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Efficacy and safety of overnight orthokeratology by means of a customized esa-curve reverse geometry lens

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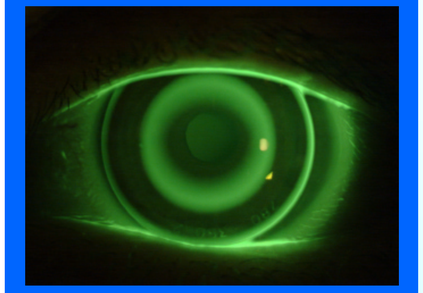
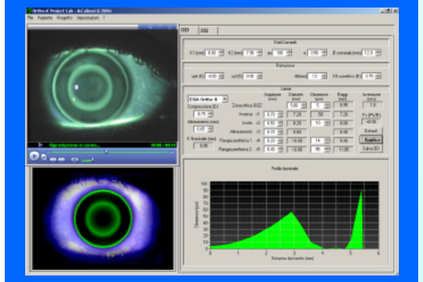
PURPOSE

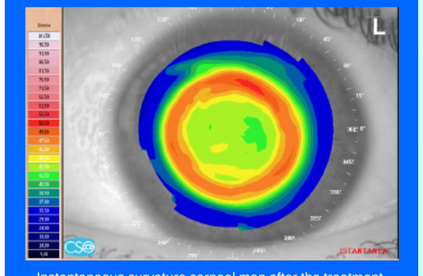
We developed and patented a new design and calculation method based on a biconic model to customize a multi-curve reverse geometry lens. A prospective, consecutive study was performed to evaluate the safety, efficacy, predictability, stability, quality of vision and adverse reactions of overnight orthokeratology by means of this customized esa-curve reverse geometry lens.



A sample lens fitted in the study



The software we used for the customization of the lenses



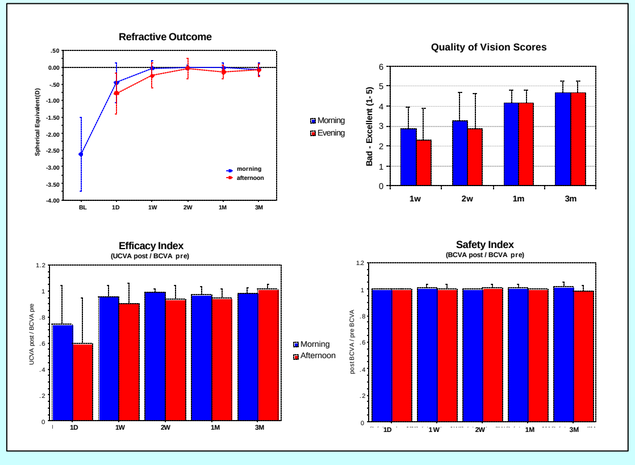
Instantaneous curvature corneal map after the treatment

MATERIALS and METHODS

We treated 50 eyes of 25 myopic patients aged from 11 to 45 years, without any tear, corneal, ocular and/or systemic disease at the baseline time and without any previous ocular surgery. The baseline refractive error was from –1.00 to –6.00 D spherical equivalent, WTR astigmatism up to 1.50 D and ATR astigmatism up to 1.00 D.

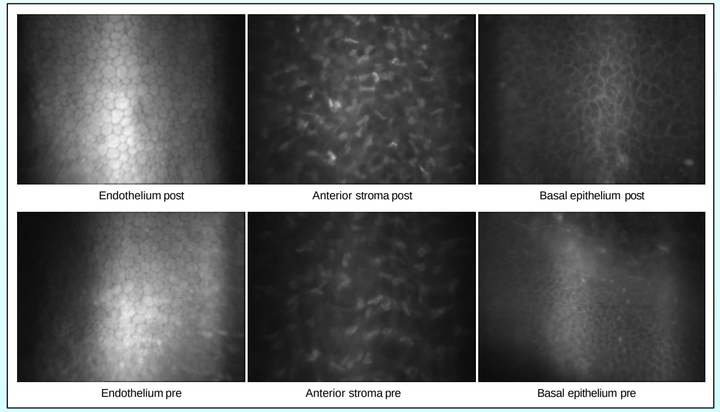
Procedures: At the baseline time we performed the following examinations: uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BCVA), manifest refraction; pupillography, corneal topography, corneal wave-front Zernike analysis (EyeTop, CSO); biomicroscopy with CCLRU grading scaling, endothelial specular non-contact microscopy, ultrasound central corneal pachimetry, tonometry and confocal microscopy (Confoscan-3, Nidek). The subjective quality of vision was checked through a questionnaire. After the baseline examinations, we calculated and fitted the lenses. The fitting of the lenses was based on a trial lens set to assess the first behavior of the lens on the eye, then the geometric parameters of the lens were optimized through a custom software. The lenses were adjusted to achieve optimal fluorescein pattern, centration and dynamic behavior. For all the patients an overnight wear was scheduled. After dispensing, all the subjects wore the same pair of lenses during the whole study. The lenses were in siloxy-fluoro-methacrylate Dk 100 gas-permeable material (Boston XO, hexafocon-A).

Follow-up: After overnight wear, the follow-up controls were performed in the morning and repeated in the evening after 1 day, 1 week, 2 weeks, 1 month, and 3 months. In the morning the lens in situ was inspected and then, after lens removal, all the examinations of the baseline time were repeated. These examinations were repeated in the evening of the same day. Confocal microscopy was performed to a subset of 12 eyes at baseline time and repeated after 1 month.



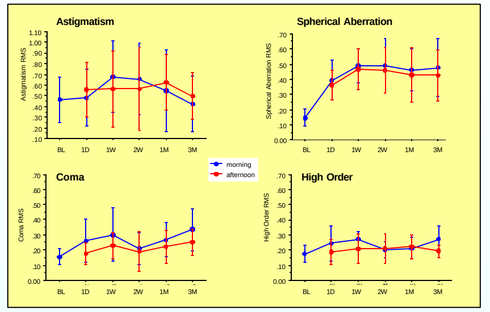
RESULTS

The cornea responded rapidly with significant ($p<0.05$) central corneal flattening and improvement in visual acuity after the first night of lens wear; the corneal shape changed from prolate to oblate asphericity after 1 night of wear. By the end of 1 week, all corneal and visual changes had reached a maximal level and remained fairly stable during the day. These changes were sustained at 2 weeks, 1 month and 3 months. No significant correlation was found between baseline corneal eccentricity and the amount of the spherical induced refractive change ($r = 0.036$). The efficacy index (UCVA post / BCVA pre) after 1 night was 70% in the morning, and 60% in the evening with large SD; after 1 week it improved to 90% with smaller regression and small SD; after 2 weeks we had a little further improvement and stabilization. For all the period of the study the safety index (BCVA post / BCVA pre) was 1, that means no lost of BCVA lines. During the first week, there was a significant increase of corneal spherical aberration ($p<0.05$) due to post-treatment oblate shape of the cornea. The spherical aberration was correlated with the amount of treated myopia and with pupil diameter, while coma aberration was correlated with the displacement of the pupil as regards the geometric center of the cornea and the center of the treatment. Subjective ratings continued to improve after objective measures stabilized at 1 week.

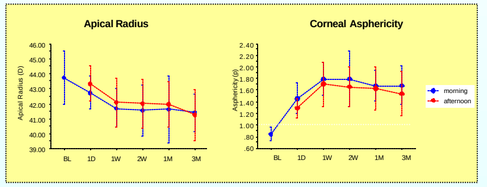


Confocal microscopy

Biomicroscopy showed no corneal infiltrates or ulcers; there were some observations of grade 1 fluorescein staining of the cornea, and imprinting in the morning that disappeared in the evening; no other significant ocular adverse events were observed during the trial. No significant change was observed in the central thickness of the cornea ($p>0.28$). No significant change was found in the intraocular pressure ($p>0.08$). Specular microscope showed no measurable changes in the endothelium. Confocal microscopy: in several subjects, basal layer of the epithelium showed larger and less regular cells after the treatment. We can explain this phenomenon with a mild cellular edema due to the hypoxia or the mechanical effect of the treatment. A few subjects showed a slight increasing in reflectivity of Bowman's layer and of anterior stroma. The appearance and the activation rate of keratocytes were not modified. Therefore, the slight increase in reflectivity could be explained by a mild increasing of corneal glycosaminoglycans production, that is a reversible phenomenon due to an aspecific reaction of anterior stroma to different traumas. No other significant alterations were observed in the anterior epithelium, sub basal nerve plexus, mid and deep stroma and endothelium.



Corneal wave-front Zernike analysis



Corneal topography

DISCUSSION

The preliminary results of this study demonstrate that these lenses were effective at producing reduction in myopia and improving unaided vision, with a high predictability of the refractive outcome. While some studies have found a predictive value for baseline eccentricity values, our findings do not support that hypothesis. This could be caused by the different geometry and behaviour of the lenses. The end point of the treatment wasn't the sphericalization of the cornea, because in all the cases the cornea became oblate, as in post-LASIK and post-PRK. The reverse of the asphericity of the cornea increased spherical aberration. The increased spherical aberration induced some visual symptoms in night vision, but improved the depth of focus. The progressive improvement in subjective quality of vision could involve a sensorial adaptation, that reduced visual symptoms even when aberrations and refraction were stabilized. Our results suggest that the corneal epithelium is able to be molded or redistributed very rapidly in response to the forces generated behind this reverse-geometry lens design. The lack of change in central pachimetry could be explained by a mechanism different from the direct compression of the central cornea. 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 the compression in the alignment zone of the lens. Safety and efficacy of the procedure appear to be favorable without significant adverse reactions; however, future studies are needed to determine the more long-term outcomes of treatment.

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