

Clinical Study of Focus NIGHT & DAY[®] contact lenses

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ABSTRACT

Objectives

To investigate the visual and ocular implications of continuous wearing a silicon hydrogel contact lens for up to 3 weeks, in a dry semi-arid climate environment.

Methods

Clinical examination of eye conditions (visual acuity, Schirmer test, corneal thickness and endothelial cells counts) for 9 healthy voluntary students was carried out between September and November of 2004 in Riyadh's King Saud University clinical facilities, using Ciba Vision's Focus Night & Day[®] lotrafilcon lenses. Which is measured weekly for 3 weeks.

Results

Visual acuity testing revealed no significant changes after three weeks of continuous wear of the Focus lens. An average minimum angle of resolution (MAR) of 1.045 min arc was maintained throughout the 3 weeks. No significant drop had been recorded ($p > 0.05$). The Schirmer test for eye lubrication showed an overall decrease in the wetting of the strip from about 36 mm to around 27 mm. Corneal thickness for the 9 subjects prior to CL wearing was 0.529 ± 0.050 mm, slightly increased to 0.533 ± 0.044 mm at the end of the study. The mean cell area value was $359 \pm 67 \mu\text{m}^2$ at first visit, becoming only marginally higher at $361 \pm 71 \mu\text{m}^2$ after three weeks of contact lens wear.

Conclusion

The Focus NIGHT & DAY[®] lenses can be worn safely as extended-wear contact lenses for up to 3 weeks without ocular complications. Visual acuity, tear functions or corneal structure are not altered.

Key words: optometry, silicone hydrogel materials, resolution, ocular.



The landscape of contact lens practice has improved over the past decade, with the introduction of new contact lens brands such as, daily-disposable contact lenses^{1,2} and silicone hydrogel materials.³ Contact lenses are classified according to the way in which they are worn. Daily-wear lenses are only worn when the person is awake, generally for a maximum period of 18 hours a day. Extended wear lenses may be worn continuously even during sleep hours⁴. This study aims to investigate the effects of Focus Night & Day[®] lenses on the eye when applied for an extended wear time of 3 weeks in a climate that is considered hostile to contact lens wear.

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Materials and Methods

Twenty four eyes from 12 university students with ages ranging from 19 to 24 years, were randomly selected for this study. Testing was conducted in the College Of Applied Medical Sciences Optometry Clinics At King Saud University In Riyadh, between September and November of 2004. Three subjects did not comply with the research schedule and had to remove their lenses before testing was complete. All remaining subjects (18 eyes) had good general health and had no complaint of any ocular disease.

Tear break up time test (TBUT) procedure, which reveals the stability of the tear film on the cornea, was carried out only to exclude subjects with major tear abnormalities. Proper evaluation was done for tear function using Schirmer tear test. Measurements were

made before and after fitting the contact lenses. Also, corneal thickness and corneal endothelial layer images were taken using a non contact specular microscope (Topcon SP2000P; Abdulrahman Al-Gosaibi GTB, Riyadh, Saudi Arabia) at the same time intervals. Subjects were examined just before contact lenses insertion, every two days in week one and every three days in weeks two and three. During these visits the cornea was assessed by slit lamp biomicroscopy, tear production by Schirmer test and MAR visual acuity values were recorded with the contact lens on.

In the final visit corneal thickness and corneal endothelial cell area values were measured and compared to the data prior to CL wear. At each visit the subjects were questioned for comfort, personal judgement about the lens or any other complaints.

Results

To evaluate the relationship between the values before lens insertion and the data of 1-week or 3-week post insertion were compared using parametric paired t test. All statistical analyses were performed using SPSS (version 12) software. The data were summarized in Table 1.

Table 1. Summary of data giving mean and standard deviation

	0	1	2	3
Visual acuity means (min of arc)	1.04	1.07	1.02	1.05
1 SD (min of arc)	(0.096)	(0.115)	(0.0625)	(0.106)
Schirmer test means (mm)				
1 SD (mm)	35.67	29.50	30	26.80
	(7.61)	(9.76)	(8.79)	(11.18)
Corneal thickness means (mm)				
1 SD (mm)	0.529	-	-	0.533
	(0.05)			(0.04)
Endothelial cell area value (μm^2)	359	-	-	361
1 SD (μm^2)	(67)			(71)

0 = Just before lens insertion, 1 = After 1 week, 2 = After 2 weeks, 3 = After 3 weeks.

Visual acuity [VA] changes were monitored every other day and the means for each week were computed and shown in figure 1. As seen from the figure, the lens wear did not greatly affect the visual acuity. An average MAR of a little less than 1 min arc was maintained throughout the 3 weeks of lens

wear. The statistical analysis using Student t-test showed no significant difference ($p = 0.25$) in the VA results before and of 1-week following contact lens wear. Similarly, VA measurements 3-week post insertion were not significantly different from those of just before lens insertion ($p = 0.31$).

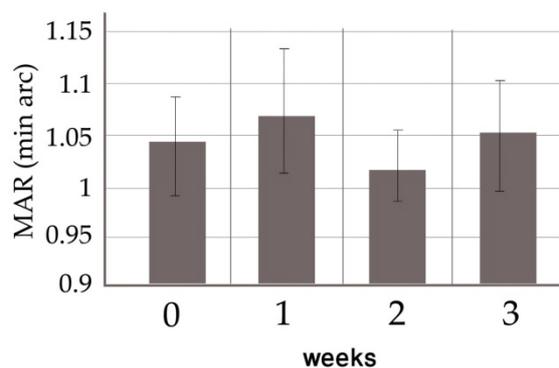


Figure 1.

The Schirmer test was used to measure the degree of dryness of the eye because it is a fast, economic and affordable. Average test findings were compared before lens insertion, 1-week, 2-week and 3-week after lens insertion (figure 2). There is an overall decrease in the wetting of the strip from about 36 mm to around 27 mm. Although the overall findings may indicate a satisfying tear quantity, the approximately reduction of 25% of tear loss between the first day and the 21st day of lens wear was not negligible. The dry climate of the region may have contributed to the drying effect of the lens. There were at least three eyes (17%) that exhibited dryness after 2 or 3 weeks of lens wear (less than 15 mm) that may relate to some kind of eye dryness.

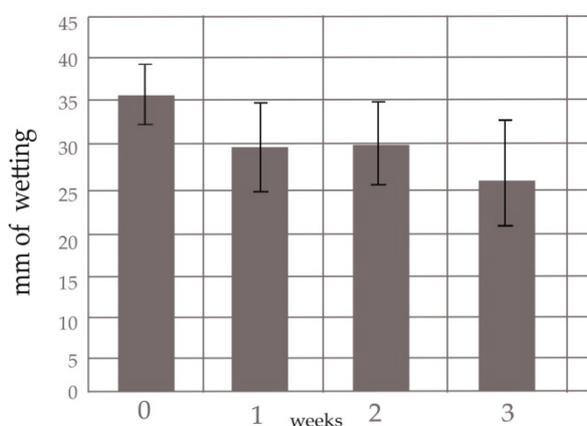


Figure 2.

Corneal thickness was assessed using a non contact specular microscope (Topcon SP2000P; Abdulrahman Al-Gosaibi GTB, Riyadh, Saudi Arabia). The average corneal thickness value for the patients prior to CL wearing was 0.529 ± 0.050 mm (mean \pm 1SD) compared to 0.533 ± 0.044 mm at the end of the study (figure 3). However, the difference in the mean corneal thickness was not statistically significant ($p > 0.05$). Six eyes (33%) had limited corneal edema, in contrast to eight eyes (44%) which showed a reduction in corneal thickness.

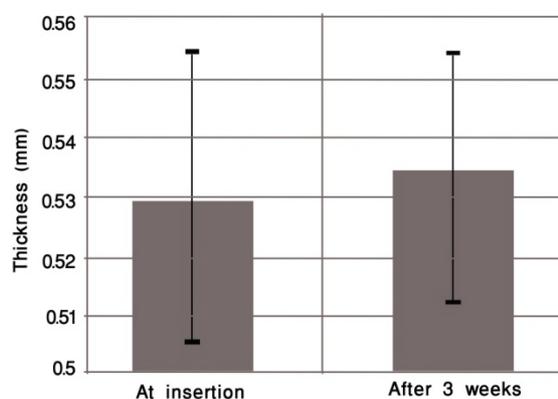


Figure 3.

The corneal endothelial cell count was also measured using the same Topcon specular microscope and the figure obtained was from the region close to the central corneal region. At the baseline, the average cell area value for any particular endothelial image ranged from 258 to 470 μm^2 , for a group average mean value of $359 \pm 67 \mu\text{m}^2$ (mean \pm 1SD). After three weeks of continuous contact lens wear, the range of average cell area was slightly larger (271 to 498 μm^2) and the group mean value was marginally higher at $361 \pm 71 \mu\text{m}^2$. Figure 4 illustrates the overall equal mean between the first and final visits, before and after completing a 3-week period of lens wear (error bars indicate 1SD). This was supported by a t-test p value of 0.49 which underlined the non significance of differences between average values of the two visits although variance values were quite high.

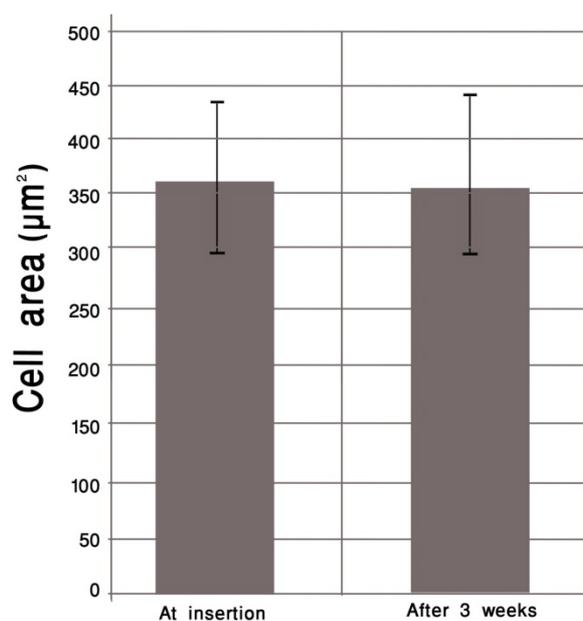


Figure 4.

Discussion

The mean VA of all subjects measured weekly shows that there was a small decrease in VA after wearing the Focus Night & Day® contact lenses over one month period. Although the changes are very small, however they cannot be neglected. The present results are supported by previous studies on similar lenses^{5,6}. A noticeable increase in corneal thickness was found in 44% of the eyes while for the rest, thickness was unchanged or even decreased in a few cases. This is not to say that Focus Night & Day® lenses are a perfect solution to decrease edema, but they increase the oxygen supply to the cornea. Lim and Vogt, laid emphasis on this, and found that apart from limited limbal vascularization and punctate epithelial corneal defects, which resolved when the contact lens was removed for one day, no serious complications were noted. However, despite the high oxygen permeability of the monthly Focus Night & Day® contact lenses, mean central and peripheral corneal thicknesses slightly increased over one month. The lenses performed better than any of the known soft conventional lenses for comfort⁷. The lenses performed better than any of the known soft

conventional lenses for comfort. Dry eye sensation was reported in three eyes of two subjects (17%) on waking, which subsides after a few minutes. This is in line with Sweeney,⁸ who reported that 25% of subjects had noticed symptoms of dryness, sometimes or often, while wearing silicone hydrogels for 30 days continuous wear. Eye dryness is often associated with foreign body sensation, and/or limbal hyperemia, a condition that subsides after a while with daily wear hydrogels. In the case of continuous wear, there is no indication that the same situation of full recovery would ever be reached⁹. Dry eye syndrome is a condition that is widely experienced by individuals living in a dry climate.

In a study by Du Toit et al,¹⁰ a reduction in hyperemia over time of the High DK lens wearing eyes was the same as in their normal non-lens fitted controls. Furthermore, a 36-month long study by Stern et al,¹¹ revealed that the performance of silicone hydrogels worn for 6- or 30-nights continuously was found to be similar. Although silicone hydrogels only constitute about 2% of current wearers, their positive effects on the eye compared with low DK hydrogel lenses should make them the most dominant lenses in the near future.¹²

Focus Night & Day® soft contact lenses have been approved by FDA for up to 30 nights of continuous wear¹³. The lenses may be left in the eyes while the wearer is both awake and asleep. The standard however has been for most high water content hydrogel contact lenses to be worn continuously for up to seven days¹⁴. The lenses should be replaced every month, as recommended by the eye care professional. Once lenses are removed, eyes should have a rest without lens wear for at least one night¹⁵.

The target group for contact lens market in Saudi Arabia is the population between 15 and 40 years. It is therefore a great ethical and medical responsibility to inform the young wearers of the risks and complications encountered while wearing a contact lens for an extended period.

Conclusion

People should never wear their contact lenses for longer periods than recommended by their eye care professional. The Focus Night & Day[®] lens have been found to cause fewer problems during extended wear, however, the study population here is small, so the findings may need to be supported by larger studies to reach firm conclusions and till then caution should be taken, since this may send the wrong signal to the wearer who could overlook the simple and constraining hygienic rules of maintaining and changing the lenses on a planned frequency and as instructed by their eye practitioner.

References

1. Solomon OD, Freeman MI, Boshnick EL, et al. A 3-year prospective study of the clinical performance of daily disposable contact lenses compared with frequent replacement and conventional daily wear contact lenses, *CLAOJ*, 1996; 22: 250-257.
2. Sankaridurg PR, Sweeney DF, Holden BA, et al. Comparison of adverse events with daily disposable hydrogels and spectacle wear results from a 12-month prospective clinical trial, *Ophthalmology* 2003; 110: 2327-2334.
3. Sweeney DF, Silicone hydrogels, Continuous wear contact lenses, 2nd Edition Oxford, Butterworth-Heinemann, 2004.
4. Franks WA, Adams GG, Dart JK, et al. Relative risks of different types of contact lenses. *BMJ* 1988; 297(6647):524-5.
5. Syam P, Hussain B, Hutchinson C., Mixed infection (Pseudomonas and coagulase negative staphylococci) microbial keratitis associated with extended wear silicone hydrogel contact lens, *Br J Ophthalmol* 2004; 88: 579
6. Sweeney D., Silicone hydrogels, clinical performance, *Contact lens monthly* 1999; 218: 25-27.
7. Lim N, Vogt U. Comparison of conventional and silicone hydrogel contact lenses for bullous keratoplasty. *Eye Contact Lens* 2006; 32: 250-253.
8. Yeniad B, Adam YS, Bilgin LKet al. Effect of 30-day continuous wear of silicone hydrogel contact lenses on corneal thickness, *Eye Contact Lens* 2004; 30: 6-9.
9. Schafer J, Mitchell GL, Chalmers RL et al. The stability of dryness symptoms after refitting with silicone hydrogel contact lenses over 3 years. *Eye Contact Lens* 2007;33(5):247-52.
10. Du Toit R, Simpson TL, Fonn D, et al. Recovery from hyperemia after overnight wear of low and high transmissibility hydrogel lenses, *Curr Eye Res* 2001; 22: 68-73.
11. Stern J, Wong R, Naduvilath TJ, et al. Comparison of the performance of 6- or 30-night extended wear schedules with silicone hydrogel lenses over 3 years, *Optom Vis Sci* 2004; 81: 398-406.
12. Fonn D, Sweeney D, Holden BA, et al. Corneal oxygen deficiency, *Eye Contact Lens* 2005; 31: 23-27.
13. Kanpolat A, Uçakhan OO. Therapeutic use of Focus Night & Day contact lenses. *Cornea*. 2003;22(8):726-34.
14. Maldonado-Codina C, Efron N. Impact of manufacturing technology and material composition on the clinical performance of hydrogel lenses. *Optom Vis Sci* 2004 Jun;81(6):442-54.
15. Nathan Efron 2002 .Contact Lenses A-Z. 2nd. Revised edition. Oxford by Elsevier Health Sciences

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