The efficacy of the Hiline® gas permeable contact lens for the management of Keratoconus

L'efficacité des lentilles cornéennes perméables au gaz Hiline® pour le traitement du kératocône

ABSTRACT

Purpose: To investigate the efficacy of the Hiline® gas permeable contact lens (Hiline® GP) for keratoconus in clinical practice in correcting visual acuity.

Methods: 218 eyes of 126 patients with keratoconus were fitted with Hiline® lenses. The fit of the lenses was evaluated. Visual acuity measurements were taken with spectacle lenses and with the Hiline lenses. The period of follow-up to observe for complications ranged from 3 to 27 months.

Results: In all eyes, the Hiline® GP provided acceptable vision. There was a statistically significant improvement in vision with the Hiline® GP compared with spectacle lenses ($t=10.90$, $p<0.0001$). Initial evaluation showed that 169 lenses (77.52%) demonstrated a three-point-touch relationship with the cornea 38 lenses (17.43%) had an apical clearance relationship with the cornea and 11 lenses (5.05%) had an apical bearing relationship. No severe complications were observed.

Conclusions: Using corneal topography as a guide, a high success rate was achieved with the Hiline® GP design. It is easy to reach the ideal fit and to improve the visual acuity. These indicate the usefulness of Hiline® lens in clinical practice.

RÉSUMÉ

But: Évaluer, pour le kératocône en pratique clinique, l'efficacité des lentilles cornéennes perméables au gaz Hiline® (Hiline® PG) à corriger l'acuité visuelle.

Méthodologie: On a utilisé des lentilles Hiline® pour 218 yeux de 126 patients souffrant de kératocône et on a évalué leur ajustement. On a mesuré l'acuité visuelle à

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Mots clés: lentilles cornéennes perméables au gaz, kératocône, conception de lentilles

l'aide de verres de lunettes et de lentilles Hiline. Un suivi allant de 3 à 27 mois a eu lieu pour observer les complications possibles.
Résultats: Les Hiline® PG ont permis une vision acceptable dans tous les yeux. On a noté une amélioration de la vision statistiquement significative avec les Hiline® PG comparativement aux verres de lunettes (t = 10,90, p<0,0001). La première évaluation a révélé que 169 lentilles (77,52 %) touchaient la cornée à trois endroits, 38 lentilles (17,43 %) présentaient une distance entre le verre et l'œil et 11 lentilles (5,05 %) s'appuyaient sur la cornée. On n'a noté aucune complication majeure.
Conclusions: En utilisant comme référence la topographie cornéenne, on constate un taux élevé de succès avec les lentilles Hiline® PG. Il est facile d'obtenir un ajustement optimal et d'améliorer l'acuité visuelle. Ces résultats démontrent l'utilité des lentilles Hiline® en pratique clinique.

INTRODUCTION

For patients with keratoconus, the first choice of corrective lens is a gas permeable (GP) contact lens in order to obtain good corrected visual acuity [1-5]. There are a lot of designs for keratoconus. The Rose K® Lens for Keratoconus is a proprietary design that has gained popularity since its introduction in the United States in 1995[5]. The best benefit of this lens is that it offers better visual acuity and increased comfort for keratoconus patients compared with a standard GP design[5].

Hiline® GP for keratoconus is another patented keratoconus design with a progressive aspheric peripheral curve design to fit Chinese eyes which is manufactured by Hiline Optical Company located in Taipei, Taiwan, China. To investigate the effect of Hiline® GP for keratoconus in clinical practice, this study represents a case series of 218 eyes of 126 patients with keratoconus who wore Hiline® GP in the period from September 2001 to December 2003.

METHODS

Subjects

There were 218 eyes of 126 patients that were definitively diagnosed with keratoconus using an Orbscan II corneal topographer in Zhong-Shang Ophthalmic Center. The criteria for diagnosing keratoconus are corneal cylinder of 2.00D or more combined with the flattest corneal curvature steeper than 7.60mm. There were 176 eyes of 100 males and 42 eyes of 26 females. The ratio of males to female was 3.85:1. The mean age was 25.1±7.9 years, ranging from 9 to 51 years old.

Hiline® GP Fitting and Follow-Up

All patients were examined with the slit-lamp biomicroscope, corneal topographer, cycloplegic retinoscopy, and non-contact tonometer to confirm eligibility for this study.

The fitting procedure followed the Hiline® fitting guide and was performed with a Hiline® diagnostic trial lens set while using the corneal topography result as a reference for fitting. The initial back optical zone radius (BOZR) of the trial lens was 0.2 mm steeper than the average readings taken with the corneal topographer. The optimum central lens-cornea relationship was "light feather-touch." After obtaining an optimal central lens-cornea relationship, the peripheral edge lift was evaluated. The appropriate edge lift, standard, increased or decreased edge lift was ordered according to the Hiline® fitting guide. When the optimal trial lens was obtained for each eye, an over-refraction was performed. The data were used to determine the contact lens power to be ordered. All Hiline® lenses were ordered from Hiline Optical Company, Taipei, Taiwan, China.

After the ordered lenses arrived in our clinic, subjects were evaluated with the ordered lens on their eye. The lens fitting was first assessed under the slit lamp with the use of sodium fluorescein and an acceptable fit would be a slight touch on the apex of the cone with no air bubbles underneath the lens along with moderate amount of edge lift. The best corrected vision was assessed via the standard Landolt C chart under standard room illumination. After the fitting, vision, and comfort were acceptable, the subject was scheduled for follow-up in 2 weeks and then once every month. If the ordered lens was not acceptable, it was reordered with the appropriate changes. Subjects were observed for at least 3 months after the initial dispensing of an acceptable lens. The best corrected visual acuity with the Hiline® lenses was recorded with the use of over-refraction and the subject completed the outcome questionnaires after 3 months of lens wear. The self-reported assessment of comfort was rated on a five-point scale where 5 = very comfortable and 1 = very irritating.

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Statistical Methods

All data were analyzed using SPSS 10.0 software where statistical significance was set at $P<0.05$.

RESULTS

The pre-wear examination

All cases had no contraindications for the wearing of GP lenses according to slit-lamp findings. Subjects were classified according to their average corneal keratometry readings: i.e., 21 eyes (9.63%) had mild keratoconus, below 45.00D, 73 eyes (33.49%) had moderate keratoconus, ranging from 45.00D to 52.00D, 116 eyes (53.21%) had advanced keratoconus, ranging from 52.00D to 62.00D, and 8 eyes (3.67%) had severe keratoconus, above 62.00D. Sub-epithelial scarring was present in 19 eyes. Refractive error was -8.26±4.79D, ranging from –2.00D to –24.00D and astigmatism was -3.85±2.07D, ranging from -1.00D to -14.00D with best corrected visual acuities.

Hiline® diagnostic lens fitting

In 169 eyes (77.52%), an ideal fit or acceptable three-point-touch relationship was achieved after an average of 3 trial fits. There was an apical clearance fitting relationship in 38 eyes (17.43%), and 11 eyes (5.05%) had an acceptable apical bearing relationship. In all 195 lenses (89.45%) were ordered with standard edge lift and 23 lenses (10.55%) required changes to edge lift or lens diameters to optimize lens fit. When apical clearance fitting was achieved, the Hiline® GP design was able to match the Chinese corneal surface more closely compared to other conventional GP lens designs in China.

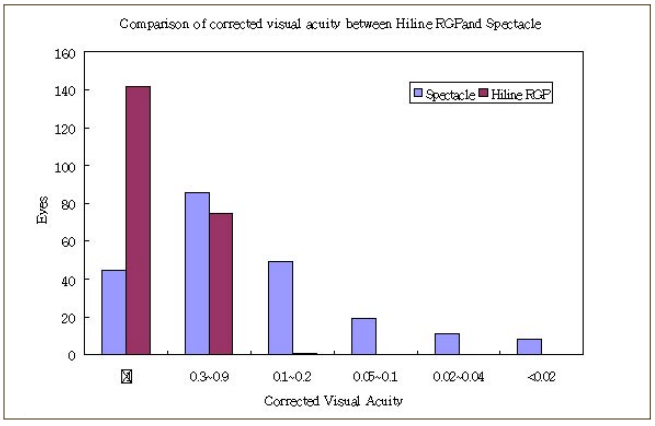

Figure 1. Comparison of corrected visual acuity between Hiline® Keratoconus RGP and Spectacles

Hiline® GP Fitting and Follow-Up

All patients were observed for 3 to 27 months. None of the 126 patients was lost to follow-up. A total of 9 lenses (4.13%) had to be re-ordered due to inadequate lens performance of tight lens fit due to progressive keratoconus. All other cases achieved better visual acuity with the Hiline® GP as compared to spectacles. Figure 1 shows the comparison of decimal visual acuity with Hiline® GP and with spectacles ($t=10.90$, $p<0.0001$). There is a linear correlation between the corrected visual acuity and the Hiline® GP lens back vertex power ($r=-0.2832$, $p=0.0003$), and the steepest corneal radius of curvature ($r=-0.4578$, $p=0.0005$) (Figure 2 and 3 respectively).

Most of the 126 patients initially complained of a foreign body sensation in the first 3 to 7 days after initial lens wear. However this completely disappeared after 1 to 3 weeks. Fluorescein staining of the cornea was observed in 18 eyes (8.26%), but all of the patients were able to continue wearing the lenses after this condition had been resolved by either temporarily discontinuing lens wear or treatment with necessary topical medication related to the appropriate ocular surface diseases. A total of 11 lenses (5.05%) were lost during the entire lens wear process and required replacement. Only one eye underwent penetrating keratoplasty (PKP) because of the instability of the lens. All other patients continued wearing the Hiline® lenses. Questionnaires were used to assess subjective vision-specific quality and contact lens comfort. 191 eyes (87.6%) of 218 eyes rated their lenses as "satisfied" or "very satisfied" after wearing their Hiline® GP lenses for 3 months.

DISCUSSION

Keratoconus is a disease where the cornea becomes thinner and protrudes forward conically, which leads to irregular astigmatism of the cornea, high myopia and visual function disorder. Today, keratoconus patients benefit most from GP lenses. Even patients who were once thought to be candidates for corneal surgery can be refitted successfully with GP lenses6-10.

For moderate or advanced keratoconus, wearing standard GP lens design often cannot achieve an ideal lens-cornea relationship. The Hiline® GP lens is a multi-curve design with spherical radii clearing the flat mid peripheral and peripheral cornea when fitted. Our data

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show that this design improves the stability of the lens. Most of the patients (125 patients) who were fitted with the Hiline® lens achieved an acceptable fit in this study and only 1 patient underwent PKP. This is a reasonable expectation for fitting GP for keratoconus in clinical practice. Based on our results, a clinician who fits Hiline® lenses should expect that an average of three diagnostic lenses will be needed per eye when determining the appropriate base curve.

Keratoconus patients wearing Hiline® GP lenses with the correct fitting relationship obtained satisfactory corrected vision, even in severe cases, where corneal scarring was already apparent. Based on our lens fitting observation, although best corrected vision was dependant on the location of the corneal scars, as long as the scars did not cover the line of sight, acceptable vision was always obtainable. This is probably one of the major reasons that keratoconus patients chose to keep wearing their Hiline GP lenses.

Of course, the safety of wearing these lenses is very important in addition to efficacy. There were no reported severe complications during the follow-up period which ranged from 3 to 27 months. Most patients can completely adapt to their GP lenses after 1 to 3 weeks, although some patients may feel some foreign body sensation initially. We found that 99.5% of all patients continued to wear their Hiline® GP lenses during the observation period. Only 18 eyes (8.26%), all in the advanced stage of keratoconus with an apical bearing and three-point-touch lens to cornea relationship, showed some fluorescein staining on the cornea. For these patients we recommended removal of their lenses to promote recovery of corneal epithelium and to prevent infection. Although traditionally fitting keratoconus with contact lenses, practitioners frequently need to deal with frequent lens replacement. During our study, only 11 eyes (5.05%) needed replacement Hiline® lenses due to lens loss. We believe the lower rate of lens loss in the Hiline® GP design was mainly due to improved mechanical stability and lens stability on the Chinese eye.

The results of this study showed that achieving the ideal fit was not difficult using Hiline® GP lens and that satisfactory corrected visual acuity was obtained in nearly all patients within 3 trial lens fitting session. This popular lens design in China showed increased lens stability as long as the lenses were correctly fitted initially. When combined with measurements taken by a corneal topographer, Orbscan II, fitting a complicated cornea such as Keratoconus becomes rather easy to manage without any severe clinical complications. After this large lens fitting trial, we strongly recommend using the corneal topographer's average readings to assist selecting the initial trial fitting lens as this can shorten the fitting examination time and thus lead to increased patient comfort and satisfaction.

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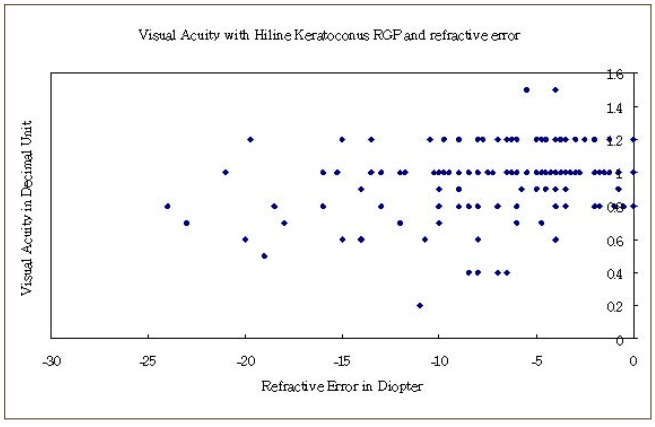

Figure 2. Corrected visual acuity as a function of back vertex power of the contact lens.

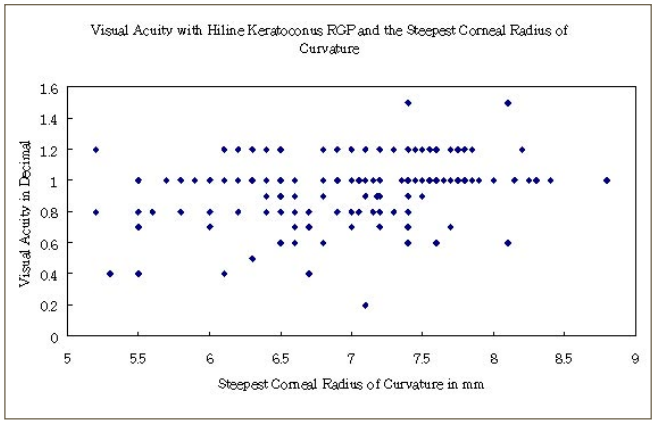

Figure 3. Corrected visual acuity as a function of steepest corneal radius of curvature.

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REFERENCES

1. Edrington TB, Gundel RE, Libassi DP et al. Variables affecting rigid contact lens comfort in the collaborative longitudinal evaluation of keratoconus (CLEK) study. Optom Vis Sci. 2004;81(3):182-8.
2. O'Donnell C, Maldonado-Codina C. Hyper-Dk Piggyback Contact Lens System for Keratoconus. Eye Contact Len. 2004;30(1):44-48.
3. Rabinowitz YS. Keratoconus. Surv Ophthalmol 1998; 42: 297 –s319.
4. Caroline PJ, Norman CW, Andre MP. The latest lens design for keratoconus. Contact Lens Spectrum 1997; 14: 36 –s41.
5. Betts AM, Mitchell GL, Zadnik K. Visual performance and comfort with the Rose K lens for keratoconus. Optom Vis Sci. 2002;79(8):493-501.
6. Leung KK. GP fitting philosophies for keratoconus. Clin Exp Optom. 1999;82(6):230-235.
7. Chung CW, Santim R, Heng WJ et al. Use of SoftPerm contact lenses when rigid gas permeable lenses fail. CLAO J. 2001;27(4):202-8.
8. Edrington TB, Szczotka LB, Barr JT, et al. Rigid contact lens fitting relationships in keratoconus. Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Group. Optom Vis Sci. 2000;77(4):177.
9. Edrington TB, Barr JT, Zadnik K, et al. Standardized rigid contact lens fitting protocol for keratoconus. Optom Vis Sci. 1996;73(6):369-75.
10. Gordon MO, Schechtman KB, Davis LJ, et al. Visual acuity repeatability in keratoconus: impact on sample size. Optom Vis Sci 1998; 75: 249 –s57.