

Research Article

Contact lens fitting in keratoconus – a prospective study on visual and functional outcomes

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Received: 02 May 2015

Revised: 06 June 2015

Accepted: 09 July 2015

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ABSTRACT

Background: Contact lenses continue to play an important role in the effective management of keratoconus. To report visual and functional outcomes of various types of *contact lenses* in *keratoconus* patients at a tertiary referral centre.

Methods: *Study design:* Prospective Cohort Study. 100 eyes of 51 patients with keratoconus were fitted with contact lenses with follow up at one and six months and evaluated. *Statistical analysis:* Paired t test, Chi Square test.

Results: Best contact lens corrected visual acuity was better than best spectacle corrected visual acuity ($p=0.000$). 78 % patients were fitted with RGP, 12% with Rose K, 6 % Soft, 2% Piggy Back and 2% with Kerasoft IC lenses. Soft lens were preferred in mild keratoconus, RGP for moderate and Rose K, Piggy Back and Kerasoft IC lenses for severe keratoconus. The mean daily wear among the lenses was 7.59 hours per day with Rose K lenses having maximum wearing time of 8.33 hours. Comfort and tolerance level was maximum in Rose K, Piggy Back, Kerasoft IC and RGP lens users whereas it was less in the soft lens group. No significant complications were noted with contact lens use.

Conclusion: Contact lenses continue to play an important role in the effective management of keratoconus. With the advent of newer designs of contact lenses for keratoconus it is possible to customize the lenses to optimize patient's requirement visually and functionally.

Keywords: Contact lenses, Keratoconus, Visual and functional outcomes

INTRODUCTION

Keratoconus is an ectatic corneal dystrophy first described in detail more than 150 years ago by Dr John Nottingham, but the understanding of the disease and its management have undergone significant changes over the last few decades.¹ Corneal specialists have adopted new techniques and technologies for the effective management of keratoconus, which ranges from spectacles and contact lenses to corneal replacement. Lamellar keratoplasty has been revived with improved outcomes and devices such as intracorneal ring segments are being used to treat cases of early keratoconus effectively.^{2,3} Contact lenses continue to play an

important role in the effective management of keratoconus.

Soft lenses have limited role in correcting corneal irregularity, as they tend to drape over the surface of the cornea and result in poor visual acuity. Early in the disease, soft lenses with toric design may be adequate to correct myopia and regular astigmatism. However, soft lenses designed specifically for keratoconus (e.g., KeraSoft) have a useful role in early keratoconus or where a patient may be intolerant of RGP. Soft lenses tend to be more comfortable compared with RGPs.

Rigid gas permeable (RGP) lenses are required as the condition progresses in order to correct the irregular

astigmatism. The aim is to provide the best vision possible with the maximum comfort. All keratoconus contact lenses should be ordered in a moderate to high Dk rigid gas permeable material to avoid epithelial hypoxia and corneal erosion during the long wearing schedule of keratoconus patient.

In some keratoconic patients, the steepness of the corneal apex and the radical flattening of the mid-peripheral and peripheral cornea limit the effective use of spherical lenses to correct irregularity. An Aspheric lens with a high eccentricity value will become flatter quicker compared to a spherical curve and provide better alignment and weight distribution over a larger area of the cornea.

The Rose K is a unique keratoconus lens design with complex computer-generated peripheral curves based on data collected by Dr. Paul Rose of Hamilton, New Zealand. The system (26 lens set) incorporates a triple peripheral curve system.

Piggyback lenses are used for difficult cases, for instance in cases of RGP lens intolerance, proud nebulae in keratoconus, or apical dimpling or where there are areas of recurrent epithelial erosion. The system consists of a rigid lens fitted on top of a soft lens aiming to obtain same visual acuity as with a single lens. Soft lens must be a silicone hydrogel lens with a high Dk/t.⁴

Hybrid lens system: The Softperm lens is a hybrid lens with a RGP centre surrounded by a soft hydrophilic skirt. The SynergEyes is relatively new and with a high Dk hybrid lens, it could be used for early keratoconus due to its aspherical design. These lenses tend to be used in cases of RGP lens intolerance.⁵

Scleral and semiscleral lenses have proven to be extremely beneficial for patients with highly irregular and/or asymmetric keratoconic corneas. These patients will benefit from a large diameter (13.5 to 16.0 mm) semiscleral lens design. Schornack et al. showed a dramatic improvement in visual acuity by using scleral lens in a study.⁶

Goal of the study

To report functional outcomes of various types of *contact lenses* in *keratoconus* patients attending the contact lens clinic at our hospital.

METHODS

Inclusion criteria

- 1) Confirmed cases of keratoconus of one or both eyes based on refraction, slit lamp and topography findings
- 2) Keratoconus patients post C3r

Exclusion criteria

- 1) Age < 12 years
- 2) Patients with any intraocular surgery in the past

Patients fulfilling the above criteria underwent detailed examination which included.

History, Baseline uncorrected visual acuity, Refraction, Baseline best spectacle corrected visual acuity, Slit lamp, Intraocular pressure, Fundus examination, Pachymetry, Keratometry, HVID, Corneal topography and location of the cone using both Pentacam and TMS Corneal Topography.

Keratoconus was graded on the basis of keratometry reading into mild (<47), moderate (48-52) and severe (>52).

Trial fit of contact lenses was done based on keratometry, Pentacam and HVID over slit lamp. After assessing the fit based on centration, movement, fluorescein pattern, the appropriate lenses were dispensed.

Also taken into account were; The amount of astigmatism (criteria:->8 cylinder; rose k and <3 cylinder; soft toric), patients comfort, tolerance level, affordability

Patients were followed up at:

- 1) one month
- 2) six months post fitting

Parameters Assessed On Each Visit were; History to grade comfort and tolerance level based upon Likert scale(score 1 :- poor and score of 5 very good), duration of wear, best contact lens corrected visual acuity, slit lamp to assess contact lens fit, movement, fluorescein pattern and any complications related to it.

Statistical analysis: SPSS statistical software, Paired t test, chi square test, MANOVA.

RESULTS

100 eyes of 51 patients with keratoconus were evaluated in our study. Maximum patients (66.7 %) were in the age group of 21-30 years; average age being 25.3 years (Figure 1) with relatively higher preponderance among the females (55%). 81% of the patients had presented with chief complaint of decreased vision, 17% distorted vision while 2% of patients for frequent change in their glass prescription. Best spectacle corrected visual acuity was in the logmar range of less than 0.5 units (20/60) in 68 % of eyes. Baseline best contact lens corrected visual acuity was 0.5 logmar units (20/60) or better in 93% of eyes and 0.6 – 0.5 logmar unit (20/80-20/60) in only 7% of eyes.

Best contact lens corrected visual acuity was better than best spectacle corrected visual acuity and this was

statistically significant (p=0.000) when analysed by student t-test thereby proving that contact lenses are a superior option to spectacles in keratoconus management.

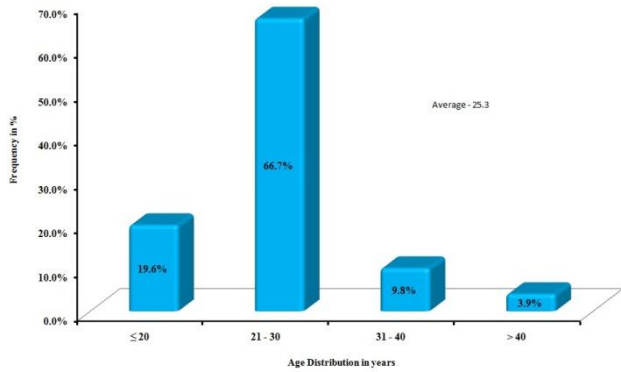


Figure 1: Age distribution.

Table 1: Age distribution.

Age distribution (in years)	Number	%
≤ 20	10	19.6%
21 - 30	34	66.7%
31 - 40	5	9.8%
> 40	2	3.9%
Total	51	

There was improvement by three lines in 12 % and two line improvement in another 12 % of patients. One line improvement was seen in 4 % cases and about four lines improvement was seen in 4% of cases. Though the numbers were statistically not significant, we found that out of the 32 cases which showed improvement 22 were RGP, 8 Rose-K and 2 Piggy Back (Figure 2).

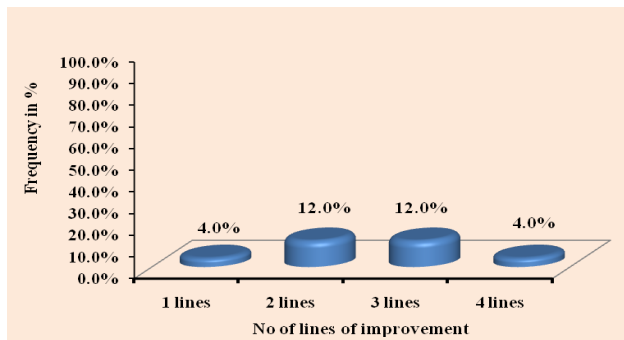


Figure 2: Number of lines of improvement of visual acuity between spectacles and contact lenses.

Table 2: Number of lines of improvement of visual acuity between spectacles and contact lenses

Lines of Improvement	% of eyes
0 lines	68.0%
1 lines	4.0%

2 lines	12.0%
3 lines	12.0%
4 lines	4.0%
Total	100%

The cases in our study were grouped into three on the basis of average keratometry readings wherein mild keratoconus was when k value was ≤47.0, moderate when k was 47.1-52.0 and severe when >52.

53% of eyes had moderate keratoconus, 25% of eyes had severe and the rest 22 % were in the mild keratoconus group. Out of the 100 eyes in our study majority;78% of them were fitted with RGP lenses, 12 % were fitted with Rose-K lenses, 6% with Soft lens and 2% each of piggy-back and Kerasoft IC lenses (Figure 3).The average base curve of the lenses was 6.99. The fit, movement and fluorescein pattern as assessed under slit lamp for the contact lenses at the time of dispensing was optimal for all 100 eyes.

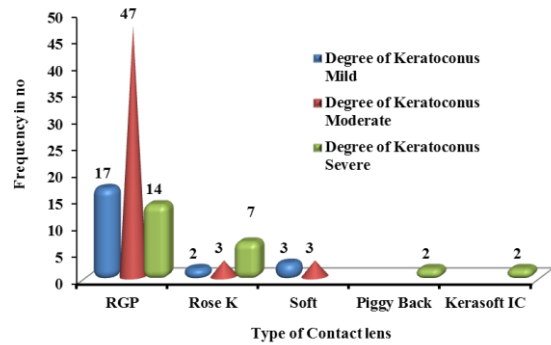


Figure 3: Degree of keratoconus and type of contact lens prescribed.

Table 3: Degree of keratoconus and type of contact lens prescribed.

Contact lens	Degree of Keratoconus			Total
	Mild	Moderate	Severe	
RGP	17	47	14	78
Rose K	2	3	7	12
Soft	3	3	0	6
Piggy Back	0	0	2	2
Kerasoft IC	0	0	2	2
Total	22	53	25	100

Table 4: Mean daily wear time of contact lens (in hours).

Contact lens	Mean Daily wear time				Total
	6 hrs	7 hrs	8 hrs	9 hrs	
RGP	4	24	50		78
Rose K			8	4	12
Soft		2	4		6
Piggy Back			2		2
Kerasoft IC			2		2
Total	4	26	66	4	100

Table 5: Comfort and tolerance level with each type of contact lens.

Contact lens	Comfort / tolerance level (average)	
	1 month	6 months
Rgp	4.7	4.8
Rosek	5	5
Soft	3.6	3.6
Piggy back	5	5
Kerasoft ic	5	5

In our study, we found an average of 7.59 hours of daily wear in the RGP group, 8.33 hours in Rose-K, 7.67 hours in the Soft lens group and 8 hours of daily wear in each of Piggy Back and Kerasoft IC group (Table 4). Thereby a high tolerability among the Rose K group on an average when compared to the other subset of lenses.

All patients in our study fitted with the contact lenses were followed up at one and six months and their comfort and tolerance level were graded based upon LIKERT scale with 1 being very poor and 5 being very good.

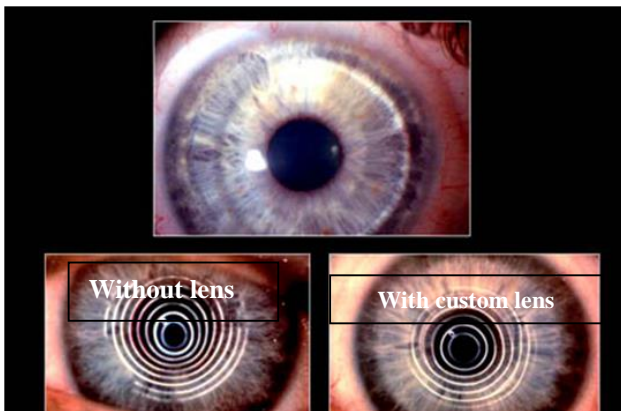


Figure 4: Keratoscopic mires with and without contact lenses.

In the Rose K group; all the patients had graded the comfort level to 5 which remained at the same level on further follow up at six months. For those patients fitted with RGP; 63% graded the comfort level to 5 (very good) which remained at the same grade in 61 eyes which was statistically significant (p value 0.003 by paired t test) but dropped down by one point in 2 eyes over 6 months follow up. 14 % of the patients had graded as 4 at the first month out of which 9 continued to be at the same grade, 3 of them stepped one point higher and 2 dropped down by 1 point over six months follow up. For the Soft lens group; 4 eyes graded comfort as 4 which remained 4 over six months follow up and 2 eyes graded their comfort level to 3 which again remained constant over the follow up period. As far as the Piggy Back and the Kerasoft IC group was concerned, the comfort level was best (5) and it remained 5 over six months follow up.

DISCUSSION

Keratoconus is a degenerative disorder that leads to thinning and ectasia of the cornea, causing characteristic irregular light reflexes on ophthalmoscopy and retinoscopy or irregular mires on keratometry. The patient develops a progressive, irregular myopic astigmatism causing reduced vision. This accounts for the most common visual complaint of the patients at presentation like blurred vision and poor visual acuity as was seen in a prospective study conducted by Lim N Vogt et al. ⁷In our study the most common visual complaint of the patients were blurred vision (81%), distorted vision(17%) and frequent change in their glass prescriptions (2%).

Keratoconus usually becomes apparent in one eye during adolescence and is slowly progressive, particularly during the second decade, before eventually stabilizing in the third and fourth decade. It may, however, commence later in life and progress or arrest at any age. In up to 90% of cases both corneas eventually become affected. Crews *et al*, conducted a retrospective analysis of keratoconic patients and found the mean age at hospital referral to be 28 years.⁸ Similarly, in our study, the mean age at presentation was 25.3 years. It was not possible to determine the mean age of onset because patients who attended the hospital contact lens department had usually been diagnosed with keratoconus already and been managed by their optometrists for some time before being referred to us. Keratoconus has been reported in children as young as 6 years old, however it rarely develops beyond 30 years of age.^{9,10} The age of the patients within our study ranged from 14 to 51.

The reported gender ratios vary for keratoconus. Prior to 1955 authors reported a higher incidence of female sufferers, however, since 1958, there has been a preponderance of male sufferers with an average male to female ratio of 3:2.¹¹⁻¹⁵ Even more recently, this ratio has been reported to be 3:1.¹⁶ In our study, however; we found the female to male ratio nearabout similar with a slight female preponderance (1.1:1).

Keratoconus is rarely unilateral and even in cases where the contralateral eye appears to be clinically normal without any visual symptoms, there will usually be mild changes of steepening seen on pentacam or topography. In our study, 49 patients (96.1%) had bilateral disease and bilateral contact lens fitted and only 2 patients had unilateral disease and thus contact lens fitted in unilaterally. Neither of the 2 patients who had unilateral disease required a contact lens in the contralateral eye throughout the follow up period i.e., 6 months.

Contact lenses remain the mainstay in the management of keratoconus. Contact lenses typically provides the patient with better visual acuity than can be obtained with glasses by neutralizing the regular and irregular refractive errors induced by the condition. As keratoconus

progresses, spectacles often fail to provide adequate visual acuity, especially at night. This can be further complicated by the fact that the patient's glass prescription may change frequently and can be limited by the degree of myopia and astigmatism that must be corrected.

A study conducted by Frederick et.al states that not only does the patient has an improvement in the total visual acuity, but they are at the same time rendered iseikonic and fully binocular with a full visual field.¹⁷ In our study also, the best contact lens corrected visual acuity was better than best spectacle corrected visual acuity and this was statistically significant ($p=0.000$). Moreover, the visual acuity was maintained at the follow up visits. Thereby, proving that contact lenses are a superior option to spectacles in keratoconus management.

Table 3 shows the different types of contact lenses used in our study. Out of the 100 eyes in our study; 78 % were fitted with rigid gas permeable (RGP) lenses. 12 % of cases with Rose-K, 6 % with Soft lenses, 2% with PiggyBack and 2 % with KeratoSoft IC lenses.

In our contact lens department, the initial choice of lens design is determined by keratometric readings. Also taken into account is the patients affordability. In our study, the patients severity of keratoconus was grouped into mild, moderate and severe on the basis of average keratometric readings. Eyes with an average keratometry of 47.1 and above are usually fitted with spherical RGP lenses such as Boston II. For very advanced keratoconic eyes with average K-readings of 52 and above, the custom conical designs such as the Rose K2 or Kerasoft IC lenses are suggested.

In our study, among the RGP group, 47 eyes were in the moderate keratoconus group, 17 mild and 14 severe.

Whereas out of the 12 Rose K fitted eyes; 7 had severe keratoconus 3 had moderate disease and 2 had mild keratoconus.

In the soft lens group 3 had mild keratoconus and 3 were in the moderate group and no eyes were in the severe disease group.

All eyes with Piggyback and kerasoft IC lenses had severe keratoconus.

When analysed, no statistical significance was seen between the choice of contact lenses and the degree of keratoconus which can be explained by the small sample size of Piggyback, Kerasoft IC lenses in contrast to the large sample size of the RGP group of lenses.

As the majority of our patients are from the middle class group with an average socio economic status, they had opted for low cost contact lenses though they had severe keratoconus for which Rose K or Kerasoft lenses would

have been an ideal choice. This explains the small sample size of Kerasoft IC and Rose K lenses in our study.

As far as Piggyback lenses were concerned, patients found it cumbersome in taking care of two lens systems and thus they were not opted by many.

Keratoconus is a progressive disease due to the alterations in central and paracentral corneal thickness. The application of soft contact lenses has two main limitations in keratoconic patients. First, in these patients the astigmatism is not equal in two meridians and soft lenses are unable to correct this type of astigmatism. Second, soft lenses need to be made thick enough to correct an irregular or high astigmatism and the resultant corneal edema is a common problem. Thus, soft lenses are not a preferred option for keratoconic eyes.

The accurate choice of rigid lens base curve with the help of the data obtained from keratometry or corneal topography is intriguing, however the literature does not provide enough supportive evidences. The selection of a base curve equal to the flatter keratometry reading or the flat keratometry measure in the initial studies in 1980's lacked to provide any supportive reference or rational related to these choices.^{18,19} In a study by Lin *et al* the authors found that the patients' keratometry has the best correlation with the selected lens base curve and this correlation was stronger when keratometry becomes flatter.²⁰

In a study by Zednik *et al*, the authors claim that no specific formula could be used to fit rigid contact lenses in keratoconic patients, however lens base curve is closer to the flattest keratometry findings.²¹ They concluded that the changes in lens base curve develops later than corneal base curve and in advanced disease the lens base curve should be chosen flatter than the flattest curve found by keratometry.

Similarly, in our study the base curve was chosen as flatter than the flat k on topography and pentacam. For the Rose K group, location of the cone was determined and base curves were calculated with pentacam values. The fitting guide recommends selecting the initial base curve 0.2 mm steeper than the mean K values. Once an appropriate base curve was determined, the lenses were dispensed after complete assessment under slit lamp to determine the fit, movement and fluorescein pattern. In our study, we found that the fit was optimal in almost all cases before dispensing as well as over all follow up visits

The average pachymetry in our study was 443.39 and it remained the same after contact lens fitting throughout the study period in all eyes unlike the decrease in corneal thickness as was noted in a study by Hwang *et al*.²²

The average contact lens wearing time was determined i.e., the number of hours the patients were with their lens

on without an enforced rest period in a day. Table 4 shows the average daily wear time for each of the contact lens in our study. We came to the conclusion that, Rose K lenses have a higher average daily wear (8.33 hours) time as compared to the other lens groups.

The comfort and tolerance level of the contact lenses were graded by the patients themselves on the basis of Likert scale where a point of 5 was very good and 1 very poor. This was assessed at 1 and 6 months of follow up.

In the Rose K group; all the patients had graded the comfort level to 5 which remained at the same level on further follow up at 6 months.

For those patients fitted with RGP; 63% graded the comfort level to 5 (very good) which remained at the same grade in 61 eyes which was statistically significant (p value 0.003) but dropped down by one point in 2 eyes over 6 months follow up.

14 % of the patients had graded as 4 at the first month out of which 9 continued to be at the same grade, 3 of them stepped one point higher and 2 dropped down by 1 point over 6 months follow up.

For the soft lens group; 4 eyes graded comfort as 4 which remained 4 over 6 months follow up and 2 eyes graded their comfort level to 3 which again remained constant over the follow up period.

As far as the Piggyback and the Kerasoft IC group was concerned, the comfort level was best (5) and it remained 5 over 6 months follow up

Thus, in our study we found that Rose K, PiggyBack and Kerasoft IC lenses are the most comfortable even in severe disease.

The tolerance level on a similar note which is closely associated with the wearing time of the lenses was graded 5 in the Kerasoft IC, PiggyBack and Rose K group.

No significant complications had been noted in the patients throughout our study. But a minority of them had complaints like dry eyes and stinging. This was statistically significant in the RGP (p=0.0000) and soft lens groups (p=0.001). There were no side effects noted in the Rose K, PiggyBack and Kerasoft IC group making these group of lenses more tolerable, comfortable and increasing their daily wear time

With the advent of newer designs of contact lenses for keratoconus our aim is to optimize the requirements of the patients in terms of visual, physiological and socioeconomic grounds. Thus, keratoconus patients are a challenge to ophthalmologists requiring continuous ongoing care. Contact lenses are a viable option in its effective management.

CONCLUSION

The mean age of keratoconus in our study was 25.3 years with maximum patients in the age group of 21-30 years. No significant sex predilection was seen in our study. Female: Male ratio was 1.1:1.96. 1% patients had bilateral keratoconus. Most common complaint of the patients at presentation was decreased vision (81%). Best contact lens corrected visual acuity was better than best spectacle corrected visual acuity and was statistically significant (p= 0.000). This was maintained at 1 and 6 months of follow up. Average of mean keratometry was 50.13. Majority of patients were in the moderate keratoconus group. 78% patients were fitted with RGP, 12% with Rose K, 6% Soft, 2% Piggy Back and the remaining 2% with Kerasoft IC lenses. Soft lens were preferred in mild keratoconus, RGP for moderate disease and Rose K, Piggy Back and Kerasoft IC lenses were the lenses of choice in severe keratoconus in our study. The average base curve of the lenses was 6.99. The fit, movement, fluorescein pattern was optimal in all cases. The mean daily wear among the lenses was 7.59 hours per day with Rose K lenses having maximum mean daily wear time of 8.33 hours. Comfort level with contact lenses was maximum in the Rose K, Piggy Back, Kerasoft IC and a majority of RGP lens users whereas it was less in the Soft lens group. Tolerance level of the patients for the contact lenses showed maximum tolerability in the Rose K, Piggy Back, Kerasoft IC and a majority of RGP users whereas it was less in the Soft lens group. No significant complications were noted with contact lens use but a minority of patients complained of dryness of eyes and this was seen mostly in the RGP and Soft lens users and was significant (p=0.0000) when compared to the other lens groups.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Das S, John B, Mohan S, Rajan M, Anantalaxmi, K. Contact lens fitting in keratoconus – a prospective study on visual and functional outcomes. *Int J Res Med Sci* 2015;3(8):1851-7.