner performed the whole routine on all the subjects. The assessment of lens fit was dynamically captured using a digital slit-lamp biomicroscope providing 6× magnification (CSO digital camera; resolution 1392 × 1024 pixels, frame rate 11 Hz). The same resulting video footage was assessed for lens fit both subjectively and objectively to ensure a like-for-like evaluation of lens fit parameters.

2.1. Subjective lens fit analysis

Four experienced investigators assessed four main lens fit variables: horizontal centration (mm), post-blink movement in up-gaze (mm), horizontal version lag (average of displacement of the lens from the primary position with nasal- and temporal-gaze; mm) and push-up speed of recovery (slow/medium/fast) following digital displacement [1]. All observers repeated the analysis of all the subjects a week later.

2.2. Objective lens fit analysis

A masked observer objectively analysed the resulting video using a purpose-developed image analysis program (LabVIEW, National Instruments, Austin, TX). Lens centration, both horizontal and vertical, was determined from the difference in millimetres between the centre of circles adjusted to circumscribe the visible limbus and contact lens edge in the horizontal and vertical axis, respectively. Movement on blink in up-gaze was assessed by the change in vertical lens position relative to the cornea from the first video frame after the blink until the lens had stabilised. Horizontal version lag was assessed as the difference in millimetres between the limbus to lens edge distance, from the primary gaze position to nasal- and temporal-gaze. Push-up recovery speed in millimetres per second was calculated from the change in vertical lens position relative to the cornea from immediately after the blink until it stabilised, divided by time (derived from the number of frames) taken for this to occur. The analysis was performed three times and repeated by the same masked researcher a week later. Imaging a graticule through the same slit-lamp and camera system determined the calibration as 1 pixel being equivalent to 0.016 mm.

2.3. Statistical analysis

As the present study evaluated lens fit characteristics between techniques of assessment, rather than between eyes (different lens type in each eye), both right and left eye data were used in the analysis. Objective data was considered in each session as the average of the three repeated measurements taken for each variable. Subjective data for lens fit characteristics was considered as the