Toric Double Tear Reservoir Contact Lens in Orthokeratology for Astigmatism

Jaume Pauné, M.Sc., Genís Cardona, Ph.D., and Lluïsa Quevedo, Ph.D.

Objectives: This study aimed at assessing the performance of a double tear reservoir toric reverse geometry contact lens design for the correction of myopic and astigmatic refractive errors through overnight orthokeratology (Ortho-K).

Methods: Consecutive records of a total of 32 patients with refractive astigmatism greater than 1.25 D at any orientation, best corrected distance monocular visual acuity ≥1.00 (decimal) before Ortho-K treatment and stable ocular refraction for at least 1 month at the time of the last visit were retrospectively examined. Preorthokeratology and postorthokeratology information included noncycloplegic subjective refraction, best-corrected visual acuity, pupil diameter, corneal topography, and ocular aberrometry. The associations between the achieved myopic and cylinder reduction and the modifications in various corneal topographic parameters were investigated. Right eyes were chosen for data analysis.

Results: A statistically significant difference ($Z=-4.805$; $P<0.001$) was encountered between initial refractive sphere and final residual refractive sphere, with a dioptric change of −2.05±1.46 D (median: −1.88; −5.25 to 0.50), accounting for a change of 106% of the initial myopia. Similarly, differences between pretreatment and posttreatment refractive cylinders were significant ($Z=-4.945$; $P<0.001$), with a dioptric change of −1.80 ±1.06 D (median: −1.50; −5.25 to −0.50), that is, a change of 85% of the initial astigmatism. Changes in topographic Best Fit Sphere and Best Fit Toric presented a strong positive correlation with the accomplished myopic and astigmatic refractive changes, respectively.

Conclusions: The results of this investigation suggest that the correction of astigmatic errors with toric orthokeratology lens designs may have a promising future.

Key Words: Corneal astigmatism—Corneal reshaping—Double tear reservoir—Orthokeratology—Special geometry contact lenses—Toric reverse geometry.

(*Eye & Contact Lens* 2012;38: 245–251)

Orthokeratology (Ortho-K), or corneal refractive therapy, is a clinical procedure aiming at the modification of the corneal contour with the programmed application of specially designed rigid contact lenses.[1,2] The final goal of Ortho-K is a change in corneal power resulting in a change in overall ocular refraction leading to clear unaided vision.

Traditional Ortho-K, until 1992, was associated with a reduction in myopia of up to 2.00 D.[3,4] However, with the advent of reverse geometry spherical lenses a refractive change of 4.00 D of myopia and a maximum of 1.50 D with-the-rule astigmatism has been considered achievable.[5] Correction of hyperopia through Ortho-K has also been attempted and met with a moderate degree of success.[6–8]

Because Ortho-K involves a change in corneal shape, several initial corneal parameters have been investigated as possible predictors to allow practitioners to estimate the outcome of the procedure. However, no definite association has been found between the amount of corrected refractive error and baseline parameters such as corneal eccentricity[9] and corneal biomechanics,[10] among other factors, resulting in the difficulty of predicting refractive changes through initial corneal parameters alone. However, a strong correlation has been found between modifications in apical corneal power (ACP) resulting from central corneal flattening and changes in refractive error, as measured by subjective refraction.[9] In addition, pupil diameter has been defined as a critical factor in determining the success of Ortho-K treatment. Larger pupils[11–13] and smaller treatment zones[14] may result in poor subjective vision secondary to increased high-order aberrations.

The correction of astigmatism with spherical lens designs has received moderate attention in the literature. Early reports[9,15] noted a reduction of approximately 60% of initial with-the-rule astigmatism with spherical reverse geometry lenses, although some patients exhibited an increase of against-the-rule astigmatism after lens wear. Similarly, Mountford and Pesudovs[16] revealed a 50% mean reduction in prefit astigmatism in a carefully selected sample of patients with with-the-rule astigmatism between 0.50 and 1.75 D, also noting that accelerated Ortho-k, as compared with conventional Ortho-k, seemed more successful in reducing with-the-rule astigmatic error. It must be mentioned, however, that all the patients from that study had their astigmatism located at the central corneal region, as opposed to limbus-to-limbus astigmatism, and presented identical refractive and corneal components. In addition, the major change in astigmatism was found to occur over the central 2.00-mm chord, with no significant reduction in astigmatism in the peripheral cornea outside the central 4.00 mm.[16] Other authors have described either an increase in regular and irregular corneal astigmatism[12], or no significant change in refractive or corneal astigmatism, in patients who had been employing their spherical lenses for different periods of overnight Ortho-K.[17–20]

Spherical Ortho-K lenses are limited in their ability to correct against-the-rule or limbus-to-limbus astigmatic errors. Indeed,

From the Ophthalmology Department (J.P.), Centro Médico Teknon, Barcelona, Spain; and Optics and Optometry Department (G.C., L.Q.), Technical University of Catalonia, Spain.

None of the authors have any proprietary interests or conflicts of interest related to this article. No support was received.

Address correspondence and reprint requests to Genís Cardona, Ph.D., Facultat d'Òptica i Optometria de Terrassa, Violinista Vellsolà, 37, 08222 Terrassa, Catalonia, Spain; e-mail: gcardona@oo.upc.edu

Accepted April 2, 2012.

DOI: 10.1097/ICL.0b013e318258789e

Ortho-K mechanisms have been described as a combination of central positive with midperipheral negative fluid pressure forces, requiring a 360° peripheral touch between the lens and the cornea to prevent fluid forces to escape along the steepest meridian.[4,21] A toric Ortho-k lens may therefore be the only available option for limbus-to-limbus astigmatisms, although anecdotal evidence of success with a spherical optical zone, peripheral toric ortho-k lens design (spherical optic zone and toric reverse and peripheral curves) has been documented.[22]

Peripheral toric Ortho-k lenses create an oval treatment zone, with different and independent topographical changes along the main corneal meridians. Preliminary nonpublished reports of these designs have been fairly positive, with a success rate ranging from 70%[23] to 82.5%.[24] The same authors described how toric Ortho-K lenses were fitted successfully in up to 3.50 D with-the-rule astigmatic corneas, even allowing for the possible correction of against-the-rule astigmatism.[22–24]

As far as our literature review has disclosed, there is an absence of published studies regarding the rate of success of toric Ortho-K lenses for the correction of significant corneal astigmatic errors, not limited to the central corneal region, and in against-the-rule astigmatisms and non matching refractive and corneal cylinders. It was the goal of the present retrospective investigation to determine the performance of a new double tear reservoir full toric Ortho-K lens design (toricity in optic zone and peripheral curves) in reducing myopic and astigmatic refractive error, and to study the association between the changes in corneal topography parameters and the achieved myopic and cylinder reduction.

MATERIALS AND METHODS

Participants

Consecutive records of 326 Ortho-K patients successfully treated at the Centro Marsden de Terapia Visual of the Centro Médico Teknon, Barcelona, Spain, between January 2008 and December 2010 were retrospectively examined. Inclusion criteria were refractive astigmatism greater than 1.25 D with the axis at any orientation, best-corrected distance monocular visual acuity (best-corrected visual acuity [BCVA]) before Ortho-K treatment 1.00 or greater (decimal notation) and stable ocular refraction for at least 1 month at the time of the last visit. All the patients were free of ocular pathologic conditions and had no history of refractive surgery. Only patients with an adequate tear film quality and volume (break up time $>$8 sec and Schirmer I test $>$ 10 mm in 3 min) and those attempting Ortho-K for the first time were included in the study.

Only 32 patients were found to fulfill the inclusion criteria, with ages ranging between 26 and 35 years and a median of 29 years. Nine were female. Right eyes were chosen for data analysis.

Lens Design and Fitting

All the patients were fitted with a Full Toric Double Reservoir Lens, manufactured by Precilens (Precilens, Creteil, France). This lens design includes a double tear reservoir zone aimed at improving lens centration and optimizing treatment efficiency. The posterior surface of the lens is toric, with five different areas: a toric back optic zone radius (BOZR), with both curvatures determined through Jessen Factor[25] (flatter than the corneal curvature by 0.20 mm for each 1.00 D of aimed refractive change, with an additional flattening of 0.20 mm as a compression factor); a first toric peripheral radius (BPR_1), or toric reverse curve (TRC), steeper than BOZR and matching the sagittal depth at each meridian; a second toric peripheral radius (BPR_2), flatter than the previous one; a third toric peripheral radius (BPR_3), steeper than BPR_2, thus generating a second TRC; and a fourth toric peripheral radius (BPR_4) with the appropriate curvature to ensure edge lift and adequate tear exchange. Overall lens diameter was 10.80 mm, with an optic zone diameter of 6.60 mm.

Contact lens parameters were determined by the sagittal height technique.[9] All topography data were calculated from the average of three consecutive measurements. Apical radius and eccentricity values, as provided by the instrument, were introduced in the contact lens fitting software to calculate lens sagittal height for an 8.00-mm chord, corresponding to the first RC, also allowing for an additional 8 μm of apical tear film thickness, and for a 10.00-mm chord (second RC). The resulting lens parameters were used to order the first lens from the manufacturer. If an acceptable initial fluorescein pattern was observed (Fig. 1) lenses were worn for a 20-min trial period (closed eye). Differential corneal topography (Fig. 2) and fluorescein pattern evaluation were performed after the initial 20 min. If acceptable and provided good lens centration was observed, lenses were overnight. Fluorescein and topography were repeated on the first morning after overnight lens wear (within 2 hrs of awakening) and at the end of the first week, 12 hrs after lens removal. The patients were instructed to wear their lenses a minimum of 8 hrs per night.

Modifications in BOZR and BPR_1, or BPR_2 and BPR_3 were introduced when treatment outcome, fluorescein patterns or differential topographical maps were considered unsatisfactory. It may be noted that an acceptable fluorescein pattern with this lens design should display a double peripheral black ring of similar amplitude, indicative of alignment and of good distribution of pressure forces. Asymmetry in the peripheral black ring widths is suggestive of a flat or steep lens fit.

Lenses were manufactured with Boston XO (Bausch & Lomb Inc., Rochester, NY), which provides an oxygen permeability of 100×10^{-11} Dk units (ISO/Fatt), optimal for overnight wear. All

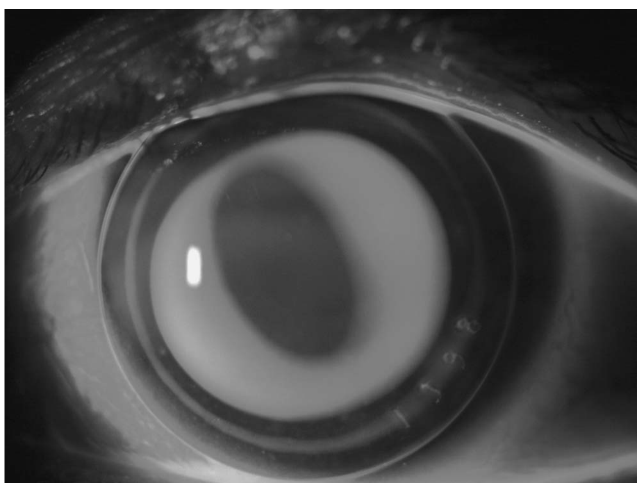

FIG. 1. Acceptable full toric double reservoir lens fluorescein view on a toric cornea (please note the ellipsoidal treatment zone; oblique astigmatism $-2.88@108°$).

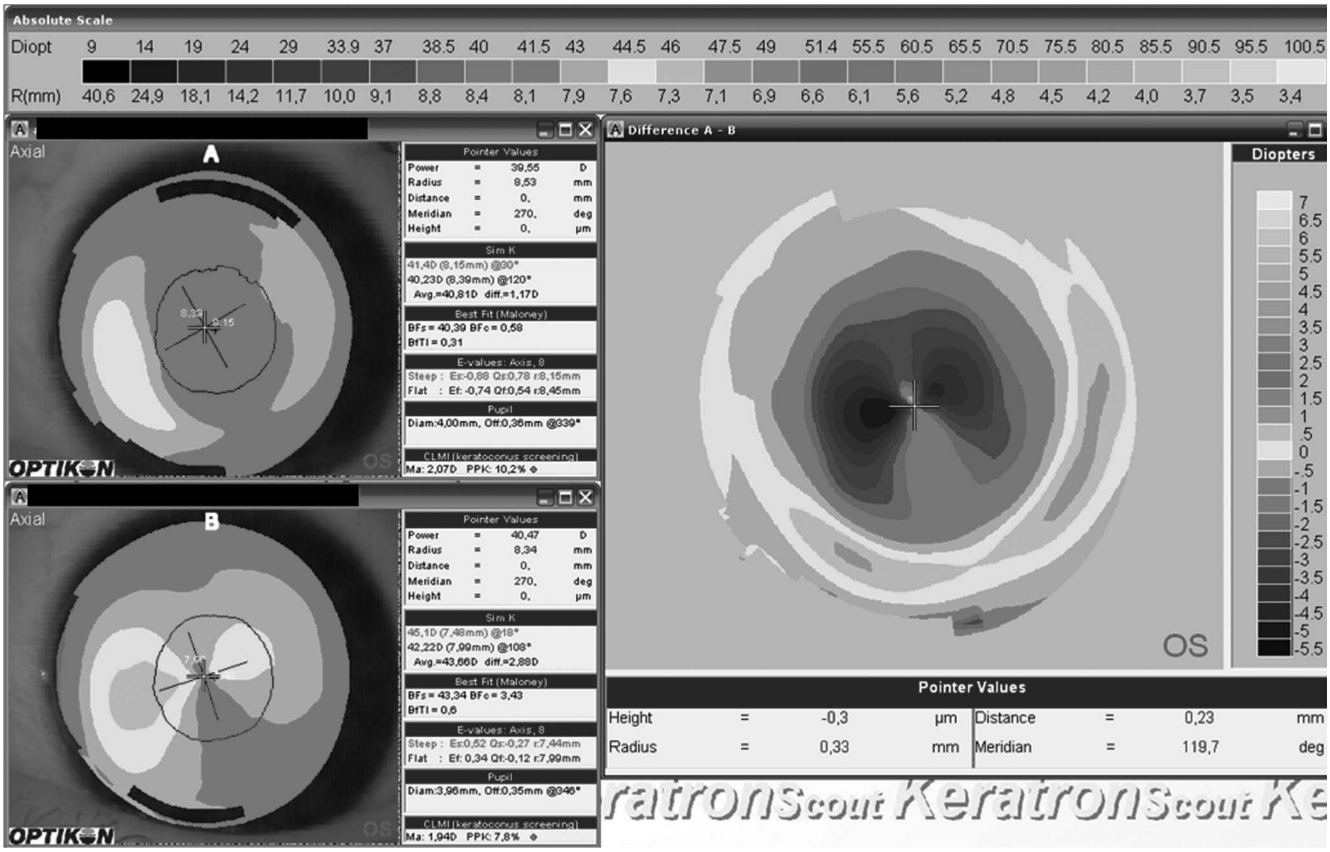

FIG. 2. Corneal topography view showing the typical centered posttreatment bulls-eye profile (axial subtractive map) on a toric cornea (corneal astigmatism −2.88@108°).

contact lens fittings were performed by the same experienced practitioner (J.P.).

Measurements

Each patient was administered a complete visual examination before Ortho-K treatment. Retrieved baseline data included noncycloplegic subjective refraction, BCVA, pupil diameter, corneal topography, and aberrometry. The same examiner (J.P.) performed all contact lens fittings and data collection. Thus, masking was not possible with this study design.

For data analysis, refractive astigmatism was converted to refraction vector components as recommended by Thibos and coworkers.[26,27] Vector components for astigmatism were determined as follows:

$$J_0 = (-C/2)\cos(2\theta),$$

$$J_{45} = (-C/2)\sin(2\theta),$$

where C is astigmatic error at axis θ, and J_0 and J_{45} denote the horizontal or vertical and the oblique components of astigmatism, respectively.

Pupil diameter was measured under examination room controlled photopic conditions with the infrared Colvard pupillometer (Oasis Medical Inc., Glendora, CA) while patients were instructed to fixate a distant target.

Corneal topography and corneal aberrometry were assessed by the Keratron Scout (Optikon 2000, Rome, Italy). Relevant topographical data included simulated keratometric flat radius (SimKf), simulated keratometric cylinder (SimKcyl), ACP and apical corneal cylinder (ACcyl), Best Fit Sphere (BFS), and Best Fit Toric (BFT). Corneal spherical aberration and coma (RMS) were evaluated for a fixed 4-mm pupil (software selection).

For comparison purposes, the same information was obtained at the last visit, after at least 1 month of stable subjective refraction, at which point the Ortho-K treatment was considered complete. All the measurements were taken in the afternoon, after a minimum of 8 hrs of lens removal after overnight wear. Achieved myopic (ΔM) and cylinder (ΔC) reduction were the differences between the subjective refractive spheres and cylinders at baseline and at the last visit, respectively.

Data Analysis

Statistical analysis of the data was performed with the SPSS software 17.0 for Windows. All data were examined for normality using the Kolmogorov–Smirnov test, revealing several instances of nonnormal distribution. Therefore, the paired Student *t*-test and the Wilcoxon signed-rank test for two-related samples were employed to analyze the statistical significance of the differences between pre- and post-Ortho-K normally and nonnormally distributed data, respectively. In addition, the Pearson or the Spearman rho correlation tests were used to determine the relationship between

TABLE 1. *Baseline and Postorthokeratology Data of Our Study Sample (as Mean ± SD, Median, and Range)*

	Baseline	Post-Ortho-K	Change	Statistic	P
BCVA	1.00±0.11 1.00 (0.80−1.20)	1.02±0.13 1.00 (0.60−1.20)	0.02±0.12 0.00 (−0.20−0.25)	Z=−0.565	0.572
Refractive sphere (D)	−1.93±1.52 −1.75 (−5.00−0.25)	0.12±0.35 0.25 (−1.00−0.50)	−2.05±1.46 −1.88 (−5.25−0.50)	Z=−4.805	<0.001[a]
Keratometry flat (D)	42.67±1.68 42.70 (40.21−45.96)	40.86±1.79 41.51 (38.10−44.28)	−1.80±0.87 −1.85 (−3.39−0.41)	Z=−4.918	<0.001[a]
Apical power flat (D)	42.94±1.75 43.07 (40.44−46.79)	40.74±1.88 41.13 (37.85−44.07)	−2.20±1.08 −2.25 (−4.50−0.25)	Z=−4.918	<0.001[a]
BFS (D)	42.58±1.70 42.82 (40.13−45.90)	40.62±1.81 40.92 (37.98−44.31)	−1.97±0.89 −1.87 (−4.30−0.20)	Z=−4.918	<0.001[a]
Refractive cylinder (D)	−2.18±1.36 −1.88 (−6.50−0.50)	−0.38±0.41 −0.25 (−1.00−0.50)	−1.80±1.06 −1.50 (−5.25−−0.50)	Z=−4.945	<0.001[a]
Corneal astigmatism (D)	−2.40±1.27 −2.09 (−6.68−−0.72)	−1.30±0.69 −1.19 (−2.67−0.26)	−1.10±1.21 0.88 (−0.71−5.80)	Z=−4.637	<0.001[a]
Apical cylinder (D)	−2.40±1.40 −2.10 (−6.97−−0.68)	−1.40±0.94 −1.32 (−3.67−0.19)	−0.99±1.64 0.79 (−1.01−7.11)	Z=−3.571	<0.001[a]
BFT (D)	−2.55±1.57 −2.15 (−7.78−0.74)	−1.17±0.69 −0.96 (−2.82−0.30)	−1.38±1.48 1.07 (−1.14−6.63)	Z=−4.581	<0.001[a]
Refractive J_0 (D)	0.68±0.95 0.72 (−1.24−3.25)	0.11±0.20 0.11 (−0.25−0.70)	−0.57±0.80 −0.67 (−2.66−1.24)	Z=−3.310	0.001[a]
Refractive J_{45} (D)	0.08±0.54 0.00 (−1.04−1.31)	0.01±0.15 0.00 (−0.38−0.63)	−0.07±0.44 0.00 (−1.06−0.67)	Z=−0.558	0.577
Pupil diameter (mm)	3.37±0.66	3.25±0.62	−0.12±0.39	t=1.717	0.096
Corneal spherical aberration (mm)	0.07±0.03	0.14±0.07	0.07±0.07	t=−5.805	<0.001[a]
Corneal coma (RMS) (μm)	0.08±0.10 0.06 (0.00−0.51)	0.09±0.08 0.06 (0.00−0.33)	0.01±0.14 0.02 (−0.45−0.29)	Z=−1.159	0.246

[a]Denotes statistical significance.

BCVA, best-corrected visual acuity; BFS, best-fit sphere; BFT, best-fit toric.

pre- and post-Ortho-K refractive sphere and cylinder and between ΔM and the change in BSF, SimKf, ACP, and corneal spherical aberration and between ΔC and the change in SimKcyl, ACcyl, and BFT. A P value of 0.05 or less was considered to denote statistical significance throughout the study.

RESULTS

Baseline and post-Ortho-K data regarding BCVA, noncycloplegic subjective refraction, corneal topography, pupil diameter, and ocular aberrometry are summarized in Table 1. Table 2 shows the association between pre- and post-Ortho-K refractive sphere and cylinder and between ΔM and ΔC and several corneal topography and aberrometry parameters.

The BCVA was unaltered by Ortho-k treatment, as was pupil diameter (with a small reduction in size of 0.12±0.39). Differences in pupil diameter were neither statistically nor clinically significant.

A statistically significant difference (Z=−4.805; P<0.001) was encountered between initial myopia and final residual refractive sphere, with a dioptric change of −2.05±1.46 D (median: −1.88; −5.25 to 0.50), accounting for a change of 106% of the initial refractive error, that is, a mean residual hyperopic error of 0.12±0.35 D (median: 0.25; −1.00 to 0.50). A weak, albeit statistically significant correlation was found between initial refractive sphere and final residual refractive sphere (rho=0.362; P=0.042). Parametric pairwise comparisons revealed that ΔM was not statistically different from the associated changes in BFS, ACP, or SimKf. In addition, moderately strong positive correlations were found between ΔM and changes in BFS (r=0.554; P=0.001; ΔM=0.91×ΔBFS−0.25) (Fig. 3), ACP (r=0.506; P=0.003; ΔM=0.68×ΔACP−0.54), and SimKf (r=0.431; P=0.014; ΔM=0.72×ΔSimKf−0.74).

A statistically significant difference (Z=−4.945; P<0.001) was found between baseline and residual refractive cylinders, with a dioptric change of −1.80±1.06 D (median: −1.50; −5.25 to −0.50), accounting for a change of 85% of the initial astigmatism and resulting in a mean residual astigmatic error of −0.38±0.41 D (median: −0.25; −1.00 to −0.50). There was also a strong, positive correlation between baseline and residual refractive cylinders (rho=0.724; P<0.001; Residual Cylinder=0.24×Baseline Cylinder +0.15) (Fig. 4). The analysis of the astigmatic vector components revealed that, whereas a statistically significant difference was found between baseline and post-Ortho-K J_0 (Z=−3.310; P=0.001), differences between pre- and post-Ortho-K J_{45} failed to achieve statistical significance. Nonparametric pairwise comparisons showed statistically significant differences between ΔC and the associated changes in BFT (Z=−2.057; P=0.040), ACcyl (Z=−4.918; P<0.001), and SimKcyl (Z=−4.937; P<0.001).

TABLE 2. *Pearson or Spearman Rho Correlation Indicators Between Pre- and Post-Orthokeratology Refractive Sphere and Cylinder and Between the Achieved Myopic (ΔM) and Cylinder (ΔC) Reduction and Diverse Corneal Topography and Aberrometry Parameters*

	Statistic	P
Initial and residual refractive spheres	rho=0.362	0.042[a]
ΔM and ΔBSF	r=0.554	0.001[a]
ΔM and ΔACP	r=0.506	0.003[a]
ΔM and ΔSimKf	r=0.341	0.014[a]
Initial and residual refractive cylinders	rho=0.724	<0.001[a]
ΔC and ΔBST	rho=0.373	0.035[a]
ΔC and ΔACcyl	rho=−0.127	0.490
ΔC and ΔSimKcyl	rho=−0.219	0.229
ΔM and ΔSA	r=−0.355	0.046[a]

[a]Denotes statistical significance.

ACcyl, apical corneal cylinder; ACP, apical corneal power; BFS, best-fit sphere; BFT, best-fit toric; SA, corneal spherical aberration; SimKcyl, simulated keratometric cylinder; SimKf, simulated keratometric flat radius.

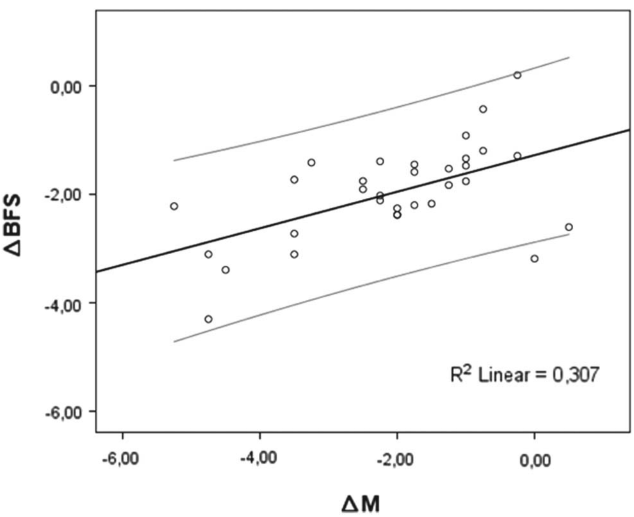

FIG. 3. Relationship between the achieved myopic reduction and changes in best fit sphere (BFS; best fit regression line and 95% confidence intervals are shown).

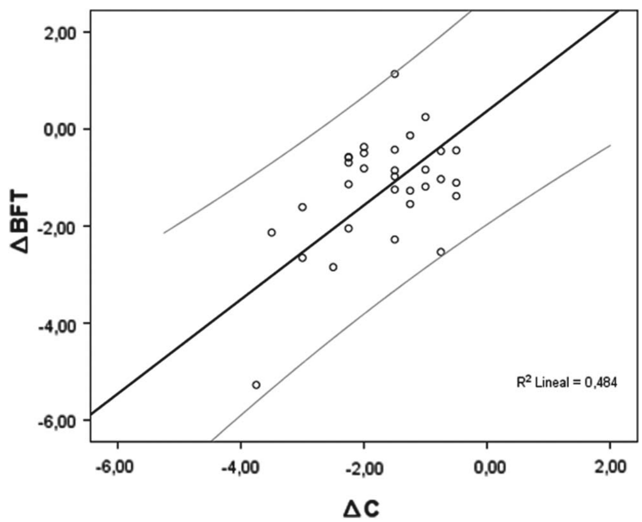

FIG. 5. Relationship between the achieved cylinder reduction and changes in best fit toric (BFT; best fit regression line and 95% confidence intervals are shown).

Although all 3 topographic parameters underestimated ΔC, changes in BFT were found to offer the best approximation, with an error of 0.43±1.06 D. A weak statistically significant correlation was found between ΔC and the associated changes in BFT (rho=0.373; P=0.035; ΔC=0.50×ΔBFT−1.12) (Fig. 5).

Finally, the statistical analysis of the changes in corneal spherical aberration and coma for a 4-mm pupil revealed significant differences in spherical aberration between pre- and post-Ortho-K (t=−5.805; $P<0.001$), with coma remaining unaltered by the treatment. A statistically significant correlation was found between ΔM and the change in spherical aberration (r=−0.355; P=0.046), that is, positive spherical aberration increased in those patients with larger corrected spherical refractive errors.

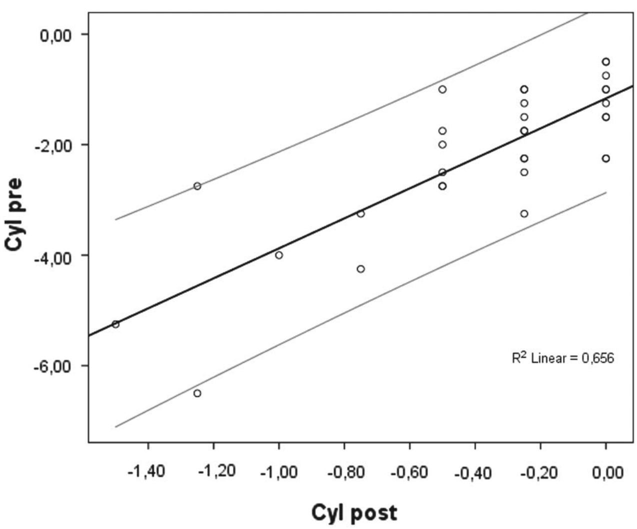

FIG. 4. Relationship between pre- and post-orthokeratology refractive astigmatic error (best fit regression line and 95% confidence intervals are shown).

DISCUSSION

This study aimed at exploring the performance of a double tear reservoir toric rigid gas permeable contact lens design for the correction of myopic and astigmatic refractive error through overnight Ortho-K. The achieved myopic and cylinder reduction was evaluated for various corneal topography parameters to assess the possible association of each of these parameters and the outcome of the Ortho-K treatment.

Spherical Ortho-K contact lenses on astigmatic corneas usually result in poor centration, leading to an unacceptable Ortho-K effect, induced irregular astigmatism, glare, and poor visual outcome. However, even if good centration is achieved, cylinder reduction with spherical lenses may be limited to a maximum of 0.50–1.75 D central with-the-rule corneal astigmatism.[16] Limbus to limbus, against-the-rule and larger astigmatic errors are contraindications for spherical Ortho-K.[17]

To obtain a good toric Ortho-K effect, mechanical and hydrodynamic forces must accomplish a different shape modification in each corneal meridian separately, with more corneal flattening in the meridian requiring a larger myopic reduction. Preliminary reports documented toric Ortho-K lenses to successfully correct up to 3.50 D of with-the-rule corneal astigmatic errors, and an unspecified amount of against-the-rule astigmatism.[22–24] However, as far as we know, no published studies have attempted a statistical analysis of the performance of a full toric Ortho-K lens design on a sample of patients with corneal and refractive astigmatism.

Information regarding a total of 32 patients fitted with Full Toric Double Tear Reservoir reverse geometry contact lenses was reviewed. Residual refractive sphere was of 0.12±0.35 D, which, compared with a baseline refractive sphere of −1.93±1.52 D, resulted in a change of 106% over the initial sphere. Baseline refractive astigmatism was of −2.40±1.27 D, with an anterior corneal component of −2.18±1.36 D, that is, it was mostly corneal in origin. Stable, post-Ortho-K residual astigmatic error was of −0.38±0.41 D, which was clinically insignificant. Therefore, a cylinder reduction of −1.80±1.06 D was achieved, which accounted for an 83% of the total initial refractive astigmatism. Analysis of both astigmatic vector components revealed statistically significant differences between pre- and post-Ortho-K horizontal and vertical component J_0. In addition, even if changes in J_{45} failed to reach statistical significance, a trend toward a reduction in oblique astigmatic error was observed (baseline J_{45} of 0.08±0.54 vs. post-Ortho-K J_{45} of 0.01±0.15 D).

It is interesting to note that, irrespective of axis orientation (with-the-rule, against-the-rule or oblique), different combinations of corneal vs. refractive astigmatism may occur, that is, corneal astigmatism may be larger than, equal to or smaller than refractive astigmatism. In addition, corneal cylinder may be limited to a central location or occur over a significant portion of the anterior corneal surface (traditionally known as limbus-to-limbus astigmatism), with similar or different amounts of central and peripheral toricity. It was the aim of the present toric Ortho-K lens design and fitting protocol to prove effective for the correction of refractive astigmatism in all combinations of axis orientation, corneal versus refractive astigmatism components and anterior corneal surface toricity position, although a minimum amount of corneal cylinder was required to ensure proper rotational stability and Ortho-K effect. Thus, although a larger sample of patients, including subsamples of all the possible combinations described above would allow for a comparison of the resulting Ortho-K outcome, the present findings must be interpreted with caution, as only 6 eyes (of 32) presented with against-the-rule or oblique corneal astigmatism and central versus limbus-to-limbus astigmatic errors were not analyzed independently.

This study revealed that changes in BFS and BFT demonstrated the highest correlation with ΔM and ΔC, respectively. Indeed, whereas changes in ACP were found to overestimate and changes in SimKf to underestimate ΔM, changes in BFS matched ΔM with an error of only 0.08±0.67 D. Similarly, even if all the evaluated corneal topography parameters underestimated ΔC, changes in BFT were found to offer the best, albeit moderate approximation to ΔC, with an error of 0.43±1.06 D. Previous researchers have assessed several initial corneal parameters to determine their predictive value of the outcome of Ortho-K.[9,28,29] Mountford suggested a relationship between ΔM and the change in ACP, as determined from the axial difference map.[9] Chan and coworkers,[25] while supporting the documented objectivity of the change in ACP in reflecting myopic reduction, concluded that this parameter underestimated the actual change in myopic refractive error. The same authors also pointed out the lack of validity of many corneal indices such as p, q, and e to correctly describe post-Ortho-K oblate corneas, as those indices may only be used to describe normal conic sections. Other authors suggested that the discrepancy between the changes in myopic and astigmatic refractive errors and the evaluated corneal topography parameters may also reflect that, as previously suggested,[22] other factors, apart from changes in corneal shape, may play a role in the outcome of Ortho-K.

In this regard, it must be mentioned that most corneal topography parameters are largely dependent on the instrumentation and algorithms employed for their measurement and determination. Thus, for example, ACP was derived from the apical corneal radius and a refractive index of 1.3375, not coincident with the mean real corneal index of 1.376, the use of which should probably be reevaluated when discussing Ortho-K, as the main Ortho-K effect has been reported to occur in the densely packed, thus with higher refractive index, corneal epithelium and anterior stroma. Also, the strong correlation between BFS and BFT and ΔM and ΔC may be explained by the fact that these parameters are derived from the central 3 mm of the cornea, that is, the area of maximum Ortho-K effect, and may be more limited in describing changes occurring in limbus-to-limbus astigmatism. In addition, the fact that this study design prevented masking of data collection may also help to explain the underestimation of change in refractive cylinder provided by topography metrics, because a certain bias toward measuring a higher correction of subjective refractive astigmatism may have occurred. These considerations may be relevant when interpreting the present findings in the light of future studies.

In conclusion, even if further research is required to verify these findings in different lens designs and larger and more heterogeneous samples of patients, the results of this investigation describe a successful attempt aimed at the correction of astigmatic refractive errors with toric Ortho-K lens designs, irrespective of axis orientation, corneal versus refractive astigmatic components and central versus limbus-to-limbus toricity. Albeit the exact mechanisms governing the corneal and refractive changes associated with Ortho-K remain controversial, the present results hint at a promising future in the correction of astigmatic errors with toric Ortho-K lens designs.

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