Fitting Outcome of A Hybrid Lens in Keratocentric Patients After Corneal Crosslinking and Intacs®

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Introduction
Visual impairment in keratoconus (KC) and post-surgical ectasia patients is commonly due to increased higher order aberrations (HOAs) induced by irregular corneal contour. Novel surgical treatment strategies to stabilize such disorders and/or reduce HOA is of special concern in KC patients, which consequently can also reduce HOAs and potentially delay the need for penetrating keratoplasty.1-3 Utilization of specialty contact lenses in KC patients continues to be the primary visual management method where rigid permeable (GP) lens is the standard treatment choice. However, for those patients who struggle with habitual contact lens wear and/or have documented progressive conditions, surgical interventions are recommended. Previous studies have demonstrated the use of new specialty contact lens design(s) may be effective in postponing the need for immediate corneal grafts.4 Nevertheless, Contact lens fitting challenges have been reported in literature after implantations of intraorbital corneal ring segments.5,6 Given newly developed Intacs® designs (Oasis Medical Inc., Glendora, CA) and surgical algorithm, and its adjunct use with CXL, clinicians may experience more encounters with patients who have undergone combined treatment of CXL and Intacs®. Therefore, it is imperative to determine fitting outcome of different types of contact lenses in these post-operative circumstances in order to maximize patient functions and outcome. In this prospective study, we evaluate the performance of a reverse geometry hybrid contact lens, Clearkone® (SynergEyes, Carlsbad, CA) in a group of 10 patients after their combined treatment of CXL and Intacs®.

Patients and Methods
After combined surgical interventions of CXL and Intacs®, 10 patients (KC = 8, Ectasia = 2) were enrolled in this prospective pilot study to assess the fitting outcomes of Clearkone® during the post-operative time period. This clinical study complied with guidelines set forth by the tenets of the Declaration of Helsinki and was conducted with the approval and active monitoring of an Investigational Review Board. 3 months after having undergone CXL and Intacs®, subjects are deemed as being qualified for study enrollment if they are to be fitted with Clearkone®, a reverse geometry hybrid contact lens with Dk of 100 in its center GP. If a subject had undergone combined CXL and Intacs® treatments in both eyes, then only one eye is designated, via randomization, as the study eye from which the clinical trial data is collected. After the initial dispensing visit, subjects are required to return to clinic on a monthly basis for a maximum of 3 study visits. At each follow up visit, patient exams including patient symptoms, new lenses with prescribed modifications may be ordered and subsequently dispensed to the subject. Hybrid lens fitting success was defined as eyes regularly wearing the prescribed lenses in KC patients continue to be the primary visual management method where rigid permeable (GP) lens is the standard treatment choice. However, for those patients who struggle with habitual contact lens wear and/or have documented progressive conditions, surgical interventions are recommended. Previous studies have demonstrated the use of new specialty contact lens design(s) may be effective in postponing the need for immediate corneal grafts.4 Nevertheless, Contact lens fitting challenges have been reported in literature after implantations of intraorbital corneal ring segments.5,6 Given newly developed Intacs® designs (Oasis Medical Inc., Glendora, CA) and surgical algorithm, and its adjunct use with CXL, clinicians may experience more encounters with patients who have undergone combined treatment of CXL and Intacs®. Therefore, it is imperative to determine fitting outcome of different types of contact lenses in these post-operative circumstances in order to maximize patient functions and outcome. In this prospective study, we evaluate the performance of a reverse geometry hybrid contact lens, Clearkone® (SynergEyes, Carlsbad, CA) in a group of 10 patients after their combined treatment of CXL and Intacs®.

Objectives
This pilot study evaluates the fitting outcome of Clearkone® in KC or ectasia patients after combined treatment procedures of CXL and Intacs®.

Results
10 eyes of 10 patients (KC = 8, Ectasia = 2) were enrolled. Mean age of the study cohort was 34.4 years ±10.5 years with 3 females and 7 males. Mean Maximum Keratometry (K_max) was 51.16-73.50D (49.43-73.50D) 60% (6/10) and 40% (4/10) were diagnosed with stage of 2 and 4 respectively using the Amsler-Krumeich keratoconus classification.

After initial dispensing visit, 10 patients with keratoconus and corneal ectasia were performed at each subsequent visit via slit lamp and observed progressive changes in corneal ectasia. In addition to patient feedback on challenges of lens adaptation, observations of signs of corneal complications (ie, hypoxia or excess bearing over an Intacs® segment) by the principal investigator (C.Y.C., GL.L.), subjects were followed for a mean of 12.0 months (11.0-20.0 months) post-CXL and Intacs®. If any visit was delayed with less than 6 days (11.0%) and but not removed. Mean % of CL wear was 76% (90.0%). At baseline 10% (1/10) with no CL wear, but only 26.8% (2/7) eyes reported tolerance with habitual lenses. At the conclusion of this study, all 10 study eyes reported satisfactory hybrid lens tolerance with their respective finalized Clearkone® for a minimum time period of 3-month (success rate=100%, n=10).

Best corrected visual acuities (BCVA) improved approximately 3 lines from mean logMAR of 0.38 ± 0.17 at baseline to 0.18 ± 0.18 at post-CXL and Intacs® (P<0.001). Improvement was also supported by aberrometric measurements taken while wearing the prescribed hybrid lenses. A mean of 30% higher total aberrations over a 2.5m pupillary area pre- and post-Clearkone® fitting was found to have improved from a RMS (root mean square) error of 2.28 ±0.25mm to the 0.73 ±0.26mm.

Conclusions
Conventional clinical wisdom within the available medical literature purports that post-intacs topography and elevation profiles may cause fitting challenges such as lens decentration, persistent retrobular air bubble formation, and epithelial bearing with potential erosion over area of segment. The above challenges are most commonly encountered using a lens design with smaller back optical zone diameter and insufficient sagittal depth. Despite these potential limitations, there has been a resurging surgical trend in utilizing intraorbital ring segments (ICRS) due to the potential benefits in delaying or even avoiding keratoplasty in KC patients. Since many of these patients will experience additional visual rehabilitation with appropriately selected specialty lenses, it is imperative to determine fitting outcome of different types of contact lenses in order to maximize the range of surgical benefits.

The fitting outcome of Clearkone® hybrid lens was evaluated in this prospective pilot study to identify any eyes after having received both CXL and Intacs®. At baseline of this prospective pilot study, only 28.6% (3/7) of study eyes reported contact lens tolerance; however, 100% (10/10) of study eyes demonstrated excellent post-operative tolerance to Clearkone®. In addition to improve subjective contact lens tolerance, visual acuity and aberrometric improvements were also observed. Minimal clinical limitations suggest future benefits in exploring customization technologies, ie, wavefront-guided optics.10 In conclusion, Clearkone® hybrid lens with incorporated reverse geometry feature may serve as an additional visual rehabilitation tool in KC or ectasia patients after combined treatments of CXL and ICRS.

Fig 1: Topography and Scheimpflug Images (Pentacam, Oculus Inc.) of Subject #TXG007, OS

Fig 2: Clearance Over Intacs® Seen on Finalized Clearkone® on Subject #TXG007, OS

Fig 3: Pre-CXL/Intacs® vs Post-CXL/Intacs® Subjective Contact Lens Tolerance

References