

ORIGINAL ARTICLE

Comparison of Reverse-Geometry Lens Designs for Overnight Orthokeratology

N. TAHHAN, BOptom, R. DU TOIT, MPhil Optom, FAAO, E. PAPAS, PhD,
H. CHUNG, BMedSc, D. LA HOOD, BOptom, and B. HOLDEN, PhD, DSc, FAAO

The Cooperative Research Centre for Eye Research and Technology and the Cornea and Contact Lens Research Unit, School of Optometry and Vision Science, The University of New South Wales, Sydney, Australia

ABSTRACT: *Purpose.* The efficacy of overnight wear of four types of reverse-geometry lenses was compared. The length of time needed to achieve correction and any adverse events that occurred during the course of the study were recorded. *Methods.* In this prospective, randomized study, 60 subjects (18 to 35 years old) with refractive error between -1.00 to -4.00 D ($\text{cyl} \leq -1.50$) wore reverse-geometry lenses overnight only. All subjects were assigned a Rinehart Reeves lens in one eye, and subsets of 20 subjects were randomly assigned a Mountford BE, DreimLens, or Contex D Series 4 lens for the contralateral eye. Visits included baseline, dispensing, 1 day, 1 week, and 1 month. Biomicroscopy, unaided visual acuity, subjective refraction, best-corrected visual acuity at high and low contrast and high and low illumination, corneal topography, and subjective rating data were collected. *Results.* Forty-six subjects completed the study. At 1 month, there were no significant differences between lens types in their effect on unaided visual acuity, subjective sphere, subjective cylinder, best-corrected visual acuity at high and low contrast at high illumination and low contrast at low illumination, apical corneal radius, corneal eccentricity, and subjective ratings. Between 1 week and 1 month, there was a significant improvement in subjective ratings of quality of day and night vision ($p < 0.05$) but no significant change in the objective measures. No significant ocular adverse events were observed during the trial. *Conclusions.* The lens types tested were all similarly effective in the reduction of myopic refractive error. Subjective ratings continued to improve after objective measures stabilized at 1 week. Overnight lens wear proceeded for 1 month without significant adverse reactions. (Optom Vis Sci 2003;80:796-804)

Key Words: orthokeratology, overnight, reverse geometry, myopia, refraction

Surgical techniques such as photorefractive keratectomy and laser-assisted *in situ* keratomileusis are the most commonly known and practiced means of reshaping the cornea to reduce or eliminate refractive error. However, recent advances in contact lens design and materials have driven a resurgence of interest in orthokeratology (ortho-k) as a nonsurgical and reversible alternative for the correction of refractive error.

The ability of contact lens wear to cause a reduction in myopia became apparent in the early 1960s with the use of polymethyl methacrylate lenses.¹ However, it was Jessen² who made the first deliberate attempt to reshape the cornea with flat-fitting lenses. Subsequent attempts were all based on flat lens fitting philosophies, but took a less aggressive approach than Jessen.³⁻⁸ Results of these early trials were unpredictable and unstable, primarily due to poor lens centration. Although the procedure appeared to be safe, unwanted corneal cylinder was often induced,^{5, 6, 8} and only relatively small amounts of reduction in myopia were possible. In

addition, lenses had to be fitted progressively flatter, so many lens parameter changes were required, and it was many months before the desired amount of myopia reduction was achieved.

The practice of ortho-k remained largely dormant until reverse-geometry lenses were produced (Contex, Sherman Oaks, CA) in the late 1980s as a result of collaboration between Wlodyga and Stoyan.⁹⁻¹¹ These lenses allowed more predictable¹² results to be achieved in shorter periods of time.^{11, 13} Now, with the advent of more highly oxygen-permeable materials, lenses can be worn overnight and removed at waking so that wearers are relieved of the need for visual aids during the day. In recent years, only a small number of studies have been published that assess the effectiveness of temporary reduction in myopia and the response of the cornea to reverse-geometry lenses.¹²⁻¹⁶

There are now a number of reverse-geometry lens designs on the market with various fitting philosophies. Practitioners are faced with the difficult choice of deciding on a lens and/or fitting phi-

losophy that is not only effective but also simple to use and convenient. The method used for lens parameter calculations varies with the various designs, and practitioners have the option of fitting empirically, trial fitting, or using nomograms or computer-assisted programs. Mountford¹⁷ described a 6-hour, retrospective study of 23 subjects comparing a rule-of-thumb fitting method used by Contex and a calculation method that is based on tear layer hydraulics. A significantly higher reduction in myopia was found with lenses fitted using the calculation method (1.38 ± 0.58 D vs. 0.91 ± 0.36 D; analysis of variance: $p = 0.0024$, $F = 10.373$). However, changes beyond the 6 hours were not reported.

Reverse-geometry lens wear alters corneal shape, resulting in a relatively more spherical and flatter central circular zone of the cornea. This zone has been reported as measuring 5 to 6 mm in diameter¹⁵ and is referred to as the treatment zone.¹⁸ Depending on pupil size, limitations in treatment zone size may adversely affect vision at low-illumination and low-contrast levels. Although information on changes in unaided acuity during different contrast conditions with ortho-k exists,^{13, 14} the effect on best-corrected visual acuity (BCVA) during low illumination and low contrast remains in question. Because the topographical appearance of the treatment zone produced after reverse-geometry lens wear is similar in appearance to the ablation zone produced by photorefractive keratectomy and laser-assisted *in situ* keratomileusis, it would be interesting to compare BCVA with these two treatment modalities. In photorefractive keratectomy subjects, it has been reported that BCVA using high- and low-contrast visual acuity charts at both high and low illumination is significantly reduced during all test conditions (range, 1.5 to 13 letters).¹⁹ Similar test conditions were set up in this study to observe these results with ortho-k.

Literature on the ocular health aspects of ortho-k with reverse-geometry lens wear is limited. Although there have been reports of serious adverse events,^{20–22} the relative risks of such complications are still unknown. In addition, there is little information on the incidence of less serious complications such as corneal abrasions or lens binding events that are known to occur with ortho-k. Recent small-scale studies where reverse-geometry lenses were worn for up to 60 days^{13, 15} reported no significant complications with sample sizes of 10 and 6 subjects, respectively. Most recently, Rah et al.¹⁴ reported no serious adverse events in a pilot study of 60 subjects who wore reverse-geometry lenses overnight for 3 months. However, four minor adverse events associated with corneal staining were documented in this study.

This study is a randomized, prospective clinical trial comparing four current brands of reverse-geometry lenses. Our primary aim was to compare the efficacy of correction using the manufacturers' recommended fitting philosophies. Our secondary aims were to investigate, with both objective and subjective methods, the length of time needed to achieve correction, to measure corrected acuity during various conditions, and to record any complications or adverse ocular events that occurred during the course of the study.

METHODS

Subjects

Sixty subjects were enrolled for an overnight trial of reverse-geometry lens wear for 1 month. Inclusion criteria were age between 18 and 37 years, distance correction (best-vision sphere)

between -1.00 to -4.00 DS, refractive cylinder up to and including -1.50 DC (at any axis), anisometropia <0.75 D, no near addition, BCVA of 0.1 logarithm of the minimum angle of resolution (logMAR) (Snellen equivalent of 6/7.5) or better in each eye with no significant difference between the eyes (up to three letters), mean keratometry reading between 7.3 and 8.4 mm in both eyes, no previous rigid lens wear experience, no known active ocular pathology, and no systemic condition that would affect contact lens wear. All experimental protocols were reviewed and approved by the Committee for Experimental Research Involving Human Subjects at the University of New South Wales, Sydney, Australia and complied with the Declaration of Helsinki as revised in 1996. All subjects signed a record of informed consent before enrolling in the study.

Lenses and Lens Fitting

Four different brands of reverse-geometry lenses were used in the study: Rinehart Reeves (R&R; Danker Laboratories, Sarasota, FL), Contex D Series 4 Zone (Contex, Sherman Oaks, CA), DreimLens (DreimLens, Melbourne, Florida) and Mountford BE (BE; Ultravision Capricornia, QLD, Australia). The lenses were all manufactured from Boston XO material (BXO; nominal $Dk = 100 \times 10^{-11}$ [$\text{cm}^2 \cdot \text{mL O}_2$]/[$\text{s} \cdot \text{mL} \cdot \text{mm Hg}$]).

The investigators in this study had limited experience fitting reverse-geometry lenses. The lenses were fitted according to the manufacturers' recommended fitting procedures. The DreimLens and Contex lenses were ordered empirically. DreimLens International laboratories required provision of central and temporal keratometry readings as well as refraction. Contex laboratories required the provision of central keratometry measurements, refraction, and corneal eccentricity. The R&R and BE lenses were fitted using a trial set. The R&R lenses were ordered once an acceptable fit was observed with a trial lens, as per manufacturer's instructions. The BE trial lens parameters were calculated using a computer program provided with the trial set by the manufacturer of the lenses. Refraction, horizontal visible iris diameter, apical corneal curvature, and corneal eccentricity from corneal topography measurements were required for this calculation. An overnight trial was conducted with the trial lens, and a lens order was generated by the program after overnight changes in corneal topography and refraction were evaluated.

Lens diameters were initially 11 mm for all lens types with the exception of the R&R lenses. Initial trial lens selection for these lenses was 10 mm. However, alterations in lens diameter were made with all lens types when indicated, and 10.6 mm diameter was the second diameter used in all cases. The Contex lenses had three 0.2-mm fenestrations placed at 120° intervals in the area of the secondary curve. The other three lens types were not fenestrated. Subjects were instructed on the use of Boston Simplicity, Polymer Technology solution for cleaning and storage of the contact lenses.

Study Procedures

All subjects were required to attend a screening visit where their suitability for the study was assessed. All suitable candidates then returned for a baseline visit where the study was explained in detail and informed consent was signed. Soft lens wearers were asked to abstain from lens wear for 1 week before this visit. All subjects were

assigned an R&R lens for one eye, and subsets of 20 subjects were randomly assigned to a test lens group: BE, DreimLens, or Contex lens for the contralateral eye. Lenses were randomly assigned to the left or right eye, and lens fitting was conducted at baseline. Subjects were masked to the identity of the lenses. The investigators were also masked at the 1 week and 1 month visits (lenses were worn by the subjects at the other, earlier visits, and, therefore, practitioners may have been able to identify the lenses).

At lens delivery, all subjects were instructed on appropriate lens handling techniques with emphasis on the management of a bound lens. Subjects were given oral and written instructions to use lubricating eye drops and to massage the eye to free a bound lens before its removal to minimize epithelial trauma.

Subjects were assessed after one night of lens wear (within 2 hours of waking, lenses still on eye) and after 1 week and 1 month of lens wear (in the afternoon, 8 hours after waking, lenses no longer on eye). The subjects who were assigned the BE lens attended an additional morning visit between the baseline and dispensing visits for trial lens reassessment (as specified in the manufacturer's fitting guide¹⁸) after one night of trial lens wear (within 2 hours of waking, lens still inserted). Subjective refraction, visual acuity at 6 m (Bailey-Lovie logMAR²³ charts), slit lamp biomicroscopy (Carl Zeiss, Jena SL 120) and corneal topography (EyeSys Version 4.2) measurements were taken at all visits.

Unaided visual acuity measurements were taken using a high-contrast visual acuity chart with high room illumination (chart luminance, 146 ± 8 cd/m²), and BCVA measurements were taken using high- and low-contrast visual acuity charts at both high and low room illumination (chart luminance, 3 ± 1 cd/m²). Visual acuities were measured in logMAR units, where 0.02 logMAR equals one letter on the five letter per line chart. A raw score of 0.0 logMAR equals 6/6 Snellen acuity, and a negative value indicates better visual acuity than 6/6, whereas a positive value indicates visual acuity worse than 6/6. Pupils were measured using a ruler during the same lighting conditions used to measure visual acuity.

Slit lamp biomicroscopy was conducted at each visit including fluorescein staining of the cornea. Corneal staining was graded using a decimal scale from 0.0 to 4.0, where 0.0 corresponds to no staining and 4.0 corresponds to severe. When lenses were inserted, lens centration (the amount the lens center is decentered from the pupil center) was assessed together with the amount of movement using a graticule within the biomicroscope eyepiece (0.1-mm increments). A positive value for horizontal (x) lens centration denoted nasal displacement of the lens, and a negative value denoted temporal displacement. For vertical (y) lens centration, a positive value denoted superior displacement, and a negative value denoted inferior displacement.

Corneal topography measurements were obtained with the EyeSys 2000 topographic analysis system Version 4.2 (EyeSys Technologies, Houston, TX). At least three measurements were taken of each eye before lens wear and at each subsequent visit. Data retrieved included radius of curvature at the center of the map (the center of the entrance pupil), which we have termed the apical radius (in millimeters), corneal eccentricity, treatment zone diameter (in millimeters), and horizontal and vertical centration of the treatment zone (the amount that the geometric center of the treatment zone is from the center of the map in millimeters). The extremities of the treatment zone were found by locating the areas where zero curvature change occurred on the EyeSys axial difference maps. As with lens centration, the horizontal

(x) treatment zone centration was positive if nasal and negative if temporal, and the vertical (y) centration was positive if superior and negative if inferior.

At the 1-week and 1-month visits, subjects were asked to rate their quality of day and night vision and any ghosting or haloes they might have experienced on a scale of 1 to 100. Each eye was rated separately, and quality of vision was rated on a scale where 1 was extremely poor and 100 was extremely good. Haloes and ghosting were rated on a scale where 1 was none and 100 was excessive. Subjects were also asked to record any occurrences of lens binding.

Statistical Analysis

After confirming normality (Shapiro-Wilk), data were analyzed using analysis of variance with repeated measures. Time was treated as the repeated factor, with lens type as a between-subject factor. Where the multivariate output indicated that the overall test was significant at the 95% confidence level, Bonferroni procedures were applied *post hoc* to distinguish between factor levels. Relationships between variables were examined by correlation analysis (Pearson).

RESULTS

There were no statistically significant differences at baseline for subjective sphere, subjective cylinder, keratometry, corneal eccentricity, or pupil sizes between subjects' right and left eyes or between groups. Biometric data at baseline for the 60 subjects dispensed with lenses are given in Table 1.

Of the 60 subjects who were dispensed lenses, 46 completed the study. Ten subjects discontinued from the study for nonlens-related reasons (e.g., time constraints, relocation, disinterest, and personal reasons). Of the remaining subjects, two discontinued before returning for their 1-week visit. One subject complained of vision problems in the eye wearing the R&R lens, and the other subject showed excessive staining in the eye wearing the DreimLens. The remaining two subjects discontinued after the 1-week visit. One of these was due to vision complaints with both eyes (R&R and Contex), and the other had vision complaints in the eye wearing the BE lens. These subjects were reluctant to have lenses refitted.

Comparison of Lens Types

Five subjects were refitted in one eye during the trial. Refitting rates were 5% with DreimLens and Contex lenses and 3% with R&R lenses. No refits were needed with the BE lenses. One subject was fitted with BE lenses bilaterally when an acceptable fit was not possible with the R&R lens.

No statistically significant differences were found between lens types for lens centration measurements at dispensing. On average, all lens types were well centered (Table 2). The R&R lenses showed significantly more movement than the DreimLens ($p = 0.05$) and BE ($p = 0.04$) lenses (Table 2).

At all visits, there were no statistically significant differences between the lens types in their effect on unaided visual acuity (Fig. 1), subjective sphere (Fig. 2), subjective cylinder (Fig. 3), apical corneal

TABLE 1.Biometric data of subjects' right and left eyes at baseline (mean \pm SD)

| | Right (OD) | Left (OS) | Range (OD) | Range (OS) |
|--------------------------|------------------|------------------|----------------|----------------|
| Gender, Male:Female | | 30:30 | — | — |
| Age (yr) | | 27 \pm 4 | | 20–37 |
| Subjective sphere (DS) | -2.24 \pm 0.77 | -2.25 \pm 0.81 | -1.00 to -4.00 | -0.75 to -4.00 |
| Subjective cylinder (DC) | -0.37 \pm 0.34 | -0.36 \pm 0.31 | 0.00 to -1.25 | 0.00 to -1.25 |
| Keratometry (mm) | | | | |
| Flat | 7.86 \pm 0.23 | 7.86 \pm 0.23 | 7.55–8.36 | 7.49–8.35 |
| Steep | 7.73 \pm 0.23 | 7.73 \pm 0.22 | 7.39–8.26 | 7.37–8.28 |
| Corneal eccentricity | 0.49 \pm 0.08 | 0.50 \pm 0.08 | 0.31–0.66 | 0.33–0.70 |
| Pupil size (mm) | | | | |
| High illumination | 4 \pm 1 | 4 \pm 1 | 3–6 | 3–6 |
| Low illumination | 6 \pm 1 | 6 \pm 1 | 3–8 | 3–8 |

TABLE 2.Group mean for lens fitting characteristics (movement, horizontal [x] and vertical [y] centration for each lens type at lens delivery^a

| | Contex (Mean \pm SD) | DreimLens (Mean \pm SD) | BE (Mean \pm SD) | R&R (Mean \pm SD) |
|---------------------------|---------------------------|------------------------------|----------------------------|-----------------------------|
| Lens movement amount (mm) | 0.7 \pm 0.4 | 0.6 \pm 0.4 ^b | 0.5 \pm 0.4 ^a | 0.9 \pm 0.5 ^{ab} |
| Lens centration, x (mm) | 0.1 \pm 0.1 | 0.0 \pm 0.2 | 0.2 \pm 0.4 | 0.1 \pm 0.4 |
| Lens centration, y (mm) | -0.2 \pm 0.2 | -0.3 \pm 0.4 | 0.0 \pm 0.6 | -0.1 \pm 0.5 |

^a Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE lens in the contralateral eye.

^b $p = 0.04$; analysis of variance (indicates a significant difference between lens types).

^c $p = 0.05$; analysis of variance (indicates a significant difference between lens types).

radius (Table 3), horizontal centration of the treatment zone (Table 4), BCVA at high and low contrast at high illumination and low contrast at low illumination (Tables 5 and 6), subjective ratings of haloes, ghosting, and quality of night vision ($p > 0.05$) (Table 7).

There were no differences between the lens types in their effect on BCVA with the high-contrast chart at low illumination at 1 day or 1 week. However, at 1 month, the BCVA during these conditions was one line poorer in eyes allocated the Contex lens compared with those allocated the BE lens ($p = 0.03$) (Table 5).

There were no statistically significant differences between lens types in their effect on corneal eccentricity measurements at baseline, 1-day, and 1-month visits. However, at the 1-week visit, the eyes fitted with the R&R lenses had a significantly higher eccentricity value (less spherical corneas) than the eyes fitted with the Contex and BE lenses ($p = 0.02$ and $p < 0.01$, respectively) (Table 3).

At the 1-day visit, the diameter of the treatment zone in the eyes that wore the BE lens was significantly larger than the eyes that wore both the DreimLens and R&R lens ($p = 0.01$ and $p < 0.01$, respectively). It was also significantly larger than the eyes that wore both the Contex and R&R lens at 1 month ($p = 0.02$ and $p = 0.01$, respectively) (Table 4). No correlation between the treatment zone size and any of the subjective ratings or visual acuity measurements was evident.

At the 1-day visit, there were statistically significant differences in vertical centration of the treatment zone between the Contex and R&R lens-wearing eyes ($p < 0.01$). However, no significant differences in vertical centration of the treatment zone were apparent at subsequent visits (Table 4). The subjective ratings of quality

of day vision were significantly lower for the R&R eyes than the DreimLens and BE eyes at the 1-week visit ($p = 0.03$ and $p = 0.05$, respectively) (Table 7). However, at the 1-month visit, there were no significant differences in ratings of quality of day vision when comparing all lens types.

Temporal Effects

When changes that occurred between visits were assessed, we found that unaided visual acuity and subjective sphere were significantly better at all visits compared with baseline ($p < 0.01$). Results at 1 week and 1 month also differed significantly from 1 day ($p < 0.01$), but there was no significant difference between the 1-week and 1-month visits (Figs. 1 and 2).

A significant reduction in BCVA was found with the high-contrast chart at both high and low illumination at 1 day ($p = 0.03$ and $p < 0.01$, respectively). However, by 1 month, the measurements did not significantly differ from baseline (Table 5).

There was a significant reduction in BCVA with the low-contrast chart at both high and low illumination at 1 day (both $p < 0.01$). There were no significant differences between the results at 1 day and the subsequent 1-week and 1-month visits. Therefore, results at 1 week and 1 month were also significantly worse than baseline (both $p < 0.03$) (Table 6).

Statistically significant apical corneal flattening occurred between baseline and 1 day ($p < 0.01$). Further significant flattening was observed when comparing 1-day results with 1 month ($p < 0.01$)

(Table 3). Corneal eccentricity measurements were significantly more spherical at all visits compared with baseline (all $p < 0.01$) (Table 3). No statistically significant change in treatment zone diameter was found between visits with any of the lens types (Table 4).

There was no significant difference in ratings of haloes and ghosting when comparing ratings at 1 week and 1 month. At 1 month, there was a significant improvement in ratings for quality of day and night vision (both $p < 0.01$) (Table 7).

Ocular Health

Twenty-four of the 29 subjects who kept a record of lens-binding events experienced lens binding on at least one occasion during the trial. One subject experienced lens binding on only one occasion in both eyes after the first night of lens wear. A second subject experienced lens binding on only two occasions in the same eye after the fourth and fifth night of lens wear. The other subjects all experienced lens binding inconsistently on multiple occasions.

Forty-two percent of eyes had mild levels of central corneal staining (grade 1), and 2% had moderate amounts (grade 2) at 1 day. Three percent and 7% exhibited mild levels of central corneal staining at the 1-week and 1-month visits, respectively. One percent exhibited moderate levels of central corneal staining at 1 month. There was no clinically significant difference between the lens types in the level of staining induced.

Three corneal erosion events (grade 4 staining) were observed at the 1-day visit. Two of the corneal erosions were central (Contex and BE lenses), and the third (DreimLens) was superior nasal. The superior nasal lesion was associated with lens binding. The subjects did not complain of any specific discomfort, only more lens awareness compared with the contralateral eye. These subjects were all followed up the same afternoon, and there was complete corneal recovery in all cases. The two cases with the central erosions continued lens wear successfully, but the third was discontinued after a second night of lens wear when excessive staining was again observed.

One very faint asymptomatic infiltrate was observed at the 1-day visit (BE). The infiltrate was focal, 0.3 mm in diameter, and 2.5 mm from the limbus at the 7-o'clock position. There was a very slight increase in bulbar conjunctival redness, but no other remarkable findings. The subject was permitted to continue lens wear with the provision that they return to the clinic immediately if any symptoms became apparent. The subject was reviewed at the 1-week visit, and the infiltrate was no longer present.

One subject had developed localized contact lens papillary conjunctivitis in one eye (R&R) at their 1-month visit. In this case, four enlarged papillae were observed on the temporal aspect of the superior tarsal conjunctiva close to the lid margin. The papillae ranged in size from 0.5 to 0.9 mm. This subject complained of discharge in the affected eye for a week before his visit. The subject was asked to discontinue lens wear until the condition resolved. The subject was monitored, and the condition resolved after 5 weeks.

One subject experienced a superficial injury (R&R) of the inferior conjunctiva after waking one morning during the third week of lens wear. The subject found that the lens had dislocated to the inferior cul de sac. The subject discontinued lens wear for one evening and resumed lens wear the following day with no further problems.

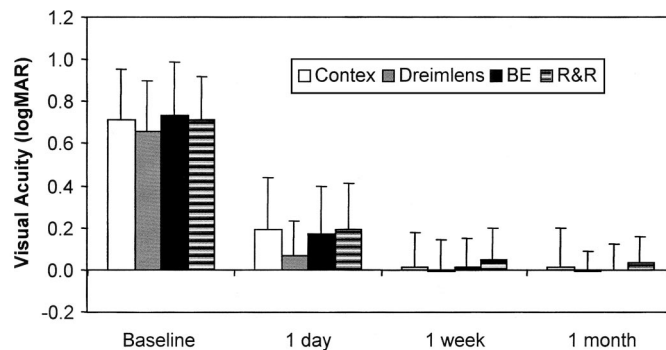


FIGURE 1.

Group mean and SD for unaided visual acuity (logarithm of the minimum angle of resolution [logMAR] units) at baseline and after 1 day, 1 week, and 1 month of overnight orthokeratology. Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE (BE) lens in the contralateral eye.

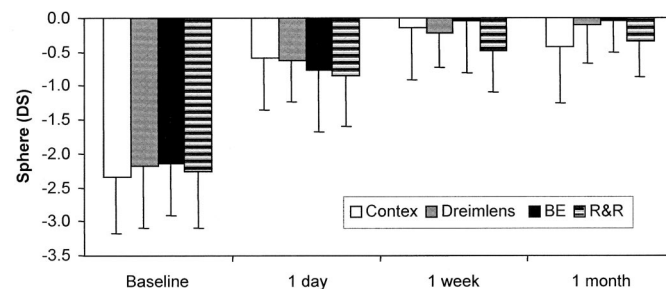


FIGURE 2.

Group mean and SD for subjective spherical refraction (DS) at baseline and after 1 day, 1 week, and 1 month of overnight orthokeratology. Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE (BE) lens in the contralateral eye.

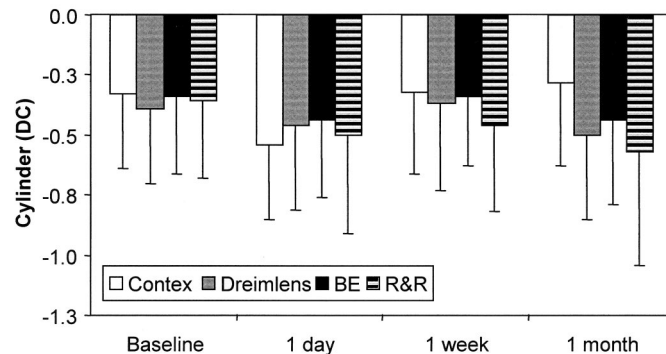


FIGURE 3.

Group mean and SD for subjective cylindrical refraction (DC) at baseline and after 1 day, 1 week, and 1 month of overnight orthokeratology. Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE (BE) lens in the contralateral eye.

DISCUSSION

The results of this study demonstrate that all four reverse-geometry lens types were similarly effective at producing reduction in myopia, despite the difference in fitting philosophies. The success rate with the initial lens was very high with all lens types, considering that the investigators fitting the lenses had little previous

TABLE 3.

Group mean apical radius (mm) and corneal eccentricity at baseline and after 1 day, 1 week, and 1 month of overnight orthokeratology^a

| | Contex (Mean ± SD) | DreimLens (Mean ± SD) | BE (Mean ± SD) | R&R (Mean ± SD) |
|-----------------------|--------------------------|--------------------------|--------------------------|---------------------------|
| Baseline | N = 20 | N = 20 | N = 21 | N = 59 |
| Apical corneal radius | 7.74 ± 0.22 | 7.78 ± 0.27 | 7.81 ± 0.23 | 7.77 ± 0.23 |
| Corneal eccentricity | 0.51 ± 0.07 | 0.47 ± 0.10 | 0.49 ± 0.07 | 0.50 ± 0.08 |
| 1 Day | N = 20 | N = 19 | N = 21 | N = 58 |
| Apical corneal radius | 8.06 ± 0.26 | 8.08 ± 0.30 | 8.08 ± 0.21 | 8.02 ± 0.31 |
| Corneal eccentricity | 0.10 ± 0.13 | 0.17 ± 0.17 | 0.20 ± 0.17 | 0.22 ± 0.17 |
| 1 Week | N = 19 | N = 15 | N = 18 | N = 50 |
| Apical corneal radius | 8.09 ± 0.29 | 8.13 ± 0.36 | 8.25 ± 0.21 | 8.02 ± 0.50 |
| Corneal eccentricity | 0.07 ± 0.11 ^b | 0.13 ± 0.17 | 0.04 ± 0.09 ^c | 0.20 ± 0.18 ^{bc} |
| 1 Month | N = 18 | N = 13 | N = 16 | N = 45 |
| Apical corneal radius | 8.18 ± 0.39 | 8.21 ± 0.34 | 8.31 ± 0.26 | 8.19 ± 0.37 |
| Corneal eccentricity | 0.07 ± 0.15 | 0.12 ± 0.19 | 0.06 ± 0.13 | 0.16 ± 0.18 |

^a Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE lens in the contralateral eye.

^b $p = 0.02$; analysis of variance (indicates a significant difference between lens types).

^c $p < 0.01$; analysis of variance (indicates a significant difference between lens types).

TABLE 4.

Group means for treatment zone characteristics (diameter and horizontal [x] and vertical [y] centration in millimeters) after 1 day, 1 week, and 1 month of overnight orthokeratology^a

| | Contex (Mean ± SD) | DreimLens (Mean ± SD) | BE (Mean ± SD) | R&R (Mean ± SD) |
|--------------|-------------------------|--------------------------|-------------------------|------------------------|
| 1 Day | N = 20 | N = 19 | N = 21 | N = 58 |
| Diameter | 5.0 ± 0.5 | 4.8 ± 0.8 ^b | 5.5 ± 0.6 ^{bc} | 4.9 ± 0.7 ^c |
| x Centration | -0.3 ± 0.3 | -0.4 ± 0.5 | -0.2 ± 0.4 | -0.3 ± 0.5 |
| y Centration | -0.2 ± 0.4 ^c | -0.1 ± 0.4 | 0.1 ± 0.5 | 0.2 ± 0.6 ^c |
| 1 Week | N = 19 | N = 15 | N = 16 | N = 50 |
| Diameter | 4.9 ± 0.5 | 4.9 ± 0.6 | 5.3 ± 1.1 | 5.1 ± 1.0 |
| x Centration | -0.5 ± 0.5 | -0.4 ± 0.4 | -0.3 ± 0.4 | -0.3 ± 0.7 |
| y Centration | -0.3 ± 0.4 | -0.2 ± 0.3 | -0.1 ± 0.4 | -0.2 ± 0.6 |
| 1 Month | N = 18 | N = 13 | N = 16 | N = 45 |
| Diameter | 4.9 ± 0.6 ^d | 5.1 ± 0.7 | 5.7 ± 0.7 ^{bd} | 5.0 ± 0.9 ^b |
| x Centration | -0.4 ± 0.5 | -0.4 ± 0.5 | -0.3 ± 0.4 | -0.3 ± 0.6 |
| y Centration | -0.2 ± 0.4 | -0.4 ± 0.4 | -0.2 ± 0.4 | -0.1 ± 0.6 |

^a Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE lens in the contralateral eye.

^b $p = 0.01$; analysis of variance (indicates a significant difference between lens types).

^c $p < 0.01$; analysis of variance (indicates a significant difference between lens types).

^d $p = 0.02$; analysis of variance (indicates a significant difference between lens types).

experience with fitting ortho-k lenses. An effective reduction in myopia despite limited practitioner experience has also been reported by Rah et al.¹⁴ Subjects in this study were fitted with the Fargo lens from GP Specialists and the CRT lens from Paragon Vision Sciences. A possible reason that the ortho-k procedure is not widely practiced may be because of the perceived difficulty in fitting and the perception that it is a specialist procedure.²⁴ In addition, in our study, empirically ordered lenses were just as effective as the lenses fitted using a trial set. In combination, these results may encourage more practitioners to incorporate ortho-k into their practice as an alternative mode of vision correction.

The discontinuation rate at 1 month in this study was similar to

that reported in the Rah et al.¹⁴ study. Most discontinuations were for reasons unrelated to lens wear. The discontinuation rate due to lens-related complaints was similar between lens types (5% with Contex, DreimLens, and BE, and 2% with R&R). As suggested by Rah et al.,¹⁴ the lack of practitioner knowledge and experience may have contributed to some of the discontinuations due to inappropriate subject selection and lack of emphasis on assessing and setting subject expectations.

After lens dispensing, the rate of lens refits was low with all lens types, and refitting was not necessary with the BE lens. Had an overnight trial not first been conducted with the BE lenses, the refit rates would have been equal for all lens types (one of the BE overnight trials

TABLE 5.

Group mean best-corrected visual acuity at high contrast (logarithm of the minimum angle of resolution units) at baseline and after 1 day, 1 week, and 1 month of overnight orthokeratology^a

| | Contex (Mean ± SD) | DreimLens (Mean ± SD) | BE (Mean ± SD) | R&R (Mean ± SD) |
|-------------------|--------------------------|--------------------------|--------------------------|--------------------|
| Baseline | N = 20 | N = 20 | N = 21 | N = 59 |
| High illumination | -0.07 ± 0.06 | -0.08 ± 0.04 | -0.07 ± 0.05 | -0.07 ± 0.06 |
| Low illumination | 0.09 ± 0.05 | 0.08 ± 0.06 | 0.07 ± 0.07 | 0.09 ± 0.06 |
| 1 Day | N = 20 | N = 19 | N = 21 | N = 58 |
| High illumination | -0.02 ± 0.13 | -0.06 ± 0.07 | -0.04 ± 0.08 | -0.06 ± 0.07 |
| Low illumination | 0.19 ± 0.16 | 0.21 ± 0.12 | 0.20 ± 0.14 | 0.16 ± 0.10 |
| 1 Week | N = 19 | N = 15 | N = 18 | N = 50 |
| High illumination | -0.08 ± 0.06 | -0.08 ± 0.06 | -0.10 ± 0.07 | -0.06 ± 0.07 |
| Low illumination | 0.12 ± 0.08 | 0.11 ± 0.08 | 0.08 ± 0.05 | 0.11 ± 0.11 |
| 1 Month | N = 18 | N = 13 | N = 16 | N = 45 |
| High illumination | -0.07 ± 0.07 | -0.09 ± 0.05 | -0.10 ± 0.08 | -0.07 ± 0.07 |
| Low illumination | 0.15 ± 0.12 ^b | 0.07 ± 0.05 | 0.05 ± 0.10 ^b | 0.12 ± 0.09 |

^a Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE lens in the contralateral eye.

^b $p = 0.03$; analysis of variance (indicates a significant difference between lens types).

TABLE 6.

Group mean best corrected visual acuity at low contrast (logMAR units) at baseline and after 1 day, 1 week, and 1 month of overnight orthokeratology^a

| | Contex (Mean ± SD) | DreimLens (Mean ± SD) | BE (Mean ± SD) | R&R (Mean ± SD) |
|-------------------|-----------------------|--------------------------|-------------------|--------------------|
| Baseline | N = 20 | N = 20 | N = 21 | N = 59 |
| High illumination | 0.10 ± 0.08 | 0.09 ± 0.08 | 0.10 ± 0.08 | 0.10 ± 0.07 |
| Low illumination | 0.51 ± 0.08 | 0.51 ± 0.09 | 0.48 ± 0.07 | 0.50 ± 0.08 |
| 1 Day | N = 20 | N = 19 | N = 21 | N = 58 |
| High illumination | 0.19 ± 0.16 | 0.17 ± 0.11 | 0.21 ± 0.14 | 0.17 ± 0.11 |
| Low illumination | 0.60 ± 0.23 | 0.66 ± 0.12 | 0.59 ± 0.25 | 0.62 ± 0.17 |
| 1 Week | N = 19 | N = 15 | N = 18 | N = 50 |
| High illumination | 0.17 ± 0.11 | 0.16 ± 0.10 | 0.14 ± 0.15 | 0.17 ± 0.12 |
| Low illumination | 0.62 ± 0.23 | 0.63 ± 0.11 | 0.56 ± 0.08 | 0.57 ± 0.23 |
| 1 Month | N = 18 | N = 13 | N = 16 | N = 45 |
| High illumination | 0.16 ± 0.10 | 0.13 ± 0.06 | 0.09 ± 0.11 | 0.16 ± 0.11 |
| Low illumination | 0.56 ± 0.22 | 0.59 ± 0.09 | 0.55 ± 0.07 | 0.62 ± 0.14 |

^a Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE lens in the contralateral eye.

had to be repeated with a different trial lens). This suggests that there may be more merit in monitoring refractive and corneal topography changes after an overnight trial as a means of assessing lens performance rather than by observing the lens fit alone.

At the 1-month visit, there was, on average, a reduction of 2 D in myopia and seven lines of improvement in unaided visual acuity when compared to baseline measurements. On average, uncorrected visual acuity was 0.02 ± 0.14 logMAR units (Snellen equivalent of $6/6^{-1}$) at 1 month. There were no significant differences in the effect of the four lens types on the reduction of myopia and unaided visual acuity. The average change in myopia found in this study is similar to what has been reported in recent studies^{12–15} and reflects the average refractive error of the study subjects before commencing therapy.

There was no significant change in subjective cylinder measure-

ments between visits. Therefore, practitioners hoping to correct or reduce significant refractive cylinder with these current ortho-k designs may be setting unreasonable expectations. However, one could regard this consistency of refractive cylinder measures with baseline as a positive finding because refractive cylinder will often increase if lens centration is poor due to poor lens fitting. Poor lens centration and subsequent corneal warpage was one of the limitations of early ortho-k^{5, 6, 8} before the introduction of the reverse-geometry lens design. The consistency of refractive cylinder measurements over time and good lens centration observed in this study may be attributed to the steeper secondary and tertiary curves that are incorporated in these newer ortho-k lens designs.

Although high-contrast BCVA at both high and low illumination was reduced at 1 day, it improved at subsequent visits so that it was not significantly different from baseline at 1 month. This

TABLE 7.

Group mean subjective ratings of haloes, ghosting, quality of day vision and quality of night vision after 1 week and 1 month of overnight orthokeratology^a

| | Contex (Mean ± SD) | DreimLens (Mean ± SD) | BE (Mean ± SD) | R&R (Mean ± SD) |
|-------------------------|-----------------------|--------------------------|---------------------|-----------------------|
| Haloes | | | | |
| 1 Week | 29 ± 33 | 23 ± 29 | 22 ± 25 | 30 ± 29 |
| 1 Month | 49 ± 37 | 27 ± 30 | 26 ± 24 | 40 ± 33 |
| Ghosting | | | | |
| 1 Week | 35 ± 40 | 22 ± 31 | 21 ± 23 | 36 ± 35 |
| 1 Month | 39 ± 32 | 12 ± 18 | 27 ± 23 | 34 ± 30 |
| Quality of day vision | | | | |
| 1 Week | 76 ± 16 | 84 ± 20 ^b | 83 ± 8 ^c | 72 ± 12 ^{bc} |
| 1 Month | 86 ± 14 | 90 ± 6 | 88 ± 11 | 81 ± 14 |
| Quality of night vision | | | | |
| 1 Week | 61 ± 21 | 64 ± 26 | 70 ± 25 | 55 ± 18 |
| 1 Month | 71 ± 21 | 78 ± 13 | 78 ± 15 | 71 ± 18 |

^a Subjects wore the Rinehart Reeves (R&R) lens in one random eye and either a Contex D Series 4 Zone, DreimLens, or Mountford BE lens in the contralateral eye. Haloes and ghosting were rating on a scale of 1–100, where 1 = none and 100 = excessive. Vision was rated on a scale of 1–100, where 1 = extremely poor and 100 = extremely good.

^b $p = 0.03$; analysis of variance (indicates a significant difference between lens types).

^c $p = 0.05$; analysis of variance (indicates a significant difference between lens types).

cannot be explained by a difference in treatment zone size because this remained constant after 1 day. Perhaps the reduction in high-contrast acuity at one day may be due to subtle corneal surface irregularities within the treatment zone that our method of analysis or instrumentation was not sensitive enough to locate. However, there was a significant reduction in low-contrast BCVA at both high and low illumination at 1 day, which remained significantly worse at 1 month compared with baseline. On average, at low contrast, corrected acuity was two letters worse with high illumination and one line (five letters) worse with low illumination at 1 month. These reductions may be attributable to the limitation in the overall size of the treatment zone.

Gauthier et al.¹⁹ measured the corrected visual acuity of patients after undergoing photorefractive keratectomy using similar test conditions as those used in this study. A reduction in corrected acuity was found with all test conditions. The reduction in high-contrast acuity was found to be up three letters (depending on the procedure at both high and low illumination). This was associated with central corneal topography irregularities, subepithelial haze, and higher myopic refractive errors. For low-contrast acuity, it was reported to be three letters with high illumination and up to 2.5 lines (13 letters) with low illumination. These reductions were also associated with irregularities in central corneal topography, subepithelial haze, higher myopic refractive errors, small optic zone sizes, and steep ablation edge profiles. Although small reductions in corrected acuity did also occur with ortho-k, the advantage of ortho-k over refractive surgery is that the procedure is reversible with discontinuation of lens wear.^{7, 16, 25, 26}

At 1 month, the diameter of the treatment zone was larger in eyes that wore the BE lenses compared with the eyes that wore the Contex and R&R lenses. The differences in the way the lens parameters are calculated and subsequent design differences might account for the differences in the size of the treatment zone. The BE lens calculation method is based on a theory of tear layer hydraulics. The belief is that

positive and negative forces are present in the tears and are dependent on the tear thickness profile beneath the lens. Therefore, positive pressure would be present beneath the central back optic zone radius where there is minimal clearance, and negative suction pressures would be present beneath the reverse curve where the tear profile is thickest.¹⁸ It is thought that these forces, rather than the physical pressure of the lens itself, is responsible for the corneal reshaping. Each of the curves on a BE reverse-geometry lens is calculated after calculations of the tear layer hydraulics are taken into account. The three other design calculations are made with more conventional rule-of-thumb approaches where the back optic zone radius is chosen relative to central or temporal keratometry measures. It should be noted, however, that we failed to find a relationship between the size of the treatment zone and subjective ratings and visual acuity measures.

The results from this study are in concordance with previous studies^{13, 15} that the largest changes in refraction and visual acuity occur after the first night of ortho-k lens wear. In this study, the refractive and visual acuity changes that occurred did not significantly change after 1 week of lens wear. Nichols et al.¹³ reported that although most of the change in vision and refraction occurred in the first 7 nights, improvement continued beyond 7 nights and leveled off by day 30. However, the differences were not statistically significant between visits on days 7 and 14 or between visits on days 14 and 30. Changes in epithelial thickness, however, do appear to occur more gradually over a 28-day period. Swarbrick et al.¹⁵ found significant changes between days 7 and 14 and again between days 14 and 28 both centrally and peripherally.

Although there were no significant changes between 1 week and 1 month for any of the objective variables in this study, there were improvements in the subjective ratings of quality of day and night vision. The improved ratings of vision could be related to changes in aspects of vision not measured in this study such as changes in the corneal epithelium. Alternatively, there may be other factors that contribute to adaptation that are not obvious or measurable

with objective measures. For instance, many patients who begin wearing monovision contact lenses report that it requires days or weeks to adjust.²⁷ It has been found that improved tolerance to anisometropia is not necessarily related to measurable changes in aspects of vision but may reflect a psychological adjustment.²⁸ Psychological adaptation may also play a role when adjusting to the new visual circumstances with ortho-k.

Six eyes of the 120 that commenced lens wear (5%) had minor adverse ocular findings during the trial. The central corneal epithelium appeared to be temporarily disrupted in almost half of the eyes immediately after lens removal after the first night of lens wear (within 2 hours of waking). Considering that the corneal epithelium heals very quickly and the subjects were generally asymptomatic, it is possible that the incidence of erosions or corneal staining was higher than that observed at the afternoon visits later in the trial. Rah et al.,¹⁴ who ran a similar trial to ours, reported that 82.3% of subjects had corneal staining in their right eye and 79.6% of subjects had staining in their left eye at their morning visit at 1 month. This incidence was lower in the afternoon on the same day (53.4% for both eyes).

Although the incidence of central epithelial erosions detected in this study was low and the level of staining only low grade, the central location of the events may be of concern. A recent article²⁰ reports two cases of permanent loss of vision caused by scarring of the central cornea in patients who developed microbial keratitis while wearing lenses for ortho-k. The design of the lenses, lens material, and patient care regimen were not reported.

The results of this study confirm that reverse-geometry lenses for overnight ortho-k are a rapid and effective means of temporarily improving unaided visual acuity and reducing myopic refractive error in young adults. The four lens types tested were similar in effectiveness despite differences in the fitting methods used. Although most refractive change occurs in the first week of lens wear, subjective ratings of vision continue to improve after this time. All adverse events observed during this short-term trial were minor and healed without sequelae. Due to recent reports of more serious adverse events,^{20–22} longer-term and larger-scale studies need to be conducted before adverse risk rates can be established.

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Nina Tahhan

*Cooperative Research Centre for Eye Research and Technology
The University of New South Wales
Sydney, NSW 2052
Australia
e-mail: n.tahhan@visioncrc.org*