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ORIGINAL ARTICLE

Quality of Vision with Spectacles, Special Silicone Hydrogel and Gas Permeable Contact Lenses in Keratoconic Patients

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ABSTRACT

Purpose: To evaluate optical quality and visual function in keratoconus patients corrected with RGP contact lenses and a novel special design of silicone hydrogel contact lens.

Materials and methods: Twelve eyes of six patients with keratoconus were enrolled to experience a new soft contact lens (Soft-K) for keratoconus made of a silicone-hydrogel material and the outcomes were compared to the performance with gas permeable lenses and spectacles. The three situations were compared for monocular and binocular high (100%) and low contrast (10%) ETDRS LogMAR visual acuity and contrast sensitivity function (CSF).

Results: On average, there was an improvement of more than two lines in visual acuity over spectacle correction and this is statistically significant for both gas permeable (GP) and Soft-K lens ($p < 0.001$). Visual acuity was not significantly different between GP and Soft-K lens for high contrast acuity but was slightly higher with GP lens for low contrast under binocular conditions. Monocular CSF showed a marked improvement with the Soft-K lens and GP, compared to spectacles correction, particularly for medium and high frequencies; conversely.

Conclusion: Soft-K silicone hydrogel soft contact lens produces a clinical and statistically significant improvement in visual acuity and contrast sensitivity function over spectacle correction.

Keywords: Keratoconus, Contact lens, Visual acuity, Contrast sensitivity, Silicone hydrogel, Visual performance.

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INTRODUCTION

Keratoconus is a progressive, asymmetric, dystrophy of the cornea characterized by steepening and distortion of the cornea, apical thinning and central scarring. It is generally bilateral and progresses asymmetrically in both eyes of the same individual.[1,2]

Keratoconus is usually treated with contact lenses before other surgical procedures should be considered in cases of lens intolerance or poor vision.[3,4] Contact lenses are most frequently used to correct irregular astigmatism and are usually made of rigid gas permeable (GP) materials either in conventional spherical or aspheric designs as well as other nonconventional designs.[5,6] Despite these materials have shown to afford the best visual performance, sometimes physical intolerance or physical trauma to the corneal epithelium forces the clinician to look for other options, using a diversity of materials, designs and fitting approaches.[7,8] Soft contact lenses certainly overcome the short-term discomfort effect induced by GP lenses. However, when it comes to regular designs (either spherical, aspheric or torics) they are useless for moderate and severe forms of keratoconus. Thick soft contact lenses are a relatively new class of CL options for keratoconus. We have described the use of the Soft-K lens back in 2004[8] and more recently other designs have been evaluated by other authors.[9] However, neither our previous report, nor the most recent publication evaluated the visual performance beyond assessment of high contrast visual acuity. This measure has limited utility as the keratoconic patients might are adapted to blurred vision what might overestimate the actual benefit of these devices when simply measuring high contrast visual acuity. Other metrics, such as low contrast visual acuity or contrast sensitivity function might provide a more realistic view of the optical benefit of these lenses to provide some degree of visual rehabilitation to the keratoconic patient. Considering the immediate comfort, convenience and rapid fit of these class of lenses for corneal ectasia and irregularities, we wanted to evaluate their visual and optical performance against other traditional nonsurgical treatments. In the present study we report on the visual performance of keratoconic eyes corrected with spectacles, rigid gas permeable and special silicone hydrogel soft contact lens. This is the first study available in the peer-review literature reporting low contrast visual acuity and contrast sensitivity function as visual outcomes for a specially designed silicone hydrogel soft contact lenses in keratoconic eyes.

MATERIALS AND METHODS

Twelve eyes from 6 patients with bilateral keratoconus (4 females and 2 males; 26.5 ± 6.3 years old) were fitted with a thick silicone hydrogel soft contact lens of (filcon III, 75%) manufactured from Soflex Ltd (Misgav, Israel). The design and on-eye lens-to-cornea relationship are presented in Figures 1 and 2, respectively. Average K readings were 45.8 ± 1.6 and 48.1 ± 2.1 in the less affected eye and 47.7 ± 3.0 and 50.1 ± 2.2 in the more affected eye, for the flattest and steepest meridian, respectively.

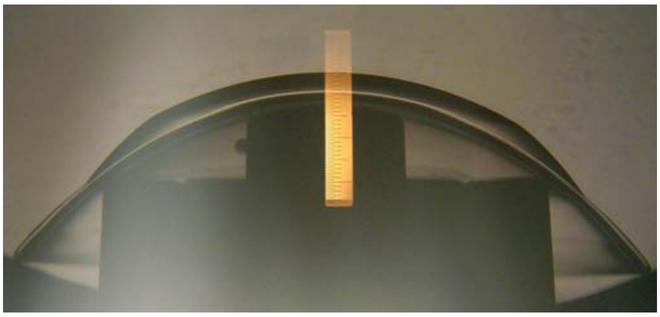
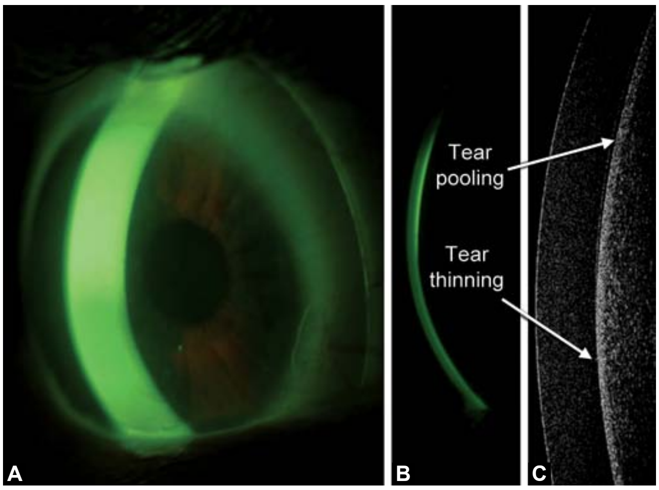


Fig. 1: Magnified visualization of the lens profile of the thick soft contact lens made of silicone-hydrogel material (Soflex Ltd, Israel)



Figs 2A to C: On eye visualization of the contact lens. High molecular weigh fluorescein pattern under a thick soft contact lens design (A), slit-lamp (B) and OCT image (C) sections show the asymmetric distribution of fluorescein along the vertical meridian of the cornea under the optical zone being thinner at the cone apex and thicker in the superior region

Patients were recruited at the Clinical and Experimental Optometry Research Lab (University of Minho, Braga, Portugal). None of them was wearing contact lenses at the time of enrollment. Informed consent was obtained after the purpose of the study and procedures had been explained. The protocol adhered to the tenets of the Declaration of Helsinki.

After an initial optometric examination, each one of the patient's eyes underwent a fitting trial with a spherical contact lens made of the same material. After insertion the lens was allowed to stabilize for 20 minutes. If centration or movement suggested the lens was too steep or too loose, a flatter or steeper base curve radius was chosen, respectively. If the centration and movement of the lens was satisfactory, the lens was allowed to stabilize for an additional 40 minutes period.

After 60 minutes with the lens in place a sphero-cylindrical over-refraction was performed on trial frame along with measurements of logMAR visual acuity under high (100%) and low (10%) contrast conditions, contrast sensitivity function (CSV1000, Vistech Consultants Inc, USA). Functional measurements of the visual performance was obtained under photopic conditions at 85 cd/m^2.

Statistical analysis was conducted using PASW Statistics 17 software (SPSS Inc, Chicago, ILL). Normality of data was assessed by means of the Shapiro-Wilk test. Visual performance was compared between both contact lenses (RGP and Si-Hy) materials and against the spectacle corrected condition using ANOVA with Bonferroni post hoc correction or Kruskal-Wallis test for parametric and non-parametrically distributed variables. The level for statistical significance was set at $p < 0.05$.

RESULTS

Average lens power trialed was –5.6 ± 1.1D in the less affected eye and –6.2 ± 1.5D in the more affected eye. All the remaining results were analyzed together for both eyes from each individual (n = 12).

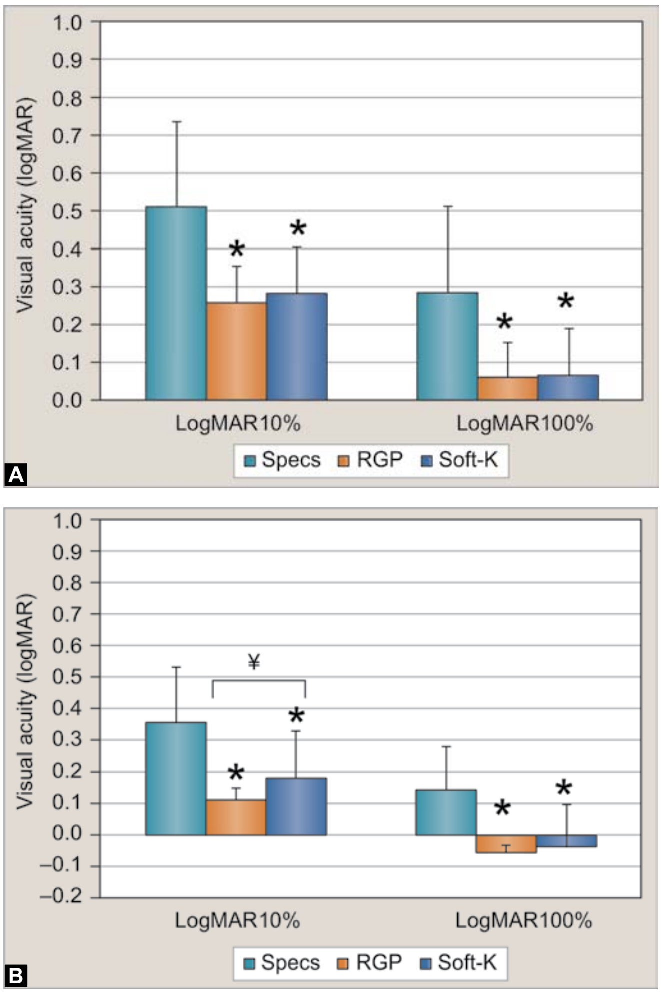
Graphs 1A and B show the average high and low contrast visual acuity achieved with spectacles and contact lenses under monocular and binocular conditions. Monocular visual acuity in LogMAR scale improved with Soft-K by two lines over spectacles alone for high and low contrast monocular and binocular visual acuity ($p < 0.05$). On the direct comparison between both contact lenses, the GP lens showed a statistically higher low contrast visual acuity under binocular conditions ($p = 0.013$).

Monocular CSF (Graph 2) showed a marked improvement with the new lens, compared to spectacles correction, particularly for the higher frequencies of 12 and 18 cycles per degree (cpd). Differences in CSF between RGP and Soft-K were non-statistically significant except for frequency 3 cpd ($p < 0.05$). Despite this, for the higher frequencies GP lens was showed a trend to present higher contrast sensitivity values, probably due to the larger standard deviation of the measurements.

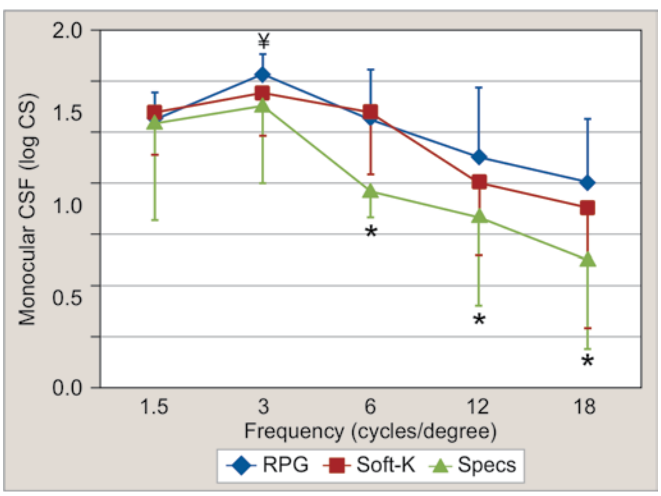
DISCUSSION

Conventional soft contact lenses are rarely considered for the optical correction of keratoconus beyond the initial stages of the disease where soft spherical and toric lenses might satisfactorily compensate for a still relatively regular refractive error induced by the ectasia. Despite RGP lenses being preferred because of their ability to mask corneal irregularities through the post-lens tear film, sometimes an optimal fitting is not achieved due to discomfort, decentration and/or corneal scarring.[10-12]

The present study has shown that a specially designed spherical soft contact lens is able to correct a significant amount of the corneal irregularities present in the moderately affected keratoconic cornea. As a result, the best spectacle



Graph 1A and B: High and low contrast visual acuity under monocular (A) and binocular (B) conditions for spectacles alone and best spectacle corrected over GP and Soft-K.* p < 0.05 on post hoc paired comparisons between contact lens and spectacles; ¥ p < 0.05 on post hoc paired comparisons between GP and Soft-K contact lens



Graph 2: Monocular contrast sensitivity function for spectacles alone and best spectacle corrected over GP and Soft-K. *p < 0.05 on post hoc paired comparisons between contact lens and spectacles; ¥ p < 0.05 on post hoc paired comparisons between GP and Soft-K contact lens

aided visual performance improved significantly either in terms of visual acuity and contrast sensitivity function. Although higher order aberrations have not been measured in this study, the visual benefit might be attributed to a reduction in the optical imperfections of the keratoconic eye. It is expected that considering the thick design of the soft lens (about 5× thicker than a conventional soft lens) the material will maintain its shape more successfully than other soft lenses. Under such circumstances, the tear film formed behind the lens will be distributed such that the irregularities of the cornea will be partially masked. This effect is observed in the fluorescein patterns obtained using high molecular weigh fluorescein staining and has been also confirmed by optical coherent tomography[13,14] and reproduced here in Figs 2A to C. A recent study with a different thick soft contact lens design claimed comparable performance against a rigid gas permeable contact lens. However, the author only reported high contrast visual acuity results. In our study, with moderately affected keratoconic eyes, we have obtained similar performance against GP lenses for high contrast visual acuity. However, for the low contrast acuity the GP lens continued to be superior under binocular conditions. Monocular CSF somewhat corroborate this finding as there was a trend (thought not statistically significant) for the GP lens to afford higher contrast sensitivity for 12 and 18 cpd frequencies. In clinical terms, our findings show that despite the performance of the Soft-K lens might not be completely comparable to the GP lens under all circumstances, the easy of fit and comfort for the patient, certainly warrants a place for these lenses between the nonsurgical options to correct keratoconus and other irregular corneas.

Other approaches to correct corneal irregularities with the use of advanced soft contact lenses has been done with the aim to correct the higher order aberrations of the keratoconic eye. However, it has been observed, either by theoretical calculations or in clinical trials that although good visual results are achievable in static conditions, the visual quality decreases even with minor decentration and rotation effects during blinking or lateral gaze movements.[15-19]

One limitation of this study is that after a short-term adaptation to the correction, we cannot obtain accurate information about the performance of contact lenses in these patients. There are two major interactions that might affect the reliability of our results. The first one is the molding effect that might be more significant after several days or weeks of wear. However, the potential effect will be toward a flattening effect, that could potentially improve the visual performance if the cornea remains clear and corneal trauma is not present. The second effect might be the neural adaptation of the patient to the new correction that might slightly change the visual outcome after several days or weeks. Again, this adaptation is expected to improve the results. Overall, although the experimental conditions do not completely account for the actual clinical situation, it might be expected that the present results are in fact underestimating the final outcomes, not the opposite. The other limitation of the study was the fact that for the contact lens tests the patient was wearing the spherocylindrical over-refraction while visual acuity and contrast sensitivity were measured. The Soft-K lens allows the incorporation of an astigmatic prescription to compensate for these errors. In the present study, all the 12 eyes showed residual cylinders over the lenses not higher than –2.50D with the Soft-K and below –1.50D with the GP lenses. The possibility of incorporating the cylindrical prescription is also an advantage over the GP lenses where stabilization is more difficult compared with soft contact lenses. Again, assuming an adequate fitting of the final lens incorporating the final power prescription, the absence of a spectacle correction over the lens it is expected to improve rather than reduce the visual performance.

SUMMARY

The present results suggest that even if silicone hydrogel soft contact lenses do not give the same visual quality that GP corneal lenses under all tested conditions for the correction of keratoconic eyes, they might be a viable option for those patients showing poor fitting with GP's either because of centration, instability, discomfort or mechanical interaction leading to corneal scarring.

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