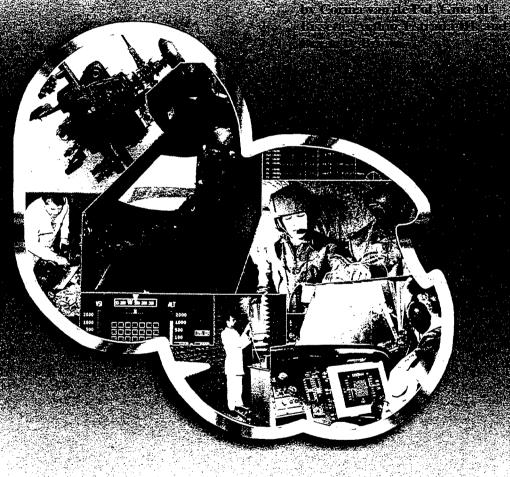
## USAARL Report No. 2005-02

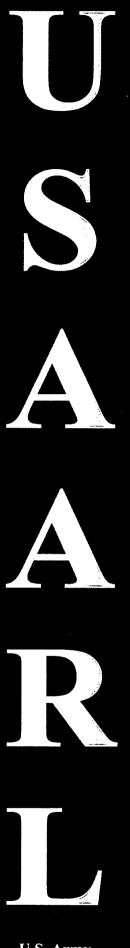
Preliminary Evaluation of Visual and Flight Performance of Three Current Multifocal Contact Lens Designs for Presbyopic U.S. Army Aviators



Aircrew Health and Performance Division

January 2005

Approved for public release, distribution unlimited.



U.S. Army Aeromedical Research Laboratory

## **Notice**

## Qualified requesters

Qualified requesters may obtain copies from the Defense Technical Information Center (DTIC), 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, Virginia 22060-6218. Orders will be expedited if placed through the librarian or other person designated to request documents from DTIC.

## Change of address

Organizations receiving reports from the U.S. Army Aeromedical Research Laboratory on automatic mailing lists should confirm correct address when corresponding about Laboratory reports.

## **Disposition**

Destroy this document when it is no longer needed. Do not return it to the originator.

### **Disclaimer**

The views, opinions, and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, or decision, unless so designated by other official documentation. Citation of trade names in this report does not constitute an official Department of the Army endorsement or approval of the use of such commercial items.

### <u>Human use</u>

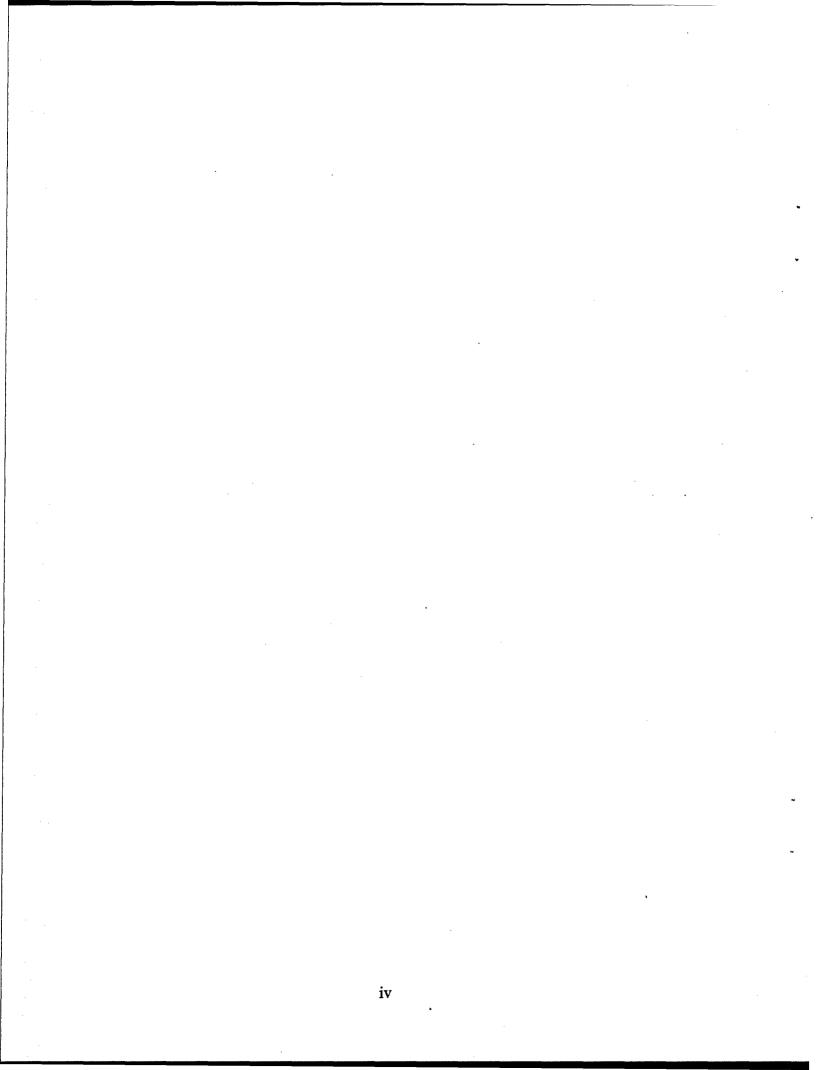
Human subjects participated in these studies after giving their free and informed voluntary consent. Investigators adhered to AR 70-25 and USAMRMC Regulation 70-25 on Use of Volunteers in Research.

REPORT D	Form Approved OMB No. 0704-0188			
Public reporting burden for this collection of infor gathering and maintaining the data needed, and o collection of information, including suggestions for Davis Highway, Suite 1204, Arlington, VA 2220	rmation is estimated to average 1 hour per res completing and reviewing the collection of info or reducing this burden, to Washington Heado 12-4302, and to the Office of Management an	ponse, including the time for review rmation. Send comments regarding uarters Services, Directorate for Inf d Budget, Paperwork Reduction Pro	ving instructions, searching existing data sources, ying instructions, searching existing data sources, if this burden estimate or any other aspect of this ormation Operations and Reports, 1215 Jefferson oject (0704-0188), Washington, DC 20503,	
1. AGENCY USE ONLY (Leave blan	DATES COVERED			
4. TITLE AND SUBTITLE Preliminary Evaluation of Visual Contact Lens Designs for Presby	5. FUNDING NUMBERS			
6. AUTHOR(S) van de Pol, Corina; Bissette, Gin	na M.; Estrada, Arthur; Brown	, Bryan D.		
7. PERFORMING ORGANIZATION N. U.S. Army Aeromedical Researc P.O. Box 620577 Fort Rucker, AL 36362-0577	8. PERFORMING ORGANIZATION REPORT NUMBER 2005-02			
9. SPONSORING / MONITORING AG U.S. Army Medical Research and 504 Scott Street Fort Detrick, MD 21702-5012	GENCY NAME(S) AND ADDRESS(I d Materiel Command	ES)	10. Sponsoring / Monitoring Agency Report Number	
·····				
11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY Approved for public release, dist		2005/	1010 NØ/	
12a. DISTRIBUTION / AVAILABILITY Approved for public release, dist 13. ABSTRACT (Maximum 200 wo U.S. Army aviators have been au authorized contact lens modality become presbyopic, they often ha complete their aviation duties. S This pilot study evaluated the pot for presbyopic aviators. Bifocal multifocal contact lenses evaluate with the multifocal contact lenses head-mounted displays or night v being considered since visual per problems with bifocal spectacles platforms. Many Apache pilots I presbyopia and spectacle compati	vrds) ithorized to wear contact lenses is the single-vision soft contact ave to return to bifocal spectact pectacles introduce interface put tential utility of multifocal com spectacles or readers provide b ed. Flight performance in a UI s evaluated in this study; hower vision goggle flight performance formance remained within norm and head-mounted displays and have been permanently grounded ibility issues in the cockpit. M	o for aviation duties with lens that corrects for 2 le wear or readers over to oblems with head-mount tact lenses to provide ad etter levels of visual per 1-60 simulator under da ver, this study did not e e. Studies specific to the ns and Apache pilots ar l protection mask config ed or converted to other ultifocal contact lenses,	their distance contact lenses in orde need displays and night vision goggl lequate visual and flight performance rformance than any of the three sytime conditions was not decremen valuate night flight, interface with he Apache flight environment are e faced with greater interface gurations than pilots in other aviation platforms due to the onset of when fit to specific parameters, ma	
12a. DISTRIBUTION / AVAILABILITY Approved for public release, dist 13. ABSTRACT (Maximum 200 wo U.S. Army aviators have been au authorized contact lens modality become presbyopic, they often ha complete their aviation duties. S This pilot study evaluated the pot for presbyopic aviators. Bifocal multifocal contact lenses evaluate with the multifocal contact lenses head-mounted displays or night v being considered since visual per problems with bifocal spectacles platforms. Many Apache pilots I presbyopia and spectacle compati be an option under special circum	ribution unlimited wds) thorized to wear contact lenses is the single-vision soft contact ave to return to bifocal spectac. pectacles introduce interface pri- tential utility of multifocal com- spectacles or readers provide b ed. Flight performance in a UI s evaluated in this study; hower vision goggle flight performance formance remained within normand head-mounted displays and have been permanently grounder ibility issues in the cockpit. Monstances where spectacles woul	a for aviation duties with elens that corrects for 2 wear or readers over to roblems with head-mount tact lenses to provide ad etter levels of visual per H-60 simulator under da ver, this study did not e e. Studies specific to the ns and Apache pilots ar l protection mask config ed or converted to other ultifocal contact lenses, d lead to reduced perfor	h special waiver since 1991. The 0/20 distance and near. As aviators their distance contact lenses in order need displays and night vision goggl lequate visual and flight performance formance than any of the three bytime conditions was not decremen valuate night flight, interface with the Apache flight environment are e faced with greater interface gurations than pilots in other aviatio platforms due to the onset of when fit to specific parameters, ma mance. 15. NUMBER OF PAGES	
12a. DISTRIBUTION / AVAILABILITY Approved for public release, dist 13. ABSTRACT (Maximum 200 wo U.S. Army aviators have been au authorized contact lens modality become presbyopic, they often ha complete their aviation duties. S This pilot study evaluated the pot for presbyopic aviators. Bifocal multifocal contact lenses evaluate with the multifocal contact lenses head-mounted displays or night v being considered since visual per problems with bifocal spectacles platforms. Many Apache pilots I presbyopia and spectacle compati be an option under special circum	ribution unlimited wds) thorized to wear contact lenses is the single-vision soft contact ave to return to bifocal spectac. pectacles introduce interface pri- tential utility of multifocal com- spectacles or readers provide b ed. Flight performance in a UI s evaluated in this study; hower vision goggle flight performance formance remained within normand head-mounted displays and have been permanently grounder ibility issues in the cockpit. Monstances where spectacles woul	a for aviation duties with elens that corrects for 2 wear or readers over to roblems with head-mount tact lenses to provide ad etter levels of visual per H-60 simulator under da ver, this study did not e e. Studies specific to the ns and Apache pilots ar l protection mask config ed or converted to other ultifocal contact lenses, d lead to reduced perfor	h special waiver since 1991. The 0/20 distance and near. As aviators their distance contact lenses in order need displays and night vision goggl lequate visual and flight performance formance than any of the three bytime conditions was not decremen valuate night flight, interface with the Apache flight environment are e faced with greater interface gurations than pilots in other aviatio platforms due to the onset of when fit to specific parameters, ma mance.	
12a. DISTRIBUTION / AVAILABILITY Approved for public release, dist 13. ABSTRACT (Maximum 200 wo U.S. Army aviators have been au authorized contact lens modality become presbyopic, they often ha complete their aviation duties. S This pilot study evaluated the pot for presbyopic aviators. Bifocal multifocal contact lenses evaluate with the multifocal contact lenses head-mounted displays or night v being considered since visual per problems with bifocal spectacles blatforms. Many Apache pilots h presbyopia and spectacle compati be an option under special circum	ribution unlimited wds) thorized to wear contact lenses is the single-vision soft contact ave to return to bifocal spectac. pectacles introduce interface pri- tential utility of multifocal com- spectacles or readers provide b ed. Flight performance in a UI s evaluated in this study; hower vision goggle flight performance formance remained within normand head-mounted displays and have been permanently grounder ibility issues in the cockpit. Monstances where spectacles woul	a for aviation duties with elens that corrects for 2 wear or readers over to roblems with head-mount tact lenses to provide ad etter levels of visual per H-60 simulator under da ver, this study did not e e. Studies specific to the ns and Apache pilots ar l protection mask config ed or converted to other ultifocal contact lenses, d lead to reduced perfor	h special waiver since 1991. The 0/20 distance and near. As aviators their distance contact lenses in order need displays and night vision goggl lequate visual and flight performance rformance than any of the three bytime conditions was not decremen valuate night flight, interface with the Apache flight environment are e faced with greater interface gurations than pilots in other aviation platforms due to the onset of when fit to specific parameters, marmance. 15. NUMBER OF PAGES 29 16. PRICE CODE	

de la

## Acknowledgements

The authors are extremely grateful to Ms. Leonita Newman for her ability to coordinate the vision and simulator testing schedules for all the subjects and for editing the text; to SPC Christopher Kanimba and Mr. Eric Harris for their diligence in collecting vision data and maintaining the database; and to Mr. Jerry Riley and Mr. Jerry Bonham for assisting in subject recruitment.



# Table of contents

Page
Introduction
Methods2
Subjects2
Materials2
Procedures
Vision testing
Flight testing
Survey
Data analysis
Results
Subjects9
Visual performance
High contrast visual acuity10
Low-contrast visual acuity11
Contrast sensitivity
Stereopsis14
Flight performance
Subjective assessment
Overall rating17
Current lenses (contact lenses) compared to spectacles

## Table of contents (continued)

	Page
Discussion	18
References	20
Appendix A. Multifocal contact lens study	21
Appendix B. Surveys	22
Appendix C. Demographics	25
Appendix D. Contact lens parameters	27
Appendix E. Multifocal contact lens study score sheet	28
Appendix F. Multifocal contact lens study score sheet	29

# List of figures

1.	High contrast distance and near visual acuity11
2.	Low contrast distance visual acuity under standard luminance, low luminance, and glare conditions and low contrast near visual acuity
3.	Contrast sensitivity under high and low luminance conditions in terms of AUCSF 14
4.	Cumulative percentage of stereopsis levels achieved on the AFVT (distance depth perception)
5.	Cumulative percentage of near stereopsis levels achieved with the Randot Stereo Test 16
6.	Mean individual flight performance scores and overall flight performance score for each correction condition

# Table of contents (continued)

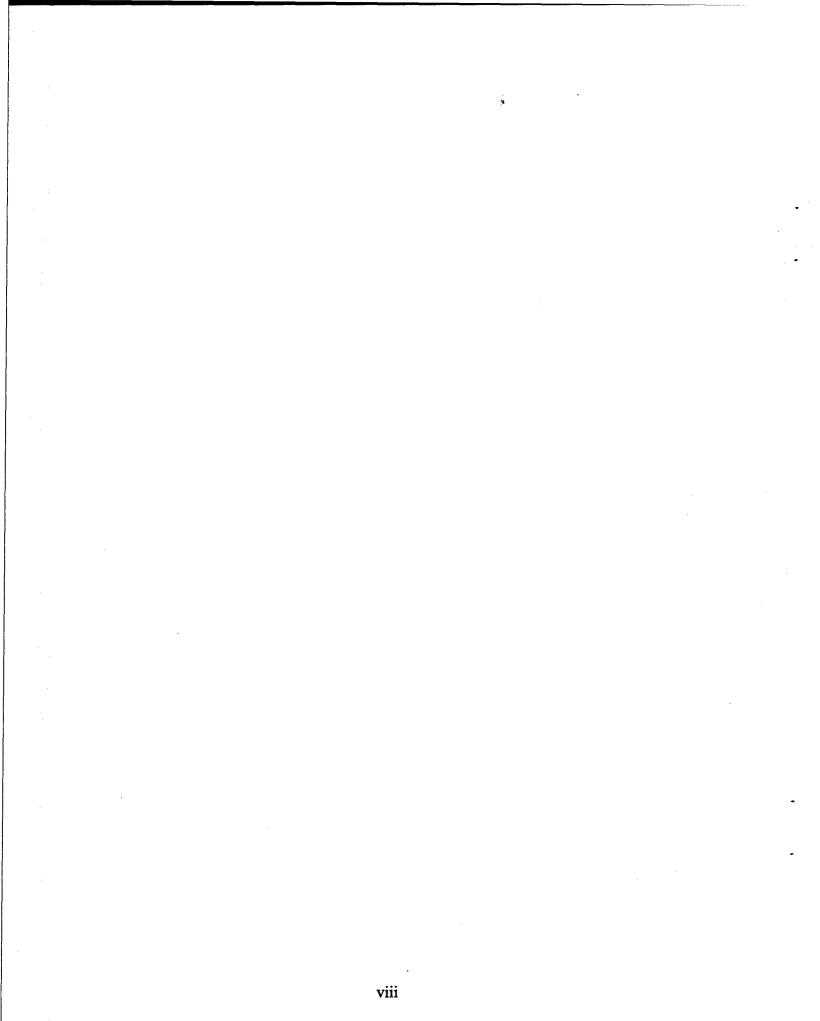
\*

## List of figures (continued)

7.	Pilot ratings of performance of bifocal spectacles and multifocal contact lenses on simulator tasks.	. 17
8.	Pilot ratings of relative performance of each multifocal contact lens compared to bifocal spectacles on simulator tasks	. 18

## List of tables

1.	Contact lens parameters.	3
2.	Vision testing	6
3.	Demographics and baseline.	9



#### Introduction

Aviators have always had to meet stringent physical standards to gain and maintain flying status. Some standards are more flexible than others; refractive error is an example of the type of standard that allows some departure from absolute emmetropia. Up to a substantial 25% of the aviation population develops ametropia requiring the use of spectacles or other refractive correction after the completion of flight training (Lattimore and Schrimsher,1993). The use of spectacles is problematic with certain electro-optical sighting systems, particularly in the Apache. Fortunately, disposable extended wear soft contact lenses have proven to be an effective solution for dealing with the spectacle compatibility problems for a large proportion of aviators requiring refractive error corrections (Lattimore,1992).

Older, more experienced aviators are naturally losing their ability to focus on near objects, a process called presbyopia. Eventually, presbyopic changes force all aviators, even those who have never worn glasses or contacts, to use a correction in order to see their flight controls and read approach plates and maps. Since single vision contact lenses only correct distance vision, the aging aviator must adapt to these changes by reverting to bifocal spectacle wear or wearing readers over their contact lenses. Bifocal spectacles or readers may lead to an inability to continue flying certain aircraft platforms such as the Apache that depend on the use of head-mounted display (HMD) systems. Therefore, it is important to take measures to prevent the loss of these most experienced and qualified aviators.

One means of correcting presbyopia using contact lenses is monovision. This method fits the patient with a distance contact lens on one eye and a near contact lens on another. While this is a very popular modality, it has limited appeal for military application due to the potential reduction in binocular vision. A 1996 civil aviation accident was attributed to the pilot's use of monovision contact lenses (Nakagawara and Veronneau,2000). Multifocal contact lenses are another modality and offer a potential improvement over the compromises of monovision. This type of lens provides both distance and near correction within each lens, often referred to as "simultaneous vision." The results of a previous study by Morse showed that multifocal contact lenses can be compatible with the Army Aviation environment. The reduced quality of vision with multifocal contact lenses and lack of a single lens type or modality best suited for all aviators across the board raised concerns (Morse and Reese, 1997).

Recent advances in multifocal contact lens designs have produced lenses potentially better suited to the visually-demanding environment of the presbyopic Army aviator. These advances include more refined aspheric designs and the development of lenses utilizing concentric alternating near and far focal zones. In this study, a preliminary evaluation of commercially available disposable multifocal soft contact lenses using the standard binocular fit was completed. The primary objectives of the study were to (1) determine whether new generation multifocal contact lens designs show potential to provide adequate vision compatible with the basic occupational tasks and environmental conditions unique to Army aviators (2) determine whether there is a general trend towards acceptance of a binocular multifocal contact lens fit (3) determine whether any of the new generation contact lenses are strongly preferred or strongly rejected by the small pilot sample and (4) determine if any of the tested new generation multifocal contact lenses or lens modalities shows a clear advantage over the others for follow-

1

on studies. Studies of the new generation of multifocal contact lenses could ultimately lead to recommended fitting procedures and clinical tests that might be relevant to visual performance in the cockpit.

This study was supported by an Independent Laboratory Innovative Research grant (Medical Research and Materiel Command, Army Medical Department).

#### <u>Methods</u>

### Subjects

Twenty-one volunteer presbyopic aviators already wearing bifocal spectacles or reading glasses in the performance of their flight duties and stationed or living in the Fort Rucker, Alabama area were identified through local advertisement. Institutional Review Board approval was obtained for the study. The risks of participation in the study were explained to potential subjects and provided in a written consent form. All participants provided informed consent for the study. Although the flight testing was completed in a UH-60 Black Hawk simulator, pilots rated in other aircraft were included since the skills required for completion of the flight tasks in this study were common to all platforms.

Subjects had to meet Flight Duty Medical Examination (FDME) standards (correctable to 20/20 distance and near) and could not have greater than or equal to 0.75 diopters of astigmatism in their dominant eye, since multifocal contact lenses do not correct for astigmatism. Medical conditions that excluded subjects from participation included: (1) chronic or acute inflammation of the anterior segment of the eye; (2) disease processes affecting the sclera, conjunctiva, or cornea of the eye; or (3) any systemic disease which affects the anterior segment of the eye.

The study was to continue until 20 subjects were able to wear contact lenses and had been entered into the study; however, only 18 subjects were able to complete the protocol. Two subjects completed some of the testing, but were unable to complete the study due to scheduling conflicts, and one subject failed to return after initial refraction and baseline testing. None of the subject withdrawals were as a result of contact lens problems or inability to wear contact lenses.

#### Materials

All multifocal contact lenses used in this study were FDA approved disposable multifocal soft contact lenses. The Acuvue® Bifocal lens uses an alternating five-zone concentric distance and near design to provide simultaneous distance and near focus for the wearer. Both the Ciba Focus® Progressive and the Bausch & Lomb Soflens® Multi-focal lenses use an aspheric design which provides increased near power towards the center of the lens. The contact lenses were fit according to the recommended fitting guide provided by the manufacturer of each contact lens design. A licensed Optometrist completed all contact lens fittings and a certified ophthalmic technician assisted in subject training. The contact lenses used in this study are listed in Table 1.

<u>Table 1.</u>
Contact lens parameters.

Lens Design	Lens Parameters			
Acuvue® Multifocal	Material:	etafilcon A		
Concentric design; center distance with 5	Water Content:	58%		
alternating zones (disposable)	Options:	Light blue tint 1-2-3 inversion indicator		
	Diameter:	14.2		
	Base Curve:	8.5		
	Center Thickness (mm):	0.075 @ -3.00 0.165 @+3.00		
Bausch & Lomb Soflens® Multi-focal	Material:	polymacon		
Aspheric design; center near (disposable)	Water Content:	38%		
Natra-Sight <sup>™</sup> Optics	Options	Light blue handling tint		
Diameter:		14.5		
	Base Curve:	8.5, 8.8		
	Center Thickness (mm):	0.10 @ -3.00		
CIBA Focus® Progressives	Material:	vifilcon A		
Aspheric design (disposable)	Water Content:	55%		
	Options:	Visitint®		
	Diameter:	14.0		
	Base Curve:	8.6, 8.9		
	Center Thickness (mm):	0.10 @ -3.00 0.16 @ +3.00		

## Procedures

Each subject received a complete eye examination to determine the appropriate spectacle prescription and ocular parameters specific to contact lens fitting, including refraction, slit lamp examination, and corneal curvature measurements using an Orbscan II corneal topographer (Bausch & Lomb, Rochester, NY). All procedures were noninvasive standard clinical tests. If the measured prescription varied by more than 0.25 diopters distance or near from the subject's habitual prescription, bifocal spectacles were fabricated into standard U.S. Army flight frames using the spectacle prescriptions determined at this first examination. Availability of trial contact lenses in the parameters needed for the subject was verified and specific trial lenses were ordered.

Subjects received a preliminary fit with one of the multifocal contact lens types using a randomization protocol. Subjects who had not worn contact lenses prior to this study received training in the insertion, removal and care of contact lenses. Subjects were not allowed to

continue contact lens wear if they did not adequately demonstrate to the optometrist that they had the capability to handle the contact lenses. Subjects who had worn contact lenses before were given an update on the procedures to handle contact lenses and their skills were evaluated by the optometrist prior to the release of their first pair of contact lenses. In keeping with standard optometric practice, all new contact lens fits were monitored for at least a half an hour prior to release of the subject. Subjects were provided with either ReNu MultiPlus® Multi-Purpose Solution or Complete® brand Multi-Purpose Solution for care of the contact lenses.

After wearing the contact lenses for 7 days, subjects returned for an adjustment examination. An adjustment of lens powers was made as needed to achieve optimal vision. Subjects were given up to two adjustment fittings, if needed, to achieve optimal vision. Inability to achieve acceptable near and far vision, at least 20/20 acuity, after two adjustments was considered a fitting failure for that lens modality. If no adjustment was needed, the subject completed the vision and flight-testing. If an adjustment was needed, the subject wore the lenses for an additional 7 days before returning for testing. Since multifocal contact lens wear is not approved for flight, subjects were not allowed to wear the contact lenses during the performance of flight duties outside of this study's control. The subject was advised to remove the contact lenses at least 1 hour prior to operating any aircraft other than during the simulator flight evaluations conducted as part of this study.

Subjects completed testing with bifocal spectacles at the beginning of the study. Testing consisted of vision evaluations (Table 2), simulator flight (Appendix A), and a survey (Appendix B). Then testing was completed after each contact lens fitting cycle for all three contact lens types. The order in which multifocal lenses were fit was randomized for each subject. After contact lens testing, the subjects again completed all testing with their bifocal spectacles. The two bifocal spectacle sessions were used to establish baseline performance levels.

#### Vision testing

<u>High contrast visual acuity</u> was evaluated with an ETDRS visual acuity chart (chart developed in the Early Treatment of Diabetic Retinopathy Study) tested at 4 meters. Unlike standard clinical projected charts, the ETDRS uses a logarithmic progression of letter size (0.1 per row), a constant number of letters per row, and letters of equal legibility, making task difficulty constant, regardless of the level of acuity tested (Bailey and Lovie,1976); (Bailey et al., 1991). Testing was conducted binocularly at standard (200 cd/m<sup>2</sup>) luminance levels. The chart was retro-illuminated by a calibrated fluorescent light box, and acuities were scored *by letter* (number of letters read correctly) in log of the minimum angle of resolution units (log MAR; 0.02 log units per letter). The chart version (i.e., letter sequence) was alternated between trials to discourage learning effects. Near high contrast visual acuity was measured using the SKILL card (developed at Smith Kettlewell Institute, California) at a 40 centimeter testing distance (Haegerstrom-Portnoy et al., 1997). Scoring of this card is the same as that used for the distance chart (logMAR units). At baseline, uncorrected visual acuity (UCVA) was measured. For all subsequent evaluations, visual acuity was measured using either bifocal spectacles, reading spectacles or the multifocal contact lens correction (HCVA).

<u>Low contrast visual acuity</u> was evaluated with the Precision Vision (LaSalle, Illinois) 5% low contrast log MAR visual acuity chart. Testing was conducted binocularly at 4 meters at normal  $(200 \text{ cd/m}^2)$  and low luminance levels  $(2 \text{ cd/m}^2)$  with spectacle or contact lens correction. The low luminance condition was achieved by placing a 2.0 neutral density filter in the illumination path of the light box. All acuities were scored by letter in log MAR units (0.02 log units per letter). Near low contrast visual acuity was measured using the reverse side of the SKILL card at 40 centimeters. The card has a contrast level of 5% (dark background with grey letters). Scoring of this card was the same as that used for the distance chart (logMAR units).

<u>Glare testing</u> was conducted with the Precision Vision Glare Test with the 5% low contrast ETDRS chart. The test utilizes two rheostat-controlled incandescent spotlights separated by 9.4 degrees, simulating oncoming headlights at 35-40 feet. The glare sources straddle the low contrast chart presented in the center of the illumination box. Testing was completed binocularly with spectacle or contact lens correction. Scoring on the glare test was recorded in terms of 5% LCVA logMAR under glare conditions.

Spatial contrast sensitivity was assessed with the Vision Works Contrast Sensitivity System, which displays periodic grating patterns of varying spatial and temporal frequency. Thresholds were determined for 1, 2, 4, 8 and 16 cycle per degree (c/deg) spatial frequencies. Testing was conducted binocularly at normal (approximately  $100 \text{ cd/m}^2$ ) and mesopic luminance levels (approximately  $1 \text{ cd/m}^2$ ) with spectacle or contact lens correction. A composite score based on the area under the contrast sensitivity function (AUCSF) was determined using the combined sensitivity scores across all the spatial frequencies tested.

<u>Stereopsis</u> was tested using the Armed Forces Vision Tester (AFVT) to determine distance stereopsis and the Randot Stereo Circles test to determine near stereopsis. Testing was completed with spectacle or contact lens correction in place. Both stereo measures were reported in seconds of arc.

<u>Pupil size</u> was assessed with an infrared digital pupillometer (Neuroptics<sup>®</sup>) while viewing the letter charts under photopic (200 cd/m<sup>2</sup>) chart luminance levels, and under mesopic (1-2 cd/m<sup>2</sup>) levels. Pupil diameter was recorded in millimeters.

,5

Visual performance measures*	Test and norms
High contrast visual acuity (HCVA)	ETDRS logMAR chart at 4 meters: 0.00 logMAR (20/20 Snellen)
	SKILL card at 40 centimeters: 0.00 logMAR (20/20 Snellen)
Low contrast visual acuity (LCVA)	ETDRS logMAR 5% low contrast chart at 4 meters: 0.30 logMAR (20/40 Snellen) ETDRS logMAR 5% low contrast chart at 4 meters (with 2.0 ND filter): 0.48 logMAR (20/60 Snellen) SKILL card (14% low contrast, luminance side) at 40 cm: 0.48 logMAR (20/60 Snellen)
Glare disability (GD)	ETDRS 5% logMAR low contrast chart with glare source at 4 meters: 0.30 logMAR (20/40 Snellen)
Contrast sensitivity (CS)	Vision Works computerized CSF: 200 AUCSF
Mesopic contrast sensitivity (MCS)	Vision Works computerized CSF (low luminance): 115 AUCSF
Stereopsis	Armed Forces Vision Tester (simulated distance): 40 seconds of arc Randot Stereo Test (near): 40 seconds of arc
Ocular parameters	Test
Pupil Size under photopic and mesopic conditions	Neuroptics® Pupillometer with standard and low ambient light levels

## <u>Table 2.</u> Vision testing.

\* All visual performance tests were completed binocularly.

### Flight testing

Simulator testing protocols were used to assess flight performance for each contact lens condition and bifocal spectacles using a 45-minute flight profile under day conditions. The flight profile and task listings are provided in Appendix B. Performance of the subject on each maneuver was rated by the research aviator in accordance with standards established in TC 1-212 Aircrew Training Manual, Utility Helicopter, UH-60/EH-60. The research aviator observing the flight entered a score from 1 to 5 for each maneuver during the flight. A score of 3 denotes performance in accordance with standards; scores of 4 or 5 indicate more precise performance and scores of 2 or 1 indicate less precise performance. The following sections detail the specific tasks in the protocol and what aspects of vision and aircraft control they represented.

#### Right hovering turn (task 1)

This task required the subject pilot to coordinate pedal input and cyclic control to pivot the aircraft through 360 degrees around a given point above the ground. Visually, the pilot had to constantly check inside and outside the aircraft to maintain power (by checking the torque), check time, and maintain height and position above the ground (visualize the radar altimeter and the horizontal situation indicator (HSI) and monitor rate of movement over the ground). The hover turn condition was the in-ground effect (IGE) at 10 feet. Standards for this task were to

complete the turn in the stated time while maintaining height and position  $\rho$  3 feet for the IGE hover turn.

Visual meteorological conditions (VMC) takeoff (tasks 2 & 6)

Takeoff from the ground required balancing input to the cyclic, collective and pedals of the aircraft maintained heading and the proper amount of acceleration. During the takeoff sequence, the pilot had to maintain 10% above hover power for acceleration to the required airspeed of 80 knots ( $\rho$  10 knots), which required vigilance of torque, heading, altimeter, and airspeed indicators, while maintaining the desired rate of climb of 500 feet per minute ( $\rho$  100 fpm) by monitoring the instantaneous vertical speed indicator (IVSI) and sustained track across the ground while minimizing drift. Up to 50 feet above ground level (AGL), the pilot had to maintain aircraft heading ( $\rho$  10 degrees), and above 50 feet AGL, the aircraft was placed in trim while maintaining track to minimize drift. Visually, the pilot had to alternate between checking inside to maintain speed, rate of climb, power (monitor torque), and heading and checking outside to maintain ground track and airspace surveillance.

Straight and level (tasks 3 & 7)

Prior to this task, the pilot made another 90-degree turn to the downwind leg. To hold the aircraft to straight and level flight at 1000 feet MSL and 100 knots, the pilot had to monitor airspeed, altitude, heading, and trim while checking outside the aircraft for ground track and airspace surveillance. During one of the two straight and level maneuvers, the simulator operator presented the subject with an emergency procedure requiring the pilot to read the emergency procedure and to visualize a control panel button and take appropriate action.

### Decelerating descent (tasks 4 & 8)

The pilot had to monitor the IVSI to establish the 500 fpm descent rate, and then started a 90-degree turn reducing airspeed to 80 knots to enter the base leg at 700 feet MSL. Crosschecks between aircraft flight instruments and the horizon and ground position were important for this maneuver.

#### Final approach (tasks 5 & 9)

The pilot determined the approach angle that allowed safe obstacle clearance while descending to the intended point of landing, in this case the departure or far end of the runway. Depth perception was very important for this task as the pilot had to maintain 80 knots until apparent rate of closure started to increase, approached angle, minimized drift and stayed on track. The pilot maintained ground track alignment with the landing direction by maintaining the aircraft in trim above 50 feet AGL and slipped (aligned) the aircraft to maintain the landing direction and straddled the center line of the runway below 50 feet AGL.

#### Formation flight (task 10)

The pilot's task was to follow a lead ship from the airfield for a 10-minute timeframe. This

task involved judgment of distance while maintaining vigilance of flight controls and instrumentation. In a staggered left trail formation, the pilot had to maintain at least 3 to 5 rotor disk diameters space from the lead aircraft, 30 to 45 degrees astern and 1 to 10 feet vertical step-up.

### Admin vectors to ILS (task 11)

The safety pilot took the controls during this segment of flight. The subject's tasks included determining frequencies using the approach plate for Cairns Army Airfield, setting frequencies for both the VOR/ILS (very high frequency omnidirectional range/ instrument landing system) radio and setting the automatic direction finder (ADF). The subject had to select the inbound course for ILS into the HSI and ensured that proper selections were made on the mode select panel for the VOR/ILS and ADF/VOR.

### ILS approach (task 12)

This task had the highest near visual demand of all the maneuvers due to the requirement to constantly cross check a number of instruments. Instrument crosscheck required observing and interpreting two or more instruments to determine altitude and aircraft performance. In instrument flight, instruments had to be properly crosschecked and correctly interpreted to detect any malfunction and to control the aircraft in the desired flight path. Instruments provided (1) a reference of aircraft altitude, (2) a reference for use of power and (3) an indication of whether the combination of altitude and power was producing the desired performance. The course deviation bar, roll command bar and the pitch command bar in the vertical speed indicator (VSI) had to be monitored. Altitude, airspeed, torque, and heading also were monitored.

#### Survey

A survey to determine how well subjects felt they were able to complete flight tasks was given to each subject following the simulator phase (Appendix C). Survey ratings for flight in *bifocal spectacles* and *contact lenses* were set up on a scale from 1 to 7, defined as (1) very difficult, (2) moderately difficult, (3) slightly difficult, (4) neither difficult nor easy, (5) slightly easy, (6) moderately easy, and (7) very easy. The items surveyed included: reading checklist, setting frequency, target/object detection, formation flight and overall performance. The subjects then rated *current lenses (contact lenses) to spectacles* on these same items on the seven point scale in terms of (1) much poorer, (2) moderately poorer, (3) slightly poorer, (4) same as glasses, (5) slightly better, (6) moderately better, and (7) much better. The *contact lense* survey included questions about the general vision, comfort and handling of the contact lenses during daily activities.

#### Data analysis

The purpose of this study was to determine general trends for or against the use of new generation disposable multifocal contact lenses in the aviation environment. A sample size of 15 subjects was sufficient to provide 90% power at  $\Delta$ = 0.05 for the proposed analysis in this

8

protocol (nQuery Advisor 4.0). This was based on the minimum analysis of 2 levels (bifocal spectacles versus best contact lens modality) and 0.01 logMAR variance of means for vision tests.

Visual performance, flight performance, as well as subjective survey assessment of the contact lenses by the pilots were analyzed relative to these measures under bifocal spectacle conditions (control). The visual performance results with each contact lens modality were compared to the bifocal spectacle condition to determine statistical differences in visual performance. The types of contact lenses were compared in general to determine whether there was any strong preference or incompatibility problem with a particular lens type or brand.

### **Results**

#### Subjects

The average subject was 52 years of age (range 44 to 60 years). All subjects enrolled were male. No female subjects applied to the study. The mean experience in flying hours of the subjects was 6624 (range 2000 to 12,000 hours). There were three OH-58 Kiowa pilots, three AH-64 Apache pilots, four UH-60 Black Hawk pilots, three UH-1 Huey pilots, three TH-67 Creek pilots, one CH-47 Chinook pilot and one C-12 pilot enrolled. Seven of the pilots were dual-rated in other aircraft. The mean refractive error across both eyes in terms of spherical equivalent was +0.10 diopters (range +1.88 hyperopia [far-sightedness] to -1.75 myopia [near-sightedness]), and a mean level of manifest presbyopia (add power) of +1.82 diopters (range +1.00 to +2.50 ADD). Mean high-contrast *uncorrected distance* visual acuity measured binocularly was 0.02 logMAR (20/21 Snellen equivalent); range -0.24 to 0.56 logMAR (20/12 to 20/73 Snellen). Average pupil size for these subjects was 2.5 millimeters (range 1.7 to 4.0) in high luminance conditions and 6.1 millimeters (range 4.1 to 7.8) in low luminance. Table 3 summarizes the subject demographics and baseline data; Appendix C provides specifics for each subject, including lens parameters for all three contact lens fits.

Demographics and Baseline					
	Mean ± SD	Range			
Age	$52 \pm 5$	44 to 60			
Flight Hours	$6624 \pm 3084$	2000 to 12000			
Vision Baseline					
Spherical Equivalent (D)	$0.10 \pm 1.0$	-1.88 to +1.75			
Add Power (D)	$1.82 \pm 0.48$	+1.00 to +2.50			
UCVA (logMAR)	$0.02 \pm 0.27$	-0.24 to 0.56			
Pupil Size (mm) - High(100 cd/m <sup>2</sup> )	$2.5 \pm 0.54$	1.7 to 4.0			
Pupil Size(mm) – Low $(1-2 \text{ cd/m}^2)$	6.1 ± 0.95	4.1 to 7.8			

<u>Table</u>	<u>3.</u>
Demographics an	nd baseline.

9

#### Visual performance

Visual performance included assessment of high and low contrast, low luminance and depth perception at distance, and near and low contrast vision in the presence of glare for distance only. In most cases, the difference between bifocal spectacle and multifocal contact lens visual performance was within norms (less than one standard deviation difference from established norms); however, for low contrast visual performance, and especially near low contrast, the difference was greater. All subjects were able to see 20/20 at distance with at least one set of contact lenses. Five subjects were unable to attain 20/20 or better at near with any of the contact lens options. Based on current Aeromedical policy standards for contact lenses (which cover single vision distance, not bifocal or multifocal lenses), 12 of the 18 subjects were successfully fit with at least one of the contact lens types. Specifically, their high contrast visual acuity was 20/20 or better at distance **and** near. This subgroup of 12 is treated separately at the end of each section as "Best Fit." In the "Best Fit" group, four subjects were best fit with the Acuvue bifocal, six subjects wore the Bausch & Lomb multi-focal, and two subjects wore the Ciba progressive.

#### High contrast visual acuity

#### Distance vision (high contrast)

Mean high-contrast binocular visual acuity with *bifocal spectacle* correction measured using the ETDRS backlit chart was  $-0.20 \log$ MAR (sd=0.05; 20/13 Snellen). High-contrast visual acuity results for the contact lens corrections were  $-0.06 \log$ MAR (sd=0.09; 20/17 Snellen) for the *Acuvue bifocal*, -0.08 logMAR (sd=0.10; 20/17 Snellen) for the *Bausch & Lomb multi-focal*, and  $-0.10 \log$ MAR (sd=0.07; 20/16 Snellen) for the *Ciba progressive*. Paired t-test results show performance with contact lenses was significantly worse (p<0.001) than with bifocal spectacles; however, mean performance was 20/20 or better with all three contact lenses, the expected standard for distance acuity. For the *Best Fit* subgroup (n=12), acuity was  $-0.12 \log$ MAR (sd=0.06; 20/15 Snellen), which was better than any one lens type, but still significantly worse (p<0.001) than with bifocal spectacles. The best distance acuity for contact lens correction under high-contrast conditions was with the *Best Fit* lens, though all contact lens modalities scored within a few letters of each other. See Figure 1.

#### Near vision (high contrast)

Mean near high-contrast binocular visual acuity with *bifocal spectacle* correction measured using the SKILL test (light side) was -0.10 logMAR (sd=0.10; 20/16 Snellen). High-contrast visual acuity results for the contact lens corrections were -0.02 logMAR (sd=0.10; 20/19 Snellen) for the *Acuvue bifocal*, 0.01 logMAR (sd=0.16; 20/20 Snellen) for the *Bausch & Lomb multi-focal* and 0.05 (sd=0.12; 20/22 Snellen) for the *Ciba progressive*. Paired t-test results show the performance with contact lenses was significantly worse (p<0.001) than with bifocal spectacles; mean performance was 20/20 or better with only the *Acuvue* contact lens, the expected standard for near acuity. For the *Best Fit* subgroup, near acuity was -0.09 logMAR (sd=0.07; 20/16 Snellen), which was better than any one lens type and not significantly different (p=0.12) from bifocal spectacles. The best near acuity under high contrast conditions in contact lenses was with the *Best Fit* lens; the three contact lens modalities scored within one line of each other. See Figure 1.

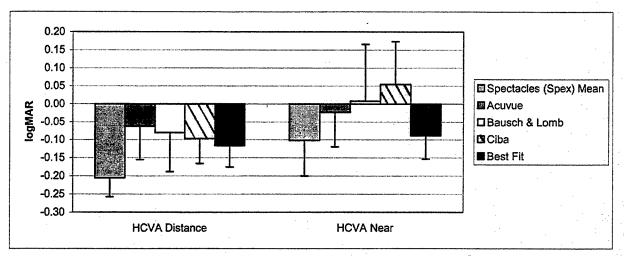


Figure 1. High contrast distance and near visual acuity.

#### Low-contrast visual acuity

Distance vision (low contrast)

Mean low-contrast binocular visual acuity with *bifocal spectacle* correction measured using the 5% ETDRS low contrast chart was 0.08 logMAR (sd=0.06; 20/24 Snellen). Low-contrast visual acuity results for the contact lens corrections were 0.28 logMAR (sd=0.11; 20/38 Snellen) for the *Acuvue bifocal*, 0.25 logMAR (sd=0.11; 20/36 Snellen) for the *Bausch & Lomb multifocal* and 0.21 logMAR (sd=0.07; 20/32 Snellen) for the *Ciba progressive*. Paired t-test results showed the performance with contact lenses was significantly worse (p<0.001) than with bifocal spectacles; mean performance was 20/40 or better with all three lenses, the expected standard for 5% low contrast distance acuity. For the *Best Fit* subgroup, low contrast acuity was 0.23 logMAR (sd=0.08; 20/34 Snellen), which was essentially the same as the *Bausch & Lomb* lens and still significantly worse (p<0.001) than the bifocal spectacles. The best acuity under low contrast conditions in contact lenses was with the *Ciba progressive contact lens*, though all contact lens modalities scored within a few letters of each other. See Figure 2.

Distance vision (low contrast under glare conditions)

Mean binocular visual acuity in the presence of glare with *bifocal spectacle* correction was 0.08 logMAR (sd=0.07; 20/24 Snellen). Glare visual acuity results for the contact lens corrections were 0.27 logMAR (sd=0.10; 20/37 Snellen) for the *Acuvue bifocal*, 0.35 logMAR (sd=0.09; 20/45 Snellen) for the *Bausch & Lomb multi-focal* and 0.21 (sd=0.06; 20/32 Snellen) for the *Ciba progressive*. Paired t-test results showed the performance with contact lenses was significantly worse (p<0.001) than with bifocal spectacles; mean performance was 20/40 or better for the *Acuvue* and *Ciba* lenses, the expected standard for 5% low contrast distance acuity under glare conditions. For the *Best Fit* subgroup, glare acuity was 0.24 logMAR (sd=0.07; 20/34 Snellen), which is essentially the same as the *Ciba* lens and still significantly worse

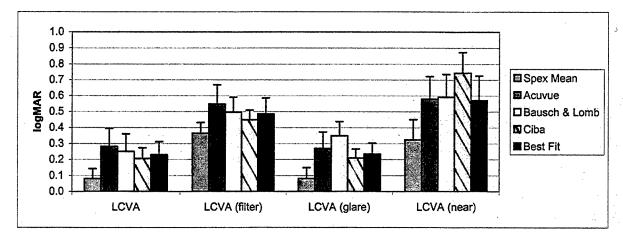
(p<0.001) than the bifocal spectacles. The best acuity under glare conditions was with the *Ciba* progressive contact lens. See Figure 2.

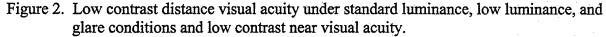
#### Distance vision (low-contrast, low luminance)

Mean low-contrast, low luminance binocular visual acuity with *bifocal spectacle* correction measured using a 5% low contrast ETDRS chart and a neutral density filter (ND 2) was 0.36 logMAR (sd=0.07; 20/46 Snellen). Low-contrast, low luminance visual acuity results for the contact lens corrections were 0.55 logMAR (sd=0.12; 20/71 Snellen) for the *Acuvue bifocal*, 0.50 logMAR (sd=0.09; 20/63 Snellen) for the *Bausch & Lomb multi-focal* and 0.45 (sd=0.06; 20/56 Snellen) for the *Ciba progressive*. Paired t-test results showed the performance with contact lenses was significantly worse (p<0.001) than with bifocal spectacles; mean performance was 20/60 or better with only the *Ciba* lens, the expected standard for 5% low contrast, low luminance distance acuity. For the *Best Fit* subgroup, low luminance acuity was 0.49 logMAR (sd=0.10; 20/61 Snellen), which is better than the *Acuvue* and *Bausch & Lomb* lens results, but still significantly worse (p<0.001) than the bifocal spectacles. The best acuity under low contrast, low luminance conditions was with the *Ciba progressive contact lens*. See Figure 2.

#### Near vision (low contrast)

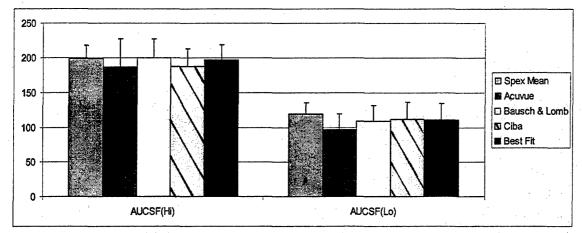
Mean near low-contrast binocular visual acuity with *bifocal spectacle* correction measured using the low contrast side of the SKILL card was 0.32 logMAR (sd=0.13; 20/42 Snellen). Low-contrast visual acuity results for the contact lens corrections were 0.58 logMAR (sd=0.14; 20/76 Snellen) for the *Acuvue bifocal*, 0.59 logMAR (sd=0.14; 20/78 Snellen) for the *Bausch & Lomb multi-focal* and 0.74 logMAR (sd=0.13; 20/110 Snellen) for the *Ciba progressive*. Paired t-test results showed the performance with contact lenses was significantly worse (p<0.0001) than with bifocal spectacles; mean performance was worse than 20/60 with all three lenses, the expected standard for 5% low contrast near acuity. For the *Best Fit* subgroup, near low contrast acuity was 0.57 logMAR (sd=0.15; 20/75 Snellen), which was essentially the same as the *Acuvue* and *Bausch & Lomb* lens results and still significantly worse (p<0.001) than the bifocal spectacles. The best acuity in contact lenses under low contrast conditions was with the *Best Fit* lens. See Figure 2.

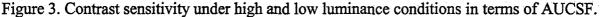




#### Contrast sensitivity

The expected norm for the AUCSF in high luminance conditions is 200, and normal AUSCF in low luminance conditions is 115. The mean high luminance AUCSF for the *bifocal spectacle* condition was 199 (sd=18). The mean high luminance AUCSF results for the contact lens corrections were 187 (sd=40) for the Acuvue bifocal, 200 (sd=28) for the Bausch & Lomb multifocal, and 187 (sd=25) for the Ciba progressive. There was not a statistically significant difference for high luminance contrast sensitivity performance with *bifocal spectacles* and any of the multifocal contact lenses (p=0.51). The mean low luminance AUCSF for the bifocal spectacle condition was 119 (sd=16). The mean low luminance AUCSF results for the contact lens corrections were 97 (sd=22) for the Acuvue bifocal, 109 (sd=23) for the Bausch & Lomb multi-focal, and 113 (sd=25) for the Ciba progressive. Paired t-test results showed the performance with the Acuvue bifocal contact lens was significantly worse (p<0.001) than with bifocal spectacles; however, there was not a statistically significant difference for low luminance contrast sensitivity performance for the Bausch & Lomb or Ciba progressive multifocal contact lenses (p=0.11). For the Best Fit subgroup, high luminance AUCSF was 198 (sd=21) and low luminance AUCSF was 112 (sd=23), which was not significantly different from the bifocal spectacles. The best CS under high luminance conditions was with the Bausch & Lomb multi-focal contact lens; and under low luminance conditions, the Ciba progressive contact lens. See Figure 3.





#### **Stereopsis**

Distance depth perception (AFVT)

Ninety-four percent of the subjects (17 out of 18) achieved 13 seconds of arc distance stereopsis with *bifocal spectacles*; only 1 subject had distance stereopsis worse than 40 seconds of arc (6%). Stereopsis measures for the Acuvue bifocal contact lens correction were 56% (10 subjects) with 13 seconds of arc and 78% (14 subjects) with 40 seconds of arc or better; for the Bausch & Lomb, multi-focal were 68% (12 subjects) with 13 seconds of arc and 89% (16 subjects) with 40 seconds of arc or better; and for the Ciba progressive were 83% (15 subjects) with 13 seconds of arc and 89% (16 subjects) with 40 seconds of arc or better. Comparison of distributions of distance stereopsis performance levels showed the performance with the Acuvue *bifocal* contact lens was significantly worse (p<0.001) than with bifocal spectacles; the distributions for the Bausch & Lomb and Ciba contact lenses did not differ significantly from the bifocal spectacles (p=0.12). For the Best Fit subgroup, stereopsis levels were 58% (7 subjects of 12) with 13 seconds of arc and 92% (11 subjects of 12) with 40 seconds of arc or better; not statistically significantly different from bifocal spectacles (p=0.07). The highest percentage of subjects with distance stereopsis within norms (40 seconds of arc) was with the Best Fit modality; both the Bausch & Lomb and Ciba lenses provided adequate stereopsis for 89% of subjects. See Figure 4.

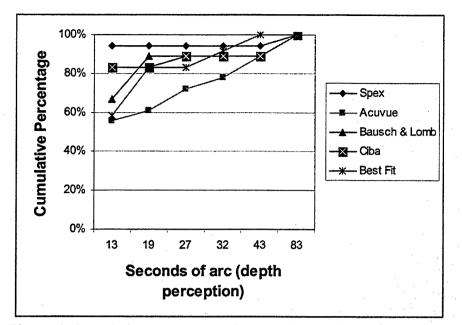
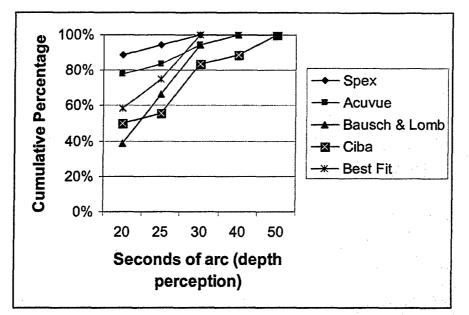
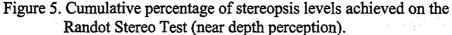


Figure 4. Cumulative percentage of stereopsis levels achieved on the AFVT (distance depth perception).

Near depth perception (Randot)

Eighty-nine percent of the subjects (16 out of 18) achieved 20 seconds of arc near stereopsis with *bifocal spectacles*; the remaining 2 subjects scored 40 seconds of arc or better (11%). Stereopsis measures for the *Acuvue bifocal* contact lens correction were 78% (14 subjects) with 20 seconds of arc and 100% with 40 seconds of arc or better; for the *Bausch & Lomb multi-focal* were 39% (7 subjects) with 20 seconds of arc and 100% with 40 seconds of arc and 89% (16 subjects) with 40 seconds of arc or better. Comparison of distributions of near stereopsis performance levels showed the performance was significantly worse than the bifocal spectacles for both the *Bausch & Lomb* contact lens (p<0.001) and the *Ciba* contact lens (p=0.02); the distribution for the *Acuvue* contact lens did not differ significantly from the bifocal spectacles (p=0.06). For the *Best Fit* subgroup, stereopsis levels were 58% (7 subjects of 12) with 20 seconds of arc and 100% with 40 seconds of arc or better; and was statistically significantly different from the bifocal spectacles (p=0.04). All contact lens modalities achieved stereopsis within norms (40 seconds of arc) for all subjects except the *Ciba progressive* lens. See Figure 5.

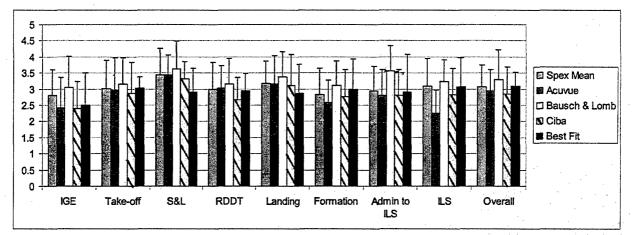


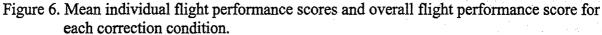


#### Flight performance

Each subject was scored by an instructor/research pilot in the UH-60 simulator in both bifocal spectacles and each of the three contact lenses. Scoring was set up for 12 separate tasks. The tasks were defined as (1) IGE Right Hovering Turn (360), (2) VMC Takeoff (500fpm) Upwind Leg, (3) Straight and Level Downwind Leg, (4) Turn/Decelerating/Descent Base Leg, (5) VMC Approach (500fpm) Final Leg, (6) VMC Takeoff (500fpm) Upwind Leg, (7) Straight and Level Downwind Leg, (8) Turn/Decelerating/Descent Base Leg, (9) VMC Approach (500fpm) Final Leg, (10) Formation Flight, (11) Admin Vectors to ILS/Emergency Procedure, and (12) ILS Runway 6. The heading, altitude and airspeed were defined for each task. Scoring was set on a scale from 1-5, with one being the lowest score and five being the highest.

In *bifocal spectacles*, the mean flight performance score was 3.07 (sd=0.59) over all 12 tasks. In the *Acuvue bifocal* contact lens, the mean flight performance score was 2.94 (sd=0.42), the *Bausch & Lomb multi-focal* contact lens score averaged 3.29 (sd=0.58), and the *Ciba progressive* contact lens score averaged 2.86 (sd=0.44) over the 12 tasks. Flight performance with any of the three contact lenses did not differ significantly from the performance with the bifocal spectacles (p=0.13). For the *Best Fit* subgroup, the mean flight performance was 3.10 (sd=0.43) and did not differ from the bifocal spectacles. See Figure 6.





#### Subjective assessment

Subjects assessed the performance of their bifocal spectacles and each of the three contact lens fits after their flight in the NUH-60 flight simulator. Performance was assessed for the individual tasks and then compared to performance with the bifocal the spectacles. The surveys for the bifocal spectacles and multifocal contact lenses are shown in Appendix B.

#### Overall rating

The mean overall rating for flight in the *bifocal spectacles* was 5.67 (sd=0.96). For the contact lens conditions, the mean rating of overall performance in the simulator with the *Acuvue bifocal* was 4.11 (sd=1.43), with the *Bausch & Lomb multi-focal* was 4.57 (sd=1.52), and with the *Ciba progressive* was 3.83 (sd=1.41). Pilot ratings of performance with each of the three contact lenses was statistically significantly worse than with the bifocal spectacles (p<0.001). See Figure 7.

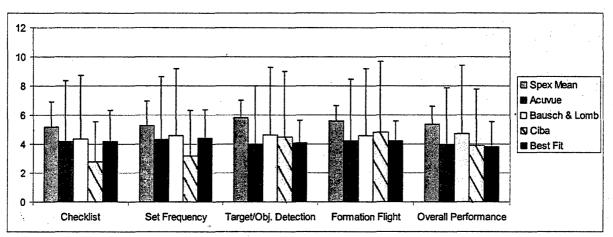


Figure 7. Pilot ratings of performance of bifocal spectacles and multifocal contact lenses on simulator tasks.

### Current lenses (contact lenses) compared to spectacles

Pilot ratings comparing each contact lens to the bifocal spectacles in the performance of tasks in the simulator was 3.04 (sd=0.33) for the *Acuvue bifocal*, 3.39 (sd=0.74) for the *Bausch & Lomb multi-focal* and 2.83 (sd=1.31) for the *Ciba progressives*. These ratings indicate a general consensus that all of the multifocal contact lenses were "slightly worse" than the bifocal spectacles. See Figure 8.

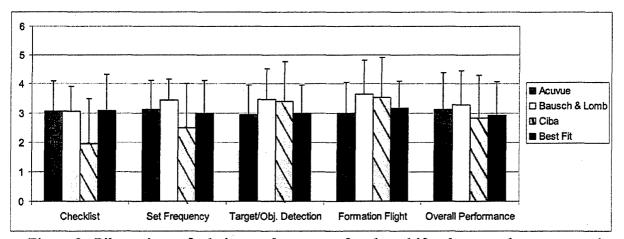


Figure 8. Pilot ratings of relative performance of each multifocal contact lens compared to bifocal spectacles on simulator tasks (5 indicates "same as spectacles" – lower values indicate "worse than spectacles").

### Discussion

One of the objectives of this study was to determine whether new generation multifocal contact lens designs show potential to provide adequate vision compatible with the basic occupational tasks and environmental conditions unique to Army aviators. Through evaluation of visual performance, flight performance and subjective assessment of the three types of contact lenses compared to spectacle correction in this study, the best option for presbyopic aviators continues to be either bifocal spectacles or "readers." Multifocal contact lenses provide a lesser level of visual performance over all measures, especially low luminance and low contrast near vision. When the contact lens fit that provides 20/20 distance and near vision is considered, only 12 of the 18 pilots were considered adequately fit. Within this subgroup, visual performance with the contact lenses was more in keeping with spectacle visual performance and tended to meet flight standards for vision (the only established standards are distance and near high contrast visual acuity and depth perception). This indicates that with careful fitting, some pilots could be successfully fit in multifocal contact lenses for aviation duties.

For performance of flight duties in a daytime environment, performance did not show a decrement. Overall, flight performance was best with the *Bausch & Lomb multi-focal* contact lens. Although not statistically significant, flight performance with the *Bausch & Lomb multi-focal* scored higher than *bifocal spectacles*. It should be noted, however, that this flight

performance assessment was completed in a simulator and does not represent the full spectrum of flying duties of an Army aviator.

Another objective of the study was to determine whether there was a general trend towards acceptance of a binocular multifocal contact lens fit. This was not directly assessed, however, of the eighteen subjects, nine requested a prescription for one of the contact lenses for continued personal use. These prescriptions are indicated in bold in Appendix D.

As to whether any of the new generation contact lenses were strongly preferred or strongly rejected by the small pilot sample, there was no evident trend. Assessments indicated that of the three lenses overall, *Ciba progressives* provided the best distance visual performance levels, while *Acuvue bifocal* gave the best near visual performance levels. The survey of pilots showed the overall ability to fly the aircraft was easiest with *bifocal spectacles* in all areas. In 5 of the 6 areas rated, the *Bausch & Lomb multi-focal* contact lens scored higher by subjective assessment than the *Acuvue bifocal* and the *Ciba progressive* lenses.

Studies specific to the Apache flight environment are being considered, since visual performance remained within norms and Apache pilots are faced with greater interface problems with bifocal spectacles, head-mounted displays and protective mask configurations than pilots in other aviation platforms. Many Apache pilots have been permanently grounded or converted to other platforms due to the onset of presbyopia and spectacle incompatibility issues in the cockpit.

#### <u>References</u>

- Bailey, I. L., Bullimore, M.A., Raasch, T.W., Taylor, H.R. 1991. Clinical grading and the effects of scaling. <u>Investigative Ophthalmology and Visual Science</u>. 32(2): 422-32.
- Bailey, I. L. and Lovie J. E. 1976. New design principles for visual acuity letter charts. <u>American Journal of Optometry and Physiological Optics</u>. 53(11): 740-5.
- Haegerstrom-Portnoy, G., Brabyn, J., Schneck, M.E., Jampolsky, A. 1997. The SKILL Card. An acuity test of reduced luminance and contrast. Smith-Kettlewell Institute Low Luminance. <u>Investigative Ophthalmology and Visual Science.</u> 38(1): 207-18.
- Lattimore, M. R., Jr. 1992. Contact lenses in the U.S. Army attack helicopter environment: an interim report. Journal of the American Optometric Association. 63(5): 322-5.
- Lattimore, M. R., Jr. and Schrimsher R. H. 1993. Refractive error distribution and incidence among U.S. Army aviators. <u>Military Medicine</u>. 158(8): 553-6.
- Morse, S. E. and Reese, M.A. 1997. <u>The use of bifocal soft contact lenses in the Fort Rucker</u> <u>aviation environment</u>. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. USAARL Report No. 97-27.
- Nakagawara, V. B. and Veronneau, S. J. 2000. Monovision contact lens use in the aviation environment: a report of a contact lens-related aircraft accident(1). <u>American Journal of Ophthalmology</u>. 130(4): 542-3.

## Appendix A.

## Multifocal Contact Lens Study Flight Profile and Score Sheet

# Date \_\_\_\_\_

Subject \_\_\_\_\_

## Run ID

## Simulator Operator Initials

		HDG/TRACK	ALTITUDE	AIRSPEED			COR		
TASK	TASK DESCRIPTION	(DEGREES)	(FEET)	(KIAS)	1	2	зок 3	⊑ 4	5
	IGE Right Hovering Turn (360)	060 - 060	10 AGL	0			-		
2	VMC Takeoff (500fpm) Upwind Leg	060	0 AGL - 1000 MSL	0 - 80					
	Straight and Level Downwind Leg/ Emergency								
3	Procedure 🗌 if checked	240	1000 MSL	100					
. 4	Tum/Decelerating/Descent Base Leg	240 - 330	1000 MSL - 700 MSL	100 - 80					
5	VMC Approach (500fpm) Final Leg	060	700 MSL - 0 AGL	80 - 0					
6	VMC Takeoff (500fpm) Upwind Leg	060	0 AGL - 1000 MSL	0 - 80					
	Straight and Level Downwind Leg/ <b>Emergency</b>								
7	Procedure 🗌 if checked	240	1000 MSL	100					
8	Turn/Decelerating/Descent Base Leg	240 - 330	1000 MSL - 700 MSL	100 - 80					
9	VMC Approach (500fpm) Final Leg	060	700 MSL - 0 AGL	80 - 0					
10	Formation Flight								
11	Admin Vectors to ILS/ Emergency Procedure								
12	ILS Rwy 6 (OZR) *Set ceiling to 250'	61	2000 MSL - 498 MSL	120					

\*Run ID = Subject Number (first 2 digits); Lens Type (01 = Multifocal Spex first run; 02 = Multifocal Spex second run; 11 = lens 1; 12 = lens 2; 13 = lens 3); Run sequence (1 thru 6 for first through sixth run in the simulator)

## Appendix B.

## Surveys.

Date: \_\_\_\_\_\_Approximate hours in UH-60 aircraft/in all aircraft \_\_\_\_/

Subject ID: \_\_\_\_\_ Approximate hours in UH-60 simulator \_\_\_\_\_

Bifocal Type (to be filled in by research staff)  $\hat{r}$ 

Check the number that most closely matches your evaluation of your Bifocal Spectacles

	Very Difficult	Moderately Difficult	Slightly Difficult	Neither Difficult nor Easy	Slightly Easy	Moderately Easy	Very Easy
Rating	1	2	3	4	5	6	7
Read Checklist							
Set Frequency							
Target/object detection							
Formation Flight							
Overall performance							

Comments?

# Multifocal Contact Lens Questionnaire

Date:	Approximate hours in UH-60 aircraft/in all aircraft/	
Subject ID:	Approximate hours in UH-60 simulator	

Multifocal Type (to be filled in by research staff) A

Part 1. Check the number that most closely matches your evaluation of your Current Lenses

	Very Difficult	Moderately Difficult	Slightly Difficult	Neither Difficult nor Easy	Slightly Easy	Moderately Easy	Very Easy
Rating	1	2	3	4	5	6	7
Read Checklist							
Set Frequency							
Target/object detection							
Formation Flight							
Overall performance	_						

Part 2. Check the number that most closely matches your evaluation of the Current Contact Lenses Compared to your Bifocal Spectacles.

	Much Poorer	Moderately Poorer	Slightly Poorer	Same as Glasses	Slightly Better	Moderately Better	Much Better
Rating	1	2	3	4	5	6	7
Read Checklist							
Set Frequency							
Target/object detection							
Formation Flight							
Overall performance							

Part 3. During any portion of this simulator evaluation, did you experience difficulties because of the contact lenses? Yes/ No

If yes, please describe (continue on the back if needed)

Date

Subject ID

Part 4. General Wear Questions

1. What is your age? \_\_\_\_\_

2. Have you ever worn contact lenses before this study? Yes/No If yes, were they Single Vision or Multifocal?

3. How many hours did you wear the contact lenses each day?

Day 1 \_\_\_\_ Day 2 \_\_\_\_ Day 3 \_\_\_\_ Day 4 \_\_\_\_ Day 5 \_\_\_\_ Day 6 \_\_\_\_ Day 7 \_\_\_\_

4. Did you experience any difficulty handling the contact lenses?

Putting them in? Yes/No Removing them? Yes/No

5. Did you experience any "settling" of the contacts after you first put them in your eyes? Yes/No If yes, how long was the "settling" period? (Check one of the boxes below)

Less than 5	5-10	11-30	31-60	1 hour or
minutes	minutes	minutes	minutes	more

6. Did you experience any fluctuation in your vision while wearing the contact lenses? Yes/No

7. Did you have to remove the contact lenses for any reason? Yes/No (if no, skip to #8) If yes, please state the reason(s):

8. Please rate the following using the 1-7 scale.

9	Very Bad	Moderately Bad	Slightly Bad	Neither Good nor Bad	Slightly Good	Moderately Good	Very Good
Rating	1	2	3	4	5	6	7
Distance vision		1					
Near vision							
Comfort							
Vision during the day							
Vision at night							
Overall performance of daily activities							

9. How comfortable would you feel wearing these contact lenses in the cockpit? (Scale of 1-7, with 1 being VERY UNCOMFORTABLE to 7 being VERY COMFORTABLE)

1 2 3 4 5 6 7

10. Any additional comments (continue on the back, if needed).

# Appendix C.

# Demographics.

Part 1.				Pun	il Sizes		
Subject Number	Age	Aircraft	Lumi	High nance ) cd/m <sup>2</sup> )	Low Luminance (3 cd/m <sup>2</sup> )		
			OD	OS	OD	OS	
001	57	OH-58/TH-67	2.3	2.4	6.3	6.5	
003	55	OH-58/TH-67	3.1	3.2	5.4	6.0	
004	49	AH-64	2.9	2.8	6.6	6.5	
005	56	C-12/TH-67	2.2	2.3	7.3	6.8	
007	49	UH-1/UH-60	2.2	2.2	6.6	6.4	
008	54	UH-1	1.9	1.7	4.5	4.4	
009	46	OH-58	2.2	2.4	5.3	5.4	
011	54	UH-60	2.1	2.1	4.1	4.8	
012	47	UH-60/UH-1	2.6	3.0	7.3	7.7	
013	48	UH-60	1.9	2.4	6.6	6.3	
014	56	CH-47	2.0	2.3	5.2	5.2	
015	46	UH-1/UH-60	2.3	2.5	6.0	6.3	
016	50	AH-64	3.7	4.0	5.7	5.8	
018	57	UH-60	2.3	2.6	6.8	7.3	
019	56	AH-64	2.2	2.3	7.8	6.9	
020	60	TH-67.	2.1	2.1	5.2	5.3	
021	46	TH-67	2.5	2.5	5.0	5.0	
022	44	TH-67/OH-58	3.5	3.5	7.0	6.5	

Part 2.							
Subject			Re	fractive Er	ror		
Subject Number		OD	·		OS		ADD
Tumper	SPH	CYL	AXIS	SPH	CYL	AXIS	
001	+2.50	-0.75	146	+1.25	-0.75	095	2.50
003	+0.75	-0.50	070	+0.50	-0.75	096	2.00
004	-1.25	-0.50	117	-1.50	-0.25	093	1.75
005	-1.00	-0.50	068	-0.25	-1.00	096	2.25
007	+0.25	-0.25	118	+0.25	-0.50	091	2.00
008	0.00	-0.25	142	0.00	-0.25	044	1.75
009	+0.75	-0.50	101	+1.00	-0.75	086	1.25
011	+0.50	-0.25	130	+0.75	sphere		2.25
012	+0.25	-0.25	085	+0.25	-0.25	111	1.00
013	+0.25	-0.25	110	0.00	-0.25	050	1.75
014	+2.50	-0.75	090	+2.00	-0.75	105	2.25
015	0.00	-0.50	180	0.00	-0.50	180	1.75
016	+1.00	-0.50	100	+0.50	-0.50	085	2.00
018	0.00	-0.50	090	+1.25	-1.50	078	1.75
019	-1.75	-0.25	020	-1.50	-0.25	102	2.00
020	+2.00	sphere		+1.75	sphere		2.50
021	0.00	sphere		-0.25	-0.75	075	0.00
022	-0.50	-0.50	084	-0.50	-0.50	095	1.00

.

Demographics.

# Appendix D.

## Contact lens parameters.

Subject Number         Acuvue 8.5 BC, 14.2 Dia. Add range +1.00 to +2.50         Bausch & Lomb 8.5 or 8.8 BC, Add High         Ciba 8.6 BC, 14.0 Dia. Add is standard           OD         OD         OS         OD         OS           01         +2.25/ +2.25/ +1.00/ +2.00 Add         +2.00 Add 8.5 BC         +1.00/ +2.02 Add         +2.25/ +1.00/ +2.00 Add         +1.00/ +2.00 Add         +2.25/ +1.00         +1.00/ +2.25         +1.00/ +1.50 Add         +2.25/ +1.00         +1.00/ +0.25         +0.25         -0.25           004         +1.50 Add         +1.50 Add         8.8 BC         8.8 BC         +8.8 BC         -1.75         -1.75           005         -1.00/ +1.50 Add         +2.00 Add         8.8 BC         8.8 BC         -1.00         -0.75           007         +0.00/ +0.00/         +0.00/ +0.00/         +0.00/ +0.00/         +0.00/ +0.00/         +0.00/ +0.50         +0.50         +0.50           008         -0.25/ +1.50 Add         +1.50 Add         8.8 BC         8.8 BC         +0.50         +0.50           011         +0.00/ +0.00/         +0.00/ +0.00/         +0.00/ +0.00/         +0.025/ +0.00         +0.75/ +1.50         +0.25         +0.25           012         +0.00/ +0.00/         +0.00/ +0.00/         +0.00/ +0.00/         +0.00/ +0.00/         +0.25/ +0.00 <th></th> <th></th> <th>Co</th> <th>ntact Lens</th> <th>Parameters</th> <th>*****</th> <th></th>			Co	ntact Lens	Parameters	*****		
Subject Number         8.5 BC, 14.2 Dia. Add range         8.5 or 8.8 BC, Add High         8.6 BC, 14.0 Dia. Add is standard           OD         OS         OD         OS         OD         OS           001 $+2.05$ / $+1.00/$ $+2.25/$ $+1.00/$ $+2.25/$ $+1.00/$ $+2.25/$ $+1.00/$ $+2.25/$ $+1.00/$ 003 $+0.00'$ $-0.50/$ $+0.00'$ $-0.75/$ $+0.25$ $-0.25$ 004 $-1.50/$ $-1.50/$ $-1.50/$ $-1.75$ $-1.75$ $-1.75$ 005 $-1.00/$ $-0.50/$ $-1.00/$ $-0.50/$ $-1.00/$ $-0.75$ 007 $+0.00/$ $+0.00/$ $+0.00/$ $+0.00/$ $+0.25$ $+0.25$ 008 $-0.25/$ $-0.25/$ $+0.00/$ $+0.00/$ $+0.00/$ $+0.50$ $+0.50$ 009 $+0.50/$ $+0.75/$ $+0.50$ $+0.75$ $+1.00$ 011 $+0.00/$ $+0.00/$ $+0.00/$ $+0.25/$ $+0.75$ 012 $+0.00/$ $+0.00/$	<b>.</b>			Bausc	h & Lomb	Ciba		
Add High         Add High         Add is standard           OD         OS         OD         OS         OD         OS           001 $+2.25/$ $+1.00/$ $+2.25/$ $+1.00/$ $+2.25/$ $+1.00/$ 003 $+0.00/$ $-0.50/$ $+0.00/$ $-0.75/$ $+0.25$ $-0.25$ 004 $+1.50$ Add $+1.50$ Add $+2.00$ Add $8.8$ BC $8.8$ BC $+0.25$ $-0.25$ 004 $-1.50/$ $-1.50/$ $-1.50/$ $-1.75$ $-1.75$ $-1.75$ 005 $-1.00/$ $-0.50/$ $-1.00/$ $-0.50/$ $-1.00$ $-0.75$ 005 $-1.00/$ $-0.50/$ $-1.00/$ $-0.75$ $+0.25$ $+0.25$ 007 $+0.00/$ $+0.00/$ $+0.00/$ $+0.00/$ $+0.25/$ $+0.25$ 008 $-0.25/$ $-0.25/$ $+0.00/$ $+0.00/$ $+0.75/$ $+0.75/$ $+0.75$ 011 $+0.00/$ $+0.00/$ $+0.00/$ $+0.25/$ $+0.75$ $+0.25/$	-							
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$	Number				,			
$\begin{array}{c c c c c c c c c c c c c c c c c c c $								
$\begin{array}{c c c c c c c c c c c c c c c c c c c $						OD	OS	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	001					+2.25	+1.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $								
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	003		÷ · = •,	1		+0.25	-0.25	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $								
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	004	1		1		-1.75	-1.75	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $			the second s					
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	005					-1.00	-0.75	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $								
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	007					+0.25	+0.25	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $							. 0.25	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	008					+0.50	+0.50	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$						. 0.50	.0.50	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	009	1		1 · · · ·		+0.75	+1.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $			· · · · · · · · · · · · · · · · · · ·			. 0.75	. 1.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	011				+0.25/	+0.75	+0.75	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $		+2.00 Add		<b>8.5 BC</b>	8.5 BC	10.75	10.75	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	012	+0.00/	+0.00/	-0.50/	-0.25/	+0.25	+0.25	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	012	+1.00 Add	+1.00 Add	8.8 BC	8.8 BC	+0.23	10.43	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	013	+0.00/	+0.00/	+0.00/		+0.25	+0.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	015	+1.50 Add	+1.50 Add	8.8 BC	8.8 BC	+0.25	+0.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	014	+2.25/	+1.75/	+2.25/	+1.75/	10 75	+2.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	014	+2.50 Add	+2.50 Add	8.5 BC	8.5 BC	+2.75	+2.00	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	015	-0.25/	-0.25/	-0.50/	-0.25/	0.25	10.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	015	+1.50 Add	+1.50 Add	8.8 BC	8.8 BC	-0.23	+0.00	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	016	+0.75/	+0.50/	+0.50/	+0.25/	11.00	10.50	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	010	+2.00 Add	+2.00 Add	8.8 BC	8.8 BC	+1.00	+0.50	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	019	-0.25/	-0.50/	-0.25/	-0.50/	10.00	10.75	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	018	+2.00 Add	+2.50 Add	8.8 BC	8.8 BC	+0.00	+0.75	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	010	-1.75/	-1.50	-1.75/	-1.50/	1 50	0.77	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	013	+2.00 Add	+2.00 Add	8.8 BC	8.8 BC	-1.30	-0./5	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	020	+2.25/	+2.25/	+2.25/	+2.25/	10 50	19.50	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	020	+2.50 Add	+2.50 Add	8.8 BC		+2.50	+2.50	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	001	+0.00/				10.00	0.05	
022 -0.75/ -0.75/ -0.75/ -0.75/ -0.75/ -0.75	021					+0.00	-0.25	
	000					o ==	0	
	022	+1.50 Add	+1.50 Add	8.8 BC	8.8 BC	-0.75	-0.75	

### Appendix E.

Multifocal contact lens study score sheet.

#### Pt ID# : Birth Date: M/F Exam Date : Visit: Lens 1 **Spectacles** Lens 2 Lens 3 **Modified Monovision** Manifest Refraction: Sphere DHCVA ADD **NHCVA** Cylinder Axis OD 20/ 14/ \_\_\_\_ os 20/\_ 14/ UCVA: OU # of letters read incorrectly logMAR HCVA: OU # of letters read incorrectly logMAR LCVA: OU # of letters read incorrectly **IogMAR** LCVA (filter): OU # of letters read incorrectly logMAR LCVA (glare): OU # of letters read incorrectly logMAR SKILL (light): OU # of letters read incorrectly logMAR SKILL (dark): # of letters read incorrectly logMAR OU (add 10 letters to compute) **RANDOT Stereo:** seconds of Arc **Dynamic Stereopsis (Pulfrich):** Ellipse seen? Yes // No Back of Ellipse? Right to left // Left to right OD OS **Pupil Size: High Luminance:** mm mm Low Luminance: mm mm OD OS Slit lamp Exam L/L Cornea Coni **Contact Lens** Centration **Movement** Surface

## **Bifocal Contact Lens Study**

28

## Appendix F.

Multifocal contact lens study score sheet.

# Bifocal Contact Lens Study Contrast Sensitivity and NVG Tests

Pt ID#		Birth Date:						
Exam Date:					M/F			
Visit:	Lens 1 Lens 2 Lens 3	Spectacles Modified Monovision						
	C	omputer	Contrast S	ensitivity				
Normal CS (hi):	1	2	4	8	<u>16</u>			
Normal CS (lo): w/ Screen Filter								
		Dep	th-No	rmal				
without NVG's	Α	В	С	D	E	F		
Far> 12	3	3	4	3	2	3		
	2	4	2	2	3	2		
	4	2	4	3	4	2		
Score:	83	43	32	27	19	13		