Simplified Recording of Soft Contact Lens Fit

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Purpose: To determine the critical parameters of modern soft contact lens fits and from this to devise a simplified recording scheme.

Methods: Ten subjects (aged 28.1 ± 7.4 years) wore ten different modern soft contact lenses (including daily disposable and monthly modalities and HEMA and silicone-hydrogel materials). Video was captured of blink (from central and up-gaze), excursion lag (up, down, right and left gaze) and push-up movement, centration and coverage. The contact lenses were marked centrally with surgical pen to enhance video movement detection by image analysis to quantify contact lens displacement and speed.

Results: Lens centration was on average close to the corneal centre. Movement on blink was significantly smaller (p<0.001) in up-gaze (0.15 ± 0.20mm) than in primary-gaze (0.22 ± 0.14mm). Lag was greatest in down-gaze and least in up-gaze (0.70 ± 0.36mm vs 0.21 ± 0.27mm, p<0.001). Push-up test recovery speed was 1.32 ± 0.73mm/s, ranging from no movement to 6.0mm/s. Overall lens movement was determined best by assessing horizontal lag, movement on blink in up-gaze and push-up recovery speed, accounting for 91% of the variance. Steeper lens base-curves did not have a significant effect on lens fit characteristics. Contact lens material did influence lens fit characteristics, particularly silicone-hydrogels which generally had lower centration (F=2.67, p<0.05) and a faster push-up speed of recovery (F=3.34, p<0.05) than HEMA lenses.

Conclusion: Lag on up and down gaze, and movement on blink in primary gaze generally provide little extra information on overall lens movement compared to horizontal lag, movement on blink in up gaze and push-up recovery speed. They can therefore be excluded from a simplified recording scheme. A simplified and comprehensive soft contact lens fit recording system could consist of a cross-hairs indicating the centre of the cornea; a circle to indicate the lens centration; a cross on the relevant position of the circle to indicate any limbal incursion; a number below for movement with blink in up-gaze, a number to the side for horizontal lag and a grade above for the assessed push-up recovery speed.
Introduction

The assessment of contact lens fit is critical to contact lens practice. While a gas permeable lens fit can be evaluated by the pattern of fluorescein under the lens, a soft contact lens drapes onto the lens surface and is stained by fluorescein dye. Therefore assessment is limited to lens centration and coverage, movement and subjective comfort. However to assess all these parameters takes time and the fit of soft lenses trialled in clinical practice are often recorded as “good” or “poor” which is highly subjective and of limited use in future patient aftercare. Therefore the relative importance of contact lens fit characteristics should be assessed to develop a time efficient, but sufficiently detailed description of lens performance for recording in clinical practice.

There is very little published evidence for the proposed damage caused by contact lenses repeatedly crossing the limbal area as assessed by lens centration and coverage. There is a relatively large change in surface curvature at the corneo-limbal junction which could result in mechanical damage from lens edge interactions. The limbus also demarks the end of the corneal avascular area. Changes in physiology with soft lens wear is known to cause chronic filling of pre-existing capillaries (McMonnies et al., 1982) and this predispose the cornea to neovascularisation from repeated mechanical insult. Finally, the cornea relies on limbal stem cells for tissue regeneration (Barrandon, 2007) and is therefore the limbal area is of vital importance. Corneal conjunctivalisation has been shown to occur in some long-standing, full day contact lenses wearers wearing high powered lenses, presumed to be the result of stem cell damage (Martin, 2007).

Poor fitting soft lenses have been shown to have a negative impact on ocular physiology than well fitting lenses in terms of greater fluorescein staining in both loose and tight fitting lenses and higher levels of bulbar and limbal hyperaemia in loose fitting lenses (Young and Coleman, 2001). It is generally it is believed that, in addition to providing sufficient oxygen levels at the tear-lens interface, it is necessary to have adequate tear interchange beneath the contact lens to remove trapped debris, inflammatory cells, and other tear components that would otherwise accumulated under the lens (McNamara et al., 1999). Smaller diameter soft lenses provide substantially better tear mixing than larger lenses, but only by 0.6% between 12.0mm and 13.5mm diameters (1.8 vs 1.2%; McNamara et al., 1999). However, this is still substantially less
than rigid contact lenses (15-16%; Koh et al., 2002). Tear mixing with differing amounts of lens movement does not seem to have been examined.

There is debate over when trial lens fit characteristics should be evaluated. Most studies have shown a decrease in lens movement over the initial 10 to 15 minutes post-insertion (e.g. Schwallie and Bauman, 1992; Brennan et al., 1994; Golding et al., 1995a; Moldonado-Codina and Efron, 2004). However, movement on blink increases again during the day, equating to the movement measured 5 minutes after insertion (Schwallie and Bauman, 1992; Brennan et al., 1994). Models have been developed to account for the lens and anterior eye parameters that influence lens movement (Martin and Holden, 1986; Bibby and Tomlinson, 1993; Cedarstaff et al., 1993). Proposed mechanisms of dehydration dependent steepening of base curve or osmotic dependent binding from hypotonic lacrimation to account for the initial decrease in lens movement post lens insertion have been disproved (Martin and Holden, 1983; Golding et al., 1995a; Pritchard and Fonn, 1995). Instead, post-lens tear film has been shown to be the major determinant of lens movement (Little and Bruce, 1994, 1995), with gradual post-lens tear film expulsion accounting for the initial decrease in lens mobility (Golding et al., 1995b). A negative pressure has been shown to build up beneath the lens, maximal at the apex, due to the hydrodynamic squeeze of the eyelid (Martin and Holden, 1986). In a lens on cornea ex-vivo model this pressure was greater for steeper, thicker and lower water content contact lenses, but in a non-linear relationship. These pressures last longer than the blink and therefore affect the dynamics of the lens movement together with the lens thickness profile and exerted lid forces. However clinically, at least HEMA material lens movement does not appear to be greatly influenced by water content or other material properties (Tranoudis and Efron, 2004), although it is affected by the method of manufacture fit, with lathe cut HEMA lenses centring lower and spun cast lenses moving less than lathe or cast moulded HEMA lenses (Moldonado-Codina and Efron, 2004).

Young (1996) has performed one of the few studies to assess all the soft lens fit characteristics (subjective evaluation), which he did retrospectively on data from several clinical studies in comparison to the examiners view of the lens suitability. He noted lenses often show conflicting fitting characteristics when assessed by direct observation and showed that push-up ease (recovery speed was not assessed) had the highest sensitivity/specificity ratio, with movement on blink in primary gaze a sensitive indicator of tight but not lose fitting lenses. Centration had poor sensitivity. Horizontal lag showed better sensitivity for loose fitting lenses whereas vertical
lag was better for tight lens fits, although the method assessment wasn’t described and he concluded the test had limited value. Some studies even advocate ignoring movement on blink over eyelid push-up findings, particularly with the Acuvue Etafilcon A material (Walker et al., 2003).

Several lens studies have tied to overcome clinical bias and lack of precession by assessing lens movement on blink from video, but not all define the direction of gaze (primary or up-gaze, and over lens movements such as lag and push-up recovery speed have not been objectively evaluated (Schwallie and Bauman, 1992; Pritchard and Fonn, 1995; Moldonado-Codina and Efron, 2004; Tranoudis and Efron, 2004). Most have gauged lens centration, but few lens lag on excursions, especially in more than one position of gaze.

Therefore this study aimed to assess objectively the relationship between soft contact lens fit characteristics, determining how these inform the clinician regarding overall lens movement. This allowed for a simplified method of recording soft lens fit of trialed lenses in clinical practice to be devised.
Method

Ten habitual contact wearing subjects (average 28.10 ± 7.37 years: 4 male, 6 female) gave informed consent to take part in the study. The study was approved by the Human Sciences Ethical Committee and conformed to the Declaration of Helsinki. All contact lenses used are commercially available and were 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, each wore eight different modern soft contact lenses chosen to allow comparison of lens material and base curve (Table 1). This allowed for a range of contact lens fit parameters that are commonly seen in clinical practice to be observed, with all patients being fitted with each of the lenses in random order.

Each contact lens was marked with a surgical pen (DeRoyal, Tennessee, USA) so that movement on blink in primary-gaze and push-up recovery speed could be observed in patients where the lower lid covered the inferior contact lens. After insertion of the contact lens, five minutes to adapt to the contact lenses was given before assessment as this period of time has been shown to best reflect the contact lens fit measured after 8 hours of wear (Schwallie and Bauman, 1992; Brennan et al., 1994). The patient was asked to look straight ahead (Figure 1), 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 (Figure 2). 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 if this was possible, before being released (Figure 3). The same experienced optometrists conducted the routine on all the patients.

----- Insert Figures 1-3 about here -----

The whole examination was video recorded through a slit-lamp biomicroscope providing 6x magnification by a JAI C-S2300 digital camera with a resolution of 767 × 569 pixel. The resulting video was objectively analysed by a second masked observer using a purpose-developed image analysis program (Labview, National Instruments, Austin Texas). Lens centration was determined from the difference in the horizontal and vertical limbus to lens edge
distance on either side of the contact lens. Lag was assessed as the difference between the
limbus to lens edge distance in each of the horizontal and vertical positions of gaze compared to
the same distances when viewing in primary gaze. Movement on blink was assessed by the
change in vertical lens position relative to the cornea from the first video frame following the
blink. Finally push-up recovery speed was calculated from the change in vertical lens position
relative to the cornea from the first video frame following the lens release, divided by the
number of frames over which the movement occurred times 25 to account for the PAL frame
refresh speed. All measurements were taken by the same individual. Repeated analysis of the
same image showed a 95% confidence limit of 0.033mm. Imaging a ruler through the same slit-
lamp and camera system determined the calibration as 1 pixel was equivalent to 0.022mm.

The relationship between contact lens fit characteristics were compared by Pearon's
correlation. The difference between contact lens fit characteristics with lens curvature were
compared by t-test (with Bonferroni correction of significant levels for multiple test) and
materials were compared with analysis of variance.
Results
Lens fit characteristics across all lenses and subjects were averaged. Lens centration was 0.06 ±0.42mm (superior) vertically and 0.07 ± 0.14 horizontally (temporal) compared to the centre of the cornea. There was no significant difference between vertical and horizontal centration (p=0.87). Movement on blink was significantly lower (p<0.001) in up-gaze (0.15 ± 0.20mm) than in primary-gaze (0.22 ± 0.14mm). Lag was 0.61 ± 0.38mm in temporal-gaze, 0.41 ± 0.25mm in nasal-gaze, 0.21 ± 0.27mm in up-gaze and 0.70 ± 0.36mm in down-gaze excursions, each being significantly different from the others (F=49.33, p<0.001). Lag was rarely a movement towards the corneal centre (1.2 to 3.8%) except for in up-gaze when the lens often drifted downwards (23.8%). Push-up test recovery speed was 1.32 ± 0.73mm/s, ranging from no movement to 3.4mm/s.

Vertical contact lens centration was correlated with all directions of gaze excursion lags except superior gaze, which was the only lag correlated with horizontal centration (p<0.05; Table 2). Centration was not related to movement on blink or push-up recovery speed as expected. Movement on blink in up-gaze was correlated to movement on blink in primary gaze (p<0.01), however the latter was also correlated to push-up recovery time and all directions of gaze excursion lags except superior gaze, which was the only lag correlated with movement on blink in up-gaze (Table 2). Lag on nasal excursion was related to temporal excursion and inferior excursion as well as push-up recovery speed. Lag on inferior gaze was correlated with all other directions of gaze as well as push-up recovery speed.

------ Insert Table 2 about here ------
Overall lens movement was objectively modelled as being the average percentage difference from the maximum movement for each of the blink, lag and push-up recovery lens fit characteristics. The direction of movement was ignored as any movement is an indicator to lens mobility and is likely to result in tear exchange. The only lens cornea combination showing excessive movement was removed from the analysis, so more movement was always a positive characteristic. Stepwise multiple regression (step-up method) identified that lag on temporal gaze was the strongest factor, accounting for 62.9% of the variance, and a combination of lag on horizontal excursions (nasal and temporal), movement on blink in up-gaze and push-up test recovery accounting for 90.9% of the variance. The remaining factors accounted for only between 2.3 and 3.5% of the variance each (Figure 4).

------ Insert Figure 4 about here ------
Steeper lens base-curves (Purevision 8.3; Acuvue Advance 8.3; 1 Day Acuvue 8.5) did not have a significant effect compared to flatter base-curves (Purevision 8.6; Acuvue Advance 8.7; 1 Day Acuvue 9.0) on lens centration, movement or excursion lags (p>0.05). However, steeper base-curves showed a trend towards small lens lag on down-gaze excursion (0.65 ± 0.33mm vs 0.77 ±0.39mm, p=0.02), but conversely a greater movement on blink in up-gaze (0.17 ± 0.21mm vs 0.09 ± 0.21mm, p=0.007) compared to flatter lenses (Bonferroni correction for multiple t-tests requires a p<0.0056 level for statistical significance).

Comparing lens material affects on contact lens fit, vertical centration was generally higher and less central in the HEMA than the silicone hydrogels, but not with the Focus Dailies lenses (F=2.67, p<0.05; Figure 5). Lag was significant in up (F=5.94, p=0.001) and downward (F=2.94, p<0.05) excursions with the Focus Dailies more prone to be located higher than the other lens materials. Push-up speed of recovery was significantly greater with the silicone hydrogel than the HEMA material contact lenses (F=3.34, p<0.05).

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Conclusion
Lag on up and down gaze, and movement on blink in primary gaze generally provide little extra information on overall lens movement compared to horizontal lag, movement on blink in up gaze and push-up recovery speed. They can therefore be excluded from a simplified recording scheme. A simplified and comprehensive soft contact lens fit recording system could consist of a cross-hairs indicating the centre of the cornea; a circle to indicate the lens centration; a cross on the relevant position of the circle to indicate any limbal incursion; a number below for movement with blink in up-gaze, a number to the side for horizontal lag and a grade above for the assessed push-up recovery speed.
Figure Legends

Figure 1: Example image of lens centration.

Figure 2: Example images of excursion lag.

Figure 3: Example image of contact lens push-up.

Figure 4: Comparison of overall contact lens movement parameter with movement on blink, excursion lag and push-up recovery speed fit characteristics. n=79.

Figure 5: Contact lens fitting characteristics with lens material. n=80. Error bars = 1S.D. *=significance at p<0.05; **=significance at p=0.001.
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<th>Total Diam (mm)</th>
<th>Power (D)</th>
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Table 1: Contact Lens characteristics
Table 2: A comparison of objective lens fit characteristics. N=10. **=significance at p<0.01; *=significance at p<0.05
Contact Lens Fit Characteristic

- Centration - Vertical
- Centration - Horizontal
- Blink - Up Gaze
- Blink - Primary Gaze
- Lag - Temporal Gaze
- Lag - Nasal Gaze
- Lag - Up Gaze
- Lag - Down Gaze
- Push-Up Recovery

Movement (mm) or Speed (mm/s)

Balafilcon A
Galyfilcon A
Etafilcon A
Nelfilcon A
Hilafilcon B

Contact Lens Fit Characteristic

- Movement (mm) or Speed (mm/s)
- Balafilcon A
- Galyfilcon A
- Etafilcon A
- Nelfilcon A
- Hilafilcon B

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