

REFRACTIVE EYECARE[®]

SPECTACLES, CONTACT LENSES, AND CORNEAL AND LENTICULAR REFRACTIVE SURGERY FOR PRACTICE GROWTH

The Dance of Design: Prescribing the SynergEyes[™] Contact Lens

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SynergEyes hybrid lenses offer practitioners the ability to fit a very large range of corneas with a lens that offers soft lens comfort and rigid lens optics.

There are two diametrically opposed approaches to contact lens product development. One has as its end the manufacturer's dream of making millions of similarly designed lenses that are able to fit a wide continuum of eyes with a single set of parameters. Success is achieved by selection of a material modulus, base curve radius, and overall diameter that straddles the distribution of corneal curvatures and diameters. Lenses of this type, when well

Success with this approach requires that the practitioner has an interest in learning novel methods of prescribing. The new SynergEyes[™] high-Dk hybrid lens is an example of a product developed by this second approach.

Form Follows Function

In September 2001, a California-based research group began development of a new high-Dk hybrid lens called SynergEyes. The lens incorporates a high-Dk rigid center (Paragon HDS[®] 100, Dk 100) and a 27% water nonionic soft lens skirt. The overall diameter of the lens is 14.5 mm.

The central (rigid) portion of the SynergEyes lens has a diameter of 8.4 mm, large enough to eliminate optical flare in unoperated ametropic eyes, even those with large pupils.

The RGP diameter also provides adequate clearance above penetrating keratoplasty wounds as well as the midperipheral "knees" and microkeratome flap irregularities that can be sequelae of refractive surgery. Additionally, in the SynergEyes lens the thickness of the RGP portion is carefully controlled across the full power range to eliminate lens flexure.

The soft skirt is an FDA group 1 (low water; non-ionic) material selected to control expansion in the manufacturing process and to be low soiling and dimensionally stable while worn as a prescribed-replacement product. An overall diameter of 14.5 mm provides on-eye stability and ease of lens re-

moval with customary techniques.

One of the most important features of the SynergEyes product is the availability of multiple skirt curve radii for

FITTING THE SYNERGEYES A LENS

- Measurements
 - HVID
 - Keratometry
 - Manifest refraction
- Enter measurements into calculator
- Calculator selects power, base curve, and skirt radius
- For unoperated eyes, calculated lens can be ordered empirically
- For irregular/operated eyes, use trial lens set
- When calculator calls for 0.7- or 1.6-mm flatter than base curve skirts
 - Try 1.0 or 1.3 mm flatter skirt first
 - If 1.0- or 1.3-mm flatter skirt fits well and is comfortable, order it
 - If 1.0-mm flatter skirt fits poorly, order 0.7-mm
 - If 1.3-mm flatter skirt fits poorly, order 1.6-mm

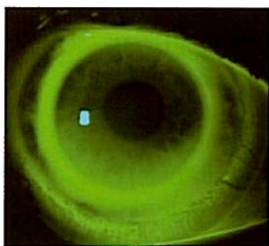


FIGURE 1A The SynergEyes A lens in an alignment fit.

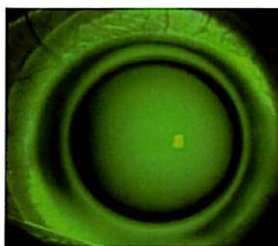


FIGURE 1B The SynergEyes A lens in an apical clearance fit.

manufactured with good edges and optics, are relatively easy to fit.

The second approach is more challenging for both the manufacturer and the fitter, but it enables the practitioner to fit a broader spectrum of eyes and to do so in a customized fashion.

each central rigid base curve. In addition to the strong bond of the RGP and soft material, the ability to vary the skirt radius independent of the base curve significantly differentiates SynergEyes from its hybrid predecessors. This feature sets the stage for the methods used for successful prescribing.

Keratometry and Corneal Diameter

Our work with SynergEyes commenced after the FDA clinical trials

were completed. We studied the successful fits in the FDA clinical trials and constructed a fitting model based on two things: the sagittal depth within the rigid portion of the lens and the overall sagittal depth. In each patient we compared the sagittal depth of the eye to sagittal depth of the lens at two reference chord diameters: the optic zone diameter of the rigid center (ie, 7.8 mm), and the diameter just within the peripheral bevel.

We developed our model to achieve apical clearance within the rigid optical zone and greater overall sagittal depth than the eye over the diameter of the lens. This model was established based on observations made during the FDA clinical trial.

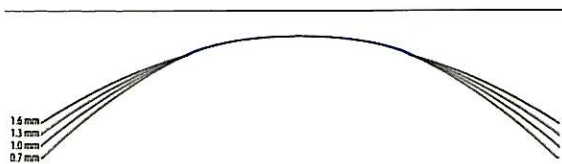


FIGURE 2 Four skirt radii of curvature are available for each base curve of the SynergEyes A lens. As a rule, smaller eyes require flatter skirts.

In the clinical trial, fitters had been encouraged to use an alignment fit. Many of the eyes were fit on K or slightly flatter than K. The 12 clinical investigators made the interesting observation of late onset tightening with alignment fits and the discovery that they could resolve this by (paradoxically) decreasing the base curve radius to produce a steeper fit.

Minimal-to-moderate apical clearance resolved the late-onset tightening (Figures 1A and 1B). The mechanism for decreased movement with the previous fitting philosophy appears to be the GP lens center's tendency for excessive alignment with the underlying cornea. This realization helped us determine an optimum starting point for empirical calculation of the base curve radius; our model uses the flat keratometry value, an average eccentricity of 0.5, and an optimum apical clearance of 30 microns. We then developed a cal-

culator that computes the nearest SynergEyes base curve that falls in the desired range of 25 to 40 microns of apical clearance.

Skirt Radius

That part was easy and straightforward. The selection of skirt radius was a bit more challenging. The SynergEyes design team discovered the need for multiple skirt radii to accommodate the range of sagittal height differences caused by the fact that different eyes can have the same keratometry measurements but different corneal diameters. Corneal diameter contributes significantly to the overall sagittal depth of an eye, and eyes with larger corneas have significantly greater depth than those with smaller corneas.

Two skirt radii were used in the FDA clinical trial; these were 1.0 and 1.3 mm flatter than the base curve radius. The 1.3-mm flatter skirt was the recommended starting point.

Outcomes data demonstrated that larger corneas required the steeper skirt (1.0 mm flatter), while smaller corneas did well with the 1.3-mm flatter skirt. We conducted additional clinical evaluation (with IRB approval) at Pacific University in a non-dispensing, 8-hour-wear protocol that aimed to determine the optimum overall sagittal depth of a SynergEyes lens.

The subjects were pre-selected to have a wide range of corneal diameters and keratometry measurements, thus giving us data from a wide distribution of corneal geometries. We found the optimum overall sagittal depth of the SynergEyes lens is 250-400 microns greater than the sagittal depth of the eye on which it is fit. While holding the base curve radius, optic zone diameter, and overall diameter constant, the skirt radius can be modulated to provide the optimum overall sagittal depth.

We also discovered that 74% of

eyes (in a 386-eye sample) having known keratometry and corneal diameter measurements could be fit with skirt curve radii that are 1.0 and 1.3 mm flatter than the base curve radii. Lenses for the remainder of the eyes would require a skirt radius of 0.7 or 1.6 mm flatter than the base curve radius (Figure 2). In other words, extremely small eyes would require the skirt radius to be 1.6 mm flatter than the base curve to keep the overall sagittal depth from being too deep and, conversely, extremely large eyes would require a skirt radius only 0.7 mm flatter than the base curve radius to make the overall sagittal depth of the lens deep enough.

We helped the SynergEyes team develop a lens calculator that uses the keratometry and horizontal visible iris diameter (HVID) measurements to determine the optimum starting base curve and skirt radius (Figure 3). When the manifest refraction is entered, the calculator also gives the necessary lens power. This calculator was developed as an "intelligent" system that allows upgrades to be produced as additional data becomes available. Our current assumed values for apical clearance and overall sagittal depth, for example, can be adjusted if the data from future fits shows that to be desirable.

Simplicity Is Advantageous

The SynergEyes A diagnostic set includes two series of 12 base curves, from 7.10 to 8.20 mm; one series has the 1.0-mm flatter skirt radius and the other has the 1.3-mm flatter skirt radius. While the lens calculator may suggest the need for a 0.7- or 1.6-mm flatter skirt radius, we suggest first trying the nearest skirt radius in the set. Thus, for example, if a 0.7-mm flatter skirt is indicated, start with a 1.0-mm flatter skirt. If the lens is placed and has good on-eye appearance, one should certainly consider ordering the 1.0-mm flatter skirt. If, on the other hand, fluting in the lens skirt is observed with the 1.0-mm flatter skirt, the 0.7-mm flatter skirt is needed.

Conversely, if a 1.6-mm flatter skirt is calculated, the 1.3-mm flatter skirt should be tried first. If it appears to have appropriate eye fit and good comfort, one should consider ordering the 1.3-mm flatter skirt. But if there is scleral impingement (a sign that the lens is too deep), the 1.6-mm flatter skirt will be required. We suggest using concept of “earning complexity” as a mnemonic. First attempt to fit eyes with the 1.0- or 1.3-mm flatter skirts; an eye can “earn” the 0.7- or 1.6-mm flatter skirt by demonstrating the need for it in the trial fit with diagnostic lenses.

Measuring Corneal Diameter

We believe that HVID is an important measurement for a number

Because there is a relationship between keratometry measurements and HVID, we strongly recommend taking this measurement with each eye. If that is not possible, however, a second calculator is available that assumes a default HVID value based on the flat keratometry measurement.

The SynergEyes A Fitting System

The SynergEyes family of lenses is among the first that can be empirically fit using technology-based measurements. The fitting system makes use of a lens calculator that incorporates both keratometry and HVID measurements. The calculator will suggest a starting lens based on optimum apical clearance and over-

all sagittal depth targets. For practitioners who will use the SynergEyes A lens primarily on unoperated eyes with naturally occurring refractive errors, the calculator allows ordering empirically, refinements can be made thereafter, if needed.

Practitioners who anticipate fitting a significant number of irregular eyes should consider having the SynergEyes diagnostic set in the office. The SynergEyes A design has been found to be

This will be followed by the SynergEyes PS, a design that incorporates a flatter radius of curvature in the center of the RGP lens and a steeper curve in the mid-peripheral radius. This lens has been designed specifically to manage patients with highly oblate corneas following refractive or corneal transplant surgery.

THE BOTTOM LINE

The SynergEyes lens has the advantages of rigid lens optics and soft lens comfort, without the disadvantages (low Dk, and skirt dehiscence) of prior-generation hybrid lenses. The lens has a very high-Dk, 8.4-mm rigid gas permeable optic in the center and a nonionic, low water content hydrogel skirt. The overall diameter is 14.5 mm. To optimize fit, the new SynergEyes A lens series offers a choice of four radii of curvature for the skirt and 12 base curves for the rigid optic zone. A calculator allows the lenses to be fit empirically on unoperated eyes with naturally occurring refractive errors. For operated and other highly irregular eyes, a fitting set allows trial fitting. In the future, new SynergEyes designs will be available for patients with keratoconus or transplanted eyes, as well as for presbyopes and eyes that have had myopic refractive surgery.

SynergEyes™ A Lens Calculator Version 1.5				synergeyes	
Keratometry:					
	Horizontal	Vertical		Select	
OD	44.00 @ 180	45.00 @ 090		Diopters	Clear all
OS	43.75 @ 180	44.75 @ 090		mm	
Manifest Refraction:					
OD	Sph -3.00	Cyl -1.00	Axis 180	HVID:	11.8
OS	Sph -2.75	Cyl -0.75	Axis 180		11.8
Recommended SynergEyes A Lens:					
OD	Base Curve 7.5	Power -4.00	Skirt Radius 8.80	Calculated Residual Astigmatism	+0.00 x 135
OS	Base Curve 7.6	Power -3.25	Skirt Radius 8.90		-0.25 x 090

FIGURE 3 The SynergEyes A lens calculator (shown) allows empirical lens selection in unoperated eyes. When manifest refraction, HVID, and keratometry data is entered, the calculator provides the base curve, lens power, and skirt radius.

of contact lens applications. Ideally, the HVID should be measured to an accuracy of approximately 0.2 mm. One of the ways to measure HVID is at the slit lamp with an eyepiece reticule. Another is the use of the measurement feature in one's corneal topographer. SynergEyes has an apparatus in development that will support the practitioner in HVID measurement.

successful in managing patients with early keratoconus and post surgical corneas in which there is minimal topographical difference between the central and mid-peripheral cornea.

In the future, two additional fitting systems will be available. The first will be the SynergEyes KC, an aspheric lens that has been designed specifically for moderate to advanced keratoconus and managing post-LASIK ectasia.

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