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Is fluorescein pattern analysis a valid method of assessing the accuracy of reverse geometry lenses for orthokeratology?

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Background: The aims of this study were to investigate the relative frequencies of correct identifications of variations in the fit of conventional rigid gas permeable (RGP) lenses and reverse geometry lenses (RGL) from fluorescein pattern analysis by orthokeratology (ortho-k) practitioners and non-ortho-k practitioners and to determine whether fluorescein pattern analysis is sensitive for assessing ortho-k lens fittings.
Methods: Slides of fluorescein patterns of different lens fittings were shown to the practitioners, who were asked to identify the ideal, flatter, flattest, steeper and steepest lens fittings.
Results: Observed frequencies of correct identifications of most of the conventional RGP lens fittingss were not significantly different from the expected frequencies for both groups of practitioners. The observed frequencies of correct identifications of all of the RGL fittings were either not significantly different or were lower than the expected frequencies.
Conclusion: The relative frequencies of correct identifications of fluorescein patterns of both conventional RGP lens and RGL fittings by experienced ortho-k practitioners were not different from those by non-experienced ortho-k practitioners. Practitioners from the two groups were not always able to diagnose conventional RGP lens and RGL fittings adequately from fluorescein pattern analysis alone. Fluorescein pattern analysis alone may not be sufficiently sensitive for assessing ortho-k lens fitting.

Key words: conventional RGP lens, fluorescein pattern, orthokeratology, reverse geometry lens

Fluorescein pattern analysis is a time-honoured routine in optometric practice.[1] The ability to accurately assess the fitting relationship between a rigid lens and the corneal surface is an integral part of contact lens fitting.[2] After a suitable period of training, some practitioners can routinely detect a variation of 0.05 mm in back optic zone radius (BOZR), which equates to a 10 μm difference in tear layer thickness, using slitlamp examination with fluorescein.[3] Fluorescein pattern analysis of aspheric lenses appears to show a sensitivity of ±0.10 mm in BOZR.[4]

Alignment fitting of a conventional rigid gas permeable (RGP) lens is characterised by an even glow of fluorescein under the centre of the lens, with the lens on centre, while steep-fitting lenses are diagnosed by increased tear layer fluorescence and flat-fitting lenses by a relative lack of fluorescence under the central part of the lens.[5] Reverse geometry lenses (RGL) are commonly used for orthokeratology (ortho-k) and one would expect that the same basic rules of fluorescein pattern analysis could be applied to achieve an accurate fitting. The validity of using fluorescein pattern analysis to determine ortho-k lens fitting may be questionable[6,7] due primarily to the extremely thin apical tear layer commonly used in fitting ortho-k lenses and the relative visibility of the fluorescein under the apex of the lens. Also, practitioners (personal communications) have reported greater difficulties in fluorescein pattern analysis with RGL compared to RGP lenses. A standard spherical alignment lens on a normal aspheric cornea is assumed to have an apical tear layer thickness of between 15 and 20 μm with an ideal fitting. This is not the case in ortho-k, where the lens is assumed to have an apical clearance of between 5 to 15 μm.[8]

A common misconception is that ortho-k lenses should be fitted with heavy apical bearing. In practice, this would cause the same problems that occur with heavy central touch in keratoconus, namely, epithelial staining and scarring.[9] Ortho-k lenses must have some degree of apical clearance to safeguard corneal epithelial integrity.

Various ortho-k lens designs are available and all provide instruction books giving a description of the static fluorescein pattern of ideal, steep and flat fittings, lens movement and centration. In general, a generic 4-curve RGL will have a fluorescein pattern that exhibits a central 3.00 mm zone of 'apical touch' (absence of visible fluorescein) surrounded by a deep and narrow annulus of fluorescein. The alignment curve appears as another zone of 'light touch' followed by the edge lift curve.

Two commonly used ortho-k lenses are the BE lens (Mountford/Noack design; BE Lens, Ultravision Capricornia, Australia) and DreimLens (Reim design; DreimLens, HK)). The BE lens requires that the initial apical radius and corneal elevation at the chord of contact of the lens be input into a dedicated computer program to calculate the trial lens that will give the closest matching sag to that of the cornea. The apical clearance between the corneal sag and the trial lens sag is displayed in the program. BE lenses have a variation of 8 μm in sag between lenses in the trial lens set, so the theoretical apical clearance of each successive lens worn by the patient could be derived by simply adding or subtracting the differences between lens sags and the initial calculated apical clearance. The DreimLens is fitted according to the keratometry readings, with the initial base curve selected according to a nomogram supplied by the manufacturer. Each lens in the set has a 10 μm difference in lens sag.

We decided to test the sensitivity of fluorescein pattern analysis with RGL by asking a group of experienced ortho-k practitioners and another group of non-ortho-k practitioners to rate the fittings of three RGL (two BE lenses and one DreimLens) and two conventional RGP lenses. The purposes of this study were:

1. To investigate whether practitioners, with and without ortho-k experience, can correctly identify the fittings of RGL and conventional RGP lenses based on the analysis of fluorescein patterns shown on slides.
2. To investigate whether there is any difference in the ability of ortho-k practitioners and non ortho-k practitioners to determine the above lens fittings.
3. To determine the sensitivity of static fluorescein pattern analysis for ortho-k lens fitting.

METHODS

Subjects

Two subjects (one Caucasian, one Chinese) with no history of ocular or general health problems were recruited for the study. Both gave informed consent prior to lens fitting.

A random group of 32 optometrists presenting for a continuing education lecture were recruited to grade the fluorescein patterns shown on projected slides. Of the group, 11 were experienced ortho-k practitioners currently practising ortho-k and had successfully fitted at least 10 cases, while the other 21 optometrists were not practising ortho-k.

Procedures

Four topography readings were taken of the right eye of each subject using the Medmont E300. The mean and standard deviation were calculated for the apical radius and elevation values at the chord of contact of the lens (9.35 for the 11.00 mm lens for the Caucasian eye and 8.95 mm for the 10.6 mm lens for the Asian eye). These values were used to determine the ideal fitting conventional alignment RGP lens and RGL for each subject. The conventional RGP lenses were Menicon design (Menicon Corp. Japan), while the RGL were BE lenses (on the Caucasian eye) and DreimLens (on the Chinese eye).

The conventional RGP lenses were fitted 'on-K' and photographed using a digital imaging system (Topcon), blue light and a Wratten yellow filter. The patients received one drop of unpreserved 0.4 per cent Benoxinate prior to lens insertion to reduce lacrimation and blepharospasm. A drop of saline was applied to a fluorescein strip and excess fluid shaken off before applying the strip flat to the superior bulbar conjunctiva within one minute of lens insertion. The subject was seated at the slitlamp and the patient advised to blink three or four times. After approximately 30 seconds, a series of photographs was taken until an 'ideal' image, that best represented the lens fitting, was achieved. The total time needed to take the desired photo was no longer than two minutes. The lenses were removed and a sequence of base curves each 0.05 mm steeper or flatter than the alignment (on-K) fit applied, so that the maximum variation was either 0.10 mm steeper or flatter. These lenses were photographed, when the lens was centred on the cornea. A resting interval of about five minutes was allowed between lens fittings.

The choice of ideal initial RGL differed for the two designs. The BE lens fitting was based on the computer determination of best fitting calculated from topographical data. For DreimLens, the trial lens was inserted by a practitioner experienced in DreimLens fitting and assessed according to the manufacturer's fitting nomograph. Modifications in lens fitting were made until an ideal fitting was achieved. The lens fitting was flattened or steepened in 10 μm steps and photographs were taken to obtain an ideal image that represented each lens fitting (steepest, steeper, ideal, flatter and flattest).

The images were imported into Photoimpact and the brightness and contrast of each of the images modified to standardise the appearance of the patterns. A collage of each lens fitting was produced using Powerpoint, so that all five fluorescein patterns of each lens type were on the same slide. The position of each of the fluorescein patterns was randomised by coin toss. Each of the patterns was assigned a letter ranging from A to E.

The optometrists were given a sheet listing the five different lens fittings and asked to assess the individual patterns, projected onto a large screen from a LCD projector, to determine in sequence the ideal fitting, the next flatter or steeper lens and the flattest and steepest lenses. A description of an ideal ortho-k lens was given to the non-ortho-k practitioners and they were requested to use the same clinical decision-making process for the ortho-k lens that they would use in assessing the accuracy of a conventional RGP lens. The flat K readings of the two subjects were given to the group and the slides were presented in turn. The practitioners were given two minutes to decide on the fitting of each lens and to complete the form, using a forced choice procedure. Participants were permitted to move closer to the screen to grade the photos.

Statistical analysis of data

The number of correct and incorrect assessments of each lens fitting was used to calculate chi-square (χ^2) to test goodness of fitting (to a uniform distribution), to determine if the observed frequencies (of correct and incorrect assessments) were attributable to chance.[10] Fisher's Exact Tests were used to determine if there were any differences in the ability to determine RGL and conventional RGP lens fits between ortho-k and non-ortho-k practitioners. The assessments of the two conventional RGP and the three RGL fittings were pooled for these tests. For the two conventional RGP lenses, the total number of observations from ortho-k practitioners was 22, while there were 42 for the non-ortho-k practitioners; for three RGL, the total number of observations from ortho-k practitioners was 33, and from non-ortho-k practitioners, 63.

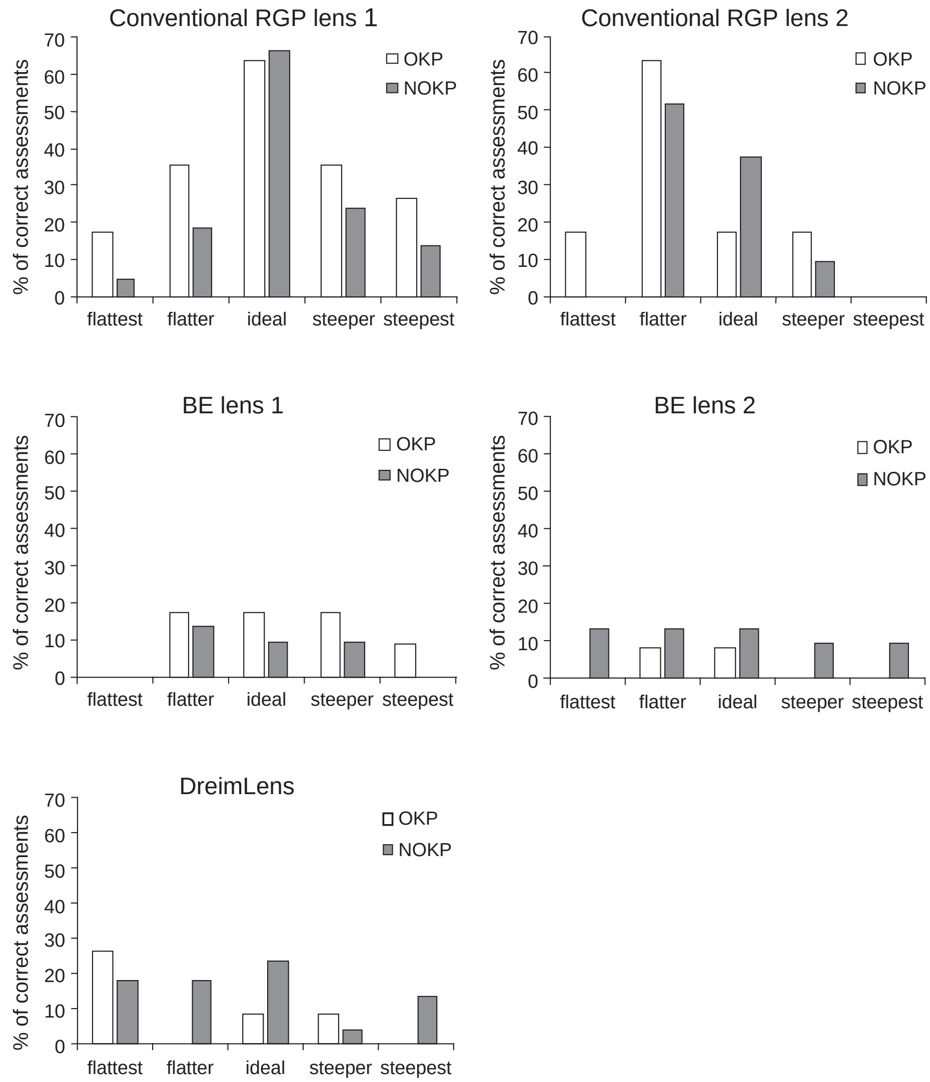

Figure 1. Percentage of correct assessments of lens fittings based on fluorescein pattern analysis for each type of lens by orthokeratology (OKP) and non-orthokeratology (NOKP) practitioners

RESULTS

Figure 1 shows the distribution of the observed frequencies (of correct and incorrect assessments) for the two groups (ortho-k and non-ortho-k) of practitioners.

For conventional RGP lens 1 (on Caucasian eye), the majority (64 per cent and 67 per cent, respectively) of the two groups of practitioners correctly identified the on-K lens fitting ($\chi^2 > 3.84$, $p < 0.05$). The observed frequencies of the other four lens fittings were not significantly different from the expected frequencies (that is, due to chance) ($\chi^2 < 3.84$, $p > 0.05$).

For conventional RGP lens 2 (on Asian eye), 64 per cent of the ortho-k practitioners correctly identified the flatter (by 0.05 mm) lens fitting ($\chi^2 > 3.84$, $p < 0.05$) but the observed frequencies for the other four lens fittings were not significantly different from expected frequencies ($\chi^2 < 3.84$, $p > 0.05$). For the non-ortho-k practitioners, 38 per cent and 52 per cent of the practitioners correctly identified the on-K and the flatter lens fittings, respectively ($\chi^2 > 3.84$, $p < 0.05$). The frequencies for the steeper (by 0.05 mm) lens fitting observed by this group of practitioners were not significantly different from the expected frequencies ($\chi^2 < 3.84$, $p > 0.05$). The flattest (by 0.10 mm) and steep-

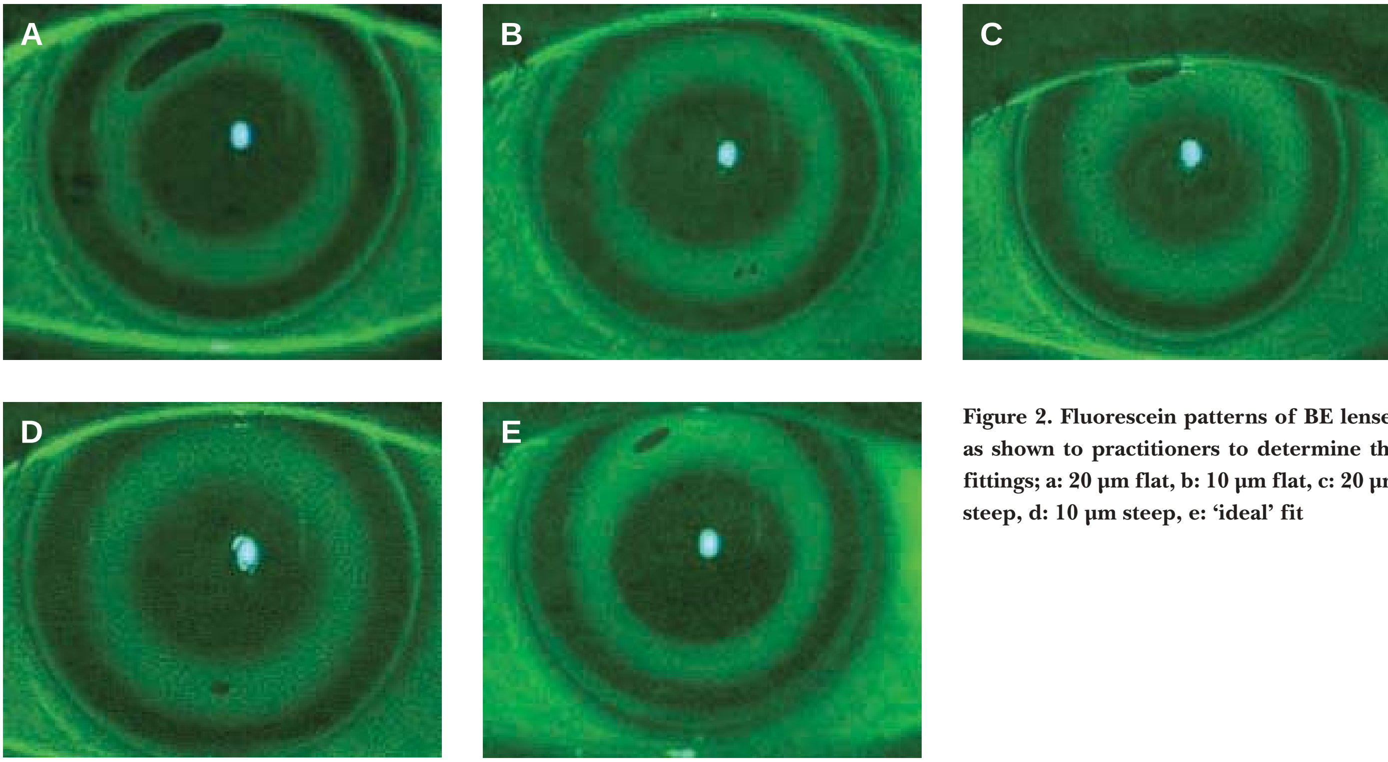

Figure 2. Fluorescein patterns of BE lenses as shown to practitioners to determine the fittings; a: 20 µm flat, b: 10 µm flat, c: 20 µm steep, d: 10 µm steep, e: 'ideal' fit

est (by 0.10 mm) lens fittings were significantly less than those expected by chance ($\chi^2 > 3.84$, $p < 0.05$).

For the three RGL, the observed frequencies were either not significantly different from expected frequencies ($\chi^2 < 3.84$, $p > 0.05$), or they were significantly less than the expected frequencies, for both groups of practitioners ($\chi^2 > 3.84$, $p < 0.05$) (Figure 1). Figure 2 shows the images of fluorescein patterns of BE lenses on the Caucasian eye.

For the conventional RGP lenses (combined observations), Fisher's Exact Tests showed no significant differences ($p > 0.05$) in the observed frequencies of correct and incorrect assessments between the ortho-k and non-ortho-k practitioners, except for the flattest lens fitting ($p < 0.05$) where the ortho-k practitioners performed significantly better than the non-ortho-k practitioners.

For the RGL, no significant differences in the observed frequencies between the ortho-k and non-ortho-k practitioners were found for the lens fittings of all the three lenses (combined observations) ($p > 0.05$). Figure 3 shows a summary of percentages of correct assessments for the two groups of practitioners for the conventional RGP lenses and RGL.

DISCUSSION

Our results show that even experienced contact lens practitioners cannot always predict lens fittings adequately from static fluorescein pattern analysis alone, for conventional RGP lenses and for RGL. Even with experience in ortho-k fitting, the ortho-k practitioners did no better than the non-ortho-k practitioners in correctly assessing the fitting of RGL (Figure 3). The ortho-k practitioners appeared to be able to assess all conventional RGP lens fittings, apart from the on-K fitting, better than the non-ortho-k practitioners based only on fluorescein pattern analysis.

In normal RGP lens fitting assessments, fluorescein patterns of lens fittings are dynamic and practitioners do not normally decide on the lens fitting based on fluorescein pattern alone but will take into account the lens movement and centration. Nevertheless, fluorescein patterns alone are used extensively to determine if the lens is too steep or too flat. The ability to understand the lens/cornea relationship is based primarily on an initial appreciation of the static pattern, followed by an examination of the dynamic state. All contact lens practitioners learn fluorescein pattern analysis from static images and it is a valid method of assessment. Unlike conventional RGP lenses (9.20 to 9.60 mm in diameter), ortho-k lenses are larger (10.6 to 11.00 mm) and exhibit little movement, so the dynamic effect of lens movement on the interpretation of the pattern is diminished.

The difference in the ability of both groups of practitioners to determine the correct conventional RGP fitting lens for the Caucasian eye (64 per cent and 67 per cent) compared to the Asian eye (64 per cent and 38 per cent), and the relative confusion between the on-K and next flatter (0.05 mm) fitting is most likely to be due to the differences in corneal asphericity and its bearing on the appearance of the fluorescein pattern. The

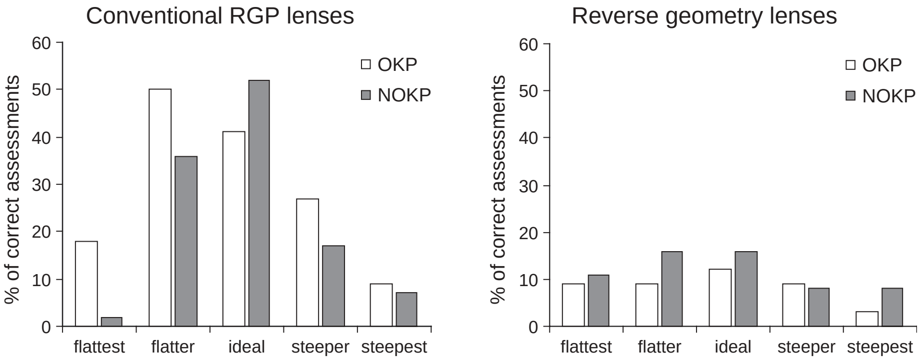

Figure 3. Overall comparisons of lens fitting assessments based on fluorescein pattern analysis of conventional rigid gas permeable and reverse geometry lenses between orthokeratology (OKP) and non-orthokeratology (NOKP) practitioners

Caucasian eye had a measured eccentricity of 0.56, while the Asian eye was 0.82. The higher eccentricity of the Asian eye may result in confusion of the relative appearance of the fluorescein patterns of the ideal and next flattest lens.[11]

In this study, the differences in apical clearance of the lenses used from flattest to steepest ranged from -15 µm to +25 µm (relative to the optimal fitting) with an overall range of 40 µm. The commonly accepted tear layer thickness (TLT) beneath a rigid contact lens at which fluorescein becomes visible is approximately 10 to 20 µm.[12] If the initial apical clearance of the ortho-k lenses was approximately 5 µm (DreimLens) or 8 µm (BE), then fluorescein should have become visible at the next steeper (by 10 µm) lens. Conversely, the flatter lenses should have exhibited greater areas of central 'touch' due to the lack of fluorescein under the lens. Our results showed that this did not occur, as the ability to judge the lens fitting based on differences in patterns was not statistically better than chance.

The images showing the fluorescein patterns of the BE lens on the Caucasian eye gave the initial impression that all the patterns looked the same, leading to an inability to distinguish fine differences between the fittings. The visibility of fluorescein depends on its concentration and the depth of the tear layer.[13,14] Assuming a relatively even concentration of fluorescein, the differences in lens fitting should have been obvious by the fluorescence in the deeper parts of the tear layer. The steepest lens has a tear layer, which is 20 µm deeper than the ideal fitting at the apex but this is not obvious to the viewer. In fact, the lens still appears to have apical touch. A similar effect occurs with the fitting of lenses for keratoconus, where the 'apical touch' appears to be present even with increased steepening of the BOZR.[15]

We propose that the cause of this effect is the difference in squeeze film force between the centre of the lens (minimal TLT) and the edge of the back optic zone diameter (BOZD) (maximum TLT). Squeeze film forces are the predominant forces affecting the tear layer under the lens[16,17] and are directly proportional to the tear layer depth at any point under the lens.

With ortho-k lenses, the force is positive centrally and negative at the edge of the BOZD. Fluorescein has a molecular weight of 376 compared to about 58.44 for the aqueous phase of the tear film.[18] The relative difference between the two will result in the 'surf and sand' effect, wherein relatively dense particles move away from areas of positive force. Therefore, this would result in fluorescein being 'dragged away' from the central area of the lens towards the deeper part of the post-lens tear film, leading to the constant appearance of apical touch. Also, the increased concentration of the fluorescein molecules in the mid-peripheral section of the post-lens tear film would lead to an increase in the relative fluorescence in that area, while the relative lack of fluorescein molecules in the tear layer at the corneal apex would reduce fluorescence in this area.

Finally, the study shows that it is not possible to identify the correctly fitting ortho-k lens by static fluorescein pattern analysis alone. An incorrectly fitting lens will lead to epithelial damage, if there is apical touch, or a lack of effect, if the lens is too steep with excessive apical clearance.

Mountford[6] has proposed that the only effective method of assessing the suitability of an ortho-k lens fitting is the interpretation of the post-trial wear topographical plots rather than fluorescein pattern analysis. Hence, in ortho-k practice, a reliable corneal topographic system is essential and the practitioner needs to know how to use it effectively to assist him or her in managing an ortho-k patient.

CONCLUSION

Our results show that for RGL, experienced ortho-k and non-ortho-k contact lens practitioners are not always able to predict lens fittings adequately from static fluorescein pattern analysis alone. There was no significant difference in the ability to determine RGL fits from fluorescein patterns between the two groups of practitioners. Fluorescein pattern analysis alone is not sufficiently sensitive for assessing ortho-k lens fitting.

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