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The Use of Bifocal Soft Contact Lenses in the Fort Rucker Aviation Environment

By

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There are problems with the compatibility of spectacles and certain helmet mounted electro-optical visual display systems. The incompatibility has been partially resolved with single vision contact lenses. However, these contact lenses have not helped senior aviators, who must wear bifocal glasses due to their presbyopia. The purpose of this study was to compare the performance of bifocal soft contact lenses with that of bifocal spectacle lenses to determine if contact lenses are an option for helping older aviators meet the visual requirements needed to fly military aircraft. METHODS. Seventeen volunteer presbyopic aviators from Fort Rucker were fitted with five bifocal soft contact lens combinations and bifocal glasses. A four-phase investigation was conducted: a clinical phase involving the fitting of the bifocal contact lenses; a laboratory phase involving measurements of visual functions; a simulator phase involving measures of visual performance in simulated flight conditions; and an operational phase consisting of subjective responses regarding in-flight use of bifocal contact lenses. RESULTS. In general, vision in the best performing bifocal contact lenses typically was slightly reduced from vision in bifocal spectacles. The amount of the reduction, and whether it

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was clinically significant, depended on the refractive error of the subject (myopes generally performed better), the add group of the subject (low add group subjects performed better), and the type of bifocal contact lens. Aviators performed flight simulation maneuvers better in bifocal contact lenses than in bifocal glasses, and they evaluated their own ease of vision while performing aviation duties to be much easier in bifocal contact lenses than in bifocal glasses. In actual flight operations, each aviator preferred bifocal contact lenses over bifocal spectacles. CONCLUSIONS. Bifocal soft contact lenses are an acceptable alternative to glasses for presbyopic aviators. However, there is not one specific bifocal lens type that performs optimally on all subjects. As a minimum, monovision, modified monovision, and selected simultaneous vision bifocal contact lenses (at least two types: center near and concentric), must be available to successfully fit presbyopic aviators with bifocal contact lenses.

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Introduction

This is the fourth in a series of studies conducted under the U.S. Army Aeromedical Research Laboratory (USAARL) protocol "The use of extended-wear soft contact lenses in military environments," approved 13 December 1984. The purpose of this study was to determine if soft bifocal contact lenses are a possible option for visual compensation of presbyopia in the U.S. Army aviator population. The study was conducted at the request of the Aviation Medicine Consultant to the Surgeon General regarding the feasibility of in-flight use of bifocal soft contact lenses for Army aircrew (appendix A). The specific project objective was to determine the bifocal contact lens design which allows for the best performance on the occupational tasks and under the environmental conditions characteristic of the Army aviator.

Approach

Volunteer presbyopic aviators from Fort Rucker, Alabama, were fitted with four different designs (six combinations) of bifocal soft contact lenses. A four-phase investigation was designed to compare the performance of bifocal soft contact lenses to spectacle bifocal lenses. The four phases were: a clinical phase involving the fitting of the bifocal contact lenses, a laboratory phase comparing visual function with spectacle bifocal and bifocal contact lenses under laboratory conditions, a simulator phase comparing visual performance with spectacle bifocal and bifocal contact lenses under simulated flight conditions, and an operational phase consisting of subjective ratings regarding the in-flight use of bifocal contact lenses. These data and user acceptability ratings were used to compare bifocal soft contact lenses with spectacle bifocal lenses in the performance of aviation duties.

Army Regulation (AR) 40-63 (Medical Services Ophthalmic Services, October 1986) and AR 40-501 (Medical Services Standards of Medical Fitness, SGPS-CP-B, 14 June 1989) prohibit the use of contact lenses by Army aircrew when flying. A temporary medical clearance (appendix B) was approved for Class 2 flying duties for subjects enrolled in the USAARL bifocal soft contact lens study enabling participating aviators to meet the medical fitness standards for Class 2 flying duties referenced under paragraph 4-11r, AR 40-501.

Military significance

The sophisticated electro-optical display devices currently found in many military aircraft can often present a compatibility problem with spectacles. In the AH-64 Apache helicopter, the problem of spectacle compatibility with the integrated helmet and display sighting system (IHADSS) was solved by having aviators wear spherical soft contact lenses (Bachman, 1988; Lattimore and Cornum, 1992). While this solution proved adequate for most aviators, one-third were not successful in the contact lens program due to either astigmatism or presbyopia. The presbyopic group is of great importance because members are typically those aviators with advanced aviation skills and experience. By fitting these older, more experienced aviators with bifocal soft contact lenses, the pool of qualified aviators available for assignment to aircraft outfitted with sophisticated aviation systems may be expanded.

Background

Aviators must meet stringent physical standards to gain entrance to flight training programs. Some particular standards are more flexible than others; refractive error is an example of the type of standard that allows some departure from those absolute criteria. Over the years, a substantial ametropic aviation population has developed, making the wearing of spectacles among the aviator population a common occurrence. 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 required to wear refractive error corrections (Lattimore and Cornum, 1992). However, conventional single vision contact lenses are not adequate for the presbyopic aviator.

The use of bifocal soft contact lenses offers a potential solution to the near vision problems experienced by older aviators who require bifocal correction, yet cannot wear spectacles due to incompatibility with the sighting systems in the aircraft they fly. The purpose of this study was to compare the performance of bifocal soft contact lenses with that of bifocal spectacle lenses so that the military community can determine the overall acceptability of this option for helping older aviators meet the visual requirements needed to fly military aircraft.

Literature review introduction

The results of a series of recent investigations (Crosley et al., 1974; Bachman et al., 1987; Bachman, 1988; Lattimore and Cornum, 1992) have shown that soft extended wear contact lenses are an effective solution to the nonpresbyopic spectacle sighting-system problems that exist in some aircraft. Furthermore, it has been established that the wearing of contact lenses in aviation and other military environments poses no significant ocular health hazard (Bachman et al., 1987; Bachman, 1988; Lattimore and Cornum, 1992).

These studies also called attention to the vision problems that older aviators had when wearing contact lenses that only corrected their far vision; i.e., they had difficulty reading small print up close. The problem was that these contact lenses lacked the capability for multi focal correction. Since there are now bifocal soft contact lenses available commercially, a potential solution to the older aviator's near vision problems seems possible. Since soft bifocal contact lenses are made of the same materials as single vision soft contact lenses, the ocular health risks they present should be no different than those found with regular single vision contact lenses. Thus, the main concern in using soft bifocal contact lenses is their effect on visual functions; i.e., how well they perform compared to spectacle bifocals. Since the various optical designs of bifocal soft contact lenses have the potential to affect visual functions differently, representative types of the different bifocal soft contact lenses were compared to bifocal spectacle lenses in order to determine which bifocal soft contact lens type resulted in the best visual performance.

There are presently four different designs available for soft bifocal contact lenses. At the time this study was approved, each bifocal contact lens design type was available. It was logistically impractical to test all available bifocal soft contact lenses, so specific lenses were selected to represent each design type or subtype. For example, the simultaneous vision (SV) design is accomplished four ways: aspheric curves with center near, aspheric curves with center far, diffraction, and concentric zones with center near. Lenses representing each type of design were chosen. It was assumed that lenses based on similar design criteria should ultimately provide similar visual functioning and, therefore, results from one lens could be generalized to others with the same design. This was based on the premise that the lenses could be optimally fitted to each subject's eyes with appropriate physiological adaptation and alignment. The selection criteria for specific lenses to represent each design type for this study was determined by several factors: (1) availability of lens parameters to allow for successful fitting of the lens; i.e., base curves, diameters, add-powers, and sphere powers (must have both plus and minus); (2) cost; and (3) literature regarding lens performance and success rates. Where appropriate, information regarding lens selection criteria will be discussed for each design type below.

Monovision (MV) design

In the MV design, one eye is corrected for distance vision while the other eye is corrected for near vision, each with a different single-power contact lens. Partial interocular suppression occurs to permit alternating distance or near vision. This partial suppression is thought to be limited to the high spatial frequency components of the image from the blurred eye, so that low spatial frequency components from the blurred image still contribute to binocular fusion (Loshin et al., 1982; Schor, et al., 1987). One documented limitation of this design is reduced stereopsis. The lenses selected for MV use represent the typical low water-content and moderate water-content extended wear lenses commercially available. While other lenses of similar design are functionally equivalent, Medalist (Bausch and Lomb [B&L]•) and Acuvue (Johnson & Johnson•) seem the most desirable choice because an extensive data base exists from their use in the previous AH-64 contact lens study (Lattimore and Cornum, 1992).

SV design

Bifocal soft contact lenses, based on the SV principle, use a central optic zone that is smaller than the pupil diameter. The surrounding peripheral zone also lies partly within the pupil so that both optic zones simultaneously focus light onto the retina. The wearer attends to the image of interest, but the other optic zone simultaneously produces a superimposed out-of-focus image. This design is modified four ways by different manufacturers. Designs differ in their use of the

•See list of manufacturers at appendix C.

center portion of the lens (either distant or near vision), their method of generating power changes (aspheric, diffraction, concentric), or a combination of both. Representative designs and manufacturers using SV and their abbreviations (which are used later in the results section) include:

Aspheric center far, more (+) peripherally = SV cen-F.

At the time this study began, Occasions (B&L•) and Allvue (Salvatori Ophthalmics•) were the only lenses representing the center-far option in the simultaneous design.

Aspheric center near, less (+) peripherally = SV cen-N.

Unilens (Unilens Corp.•) was chosen due to the availability of many fitting parameters and the literature base evaluating its performance.

Diffraction "phase-plate" aspheric - SV diffr.

Echelon (Allergan•) was the only representative of the simultaneous design based on diffraction and refraction principles.

Concentric center near, 2 optic zone options - SV conc.

Spectrum (CIBA•) was chosen due to the availability of fitting parameters.

Alternating vision (AV) design

The goal of this design type is to avoid the simultaneous sharing of the pupil by distant and near optical zones. There is an important mechanical/optical factor in fitting this lens type. Unless the lower lid can support the inferior aspect of the lens as the patient changes gaze from primary position to down gaze, the lens will not move on the cornea sufficiently, and the near vision sector will not be reached. Conversely, the lens may ride too high constantly, causing poor distant vision (Robboy, 1985). Thus, the lens has the potential to act as a simultaneous design lens by improper centration. At the time the study began, Bi-tech (B&L•) was the only lens available based on this design.

Modified MV design

This fitting concept involves fitting one eye with a spherical single vision distant-vision prescription contact lens, while fitting the other eye with a bifocal contact lens. This design presents a potential design limitation not found in the other lens designs; i.e., anisometropia for near-vision tasks due to only one eye having a near power. This may or may not produce reduced stereopsis, depending on the amount of the near lens power in one eye. The lenses used in this experimental condition consisted of a spherical single-power distant-vision lens on the subject's right eye, and the bifocal soft contact lens that provided the best laboratory-phase visual performance on the left eye.

Literature review - visual functioning with bifocal soft contact lenses

While the use of soft bifocal contact lenses for presbyopic aviators appears to be a potential solution to the visual problems of older aviators, there is some evidence that the different bifocal soft contact lens designs impair certain visual functions under specific conditions.

Contrast sensitivity

Different visual tasks rely on selective ranges of spatial frequency. For example, high frequencies are important for obstacle avoidance in walking. The contrast sensitivity function (CSF) profiles the lowest contrast required for stimuli of various spatial frequencies to be detected.

Both MV and SV have been reported to produce some reduction in contrast sensitivity. Theoretically, the AV design should provide excellent optics and contrast sensitivity similar to normal binocular vision, but typically, AV bifocal contact lenses often provide only partial pupillary coverage by the appropriate zone (Robboy and Erickson, 1985; Ames et al., 1989), so these lenses may function as SV lenses for some patients with less than optimal fits. Among AV lenses, a concentric design apparently causes more reduction in contrast sensitivity than an aspheric design at both near and far distances (McGill et al., 1987). Collins et al. (1989) found similar contrast thresholds for various SV and MV lenses at three distances under low illumination conditions. Charman and Walsh (1986) measured modulation transfer functions (MTFs) (the optical correlate of the CSF) for a range of bifocal contact lens corrections. They reported that the MTF of centered bifocals was never as good as that for single vision lenses. Sanislo et al. (1992) measured contrast sensitivity in the Echelon lens (a diffraction design) and found the CSF significantly reduced compared to bifocal spectacles.

In our study, contrast sensitivity with the different bifocal contact lens designs and spectacle bifocal lenses was measured during the laboratory evaluation.

Visual acuity (VA)

Literature reports that MV lenses produce the smallest reduction in high contrast VA compared to SV and AV design types (McGill and Erickson, 1988a). However, there is some disagreement regarding acuity measures under various illuminations and with differing distances. Back et al. (1987) reported reductions in high and low contrast VA for both MV and SV lenses, with MV lenses providing significantly better VA at near. In contrast, Brown et al. (1987) measured VA at various near and intermediate distances and found greater reductions with MV than with SV lenses. Papas et al. (1990) reported that MV lenses provide better VA than diffraction design lenses at near and under low contrast conditions.

In this study, VA was assessed at far, intermediate, and near viewing distances for spectacle bifocal lenses and all bifocal contact lens types. Low and high contrast letter charts were used under conditions of low and high luminance.

Stereopsis and depth perception

The ability to judge absolute and relative distances is an obviously important visual function for aviators, especially rotary-wing aviators. Since perturbations in the quality of the stimulus (e.g., reduced contrast or blur) reduce stereopsis thresholds, changes induced by contact lenses possibly could degrade the image, causing an unacceptable loss in stereopsis. For example, it is generally thought that reduced stereopsis is the major disadvantage associated with the blur encountered with MV (Beddow et al., 1966; McLendon et al., 1968; Koetting, 1970; Lebow and Goldberg, 1975; Back et al., 1987; McGill and Erickson, 1988a). However, it has not been demonstrated conclusively that blur is the cause of the reduced stereopsis associated with MV. Regardless, numerous studies have shown that stereo acuity is substantially reduced under anisometropic (Peters, 1969; Ong and Burley, 1972; Lèvy and Glick, 1974) and aniseikonic (Lovasik and Szymkiw, 1985) viewing conditions similar to that produced by MV and SV designs, respectively.

It should be remembered that stereopsis is only one cue to judging distances and depth. There are many monocular cues. For distances which are relevant for aviation operations, the monocular cues probably are more important. However, since stereopsis is easy to assess clinically and is one of the few tests that measures binocular cooperation, it continues to be a requirement for medical qualification for flight duty.

For the present investigation, clinical measurements of stereopsis were included for both near (40 cm) and far (6 m) viewing distances using conventional instrumentation and procedures.

Peripheral vision

An area of concern for a pilot wearing MV bifocal contact lenses is the potential effect of monocular blur on the pilot's peripheral, or outside cockpit, vision caused by the near powered contact lens on one eye. The potentially limiting visual functions are peripheral VA and peripheral motion detection.

Peripheral VA

Peripheral VA is the resolution ability of the nasal hemi-retinas of the eyes when attention is directed forward. The question of concern is whether the eye corrected for near in MV (and in other bifocal contact lens types where the lens may decenter and effectively be an MV fit) has the potential to significantly blur the nasal retina and thereby reduce peripheral VA.

The net impact of wearing a near correction in one eye is not obvious. It is generally known that resolution diminishes rapidly as retinal eccentricity increases. In the nasal hemi-retina, high contrast VA is roughly 20/40 at 5 degrees eccentricity and 20/270 at 30 degrees eccentricity (Burian and Von Noorden, 1974). The situation is more complex for targets of greater eccentricity, mainly because the optical quality of the retinal image changes substantially as eccentricity increases. In terms of spherical equivalent refractions, hyperopes become more hyperopic while myopes become slightly less myopic (Millodot, 1981). Thus, the additional plus in the eye corrected for near (in MV) might actually produce slightly better nasal acuity than if corrected with a distance lens.

Limited data are available on subjects wearing SV corrections where both eyes receive degraded optical images. Existing studies tend to show that peripheral VA is not significantly reduced with the slight amount of blur potentially caused by bifocal contact lenses. Brown et al. (1987), using a simple bar target, found that MV and SV subjects had slightly better peripheral VA than spectacle-corrected subjects, and no significant differences in peripheral VA were found between MV and SV corrections. Collins et al. (1989) similarly found no significant differences in peripheral VA with any of the bifocal contact lens types they evaluated (MV, SV-Hydrocurve II aspheric, Hydron-concentric, and modified MV single vision far distance with near concentric bifocal lens). These studies suggest that static visual fields are not adversely affected by MV, SV, or modified MV correction, and for that reason, the present study did not include measurements of peripheral VA with different bifocal contact lenses. However, the in-flight phase asked for subjective comparisons on the bifocal contact lens types and the control condition of bifocal spectacle lenses in order to evaluate the presence of any effects on peripheral VA.

Peripheral motion perception

Motion perception is one of the most important functions of peripheral vision and, of all visual functions in the periphery, it appears to be least affected by blur. For example, while VA thresholds increase from 15 arc sec at the fovea to 18 arc min at 30 degrees eccentricity (a 72-fold increase), thresholds for detecting motion increase from 1 arc min at the fovea to 6 arc min at 30 degrees (a 6-fold increase) (Liebowitz, Johnson, and Isabelle, 1972). However, these thresholds were obtained at optimal refractive conditions. When peripheral refractive errors were uncorrected (as in normal vision), motion thresholds increased in spite of the presumed insensitivity to refractive defocus in the periphery. For example, 2 diopters of refractive error in the periphery can almost double the motion detection threshold at 30 degrees eccentricity (Dighans and Brandt, 1978).

Both MV and SV have the potential to affect the sensitivity for detecting object motion in blurred portions of the visual field. The extent of the effect will depend on the pattern of refractive error change in the periphery mentioned earlier; i.e., hyperopes may actually perform better with bifocal contact lenses when the add power is in the periphery of the lens.

In this proposal, there was no planned procedure to measure peripheral motion detection in the laboratory. The flight simulation questionnaire asked for subjective comparisons between the bifocal contact lens types and the control condition of bifocal spectacle lenses in order to evaluate any effects on peripheral motion perception.

Peripheral field of view (FOV)

Westheimer (1962) pointed out that the contact lens wearer benefits from the absence of a spectacle frame restricting the FOV. Also, the reduced prismatic and magnification effects due to contact lenses (instead of spectacle lenses) result in smaller eye movements for hyperopic contact lens wearers and larger image sizes for myopic contact lens wearers. Thus, both hyperopes and myopes receive beneficial effects when switching from spectacles to contact lenses. However, for moderate prescriptions, as are typically found among the aviator population, these effects are small.

This study did not include measurements of peripheral FOV, as there is sufficient evidence to indicate that contact lenses allow for a significant improvement in FOV compared to spectacles. The questionnaire in the flight simulation phase asked for subjective comparisons between the bifocal contact lens types and the control condition of bifocal spectacle lenses in order to evaluate any differences in peripheral FOV.

Night flying conditions

There is a potential visual problem associated with the reported decrease in contrast sensitivity caused by soft bifocal contact lenses while flying at night. Specifically, the aviator who is relying on the aviator night vision imaging system (ANVIS) display for pilotage may be placed at a disadvantage when wearing soft bifocal contact lenses as reduced contrast sensitivity may be experienced. Under normal daylight flying conditions, when targets are primarily high contrast-high luminance, there appears to be little evidence of a decrement in visual performance with bifocal contact lenses. However, at night, when most viewing conditions are low contrast-low luminance, contact lenses may result in a decrement in sensitivity.

In this study, the effects of reduced contrast upon VA were measured for all bifocal contact lens types through ANVIS using high and low contrast targets. Also, VA without ANVIS was measured under high and low luminance conditions while using high and low contrast targets. Furthermore, during flight simulation exercises, the effect of low luminance was indirectly measured by scoring pilotage performance during flight simulation maneuvers.

Background summary and general study design

The four different designs of bifocal soft contact lenses have potential visual functional deficits as discussed above. Our goal was to determine which of the four designs provided the maximum visual performance (with the least visual impairment) for presbyopic aviators. The study design involved four phases: clinical, laboratory, flight simulator, and operational.

During the clinical phase, the different types of bifocal contact lenses were compared to spectacle bifocal lenses (and to each other) and were evaluated on their ability to correct refractive error without compromising the normal physiology of the eye. Each bifocal soft contact lens had to provide acceptable comfort with optimal centration and alignment.

During the laboratory phase, different visual functional tests were conducted to quantitatively assess visual performance while wearing spectacle bifocal lenses and the different bifocal lens designs.

During the flight simulation phase, aviators were graded on specific flight maneuvers that relied heavily on visual information processing. The series of maneuvers were performed wearing bifocal spectacles and the different bifocal soft contact lens designs. In addition to pilotage performance data, subjects were asked to respond to a questionnaire designed to address specific visual task performance while wearing bifocal soft contact lenses.

During the operational phase, the volunteers performed normal flight duties in their current rated aircraft wearing the different types of bifocal contact lenses after receiving a temporary medical clearance to perform flight duties while wearing bifocal contact lenses (appendix B). After flights using all the different "approved for flight contact lenses," the subjects were asked to determine a preferred lens type.

Materials and methods

Subjects

Volunteer presbyopic aviators assigned to Fort Rucker, Alabama, were recruited through local advertisement. Potential subjects were provided with an informed consent briefing and their health records were screened for medical acceptability. Medical conditions excluding 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 affecting the anterior segment of the eye.

Each eligible individual had the risks and benefits of study participation carefully explained and, if they chose to volunteer, were asked to read and sign the Volunteer Agreement Affidavit and a Volunteer Registry Data Sheet.

All subjects received a vision examination and were assigned to either the myopic or hyperopic refractive error group and to the low-add or high-add bifocal segment-power group, depending on the results of the vision examination. The subject groupings were chosen because both the type of refractive error (hyperopia or myopia) and the magnitude of the bifocal segment-power (high, > +1.25 D or low, ≤ +1.25 D) are known to influence the way contact lenses fit on the eye. The fit, or centration of the lens on the eye, is important in order to align the optical correction in the lens with the subject's line of sight. Therefore, both the refractive error and the bifocal segment-power had to be included in the analysis in order to correctly identify factors which affected the measures of visual performance.

A total of 22 subjects, all rated aviators with full flight duties, were recruited for the study. Five aviators were unable to complete the study either due to reassignment or retirement (N=3) or lack of time to participate (N=2). No subjects were dropped due to unsatisfactory contact lens experiences. The remaining 17 subjects who completed the study were qualified in various aircraft so that all the aircraft in the U.S. Army inventory were covered (see tables 1 and 2). All subjects had aided visual acuities of at least 20/20 Snellen in each eye at far and near distances and were free from eye disease and other ocular anomalies.

Table 1.
Age and refractive error data of subjects (N=17).

Variable	Mean	SD	Median	Range
Age (years)	0.44	3.12	44	39-50
Equivalent sphere (D)	-0.48	1.04	-0.01	-2.25-1.04
Sphere (D)	-0.28	1.04	0.01	-2.00-1.25
Cylinder (D)	-0.50	0.39	-0.50	-1.50-(-0.01)
Segment add-power (D)	1.31	0.36	1.00	1.00-2.00
Myopic group (N=9)	-1.22 D	0.88	-1.50	-2.25-(-0.01)
Hyperopic group (N=8)	0.35 D	0.34	0.37	0.01-1.25
High add-group (N=8)	1.66 D	0.19	1.62	1.50-2.00
Low add-group (N=9)	1.00 D	0.00	1.00	0.00

Table 2.
Aircraft represented in USAARL bifocal soft contact lens study.

	AH-1	AH-64	UH-1	UH-60	OH-58	CH-47	C-12	U-21
No. of Subjects (N=17)	1	1	4	4	3	2	1	1

Equipment and procedures

All the bifocal soft contact lenses used in this study were approved by the U.S. Food and Drug Administration for daily wear. The contact lenses were fit according to the fitting guide recommendations provided by the manufacturer of each contact lens design. Seven different contact lens conditions, which included six different bifocal soft contact lenses from the four different lens design types, were included in the study (see table 3).

Table 3.
Bifocal soft contact lens design types and candidate lenses for each design type.

Type of lens	Name of lens type
Control	Bifocal spectacles
Monovision	Medalist® or Acuvue®
Alternating vision	Bi-tech®
Simultaneous Vision Sim cen far Sim cen near Sim diffr Sim conc cen near	 Occasions® or Allvue® Unilens® Echelon® Spectrum®
Modified monovision	Single vision (far) right eye Best bifocal lens left eye

Procedures, experimental design, and data analysis

The study consisted of four phases:

Phase I

This was the clinical portion of the investigation during which standard clinical tests were used to determine the fitting characteristics of each of the different bifocal contact lens types. Once an acceptable contact lens fit was achieved, the subjects were given instructions concerning lens insertion, removal, and care. As all the lenses were daily-wear, instructions were given on cleaning and overnight disinfection procedures. Lenses were replenished on an as-needed basis. The subjects were also instructed regarding symptoms which might necessitate lens removal or unscheduled professional examinations. Subjects were seen for follow-up examinations after 3-4 days and again after 10-12 days. The fit of each of the different contact lens conditions was assessed with clinical instruments to determine how closely they met the recommended standards of proper centration (lens edge over the corneal limbus in all directions), movement (not less than 1 mm, nor greater than 2 mm after blinking), and acuity (not less than 20/40 far, 20/30 near Snellen). To establish a performance baseline, bifocal spectacle tests were performed first in all phases. Since the MV condition was based on the best performing bifocal contact lens, it was always the last condition tested. In order to determine how well each contact lens met the recommended standards, the following clinical measures were made:

- Physiological alignment - the amount of decentration and movement was determined by slit lamp biomicroscopy. These data were recorded but not included in the statistical analysis.

- Optical performance - clinical VA was determined at far (6 m) and near (40 cm) distances.

A complete clinical data record was maintained and updated during each vision examination for all subjects. Standardized data collection forms developed in previous contact lens investigations conducted by USAARL were used (appendix D).

Phase II

The laboratory portion of the investigation consisted of tests designed to measure visual functional performance of the different bifocal contact lens conditions and the control condition of bifocal spectacle lenses.

- VA was measured using high (90 percent) and low (8 percent) contrast Bailey-Lovie test charts (high contrast - Bailey and Lovie, 1976; low contrast - Bailey, 1982) under high (80 cd/m^2) and low (0.8 cd/m^2) illumination at three distances (6 m, 80 cm, and 40 cm) for high contrast charts, and one distance (6 m) for the low contrast chart. Two versions of the Bailey-Lovie chart, differing only in letter sequence, were utilized, and low illumination conditions preceded high illumination conditions to minimize learning effects. For the high contrast test, a 5-factor analysis of variance (ANOVA) was conducted with two between (add and refractive groups) and three within group factors (bifocal lens design, luminance and distance). For the low contrast condition, a 4-factor ANOVA was conducted with two between (add and refractive groups) and two within group factors (bifocal lens design and luminance).

- VA was also measured through the ANVIS using the Armed Forces Vision Tester (AFVT). In the ANVIS conditions, the ANVIS was adjusted as outlined by Loro (1991). In order to use the ANVIS with the AFVT apparatus, Gentex· polished-surface filters were placed over the objective lenses. These filters attenuate incident radiant flux approximately 5 log units across the wavelengths to which ANVIS is sensitive (Rash and Martin, 1989). In terms of equivalent light levels for ANVIS, the average luminance of the AFVT resolution chart would be 5 cd/m^2 through ANVIS, which corresponds to night conditions of 1/4 moon or greater. These data were analyzed using a 3-factor ANOVA (add group, refractive group, with repeated measures over lens design).

- Central visual contrast sensitivity was measured with Ginsburg's (1984) "functional acuity contrast test." The test consists of two charts (sized for far and near testing distances) with five circular grating targets of 1.5, 3.0, 6.0, 12.0, and 18.0 cycles per degree that decrease in contrast. The test was conducted at two distances (3 m and 46 cm) under a luminance of 85 cd/m^2. The data were analyzed using a 5-way ANOVA with two between (add and refractive groups) and three within group factors (distance, cycles per degree, and lens design).

- Stereopsis was measured at both near (40 cm) and far (6 m) without ANVIS, and at far (6 m) with ANVIS using the AFVT. Gentex· polished-surface filters were placed over the objective lenses as noted above. For stereopsis without ANVIS, these data were analyzed using a 4-way ANOVA with two between (add and refractive groups) and two within group factors (distance and lens design). For the stereopsis with ANVIS, these data were analyzed using a 3-way ANOVA (add group and refractive group, with repeated measures over bifocal lens design).

Phase III

This was the flight simulation portion of the investigation and consisted of specific flight maneuvers selected for their heavy reliance on visual functioning (see appendix E for specific maneuvers). The aviator repeated the series of flight maneuvers with each bifocal contact lens condition plus the control condition of bifocal spectacle lenses. Sufficient practice periods (wearing spectacle bifocal lenses) were conducted before actual data collection in order for each subject to reach asymptotic performance for the sequence of maneuvers. The simulation phase was conducted under conditions of normal daylight, low luminance, and with ANVIS (see appendix E). USAARL's DEC VAX 11/785 computer acquired data in a manner that permitted flight performance to be quantified for later analysis (e.g., airspeed, altitude, and heading were monitored and compared to standards for assessing performance differences using various bifocal contact lenses). A number of flight measures were graded for each of the maneuvers. The graded measures differed by maneuver as course heading had little meaning, for example, in a climbing turn. A scoring system was devised in order to compare data between and within subjects. This composite score had a maximum of 100 and minimum of 0.0 and was based on

Aircrew Training Manual standard performance criteria for specific flight maneuvers. The individual maneuvers are listed in appendix E.

Bifocal contact lens related changes in flight performance were assessed by a 4-factor ANOVA (add group, refractive group, and maneuver, with repeated measures over bifocal lens design). Also, maneuvers were grouped into "hover-type," "terrain-type," and "night vision goggle (NVG)-type." These data were then analyzed using three different 3-way ANOVAs (one for each group of maneuvers), consisting of add group and refractive group, with repeated measures over bifocal lens and with case selection options to select only those maneuvers which were in the separate groups. In addition, all aviators were asked to complete a questionnaire regarding subjective visual performance of each bifocal contact lens condition (see appendix F). Part 1 of the questionnaire was designed to provide information regarding user acceptance of the different bifocal lens designs (including bifocal glasses), and part 2 was a comparison of the currently worn bifocal soft contact lens to bifocal glasses. The two-part questionnaire data were analyzed using two separate 3-way ANOVAs (add group and refractive group, with repeated measures over bifocal lens).

In all of the preceding ANOVA procedures, corrections were calculated and adjustments made when appropriate (Greenhouse and Geisser, 1958; 1959).

Phase IV

The operation flight phase was the only phase that had limited bifocal contact lens conditions because only bifocal soft contact lenses that performed equally to bifocal spectacle lenses during the flight simulation phase were selected for use. During the operational phase, the presbyopic volunteer aviator subjects performed normal flight duties in their current rated aircraft wearing the selected bifocal contact lenses. After flights, subjects were debriefed and completed a questionnaire to evaluate the visual performance of each lens type, which usually resulted in their developing a definite preference for one lens type. The reported data were analyzed with descriptive statistics to provide information regarding user acceptance of the different bifocal soft contact lens designs in actual flight and to compare subjective assessments of the visual performance of the bifocal lens types relative to spectacle bifocal lenses.

Results

Phase I: Clinical

During this phase of the study, Bausch & Lomb discontinued the Bi-tech translational bifocal soft contact lens. Therefore, the translational design type was eliminated from our study design.

Two other bifocal soft contact lenses (Allvue and Occasions) were eliminated from the later phases of the study because the lenses could not be fit successfully on all subjects so as to achieve proper alignment to provide the minimal acceptable VA standards of not less than 20/40 far and 20/30 near Snellen acuity. Therefore, the results of the other phases of this study include five bifocal soft contact lenses representing three different designs (see table 4).

Table 4.
Bifocal soft contact lens design types (specific lenses used in study).

Type of lens	Name of lens type
Control	Bifocal spectacles
Monovision	Medalist® or Acuvue®
Simultaneous Vision Sim cen-near Sim diffr Sim conc cen-near	 Unilens® Echelon® Spectrum®
Modified Monovision	Single vision (far) right eye Best bifocal lens left eye

Phase II: Laboratory

Seventeen subjects wore three different bifocal soft contact lenses of SV design and spherical soft contact lenses in combination to provide three different designs (MV, SV, and modified MV) for correcting both near and far vision. The statistical analyses were performed using the right eye for far and mid-distance measures and the left eye for near measures (to allow MV and modified MV lens types to have comparable near vision to the other lens types; i.e., MV had the left eye focused for near vision and modified MV had the bifocal lens on the left eye and the single vision far focused lens on the right eye).

High contrast VA

The high contrast VA data are summarized in figures 1 and 2. High contrast acuity was measured at high and low luminance at three distances in all bifocal contact lenses and bifocal glasses. The figures illustrate the complex interaction between add-group, refractive-group, distance, and bifocal lens type. The results of the statistical analyses are presented in tabular format in table G-1 of appendix G. A summary of the important findings are presented below.

Figure 1 displays average acuities for all the different bifocal lenses across independent variables (luminance, distance, add group, and refractive group). This can be viewed as an overall performance indicator of the bifocal lenses for high contrast VA. VA with glasses was superior to that found with all bifocal contact lenses. As can be seen, acuity with the MV and modified MV lenses was superior to that with all the other bifocal lens types. The simultaneous center-near, the simultaneous concentric center-near, and the simultaneous diffraction lenses all had approximately equivalent acuities which were worse than the acuities measured with glasses, MV, and modified MV lenses. Acuity with the simultaneous diffraction lens was inferior to all the other lens conditions. The underlying reasons why one bifocal lens type performed better than another are discussed below and shown in figure 2.

Luminance had no differential effect on acuity with the different bifocal lens types. The results indicate that, while there was a significant difference between acuity measured at high luminance (mean = 20/20 Snellen) and at low luminance (mean = 20/40 Snellen), the impact of reduced luminance was simply a proportional decrease in acuity across the different bifocal types.

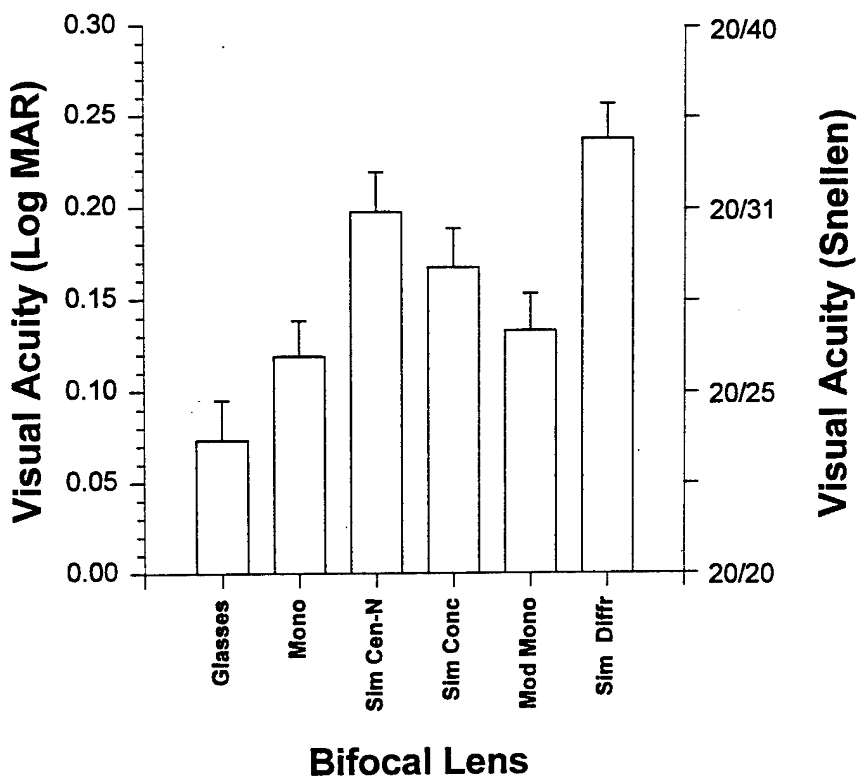

Figure 1. High contrast VA as a function of bifocal lens type for add group, refractive group, luminance, and distance. Error bars are 1 SEM.

It was found that acuity measured at different distances varied by bifocal lens type. It was also found that the add group and refractive group to which the subject belonged had an effect on the acuity measured at different distances. These results are displayed in figure 2. The results showed that while there was a difference in acuity measured at different distances, with acuity at far being best (mean = 20/24 Snellen), acuity at mid being second (mean = 20/28), followed by acuity at near (mean = 20/33), the degree of decrease depended on the lens type. That is, all the bifocal lenses demonstrated a decrease in acuity from far to mid to near, except for the MV and modified MV. Furthermore, the degree of decrease for different bifocals appeared to be related to the subject's refractive error group and add group. Hyperopes tended to have less difference between the high and low add groups than myopes at all three distances. The low add group myopes clearly had superior acuity than the hyperopes at all distances. This was in contrast to the high add group myopes who had the worst acuity of any group at every distance except far.

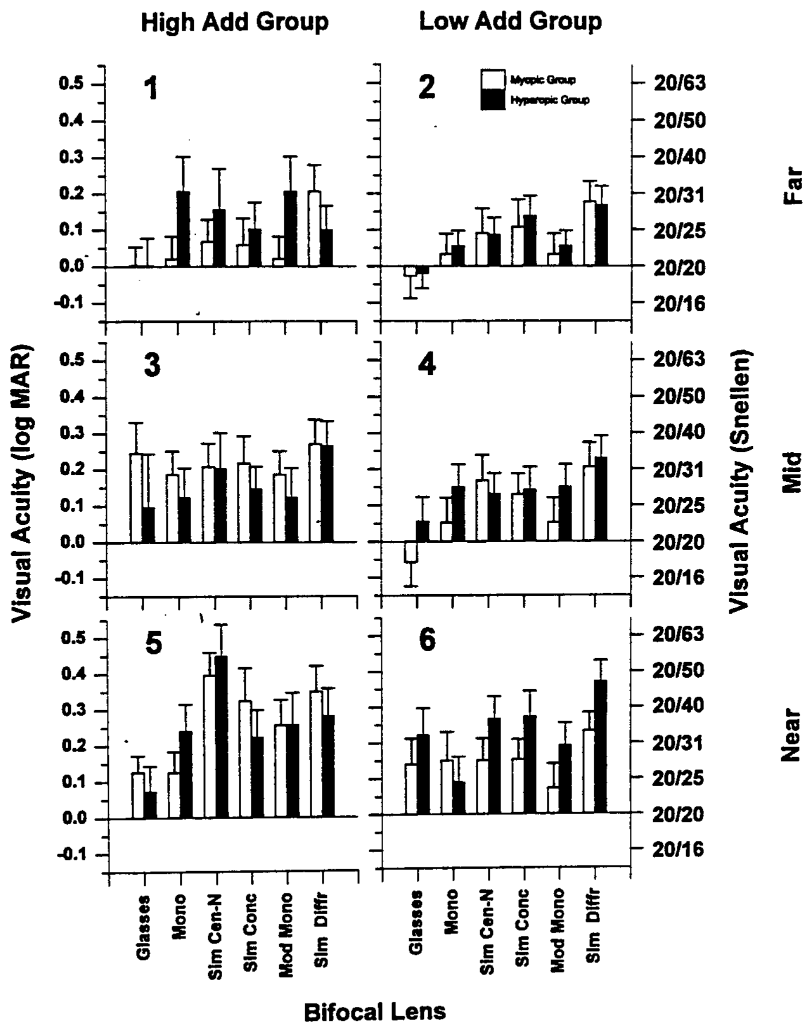

Figure 2. High contrast VA for all bifocal lens types for far, mid, and near distance for the hyperopes and myopes in both the low and high add groups. Error bars are 1 SEM.

While complex, the relationship among add group, refractive group and bifocal lens type found with the high contrast acuity data does allow for some cautious generalizations:

1. VA was slightly, but significantly better for the low add group (mean across all conditions = 20/26 Snellen) than for the high add group (mean across all conditions = 20/30).

2. At all distances, myopic subjects in both add groups tended to have the superior acuity whenever there was a difference in acuity between corrective refractive error groups.

3. While the myopic and low add groups tended to have better acuity, the degree of difference depended on the bifocal lens type. Bifocal glasses showed the least effect (no significant difference); the simultaneous center near lens showed the greatest effect (increased variability in acuity between both add group and refractive group). The other lenses showed either a moderate effect or no effect.

4. Whenever there was a significant difference in VA between contact lens types, the MV and modified MV bifocal contact lenses provided the best VA for both add groups and for both refractive groups at every distance.

Low contrast VA

Low contrast VA was measured only at the far distance. Just as with high contrast acuity, low contrast acuity was measured at high and low luminance with all bifocal contact lenses and spectacle bifocals. The data are summarized in figures 3, 4, and 5, and in table G-2, appendix G.

We found results similar to the high contrast data when the low contrast data were collapsed across all conditions (figure 3). The main difference was that at low contrast there was less difference between the bifocal lens types than at high contrast. Bifocal glasses provided the best acuity, and the simultaneous diffraction lens provided the worst acuity at both high and low contrast. However, differences observed between the other bifocal lenses at high contrast were not evident under low contrast conditions.

The magnitude of the add power and refraction continued to affect the acuity in the different bifocal lens types, but the effect was much more limited at low contrast than at high contrast. For example (as shown in figure 4), the low add group tended to have better low contrast acuity than the high add group. However, significant differences among add group acuity were found only with the MV lens and the modified MV lens, both of which resulted in better acuity for the low add group than for the high add group. Figure 5 shows the influence of the refractive group on acuity with the different bifocal lenses. Low contrast acuity tended to be better for individuals in the myopic refractive error group. However, the only bifocal lens types with a difference between refractive group acuity were the MV lens and the modified MV lens, both having superior acuity for the myopic group.

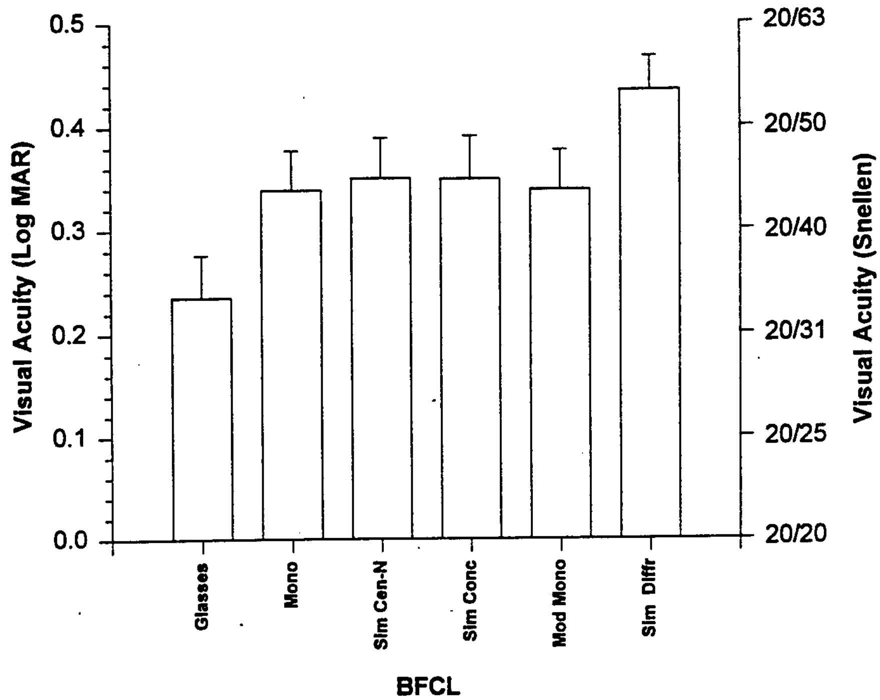

Figure 3. Low contrast VA for all bifocal lens types for add group, refractive group, and luminance. Error bars are 1 SEM.

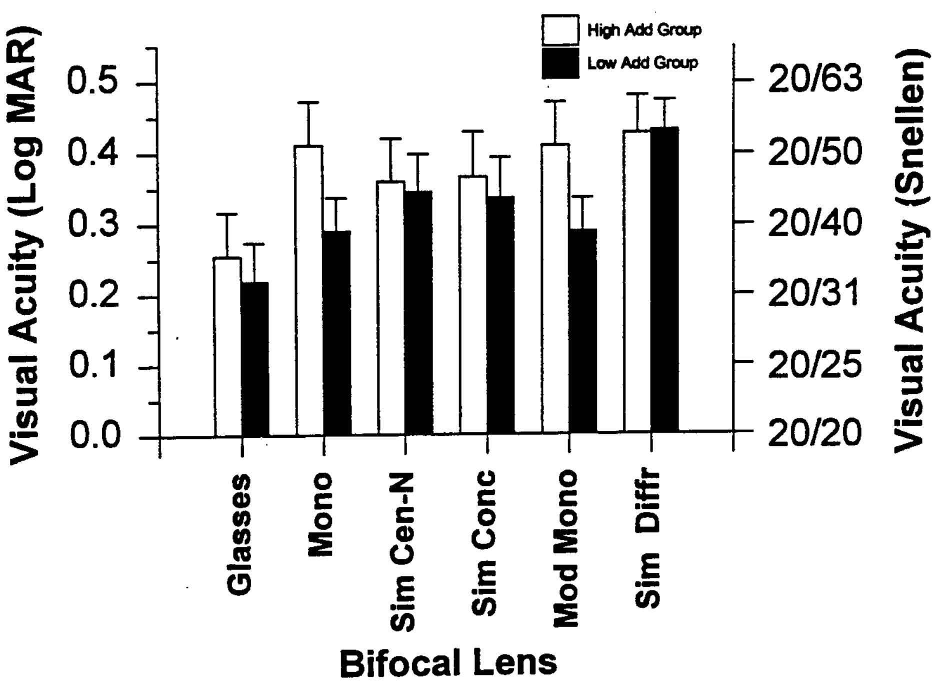

Figure 4. Low contrast VA for all bifocal lens types for high add and low add groups. Data are collapsed across luminance. Error bars are 1 SEM.

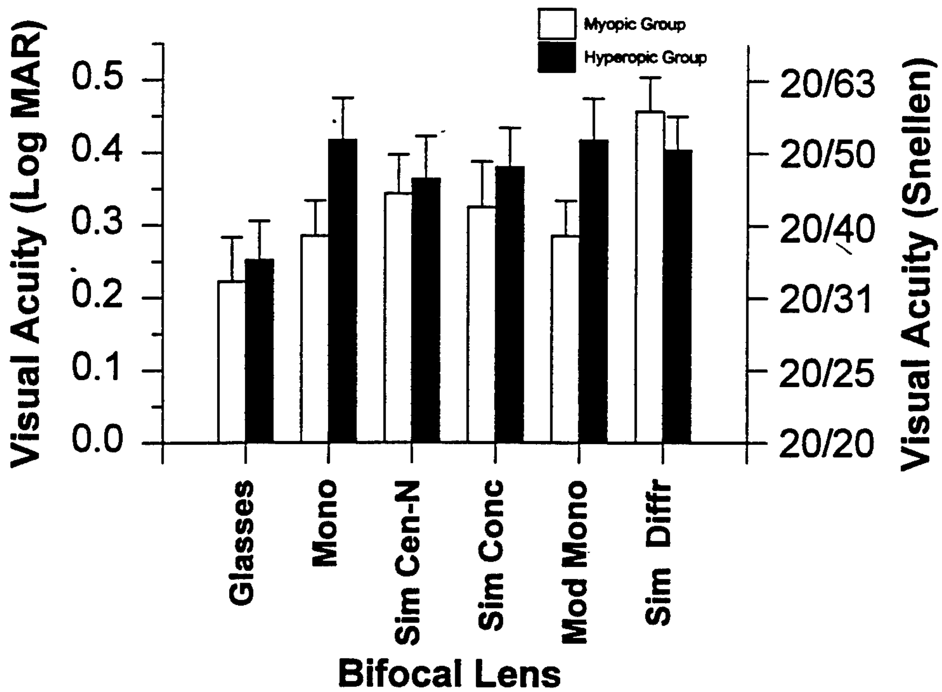

Figure 5. Low contrast VA for all bifocal lenses for the myopic and hyperopic refractive error groups for luminance. Error bars are 1 SEM.

ANVIS VA

ANVIS VA also was measured only at the far distance and at one luminance, but measurements were made in all bifocal contact lenses and spectacle bifocals. The data are summarized in figures 6 and 7, and in table G-3, appendix G.

Figure 6 shows that, while the same trend was observed for ANVIS VA as for unaided VA, the difference between bifocal groups was less for ANVIS VA.

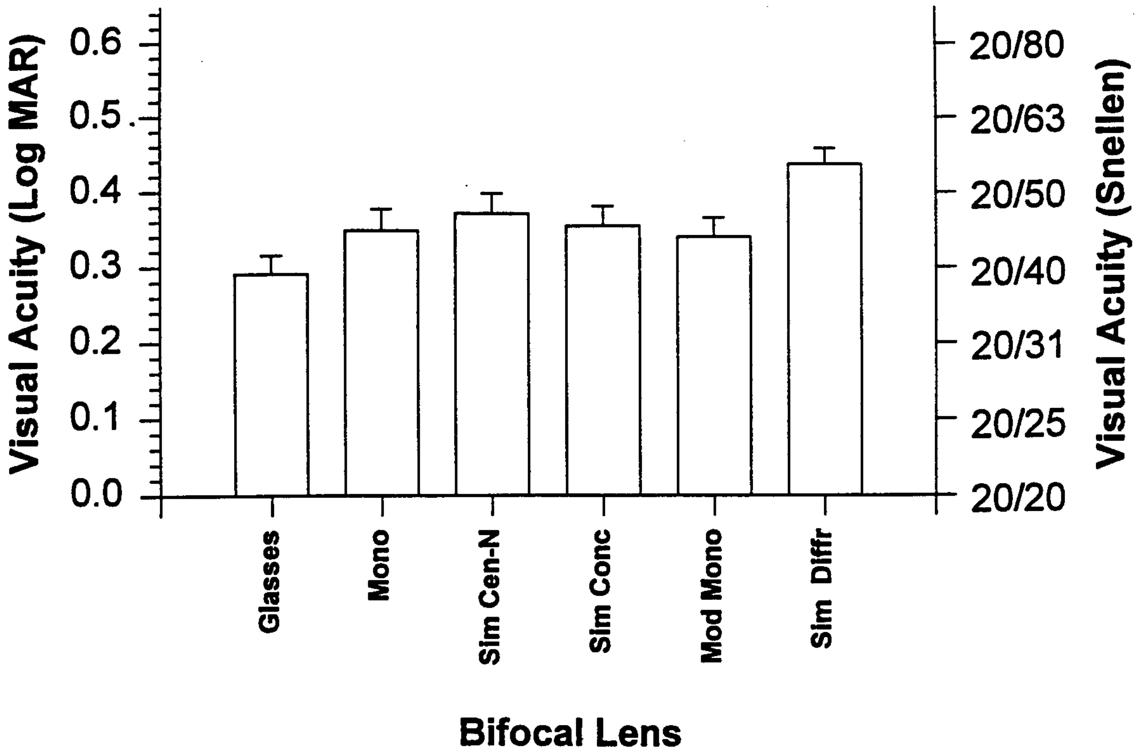

Figure 6. ANVIS VA for all bifocal lens types for add group and refractive group. Error bars are 1 SEM.

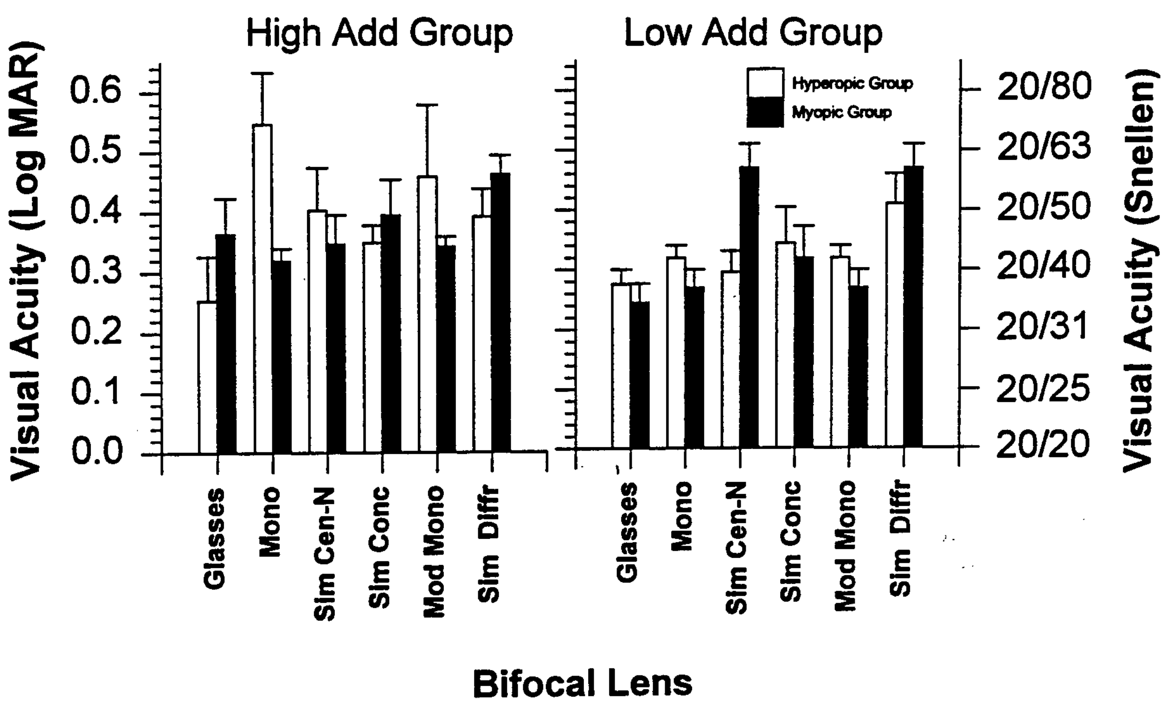

Figure 7. ANVIS VA for all bifocal lens types for both myopes and hyperopes in the low and high add groups. Error bars are 1 SEM.

The amount of add power and refractive error continued to have an effect. ANVIS acuity with the different bifocal lens types, while in general being superior for the low add group, depended on the refractive error group (figure 7). Specifically, ANVIS acuity tended to be superior for both hyperopes and myopes in the low add group than for those in the high add group. However, in the high add group, myopes had significantly better acuity only in the MV lens. In the low add group, myopes actually had worse acuity in the simultaneous center near lens.

Contrast sensitivity

The contrast sensitivity data for visual stimuli at five different spatial frequencies measured at far and near distances in all bifocal contact lenses and spectacle bifocals are summarized in figures 8, 9, 10, and in table G-4, appendix G.

Figure 8 shows the same performance profile for the contrast sensitivity data as was observed in the high contrast acuity data. That is, bifocal glasses provided the best performance. MV and modified MV were equivalent and slightly worse than glasses. The simultaneous lenses performed second best, and the diffraction lenses provided decidedly poorer contrast sensitivity.

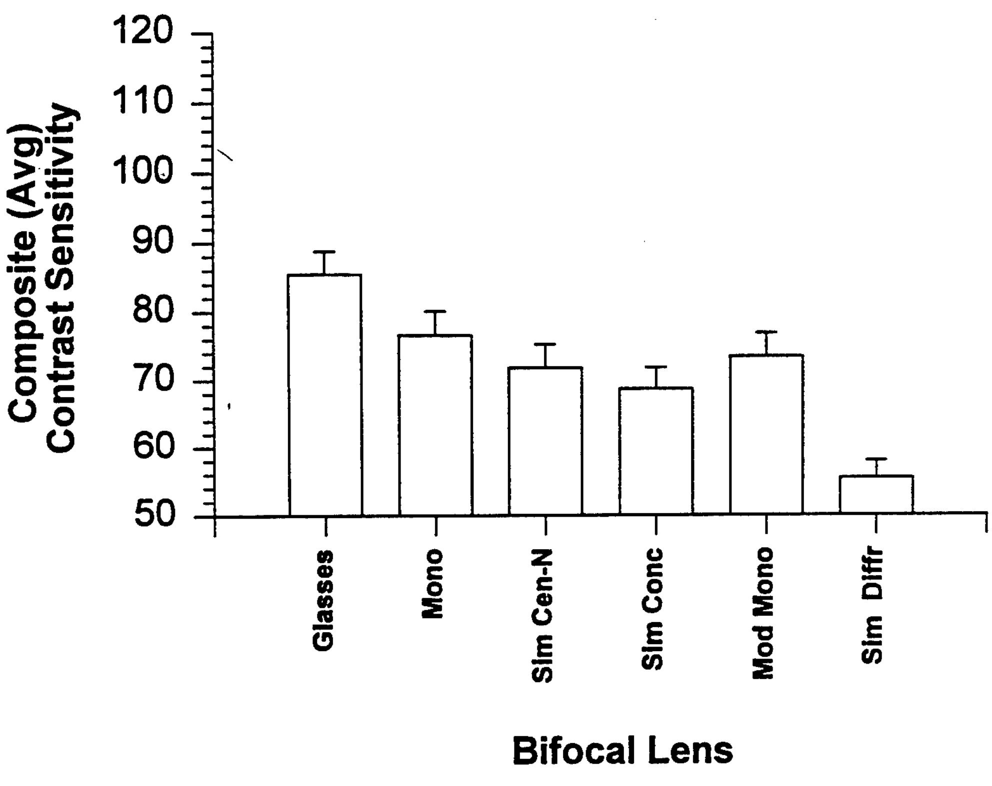

Figure 8. Contrast sensitivity for all bifocal lenses for add group, refractive group, cycle per degree, and distance. Error bars are 1 SEM.

Figure 9 demonstrates that decreased contrast sensitivity with bifocal contact lenses compared to bifocal glasses was not spatial frequency specific; i.e., decreased performance was not due to decreased performance at certain spatial frequencies only, but was consistent across all spatial frequencies. Contrast sensitivity with bifocal glasses, MV, and modified MV contact lenses was equivalent for virtually all spatial frequencies, while the simultaneous bifocal designs performed significantly worse.

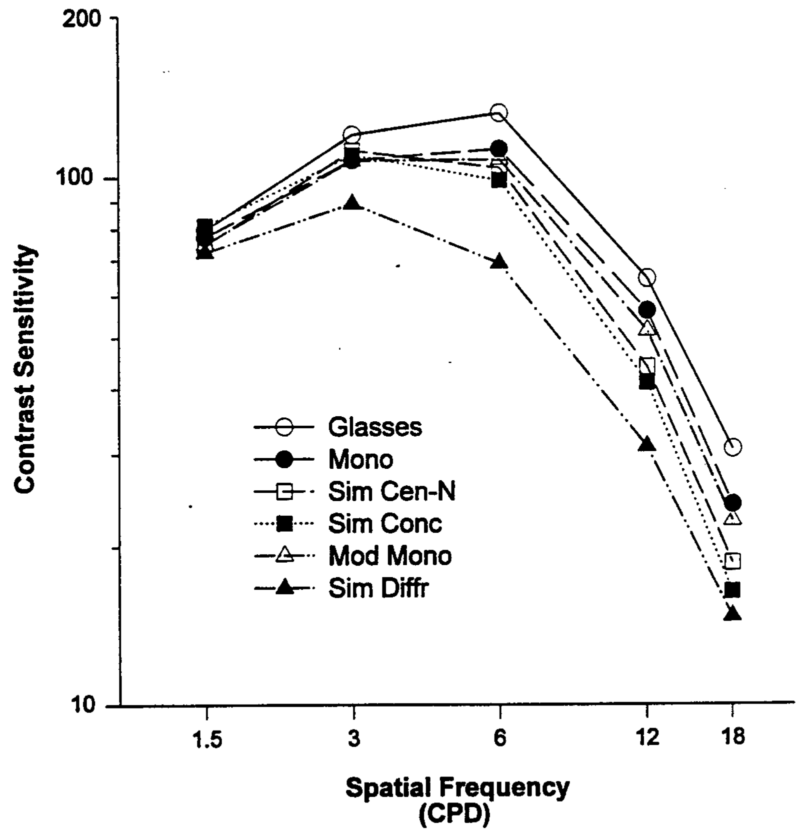

Figure 9. Contrast sensitivity at five test spatial frequencies for all subjects in all bifocal lenses for add group, refractive group, and distance.

Once again, it was observed that the magnitude of add power and the refractive error had a significant effect on performance with the different bifocal lenses. Specifically, figure 10 shows that contrast sensitivity was significantly better for the low add group with all lenses except the simultaneous concentric center near and simultaneous diffraction lenses. Also, low add myopes had better contrast sensitivity than the hyperopic low add group for MV, simultaneous concentric, and modified MV bifocal lenses. Furthermore, low add myopes had significantly better contrast sensitivity than both hyperopes and myopes in the high add group for every bifocal lens except the simultaneous diffraction lens (which performed consistently worse than the other bifocal lenses).

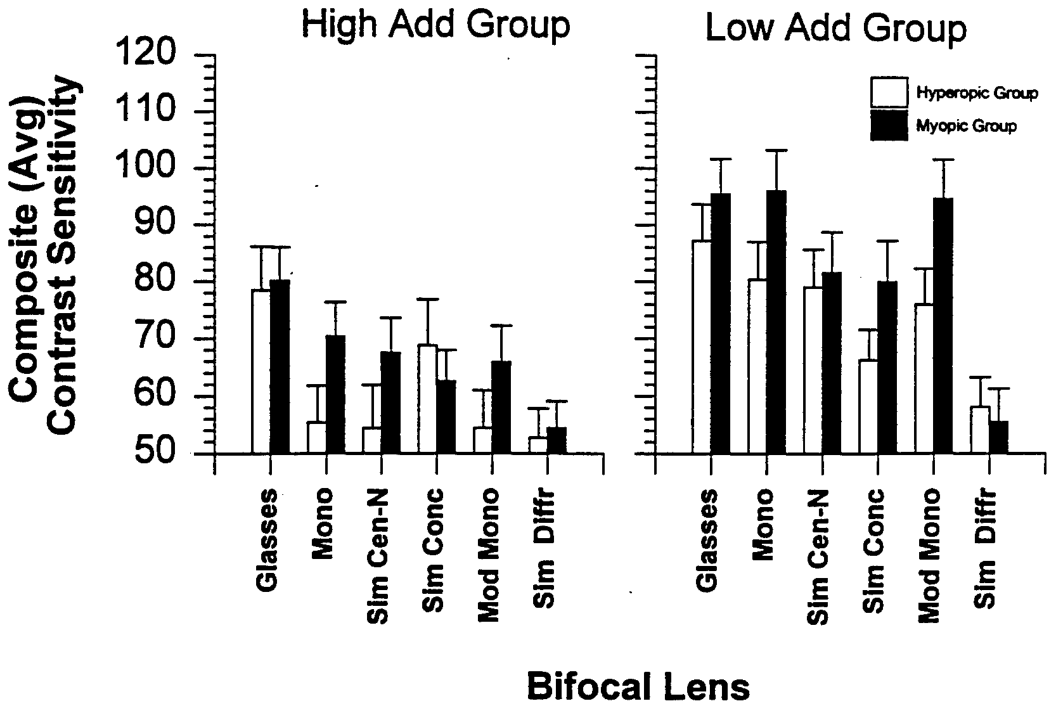

Figure 10. Contrast sensitivity for all bifocal lens types for myopic and hyperopic refractive groups in both low and high add groups across all cycles per degree and distance. Error bars are 1 SEM.

Stereopsis without ANVIS

The stereopsis data (without ANVIS) for high contrast, high luminance visual stimuli measured at far and near distance conditions in all bifocal contact lenses and spectacle bifocals are shown in figures 11 and 12, and in table G-5 of appendix G.

In the stereopsis without ANVIS data, we observed a departure from the bifocal lens performance profile previously noted for high and low contrast acuity, ANVIS acuity, and contrast sensitivity (figures 1, 3, 6, and 8, respectively). The main difference is attributed to the poor stereopsis measured with the MV lens, which is not surprising due to the nature of its design (one eye focused for near, one eye focused for far). Performance of the other bifocal lens types remained basically consistent with performance measured on other laboratory tests. Specifically, stereopsis was best for bifocal glasses, almost as good as glasses for the modified MV lens type, and tended to be worse for the simultaneous lens types.

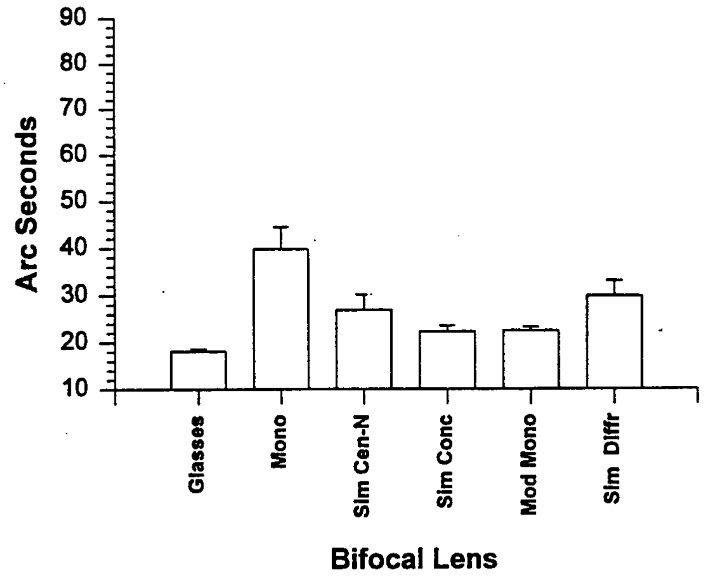

Figure 11. Stereopsis without ANVIS for all bifocal lens types for add group, refractive group, and distance. Error bars are 1 SEM.

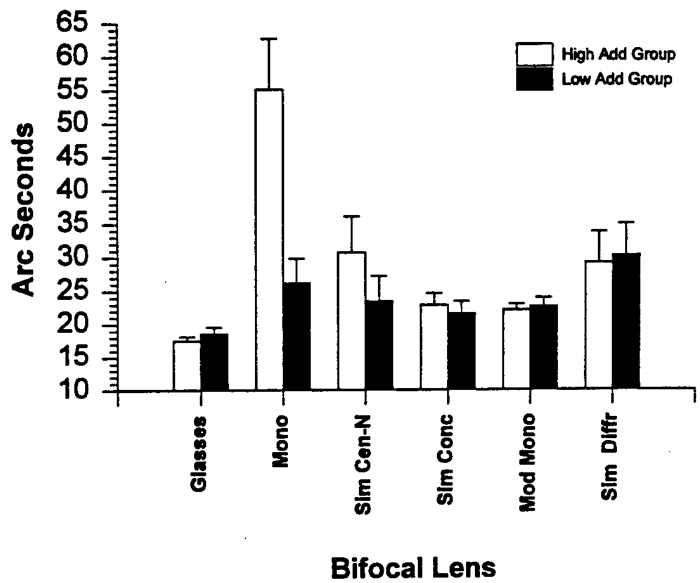

Figure 12. Stereopsis without ANVIS for all bifocal lens types for both low and high add groups for refractive group and distance. Error bars are 1 SEM.

The add group continued to have an effect on the stereopsis without ANVIS data as shown in figure 12. Part of the reason for the poor performance of the MV lens is clearly shown; i.e., the MV lens design had very poor stereopsis for the high add power group. All other bifocal lens types had equivalent stereopsis for both low and high add groups.

Another reason behind the poor performance of the MV lens type is shown in figure 13, which shows that stereopsis with the MV lens type was very poor at the far viewing distance. None of the other bifocal lenses were significantly affected by distance. Although, in general, it can be seen that stereopsis at near tended to be reduced compared to stereopsis at far.

Stereopsis with ANVIS

As discussed previously, stereopsis while viewing with ANVIS was measured with the AFVT under approximately quarter-moon luminance conditions. These data are shown in figure 14, and in table G-6 of appendix G.

This is the only test condition in the laboratory phase where there were no statistical differences among any of the bifocal lens types when the data were averaged across independent variables.

The magnitude of subject add power and refractive error continued to affect measurements, but only in a minor way. Specifically, stereopsis for the myopic group tended to be superior to the hyperopic group, but was statistically significant only for the MV lens. Furthermore, only three lenses were affected by the interaction of add group, refractive group, and bifocal lens type (shown in figure 14). The high add group myopes had significantly better ANVIS stereopsis than hyperopes with both MV and simultaneous center near lenses, and the low add group myopes had significantly better ANVIS stereopsis than hyperopes with both MV and simultaneous concentric center near lenses.

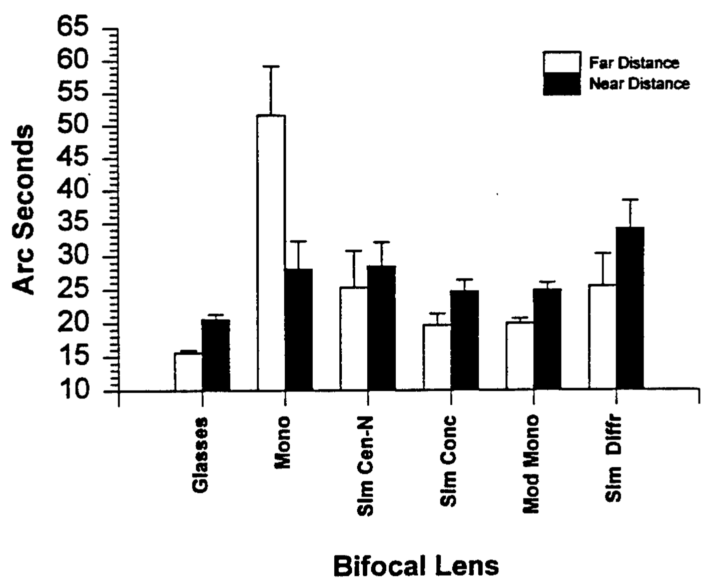

Figure 13. Stereopsis without ANVIS at far and near distance for all bifocal lens types for add group and refractive group. Error bars are 1 SEM.

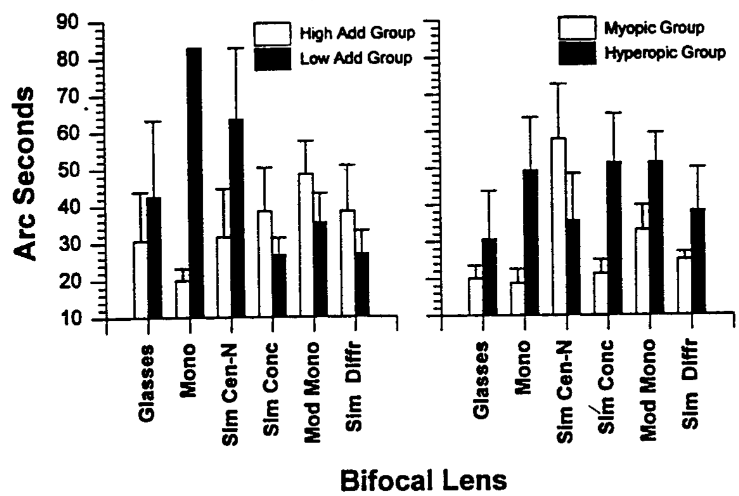

Figure 14. Stereopsis with ANVIS for high and low add groups for myopic and hyperopic refractive groups. All high add group hyperopes wearing the MV lens design scored minimum for the test (83 arc seconds). Error bars are 1 SEM.

Phase III: Flight simulation

Flight simulation maneuvers

The flight simulation data for 14 graded maneuvers measured in all bifocal contact lenses and spectacle bifocals are summarized in figures 15 and 16 and in table G-7, appendix G. The 14 different maneuvers fell into 3 general groups: hover maneuvers, terrain flight maneuvers, and NVG maneuvers (night formation and terrain flight). These groupings were analyzed to determine if any bifocal lens types provided superior performance in a specific type of maneuver.

The results for the 14 flight simulation maneuvers are summarized in figure 15. As can be seen, bifocal glasses no longer provided the best performance. The modified MV lens type was superior to all the other bifocal lenses, including bifocal glasses.

When the maneuvers were grouped into three types, we observed the following: for the hover maneuvers and the terrain flight maneuvers, there were no differences among the composite scores for any of the bifocal lens types; in the NVG maneuvers we observed that the modified MV lens type was significantly superior to any of the other bifocal lens types (including bifocal glasses).

Magnitude of add power and refractive error continued to influence performance of the different bifocal lenses. The influence remained similar to what we observed in earlier tests; i.e., while the myopic group tended to have better composite scores than the hyperope group, the degree of difference between them depended on which add group they were in. For example, figure 16 shows that the high add group hyperopes all had equal maneuver scores for all bifocal lenses except the superior score of the modified MV lens. The high add group myopes had equivalent maneuver scores for all bifocal lenses except the superior scores of the MV and the modified MV lenses.

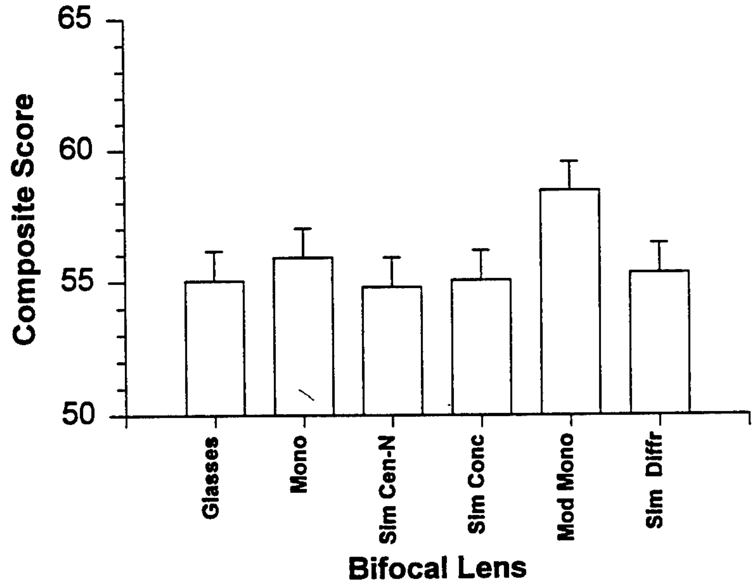

Figure 15. Flight simulation composite score for all bifocal lens conditions for add group, refractive group, and maneuver. Error bars are 1 SEM.

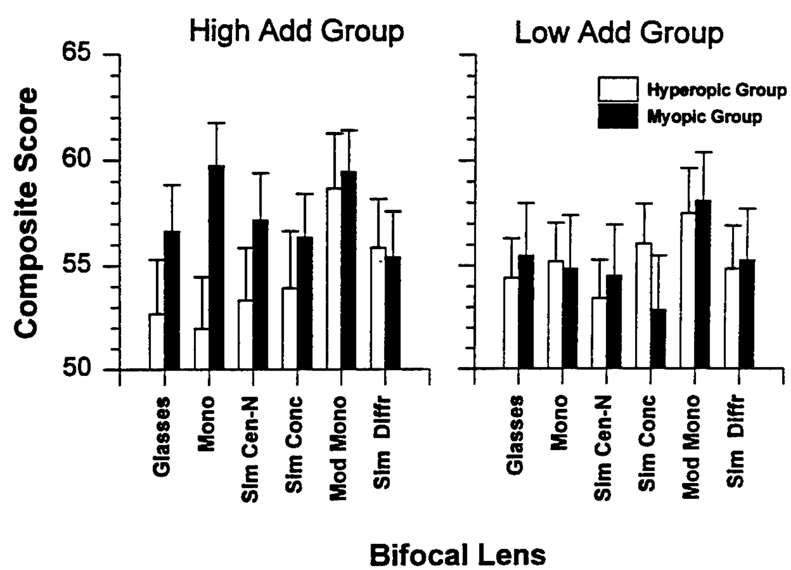

Figure 16. Flight simulation score for high and low add groups and myopic and hyperopic refractive groups for all bifocal lens types. Data are collapsed across maneuvers. Error bars are 1 SEM.

Questionnaire

The questionnaire data consisted of responses to a 2-part series of 14 questions administered to aviator subjects after each bifocal lens simulator flight (see appendix F). Part 1 of the questionnaire asked the subject to answer 14 questions regarding the "current bifocal lens (including bifocal spectacles)." Part 2 asked 14 questions regarding "how the current bifocal lens compared to bifocal spectacles." Tables G-8 and G-9, appendix G, present the complete questionnaire analysis. A summary of the analysis follows:

The results of part 1 showed that the subjects found the tasks "slightly" to "moderately easy" to perform in all the bifocal lenses including bifocal spectacles. There was no statistical difference among the mean ratings for any of the bifocal lenses in part 1 of the questionnaire.

Interestingly, it was observed that more hyperopic subjects reported they could more easily perform instrument panel viewing than myopic subjects (question 5, "instrument panel visibility"). This appears consistent with the results of the high contrast VA data displayed in panel 3 of figure 2 (which represents mid-distance or "instrument panel" acuity for both the hyperopes and myopes in the high add group), which would be the appropriate distance corresponding to instrument panel viewing. This figure shows that hyperopes in the high add group have significantly superior mid-distance acuity, which may account for the questionnaire response of hyperopes who tend to find instrument panel viewing easier than myopes.

The results to part 2 of the questionnaire indicate that subjects found the tasks "slightly" to "moderately better" to perform in all the bifocal lenses than with bifocal spectacles.

For most questions, there were no differences among the bifocal lens types, except for the important result that all forms of bifocal contact lenses were preferred over bifocal spectacles as mentioned above. However, there were two questions (numbers 9 and 12) where there was a significant difference in how subjects evaluated their vision with bifocal contact lenses compared to bifocal glasses for the different viewing tasks. The task in question 9 was "peripheral motion detection," where the modified MV lens was rated significantly better than the simultaneous diffraction lens. The task in question 12 involved "maintaining FOV." For this question, the modified MV lens was rated significantly better than both the simultaneous diffraction lens and the simultaneous center near lens.

The magnitude of the add power had a minor effect on the part 2 questionnaire data. Subjects in the high add group found it significantly easier to read gauges and displays than those in the low add group. This may be related to another main effect for add power found in part I, question 5 (instrument panel), which also showed that subjects in the high add group found visibility of mid-distance gauges and instruments significantly easier to view than subjects in the low add group. Again, we feel that this may be related to the high contrast VA data showing that the high add group subjects had significantly superior acuity than the low add group subjects for mid-distance.

Phase IV: Operational flight

This was the only phase that had limited bifocal contact lens conditions. Only the bifocal soft contact lens conditions that performed equivalent to bifocal spectacle lenses during the flight simulation phase, and scored high on all the other laboratory tests, were selected for use in actual flight. As a precaution, all subjects flew USAARL's JUH-1 research aircraft with a standardization/instructor qualified aviator for a pre-operational "checkout" flight in each set of contact lenses that were tentatively approved for in-flight operations. This allowed the aviator subject to test his vision under actual flight conditions with a highly qualified copilot in order to prevent any unforeseen vision problems the laboratory tests may not have uncovered.

During the operational phase, the presbyopic volunteer aviator subjects performed normal flight duties in their current rated aircraft wearing the selected bifocal contact lenses. After flights, subjects evaluated the visual performance in each lens type, which usually resulted in a definite preference for a single lens type. The reported data were analyzed to provide information regarding user acceptance of the different bifocal soft contact lens designs in actual flight, and to compare subjective assessments of the visual performance of the bifocal lens types relative to spectacle bifocal correction. These data are shown in table 5.

Immediately apparent from inspection of table 5 is that almost every subject was fitted successfully and qualified for the operational phase in three different contact lens types. Some useful success rates for the different bifocal lens types can be determined from the data presented in table 5. In order of decreasing frequency, the most frequent successfully fitted bifocal contact lenses were:

- modified MV and simultaneous center near: 14 of 17 subjects (82 percent). In the modified MV design, 9 of 14 (64 percent) were simultaneous center near, 4 of 14 (29 percent) were simultaneous concentric center near, and 1 of 14 (7 percent) was simultaneous diffraction.

- simultaneous concentric center near: 9 of 17 (53 percent)

- MV type: 7 of 17 (41 percent)

- diffraction lens: 2 of 17 (12 percent)

In order of descending frequency, the most preferred bifocal soft contact lenses were:

- modified MV 8 of 17 (47 percent), (5 were simultaneous center near, 2 were simultaneous concentric center near, and 1 was simultaneous diffraction). Among the modified MV preferred lenses, 4 of 8 (50 percent) were one lens only, indicating that these subjects were basically emmetropic presbyopes.

- simultaneous center near 4 of 17 (24 percent) o simultaneous concentric center near 3 of 17 (18 percent)

o MV 2 of 17 (12 percent)

Table 5.
Operational flight data.

No.	Lenses in flight operations	Preferred lens
1	sim-cen-n, sim-concen, sim-diffr	sim-cen-n
2	sim-cen-n, mod-m (simul-cen-n)	mod-m (simul-cen-n) one lens only
3	sim-concen, mod-m (simul-concen)	simul-concen
4	mono, sim-cen-n, mod-m (sim-cen-n) (Visor VA problem in check-out)	mod-m (simul-cen-n) one lens only
5	mono, sim-cen-n, mod-m (sim-cen-n)	sim-cen-n
6	mono, sim-cen-n, mod-m (sim-cen-n)	mono
7	mono, sim-concen, mod-m (sim-concen)	mod-m (sim-concen)
8	sim-cen-n, mod-m (sim-cen-n) (VA problems check-out, sim-concen elim.)	mod-m (sim-cen-n) one lens only
9	sim-cen-n, sim-concen, mod-m (sim-cen-n	sim-cen-n
10	sim-cen-n, sim-diffr, mod-m (sim-diffr) (dry eye check-out, sim-cen-n)	mod-m (sim-diffr) one lens only
11	mono, mod-m (sim-concen)	mod-m (sim-concen) one lens only
12	Sim-concen, sim-cen-n, mono, mod-m (sim-cen-n)	Sim-concen
13	sim-cen-n, mod-m (sim-cen-n)	mod-m (sim-cen-n)
14	mono, sim-cen-n, sim-concen (poor low-lum VA in both bfcls at checkout)	mono
15	sim-cen-n, sim-concen, mod-m (sim-cen-n)	sim-cen-n
16	sim-cen-n, sim-concen, mod-m (sim-cen-n)	mod-m (sim-cen-n) one lens only
17	sim-cen-n, sim-concen (Needs unequal adds pseudo-aphake)	sim-concen

Discussion

Phase I: Clinical

This study originally included representative lenses for four different bifocal contact lens design types: MV (Medalist or Acuvue single vision lenses); AV (Bi-tech lens); SV (Unilens for center near, Allvue and Occasions for center far, Spectrum for concentric center near, and Echelon for diffraction lens); and modified MV (best performing bifocal lens combined with single vision distance correction for companion eye). Thus, our study initially included a total of six different bifocal soft contact lenses. Unfortunately, the lens we chose to represent the AV design was discontinued during the study, and it was not possible to substitute another representative lens having the same design. Two other bifocal soft contact lenses (Occasions and Allvue, both center far SV design bifocal lenses) were necessarily eliminated from our analysis because they failed to meet our required success criterion for inclusion in the study. Our study design required that subjects be clinically successful in <u>all</u> bifocal lenses to be included in the analysis. Therefore, the success rate for all individual bifocal lenses in the study was actually required to be 100 percent for each bifocal lens type for the 17 subjects that were included in the analysis.

Phase II: Laboratory

It was expected that different bifocal contact lens designs would differentially affect VA at different viewing distances. Our results are consistent with a previous report (Heron et al., 1994) of distant VA being superior to near VA. Bifocal designs significantly affected performance at near viewing distances. The MV and modified MV designs provided better near acuity than the other lens designs. For distance viewing, the MV and modified MV lenses provided the best vision for nearly all subjects, while the other bifocal contact lens designs gave equivalent performance, except for the diffraction lens, which was usually poorer. Previous investigations have reported similar acuity differences between bifocal contact lenses (Papas et al., 1990) and simultaneous designs (Back et al., 1987).

While a subject's refractive error by itself had little influence on acuity performance in the different bifocal lens types, the combination of myopic refractive error with low add power often resulted in better acuity with most of the bifocal lens types. Also, add power often had a significant effect on acuity by itself. For example, for distance VA, subjects requiring higher add powers did not perform as well as subjects with smaller amounts of add power. Cox et al. (1993) reported similar results.

As expected, VA with all bifocal lens designs was superior at high luminance compared to low luminance. However, contrary to our expectation, bifocal design did not differentially affect acuity performance under low luminance conditions. The lack of a significant effect may have been due to the very low luminance level (0.8 cd/m^2) selected to simulate an NVG viewing condition. Acuity is relatively gross at this level and probably masks the small differences that might be attributable to bifocal lens design.

The data from high contrast and low contrast VA tests were quite similar, although measurements for low contrast acuity were acquired only for the far viewing distance. In general, when acuity was measured under low luminance, no difference among the various bifocal contact lenses was evident, while acuity measured at high luminance produced distinct differences in acuity among lens types. We attribute the lack of any difference in acuity under low luminance to the low luminance (0.8 cd/m^2) used. Also, we generally found that refractive error by itself had no significant impact on high contrast acuity. However, under low contrast conditions, subjects with myopic corrections had better acuity, and those myopic subjects fitted with MV or modified MV designs tended to have better acuity than hyperopes.

Acuity measurements with ANVIS varied somewhat by bifocal lens type. The MV, the modified MV, and the simultaneous concentric center near lens designs all yielded VAs equivalent to the bifocal spectacle control. This finding is probably related to the masking effect with low luminance discussed previously, and the limited detail in the ANVIS image. Luminance output from ANVIS is reduced (5 cd/m^2), and the amount of detail (i.e., high spatial frequencies) in the image also is reduced, making ANVIS performance less susceptible to the degradation of fine detail produced by the various bifocal lenses. Thus, acuity performance differences between the various correction options are minimal, and the noteworthy finding is that a bifocal contact lens correction option provides performance equivalent to the conventional spectacle correction.

Similar to previous reports (Robboy and Erickson, 1985; Ames et al., 1989), our results demonstrated that correction with bifocal contact lenses caused some reduction in contrast sensitivity. As shown in figure 9, the reduction in contrast sensitivity was relatively uniform across all spatial frequencies (rather than simply a loss of higher spatial frequencies which would be more directly related to VA). As can be seen, the simultaneous diffraction design caused the greatest reduction in contrast sensitivity compared to all other lenses. This result is similar to that reported by Sanislo et al. (1992), who found reduced contrast sensitivity in the diffraction lens compared to conventional spectacle correction. We continued to find an effect for both add group (low add group scored better) and for refractive error group (myopes scored better). However, this relationship often was influenced by bifocal lens type, the spatial frequency of the target, and the combination of add power and refractive error.

For all the acuity measures (high contrast, low contrast, ANVIS, and contrast sensitivity), our analyses showed significant differences between bifocal lens types when data were collapsed across independent variables. We consistently found: (1) generally better acuity with glasses than with the bifocal contact lens designs; (2) only slightly worse MV and modified MV acuity than with bifocal glasses, and both better than any of the other contact lens designs; and (3) of the simultaneous lenses, the best acuity was achieved with the concentric center near design while the diffraction lens provided the worst.

Among the different lens designs, MV lenses reduced stereopsis the most. This impact on stereopsis is generally considered to be the major disadvantage of the MV design (Back et al., 1987; McGill and Erickson, 1988). Of equal importance was our result showing that the modified MV design and the simultaneous concentric center near design both provided stereopsis thresholds statistically equivalent to bifocal spectacle performance. Similar to the other performance measurements, we again found that the low add correction subjects had better stereopsis than the high add group, and that myopes performed better than hyperopes. We observed that stereopsis through ANVIS is generally poor, so that the use of bifocal contact lenses would not be expected to have a significant impact. Also, the luminance conditions under which stereopsis with ANVIS were measured were low so that differences caused by add group, refractive group, and bifocal lens design were diminished.

Phase III: Flight simulation

The only quantitative flight data obtained in this study were on simulator flight performance. As shown in figure 15, the performance with the modified MV lens design was significantly superior to any other bifocal lens, including bifocal spectacles. The basis for this superior composite score was primarily due to the very high scores measured with this lens design during "NVG-type" maneuvers. Another reason for the better score with the modified MV design is suggested by the interaction between add group, refractive group, and bifocal lens (figure 16). For both high and low add groups, the modified MV lens performed best for both hyperopes and myopes. This is very likely due to the modified MV design consisting of a single vision lens on one eye for distant vision, and the best performing bifocal contact lens on the other eye. While there were occasional instances where the myopic group scored higher than the hyperopic group, this effect was not generally of great importance.

The information acquired from the questionnaire administered to the subjects after each simulator flight provided some additional insight. In part I, the subjects rated all bifocal lens types (including glasses) equally "easy" to use to perform each task. There were some specific instances which supported results observed in the previous phases of this investigation. First, for "ease of viewing" of the cockpit instruments, there were no significant differences between any of the bifocal lens designs, including spectacle bifocals. However, the magnitude of the subject's refractive error influenced instrument panel visibility. The more hyperopic subjects reported that instrument panel viewing was significantly easier than the more myopic subjects. This is consistent with the results of the VA data displayed in panel 3 of figure 2. Hyperopes in the high-add group had better mid-distance VA than myopes. This distance would correspond to the cockpit instrument viewing distance. In part 2 of the questionnaire, all subjects rated bifocal contact lenses "slightly-" to "moderately-better" than glasses to perform the visual tasks. While this part of the questionnaire tended to show that all bifocal contact lenses were preferred to bifocal glasses and were considered equivalent in ease of performing the visual tasks, there were instances where one lens type was perceived as being superior. When this occurred, it was typically the modified MV lens that was preferred.

Phase IV: Operational flight

In table 5, data are displayed on the bifocal lenses selected for flight operations and on the preferred lens for each of the 17 aviator subjects. These lenses were provided to the subjects, and waivers were granted allowing them to fly their own aircraft under restricted conditions. The intent of this phase was to acquire operationally relevant flight line information regarding the acceptability of bifocal contact lenses in a variety of environments. However, the questionnaire data acquired were not of sufficient quantity or quality to support any conclusive decisions. We do, however, report which bifocal contact lenses were selected to participate in the operational phase and which bifocal contact lenses were preferred by the subjects. Of particular note was that almost half (8 of 17) of the aviators preferred the modified MV design, and half of those that preferred modified MV (4 of 8) only required a single bifocal contact lens to be worn on one eye. These subjects were basically emmetropic presbyopes, a common category of refractive status among the aviator population.

Comparison with vision requirements for aviation duty

An important question that must be addressed when considering the acceptability of bifocal contact lenses as an option to bifocal glasses is their performance compared to the visual requirements for aviation duty listed in AR 40-501. Would our subjects have passed the retention standards for distance and near VA and stereopsis while wearing bifocal contact lenses?

Figure 17 shows averaged distance VA performance achieved with each bifocal lens type that was selected for operational flight. Therefore, the average acuity for each lens type will not represent data from all subjects, but only those subjects that wore the lens type in the operational flight phase (see table 5, column 2, "Lenses in flight operations").

The performance for each eye in the selected bifocal lenses was averaged across subjects. The average distance VA for our subjects was better than the required 20/20 Snellen, except for the left eye with the MV fit and the right eye with the diffraction lens. The 20/30 averaged left eye acuity for far distance found with the MV fit was better than expected since the left eyes were corrected for near vision. An indication of the variation in the averaged data is provided by the standard deviations shown with the averages. Obviously, some of our subjects would not have passed the 20/20 criterion, but except for the MV left eye and diffraction right eye, a large proportion of them would have been able to achieve the present standard and would "pass" the distance VA test on the flight physical.

The average near acuity performance with the different lenses is shown in figure 18. Unlike the results for distance VA, figure 18 shows that average acuity did not reach the 20/20 score. While some subjects would pass in all bifocal contact lens types, most would not. Although variability was greater than that found when measuring distance acuity, as shown by the larger standard deviations, more than half of our subjects would have failed the 20/20 criterion.

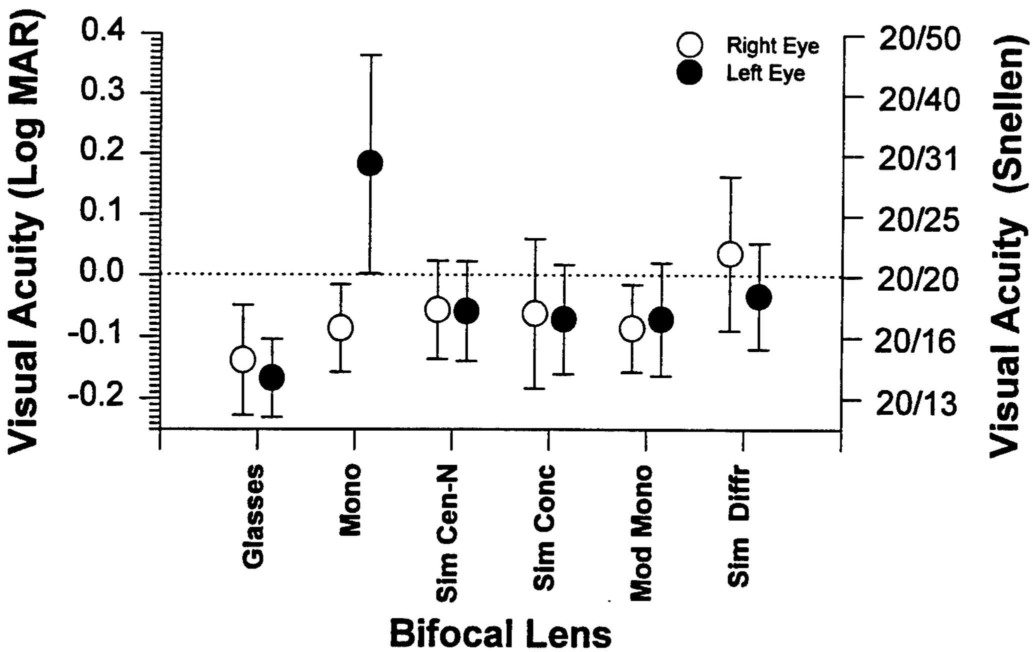

Figure 17. Average high contrast, high luminance, far (6 m) acuity for right and left eyes of subjects in all bifocal lenses. Broken line indicates "standard" score. Bars are 1 SD.

However, with respect to corrected near acuity, there is an anomaly between the published medical standard and the operational requirement. The medical standard requires measurement of near acuity at 16 inches, and it is that distance for which corrected VA is optimized. However, with any significant presbyopia, correction to 16 inches will overcorrect for the actual operationally required distance (20-26 inches) of cockpit instruments. Correcting a presbyopic aviator to 16 inches will cause his cockpit instruments to be slightly out of focus. While acuity at precisely 26 inches was not measured, acuity at mid-distance (80 cm, 31.5 inches) was measured, where the aviator subjects were observed having equivalent or better acuity in some bifocal contact lenses compared to glasses (figure 2, panels 3 and 4). If the lack of 20/20 near acuity was an operational disadvantage, presbyopic aviators would be expected to report difficulty reading instruments and/or maps while wearing some bifocal contact lenses. An assessment of near vision in all bifocal contact lenses was specifically asked for, and no problems were consistently found.

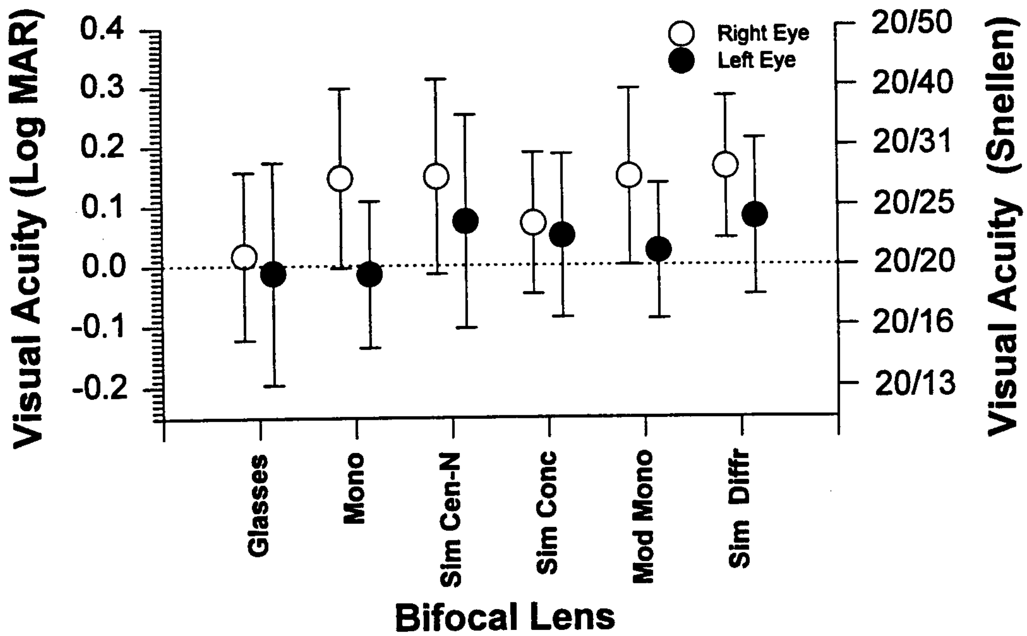

Figure 18. Average high contrast, high luminance, near (40 cm) acuity for right and left eyes of subjects in all bifocal lenses. Broken line indicates "standard" score. Bars are 1 SD.

Acceptable stereopsis for medical retention in aviation is not straightforward. Screening is normally completed using an optically simulated distance or near target with the AFVT. Twenty-five seconds of arc disparity is the passing score. However, if an aviator fails this test, a professional evaluation, which includes either the Randot book test (where a passing score is 30 seconds of arc), or the Verhoeff stereopter (where a passing score is 32 seconds of arc), is given. For our analysis, we chose a score of 30 seconds of arc as an acceptable stereopsis threshold. Again, the scores from subjects wearing bifocal lenses selected for the operational phase were averaged and the data are presented in figure 19. Not surprisingly, all aviators passed the 30 sec of arc standard in their bifocal glasses at both far and near distance. Also, the average scores with the other bifocal corrections were below the 30 arc seconds criterion at both distant and near test distances for all bifocal contact lenses, except the MV and the simultaneous diffraction lenses. It should be noted that these data were not gathered with the best bifocal contact lens, but with all the bifocal contact lenses that were selected for the operational flight phase. Passing scores with only the best (preferred) bifocal contact lens would be expected to approach 100 percent.

The preceding discussions, which consider average performance across all subjects with each lens compared to medical standards, provide insight for predicted usefulness of a bifocal contact lens correction option. However, what is not apparent from this analysis is individual performance. It is important to note that all of our subjects could have passed the VA and stereopsis criteria with one of the available bifocal contact lens options.

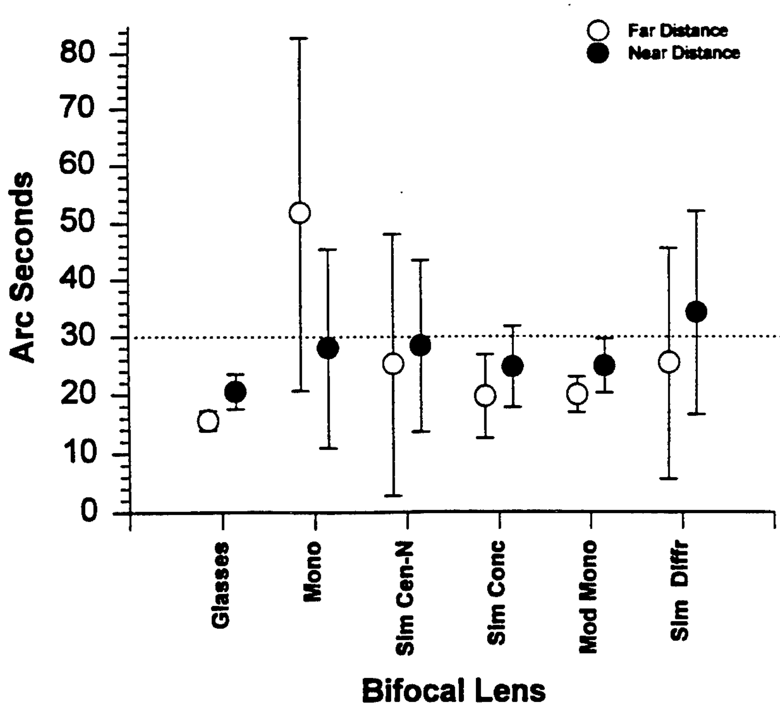

Figure 19. Average stereopsis at far and near distances collapsed across subjects and lenses. Bars are 1 SD. Population normal stereopsis is indicated at 30 seconds of arc.

Conclusions

This study was designed to determine if bifocal contact lenses are a reasonable vision correction option for presbyopic aviators who normally are required to wear bifocal spectacles when they perform flight duties. Seventeen presbyopic aviators volunteered to participate in the study and were selected to represent both myopic and hyperopic refractive error groups and low and high power add bifocal correction groups. To allow a comparison of vision performance with bifocal spectacles and bifocal contact lenses, each subject wore each type of bifocal contact lens and bifocal glasses in a four phase, repeated measures study.

Phase I - Clinical. Results of this phase demonstrated that all aviators could be fit successfully with at least three different bifocal lens types: MV, modified MV, and SV.

Phase II - Laboratory. Vision in the best performing set of bifocal contact lenses was typically slightly reduced from vision with bifocal spectacles. The amount of the reduction, and whether the reduction was clinically significant, depended on both subject characteristics and bifocal lens type. Myopes typically performed better than hyperopes. Subjects requiring low power bifocal adds performed better than high add power subjects. Scores obtained while subjects wore the MV, the modified MV, and the simultaneous center near lens, were better than those obtained while wearing other bifocal lens correction options.

Phase III - Flight simulation. The composite simulator scores demonstrated that the aviators' performance in the visual flight simulator was better when wearing bifocal contact lenses than performance while wearing bifocal spectacles. The modified MV lens design was particularly effective in the NVG portion of the flight profile. The subjects also judged their flights in the simulator as easier to perform while wearing contact lenses than while wearing bifocal glasses.

Phase IV - Operational flight. While the data from this phase are somewhat limited in scope, all subject aviators preferred flying in bifocal contact lenses than in bifocal spectacles.

One of the objectives of this study was to determine a single, best fitting option among the available bifocal contact lens designs. However, it is apparent that using a single lens design is not possible. If bifocal contact lens wear is available to the presbyopic aviator population, the supporting medical facilities must be prepared to have a variety of design options available. As a minimum, MV, modified MV, and selected SV bifocal contact lenses (at least two types: center near and concentric) must be available to successfully fit presbyopic aviators with bifocal contact lenses.

The results of this study demonstrate that a bifocal contact lens can be successfully fit to allow adequate visual performance to conduct flight operations. Although there was probably bias introduced by self-selection of volunteer aviators, all subjects in this study preferred bifocal contact lenses over bifocal spectacles. However, before a final decision regarding acceptability of bifocal contact lenses will be possible, it is recommended that a more operationally-oriented evaluation be conducted using a larger sample size.

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Appendix A

Tasking letter

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

SGCP-CP-A 6 March 1992

MEMORANDUM FOR COMMANDER, U.S. ARMY AEROMEDICAL RESEARCH LABORATORY, P.O. BOX 577, FORT RUCKER, AL 36362-5292

SUBJECT: Bifocal Contact Lens Research

1. Based on the successful completion of USAARL's Army-wide contact lens research protocol, and the positive atmosphere of the IPR, MEDTECH, and Aviation Center follow-on meetings, routine contact lens wear by Army aircrew may become a reality in the near future. Current deliberations are centered on personnel authorization and cost issues secondary to this new aeromedical mission. This appears to bring an important aeromedical research issue to a successful close.

2. However, nearly a third of the active component spectacle-wearing aviators are presbyopic or in need of a bifocal correction. The recently concluded study dealt with single vision, distance corrections only. Therefore, a large segment of the aviation population is still faced with a critical spectacle-incompatibility problem.

3. The use of bifocal contact lens wear for in-flight use has not yet been explored by the Army or any of the sister services. This continued operational need faced by our older, experienced aviators represents an important shortfall. Therefore, I'm formally requesting USAARL investigate the feasibility of in-flight use of bifocal contact lens corrections by Army aircrew.

ELRAY JENKINS
COL, MC, MFS
Aviation Medicine Consultant

Appendix B

Temporary medical clearance

Request for Temporary Medical Clearance to Allow Bifocal Contact Lens Wear

Commander
USAAMC

Volunteer
Subject

Date:

As a subject in the USAARL research project entitled, "The use of Bifocal soft contact lenses in the Fort Rucker aviation environment,"

I, ____
print name

____
ssn

hereby request a temporary medical clearance to conduct all flight operations while wearing bifocal soft contact lenses as a study participant.

____
signature

SGRD-UAS-VS (70-45) Date:

MEMORANDUM THRU: USAARL Flight Surgeon

FOR: Unit Flight Surgeon of Requesting Subject

SUBJECT: Request for Temporary Medical Clearance to Allow Bifocal Contact Lens Wear for Aviation Duties

1. The following individual has been enrolled in the USAARL study entitled, "The use of bifocal soft contact lenses in the Fort Rucker aviation environment" and is applying for a temporary medical clearance to conduct flight operations while wearing bifocal soft contact lenses during the time period of the study.

____________________________, __________________

name ssn

2. Bifocal soft contact lenses will be worn only in dual-pilot flight operations and during these flights only one aviator will be allowed to wear bifocal soft contact lenses.

3. Among the different bifocal contact lenses, there is the potential for near or far visual acuity to be slightly reduced in one or both eyes. However, no flight operations will be allowed should far or near visual acuity be worse than 20/40.

4. Data pertinent to the request are as follows:

Refractive Error OD ____________________
OS ____________________

Corrected Acuity with listed bifocal soft contact lenses:

FAR (MONOVISION) NEAR
OD ______ OD ______
OS ______ OS ______

FAR (ALLVUE) NEAR
OD ______ OD ______
OS ______ OS ______

FAR (UNILENS) NEAR
OD ______ OD ______
OD ______ OD ______

FAR (SPECTRUM) NEAR
OD ______ OD ______
OD ______ OD ______

FAR (MOD-MONO) NEAR
OD ______ OD ______
OS ______ OS ______

FAR (ECHELON) NEAR
OD ______ OD ______
OS ______ OS ______

FAR (OCCASIONS) NEAR
OD ______ OD ______
OS ______ OS ______

FAR (   ) NEAR
OD ______ OD ______
OS ______ OS ______

STEPHEN E. MORSE
LTC, MS
Research Optometrist
Principal Investigator

SGRD-UAS-VS Date:________

FROM: USAARL, VISION SCIENCE BRANCH

MEMORANDUM FOR: COMMANDER of requesting subject.

SUBJECT: Temporary Medical Clearance for Bifocal Contact Lenses

1. The following individual has been enrolled in the USAARL study entitled, "The use of bifocal soft contact lenses in the Fort Rucker aviation environment" and has been given a temporary medical clearance to conduct flight operations while wearing bifocal soft contact lenses during the time period of the study.

______________________________, ______________________

name ssn

2. Bifocal soft contact lenses should be worn only in dual-pilot flight operations and during these flights only one aviator will be allowed to wear contact lenses.

3. USAARL is thankful for the cooperation and assistance of the Aviation Units that reside at Fort Rucker. The participation of volunteer aviators in reseach projects is greatly appreciated. If you have any concerns or questions regarding the bifocal soft contact lens study, please contact the undersigned at 255-6812.

Stephen E. Morse
LTC, MS
Research Optometrist
Principal Investigator

DEPARTMENT OF THE ARMY
HEADQUARTERS UNITED STATES ARMY AEROMEDICAL CENTER
FORT RUCKER, ALABAMA 36362-5333

HSXY-AER (40-501) 27 September 1994

MEMORANDUM FOR All Flight Surgeons Caring For Subjects in the U.S. Army Aeromedical Research Laboratory (USAARL) Bifocal Soft Contact Lenses Study

SUBJECT: Interim Policy Letter (IPL)- Temporary Medical Clearance to Allow Bifocal Contact Lenses Wear for Flight Duties

1. Reference:

a. AR 40-501, 14 Jun 89, Standards of Medical Fitness, SGPS-CP-B.

b. "The use of bifocal soft contact lenses in the Ft Rucker aviation environment" USAARL Project # 3M16278A879, Work Unit # 168, Number 1248, 1 Jul 93.

2. A temporary medical clearance is authorized for Class 2 flying duties for subjects enrolled in the referenced USAARL study so that participating aviators will be able to meet the medical fitness standards for Class 2 flying duties referenced under paragraph 4-11r, AR 40-501.

3. The preprinted temporary medical clearance (DA 4186) issued by USAARL and countersigned by the unit flight surgeon will remain in effect until the conclusion of the study and in no case will extend beyond 180 days.

4. The temporary medical clearance is contingent upon the aviator:

a. Adhering to the written restrictions of the study group protocol, e.g., flying duties only in two-pilot aircraft with only one aviator wearing contact lenses.

b. Wearing only lenses approved by the study group protocol.

c. Not wearing contact lenses during prolonged off-duty periods in locations where specialized eye medical care is not readily available.

5. The temporary medical clearance will only be for specific bifocal contact lenses for each aviator. These lenses will be specified on the summary data sheet for each aviator submitted by the principal investigator of the USAARL bifocal study (see Enclosure 1, Example Form).

6. All study subjects must be assigned to Ft Rucker during the study.

7. LTC Stephen E. Morse, telephone # 205-255-6811, is the point of contact.

Encl
as

GLENN W. MITCHELL
COL, MC, SFS
Commander

Appendix C

List of manufacturers

Allergan
Irvine, CA 92715

Bausch & Lomb, Inc.
42 East Avenue
Rochester, NY 14604

CIBA Vision Corp.
P.O. Box 105069
Atlanta, GA 30348

Johnson & Johnson Vision Products, Inc.
P.O. Box 10157
Jacksonville, FL 32247-0157

Salvatori Ophthalmics, Inc.
6416-T Parkland Dr.
Sarasota, FL 34243

Unilens Corp.
10431-72nd Street North
Largo, FL 34647-1511

Appendix D

Clinical data records

Initial contact lens exam

Name__________________________________.   Rank__________.
SSN___________________________________.   Unit__________.
Date/Time_____________________________.   Age __________.

Aircraft: AH-64, UH-60, OH-58.
Job title: pilot, crew, FS.

1. Habitual R_x:
OD____.

OS____.

		Far	Int.	Near
2. Visual acuity: (spectacle R_x)	OD.	______	_____	_____
	OS.	______	_____	_____

3. Slit lamp examination:

<u>Observation code</u>   <u>Classification</u>

I. Limbal injection

A. Severity

No injection.....................................0
Minimal (within normal limits)..................1
Mild...2
Moderate...3
Severe...4

B. Location

Nasal quadrant only..............................N
Temporal quadrant only...........................T
Inferior quadrant only...........................I
Superior quadrant only...........................S
Two quadrants....................................X,X
Three quadrants..................................X,X,X
Circumlimbal.....................................C

II. Bulbar injection

A. Severity

No injection.....................................0
Minimal..1
Mild...2
Moderate...3
Severe...4

B. Location

Superficial vessels (diffuse)....................A
Superficial vessels (localized)..................B
Deep vessels (diffuse)...........................C
Deep vessels (localized).........................D
Combined involvement.............................E

III. Corneal edema

A. Severity

No edema....................................0
Faint or minimal............................1
Mild..2
Moderate....................................3
Severe......................................4

B. Type

Central corneal clouding....................C
Diffuse epithelial..........................D
Microcystic.................................M
Stromal.....................................S
Striae......................................V

IV. Corneal vascularization

A. Extent (from sclero-corneal junction)

0 to 1 mm onto cornea.......................0
1 to 1.5 mm onto cornea.....................1
1.5 to 2.0 mm onto cornea...................2
2.0 to 3.0 mm onto cornea...................3
>3.00 mm onto cornea.......................4

B. Location

Nasal quadrant only.........................N
Temporal quadrantonly.......................T
Inferior quadrant only......................I
Superior quadrantonly.......................S
Two quadrants...............................X,X
Three quadrants.............................X,X,X
Circumlimbal................................C

V. Inflammation

A. Degree

No inflammation.............................0
Faint to slight.............................1
Mild..2
Moderate....................................3
Severe......................................4

B. Location

Subepithelial infiltrates...................S
Aqueous flare...............................A
Iris turbidity..............................I
Pupillary miosis............................P

VI. Tarsal conjunctiva

A. Status

No involvement..............................0
Faint to slight irritation..................1
Mild..2
Moderate....................................3
Severe......................................4

B. Anomaly

Follicles...................................F
Papillae....................................P
Simple injection............................S

VII. Fluorescein staining

A. Severity

No staining.....................................0
Faint or minimal................................1
Mild..2
Moderate..3
Severe..4

B. Type

Abrasion..A
Foreign body....................................F
3:9...N
Punctate..P
Ulcer...U

4. Tear BUT: OD_________sec.
(without lenses):
OS_________sec.

---

5. Dispensed Contact lens R_x ____________________ manufacturer

OD_______________________________________.
power base curve diameter

OS_______________________________________.
power base curve diameter

		FAR	INT.	NEAR
6. Visual acuity: (contact lenses)	OD	_______	_______	_______
	OS	_______	_______	_______

7. Keratometry readings: (with contact lenses in place)

8. Autorefractor: (with contact lenses in place)

Followup contact lens exam

Name______________________________. Rank_____.
SSN______________. Unit______________________________.
Date/time_________________. Aircraft: AH-64, UH-60, OH-58.

1. Number of days present lens has been worn___________.
2. Visual acuity: (with contact lenses)

	Far	Int.	Near
OD	______	______	______
OS	______	______	______

3. Contact lens: (manufacturer)

OD____.
power base curve diameter

OS____.
power base curve diameter

4. Keratometry readings: (with contact lenses in place)
5. Autorefractor Readings: (with contact lenses in place)
6. Slit lamp examination:
   Observation classification code (Only changes from initial fitting examination are recorded here)

I. Limbal injection
II. Bulbar injection
III. Corneal edema
IV. Corneal vascularization
V. Inflammation
VI. Tarsal conjunctiva

7. Lens Movement: OD ______ mm. OS______ mm.

Remove old lenses____

VII. Fluorescein staining
A. Severity
No staining...........0
Faint or minimal......1
Mild..................2
Moderate..............3
Severe................4
B. Type
Abrasion..............A
Foreign body..........F
3:9...................N
Punctate..............P
Ulcer.................U

8. Tear BUT: OD_________sec. OS_________sec.
9. Keratometry readings: 10. Autorefractor readings:

PLAN:

Appendix E

Flight simulation profile

All simulator flights will be conducted using the U.S. Army Aeromedical Research Laboratory (USAARL) JUH-60 research flight simulator. This system includes an operational crew station, computer generated visual display, environmental controls (set at a constant temperature of 72 degrees Fahrenheit and a humidity of 70%), and a multi-channel data acquisition system.

This flight simulation system is capable of monitoring a wide range of measures that allow assessment of performance. For the purposes of this investigation, the channels of data listed below will be monitored:

1. Heading (degrees)
2. Indicated altitude (feet)
3. Indicated airspeed (knots)
4. Trim
5. Turn rate (deg/sec)
6. Roll angle (degrees)
7. Position relative to lead ship

These in-flight data will be acquired on a VAX 11/780 interfaced to a Perkin-Elmer digital computer which controls the UH-60 flight simulator. At the end of each flight, the data will be transferred to the main USAARL computer, a VAX 11/785. Flight performance scores will be derived using specialized software routines developed in the Laboratory (Jones and Higdon, 1991).

The flight performance evaluations will require subjects to perform the maneuvers listed below:

1. Hovering flight/terrain flight.
2. Instrument approach/landing (VMC)
3. NVG formation takeoff/flight/approach

These maneuvers are of the type typically flown in a UH-60 aircraft, and are fully described in the Aircrew Training Manual (ATM). The flights are designed to place the aviator in tasks where many changes in visual attention are required to successfully complete the task/maneuver. The visual situations that require fast and accurate inside to outside or outside to inside visual changes will most likely be adversely affected by bifocal contact lenses.

The simulator flight will be performed once with each bifocal contact lens type and once with bifocal spectacles. Prior to actual testing, subjects will receive 4 training sessions on the flight profile described above. During training and test flights, subjects will be told when to start each of the maneuvers, and the scorer will mark the start and stop of each maneuver for analysis purposes. Each flight takes approximately 1 hour to complete.

SIMULATOR FLIGHT PROFILE FOR BIFOCAL SOFT CONTACT LENS STUDY

Maneuver	Description
1. Low hover	Maintain heading 150°, altitude 10 ft
2. Low hover turn	Heading from 150° to 330° while holding altitude of 10 ft above ground level
3. High hover	Maintain heading 330°, altitude 40 ft
4. High hover turn	Heading from 330° to 150°, while holding altitude of 40 ft above ground level
5. Navigate to chkpt 1	Maintain GPS heading within +/- 2 deg Maintain 700 feet MSL within +/- 25 feet Arrive at checkpoint in 3 minutes
6. Navigate to chkpt 2	Maintain GPS heading within +/- 2 deg Maintain 600 feet MSL within +/- 25 feet Arrive at checkpoint in 2 minutes
7. Navigate to chkpt 3	Maintain GPS heading within +/- 2 deg Maintain 600 feet MSL within +/- 25 feet Arrive at checkpoint in 5 minutes
8. Navigate to chkpt 4	Maintain GPS heading within +/- 2 deg Maintain 600 feet MSL within +/- 25 feet Arrive at checkpoint in 2 minutes
9. Navigate to chkpt 5	Maintain GPS heading within +/- 2 deg Maintain 700 feet MSL within +/- 25 feet Arrive at checkpoint in 4 minutes
10. Transition	Establish heading 240°, airspeed 120 k, altitude 2000 ft MSL
11. Instrument Approach	Maintain the parameters given by instructor and Approach Plate i.e., airspeed 120, alt 2000 ft MSL.
12. Perform VMC approach	Maintain airspeed until approach angle intercept (VASI), touchdown on runway.

MOVE TO COORDINATES	The following maneuvers are NVG:
13. Execute NVG terrain flt Approach to LZ	Maintain airspeed until approach angle intercept; touch down in Y zero ground speed
14. Perform NVG format-ion flt takeoff (staggered left)	Maintain 3 rotor disk separation at 30° angle of leadship. Depart ground simultaneously with lead ship
15. Perform NVG format-ion flt (stag. left)	Maintain 3 rotor disk separation at 30° angle; maintain altitude and airspeed
16. Perform NVG format-ion flt (trail)	Maintain 3 rotor disk separation behind leadship; maintain altitude and airspeed
17. Perform NVG format-ion flt app. (trail)	Maintain 3 rotor disk separation behind leadship; touch down simultaneously with leadship

Appendix F

Aviator questionnaire

AVIATOR QUESTIONNAIRE

Subject ID:__________. Bifocal type: ______________________.

Approximate hours in this aircraft: __________.

Approximate hours in all aircraft: ___________.

Approximate hours in UH-60 simulator:__________.

Part 1. Circle the number which most closely matches your evaluation of the **CURRENT BIFOCAL CONTACT LENSES.**

Very Difficult	Moderately Difficult	Slightly Difficult	Neither Difficult Nor Easy	Slightly Easy	Moderately Easy	Very Easy
1	2	3	4	5	6	7

Read gauges, displays, control settings	1	2	3	4	5	6	7
Upper console	1	2	3	4	5	6	7
Lower console	1	2	3	4	5	6	7
Battery circuit breaker panel	1	2	3	4	5	6	7
Instrument panel	1	2	3	4	5	6	7
Perform flight maneuvers	1	2	3	4	5	6	7
Read maps or checklists	1	2	3	4	5	6	7
Judge depth and distance	1	2	3	4	5	6	7
Peripheral motion detection	1	2	3	4	5	6	7
Vision with ANVIS	1	2	3	4	5	6	7
Target/object detection	1	2	3	4	5	6	7
Maintain field of view	1	2	3	4	5	6	7
Coping with glare/reflections	1	2	3	4	5	6	7
Overall performance/ease of use	1	2	3	4	5	6	7

Part 2. Circle the number which most closely matches your evaluation of the **CURRENT BIFOCAL CONTACT LENSES COMPARED TO YOUR BIFOCAL SPECTACLES.**

Much Poorer	Moderately Poorer	Slightly Poorer	Same as glasses	Slightly Better	Moderately better	Much better
1	2	3	4	5	6	7

Read gauges, displays, control settings	1	2	3	4	5	6	7
Upper console	1	2	3	4	5	6	7
Lower console	1	2	3	4	5	6	7
Battery circuit breaker panel	1	2	3	4	5	6	7
Instrument panel	1	2	3	4	5	6	7
Perform flight maneuvers	1	2	3	4	5	6	7
Read maps or checklists	1	2	3	4	5	6	7
Judge depth and distance	1	2	3	4	5	6	7
Peripheral motion detection	1	2	3	4	5	6	7
Vision with ANVIS	1	2	3	4	5	6	7
Target/object detection	1	2	3	4	5	6	7
Maintain field of view	1	2	3	4	5	6	7
Coping with glare/reflections	1	2	3	4	5	6	7
Overall performance/utility	1	2	3	4	5	6	7

During any portion of your flight, or evaluation, did you experience difficulties because of the bifocal soft contact lenses? If yes, please describe them briefly.

Appendix G.

Statistical tables from ANOVAs.

Tables from the ANOVAs for each different laboratory phase test and for the simulator flight phase are presented. Post hoc multiple comparison testing was accomplished with the Tukey HSD test unless otherwise noted. Tables are presented at the beginning of each test/evaluation followed by an explanation of each significant main effect or interaction.

Table G-1.
Summary of all effects table for high contrast VA

Factors: 1-Add Gp, 2-Ref Gp, 3-Luminance, 4-Distance, 5-Bifocal Lens

*	Effect	df Effect	MS Effect	df Error	MS Error	F	p-level
1	1	1	0.409	78	0.026	15.937	0.000*
	2	1	0.088	78	0.026	3.442	0.067
2	3	1	14.099	78	0.026	549.194	0.000*
3	4	2	0.964	78	0.026	37.563	0.000*
4	5	5	0.344	390	0.011	30.477	0.000*
	12	1	0.093	78	0.026	3.621	0.061
	13	1	0.035	78	0.026	1.344	0.250
	23	1	0.016	78	0.026	0.623	0.432
	14	2	0.038	78	0.026	1.469	0.236
	24	2	0.029	78	0.026	1.141	0.325
	34	2	0.009	78	0.026	0.369	0.693
5	15	5	0.028	390	0.011	2.463	0.033*
	25	5	0.019	390	0.011	1.670	0.141
	35	5	0.044	390	0.011	0.332	0.894
6	45	10	0.022	390	0.011	1.916	0.042*
	123	1	0.010	78	0.026	0.408	0.525
7	124	2	0.102	78	0.026	3.968	0.023*
	134	2	0.005	78	0.026	0.184	0.832
	234	2	0.001	78	0.026	0.053	0.948
8	125	5	0.037	390	0.011	3.283	0.006*
	135	5	0.006	390	0.011	0.500	0.776
	235	5	0.005	390	0.011	0.485	0.787
9	145	10	0.045	390	0.011	4.002	0.000*
	245	10	0.012	390	0.011	1.023	0.423
	345	10	0.009	390	0.011	0.772	0.656
	1234	2	0.014	78	0.026	0.555	0.576
	1235	5	0.002	390	0.011	0.160	0.977
10	1245	10	0.025	390	0.011	2.201	0.017*
	1345	10	0.009	390	0.011	0.789	0.639
	2345	10	0.002	390	0.011	0.182	0.997
	12345	10	0.003	390	0.011	0.226	0.994

The analysis of the VA data for high contrast VA measured at high and low luminance and at far, mid, and near distance conditions in all bifocal contact lenses and spectacle bifocals are presented in table G-1. The numbered paragraphs below correspond to the significant effects and interactions in the table which are designated by an asterisk (*) and consecutively numbered.

1. Main effect for add group, indicating that the low add group had better acuity than the high add group.

2. Main effect for luminance, indicating that acuity was better at high luminance than at low.

3. Main effect for distance, indicating that acuity was best at far, next best at mid, and worst at near.

4. Main effect for type of bifocal lens. Multiple comparison testing (Tukey HSD) showed that:

a. VA with glasses was superior to all bifocal contact lenses;

b. MV acuity was superior to all lens conditions except modified MV;

c. Simultaneous center near, simultaneous concentric center near, and the simultaneous diffraction lens all had equivalent acuity which was worse than all other bifocal lens conditions;

d. Simultaneous concentric center near, simultaneous center near, and the modified MV lens had equivalent acuity which was not as good as MV and glasses, but better than the simultaneous diffraction lens;

e. Modified MV acuity was equivalent to the MV and the simultaneous concentric center near designs, slightly worse than glasses, and superior to the other designs; and

f. Simultaneous diffraction acuity was poorer than all the other lens conditions.

5. Significant interaction between add group and bifocal lens type, indicating that while VA with different bifocal lens types tended to be better for the low add group subjects, the degree of improvement over the high add group depended on the bifocal lens type. Multiple comparison testing (Tukey HSD) substantiated the observation that the only bifocal lens types with a difference between add group acuity were the simultaneous center near lens and the modified MV lens, both of which demonstrated better acuity for the low add group.

6. Significant interaction between distance and bifocal type, indicating that while acuity tended to decrease from far to mid to near distance, the degree of decrease was dependent on the lens type. There was a significant decrease in acuity from far to mid to near for the bifocal spectacles, the simultaneous center near lens, the simultaneous concentric center near lens, and the simultaneous diffraction lens. There was no significant difference in acuity at far, mid, or near

for the MV lens, nor was there a difference between the far and mid acuity for the modified MV lens.

7. Significant three-way interaction between add group, refractive group, and distance, indicating that while acuity tended to decrease far, to mid, to near, the degree of decrease depended on the refractive error group and the add group. (Hyperopes tended to have less difference between the high and low add groups at all three distances, while the myopic low add group clearly had superior acuity at all distances, in contrast to the high add group myopes who had the worst acuity of any group at every distance except far).

8. Significant three-way interaction between add group, refractive group, and bifocal lens type, indicating that while the myopic and low add groups tended to have better acuity, the degree of difference was dependent on the bifocal lens type, with bifocal glasses showing the least effect (no significant differences), the simultaneous center near lens showing the most effect (great variability in acuity between both add group and refractive group), and the other lenses showing a moderate effect or no effect.

9. Significant three-way interaction between add group, distance and bifocal lens type, indicating that while acuity decreases from far, to mid, to near, and while the low add group tended to have better acuity at each distance than the high add group, the degree of difference was dependent on the bifocal lens type.

10. Significant four-way interaction between add group, refractive group, distance, and bifocal lens type. Several features warrant comment.

a. At far distance (panel 1, figure 1), hyperopes had significantly worse acuity than myopes for MV, modified MV, and diffraction lenses. Myopes in both high and low add groups tended to have equal acuity, while hyperopes in the high add group tended to have worse acuity than hyperopes in the low add group.

b. At far distance (panel 2, figure 1), myopes and hyperopes in the low add group had virtually identical acuity with each bifocal lens type. They also had statistically equivalent acuity to bifocal spectacles in both the MV and modified MV lenses.

c. At mid distance (panel 3, figure 1), both hyperopes and myopes in the high add group had equivalent acuity with all bifocal lenses, except with the simultaneous diffraction lens which was statistically worse for the hyperopes.

d. At mid distance (panel 4, figure 1), the hyperopes in the low add group had equivalent acuity for the simultaneous lenses, with glasses providing the best acuity. Other than the myope's better acuity in glasses, acuity for myopes and hyperopes was equivalent.

e. At near distance (panel 5, figure 1), both the hyperopes and the myopes tended to have worse acuity than at any other distance. Myopes and hyperopes tended to have similar acuity in each lens type. The MV lens was the only one with which the myopes had better acuity than the hyperopes.

f. At near distance (panel 6, figure 1), the hyperopes in the low add group tended to have poorer acuity than the myopes in all lenses. Also, the myopes in the low add group had statistically equivalent acuity with all bifocal lenses.

Table G-2.
Summary of all effects table for low contrast VA.

Factors: 1-Add Gp, 2-Ref Gp, 3-Luminance, 4-Bifocal Lens

*	Effect	df Effect	MS Effect	df Error	MS Error	F	p-level
1	1	1	0.136	26	0.022	6.18	0.020*
2	2	1	0.137	26	0.022	6.22	0.019*
3	3	1	7.731	26	0.022	351.59	0.000*
4	4	5	0.125	130	0.008	16.28	0.000*
	12	1	0.012	26	0.022	0.55	0.466
	13	1	0.013	26	0.022	0.60	0.445
	23	1	0.003	26	0.022	0.15	0.700
5	14	5	0.024	130	0.008	3.13	0.011*
6	24	5	0.042	130	0.008	5.42	0.000*
	34	5	0.010	130	0.008	1.36	0.242
	123	1	0.018	26	0.022	0.83	0.370
	124	5	0.007	130	0.008	0.97	0.439
	134	5	0.003	130	0.008	0.36	0.876
	234	5	0.004	130	0.008	0.54	0.744
	1234	5	0.002	130	0.008	0.24	0.943

The data for low contrast VA measured at high and low luminance at the 6 m distance condition in all bifocal contact lenses and spectacle bifocals are summarized in table G-2. The numbered paragraphs below correspond to the significant effects and interactions in the table which are designated by an asterisk (*) and consecutively numbered.

1. Main effect for add group, indicating that low contrast VA in the low add group (mean across all conditions = 20/40 Snellen) was better than low contrast acuity in the high add group (mean across all conditions = 20/46 Snellen).

2. Main effect for refractive group, indicating that low contrast vision was superior for the myopic group (mean across all conditions = 20/40 Snellen) than for the low contrast acuity in the hyperopic group (mean across all conditions = 20/45).

3. Main effect for luminance, indicating that low contrast VA was better under high luminance (mean across all conditions = 20/27 Snellen) than under low luminance (mean across all conditions = 20/70 Snellen).

4. Main effect for type of bifocal lens, indicating that low contrast acuity depended on bifocal lens type (see figure 3).

a. Low contrast VA with glasses was superior to all bifocal soft lens conditions.

b. Simultaneous diffraction acuity was worse than any other lens condition.

c. Acuity with all other bifocal lens conditions was equivalent; i.e., MV, modified MV, aspheric center near, aspheric concentric are all equivalent.

5. Two-way interaction between add group and bifocal lens type, indicating that while the low add group tended to have better low contrast acuity than the high add group, the difference was dependent on the type of bifocal lens (see figure 4). Multiple comparison testing (Tukey HSD) showed that the only bifocal lens types with a difference between add group acuity were the MV lens and the modified MV lens, both of which had superior acuity than the low add group.

6. Interaction between refractive error group and type of bifocal lens, indicating that while low contrast acuity tends to be better for individuals in the myopic refractive error group, the degree of improvement over hyperopic acuity depends on the bifocal lens type (see figure 4). Multiple comparison testing (Tukey HSD) substantiated the observation that the only bifocal lens types with a difference between refractive group acuity were the MV lens and the modified MV lens, both of which demonstrated better acuity than the hyperopic refractive group.

Table G-3.
Summary of all effects table for ANVIS VA.

Factors: 1-Add Gp, 2-Ref Gp, 3-Bifocal Lens

*	Effect	df Effect	MS Effect	df Error	MS Error	F	p-level
	1	1	0.068	13	0.019	3.625	0.079
	2	1	0.001	13	0.019	0.076	0.787
1	3	5	0.038	65	0.007	5.289	0.000*
	12	1	0.011	13	0.019	0.566	0.465
	13	5	0.015	65	0.007	0.035	0.085
2	23	5	0.029	65	0.007	3.944	0.003*
3	123	5	0.021	65	0.007	2.884	0.021*

The following numbered paragraphs correspond to the significant effects and interactions in the table which are designated by an asterisk (*) and consecutively numbered. The VA data for ANVIS VA measured at approximately quarter-moon night luminance (through Gentex filters) at optical infinity (using the AFVT) in all bifocal contact lenses and spectacle bifocals are summarized in figures 6 and 7 and in table G-3.

1. Main effect for bifocal lens type, indicating that ANVIS VA varied with bifocal lens type (figure 6). Multiple comparison testing (Tukey HSD test) established that ANVIS acuity with bifocal glasses was equal to acuity with MV, simultaneous concentric, and modified MV lenses, which were all significantly better than acuity with either the simultaneous center near or the simultaneous diffractive lens. ANVIS acuity with the simultaneous diffraction lens was inferior to the bifocal glasses and the modified MV lens, and not significantly different from the other lens designs.

2. Interaction between refractive error group and type of bifocal contact lens, indicating that while ANVIS acuity for the myopic group tended to be superior to acuity for the hyperopic group, the difference was dependent on the bifocal lens type. However, multiple comparison testing (Tukey HSD) showed that there were no significant differences of interest.

3. Three-way interaction between add group, refractive group, and bifocal lens type, indicating that ANVIS acuity with the different bifocal lens types, while in general being superior for the low add group, depended on the refractive error group (see figure 7). Specifically, ANVIS acuity tended to be superior for both hyperopes and myopes in the low add group than for those in the high add group. Also, in the high add group, myopes only had significantly better acuity in the MV lens, and in the low add group myopes actually had worse acuity in the simultaneous center near lens.

Table G-4.
Summary of all effects table for contrast sensitivity.

Factors: 1-Add Gp, 2-Ref Gp, 3-cpd, 4-Distance, 5-Bifocal Lens

*	Effect	df Effect	MS Effect	df Error	MS Error	F	p-level
1	1	1	58029.370	130	1236.385	45.935	0.000*
2	2	1	14763.160	130	1236.385	11.941	0.001*
3	3	4	267597.300	130	1236.385	216.435	0.000*
4	4	1	15918.050	130	1236.385	12.875	0.000*
5	5	5	15610.700	650	427.241	36.538	0.000*
	12	1	656.177	130	1236.385	0.531	0.468
	13	4	2480.456	130	1236.385	2.006	0.097
	23	4	817.964	130	1236.385	0.662	0.620
	14	1	1262.240	130	1236.385	1.021	0.314
	24	1	341.656	130	1236.385	0.276	0.600
	34	4	623.993	130	1236.385	0.505	0.732
6	15	5	3531.913	650	427.241	8.267	0.000*
7	25	5	1657.595	650	427.241	3.880	0.002*
8	35	20	1920.336	650	427.241	4.495	0.000*
	45	5	856.210	650	427.241	2.004	0.076
	123	4	225.361	130	1236.385	0.182	0.947
	124	1	4156.274	130	1236.385	3.362	0.069
	134	4	1095.764	130	1236.385	0.886	0.474
	234	4	668.002	130	1236.385	0.540	0.706
9	125	5	1150.450	650	427.241	2.693	0.020*
	135	20	266.423	650	427.241	2.693	0.020*
	235	20	310.727	650	427.241	0.624	0.897
	145	5	359.529	650	427.241	0.841	0.520
	245	5	671.228	650	427.241	4.571	0.166
	345	20	277.898	650	427.241	1.353	0.139
	1234	4	888.434	130	1236.385	0.719	0.581
	1235	20	558.964	650	427.241	1.308	0.166
	1245	5	350.998	650	427.241	0.822	0.535
	1345	20	155.522	650	427.241	0.364	0.995
	2345	20	228.362	650	427.241	0.535	0.952
	12345	20	189.970	650	427.241	0.445	0.983

The contrast sensitivity data for visual stimuli at five different spatial frequencies measured at far and near distances in all bifocal contact lenses and spectacle bifocals are summarized in table G-4. The numbered paragraphs below correspond to the significant effects and interactions in the table which are designated by an asterisk (*) and consecutively numbered.

1. Main effect for add group, indicating that contrast sensitivity in the low add group (mean across all conditions = 79.18) was better than contrast sensitivity in the high add group (mean across all conditions = 63.77).

2. Main effect for refractive group, indicating that contrast sensitivity was superior for the myopic group (mean across all conditions = 75.37) than for the contrast sensitivity in the hyperopic group (mean across all conditions = 67.59).

3. Main effect for cycle per degree (cpd), indicating that contrast sensitivity was better at middle spatial frequencies and decreased at higher and lower spatial frequencies (mean across cpd conditions: 1.5 cpd = 76.57, 3.0 cpd = 107.71, 6.0 cpd = 104.01, 12 cpd = 47.94, 18 cpd = 21.16). Differences between cpd were all significant except between 3 and 6 cpd (Tukey HSD).

4. Main effect for distance, indicating that contrast sensitivity was better at far (mean across all conditions = 75.55) compared to near distance (mean across all conditions = 67.44).

5. Main effect for type of bifocal lens, indicating that contrast sensitivity depended on bifocal lens type. Figure 8 collapses across add group, refractive group, cpd and distance to show that:

   a. Bifocal glasses have the highest contrast sensitivity.

   b. MV, simultaneous center near, simultaneous concentric center near and modified MV have worse contrast sensitivity than bifocal glasses, better contrast sensitivity than the simultaneous diffraction lens, and equal contrast sensitivity to each other; and

   c. The simultaneous diffraction lens has worse contrast sensitivity than any other lens.

6. Two-way interaction between add group and bifocal lens type, indicating that while the low add group had higher contrast sensitivity than the high add group, the degree of improvement was dependent on the type of bifocal lens. Specifically, contrast sensitivity was significantly better for the low add group for all lenses except the simultaneous concentric center near and simultaneous diffraction lenses.

7. Two-way interaction between refractive group and bifocal lens type, indicating that while the myopic group had higher contrast sensitivity than the hyperopic group, the degree of improvement was dependent on the type of bifocal lens. Specifically, the myopic group had significantly higher contrast sensitivity than the hyperopic group in the MV and modified MV lenses. Contrast sensitivity was equal for myopes and hyperopes for all other lenses.

8. Two-way interaction between cpd and bifocal lens type, indicating that contrast sensitivity at each cpd was dependent on the type of bifocal lens. Specifically:

a. All bifocal lenses produced equivalent contrast sensitivity at 1.5 cpd;

b. Bifocal glasses were significantly higher at all other cpd's than all other bifocal lenses except MV, which had contrast sensitivity equal to bifocal glasses at 1.5, 6, 12, and 18 cpd, and modified MV, which was equal to bifocal glasses at 1.5, and 18 cpd;

c. The simultaneous center near, and simultaneous concentric center near lenses provided equivalent contrast sensitivity which was lower than bifocal glasses, MV, and modified MV lenses; and

d. The simultaneous diffraction lens was significantly worse in contrast sensitivity than all other lens conditions except at the 1.5 cpd spatial frequency.

9. Three-way interaction between add group, refractive group, and bifocal lens type, indicating that low add group myopes tended to have higher contrast sensitivity than low add group hyperopes, and high add myopes and hyperopes, with the degree of improvement dependent upon the type of bifocal lens (see figure 10). Specifically:

a. Low add myopes had significantly better contrast sensitivity than high add hyperopes and myopes for every bifocal lens except the simultaneous diffraction lens. Low add myopes also had significantly better contrast sensitivity than the low add hyperopes for MV, simultaneous concentric, and modified MV bifocal lenses; and

b. When averaged across cpd and distance, high add myopes had significantly better contrast sensitivity than high add hyperopes for MV, simultaneous center near, and modified MV bifocal lenses.

Table G-5.
Summary of all effects table for stereopsis without ANVIS.

Factors: Add Gp, 2-Ref Gp, 3-Distance, 4-Bifocal Lens

*	Effect	df Effect	MS Effect	df Error	MS Error	F	p-level
1	1	1	2427.140	26.0	276.164	8.789	0.006*
2	2	1	2684.396	26.0	276.164	9.720	0.004*
	3	1	30.041	26.0	276.164	0.109	0.744
3	4	5	2153.795	130.0	172.091	12.515	0.000*
	12	1	76.606	26.0	276.164	0.277	0.603
	13	1	153.489	26.0	276.164	0.556	0.463
	23	1	5.598	26.0	276.164	0.020	0.888
4	14	5	1274.841	130.0	172.091	7.408	0.000*
	24	5	355.861	130.0	172.091	2.068	0.073
5	34	5	1236.994	130.0	172.091	7.188	0.000*
	123	1	147.662	26.0	276.164	0.535	0.471
	124	5	185.362	130.0	172.091	1.077	0.376
	134	5	350.742	130.0	172.091	2.038	0.077
	234	5	129.848	130.0	172.091	0.755	0.584
	1234	5	16.038	130.0	172.091	0.093	0.993

The stereopsis data without ANVIS for high contrast, high luminance visual stimuli measured at far and near distance conditions in all bifocal contact lenses and spectacle bifocals are summarized in figures 10 and 11, and table G-5 above. The following numbered paragraphs correspond to the significant effects and interactions in the table which are designated by an asterisk (*) and consecutively numbered.

1. Main effect for add group, indicating that stereopsis for the low add group (mean across all conditions = 23.39 arc seconds) was better than that for the high add group (mean across all conditions = 30.45 arc seconds).

2. Main effect for refractive group, indicating that stereopsis was better for the myopic group (mean across all conditions = 23.21 arc seconds) compared to the hyperopic group (mean across all conditions = 30.63 arc seconds).

3. Main effect for type of bifocal lens, indicating that stereopsis depended on bifocal lens type. Figure 12 collapses across add group, refractive group, and distance to show that:

a. Stereopsis was equivalent with bifocal glasses, simultaneous concentric center near, and modified MV lenses;

b. Stereopsis with the MV lens was worse than all other lens types; and

c. Stereopsis with the simultaneous center near and the simultaneous diffraction lens was equivalent to the stereopsis for the simultaneous concentric center near and modified MV lenses, but not as good as for bifocal glasses. All differences mentioned were statistically significant (Tukey HSD).

4. Two-way interaction between add group and bifocal lens type, indicating that stereopsis for the low add group tended to be superior to the high add group, but the degree of difference depended on the different bifocal lens type (see figure 12). Specifically, there was only one bifocal lens type (MV) where the low add group had significantly better stereopsis than the high add group (Tukey HSD).

5. Two-way interaction between distance and bifocal lens type, indicating that stereopsis tended to be better at far distances, but the degree of difference depended on the bifocal lens type (see figure 13). Specifically, there was only one bifocal lens type (MV) where stereopsis was significantly better at far (Tukey HSD).

Table G-6.

Summary of all effects table for stereopsis with ANVIS.

Factors: 1-Add Gp, 2-Ref Gp, 3-Bifocal Lens

*	Effect	df Effect	MS Effect	df Error	MS Error	F	p-level
	1	1	514.7	13	1394.8	0.369	0.554
	2	1	3886.2	13	1394.8	2.786	0.119
	3	5	710.0	65	371.3	1.913	0.104
	12	1	15.6	13	1394.8	0.011	0.917
	13	5	263.3	65	371.3	0.709	0.619
1	23	5	1197.1	65	371.3	3.220	0.012*
2	123	5	1489.2	65	371.3	4.011	0.003*

The stereopsis data for approximate quarter-mood luminance visual stimuli measured at far using Gentex filters over the ANVIS objective lens in conjunction with the AFVT in all bifocal contact lenses and spectacle bifocals are summarized in figure 13 and table G-6. The following numbered paragraphs correspond to the significant effects and interactions in the table which are designated by an asterisk (*) and consecutively numbered.

1. Two-way interaction between refractive group and bifocal lens type, indicating that stereopsis for the myopic group tended to be superior to the hyperopic group, but the degree of difference depended on the different bifocal lens types. However, multiple comparison testing showed that stereopsis was better for the myopic group over the hyperopic group only for the MV lens.

2. Three-way interaction between add group, refractive group and bifocal lens type, indicating that while the low add group tended to have better ANVIS stereopsis in the different bifocal lenses than the high add group, the difference was dependent on the refractive group (see figure 14). Specifically:

a. The high add group myopes had no significant difference between ANVIS stereopsis with any bifocal lens;

b. The low add group myopes had no significant difference between ANVIS stereopsis with any bifocal lens except for the simultaneous center near lens, which was significantly poorer;

c. The high add group hyperopes had no significant difference between ANVIS stereopsis with any bifocal lens except for the MV lens, which was significantly poorer;

d. The low add group hyperopes had no significant difference between ANVIS stereopsis with any bifocal lens;

e. In the high add group, myopes had significantly better ANVIS stereopsis than hyperopes with both MV and simultaneous center near lenses; and

f. In the low add group, myopes had significantly better ANVIS stereopsis than hyperopes with both MV and simultaneous concentric center near lenses.

Table G-7.
Summary of all effects table for flight simulation.

Factors: 1-Add Gp, 2-Ref Gp, 3-Maneuver, 4-Bifocal Lens

*	Effect	df Effect	MS Effect	df Error	MS Error	F	p-level
	1	1	185.90	182	315.371	0.589	0.444
	2	1	770.82	182	315.371	2.444	0.120
1	3	13	20498.93	182	315.371	64.999	0.000*
2	4	5	473.00	910	68.763	6.879	0.000*
	12	1	832.40	182	315.371	2.639	0.106
	13	13	180.51	182	315.371	0.572	0.874
	23	13	159.94	182	315.371	0.507	0.918
	14	5	19.10	910	68.763	0.278	0.925
	24	5	151.94	910	68.763	2.210	0.051
	34	65	83.58	910	68.763	1.215	0.124
	123	13	147.62	182	315.371	0.468	0.940
3	124	5	158.73	910	68.763	2.308	0.043*
	134	65	48.05	910	68.763	0.699	0.966
	234	65	41.38	910	68.763	0.602	0.995
	1234	65	53.86	910	68.763	0.783	0.893

The flight simulation data for 14 specific graded maneuvers measured in all bifocal contact lenses and spectacle bifocals are summarized in figure 14 and in table G-7 above. The numbered paragraphs below correspond to the significant effects and interactions in the table which are designated by an asterisk (*) and consecutively numbered.

1. Main effect for maneuver, indicating that there were significant differences in the composite scores for the different maneuvers. This was expected, and not an important finding in isolation.

2. Main effect for type of bifocal lens, indicating that total composite score for the maneuvers depended on bifocal lens type. Specifically, figure 15 shows that the modified MV lens was superior to all the other bifocal lenses, including glasses. All other lenses were not significantly different from each other (Tukey HSD).

3. Three-way interaction between add group, refractive group, and bifocal lens type, indicating that while the myopic group tended to have higher composite scores, the degree of difference

between the myopic and hyperopic refractive group depended on which add group they were in. Specifically, figure 16 shows:

a. The high add group hyperopes all had statistically equal composite maneuver scores for all bifocal lenses except for the modified MV lens, which was statistically superior to all other lens conditions;

b. The high add group myopes all had statistically equal composite maneuver scores for all bifocal lenses except for the MV and the modified MV lenses, which were statistically superior to all other lens conditions;

c. The high add group myopes had statistically superior composite maneuver scores than the hyperopes, for all bifocal lenses except for the simultaneous concentric center near, the modified MV, and the simultaneous diffraction lens;

d. The low add group hyperopes all had statistically equal composite maneuver scores for all bifocal lenses except for the modified MV lens, which was statistically superior to all other lens conditions;

e. The low add group myopes all had statistically equal composite maneuver scores for all bifocal lenses; and

f. The low add group myopes and hyperopes all had statistically equal composite maneuver scores for all bifocal lenses except for the simultaneous concentric center near lens, which was statistically superior for the hyperopic refractive group.

The 14 different flight simulation maneuvers fell into three general groups: hover maneuvers, terrain flight maneuvers, and NVG maneuvers (night formation and terrain flight). Since there was no significant interaction between bifocal lens type and maneuver in the four-way ANOVA which included add group, refractive group, maneuver, and bifocal lens type (reported above), it was decided to group the maneuvers to ensure an important interaction between bifocal lens type and maneuver type was not overlooked. The three-way ANOVA design with add group, refractive group, and bifocal lens design, while grouping maneuvers by first hover maneuvers, then terrain flight maneuvers, and then NVG maneuvers is reported below.

a. Hover maneuvers: There were no significant main effects or interactions for this group of maneuvers, indicating that the composite scores for all bifocal lens types was equivalent for all maneuvers in this group.

b. Terrain flight maneuvers: There were no significant main effects. There was a significant interaction between add group and refractive group (F[1,30] = 9.135, p = 0.005), indicating that myopes in the high add group had superior composite scores for the terrain flight maneuvers than the low add group myopes. There were no other significant interactions.

c. NVG maneuvers: There was a significant main effect for bifocal lens type (F[5,490] = 8.097, p < 0.000000), indicating that the modified MV lens type was significantly superior in composite score to any of the other bifocal lens types (including bifocal glasses). All the other bifocal lens scores were equivalent (Tukey HSD).

There was also a significant three-way interaction between add group, refractive group and bifocal lens type (F[5,490] = 3.363, p = 0.005), indicating that while the myopic group tended to have a higher composite score than the hyperopes, the degree of the difference depended on the add group. However, this interaction proved to be of little consequence. Specifically, in the high add group, the hyperopes were equivalent to each other and to the myopes for all lens conditions, with only one difference between bifocal lens for the high add myopes being significant (the modified MV lens being significantly higher than the simultaneous diffraction lens, a relationship that was observed throughout this study). In the low add group, the refractive groups were once again essentially equivalent, with only one difference between bifocal lenses for myopes being significant (myopes had significantly superior scores in the modified MV lenses than in the simultaneous concentric center near lens), and only one difference between refractive groups in a single bifocal lens type (hyperopes in the simultaneous concentric center near lens had a higher score than the myopes).

Table G-8.
Questionnaire: Part 1.

Part 1. Circle the number which most closely matches your evaluation of the **CURRENT BIFOCAL CONTACT LENSES** (including bifocal spectacles).

Very Difficult	Moderately Difficult	Slightly Difficult	Neither Difficult Nor Easy	Slightly Easy	Moderately Easy	Very Easy
1	2	3	4	5	6	7

NO.	QUESTION	RESPONSES - STATISTICAL DIFFERENCES
1	Read gauges, displays	no diff. between bifocal lenses (ave=5.4)
2	Upper console	no diff. between bifocal lenses (ave=5.2)
3	Lower console	no diff. between bifocal lenses (ave=5.4)
4	Battery circ. breaker	no diff. Between bifocal lenses (ave=5.5)
5	Instrument panel	Main effect refr. gp. (F= 4.78, p= 0.048) hyperopes = 5.98, myopes =5.05
6	Perform flight maneuvers	no diff. between bifocal lenses (ave=5.7)
7	Read maps or checklists	no diff. between bifocal lenses (ave=5.4)
8	Judge depth and distance	no diff. between bifocal lenses (ave=5.3)
9	Peripheral motion detection	no diff. between bifocal lenses (ave=5.7)
10	Vision with ANVIS	no diff. between bifocal lenses (ave=5.6)
11	Target/object detection	no diff. between bifocal lenses (ave=5.6)
12	Maintain field of view	no diff. between bifocal lenses (ave=5.7)
13	Coping with glare, reflections	no diff. between bifocal lenses (ave=5.7)
14	Overall perform./ ease of use	no diff. between bifocal lenses (ave=5.6)

The questionnaire data consisted of responses to a two-part series of 14 questions administered to aviator volunteers after each bifocal lens simulator flight. Part 1 of the questionnaire asked the subject to answer 14 questions regarding the "current bifocal lens (including bifocal spectacles)." Part 2 asked 14 questions regarding "how the current bifocal lens compares to bifocal spectacles."

Table G-8 presents the results of part 1 of the questionnaire, and, as the average responses indicate (between 5 and 6 on the scale), the subjects found the tasks "slightly-" to "moderately-easy" in all the bifocal lenses, including bifocal spectacles. There were no statistical differences between the bifocal lenses for any question in part 1 of the questionnaire. However, there was a significant main effect for refractive group for question 5 "instrument panel visibility," indicating that the hyperopic refractive group found instrument panel viewing significantly easier than the myopic group. This appears consistent with the results of the high contrast VA data displayed in panel 3 of figure 2, which represents mid-distance acuity for both the hyperopes and myopes in the high add group, and which would be the appropriate distance corresponding to instrument panel viewing. It can be seen from this figure that hyperopes in the high add group have significantly superior mid-distance acuity, which is believed to account for the questionnaire response that hyperopes find the instrument panel significantly easier to view than myopes.

Table G-9
Questionnaire: Part 2

Part 2. Circle the number which most closely matches your evaluation of the **CURRENT BIFOCAL CONTACT LENSES COMPARED TO YOUR BIFOCAL SPECTACLES.**

Much Poorer	Moderately Poorer	Slightly Poorer	Same as glasses	Slightly Better	Moderately better	Much better
1	2	3	4	5	6	7

NO.	QUESTION	RESPONSES - STATISTICAL DIFFERENCES
1	Read guages, displays	Main effect add gp. (F= 7.50, p= 0.017) hi add = 5.75, lo add = 4.40
2	Upper console	no diff. between bifocal lenses (ave=5.2)
3	Lower console	no diff. between bifocal lenses (ave=5.0)
4	Battery circ. breaker	no diff. between bifocal lenses (ave=5.0)
5	Instrument panel	Main effect add gp. (F= 5.63, p= 0.034) hi add = 5.75, lo add = 4.63
6	Perform flight maneuvers	no diff. between bifocal lenses (ave=5.2)
7	Read maps or checklists	no diff. between bifocal lenses (ave=4.86)
8	Judge depth and distance	interaction: add group and bifocal lens type (see text - this result was not clinically sig.)
9	Peripheral motion detection	Main effect bifocal lens type (F= 3.14, p=0.022)-see text for comments
10	Vision with ANVIS	no diff. between bifocal lenses (ave=5.2)
11	Target/object detection	Main effect bifocal lens (see text - this result was not clinically sig.)
12	Maintain field of view	Main effect bifocal lens type (F= 3.10, p= 0.023)-see text for comments
13	Coping with glare, reflections	Main effect bifocal lens (see text - this result was not clinically sig.)
14	Overall perform./ utility	no diff. between bifocal lenses (ave=5.5)

Table G-9 presents the results of part 2 of the questionnaire, and, as the average responses indicate (from high 4's to between 5 and 6 on the scale), the subjects found the tasks "slightly-" to "moderately-better" to perform in all the bifocal lenses, than with bifocal spectacles.

There were two significant main effects for add group in the part 2 questionnaire data. One main effect for question 1 (reads guages, displays) indicates that the high add group found it significantly easier to read guages and displays (when compared to bifocal spectacles) than the low add group. This may be related to another main effect for add group found in question 5 (instrument panel), also showing that the high add group found visibility of these mid-distance guages and instruments significantly easier (than the low add group) to view than bifocal spectacles. Again, we feel that this may be related to the high contrast VA data displayed in panel 3 of figure 1, which shows that the high add group had significantly better acuity than the low add group for mid distance.

There were four questions (numbers 9, 11, 12, and 13) displaying a main effect for bifocal lenses, indicating that there was a significant difference in how subjects evaluated their vision with the different bifocal contact lenses compared to bifocal glasses for the different viewing tasks. The bifocal lens main effect for question 9 indicated that there were significant differences in how subjects wearing different bifocal lenses compared their vision to bifocal spectacles for "peripheral motion detection." However, multiple comparison testing showed that actually all bifocal lenses were equivalent and that the only difference between lenses was between modified MV and simultaneous diffraction lens, with the modified MV lens being significantly better (than the simultaneous diffraction lens) compared to bifocal spectacles.

The bifocal lens main effect for question 11 indicated that there were significant differences in how subjects wearing different bifocal lenses (compared to bifocal spectacles) evaluated their vision for "target/object detection." However, conservative multiple comparison testing (Tukey HSD) failed to show any significant difference between bifocal lenses for this question. It was only under the least conservative multiple comparison test that the differences proved significant (LSD or planned comparison test). In the interest of conservative reporting of significance, we feel that it is best to adopt the view that there are no significant differences between the bifocal lenses for this question.

The bifocal lens main effect for question 12 indicated that there were significant differences in how subjects wearing different bifocal lenses (compared to bifocal spectacles) evaluated their vision for "maintaining FOV." However, multiple comparison testing showed that, in general, all bifocal lenses were equivalent, and that the only difference between lenses was between the modified MV and simultaneous diffraction lens, with the modified MV lens being significantly better than bifocal spectacles, and between the modified MV and the simultaneous center near lens, with the modified MV lens being significantly better than bifocal spectacles.

The bifocal lens main effect for question 13 indicated that there were significant differences in how subjects wearing different bifocal lenses (compared to bifocal spectacles) evaluated vision for "coping with glare, reflections." However, conservative multiple comparison testing (Tukey HSD) failed to show any significant difference between bifocal lenses for this question. It was only under the least conservative multiple comparison test that the differences proved significant (LSD or planned comparison test). In the interest of conservative reporting of significance, we feel that it is best to adopt the view that there are no significant differences between the bifocal lenses for this question.

There was one significant interaction between add group and bifocal lens type for question 8 ("judge depth and distance"). However, upon close inspection and multiple comparison testing, the only significant differences were between lens conditions that were not clinically significant for this study; i.e., the lenses in the high add group were equivalent, the lenses in the low add group were equivalent, and there were no significant differences for any bifocal lens type between the high and low add group. The only significant difference was between the low add group in the simultaneous diffraction lens and the high add group in the modified MV lens (which was rated higher).