Original Article

Rose-K contact lens for keratoconus

Arun K Jain, *MD;* ***Jaspreet Sukhija,*** *MS*

Aim: To report clinical experience and the comparative value of axial and instantaneous topography data in fitting Rose-K design contact lenses in moderate and severe keratoconus.

Materials and Methods: Thirty-eight eyes (of 23 patients) with keratoconus were fitted with Rose-K design contact lenses and followed up for at least six months or more. Visual acuity with habitual vision correction available was measured. Axial and instantaneous topography maps for each eye were recorded. Contact lens wear comfort was graded on a ten point rating scale every three months.

Results: Fourteen (100%) moderate keratoconus eyes (average Sim K 48.61 ± 1.24D) and 23 of 24 (96%) of severe keratoconus eyes (average Sim K 60.88 ± 5.31D) were successfully fitted with the Rose-K lenses. Final fit contact lenses in severe keratoconus had statistically significant steeper base curves compared to average axial corneal curvature than in moderate keratoconus eyes. Average simulated corneal curvature on axial maps predicted final fit contact lens base curves significantly better than on instantaneous maps. Thirty-three of the 37 eyes fitted with contact lenses maintained wear comfort over average follow up period of 13 ± 3.5 months.

Conclusions: Rose-K design rigid contact lenses are successful in visually rehabilitating 100% of moderate and 96% of severe keratoconus eyes. Most patients (90%) maintained contact lens wear comfort. Corneal curvature on axial maps is a better predictive of base curve of final fit contact lens.

Key words: Axial topography, contact lenses, fitting relationship, instantaneous topography, Keratoconus, Rose-K, simulated keratometry.

Indian J Ophthalmol 2007;55:121-5

Progressive ectasia in keratoconus is associated with decreased vision and clinical signs such as Vogt's striae, Fleischer's ring, stromal thinning and apical corneal scarring.[1] Advancing corneal ectasia results in more irregular astigmatism that may require rigid contact lens wear.[2–5] Keratoconus eyes treated with corneal transplants also frequently need contact lenses for vision gain.[3] Several rigid contact lens fitting sets available have their origin in one of the three fitting philosophies: apical clearance, three-point touch, and apical bearing.[6–8] However, there are no accepted standardized protocols. The 'three-point-touch' approach is now the most widely accepted corneal lens fitting philosophy in clinical practice.[6] Practitioners often resort to custom-designed rigid lenses for their patients.[9–11] Fitting contact lenses in keratoconus becomes less successful as the disease severity advances.[12]

There is a lack of consensus on the success and the type of contact lens most suited for severe keratoconus eyes (average Sim K >52 D). Recently Betts and colleagues reported better visual performance and lens comfort with the Rose-K design rigid gas permeable lenses as compared to other contact lenses in 43 moderate and nine severe keratoconus eyes of 26 patients.[13]

This report discusses the results of fitting Rose-K design of contact lenses in moderate and severe keratoconus in Asian (Indian) eyes. In addition, we also report on the contact lens fitting relationships and the value of topography data in keratoconus eyes.

Materials and Methods

Thirty-eight eyes (of 23 patients) with keratoconus were prospectively fitted with Rose-K design contact lenses. Keratoconus was diagnosed based on clinical signs of irregular keratometric mires, scissoring of the retinoscopic reflex or irregularity in the red reflex with the direct ophthalmoscope and biomicroscopic signs such as Vogt's striae, Fleischer's ring or stromal thinning and apical corneal scarring. On topography keratoconus eyes demonstrated an average simulated keratometry of more than 45.2 D, central corneal power of more than 47.2 D or inferosuperior asymmetry higher than 1.4 D. We excluded eyes with prior surgical procedure or any active eye disease like active vernal keratoconjunctivitis, hydrops of cornea or any ocular inflammation. A follow up record of 6 months or longer contact lens wear was available for each eye included in this analysis. This study has the approval of Institutional Ethics and Review Committee.

Objective refraction followed by subjective refraction, keratometry, and topography (Nidek OPD – Scan, ARK 10000

Department of Ophthalmology, Postgraduate Institute of Medical Education and Research, Chandigarh, India

Correspondence to Arun K Jain, Department of Ophthalmology, Postgraduate Institute of Medical Education and Research, Chandigarh - 160 012, India. E-mail: aronkjain@yahoo.com

Manuscript received: 18.04.05; Revision accepted: 18.09.06

Model) was performed for each eye. Slit lamp signs were recorded on a digital camera system (Eyecap, Haag-Streit, Switzerland). Topography analysis was performed using NIDEK ARK 10000 corneal analyzer. We performed the standard method of video-keratography and produced axial and instantaneous maps, displayed side by side with same color scale. Several images were obtained from each eye, out of which the highest quality image with best alignment and at least six digitized rings were selected for analysis. The central corneal power, the corneal apex, and the simulated keratometry values in the two major axes were noted from the selected axial map and instantaneous maps. The corneal apex was defined as the point of greatest curvature and was determined by movement of the interactive cursor on both the axial and instantaneous maps produced with standard alignment. The average of simulated keratometry [axial] values (average Sim K) was used to categorize keratoconus eyes into severity grades of mild (average Sim K < 45D), moderate (average Sim K 45-52D), and severe (average K > 52D). The diopteric value of the average simulated K was converted to radius of curvature (*r*) in millimeters using the keratometric assumption that the index of refraction of the cornea is 1.3375.

The Rose-K diagnostic lens set and fitting procedure were followed. The diagnostic lens set consists of 26 lenses with base curves ranging from 5.1 to 7.6 mm in 0.1 mm increments with a standard lens diameter of 8.7 mm and standard, increased, or decreased peripheral edge lift. The trial sets are fabricated in Boston ES non-UV light blue material. The base curve of initial lens applied was 0.2 mm [steeper] more than the average corneal radius of curvature calculated from the average Sim K values on axial topography map. Based on the evaluation of initial lens fit on slit lamp, new trial lens base curve were chosen until 2-3 mm of apical touch and horizontal mid-peripheral bearing at 3 and 9 o'clock was achieved. After determining the base curve of the lens the peripheral lens fit was then adjusted in order to obtain approximately 0.5-0.7 mm wide peripheral lift. Retrial with trial lens of increased or decreased peripheral lift was done in eyes demonstrating peripheral fluorescent band of less than 0.5 mm or more than 0.7 mm. Trial contact lens fitting parameters were evaluated and completed in one eye first before attempting the same in the other eye. Generally, we preferred to fit the less advanced keratoconus eye first. Each patient was then given the option to wear trial lenses for 30 minutes to an hour and report wear comfort in this period. Contact lens power was then determined by performing refraction over the contact lens. All contact lenses were ordered from Nova Contact Lenses, Hampstead, England.

After the ordered Rose-K lenses were procured, the patient was called to the clinic and fitted with the lens. If the fit was acceptable to the patient, a return visit was scheduled at one week when fitting relationship, contact lens wear comfort, and daily contact lens wear duration were recorded. Subsequent clinic visits were scheduled at 3 months and then every 6 months. At each visit, contact lens comfort was graded on a ten -point scale. At every visit patients had access to the wear comfort score achieved at an earlier evaluation.

Statistical methods

Chi square tests were performed for categorical variables. Self-reported contact lens wear comfort was graded on a ten point rating scale in which 10 = very comfortable and 1 = very irritating. When the unit of analysis was the eye, separate analysis was done for left and right eye to satisfy the assumption of independence between observations. All tests were two tailed and $P<0.05$ was considered significant. Delta K (Contact lens base curve-average Sim K) values were calculated for average axial and instantaneous keratometric readings and plotted against average axial K and instantaneous keratometric values. Regression analysis was performed and trend line depicted in the scatter diagram (r^2 value).

Results

This study included 38 eyes of 23 keratoconus patients. In all, eight eyes of these 23 patients were excluded because of hydrops (3 eyes), prior corneal transplant (2 eyes), macular scar (1 eye), and unwillingness to wear contact lenses (two eyes of two patients, because of very advanced keratoconus, the fit was not very comfortable. So patients opted to wear contact lens in one eye only).

There were 13 male and 10 female patients. The age of these patients ranged from 12 to 61 (mean 21.2 ± 10.54) years. Based on axial keratometric values (average Sim K), 14 eyes demonstrated moderate keratoconus (average Sim K 48.61 ± 1.24D) and 24 eyes demonstrated severe keratoconus (average Sim K 60.88 ± 5.31D). The refractive cylinder in these 38 eyes ranged from one to 11 diopters (mean 4.43 ± 2.24D). Axial maps of topography documented corneal astigmatism of 2 to 14.5D (mean 6.2 ± 3.27D).

Majority of these patients (24 eyes, 63%) were dependent upon glasses only. Three eyes (8%) habitually used PMMA contact lenses. Eleven eyes (29%) did not have any vision correction prescribed. The baseline visual acuity with the habitual corrective device in different grades of keratoconus is depicted in Table 1. Visual acuity achieved with the Rose-K lens was 20/40 or better in 36 (94.7%) eyes and 20/60 in two eyes. Contact lens power ranged from -1 to -18 dioptres.

Trial contact lens fitting succeeded in 37 (97%) eyes. The one eye in which the contact lens trial failed had an average keratometry of 70.3 D. Average number of times we changed contact lenses in moderate and severe keratoconus was

Table 1: Visual acuity at baseline with the habitual correction device in moderate and severe keratoconus eyes

Habitual correction	Visual acuity	Moderate keratoconus eyes	Severe keratoconus eyes
Glasses	>20/40	4	3
	20/40-20/80	2	5
	<20/80	5	5
Contact lenses	>20/40	1	1
	20/40-20/80	–	–
	<20/80	–	1
No correction	>20/40	1	
	20/40-20/80	1	3
	<20/80	1	6

2.2 ± 0.45 and 3.2 ± 0.59, respectively. Of these 37 eyes, 25(67.3%) eyes achieved a successful fit with a contact lens of base curve steeper or on the average radius of curvature of the cornea. In 8 (32%) of these 25 steep fit eyes, contact lens measured more than 0.2 mm steeper than average cornea curvature. In 12 (32.7%) eyes contact lens measured flatter than the average radius of curvature of the cornea. Delta K (Contact lens base curve-average Sim K) measured in moderate keratoconus (0.243 mm ± 0.155) was significantly higher than the delta K measured in severe keratoconus (–0.069 mm ± 0.261) ($P<0.05$). Contact lens qualifying for final prescription were generally flatter than average Sim K on axial maps in moderate keratoconus and steeper in severe keratoconus.

Delta K determined from average Sim K on instantaneous topography maps differed significantly from delta K values based on axial map average Sim K in both moderate (0.571 mm ± 0.319 vs. 0.243 mm ± 0.155) and severe (0.635 mm ± 0.716 vs. –0.069 mm ± 0.261) keratoconus eyes ($P<0.05$). Contact lens base curves have better correlation ($r^2=0.59$) with axial map average Sim K than instantaneous map ($r^2=0.34$) average Sim K [Figs. 1 and 2]. Moderate and severe keratoconus eyes needed 2.2 ± 0.45 and 3.2 ± 0.59 diagnostic lens trials, respectively.

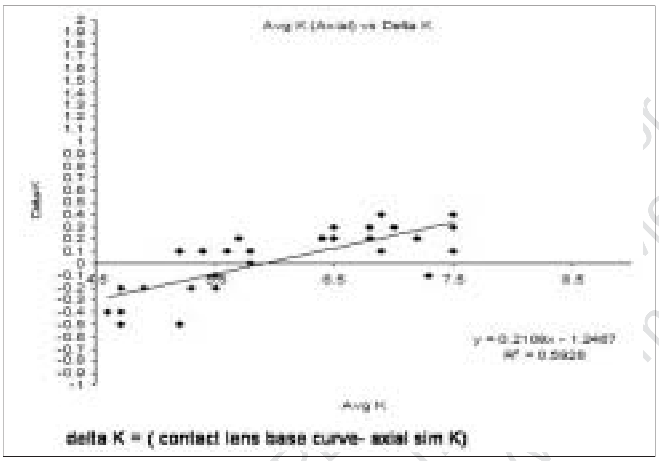

Figure 1: Scatter diagram depicting average simulated K on axial maps and delta K (contact lens base curve-axial sim K)

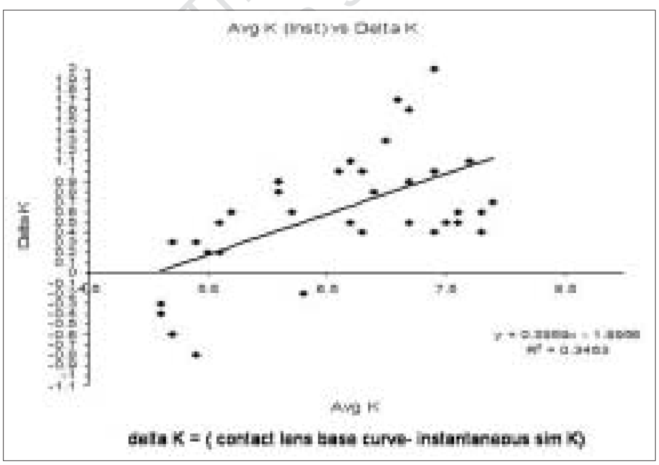

Figure 2: Scatter diagram depicting average simulated K on instantaneous maps and delta K (contact lens base curve-instantaneous sim K)

Follow-up period ranged from 6 to 24 months (average 13 ± 3.5 months). Contact lens wear comfort, as recorded on the rating scale, documented a score of eight or more in all eyes at trial lens fitting. In only three eyes, deterioration in comfort score of two to five grades was documented over the period of follow up. Complications noted included epithelial abrasion in two eyes of one patient at intervals of 12 and 14 months and hydrops in one eye at 7 months interval. These three eyes had been fitted with lenses flatter than average cornea curvature. Thirty-four eyes continued to score contact lens wear comfort of grade eight or more on the rating scale over the entire follow up period. Thirty-two of these 34 eyes tolerated contact lenses for 12 to 14 hours a day.

Discussion

Fitting of contact lenses for visual rehabilitation of keratoconus patients is very challenging.[6,14,15] Efforts at improvement in contact lens design have decreased the number of patients who would require penetrating keratoplasty.[16]

The results of this study indicate that 97% of keratoconus eyes could be successfully fitted with Rose-K contact lenses. Majority (34 eyes, 92%) of patients reported maintained wear comfort over a long period (average 13 ± 3.5 months) with good visual acuity. Corneal abrasions occurred in two eyes and hydrops in one eye wearing flatter lenses. These eyes were fitted with flatter base curves. It may be prudent to fit contact lenses with minimal touch with mid-peripheral bearing to avoid corneal staining and other complications. There are various approaches to fitting a rigid lenses - flat, steep or with divided support.[6] Although the relation between rigid lenses fitting and apical corneal scarring has been postulated, the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study found that 88% of rigid contact lens wearing eyes were fitted with apical touch.[14]

The results of this study are comparable to the earlier reported success with Rose- K lenses.[13] Descriptions of successful fitting of severe keratoconus eyes are scanty. Smiddy *et al.* reported with another contact lens design that keratoconus eyes with successful and failed contact lens fit demonstrated mean keratometry value at 51.8 diopters and 59.2 diopters, respectively.[17] Crews *et al.* reported successful contact lens fitting in 53.4% eyes with keratometry values ranging from 48.9 to 53.7D and failure in 29% eyes with a mean keratometry of 56.5D.[18] Keratoconus eyes in the pool of patients for this report demonstrated average curvature of 55.3 ± 7.49D (range 44-70.4D). Twenty-four (63%) of these eyes were documented to have severe keratoconus (average K 60.1 ± 5.15D, range from 52.5 to 70.4D).

Recently, axial steep SIM-K or the average of axial SIM-K curvature values have been used to guide fitting of contact lenses in keratoconus.[7,19]

In the present study we chose a trial lens, which was 0.2 mm steeper than average SIM –K values. With apical bearing of 2-3 mm, contact lens, which is 0.2 mm steeper than average SIM –K will closely match the sagittal depth of the properly fitting contact lens, because in keratoconus, topography underestimates the axial curvatures.[19] It is reasonable that axial values better matched the contact lens base curves because the contact lens base curve and axial distance are both spherically biased. In a minimal apical clearance fit, the sagittal depth of the lens closely matches the sagittal depth of the cone.

In the standard method of videokeratogrphy, axial distance is a reference distance [and not a true curvature] that is spherically biased and used in standard keratometry.[20,21] When there is a de-centered cone apex, videokeratograph power errors are greater with the axial power map than with the instantaneous map.[21] The axial power map produces values for the apex position that are about 50% too high and values for the apex power that are 10-40% lower than actual axial power.[21] Instantaneous radius or power provides a better measure of the corneal shape for keratoconus.[22] But instantaneous powers cannot be used for contact lens fitting, probably because these maps display steeper apices but flatter peripheries than the axial counterpart, which alters the contact lens sagittal depth relationship.[19] Contact lens rests predominantly on the flatter mid periphery, so an instantaneous apex radius would result in an excessively steep fit. A fit based on an instantaneous steep SIM-K significantly underestimates the base curve, because the flatter corneal curvatures surrounding the cone are averaged into the output of topography.[19]

These observations have application in the fitting of contact lenses in keratoconus using videokeratography, where lack of success may be due to the corneal measurement errors from the decentration of the corneal apex. The effect of this error is especially important in fitting rigid contact lenses, where there are two errors produced: a fitting error and a power error, because of choice of wrong base curve of contact lens and the resulting tear cylinder.

Delta K calculated from axial maps was significantly higher in moderate keratoconus than in severe keratoconus, indicating contact lens base curve of final contact lens was generally flatter than average SIM-K on axial maps in moderate keratoconus and steeper in severe keratoconus. This can be explained by the fact that in severe keratoconus there is less decentration of the corneal apex, thereby producing less faulty axial powers.

Delta K values [Difference of final contact lens base curve from average SIM –K on instantaneous map] measured from instantaneous map were consistently and significantly much higher than final contact lens base curve as compared to delta K from axial map [also evident from Figs. 1 and 2]. This also indicates that instantaneous SIM –K values are much higher than final base curve of the contact lens [in terms of diopters] because a lesser value in mm means higher diopters. In severe keratoconus these values are even higher and more variable, as indicated by higher standard deviation. Thereby, if you choose initial base curve of contact lens based on instantaneous curvature, it will result in a steep fit. The contact lens base curves are generally closer to axial map average SIM-K than instantaneous map average SIM –K as seen in Figs. 1 and 2.

Although, we intended to fit lenses 0.2 mm steeper than the average simulated keratometry value as recommended, we ended up fitting lenses with base curves 0.5 mm steeper to 0.5 mm flatter. The data also document that the relationship of axial corneal curvature to final Rose-K lens base curve is not constant. Known difficulties in documenting repeatability of measured ocular refraction, visual acuity, and topography curvature in keratoconus eye could explain the varying relationship of final contact lens base curve to measured curvature.[23,24] In our experience 2-4 diagnostic lens trials are needed per eye when determining the appropriate base curve. Our results are consistent with a recent work[16] and do not substantiate the first-fit success rate of 80-90% reported earlier.[25]

Conclusion

Fitting of specialty contact lenses is quite challenging in keratoconus. The proprietary Rose-K contact lens is appropriate for use in management of keratoconus eyes and axial curvature predicts better the final Rose-K contact lens base curve. Further studies with this lens design should look at claims of first fit and consider factors related to axial curvature based versus true elevation based topography values in fitting of contact lens and also address the issue of higher order aberrations common to keratoconus eyes.

References

1. Krachmer JH, Feder RS, Belin MW. Keratoconus and related non inflammatory corneal thinning disorders. *Surv Ophthalmol* 1984;28:293-322.
2. Zadnik K. Keratoconus. *In*: Bennet ES, Weissman BA (editors). Clinical contact lens practice. Lippincott: Philadelphia; 1993. p. 1-10.
3. Weed KH, McGhee CN. Referral patterns, treatment management and visual outcome in keratoconus. *Eye* 1998;12:663-8.
4. Lass JH, Lembach RG, Park SB, Hom DL, Fritz ME, Svilar GM, *et al*. Clinical management of keratoconus: A multicentric analysis. *Ophthalmology* 1990;97:433-45.
5. Lim N, Vogt U. Characteristics and functional outcomes of 130 patients with keratoconus attending a specialist contact lens clinic. *Eye* 2002;16:54-9.
6. Leung KK. RGP fitting philosophies for keratoconus. *Clin Exp Optom* 1999;82:230-5.
7. Lee JL, Kim MK. Clinical performance and fitting characteristics with a multicurve lens for keratoconus. *Eye Contact Lens* 2004;30:20-4.
8. McMonnies CW. Keratoconus fittings: Apical clearance or apical support? *Eye Contact Lens* 2004;30:147-55.
9. Edrington TB, Barr JT, Zadnik K, Davis LJ, Gundel RE, Libassi DP, *et al*. Standardized rigid contact lens fitting protocol for keratoconus. *Optom Vis Sci* 1996;73:369-75.
10. Lembach RG. Use of contact lenses for management of keratoconus. *Ophthalmol Clin North Am* 2003;16:383-94.
11. Pullum KW, Whiting MA, Buckley RJ. Scleral contact lenses: The expanding role. *Cornea* 2005;24:269-77.
12. Dana MR, Putz JL, Viana MA, Sugar J, McMahon TT. Contact lens failure in keratoconus management. *Ophthalmology* 1992;99:1187-92.
13. Betts AM, Mitchell GL, Zadnik K. Visual performance and comfort with the Rose K lens for Keratoconus. *Optom Vis Sci* 2002;79:493-501.
14. Edrington TB, Szczotka LB, Barr JT, Achtenberg JF, Burger DS, Janoff AM, *et al*. Rigid contact lens fitting relationship in Keratoconus. *Optom Vis Sci* 1999;76:692-9.
15. Chung CW, Santim R, Heng WJ, Cohen EJ. Use of SoftPerm contact lenses where rigid gas permeable lenses fail. *CLAO J* 2001;27:202-8.

16. Belin MW, Fowler CW, Chambers WA. Evaluation of recent trends in the surgical and nonsurgical management of keratoconus. *Ophthalmology* 1988;95:335-9.
17. Smiddy WE, Hamburg TR, Kracher GP, Stark WJ. Keratoconus: Contact lenses or keratoplasty? *Ophthalmology* 1988;95:487-92.
18. Crews MJ, Driebe WT Jr, Stern GA. The clinical management of Keratoconus: A 6 year retrospective study. *CLAO J* 1994:20:194-7.
19. Szczotka LB, Thomas J. Comparison of axial and instantaneous videokeratographic data in keratoconus and utility in contact lens curvature prediction. *CLAO J* 1998;24:22-8.
20. Roberts C. Characterization of the inherent error in a spherically biased corneal topography system in mapping a radially aspheric surface. *Refract Corneal Surg* 1989;10:103-11.
21. Chan JS, Mandell RB. Alignment effects in videokeratography of keratoconus. *CLAO J* 1997;23:24-8.
22. Chan JS, Mandell RB, Burger DS, Fusaro RE. Accuracy of videokeratography for instantaneous radius in keratoconus. *Optometry Vis Sci* 1995;72:793-9.
23. McMahon TT anderson RJ, Joslin CE, Rossa GA; CLEK Topography analysis group. Precision of three topography instruements in keratoconus subjects. *Optom Vis Sci* 2001;78: 599-604.
24. Raasch TW, Schechtman KS, Davis LJ, Zadnik K; CLEK study group. Repeatability of subjective refraction in myopic and keratoconic subjects: Results of vector analysis. *Ophthal Physiol Opt* 2001;21:376-83.
25. Rose P. Unanswered questions: Letter. *Contact Lens Spectrum* 1990;14:15.

Source of Support: Nil, **Conflict of Interest:** None declared.