

Clinical White Paper

Case Reports: The UltraHealth™ Silicone-Hydrogel Contact Lens for Keratoconus and Irregular Corneas

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SynergEyes®

ULTRAHEALTH™

Case Reports – The UltraHealth™ Silicone-Hydrogel Contact Lens for Keratoconus and Irregular Corneas¹

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Prologue

When presented with a patient with keratoconus or highly irregular astigmatism, optometric professionals know they face a challenge. Such cases can test the limits of training and experience, but in the hands of a skilled practitioner, can provide the potential for immediate feedback and a rewarding outcome. Some of the complicating factors, however, are the boundaries presented by current-technology contact lenses. Whether an RGP contact lens, piggyback lenses, a scleral lens or a hybrid contact lens is chosen, significant trade-offs in ease of use for patients or average wear time are required with each.

In this White Paper, five eye care professionals describe their early experience with a new silicone-hydrogel contact lens for keratoconus and irregular corneas. These are case details presented in near-real-time, as the UltraHealth contact lens was introduced to these professionals only 2-3 months prior to this publication. While some of these patients are still being evaluated and some minor fitting details may change in the future, they nonetheless represent fitting successes in a variety of typical and untypical cases. These reports introduce a new tool to the armamentarium of the practitioner treating these types of eyes. All of these cases represent patients who have tried, and failed, other contact lens modalities so this data may extend the boundaries of current technology for addressing keratoconus. The case summaries come from contributors who chose the patient summaries with no changes in case-details made by SynergEyes. We think you will find these interesting.

Introduction

The “Gold Standard” for many practices when fitting most keratoconic eyes has long been the type of contact lens (e.g., the Rose K) most practitioners originally trained on. While these RGP lenses can be customized to any eye, careful corneal assessment and fitting is required to ensure the lens matches the eye for which it was manufactured. RGP keratoconic-design contact lenses “hug” the cornea to provide vision, albeit not without potential for scarring. Factors such as a brief patient learning curve for insertion/removal, relatively low cost, and the familiarity to practitioners makes RGP designs a viable choice. Scleral lenses also are an option, especially for patients with highly damaged corneas or who otherwise cannot tolerate RGP contact lens wear. They are designed to vault over the entire cornea and the resultant lacrimal lens produces excellent visual results. The effort needed to achieve the “right fit” can be tedious, require several visits and be quite expensive to the practitioner and patient. In some eyes, impingement of scleral vessels leading to paralimbal edema and seal-off can result in discomfort and difficulty with lens removal. Properly fit, scleral lenses are generally more comfortable than RGP lenses, but

many patients find it difficult to master the insertion/removal technique, which limits acceptance.

The ClearKone® contact lens for keratoconus and irregular corneas was introduced by SynergEyes in 2008 as a hybrid contact lens that provided excellent centration and stability, regardless of the cone location. The reliable centration of the ClearKone results in a lacrimal lens power that is therefore predictable. The design of the ClearKone contact lens allows close corneal alignment, giving the practitioner the ability to prescribe a reduced power in the contact lens, reducing the potential for optical aberrations. The hybrid hard-RGP/soft-skirt design of the ClearKone lens also allows easier insertion/removal leading to excellent patient acceptance. Diagnostic fitting usually can be completed with greater ease than with rigid lenses, frequently requiring a brief fitting exam with 1-2 follow-up exams.

The vault in the ClearKone lens is designed to minimize the potential for scarring which has been reported in as many as 8% of patients wearing scleral contact lenses. The vault of the RGP over the cornea maximizes comfort, allowing several hours/day of wear time. For the ClearKone’s target population, this is vitally important to these visually debilitated patients who need to be able to count on correction that restores their quality of life and gives them all day comfort.

The HEMA soft skirt of the ClearKone works in conjunction with the reverse geometry RGP optics to provide vault over most cones and eliminate painful bearing on the cornea. As shown in the FDA study of the ClearKone contact lens reliable vaulting decreases the possibility of corneal staining (only 2.7% of subjects reported trace-mild corneal staining after 3 months of wear; data provided by SynergEyes). Other lenses, such as KeraSoft, increase skirt thickness using a low-Dk silicone-hydrogel (SiHy) material to achieve needed vault, which results in a low Dk/T (15). So, overreliance on the lens skirt or periphery to create vault comes at the price of oxygen transmission. Thus, while excellent VA or comfort may “encourage” patients to extend their wear-time, they should do so with regular monitoring to detect nascent neovascularization of the cornea.

The UltraHealth™ silicone-hydrogel contact lens for keratoconus and irregular corneas (SynergEyes, Inc., Carlsbad, CA) is intended to address the limitations and downsides of scleral, hybrid, or low-Dk SiHy contact lenses without a diminution in comfort, visual outcomes or safety. The variable lift-curve and reverse-geometry of the UltraHealth design, which is somewhat similar to the RGP portion of the ClearKone hybrid lens, provides most of the vault. The introduction of a proprietary “soft-lift curve” in the high-Dk silicone-hydrogel

skirt also allows it to “assist” in the vault while providing excellent oxygen transmission (Figure 1).

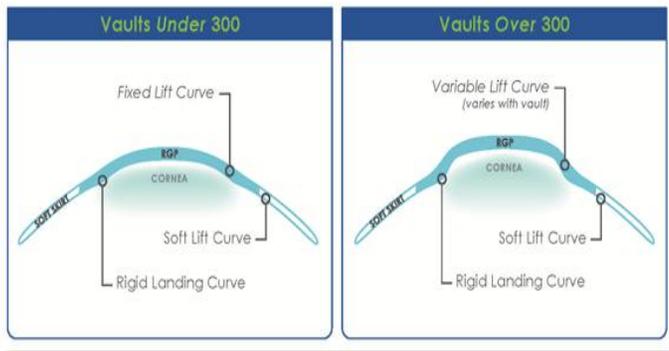


Figure 1: Soft Lift Curve and Variable Lift Curve of UltraHealth Lens

The base curve of UltraHealth lenses varies differentially with vault so the SiHy skirt doesn’t have to do all of the “heavy-lifting” to achieve apical clearance. The design of the SiHy skirt therefore ensures excellent and reliable centration with outstanding visual outcomes while ensuring patient comfort. The greatly improved oxygen transmission through the skirt material (Dk=84) also reduces potential for corneal neovascularization and may even allow regression if neovascularization is already present. Since the UltraHealth can be diagnostically fit using a nomogram familiar to ClearKone users, chair time for fitting remains quick compared to RGP or scleral contact lenses.

The soft lift curve of the UltraHealth lens (a part of the peripheral lift curve found in reverse-geometry lenses) ensures apical clearance without the need for a hard corneal or scleral landing zone which can lead to excessive tightening of the lens. This softer landing zone reduces the possibility of seal-off and also allows an increased chord length so the UltraHealth can be easily fit on a wider range of irregular corneas and ectasias.

Like most reverse-geometry lenses, the vaulting of the UltraHealth lens is produced by changes in base curve, but in this case, vault changes in a unique bi-modal manner (Figure 2). This is what allows vault with much less reliance on the high Dk skirt. Like other hybrid lenses, the power of UltraHealth diagnostic lenses have been individually adjusted to allow the over-refraction (OR) to remain constant regardless of vault so the practitioner can change to steeper or flatter vaults on the fly without repeating the OR.

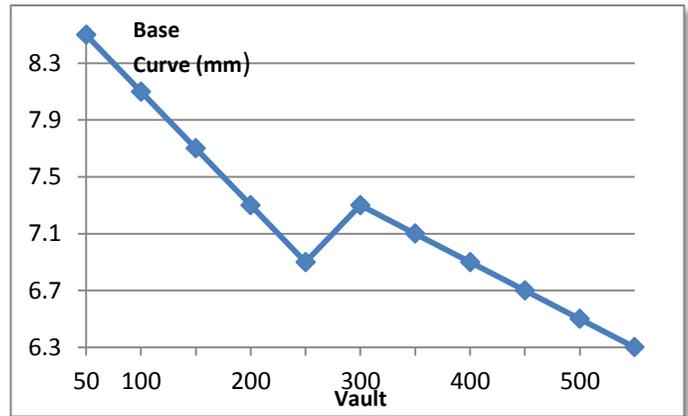


Figure 2: Vaulting of the UltraHealth lens results primarily from base curve changes (0.4 mm increments) from 50-250 microns of lens vault. For lens vaults ranging from 300-550 microns, vaulting results from base curve changes (0.2 mm increments) and the variable lift curve of the optic.

This paper presents case reports that highlight the potential benefits of the UltraHealth lens. Namely, that the unique geometry and high Dk material of this new contact lens allow for less concern about seal-off and corneal clearance. UltraHealth lenses provide excellent wearability, ease of fitting and use, as well as patient comfort for those with irregular corneas.

Case Reports

Case #1: 65 year old female referred from optometric clinic 100 miles away. Presented with no usable vision for last 3+ years; 50-year history of keratoconus with large oval cones (OU). Currently wearing Jupiter scleral lens in right eye, 12-14 hrs/day. Jupiter scleral lens failed in left eye.

At fitting with UltraHealth contact lens using sodium fluorescein (NaFl), demonstrated excellent fit (no apical bearing, good movement on blink) with first diagnostic lens (250 micron vault, flat skirt).

Over-refraction indicated a required contact lens power of -10.0D (Best Corrected Visual Acuity with UltraHealth = 20/25). At dispensing, contact lens visual acuity with the UltraHealth was 20/25+ with excellent comfort and no evidence of corneal abrasion or significant staining after 30 minutes. At same exam, patient had discontinued Jupiter lens in right eye due to abrasion and begged to be fit with UltraHealth in that eye. Diagnostic fitting started with UltraHealth lens having a 250 micron vault and flat skirt; sodium fluorescein in bowl of lens and subsequent over-refraction indicated final lens should be 300 micron vault/ medium skirt/ -6.50 D. Lens showed no apical bearing and good movement on blink after 30 minutes. Lens ordered but not yet dispensed at time of this writing.

Left eye has been seen at 28 days follow-up; contact lens visual acuity remains at 20/25+, feather-light bearing observed centrally which was first seen a two-week follow-up, but patient

reports excellent comfort, no corneal staining and no evidence of abrasion.

Case #2: 40 year old male with clinically significant pellucid marginal degeneration OS for 7-8 years. Was previously fit (2011) with SynergEyes Duette HD in both eyes (OD: 7.7mm/Medium skirt/-5.75; OS: 7.7mm/Steep skirt/-5.00). Although Duette HD is not indicated for PMD, K readings were within normal range (OD: 42.52 x 42.10 @ 27 and 43.50 x 41.59 @ 101) for this lens. Although comfort and visual acuity were good in both eyes, increasing haze, redness and irritation were evident after 3-4 months. Corneal staining was evident with mild edema due to tight fit of skirt resulting in lenses being too steep centrally with mid peripheral bearing. Impression rings were evident on removal. Fitting with Duette HD with a flatter base curve (i.e., 7.9 mm) was ruled out due to irregular topography in left eye. Diagnostic fitting with NaFl in the bowl of UltraHealth contact lens was started with 250 micron vault and flat skirt OU, which showed significant pooling; vault was sequentially reduced to 100 micron vault, flat skirts OU with -4.00 OD and -3.25 OS, which was ultimately prescribed. Apical and peripheral clearance, good movement on blink was observed in both eyes after 20-30 minutes.

Two weeks after fitting, visual acuity with UltraHealth lens was 20/20 OU, good movement on blink with apical vault of approximately 20 microns in right eye and 20 microns in left eye with peripheral vault still evident OU. Patient reports all-day comfort with no evidence of corneal staining or corneal abrasion in either eye.

Case #3: 42 year old male. Uncorrected visual acuity with a history of Intacs and corneal cross-linking (CXL); 20/80 in right eye and 20/50 in left eye. Best corrected vision with glasses was: 20/50 OD with -6.50 -5.75 x 035 and 20/30 OS with -4.75 -1.75 x 170. Has a history of RGP intolerance and could not wear glasses due to significant anisometropia and fluctuating vision due to the Intacs and CXL. Corneal topography revealed classic keratoconus despite reduced astigmatism and flatter K readings (OD: 49.31 x 45.27 @ 022, and OS: 47.89 x 45.50 @ 155). Diagnostic fitting with UltraHealth contact lenses and NaFl was started with 250 micron vault and flat skirt OU; central pooling observed. UltraHealth lens with 200 micron vault and flat skirts OU showed apical clearance without significant pooling, good movement on blink after 20-30 minutes; with OD: -4.50 distance and -3.75 for near; OS: -4.50 for distance and -3.75 for near. Best corrected vision (bilateral) was 20/20-2 for distance and J1 for near. Two weeks after fitting, contact lens visual acuity with UltraHealth lens was 20/20, good movement on blink with apical vault of approximately 20 microns in right eye and 20 microns in left eye with. Patient reports ease of insertion/removal, all-day comfort with no evidence of corneal staining or corneal abrasion in either eye.

Case #4: 30 year old, male engineer with bilateral ovular cones that contributed having his driver's license revoked and losing his job. Intolerant of RGPs with previous history of trying to wear soft contact lenses (10 years) but gave up due to

inadequate visual correction and has worn no correction for 5 years. Topographic K reading across center of cone = 58.4 D. Glasses Rx = +1.00 -4.00 x 100 with Best Corrected visual acuity with glasses (which patient found intolerable) was 20/50.

Right eye was fit with Diagnostic fitting using NaFl indicated with UltraHealth contact lens (250 micron vault/steep skirt/-10.75D) which showed apical clearance and good movement on blink. Best Corrected VA at 6 months of follow-up was 20/15 (using previous glasses) with no evidence of corneal staining or abrasion and good movement on blink. Average wear time was 15 hours/day, no discomfort, no evidence of neovascularization.

Left eye was beyond range of UltraHealth lens parameters (topographic K reading across center of cone = 77.6D). One week after dispensing the UltraHealth lens OD only), patient re-applied and was approved for driver's license, and became employed three weeks after fitting. Referred to another practice after moving out-of-state due to job promotions.

Case #5: 48 year old male with history of post-LASIK ectasia in left eye and was surgically treated with Intacs 7 months prior. He reported mild improvement in UCVA and BSVA post Intacs albeit still symptomatic with monocular diplopia. Patient declined RGP lens fitting prior to surgical intervention due to concerns of RGP intolerance. At baseline, UCVA was at 20/20 OD and 20/70 OS with following MRVA:

OD	+1.25, -1.25 x090 20/20
OS	+3.75, -5.25 x093 20/25-

His left eye only was initially fit with ClearKone lens (150 micron vault/steep skirt/-4.00 D). Subjective comfort was good in chair with BCVA of 20/25. After 6 weeks, vision and comfort remained good with subjective resolution of monocular diplopia. Patient reported wear time of 12-14 hours/day but required frequent lens rewetting toward the end of day. Corneal clearance was estimated at 80 microns with white illumination. No corneal staining or other corneal complications seen after removal of lens. With NaFl, central corneal clearance was approximately 120 microns with full inner landing zone clearance using cobalt blue illumination with Wratten filter.

To improve full-day comfort, patient was fit with UltraHealth lens (150 micron vault/Medium skirt/-6.00 D). BCVA at fitting was 20/25 with same Rx equivalent as with ClearKone. At 3 week follow-up, lens comfort had improved with 14+ hours wearing time; patient reported "rarely" needing rewetting drops. BCVA was 20/25, and improved to 20/20 with spherical cylindrical over-refraction (Plano, -1.25 x 045). No corneal complications observed with slit lamp microscopy and central clearance was estimated to be 70 microns with full inner landing zone clearance. Patient declined additional glasses Rx due to satisfaction with current outcome.

Case #6: 27 year old, male with history of bilateral nipple cones. Tried RGP contact lenses 7 years previous but discontinued due to comfort problems. Wearing glasses or no correction with

BCVA of 20/100 in right eye and 20/40 in left eye. Diagnostic fitting for UltraHealth contact lens with NaFl completed after trying 250 micron vault OD and 200 micron vault OS and flat skirts OU. No apical bearing, good movement on blink observed and BCVA with UltraHealth was 20/30 OD and 20/20- OS. Ordered -9.00 D and -8.00 D for right and left eyes, respectively.

At five weeks follow-up, patient reports great comfort and all-day wear with “good vision but focusing problems”. BCVA in right eye was 20/25 with -1.75 +1.75 x 95; left eye was 20/20 with -0.25 +1.75 x 86 with both lenses displaying about 2.0 D of flexure. Light 3-point touch seen OD and very light to thinning touch seen OS with little/no movement OU. No evidence of staining or corneal abrasion observed, but impression rings evident at inner landing zones OU.

Patient re-fit with UltraHealth contact lenses; OD: 300 micron vault/medium skirt/-6.50D and OS: 250 micron vault/medium skirt/-11.0D. Good inner landing zone OD and greater than average inner landing zone bearing at 3/9 o'clock OS. Follow-up to continue after dispensing.

Case #7: 53 year old male with irregular cornea in left eye secondary to herpes zoster ophthalmicus. No history of contact lens wear; current BCVA = 20/50 with shadows and distortions. Diagnostic fit in left eye with sodium fluorescein required one lens-fit only using 250 micron vault/flat skirt. UltraHealth contact lens showed no apical bearing, some pooling and good movement on blink. Switched to 150 micron vault/flat skirt UltraHealth contact lens which showed apical clearance without pooling and good movement on blink. VA with UltraHealth lens was 20/20-, ordered 150 micron vault/flat skirt/-5.25 D.

At 5 weeks follow-up, patient reports being delighted with comfort and vision (“never thought I would see decently again”). No discomfort, no corneal staining, no evidence of abrasion or apical bearing observed. Lens shows little-to-no movement on blink and mild imprint at inner landing zone 360o observed. Clinical impression is good “text-book” fit, good movement 45 minutes after reinsertion, VA as predicted, and excellent patient comfort. Re-trained patient on insertion/removal, suggested artificial tears and periodic rinsing/refilling as needed during day and discharged patient with follow-up in 6 months.

Discussion

All of these practitioners are to be congratulated for doing whatever it takes to restore vision and improve quality of life in these interesting cases. Their reports demonstrate that the UltraHealth contact lens can be successfully fit and restore excellent vision on a wide range of irregular corneas or keratoconic patients. These cases are typical of what many practitioners may see on a given day. Whether the patients presented with an ovular or nipple cone, pellucid marginal degeneration, an irregular cornea, or an eye with post-LASIK ectasia, these data show that the UltraHealth silicone-hydrogel contact lens can address the needs of a large variety of atypical eyes. This is due, in part, to the advanced modified reverse-

geometry design of the UltraHealth contact lens that allows the optic vault to increase without relying on the skirt or lens periphery which commonly rests heavily on either the cornea or sclera. As the UltraHealth vault increases, the distance between peripheral landing areas also increases enabling the practitioner to fit the UltraHealth contact lens on advanced steep cones without hard-bearing on the cornea. This reduces the risk of impingement of scleral vessels or staining.

All of these patients report excellent comfort and no evidence of corneal staining or abrasion at follow-up. This observation is important as the central vault of an UltraHealth contact lens can be expected to decrease somewhat with extended wearing. The relatively flexible high-DK skirt settles with bearing and the vault may slightly decrease. However, as these cases show, light apical touch without evidence of staining should not produce the discomfort or latent corneal abrasion that might be expected with scleral RGP or other lenses available for these types of eyes. The soft lift curve in the UltraHealth lens provides a larger area wherein there is either no bearing or very light bearing that appears to enhance comfort and decrease corneal distress.

The diagnostic fitting method for the UltraHealth contact lens recommended by Synergeyes suggests starting with a flat skirt and enough vault to provide approximately 100 microns of apical clearance after the patient has worn the lens for at least 20-30 minutes. The lens should also be well centered, show good movement (at least 1 mm) on blink, and of course, be comfortable. It is equally important to assess apical clearance, lens movement and corneal health at a follow-up exam. At follow-up, if feather-light apical touch is observed with no comfort complaints, there is movement on blink and no evidence of abrasion or staining, the fit is successful. As these cases show, a successful fit can be determined within 1-2 visits after the diagnostic exam.

A key to success with the UltraHealth is choosing the right skirt. Synergeyes recommends, and these data confirm, that the goal is to find the flattest skirt the patient will tolerate in order to ensure some movement and tear exchange under the lens. While the fitting guide recommends starting with a flat skirt, some patients may need a steeper skirt to enhance vault. A word of caution is that skirts that are too tight at fitting may later seal-off after the lens settles. In such cases, the patient may express no immediate comfort issues but the tight skirt will eventually result in tear stagnation under the lens which may lead to discomfort and filming on the lens. While some eyes may show little/no lens movement, it is possible that if sodium fluorescein was instilled in the cul-de-sac after lens insertion, some tear flow under the UltraHealth lenses may be evident in such cases and movement may have been confirmed.

Thus, the basic fitting strategy for the UltraHealth lens is to fit with some apical clearance; if the lens shows some light bearing at follow-up with no discomfort, full wearing time, movement on blink and no evidence of corneal staining or abrasion, the fit is successful.

The cases presented are all patients who tried other methods of vision correction and failed. While these reports show that the UltraHealth can be targeted to patients who have failed in scleral lenses, they also show that the lens may be appropriate for patients with oval cones that have failed in other contact lenses, for atypical patients with pellucid marginal degeneration even if paralimbal thinning is evident, and for patients with Intacs or who have undergone cross-linking. Even in eyes with a history significant corneal disease, correct fitting of the UltraHealth contact lens can be employed to restore excellent vision with all-day comfort.

These cases indicate that feather-light bearing in a hybrid lens having a high-Dk skirt will be well tolerated over the longer term for typical and atypical eyes. However, it is unlikely the UltraHealth contact lens can be fit on globus cones due to their extreme height and wide footprint. For those eyes, a contact lens with a HEMA skirt such as the SynergEyes ClearKone, or a Rose K scleral contact lens (or similar lens) may be the best choice because of the need for clearance over both the apex of the cone as well as the periphery.

Notes

Case #1: contributed by Dr. Roddy

Cases 2&3: contributed by Dr. Anderson

Case #4: contributed by Dr. Kusy

Case #5: contributed by Dr. Chang

Cases #6&7 contributed by Dr. Olafsson

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