CASE SERIES

Keratoconic Bi-aspheric Contact Lenses

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ABSTRACT

Aim: This observational clinical case series examined patients with keratoconus (KC) fit with keratoconic bi-aspheric (KBA) lenses to assess visual acuity (VA), wavefront aberrations, physiological fitting, subjective comfort, and manufacturer's fitting guidelines.

Materials and methods: Seven adult patients (11 eyes, four females, mean age: 34.15 ± 14.12) with nipple cones from the Hadassah Academic College contact lens clinic (Jerusalem, Israel) were fit with KBA lenses by modifying the initial base curve (BC) to obtain an acceptable physiological fit. The uncorrected and corrected distance (D) and near (N) Snellen VA and the ocular wavefront measurements, and responses to a self-administered five-point scale questionnaire were compared after 2 weeks of wear using paired two-tailed t-test or Mann-Whitney U test, as appropriate.

Results: Visual acuity and total root mean square (RMS) improved significantly with the lenses ($DVA_{uncorrected}$ = 0.04 ± 0.02, $DVA_{corrected}$ = 0.66 ± 0.22, $NVA_{uncorrected}$ = 0.34 ± 0.30, $NVA_{corrected}$ = 0.95 ± 0.12). Subjects reported an average of 7.0 ± 2.7 hours of wear daily, with good scores in visual stability, satisfaction with VA and quality of vision, improvement of mood and quality of life, and low scores in foreign body sensation, pain, red eye, and itching during wear, and difficulty with lens removal. An average of two BC modifications from the diagnostic lens were necessary (0.16 mm steeper in nine eyes, 0.27 mm flatter in two eyes).

Conclusion: Keratoconic bi-aspheric lenses can provide 7 hours of comfortable wear, significantly improved VA and total RMS aberrations, alongside subjective satisfaction. Base curve modifications can be reduced by fitting a diagnostic lens 0.75 mm steeper than the flattest keratometry reading.

Keywords: Contact lenses, Gas permeable contact lenses, Higher order aberrations, Keratoconus, Visual acuity.

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INTRODUCTION

Keratoconus (KC) is an ectasia of the axial portion of the cornea resulting in a progressive thinning and steepening of the cornea leading to optical distortion.[1] These corneal changes may lead to irregular astigmatism and corneal scarring, both of which reduce the best-corrected visual acuity (BCVA) of the patient.[2] The etiology of KC is unknown but may be due to environmental and genetic factors.[3] The prevalence of the disease has been shown to be high in Israel,[4,5] as well as in other places in the Middle East, such as Lebanon[6] and Iran.[7-9]

Keratoconus usually begins at puberty and tends to progress during adolescence.[10] It is initially treated using spectacles to improve vision, but as the disease progresses spectacles no longer suffice, so rigid gas permeable (RGP) contact lenses become an option.[1] When the disease progresses even further, specialty contact lenses are needed.[11] Keratoconic bi-aspheric (KBA) lenses are specialty lenses intended for nipple and oval cones as well as mild pellucid marginal degeneration (PMD). To the best of our knowledge, a clinical case study involving KBA lenses in peer-reviewed journals does not exist. As such, this observational clinical case series examined whether KBA contact lenses can provide an optimal physiological and subjectively comfortable fit for patients with KC. Additionally, the manufacturer-recommended KBA fitting guidelines were evaluated.

MATERIALS AND METHODS

Keratoconic subjects were selected from the Hadassah Academic College's (HAC) contact lens clinics in Jerusalem. Subjects suffering from systemic diseases (such as diabetes, hypertension, multiple sclerosis, Myasthenia gravis, etc.), ocular pathologies other than KC or corneal warpage, or amblyopia were excluded. The study adhered to the tenets of Helsinki and was approved by the HAC Ethics Committee.

After receiving an oral explanation about the nature of the study, participants signed a statement of informed consent. Participants did not receive remuneration aside from the contact lenses and solutions used in the study. Diagnosis of KC was made based on a clinical examination and corneal topography findings.[12,13] The type and stage of the KC was classified based on the topographic map and at least one the following signs: Stromal thinning, Fleischer's ring, and Vogt's striae observed with

slit-lamp examination, and Munson's sign. Cone type was defined based on the topography map according to Zadnik et al.[14] Patients were examined by using the same procedures and devices using a consistent protocol in two examination rooms with the same Snellen charts. Subjects participated in three or four study visits. The first study visit included an ocular and general health history, family history, and general information (occupation, etc.) questionnaire alongside a standard optometric contact lens examination. Eligible subjects were enrolled and were fit with the initial diagnostic lenses.

LENSES

Keratoconic bi-aspheric lenses are large diameter (10.2 mm compared with traditional 8.0-9.0 mm diameter) RGP lenses that are made of Hexafilcon A with ultra-violet ray blocker, oxygen permeability of 100, a 9.2 mm optic zone, and two possible eccentricity values (0.98 or 1.30). Only 0.98 eccentricity was used in the study. The lens design incorporates a central aspheric zone extending to 0.5 mm from the edge, with a compensating front surface aspheric curve that renders the lens optically spherical instead of aspheric.

The KBA lens is distributed by Essilor in the USA and Australia. In Israel, during the time of the study, it was distributed by Teva-Hanita vision care (Teva-Hanita Vision Care, Kibutz Hanita, Israel), and is now available through Shamir (Kibutz Shamir, Israel).

Based on the manufacturer's instructions, the initial diagnostic lens had a base curve (BC) of 0.6 mm steeper than the flattest K reading value of the keratometry reading. The fluorescein pattern of the center, mid periphery, and edge lift of the diagnostic lens was observed, and the parameters of the lens were modified to obtain the end-point goal. This end-point goal was defined as centration with an average resting place between blinks within the limbus area, and movement of 0.25 and 0.50 mm to allow tear exchange in the white light picture, alongside mid-peripheral alignment, good edge clearance in the horizontal meridian, and an even edge lift in the fluorescein picture. For nipple cones, central apical clearance is expected. For oval cones, an inferior crescent of benign touch is expected.

All lens parameters were maintained constant, and the BC was adjusted until the end-point goal was obtained as described above. After an acceptable physiological fit was achieved, an over refraction was performed for maximal visual acuity (VA), and a lens was ordered.

During the second visit and after measuring the baseline uncorrected aberrometry with the L-80+ wavefront aberrometer (Leneau, FR), subjects inserted their lenses. After 30 minutes for settling, the physiological fit was assessed based on the white light and fluorescein pattern as described above. If an acceptable physiological fit was

obtained, the Snellen VA and aberrometry were measured with the contact lenses. Subsequently, the lenses were dispensed for a period of 2 weeks. The maintenance and care protocol was reviewed with the subjects orally, and written instructions were dispensed. Subjects were instructed to wear the lenses gradually starting from 2 hours for the first day, and increase the wear time by 2 hours daily until reaching at least 8 hours of wear for a period of 2 weeks total. If the physiological fit was not acceptable, appropriate adjustments to the BC were made, a new lens was ordered, and subjects repeated the second visit with the newly ordered lens. If the physiological fit of the third ordered lens was unacceptable, the subject was removed from the study.

Subjects returned for a third study visit after two weeks. They were instructed to arrive to the visit after having worn the lenses for at least two hours. The Snellen VA was measured and the white light and fluorescein patterns were examined with staining graded using the Efron[15] scale. Subjects were asked to complete a questionnaire (Appendix 1), which was based on two previously validated questionnaires and adapted to cultural needs when required: The Contact Lens Impact on Quality of Life Questionnaire[16] and the Contact Lens Dry Eye Questionnaire.[17] The questionnaires assessed visual quality, ease of handling, hours of use, and such other subjective parameters while wearing the lenses during the preceding two weeks. The questionnaire rated parameters for each eye with a five-point scale in which (5) was excellent and (1) was poor. Questions in the negative form, in which a grading of one was optimal and a grading of five was the worst, were transposed for analysis purposes.

DATA ANALYSIS

Because KC is an asymmetrical disease,[12] if both eyes were affected, they were included in the analysis.[18]

The root mean square (RMS) values obtained from the L-80+ wavefront aberrometer were calculated by taking the square root of the sum of the squares of the Zernike polynomials,[19] using the standard nomenclature for describing Zernike terms found in Atchison.[20] The values for specific aberration groups were calculated from the combination of J values that represent each specific aberration, including lower order astigmatism (J3 + J5), higher order astigmatism (J11 + J13 + J23 + 25), coma (J7, J8, J17, and J18), trefoil (J6, J9, J16, and J19), tetrafoil (J10, J14, J22, and J26), total higher order aberrations (J6–J35), and total higher order spherical aberration (J12 + J24).[19,21]

The uncorrected and corrected values for each aberration term and the Snellen decimal VA were examined for normality using an Anderson-Darling test. Normally distributed data was compared with a paired two-tailed t-test with 95% confidence. Data that was not

distributed normally was compared with a two-tailed Mann-Whitney U test with 95% confidence. Based on a previous study, a clinically meaningful change in RMS was defined *a priori* as a change greater than 0.10 μm.[19]

The physiological assessment of the lens fitting and subjective five-point scale questionnaire was analyzed and reported.

RESULTS

Eleven subjects (19 eyes) were screened for inclusion in the study. Four subjects were ineligible for participation due to severely distorted corneas due to contact lens warpage (2), or a preexisting systemic disease (2). Seven subjects (eleven eyes; 3 males, 4 females) suffering from varying degrees of KC were eligible for inclusion in the study (age range: 21–60, mean age: 34.14 ± 14.11). All subjects had nipple cones. Two subjects were current RGP wearers, and five subjects were first-time RGP wearers.

Dropouts

Subject #7 was originally fit with the KBA lens in both eyes. After receiving the ordered lenses, both needed modification to obtain a physiologically acceptable fit.

After the reordered lenses were received, only the physiological fit to the right eye was acceptable. As such, based on the protocol (described in the methods), the left eye was removed from the study. All subsequently described results were analyzed based on the eyes to whom the KBA lenses were dispensed.

Visual Acuity Outcomes

All subjects improved in both distance and near VA with the KBA lens. The mean distance Snellen decimal fraction VA at baseline (before the fitting) was 0.04 ± 0.02 which improved to 0.66 ± 0.22 after the fitting. The mean near Snellen decimal fraction VA at baseline was 0.34 ± 0.30, which improved to 0.95 ± 0.12 after the fitting (Table 1). This improvement was statistically significant (p < 0.001, Mann-Whitney).

Wavefront Aberrations

The total RMS error was significantly reduced by 81% with the KBA lenses (p = 0.01). All other higher order aberrations (HOA) parameters were reduced, but not significantly (Table 2). All but the total tetrafoil RMS error were reduced (more than 0.1 μm) in a clinically significant way with the KBA lenses.

Table 1: Comparative results before and after KBA lens fitting for all subjects

| Subject	Age	Gender	# Trial lenses till best fit	Avg K (mm)	Flat K (mm)	Steep K (mm)	VA Ncc	VA Nsc	VA Dcc	VA Dsc
1 OD	24	F	3	6.78	7.00	6.55	1.00	0.63	0.66	0.05
1 OS			3	6.71	6.99	6.43	1.00	0.63	0.79	0.05
2 OD	43	M	3	7.48	7.66	7.30	1.00	1.00	0.76	0.05
3 OD	22	F	2	6.49	6.93	6.04	0.80	0.10	0.66	0.03
4 OD	60	F	3	6.31	6.36	6.26	1.00	0.13	0.78	0.08
4 OS			4	7.12	7.17	7.07	1.00	0.13	0.78	0.08
5 OD	21	F	4	7.14	7.42	6.86	1.00	0.40	0.79	0.03
5 OS			4	7.36	7.46	7.25	1.00	0.40	0.05	0.05
6 OD	38	M	3	7.51	7.72	7.30	0.63	0.10	0.77	0.01
6 OS			2	7.73	7.77	7.69	1.00	0.10	0.47	0.01
7 OD	31	M	2	6.90	7.20	6.60	1.00	0.10	0.79	0.03
Avg	34.14		3	7.04	7.24	6.85	0.95	0.34	0.66	0.04
SD	14.11		0.77	0.45	0.42	0.51	0.12	0.31	0.23	0.02

Abbreviations: VA Ncc: Visual acuity at near with correction; VA Nsc: Visual acuity at near without correction; VA Dcc: Visual acuity at distance with correction; VA Dsc: Visual acuity at distance without correction

Table 2: Summary of higher order aberrations in the uncorrected and KBA-corrected states

	Zernike terms	Uncorrected Avg	Uncorrected SD	KBA Avg	KBA SD	p-value[a]	Avg reduction (%)
Total RMS*	J3–J35	5.93	2.40	1.14	0.45	0.014	81
Lower order Astigmatism RMS*	J3 + J5	1.51	1.48	0.34	0.15	0.49	90
Total HO RMS*	J6–J35	0.96	0.65	0.41	0.22	0.14	66
Total coma RMS*	J7 + J8 + J17 + J18	0.80	0.54	0.36	0.22	0.12	59
Total trefoil RMS	J6 + J9 + J16 + J19	0.36	0.31	0.10	0.03	0.015[Ψ]	91
Total tetrafoil RMS*	J10 + J14 + J22 + J26	0.11	0.06	0.06	0.03	0.84	56
Total HO spherical aberration*	J12 + J24	0.24	0.25	0.08	0.10	0.07[Ψ]	61

*Signifies statistically significant reductions; [a]Paired, two-tailed, t-test value, Bonferroni corrected (unless otherwise specified); [Ψ]Mann-Whitney p-value
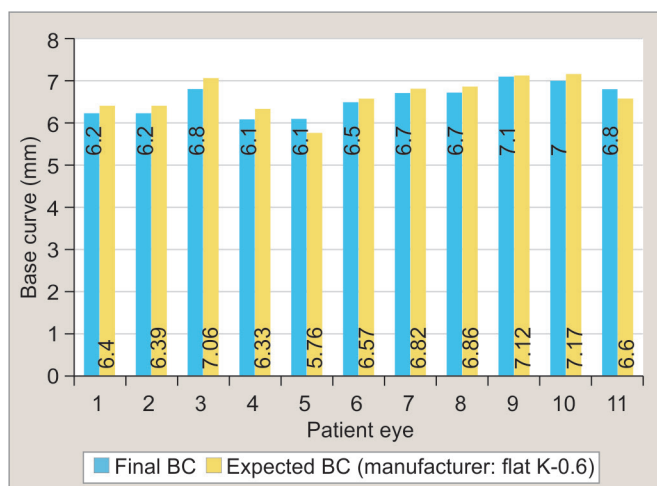
Graph 1: Histogram depicting the difference between manufacturer-recommended base curve and final prescribed BC

Graph 2: Average questionnaire responses for seven subjects based on five-point scale, (1) – poor; (5) – excellent. Questions with reverse scaling were transposed such that 5 was the best option and 1 was the worst option

Diagnostic Trial Set Lenses

As shown in Table 1, during the initial study visit, an average of two modifications from the initial diagnostic lens was necessary to obtain a final physiologically acceptable fit. As shown in Graph 1, for 80% (nine eyes) of the eyes the final BC was an average of 0.16 mm steeper than the initial diagnostic lens. For 18% (two eyes) the final BC was an average of 0.27 mm flatter than the initial diagnostic lens.
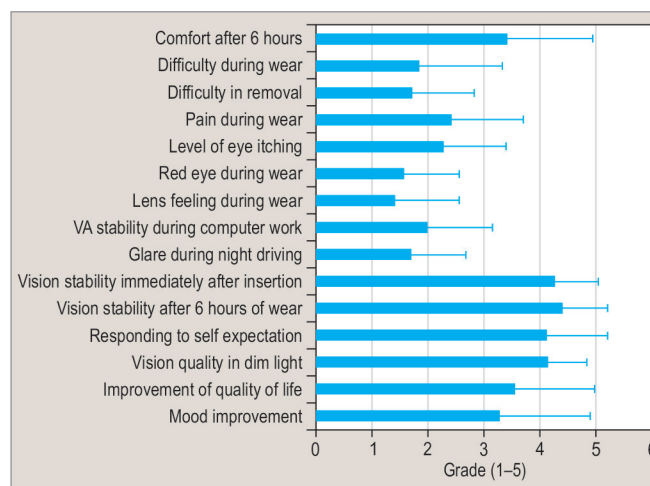
In addition, despite performing an overrefraction with the final trial set lens prior to ordering a lens for dispensing, nine eyes required an average overrefraction of +0.55 DS, one eye required no overrefraction and one eye required −0.75 DS to achieve BCVA with the dispensed lens. Lenses with a modified refraction were ordered for those eyes requiring an overrefraction higher than 0.50 DS. Therefore, the lenses were reordered for three eyes of two subjects (overrefraction = +0.75 DS for two eyes and +1.00 DS for one eye). However, the one eye that required a −0.75 DS overrefraction was not reordered because the patient suffered from pain during lens wear (as described below).

Subjective Evaluation

The subjects' responses to the questionnaire are summarized in Graph 2.

In terms of hours of wear, the mean reported daily hours of wear was 7.00 ± 2.70, with four subjects reporting a daily wear time of 8 hours or more, one reporting 5 hours, one 4 hours, and one 3 hours. The subject reporting only 3 hours of wear (subject #6) was unhappy with the lens as a whole, and his scores reflect the dissatisfaction across all parameters examined.

Most questions in the questionnaire were on a scale of one to five, with one being not satisfied and five being completely satisfied. All seven subjects completed the questionnaire. In general, there was a large standard deviation for every question, reflecting the subjective nature of contact lens comfort. We considered questions with an average of 3 to 5, areas where subjects were satisfied and questions with an average below 3 as areas where subjects were not satisfied. Subjects reported being satisfied in the following areas: Improvement in mood and quality of life with the contact lenses, stability of vision immediately after contact lens insertion as well as after 6 hours of wear, lens comfort parameters (feeling of foreign body, eye redness, itching, comfort of wear after 6 hours), lens handling upon insertion, and lens meeting expectations.

One subject (subject #6) gave low scores to several subjective parameters, including pain during lens wear, feeling grittiness or itching of the eye by the lens, and a medium level of red eyes. This subject also gave a low score to visual stability immediately upon lens insertion and after 6 hours of wear, and to the lens meeting expectations.

Only five of the subjects could answer the questions pertaining to driving with the lenses. Subjects as a whole did not experience glare during driving (average score: 4.33 ± 1.03) with two grading vision during driving a score of 3, and the rest scoring the driving with the lenses a score of 5.

DISCUSSION

Based on this case series, KBA lenses can provide up to an average of 7 hours of comfortable wear, significantly improved VA and total RMS, alongside subjective comfort, satisfaction with visual quality, satisfaction with visual stability and minimal difficulty with lens handling, eye itch and discomfort during lens wear. Despite the success of the lenses on average, the lens was not favored by one subject (subject #6). However, considering that KBA lenses are an optical solution for KC, the fact that it was not an

acceptable solution for only one of seven patients can be interpreted as a successful lens. Keratoconus fitting can often be challenging for optometrists, and as the severity of KC increases, fitting the contact lens becomes more challenging.[22] The fitting of the KBA lenses used in this study required only knowledge in fitting of RGP lenses, making it a simple lens to fit, and as the KBA trial set had only one eccentricity value, only the BC was modified, facilitating the fitting process.

An average of three trial lenses was necessary to obtain an acceptable fit in this cohort, which is similar to other lenses, such as the RoseK (2–4 trials),[23] and scleral lenses (2 trials).[24] The mean difference in the BC between the manufacturer recommendation and the final BC ordered in this study was 0.16 ± 0.08 mm steeper for 80% of the fitted eyes. Had a steeper lens been fit from the beginning, fewer modifications would have been necessary for each subject, which would have shortened the entire fitting procedure. As such, based on the results of this study, manufacturer and clinicians can modify the preliminary suggested diagnostic lens to 0.76 mm steeper than the flattest K reading value of the keratometry reading.

Additionally, nearly 82% (9 eyes) of the eyes required a mild hyperopic (plus lens) over-minus refraction, which suggests that the calculation based on the initial diagnostic lens is inaccurate and should be ordered with an addition of +0.50 DS. This difference might be due to influence of the RGP lens on the tear film over time.[25]

The main goal of fitting contact lenses is to improve VA with comfort without compromising the health of the cornea.[22] For patients with KC as the cone advances, it is difficult to obtain an ideal fit, often requiring a compromised fit that does not damage the cornea.[23]

In a study of visual performance and comfort with Rose K lenses,[26] 90% of the subjects achieved a physiologically acceptable fit, suggesting that Rose K lenses provide an improvement in vision aside comfort in wearing the lens, and for RGP scleral lenses study, 82% of the participants were satisfied with the lens.[27] In the present study, there was an overall satisfaction with vision performance, vision stability, and comfort. Aside from subject #6, 82% (9 eyes) of the fitted eyes obtained a physiologically acceptable fit, and only 18% (2 eyes) of the eyes had corneal staining requiring monitoring. These findings suggest that the KBA lens can also offer a good choice for KC patients with mild to moderate stages even advanced. That said, an investigation with a larger cohort would provide a stronger evidence base.

The KBA lenses produced a clinically significant reduction of all the higher order aberrations except for the total tetrafoil RMS error. However, the reduction was only statistically significant for total RMS error. This statistically significant reduction of the total RMS may stem from the error term, which includes both lower order and higher order terms, and may reflect the improvement of the spherical and cylindrical aberrations. It is apparent that the KBA lenses significantly improve lower order aberrations [sphere and cylindrical aberrations (J3-5)] which are also substantially worse than the HOA (J6-35).

Limitations of this case series include the limited sample size and the fact that the staining was only inspected during the third study visit. Had the staining been assessed during the baseline visit, it would have been possible to ascertain if there was a significant change from the baseline condition due to the KBA lenses. Based on data from the third visit only, we can assume that the staining is KBA lens related. However, there is always the possibility that it existed prior to the contact lens fit.

CONCLUSION

This clinical case series demonstrates that KBA lenses can provide on average 7 hours of comfortable wear, significantly improved VA and total RMS aberrations, with subjective satisfaction, alongside minimal staining. The number trial lenses can be reduced by fitting a diagnostic lens 0.75 mm steeper than the flattest keratometry reading.

ACKNOWLEDGMENTS

REFERENCES

1. Edrington TB, Szczotka LB, Barr JT, Achtenberg JF, Burger DS, Janoff AM, Olafsson HE, Chun MW, Boyle JW, Gordon MO, et al. Rigid contact lens fitting relationships in keratoconus. Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Group. Optom Vis Sci 1999 Oct;76(10):692-699.
2. Nejabat M, Khalili MR, Dehghani C. Cone location and correction of keratoconus with rigid gas-permeable contact lenses. Cont Lens Anterior Eye 2012 Feb;35(1):17-21.
3. Gordon-Shaag A, Shneor E, Millodot M. The epidemiology and etiology of keratoconus. Int J Kerat Ect Cor Dis 2012 Jan-Apr;1(1):7-15.
4. Millodot M, Shneor E, Albou S, Atlani E, Gordon-Shaag A. Prevalence and associated factors of keratoconus in Jerusalem: a cross-sectional study. Ophthalmic Epidemiol 2011 Apr;18(2):91-97.
5. Shneor E, Millodot M, Gordon-Shaag A, Essa M, Anton M, Barbara R, Barbara A. Prevalence of keratoconus among young Arab students in Israel. Int J Ker Ect Cor Dis 2014 Jan-Apr;3(1):9-14.
6. Waked N, Fayad AM, Fadlallah A, El Rami H. Keratoconus screening in a Lebanese students' population. J Fr Ophtalmol 2012 Jan;35(1):23-29.

7. Hashemi H, Beiranvand A, Khabazkhoob M, Asgari S, Emamian MH, Shariati M, Fotouhi A. Prevalence of keratoconus in a population-based study in Shahroud. Cornea 2013 Nov;32(11):1441-1445.

8. Hashemi H, Khabazkhoob M, Fotouhi A. Topographic Keratoconus is not Rare in an Iranian population: the Tehran Eye Study. Ophthalmic Epidemiol 2013 Dec;20(6):385-391.

9. Hashemi H, Khabazkhoob M, Yazdani N, Ostadimoghaddam H, Norouzirad R, Amanzadeh K, Miraftab M, Derakhshan A, Yekta A. The prevalence of keratoconus in a young population in Mashhad, Iran. Ophthalmic Physiol Opt 2014 Sep;34(5):519-527.

10. Derakhshan A, Shandiz JH, Ahadi M, Daneshvar R, Esmaily H. Short-term outcomes of collagen crosslinking for early keratoconus. J Ophthalmic Vis Res 2011 Jul;6(3):155-159.

11. Rajabi MT, Mohajernezhad-Fard Z, Naseri SK, Jafari F, Doostdar A, Zarrinbakhsh P, Rajabi MB, Kohansal S. Rigid contact lens fitting based on keratometry readings in keratoconus patients: predicting formula. Int J Ophthalmol 2011;4(5):525-528.

12. Rabinowitz YS. Keratoconus. Surv ophthalmol 1998 Jan-Feb;42(4):297-319.

13. Rabinowitz YS. The genetics of keratoconus. Ophthalmol Clin North Am 2003 Dec;16(4):607-620, vii.

14. Zadnik K, Barr JT, Edrington TB, Everett DF, Jameson M, McMahon TT, Shin JA, Sterling JL, Wagner H, Gordon MO. Baseline findings in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study. Invest Ophthalmol Vis Sci 1998 Dec;39(13):2537-2546.

15. Efron N. Efron grading scales for contact lens complications. Butterworth-Heinemann, Edinburgh, UK; 1997.

16. Pesudovs K, Garamendi E, Elliott DB. The Contact Lens Impact on Quality of Life (CLIQ) Questionnaire: development and validation. Invest Ophthalmol Vis Sci 2006 Jul;47(7):2789-2796.

17. Nichols JJ, Mitchell GL, Nichols KK, Chalmers R, Begley C. The performance of the contact lens dry eye questionnaire as a screening survey for contact lens-related dry eye. Cornea 2002 Jul;21(5):469-475.

18. McAlinden C, Khadka J, Pesudovs K. Statistical methods for conducting agreement (comparison of clinical tests) and precision (repeatability or reproducibility) studies in optometry and ophthalmology. Ophthalmic Physiol Opt 2011 Jul;31(4):330-338.

19. Gordon-Shaag A, Millodot M, Ifrah R, Shneor E. Aberrations and topography in normal, keratoconus-suspect, and keratoconic eyes. Optom Vis Sci 2012 Apr;89(4):411-418.

20. Atchison DA. Recent advances in representation of monochromatic aberrations of human eyes. Clin Exp Optom 2004 May;87(3):138-148.

21. Thibos LN, Bradley A, Hong X. A statistical model of the aberration structure of normal, well-corrected eyes. Ophthalmic Physiol Opt 2002 Sep;22(5):427-433.

22. Barnett M, Mannis MJ. Contact lenses in the management of keratoconus. Cornea 2011 Dec;30(12):1510-1516.

23. Rathi VM, Mandathara PS, Dumpati S. Contact lens in keratoconus. Indian J Ophthalmol 2013 Aug;61(8):410-415.

24. Romero-Jiménez M, Santodomingo-Rubido J, González-Méijome JM. An assessment of the optimal lens fit rate in keratoconus subjects using three-point-touch and apical touch fitting approaches with the rose K2 lens. Eye Contact Lens 2013 Jul;39(4):269-272.

25. Cardona G, Isern R. Topography-based RGP lens fitting in normal corneas: the relevance of eyelid and tear film attributes. Eye Contact Lens 2011 Nov;37(6):359-364.

26. Betts AM, Mitchell GL, Zadnik K. Visual performance and comfort with the Rose K lens for keratoconus. Optom Vis Sci 2002 Aug;79(8):493-501.

27. Fine P, Gordon-Shaag A, Leibowitz E, Lahav AC, Jackson S, Halperin R, Gantz L. A prospective clinical evaluation of a new scleral contact lens for patients with distorted corneas. Int J Kerat Ect Cor Dis 2013;2(1):1-11.

APPENDIX 1: SATISFACTION QUESTIONNAIRE

1. How many hours on average did you wear your contact lenses daily?
   1. Less than 4 hours
   2. Between 4-8 hours
   3. Between 8-10 hours
   4. Over 10 hours

Lens Comfort

2. How would you grade the general comfort of the lenses in your eye?

Not Comfortable	1	2	3	4	5	Very comfortable

3. How would you grade the comfort of the lenses in your eyes throughout the day, for example after 6 hours of wear?

Not Comfortable	1	2	3	4	5	Very comfortable

4. Did you feel itchiness while wearing the lenses?

No Itch	1	2	3	4	5	Very Itchy

5. Did you experience pain during lens wear?

No Pain	1	2	3	4	5	Very Painful

6. Were your eyes red during lens wear?

No Redness	1	2	3	4	5	Very Red

Lens Handling

7. How would you grade the difficulty of lens insertion?

Easy	1	2	3	4	5	Very Difficult

8. How would you grade the difficulty of lens removal?

Easy	1	2	3	4	5	Very Difficult

Visual Quality

9. How would you grade the quality of vision with the lenses during extended work in front of the computer

Low Quality	1	2	3	4	5	Good Quality

10. If you drive, please respond to the following question. Otherwise skip to question 12.
How would you grade your visual quality during nighttime driving?

Low Quality	1	2	3	4	5	Good Quality

11. If you drive, please respond to the following question. Otherwise skip to question 12.
How would you grade your visual quality during daytime driving?

Low Quality	1	2	3	4	5	Good Quality

12. How would you grade the stability of your vision immediately with lens insertion?

Low Quality	1	2	3	4	5	Good Quality

13. How would you grade the stability of your vision after six hours of lens wear?

Low Quality	1	2	3	4	5	Good Quality

14. How would you grade the quality of your vision in dim lighting?

Low Quality	1	2	3	4	5	Good Quality

Overall Impression
15. Did the lens meet your expectations?

Did not meet expectation	1	2	3	4	5	Exceeded expectation

16. Did the lens improve your quality of life?

No	1	2	3	4	5	Yes

17. Did wearing the lenses improve your mood?

No	1	2	3	4	5	Yes