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INTRODUCTION

Rigid gas permeable (RGP) contact lenses are considered the primary visual correction tool for keratoconus¹. Even with the variety of designs currently available, RGP lenses are often difficult to fit for some keratoconic eyes, with patients sometimes experiencing fluctuating vision and discomfort which may lead to RGP lens intolerance¹. To increase comfort, lens centration and visual quality hybrid contact lenses today represent an effective solution for keratoconus correction^{2,3}. SynergEyes offers UltraHealth a hybrid lens with an improved design and an increased Dk/t compared to previous lens generations. This lens, with a total diameter of 14,5mm, is fitted considering the lens vault and the skirt curvature⁴ (Fig.1). Lens vault is a descriptor for the relative depth of the reverse geometry aspheric RGP part and is available in 11 different steps from 50 to 550 μm . The skirt part, available with curvature from 7,9 to 8,7 mm, modulates the corneal-lens fitting relationship at the rigid-soft junction zone, allowing the rigid portion to center better and the soft component to extend onto the conjunctiva. The recommended fitting procedures involves the initial application of a 250 μm lens vault and a 8,4 mm skirt curvature. An initial apical clearance of 100-150 μm is expected with a soft skirt thin bearing ring at the inner landing zone (Fig.1). These lenses, like scleral ones, gradually sink after the initial fit reducing their apical clearance, to obtain an optimal stable value of $\sim 50\mu\text{m}$. This clearance value is very important for an effective fitting since an apical bearing may eventually lead to mechanical damage to the epithelium and patient discomfort while a higher apical clearance can introduce an excessive negative pressure, a reduction of tear exchange and a reduction of oxygen transmission. The amount of settling, as well as the amount of time for this to occur, appears to vary with the patient⁵. In fact in some cases starting from the manufacturer's indication after several hours of wear the lens collapses on the cornea or remains higher than expected. The purpose of this study was to evaluate the settling behaviour, amount and time needed, of Ultra Health hybrid contact lens fitted on keratoconic eyes. A further aim of the study was to evaluate if it is indicatively possible to foresee the final behaviour of contact lens fitted starting from the first minutes of its use.

METHODS

Twenty eyes with a diagnosis of keratoconus were fitted with UltraHealth. In each eye the average corneal sagittal depth for a chord of 14,50 mm was measured using a Fourier transform profilometer (Eye Surface Profiler, Eaglet eye, Roermond, NI) and corneal topography was measured using a rotating Scheimpflug camera plus a Placido disk tomographer (Sirius, CSO, Firenze, It). The first trial lens was selected from a diagnostic set, using the fitting guide proposed by the manufacturer⁸ and modified if necessary to obtain after 4 hours of wear an apical clearance of $\sim 50 \mu\text{m}$, measured with a slit lamp-adapted Fourier-Domain OCT (SL-SCAN 1, Topcon, Chapelle, NI) and a thin bearing ring at the inner landing zone. The settling behaviour of the best fitted lenses was evaluated during a new fitting session measuring the apical clearance at insertion, 15, 30, 45 min, 1, 2, 3 and 4 hrs. While measuring apical clearance with OCT, two images were taken considering always the same point and corneal apical clearance was measured manually. With the results obtained, we also elaborated a way to predict indicatively the final apical clearance without having to wait for the lens to settle completely.

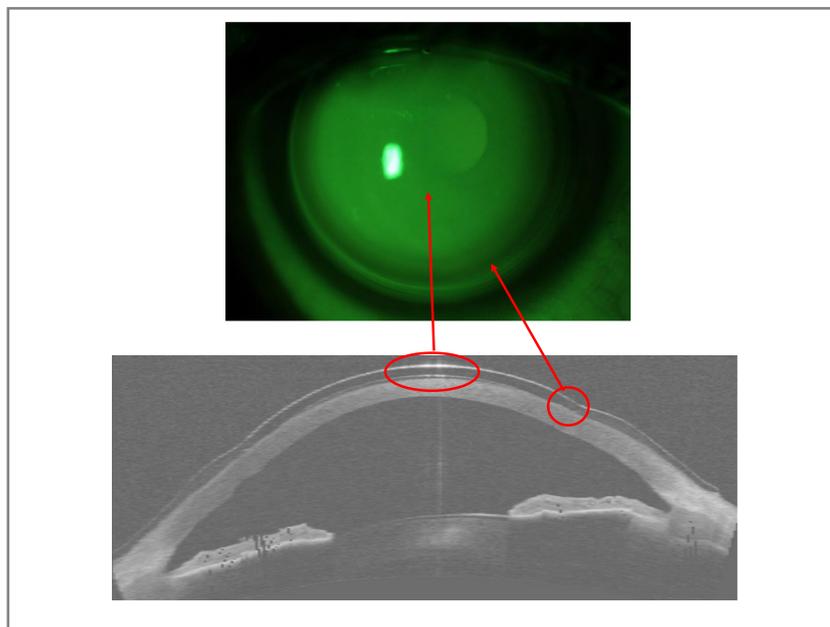


Figure 1. Apical clearance and thin bearing at the inner landing zone

RESULTS

The keratoconic eyes selected for the study presented an anterior segment sagittal depth of $3569 \pm 197 \mu\text{m}$, flat sink was $7,32 \pm 0,43\text{mm}$ and steep sink $6,47 \pm 0,51\text{mm}$. The mean initial apical clearance was $165,44 \pm 16,69 \mu\text{m}$, and at 4 hrs was reduced to $45,78 \pm 6,01 \mu\text{m}$ with a settling of $119,67 \pm 20,31 \mu\text{m}$ (Fig. 2) associated to significant intersubject variability (range 149-90 μm). The average amount of settling at 15 min was $20,56 \pm 12,64 \mu\text{m}$ equal to 17,18% of total settling, at 30 min was $35,78 \pm 12,11 \mu\text{m}$ (29,91%), at 45 min was $48,72 \pm 17,75 \mu\text{m}$ (40,11%), at 1 hr was $60,22 \pm 20,40 \mu\text{m}$ (50,32%), at 2 hrs was $89,67 \pm 22,48 \mu\text{m}$ (74,93%) and at 3 hrs was $118,22 \pm 6,92 \mu\text{m}$ (98,79%) (Fig. 3). From our results, using OCT instruments, the best way to indicatively predict the final apical clearance is to subtract from initial apical clearance the settling measured after 30 min of lens wear multiplied by 3. With results between 40-80 the final apical clearance will be $\sim 50\mu\text{m}$, with lower values the lens will have an apical touch and with higher values an excessive clearance. For example with an initial apical clearance of 160 μm and a settling of 40 μm after 30 min of lens wear we expect the settling to be 120 μm after 4 hrs with a score of 40. If the lens settled 50 μm , total settling is 150 μm with a final score is 10. We would expect apical bearing. With a settling of 20 μm , total settling would be $\sim 60\mu\text{m}$ the score is 100 and we could expect an excessive apical clearance.

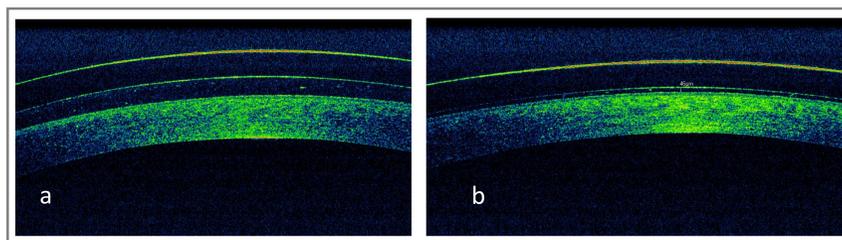


Figure 2. Change of apical clearance over time : at insertion (a) after 4 hrs (b)

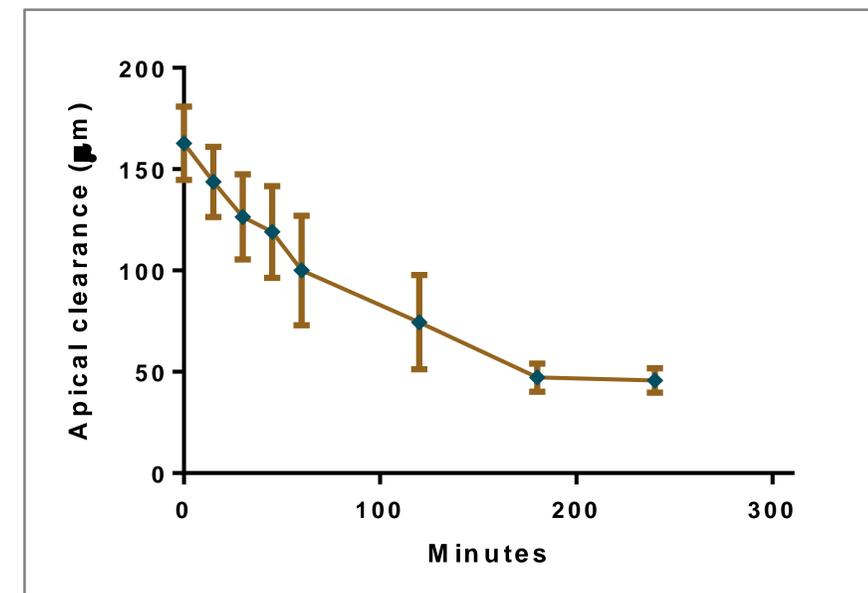


Figure 3. Modification of apical clearance over time.

CONCLUSIONS

From the results of the study, we concluded that settling behavior over time of UltraHealth is similar to that of scleral contact lenses^{6,7} with 50% of settling during first hour of lens wear and a stabilization after 3 hours. Despite the similar settling behavior there can be different causes of this effect; in scleral contact lenses as the periphery rests on the bulbar conjunctiva, which is an extremely soft tissue, compression is induced and leaves an impression ring that will be noticeable after removal. This effect is not very evident with hybrid contact lenses therefore we can assume a greater involvement of the low modulus (0,5 – 0,8 Mpa)⁴ soft part, that could introduce a reduction of sagittal depth of the lens with a reduction of apical clearance. We observed also that settling showed high intra-subject variances. This finding supports the necessity of a proper time period to properly observe the settling rate of UltraHealth lenses before prescription at each fit. This method may be time consuming if different lenses must be tried to find the final one. To reduce the time required to find the final lens we proposed also a simple and indicative way to foresee final apical clearance after 30 min of lens wear. It is however important to emphasize that the final lens in any case must be confirmed after a minimum of 3 hrs of wear.

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