A comparative study between RGP contact lens and Rose K contact lens in various grades of keratoconus

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Abstract
Introduction: Keratoconus is a developmental anomaly of cornea. Non inflammatory thinning and cone shaped protrusion of cornea causes significant visual disturbance and discomfort.
Objectives: This study was done with prime objective of choosing appropriate contact lens from available two options (RGP lens and Rose K lens) for various grades of keratoconus.
Materials and Methods: In present study 21 eyes of 14 patients were selected; who presented in our hospital with various grades of keratoconus. Time period of study is twelve months.
Result: In present study 3 eyes of mild keratoconus, 11 eyes of moderate keratoconus, 6 eyes of advanced keratoconus and 1 of severe keratoconus were included.
Conclusion: Overall visual acuity and comfort is more with Rose K lens in comparison with RGP lens especially in advanced and severe cases.

Keywords: Keratoconus, RGP lens, Rose K lens, Visual acuity, Subjective comfort.

Introduction
Keratoconus is a Greek word (Kerato: Cornea; Konos: Cone) which means cone-shaped protrusion of the cornea. Keratoconus is a type of developmental anomaly and in this disease non inflammatory thinning of the corneal stroma occurs. Thinning of inferior or central portion of the cornea produces a cone shaped forward bulging.¹² It is characterized by progressive corneal steepening, most typically inferior to the center of the cornea, with eventual corneal thinning, induced myopia, and both regular and irregular astigmatism. The hereditary pattern is not predictable although the strongest evidence of genetic involvement is a high concordance rate in monozygotic twins.³ The incidence and severity of keratoconus were found to be more in Asians compared with whites.⁴⁵
A positive family history has been reported in 6-8% of the cases and its prevalence in first-degree relatives is 15-67 times higher than the general population.⁶ The incidence and severity of keratoconus in Asian eyes may be high with an early onset and more rapid progress to the severe disease stage at a young age; frequently by the second decade.⁷
Manifestations of keratoconus are limited to the cornea. They include steepening of the cornea, especially inferiorly, thinning of the corneal apex, clearing zones in the region of Bowman's layer, scarring at the level of Bowman's layer, and deep stromal stress lines that clear when pressure is applied to the globe.
Spectacles are not good option, contact lenses used in mild cases as they are masking irregular astigmatism and offer better vision acuity. For mild to moderate irregularities- soft, soft toric or custom soft toric-contact lenses can be used. Severe irregularities require rigid gas permeable (RGP) lenses in order to mask the irregular astigmatism. Different CL designs are available based on one of these fitting techniques, and of these, Rose K lens is a proprietary lens design introduced by Paul Rose from New Zealand⁸⁹ Various specialized RGP lenses, such as Super Cone, and Rose K, have been developed for keratoconus, with a steep central posterior curve to vault over the cone and flatter peripheral curves to approximate the more normal peripheral curvature.
In present study we are doing comparison between RGP lens and Rose K lens (a specialized RGP lens) in patients of keratoconus in terms of visual outcome and comfort.

Materials and Methods
A longitudinal interventional study was done at an Eye Hospital and Post Graduate Institute over a period of 12 Months (January 2012 to December 2012) and includes 21 eyes of 14 patients of keratoconus. All patients were fitted with RGP lenses and Rose K contact lenses and after that visual acuity and comfort were noted. The study was approved by Institutional ethics committee. Informed consent was taken in each case.
Inclusion Criteria
1. Motivated patient with keratoconus and no other ocular cause of low vision.
2. Keratoconus patient age more than 16 yrs.
3. Patients already using other contact lens, or who had underwent C3R procedure for keratoconus.

**Exclusion Criteria**

1. Patient with anterior or posterior segment pathology
2. Unwilling patient and patient below 16 yrs.
3. Patient with CNS disorder and Ocular allergies (veneral keratoconjunctivitis and others)
4. Patient having Dry eye
5. Pregnancy

Detailed history of any ocular surgeries, glare, distortion of images were taken and questions were also asked for eye rubbing habits, any other associated ocular or systemic disease and also about any family history of keratoconus. Patients were asked to tell their answers in form of ‘yes’ or ‘no’ for their eye rubbing habits and ‘can tolerate ’ or ‘cannot tolerate’ for contact lens comfort, separately for each eyes.

The patients in the study had unilateral or bilateral keratoconus as evidenced by clinical and slit lamp examination. The visual acuity was assessed using LOG MAR visual acuity chart for distance and near. Objective and subjective refraction was done in each case. Thorough systemic examination, evaluation of adnexa, fundus examination and schirmer’s test was done by in each case. Objective findings necessary for enrollment were corneal distortion in either eye (as seen with keratometry or retinoscopy) or the presence of either Fleischer’s ring, Vogt’s striae, scarring consistent with keratoconus or the presence of topographic evidence suggestive of keratoconus. Values of keratometry (Bausch & Lomb type keratometer), corneal topography with ORB scan (slit scanning Bausch & Lomb) were noted.

The grading of keratoconus based on keratometry value was done for every patient. The keratoconus was sub grouped as:
- Mild (average Sim K: >45 diopter [D]),
- Moderate (average Sim K: 45–52 D),
- Advanced (average Sim K: 52–62 D), and
- Severe (average Sim K: >62 D).

Contact lens base curve was selected according to the flat k value. Lenses were fitted on the basis of flat K.

**Common Procedure**: A drop of proparacaine 0.5% was put as a topical anesthesia and the lens was allowed to settle for about 5-10 minutes before evaluating the fluorescein pattern. According to fluorescein staining fitting assessment was done. The dynamic and static fit was assessed. In dynamic fit assessment, the lens was considered to be acceptable when the lens was centered adequately on the cornea with good post blink movement.

**Procedure for RGP Lens Trial**: In static fit, the goal was to achieve a “3 point touch” (Fig. 1). If first trial lens was steep then a flatter base curve was taken. The trial was repeated until we achieved an acceptable dynamic and static fit. After finding the optimal lens fit, the final power was calculated after performing a spherical objective and subjective over refraction over the trial lens. Any ocular discomfort or foreign body sensation with the lens was noted.

**Procedure for Rose - K Lens Trial**: In static fit, the goal was to achieve a “feather touch” in the centre with mid peripheral bearing and peripheral clearance (Fig. 2). If first trial lens was steep then a flatter base curve was taken. The trial was repeated until we achieved an acceptable dynamic and static fit. After finding the optimal lens fit, the final power was calculated by performing a spherical objective and subjective over refraction over the trial lens. Any ocular discomfort or foreign body sensation with the lens was noted.

A comparison was done on the basis of BCVA (Log MAR) and subjective comfort between two lenses.

**Results**

In our study included total 21 eyes of 14 patients. Detailed observations and results were shown by Figures (Fig. 3 and Fig. 4) and written in tabulated format (Table 1-5). Statistical analyses are done on SPSS 16 software.

Fig. 3 shows that in present study population comprised of 12 males (85.71%), and 2 females (14.29%). 6 patients (42.85%) were in the age group of 16-25 years, 6 patients (42.85%) were in the age group of 26-35 years and 2 patients were in the age group of above 35 years (14.28%).

Fig. 4 shows that in present study 50% (7) of patients had bilateral keratoconus and another 50% (7) patients had unilateral keratoconus. In unilateral cases, in 28.57% cases were of right eyes and 21.42% were of left eyes.

Table 1 shows that 3 (14.28%) eyes in our study group had mild keratoconus, 11 eyes (52.38%) had moderate keratoconus, 6 eyes (28.57%) had advanced keratoconus and 1 (4.76%) had severe keratoconus.

**Comparison between RGP & Rose K Lens Parameters**

1. **Comparison of overall diameter**
   - The range of overall diameter is 8.5 mm to 9.2 mm which was same for both RGP & Rose K lens in each patient.
2. **Comparison of Diopteric power**
   - Range and average value of Diopteric power of RGP & Rose K lens in present study is shown in table 3.

**Comparisons of Visual Acuity and Patient Comfort**

1. **Comparison of improvement of vision in different stages of keratoconus**
   - We used both type of lenses on all the eyes included in the present study and after that visual acuity was checked in each case.

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In mild cases there is no difference in improvement of vision by both type of lenses and in moderate cases there are 2 cases out of 11 which shows better visual acuity by using Rose K lens. There is significant improvement of vision in advance and severe cases by the use of Rose K lens in compare to the use of RGP lens. In 4 out of 6 advanced cases shows better visual acuity by Rose K lens and there is only one case of severe grade which shows improvement by Rose K lens (Table 4).

Visual acuity was noted in terms of improvement of average Log MAR value. In moderate cases value improved from 0.10 +/- 0.09 to 0.11 +/- 0.10, in advanced cases value improved from 0.22 +/- 0.11 to 0.29 +/- 0.13 and in severe cases value improved from 0.47 to 0.52. Improvement of Vision with Rose K lens was statistically significant in comparison to RGP lens (p = 0.05).

2. Comparison of comfort in different stages of keratoconus.

There is equal level of comfort was noticed in all cases of mild grade of keratoconus by using both type of lenses one by one and in moderate cases in 6 out of 11 cases there was more comfort with Rose K lens. While in advanced and severe cases all cases (6 eyes of advanced grades and 1 eye of severe grade) shows more comfort with Rose K in comparison to RGP lens (Table 5).
Table 1: Distribution of study population according to severity of keratoconus

| S. No. | Group   | Number of eyes | Percentage |
|-------|---------|----------------|------------|
| 1     | Mild    | 3              | 14.28%     |
| 2     | Moderate| 11             | 52.38%     |
| 3     | Advanced| 6              | 28.57%     |
| 4     | Severe  | 1              | 4.76%      |
| Total |         | 21             | 100%       |

Table 2: Comparison of base curve in RGP & Rose K lenses

| Base curve          | Rose K Lens | RGP Lens       |
|---------------------|-------------|----------------|
| Range               | Average     | Range          | Average       |
| 6.4 mm to 7.8 mm    | 7.09 +/- 0.42 mm | 6.3 mm to 7.8 mm | 7.16 +/- 0.46 mm |

Table 3: Comparison of diopteric power in RGP & Rose K lenses

| Diopteric power | Rose K Lens | RGP Lens       |
|-----------------|-------------|----------------|
| Range           | Average     | Range          | Average       |
| -1.25 D to -14 D | -5.09 +/- 3.76 D | +0.0 D to -14.5 D | -4.43 +/- 3.82 D |

Table 4: Improvement in vision by using RGP & Rose K lens

| S. No. | Grades of keratoconus | No. of eyes | Improvement in vision |
|--------|-----------------------|-------------|-----------------------|
|        |                       |             | Better with Rose K    | Equal with both (Rose K and RGP) |
| 1      | Mild                  | 3           | -                     | 3                         |
| 2      | Moderate              | 11          | 2                     | 9                         |
| 3      | Advanced              | 6           | 4                     | 2                         |
| 4      | Severe                | 1           | 1                     | -                         |
| Total  |                       | 21          | 7                     | 14                        |

Table 5: Level of comfort after wearing RGP & Rose K lenses in different stages

| S. No. | Grades of keratoconus | No. of cases | Level of comfort |
|--------|-----------------------|--------------|-----------------|
|        |                       |              | Better with Rose K | Equal with both |
| 1      | Mild                  | 3            | 0                | 3               |
| 2      | Moderate              | 11           | 6                | 5               |
| 3      | Advanced              | 6            | 6                | 0               |
| 4      | Severe                | 1            | 1                | 0               |
| Total  |                       | 21           | 13               | 8               |

Discussion
The mean age of the patients was 27.71 +/- 8.29 and 85.71% were male and 14.29% were females. Many previous studies show a clear male preponderance. In a study in south India by Sudharman et al, 128 eyes of 80 patients were analyzed; the mean age of the patients was 21.92 +/- 7.15. Similar studies done by Crews et al and Das S et al shows mean age 28 years and 25.3 years respectively.

In one study in Dr. Shroff’s eye hospital, Delhi by Fatima T et al, 68 eyes of 41 patients were analyzed, median age was 26 years of which 58.5% were male and 41.5% were females. Of the 21 eyes 3 were mild, 11 were moderate, 6 were advanced and 1 was severe grade of keratoconus. Keratoconus was sub grouped on basis of average Sim K value. In the study of Sudharman et al prevalence of keratoconus was 8 mild, 35 moderate, 40 advanced and 11 cases were severe. In study of Fatima T et al 6 eyes were mild grade, 20 eyes of moderate grade, 37 eyes had advanced and 4 eyes had severe grade of keratoconus.13

In study of Ozkurt et al 1 eye had mild keratoconus, 20 eyes had moderate and 7 eyes had advanced grade of keratoconus.14 The mean power (D) of Rose K lens in mild cases was -2.58 +/- 2.1, for moderate cases -3.20 +/- 2.01, for advanced cases mean value was -8.33 +/- 2.6, and for severe it was -14. Sudherman et al10 also reported mean power (D) of Rose K lens for different grades of keratoconus in mild cases it was reported -5.00 +/- 2.93, for moderate cases -7.90 +/- 3.63, advanced cases -10.48 +/- 5.12, and for severe cases -16.34 +/- 3.92.

Average value of Rose K contact lens base curve (mm), in our study for mild cases was 45.12 +/- 2.73, moderate cases 46.72 +/- 2.14, for advanced cases 50.13 +/- 1.58, and for severe case 52.16. While Sudherman et al reported mean value of contact lens base curve (mm) for mild cases was 45.24 +/- 0.86, moderate cases 50.24 +/- 3.24, for advanced cases...
52.99±/-4.08 and for severe cases it was maximum 58.60±/2.9510.

In our study with Rose K contact lens BCVA improved to 0.18 LogMAR or better in 90.47% and all improved to 0.48 LogMAR. As compared to RGP contact lenses where 71.42% cases improved to 0.18 LogMAR / better.

While Fatima T et al analyzed that with Rose K contact lens BCVA improved to 0.18 LogMAR or better in 91.2% and all improved to 0.48 LogMAR. As compared to RGP contact lenses where 60.2% cases improved to 0.18 LogMAR / better.13

In our study we compared RGP lens with Rose K lens in terms of visual acuity and subjective comfort, and we concluded that in mild cases no difference in BCVA was noticed. In mild cases there was no improvement of vision, 18.18% of moderate cases there was improvement in vision, in advanced cases 66.66% cases while in severe cases 100% cases there was improvement in vision (as compared to RGP lens). Vision improvement with Rose K lens was significant as compared to RGP lens. We also compared subjective comfort between two lenses In mild cases equal comfort was noticed in all cases, moderate cases in 83.33% cases there was more comfort, in advanced cases 100% cases, also in severe cases 100% cases there was more comfort with Rose K lens (as compared to RGP lens).

Conclusion

Present study showed that the Rose K lens is useful in the management of all grades of keratoconus. Rigid gas permeable lens is also a modality of choice for keratoconus but vision improvement and subjective comfort is better with Rose K lens especially in moderate and severe grades of keratoconus. The Rose K Lens is a proprietary contact lens design that is appropriate for the management of keratoconus.

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