SynergEyes post-refractive contact lens fitting

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Abstract
Purpose: To evaluate the fitting characteristics of SynergEyes PS hybrid contact lenses in post-refractive patients and how to adjust the parameters for the best possible fit. Four cases are presented demonstrating the fitting characteristics and comfort of the SynergEyes PS hybrid contact lenses. The lenses are designed with reverse geometry to better match the changes in corneal curvature following refractive surgery.

Methods: Baseline corneal topographies of each of the subjects were taken. From these topographies, only 4 of 12 subjects were fitted with the lenses based on the amount of ablation from the refractive procedure. These 4 subjects were fitted with different parameters of the SynergEyes PS hybrid contact lenses and evaluated on a number of fitting characteristics. Comfort upon initial instillation and after 8 hours of wearing time was also evaluated.

Results: The cases all demonstrated the need to steepen the base curve of the lenses at least 1.0 diopter more than the flat keratometric reading to create appropriate movement of the lenses after an eight hour trial. All patients felt that the lenses were reasonably comfortable throughout the trial.

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SYNERGEYES
POST-REFRACTIVE
CONTACT LENS FITTING

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A thesis submitted to the faculty of the College of Optometry
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Biographies

Brendan Kelly grew up in Lisbon, ND, and earned his BS degree in zoology from North Dakota State University in Fargo, ND. He is currently attending Pacific University College of Optometry. Upon graduation in May of 2007, he plans on moving back to the Midwest somewhere to practice.

Rebecca Schuller received her Bachelor of Science in Biology from Dordt College. She is currently in her final year at Pacific University College of Optometry where she is pursuing a degree in optometry. Upon completion of the program, she plans on moving to Minnesota to practice optometry in either a private or group optometric practice.

Maggie Suby grew up in Fargo, ND, and earned her BA degree in biology from Gustavus Adolphus College in St. Peter, MN. She is currently attending Pacific University College of Optometry. Upon graduation in May of 2007, she plans on moving to Denver, CO to work at a LASIK eye center.

Eric Torgerson received his Bachelor of Science in Biology with a minor in Anatomy and Neurobiology from Colorado State University. He is currently in his final year at Pacific University College of Optometry where he is pursuing a degree in optometry. Upon completion of the program, he plans on joining his father in a family owned primary care practice in Fort Collins, Colorado.
Abstract

Purpose: To evaluate the fitting characteristics of SynergEyes PS hybrid contact lenses in post-refractive patients and how to adjust the parameters for the best possible fit. Four cases are presented demonstrating the fitting characteristics and comfort of the SynergEyes PS hybrid contact lenses. The lenses are designed with reverse geometry to better match the changes in corneal curvature following refractive surgery. Methods: Baseline corneal topographies of each of the subjects were taken. From these topographies, only 4 of 12 subjects were fitted with the lenses based on the amount of ablation from the refractive procedure. These 4 subjects were fitted with different parameters of the SynergEyes PS hybrid contact lenses and evaluated on a number of fitting characteristics. Comfort upon initial instillation and after 8 hours of wearing time was also evaluated. Results: The cases all demonstrated the need to steepen the base curve of the lenses at least 1.0 diopter more than the flat keratometric reading to create appropriate movement of the lenses after an eight hour trial. All patients felt that the lenses were reasonably comfortable throughout the trial.
Introduction

For the past thirty years visual scientists from around the world have struggled with the challenge of surgically correcting human refractive error. While great strides have been made in recent years, the nature of ocular surgery, and its inherent complications, has left in its wake a growing number of patients with suboptimal visual results. For a number of these patients, contact lenses may provide the best means for visual correction and restoration of binocular vision (McDonnell et al. 1989, Szczotka 2001).

Throughout the evolution of refractive surgery many experimental and poorly understood procedures have been attempted on millions of patient eyes. While some patients have obtained successful outcomes, others have been left with permanently scarred and/or irregular corneas. More recent surgical procedures such as photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) have provided improved outcomes however, in a study by Stulting et al. in 1999, involving 14 surgeons and 1062 eyes, 4.8% of the eyes lost 2 or more lines of best spectacle corrected visual acuity.

Since 1999, in the United States alone, approximately one million people per year have undergone refractive surgery. If 3% of these patients are experiencing significant postoperative visual problems, this represents 30,000 patients a year. When this number is added to the previous 25 years of pre-existing refractive surgery failures, the pool of potential patients requiring post surgical contact lens correction is significant.
Laser procedures such as LASIK are tissue subtraction techniques in which an argon-fluorine excimer laser is used to sculpt the cornea into a new shape. The high energy ultraviolet light (193 nanometers) is delivered to the cornea through a pulsating spot or slit. A single pulse of focused light enters the corneal tissue and within 1 picosecond the intermolecular bonds (holding the tissue together) are broken. The intense build up of energy and pressure ejects the fragmented tissue off the surface of the cornea and then the pulse terminates. Repeated laser pulses ablate the corneal tissue to allow a remodeling of the corneal shape to correct myopia, hyperopia, and astigmatism or presbyopia Seiler et.al. (1992). Today, LASIK has evolved to become the most commonly performed refractive procedure throughout the world. The principle indication for post surgical contact lenses is residual refractive error that includes undercorrection, overcorrection, and residual or induced astigmatism. Other less common indications include decentered ablations, central islands, and keratectasia.

The post LASIK corneal topography is hallmarked by a flattened central cornea over a cord of 5 to 7 mm. This ablation area is surrounded by a 0.5 to 1.5 mm zone that transitions the treated portion of the cornea into the normal untreated mid-peripheral cornea. However, as with all surgical procedures, intraoperative and postoperative complications can compromise the depth, position and contour of the ablation zone.

In the case where a contact lens is considered necessary, it is important to delay any lens fittings until the cornea has completely epithelialized and the refractive error is stable. In the case of LASIK, epithelialization is usually completed within one week. However, the refractive error and corneal topography may not stabilize for six weeks. At
this point the integrity of the cornea and the flap interface is usually sufficient to withstand the minor trauma associated with contact lens wear.

The History of Hybrid Lenses

For many clinicians, the ultimate modality for managing irregular astigmatism has been a lens that combines the vision correcting attributes of a rigid GP, and a soft peripheral skirt to provide comfort and centration. Surprisingly, the history of these lenses dates back almost 30 years to 1977 when Precision-Cosmet, in Minneapolis, acquired the rights to a rigid-soft bonding technology developed by Erickson and Neogi. This eventually evolved into the first commercially available hybrid lens, the Saturn II, released in 1985. This lens incorporated a 6.5 mm monocurve, styrene based center called the Opus III, which had a nominal Dk of 14. The soft skirt was a 25% water content HEMA material.

The hybrid technology was then sold to Sola-Barns Hind, and in 1989 they released an improved hybrid lens design called SoftPerm. The diameter of the Opus III center was increased from 6.5 mm to 8.0 mm and the rigid lens was manufactured in a biconvex design. The soft peripheral skirt remained unchanged, a 25% water HEMA based material. In the 1990’s the SoftPerm design and its patents were sold to Wesley Jesson and ultimately acquired by Ciba Vision.

Advances in Hybrid Technology

In 2001, a California based research group began development of a new high Dk hybrid lens that today is called SynergEyes. The new lens incorporates a high Dk rigid center, (Paragon HDS 100, Dk 100) with a 31% water non-ionic soft lens skirt. The overall lens diameter is 14.5 mm. The lenses are manufactured with an advanced binding
technology and state-of-the-art production techniques for improved lens durability and quality control. And, unlike previous generations of hybrid designs, the lenses are available with multiple soft skirt radii that can be independently varied from the base curve.

**Materials**

The present study was designed to evaluate the fitting techniques and comfort of the SynergEyes PS hybrid lens. The SynergEyes® PS contact lens is a non-FDA approved, daily wear, combination (hybrid) contact lens that is rigid in the center and soft in the periphery. The central (8.4 mm) rigid portion of the lens is manufactured from Paragon HDS® 100 (paflufocon D) and the peripheral soft skirt (14.5 mm) is manufactured from a 31% water poly-HEMA material.

**Methods**

The protocol for this study was submitted to and approved by the IRB of Pacific University. All twelve of the initial screened subjects met the inclusion criteria for our study. The inclusion criteria were as follows: Subjects may be male or female, of any race, and at least 18 years old at the time of the initial, baseline examination. The ametropic prospective eye(s) may have refractive myopia from -0.25 D to -12.00 D or hyperopia from +0.25 to 6.00 D sphere (spectacle plane), with up to -6.00 D of refractive astigmatism (spectacle plane), as determined by manifest refraction (phoropter or trial frame with a 12.5 mm vertex distance). Subjects must have had PRK, RK, LASIK, LASEK, or other forms of refractive surgery in one or both eyes. Subjects must have willingness and capability to participate in the fitting
visit for the designated amount of time. Selected subjects may elect to undergo dispensing of the lenses following the study.

The exclusion criteria were as follows:

- Female subjects who were pregnant, breast-feeding or intend to become pregnant over the course of the study.

- Subjects with a history of any of the following medical conditions: collagen vascular disease, auto-immune disease, immunodeficiency diseases, ocular herpes zoster or simplex, endocrine disorders (including, but not limited to active thyroid disorders and diabetes), lupus, and rheumatoid arthritis.

- The presence of diabetes (either type 1 or 2), regardless of disease duration, severity, or control.

- Subjects with a history of active ophthalmic disease or abnormality (including, but not limited to, blepharitis, recurrent corneal erosion, dry eye syndrome, neovascularization > 1mm from limbus), clinically significant lens opacity, clinical evidence of trauma (including scarring), or with evidence of glaucoma or propensity for narrow angle glaucoma as determined by gonioscopic examination in either eye. This included any person with open angle glaucoma, regardless of medication regimen or control.

- Subjects with an IOP greater than 21 mm Hg at baseline.

- Subjects who are participating in any other clinical trial (FDA or other) that could adversely affect our results.
Twelve subjects were initially included based on these guidelines. Potential subject were then screened again with corneal topography to ensure the need for a reverse geometry lens based. A 2.0 diopter difference between ablation zone curvature and peripheral curve was used. Only four of the twelve subjects had acceptable corneal topographies, therefore only four subjects were included in this study. Informed consent was obtained from all subjects.

At the initial fitting, subject’s refractive surgery history was obtained along with visual acuities, sphero-cylinder refraction, and Medmont topography maps. Subjects were fit with the SynergEyes PS lens based on central flat K readings from the topographer. Lenses were fitted steeper than K, on K, and flatter than K. Sodium fluorescein was instilled with the lenses and a slit lamp exam was performed followed by photographs and video to observe the movement of the lens. Subjects wore the lenses for an eight hour period. They returned for a follow-up after eight hours to assess the movement and fit of the lens through slit lamp and video. At this point we surveyed the subject to assess comfort levels with the lens for the eight hour period. Comfort was rated on a scale of 1-5, one being very uncomfortable to five being very comfortable. After the lens was removed, sodium fluorescein was instilled to check for corneal staining due to lens wear, and Medmont topography was repeated to check for corneal warpage changes.
Case One

Subject 1 is a 43-year-old female who had LASIK surgery in both eyes eight years previously. Her refractive error prior to surgery was approximately -5.00 diopters OU. She has not had any repeated surgery and reports no major problems with her vision now except for halos at night. We did one fitting with an 8 hour follow up visit on the same day.

Entering Acuities:
  OD: 20/20 +1
  OS : 20/20 +1

Sphero-Cylinder Refraction
  OD: +0.50 - 0.50 x 059  20/10 -2
  OS: +0.25 - 0.50 x 120  20/15

Topography: Attached

Ks From Topography:
  OD  41.00 @ 164
      40.50 @ 074
  OS  40.50 @ 150
      40.00 @ 060

Lens Parameters:
  OD: 8.1 BC (41.67D), 8.6 Pic (1.2D steeper than flat K)
  OS: 8.4 BC (40.18D), 8.6 Pic (on flat K)

Movement at fitting:
  OD: 0.50 mm
  OS: 0.25 mm

Movement at 8 hour follow up:
  OD: 0.40 mm
  OS: no movement
Discussion:

For the right eye of Subject 1, we chose a lens with a BC of 8.1, which is approximately 1.2 diopters steeper than flat K. Our findings showed that fitting 1.2D steeper than Flat K gave us good central pooling, 360 degree touch, and good movement at the time of fitting and at the eight hour follow up. Comfort of this lens was rated a 3 out of 5 at 8 hours.

On her left eye, we chose a BC of 8.4, which is approximately on flat K. Fitting on flat K gave very little central pooling with little movement at the time of fitting, and no movement at the eight hour follow up. Comfort for this lens was rated a 4 out of 5 at 8 hours.
Case 2

Subject 2 is a 23 year old female who had LASIK surgery in both eyes almost two years previously. Her refractive error prior to surgery was approximately -6.00 diopters OU. She has not had any repeated surgery and reports no major problems with her vision now. We did two separate fittings on subject 2, and each fitting had an 8 hour evaluation.

Entering Acuities:
OD: 20/20
OS: 20/20

Sphero-Cylinder Refraction
OD: Plano - 0.50 x 089 20/15
OS: +0.25 - 0.25 x 064 20/15

Topography: Attached

K’s from Topography:
OD: 40.20 @091
39.20 @001

OS: 40.40 @067
39.40 @157

First Fitting

Lens Parameters:
OD: 8.7 BC (38.79D), 8.9 Pic (0.5D flatter than flat K)
OS: 8.4 BC (40.18D), 8.6 Pic (0.6D steeper than flat K)

Movement at fitting:
OD: 0.125 mm
OS: 0.5 mm

Movement at 8 hour follow up:
OD: No movement
OS: No movement
Second Fitting

Lens Parameters:
  OD: 8.4 BC (40.18D), 8.6 Pic (1.0 D steeper than flat K)
  OS: 8.1 BC (41.67D), 8.6 Pic (2.2 D steeper than flat K)

Movement at fitting:
  OD: 0.75 mm
  OS: 0.5 mm

Movement at 8 hour follow up:
  OD: No movement
  OS: 0.5 mm
Discussion:

In our first fitting with Subject 2, we chose a lens for her right eye with a BC that was 0.5 D flatter than flat K. This fit gave little central pooling, very little movement at the time of fitting, and no movement at the 8 hour follow up. Comfort for this lens was rated a 4 out of 5 at 8 hours. We chose a lens for her left eye with a BC that was 0.6 D steeper than flat K. This lens gave a little better central pooling with good initial movement, but with subsequent no movement at the 8 hour fitting period. Comfort for this lens was rated a 5 out of 5 at 8 hours.

In our second fitting with Subject 2, we chose a lens for her right eye with a BC that was 1.0 D steeper than flat K. This lens gave good central pooling with good movement at the time of fitting, but no movement at the 8 hour follow up. We chose a lens for her left eye with a BC that was 2.0 D steeper than flat K. This lens gave good central pooling and good movement, both at the time of fitting and at the 8 hour follow up. Comfort for both of these lenses was rated a 4 out of 5 at 8 hours.
Case 3

Subject 3 is a 26 year old female who had LASIK surgery on both eyes 4 years prior. Her refractive error prior to surgery was approximately -7.00 diopters OU. She has not had any repeated surgery and reports complaints of dry eye since surgery. We did two separate fittings with 8 hour evaluations on Subject 3.

Entering Acuities:
OD: 20/25
OS: 20/25

Sphero-Cylinder Refraction
OD: + 0.50 - 0.75 x 084 20/20
OS: Plano - 0.75 x 086 20/20

Topography: Attached

K’s from Topography:
OD: 41.40 @106
    41.80 @016

OS: 41.80 @118
    42.40 @028

First Fitting

Lens Parameters:
OD: 8.1 BC (41.67D), 8.6 Pic (0.25 steeper than flat K)
OS: 7.8 BC (43.27D), 8.6 Pic (1.5D steeper than flat K)

Movement at fitting:
OD: 0.2 mm
OS: 0.5 mm

Movement at 8 hour follow up:
OD: No movement
OS: 0.5 mm
Second Fitting

Lens Parameters:
- OD: 7.8 BC (43.27D), 8.3 Pic (1.85D steeper than flat K)
- OS: 8.1 BC (41.67D), 8.6 Pic (0.15D flatter than flat K)

Movement at fitting:
- OD: 0.4 mm
- OS: 0.25 mm

Movement at 8 hour follow up:
- OD: 0.4 mm
- OS: no movement

No Pictures at this fitting

Discussion:
In our first fitting with Subject 3 we chose a lens for her right eye with a BC that was 0.25 D steeper than flat K. This gave little central pooling, little movement at the time of fitting, and no movement at the 8 hour follow up. We chose a lens for her left eye that was 1.5 D steeper than flat K. This lens gave good central pooling, with good movement at the time of fitting and at 8 hours. The subject rated the comfort for both of these lenses a 4 out of 5 at 8 hours.

In our second fitting, we chose a lens for her right eye with a BC that was 1.85 D steeper than flat K. This lens gave good central pooling, with good movement at the time of fitting and at 8 hours. Comfort for this lens was rated a 3 out of 5. We chose a lens for her left eye with a BC that was 0.15 D flatter than flat K. This lens gave no central pooling, with little movement at time of fitting, and no movement at 8 hours. Comfort for this lens was rated a 4 out of 5.
Case 4

Subject 4 is a 30 year old female who had LASIK surgery in both eye four years previously. Her approximate refractive error prior to surgery was -7.00 diopters OU. She has not had any repeated surgery and reports no major complaints with her vision except occasional halos at night. The curvature of her left cornea was not suitable to be fit with a reverse geometry style lens, so only the right eye was used for fittings. We did two separate fittings Subject 4’s right eye, both with 8 hour evaluations.

Entering Acuities:
   OD: 20/20
   OS: 20/20

Sphero-Cylinder Refraction
   OD: -0.25 DS 20/20
   OS: -0.25 -0.25 x 180 20/20

Topography: Attached

K’s from Topography:
   OD: 41.00 @080
       40.20 @170

   OS: 42.60 @120
       41.80 @030

First Fitting

Lens Parameters:
   OD: 8.1 BC (41.67D), 8.6 Pic (1.45 D steeper than flat K)

Movement at fitting:
   OD: 0.5 mm

Movement at 8 hour follow up:
   OD: 0.5 mm
Second Fitting

Lens Parameters:
OD: 7.8 BC (43.27D), 8.6 Pic (3 D steeper than flat K)

Movement at fitting:
OD: 0.75 mm

Movement at 8 hour follow up:
OD: 0.5 mm

Discussion:
In our first fitting on Subject 4, we chose a lens for her right eye with a BC that was 1.45 D steeper than flat K. This lens gave good central pooling with good movement at the time of fitting and at the 8 hour follow up. Comfort for this lens was rated a 3 out of 5.

In our second fitting, we chose a lens for her right eye with a BC that was 3.00 D steeper than flat K. This lens gave excessive central pooling, but movement at time of fitting and at the 8 hour follow up was good. Comfort for this lens was rated a 3 out of 5.
Results

When deciding on lenses for each of our patients, we chose a lens based on flat K. Each of our studies showed the same trend. When fitting flatter than K, on K, or less than 1 D steeper than K, the lenses tended to tighten down at the 8 hour recheck even if they had good movement at the time of fitting. On the other hand, when we fit lenses that were more than 1 D steeper than flat K, all had good movement at the time of fitting and at the 8 hour recheck. The opposite of what would be expected happens: when steepening the BC, the lens actually loosens up and allows for more movement, while flattening the BC tends to tighten the lenses up. Therefore, we recommend fitting the SynergEyes at least 1 D steeper than flat K in order to get sufficient movement of the lens throughout the day.

Comfort didn’t seem to depend on how the lenses were fit. Fitting flatter than K, on K, or steeper than K all gave overall good comfort in our patients’ subjective responses. No corneal defects by sodium flourescein staining and no corneal warpage by repeated corneal topographies were noted after 8 hours of wearing these lenses on any of our patients.
Case #1
Case #2
References


