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One of the concerns of myopia correction by contact lens corneal molding is the thinning of central epithelium of the cornea induced by a direct compression of the optical zone. As it happened in the radial keratotomy or intastromal corneal rings procedures, we think that it is possible to bring on a central flattening, working in the periphery of the cornea and we designed a lens geometry that would aid the displacement of peripheral epithelium towards the optical zone. Our biomechanical hypothesis is that the central flattening might be secondary to a mid-peripheral steepening, induced by a displacement of the epithelium that results from a proper compression in the alignment zone of this lens.



Fig. 1 – The displacement of the epithelium that results from a compression in the alignment zone

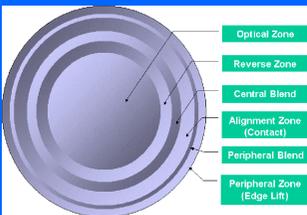


Fig. 2 – ESA ortho-6[®] lens Hexa-curve reverse geometry, IT Patent 2002 Antonio Calossi Material: Boston XO[®], siloxy-fluoro-methacrylate, Dk 100 x 10⁻¹¹

Overnight Orthokeratology Flattening the Cornea Without Direct Compression of the Center

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PURPOSE

We developed a new hexa-curve reverse geometry lens design (fig. 2) based on a biconic model that attempts to mold the periphery of the cornea with a minimum compression in the centre of the lens.^{1,2} A prospective, consecutive study was performed to evaluate the corneal response and central corneal thickness (CCT) changes after overnight orthokeratology by means of this customized hexa-curve reverse geometry lens in hyper-Dk gas-permeable material.

MATERIALS and METHODS

We fitted 28 eyes of 14 myopic patients aged from 17 to 44 years with a baseline spherical equivalent ranging from -1.00 to -4.25 D, and astigmatism up to 1.00 D. The lenses were in siloxy-fluoro-methacrylate Dk 100 gas-permeable material (Boston XO, hexafocon-A). All patients enrolled in the study were fitted with the overnight contact lenses. Assessment criteria included uncorrected visual acuity, best-corrected visual acuity, manifest refraction, ultrasound pachymetry, corneal topography, and biomicroscopic data. These data were collected at baseline, and then after one night, one week, two weeks, one month, and three months of lens wear. All the examinations were performed in the morning immediately after lens removal and repeated in the evening of the same day.

Corneal Thickness: An ultrasound pachymeter (Allergan Humphrey model 850, Carl Zeiss Meditec, Dublin, CA), using a velocity of 1640 m/s, was used to measure central corneal thickness. Observing the examined eye through a slitlamp biomicroscope, the probe tip of the pachymeter was held perpendicular to the cornea and centered over the pupil while the patient leaned upon the chinrest. Three consecutive readings were taken at the same location to improve the confidence in the data, and the average of these three readings was recorded as the corneal thickness at that point.

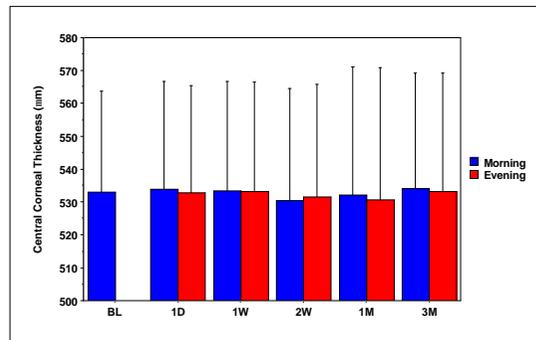


Fig. 3 – Changes in central corneal thickness over time

RESULTS

The cornea responded rapidly with significant ($p < 0.05$) central corneal flattening and improvement in visual acuity after the first night of contact lens wear. The corneal shape changed from prolate to oblate after one night of wear. By the end of one week, all corneal and visual changes had reached a maximal level and remained fairly stable during the day. These changes were sustained at the following visits. Biomicroscopy showed no significant ocular adverse events.

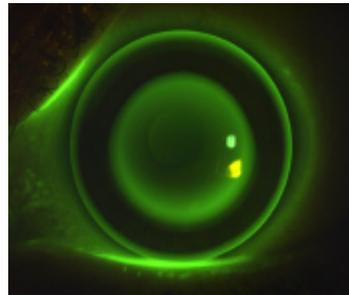


Fig.4 - After the first molding the fluoroscopic pattern showed an evident clearance in the center of the lens that demonstrated a minimal central touch.

The average pre-treatment CCT was $533 \pm 31 \mu\text{m}$. During all the period of the study, ultrasound pachymetry didn't show any significant change in the central thickness of the cornea (repeated measures ANOVA: $F = 0.308$, $p = 0.978$), both in the morning and in the evening (Bonferroni/Dunn post-hoc test: $p > 0.414$). Tab. 1 and fig. 3 show the details of the difference in CCT.

Comparison Time	Mean Diff.	Crit. Diff.	P-Value	Comparison Time	Mean Diff.	Crit. Diff.	P-Value
BL, 1D Morning	-0.86	10.94	0.791	1D Morning, 1D Evening	1.07	10.94	0.740
BL, 1D Evening	0.21	10.94	0.947	1W Morning, 1W Evening	0.14	10.94	0.965
BL, 1W Morning	-0.36	10.94	0.912	2W Morning, 2W Evening	-1.00	10.94	0.757
BL, 1W Evening	-0.21	10.94	0.947	1M Morning, 1M Evening	1.50	10.94	0.642
BL, 2W Morning	2.64	10.94	0.414	3M Morning, 3M Evening	0.79	10.94	0.808
BL, 2W Evening	1.64	10.94	0.611				
BL, 1M Morning	0.93	10.94	0.774				
BL, 1M Evening	2.43	10.94	0.452				
BL, 3M Morning	-1.00	10.94	0.757				
BL, 3M Evening	-0.21	10.94	0.947				

Tab. 1 – Bonferroni/Dunn post-hoc test for CCT. Significance Level: 5 %.

DISCUSSION

The lack of change found in the central pachymetry data suggests that our overnight contact lens can successfully flatten the cornea without direct compression of the centre of the cornea. The absence of change in CCT during the day seems to exclude a masking effect due to edema.³ Contrary to our finding, the majority of the previous studies reported that orthokeratology and corneal refractive therapy caused epithelial and total central corneal thinning.^{4,8}

This difference could be caused by the different geometry and behavior of the lenses. The absence of change found in the central pachymetry data suggests that this overnight contact lens design can successfully flatten the cornea without direct compression of the center of the cornea. The absence of change in CCT during the day seems to exclude a masking effect due to edema. Contrary to our finding, the majority of previous studies reported that orthokeratology caused epithelial and total central corneal thinning. This difference could be caused by differing lens geometry and differing lens behavior during overnight.

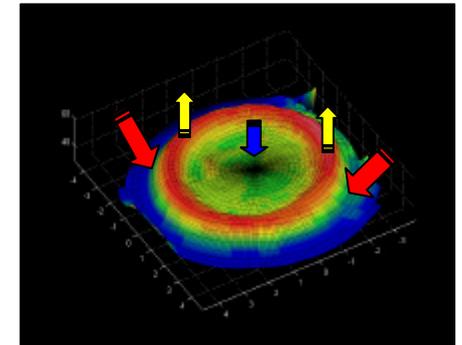


Fig. 5 – The instantaneous curvature map of a treated eye shows a flattening in the alignment zone (red arrows) that induced a secondary steepening in the tear reservoir zone (yellow arrows), with a secondary flattening in the center (blue arrow)

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Author Disclosure: A. Calossi, Inventor/developer, P; M.R. Romano, None; F. Romano, None; G. Ferraioli, None

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