12-1999

Paflufocon B in reverse geometry design

Kelsey Ford
Pacific University

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Pacific University

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Abstract

The practice of Orthokeratology has been around since the invention of contact lenses. As techniques in manufacturing contacts have evolved, so have the results obtainable in Orthokeratology. The newer "reverse geometry" lenses have allowed practitioners to produce dramatic alterations in corneal curvature in a short period of time. This study was a prospective, multi-center, open-label, non-randomized study to determine the safety; efficacy and acceptability of a new reverse geometry lens design. Traditional orthokeratology lens designs have relied on spherical radii in the lens periphery to create the desired flattening effect. The study design incorporates a series of aspheric curves in the lens mid-periphery to permit better lens alignment with the aspheric peripheral cornea. All lenses will be manufactured in a FDA approved RGP lens material, Paflufocon B. The study will enroll 14 patients, all who are currently optometry students. Subjects must meet the eligibility as outlined in the investigational protocol. All patients will be fitted with the new lens design that is flatter centrally and steeper in the periphery. Scheduled follow-up examinations will be conducted at two weeks, one, two, and three months after dispensing. Additional visits will be conducted at eight, twenty-four, fortyeight, and seventy-two hours after the three-month visit to determine the half-life of the unaided visual acuity improvement. It is hypothesized that the lenses are safe and effective and accepted by the usual population to be treated, for the reduction of the magnitude of naturally occurring myopia with refractive astigmatism when used according to the protocol of the study.

Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

Roxanne Achong

Subject Categories

Optometry

Paflufocon B in Reverse Geometry Design

For Daily Wear in Myopia
And Myopia with Astigmatism

By

Kelsey Ford
Michael Joljart

A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon

For the degree of
Doctor of Optometry
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Advisors:

Roxanne Achong O.D.
Patrick Caroline C.O.T.

Biography Page

Kelsey Ford:

Kelsey Ford graduated from Colorado State University with a B.S. in Biological science with a minor in anatomy and neurobiology prior to entering Pacific University College of Optometry. Kelsey hopes to soon be in private practice with an emphasis on contact lenses.

Michael Joljart:

Michael Joljart graduated from the University of Alberta with a B.Sc. in Genetics prior to entering Pacific University College of Optometry. Michael hopes to join a private practice and provide low vision services along with a specialty in contact lenses.

Signature Page

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It is hypothesized that the lenses are safe and effective and accepted by the usual population to be treated, for the reduction of the magnitude of naturally occurring myopia with refractive astigmatism when used according to the protocol of the study.

Acknowledgments

The authors would like to thank the many people who have helped plan, organize and execute this project. First we would like to thank Pat Caroline and Dr. Roxanne Achong for their time and patience while teaching us how to be better clinicians as well as the methods for fitting these specialty contact lenses.

We would also like to thank Paragon for the lenses and the opportunity to work on such a great project.

This project would not have been possible without the use of the Forest Grove Family Vision Center and the equipment. We would also like to thank Launa Kind for her help in obtaining solutions and answering our never ending questions.

Thanks are also in order for our subjects who kept their schedules open for us.

Introduction

Reverse geometry lenses were first reported in the literature over ten years ago. The purpose of the design was lens centration and surface area equivalence while providing a central radius of curvature that was longer than the keratometric measured radius of the patient's cornea. Reverse geometry lenses were observed to provide better centration than conventional designs in cases of low corneal eccentricity and in cases where greater amounts of myopia were targeted for reduction.

The main objective of this study is to confirm the safety and effectiveness of the use of reverse geometry lenses in Paflufocon B material to treat myopia with refractive astigmatism. The purpose of the study is to determine the patient acceptance of the therapeutic procedure.

Methods

Subjects were included based on the following criteria:

1. Patients may be male or female, of any race, and at least 12 years old at the time of the pre-treatment exam.
2. The prospective eye(s) must have naturally occurring refractive myopia from –0.50 to –6.00 diopters sphere (spectacle plane), with up to –1.50 diopters of refractive astigmatism, as determined by manifest refraction. Patients must have spectacle corrected visual acuity of at least 0.04 logMAR in each eye.
3. The prospective eye(s) must demonstrate refractive stability, confirmed by clinical records. Neither their spherical nor the cylindrical portion of the manifest refraction may have changed more than 0.50 diopters during the twelve month period immediately preceding the baseline examination. The astigmatic axis may not vary by more than 15 degrees.
4. If the patient wears rigid contact lenses in the prospective eye(s), lens use must cease at least four weeks prior to the pre-treatment exam. The subject must have two central keratometry readings taken that are at least one week apart. The two readings shall not differ by more than 0.50 diopters in either meridian. The mires should be regular.
5. Patients must be willing and capable to return for all scheduled follow-up visits for a period of at least three months.

Exclusion Criteria

1. Female patients who are pregnant, breast-feeding or intend to become pregnant over the course of the study.
2. Patients with a history of any of the following medical conditions: collagen vascular disease, autoimmune disease, immunodeficiency diseases, ocular herpes zoster or simplex, endocrine disorders (including, but not limited to active thyroid disorders and diabetes), lupus, and rheumatoid arthritis.
3. Patients with a history of intraocular or corneal surgery (including cataract extraction), 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 includes any patient with open angle glaucoma, regardless of medication regimen or control. Additionally, any patient with an IOP greater than 21mm Hg at baseline is specifically excluded from eligibility.

4. Patients with evidence of keratoconus, corneal irregularity, or abnormal video keratography in either eye.
5. Patients with pupil size greater than 5.5mm in photopic illumination as measured with infrared pupilometry; pupil detection component of computer assisted video keratography, or slit lamp reticule.
6. Patients who are participating in any other clinical trial (FDA or other).

Subject Withdrawl

Study subjects were told that they were free to withdraw from the study at anytime without any penalties. Subjects who move away form the study and are unable to return for follow-up will be considered withdrawn from the study. If a subject does not return for two consecutive follow-up visits after 1 month following treatment, and phone calls and written correspondence from the investigator to the subject does not elicit a response, the subject will be considered voluntarily withdrawn from the study.

Data Collection

All clinical data relevant to the conduct and results of this study shall be collected for the purpose of analysis. The data collected for the purpose of the study shall be made available to the sponsor and FDA for comparison to the medical records to assure completeness and accuracy of the data.

Pre-Treatment Exam

The pre-treatment exam must be performed no more than thirty days before the date of dispensing. In the case of patients wearing rigid contact lenses, lens wear must cease at least four weeks prior to the pre-treatment exam.

Refraction:
- Distance uncorrected logMar VA
- Manifest Refraction
- Best Corrected logMar VA
- Pupil Size

Corneal Shape Evaluation
- Manual Keratometry
- Corneal Videokeratography

Ocular Examination
- Applanation Tonometry
- Anterior Segment Examination
- Lid Position
- Horizontal Visible Iris Diameter

Dilated Fundus Exam if not conducted within nine months of pre-treatment

Psychometric Evaluation

Diagnostic lens Evaluation

Lens Dispensing

The following data shall be assessed and recorded for the treated eyes after lenses have been dispensed and equilibrated for fifteen minutes.

- Refraction and visual performance
  - Manifest Sphero-cylinder Over Refraction
  - Best Corrected VA
- Lens-Cornea Relationship
  - Central Zone
  - Paracentral Zone
  - Peripheral Zone
- Lens Dynamics
  - Centration
  - Movement
- Lens Comfort
- Wearing Regimen
- Assessment of Adverse Events and/or complications

Follow-up Visits

The following data shall be assessed and recorded for the treated eyes during scheduled periodic examinations at two weeks, 1, 2, and 3 months:

- Wearing schedule
- Over Refraction and Visual Performance
- Lens-Cornea Relationship
- Lens Dynamics
- Lens Comfort
- Removal of Lenses: Refraction and Visual Performance
- Corneal Shape Evaluation
- Ocular Examination
- Psychometric Evaluation
- Assessment of Adverse Events and/or complications

The following data shall be assessed and recorded for a single treated eye during scheduled examinations 8, 24, 48 and 72 hours after the three month follow up visit:

- Refraction and Visual performance
- Corneal Shape Evaluation
- Ocular Examination
- Psychometric Evaluation
- Assessment of Adverse Events and/or complications

Results

Of the 14 subjects enrolled in the study, a total of five subjects completed up to the one month follow-up visit. Although the study was intended to progress through a three month course, the restrictions imposed by the college schedule restricted the results of this study to a one month period. At the baseline visit (see table 1 below), the mean unaided acuity of the subjects was measured using the Logmar system and a mean acuity of the five subjects was found to be 20/122 in the right eye and 20/129 in the left eye at a calibrated distance of 14 feet. The mean subjective refraction using a spherical equivalent was –2.08 diopters in the right eye and –2.28 diopters in the left eye. The mean photopic pupil size was 4.4 mm in both eyes. The corneal shape as determined by the corneal topographer was 0.25 in the right eye, and 0.24 in the left eye. Other data obtained at the baseline visit is not presented in this document.

Table 1. Baseline Data

No.	Unaided VA		Subjective Refraction		Pupil Size		Corneal Shape Factor	
	OD	OS	OD	OS	OD	OS	OD	OS
1 BK	20/60	20/80	-1.00-0.25X165	-1.50-0.25X105	5.5	5.5	0.42	0.33
2 AP	20/100	20/125	-2.75	-2.75-0.50X020	3.0	3.0	0.30	0.30
3 SS	20/50	20/40	-1.50	-1.50	5.0	5.0	0.07	0.06
4 AH	20/200	20/200	-2.50	-2.75	4.5	4.5	0.19	0.21
5 CB	20/200	20/200	-2.50	-2.25-0.50X180	4.0	4.0	0.27	0.29
AV G	20/122	20/129	-2.08*	-2.28*	4.4	4.4	0.25	0.24

* These means were calculated using a spherical equivalent value.

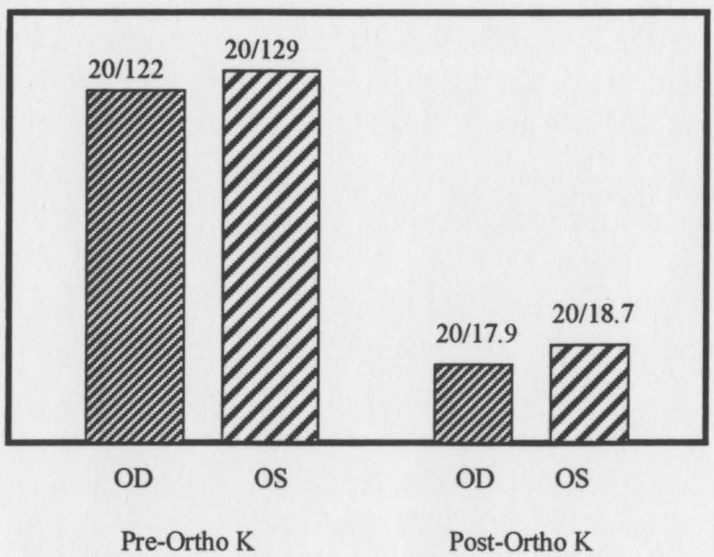
At the one month follow-up visit (see table 2), the hours of wear time were recorded and the mean time was 9 hours of wearing time per day. The mean unaided visual acuity was again measured using the Logmar method. The mean visual acuities were 20/17.9 in the right eye and 20/18.7 in the left eye (see graph 1). A subjective refraction was performed for each eye and the mean spherical refractions were –0.25 diopters in the right eye and –0.25 in the left eye. Patient reports of comfort were recorded at the one month visit. The most common complaints were itching / burning in 2/5 subjects, dryness / srcatchiness in 2/5 subjects, and one patient reported significant glare problems. The adverse reactions observed included two patients with mild tarsal abnormalities, and two patients with mild corneal staining.

Table 2. 1 Month Data

No.	Avg. Lens Wear / Day (Hr.)	Unaided VA		Subj. Refraction		Comfort	Complications
		OD	OS	OD	OS		
1 BK	11	20/20	20/20	+0.25	Plano	G,IB	S,MTA
2 AP	10	20/12.5	20/12.5	Plano	Plano	DS	MTA
3 SS	7	20/16	20/16	-0.25	Plano	none	none
4 AH	7	20/25	20/25	-0.50	-0.75	DA	S
5 CB	10	20/16	20/20	-0.75	-0.50	IB, DS	none
AVG	9	20/17.9	20/18.7	-0.25	-0.25		

G= glare IB= itching/ burning DS= dryness/ scratchiness DA= discomfort/ awareness
S= staining MTA= mild tarsal abnormality

Graph 1. Pre- vs. Post-Ortho K Average Uncorrected Visual Acuities



Discussion

The art and science of orthokeratology has been under investigation for some time. There are skeptics who do not believe that this method of myopia reduction will become a popular method used by eye care practitioners. However, there is no doubt from our results, and the results of others, that ortho-k can be effective way to reduce myopia in select candidates. It has been illustrated by this study that the selection of patients is crucial to the success of the patient with this method of myopia correction. The study to one month was completed for 5 of the 14 patients who enrolled originally. Motivation, desired goals, and commitment to the lens wearing schedule are important when selecting and explaining to candidates what is required if success is to be likely. In addition, previous RGP wear presented as an aid to the adaptation period in wearing these rigid lenses, and did not seem to have a significant impact on the end results. The results can be projected to produce some promising future uses of this lens material for the purposes of ortho-k.

Appendix 1

INFORMED CONSENT DOCUMENT

Study

Paflufocon B in Reverse Geometry Design for Daily Wear for Myopia and Myopia With Astigmatism

Institution:

A. Title	Paflufocon B in Reverse Geometry Design for Daily Wear for Myopia and Myopia With Astigmatism.
B. Principal Investigator	Dr. Roxanne A. Achong (503)359-2823 *office* (503)297-5775 *home*
C. Location	Pacific University College of Optometry 2043 College Way, UC 692 Forest Grove, Oregon 97116 (503) 359-2202
D. Dates of project:	November 1998 - November 1999

1. Description of Project

The technique of orthokeratology can be defined as the reduction or modification of refractive errors by the programmed application of contact lenses. The technique is accomplished through a single or series of progressively flattening lenses which flatten the central anterior corneal radius, reducing myopia and myopic astigmatism, thereby improving unaided visual acuity.

You are invited to participate in a six month study to determine the safety, efficacy and acceptability of a new contact lens design for orthokeratology. Traditional orthokeratology lens designs have relied on spherical radii in the lens periphery to create the desired flattening effect. The design in this study incorporates a series aspheric curves in the lens mid-periphery to permit better lens alignment with the aspheric peripheral cornea.

All lenses will be manufactured in a FDA approved RGP lens material, Pafulfocon B. Each patient will undergo a comprehensive eye exam to determine eligibility. Subjects must meet the eligibility as described in the Investigational Protocol.

If you meet the inclusion criteria you will be fitted with the new RGP lens design and placed on a daily wearing schedule. The central portion of the lens will be fitted flatter than the central radius of curvature of the cornea. This will flatten the central cornea thereby temporally correcting your myopia (nearsidedness).

Scheduled follow-up examinations will be conducted at two weeks, 1, 2, and 3 months after dispensing. Additional visits will be conducted at 8, 24, 48, and 72 hours after the 3 month visit to determine the half life of the unaided visual acuity improvement.

2. Description of Risks:

All procedures performed in this study will be current, accepted clinical procedures for the fitting and management of contact lens for orthokeratology. Small amounts of ocular redness and lens awareness may occur with lens wear, and there is an extremely small risk of ocular infection and/or loss of vision with the use of daily wear contact lenses. This risk increases with non-compliance to care and follow-up schedules. Subjects who do not comply with prescribed regimens will be discontinued from the study and will be required to forfeit their lenses. All subjects will sign the informed consent document.

3. Description of Benefits:

Subjects accepted for study participation will be supplied with state of the art product representing the newest technologies in orthokeratology contact lens. Throughout the **duration of the study**, lenses and care solutions and professional fitting fees will be complimentary.

4. Alternatives Advantageous to Subjects:

Some subjects may be better suited to other types of contact lens wear or spectacles. The investigator will endeavor to provide subjects unsuited to the study protocol with a prescription for their optimum form of vision correction.

5. Confidentiality of Records:

Records of this project will be maintained in a confidential manner and no name-identifiable information will be released.

6. Compensation and Medical Care:

If you are injured in this study, it is possible that you will not receive compensation or medical care from Pacific University, the investigators, or any organization associated with the project. However, all responsible care will be used to prevent injury..

7. Offer to Answer Any Inquiries:

The investigators will be happy to answer any questions you may have at any time during the study. If you are not satisfied with the answers you receive, please call Dr. Jennifer Smythe (503) 359-2770

8. Freedom to Withdraw:

You are free to withdraw your consent and to discontinue participation in this project at any time without prejudice to you.

I have read the above and understand its meaning. I am 18 years of age or over, or this form is signed for me by my parent or guardian.

Printed Name: _____

Signed: _____ Date: _____

Address: _____ Phone: _____

City: _____ State: _____ Zip: _____

Name and address of a person not living with you who will always know your address:

Name: _____

Address: _____

_____

PATIENT COPY

PACIFIC UNIVERSITY FAMILY VISION CENTER STUDY POLICIES:

Subjects accepted for participation in this study will receive complimentary contact lenses, lens care products and professional fitting services throughout the duration of the study. If you prefer to transfer your care to a different practitioner, we will be happy to forward our data concerning the study upon your written request.

Subjects not able to successfully complete the study will be given a the opportunity to be fitted with an alternate type of contact lens or glasses at standard clinic fees.

NOTE: Subjects who chose to continue in another type of contact lens will not receive a refund of the annual care agreement fee; however, their services will be covered until their agreement expires.

During your participation in this project, you are not a Pacific University clinic patient for contact lens care. All questions should be addressed to the study investigators, who will be solely responsible for any treatment (except for an emergency). It is imperative that you keep your scheduled appointments to ensure continuity of care and data collection by each investigator.

I UNDERSTAND AND AGREE TO THE POLICIES FOR PARTICIPATION IN THIS CONTACT LENS RESEARCH PROJECT AT THE PACIFIC UNIVERSITY COLLEGE OF OPTOMETRY

Name: _____

Signature: _____

Date: _____

PATIENT COPY

Appendix 2

EVALUATION OF THE SAFETY AND EFFECTIVENESS OF LENSES MADE IN PAFLUFOCON B MATERIAL IN REVERSE GEOMETRY DESIGN FOR MYOPIA AND MYOPIA WITH ASTIGMATISM
GENERAL INFORMATION STUDY: PVS 98 - 2

INTRODUCTION: PARAGON Vision Sciences is evaluating a new lens design for rigid gas permeable contact lenses. PARAGON Vision Sciences believes the new design will be safe and effective for the reduction of naturally occurring myopia and myopia with astigmatism with resultant improvement in uncorrected distance visual acuity.

THE LENS: The study lenses are manufactured from Paflufocon B, a rigid lens plastic that has been found to be safe as a lens material. Thousands of people are now wearing lenses made from this material. The Paflufocon B lenses in reverse geometry design are currently available ONLY from qualified clinical investigators and will be dispensed for the sole purpose of conducting this study.

PROCEDURES: As a study volunteer you will first be examined by your doctor to determine your eligibility and lens prescription. If you are eligible, you will receive a pair of study lenses and will be instructed to wear these study lenses during waking hours for prescribed periods up to 16 hours per day. During the study you will attend a minimum of five office visits: Initial, 2 Week, 1 month, 2 month and 3 month. Each visit should require 30-45 minutes. During each visit you will receive an eye examination. You will be issued and instructed to use a currently marketed, FDA approved cleaning and disinfecting regimen. At the end of the study, at your practitioner's discretion, you will be allowed to keep the test pair of study lenses.

BENEFITS: The study lenses have been designed to provide excellent visual acuity and oxygen transmission to the eye The lens design is believed to provide a reduction in the refractive error of a treated eye with a resultant improvement in the unaided vision. This change is believed to be completely reversible and temporary in nature.

RISKS: No harmful health risks to your eyes are anticipated from using the lenses. As with any contact lens, there are potential risks of irritation to the eye and corneal ulcers. Transient distorted vision may occur after removal of the lenses that is not corrected with spectacle lenses. No harmful effects are expected from any of the examination procedures used in the study.

ALTERNATIVES: Currently available alternatives to the study lenses are spectacles or other types of soft, conventional hard or rigid gas permeable contact lenses or surgical vision correction. Your eye care professional can discuss these alternatives.

PARTICIPATION: Your participation in this study is voluntary, and you may refuse to participate without prejudice to your care. You are also free to withdraw your consent and to discontinue your participation in this study at any time without prejudice to your care. If you miss a study visit or move out of the area, you will be discontinued from the study and you must return your lenses. A total of 75 subjects will be enrolled in the study.

CONFIDENTIALITY: The information collected during this study will be submitted to the sponsor, PARAGON Vision Sciences. The U.S. Food and Drug Administration and PARAGON Vision Sciences may review any of your records that pertain to this study. The information collected in this study will remain confidential. Your permission for the review of confidential information by PARAGON Vision Sciences and the U.S. Food and Drug Administration is granted by signing this document.

MEDICAL TREATMENT: Reasonable medical treatment will be available for any subject incurring physical injuries reasonably related to this clinical investigation. For further information, contact William Meyers, Vice President, Science and Technology, PARAGON Vision Sciences, 947 East Impala Ave., Mesa AZ 85204.

QUESTIONS: Your doctor will answer any questions you might have regarding this study. Your doctor is a qualified clinical investigator and has been provided with full background information. If a question comes up that your doctor cannot answer, he/she can obtain the information from PARAGON Vision Sciences.

STATEMENT OF INFORMED CONSENT

I have read all of the above information regarding trial lenses. I understand what I have read and the circumstances have been explained to me by my eye care professional.

I wish to participate in this study under the conditions explained to me and described above.

Subject Signature:_____

Subject Name (Print):_____ Doctor Name:_____

Witness:_____ Date:_____

Office Phone No.:_____ Emergency Phone No.:_____

If subject is a minor, parental or guardian signature and relationship to subject are required:

Parent or Guardian Signature:_____Relationship to Subject:_____

EXPERIMENTAL SUBJECT'S

BILL OF RIGHTS

California law states that persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and of any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected from your participation in the experiment;
- be given an explanation of any benefits to the subject reasonably to be expected from participation in the experiment;
- be given a disclosure of any appropriate alternatives, procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;
- be informed of the avenues of medical treatment, if any, available to you after the experimental procedure, if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation with prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on your decision.

APPENDIX D: CASE REPORT FORMS

PSYCHOMETRIC QUESTIONNAIRES

PARAGON VISION SCIENCES

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:	
Subject Name:	Subject No.:	Age:	Gender: (circle) M F

PART II: SUBJECT MUST COMPLETE INFORMED CONSENT

Informed Consent Complete? (Circle) YES NO

PART III: SUBJECT MUST COMPLETE HABITUAL LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART IV: BASELINE EXAMINATION

OD		OS
Letters @ ft.	**1. Unaided LogMar High Contrast Acuity** Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	**2. Subjective Refraction**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with Subjective Refraction (Record test distance in feet from patient)	Letters @ ft.
Horizontal Vertical @	**4. Keratometry**	Horizontal Vertical @
mm.	**5. HVID**	mm.
Upper +/- mm Lower +/- mm	**6. Position of Lids** (From limbus - Algebraic in mm)	Upper +/- mm Lower +/- mm
Photopic mm	**7. Pupilometry**	Photopic mm
mm./ hg	**8. IOP**	mm. / hg

PART V: CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

OD	1. Instrument Used:	OS
	2. e Value or Shape Factor Circle measure reported	

PART VI: SLIT LAMP EXAMINATION

OD	(circle grade)	OS
0 1 2 3 4	1. Edema	0 1 2 3 4
0 1 2 3 4	2. Neovascularization	0 1 2 3 4
0 1 2 3 4	3. Staining	0 1 2 3 4
0 1 2 3 4	4. Injection	0 1 2 3 4
0 1 2 3 4	5. Tarsal Abnormalities	0 1 2 3 4
0 1 2 3 4	6. Other	0 1 2 3 4
Explain:		**Explain:**

Describe any SLE findings **Grade 2** or greater:

PARAGON VISION SCIENCES

SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART VII: Select Diagnostic Lens

D / mm	Lens Power / Base Curve	D / mm
mm. / mm	Total Diameter/ Optic Zone	mm. / mm
mm. / mm	Secondary Curve Radius / Width	mm. / mm
mm. / mm	Intermediate Curve Radius / Width	mm. / mm
mm. / mm	Peripheral Curve Radius / Width	mm. / mm
mm	Center Thickness	mm
Light Medium Heavy	Blend	Light Medium Heavy

PART VIII: APPLY DIAGNOSTIC LENS AND ALLOW TO EQUILIBRATE FOR 15 MINUTES

OD		OS
Excellent Good Poor 5 4 3 2 1	1. Lens Comfort:	Excellent Good Poor 5 4 3 2 1
Sphere Cylinder X	2. SCOR	Sphere Cylinder X
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with SCOR / test distance	Letters @ ft.
X Y	4. Lens Centration: (In straight ahead gaze, 0.5 mm steps)	X Y
0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm	5. Lens Movement: (After normal blink in primary gaze)	0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	6. Lens/Eye Relationship: Optic Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	7. Lens/Eye Relationship: Reverse Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	8. Lens/Eye Relationship: Peripheral Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10

PART IX: DILATED FUNDUS EXAMINATION [From records if within 9 months]

OD	Describe any findings outside normal limits	OS
	1. Crystalline Lens	
	2. Pre Retinal Media	
	3. Central Retina	
	4. Peripheral Retina	
	5. Optic Nerve	
	6. Other	

Comments on Baseline Examination:

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SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART X: SUBJECT MEETS ALL INCLUSION CRITERIA? YES / NO

IF NO: Describe conditions subject fails to meet:

IF YES: Will the Subject Enroll in the Study? YES / NO

IF NO: Check Reason for Not Enrolling

- ❑ Reverse Geometry not indicated
- ❑ Lack of Comfort
- ❑ Lack of Interest
- ❑ Poor lens centration
- ❑ Other: _____

IF YES: Record Target Refractive Error and Lens Prescription Order

Diopters	**Target Post Treatment Spherical Equivalent (Spectacle Plane)**	Diopters

Design from Diagnostic Lens Evaluation

D / mm	**Lens Power / Base Curve**	D / mm
mm. / mm	**Total Diameter/ Optic Zone**	mm. / mm
mm. / mm	**Secondary Curve Radius / Width**	mm. / mm
mm. / mm	**Intermediate Curve Radius / Width**	mm. / mm
mm. / mm	**Peripheral Curve Radius / Width**	mm. / mm
mm	**Center Thickness**	mm
Light Medium Heavy	**Blend**	Light Medium Heavy

OR Direct Order Method (Outside of range of diagnostic lenses)

mm	**Base Curve (assuming +1.00 Diopter Lens Power to achieve Target Post Treatment Refractive Error)**	mm

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

DISPENSING VISIT 1

USE BLACK INK ONLY

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART I: INSERT STUDY LENSES - Wait 15 Minutes

OD: Power:_____ Base Curve:_____ OS: Power:_____ Base Curve:_____

PART II: OCULAR EXAM WITH STUDY LENSES

OD		OS
Excellent Good Poor 5 4 3 2 1	**1. Lens Comfort:**	Excellent Good Poor 5 4 3 2 1
Sphere Cylinder X	**2. SCOR**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with SCOR / test distance	Letters @ ft.
X Y	**4. Lens Centration:** (In straight ahead gaze, 0.5 mm steps)	X Y
0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm	**5. Lens Movement:** (After normal blink in primary gaze)	0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**6. Lens/Eye Relationship:** Optic Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**7. Lens/Eye Relationship:** Reverse Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**8. Lens/Eye Relationship:** Peripheral Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10

PART III: SUBJECT SYMPTOMS

	OD	OS
1. None	❑	❑
2. Discomfort/Awareness	❑	❑
3. Itching/Burning	❑	❑
4. Blurred Vision	❑	❑
5. Dryness/Scratchiness	❑	❑
6. Variable Vision	❑	❑
7. Photophobia	❑	❑
8. Halos	❑	❑
9. Lens Needs Cleaning	❑	❑
10. Other	❑	❑

Explain Other: OD:_____
OS:_____

PART IV: COMMENTS

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 1
TWO WEEK VISIT

USE BLACK INK ONLY

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

1. Number of days of lens wear since last visit

2. Average lens wearing time per day since last visit: Hours

3. Number of hours of lens wear today: Hours

PART II: SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH STUDY LENSES

OD: Power:_____ Base Curve:_____ | OS: Power:_____ Base Curve:_____

OD		OS
Excellent Good Poor 5 4 3 2 1	**1. Lens Comfort:**	Excellent Good Poor 5 4 3 2 1
Sphere Cylinder X	**2. SCOR**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with SCOR / test distance	Letters @ ft.
X Y	**4. Lens Centration:** (In straight ahead gaze, 0.5 mm steps)	X Y
0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm	**5. Lens Movement:** (After normal blink in primary gaze)	0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**6. Lens/Eye Relationship:** Optic Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**7. Lens/Eye Relationship:** Reverse Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**8. Lens/Eye Relationship:** Peripheral Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10

PART IV: SUBJECT SYMPTOMS

	OD	OS
1. None	❑	❑
2. Discomfort/Awareness	❑	❑
3. Itching/Burning	❑	❑
4. Blurred Vision	❑	❑
5. Dryness/Scratchiness	❑	❑
6. Variable Vision	❑	❑
7. Photophobia	❑	❑
8. Halos	❑	❑
9. Lens Needs Cleaning	❑	❑
10. Other	❑	❑

Explain Other: OD:_____
OS:_____

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E REPORT FORM
DY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 1
TWO WEEK VISIT

PAGE 2 OF 2

RLACK INK ONLY

SUBJECT INFORMATION

tigator Name:	Investigator No.:	Date of Visit:
ct Name:		Subject No.:

Remove lenses and allow 10 minute tear film equilibration

PART V: SLIT LAMP EXAMINATION (After Lens Removal)

OD	(circle grade)	OS
1 2 3 4	1. Edema	0 1 2 3 4
1 2 3 4	2. Neovascularization	0 1 2 3 4
1 2 3 4	3. Staining	0 1 2 3 4
1 2 3 4	4. Injection	0 1 2 3 4
1 2 3 4	5. Tarsal Abnormalities	0 1 2 3 4
1 2 3 4	6. Other	0 1 2 3 4

in: Explain:

be any abnormal SLE findings:

PART VI: OCULAR EXAMINATION (After Lens Removal)

OD		OS
Letters @ ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Cylinder X	2. Subjective Refraction	Sphere Cylinder X
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	Letters @ ft.
al Vertical @	4. Keratometry	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

mm./ hg	6. IOP	mm. / hg

PART VIII: Lens Replacement Required? YES / NO; If yes complete lens replacement form

TIGATOR COMMENTS:

tor Signature:	Date:

FOLLOW-UP VISIT
ONTH VIS

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.0 1.25 1.5
.5 >2.5 mm

Vaulting
7 8 9 10

Vaulting
7 8 9 10

Vaulting
7 8 9 10

OD OS
ing ☐ ☐
☐ ☐

D:_____
S:_____

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 2
ONE MONTH VISIT

USE BLACK INK ONLY

SUBJECT INFORMATION		
Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

Remove lenses and allow 10 minute tear film equilibration

PART V: SLIT LAMP EXAMINATION (After Lens Removal)

OD (circle grade)						OS (circle grade)				
0	1	2	3	4	1. Edema	0	1	2	3	4
0	1	2	3	4	2. Neovascularization	0	1	2	3	4
0	1	2	3	4	3. Staining	0	1	2	3	4
0	1	2	3	4	4. Injection	0	1	2	3	4
0	1	2	3	4	5. Tarsal Abnormalities	0	1	2	3	4
0	1	2	3	4	6. Other	0	1	2	3	4
Explain:						Explain:				

Describe any abnormal SLE findings:

PART VI: OCULAR EXAMINATION (After Lens Removal)

OD		OS
Letters @ ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	2. Subjective Refraction	Sphere Cylinder X
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	4. Keratometry	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

mm./ hg	6. IOP	mm. / hg

PART VIII: Lens Replacement Required? YES / NO; If yes complete lens replacement form

INVESTIGATOR COMMENTS:

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 3
TWO MONTH VISIT

USE BLACK INK ONLY

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

1. Number of days of lens wear since last visit

2. Average lens wearing time per day since last visit: Hours

3. Number of hours of lens wear today: / Hours

PART II: SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH STUDY LENSES

OD: Power:_____ Base Curve:_____ OS: Power:_____ Base Curve:_____

OD		OS
Excellent Good Poor 5 4 3 2 1	**1. Lens Comfort:**	Excellent Good Poor 5 4 3 2 1
Sphere Cylinder X	**2. SCOR**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with SCOR / test distance	Letters @ ft.
X Y	**4. Lens Centration:** (In straight ahead gaze, 0.5 mm steps)	X Y
0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm	**5. Lens Movement:** (After normal blink in primary gaze)	0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**6. Lens/Eye Relationship:** Optic Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**7. Lens/Eye Relationship:** Reverse Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**8. Lens/Eye Relationship:** Peripheral Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10

PART IV: SUBJECT SYMPTOMS

	OD	OS		OD	OS		OD	OS
1. None	☐	☐	5. Dryness/Scratchiness	☐	☐	9. Lens Needs Cleaning	☐	☐
2. Discomfort/Awareness	☐	☐	6. Variable Vision	☐	☐	10. Other	☐	☐
3. Itching/Burning	☐	☐	7. Photophobia	☐	☐	Explain Other: OD:_____		
4. Blurred Vision	☐	☐	8. Halos	☐	☐	OS:_____		

CONTINUE ON THE NEXT PAGE

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 3
TWO MONTH VISIT

USE BLACK INK ONLY

SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

Remove lenses and allow 10 minute tear film equilibration

PART V: SLIT LAMP EXAMINATION (After Lens Removal)

OD (circle grade)						OS (circle grade)				
0	1	2	3	4	1. Edema	0	1	2	3	4
0	1	2	3	4	2. Neovascularization	0	1	2	3	4
0	1	2	3	4	3. Staining	0	1	2	3	4
0	1	2	3	4	4. Injection	0	1	2	3	4
0	1	2	3	4	5. Tarsal Abnormalities	0	1	2	3	4
0	1	2	3	4	6. Other	0	1	2	3	4
Explain:						Explain:				

Describe any abnormal SLE findings:

PART VI: OCULAR EXAMINATION (After Lens Removal)

OD		OS
Letters @ ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	2. Subjective Refraction	Sphere Cylinder X
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	4. Keratometry	Horizontal Vertical @
5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)		
mm./ hg	6. IOP	mm. / hg

INVESTIGATOR COMMENTS:

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 4
THREE MONTH VISIT

USE BLACK INK ONLY

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

1. Number of days of lens wear since last visit

2. Average lens wearing time per day since last visit: Hours

3. Number of hours of lens wear today: Hours

PART II: SUBJECT MUST COMPLETE CORRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH STUDY LENSES

OD: Power:_____ Base Curve:_____ OS: Power:_____ Base Curve:_____

OD		OS
Excellent Good Poor 5 4 3 2 1	**1. Lens Comfort:**	Excellent Good Poor 5 4 3 2 1
Sphere Cylinder X	**2. SCOR**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with SCOR / test distance	Letters @ ft.
X Y	**4. Lens Centration:** (In straight ahead gaze, 0.5 mm steps)	X Y
0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm	**5. Lens Movement:** (After normal blink in primary gaze)	0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**6. Lens/Eye Relationship:** Optic Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**7. Lens/Eye Relationship:** Reverse Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	**8. Lens/Eye Relationship:** Peripheral Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10

PART IV: SUBJECT SYMPTOMS

	OD	OS
1. None	☐	☐
2. Discomfort/Awareness	☐	☐
3. Itching/Burning	☐	☐
4. Blurred Vision	☐	☐
5. Dryness/Scratchiness	☐	☐
6. Variable Vision	☐	☐
7. Photophobia	☐	☐
8. Halos	☐	☐
9. Lens Needs Cleaning	☐	☐
10. Other	☐	☐

Explain Other: OD:_____
OS:_____

CONTINUE ON THE NEXT PAGE

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 4
THREE MONTH VISIT

USE BLACK INK ONLY

SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

Remove lenses and allow 10 minute tear film equilibration

PART V: SLIT LAMP EXAMINATION (After Lens Removal)

OD	(circle grade)	OS
0 1 2 3 4	1. Edema	0 1 2 3 4
0 1 2 3 4	2. Neovascularization	0 1 2 3 4
0 1 2 3 4	3. Staining	0 1 2 3 4
0 1 2 3 4	4. Injection	0 1 2 3 4
0 1 2 3 4	5. Tarsal Abnormalities	0 1 2 3 4
0 1 2 3 4	6. Other	0 1 2 3 4
Explain:		Explain:

Describe any abnormal SLE findings:

PART VI: OCULAR EXAMINATION (After Lens Removal)

OD		OS
Letters @ ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	2. Subjective Refraction	Sphere Cylinder X
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	4. Keratometry	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

mm./ hg	6. IOP	mm. / hg

INVESTIGATOR COMMENTS:

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

USE BLACK INK ONLY

PARAGON VISION SCIENCES

☐ Unscheduled Visit
☐ Discontinuation Visit

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

1. Number of days of lens wear since last visit
2. Average lens wearing time per day since last visit: Hours
3. Number of hours of lens wear today: Hours

PART II: SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH STUDY LENSES (If on at arrival for visit)

OD: Power:_____ Base Curve:_____ OS: Power:_____ Base Curve:_____

OD		OS
Excellent Good Poor 5 4 3 2 1	1. Lens Comfort:	Excellent Good Poor 5 4 3 2 1
Sphere Cylinder X	2. SCOR	Sphere Cylinder X
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with SCOR / test distance	Letters @ ft.
X Y	4. Lens Centration: (In straight ahead gaze, 0.5 mm steps)	X Y
0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm	5. Lens Movement: (After normal blink in primary gaze)	0.25 0.5 0.75 1.0 1.25 1.5 1.75 2.0 2.25 2.5 >2.5 mm
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	6. Lens/Eye Relationship: Optic Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	7. Lens/Eye Relationship: Reverse Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10
Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10	8. Lens/Eye Relationship: Peripheral Zone	Bearing Aligned Vaulting 1 2 3 4 5 6 7 8 9 10

PART IV: SUBJECT SYMPTOMS

	OD	OS		OD	OS		OD	OS
1. None	☐	☐	5. Dryness/Scratchiness	☐	☐	9. Lens Needs Cleaning	☐	☐
2. Discomfort/Awareness	☐	☐	6. Variable Vision	☐	☐	10. Other	☐	☐
3. Itching/Burning	☐	☐	7. Photophobia	☐	☐	Explain Other: OD:_____		
4. Blurred Vision	☐	☐	8. Halos	☐	☐	OS:_____		

CONTINUE ON THE NEXT PAGE

CASE REPORT FORM
STUDY ID: PVS 98 - 2
USE BLACK INK ONLY

PARAGON VISION SCIENCES

☐ Unscheduled Visit
☐ Discontinuation Visit

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART V: SLIT LAMP EXAMINATION (After Lens Removal)

OD	(circle grade)	OS
0 1 2 3 4	1. Edema	0 1 2 3 4
0 1 2 3 4	2. Neovascularization	0 1 2 3 4
0 1 2 3 4	3. Staining	0 1 2 3 4
0 1 2 3 4	4. Injection	0 1 2 3 4
0 1 2 3 4	5. Tarsal Abnormalities	0 1 2 3 4
0 1 2 3 4	6. Other	0 1 2 3 4
Explain:		Explain:

Describe any abnormal SLE findings:

PART VI: OCULAR EXAMINATION (Without Lens or After Lens Removal)

OD		OS
Letters @ ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	2. Subjective Refraction	Sphere Cylinder X
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	4. Keratometry	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)		
mm./ hg	6. IOP	mm. / hg

PART VII: REASON FOR VISIT OR DISCONTINUATION (Select only one)

- ☐ Unacceptable Visual Acuity
- ☐ Lack of Comfort
- ☐ Lack of Interest
- ☐ Lost to Follow-Up
- ☐ Protocol Violation
- ☐ Missed Visits
- ☐ Pathology/Adverse Reaction (Complete Adverse Reaction Form)
- ☐ Other: _____

PART VIII: Lens Replacement Required? YES / NO; If yes complete lens replacement form

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 5
8 HOURS POST 3 MONTH

USE BLACK INK ONLY

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART II: SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH NO LENS WEAR FOR _____ HOURS

NOTE: Examine ONLY the eye that has had NO LENS WEAR

OD		OS
Letters @ ft.	**1. Unaided LogMar High Contrast Acuity** Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	**2. Subjective Refraction**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	**4. Keratometry**	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

PART V: SLIT LAMP EXAMINATION

OD	(circle grade)	OS
0 1 2 3 4	**1. Edema**	0 1 2 3 4
0 1 2 3 4	**2. Neovascularization**	0 1 2 3 4
0 1 2 3 4	**3. Staining**	0 1 2 3 4
0 1 2 3 4	**4. Injection**	0 1 2 3 4
0 1 2 3 4	**5. Tarsal Abnormalities**	0 1 2 3 4
0 1 2 3 4	**6. Other**	0 1 2 3 4
Explain:		**Explain:**

Describe any abnormal SLE findings:

INVESTIGATOR COMMENTS:

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 6
24 HOURS POST 3 MONTH

USE BLACK INK ONLY

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART II: SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH NO LENS WEAR FOR ____ HOURS

NOTE: Examine ONLY the eye that has had NO LENS WEAR

OD		OS
Letters @ ft.	**1. Unaided LogMar High Contrast Acuity** Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	**2. Subjective Refraction**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	**4. Keratometry**	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

PART V: SLIT LAMP EXAMINATION

OD	(circle grade)	OS
0 1 2 3 4	**1. Edema**	0 1 2 3 4
0 1 2 3 4	**2. Neovascularization**	0 1 2 3 4
0 1 2 3 4	**3. Staining**	0 1 2 3 4
0 1 2 3 4	**4. Injection**	0 1 2 3 4
0 1 2 3 4	**5. Tarsal Abnormalities**	0 1 2 3 4
0 1 2 3 4	**6. Other**	0 1 2 3 4
Explain:		**Explain:**

Describe any abnormal SLE findings:

INVESTIGATOR COMMENTS:

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 7
48 HOURS POST 3 MONTH

USE BLACK INK ONLY

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART II: SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH NO LENS WEAR FOR ____ HOURS

OD		OS
Letters @ ft.	**1. Unaided LogMar High Contrast Acuity** Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	**2. Subjective Refraction**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	**4. Keratometry**	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

PART V: SLIT LAMP EXAMINATION

OD	(circle grade)	OS
0 1 2 3 4	**1. Edema**	0 1 2 3 4
0 1 2 3 4	**2. Neovascularization**	0 1 2 3 4
0 1 2 3 4	**3. Staining**	0 1 2 3 4
0 1 2 3 4	**4. Injection**	0 1 2 3 4
0 1 2 3 4	**5. Tarsal Abnormalities**	0 1 2 3 4
0 1 2 3 4	**6. Other**	0 1 2 3 4
Explain:		**Explain:**

Describe any abnormal SLE findings:

INVESTIGATOR COMMENTS:

Investigator Signature:	Date:

CASE REPORT FORM
STUDY ID: PVS 98 - 2

PARAGON VISION SCIENCES

FOLLOW-UP VISIT 8
72 HOURS POST 3 MONTH

USE BLACK INK ONLY

PART I: SUBJECT INFORMATION

Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:

PART II: SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE

Questionnaire Complete? (Circle) YES NO

PART III: OCULAR EXAM WITH NO LENS WEAR FOR _____ HOURS

NOTE: Examine ONLY the eye that has had NO LENS WEAR

OD		OS
Letters @ ft.	**1. Unaided LogMar High Contrast Acuity** Single Letter VA Unaided (Record test distance in feet from patient)	Letters @ ft.
Sphere Cylinder X	**2. Subjective Refraction**	Sphere Cylinder X
Letters @ ft.	**3. LogMar High Contrast Acuity** Single Letter VA with Subjective Refraction	Letters @ ft.
Horizontal Vertical @	**4. Keratometry**	Horizontal Vertical @

5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map)

PART V: SLIT LAMP EXAMINATION

OD	(circle grade)	OS
0 1 2 3 4	**1. Edema**	0 1 2 3 4
0 1 2 3 4	**2. Neovascularization**	0 1 2 3 4
0 1 2 3 4	**3. Staining**	0 1 2 3 4
0 1 2 3 4	**4. Injection**	0 1 2 3 4
0 1 2 3 4	**5. Tarsal Abnormalities**	0 1 2 3 4
0 1 2 3 4	**6. Other**	0 1 2 3 4
Explain:		**Explain:**

Describe any abnormal SLE findings:

INVESTIGATOR COMMENTS:

Investigator Signature:	Date:

Questionnaire to be administered at the **BASELINE** Visit prior to removing the subjects habitually worn correction. The patient must be wearing the correction while filling out the questionnaire.

Patient Questionnaire - Habitual Correction

Patient Name _____ Date _____

1. A. What, if anything, do you like about your current correction for your vision?

_____

_____

_____

B. What, if anything, do you dislike about your current correction for your vision?

_____

_____

_____

2. On average, how many days a week do you wear your correction for your vision?

_____

3. On average, how many hours a day do you wear your correction for your vision?

_____

4. Please rate the current correction for your vision on the following visual attributes.

Check only one box per line.

	Excellent 10	9	8	7	6	5	4	3	2	Poor 1
Overall visual sharpness and clarity	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Night Vision/low or dim light situations (such as driving at night or reading a menu in a dark restaurant)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Consistent vision throughout the day (Stable or variable vision while wearing your correction?)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while participating in sport activities (if applicable) Which sport(s)? _____	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while working (such as working at a computer, reading fine print, long periods of close work)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

5. Please rate your **unaided vision** on the following visual attributes.

Check only one box per line.

	Excellent 10	9	8	7	6	5	4	3	2	Poor 1
Overall visual sharpness and clarity	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Night Vision/low or dim light situations (such as driving at night or reading a menu in a dark restaurant)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Consistent vision throughout the day (Stable or variable unaided vision)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while participating in sport activities (if applicable) Which sport(s)? _____	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while working (such as working at a computer, reading fine print, long periods of close work)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

6. Overall, how satisfied are you **with the correction for your vision you currently wear**?

Very Satisfied 10	9	8	7	6	5	4	3	2	Not At All Satisfied 1
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

7. Overall, how satisfied are you **with your unaided vision**?

Very Satisfied 10	9	8	7	6	5	4	3	2	Not At All Satisfied 1
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

Questionnaire to be administered at the Follow-Up Visit before removing the clinical study lenses. The patient must be wearing the study lenses while filling out the questionnaire.

Patient Questionnaire - Study Lenses: Two Week

Patient Name _____ Date _____

1. A. What, if anything, do you like about this pair of study lenses?

_____

_____

_____

B. What, if anything, do you dislike about this pair of study lenses?

_____

_____

_____

2. On average, how many days a week did you wear your study lenses? _____

3. On average, how many hours a day did you wear your study lenses? _____

4. Please rate the study contact lenses on the following visual attributes.
Check only one box per line.

	Excellent 10	9	8	7	6	5	4	3	2	Poor 1
Overall visual sharpness and clarity	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Night Vision/low or dim light situations (such as driving at night or reading a menu in a dark restaurant)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Consistent vision throughout the day (Stable or variable vision with the study lenses)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while participating in sport activities (if applicable) Which sport(s)? _____	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while working (such as working at a computer, reading fine print, long periods of close work)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

5. Please rate the contact lenses used during the study on the following comfort attributes.
Check only one box per line.

	Excellent									Poor
	10	9	8	7	6	5	4	3	2	1
Comfort of the lenses when you first put them in	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Comfort of the lenses at the end of the wear	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Overall comfort	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

6. Please rate your **unaided vision** on the following visual attributes.

Check only one box per line.

	Excellent									Poor
	10	9	8	7	6	5	4	3	2	1
Overall visual sharpness and clarity	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Night Vision/low or dim light situations (such as driving at night or reading a menu in a dark restaurant)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Consistent vision throughout the day (Stable or variable unaided vision)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while participating in sport activities (if applicable) Which sport(s)? _____	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while working (such as working at a computer, reading fine print, long periods of close work)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

7. Overall, how satisfied are you with the correction for your vision **with the study lenses**?

Very Satisfied									Not At All Satisfied
10	9	8	7	6	5	4	3	2	1
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

8. Overall, how satisfied are you **with your unaided vision**?

Very Satisfied									Not At All Satisfied
10	9	8	7	6	5	4	3	2	1
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

Questionnaire to be administered at the Follow-Up Visit before removing the clinical study lenses. The patient must be wearing the lenses while filling out the questionnaire.

Patient Questionnaire - Study Lenses: One Month

Patient Name _____ Date _____

1. A. What, if anything, do you like about this pair of study lenses?

_____

_____

_____

B. What, if anything, do you dislike about this pair of study lenses?

_____

_____

_____

2. On average, how many days a week did you wear your study lenses? _____

3. On average, how many hours a day did you wear your study lenses? _____

4. Please rate the study contact lenses on the following visual attributes.
Check only one box per line.

	Excellent									Poor
	10	9	8	7	6	5	4	3	2	1
Overall visual sharpness and clarity	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
	10	9	8	7	6	5	4	3	2	1
Night Vision/low or dim light situations (such as driving at night or reading a menu in a dark restaurant)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
	10	9	8	7	6	5	4	3	2	1
Consistent vision throughout the day (Stable or variable vision with the study lenses)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
	10	9	8	7	6	5	4	3	2	1
Vision while participating in sport activities (if applicable) Which sport(s)? _____	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
	10	9	8	7	6	5	4	3	2	1
Vision while working (such as working at a computer, reading fine print, long periods of close work)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

5. Please rate the contact lenses used during the study on the following comfort attributes. **Check only one box per line.**

	Excellent 10	9	8	7	6	5	4	3	2	Poor 1
Comfort of the lenses when you first put them in	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Comfort of the lenses at the end of the wear	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Overall comfort	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

6. Please rate your **unaided vision** on the following visual attributes.

Check only one box per line.

	Excellent 10	9	8	7	6	5	4	3	2	Poor 1
Overall visual sharpness and clarity	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Night Vision/low or dim light situations (such as driving at night or reading a menu in a dark restaurant)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Consistent vision throughout the day (Stable or variable unaided vision)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while participating in sport activities (if applicable) Which sport(s)? _____	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Vision while working (such as working at a computer, reading fine print, long periods of close work)	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

7. Overall, how satisfied are you with the correction for your vision **with the study lenses**?

Very Satisfied 10	9	8	7	6	5	4	3	2	Not At All Satisfied 1
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

8. Overall, how satisfied are you **with your unaided vision**?

Very Satisfied 10	9	8	7	6	5	4	3	2	Not At All Satisfied 1
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑