Consensus on Recording of Gas Permeable Contact Lens Fit

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Abstract

Purpose: To develop a new schematic scheme for efficiently recording the key parameters of gas permeable contact lens (GP) fits based on current consensus.

Methods: Over 100 established GP fitters and educators met to discuss the parameters proposed in educational material for evaluating GP fit and concluded on the key parameters that should be recorded. The accuracy and variability of evaluating the fluorescein pattern of GP fit was determined by having 35 experienced contact lens practitioners from across the world, grading 5 images of a range of fits and the topographer simulation of the same fits in random order using the proposed scheme. The accuracy of the grading was compared to objective image analysis of the fluorescein intensity of the same images.

Results: The key information to record to adequately describe the fit of an GP was agreed as: the manufacturer, brand and lens parameters; settling time; comfort on a 5 point scale; centration; movement on blink on a ±2 scale; and the Primary Fluorescein Pattern in the central, mid-peripheral and edge regions of the lens averaged along the horizontal and vertical lens axes, on a ±2 scale. On average 50-60% of practitioners selected the median grade when subjectively rating fluorescein intensity and this was correlated to objective quantification ($r=0.602, p <0.001$). Objective grading suggesting horizontal median fluorescein intensity was generally symmetrical, as was the vertical meridian, but this was not the case for subjective grading. Simulated fluorescein patterns were subjectively and objectively graded as being less intense than real photographs ($p<0.01$).

Conclusion: GP fit recording can be standardised and simplified to enhance GP practice.

Keywords: rigid gas permeable contact lenses (RGP); fitting characteristics; lens evaluation; record keeping; fluorescein pattern observation

Introduction

Accurate record keeping when fitting contact lenses is essential for medico-legal protection as well as to allow informed refitting decisions to be made in the future. This is particularly important if follow-up care is undertaken by a different eye care practitioner. While soft lenses fit evaluation has been analysed objectively, and a simplified but comprehensive schematic for recording the findings has been developed,[1] no such research has been published on gas permeable contact lenses (GPs).

Unlike soft lenses which largely conform to the contour of the ocular surface, GP fit can be evaluated by the pattern of fluorescein under the lens. Evaluation of the lens fit with fluorescein has been used ever since rigid lenses came on to the market in the 1950s. It has been proven to be very useful in clinical practice to identify where the lens comes on contact with the corneal surface (termed 'touch'), although the human eye is only able to detect fluorescein layers with a thickness of at least 20 μm.[2,3] This results in tear layers thinner than 20 μm appear dark. For this reason for instance, it is difficult to fit orthokeratology lenses relying on fluorescein patterns alone.[4]

Suboptimal lens fit has been proven to be of influence on comfort of GP lens wear. In a study at the University of Maastricht it was found that comfort improved over a period of three months in the optimal lens fit group, but not in the sub-optimal lens fit group. The difference after three months between these two groups was 2 on a 10 point scale; a statistically and most probably clinically significant difference.[5]

One of the few complications that is typical for, and exclusively seen in, GP lens wear is 3-

and 9-o'clock staining. The prevalence of 3- and 9-o'clock staining is reported to be up to 80%, of which 10-15% is estimated to be of clinical significance. In a review paper, five out of the total of eleven treatment options to decrease or remedy 3- and 9-o'clock staining identified in the academic literature were related to lens parameters, three to lens performance.[6] Hence improving lens fit, by following the shape of the cornea more closely, could remedy the condition of 3- and 9-o'clock staining.[7]

Corneal topography could be beneficial in this process, but fluorescein evaluation is crucial in the final judgment of the lens fit. In addition, suboptimal GP lens fit leads to corneal warpage.[8-10] The mean recovery time for corneal warpage in GP lens wearers (as assessed by a topography change less than 0.5 D) is 8.8 ± 6.8 weeks.[12] The resting position of the lens on the cornea seems to play an important role; the topography of warped corneas is usually characterised by a relative flattening of the cornea underlying the GP contact lens in its resting position. Lenses that ride high, for example, produce flattening superiorly and result in a relatively steeper contour inferiorly.[11]

As well as the fluorescein pattern, other aspects of GP fit have also been proposed to be important to optimised fitting such as centration and coverage, lid attachment and surface wettability.[13-16] However, there is little evidence in the academic literature as to which of these parameters independently contribute to comfortable, healthy GP lens wear. Unlike soft lenses,[17,18] there are no studies modelling how lens design, material and anterior eye parameters influence lens movement.

An added level of complexity results from the dynamic nature of an GP fit, with the movement on blink typically an order of magnitude larger than that of a soft contact lens. Movement of a lens is critical to provide sufficient oxygen exchange over the corneal surface as well as to remove trapped debris, inflammatory cells, and other tear components that would otherwise accumulate under the lens.[19] The tear layer between the contact lens and cornea also reduce the friction between the surfaces, avoiding significant mechanical interaction. While soft lenses with limited mobility have been shown to have a more negative impact on ocular physiology than well fitting soft lenses,[20] this is not well researched for GPs. This is probably because tear exchange beneath an GP is typically 15-16% compared to 1-2% for soft lenses,[19,21] although tear mixing with differing amounts of lens movement does not seem to have been examined.

Therefore, to assess all these parameters takes a significant amount of time. Time pressures of clinical practice and a lack of consensus as to the key parameters that need to be optimised to achieve an appropriate GP fit results in varied and sometimes minimal documentation of GP fit characteristics. Notations such as "good" or "adequate" can be highly subjective and of limited use in future patient aftercare. This is especially the case in large practices with multiple eye care specialists, or when communicating with colleagues or lens manufacturer/consultants. Therefore, the relative importance of contact lens fit characteristics should be decided upon to develop a time efficient, but sufficiently detailed, description of lens performance for recording in clinical practice.

This study aimed to gain consensus from GP practitioners across the world as to the key parameters that should be observed and recorded and characterized to characterize

corneal GP contact lens fit. In addition, practitioner's ability to subjectively scale fluorescein patterns was assessed against objective image analysis. This allowed for a simplified method of recording the GP lens fit of trialed lenses in clinical practice to be devised.

Method

Over one hundred established GP fitters and educators met to discuss the parameters proposed in educational material for evaluating GP fit and concluded on the key parameters that should be recorded. These focus groups were held in 2011-13 at the British Contact Lens Association Conference, Netherlands Contact Lens Conference and British Committee of Contact Lens Educators (BUCCLE). In addition, members of the International Association of Contact Lens Educators (IACLE) and the Association of Optometric Contact Lens Educators (AOCLE) were contacted for their opinions and comment.

The focus groups were facilitated by the authors to discuss all elements that contribute to the GP fit decision making process and to debate over those elements that are critical to the decision to modify lens parameters. It was emphasised that while making clinical decisions cannot be prescriptive on a limited range of findings and the GP fitted should be based on clinical interpretation and experience, the recording of the key parameters could be standardised and terminology emotive of clinical decisions, such as "excessive", were hence avoided. Observation should also be totally independent of clinical consequences, as something isn't necessarily 'worse' because a different treatment plan is required.

The accuracy and variability of evaluating the fluorescein pattern of central the GP fit using the scheme proposed and agreed on by the consensus groups was determined by 35 experienced GP practitioners from around the world using five photographic images captured through a yellow filter chosen to represent a range of steep-to-flat and spherical-to-toric fits and the five topographer simulations of the same fits with the Medmont E300

corneal topographyer (Medmont Ltd, Melbourne, Australia). These were presented in random order and the practitioners were not aware that the topographer simulations were paired with photographs of lens fits to avoid bias in their grading. The graded regions of the photographs and simulations were objectively analysed using bespoke Labview Vision software (National Instruments, Austin, Texas, USA) using the 256 point 8 bit) intensity scale for green light for comparison with the average practitioner grading. Concordance was assessed between practitioners as to the percentage selecting the median grade for each corneal zone. The average grade was correlated to the image analysis objectively measured green intensity across all zones and meridians using Spearman's rank correlation.

Results

It was agreed in the workshop that the following should be recorded when fitting or checking an GP contact lens fit:

- Lens specifications including the lens design and manufacturer, base curves and associated diameters and lens power (as well as centre thickness, edge lift design, material, colour and any special requests such as prism, truncation or lenticularization if not previously recorded in the notes) Even if the patient was previously fitted in the practice, it is often not clear which lens the patient is wearing if it is not recorded along with the lens fit evaluation.

- The settling time in minutes, which should be sufficient for initial adaptation to have occurred, any induced tearing to have subsided and the lens to be comfortable. The consensus was that 20 minutes should meet these criteria in most cases. If this is not the case, the lens fit recorded will not be representative of the true fit, and if the lens does not fully settle, then it is unlikely the lens would be prescribed.

- Comfort on a 0 (poor) to 4 (perfect) scale. The 5 point range was determined to be sufficient to differentiate between comfort states, without scale grades being redundant. This matches familiar grading scale increments, although in reverse as asking a patient about any discomfort has the potential to negatively influence the patients reflection on the lens fitting experience.

- White diffuse light to evaluate:
  - Centration - as the lens is mobile, the amount of decentration will change with time after each blink, so to make clinical decisions, centration would be noted as 'L' to indicate the GP is crossing the limbus or 'P' when the optic

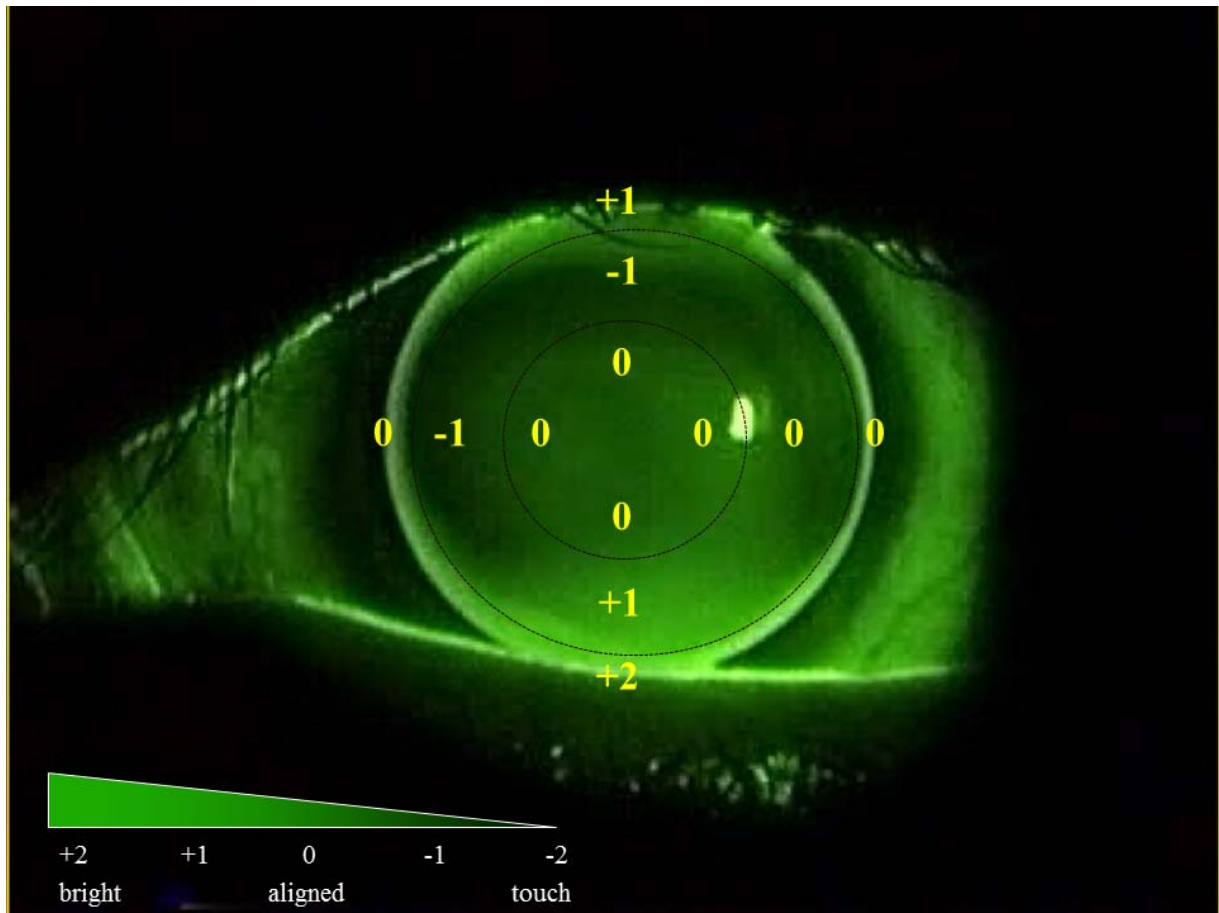zone encroaches across the pupil in dim light (mesopic conditions), together with the direction; otherwise a 'C' could indicate adequate centration. Coverage was felt to be largely covered by centration indicators, with an 'X' denoting the diameter is insufficient for the optic zone to encompass the pupil throughout the inter- blink period.

- o Movement – the amount of movement on blink should be recorded on a -2 to +2 scale:
    - +2: > 2 mm movement
    - +1   1.6 to 2.0 mm movement
    - 0   1.0 to 1.5 mm movement
    - -1   0.5 to 0.9 mm movement
    - -2   < 0.5 mm movement

Fluorescein assessment – sodium fluorescein should be applied using a fluoret with excess saline removed[22] ideally to the temporal superior conjunctiva to maximise longevity on the ocular surface and the GP lens evaluated when centred, after a few blinks. A yellow filter should be used in front of the observation system to optimally view the fluorescein fluorescence.[22] While some practitioners like to evaluate the lens in its resting position after a blink as well, the lens parameters are traditionally chosen to conform with the central cornea and if the lens is too far decentred from the central cornea, its parameters should be altered to improve centration. Hence the fluorescein pattern when the GP is centred (which can involve lid manipulation by the practitioner) should be recorded. The 'Primary Fluorescein Pattern' should be graded in the two principal meridians, recording the central (the inner 50 % of the radius except the very centre where the two meridians cross), mid peripheral (the outer 50 % of the radius except for the final edge curve) and
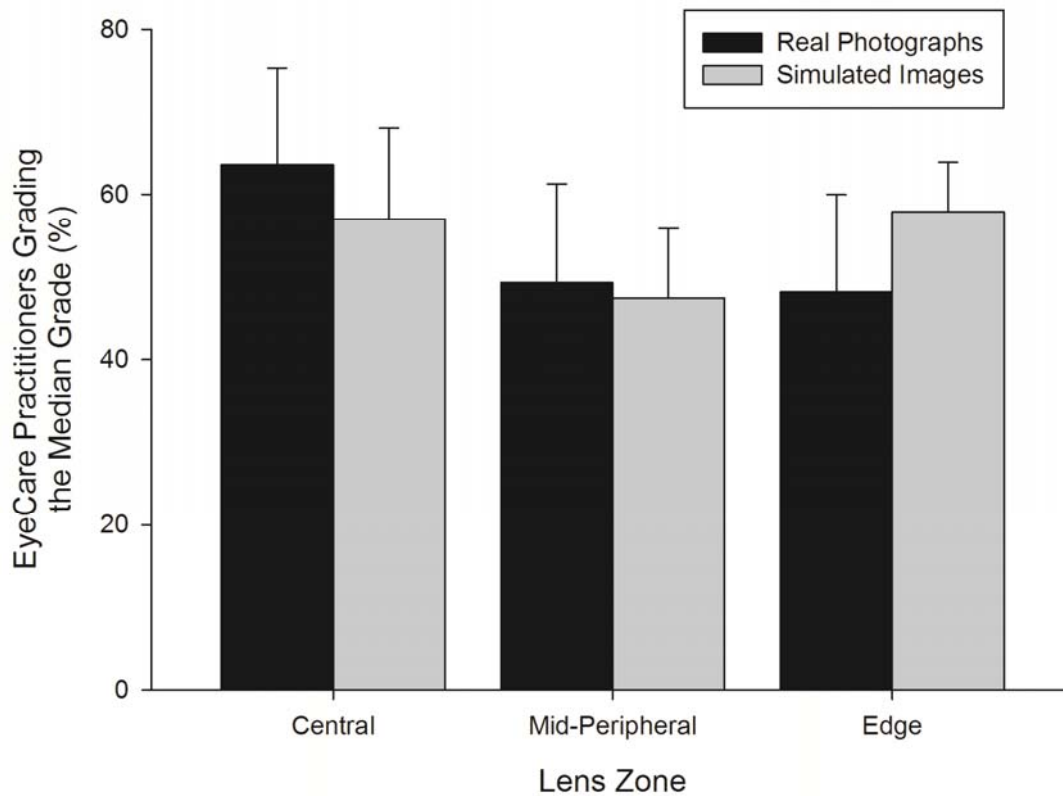
edge zone (the final edge curve) fluorescein intensity (Figure 1). If the Primary Fluorescein Pattern shows clear oblique astigmatism, the fluorescein intensity should be graded along these meridians and a note made of the oblique angle under which the grading is conducted.

Figure 1:   Fluorescein picture with overlaid central, mid-peripheral and edge zones, graded for fluorescein intensity on a +2 to -2 scale along the principal meridians (image courtesy of Ron Beerten, Procornea, The Netherlands).

Fluorescein intensity grading concordance was assessed between practitioners as to the percentage selecting the median grade for each corneal zone (i.e. the one chosen most commonly by the graders). For the inner ring concordance was 60 ± 11 % which was

significantly greater than the mid-peripheral grading (48 ± 10%; p = 0.036), but not significantly different compared to the edge zone (53 ± 10 %; p = 0.248; Figure 2). The average grade was correlated to the image analysis objectively measured green intensity across all zones and meridians using Spearman's rank correlation. There was a strong correlation between the average subjective grading and objective quantification of fluorescein intensity (r = 0.602, p <0.001).

Figure 2: Concordance (eyecare practitioners selecting the median grade) in the central, mid-peripheral and edge lens zones for both real photographs and simulated images of fluorescein patterns. Error bars = 1 S.D. n=35 practitioners and 5 averages of fluorescein pattern intensity grading on a +2 to -2 scale along the principal meridians.

The subjective grading was not symmetrical between superior and inferior or between nasal and temporal for the inner (F = 70.318, p < 0.001; F = 28.533, P <0.001) or mid peripheral (F = 22.831, p < 0.001; F = 14.969, P <0.001) fluorescein intensity grading zones (respectively). However edge fluorescein intensity grading was symmetrical between superior and inferior (F = 3.477, p = 0.071), although not between nasal and temporal (F = 36.869, P <0.001) zones. Hence the fluorescein intensity grades in the steeper and flatter meridians generally differed on either side of the lens centre. Conversely, objective grading was not significantly different between superior and inferior (F = 1.256, p = 0.292) or between nasal and temporal (F = 0.833, p = 0.385) positions.

Simulated fluorescein patterns were subjectively graded significantly differently to real photographs (average grade -0.3 ± 1.3 vs 0.2 ± 1.2; F = 47.069, p < 0.001), and there was an interaction with grading zone (inner -0.1 ± 1.3 vs 0.6 ± 1.0; mid-peripheral -0.2 ±1.2 vs 0.2 ± 1.2; edge -0.5 ± 1.5 vs -0.3 ± 1.3; F = 5.950, p = 0.003) and position on the GP (superior 0.5 ± 1.1 vs 0.4 ± 1.1; temporal -0.8 ± 1.2 vs -0.1 ± 1.3; inferior 0.1 ± 1.3 vs 0.5 ± 1.1; nasal -0.8 ± 1.2 vs -0.2 ± 1.2; F = 27.178, p < 0.001) respectively. The correlation between the objective quantification of the real and simulated fluorescein patterns was also only moderate (r = 0.256, p = 0.048), with the 'brightness' of the real photographs being greater (40.2 ± 17.2%) than the simulated images (30.4 ± 24.7 %; t-test p = 0.008).

Discussion

This study set out to establish a consensus on the recording of GP lens fit. While grading is sometimes directly related to management, recording of GP fitting characteristics should be informative to the management process based on clinical judgment using all the available information, rather than dictate it. Based on clinical and anecdotal feedback, consensus was reached on the ideal settling time being 20 minutes; the rating of discomfort on a 5 point scale, which has previously been shown to sufficiently differentiate between comfort states, without scale grades being redundant[1]; white diffuse light evaluation of centration and coverage, with recording linked to issues that would affect clinical management such as crossing the limbus or the optic zone is encroaching across the pupil; and movement on blink which is critical to healthy ocular physiology.[19,21]

Fluorescein assessment was concluded to be best evaluated with the GP lens centred, using lid manipulation if necessary, using a ± 2 grading system in the four principal meridians, recording the central, mid peripheral and edge zone fluorescein intensity. This 'Primary Fluorescein Pattern' evaluation was utilised by thirty-five experienced practitioners on both real and topographer simulated fluorescein images. Concordance between practitioners was moderate, with approximately 50-60% agreeing on the same grade, although it was slightly worse for the mid-peripheral zone. This may be due to difficulties in judging the most appropriate position to grade the fluorescein intensity for this zone. The zones were arbitrarily chosen to be approximately 5 mm and 8 mm in diameter, but a graticule in the slit lamp eye-piece or the imaging software depicting these zones should assist the practitioner in enhancing their grading. The correlation with objective analysis of
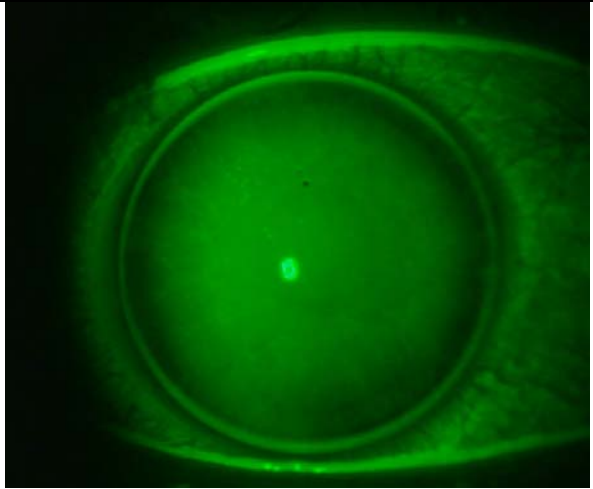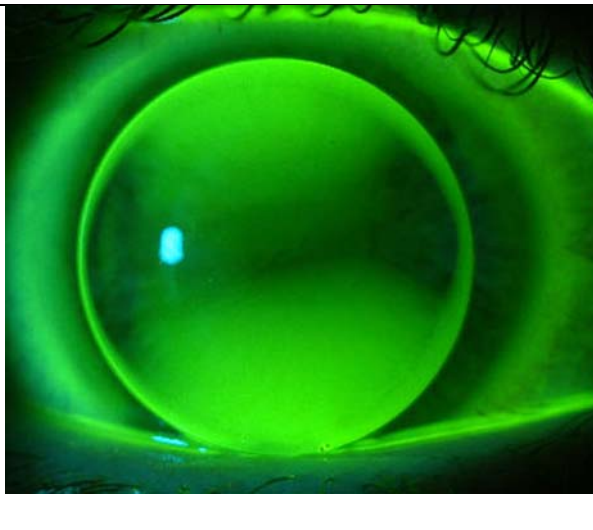
fluorescein intensity was also moderate, with subjective grading accounting for 36% of the variance.

While objective measurement of fluorescein intensity was symmetrical in the vertical and horizontal meridians; however, this was not generally the case for subjective grading. The intensity of the fluorescein was consistently graded as greater in the superior position compared to the nasal, and greater in the temporal position compared to the nasal, for each of the zones. This would suggest that the lack of symmetrical subjective fluorescein pattern grading may be due to off-axis clinical positioning of the slit-lamp illumination system rather than differences in fit. Hence it would seem appropriate to average the grading along the vertical median (so one grade for edge fluorescein intensity as the average at the top and bottom of the lens, one grade for mid-peripheral fluorescein intensity and one grade for central lens fluorescein intensity) and along the horizontal meridian to halve the number of fluorescein intensity grades to record.
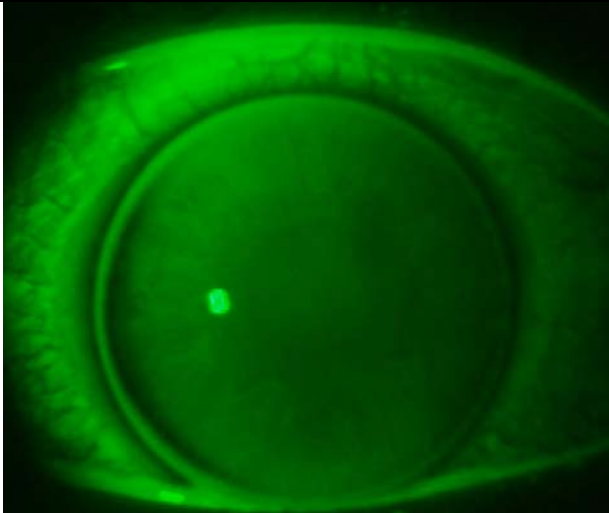
Interestingly, simulated fluorescein patterns were subjectively graded as significantly less intense than actual photographs in each zone and this was confirmed objectively. In addition, the correlation between the objective quantification of the real and simulated fluorescein patterns was significant, but only just. Hence this would suggest that topographer simulation images could be made more intense to more closely depict clinical images when an GP of these parameters is fitted to the eye.

Hence, from this research the suggested schematic for recording GP fit is demonstrated in Figure 3 examples. While more could be recorded regarding GP lens fit particularly when

fitting irregular corneas, this standardised schematic format is quick to notate and should

be sufficient for most decision making, providing a substantial benefit over current

practice.

	A) Manufacturer, Brand, 7.80/9.8 +3.50 Settling time: 20 mins Comfort: 4 Centration: C Movement on blink: -1 PFP; C M E V: +2 0 -1 H: +2 0 -1
Figure 3A: Example of how to record a well centred, steep lens (fluorescein grading median of 35 experts)	
	B) Manufacturer, Brand, 8.20/9.8 -2.50 Settling time: 20 mins Comfort: 2 Centration: L temporally Movement on blink: +1 PFP; C M E $V100^0$: +1+2+2 $H10^0$: -1 -2 +1
Figure 3B: Example of how to record a slightly oblique toric lens fit, which is mobile and crosses the limbus (fluorescein grading median of 35 experts)	

	C) Manufacturer, Brand, 8.10/9.8 -1.50
	Settling time: 20 mins
	Comfort: 3
	Centration: C
	Movement on blink: 0
	PFP; C M E
	V: 0 0 0
	H: 0 0 -1

Figure 3C: Example of how to record a largely aligned lens with little edge lift (fluorescein grading median of 35 experts)

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