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The SynergEyes hybrid contact lens fitting guide and information

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THE SYNERGEYES HYBRID CONTACT LENS

FITTING GUIDE AND INFORMATION

By

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A thesis submitted to the faculty of the Pacific University College of Optometry, Forest Grove, Oregon for the degree of Doctor of Optometry May 2007.
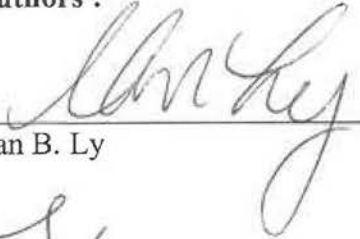
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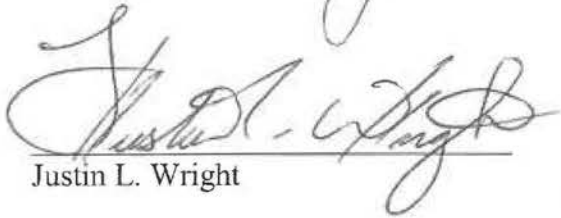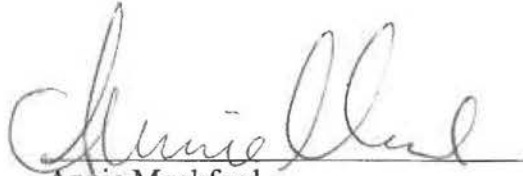JENNIFER SMYTHE, O.D.

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AUTHOR INFORMATION

Van B. Ly

Van Ly attended the University of Washington in Seattle where she received her Bachelor of Arts in Psychology in 2003. She has gone on to pursue her Doctor of Optometry degree at the Pacific University College of Optometry. During her time at Pacific University she has served as a member of the admissions committee and also worked as the graduate assistant to the optometry program. Van also served as a co-chair for the SOA speaker series where she helped to provide wonderful educational opportunities for students by bringing in distinguished guest lecturers.

Van plans to return to her home state of Washington to practice optometry. Her special interests in optometry include specialty contact lenses and corneal disease.

Sarah J. Anderson

Sarah Anderson completed her undergraduate work at the University of Saskatchewan, graduating in 2002 with a Bachelor of Science degree in Anatomy and Cell Biology. She is currently attending the Pacific University College of Optometry in the Class of 2007. Sarah plans to return to the Canadian Midwest to practice primary care optometry in the private sector.

Justin L. Wright

Justin Wright received a Bachelor of Science degree in Exercise and Sport Science from the University of Utah in 2003. Throughout his studies at the College of Optometry Justin has served as the class President of the Class of 2007 and worked as a teacher's assistant for both the ocular anatomy and second year procedures courses. Justin hopes to establish a career in the Northwest where he wants to practice full scope optometry with an emphasis on ocular disease.

Anne Mockford

Annie Mockford attended Willamette University where she received a bachelor degree with honors in biology. She is currently in her third year at Pacific University College of Optometry. She is a member of the AOA, SOA and AOSA. Annie works as a Contact Lens Technician part time. After graduating, she hopes to stay in the Northwest and work in a private practice as a contact lens specialist. She also enjoys working with children.

Drew Aldrich

Drew Aldrich received his degree in chemistry from Westmont College in 2000. He then attended graduate school at the University of California, Irvine where he received his Master of Science degree in chemistry. While finalizing his degree at UCI, Drew realized that optometry would be better career fit and is currently a 3rd year student at Pacific University College of Optometry.

As an optometry student Drew has been actively involved as a teaching assistant and with the ACHIEVE study. He was recently awarded the Dr. Norman E. Wallis Award for Excellence by the National Board of Examiners in optometry. Upon graduation, he plans on practicing in a private practice setting on the Central California coast.

Abstract

Historically, creating a lens with the optics of a rigid contact lens and the comfort of a soft contact lens has been fraught with difficulty. New technology, however has enabled us to create a hybrid lens that would greatly benefit people who suffer from corneal problems that prevent them from using conventional contact lenses. This paper describes a fitting guide for the new SynergEyes A hybrid contact lens based on a two part series of on-eye fitting trials.

Acknowledgments

We would like to acknowledge Dr. Peter Bergenske O.D., Timothy Koch, COT, FCLSA, and Patrick Caroline, FAAO, for their insight and expertise provided throughout this endeavor. Their enthusiasm for this new contact lens modality was outshone only by their passion for teaching and we give you our most sincere thanks.

Rigid gas permeable contact lenses have historically been a first choice in the refractive correction of individuals with irregular corneas post surgery or those who suffer from a corneal ectasia. However, these often fail due to the cornea being too steep or irregular for a traditional RGP. Likewise, many other patients who would have benefited greatly from the improved optics of an RGP, cannot tolerate the lens due to discomfort.

In 1985, the first alternative to contact lens failure for these challenging cases was made available to the marketplace. Precision-Cosmet introduced a novel hybrid lens, the Saturn II, incorporating both a rigid gas permeable center surrounded by a soft contact lens skirt. The goal was to combine the excellent optical characteristics of rigid contact lenses with the good initial comfort and centering abilities inherent to the large diameter and thin edge design of soft lens modalities. This hybrid technology employed by Precision-Cosmet was based on a unique bonding of the two materials developed by Erickson and Neogi in 1977.

The 6.5mm diameter rigid center of the Saturn II was comprised of the Opus III oxygen-permeable material (Dk 14×10^{-11}) and was available in base curves ranging from 7.20mm to 8.20mm in 0.10mm increments. Opus III's unique formulation of hydrophilic silicone and PMMA garnered it increased wettability and decreased weight compared to other silicone/PMMA materials (Bailey, 1984). The Opus III was surrounded by a 25% water hydrogel skirt (HEMA, Dk 5.5×10^{-11}) with a radius of curvature 6 to 7 diopters flatter than the rigid lens base curve. The overall lens diameter was 13.00mm and had a power range from -13.00D to +6.00 (Zadnick & Mannis, 1987).

In fitting the Saturn II lens, the initial lens selected was that of the flattest curve of the cornea. If corneal astigmatism equal to or greater than 1.50D was present, a lens 0.10mm steeper than K was fitted. A well-fit lens would show good centration and 1 to 1.5 mm of movement

with blinking(Zilliox, 1985). Unlike traditional rigid lens, if a lack of movement was noted, the base curve was steepened. This resulted in the most common fit being 0.75-1.25D steeper than K (Jurkus & Barabas, 1988). By fitting the lens steeper, the soft skirt could provide greater support. This allowed the lens to float freely on a layer of tears due to the transition zone no longer bearing on the cornea. A Saturn II lens fit too tight, however, will result in symptoms similar to a tight-fitting soft lens such as redness and blanching of limbal vessels.

The benefits of the Saturn II were seen in patients who failed with traditional RGP lenses due to oblique cylinder, tight upper lids, and "dry eye" symptoms (Minarik, 1987). Likewise, there were cases in which the Saturn II provided significant improvement in visual acuity in those patients suffering from keratoconus and/or keratoplasty (Boucher, 1992; Maguen et al., 1991) However, the disadvantages of the Saturn II outweighed the benefits. The most common causes of lens discontinuation included poor vision, discomfort, handling difficulties, and breakage along the rigid-soft interface. A lack of lens movement and tear flow was postulated as the cause for much of the discomfort and physiological complications (Maguen et al., 1991; Zadnick & Mannis, 1987).

In 1986 Sola/Barnes-Hind purchased Precision-Cosmet and the rights to the Saturn II. In order to improve tear circulation several parameters were modified. The re-designed lens was introduced as the SoftPerm in 1989 and had an overall diameter of 14.3mm and a modified edge-design, namely peripheral curves in both materials. The center RGP portion had an 8.0mm diameter (7.0mm optical zone) with bases curves ranging from 7.10mm to 8.10mm in 0.1mm increments. Powers ranged from -13.00D to +6.00D. Steeper base curves of 6.5mm, 6.7mm, and 6.9mm were also available (-3.00D to -16.00D). The soft lens skirt remained unchanged from the Saturn II predecessor (Chung, Santim, Heng, & Cohen, 2001). Fitting of the SoftPerm

lens was conducted in a manner very similar to that of the Saturn II. Lenses were initially fit on flat K and then steepened accordingly if a lack of lens movement was noted.

With the SoftPerm lens there was a reduction in the frequency of adverse findings such as lens cornea touch, lack of lens movement, and stagnation of tears and debris beneath the lens. However, many of the problems associated with Saturn II lens still existed (Chung et al., 2001; Maguen, Caroline, Rosner, Macy, & Nesburn, 1992).

In September of 2005 the FDA approved a new high Dk hybrid lens, the *SynergEyes A*. The development of this new design began in late 2001 by the California based research company Quarter Lambda Technologies in an attempt to overcome many of the problems that had plagued the previous hybrid designs. The *SynergEyes A* is comprised of an 8.2mm high Dk rigid center (Paragon HDS 100, Dk 100) and a 27% water non-ionic soft lens skirt. The overall lens diameter is 14.5mm. Initial studies have shown the *SynergEyes* design to be successful modality on patients in which traditional RGP and soft lenses have failed to provide adequate comfort and/or vision. In addition to the *SynergEyes A*, two additional designs are currently under investigation: the *SynergEyes KC,* which incorporates an aspheric lens and is for keratoconus and post-LASIK ectasias, and the *SynergEyes PS,* designed for patients with highly oblate corneas post refractive surgery. The aim of this project is develop fitting nomogram for the *Synergeyes A* lens which is sufficiently generalized to allow for the successful fit on the majority of patients.

STAGE 1: Fitting the proper Central Base Curve

Methods

The protocol of this study was approved by the Investigational Review Board at Pacific University College of Optometry (PUCO).

Instrumentation utilized during both the prescreening as well as stages one and two of the study included: Medmont E300 Corneal topographer, slit lamp with video taping capability, SynergEyes A trial lenses, and high molecular weight fluorescein.

Prescreening of potential subjects was performed on sixty-three individuals. All candidates were students at PUCO. Keratometric and topographical measurements were taken on each pt. at this time. We utilized the topography findings to more accurately assess the horizontal visible iris diameter (HVID) on each candidate.

Subject Selection

Utilizing the data collected during prescreening, 14 subjects were selected to provide a wide range of corneal geometries. The HVID measurements for these subjects ranged from 10.89mm to 12.22mm with an average HVID of 11.5mm. The flat keratometric (flat K) measurements ranged from 45.37 D steepest and 41.37 D flattest with an average of 43.37. The subject's age, sex and ethnicity were not considered in the selection process. Each subject received monetary compensation for their participation.

Phase 1 Trial

During this phase of the trial each subject was fit with a total of 6 lenses, all with plano power. The researchers randomly conducted six different fits in which only the right eye was fit with the following parameters: three different base curves (On flat K, 0.5 D steeper, and 0.5D flatter) and two skirt radii (1.0mm and 1.3 mm flatter than the base curve radii of the lens). The purpose of the randomization of the lens placement was to mask the SynergEyes team so that their objective analysis was not influenced by the knowledge of the parameters of the lens currently on a subject's eye.

Prior to insertion of each lens, sodium fluorescein was instilled onto the back surface. A high molecular weight fluorescein was used to prevent discoloration of the soft skirt. After placing the lenses on the eyes, each lens was videotaped and objectively evaluated by the SynergEyes team using the following criteria: lens centration, amount of on eye movement, central apical clearance of the lens, and scleral-skirt relationship (See table 1).

Table 1 – Example of fit evaluation form

1. Lens Comfort	Excellent		Good		Poor
	5 4		3	2	1
2. Lens Centration	**X – axis**				
(In straight ahead gaze, 0.5mm steps)	**Y – axis**				
3. Lens Movement	0 0.1 0.2 0.3 0.4 0.5 0.6				
(After normal blink in primary gaze)	0.7 0.8 0.9 >1.0mm				
4. Central Lens Eye Relationship	**Bearing**	**Aligned**		**Clearance**	
(After normal blink in primary gaze with large molecule NaFl)	1	2 3		4 5	
5. Skirt Sclera Relationship	**Fluting**	**Aligned**		**Impinging**	
(After normal blink in primary gaze)	1	2 3		4 5	

The subjects were then asked to subjectively judge the comfort of each lens. A scale of 1 to 5 was utilized (5 being "excellent - no lens awareness", and 1 being "Poor – much lens discomfort"). Topography measurements were then completed over each lens.

The lens was then removed and another different lens was randomly placed on the eye until all 6 lenses had been both objectively and subjectively evaluated in the same manner.

Results

The data showed that twelve of the fourteen subjects rated comfort of the 0.5 D steeper than flat K lens as 4 or 5. The skirt alignment of this 0.5 D steeper lens was also ranked as a 3 which indicates that it was aligned.

Discussion

In this first stage of the study an understanding of proper lens selection based on patient keratometric measurements and HVID was discovered. Furthermore, the researchers determined the most successful method for insertion and removal of the SynergEyes lens.

Lens Base Curve

Data and observations showed that an optimal fitting relationship was achieved by placing a lens on the eye which was 0.5 D steeper than each subject's flat K measurements. Initially fitters were encouraged to use an alignment fit, but these parameters resulted in late onset tightening of the lenses. It was found that this was best resolved by decreasing the base curve radius to provide minimal to moderate apical clearance. Contrary to conventional rigid gas permeable lens fitting (apical clearance of 10-15 microns) the SynergEyes team concluded that an apical clearance range of 25-40 microns provided optimal comfort and lens fit.

Skirt Radius

Selection of the skirt radius was also refined during this stage of the trial. The wide diversity of corneal diameters proved to make the skirt selection a bit more challenging as larger corneas have greater sagittal depths then smaller corneas. Of the two skirt radii utilized in this stage it was concluded that larger corneas require the steeper skirt (1.0mm) while smaller corneas were better fit with the flatter of the two skirts (1.3mm). These discoveries provided the necessary information for the initial construction of the SynergEyes lens calculator.

Insertion and Removal

Most evaluations of hard gas permeable lenses are performed with sodium fluorescein under the lens to properly detect apical clearance and other fitting parameters. However, since the SynergEyes lens has an outer soft lens skirt, a high molecular weight sodium fluorescein solution must be placed in the back surface of the lens prior to insertion.

Proper insertion then includes having the patient lean forward with head in a downward position looking into a mirror. The patient then assists in the insertion by holding their upper lid while the researcher pulls the lower lid to widen the palpebral fissure. It is important to create a large palpebral separation since the lens is such a large diameter. Due to the high weight and large diameter, it is best to balance the lens between the index and middle fingers. The patient is instructed to focus at his or her own image in the mirror while the lens is inserted directly onto the cornea.

Removal of the lens is most safely completed by having the patient look slightly upwards while the researcher pinches the lower portion of the soft skirt between the thumb and index finger and then slides the lens off of the eye in a downward motion.

STAGE 2: Eight-hour on eye trial

A second clinical evaluation was conducted with additional approval from the Investigational Review Board (IRB) at Pacific University College of Optometry.

Subject Selection

During this stage of the evaluation, four subjects were selected using flat keratometry measurements, HVID, and manifest spectacle prescription. For exact measurements on each subject see Table 2 below.

Table 2 – Individual data collected for four Stage 2 subjects

	AW	CE	RS	CG
Keratometry				
OD	44.25	42.75	44.37	45.00
OS	44.50	42.62	44.25	44.50
HVID (mm)				
OD	11.6	11.4	11.2	11.5
OS	11.6	11.4	11.2	11.5
Spectacle Rx				
OD	-2.50 DS	-1.50 DS	-1.75 - 0.25 X 005	Plano DS
OS	-2.50 DS	-1.25 DS	-1.75 - 0.25 X 180	Plano DS

Methods

The subjects were scheduled to be fit with the SynergEyes lenses on days when they could conveniently comply with an 8 hour wearing schedule. Subjects were fit binocularly for each trial.

A computer-based calculator was developed by the SynergEyes team, which utilizes HVID and keratometry measurements to compute the optimum lens base curve and skirt radius. When the manifest refraction is entered, the calculator also gives the necessary lens power.

Based on each of the subject's corneal measurement the calculator assigned a base curve radius and the skirt radius for both eyes. Initially the flatter 1.3mm skirt was recommended for both eyes. However, in order to have the ability to compare skirt radii the left eye was fitted with the steeper 1.0mm skirt.

Upon insertion of each lens, the on eye fit was video recorded using a biomicroscope. At this time topography measurements over each lens were also taken. At the conclusion of the eight-hour wearing schedule the lenses were again video documented and then removed. Following removal, additional topography measurements were taken to look for any lens induced corneal distortions. Any such distortion was rated on a scale of 1 to 5 with 1 being a faint lens induced ring, and 5 being a significant ring.

Results

Each patient provided an initial comfort rating of 5 (no lens awareness) for the lens with the steeper (1.0mm) skirt that was placed on the left eye. Two of the four subjects also rated the comfort as 5 of the flatter skirt (1.3mm) lens on the right eye. The other two patients gave ratings of 3 (good comfort).

Following the eight-hour wear schedule the comfort rating of the left lenses was 4 or 5. The right eye lens comfort was rated as 4 or 5 by three of the 4 subjects, and as 2 (slight lens awareness) by the fourth subject.

After the wearing schedule all four patients had residual rings rated from 1 to 4 as shown on topography images (See table 3). It was found that the ring appeared less with the steeper (1.0mm) skirt.

Table 3 – see next page

Table 3 (Part A) – Results of the eight hour wearing schedule

	AW		CE	
	Right Eye	*Left Eye*	*Right Eye*	*Left Eye*
SynergEyes Calculator	7.40 / 8.7	7.30 / 8.6	7.60 / 8.9	7.60 / 8.9
Dispensed Lens	7.30 -3.50 14.5 **8.6 skirt** (Calculator Lens)	7.30 -4.00 14.5 **8.3 skirt**	7.60 -2.75 14.5 **8.9 skirt** (Calculator Lens)	7.60 -2.50 14.5 **8.6 skirt**
Lens Comfort at Dispensing	5	5	5	5
Lens Fit at Dispensing:				
Lens centration	Good	Good	Good	Good
Apical relationship	3	2	3	3
Lens movement	0.25 mm	0.25 mm	0.25 mm	0.25 mm
Lens Comfort at Eight Hour Follow-up	5	5	4	4
Lens Fit at Eight Hour Follow-up:				
Lens centration	Good	Good	Good	Good
Lens movement	0.25 mm	0.25 mm	0.25 mm	0.25 mm
Post Removal Ring	Yes 4 +	*Yes 2 +	Yes 4 +	*Yes 3 +

* The ring appeared slightly less with the steeper skirt (the 1.0mm skirt)

Table 3 (Part B) – Results of the eight hour wearing schedule

	RS		CG	
	Right Eye	*Left Eye*	*Right Eye*	*Left Eye*
SynergEyes Calculator	7.40 / 8.7	7.40 / 8.7	7.30 / 8.6	7.30 / 8.6
Dispensed Lens	7.30 -3.25 14.5 **8.6 skirt** (Calculator Lens)	7.30 -3.25 14.5 **8.3 skirt**	7.6 -0.50 14.5 **8.6 skirt** (Calculator Lens)	7.6 -0.50 14.5 **8.3 skirt**
Lens Comfort at Dispensing	3	5	3	5
Lens Fit at Dispensing:				
Lens centration	Slightly Low	Slightly Low	Good	Good
Apical relationship	4	4	4	4
Lens movement	Minimal (slightly tight)	Minimal (slightly tight)	0.25 mm	Minimal
Lens Comfort at Eight Hour Follow-up	2	5	**4	**4
Lens Fit at Eight Hour Follow-up: Lens centration	Good	Good	Good	Good
Lens movement	0.25 mm	Minimal (slightly tight)	0.25 mm	Minimal
Post Removal Ring	Yes 2 +	Yes 2 +	Yes 1 +	Yes 1 +

**Subject reported slight dryness OU – subject has a history of dryness with all soft contact lenses.

Case Example

This patient example is provided in order to provide a more complete look at how the SynergEyes lens is properly fit from start to finish. Patient CC is a 20 year old college baseball player with professional baseball aspirations. The patient has moderate myopia and astigmatism and has failed to achieve adequate visual acuities with soft toric contact lenses. Based on this patient's visual demands and previous history with contacts, it was decided to trial this patient in the SynergEyes hybrid design.

Initial examination revealed the findings as listed below:

Manifest Refraction	VA:
OD: -4.50 – 1.25 x 175	20/15
OS : -3.75 – 1.25 x 180	20/15

Keratometric measurements (See Figure 1):	HVID:
OD: 43.87 @ 175 / 45.37 @ 085	12
OS : 43.75 @ 178 / 45.37 @ 088	12

Figure 1
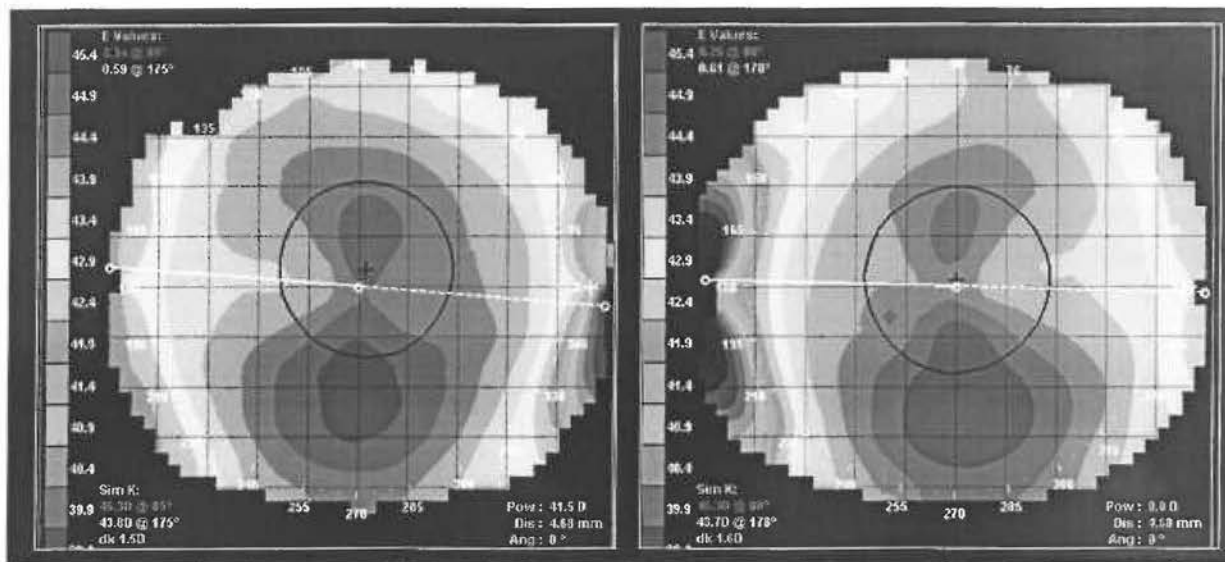
Next, these measurements were conveniently entered into the SynergEyes A Lens Calculator to obtain the initial trial lens. The calculator selected these lens parameters (a screen image of the calculator is provided):

Recommended SynergEyes A lens (See Figure 2):

	Base Curve	Power	Skirt Radius
OD:	7.5	-4.25	8.50
OS:	7.5	-4.00	8.50

Figure 2

SynergEyes™ A Lens Calculator   Version1.4   synergeyes

Keratometry: D.Merz, 25-Aug-2005

	Horizontal			Vertical			Select
OD	43.75	@	175	45.50	@	085	⊙ Diopters
OS	43.75	@	178	45.37	@	088	○ mm

Clear all

Manifest Refraction: HVID :

OD	Sph	-4.00	Cyl	-1.25	Axis	180	12
OS	Sph	-3.75	Cyl	-1.25	Axis	180	12

Recommended SynerEyes A Lens :   Calculated Residual Astigmatism

OD	Base Curve	7.5	Power	-4.25	Skirt Radius	8.50	-0.25	x	017
OS	Base Curve	7.5	Power	-4.00	Skirt Radius	8.50	-0.50	x	005

Notice that the calculator selected a base curve of 7.5 which is about 0.20mm steeper than the flat keratometric measurement (43.75D would be a radius of 7.71 mm). The clinical trials have shown that the base curve of the SynergEyes lens be slightly steeper than flat K in order to allow the lens to cornea apex, thus providing the proper 25-40 microns of apical clearance. This lens to corneal relationship also helps to avoid late onset tightening that was commonly seen with more alignment fitting relationships.

Pictures of the fluorescein pattern as seen with slit lamp evaluation are provided for each eye (See figures 3-6). Note the amount of apical clearance as shown by the solid green fluorescence under the center of the lens. Also note here that the lens is not too steep as would be indicated by a bubble under the lens or decreased movement of the lens.

Further it should be noted that the recommended skirt radius is the steeper of the two standard skirts (1.0 mm flatter than base curve in this case as compared to 1.3 mm flatter). For this patient with a larger HVID the steeper (1.0mm) of the two skirts has been shown to be the skirt of choice, whereas smaller diameter corneas are best fit with the flatter (1.3mm) skirt.

With these lenses in place patient CC was able to achieve consistent 20/15 acuity and comfortably wears the SynergEyes lenses 16 hours a day.
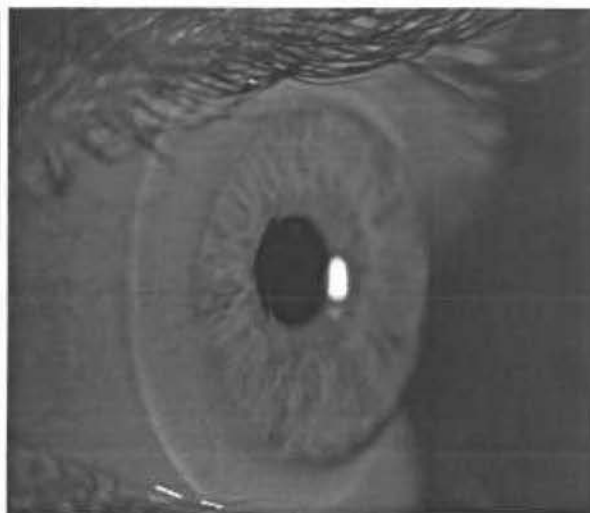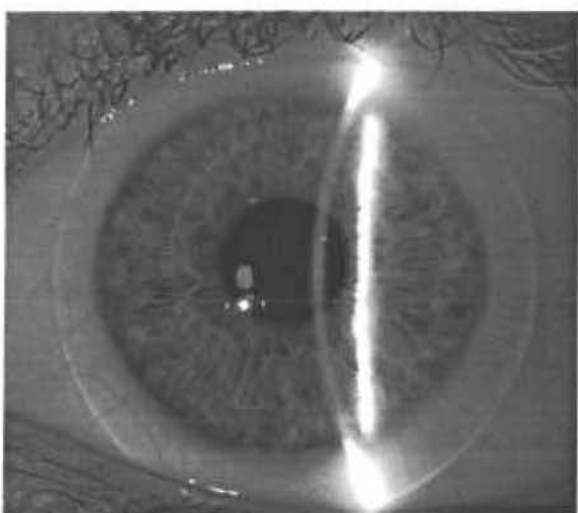
Figure 3 - Right Eye fluorescein pattern

Figure 4 - Left Eye fluorescein pattern
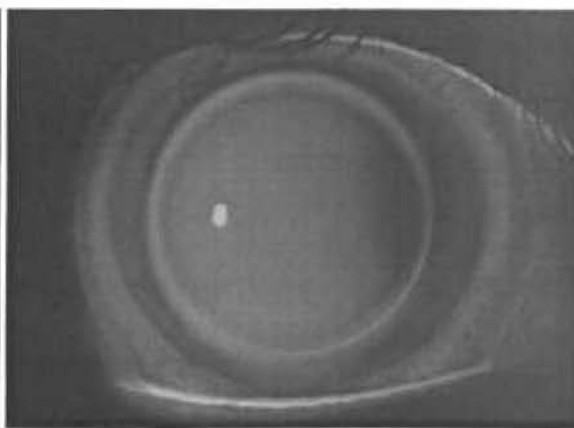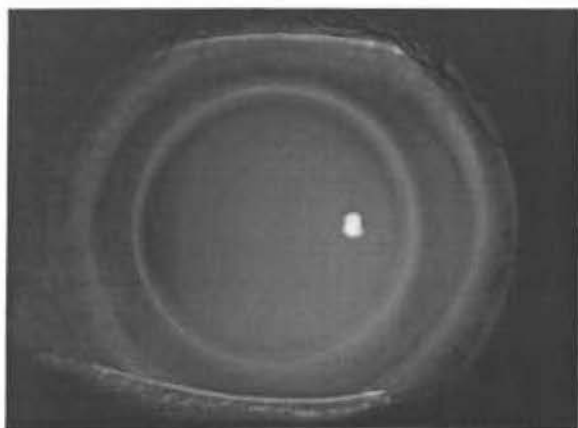
Figure 5 - Right eye Lens appearance

Figure 6 - Left Eye Lens Appearance

Conclusion

The purpose of this trial was to discover the on-eye fitting relationship of the SynergEyes A lens design. Two stages of this clinical trial were completed from which a fitting model was constructed based on two things: the sagittal depth (otherwise called corneal apical clearance) within the center of the rigid portion of the lens, and the skirt radius of the lens.

In the initial stage of the study the investigators made observations of late onset tightening when the lenses were fit on flat K. It was discovered that this could be resolved by decreasing the base curve radius to produce a steeper fit. The optimal corneal apical clearance of 30 microns was achieved by placing a lens on the eye that had a base curve 0.50 D steeper than flat K measurements. From these observations a fitting calculator was developed by the SynergEyes team that computes the nearest SynergEyes A lens base curve to produce the desired range of 25 to 40 microns of apical clearance.

Further analysis of the two standard soft skirt radii also was conducted to further refine the proper fit and calculator definitions. Of the two skirt radii used in the clinical trial, 1.0 mm and 1.3 mm flatter than the base curve radius, it was demonstrated that larger corneas required the steeper skirt (1.0), while smaller corneas performed better with the 1.3 mm skirt.

From both findings of optimal apical clearance and proper skirt radii selection, a final calculator was developed. The "SynergEyes A lens calculator version 1.4", uses keratometry and horizontal visible iris diameter (HVID) measurements to determine the optimum starting lens for most patients. The calculator also provides the power of the starting lens when the manifest refraction is entered. Through further clinical trials of the SynergEyes A lenses, the calculator can be adjusted if future data shows a need for a different starting point.

The Future of the SynergEyes lens

The SynergEyes A lens received FDA approval in September of 2005. This design is to be primarily used for fitting patients who are good candidates for hard lenses but desire the fitting comfort of a soft lens. This design has also been found to be successful in managing patients with early keratoconus and post surgical corneas.

Two additional designs will be available in the future. The SynergEyes KC lens, which totes an aspheric design, has been specifically designed for moderated to advanced keratoconus patients and for managing post-LASIK ectasia. The third design, SynergEyes PS, incorporates a flatter radius of curvature in the center of the RGP lens and a steeper curve in the mid-peripheral radius. This lens is planned to be best utilized to manage patients with highly oblate corneas following refractive or corneal transplant surgery.

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