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### Paflufocon B in reverse geometry design

Kelsey Ford Pacific University

Michael Joljart Pacific University

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#### Paflufocon B in reverse geometry design

#### 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, forty-eight, 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

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#### Paflufocon B in Reverse Geometry Design

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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 December, 1999

> > 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.

Patrick Geroline C.O.T., F.A.A.O.

#### Signature Page

Authors:

Advisors:

Kelsey A. Ford

Michael J. Joljart Additional visite will be conducted at eight, twenty-four, fatty-

Roxanne Achong O.D.

Patrick Caroline C.O.T., F.A.A.O.

#### 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, forty-eight, 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.

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.

The prospective eye(s) must have naturally occurring refractive myopia tro 0.50 to -6.00 diopters sphere (spectacle piene), with up to -1.50 cliques if refractive astigmatism, as determined by mentilest refraction. Patients must have spectacle connected visual acuity of at least 0.04 logMAR in lach eye.

- 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 sectionatic rate may not vary by more than 15 degrees.
- If the patient wears rigid contact lenses in the prospective eye(s), lens use must cease at least four works 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 directors in either meridian. The mires should be require.
- Patients must be willing and expable to return for all scheduled follow-up visits for a period of at least three months.

#### aduation Critistia

- Female patients who are pregnant, breast-feeding or intend to become pregnant over the course of the study.
- Patients with a history of any of the following medical conditions: collagen vascular disease, autoimmune disease, immunodeliciency diseases, ocular herpes zostar or simplex, endocrine disorders (including, but not limited to active thyroid disorders and disbetios), lupus, and mecmatoid arthritis.
  - 1. Patients with a natory or intropoular or comparisurgery (including, but not extraction), active ophthalmic disease or abnormality (including, but not limited to, blaphantis, recurrent comparisonation, dry eye syndrome, neovescularization > 1mm from timbus), obtically significant liens opacity, clinical enderice of trauma (including scarring), or with evidence of

#### 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.
- 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.
- 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 pretreatment

**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 P	erforma	ance
Corneal Shape Evaluation		
Ocular Examination		
Psychometric Evaluation Assessment of Adverse Events and/or comp	lications	6

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.

No.	Unaio	led 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.

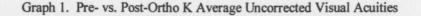
Table 1 Baseline Data

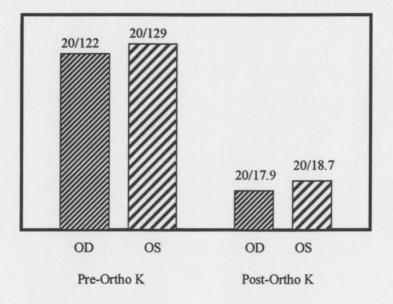
At the one month follow-up visit (see table 2), the hours of wear time were recorded and the mean time was 9 hours of wearing time per day. The mean unaided visual acuity was again measured using the Logmar method. The mean visual acuities were 20/17.9 in the right eye and 20/18.7 in the left eye (see 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.

No.	Avg. Lens	Unaic	led VA	Subj. Re	efraction	Comfort	rt Complications
rucisi to	Wear / Day (Hr.)	OD	OS	OD	OS	correction.	The study to
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





#### 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

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

institution:

Description of Project

The technique of orthokeratology can be defined as the reduction of 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 comeal 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 comea.

## 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 <i>office</i> (503)297-5775 <i>home</i>
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:

5. Confidentiality of Records:

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.

Signed:	HIS CONTACT LENS	Date:		
Address:	VERSITY COLLEGE O	Phone:		
City:	State:	Zip:		
Name and address of know your address:	a person not living with	you who will always		
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 <u>not</u> 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

RODUCTION: PARAGON Meden Scinoces is evaluating a new long design for rigid gas permeable contact leaves.

RACION Vision Sciences believes the new design will be safe and effective for the reduction of naturally occurring myopla Appendix 2 what. Thousands of people are new wearing leaves atode from this material. The Patholicity B leaves in several successry

#### PARAGON VISION SCIENCES

#### 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 signa	iture 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 disconiforts 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.

CONFIDENTIAL

#### APPENDIX D: CASE REPORT FORMS

#### **PSYCHOMETRIC QUESTIONNAIRES**

OKDW-98-2 16 10/5/98

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

## PARAGON VISION SCIENCES

**BASELINE VISIT** 

PAGE 1 OF 3

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Investi	gator l	Name:		**	Investigator N	0.:	Date of	f Visit	:		
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				p	ART IV: BAS	ELINE EXAMINAT	ION				
		OD			Partichand &	Second Station / Withold			OS	1	inite
Lintz	I	Letters (	@	ft.	Acuity Single	bgMar High Contrast e Letter VA Unaided ance in feet from patient)	Light	1	Letters	@	ft.
Sphere	-ii	Cylinde	x X	· Pros	2. Subjective	Refraction	Sphere		Cylind	ier X	Poor
5	I	etters (	@	ft.	3. LogMar Hi Single Letter VA (Record test dista	5	I	Letters	@	ft.	
Horizont	tal	Vertica	al	@	4. Keratometr		Horizont	al	Verti	cal	@
		Collection -	mm.		5. HVID	tration:	X			mm.	
Upper +/-	mn	Lov 1 +/		mm	6. Position of (From limbus -	Lids Algebraic in mm )	Upper +/-	mn		ower /-	mm
Photop	ic	2.25 2.5 Aligner	mm	5 em Vaulting	7. Pupilometry	y Roman analysis	Photopi	ic	2.25 2 Abgues	mm	2.5 mm faulting
Bearing	ng	Aligned	mm./	' hg	8. IOP	Relationship:	Bearing	3 4	Aligned 5 \ 6	mm.	/ hg
	F	2ASTAV		FINEAL	TOPOGRAP	HY (Attach Tange	ntial Ple	11:00	wer M	ap)	
	3	OD	7	9 11	1. Instrument		1 1 2	3	OS	1 8	9.10
		NA.A.		1.44	2. e Value or Circle	Shape Factor measure reported			05		
				P/s	ART VI: SLIT	LAMP EXAMINAT	ION				
1		OD				rcle grade)			OS		
0	1	2	3	4	1. E		0	1	2	3	4
0	1	2	3	4		eovascularization	0	1	2	3	4
0	1	2	3	4		aining	0	1	2	3	4
0	1	2	3	4		jection	0	1	2	3	4
0	1	2	3	4		arsal Abnormalities	0	1	2	3	4
0 Explain	the second s	2	3	4	6. 0	ther	0 Explain	1 1:	2	3	4
Descrit	be any	SLE find	ings G	Grade 2 of	r greater:						

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

## PARAGON VISION SCIENCES

**BASELINE VISIT** 

PAGE 2 OF 3

·	SUBJECT INFORMATION					
Investigator Name:	Investigator No.:	Date of Visit:				
Subject Name:		Subject No.:				
	PART VII: Select Diagnostic Le	ins				
D/mm	Lens Power / Base Curve	· D / m				
mm. / mm	Total Diameter/ Optic Zone	mm. / m				
mm. / mm	Secondary Curve Radius / Width	mm. / m				
mm. / mm	Intermediate Curve Radius / Width	mm. / m				
mm. / mm	Peripheral Curve Radius / Width	mm. / m				
mm	Center Thickness	m				
Light Medium Heavy	Blend	Light Medium Heav				
	STIC LENS AND ALLOW TO EC					
OD		OS				
Excellent Good Poor	1. Lens Comfort:	Excellent Good Poor				
5 4 3 2 1	a laber a spectrum production of the second s	5 4 3 2 1				
Olisia	2. SCOR	Salara Odiadaa				
Sphere Cylinder X		Sphere Cylinder X				
Λ	3. LogMar High Contrast Acuity	A				
Letters @ ft.	Single Letter VA with SCOR / test distance	Letters @ ft.				
Х	4. Lens Centration:	X				
Y	(In straight ahead gaze, 0.5 mm steps)	Y				
0.25 0.5 0.75 1.0 1.25 1.5	5. Lens Movement:	0.25 0.5 0.75 1.0 1.25 1.5				
1.75 2.0 2.25 2.5 >2.5 mm	(After normal blink in primary gaze)	1.75 2.0 2.25 2.5 >2.5 mm				
Bearing Aligned Vaulting	6. Lens/Eye Relationship:	Bearing Aligned Vaulting				
1 2 3 4 5 6 7 8 9 10	Optic Zone	1 2 3 4 5 6 7 8 9 10				
Bearing Aligned Vaulting	7. Lens/Eye Relationship:	Bearing Aligned Vaulting				
1 2 3 4 5 6 7 8 9 10	Reverse Zone	1 2 3 4 5 6 7 8 9 10				
Bearing Aligned Vaulting	8. Lens/Eye Relationship:	Bearing Aligned Vaulting				
1 2 3 4 5 6 7 8 9 10	Peripheral Zone	1 2 3 4 5 6 7 8 9 10				
PART IX: DILATED FUI	NDUS EXAMINATION (From rec	ords if within 9 months				
OD	Describe any findings outside normal limits	OS				
	1. Crystalline Lens					
inertia store Silentemore	2. Pre Retinal Media					
	3. Central Retina					
	4. Peripheral Retina					
	5. Optic Nerve					
	6. Other	the second s				

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

## PARAGON VISION SCIENCES

**BASELINE VISIT** 

PAGE 3 OF 3

SUBJECT INFORMATION								
Investigator Name:	Investigator No.:	Dat	te of Visit:					
Subject Name:		Sut	oject No.:					
PART X: SUBJECT ME	PART X: SUBJECT MEETS ALL INCLUSION CRITERIA? YES / NO							
IF NO: D	IF NO: Describe conditions subject fails to meet:							
OD	1							
IF YES: Will the	Subject Enroll in the Study	? YES	i / N	0				
IF N	O: Check Reason for Not	Enrolling	3					
	<ul> <li>Poor lens centration</li> <li>Other:</li> </ul>	auty 7			X. 8.			
IF YES: Record Ta	arget Refractive Error and L		scription Or	der				
Diopters	Target Post Treatment Spheric Equivalent (Spectacle Plane)				Diopters			
Desi	gn from Diagnostic Lens E	valuatio	n					
D / mm mm. / mm mm. / mm mm. / mm mm. / mm mm Light Medium Heavy	Lens Power / Base Curve Total Diameter/ Optic Zone Secondary Curve Radius / Wio Intermediate Curve Radius / Wio Peripheral Curve Radius / Wio Center Thickness Blend	dth idth dth Li	mm. mm. mm. mm. ght Med		mm mm mm mm mm Heavy			
OR Direct Order	Method (Outside of range	ত বিষয়	nostic lenses	s)				
A Bluend Vision D D mm	Base Curve (assuming +1.00 Diopter Lens Pow to achieve Target Post Treatment Refractive Error)		Explain Otler		mm			
Investigator Signature:	· · · · ·	Date:						

## **PARAGON VISION** SCIENCES

**DISPENSING VISIT 1** 

#### USE BLACK INK ONLY

USE BLACK INK ONLY		PAGE 1 OF 1		
Investigator Name:	Investigator No.:	Date of Visit:		
Subject Name:		Subject No.:		
PART I: I	NSERT STUDY LENSES - Wait	15 Minutes		
OD: Power: Base Cu	rve:OS: Power:	Base Curve:		
PARTI	OCULAR EXAM WITH STUD	(LENSES		
OD	o Comprote And (Critice) Manual	OS		
ExcellentGoodPoor54321	1. Lens Comfort:	ExcellentGoodPoor54321		
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		
BearingAlignedVaulting12345678910	6. Lens/Eye Relationship: Optic Zone	BearingAlignedVaulting12345678910		
BearingAlignedVaulting12345678910	7. Lens/Eye Relationship: Reverse Zone	BearingAlignedVaulting12345678910		
BearingAlignedVaulting12345678910	8. Lens/Eye Relationship: Peripheral Zone	BearingAlignedVaulting12345678910		
	PART III: SUBJECT SYMPTOM	S		
ODOS1. NoneImage: Image: Im	ODOS5. Dryness/Scratchiness□6. Variable Vision□7. Photophobia□8. Halos□	OD OS 9. Lens Needs Cleaning 10. Other Explain Other: OD: OS:		
	PART IV: COMMENTS			
		Explain Other: OD: OS:		
Investigator Signature:	Date			

## PARAGON VISION SCIENCES

FOLLOW-UP VISIT 1 TWO WEEK VISIT

#### USE BLACK INK ONLY

PAGE 1 OF 2

1	PART I: SUBJECT INFORMATI	ON			
Investigator Name:	Investigator No.:	Date of Visit:			
Subject Name:	Subject No.:	Subject No.:			
1. Number of days of lens we	ar since last visit				
2. Average lens wearing time	per day since last visit:	Hours			
3. Number of hours of lens we					
	NUST COMPLETE CURRENT L				
	hire Complete? (Circle)	YES NO			
PARTI	OCULAR EXAM WITH STUD	T LENSES			
OD: Power: Base Cur	rve: OS: Power:	Base Curve:			
OD		OS			
ExcellentGoodPoor54321	1. Lens Comfort:	ExcellentGoodPoor54321			
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			
BearingAlignedVaulting12345678910	6. Lens/Eye Relationship: Optic Zone	BearingAlignedVaulting12345678910			
Bearing         Aligned         Vaulting           1         2         3         4         5         6         7         8         9         10	7. Lens/Eye Relationship: Reverse Zone	BearingAlignedVaulting12345678910			
Bearing         Aligned         Vaulting           1         2         3         4         5         6         7         8         9         10	8. Lens/Eye Relationship: Peripheral Zone	BearingAlignedVaulting12345678910			
	PART IV: SUBJECT SYMPTOM				
OD OS 1. None 2. Discomfort/Awareness 3. Itching/Burning 4. Blurred Vision COD OS COD OS	ODOS5. Dryness/ScratchinessI6. Variable VisionI7. PhotophobiaI8. HalosI	OD OS 9. Lens Needs Cleaning 10. Other Explain Other: OD: OS: OS:			
	CONTINUE ON THE NEXT PAG	E			

## EREPORT FORM DY ID: PVS 98 - 2

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## **PARAGON VISION SCIENCES**

#### FOLLOW-UP VISIT 1 **TWO WEEK VISIT**

-UP VISIT ONTH VIS

AC	GE	2	OF	2
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LACKINKONLY	•*	PAGE 2 OF 2	AGE 1 OF
2	SUBJECT INFORMATION		
ator Name:	Investigator No.:	Date of Visit:	
Name:		Subject No.:	
Remove	enses and allow 10 minute tear fi	Im equilibration	
	SLIT LAMP EXAMINATION (After		
OD	(circle grade)	, OS	
1 2 3	4 1. Edema	0 1 2 3 4	RE
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	3 4
	2 3	Explain:	Poor
any abnormal SLE find	ngs:		2 1
PART V	OCULAR EXAMINATION (After	.ens Removal)	r X
OD		OS	
Letters @	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided	Letters @ ft.	@ ft.
Louis @	(Record test distance in feet from patient)	Letters & In	1 (1) (1) (1) (1)
Cylinder	2. Subjective Refraction	Sphere Cylinder	-der
X	Cylader Z. Subjective Real	X	.0 1.25
	3. LogMar High Contrast Acuity		.0 1.25 m
Letters @	t. Single Letter VA with Subjective Refraction	Letters @ ft.	i Vaultin
Vertical	4. Keratometry	Horizontal Vertical	7 8 9
@	Vertical 4. Kermiometry	@	Vaultin
5. CORNEAL	TOPOGRAPHY (Attach Tangenti	al Plot Power Map)	7 8 9
	6. IOP		Vaultin 7 8 9
mm./ hg	G. IOP	mm. / hg	7 8 9
DADT	/III: Lens Replacement Required	2 VES/NO	OD OS
1 AUT	If yes complete lens replacement		ing 🗆 🗖
GATOR COMMEN	TS:		
or comment	TOR COMMENTS:		D:
		•	S:
ator Signature:	Dat	e:	
Investigator S	ignations:	Date:	

## PARAGON VISION SCIENCES

#### FOLLOW-UP VISIT 2 ONE MONTH VISIT

## USE BLACK INK ONLY

#### PAGE 2 OF 2

	SUBJECT INFORMATION							
Investigator Name:	Investigator No.:	Date of	of Visit	:				
Subject Name:		Subjec	ct No.:					
Remove ler	ises and allow 10 minute tear fill	n equil	il inatit	m				
	IT LAMP EXAMINATION (After L							
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:	and and the state of the state	Explain	n:	Course S		Prop		
Describe any abnormal SLE findings	5:	5	4	3 .	2	1		
PART VI: (	OCULAR EXAMINATION (After L	:);:::::::::::::::::::::::::::::::::::	8810347	1				
OD	1.1.2. LogMar High Control Aculty			OS				
Letters @ ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided Letters (Record test distance in feet from patient)			alugits -	@	ft.		
Sphere Cylinder X	2. Subjective Refraction	Sphere	0.5	Cylind	er X	5 1.5		
Letters @ ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	1.75 Bearl	L	etters	@	ft.		
Horizontal Vertical	4. Keratometry	Horizon	tal	Vertic	al Ø	0		
5. CORNEAL T	<b>OPOGRAPHY</b> (Attach Tangentia	I Plot F	ower	Map)	V	alting		
. mm./ hg	6. IOP	12		5 6	mm. /	hg		
	I: Lens Replacement Required? yes complete lens replacement f		NO;					
INVESTIGATOR COMMENTS	7. Photophobia Q Q		xplain (	other O	D S			
Investigator Signature:	Date	:						

## PARAGON VISION SCIENCES

#### FOLLOW-UP VISIT 3 TWO MONTH VISIT

#### USE BLACK INK ONLY

### PAGE 1 OF 2

	PART I: SUBJECT INFORMATI	ON
Investigator Name:	Investigator No.:	Date of Visit:
Subject Name:		Subject No.:
1. Number of days of lens we	ar since last visit	
2. Average lens wearing time	per day since last visit:	Hours
3. Number of hours of lens w	ear today: / Hours	0.5
PART II: SUBJECT I	NUST COMPLETE CURRENT L	ENS QUESTIONNAIRE
Questionna	aire Complete? (Circle)	YES NO
PART III	: OCULAR EXAM WITH STUD	Y LENSES
OD: Power: Base Cu	rve: OS: Power:	Base Curve:
OD .		OS
ExcellentGoodPoor54321	1. Lens Comfort:	ExcellentGoodPoor54321
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	BearingAlignedVaulting12345678910
Bearing         Aligned         Vaulting           1         2         3         4         5         6         7         8         9         10	7. Lens/Eye Relationship: Reverse Zone	BearingAlignedVaulting12345678910
Bearing         Aligned         Vaulting           1         2         3         4         5         6         7         8         9         10	8. Lens/Eye Relationship: Peripheral Zone	BearingAlignedVaulting12345678910
	PART IV: SUBJECT SYMPTON	
ODOS1. NoneImage: Constraint of the second secon	ODOS5. Dryness/ScratchinessI6. Variable VisionI7. PhotophobiaI8. HalosI	OD OS 9. Lens Needs Cleaning 10. Other Explain Other: OD: OS:
	CONTINUE ON THE NEXT PAG	E

## PARAGON VISION SCIENCES

FOLLOW-UP VISIT 3 TWO MONTH VISIT

#### USE BLACK INK ONLY

#### PAGE 2 OF 2

					SUBJECT INFORMATION					
Investi	gator l	Name:			Investigator No.:	Date of	Visit:			
Subject	t Name	e:				Subject No.:				
		R	emov	e len:	ses and allow 10 minute tear filn	n equilit	mation			
					IT LAMP EXAMINATION (After L					
	mhet	OD	13 61	0001	(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 Explain	1 n:	2	3	4	6. Other	0 Explain:		2	3	4
		bnormal	SLE fit	ndings:	AT EASER CARRIER D	1	4		2/10	1
		1	PART	VI: C	CULAR EXAMINATION (After Le	ans Ron	ioval)			
		OD			1.3. Logister fligh Contrast Acidly			OS		
	Le	etters @	D	ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)	X	Lette	rs @	>	ft.
Sphere	0.5	Cylinder	x		2. Subjective Refraction	Sphere	C	ylinder	x	5 1.5
1.75 Beari	Le	etters @	D	ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	1.75 Bearing	Lette	rs @	>	ft.
Horizonta	al	Vertical		<u>g</u>	4. Keratometry	Horizontal	AB	Vertical		<u>@</u>
1		5. CC	ORNE	AL TO	<b>OPOGRAPHY</b> (Attach Tangential	Plot Po	wer Ma	ap)	Vi	intring
1 2	3 4	5 6	mm./ h	9 1	6. IOP	1.2.2	4 5	6	mm. /	hg
	TIGA		OMME	ENTS:	5. Crymensscencemens G G 6. Variable Vision G G 7. Photophobia G G 8. Halos G G	10. Othe Exp	ain Oth	r: OD OS:	0	0
Investig	ator Si	gnature:			Date:	:				

## PARAGON VISION SCIENCES

FOLLOW-UP VISIT 4 THREE MONTH VISIT

#### USE BLACK INK ONLY

PAGE 1 OF 2

	PARTI: SUBJEC	T INFORMATI	ON		
Investigator Name:	Investigator No.:		Date of Visit:		
Subject Name:		Aller - Marrie	Subject No.:		
1. Number of days of lens we	ar since last visi	t			
2. Average lens wearing time	per day since las	st visit:	Hours		
3. Number of hours of lens we	ear today:	/ Hours	OS		
PART II: SUBJECT I	NUSTICOMPLET	- Muthanne	ENS QUESTIONNAIRE		
Questionna	aire Complete?	(Circle)	YES NO		
PART III	: OCULAR EXAN	A WITH STUD	Y LENSES		
OD: Power: Base Cu	S. Tarea	OS: Power:	Base Curve:		
OD: Power Base Cu	Ive:	US: Power:	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 C Single Letter VA with S		Letters @ ft.		
X Y	4. Lens Centrati (In straight ahead	ON: I 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 Moveme (After normal blin	nt: k 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		
BearingAlignedVaulting12345678910	6. Lens/Eye Rela Optic 2	tionship:	BearingAlignedVaulting12345678910		
BearingAlignedVaulting12345678910	7. Lens/Eye Rela Reverse	tionship:	BearingAlignedVaulting12345678910		
BearingAlignedVaulting12345678910	8. Lens/Eye Rela Periphera		BearingAlignedVaulting12345678910		
	PART IVA SUBJE	the second se	S		
ODOS1. NoneImage: Image: Im	<ol> <li>Dryness/Scratchin</li> <li>Variable Vision</li> <li>Photophobia</li> <li>Halos</li> </ol>	OD OS ness	OD OS 9. Lens Needs Cleaning		
	CONTINUE ON T		Ξ.		

## PARAGON VISION SCIENCES

FOLLOW-UP VISIT 4 THREE MONTH VISIT

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PAGE 2 OF 2

					SUBJECT INFORMATION					
Investig	gator N	Vame:			Investigator No.:	Date of	of Visit	::		
Subject	t Name	:			the states that wait	Subjec	et No.:			
		R	emov	e len	ses and allow 10 minute tear filr	n eetiil	ibrati	on		
					IT LAMP EXAMINATION (After L					
		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 Explain	1 n:	2	3	4	6. Other	0 Explain	1 n:	2	3	4
Describe	e any a	bnormal	-		CULAR EXAMINATION (After L	ans fa	mova	6		
		OD						OS		
X	Le	etters @	Ď	ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)					ft.
Sphere	0.5	Cylinder	X	5 1.	2. Subjective Refraction	Sphere	1 0.5 5 2.0	Cylinde	er X	25 1.5 2.5 mm
Benfe 2 B	Le	etters @	Ð	ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	Beeri 1 2	L	etters (	@	ft.
Horizonta	4 5	Vertical	1 @	>	4. Keratometry	Horizon	tal	Vertic		<u>@</u>
1	1 5	5. CC	DRNE/	AL TO	<b>OPOGRAPHY</b> (Attach Tangentia	I Plot P	ower	Map)	7 8	9 10
		1.1	mm./ hg		6. IOP				mm. /	hg
	TIGA	TOR CO	OMME	NTS:	7. Photopheteia 0 0			Other: 0		
Investig	ator Sig	mature:			Date	:				

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## PARAGON VISION SCIENCES

Unscheduled Visit

Discontinuation Visit

PAGE 1 OF 2

OSE BEACK INK ONET		TAGE FOR 2
	PART I: SUBJECT INFORMATIO	ON
Investigator Name: In	vestigator No.:	Date of Visit:
Subject Name:		Subject No.:
1. Number of days of lens we	ar since last visit	
2. Average lens wearing time		Hours
3. Number of hours of lens we		0 1 2 3 4
PART II: SUBJECT N	NUST COMPLETE CURRENT LE	NS QUESTIONNAIRE
Questionna	ire Complete? (Circle)	YES NO
PART III: OCULAR I	EXAM WITH STUDY LENSES (If	on at arrival for visit)
OD: Power: Base Cur	ve: OS: Power:	Base Curve:
OD		OS
ExcellentGoodPoor54321	1. Lens Comfort:	ExcellentGoodPoor5432
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	BearingAlignedVaulting12345678910
Bearing         Aligned         Vaulting 1           2         3         4         5         6         7         8         9         10	7. Lens/Eye Relationship: Reverse Zone	BearingAlignedVaulting12345678910
Bearing         Aligned         Vaulting 1           2         3         4         5         6         7         8         9         10	8. Lens/Eye Relationship: Peripheral Zone	BearingAlignedVaulting12345678910
	PART IV: SUBJECT SYMPTOMS	3
OD OS 1. None 2. Discomfort/Awareness 3. Itching/Burning 4. Blurred Vision	OD OS 5. Dryness/Scratchiness 6. Variable Vision 7. Photophobia 8. Halos CONTINUE ON THE NEXT PAGE	OD OS 9. Lens Needs Cleaning  10. Other Explain Other: OD: OS: OS:

## PARAGON VISION SCIENCES

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Unscheduled Visit

Discontinuation Visit

#### USE BLACK INK ONLY

PAGE 2 OF 2

Invest	igator	Name:			Investigator No.:	Date of Visit:				
Subjec	ct Nam	ne:			Investigner No.:	Subject	: No.:	C		
			PART	V: SI	LIT LAMP EXAMINATION (After L	ens Rei	mova	al)		
		OD	0	Cotton Contraction	(circle grade)		20000	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 Explain	0 1 2 3 4 Explain:			4	6. Other	0 1 2 3 Explain:			4	
	the second s	abnorma	I SLE fi	indings:	(Record and Galaria v. (bit from patient) 2. Subjective Refraction	Sphtre		0/40		
	F		- OC		EXAMINATION (Without Lens of	AfterL	ens		<i>i</i> al)	
		OD			3. Lagither High Constrait Acadey			OS		
Letters @ ft.					1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)	Horizon	Letters @ ft.			
Sphere		Cylinde	er X	EAL	2. Subjective Refraction	Sphere	Sphere Cylinder X			x
	I	Letters (	@	ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction		L	Letters	@	ft.
Horizont	al	Vertic		@	4. Keratometry	Horizonta	म	Vertic		@
		5. 0	CORNE	EAL T	OPOGRAPHY (Attach Tangential	I Plot Po	ower	Map)		4
1	1	2	<b>mm./</b> h		6. IOP	0 O Eventain		2	mm.	/ hg
	ī	PART V	/II: RE	4.(S(0))	N FOR VISIT OR DISCONTINUATI	ON (Se	લ્ભો (	only or	ie)	
	k of Co k of Int	ble Visua omfort			<ul> <li>Protocol Violation</li> <li>Missed Visits</li> <li>Pathology/Adverse Reaction (Comple</li> <li>Other:</li></ul>					
			PAI		I: Lens Replacement Required? yes complete lens replacement f	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	10;			
Investig	gator S	Signature:			Dat	te:				

### PARAGON VISION SCIENCES

FOLLOW-UP VISIT 5 8 HOURS POST 3 MONTH

PAGE 1 OF 2

#### USE BLACK INK ONLY

PART I: SUBJECT INFORMATION Investigator No.: Investigator Name: Date of Visit: Subject Name: Subject No .: PART IP SUBJECT MUST COMPLETE CURRENT LENS QUESTIONNAIRE Questionnaire Complete? (Circle) NO YES PART III: OCULAR EXAM WITH NO LENS WEAR FOR \$ (@) \$ ! <del>:</del> ! : : : : : NOTE: Examine ONLY the eye that has had NO LENS WEAR OD OS 1. Unaided LogMar High Contrast Letters @ ft. Letters @ ft Acuity Single Letter VA Unaided (Record test distance in feet from patient) Cylinder Cylinder Sphere Sphere 2. Subjective Refraction X X 3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction ft. Letters @ ft. Letters @ Vertical Vertical Horizontal Horizontal 4. Keratometry @ @ 5. CORNEAL TOPOGRAPHY (Attach Tangential Plot Power Map) PART V: SLIT LAMP EXAMINATION (circle grade) OS OD 3 0 2 3 0 2 4 1. Edema 1 4 1 3 0 2 3 0 1 2 4 2. Neovascularization 1 4 2 3 1 2 3 0 1 4 0 4 3. Staining 2 3 2 3 4 0 1 0 1 4 4. Injection 2 3 0 1 2 3 5. Tarsal Abnormalities 0 1 4 4 3 0 1 2 3 4 0 1 2 4 6. Other **Explain:** Explain: Describe any abnormal SLE findings: INVESTIGATOR COMMENTS: Investigator Signature: Date:

## PARAGON VISION SCIENCES

#### FOLLOW-UP VISIT 6 24 HOURS POST 3 MONTH

### USE BLACK INK ONLY

PAGE 1 OF 2

				PART I: SUBJECT INFORMATI	ON				
Investig	ator Name	:		Investigator No.:	Date of	Visit	:		
Subject	Name:			1	Subject	No.:		-	
	PART	10911		MUST COMPLETE CURRENT L	ENSION		ONNA		
				aire Complete? (Circle)	YES	NC			
	PAR	THE OWNERS OF THE PARTY OF THE	THE OWNER AND A DESCRIPTION OF	R EXAM WITH NO LENS WEAR				8	
				ine ONLY the eye that has had	·/////////////////////////////////////				
	OD						OS		
	Letters	@	ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)		L	etters	@	ft.
Sphere	Cylin		x	2. Subjective Refraction	Sphere	4	Cylind		x
-	Letters	@	ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction		L	etters	@	ft.
Horizontal	Ver	tical	@	4. Keratometry	Horizonta	ग	Vertic	al	@
	5.	CORN	IEAL TO	<b>OPOGRAPHY</b> (Attach Tangentia	al Plot P	ower	Map)		
				ART V: SLIT LAMP EXAMINATI					
	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 Explain:	1 2	3	4	6. Other	0 Explain	1	2	3	4
Describe	any abnorn	nal SLE	findings:						
INVEST	IGATOR	COMN	MENTS:						
Investigat	tor Signatur	re:		Date	e:				

## PARAGON VISION SCIENCES

FOLLOW-UP VISIT 7 48 HOURS POST 3 MONTH

PAGE 1 OF 2

#### USE BLACK INK ONLY

				PART I: SUBJECT INFORMATI	ON			
Investig	ator Nam	ie:		Investigator No.:	Date of	Visit:		
Subject	Name:			A A DA	Subject	No.:		
	PART	11:51	ાગાલભા	MUST COMPLETE CURRENT L	INS QUE	STIONN	AIRE	
		Qu	estionn	aire Complete? (Circle)	YES	NO		
	PAR	it III:	OCULA	R EXAM WITH NO LENS WEAR	FOR	HOU	RS	
	OI	)				09	5	
	Letters	6 @	ft.	1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)		Letters	@	ft.
Sphere	Cyl	inder	X	2. Subjective Refraction	Sphere	Cylin	nder	x
	Letters	. @	ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction		Letters	@	ft.
Horizontal	Ve	ertical	@	4. Keratometry	Horizontal	Ver	tical	@
	5.	COR	NEAL TO	<b>OPOGRAPHY</b> (Attach Tangentia	I Plot Po	wer Map	)	
			F	ART V: SLIT LAMP EXAMINATI	ON			
	OI	)		(circle grade)		OS		
0	1 2	3		1. Edema	. 0	1 2	3	4
0	1 2	3		2. Neovascularization	0	1 2	3	4
0	1 2	3		3. Staining	0	1 2	3	4
0	1 2	3		4. Injection	0	1 2	3	4
0	1 2	3		5. Tarsal Abnormalities	0	1 2	3	4
0		-						4
Explain:	1 2	3		6. Other	0 Explain:	1 2	3	4
Explain:	any abnor					1 2	3	4
Explain: Describe		mal SLI	E findings:			1 2	3	4

## PARAGON VISION SCIENCES

FOLLOW-UP VISIT 8 72 HOURS POST 3 MONTH

PAGE 1 OF 2

## USE BLACK INK ONLY

					PART I: SUBJECT INFORMATI	ON				
Investig	gator 1	Name:			Investigator No.:	Date of	Visit	:		
Subject	Name	e:				Subject	No.:			1
	2	Aria de	SUE	NE(OT)	MUST COMPLETE CURRENT L	ens Qu	#3911	ONNA	IRE	
			Que	stionna	aire Complete? (Circle)	YES	NC	)		
					R EXAM WITH NO LENS WEAR			HOUN	S	
			2.1		ne ONLY the eye that has had	<u>//@@@@</u> //	S. 172			
		OD						OS		
Letters @ ft.					1. Unaided LogMar High Contrast Acuity Single Letter VA Unaided (Record test distance in feet from patient)		L	etters	@	ft.
Sphere	On-a	Cylinde		x	2. Subjective Refraction	Sphere	for ye	Cylind		X
	Le	etters (	@	ft.	3. LogMar High Contrast Acuity Single Letter VA with Subjective Refraction	etters	@	ft.		
Horizonta	1	Vertica	al	@	4. Keratometry	Horizonta	d.	Verti	cal	@
4.	Plés	5. C	ORN	EAL TO	<b>DPOGRAPHY</b> (Attach Tangentia	al Plot P	ower	Map)	COS.	
				~~~~~	ART V: SLIT LAMP EXAMINATI					
		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 Explain:	1	2	3	4	6. Other	0 Emploin	1	2	3	4
	the second se			C" 1'	1997	Explain			-	
Describe	Cons				hout the day D D D.O				à	
INVES				ENTS:	7) g in sport activities					
Investiga	ator Si			king (si	Date	e:	5 4	3 2	1	

(show eaclo to

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 Nam
-------------

e+\*

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.

10 9 8 7 8 5	E	cell	ent							1	Poor	
		10	9	8	7	6	5	4	3	2	1	
Overall visual sharpness and clarity		10	9	8		6	<b>□</b> 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)					<b>•</b>	ā	ū	ā	ă	ā	ġ	
		10	9	8	7	6	5	4	3	2	1	
Consistent vision throughout the day (Stable or variable vision while wearing your correction?)												
		10	9	8	7	6	5	4	3	2	1	
Vision while participating in sport activitie (if applicable) Which sport(s)?	es											
	_	10	9	8	7	6	5	4	3	2	1	
Vision while working (such as working at computer, reading fine print, long periods of close work)			Ō	Ō		à						

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

Check only one box per line.

4 <sup>4</sup>	Excell	ent								Poor
	10	9	8	7	6	5	4	3	2	1
Overall visual sharpness and clarity										
A. What, If anything, do you like about this	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 unaided vision)	10									
	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)									ā	

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

Very Satisfied									ot At A atisfied	
10	9	8	7	6	5	4	3	2	1	

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

Very Satisfie									ot At Allatisfied	
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 study lenses while filling out the questionnaire.

Pat	ient Name	**	Date
			10.9 8 7 6 5 4 3 2
۱.	A. What, if anythin	ng, do you like abo	out this pair of study lenses?
	Overall contort		16 9 8 7 8 5 4 3 2 0 0 0 0 0 0 0 0
	B What if anythin	na do vou dislike	about this pair of study lenses?
	tok only one box p	ng, do you diointo t	about the pair of oldey foneco.
	Chapteril viewed etca	more and Sarth	10.0.8.7.6.6.4.9.2.4
2.	On average, how r	many days a week	did you wear your study lenses?
3.	(such as driving at	I night or reading a	did you wear your study lenses?
l. Che	Please rate the stu ck only one box p		on the following visual attributes.
			Excellent Poo
			10 9 8 7 6 5 4 3 2 1
	Overall visual shar	rpness and clarity	
		n alian limba aitu ati a a	10 9 8 7 6 5 4 3 2 1
	Night Vision/low or (such as driving at menu in a dark res	night or reading a	

5 10 9 8 7 6 Consistent vision throughout the day (Stable or variable vision with the study lenses) 10 9 8 7 6 5 Vision while participating in sport activities (if applicable) Which sport(s)?

10 9

8

3 2 1

3 2 1

3 2 1

4

4

7 6 5 4

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.

tent Neme	Excellent									
	10 9 8 7 6 5 4	3 2 1								
Comfort of the lenses when you first put then										
A. What, if enviting, do you like about this r	10 9 8 7 6 5 4	3 2 1								
Comfort of the lenses at the end of the wear										
	10 9 8 7 6 5 4 3	3 2 1								
Overall comfort										

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

Check only one box per line.

		Excell	ent							1	Poor
		10	9	8	7	6	5	4	3	2	1
Overall	visual sharpness and clarity	10	9	8	<b>□</b> 7	6	5	4	3	2	1
(such a	(ision/low or dim light situations as driving at night or reading a n a dark restaurant)					ā					
		10	9	8	7	6	5	4	3	2	1
	tent vision throughout the day or variable unaided vision)										
		10	9	8	7	6	5	4	3	2	1
(if appli	while participating in sport activities icable) sport(s)?		Ŏ			ū	ū			ā	
(autoria a	e device at sight or reading a	10	9	8	7	6	5	4	3	2	1
	while working (such as working at a ter, reading fine print, long periods e work)		0	8	0		0			0	

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

Very Satisfie	d								ot At atisfie	
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			

Questio	nnaire to be	administe	ered at the	Follow-U	p Visit	before	removing th	ne clinical	study
lenses.	The patient	must be v	vearing the	e lenses v	while fil	ling out	the question	onnaire.	

	Patient Questionnaire - Study Lenses: One Month
Pa	itient Name Date
1.	A. What, if anything, do you like about this pair of study lenses?
	Please rate your unaided station or the featureline mean attributes
	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?
	Please rate the study contact lenses on the following visual attributes. eck 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
	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)										
Settered	10	9	8	7	6	5	4	3	2	1
Vision while participating in sport activities (if applicable) Which sport(s)?										
Overall, how satisfied are you with sever environments	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)	•									
10 9 4 7 6 4 4										

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

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

1

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

Check	only	one	box	per	line.	
-------	------	-----	-----	-----	-------	--

	Ex	cell	ent							•	Poor	
		10	9	8	7	6	5	4	3	2	1	
Overall visual sharpness and clarity		10	9	8	<b>□</b> 7	<b>1</b> 6	<b>□</b> 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 unaided vision)												
		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)												

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

Very Satisfie									ot At A atisfie	
10	9	8	7	6	5	4	3	2	1	

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

Very Satisfie									ot At Al atisfied	
10	9	8	7	6	5	4	3	2	1	